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EVALUATION OF THE STABILITY OF IMMEDIATE IMPLANT PLACEMENT IN MANDIBULAR MOLAR INTER-RADICULAR SEPTUM USING OSSEODENSIFICATION TECHNIQUE (CLINICAL TRIAL)

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ABSTRACT

BACKGROUND: Immediate implant placement (IIP) is a valid technique for replacement of badly destructed teeth with fewer surgical procedures and increased levels of patient comfort.

OBJECTIVES: To evaluate the stability of immediate implant inserted in mandibular molar inter-radicular septum using osseodensification technique.

MATERIALS AND METHODS: Ten patients with ten lower molars to be extracted were chosen according to a list of inclusion and exclusion criteria. The participants undergone atraumatic tooth extraction, then the inter-radicular septum was densified using densah burs, immediate implants were installed, followed by bone graft placement in the gap between the implant and the socket walls, and a healing abutment was placed. Interrupted sutures were then placed around the healing abutment.

Assessment included measurements of implant stability using the Osstell device immediatel after implant placement and after 3 months post-operatively. Also, bone density surrounding the implant was measured pre-operatively, immediately post-operatively and after 3 months post-operatively.

RESULTS: The results revealed that Secondary Stability (ISQ) three months postoperatively with a mean±SD. of 76.20±5.43 was statistically significantly increased compared to Primary Stability (ISQ) immediately after implant insertion with a mean±SD. of 65.20±4.96(p<0.001). The bone density was significantly increased immediately postoperatively and three months postoperatively compared with preoperatively (p<0.001, p=0.002; respectively).

CONCLUSION: Osseodensification using densah burs was found to be an efficient procedure in increasing stability of immediately placed dental implants in molar inter-radicular septum.

KEYWORDS: Tooth extraction, osseodensification, immediate placement, implant osseointegration, implant stability.

RUNNING TITLE: Osseodensification of molar inter-radicular septum using densah burs.

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INTRODUCTION

Immediate implants have been a favorable treatment option to dental health workers and patients (1). Several challenges were identified in the aim of achieving early stability in molar extraction sockets. Anatomical restrictions that extend past the apex of the roots include the maxillary sinus above the maxillary teeth and the inferior alveolar canal below the mandibular teeth, as well as the unfavorable interradicular bone septum width, poor bone density and the extraction socket size (2). fortunately, the challenges may be solved by using atraumatic tooth extraction techniques that include meticulous root separation (3).

The osseodensification technique was first developed by Huwais and Meyer in 2016 (4). The utilization of densah burs in the preparation of implant sites has many benefits, as the enhancement of implant-bone contact via the process of compaction autografting, as opposed to the typical method of bone excavation using drills. The viscoelastic properties of bone play a significant role in this phenomenon. When tension is applied to bone over time, it results in strain that is also time-dependent. This characteristic enables dental implants to be inserted with greater torque and provides enhanced stability (4).

Instead of excavating bone, as is done in conventional osteotomy, Osseodensification (OD) using densah burs creates the osteotomy by simultaneously compacting and autografting the bone particles in an outward direction along the osteotomy

walls. This can be achieved by using the densah bur at a high velocity in a counterclockwise orientation (Densifying Mode) while maintaining a consistent copious irrigation (5).

Bone graft materials are frequently employed in various clinical cases, including ridge preservation, ridge augmentation, jumping gap filling in cases of immediate implants, and peri-implantitis. Alloplastic bone grafts provide many notable benefits as a reduced risk of infectious diseases compared to allogeneic and xenogenic bone grafts, and uniform product quality. The primary benefits of alloplastic bone grafts are to their inherent biological stability and capacity to maintain volume, hence facilitating cellular infiltration and remodeling (6).

β-tricalcium phosphate (β-TCP) is an osteoconductive material. It has a strong affinity for proteins that can stimulate stem cell differentiation and proliferation, resulting in new bone production and it can partly integrate into normal bone tissue (7).

The literature on osseodensification is limited to studies on animals and clinical cases with short-term follow-up, which hinders an objective assessment of the technique's advantages. One of the reasons for this limitation is the innovative nature of osseodensification drills, which are not yet widely used in standard implant clinical practice. This approach seems to be very promising when the bone is of poor quality (8).

The prime goal of the recent study was to evaluate the stability of immediately placed implants in mandibular inter-radicular molar septum using osseodensification technique. The null hypotheses of the recent study was that there wouldn't be significant effect for osseodensification on the stability of immediately placed dental implants in mandibular molar inter-radicular septum.

MATERIALS AND METHODS

This study is a single-arm clinical trial. Ten Participants were recruited from the Outpatient Clinic of Alexandria University Teaching Hospital and operated in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University. Research had been approved by the ethics committee at Faculty of Dentistry, Alexandria University. Approval number: 0589-01/2023 - 22/3/2023.

Materials

Vitronex- V-line dental implant system (Vitronex Milano, Italy).

Densah burs kit (ZGO™ DENSAH® BURS.USA).

Osstell ISQ – Monitor: OsstellTM device (Osstell ISQ, Stampgatan 14 SE 411 01 Gothenburg, Sweden, http://osstell.com).

β-tricalcium phosphate bone graft: Medbone (Medbone® – Biomaterials- Portugal).

Sample size estimation

The minimal sample size is calculated based on a previous study aimed to evaluate the precision of implant positioning utilizing the remaining roots of multi-radicular mandibular molars. Additionally, the study aimed to analyze bone density surrounding the implants and the stability of implants in freshly extracted sites (9). the minimum required sample size for this single-arm clinical trial was found to be 8 patients (10, 11). After adjustment for a dropout rate of 10%, the sample size was increased to 10 patients (12).

Eligibility criteria

The criteria for including patients were as follow:

Inclusion criteria

Patients age ranging between 25-40 years, with mandibular molar inter-radicular septum of 2.5 mm width or more with no periapical pathologies, or suppuration at the time of installing the implants and Non-smokers.

Exclusion criteria

Patients having systemic conditions which could alter the healing potential; examples are uncontrolled Diabetes Mellitus, metabolic bone disorders, autoimmune diseases, or Bisphosphonate therapy (13).

Pre-operative procedure (Figure 1)

Proper history taking was made for each patient.

Clinical investigation: Inspection and palpation to detect any swelling or abnormality in the implant site.

radiographic investigation: Cone-beam computed tomography (CBCT) (J. Morita Corp., Kyoto, Japan), was done to assess the septum size, bone density and bone height for proper implant selection and to elect the appropriate implant size.

Operative procedure (Figure 2) (14)

All the procedure was done on the dental chair under local anesthesia with inferior alveolar and buccal nerve block (4% articaine with 1:100,000 epinephrine).

Atraumatic removal of teeth was done by dividing the roots at the furcation without harming of the septum.

A pilot drill that is 1.3mm was used in clock-wise mode at 800-1200 rpm in the middle of the septum and advanced to a depth 1mm more than the intended length of the implant.

Subsequent densah burs were employed in the osseodensification (OD) mode, specifically in a counterclockwise direction at a drilling speed ranging from 800 to 1500 rpm with irrigation to gradually enlarge the osteotomy in a bouncing up and down motion (Figure 2A), until reaching the appropriate depth and diameter for the intended implant. All implants were seated with the aid of a manual ratchet, while recording the peak insertion torque (PIT).

Primary stability was measured using the Osstell device (Figure 2C). The gap was filled with

bone graft material (Figure 2D). The appropriate size of healing abutments was placed. Interrupted sutures around the healing abutment were placed using black silk 3-0 (Figure 2E).

Early postoperative care

Patients were given oral hygiene instructions.

Patients were given post-surgical medications including:

Amoxicillin 875mg + Clavulanic acid 125mg every 12 hours for 5 days (Augmentin: GalaxoSmithKline, UK).

Diclofenac potassium 50 mg every 8 hours for 3 days, then when needed (Cataflam: diclofenac potassium 50 mg: Novartis - Switzerland).

Chlorhexidine antiseptic mouth wash wash two times daily for 1 week starting from the second postoperative day. (Hexitol: Chlorhexidine 125mg / 100ml, concentration 0.125%: Arabic drug company, ADCO).

Sutures will be removed one-week post-surgery.

Post-operative evaluation

Clinical evaluation

Postoperative pain

Pain was assessed through a 10-point Visual Analogue Scale (VAS) (15). The patients were asked about the pain and discomfort from zero to ten (0-1 = none, 2-4 = mild, 5-7 = moderate, 8-10 = severe) every day after the surgery for one week.

Wound healing

The wound was examined at the 7th day and one month post-operatively for signs and symptoms of infection including swelling, redness, hotness and pus discharge in addition to observation for any manifestations of wound healing disturbance, as wound dehiscence.

Implant stability Quotient (ISQ) (Figure 3).

Implant stability Quotient (ISQ): The primary stability was measured during the operative stage immediately after implant placement, and the secondary stability was measured 3 months post-operatively to all the installed fixture.

Radiographical evaluation

Bone density: (Figure 4).

CBCT was performed pre-operatively to assess bone density of the inter-radicular septum by taking the mean value of 6 points in the septum along the roots of the tooth to be extracted by using OnDemand 3D™ sotware.

CBCT was also performed for the assessment of bone surrounding the dental implant immediately after implant procedure and after 3 months.

The bone density was measured in HU by taking the mean value of six points around the dental implant.

Prosthetic restoration (Figure 5).

Impressions were obtained after a period of three months, following which the prosthesis was then provided to all individuals within a span of two weeks.

Statistical analysis

The statistical analyzing of the obtained data

Data were collected and analyzed using Statistical Package for Social Science (SPSS) program (version 25). Kolmogorov-Smirnov test of normality of the distribution of the variables was not statistically significant, so parametric statistics was adopted. Data were described using minimum, maximum, mean, Standard Deviation (SD). Paired-sample t test was used for comparison between two time points of measurement.

During sample size calculation, beta error accepted up to 20% with a power of study of 80%. An alpha level was set to 5% with a significance level of 95%. Statistical significance was tested at p <.05.

Used tests were:

Paired-sample t test was used for comparison between two time points of measurement.

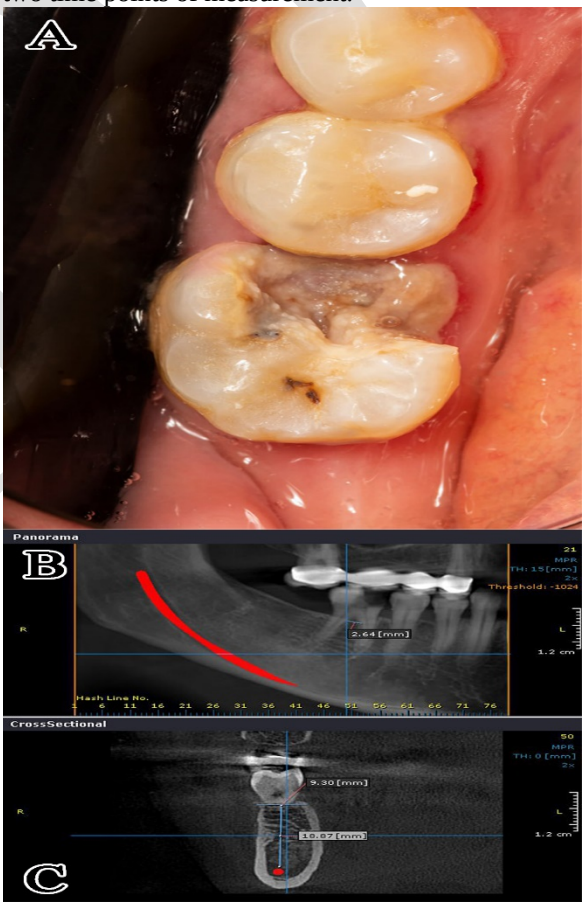

Figure (1): (A): Photograph showing lower right first molar (B, C): Preoperative CBCT.

