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The Effect of Passive Ultrasonic Irrigation and XP-Endo Finisher on Post-operative Pain after Endodontic Retreatment on Patients (Randomized Controlled Clinical Trial)

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Abstract

AIM: To evaluate the effect of passive ultrasonic irrigation or XP-Endo Finisher on postoperative pain in patients with underextended filling in previously endodontically treated mandibular first molar teeth requiring endodontic retreatment using visual analog scale (VAS) scale at 6, 12, 24, 48, 72 h, and 7 daytime intervals.

METHODS: Seventy-eight patients with mandibular first molars which need endodontic retreatment were randomly allocated into one of three separate groups (n = 26); NaviTip group (control), XP-Endo Finisher group, or Ultra X group. Data were statistically analyzed with a significance level of $p \leq 0.05$.

RESULTS: XP-Endo Finisher agitation and ultrasonic agitation as a final irrigation protocol showed significantly lower pain values than the control group, but there was no significant difference in pain values between the experimental groups.

CONCLUSION: Within the limitation of this study, it can be concluded that agitation techniques used during endodontic retreatment decreased the incidence and intensity of post-operative pain.

Introduction

Non-surgical endodontic retreatment is considered a good treatment option when endodontic therapy fails. Persistence of microorganisms within the root canal system, inadequate root canal filling, and coronal restoration are listed as main causes of treatment failure [1]. Endodontic retreatment aims to establish a favorable environment for periapical healing through the complete removal of the existing filling materials, debris and microorganisms [2]. However, complete removal of endodontic filling materials from the root canal system is still considered one of the main challenges in endodontics.

The purpose of preparing and shaping the root canal is to facilitate canal irrigation, disinfection, and obturation. Instruments used to shape the root canal do not touch all canal walls [3]. There are always parts of the canal, especially in the apical one-third and the isthmus region, left untouched by the tools used in mechanical preparation. Irrigation plays a major role in the cleaning and disinfection of the root canals, thus improving the success rate of the root canal treatment [4].

Delivering the irrigant using the traditional syringe and needle irrigation technique results in an ineffective disinfection in particular areas such as isthmus and apical regions [5] Adequate agitation following proper instrumentation improves the irrigant penetration to reach the untouched part. XP-Endo Finisher (FKG Dentaire, La Chaux de Fonds, Switzerland) has been introduced to be used in the final root canal irrigation protocol to enhance the cleaning efficacy by removing hard-tissue debris and smear layer especially in irregular areas while maintaining the original root canal anatomy [6].

On the other hand, there are a couple of methods that can be performed to deliver the irrigant during ultrasonic activation; continuous, and intermittent flush. It utilizes the principle of acoustic microstreaming, agitation, and cavitation. Its rapid movement enables penetration into untouched areas and enhances shear stress on tissue remnants leading to reduction of the post-operative pain [7].

Debris and irrigant extrusion during endodontic procedures is considered to be one of the main causes of post-operative pain [8]. Unfortunately, it is inevitable unless a negative apical pressure irrigation system is used. However, the measured amounts of extruded debris or irrigants shown in *ex vivo* studies are not confirmed to occur clinically or to be significant to stimulate pain or damage tissues [9].

This study will discuss whether the use of different irrigant activation methods will affect post-operative pain. The null hypothesis of this research is that there is no difference in post-operative pain between the different activation methods.

Methods

Sample size calculation

Based on a previous study [10], the outcome variable was post-operative pain assessed by visual analog scale (VAS). Using power 80% and 5% significance level, we needed to study a total sample size of 60 in which divided into three groups (20 per each group). This number was increased to a total of 66 to adjust for using a nonparametric test. Further increase of 25% to allow for least frequently used. The number was increased to a total of 78 (26 in each group) to compensate for losses during follow-up. The sample size was calculated by Power and sample size G* program [11].

Sample selection

After approval of the Local Ethics Committee (FUE.REC code (15)/6-2020), 78 patients from the outpatient clinic of endodontics at the faculty of oral and dental medicine, Future University in Egypt, were diagnosed with underextended filling in previously endodontically treated mandibular first molar teeth requiring endodontic retreatment. The exclusion criteria comprised medically compromised patients, pregnant or lactating females, psychologically disturbed patients, patients allergic to any medication used in this study, patients who administered anti-inflammatory analgesics, or antibiotics 12 h preoperatively. The exclusion criteria also comprised teeth with wide or open apex, no possible restorability, abnormal anatomy or calcified canals, or periodontally affected with Grade 2 or 3 mobility. Pre-operative pain scores were recorded in all cases for standardization.

