The inner end portion of an endotracheal tube is encircled by an inflatable cuff, to which is connected a tubule that extends toward the opposite end of the tube and is formed for connection to a source of air pressure. In communication with the tubule is an expandable chamber having an elastic wall. The chamber is expandable as long as air is forced into the tubule and is so formed that after it has expanded to a predetermined size, at which the air pressure therein is the same as the maximum air pressure desired in the cuff, additional air forced into the chamber will expand it further without substantially changing the pressure in the cuff.
ENDOTRACHEAL TUBE WITH INFLATABLE CUFF

For medical patients who require a chronic intubation for periods of several days to weeks, a tracheotomy is performed and a tube is passed through the wall of the trachea and down several inches into the trachea. In other cases the tube may be inserted by way of the mouth. In order that intermittent positive ventilation can be provided, there must be a seal around the outside of the endotracheal tube, between it and the trachea wall. Such a seal is provided by a flexible cuff which can be inflated by a syringe or the like that can increase the pressure of the air in the cuff. Correct inflation of the cuff is a difficult procedure and, in attempting to make sure of an effective seal, the cuff often is overpressurized. This results in an unnecessarily high occlusion pressure, which may cause dilation of the trachea and/or blockage of circulation, leading to necrosis at the cuff seal.

This overinflation problem is brought about by two situations. First, the person inflating the cuff has little or no feedback showing the quality of the seal obtained or the pressure at the interface. Second, a typical cuff must be elastically extended in order to provide a seal, so that even though the air pressure inside the inflated cuff is known, the attendant has no way of knowing the pressure exerted by the cuff against the wall of the trachea. It is these two factors that have given rise to this invention. Others have attempted to solve the problem by making use of pilot or tell-tale balloons connected with the tubes through which the cuffs are inflated, but all that such balloons indicate is whether or not there is air pressure in the cuffs. They do not tell how much pressure the cuffs are exerting against trachea walls, and they do not control that pressure.

It is an object of this invention to provide an endotracheal tube that carries an inflatable cuff which will make a good seal against the trachea wall and never exert too much pressure on it. Another object is to provide such a tube with a visible indicator of the pressure exerted by the cuff, and with means for maintaining that pressure substantially constant.

The preferred embodiment of the invention is illustrated in the accompanying drawings, in which FIG. 1 is a side view of one endotracheal tube; and FIG. 2 is an enlarged cross section taken on the line II—II of FIG. 1.

Referring to the drawing, a flexible breathing tube 1, adapted to be inserted in the trachea 2, has an outer end that is exposed for connection to breathing apparatus. The tube is encircled near its inner or lower end by a flexible cuff 3 that is sealed to the tube. The cuff normally is collapsed against the tube so that it and the tube can be inserted in the trachea. The surgeon selects a tube diameter based on his estimate of the diameter of the trachea. In order to inflate the cuff, a much smaller tube or tubule 4 is connected with the inside of the cuff and extends out along the larger tube, to which it may be attached. The outer end of the tubule is formed for connection to a device that forces air into it. Generally, a syringe is used for this purpose, with its nozzle or needle inserted in the outer end of the tubule. After the cuff has been inflated properly, the outer end of the tubule is clamped to maintain the pressure in the cuff, unless the tubule is provided with a valve that will close when the syringe is removed.

It is a feature of this invention that there is no danger of overpressurizing the cuff and thereby causing it to exert too much pressure against the trachea wall. Accordingly, an expandable chamber, preferably an elastic balloon 6, is connected with the exposed portion of the tubule near its outer end. Most conveniently, the balloon incircles a length of the tubule that is provided with radial openings 7 communicating with the inside of the balloon. The balloon is sealed to the tubule. The use of a balloon for the purpose of indicating whether or not there is internal pressure within a cuff is not new, but the additional function of my balloon as designed herein, i.e., control of pressure, is new and very important. Its side wall must be thin and elastic enough to expand as long as air is forced into the tubule. Thus, as the cuff is inflated, the balloon expands. Also, the balloon is so formed that although it requires a predetermined pressure to expand it to a given size, any additional air that is forced into it will cause it to continue to expand without any increase in air pressure. In fact, the pressure may decrease slightly as the balloon gets larger. The balloon is designed so that the point at which this changeover to a substantially constant air pressure is made is one at which the air pressure in the balloon will be the same as the maximum air pressure desired in the cuff. Consequently, it will be understood that when further air is forced into the tubule after that desired maximum pressure has been reached, the balloon will continue to expand but the pressure in the system will not increase.

There are two big advantages of this arrangement. In the first place, when the balloon has been expanded beyond a predetermined size the air pressure in the cuff is known and it also is known that the cuff will not exert a dangerous pressure on the wall of the trachea. In the second place, as long as the balloon is larger than the predetermined size just mentioned, it forms a reservoir of air that will maintain the pressure in the cuff substantially constant even though there may be slow leakage from it. The general practice is to stretch the balloon to more than twice its inflated but unexpanded diameter, so the attendant can readily tell by the appearance of the balloon that there is the correct air pressure in the cuff. To make sure that the balloon is properly inflated, this device can be furnished with instructions to force a certain minimum volume of air into it, such, for example, as at least 4 cubic centimeters of air that can be delivered by a 50 cc. syringe.