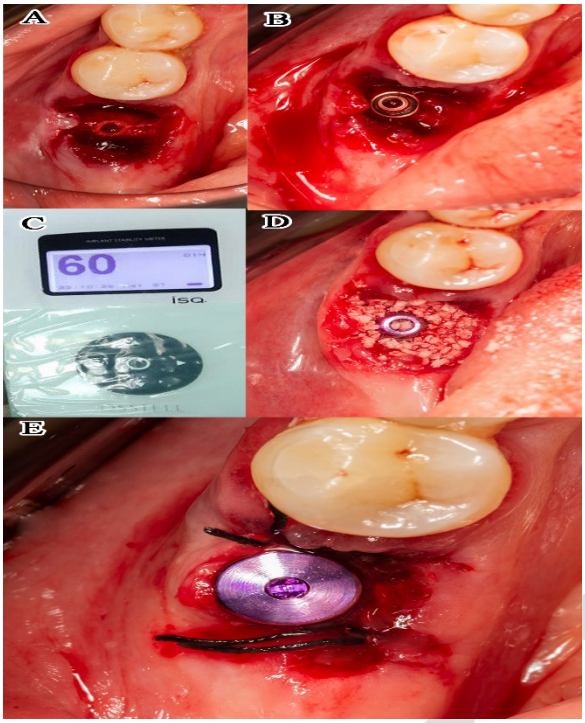

Figure (2): (A) Photograph showing osteotomy prepared by densah burs. (B) Photograph showing implant placed in the inter-radicular bone. (C) Photograph showing primary stability measured using ostell. (D) Photograph showing bone graft placed in the gap. (E) Photograph showing interrupted suture around the healing abutment.

Figure (3): Photograph showing secondary stability measured using ostell.

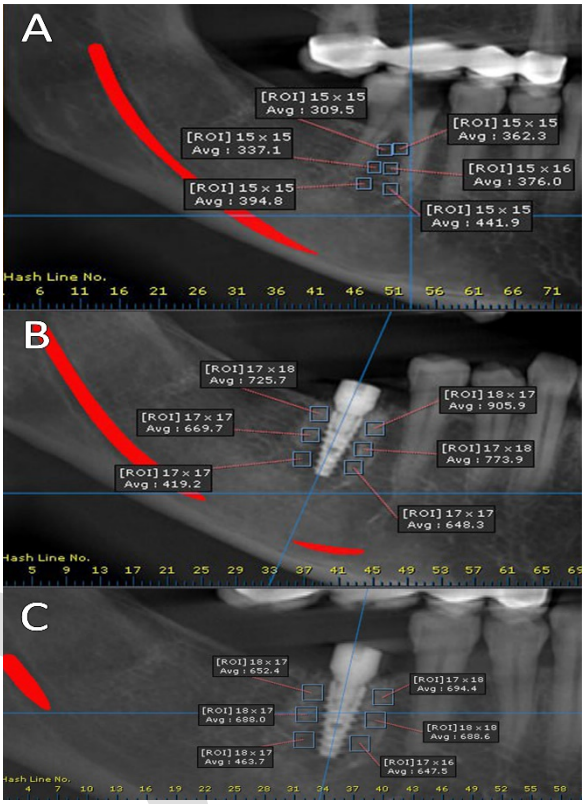

Figure (4): Radiographic CBCT showing (A): preoperative density of the inter-radicular molar septum. (B) Immediate post-operative density of the bone surrounding the implant. (C) 3 months post-operative density of the bone surrounding the implant.

Figure (5): Photograph showing final restoration

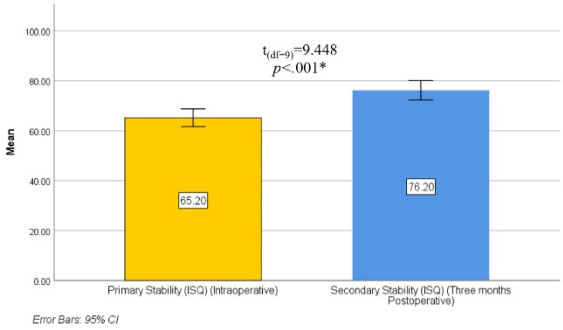

Figure (6): Mean Primary and Secondary stability in the studied group.

RESULTS

Demographic data (table 1)

A total of ten patients (3 males, 7 females) were enrolled in this study. They sought for replacement of badly destructed mandibular molar. The participants age ranged from 26 to 40 years with a mean±SD. Of 32.80±4.85 years. All patients were selected from the outpatient clinic of oral and maxillofacial surgery department, faculty of Dentistry, Alexandria university. 7/10 (70%) of implants replaced the first molars, and 3/10 (30%) of implants replaced the second molars.

Clinical evaluation data

Pain (VAS) score:

The pain was recorded every day after the surgery for one week by Visual Analogue Scale (VAS).

In Day 1 postoperative, VAS score ranged from 4.00 to 6.00 with a median of 5.00, in Day 2 postoperative it ranged from 1.00 to 5.00 with a median of 3.00, in Day 3 postoperative it ranged from 0.00 to 3.00 with a median of 1.00, in Day 4 postoperative it ranged 0.00 to 2.00 with a median of 0.50, in Day 5 postoperative it ranged 0.00 to 1.00 with a median of 0.00, in Day 6 postoperative it ranged 0.00 to 1.00 with a median of 0.00, in Day 7 postoperative it ranged 0.00 to 1.00 with a median of 0.00.

One day postoperative 10/10 (100.00%) patients had moderate pain. Two days postoperatively, 6/10 (60.00%) had mild pain and 4/10 (40.00%) had moderate pain. Three days postoperatively, 3/10 (30.00%) had no pain, and 7 (70.00%) had mild pain. Four days postoperatively, 5/10 (50.00%) had no pain, and 5 (50.00%) had mild pain. Five days postoperatively, 9/10 (90.00%) had no pain, and 1 (10.00%) had mild pain. Six days postoperatively, 9/10 (90.00%) had no pain, and 1 (10.00%) had mild pain. Seven days postoperatively, 10/10 (100.00%) had no pain.

VAS was significantly changed (in the direction of no pain) throughout the different time points of meaurements (p<0.001).

Wound healing:

The wound healing was evaluated after 7 days and one month postoperatively. All cases show normal healing; no signs of infection were observed.

Implant stability

Implant stability was measured immediately after implant placement and after 3 months post-operatively. (Table 2, Figure 6)

During the operative stage, the Primary Stability (ISQ) ranged from 58.00 to 71.00 with a mean±SD. of 65.20±4.96,

Three months postoperatively, the Secondary Stability (ISQ) ranged from 70.00 to 85.00 with a mean±SD. of 76.20±5.43,

The paired comparison revealed that Secondary Stability (ISQ) three months postoperatively was statistically significantly increased compared to Primary Stability (ISQ) immediately postoperative (p<.001).

The Implant Stability (ISQ) percentage change ranged from 6.06 to 26.67 with a mean±SD. of 17.07±6.27,

Radiographic evaluation data

Bone density

Evaluation of bone density follow up has been measured as: (Table 3,Figure 4)

Preoperatively, the bone density ranged from 180.00 to 450.00 with a mean±SD of 347.90±93.54 HU.

Immediate postoperatively, the bone density ranged from 406.00 to 966.00 HU with a mean±SD of 705.20±195.38 HU.

Three months postoperatively, the bone density ranged from 384.00 to 920.00 HU with a mean±SD of 622.00±183.07 HU.

The pairwise comparison revealed that bone density significantly increased immediately postoperative and three months postoperative compared with preoperative (p<.001, p=.002; respectively)

Table (1): Age and sex in the studied group.

	(n=10)
Age (years)	
n	10
Min. – Max.	26.00-40.00
Mean ± SD	32.80±4.85
SE of the mean	1.53
95% CI of the mean	29.33-36.27
Sex	
Male	3 (30.00%)
Female	7 (70.00%)
Tooth type	
First molar	7 (70.00%)
Second molar	3 (30.00%)

n: Number of patients

Min-Max: Minimum – Maximum

S.D.: Standard Deviation

Table (2): Primary Stability (ISQ) immediate post-operative and three months postoperative in the studied group.

Stability (ISQ)	Primary stability (intraoperative)	Secondary stability three months Postoperative	t	P
n Min. – Max. Mean ± SD	10 58.00-71.00 65.20±4.96	10 70.00-85.00 76.20±5.43	9.448*	0.001*

n: Number of patients
Min-Max: Minimum – Maximum
SD: Standard Deviation
t: Paired t-test
p: p value for comparing between the studied periods
*: Statistically significant (p<.05)

Table (3): Comparison of bone density (HU) in the studied group at different measurement time intervals.

