To The Editor: We would like to report a problem we encountered with laryngeal mask airway (LMA)-ProSeal™ (The Laryngeal Mask Company (UK) Limited), intended for use in a healthy 30-year-old female presenting for an elective orthopaedic procedure. During the routine pre-insertion preparation, whilst we were deflating the LMA-Proseal™ with a gentle pull on the inflation line,1 the inflation line along with the pilot balloon broke at the point of its attachment to the cuff (Figure 1). As a buffer stock of the same size was not available at that time, Classic™ LMA was used for the procedure. This Proseal™ LMA had been cleaned and sterilised as per the manufacturer guidelines but we have no record of the number of times it had been autoclaved and used.

Figure 1: Arrow showing damaged Proseal™ LMA cuff along with the broken inflation line with ruptured cuff fragment

The LMA-Proseal™ is a new and complex reusable LMA device, which differs from the classic™ LMA in that it has a larger ventral cuff, a dorsal cuff, a drain tube and a built-in bite block. All reusable LMA devices are subject to degradation due to repeated sterilisation and damage during clinical use (from biting, overinflation, surgical instruments, failure to evacuate air from the cuff during sterilisation methods/materials etc). However, Proseal™ LMA is more susceptible to these insults owing to its special design. Its cuff has a complex shape with more folds and seams and these are the areas that are more likely to fail in any inflatable structure. The cuff wall may be subject to greater stresses during autoclaving because of a larger residual volume. The larger cuff is also more likely to get damaged by teeth. The drain tube has a gentle S-curve within the bowl which is liable to get punctured during cleaning. Indeed, reports of damage to Proseal™ LMA have appeared in literature.2,3 Doneley et al1 in an audit of their institute found that many of the Proseal™ LMAs were not lasting for 40 uses, despite strict adherence to the manufacturer’s guidelines for cleaning and sterilisation. In their study on the life-span of Proseal™ LMA and Classic™ LMA, they observed that Proseal™ LMA has a shorter life-span than the Classic™ LMA and attributed it to the increased weakness of the Proseal™ LMA cuff as the inflation line and pilot balloon are identical for the two LMAs. Manufacturers should identify and reinforce these vulnerable areas, so that not only the investment in the product is justified but the patient safety is also optimised.

References:

To The Editor: We are grateful for the opportunity to respond to the article “Damaged Proseal™ LMA Cuff at the inflation line site”. The authors are to be commended for following the instructions for pre-use preparation of the device. The ‘breakage’ of the pilot tube from its point of attachment to the cuff, was probably caused by the adhesive deteriorating after too many uses of the device (>than 40 uses). Doneley et al,1 reported a comparison carried out between 6 new size 4 LMA ProSeal™ and 6 new size 4 LMA Classic™. A simulated clinical cycle was performed, and repeated until the devices failed the pre-use tests. The LMA ProSeal™ (PLMA) lasted 82 ± 23 (45-109) and the LMA Classic™ (cLMA) lasted 135 ± 35 (76-176) uses respectively. Neither device failed the pre-op usage tests after 40 uses.

Jolly et al,2 reported damage to the cuff of the LMA ProSeal™ following steam autoclaving. The red plug was not left open to air, as recommended, during autoclaving, resulting in damage to the cuff. Stix et al,2 reported damage to the drain tube caused by an inappropriate cleaning brush during manual cleaning of the PLMA drain tube. Both groups recommended strict adherence to the manufacturer’s recommendations for cleaning and autoclaving the device.

The other clinical causes cited for damage to the cuff and drain tube by the authors are easily preventable with careful attention to detail during insertion, cuff inflation, device fixation and device removal.

The LMA Proseal™ is manufactured with a great deal of attention to detail, and much of the device is ‘hand assembled’. It is recommended that the number of uses/cleanings and autoclavings is documented and that the device is discarded after 40 uses. Manufacturer’s instructions on sterilization and autoclaving should be implemented.1

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References: