

# Occlusal Assessment of Pediatric Mandibular Fractures Managed by 3D-Printed Acrylic Occlusal Cap Splint: A Case Series

تقييم الإطباق في حالات كسور الفك السفلي في المرضى الأطفال المعالجين باستخدام جبيرة إطباقية ثلاثية الأبعاد من الأكريليك: سلسلة حالات

Protocol submitted to

Faculty of Dentistry, Cairo University, Egypt.

for partial fulfillment of the requirements for the Master Degree in Oral and Maxillofacial Surgery.

By:

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Code:

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Date

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## I. Administrative Information:

### 1. Title:

Occlusal Assessment of Pediatric Mandibular Fractures Managed by 3D-Printed Acrylic Occlusal Cap Splint: A Case Series

### 2. Protocol Registration:

Trial will be registered at [clinicaltrials.gov](https://clinicaltrials.gov)

### 3. Protocol Version:

First version (April 2026)

### 4. Funding:

Self-funded

### 5. Roles and Responsibilities:

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Trail Responsibility:

Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University, Egypt.

## II. Introduction

### 6. Background

#### Research Question:

Does the 3D-printed acrylic occlusal cap splint is accurate in management of mandibular fractures in pediatric patients?

PIO elements:

Population (P):

Pediatric patients with mandibular fracture.

Intervention (I):

3D-printed acrylic occlusal cap splint.

Outcome (O):

Primary Outcome: Occlusion

Secondary Outcome: Radiographic evidence of fracture reduction, maximum mouth opening, and post-operative pain.

#### Statement of the Problem

Pediatric mandibular fractures count for 32.7% of all facial fractures (Luhr, 1998). Symphyseal and parasymphiseal fractures account for approximately 2% to 30% of all mandible fractures, with higher male predilection (Zimmermann et al., 2005). These fractures occur more often in children than in adults, which may be partially explained by the presence of developing canine tooth buds resulting in a stress point at the inferior border of the mandible (Chacon et al., 2003). It is noteworthy that, one of the most common causes of trauma in children is motor vehicle-related accidents followed by falls, sports injuries and interpersonal violence (Morris et al., 2012). Moreover, the injury of the mandible has a serious impact on the functions of children's mouth opening, chewing, pronunciation, and occlusion.(Yang et al., 2022). Inadequately or incorrectly-treated fractures in growing children may lead to serious complications including asymmetric mandibular growth and temporomandibular joint (TMJ) ankylosis (Joshi et al., 2015).

## Rationale for Conducting the Research

This study is conducted to evaluate the accuracy of 3D-printed acrylic occlusal cap splint fabricated by computer-guided software in reduction and fixation of pediatric mandibular fractures. There are a wide range of choices in the management of mandibular pediatric trauma, ranging from observation and follow-up, conservative treatment, and open reduction and internal fixation (ORIF) (Chakravarthy et al., 2019).

Mandibular growth, with the presence of tooth buds, along with deciduous/ permanent teeth eruption (mixed dentition) favor the use of conservative approaches in the management of pediatric mandibular fractures, where splints are fixed over the mandible by the use of circum-mandibular wiring (non-rigid fixation) (Tandon et al., 2020). The virtual surgical planning is increasing in popularity in craniomaxillofacial surgery (Abo Sharkh and Makhoul, 2020).

There are multiple advantages that this study offers. First, it is suitable for the patients with a complete primary dentition as well as those in mixed dentition. Second, the fracture segments will be reduced accurately during virtual surgical simulation, improving the accuracy of the operation. Third, due to the splint is done according to the individual dentition of the child, it is more stable than the traditional dental arch splint ligation. Fourth, compared with intraoperative impression taking, pouring them into casts, fracturing and reattaching them in the correct positions to fabricate the splints, it avoids the contamination of the operation area and helps shorten the operation's time spent, and improves the safety and efficiency of the operation (Yang et al., 2022).

## Review of literature

Hyperactivity, road traffic accidents (RTA), falls, abuses, and assaults make children the most unfortunate victims of facial trauma and bone fractures (Kaur et al., 2020). Most pediatric mandibular fractures are non-displaced due to the resiliency of the mandible and the presence of tooth buds that act as small anchors to keep the fractured segments together (Fortunato et al., 1982).

However, displaced mandibular fractures in children need to be reduced and immobilized. Such fixation can be achieved with maxillomandibular fixation (MMF) or open reduction and internal fixation (ORIF) or a combination of both. MMF is more difficult in children than in adult. This is due to a number of factors, including fewer available teeth, resorption in roots of deciduous, non-retentive surfaces of deciduous teeth, and the crowns of incisors and canines and partially erupted permanent teeth having unfavorable shape for fixation of interdental wires and Erich arch bars (El-Anwar et al., 2018).

The objective of any surgical intervention is to restore and maintain a stable occlusion. Treatment for children is generally conservative. Reconstruction of pediatric facial fractures, mandibular fractures in particular, requires an understanding of craniofacial development and the consequences of injury on further growth. Appropriate treatment will depend on the age of the patient, the location, and the nature of the fracture (Goth et al., 2012).

For the young pediatric patients, with fractures that are not displaced and present without malocclusion often only require analgesics, close observation, and a liquid or soft diet. These patients should avoid strenuous physical activities for several weeks to avoid further accidental trauma to the mandible (Smartt et al., 2005). Spiessl stated in 1988 that rigid plate fixation is not indicated in mandible fractures in growing younger children, and it is usually reserved for difficult fractures when three-dimensional control is required. When ORIF is performed in young patients, minimal periosteal manipulation is desirable. Alloplastic materials should be avoided. Because of the changes a child experiences during growth, long term follow-up of these patients is required to identify and monitor any potential growth disturbance or abnormality (Goth et al., 2012).

Acrylic splints, which were fabricated intraoperatively, are effective to provide stability to the mandible; however, they usually require intraoperative impressions and model fabrication. In young patients, it is possible to use a single-arch splint and circum-mandibular wires to stabilize the lower jaw, while allowing the patient to swing freely and thus facilitate nutritional intake with less discomfort and anxiety for the patient. This is an attractive option for someone who would otherwise need to be wired closed for several weeks. However, these splints can be difficult to fabricate in the operating room, especially

because operating room time is expensive, and the appropriate materials or expertise may not be readily available (Zide, 1989).

An alternative fixation method is carried out by taking alginate impressions and pouring them into casts, then fracturing and reattaching them in their correct position to fabricate the splints prior surgery (Kaur et al., 2020). Furthermore, in facial fractures trans-nasal wiring combined with circum-mandibular wiring effectively immobilizes the patient's jaws. Although it presents with a risk of injury to the developing teeth along the piriform aperture. The surgeon has to be cautious when using this technique because often times, the bone in the piriform rim and paranasal area is not dense enough to secure wires. If treated in this manner, children will also generally require another general anesthesia to remove the wires (Nishioka et al., 1997).

Besides, Laster et al., 2008 have described another approach for placing specialized, pre-formed nickel titanium staples across a fracture line for minimally invasive ORIF of mandible fractures, particularly in younger patients. After intermaxillary fixation, or manual stabilization of fracture, a small incision, 10 to 15 mm on average, is made to expose the fracture. A small hole is then drilled 3 to 4 mm from the fracture line, 1 on each side. The 2 holes should be placed at the center, so that the shrinkage of the staple will compress the fracture line into place. The staple should be as perpendicular to the fracture line as possible. The distance between the 2 holes is measured between the 2 closest points of the holes' edges. The appropriate staple size is then selected and cooled below 0 °C by using a commercial spray coolant. Cooling enables momentary straightening of the staple arms to a vertical position to facilitate insertion of the staple into the holes. The body heat warms the staple and causes closure of the arms, compressing the fracture segments together. Additional staples are placed above and below the first one as needed. Any loose staples are then replaced to achieve even stability. This technique allows for easy placement and easy retrieval of the metal components, while minimizing the number of foreign bodies placed at the fracture site.