Bone density (HU)	Preoperative	Immediate Postoperative	Three months Postoperative
n Min. – Max. Mean ± SD	10 180.00-450.00 347.90[a]±93.54	10 406.00-966.00 705.20[b,c]±195.38	10 384.00-920.00 622.00[b,c]±183.07
Repeated-measures ANOVA p Partial Eta Squared Observed Power	$F_{(df=2)}$=25.624 p<.001* η^2=0.740 (74.00%) 1 (100.00)		
	Percentage change[1] (%) (Immediate postoperative vs preoperative)	Percentage change[2] (%) (Three months postoperative vs preoperative)	Percentage change[2] (%) (Three months postoperative vs immediate postoperative)
n Min. – Max. Mean ± SD	10 35.11-162.57 107.63±42.58	10 17.73-167.84 85.80±53.20	10 -42.44 - 3.26 -9.98±18.20

n: Number of patients Min-Max: Minimum – Maximum SD: Standard Deviation F: F ratio of Repeated measures ANalysis Of VAriance (ANOVA) test.
[a,b,c]: different superscript letters indicate pairwise significance based on estimated marginal means (p value adjustment for multiple comparisons using Bonferroni method)
*: Statistically significant (p<.05)

DISCUSSION

The immediate installation of dental implants into a recent extraction socket has gained acceptance among both dentists and patients. This approach offers several clinical benifits, including a decrease in overall treatment duration, a decrease in surgical sessions number, and enhanced satisfaction for patients (16). Particularly, these benefits are more pronounced when employing a minimally invasive technique and a gentle tooth extraction method to preserve the socket's favorable anatomy. However, achieving stability and successful osseointegration of implants placed immediately poses a challenge. This challenge necessitates careful consideration and effort to guarantee the smooth incorporation of the implant (17).

The present study is done to evaluate the impact of the osseodensification technique on the stability of immediately placed implant within the mandibular molar inter-radicular septum using Densah burs. Primary stability was assessed immediately after surgery using resonance frequency analysis (RFA) of the Osstell ISQ system, and secondary stability was evaluated three months later. The utilization of RFA was selected as a non-invasive and dependable approach for evaluating the stability over changes in implant a period of time. The registrations of Resonance Frequency Analysis (RFA) exhibit a direct correlation with the firmness of the implant within the bone. This review is supported by *Meredith* et al 1996 and 1997 (18, 19) in the statement that RFA can be a beneficial research tool and can prove useful in examining the behavior of implants in the surrounding bone.

Regarding the implant stability in this study, it was found that the secondary stability three months post-operatively was statistically significantly increased compared to primary stability immediately post-operative (p<0.001), which is compatible with *Ibrahim* et al. 2020, (20) who evaluated the osseodensification (OD) method using Densah burs used in preparation of the implant site on twenty dental implants that were surgically inserted into ten patients, with each patient receiving one implant utilizing the Osseodensification drilling method and another implant using the traditional drilling technique and

found a significant increase between the primary stability and secondary stability four months post-operatively in osseodensification group (p<0.001).

Furthermore, these findings align with a research by *Lehens* et al. (2016) (21), which conducted similar assessments using the Osseodensification (OD) technique in vivo. *Lehens* reported significant success of the OD technique over conventional drilling, assessing the success both microscopically utilizing histomorphometry and mechanically using pull-out testing.

Regarding bone density, it was found in this study that the bone density significantly increased immediately postoperative and three months postoperative compared with preoperative (p<.001, p=.002; respectively), and this agrees with *Hindi et al.* in 2020 (22), Who examined the impact of osseodensification in a low-density bone, and found that there was a notable and significant increase in bone density post-operatively compared to the preoperative bone density. ($p < 0.0001$) (22).

There is a strong relationship between bone density and implant stability, increasing the density of the bone surrounding the implant by compaction autografting effect of the osseodensification technique leads to increase the primary stability (mechanical stability) of the implant, therefore improving the secondary stability. This is in accordance with *TURKYILMAZ* et al. (23) and *Farré-Pagés* et al. (24), who found that there was a significant correlation between bone density and the ISQ values of the primary stability.

CONCLUSION

From the results of this study, the following was concluded:

Immediate implant placement with molar septal expansion using osseodensification is a reliable technique for the replacement of badly destructed mandibular molars.

Densah burs produce an increase in bone density around the implant, improving the primary and secondary stability.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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