The correct dimensions of the balloon for any given air pressure in the cuff can be predetermined. It is a matter of the relationship of material properties, unstretched balloon diameter and wall thickness. For example, when the rubber of which the balloon is made has a substantially constant modulus of elasticity, the maximum air pressure in millimeters of mercury required by the balloon will be equal to the modulus divided by wall thickness of the balloon divided by its free or unstretched diameter, as demonstrated by the following equation for a cylindrical balloon:

\[ P = \frac{2E}{d_t} \left( \frac{d - 1}{d_s - \frac{d_s - d_t}{d_s}} \right) \]

where

- \( P \) is the pressure inside the balloon and cuff
- \( E \) is the effective modulus of elasticity of the balloon material
- \( t_s \) is the unstretched thickness of the balloon wall
- \( d_t \) is the unstretched or free diameter of the balloon
- \( d_s \) is the diameter of the stretched balloon

This equation is theoretical and deviations may exist, but the equation remains within practical working limits. In actual practice it may be necessary to determine the final dimensions empirically on the basis of this equation.

If the modulus of elasticity is not constant, a different proportion than one-half of the modulus is taken and the unstretched diameter of the balloon will be different and it will need to be stretched a different amount before maximum pressure is reached.

This invention contemplates both elastic and inelastic materials for the cuffs. Inelastic material has advantages in the manufacture of the device. On the other hand, if the cuff is elastic an inflation balloon can be chosen that will expand the cuff in a controlled manner and still accomplish the objectives of this invention. In such case the cuff should be made similar to the balloon, by which is meant that after the cuff has been inflated to a predetermined diameter, further inflation will not result in an increase in air pressure inside the cuff. Consequently, if the trachea is larger than expected so that the cuff does not seal against it after receiving maximum air pressure, the cuff can continue to expand until a seal is formed and
yet the pressure of the cuff against the trachea wall will not exceed the maximum desired.

This invention also is applicable when the expandable chamber is not elastic throughout its area. Part of the chamber may be rigid, such as a cup, with its open side closed by an elastic diaphragm or hemisphere that balloons out when air is forced into the chamber.

I claim:

1. The combination with an endotracheal tube having distal and proximal ends, of a normally collapsed flexible tubular cuff encircling the tube near its distal end and having opposite ends sealed thereto, a tubule extending from the cuff outwardly along said tube and having a distal end communicating with the inside of the cuff between the scale ends, the proximal end of the tubule having an inlet for air under pressure for inflating the cuff, and an expandable chamber having an elastic wall, the chamber being in communication with the tubule and being expandable by air forced into the chamber, said elastic wall being formed of material that will continue to stretch without a further increase in air pressure in the chamber as air continues to be forced into the chamber after reaching a predetermined pressure, said wall having an effective modulus of elasticity and unstretched thickness that will limit said predetermined air pressure to the pressure desired in the cuff.

2. The combination with an endotracheal tube having distal and proximal ends, of a normally collapsed flexible tubular cuff encircling the tube near its distal end and having opposite ends sealed thereto, a tubule extending from the cuff outwardly along said tube and having a distal end communicating with the inside of the cuff between the sealed ends, the proximal end of the tubule having an inlet for air under pressure for inflating the cuff, and an expandable chamber having an elastic wall, the chamber being in communication with the tubule and being expandable by air forced into the chamber, said elastic wall being formed of material that decreases in thickness as it is stretched by air forced into the chamber until the chamber has expanded to a size at which the air pressure therein is the same as the maximum air pressure desired in the cuff, and said wall having the property of then stretching further without increase in said maximum pressure as additional air is forced into the chamber to expand it more, whereby the desired air pressure in the cuff will be maintained as long as the chamber is larger than said size.

3. The combination recited in claim 2, in which said cuff is made of elastic material having the said property of said chamber elastic wall.

4. The combination recited in claim 2, in which said chamber is a balloon having a wall thickness and free diameter derived from the following equation as a guide:

\[ p = 2E \frac{1}{d_n} \left[ \frac{d - 1}{d_d} \right] \left[ \frac{d}{d} \right]^2 \]

where

- \( p \) is the pressure inside the balloon and cuff
- \( E \) is the effective modulus of elasticity of the balloon material
- \( d_n \) is the unstretched thickness of the balloon wall
- \( d_d \) is the unstretched or free diameter of the balloon
- \( d \) is the diameter of the stretched balloon.

5. The combination recited in claim 2, in which said cuff is made of inelastic material.

6. The combination recited in claim 2, in which said chamber is a balloon.

7. The combination recited in claim 6, in which said tubule is provided with a lateral opening, and said balloon encircles the tubule and is sealed to it at opposite sides of said opening.

8. The combination recited in claim 6, in which the modulus of elasticity of the balloon material is substantially constant and the ratio of balloon wall thickness to the free diameter of the balloon multiplied by half said modulus is substantially equal to said maximum air pressure.

* * *
UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,642,005 Dated February 15, 1972

Inventor(s) Gerald E. McGinnis

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Claim 1, line 6, change "scale" to --sealed--.

Signed and sealed this 30th day of May 1972.

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents