US 20070066961A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2007/0066961 A1**

Rutter (43) **Pub. Date: Mar. 22, 2007**

(54) **AIRWAY BALLOON DILATOR**

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(21) Appl. No.: **11/231,457**

(22) Filed: **Sep. 21, 2005**

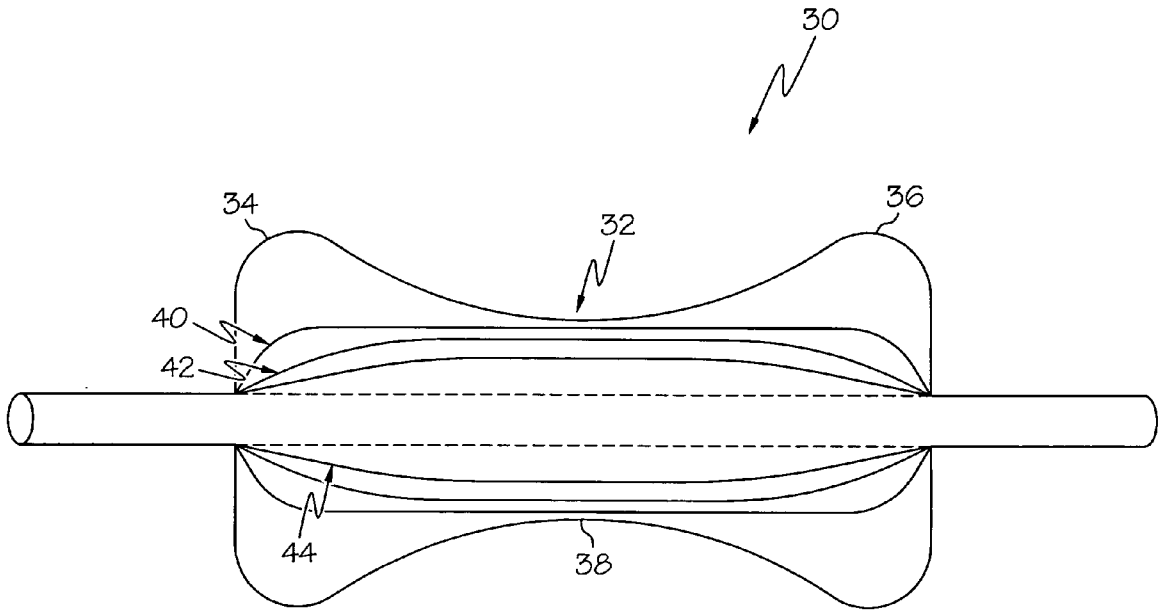
Publication Classification

(51) **Int. Cl.**
A61M 31/00 (2006.01)

(52) **U.S. Cl.** **604/509**; 604/96.01; 604/22

(57) **ABSTRACT**

A medical apparatus for widening a stenosis in the airway of a patient which includes a central hollow core, an inflatable outer balloon, and at least one inner balloon inside the outer balloon. The apparatus also can include a flexible support member mounted on the external surface of the outer balloon with at least one microsurgical blade. The outer balloon can be dumbbell-shaped to keep the balloon in position over the stenosis when the balloon is inflated. The hollow core allows the patient to be ventilated during the procedure, the inner balloon(s) allow higher dilation pressures to be generated from inside the outer balloon, and the blade can form an effective cutting edge upon inflation of the outer balloon.



