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## **Stability of Single 3-D Trapezoidal Plate in Condylar Fracture in Comparison to 2 Miniplates: A Prospective Clinical Study**

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**Abstract---Background:** Condylar fractures account for one third of all mandibular fractures being in the range of 17.5–52%1, 2 of all mandibular fractures. The main goal in the treatment of condylar fractures is to predictably restore pre-injury anatomical form, with associated aesthetics and function. **Aim:** The aim of this study is to assess the efficacy and stability of single 3-D trapezoidal condylar plate and compare it with 2.0mm conventional miniplates in the Open Reduction and Internal Fixation of mandibular sub-condylar fractures. **Methods:** This study was conducted on 20 patients with subcondylar fracture. 10 patients were allotted by random sampling in each Group. 3-D trapezoidal condylar plates were used in Group A and 2.0mm conventional minplates were used in Group B. The mini

retromandibular surgical approach was common to both the groups. Function and stability was assessed post operatively at 1st, 3rd and 6th month respectively. **Results:** Intergroup analysis showed no statistically significant difference in results with respect to function and the stability of the fractured fragments. **Conclusion:** 3D trapezoidal condylar plates are more stable and structurally more efficient in reducing the torque forces leading to better osteosynthesis.

**Keywords**--condylar fracture, condylar head, fixation methods, internal fixation, open reduction.

## Introduction

Condylar fractures account for one third of all mandibular fractures being in the range of 17.5–52% of all mandibular fractures (Ellis III et al., 1985; Zachariades et al., 2006). They are usually caused by a force transmitted from chin to the condylar process resulting in a fracture of the condylar neck in adults (Oikarinen & Lindqvist, 1975). The most common unilateral fracture is of sub-condyle, and the most common bilateral fracture occurs in condylar heads<sup>4</sup>, mostly caused by direct trauma, but may also be due to indirect forces. The main goal in the treatment of condylar fractures is to predictably restore pre-injury anatomical form, with associated aesthetics and function (Parascandolo et al., 2010). Meyer et al. (2002), emphasized on the existence of compressive strains organized along the posterior border of the ramus whereas tensile strains located parallel to and beneath the sigmoid notch. The tensile strains lines are primarily accountable for the complications relating to plate fracture or screw loosening (Meyer et al., 2002). In the past various treatment techniques were used for open reduction and internal fixation (ORIF) of condylar fractures Meyer et al. (2006); Kallela et al. (1995); Messer (1972), but there is still no consensus regarding the ideal osteosynthesis device to be used.

From a review of the literature Ehrenfeld et al. (1996); Undt et al. (1999); Ellis III et al. (2000); Haug & Assael (2001); Hyde et al. (2002); Wagner et al. (2002), it is apparent that single miniplate fixation is the most frequently used technique, but it is not capable of resisting the biomechanical strains that arise in the condylar region during mastication. Many authors have reported evidence of the high failure rate associated with positioning of a single plate technique accounting up to 35% due to plate fracture, screw loosening and structural instability. The main explanation for this is that this technique does not comply with the osteosynthesis principles regarding functional stability (Widmark et al., 1996).

Recently, more authors have reported significantly better results with the use of two 2.0mm miniplates, one plate is secured along the axis of the condylar neck and the second one is placed beneath the mandibular notch. This is in accordance with Champy's concept of stable osteosynthesis functionality (Champy et al., 1986). Two-plate fixation fulfills the criteria of dynamic osteosynthesis, but their adaptation in the region of condylar axis is difficult due to constricted condylar neck.<sup>19</sup> In the condylar neck region, the amount of bone is not always adequate to permit the placement of 2–3 screws per fragment, to

overcome this drawback the 3-dimensional osteosynthesis plates were introduced in maxillofacial surgery in the early 1990s by Farmand (Farmand & Dupoirieux, 1992; Farmand, 1993; Farmand, 1995).

3-D trapezoidal condylar plate (TCP) is placed in such a way that one arm is parallel to the condylar axis whereas the second arm is parallel to the mandibular notch. Hardware is less thus the infection rate is low, the surgical exposure is also reduced as compared to that for two–4 hole straight miniplates Chaudhary et al. (2015), therefore TCP can be effectively used as a substitute to the modified 2-miniplate technique. The aim of this study was to assess the efficacy and stability of single 3-D TCP and compare it with two 2.0mm conventional miniplate technique for ORIF of mandibular sub-condylar fractures.

