

A comparison of usage of the laryngeal mask Unique™ in denticulate and edentulate geriatric patients

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Background/aim: Mask ventilation in geriatric and edentulous patients can be ineffective or even impossible because of the shape inside the patients' cheeks. For patients for whom a mask cannot be used for long, the use of a laryngeal mask can ease the administration of anesthesia. The aim of this study was to compare the use of the laryngeal mask Unique™ in denticulate and edentulate patients aged over 65 years.

Materials and methods: This prospective study included patients according to the American Society of Anesthesiologists I–III classification, aged 65 years or more. The patients were divided into two groups: a dentulous group (n = 33) and an edentulous group (n = 33). The success of the first attempt of insertion, ease of insertion, time taken to insert, and oropharyngeal leak pressure were measured. After insertion of the laryngeal mask Unique™, a researcher who was unaware of whether the patients had teeth or not conducted an oropharyngeal leak test.

Results: The success rate of inserting the laryngeal mask Unique™ on the first attempt was higher in the dentulous group than in the edentulous group. Ease of insertion, time taken to insert, oropharyngeal leak pressure, and laryngopharyngeal morbidity were similar for each group.

Conclusion: In this study, successful insertion of the laryngeal mask Unique™ was higher in dentulous than in edentulous patients. We conclude that this effect could have important implications for anesthesiologists managing edentulous geriatric patients with supraglottic airway devices.

Key words: Laryngeal mask airway, edentulous, geriatric

1. Introduction

As a result of higher living standards, quality of life has progressively increased. Combined with developments in anesthesia, modern surgical techniques and medication that allow for increasingly complicated interventions to be performed have led to elderly patients being encountered more often in daily anesthetic practice (1).

Sixty percent of patients older than 65 years of age are edentulous, i.e. they have no teeth. In anesthetic practices, ventilation with a mask is more difficult for edentulous patients than for those who are dentulous (1). For example, reduced tone in the upper airways of geriatric patients increases the possibility of airway obstruction (1). In older patients with no teeth, sunken cheeks can also render ventilation with a mask ineffective and sometimes impossible (2). The laryngeal mask (LM) is an alternative

airway device that can be used for edentulous patients when the classic facemask does not sit correctly (3).

The LM is frequently used in situations that do not require endotracheal intubation. It has the major advantage of enabling reliable airway control in patients with both difficult tracheal intubation and difficult mask anesthesia (4,5). The laryngeal mask Unique™ (LMU) appeared on the market in 1997. It is made of polyvinylchloride, the airway tube is clear and semirigid, and it is more convex than classic laryngeal masks (6,7).

Except for our observation that LMs are more difficult to place on older patients, very few studies have been conducted on the use of LMs in the elderly (8). Therefore, the primary aim of this study was to investigate the use of the LMU in edentulous patients aged >65 years. This aim was achieved by evaluating the success of LMU placement

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on the first attempt, ease and duration of insertion, and oropharyngeal leak pressure (OLP).

2. Materials and methods

This study was registered at ClinicalTrials.gov (Identifier: NCT02219282) on 15 August 2014 by Şule Özbilgin. Institutional review board approval (Dokuz Eylül University Ethics Committee for Clinical Research No. 140-İOÇ/2010, İzmir, Turkey) was obtained, and the patients provided written informed consent. Sixty-six patients older than 65 years in American Society of Anesthesiologists (ASA) physiological classification groups I–III, who underwent elective urologic surgery with the need for laryngeal mask placement, participated in this prospective, double-blind study. All the procedures were conducted by two researchers, who were anesthesiologists with more than 3 years' experience in laryngeal mask airway insertion.

Patients were excluded if they had any neck and upper respiratory pathology; were at risk of gastric content regurgitation/aspiration (e.g., they had previously undergone upper gastrointestinal surgery, had a known hiatal hernia, suffered from gastroesophageal reflux, had a history of peptic ulcers, had a full stomach, or were pregnant); had low pulmonary compliance or high airway resistance (e.g., suffered from chronic lung diseases); were obese (BMI of >35); had a sore throat, dysphagia or dysphonia; or had any possibility or history of a difficult airway.

