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Removal of Endotracheal Tube Debris Obstruction by a Clearing Secretion Device.

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ABSTRACT

Accumulation of secretions may suddenly occlude the endotracheal tube (ETT) requiring immediate medical attention. The endOclear® catheter (EndOclear LLC, Petoskey, MI) is a novel device designed to clean the ETT from mucus debris and restore the luminal patency.

We present a series of three subsequent cases of life-threatening partial ETT-occlusion recorded over a period of six months at Massachusetts General Hospital. After the failure of conventional methods, standard tracheal suctioning and bronchoscopy, the endOclear® device was implemented with successful restoration of the airways in all three cases. The three patients rapidly improved their respiratory conditions and tolerate well the ETT-clearing manoeuvre.

These observations showed that such device is (I) safe, (II) easy to use during an emergent-airway situation, and (III) efficient to rapidly remove secretions in the setting of ETT obstruction by the respiratory therapist personnel.

Key Words: Respiration, Artificial; Positive-Pressure Ventilation; Respiratory Failure; Airway Obstruction; Airway Resistance; Pneumonia, Ventilator-Associated; Biofilms

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INTRODUCTION

Patency of the endotracheal tube (ETT) during mechanical ventilation (MV) is often compromised by the accumulation of luminal debris. A flexible catheter is generally used to remove these secretions by suctioning, a manoeuvre that can be performed either in a closed or open fashion, according to local clinical practice (1). Nevertheless, evidence suggests that, even if periodically repeated during MV, standard suctioning is not efficient enough in order to preserve the ETT's original lumen size, and then its nominal function (2). Abrupt occlusion is rare, but can be life-threatening, potentially requiring emergent airway restoration. Endotracheal tube ex-change may be required to ventilate and oxygenate the patient, a high-risk procedure in an emergency ICU setting (3). On the contrary, partial occlusion due to secretion accumulation is ubiquitous and recklessly snubbed, with an average estimated loss of intra-luminal ETT volume between 9% and 15% (4, 5). The occlusion percentage increases the resistance to airflow within the ETT, thereby imposing additional work of breathing to critically ill patients (6, 7). Moreover, pathogens-laden secretions stationed within the tube may migrate and colonize the lower respiratory tract, causing pneumonia (8, 9).

Thus, theoretical benefits of preserving the ETT's original function include: (I) reducing the likelihood of hazardous sudden ETT occlusions and the subsequent need of emergent interventions; (II) decreasing airway resistance and work of breathing of critically ill intubated patients, eventually facilitating their weaning process, which might ultimately lead to a reduced time of MV (III) reducing the incidence of Ventilator-Associated Events by preventing pathogens to form bacterial biofilm within the ETT.

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Since April 2013, at the Respiratory Care Department of the Massachusetts General Hospital (Boston, MA), we have adopted the use of the endOclear® device (EndOclear, LLC., Petoskey, MI) for clearance of secretions from the ETT lumen (figure 1).

Here we present a series of three subsequent life-threatening cases recorded over the past six months. In all of them, the device was used by the staff respiratory therapists in order to emergently resume MV after standard ETT-cleaning methods had failed.

The endOclear® device and function

The endOclear® catheter (ENDOCLEAR LLC, Petoskey MI) is a novel medical device designed to clean the endotracheal tube without interrupting mechanical ventilation (Figure 1). Essentially, it consists of a flexible central tube and a smooth disc-shaped wiper at its distal end (Figure 1. D, D_1, D_2).

In operation, the device is inserted into an ETT through a dedicated adapter, until touching the adjustable blue safety stop (Figure 1. A), therefore preventing over-insertion. The patient continues to be mechanically ventilated throughout the procedure thanks to the particular Y-shape of the adapter. The red safety toggle (Figure 1. B) is then disengaged to allow subsequent active deployment of the distal end of the device. Firmly grasping the handle, the trigger is fired (Figure 1. C) in order to deploy and expand the smooth wiper end (Figure 1. D). When activated, the distal cleaning apparatus shifts from a closed (Figure 1. D_1), to an open position (Figure 1. D_2). Once deployed, the wiper can firmly engage the inside walls of the endotracheal tube. The endOclear® device is then pulled back out of the ETT, thereby remoing

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secretions and biofilm from inside the lumen. Overall, the process of insertion, activation, and clearing of the ETT (distal to proximal end) requires 3 to 5 seconds. Collected secretions are trapped inside a side port of the device connector (not shown in Figure 1) and the whole system can be then disregard.