### Materials and Method

This study included 20 cases of mandibular sub-condylar fractures who reported to the department of Oral and Maxillofacial Surgery. All these patients were randomly divided into two groups i.e. Group A and Group B, with 10 patients in each group. Group A patients were treated with 3-D TCP and Group B patients with two four hole 2mm thickness conventional miniplates. Many of these cases had other concomitant facial fractures. The study was conducted after obtaining the approval of the institutional ethical committee and informed written consent from the participants. Patients with condylar head fractures, pediatric patients, patients medically unfit for surgery and those who could not be followed up postoperatively over a minimum period of 6 months, were excluded from the study. Routine preoperative investigations included ortho-pantomogram (OPG) and posteroanterior (PA) view of mandible which were assessed for the degree of displacement of the fracture fragments (Fig 3). Erich's arch bar was secured for all patients. Post-operative clinical examination was carried out as per protocol, variables taken into account were range of mandibular movements, post-operative bite efficiency and maximum inter-incisal mouth opening whereas, radiographical evaluation was focused on plate fracture, and screw loosening using OPG and PA view of mandible.



Figure 3. Post operative OPG of patient with fixation using a 3-D trapezoidal condylar plate

### **Surgical procedure**

Surgery was performed under general anesthesia using naso-endotracheal intubation. Reduction and stabilization of other mandibular fractures were done first via intraoral approach to get the continuity of the arch. Retromandibular incision was used to access the subcondylar fracture. The skin marking was done for retromandibular approach incision (Figure 1). 1;2,00,000 Adrenaline was infiltrated along the incision as vasoconstrictor. The dissection was done through superficial fascia, SMAS layer and parotid capsule. The facial nerve was identified and protected if found—then the dissection was carried antero-medially to reach the posterior border of the Pterygomasseteric sling. This sling was incised from the posterior border, the masseter muscles was stripped laterally to reach the fractured site. Fracture site was exposed and identified and reduced in normal anatomic position. Maxillo-mandibular fixation was done and fracture fragments were fixed with either TCP using 6 or 8 mm screws or with two 2mm conventional miniplates.



Figure 1. Markings of Incision

(Figure 2; a-b) The clinical parameters evaluated in our study were maximum inter-incisal mouth opening, range of mandibular movements and bite force efficiency, measured by using a bite force evaluating machine. Radiographical evaluation was done for assessing plate fracture, and loosening of screws using the OPG and PA view of the mandible (Figure 3). These parameters were evaluated pre-operatively, immediate postoperatively, 3 months and 6 months post-operatively. Descriptive statistical analysis was done using unpaired t-test, Chi square test and p-values were calculated to establish the significance level. P value of < 0.05 was considered to be significant.



Figure 2. Showing surgical site after reduction and fixation with (a) 3-D trapezoidal condylar plate and (b) Conventional miniplate

### Results

Out of the 20 patients in our study, 16 patients were male and 4 were females, mean age of patients was 38.85 years. Mouth opening was found to be increased in both the groups, with time. Maximum inter-incisal mouth opening (measured at immediate postop, 3months and 6 months) and an intergroup comparison was done (Figure 4, Figure 5) Statistically significant results were seen only in case of immediate post operative mouth opening where p value calculated was  $0.023 < 0.05$  with Group A(TCP) showing better results than group B. Mean values of Right lateral movements, left lateral movements and protrusive movements together in a single variable called as Range of Mandibular Movements and the mean value for each movement were calculated (Figure 6-8).