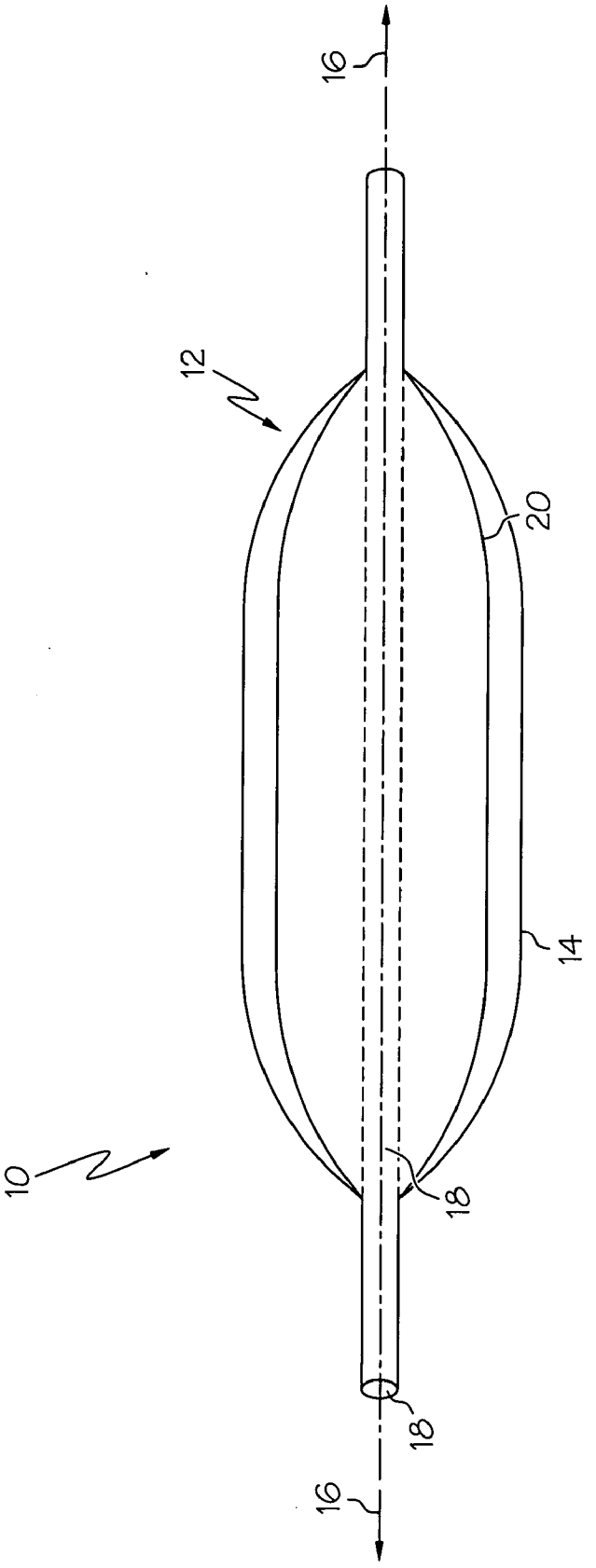


FIG. 1

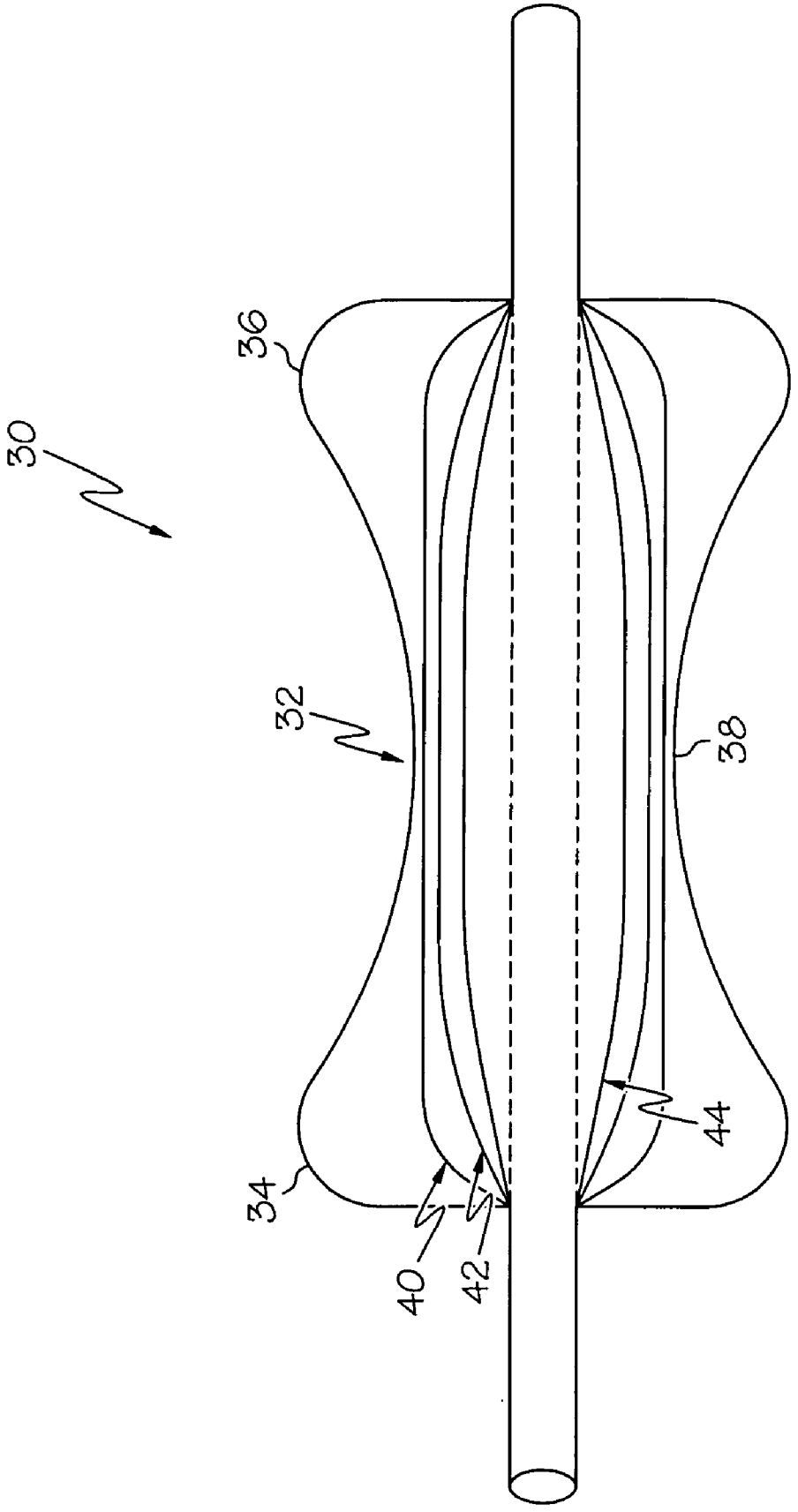


FIG. 2

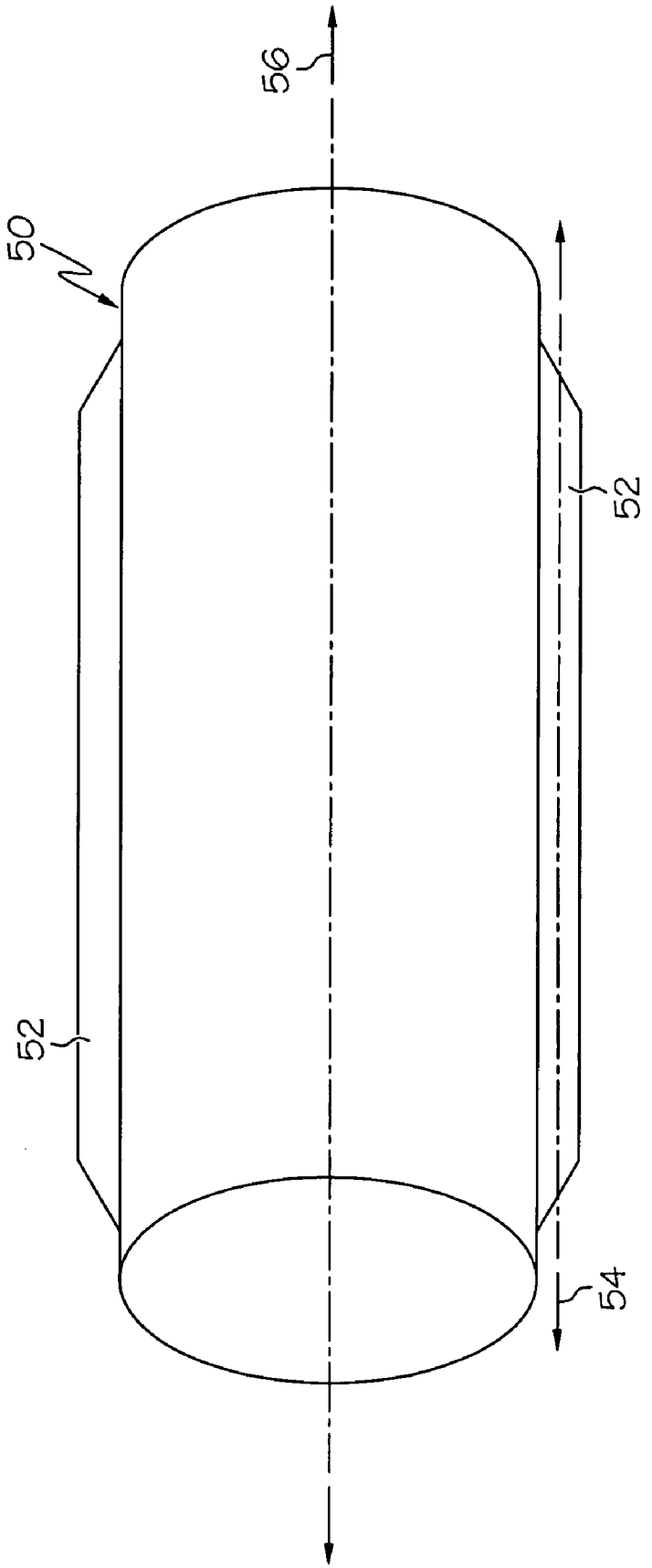


FIG. 3

AIRWAY BALLOON DILATOR

FIELD OF THE INVENTION

[0001] The present invention relates to medical care for the larynx, trachea or bronchi to relieve a stenosis. In particular, the invention relates to a device for performing dilation of the larynx, trachea or bronchi.

BACKGROUND OF THE INVENTION

[0002] Management of stenosis of the trachea and bronchi, including laryngotracheal and subglottic stenosis, is one of the most challenging problems for the head and neck surgeon. Subglottic stenosis is a congenital or acquired narrowing of the subglottic airway. In the early twentieth century subglottic stenosis was rare, and most cases occurred in adults. In the 1960's the incidence of acquired subglottic stenosis began to dramatically increase in the neonatal population, most likely the result of increased survival of low-birth-weight infants and the increased use of intubation in this population. In