CASE 1: Medical ICU, Massachusetts General Hospital

An obese 60 year old woman was admitted to the Medical Intensive Care Unit (ICU) at our institution from an outside hospital for management of severe Acute Respiratory Distress Syndrome (ARDS) due to *Legionella pneumophila* pneumonia. Patient was already sedated and intubated with a 7.5mm I.D. (Internal Diameter). Chest x-ray showed diffuse opacifications on the right lung, as well as patchy opacification in the left mid and lower lung, consistent with pneumonia. Humidification of the airways was provided by a dual-heated-wire circuit (Neptune powered by ConchaTherm). Upon arrival, the ventilator settings were volume-controlled ventilation at 14 breath/min, Vt 6 cc/Kg of ideal body weight (IBW), positive end expiratory pressure (PEEP) 18 cm H_2O, and F_{IO2} 0.80 (PaO_2 /F_{IO2} ratio 90). Overnight, the respiratory therapist noted that the patient was not synchronized with the ventilator due to double triggering from abdominal rebound. Meanwhile, the peak pressure was progressively increasing for the same ventilator setting. Once switched to pressure controlled ventilation, the tidal volume was remarkably reduced and the ventilator was repeatedly auto-triggering. The ICU team tried to suction with standard closed system suctioning (Closed system suctioning #14, Kimberley Clark) but were unable to pass the catheter through the ETT lumen. After installation of saline and multiple attempts to *lavage* the ETT to help break up the occlusion, only minimal secretions

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were retrieved. While ventilation was increasingly difficult, patient was disconnected from the ventilator and manual bag ventilation was initiated, saline was instilled and suctioning was attempted again which pulled out some dark colored secretions. At that point the endOclear® device was inserted and a large dark dry mucus plug was retrieved (figure 2. A). The patient-ventilator breathing synchrony was restored, and ventilation was immediately resumed.

The rapid recognition by the respiratory therapist combined with the prompt resolution of the ETT occlusion by the endOclear® device prevented a hazardous re-intubation in this hypoxic patient with severe ARDS and high-pressure ventilator settings.

CASE 2: Medical ICU, Massachusetts General Hospital

An adult male patient with a history of multiple hospitalizations for bronchiectasis was admitted in the Medical-ICU with pneumonia. The patient was intubated with an 8.0 mm I.D. endotracheal tube and mechanically ventilated for several days for respiratory failure, and treated with appropriate antibiotics. Readiness for extubation was assessed daily with a spontaneous breathing trial (PEEP 2 cm H_2O, Pressure Support 0 cm H_2O and F_{IO2} 0.40). On day 8 of mechanical ventilation, the respiratory therapist found the patient in distress during his trial secondary to high respiratory rates within minutes of starting the trial. On exam the patient was using accessory muscles; on auscultation he had diminished breath sounds bilaterally; oxygen saturation decreased from 100% to low 90's. A picture of the ventilator screen showing early changes in the pressure/flow curves due to secretion accumulation in the ETT are depicted in Figure. 3.A. After standard suctioning of the ETT, the patient became more agitated and

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marginal secretions were retrieved from the ETT lumen. The respiratory therapist decided to try the endOclear® tube scraper and was able to remove a large amount of secretions Figure. 2.B. Within a few minutes the patient's respiratory rate slowed to high teens, breathing pattern improved and oxygen saturation increased to high 90's and normal pressure/flow curves were recorded on the ventilator (Figure. 3). The spontaneous breathing trial was resumed and the patient successfully passed the trial within the hour and was eventually extubated later on that day.

The intervention of the respiratory therapist allowed this prolonged mechanically ventilated patient to pass his breathing trial and being successfully extubated on the same day, avoiding extra-ventilator days and a possible tracheostomy.

CASE 3: Surgical ICU, Massachusetts General Hospital

A 70 year- old male with a significant past medical history of chronic obstructive lung disease and 100-pack-year smoking history was admitted to our institution from an outside hospital for management of severe hypernatremia, a right exudative pleural effusion of uncertain etiology, and respiratory failure due to right middle and lower lobe pneumonia. Patient was intubated with a 7.5mm I.D. (internal diameter) ETT and transferred to the Surgical Intensive Care Unit (ICU) after insertion of a chest tube for a right pleural effusion and bronchoscopy showing thick secretions. Patient was diagnosed of angioimmunoblastic T cell lymphoma stage 4 and hemolytic anemia. Patient's ICU stay was complicated by bone marrow suppression, acute kidney injury and *Enterobacter sp.* pneumonia requiring prolonged ventilation.

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Mechanical ventilation was changed accordingly during the ICU course. Humidification was provided by Neptune powered by ConchaTherm and a dual-heated-wire circuit was implemented. On day 14 ventilator settings were volume controlled ventilation at 18 breath/min, Vt 400 mL (7cc/Kg ideal body weight), PEEP 5 cm H_2O, and F_{IO2} 0.40. Early in the day, peak pressure showed to be increased from the low 20s' to mid 20s'-high 20s'.

Vital signs were stable until the respiratory therapist noticed an acute airway obstruction and called the anesthesiologist to the bedside after trying to advance a suction catheter through a 7.5 mm ETT without success. Peak respiratory pressure was in the mid-50s and minute volume dropped to less than a liter per minute. Auscultation revealed louder breath sounds on the left than the right. Mucus plug was suspected and an anesthesiologist performed emergent bronchoscope. Bronchoscopy revealed copious thick, tenacious yellow mucus lining the entire ETT. Interestingly, all of the airways below the ET tube were clear. The bronchoscopy was unable to reduce peak pressure and resume ventilation. The ICU team considered re-intubation with a new ET tube but the respiratory therapist suggested the use of the endOclear® device to pull out the rest of the mucus. After the first pass a large mucus plug of about 4 mL of thick secretions was retrieved and the obstruction was cleared. Bronchoscopy confirmed the patency and clearance of the lumen of the ETT after the use of the endOclear® device. The peak airway pressures returned to the 20's.

The cleaning of the ETT with the endOclear® device avoided unnecessary re-intubation and prolonged bronchoscopy to retrieve secretions from the ETT.

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DISCUSSION

We reported three cases at our institution over a period of 6 months in which the endOclear® catheter was used effectively to remove ETT occlusions when standard methods to clean ETT had failed. During this period of time a total of 1,792 patients have been admitted to the ICUs at our Institution. Eight hundreds patients were ventilated for more than 48 hours, equal to 133 patients/month.

In all cases, the use of the device was associated with a rapid improvement of the clinical condition of the critically ill patients, avoiding risky and otherwise inevitable reintubation.

Despite the rapid deterioration of the patient conditions, the maneuvers were effective and safely accomplished in all cases by the respiratory therapists in conjunction with the ICU team.

While better humidification has dropped the acute events of ETT occlusions, it is not such a rare event to exchange ETTs in ICU patients due to inability of clearing secretions from the lumen of the ETT. Indeed, just before adopting the endOclear® device, common practice at our institution was to immediately exchange the ETT if the emergent bronchoscopy didn't restore adequate airflow through the ETT lumen (figure 2 C).

Moreover abundant literature shows that partial obstruction of the ETT is a universal problem in intubated and mechanically ventilated patients (2, 4-7). Standard methods to clean the ETT have failed to show optimal ETT integrity and debris always accumulates the entire length of the ETT (10). Endotracheal tube cleaning devices specifically aim to remove the secretions attached to the ETT, acting like a wiper on the internal surface of the tube (11). In table 1, we

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summarized some of the not-standard catheters that effectively clean secretions from within the ETT, however, none of these devices has been systematically tested in large clinical trials to show clinical benefits and improved outcomes. The Mucus Shaver showed to be safe in a clinical setting and to effectively remove mucus deposits from the ETT (12).

Based on these observations, we designed a randomized clinical trial at the Massachusetts General Hospital to evaluate efficacy of the endOclear® device to maintain the patency of the endotracheal tube (ETT) lumen from secretions in prolonged ventilated patients compared to standard suctioning alone (ClinicalTrials.gov: NCT01765530) (13).

These observations showed the efficacy of a device such as the endOclear® to acutely remove secretions in the setting of complete ETT obstruction, this trial will enable us to understand whether such a device should be implemented in all patients that are ventilated for longer than 48 hours.

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Table 1

Name of the device	**Findings**	**Reference**
The *Obstruction Remover*	This device was used in 8 consecutive unselected mechanically ventilated, critically ill patients in which a partial obstruction of ETT was suspected. The authors found that their device could be safely and successfully used to remove obstructions from the ETT lumen, without suspending mechanical ventilation, reducing the need for rapid ETT substitution in emergency and life-threatening situations.	Conti G 1994(14)
The *Mucus Shaver*	The Mucus Shaver was tested in 12 patients ventilated for >72 hours and showed to be safe, and effective device for endotracheal tube cleaning	Berra L 2012(12)
The *Mucus Slurper*	No clinical trials have been carried out on the use of the Mucus Slurper. A laboratory study of the device showed that it is able to prevent accumulation of secretions in sheep ventilated for 72hours.	Li Bassi G 2007(15)
The *AirwayMedix*	Currently under experimentation	

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The *endOclear*®	The present report showed safety and efficacy in remove ETT occlusions	Current report
The *Rescue Cath*	The authors reported a case report series of 3 obstructed ETTs where the catheter successfully removed secretions	Stone RH 2011(16)
Sterile urethral catheters	45 children where randomized to standard of care or to the cleaning of the ETT with an urethral catheter every 8 or 12 hours. The mechanincal cleaning proved efficacy in reducing the bacterial colonization and preventing biofilm formation.	Liu W 2013(17)

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Figure 1. Representation of the endOclear® endotracheal tube clearing device

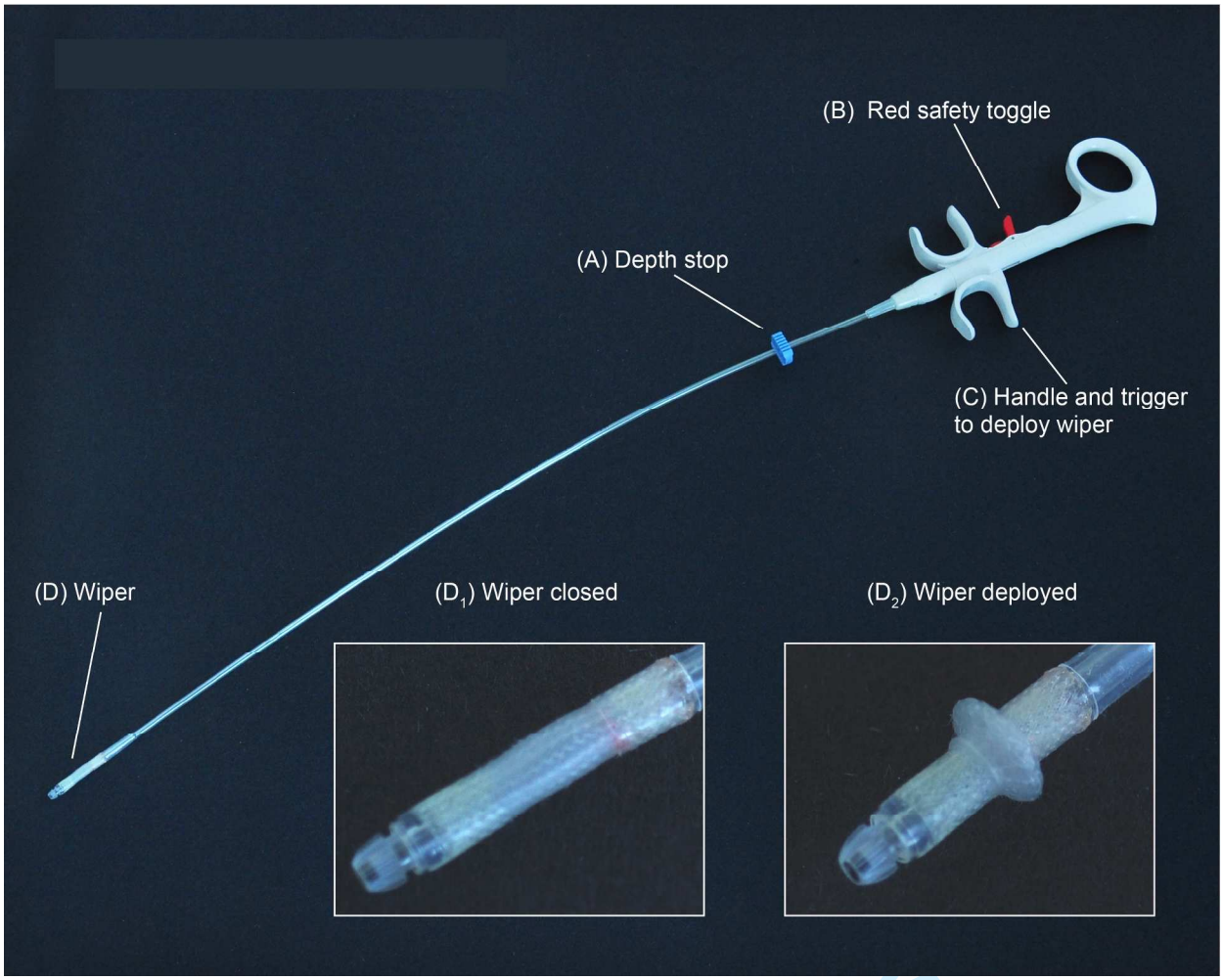

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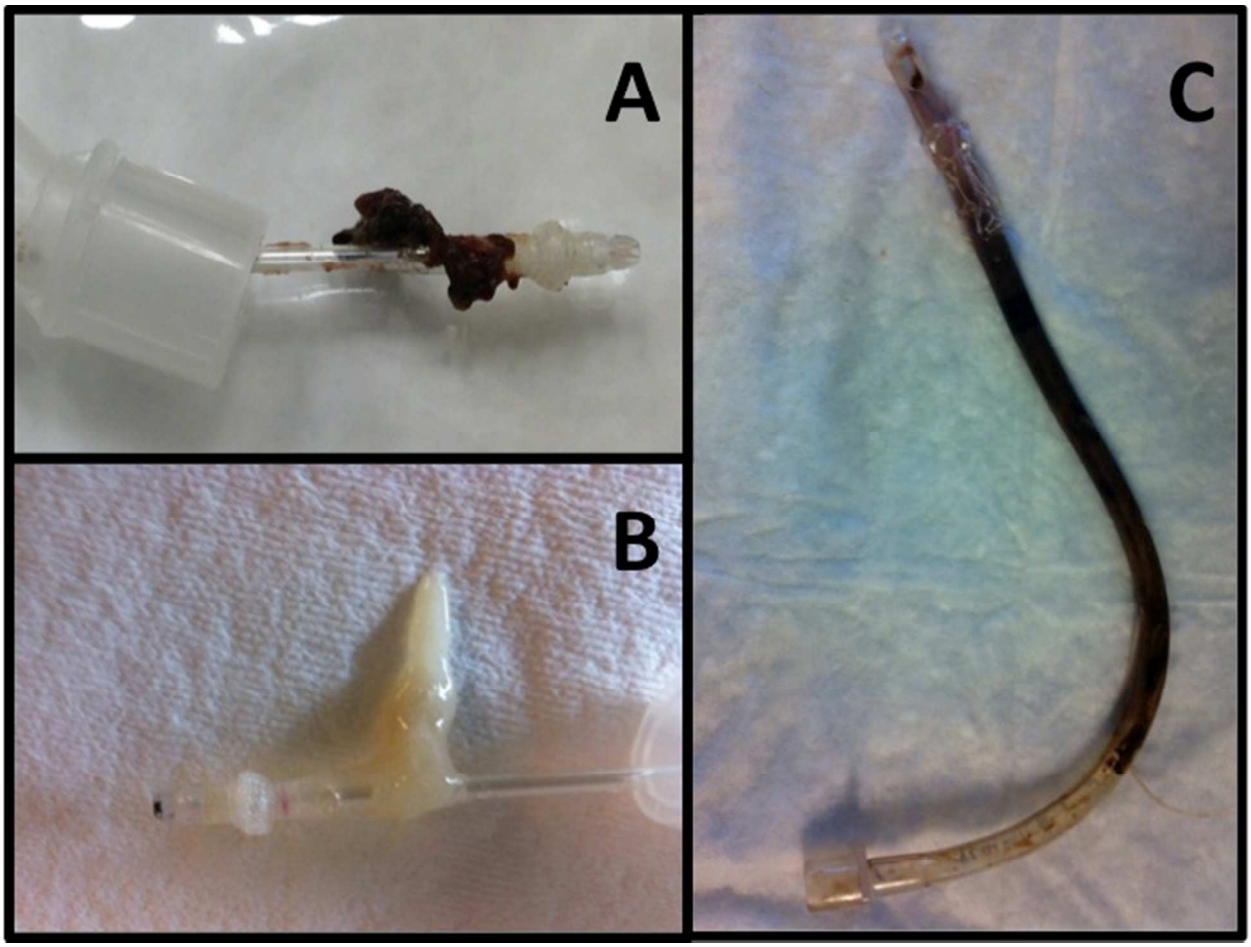
Figure 2. ETT occluded and restored by the use of the endOclear® device.



2 A. Tip of the endOclear® device engaged with dried secretions after ETT cleaning (case 1).

2 B. Tip of the endOclear® device engaged with a large mucus plug after ETT cleaning (case 2).

2 C. Picture of an occluded ETT of a burn ICU patient (case not presented in the text). Standard suctioning and emergent bronchoscopy were unable to maintain normal gas exchange and ventilation. Patient had to be re-intubated to resume oxygenation and ventilation.

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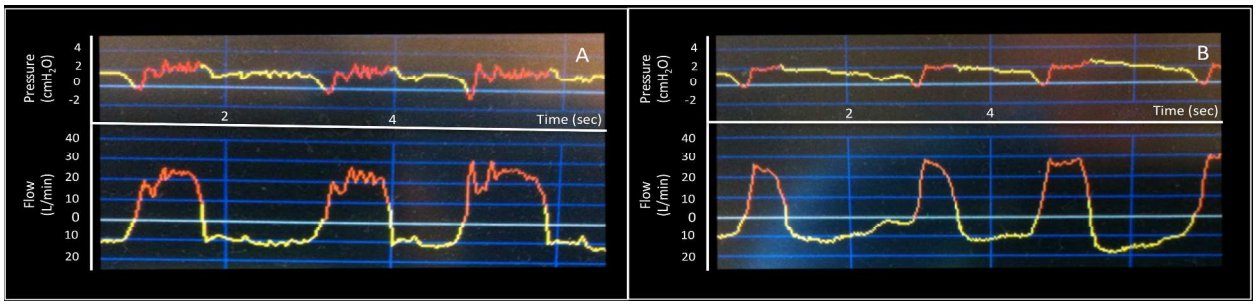
Figure 3. Flow and Pressure curves on the ventilator, before and after the use of the endOclear® device.



In picture 3.A. the patient is failing his spontaneous breathing trial, note the early changes on the pressure and flow curves that have been restored to normal baseline in picture 3.B. after the use of the endOclear® device.