FIGURE 2 Traction on the connector leads to displacement of the cannula within the flange with subsequent tracheal obstruction and inability to ventilate.

accidental traction on the cannula firmly connected to the breathing tubes of the respirator by the built-in connector. We believe that outward displacement of the cannula (1) led to tracheal obstruction, the cannula being perpendicular to the trachea, and (2) rendered ventilation impossible, the distal orifice of the cannula lying against the posterior tracheal wall (Figure 2). Initially it was thought that the locking ring had been insufficiently tightened, but manipulation of the tracheostomy set after the incident disclosed that while maximal tightening of the screw ring made slipping of the cannula more difficult, it could still be moved within the flange quite easily.

While the Rüsch Ultra Tracheoflex® set presents some interesting characteristics such as a built-in connector and a construction designed to minimize tracheal trauma, we believe the design of the restraining collar should be improved. Fenestration of the cannula may help prevent total respiratory obstruction.

We wish to thank Dr. Tack Ki Leung, Department of Pathology, for his collaboration with the illustrations.

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REPLY (1)

Thank you for the opportunity to reply to the letter from Doctors Hardy, Taillefer and Hébert re their experience with the Rüsch Ultra Tracheoflex®.

Normally it is very difficult to move the adjustable flange on the screw ring once it has been firmly tightened. However, it is possible to do so if the circumference of the cannula is reduced by applying traction to the cannula and stretching it. The softness of the PVC used plus the reinforcing wire in the wall of the tube will permit a small amount of stretching. By applying opposing forces, traction at the machine end (respirator breathing tubes) and pulling on the patient end (the adjustable flange), it is possible to slide the screw ring towards the patient over the reduced circumference of the tube. Continued traction on the collar could allow the cuff to be rotated... "perpendicular rather than parallel to the axis of the trachea."

With a fixed collar model tracheostomy tube it is probable that these forces would have caused either a disconnect or extubation. It is unfortunate that the very features which benefit the patient, the adjustable flange and soft, flexible cannula, might have been involved in a tragedy. However, it is recognized that the application of abnormal forces to connecting parts can produce abnormal results. That a life-threatening situation was the result in this instance is indeed regrettable and we can all be thankful that the patient experienced an uneventful recovery.

In light of their reported experience we have withdrawn the Ultra Tracheoflex® from the market.

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REPLY (2)

The clinical incident reported by Hardy, Taillefer and Hébert on the Rüsch Ultra Tracheoflex® Tracheostomy tube was brought to the attention of the Health Protection Branch, Health and Welfare Canada.

As part of our regulatory assessment, we conducted laboratory simulations of the extubation process to determine the force levels causing the flange to slip on the cannula. An Instron Mechanical Tester pulled on the tracheostomy connector (10