addition, long term intubation has become an accepted alternative to tracheotomy, leading to more and more incidences of tracheal stenosis. Accordingly, the management of this condition has undergone a revolution, and reconstructive surgery efforts have been directed towards this population.

[0003] Most patients with stenosis of the airway are referred to and are treated at large academic centers by physicians specialty trained in this area. There is a wide range of presentation of subglottic stenosis with similarities and differences in the pediatric age group compared to adults. If the stenosis is severe and congenital, the patient will show signs of airway distress at birth. More commonly, the pediatric patient with subglottic stenosis is a neonate in the intensive care unit who has failed extubation, usually multiple times. Occasionally patients will present in clinic with a tracheotomy and the report of some airway obstruction. Infants with mild subglottic stenosis may present with recurrent croup-like illnesses and poor feeding. Adults usually have a history of prior intubation with symptoms of progressive shortness of breath and noisy breathing.

[0004] Airway balloon dilation has been shown to be a safe and effective palliative procedure for treatment of mild congenital and acquired stenosis of the trachea and bronchi. Dilation of luminal human anatomy to treat stenoses can be dated back to the 16th Century with esophageal "bougie" dilation. Specific medical applications of luminal balloon dilation range from alimentary canal and airway dilation to dilation of the vasculature. Airway dilation dates back over 100 years ago with the invention and subsequent use of the first beveled rigid bronchoscopes for stricture management. The use of balloons to dilate airway strictures emerged in the mid-1980's with reports describing more specific utility of this procedure exclusively and in combination with other treatment modalities for airway stenosis. It was not until the early 1990's that the first balloon dilation involving flexible bronchoscopy was described.