Another useful tool in the management of pediatric mandible fractures is the Risdon cable. First described by Risdon (Risdon, 1938), the Risdon cable is made from simply twisting together a long circum-dental 24-gauge stainless steel wire. Because full-sized arch bars can be too bulky for working around the short bulbous teeth of small patients, the Risdon cable offers a more malleable and low-profile substitute for the adult arch bars. The cable extends from one side of the dental arch to the opposite side and is secured to each tooth with circum-dental 24-gauge wires. Variations on this theme are used to deal with specific fracture locations in the mandible (Kushner and Tiwana, 2009).

Additional technique has been reported by making use of resorbable screws and large sutures to stabilize the mandible. One small drill hole is placed in each zygoma after a small full thickness mucoperiosteal flap is raised. This hole is tapped, and a custom-resorbable screw is placed into each zygoma. This custom screw has a special hole in the screw head, created during the manufacturing process. An awl is then used to pass a large 0, or 2-0, monofilament suture under the mandible. The patient is placed in maximum intercuspation using the free-hand stabilization technique with the help of an assistant, and the suture is passed through the screw head and tied in a knot. At this point, the suture appears as an ellipse, with one end wrapped around the mandible and one end wrapping through the hole in the screw head. The knot is placed high in the vestibule, free from the screw head, to minimize irritation to the patient. After a period of 3 weeks, the surgeon can then cut and remove the suture. The custom screw is then left in the zygoma undisturbed, left to resorb on its own with no further invasive procedure required to retrieve it. Although the initial procedure to place this maxillomandibular fixation requires a general anesthetic, it is rapid, secure, and does not damage the teeth; no further second general anesthetic is required. Case selection is important because older children will generate jaw forces too strong to be stabilized by this technique (Cole et al., 2009).

Owing to the mandibular growth restriction associated with the traditional permanent plates, various resorbable plates have been developed. Several biodegradable materials have been examined during the last 40 years. These systems use high molecular weight polyhydroxy acids. Polylactic acid (PLA), polyglycolic acid (PGA), and their copolymers have been the most commonly used materials to fabricate plates and screws (Ashammakhi et al., 2001; Landes and Ballon, 2006). Resorbable plating systems have traditionally been bulkier and more difficult to handle when compared to titanium plates and screws. Resorbable screws require predrilling and tapping. There have also been published complications including infection, plate fracture, and fistula formation. Another major concern with resorbable systems has been the ability of the plate to withstand the forces produced by the functioning mandible (Bos, 2005).

## 7. Objectives

### Aim of the Study

To evaluate the occlusal accuracy of 3D-printed acrylic occlusal cap splint fabricated by computer-guided software in reduction and fixation of pediatric mandibular fractures.

## 8. Trial Design

Prospective consecutive, single-arm, case series trial.

### III. Methods

#### A) Participants, Interventions and Outcomes

##### 9. Study Settings

Participants will be recruited from Oral and Maxillofacial department, Faculty of Dentistry, Cairo University, Egypt. The study is to be conducted in the same setting. The start of the study is expected to be on June 2026, and to extend till June 2027.

##### 10. Eligibility Criteria

Inclusion criteria:

- Pediatric patients in the mixed dentition phase, aged from 6 to 12 years, with no gender predilection.
- Recent fracture.
- Single line of fracture; symphyseal, parasymphyseal or body fracture.

Exclusion criteria:

- Patients with systemic diseases that may impair bone repair.
- Patients with more than one line of fracture.
- Patients with pan-facial, ramus, or condylar fractures.
- Patients with comminuted mandibular fractures.
- Patients with infection or pre-existing mandibular pathology at the fracture site.
- Patients who are unable to tolerate follow-up intervals.

## 11. Intervention

### Pre-operative Procedures

Firstly, patients will go to the polytrauma center to have physical examination to exclude any neurosurgical conditions. CBCT imaging will be done at hospital basis and DICOM file will be used on Materialize Mimics software (Mimics Medical 21.0, Belgian) to virtually reconstruct the patients' mandible and maxilla, and reduce the fractured bony segments. An occlusal cap splint will be designed with thickness of 3 mm, and will be converted to STL file to be 3D-printed.

