Original Article

Efficacy of bioresorbable plates in the osteosynthesis of linear mandibular fractures

ABSTRACT

Background and Objectives: There are limited evidences available about the performance of biodegradable system in the treatment of linear mandibular fractures without the aid of postoperative maxillomandibular fixation (MMF). Hence, the present study was planned to evaluate the treatment outcomes in mandibular fractures, using 2.5 mm bioresorbable plates and screws without postoperative MMF.

Methodology: This cohort study compares both prospective and retrospective data. The prospective study treated 20 adult patients with linear mandibular fracture using bioresorbable plates and screws, without using postoperative MMF (Group 1). Retrospective data were collected from a previous published study in which patients were treated with bioresorbable plates and screws with 2 weeks postoperative MMF (Group 2) and those treated with metal plates and screws without postoperative MMF (Group 3). Group 1 patients were followed up at 2 and 4 months to evaluate the functional outcomes in terms of fracture mobility, malocclusion, pain, and soft-tissue deformity and compared with its preoperative findings. Further, the treatment outcomes of Group 1, Group 2, and Group 3 were compared among themselves at 2-month follow-up.

Results: Group 1 patients showed a significant improvement in the treatment outcomes at 2 and 4-month follow-up. In addition, when 2 months postoperative outcomes were compared among the three groups, no statistically significant difference was observed in the treatment outcomes.

Conclusion: Endpoint osteosynthesis can be achieved with the bioresorbable fixation system when used in the treatment of un-displaced linear mandibular fractures, without postoperative MMF. A minor modification of using a lower size osteotomy drill can prevent screw loosening.

Keywords: Bioresorbable plates, mandibular fracture, maxillofacial trauma, maxillomandibular fixation, screws, titanium plates

INTRODUCTION

With the current understanding of maxillofacial trauma, most fractures are being treated with open reduction and internal fixation. The desire for precision and predictability have led to leap and bound innovations in the field of craniomaxillofacial (CMF) implants. Today, three-dimensional (3D) printing allows us to customize implants, which are precise to millimeters.[1-5] This facilitates ease of handling, quality control, and higher biomechanical strength.

Perhaps, metallic plates and screws seem to be perfect for the job, but the requirement of fixation is only temporary, and removal of the implant becomes desirable in most situations.[5,6] Thermal sensitivity, the potential effect on bony growth, migration of plates, and interferences with imaging are some of the major drawbacks of metallic CMF implants, which necessitates their retrieval after complete osteosynthesis. Medication-associated jaw necrosis in the presence of titanium CMF implants has also been reported.[7,8]

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Figure 1: Preoperative occlusion (left posterior open bite)

Figure2: Preoperative radiograph showing fracture at right parasymphysis and left angle (arrow)