The patients were divided into two groups as either dentulous or edentulous. They were taken to the operating room and were monitored for heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean blood pressure (MBP), electrocardiography (ECG - derivation II), and peripheral oxygen saturation (SpO₂) before the induction of anesthesia. Depth of anesthesia was evaluated with a bispectral index (BIS) monitor (BIS-Vista™ [Aspect Medical Systems, Newton, MA, USA]). The patients were preoxygenated with 6 L min⁻¹ oxygen through a face mask for 3 min. For the induction of anesthesia, 0.02 mg kg⁻¹ midazolam (Dormicum® ampule; Roche Company Limited, İstanbul, Turkey), 1–2 µg kg⁻¹ fentanyl (Fentanyl® 0.05 mg mL⁻¹ ampule; Janssen Pharmaceutica, Beerse, Belgium), and 1–2 mg kg⁻¹ propofol (Propofol 1% Fresenius®; Fresenius Kabi, Uppsala, Sweden) were used. Thereafter, the patients were administered mask ventilation with 100% oxygen. Before laryngeal masks were inserted, they were lubricated with water-based gel, and the cuffs were completely deflated.

After the induction of anesthesia, agents were administered when BIS values were 40–60 and sufficient chin relaxation was obtained. The LMU was inserted using the insertion technique recommended by the manufacturer. The size of the LMU was chosen based on

the patient's body weight: 30–50 kg, no. 3 LMU; 50–70 kg, no. 4 LMU; and 70–100 kg, no. 5 LMU. During placement of the LMU, an additional dose of 0.5 mg/kg propofol was administered depending on the patient's reaction, to keep the BIS values at 40–60.

The cuffs of the laryngeal mask were inflated and maintained at 60 cmH₂O (cuff pressure manometer; Rüşch, Kiel, Germany) (9). According to the manufacturer's recommendation, after the first volume had been inflated, the pressure was measured with a cuff measurement device. Volumes added or removed to achieve a pressure of 60 mmHg were measured with an injector and recorded. After the operation and before the LMU was removed, the cuff inner pressure was again measured and recorded. The success of the first attempt to insert the LMU was also recorded. During placement, in cases with three unsuccessful attempts, the patients were intubated to provide airway management.

Anesthesia was maintained with a 50% O₂/air mix with 1.5%–2.5% sevoflurane. The concentration of sevoflurane was set to maintain BIS at 40–60. SBP, DBP, MBP, HR, and BIS were recorded before the induction of anesthesia, before the insertion of the LMU, and 1, 2, 3, and 5 min after LMU insertion was confirmed.

The time required for successful insertion was defined as the duration from the mouth opening to the first successful ventilation (10). This duration was recorded along with the number of insertion attempts and the ease of insertion.

The criteria indicating successful LMU placement were as follows (11): waves with square shapes on a capnogram; easy ventilation with a respiration balloon; and observed chest movement and no ventilation leakage, with positive pressure of approximately 20 cmH₂O.

Evaluation of the ease of insertion was based on a Likert scale (a 4-point scale from easy to unsuccessful) (12). The scale was defined as follows: 1 = easy (LMU inserted in a single attempt, no resistance observed, insertion with only chin-opening movement); 2 = moderately difficult (LMU inserted in a single attempt, slight resistance observed); 3 = difficult (LMU inserted on the second attempt, clear movement observed); and 4 = unsuccessful (alternative airway management applied).

Before the oropharyngeal leak test was performed, the face of the patient was covered so that the observer was blinded to the airway device. After LMU insertion, an oropharyngeal leak test was conducted by a researcher who was unaware of whether the patient had teeth or not. To complete the test after the expiratory valve was closed, the fresh gas flow was reduced to 3 L/min. When the sound of a leak was heard from the mouth, the airway pressure value, i.e. the OLP, was recorded (13). During this test, airway pressure was not allowed to increase to

higher than 40 cmH₂O. From the start to the end of the operation, the patients were monitored for hypoxia (SpO₂ decreasing to less than 90%) and laryngospasm. Patients were excluded from the study in cases where the third attempt at LMU insertion was unsuccessful, the SpO₂ value decreased to less than 90% at any time during the process, or laryngospasm developed.

Patients were interviewed by a research assistant unaware of the group in the postanesthesia care unit. The researcher obtained information about negative postoperative events linked to the pharynx and larynx using a prepared survey form. At 1 h and at 1 day postoperative, sore throat, dysphonia, and dysphagia were evaluated. Throat pain was evaluated using a visual analog scale (VAS).