[0005] Airway balloon dilation can be used to quickly re-establish tracheal or bronchial luminal patency to restore airflow in a way that doesn't cause excessive trauma to the patient. According to Poiseuille's Law, an increase in a tube's radius (such as the trachea or bronchus) can increase airflow by a power of 4 (airflow =radius of the tube^4). That is, very small increases in the luminal diameter of the airway can lead to large increases in airflow through the lungs. Literature has reported the use of balloon dilation for the treatment of benign strictures of the airway. Fibrotic strictures, such as those secondary to tuberculosis, long-term endotracheal or tracheostomy tube placement, berylliosis, Wegener's granulomatosis, or sarcoidosis have been shown to be treatable with airway balloon dilation therapy with general success. Additionally, balloon dilation has been useful in treating strictures secondary to major surgical interventions such as lung transplantation, sleeve resection, bronchial re-implantation, and lobectomy. For the purpose of treating strictures secondary to malignant obstruction, dilation therapy can be used alone or in combination with other techniques such as surgical resection, cryotherapy, laser therapy, and stent placement, depending on the desired outcome for the patient.

[0006] Treatment with airway dilation can involve the clinician inserting increasingly larger tubes into the airway (e.g. endotracheal tubes or cat-tail (bougie) dilators), which creates significant shear forces on the airway mucosa. Although safe when performed by a skilled clinician, such a procedure sometimes induces unwanted trauma to the airway in the form of deep lacerations and hemoptysis. Further, current dilation practices do not permit dilation of a tracheal stenosis that is distal to a narrowing of the proximal airway (i.e. a mild subglottic stenosis).

[0007] Current airway balloon dilation procedures are typically carried out using angioplasty balloons; however, several limitations to the use of angioplasty balloons become evident when used on the airway. For example, it may be difficult to adequately ventilate the patient during the dilation period, since the typical angioplasty balloon does not include a connection to an oxygen source. Further, the shape of the angioplasty balloon may predispose the balloon to slide out of place during dilation, or the balloon may be limited to the amount of pressure that can be applied before the balloon bursts. Also, the typical angioplasty balloon can usually stretch the airway lumen but not permanently dilate it. Other factors associated with failure of airway balloon dilation include previous attempts at endoscopic repair, circumferential scarring, and loss of cartilaginous support.

[0008] In light of the foregoing, it would be advantageous to provide a balloon dilator for the airway of a patient that is able to allow ventilation of the patient during balloon inflation. It would also be helpful to provide an airway balloon dilator that can provide increased inflation pressures during balloon dilation of the airway without balloon rupture. Further, it would be beneficial to provide a balloon that will not slip out of place in the patient's airway during balloon inflation. Finally, it is desirable to provide an airway balloon dilator that is capable of controlled cutting of scar tissue.

SUMMARY OF THE INVENTION

[0009] The present invention provides an airway balloon dilator for use to quickly re-establish laryngeal, tracheal or bronchial luminal patency to restore airflow in a way that avoids excessive trauma to the patient.

[0010] One aspect of the invention provides an apparatus for performing an airway balloon dilation procedure at the site of a stenosis in the airway of a patient, the apparatus

comprising a central axis, a hollow core adapted to allow the patient to be ventilated therethrough, an inflatable outer balloon having an external surface, and at least one inflatable inner balloon, the apparatus being insertable into the airway of a patient for movement of the balloons therein between a deflated configuration and an inflated configuration, the at least one inner balloon configured to inflate inside the outer balloon yet separately from the outer balloon.

[0011] Another aspect of the invention provides a method for performing an airway balloon dilation procedure at the site of a stenosis in the airway of a patient, the method comprising: (1) inserting an apparatus into the airway, the apparatus including a central axis, a hollow core adapted to allow the patient to be ventilated therethrough, an inflatable outer balloon having an external surface, and at least one inflatable inner balloon, the apparatus being insertable into the airway of a patient for movement of the balloons therein between a deflated configuration and an inflated configuration, the at least one inner balloon configured to inflate inside the outer balloon yet separately from the outer balloon; (2) advancing the apparatus within the airway until the outer balloon is across the stenosis; and (3) inflating the balloon to cause and allow the external surface of the balloon to expand upon and dilate the stenosis.