Gutta percha removal and working length determination

Each tooth was isolated using rubber dam (Sanctuary Powder Free Latex Dental Dam, Malaysia) followed by removal of gutta percha using Protaper Universal Retreatment files (Dentsply, Tulsa Dental, Dentsply Maillefer, TN, USA) in the following sequence:

- D1(30/09)
- D2(25/08)
- D3(20/07)

Root canal preparation

The patency of the canals was done using stainless steel hand K-file (MANI-MANI, INC. Industrial Park, Utsunomiya, Tochigi, Japan) sizes 15. Working length was measured using electronic apex locator (Root ZX, J. Morita USA, Irvine, USA) and was then confirmed with intraoral periapical radiograph (Ateco AT303, Ateco technology, London, UK) to be 0.5–1 mm shorter than radiographic apex using bisecting angle technique.

Root canals were mechanically prepared by crown down technique using ProTaper Next (Dentsply) nickel-titanium rotary instruments according to the manufacturer's instructions as follows:

- ProTaper Next rotary file set on electric motor (X-Smart, Dentsply) at a rotational speed of 300 rpm and 2 N cm torque using a gentle in and out brushing motion until the working length was passively reached.
- In the presence of sodium hypochlorite (NaOCl) solution, X1 (17/04) file was used in one or more passes, alternatively with small-sized hand files if necessary, until the working length was reached.
- X2 (25/06) file was exactly used as described for X1 file, until the working length was passively reached. Afterward, the canal was gauged with a size 25 K-file and, if the size 25 K-file was loose at length, canal shaping was continued with X3 (30/07) master apical file.

Preparation of all canals was completed when a hand K-file whose ISO size corresponding to the tip size of the used ProTaper Next file snugly fits the apical third of the canal at the working length. The canals were thoroughly irrigated with 2 ml of freshly prepared 2.6% NaOCl solution using plastic disposable syringe with side-vented needle (NaviTip; Ultradent, South Jordan, UT, USA) gauge 30 between every subsequent instrument. It was used passively into the canal, without forceful dispensing of the irrigant, placed 2 mm short from the working length, which was verified by rubber stoppers. To achieve standardization, the volume of irrigating solution was fixed (2 ml) after each file. A lubricant of 17% EDTA gel (EDTA, Meta, Biomed co. ltd, Korea) was used with each file.

Final irrigation protocol

NaviTip group (control group)

Root canals were irrigated using 2 ml of 2.6% NaOCl with NaviTip double side-port 1 mm shorter than the working length but without agitation.

XP-endo finisher group

2 ml of 2.6% NaOCl was delivered into the canal using NaviTip double side-port irrigation needle which

was used passively without forceful dispensing of the irrigant. Working length for each canal was determined using plastic ruler tube to adjust the rubber stop. After which, XP-Endo Finisher was cooled using spray Endo Frost through the plastic tube. The XP-Endo Finisher was set in rotation mode and removed from the tube by applying a lateral movement to ensure the file remains straight then the rotation was turned off.

The XP-Endo Finisher was taken from sterile packaging and placed in the handpiece. Then, it was inserted into the first canal of the tooth while straight. Speed and torque were adjusted on the endodontic motor to be 800 rpm and 1 Ncm, respectively, according to the manufacturer's instructions [12]. Once the tip was inside, rotation was turned on and the file was inserted further in. The irrigant was mechanically agitated for 60 s with XP-Endo Finisher using slow and gentle 7–8 mm lengthwise (in and out) small multidirectional movements to contact the full length of the canal. After 1 min, the file was removed from the canal while it was still in rotation followed by irrigation of the canal with NaOCl to remove the suspended debris.

Ultra X group

2 ml of 2.6% NaOCl was delivered into the canal using NaviTip double side-port irrigation needle which was used passively without forceful dispensing of the irrigant. The irrigant was then ultrasonically activated for 60 s with an ultrasonic device (Ultra X, Eighteeth, Orikam) at 45 kHz using X-blue (bendable) metal ultrasonic tip (Length: 18 mm, Size: 20/2%) in an up-and-down motion where the tip was 1 mm short of the canal's working length.

