Research Protocol

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Dentistry Section

Comparison of Clinico-radiologic Outcome of Direct Palatal Vault Plating as against CAD/CAM-assisted Patient-specific Palatal Splint in Patients with Palatal Fractures of Maxilla: A Protocol for Randomised Clinical Trial

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ABSTRACT

Introduction: Palatal fractures are associated with Le Fort fractures and have an incidence ranging from 8 to 46.4%. They rarely occur in isolation and are typically treated using either a closed or open method.

Need of the study: The closed method, although less invasive and simple, has drawbacks such as bone mismatch since the fractures are not directly visualised and the stability of wires used is questionable. On the other hand, the open method is considered the gold standard but is a complex technique with drawbacks like wound dehiscence and implant exposure. In this study, we are introducing a newer modality, Computer-Aided Design (CAD)/Computer-Aided Manufacturing (CAM)-assisted Patient-specific Palatal Splint (CAPSPS), which aims to combine the simplicity of the closed method with the precision of reduction seen in the open method.

Aim: To evaluate and compare the clinical and radiologic outcomes of direct palatal vault plating against CAPSPS in patients with palatal fractures of the maxilla.

Materials and Methods: The current prospective, interventional, randomised parallel-arm controlled trial will be conducted at Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College, Wardha, Maharashtra, India, from July 2023 to July 2026 which will include 60 patients with palatal fractures of the maxilla. The patients will be randomly assigned to two groups using computer-generated randomisation. Group-A comprising 30 patients will undergo treatment with direct palatal vault plating, while 30 patients in Group-B will be treated with CAPSPS. Clinical outcomes, including fracture stability and occlusion, will be assessed intraoperatively and at one week, one month, third month and 6-month follow-up. Radiologic outcomes will be evaluated using Computed Tomography (CT) scans, with reduction and midface width assessed at the one week and six months. Scales proposed for assessing clinical and radiologic outcomes will be validated during the study. Intraoperative and postoperative complications will be qualitatively assessed and the intraoperative time will be compared between the two groups. Data will be recorded in a Microsoft Excel sheet and analysis will be conducted using Statistical Package for the Social Sciences (SPSS) version 23.0 software. Group comparisons to determine outcomes will be assessed using the independent sample t-test for continuous data with a normal distribution and the Chi-square test for identifying relationships between variables. Repeated measures Analysis of Variance (ANOVA) will be employed at different time intervals within both Group-A and Group-B. The statistical significance level will be set at $p<0.05$.

Keywords: Computer-aided design, Computer-aided manufacturing, Maxillary fracture, Open fracture reduction, Osteosynthesis, Palate

INTRODUCTION

Palatal fractures are commonly observed along with maxillary fractures. They have an occurrence ranging from 8 to 46.4% [1,2]. These fractures are more common in the adult population with a male predilection and result from motor vehicle injuries, assaults, industrial accidents, ballistic injuries, etc. These fractures result from high-impact injuries; hence, they are comminuted, rarely occur in isolation and tend to be associated with other severe injuries like head injury, panfacial trauma, etc. Clinically, they present as lacerations over the palatal vault, malocclusion, lip and mucosal lacerations (65% of cases) and maxillary dentoalveolar injuries. The definitive diagnosis can be established radiographically with the help of axial, coronal and sagittal CT cuts [2,3].

In 1998, Hendrickson M et al., studied the sagittal and coronal cuts of a CT scan of 29 patients and classified these fractures into six categories: alveolar fractures (anterolateral and posterolateral), sagittal, parasagittal, para-alveolar, transverse and comminuted. A parasagittal pattern was most common [2]. In 2008, Chen CH et al., proposed a simplified classification based on the fracture pattern and desired management as follows: Type 1: sagittal, Type 2: transverse and Type 3: comminuted [1]. Management of such fractures is essential, as failure to treat early can cause midface widening due to palatal splaying and malocclusion, compromising function and aesthetics [4].

Palatal fractures barely occur in isolation and are usually managed along with other concomitant fractures. There are two methods stated in the literature for addressing these fractures, which are the closed and open methods. The closed method is more commonly used because it is less invasive and simple, mainly including wiring like transpalatal wiring, the figure-of-eight technique, arch bars and splints. As the fracture is not directly visualised, there are chances of bony mismatch, the stability of the wires is questionable, hence, the risk of relapse is high. In literature, the incidence of postoperative malocclusion ranges between 8 to 39%. When wires are placed, there is irritation to the tongue, interference with speech and mastication and difficulty in maintaining oral hygiene. Prolonged IMF

compromises nutrition and stiffness in the temporomandibular joint and subsequently compromises mouth opening [5,6].