Figure 4. Three months post operative picture showing adequate mouth opening

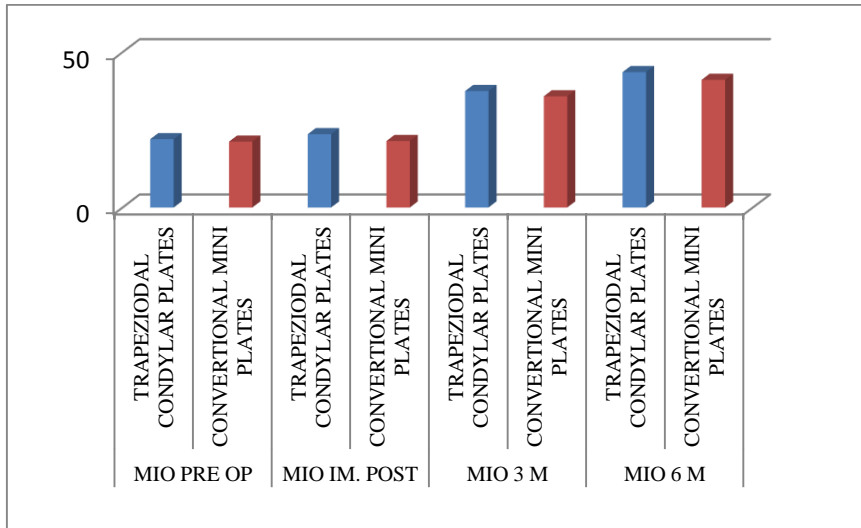


Figure 5. Maximum inter-incisal mouth opening (MIO) measured in mm

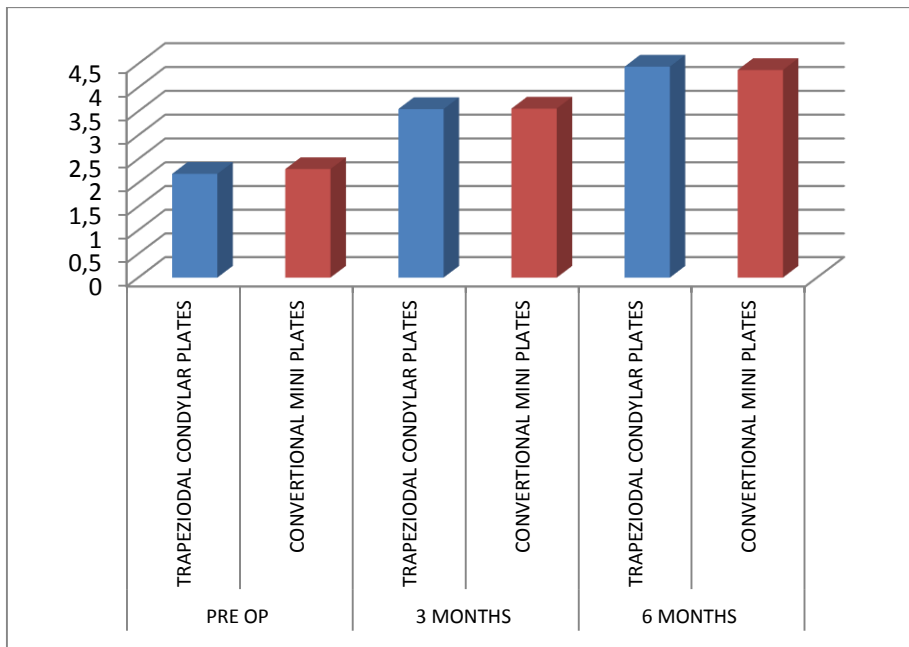


Figure 6. Protrusive movements (mm)



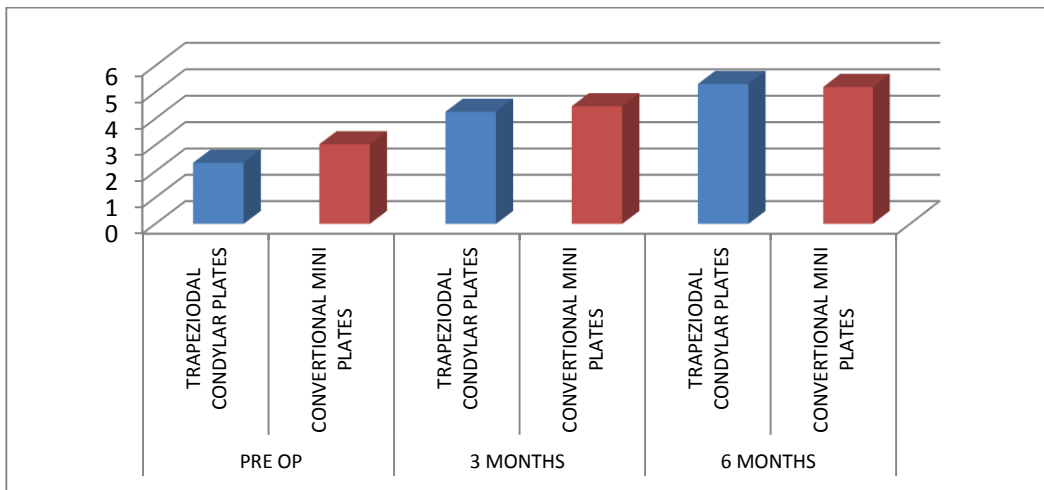


Figure 7. Right lateral movements (mm)