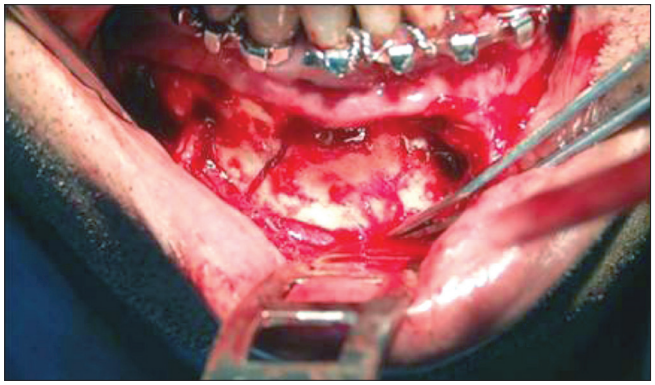

Figure 3: Parasymphysis fracture

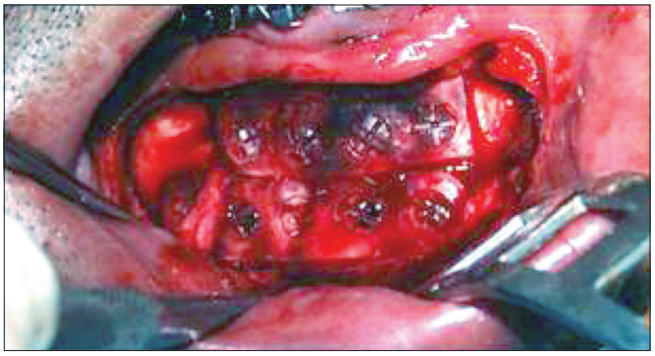

Figure 4: Bioresorbable plates and screws in place at parasymphysis fracture

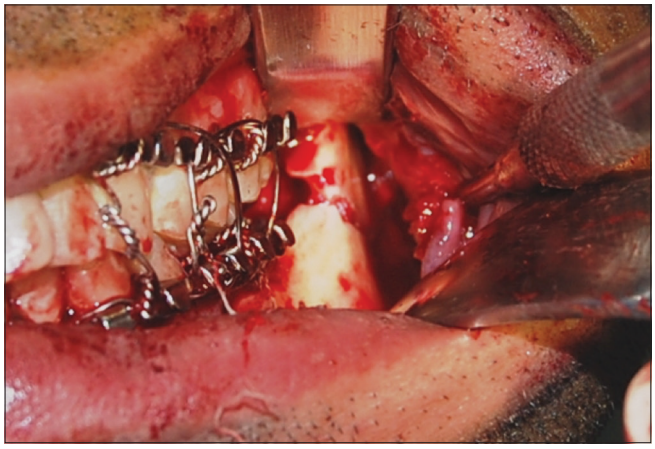

Figure 5: Left mandibular angle fracture

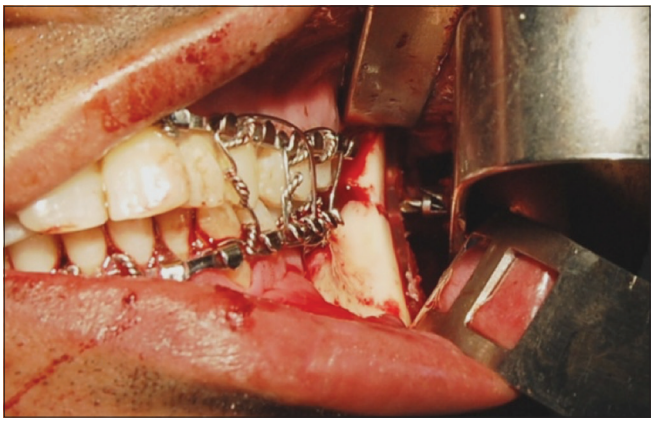

Figure 6: Fixation using transbuccal instrumentation at left mandibular angle. Arrow showing bioresorbable plate in place

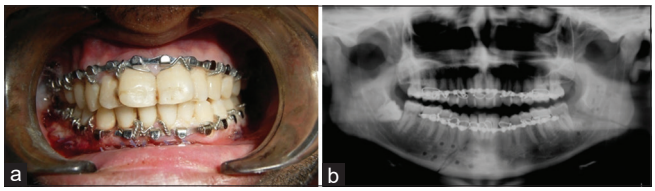

Figure 7: (a and b) Immediate postoperative occlusion and radiograph

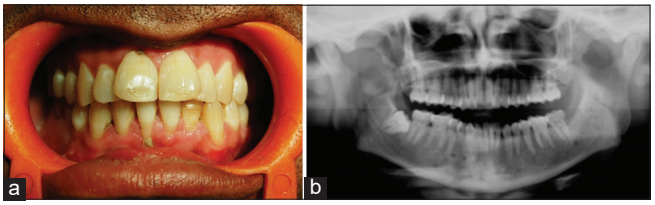

Figure 8: (a and b) Four months follow-up occlusion and radiograph showing fracture segment in proper reduction

To overcome such limitations, bioresorbable fixation system has been developed. They provide several advantages and are being considered as a reliable and effective fixation system. There were no need for implant removal, complete resorption, less postoperative pain, not much affected by extreme climate changes, minimal stress shielding effect (as

Figure 9: The lines drawn at the screw holes are unparallel, suggesting a fracture of the plate. The arrow shows the displaced fracture segment

they resorb over time), and qualifies them over metallic counterparts.[9,10] Early studies of the bioresorbable system observed uneventful primary healing of fractures, with progressive degradation of the implants.[11,12] Many recent innovations have been made since then to improve the bioresorbable fixation system.[13]

However, an inflammatory response to the by-products and lesser mechanical strength make it use questionable.[14-17]

Despite all, the use of bioresorbable system is becoming common because of its ease of use, easy adaptability, safe material, and complete absorbability.[14-18] The challenge of its mechanical inferiority is well taken by various researchers and have concluded no statistically significant difference between Ti and bioresorbable plates and screws in osteosynthesis of mandibular fracture.[19-22] However, postoperative MMF (for various durations) was used as an aid where bioresorbable fixation was applied.[20-22] This is in contrast with the AO principal of early mobilization and function.