For all root canals in tested groups, 2 ml of 17% EDTA solution was then introduced into each canal for 1 min to remove smear layer, followed by 2 ml of distilled water were used as a final flush of the canals to prevent erosion of the dentinal tubules.

Root canal obturation

After completion of the biomechanical instrumentation of the root canals, each root canal was completely dried using ProTaper Next absorbent paper points corresponding to the same size of the master file (X3). The root canals were obturated using the modified single cone technique by proper selection of gutta percha master cone corresponding to the same size as the master apical file (X3) and ADSEAL (ADSEAL, Meta) resin root canal sealer.

Cone fitness radiograph was taken to ensure proper length and preparation of the root canals. The ADSEAL sealer base and the catalyst were mixed till forming a mix with homogenous consistency. The mixed sealer was introduced into the canal through the master cone coated with sealer to the full working length. A spreader of # 25 was selected and auxiliary cones of # 25 were placed. Obturation was considered completed when the spreader no longer penetrates beyond the cervical line, and excess gutta percha was sealed off using heated condenser tip.

Post-operative radiographs were taken to ensure proper obturation. No apical extrusion of gutta percha beyond the apex was observed in any of the cases included. The access cavity was sealed using resin-modified glass ionomer. All canals were shaped, cleaned, and obturated in a single visit. The details of each step were recorded in the patients endodontic procedure form.

Post-operative instructions

Every patient was instructed to mark the VAS scale between (0 and 10) to determine incidence and intensity of pain preoperatively and postoperatively after obturation at 6, 12, 24, 48, 72 h, and 7 days. VAS scale was explained in different ways to the patient to facilitate the understanding and recording of the pain intensity. It expressed pain numerically and verbally in Arabic. Numerical description was presented as a scale beginning from zero (0) representing no pain to ten (10) representing maximum possible pain. Pain level was documented in the range of 0–10 numerically as no pain (0), mild pain (1–3), moderate pain (4–6), and severe pain (7–10).

The participants were instructed in case of presence of moderate (4–6 on VAS) or severe (7–10 on VAS) post-operative pain to take only one capsule of placebo (powdered milk packed in opaque capsules) which was given to them. If the moderate or severe pain persist, patients were instructed to call the operator and were allowed to take 400 mg Ibuprofen (Dailymed, USA). They were instructed to record the number of analgesic tablets taken. If there was still pain indicating a flare up (emergency), the patients were informed to contact the dentist for an emergency intervention. After 7 days, the patient delivered the assigned paper record.

Statistical analysis

The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov–Smirnov and Shapiro–Wilk tests and showed parametric (normal) distribution. The mean and standard deviation values were calculated for each group in each test (Pain Evaluation and Bacterial count). Data were explored for normality using Kolmogorov–Smirnov and Shapiro–Wilk tests. Friedman test was used to test the difference between more than two groups in related samples while Wilcoxon test was used to test the difference between two groups in related samples. Mann–Whitney U test was used to compare the difference between two

groups in non-related samples for pain evaluation. The significance level was set at $p \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

Results

XP-Endo Finisher group (Group B) and Ultra X group (Group C) showed significantly lower incidence and intensity of pain than the control group at 6, 12, and 24 h follow-up periods. Figure 1 shows the incidence of pain at different time intervals for each group. Table 1 shows the intensity of pre-operative and post-operative pain of the tested groups at different time intervals.

Table 1: Intensity of pre- and post-operative pain of the tested groups after 6 h, 12 h, 24 h, 48 h, 72 h, and 7 days

Period	Pain intensity						
	Control		XP Finisher		Ultra X		p-value
	Mean	SD	Mean	SD	Mean	SD	
Preoperative	5.19	2.38	4.58	2.42	4.85	2.59	0.555ns
After 6 h	5.08	1.92	3.35	1.32	3.15	1.54	<0.001*
After 12 h	4.12	2.55	2.27	0.87	2.08	1.09	0.001*
After 24 h	2.46	1.86	1.31	0.68	1.27	0.78	0.020*
After 48 h	1.19	1.27	1.00	0.80	1.04	0.72	0.937ns
After 72 h	0.15	0.37	0.12	0.43	0.08	0.27	0.601ns
After 7 days	0.00	0.00	0.00	0.00	0.00	0.00	1ns
p-value	<0.001*		<0.001*		<0.001*		

*: Significant ($p < 0.05$), ns: Non-significant ($p > 0.05$).

The frequency of analgesics taken by patients decreased by time in each tested group. The highest mean value was recorded at 6 h for all groups, while no pain after 48 h in PUI group and 72 h in the NaviTip and XP-Endo Finisher groups.

Discussion

The goal of performing root canal treatment is biomechanical preparation and hermetic sealing of the root canal without any unpleasant outcome to the patient, and provide favorable conditions for the periradicular tissues to heal [13]. Since root canal treatment induce more frequent and more severe post-operative pain than do other dental operative procedure, prevention, and management of post-operative pain is an integral part in such cases. Mechanical, chemical, host, and microbiological factors have been described as important for inducing pain following root canal treatment [14].

Post-operative pain was found to be significantly higher in the mandible compared to the maxilla because the mandible has a dense trabecular pattern, thus there is reduced blood flow and more localization of infection and inflammation, which might delay healing [15]. Iatrogenic procedural errors such as poor access cavity design and complications of instrumentation (ledges, perforations, or separated instruments) are some of the commonly attributable causes of failure. Inappropriate mechanical debridement, persistence of bacteria in the canals and apex, poor obturation quality, over and under extension of the root canal filling, and coronal leakage are also attributable causes of failure. Despite the high success rate of endodontic treatment, failures do occur in a large number of cases and most of the times can be attributed to the already stated causes [16]. Cases with radiographically inadequate or underextended root filling that require endodontic retreatment were selected as a main inclusion criterion.