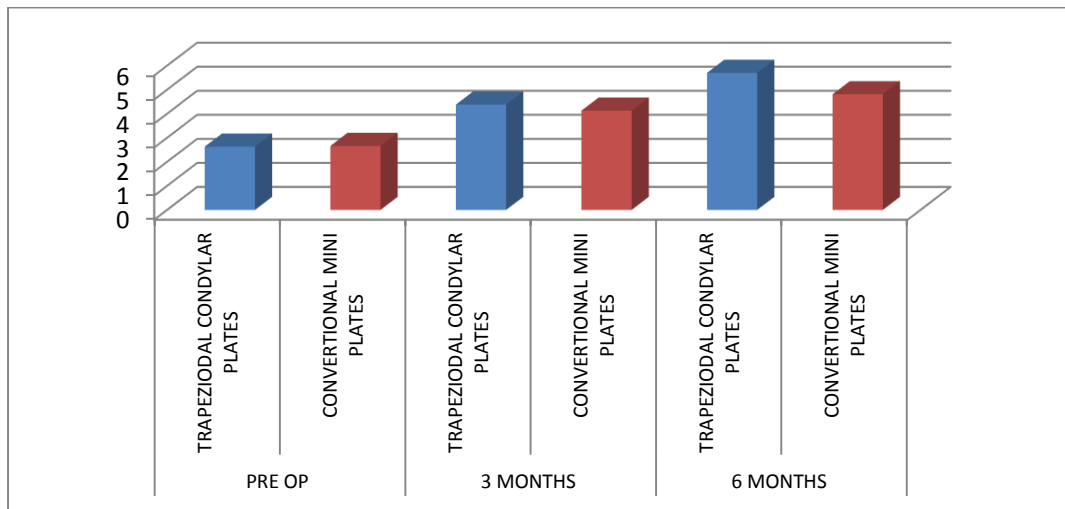


Figure 8. Left lateral movements (mm)

The results of the intergroup analysis were found to be statistically insignificant, though the results obtained by using 3D-TCP plates (Group A) were marginally better. The p values comparing bite force between Group A and Group B for bite force efficiency present at immediate post op, 3 months and 6 months were 0.330, 0.093 and 0.515 respectively which were more than  $> 0.05$  thus making the statistical results to be insignificant for this variable in our study (figure 9). Plate fracture was not seen in any of the two groups at any stage of the study postoperatively. 2 out of a total of 10 patients in Group A (TCP) showed evident screw loosening after 3months postoperatively with no clinical implications reported but no case of screw loosening was reported in Group B where conventional miniplates were used (Figure 10).