Manson PN et al., stated that rigid fixation of the palatal vault boosts stability, redefines maxillary arch width and prevents rotation of the dento-alveolar segment [4]. Open Reduction and Internal Fixation (ORIF) is considered the gold standard as it can overcome these disadvantages but is itself a complex technique with postoperative complications like wound dehiscence, implant exposure and infection requiring further intervention, hence not usually preferred [7].

The CAD/CAM technology has been broadly utilised in maxillofacial surgery for performing virtual surgery, designing surgical guides and creating customised implants. Computerised reduction of fractures followed by designing implants is carried out in reconstructing complex post-traumatic defects [8]. Historically, conventional splints were fabricated for the treatment of palatal fractures but are now omitted due to the cumbersome nature of the technique [2]. With the aid of CAD/CAM technology, CAPSPS have been designed as a newer modality for stabilising these fractures.

Over the years, studies have been conducted to find out the supreme method for the reduction and stabilisation of the hard palate. Some of the recent methods include transpalatal screw traction, external fixation using a miniplate, light-cured resin splint and 3-dimensional miniplate [6,9-15]. In this study, CAPSPS will be introduced to manage palatal fractures. It is a blend of the simplicity of the closed method and accuracy in the reduction of the open method. Here, the virtual reduction of the fracture will be carried out using the Digital Imaging and Communication in Medicine (DICOM) file. A splint will be designed over an anatomically reduced fracture site. This technique may aid in overcoming the drawbacks of the closed method like post-operative malocclusion and implant-related complications of the open method [5-7]. It will be compared to the gold standard open reduction and direct palatal vault plating. The study is based on the hypothesis that CAPSPS will offer a similar radiologic outcome and superior clinical outcome compared to direct palatal vault plating in the management of patients with palatal fractures of the maxilla. Hence the aim of the present study is to evaluate and compare the clinico-radiologic outcome of direct palatal vault plating against CAPSPS in the management of patients with palatal fractures of the maxilla.

Objectives

Primary objective:

1. To evaluate and compare clinical outcomes at the 1st week, 1st month, 3rd month and 6th month postoperatively in both groups.
2. To evaluate and compare radiologic outcomes at the 1st week and 6th month postoperatively in both groups.

Secondary objective:

1. To evaluate postoperative complications in both groups.
2. To assess and compare the intraoperative time period utilised for direct palatal vault plating and palatal splinting.

REVIEW OF LITERATURE

Park S and Ock JJ derived an algorithm for fracture management and classified fractures based on their management into four categories: closed reduction, anterior plating, anterior and palatal plating and combined, i.e., plating and Intermaxillary Fixation (IMF) [16]. Chen CH et al., proposed a more simplified classification based on fracture pattern and desired management on 162 cases with palatal fractures of the maxilla: Type I: Sagittal, which included median (13.7%) and paramedian (77.3%), Type II: Transverse (4.8%) and Type III: Comminuted (4.2%). Sagittal maxillary fracture is the most common among all [1]. Paramedian fractures are more common as the thin shelves lie just lateral to the thick midpalatal suture synostosis site [17].

In 2008, Pollock RA shared an innovative experience of external fixation of a hard palate fracture using a 2 mm miniplate placed in eight patients [9]. In 2010, a prospective single-arm study on the same technique was conducted by Cienfuegos R et al., in 45 patients and found satisfactory results at 12-week follow-up [10]. In 2016, Bhargava D et al., compared transmucosal plating against intra-arch wiring. The transmucosal plating technique had a more reliable and superior result when compared to intra-arch wiring [11].

In 2015, Ma D et al., introduced the transpalatal screw traction technique for stabilisation of the palatal vault in 11 patients and found it to be simple, cost-effective and provided a good clinical outcome [12]. In 2015, Waldrop J et al., on 13 patients fabricated a rapid light-cure resin splint for stabilisation of the palatal fractures and found it to be cost-effective and successful. It may be useful in fractures which are comminuted, cannot be adequately stabilised, or are not compliant with rigid fixation [13]. In 2018, Karthik R et al., used 3-dimensional plates in 18 patients for fixation of palatal fractures and came to the conclusion that rigid fixation of the palate is a crucial step in the treatment of complex fractures [6]. In 2021, Kumar U and Jain P evaluated 60 patients presenting with palatal fractures and stated that plating is required in displaced sagittal and parasagittal fractures at the posterior half of the middle one-third of the palate [14]. In 2022, Tiwari P et al., employed Rapid Maxillary Expansion (RME) technique in five patients to correct the transverse width of the maxilla in sagittal palatal fractures and found it to be effective, with the expander serving as external fixation during the bone healing process [15].

MATERIALS AND METHODS

The present prospective, interventional, randomised, parallel-arm controlled trial will be conducted in the Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College, Wardha, Maharashtra, India, from July 2023 to July 2026. Ethical clearance has been obtained from the Institutional Ethical Committee (IEC/2022/04). The trial is registered with the Clinical Trial Registry-India (CTRI/2023/05/052582).