### Procedure:

All the patients will be treated with circummandibular wiring under GA. Local anesthetic solution (4% articaine with 1:100,000 epinephrine) will be administered extra-orally at the point where the bone awl to be inserted. The bone awl will be then guided along the body of the mandible and enter lingually piercing the mucosa. Once the awl tip is seen, a 26-gauge wire will be secured to its head. It will then be withdrawn till its tip reach the inferior border of the mandible and then pass along the buccal side into the sulcus. Same procedure will be repeated on the other side of the mandible and wires held in position. Extra-oral sutures can be made if needed.

### Post-operative Instructions and Medication:

- Ice packs will be placed for 15 minutes every 1 hour for the first 12 hours.
- A liquid diet will be initiated on the first post-operative day, followed by instruction for a soft diet for the next 4 weeks.
- Strict oral hygiene measures including brushing and rinsing.
- Antibiotic, analgesic, and anti-inflammatory drugs will be prescribed, and doses will be calculated according to patients' age and weight.
- Occlusal cap splint will be removed after one month, under sedation.

### Follow-up:

- One-week post-operative.
- Two-week post-operative.
- One-month post-operative.
- Three-month post-operative.

### Strategies to Improve Adherence to Intervention:

Prior to the procedure, A.H. will carry out the following:

- Detailed explanation of the procedure.
- Settling exact follow-up dates.
- Obtaining a signed informed consent from the patients' guardian.

### Relevant Concomitant Care:

A.H. will instruct the patients to strictly maintain good oral hygiene, and to avoid any mechanical trauma during the healing period.

### Criteria for Discontinuing or Modifying Intervention:

- None.

## 12. Outcomes

### Primary Outcome:

- Occlusion

It will be assessed to be satisfactory or not, according to Angle classification, absence of midline shift, cross-bite or open-bite after one month, and three months.

### Secondary Outcomes:

- Radiographic evidence of fracture reduction

Will be assessed by panoramic radiograph immediate post-operative and after three months.

- Post-operative pain and discomfort

Will be measured by visual analogue scale (VAS), on a scale from 1 to 10.

- Maximum mouth opening

Will be measured by a ruler in mm.

	Outcome	Measuring Device	Measuring Unit
Primary outcome	Occlusion	Binary	Yes or no
Secondary outcomes	Radiographic evidence of fracture reduction	Panorama	Yes or no
	Maximum mouth opening	Ruler	Mm
	Post-operative pain	VAS score	1-10

### 13. Participant timeline

Visit	Procedure(s)	Measuring device
First visit	Pre-operative records CBCT scan done	
Second visit	Operative procedures of placing occlusal cap splint using circummandibular wires under GA. Immediate post-operative panorama to assess fracture reduction.	-Binary
Third visit (one-week post-operative)	-Post-operative pain -Maximum mouth opening	-VAS (1-10) -Ruler in mm
Fourth visit (two-week post-operative)		
Fifth visit (one-month post-operative)	Splint removal under sedation -Occlusion -Post-operative pain -Maximum mouth opening	-Binary -VAS (1-10) -Ruler in mm
Sixth visit (three-month post-operative)	-Occlusion -Radiographic evidence of fracture reduction -Maximum mouth opening	-Binary -Binary -Ruler in mm

### 14. Sample Size

- This study will be conducted on 10 patients.

### 15. Recruitment

- Patients will be recruited and selected by A.H. from the outpatient clinic of Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University, Egypt.
- Expected duration of recruitment is one year, from June 2026 to June 2027.

## B) Data Collection, Management, and Analysis

### 16. Data Collection Methods

- Occlusion will be assessed visually by A.H., in the follow-up visits (one-month, and three-month post-operative) and given values of either intact or deranged.
- Radiographic evidence of fracture reduction will be assessed by a panoramic radiograph, immediate post-operative and three-month post-operative.
- Post-operative pain will be assessed using visual analogue scale (VAS), with score from 1 to 10, in the follow-up visits (one-week, two-week, and one-month post-operative).
- Maximum mouth opening will be assessed by ruler in mm in the follow-up visits (one-week, two-week, and one-month and three-month post-operative).
- Recorded data will be kept in the patients file and as a softcopy in Microsoft Excel sheet.
- Patients' full name, contacts (home and mobile numbers), and ID number will be recorded, so reminder calls can be done prior to follow-up visits.