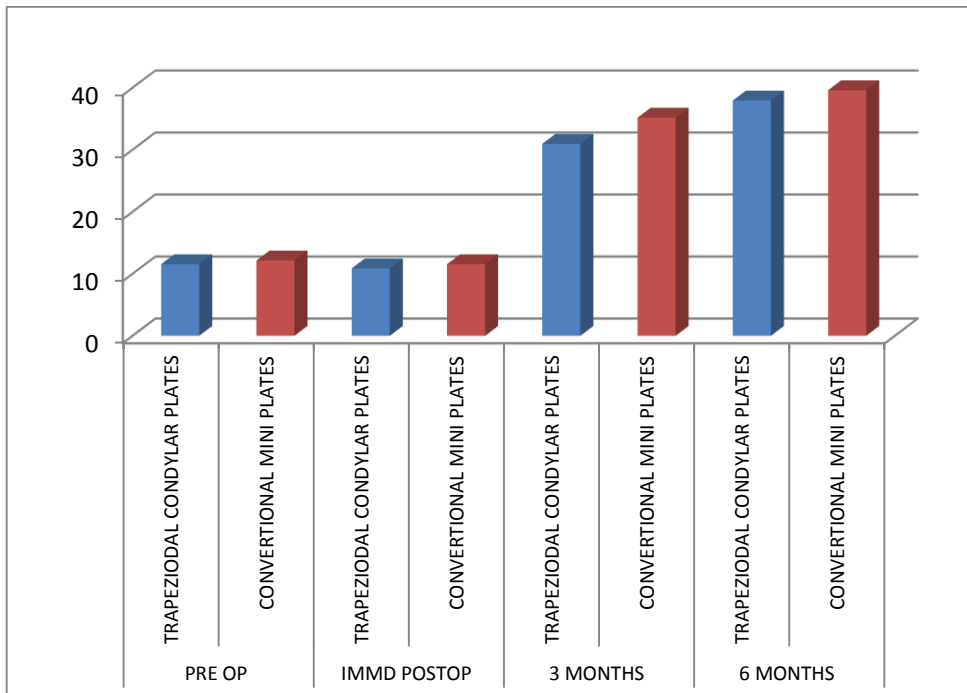


Figure 9. Post operative bite efficiency (KG/CM<sup>2</sup>)

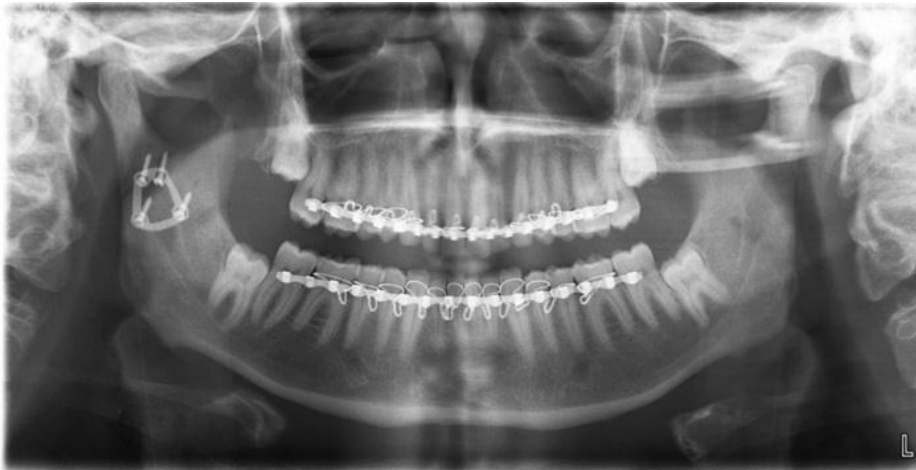


Figure 10. Screw loosening seen in a case of fixation with TCP

## Discussion

Open reduction and internal fixation of condylar fractures is a suitable method for managing condylar fractures, especially in cases with gross displacement of condylar fragment, considerable reduction in posterior facial height and deranged occlusion. The placement of a single 4- or 6-hole straight miniplate vertically on the posterior border of the condylar neck remains the most commonly used technique worldwide (Ehrenfeld et al. (1996); Undt et al. (1999); Ellis III et al. (2000); Haug & Assael (2001); Hyde et al. (2002); Wagner et al. (2002)). Many



authors reported evidence of the high failure rate with this technique (up to 35%), including plate fractures, screw loosening and structural instability (Klotch & Lundy, 1991; Iizuka et al., 1998; Ellis III & Dean, 1993; Sugiura et al., 2001; Rallis et al., 2003). Then the use of two 2.0 mm miniplate technique (one is placed along the axis of the condylar neck and the other is placed obliquely beneath the mandibular notch) was advocated which provided significantly better results (Tominaga et al., 2006; Asprino et al., 2006; Martini et al., 2006).

However, it is sometimes difficult to position 4 screws in the condylar fragment due to its small size and thus it is almost impossible to use it in cases of high sub-condylar fracture which resulted in the development of the 3-D trapezoidal plates for the stabilization of subcondylar fracture (Giroto et al., 2012). The aims of these trapezoidal-shaped plates are to respect the principles of functionally stable osteosynthesis stated Champy et al. (1986), which was later modified (Meyer et al., 2002). The 3-D plate holds the fracture fragments rigidly by resisting the forces in three dimensions namely shearing, bending, and torsional force. TCP is placed in such a way that one arm lies parallel to the condylar axis and the second one is placed obliquely, corresponding to the mandibular notch. Infection rate is low because of the reduced hardware and less surgical exposure as compared to two–4 hole straight miniplate technique (Chaudhary et al., 2015). Biomechanical and clinical studies have confirmed that 3-D plates allow for sufficient neutralization of strains. The trapezoidal shaped condylar 3-D plates fulfill most of the required prerequisites for rigid fixation of sub-condylar fractures which allows for an increased number of screws, stability in three dimensions and resistance against torque forces while maintaining a low profile and malleability<sup>33</sup>, so it can be effectively used as an alternative to the modified 2-miniplate technique.