Inclusion criteria: Adult patients aged between 18 and 60 years, diagnosed with a sagittal/parasagittal fracture of the hard palate and willing to consent, will be part of the study.

Exclusion criteria: Patients who are medically compromised, edentulous, or refusing to consent for the study and follow-up will be excluded.

Sample size calculation: Sample size is determined using the following formula:

$$n=\frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2\, p_1(1-p_1)+p_2\,(1-p_2)}{(p_1-p_2)^2}$$

Proportion of outcome (p_1)=10.9

Proportion of outcome (p_2)=14.2 [11]

Level of significance (α)=0.05

Power (1-β)=0.80

Z alpha value=1.96

Z beta value=0.84

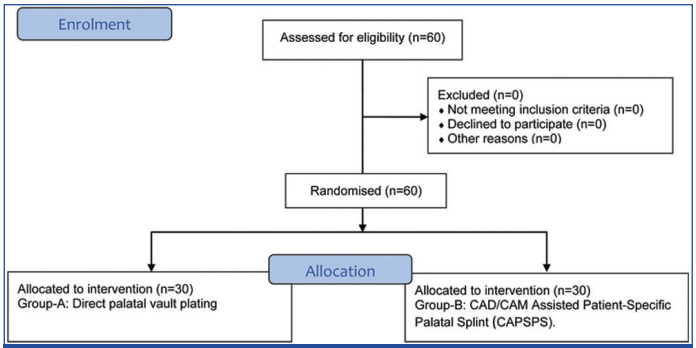
Total Sample size=60

Study Procedure

Based on the Consolidated Standards of Reporting Trials (CONSORT) guidelines [Table/Fig-1], 60 patients will be randomly divided equally into two groups using computer-generated random numbers. Patients will be informed about their allocated group before the intervention.

Group-A: Patients will be treated with open reduction and direct palatal vault plating.

Group-B: Patients will be treated with CAD/CAM-assisted patient-specific splints.



[Table/Fig-1]: Protocol for randomised controlled parallel arm study based on CONSORT guidelines.

Surgical protocol: A comprehensive case history will be obtained. A clinical examination of the maxillofacial region will be conducted and data will be compiled based on clinical findings. Extraoral and intraoral findings will be noted and details will be preserved photographically. A CT scan of the face with 3-D reconstruction will be performed. A CT with 16 slices/cuts will be obtained, including axial, coronal and sagittal cuts. Blood investigations, a chest X-ray and an electrocardiogram will be conducted. Fitness will be assessed by the anaesthetist, physician and other relevant departments, if necessary. Arch bars will be placed preoperatively in all patients.

For patients in Group B, diagnostic CT scan images will be saved as DICOM files. The fracture will be virtually reduced using CAD/CAM software. A three-dimensional stereolithographic cast will be printed, over which a palatal splint will be fabricated using heat-cure clear acrylic resin. The splint will be secured with wire. All cases will be operated on by a single surgeon to avoid bias. After obtaining preanaesthetic fitness and relevant consent, the patients will be scheduled for surgery.

Surgical technique:

- **Group-A: Open Reduction and Internal Fixation (ORIF) with direct palatal vault plating:** Keen's Vestibular Incision will be made in the maxillary buccal vestibule and the fracture site will be exposed after performing subperiosteal dissection. Disimpaction of the maxilla (if required) will be done using Rowe's maxillary disimpaction forceps. Palatal fracture is approached through either an existing laceration or a crevicular/vertical midline incision. Anatomic reduction of the palatal fracture fragment will be done by applying digital pressure, followed by fixation using a 2 mm miniplate and 2×6 mm screws [2]. Occlusion will be manipulated into satisfactory relation and IMF will be placed. Fixation of the zygomaticomaxillary buttress, nasomaxillary buttress and other concomitant fractures (if present) will be performed. IMF will be removed and occlusion will be reassessed. The surgical site will be closed using a resorbable suture.
- **Group-B: CAD/CAM assisted patient specific palatal splint:** Keen's Vestibular Incision will be made in the maxillary buccal vestibule and the fracture site will be exposed after performing subperiosteal dissection. Disimpaction of the maxilla (if required) will be done using Rowe's maxillary disimpaction forceps. Reduction of the palatal fracture will be performed by applying digital pressure and a splint will be placed. Occlusion will be manipulated to ensure satisfactory relation and IMF will be placed. Fixation of the zygomaticomaxillary buttress, nasomaxillary buttress and other concomitant fractures (if present) will be performed. IMF will be removed and occlusion will be reassessed. The surgical site will be closed using a resorbable suture. Palatal splints will be fixed on the occlusal aspect of the posterior teeth using wires.