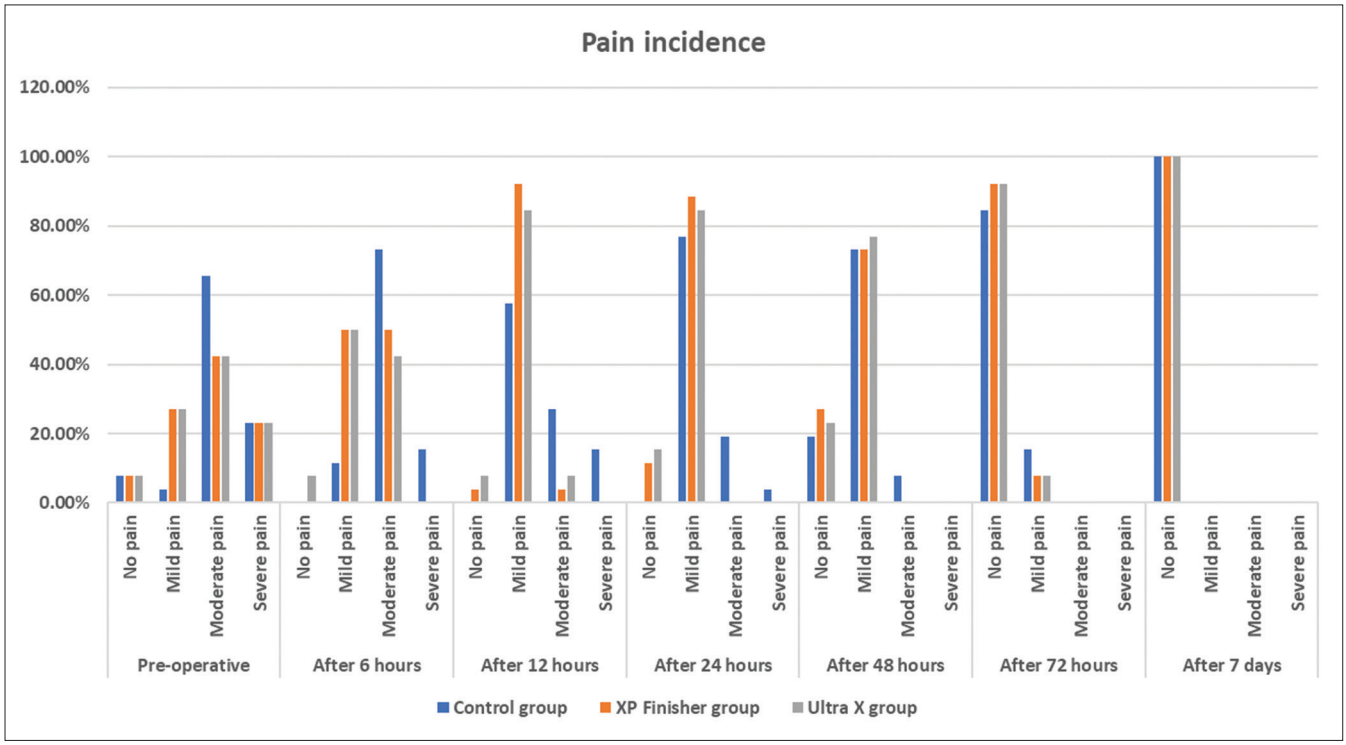

Figure 1: Bar chart representing the incidence of pain at different time intervals for each group

In the present study, doses of anesthetic solutions selected were 1.8 mL (equivalent to 1 cartridge) of 2% mepivacaine with 1:100,000 epinephrine. A waiting period of 15 min was allowed before initiation of endodontic treatment to allow for blockage of the nerve induction [17]. Patients with medical conditions or those who have taken any medication (analgesics or antibiotics) in the 12 h before the endodontic visit and pregnant females were excluded to avoid any variable from influencing the results of the study [18].

The aim of the present study was to evaluate post-operative pain after endodontic retreatment because such cases pose high magnitude of post-operative pain in our day-to-day practice [19]. In this study, the pain intensity was recorded preoperatively as base line data and postoperatively at different time intervals. Six h was chosen as it is the time that the effect of anesthetic solution starts to fade [20]. Twelve, 24, and 48 h were chosen as it was proven that most of post-operative pain occurred between these time intervals after chemomechanical preparation [21].

In the present study, the VAS was used for measuring the pain intensity. After treatment, the participants were given placebo and were asked to take it in case of moderate or severe pain. Placebo is a pharmacologically inert substance that has no therapeutic effect, but it has been used as a pain reducing and anxiety control agent [22].

XP-Endo Finisher group (Group B) and Ultra X group (Group C) showed significantly lower incidence of pain than the control group, which is supported by other studies including Alves *et al.* [23] and Azim *et al.* [24] who demonstrated that the use of XP-Endo Finisher showed high efficiency in reducing bacterial counts and exhibited adequate disinfection, and Layton *et al.* [25] who stated that passive ultrasonic irrigation generates high shear stress in apical third of the root canal that enhanced reduction of strictly adherent bacterial biofilm in comparison to syringe irrigation. Better microbial control of passive ultrasonic irrigation may be attributed to the advantage of passive ultrasonic irrigation over the other irrigation techniques, in which passive ultrasonic irrigation enhances delivery of irrigation to uninstrumented areas of root canal and helps in removal of remnant bacteria by inducing acoustic streaming and cavitation of the irrigant [26]. Seltzer and Naidorf [27] suggested that bacteria present in the root canal system can be responsible for post-operative pain. Furthermore, the inability of NaviTip to completely reach the full working length can leave behind vital pulp remnants and microbes that could contribute to the reported post-operative pain [28].

Regardless of the chief complaint, the mean scores of post-operative pain intensity were higher in control group than in intervention groups (Ultra X and XP-Endo Finisher) at 6, 12, and 24 h follow-up periods. These results are in accordance with Elnaghy *et al*. [12], Carvalho *et al* [29], Xin *et al*. [30], Nangia *et al*. [31], Gündoğar *et al*. [32], and Yusufoglu *et al*. [33]. This may be attributed to, in the use of XP-Endo Finisher, the highly flexible proprietary alloy together with the small core size and zero taper which allowed it to expand its reach while rotating [34]. The file is straight in the Martensitic phase at the room temperature. However, the phase and the shape of file change when inserted into the root canal to adapt to the three dimensional root canal anatomy to access and clean the root canal irregularities. This is in addition to removal of packed debris from the complexities of the root canal system [6].