In our study maximal Interincisal mouth-opening (MIO) was restored to normal in all the cases. Mouth opening gradually increased at successive follow ups done at 3 months and 6 months for each Group A and Group B respectively, Group A showed better clinical results showing greater increase in mouth opening as compared to Group B. Similar results were also obtained in the studies done (Gupta et al., 2012; Spinzia et al., 2014). The range of mandibular movement was assessed by calculating the mean values of protrusive and right and left laterotrussive movements of the mandible taken at 3 and 6 months follow up in both groups. The mandibular movements increased gradually from pre-op to 3 and 6 months post-operatively in both the groups respectively. The mean values of all the excursive movements were greater at successive follow ups. Studies by Gupta et al. (2012); Spinzia et al. (2014), also showed similar kind of results. As the p values obtained after comparing the left lateral, right lateral and protrusive movements for both the groups were more than 0.05, so the results of the intergroup analysis were found to be statistically insignificant, though the results obtained by using 3D-TCP plates (Group A) were marginally better as compared to Group B.

Post-operative bite force efficiency was accessed by measuring the maximum voluntary bite force by a simple customized bite force recorder measured at the 1st molar region on both the fractured and the non-fractured side and then a mean value was taken as the representative value which is accordance with a

study by [Shinogaya et al. \(2002\)](#), which reported that 80% of the total bite force is disseminated in the molar region. Mean maximum bite force was found to be significantly higher in males than females which is in accordance with a study ([Jain et al., 2013](#)). p values comparison of recorded bite force between Group A and Group B at immediate post op, 3 months and 6 months were 0.330, 0.093 and 0.515 respectively which was greater than  $> 0.05$  thus making the statistical results to be insignificant for this variable in our study, though Group B had shown better clinical results than Group A under this parameter, this might be due to the presence of gender bias arising in our study with more number of females in Group A as compared to group B giving rise to false positive results in favour of Group B (2 mm Conventional miniplates).

Plate fracture was not seen in any of the patients, this is in accordance ([Singh et al., 2013](#); [Meyer et al., 2008](#)). The incidence of screw loosening was encountered in 2 cases (20%) out of 10 patients in Group A (TCP) only; no screw loosening was seen in Group B (Conventional miniplates). Screw loosening, resulting in inadequate fracture stability in case of TCP have been reported at a rate of 4% to 20% by [Ellis III \(1998\)](#); [Hammer et al. \(1997\)](#); [Klotch & Lundy \(1991\)](#), which is in accordance with our study. The screw loosening seen in Group A was from the proximal fragment that too recorded only on 2nd follow up i.e. 3 month similar to what was observed ([Spinzia et al., 2014](#)). The main explanation for the screw loosening seen in the proximal segment in Group A (TCP) in 2 cases might be due the anatomical variations seen in the high sub-condylar fracture patients with thin and narrow condylar neck, thus making it difficult to place two screws in the proximal segment where less space is available, thus eventually leading to the development of 3D Delta plating systems. In this study we achieved reasonably better results with 3D- TCP as compared to 2mm conventional miniplates, though our intergroup analysis did not give us statistically significant results in all our variables.

### **Summary and Conclusion**

In this study we found both the plating systems equally effective with respect to stability and function in the management of subcondylar fracture. Even though 3D TCP were more stable but it has its limitations in the proximal fragment of the fracture. The width of the TCP plate is predetermined by the manufacturer. This is more suitable for the cases where good width of bone is present at the fractured site. Conventional miniplates can be still used successfully in the management of condylar fractures depending upon numerous factors like the cost involved and space available for plating. The small sample size arising in the inter group analysis could be considered as the limitations of this study. Further study with larger sample size is required for establishment of these results.

### **Conflict of interest**

The authors disclose no conflict of interest.

### **Declaration of patient consent**

The authors certify that they have obtained all appropriate patient consent forms. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be warranted

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### **Availability of data and material**

The authors confirm that the data supporting the findings of this study are available within the article.

### **Guarantor of submission**

The corresponding author is the guarantor of submission

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