Plans to promote participant retention and complete follow-up:

- Prior to the surgery, A.H. will inform the patients about the importance of the follow-up visits, and their effects on the outcome of the procedure.

### 17. Data Management

- All the data will be saved on a Microsoft Excel sheet, encrypted using a password, kept on A.H. laptop, and on an external hard drive.
- Each patient will be assigned a folder containing all his (her) data, including personal data, and the measured outcomes (occlusion, radiographic evidence of fracture reduction, maximum mouth opening, and post-operative pain), as well as a copy of the signed informed consent.

## 18. Statistical Methods:

- Categorical data will be presented as frequencies (n) and percentages (%) and will be analyzed using chi-square test.
- Numerical data will be explored for normality by checking the data distribution, calculating the mean and median values, and using Kolmogorov-Smirnov and Shapiro-Wilk tests.
- If the data is normally distributed, it will be analyzed using paired t-test. If it is non-parametric, it will be analyzed using Wilcoxon signed rank test.
- The significance level will be set at  $P \leq 0.05$  for all tests.
- Statistical analysis will be performed with IBM® SPSS® Statistics Version 25 for Windows.

## C) Data Monitoring

### 19. Monitoring

- Oral and Maxillofacial department council.

### 20. Harms

- Any temporary or permanent adverse effects will be recorded, documented and treated.

### 21. Audit

- The study supervisors; Assoc. Prof. Dr. Mostafa Talaat, and Dr. Ahmed Youssef, will regularly assess the trial process and documents. They will be involved in participants enrollment, consent, eligibility and allocation to study groups, as well as adherence to trial interventions and policies to protect participants, including reporting of complications and their treatment. Operative procedures will be performed under their supervision.

## IV. Ethics and Dissemination

### 22. Research Ethics Approval

- This protocol and the template informed consent form will be reviewed by the Ethics Committee of Scientific Research, Faculty of Dentistry, Cairo University.

### 23. Protocol Amendments

- This protocol will be registered on (clinicaltrials.gov) in its current form.
- Any modifications to the protocol which may have an impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by the Periodontology department council.

### 24. Informed Consent

- Researcher will introduce the trial to patients and provide full explanation of its aim and benefits in simple language. Patients will then be able to have an informed discussion with the researcher to explain all the procedures, and any complication that can be met. Researcher will obtain written consent from all patients willing to participate in the trial.
- All consent forms will be in simple Arabic language.

### 25. Confidentiality

- All study-related information will be stored securely. All participant information will be stored in locked file cabinets in areas with limited access. All reports, data collection, process, and administrative forms will be identified by a coded ID [identification] number only to maintain participant confidentiality. All records that contain names or other personal identifiers will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems.
- Patients' personal information will be available to the researcher only, while clinical and analytical data will be available to the entire research team.

## 26. Declaration of Interest

- This study is a part of a Master's Degree in Oral and Maxillofacial Surgery, from Faculty of Dentistry, Cairo University.
- No financial conflict of interest, as it is self-funded by main researcher.

## 27. Access to Data

- The principal investigator and the supervisors will be given access to the data sets. All data sets will be password protected. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.
- Clinical and analytical data may be made available at a data repository if requested by a publishing journal.

## 28. Ancillary and Post-trial Care

- All patients will be followed-up until complete healing and satisfactory results occur.
- Dental and oral treatment will be provided if needed.

## 29. Dissemination Policy

- Study results will be published as partial fulfillment of the requirements for Master's Degree in Oral and Maxillofacial Surgery. Topics suggested for presentation or publication will be circulated to the authors. Study result will be published in international journal.

## V. Appendices

### 30. Informed Consent

- Informed consent template is attached.

### 31. Biological Specimen

- No samples will be collected.

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