Evaluation

Following evaluation will be done for both groups:

Evaluation of clinical outcome:

Stability of fracture: The stability of the fracture will be assessed after the fixation of the miniplate in Group A and the fixation of the splint in Group-B. Bi-digital manipulation will be done by placing the thumb over the palatal shelf and the index finger over the depth of the buccal mucosa on both sides. The segment will be gently manipulated in the buccopalatal and superioinferior directions to check for intersegmental mobility. The stability of the fixation will be scored accordingly:

0- no interfragmentary mobility;

1- interfragmentary mobility in one direction; and

2- interfragmentary mobility in both directions.

The present scale to assess occlusion will be evaluated and validated during the study period. The scale may be modified based on observations.

Occlusion: Inter-molar relations will be recorded. In case molars are missing or grossly decayed, inter-canine relation will be recorded. The disparity in occlusion will be measured with the help of the Castroviejo caliper.

The occlusion will be scored accordingly:

0- maximum intercuspation in the molar and premolar regions;

1- up to 2 mm of discrepancy on the buccal/palatal side;

2- 2 to 4 mm of discrepancy on the buccal/palatal side; and

3- more than 4 mm of discrepancy on the buccal/palatal side.

The need for the placement of postoperative IMF and its duration will be recorded. The current scale to assess occlusion will be evaluated and validated during the study period. The scale may be modified based on observations.

The clinical outcomes will be evaluated intraoperatively, in the first week, the first month, the third month and the sixth month postoperatively.

Evaluation of radiologic outcome:

Assessment of reduction: A CT scan will be done in the 1st week postoperatively to assess reduction. Bone fragments will be assessed for proper alignment. Gaps or bone overlapping between bone fragments of the hard palate will be assessed.

The bone interfragmentary gap will be measured and scored as follows:

1- 0 to 0.5 mm;

2- 0.6 to 1 mm;

3- 1.1 to 1.5 mm;

4- 1.6 to 2.0 mm;

5- >2 mm.

A CT scan will be repeated after 6 months to assess bony healing. The current scale used to assess reduction will be evaluated and validated during the study period. The scale may be modified based on observations.

Assessment of midface widening: Midface widening refers to an increase in the transverse width of the maxilla. The midline will be marked on the coronal cut of the CT scan. Symmetry of the Maxillary Arch Base Width will be assessed by measuring the linear distance from the lateral wall of the maxilla to the midline intersecting the lowest point on the contour of the nasal cavity on the right-side (R) and the left-side (L). The discrepancy between both readings will be calculated and scored accordingly.

0- 0 mm

1- 1 to 5 mm (mild discrepancy);

2- 6 to 10 mm (moderate discrepancy);

3- 11 to 15 mm (severe discrepancy).

The readings will be recorded preoperatively and at 1st week and six months postoperatively. The present scale to assess midface widening will be evaluated and validated during the study period. The scale may be modified based on observations.

Evaluation of complications: Both groups will be assessed for complications both intraoperatively and postoperatively. Intraoperatively, the following complications may occur:

In Group-A: soft-tissue injury to the palatal mucosa, intraoperative blood loss, epistaxis and malocclusion.

In Group-B: Inability to fix the splint and malocclusion.

Intraoperative blood loss in the Group-A patients will be estimated by measuring the weight of the blood-soaked gauze piece, from which the initial weight of the dry gauze piece will be subtracted. One gram of weight will be considered equal to one millilitre of blood.

Postoperatively, the following complications will be assessed:

In Group-A: Mid-face widening, malocclusion, gapping/dehiscence, implant exposure, implant failure, infection, non union, malunion, oronasal communication/fistula, oro-antral communication/fistula and neurological deficits along the greater palatine nerve. Deficits around the greater palatine nerve will be assessed using a static light touch test.

In Group-B: Mid-face widening, malocclusion, splint fracture, non union and malunion.

Evaluation of intraoperative surgical time: The operative time taken for Group-A will be measured using a digital timer. The timer will be started just before making an incision and will be stopped after the placement of the last suture. In Group-B, the timer will be started just before the placement of the splint and will be stopped once the splint is fixed.

STATISTICAL ANALYSIS

The ongoing study aims to evaluate the clinical and radiologic outcomes of CAPSPS and to compare them with direct palatal vault plating. Data collection is expected to be complete by the end of December 2025. Appropriate data analysis will be done with the statistician's help later. Final data will be recorded in the Microsoft Excel sheet and the analysis will be conducted using the SPSS version 23.0 software. The comparison between the groups to determine the outcomes will be evaluated using the independent sample t-test for continuous data with a normal distribution and the Chi-square test for identifying the relationship between variables. Repeated measures ANOVA at different time intervals within Group-A and Group-B will be performed. The statistical significance difference will be set at $p<0.05$.

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