2.1. Statistical analysis

Assuming a difference of 10% in successful LMU insertion on the first attempt between the groups, with an alpha of 0.05 and 90% strength, the total number of patients required was calculated as 66 (14). For statistical evaluation, SPSS 15.0 was used (SPSS Inc., Chicago, IL, USA). For parametric data, Student's t-test was used to

compare the groups, whereas the chi-square test was used to compare nonparametric data. $P < 0.05$ was considered statistically significant.

3. Results

For one patient in each group, dentulous and edentulous, insertion of the LMU was unsuccessful on the third attempt, and these patients were intubated; therefore, these two patients were excluded from the study and were not included in the statistical analysis of the data (Figure). The demographic data of the patients included in the study are shown in Table 1.

There was a significant difference between the dentulous and edentulous groups in the success rate of LMU insertion on the first attempt ($P = 0.047$) (Table 2). The LMU was successfully inserted on the first attempt in 78.7% of dentulous patients and 60.6% of edentulous patients (Table 2). Ease of insertion was not significantly different between the two groups ($P = 0.07$) (Table 2). The mean duration of insertion time was 14.40 ± 4.80 s in the dentulous group and 13.43 ± 4.11 s in the edentulous groups. The differences were not significant ($P = 0.92$).

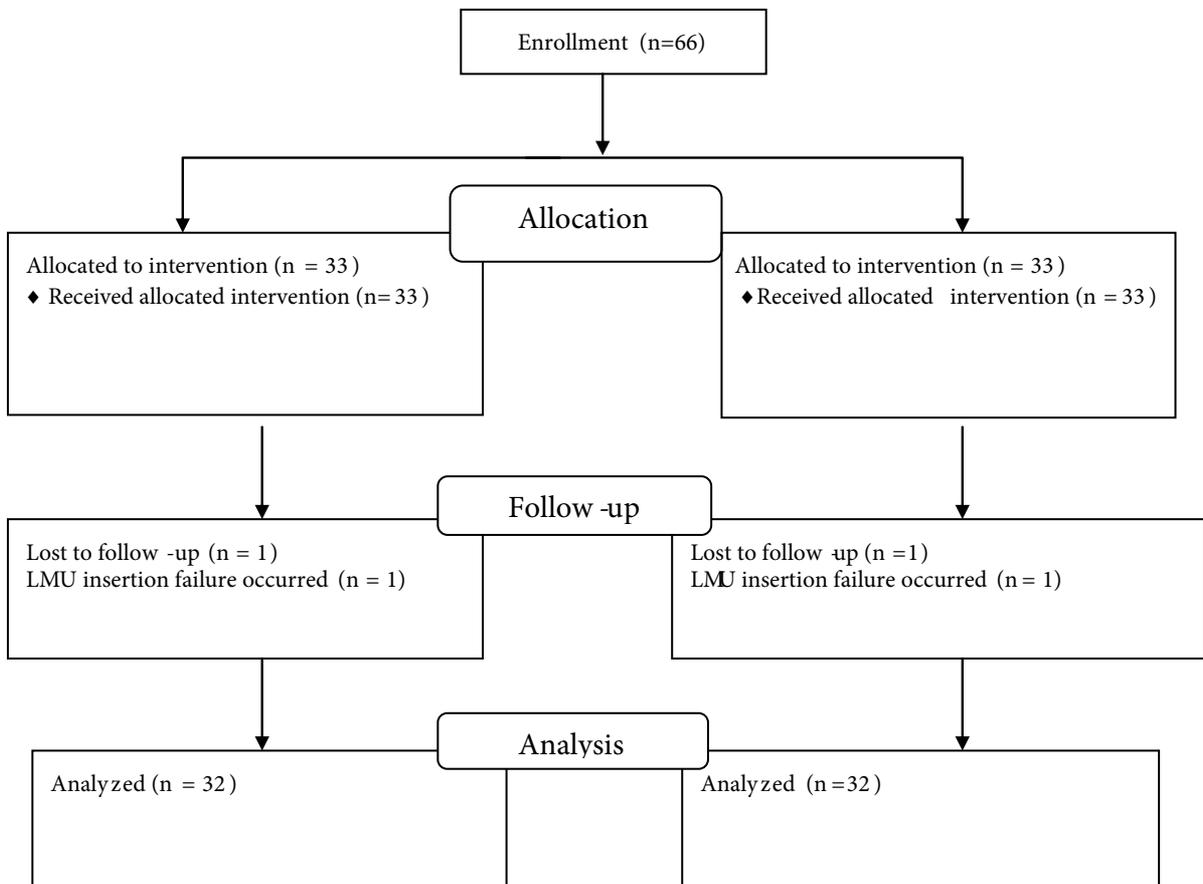


Figure. Cohort flow diagram.

Table 1. Demographic data as mean \pm SD and numbers.

| Group | Dentulous group (n = 32) | Edentulous group (n = 32) |
|--------------------|-----------------------------|------------------------------|
| Age (years) | 72.01 \pm 6.73 | 73.94 \pm 6.14 |
| Sex (F/M) | 22/10 | 23/9 |
| ASA (I/II/III) | 2/24/6 | 1/20/11 |
| Height (cm) | 165.84 \pm 9.92 | 166.74 \pm 10.07 |
| Weight (kg) | 72.15 \pm 11.60 | 71.18 \pm 10.34 |
| Mallampati (1/2/3) | 5/21/6 | 6/20/6 |

Data presented as mean \pm SD.

ASA = American Society of Anesthesiologists.

Table 2. Insertion success, insertion time, ease of insertion, and oropharyngeal leak pressure among groups. Data are presented as percent (%), mean \pm SD, and number.