[0012] Another aspect of the invention provides an apparatus for performing an airway balloon dilation procedure at the site of a stenosis in the airway of a patient, the apparatus comprising a central axis, a hollow core adapted to allow the patient to be ventilated therethrough, an inflatable, dumbbell-shaped outer balloon having an external surface, at least one inflatable inner balloon, a flexible support member mounted along the central axis of the apparatus and on the external surface of the outer balloon, the flexible support member being substantially compliant with the external surface of the outer balloon during movement therewith, and at least one microsurgical blade attached to the support member and adapted to form an effective cutting edge upon inflation of the outer balloon, the apparatus being insertable into the airway of a patient for movement of the balloons therein between a deflated configuration and an inflated configuration, the at least one inner balloon configured to inflate inside the outer balloon yet separately from the outer balloon, the dumbbell shape of the outer balloon adapted to hold the outer balloon in position over the stenosis, and the at least one blade adapted to form an effective cutting edge upon inflation of the outer balloon.

[0013] The nature and advantages of the present invention will be more fully appreciated from the following drawings, detailed description and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The accompanying drawings illustrate embodiments of the invention and, together with a general description of the invention given above, and the detailed description given below, serve to explain the principles of the invention.

[0015] FIG. **1** is a perspective view of one embodiment of the balloon dilator of the present invention.

[0016] FIG. **2** is a perspective view of one embodiment of the balloon dilator in which the outer balloon has a dumbbell shape and multiple inner balloons.

[0017] FIG. **3** is a perspective view of a flexible support member having microsurgical blades, the support member adapted to fit over the outer balloon according to one aspect of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0018] As illustrated in FIG. **1**, one embodiment of the present invention is an apparatus **10** for performing an airway balloon dilation procedure at the site of a stenosis in the airway of a patient, the apparatus comprising an inflatable outer balloon **12** which has an external surface **14**. The apparatus also comprises a central axis **16**, a hollow core **18**, and at least one inflatable inner balloon **20** adapted to inflate inside the outer balloon. The apparatus **10** is typically insertable into the airway of a patient for movement of the balloons **12**, **20** between a deflated configuration and an inflated configuration. Further, the inner balloon **20** is designed to inflate inside the outer balloon **12** yet separately from the outer balloon, adding the ability of the apparatus to produce high dilation pressures without balloon rupture.

[0019] As shown in FIG. **1**, the hollow core **18** traverses the entire apparatus **10**. Typically the hollow core connects via a proximal ISO connector to an oxygen source such as an anesthesia circuit or the like, and is designed to allow the patient to be ventilated upon inflation of the balloons during the procedure, when the airway is otherwise occluded. The hollow core **18** is typically in the form of a central ventilating tube which is necessarily strong to prevent the pressure of the balloons from crushing the ventilating tube. The structure of the hollow core **18** is typically similar to a small endotracheal tube with a dilating cuff, and the tube may be reinforced, e.g. with wire, in the area of the cuff.

[0020] As illustrated in FIG. **2**, one embodiment of the invention is a balloon dilator apparatus **30** in which the inflatable outer balloon **32** is dumbbell-shaped. This dumbbell shape typically has a variable thickness at the proximal **34** and distal **36** ends of the balloon which allows the outer balloon **32** to stay in position over the stenosis during inflation. In the embodiment of FIG. **2**, the apparatus **30** can include a plurality of inner balloons **40**, **42**, **44**, wherein inner balloon **44** is contained inside inner balloon **42**, which is contained inside inner balloon **40**. All of the inner balloons **40**, **42**, **44** are contained inside outer balloon **32**, and are typically separately inflatable. Such an embodiment could be used with larger diameter outer balloons, e.g. between about 10 to about 20 mm. In this embodiment, the inner balloons **40**, **42**, **44** can be either dumbbell shaped or a "double cone" shape as seen with most angioplasty type balloons, and are inflated sequentially if higher pressures cannot be achieved by the outer balloon. Having a balloon dilator that incorporates multiple interconnected smaller balloons can achieve the desired pressure without risking balloon rupture during inflation.

[0021] During inflation, the proximal **34** and distal **36** ends of the outer balloon **32** inflate first, forming the "dumbbell" shape, thereby trapping the stenotic airway segment at the central portion **38** of the balloon **32**, so that the outer balloon **32** does not slip out of position. Then, as the pressure in the balloon is increased, the central portion **38** of the balloon fully inflates at the site of the stenosis.