Thus, the present study was planned to evaluate the treatment outcomes of mandibular fractures, using 2.5 mm bioresorbable plates and screws without postoperative MMF, according to the parameters of care given by the American Association of Oral and Maxillofacial Surgeons (AAOMS).

Objectives

Primary objective

The primary objective was to assess the treatment outcome of simple mandibular fractures in terms of mobility, malocclusion, pain, and paresthesia using bioresorbable plates and screws without postoperative MMF at 2 and 4-month follow-up.

Secondary objective

The secondary objective was to assess the treatment outcome of simple mandibular fractures (in terms of mobility, malocclusion, soft-tissue deformity, pain, and ability to eat hard foods) using three different methods of treatment, that is, bioresorbable plates and screws without postoperative MMF (Group 1), bioresorbable plates and screws with postoperative MMF (Group 2), and titanium plates and screws (Group 3) at the end of 2 months.

Research question

1. Is postoperative MMF required in the osteosynthesis of linear mandibular fractures when treated with 2.5 mm bioresorbable plates and screws?
2. Is there any significant difference in the treatment outcomes of linear mandibular fractures using three different treatment modalities (bioresorbable plates without postoperative MMF, bioresorbable plates with postoperative MMF and metallic plates)?

METHODOLOGY

This cohort study was conducted in the Department of Oral and Maxillofacial Surgery, Center for Dental Education and Research at All India Institute of Medical Sciences in New Delhi (India) from May 2009 to Dec 2010. The permission to conduct this study was granted by the Institute's Ethical Committee.

Based on the study objectives to compare the treatment outcomes of linear mandibular fractures using three different methods of fracture reduction and fixation, we used two types of data collection process; prospective and retrospective.

Prospective data collection (Group 1)

We enrolled 20 adult patients aged 18–60 years, who presented with linear mandibular fractures (symphysis, parasymphysis, body, or angle) to the department after taking their informed consent. This sample size was estimated on the number of such patients we expected to visit the department during the data collection period based on the previous year's medical records. Patients with mid-face trauma, comminution or bone loss, fracture more than 10 days old with or without signs of infection, condylar or subcondylar, and ASA-3 and above were excluded from the sample.

In this part of the study, we used a bioresorbable fixation system (Inion, Tempere, Finland 2.5) for treating mandibular fractures to achieve the primary endpoint of the clinical union without postoperative MMF (Group 1). An individual patient record sheet was used to collect the data. After recording the relevant baseline data (age, sex, mode of trauma, site of fracture, findings of clinical examination, and radiographic investigations), closed reduction and MMF were

done for all the enrolled patients. Antibiotic and analgesics premedication were prescribed and chlorhexidine/betadine mouthwash was advised.

After completing the basic laboratory investigations, patients were posted for (Open Reduction and Internal Fixation)ORIF under general anesthesia or local anesthesia within 72 h of reporting. Both intraoral and extraoral approaches were used as per the requirement. These data were also recorded for every patient. The fracture was exposed and anatomically reduced using the standard approach. Plates were placed along the Champy's ideal lines of osteosynthesis for anterior fractures and on the lateral surface for angle fractures. The resorbable plates were preheated in water bath at 55°C for 1 min and then adapted to the fracture site with the special plate bending pliers. 2.0 mm drill bit, with a maximum speed of 2000 rpm, with copious irrigation, was used to create a minimum of two holes on either side of the fracture line followed by 2.5 mm tap. Plates were stabilized with 2.5 mm diameter screws. MMF was removed. Stability and occlusion were checked. Antibiotics with analgesics were continued for 3 postoperative days. Patients were kept on a semisolid diet for 2 weeks. Follow-up data were collected after 3, 10, 30, 60, and 120 days postoperatively [Figures 1-8].

The postoperative data consisted of findings from clinical examination based on AAOMS parameters of care such as stable occlusion, plate exposure, segments mobility, signs and symptoms of infection, and pain using a visual analog scale. Radiographic evaluation (panorex/posteroanterior view of the mandible) was done and recorded to check for proper reduction and alignment of the lower border of the mandible, immediately and 120 days postoperatively.

Retrospective data collection (Group 2 and Group 3)

This data collection method consisted of the previously published data which used other two types of treatment methods for reducing and fixing the simple mandibular fractures. In one method, the patients were treated with bioresorbable plates and screws with 2 weeks postoperative MMF (Group 2).[19] In the other method, similar patients were treated with titanium plates and screws, without postoperative MMF (Group 3).[19]

The same patient record file was used to collect data so that we could compare the three treatment methods of simple mandibular fractures. The data were entered into Microsoft Excel and analyzed using SPSS 22.0 v software (IBM corporation).

Preoperative and postoperative variables were analyzed among the three groups; the present study (Group 1), published data with postoperative MMF (Group 2), and published data with titanium plates and screws (Group 3). Fisher's exact test was applied for the statistical analysis. For age preoperative variables, one-way ANOVA was used.

RESULTS

General characteristics of patients from whom data was collected prospectively (Group 1)

This group consisted of 20 patients (male: 19; female: 1) with a total of 25 mandibular fractures having a mean age of 32.75 years (SD 11.07; range 18–56). Of the total 20 patients, 75% ($n = 15$) suffered single fractures and 25% ($n = 5$) suffered combined fractures of the mandible, excluding condyle. There were 16% (4) displaced fractures without overriding. No bone loss or infection was observed at the time of intervention. All patients reported within 10 days of trauma. The treatment was done under local anesthesia for 80 cases ($n = 16$) and 20 ($n = 4$) were operated under general anesthesia. All the anterior mandibular fractures were approached intraorally, whereas angle fractures were approached using transbuccal technique except one which was exposed via a submandibular approach.

Comparing preoperative baseline characteristics of participants in three groups

There was no significant difference in the baseline characteristics of the three treatment groups, as shown in Table 1 ($P \geq 0.05$).

Postoperative functional outcome of Group 1 patients

The postoperative functional outcomes of Group 1 patients were observed and compared based on the AAOMS parameters of care, at the end of 2 and 4 months [Table 2]. Significant reduction in the mobility and pain was noted at 2 and 4 months postoperatively. Similarly, paresthesia was reduced to zero after 4 months. One patient developed malocclusion 2 weeks postoperatively and was subjected to 8 weeks MMF. Thereby, normal occlusion was achieved by the end of the last follow-up, as shown in Table 2.

Comparing the postoperative functional outcomes among the three different treatment groups at 2-month follow-up

The three treatment groups Group 1 (bioresorbable without postoperative MMF) vs. Group 2 (bioresorbable with 2 weeks postoperative MMF) vs. Group 3 (Titanium plates and screws) were compared in terms of functional outcome after 2 months postoperatively. No difference was found among the three groups in achieving a good functional outcome in terms of reducing mobility, malocclusion, soft-tissue deformity, pain, and inability to chew hard food, suggesting that all the three

Table 1: Preoperative baseline characteristics of three treatment groups

Preoperative baseline characteristics	Group 1 (*n*=20)	Group 2 (*n*=19)	Group 3 (Ti) (*n*=21)	*P**
Age**, mean (SD)	32.75 (11.07)	26.63 (8.13)	28.7 (10.04)	0.546**
Sex				
Male	19 (95)	18 (94.74)	20 (95.24)	0.997
Female	1 (5)	1 (5.26)	1 (4.76)	
Site of fracture				
Angle	8 (40)	5 (26.3)	5 (23.8)	0.657
Symphysis	0	0	1 (4.7)	
Parasymphysis	5 (25)	7 (36.8)	2 (9.5)	
Body	2 (10)	1 (5.2)	2 (9.5)	
Combined fractures	5 (25)	6 (31.6)	11 (52.4)	
Number of fractures				
1 (single)	15 (75)	13 (68.4)	10 (47.61)	0.164
2 (double)	5 (25)	6 (31.6)	11 (52.38)	
Tooth in fracture				
Present	14 (70)	14 (73.68)	18 (85.71)	0.46
Absent	6 (30)	5 (26.32)	3 (14.28)	
Displaced fractures				
Yes	4 (16)	8 (32)	12 (37.5)	0.05

All numbers in parenthesis are percentages. *Fisher exact test, **One-way ANOVA test. SD: Standard deviation

Table 2: Postoperative findings (at 2 months and 4 months) of Group 1 compared with preoperative measures

	Preoperative	At 2 months postoperative	At 4 months postoperative	*P**	*P***
Mobility	20	1	0	**0.0001**	**0.0000**
Malocclusion	4	1	0	0.08	**0.045**
Pain	20	4	0	**0.0001**	**0.0000**
Paresthesia	10	4	0	**0.014**	**0.0016**
Inability to chew hard food	5	0	0	NA	NA

Fischer exact test was used, **P*: Significance testing of Group 1 patients preoperatively and at 2 months postoperatively, ***P*: Significance testing of Group 1 patients preoperatively and at 4 months postoperatively. *P* values in bold indicate significant value ≤0.05. NA: Not available

Table 3: Postoperative comparison among three treatment groups at 2 months postoperative

Postoperative parameters	Group 1	Group 2	Group 3	*P**
Mobility	1 (5)	1 (4.17)	0	0.891
Malocclusion	1 (25)	2 (11.1)	1 (7.7)	0.716
Moderate soft tissue deformity	0	2 (8.3)	0	0.816
Inability to chew hard food at 2 months	0	2 (11.1)	1 (7.7)	0.756

All numbers in parenthesis are percentages. *Fischer exact test was used

types of treatment modalities could achieve similar functional status by the end of 2-month follow-up [Table 3].

DISCUSSION

Early pain-free mobilization is the primary goal of fracture treatment.[23] The fixation system has been advanced form transosseous wiring to today's 3D-printed implants to match the finest requirements of biomechanics.[1,3-5] However, the challenge of a metallic fixation system still prevails.[5-8] To counter such complications, much development has been made in bioresorbable plates and screws which allows early pain-free fracture healing.[12,24-28] However, their efficacy in providing stability to the fracture of high load-bearing regions such as mandibular fractures is still under research.

To counteract its weak mechanical properties, manufacturer advises (via vitro study) MMF for 3 postoperative days.[29] However, soft-tissue stabilization, bony biomechanics, and reduced bite forces (immediately after fracture) differ in real-time situation than laboratory scenarios. Various researchers have tried different timeline for post-operative MMF for various reasons.[19-22,29,30] Perhaps, 1–2 week postoperative MMF will probably not cause "fracture disease," but it is in contrast with the principle of early mobilization. Thus, keeping the possibilities of avoiding post-operative maxillomandibular fixation (MMF) without compromising on the stability of fracture segments, the present study was planned.

Loss of stability has always been a major concern and its incidence from the previous titanium mini plates studies ranged from 0 to 8.7.[31-33] Wood[29] and Ferretti [21]in their study used 4 weeks of postoperative MMF with bioresorbable plates and screws and found no case of nonunion at the end of the study. Similarly, Bayat *et al.*,[22] Laughlin *et al.*,[20]

and Group 2 of the present study[19] used MMF for 2 weeks postoperatively with 0–5 of early malocclusion with satisfactory performance of the bioresorbable material in terms of stability. In the present study, no malocclusion was found either at the 1st week or on subsequent follow-ups, without the aid of postoperative MMF, although some minor occlusion discrepancies were observed on initial follow-ups, which got corrected by its own.

It seems that the less rigid biodegradable implants allow a minimal but smooth settling of the occlusion while at the same time providing a stable reduction of the fracture. Leonhardt *et al*.[34] also used the bioresorbable system without MMF. However, in contrast to our findings, they found malocclusion in 40 patients at the 1st postoperative week, for which MMF was given for 1 week. No malocclusion was found at 24-week follow-up. This difference could be because of the lesser number of angle fractures in the present study (40) as compared to Leonhardt study (60). Angle fractures are been reported with most complications.[35] Furthermore, 32 cases in Leonhardt study were displaced and overlapped which is in contrast to the present study. Thus, it could be inferred that the 2.5 mm bioresorbable plates and screws can be used in linear un-displaced mandibular fractures predictably to achieve endpoint osteosynthesis.

The incidence of initial fracture mobility ranges up to 4%.[19,20,22] One patient in the present study developed malocclusion 2 weeks postoperatively due to plate fracture. Such implant failure could have been appreciated on panorama by locating displaced screw holes and discontinuity of the lower border of the mandible [Figure 9]. This could be attributed to the heavy perioral musculature of the patient which produced forces above the biomechanical strength of the plate. For this patient, 8 weeks of rigid MMF restored preinjury occlusion and bony union. However, the rest of the present study patients achieved endpoint bony union without postoperative MMF. This is further supported by similar studies which did not use postoperative MMF, and all fractures healed both clinically and radiologically.[36,37]

Various incidences of infection and wound dehiscence have been reported by various authors while using both metal and bioresorbable fixation system as a treatment modality [Table 4].[19,21,38,39] In these reports, most complications were observed when bioresorbable plates were used in the treatment of angle fracture. This may be due to the bulky size of these plates which makes their application difficult on the external oblique ridge.[35] Comparable complication rates (5%) were observed in the present study. One patient reported 1 week postoperatively with soft-tissue dehiscence without plate exposure. It responded well to wound dressing and resuturing.

Table 4: Comparison of complication rates of various authors with the present study

Author	Sample size	Duration of MMF	Healing and other complications (%)*
Ferretti[21]	45 fractures	4 weeks	22
Laughlin *et al*. (2007)[20]	50 fractures	2 weeks	6
Bayat *et al*.[22]	19 angle fractures	2 weeks	10.5
Bhatt *et al*.[19] (Group 2)	25 fractures	2 weeks	11
Leonhardt *et al*.[34]	30 patients	NA	33
Yerit *et al*.[37]	89 fractures	NA	2.5
Ylikontiola *et al*.[36]	10 fractures	NA	10
Lee *et al*.[35]	47 patients	NA	4.26
Present study (Group 1)	25 fractures	NA	5

*Complication mostly included soft tissue dehiscence and plate exposure. MMF: Maxillomandibular fixation, NA: Not available

Chronic pain has been reported in both metallic (2%–8%) and bioresorbable fixation system (0%–14%).[19,20,39,40] In the present study, 4 patients (20%) reported mild pain with a VAS score of 1–3 at 2 months which reduced to nil at 4-month follow-up. This complication is more or less related to the surgical technique rather than the plate stability and MMF.

The need of implant removal is a major drawback with metal plates and screws. Various reports suggest the requirement in 12–33 of the cases.[38,40] In Group 3 of the present study, 31 metal plates were removed after healing. Patients request for implant removal predominates over the other causes. Inflammatory reactions around a metallic implant are also well-documented. Similarly, degradation of bioresorbable plats and screws elicits mild-to-moderate inflammatory reaction.[6,13-15,41] In the present study, no inflammatory repose was noted till 4 months. This is attributed to the fact that the biodegradation process depends on the mechanical structure of the implant and host response.[6,15,41]

Novel modification in the technique

Instead of using the recommended 2.25 mm drill with 2.5 mmm tap (thread width of 0.25 mm), a 2.0 mm drill with a 2.5 mm tap (thread width of 0.5 mm) was used in our study. This avoided frequent screw loosening. Where screw loosing was observed, emergency screws were used.[19]

Study limitation

In our study, we found that the treatment outcomes among all the three treatment groups were statistically similar. This suggests that the biodegradable plates and screws can be effectively used with or without MMF to achieve the functional outcome in linear un-displaced mandibular

fractures. However, this finding needs to be interpreted with a lot of caution. This may be due to the small size of the current study that we could not assess the real difference between the three groups. For this, a well-planned randomized controlled trial with a sample size of at least 39 patients in each group will be needed.

CONCLUSION

The present prospective study and comparison with published data suggest that endpoint osteosynthesis can be achieved with the bioresorbable fixation system when used in the treatment of un-displaced linear mandibular fractures without postoperative MMF. A minor modification of using a lower size osteotomy drill can prevent screw loosening. The system itself is technique sensitive and thus has a relatively steep learning curve. In mandibular angle fractures, relatively wide exposure and lateral border fixation using a transbuccal trocar are required due to the bulkiness of plates.

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Conflicts of interest

There are no conflicts of interest.

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