| Group | Dentulous group (n = 32) | Edentulous group (n = 32) | P-value |
|---------------------------------------|-----------------------------|------------------------------|---------|
| First attempt success rate (%) | 78.7 | 60.6 | 0.047* |
| Number of insertion attempts 1/2/3 | 26/6/0 | 20/11/1 | |
| Insertion time (s) | 14.40 \pm 4.80 | 13.43 \pm 4.11 | 0.92 |
| Reported ease of insertion | | | 0.07 |
| 1 = Easy | 30 | 25 | |
| 2 = Not so easy 3 = Difficult | 2 0 | 7 0 | |

*P < 0.05.

The average OLP values were 21.75 \pm 4.62 cmH₂O in the dentulous group and 20.75 \pm 5.04 cmH₂O in the edentulous groups. The difference was not significant (P = 0.82). There were no significant differences between the dentulous group (59.84 \pm 0.88 cmH₂O) and the edentulous group (60.00 \pm 0.00 cmH₂O) in the LMU cuff pressure after the insertion (P = 0.13). There were no significant differences between the dentulous and edentulous groups in the LMU cuff pressure at the end of the surgery (respectively 58.00 \pm 8.50 and 54.75 \pm 8.28, P = 0.80). The initial and final volumes required to inflate the LMU cuff were comparable in both groups, at 17.13 \pm 2.36 mL in the dentulous group and 17.06 \pm 2.3 mL in the edentulous group (P = 0.83).

Mean time taken for LMU was 62.50 \pm 40.91 min in the dentulous group and 53.12 \pm 29.93 min in the edentulous group (P = 0.11). There was no significant difference between the two groups.

No significant differences were observed when comparing mean blood pressure and HR of the dentulous and edentulous patients at the time of measurement (P > 0.05).

Appearance of blood was noted after removal of the airway device in two patients in the dentulous group vs. one patient in the edentulous group (P = 0.46). None of the patients developed pharyngolaryngeal adverse events.

4. Discussion

In our study, we found that the success rate of LMU insertion on the first attempt was higher in dentulous than edentulous geriatric patients. The widespread use of supraglottic airway devices created a revolution in modern anesthetic practice in some clinical scenarios (15) and they are often a good alternative to endotracheal tubes.

With an aging population, the prevalence of edentulous patients has increased above 60% among individuals aged

≥65 years (16). The presence of teeth is helpful in shaping the facial soft tissue; thus, the mask sits comfortably around the mouth (17). Because a standard mask does not fit easily onto the cheeks of edentulous patients, face mask ventilation may be hard to perform (18). The airway may also be obstructed by movement of the tongue, soft palate, and epiglottis to the rear, whereas the space for air is lessened in the oropharynx due to low muscle tone caused by general anesthesia (19). In edentulous geriatric patients, sunken cheeks may make ventilation with a mask ineffective and perhaps even impossible (20). In a previous study, the 12.6% rate of difficult mask ventilation (DMV) comprised both dentulous and edentulous geriatric patients; therefore, the presence of patients with teeth may have reduced the relative incidence of DMV in the study (17). The results showed no link between lack of teeth and mask ventilation; however, other studies have shown that mask ventilation is more difficult in edentulous patients. Several previous studies have described the difficulties experienced by elderly patients during mask ventilation (4,7,14,16,17). However, very few studies have investigated the insertion of laryngeal masks and the possible problems related to this process in patients in this age group (7,8). There are studies on the use of first- and second-generation LMUs in edentulous geriatric patients. Beydeş et al. (21) demonstrated that the success rate in the first insertion attempt was higher with LM-Supreme than with the LMU, but the ease of insertion and OLP were similar. They reported that findings can have important implications for anesthesiologists managing edentulous geriatric patients with supraglottic airway devices. Ezri et al. (8) demonstrated that although more head/jaw manipulations were required to maintain a patent airway, LMs such as the cuffed oropharyngeal airway (COPA) allowed for safe, hands-free anesthesia with good control in most patients. A COPA was an equally effective airway device to the LMA in providing anesthesia for short procedures for this elderly patient group.

Although there are studies in the literature related to LMU use in geriatric patients, to the best of our knowledge there is no study comparing the use of LMU in dentulous and edentulous patients. We planned this study as a result of our observations of difficulties in inserting the classic LMU and problems with providing a continuous airway with LMUs in edentulous patients compared to dentulous patients during LMU use in outpatient anesthesia administration in the geriatric population. In this study, insertion of the LMU on the first attempt was successful for 78.7% of dentulous patients and 60.6% of edentulous patients. Previous studies on the LMU have reported first-attempt insertion success rates of 88%–100% (5,11,22–25). Compared to our study, these higher success rates might have been related to the use of muscle relaxants during

LMU insertion. Additionally, a previous study (13) found that high first-attempt LMU insertion success rates (e.g., 100%) might be due to the effects of muscle relaxants and could be related to insertion of the LMU after train-of-four (TOF) monitoring showed sufficient muscle relaxation. However, a limitation of that study was that the LMU was inserted by a single very experienced operator; thus, an inexperienced operator would be unlikely to achieve a similarly high rate of success. Insertion success rate of the LMU on the first attempt by inexperienced health personnel was found to be 77% (26). However, in another study investigating the effects of the experience level of anesthesia experts, assistants, and technicians on LM application and pharyngolaryngeal side effects, operator experience was found to have no effect on the application of LMs (27).

In our study, the LMUs were inserted in all patients by two researchers, each with more than 3 years of experience. The oral opening in elderly patients is narrow because of temporomandibular joint arthrosis, and neck flexion and head extension are limited by cervical spondylosis (28). Therefore, airway management is more difficult than we typically expect. Regarding ease of insertion of the LMU, we did observe some apparent differences between the two groups (90.0% vs. 75.7% in dentulous vs. edentulous patients). However, there were no statistically significant differences between the groups. Similarly, ease of insertion of the LMA in Ezri et al.'s study (8) on the geriatric age group was 97.5% in the COPA group and 87.5% in the LMA group. In addition, van Zundert et al. (29) found that ease of insertion was 94.3%. In contrast to these high rates, studies by Francksen et al. (11,22), López et al. (12), and Cook et al. (30) found that the ease of insertion with the LMU was 80%, 75%, 76%, and 70%, respectively. Muscle relaxants were not used in these studies, and although the patients were in a younger age group, the observed success rates were similar to those in our study. Brimacombe et al. (6) and Brimacombe and Berry (23) used muscle-relaxing agents and found that the ease of insertion of the LMU in patients was 98%. Although muscle relaxants were used in their study, the researchers concluded that once sufficient anesthetic depth was obtained, the use of muscle relaxants did not affect the ease of insertion. In our study, the reason for the somewhat lower ease of insertion observed in the edentulous group might have been related to the mucosal and pharyngeal structures of the patients being looser because of their lack of teeth. Additionally, previous studies have concluded that one reason for unsuccessful insertion is the reactive spasm of the pharynx inferior constrictor muscles during insertion of the LM, which prevents the tip of the mask from advancing downward and, as a result, disrupts function (31,32).

In a study comparing the use of the laryngeal mask airway Classic™ (LMAC) and the COPA in patients older than 65 years, Ezri et al. (8) found that manipulation was required during insertion in 5% of the LMAC group and 25% of the COPA group. Although we did not require any maneuvers during LMU insertion in our study, there have been several difficulties in securing the inserted laryngeal masks, as in this study. These difficulties might be related to the research group being chosen from patients in the geriatric age group.

The durations of LMU insertion were 14.40 ± 4.80 s and 13.43 ± 4.11 s in the dentulous and edentulous groups, respectively. In previous studies (11,14,22) of the application of the LMU, the duration of insertion was found to be 15.2–19.0 s. In all three of those studies, experienced researchers conducted the insertions without using muscle relaxants, and the duration of insertion was similar to that in our study. However, in contrast to our study, the populations of two of these studies (11,22) consisted of female patients only.

In our study, the OLP in the dentulous group was 21.75 ± 4.62 cmH₂O, whereas it was 20.75 ± 5.04 cmH₂O in the edentulous group; this difference was not statistically significant. The OLP values observed in our study were similar to those found in the studies of López et al. (12), van Zundert et al. (29), and Cook et al. (30) when the cuff inner pressure was maintained at 60 cmH₂O, i.e. 22 ± 6 , 25 ± 6 , and 20.5 cmH₂O, respectively. Similar to our study, muscle relaxants were not used in these studies. However, in other studies (13,27), muscle-relaxing agents were used and the OLP values for the LMU were 22 cmH₂O and 24 ± 4 cmH₂O, respectively, which were similar to the results from studies without muscle relaxants. However, the age groups were younger in these studies than in our study. This might be related to possible anatomic changes linked to the geriatric age group of the patients.

Previous authors (27) measured the OLP values after inflating the cuffs with volumes of 10, 20, 30, and 40 mL as 19 ± 5 , 25 ± 4 , 27 ± 4 , and 25 ± 4 cmH₂O, respectively. They showed that when the cuff volumes increased to greater than 30 mL, the OLP values decreased. Brimacombe et al. (6) maintained the cuff inner pressure at 60 and 180

cmH₂O and measured OLP values of 18.0 ± 5.8 and 15.6 ± 4.6 cmH₂O, respectively. These researchers found that although the OLP values at 180 cmH₂O were lower, the lower cuff inner pressure of 60 cmH₂O was related to better placement of the LM. In our study, the volumes provided to maintain the cuff inner pressure steady at 60 cmH₂O were measured as 17.13 ± 2.36 and 17.06 ± 2.3 mL in the dentulous and edentulous groups, respectively. No throat pain was observed in the patients at the 1st and 24th postoperative hours. We suggest that this situation is related to maintaining the LMU cuff inner pressure at 60 cmH₂O, limiting the insertion attempts to three, and monitoring the BIS to ensure sufficient anesthetic depth, as well as the long duration of anesthesia. Additionally, nitrous oxide was not used in our study, which might have reduced the incidence of laryngeal complications.

Our study has certain limitations. For example, after insertion of the LMU, imaging with a fiberoptic bronchoscope was not performed, and the position of the supraglottic airway device in the hypopharynx was not evaluated. In two cases in which ventilation was unsuccessful after three attempts at LMU placement, alternative airway management was provided. Had fiberoptic imaging been performed in cases in which the LMU could not be inserted or ventilation could not be provided, it might have provided information about the causes of these problems. Another limitation of our study was that ventilation parameters were not recorded. During controlled respiration with the LMU, airway pressure and volume were not monitored, and the lowest pressure and volumes providing sufficient ventilation were not chosen. Measuring the airway pressure and volume, which are indicators of the placement and efficiency of LMs, would have provided more information about pressure during the use of the LMU in elderly patients (33).

In conclusion, our observations of LMU usage in geriatric patients could have important implications for anesthesiologists managing edentulous geriatric patients with supraglottic airway devices. In further research, studies into airway management with larger groups of dentulous and edentulous geriatric population and different generations of LMUs will be completed.

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