[0022] As illustrated in FIG. **3**, one embodiment of the invention can include a flexible support member **50** that can

fit over the apparatus, specifically fitting over the outer balloon. The flexible support member **50** is typically made of a polyurethane material and includes a central axis **56** mounted along the central axis of the apparatus. The support member is adapted to fit over the external surface of the outer balloon, and is typically substantially compliant therewith during inflation and deflation. Support member **50** also includes at least one microsurgical blade, and in FIG. **3** two surgical blades **52** are attached. Blades **52** form an effective cutting edge upon inflation of the outer balloon. Blades **52** are typically made of stainless steel, and are elongated and permanently mounted on the flexible support member **50**. In use, when the support member **50** is placed over the outer balloon, the blade axis **54** is parallel to the central axis **56** of the support member **50**, which is substantially parallel to the central axis of the apparatus.

[**0023**] Having surgical blades **52** present on the apparatus during dilation typically permits controlled cutting or lysis of any scar tissue present in the patient's airway. The blades **52** should be clearly marked so that users can avoid inadvertently cutting themselves during placement of the support member **50** over the outer balloon. In one embodiment, the blades **52** lay flat on the surface of the support member prior to use and prior to inflation of the outer balloon **12**, and then when the outer balloon reaches a certain pressure upon inflation the blades **52** will typically "stand up" or otherwise protrude or expose their cutting edge atop the flexible support member **50**. Once fully deployed, the exposed edge of the blade **52** typically only protrudes between about 0.2 to about 0.4 mm, and the length of the blade is typically less than the length of the outer balloon **12**. Typically there are a plurality of blades which are able to work together to embed into the stenosis or scar at a substantially uniform depth. For example, three blades could be permanently mounted on the flexible support member, each of the blades being separated from the other blades so that each blade is free to move from a relatively flat position to a cutting position on the flexible support member upon inflation of the outer balloon.

[**0024**] In practice, the airway balloon dilation procedure is typically performed at the site of a stenosis in the airway of a patient (i.e. the larynx, trachea or bronchi). Using the apparatus shown in FIG. **1**, the surgeon or clinician first inserts the apparatus **10** into the airway, then advances the apparatus within the airway until the outer balloon **12** is across the stenosis. At this point, the surgeon or clinician inflates the outer balloon **12** to cause and allow the external surface **14** of the outer balloon **12** to expand upon and dilate the stenosis. To increase dilation pressures, the inner balloon **20** is then slowly inflated. Typically the inner balloon **20** is inflated after the inflation of the outer balloon **12**. Under direct visualization, the balloons are typically inflated from between about 30 to about 120 seconds. The apparatus **10** can also be threaded over a guidewire (not shown) which fits through the hollow core **18** and is positioned across the stenosis. Repeat inflation-deflation cycles can be done if airway narrowing remains after the initial attempt.

[**0025**] During balloon dilation, the size of the balloon is first selected by the clinician, which depends upon the size of the stenosis in the patient's airway. The balloon size is typically between about 10 mm to about 40 mm in length. The outer balloon is positioned over the stenosis and then each balloon is individually dilated to the desired pressure with a balloon pump, typically to between about 8 to about 20 atmospheres. After these pressures are maintained for a predetermined period of time, typically between about 60 to about 180 seconds, the balloons are deflated and the clinician determines if repeat inflation is necessary. Repeat inflation can be safely performed if there is no obvious trauma to the airway.

[**0026**] While the present invention has been illustrated by the description of embodiments and examples thereof, it is not intended to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will be readily apparent to those skilled in the art. Accordingly, departures may be made from such details without departing from the scope or spirit of the invention.

What is claimed is:

1. An apparatus for performing an airway balloon dilation procedure at the site of a stenosis in the airway of a patient, the apparatus comprising:

a central axis;

a hollow core adapted to allow the patient to be ventilated therethrough;

an inflatable outer balloon having an external surface; and

at least one inflatable inner balloon,

the apparatus being insertable into the airway of a patient for movement of the balloons therein between a deflated configuration and an inflated configuration, the at least one inner balloon configured to inflate inside the outer balloon yet separately from the outer balloon.

2. The apparatus according to claim 1, wherein the inflatable outer balloon is dumbbell-shaped to hold the outer balloon in position over the stenosis.

3. The apparatus according to claim 1, comprising a plurality of inner balloons.

4. The apparatus according to claim 3, wherein there are three inner balloons including a first inner balloon contained inside a second inner balloon, the second inner balloon being contained inside a third inner balloon, all inner balloons being contained inside the outer balloon and being separately inflatable.

5. The apparatus according to claim 1, further comprising a flexible support member mounted along the central axis of the apparatus and on the external surface of the outer balloon, the flexible support member being substantially compliant with the external surface of the outer balloon during movement therewith, and at least one microsurgical blade attached to the support member and adapted to form an effective cutting edge upon inflation of the outer balloon.

6. The apparatus according to claim 5, wherein the apparatus comprises a plurality of blades adapted to embed into the stenosis at a substantially uniform depth.

7. The apparatus according to claim 5, wherein the support member is made of a polyurethane material.

8. The apparatus according to claim 5, wherein the at least one blade is made of stainless steel.

9. The apparatus according to claim 5, wherein the at least one blade includes a blade axis, the at least one blade being elongated and mounted on the support member with the blade axis substantially parallel to the central axis of the apparatus.

10. A method for performing an airway balloon dilation procedure at the site of a stenosis in the airway of a patient, the method comprising:

(1) inserting an apparatus into the airway, the apparatus including a central axis, a hollow core adapted to allow the patient to be ventilated therethrough, an inflatable outer balloon having an external surface, and at least one inflatable inner balloon, the apparatus being insertable into the airway of a patient for movement of the balloons therein between a deflated configuration and an inflated configuration, the at least one inner balloon configured to inflate inside the outer balloon yet separately from the outer balloon;

(2) advancing the apparatus within the airway until the outer balloon is positioned within the area of the stenosis; and

(3) inflating the balloon to cause and allow the external surface of the balloon to expand upon and dilate the stenosis.

11. The method according to claim 10, wherein the apparatus further comprises a flexible support member mounted along the central axis of the apparatus and on the external surface of the outer balloon, the flexible support member being substantially compliant with the external surface of the outer balloon during movement therewith, and at least one microsurgical blade attached to the support member and adapted to form an effective cutting edge upon inflation of the outer balloon, wherein the inflating step allows the at least one blade to form an effective cutting edge upon inflation of the outer balloon.

12. The method according to claim 11, wherein the apparatus comprises a plurality of blades adapted to embed into the stenosis at a substantially uniform depth.

13. The method according to claim 10, wherein the advancing step comprises the steps of:

(i) inserting a guidewire into the airway of the patient; and

(ii) tracking the guidewire with the apparatus to position the outer balloon across the stenosis.

14. The method according to claim 10, further comprising the steps of:

(4) deflating the balloons after a predetermined amount of time;

(5) repeating steps (1) through (4) if airway narrowing remains after the initial attempt to dilate the stenosis fails; and

(6) removing the apparatus from the patient.

15. An apparatus for performing an airway balloon dilation procedure at the site of a stenosis in the airway of a patient, the apparatus comprising:

a central axis;

a hollow core adapted to allow.the patient to be ventilated therethrough;

an inflatable, dumbbell-shaped outer balloon having an external surface;

at least one inflatable inner balloon;

a flexible support member mounted along the central axis of the apparatus and on the external surface of the outer balloon, the flexible support member being substantially compliant with the external surface of the outer balloon during movement therewith; and

at least one microsurgical blade attached to the support member and adapted to form an effective cutting edge upon inflation of the outer balloon, the apparatus being insertable into the airway of a patient for movement of the balloons therein between a deflated configuration and an inflated configuration, the at least one inner balloon configured to inflate inside the outer balloon yet separately from the outer balloon, the dumbbell shape of the outer balloon adapted to hold the outer balloon in position over the stenosis, and the at least one blade adapted to form an effective cutting edge upon inflation of the outer balloon.

16. The apparatus according to claim 15, wherein the apparatus comprises a plurality of blades adapted to embed into the stenosis at a substantially uniform depth.

17. The apparatus according to claim 15, wherein the support member is made, of a polyurethane material.

18. The apparatus according to claim 15, wherein the at least one blade is made of stainless steel.

19. The apparatus according to claim 15, wherein the at least one blade includes a blade axis, the at least one blade being elongated and mounted on the support member with the blade axis substantially parallel to the central axis of the apparatus.

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