XP-Endo Finisher is designed to reach spaces and aspects in root canal system that were not shaped using either rotary or reciprocating techniques [35]. XP-Endo Finisher showed high ability in reaching the inaccessible and untouched canal areas, thereby, providing improved cleaning and superior removal of smear layer and bacterial biofilms, in accordance with Živković *et al.* [36], Bao *et al.* [37], and Elnaghy *et al.* [12].

On the other hand, regardless of different times used for evaluation, passive ultrasonic irrigation using Ultra X as a final irrigation protocol showed lowest pain intensity which may be explained by the irrigation method using apical negative pressure preventing the apical extrusion of the irrigant compared with methods using positive pressure (Manual Dynamic Agitation and needle). Ultra X is a cordless ultrasonic irrigation device that oscillates at 45,000 kHz ultrasonic frequencies using the acoustic microstreaming, agitation, and cavitation principle that can reach difficult inaccessible areas of the complex root canal system [38].

These results are against Kfir *et al.* [39], Azimian *et al.* [40]. Furthermore, De-Deus *et al*. [41] reported that neither XP-Endo finisher nor passive ultrasonic irrigation completely removed the accumulated hard tissue debris from oval-shaped canals. Debris and irrigant extrusion during endodontic procedures are considered to be one of the main causes of post-operative pain.

On the other hand, at 48, 72 h, and 7 days, there was statistically no significant difference in pain between the tested groups. Intensity of post-operative pain was higher at 6, 12, and 24-h time intervals. Then, it decreased along the following time intervals within each group. This is in accordance to Singh *et al.* [42] and Elsaka *et al.* [43] who stated that most of the post-operative pain occurred on the 1st day after chemomechanical preparation. This may be related to the exacerbation or induction of the inflammatory response in the periapical tissues due to endodontic treatment. The polymorphonuclear leukocytes (PMNs) begin to enter the injured site within 6 h followed by increase in the release of inflammatory mediators and neuropeptides. The proliferative process begins after 48 h which is characterized by decrease in the PMNs population, and the beginning of the macrophages entering the wound site [44].

In the present study, the incidence of analgesics intake also has been assessed as a secondary outcome. The frequency of analgesics taken by patients decreased by the time in each tested group. The highest mean value was recorded at 6 h for all groups, while no pain after 48 h in Ultra X group and 72 h in the NaviTip and XP-Endo Finisher groups. This is in accordance to systematic review published by Romualdo *et al.* [28]; they reported that the irrigation method using apical negative pressure prevents the apical extrusion of the irrigant compared with methods using positive pressure (MDA and needle). Shetty *et al.* [45] stated that positive pressure of conventional irrigation extruded greater weight of debris apically. This might be because of the positive pressure exerted by the needle leads to greater hydraulic pressure which may result in post-operative pain.

The amount of irrigant and/or debris extruded could initiate chemical irritation of periapical tissues, thereby causing post-operative pain. Passive ultrasonic irrigation induces small, intense, and circular fluid movement around the instruments causing movement of the irrigating solution inside the root canal in the cervical direction, thereby reducing the amount of irrigant and/or debris extrusion to the periapical region which can explain why the Ultra X group consumed the least number of analgesics compared to the other groups [46]. This does not coincide with the results of Middha *et al.* [47], where there was no significant difference in analgesic consumption between ultrasonic irrigation group and conventional needle group. This finding was consistent with other researchers attributed this to the fact that the use of sonic activated method results in less apical extrusion compared to the conventional endodontic syringe, which is accepted as one of the most important factors affecting post-operative pain intensity, may cause chemical irritations in the periapical zone and result in post-operative pain [10], [48]. Hence, the possible reasons for the decrease in post-operative pain with the use of machine-assisted agitation may be related to the movement in the cervical direction of the irrigating solution inside the root canal and a reduction of the risk and/or amount of extrusion and damage to the periapical region [49], [50].

The null hypothesis is not accepted since postoperative pain incidence and intensity were significantly less in the experimental groups at 6, 12, and 24 h than the control group.

Conclusion

The incidence and intensity of post-operative pain decreased with time regardless the final irrigation protocol used. Machine-assisted irrigation agitation devices are considered reliable and safe to clinicians and effective method as a final step irrigation protocol with successful management of post-operative pain in root canal retreatment in permanent mandibular molar teeth with under extended filling.

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