ENDOTRACHEAL TUBE SHAPE MODULATING DEVICE

(57) Abstract: The present invention discloses an endotracheal tube shape modulating device (1000) comprising a proximal casing (100), from which a rigid hollow member (400) is extending in a forward caudal direction, a directing mechanism (600) attached at the distal end of the rigid hollow member (400) and an operating handle (200) extending from the casing (100). The operating handle (200) is pivotally connected to the casing (100) such that it may pivot around a operating handle pivot axis (250) from a forward position in a sagittal relaxed state to a backward position in a sagittal compressed state. The operating handle (200) is mechanically connected to the directing mechanism (600) by means of an upper directing wire (510), attached at its proximal end to an upper attachment point (210) of the operating handle (200) and at its distal end to a point on the ventral side of the directing mechanism (600), and by means of a lower directing wire (515), attached at its proximal end to a lower attachment point (215) of the operating handle (200) and at its distal end to a point on the dorsal side of the directing mechanism (600).

The operating handle pivot axis (250) is located dorsally relative the upper attachment point (210) and ventrally relative the lower attachment point (215).
ENDOTRACHEAL TUBE SHAPE MODULATING DEVICE

TECHNICAL FIELD

The present invention relates to an endotracheal tube shape modulating device for user control of the orientation of the distal end of an associated endotracheal tube during intubation.

BACKGROUND

Endotracheal tubes are used in a variety of medical situations to provide a conduit to a patient’s trachea. In situations when medical attention is needed, medical personnel will determine if the patient’s airways are uncompromised and functional. If not, an emergent life threatening situation arises whereby the medical personnel need to secure a route of artificial ventilation, commonly by placement of an endotracheal tube through the mouth into the tracheobronchial tree. Such oraltracheal placement of an endotracheal tube is often found to be a difficult procedure, even for well trained medical personnel and particularly in stressful situations. This difficulty can partly be attributed to anatomic variations of the patient, and partly to the fact that an object, e.g. an endotracheal tube, inserted through the throat has to be guided into one of two possible routes, the tracheal and the esophageal. It is not uncommon that esophageal intubation is unintentionally achieved instead of the intended tracheal intubation. The combination of a generally soft and pliable endotracheal tube, and the critical passage through the glottic opening, often results in great difficulties to perform a rapid and correct intubation even under optimal conditions. Instead of using tubes made of a stiffer material, which is not acceptable due to the increased risk of causing trauma and swelling of the delicate surrounding tissue, removable stiffening devices placed on the outside or inside of the tube are often used to maintain the desired contour of the tube during the intubation. Routinely, a laryngoscope is used to visualize the patient's airway during intubation to allow the user to directly observe the passage of the tube and associated stiffening device. Preferably, a stiffening device should allow for in-situ change of contour and orientation of the tube, in particular the front part of the tube, in order to achieve a correct a rapid placement with minimal trauma to the surrounding tissue.

WO2007/138569 discloses an intubation stylet with a pivotally attached link at its distal end and an L-shaped lever with a downward depending handle at its proximal end, for insertion into an endotracheal tube. Upon tautening a flexible wire by employment of the handle, the link is flexed to form a hook-like configuration for manipulating an endotracheal tube's outboard end. Disadvantages of this stylet include, for example, a sub-optimal lateral control of the tube's end at all positions of the handle.
Due to the design of the proximal part of the stylet, user controlled lateral movement of
the distal end is achieved by a rotating movement of the user's hand and wrist to rotate
the, relative the hand, downwards directed stylet, which is cumbersome for the user.
Additional disadvantages include the ability of the wire to contact the inside of the tube
along the major part of the tubes length. This mechanic interaction, in particular during
relative movement when the handle is manipulated, may cause damage to the inside of
the tube and increase the risk of formation of loosening fragments from the same. Such
fragments are related to a serious health hazard for the patient.

WO97/26036 discloses a tool similar to the intubation stylet of
WO2007/138569, with exception for e.g. a control line, corresponding to the wire of
WO2007/138569, being partly protected from contacting the endotracheal tube by being
extended inside a part of the tool. Disadvantages of this tool include, for example, the
same disadvantages as related to the stylet of WO2007/138569 regarding sub-optimal
lateral control of the tube's end.

WO2008/030349 and WO2007/035297 disclose endotracheal intubation
devices comprising gripping means, control means and a tubular element with a
curvable portion. The curvable portion may have one or more slits or may comprise a
series of asymmetric vertebra to provide flexibility. Means for transmitting user force,
such as a wire attached to the control means, is provided to curve the curvable portion in
a controlled manner from a fully straight configuration to a curved configuration.
Disadvantages of these devices include, for example, the dependency on the inherent
ability of the devices to accomplish a return from a curved to a less curved
configuration when correct placement of an associated endotracheal tube so requires
when being guided through various anatomical features by a user. Hence, such return of
the devices is passive and not actively controllable by the user, i.e. user control of the
devices is sub-optimal.

WO201/065963 discloses an endotracheal intubation device including a
stylet, an elongated rod mounted therein and adapted curve the stylet and an
endotracheal tube mounted on the device. A handle mounted to the stylet is adapted to
actuate the elongated rod to curve the stylet. In similarity to disadvantages associated
with the devices of WO2008/030349 and WO2007/035297, return of the devices from a
curved configuration is passive and not actively controllable by the user, i.e. user
control of the devices is sub-optimal

Hence, an improved device for improved in-situ change of the shape and
orientation of an endotracheal tube during intubation is desired.
SUMMARY

It is an object of the present invention, considering the disadvantages mentioned above, to provide an endotracheal tube shape modulating device with improved user control of the orientation of the distal end of an endotracheal tube during intubation.

It is another object of the present invention to provide an endotracheal tube shape modulating device with active user control of change of direction of the distal end of an endotracheal tube in both of the ventral and the dorsal direction.

It is yet another object of the present invention to provide an endotracheal tube shape modulating device which is relatively insensitive to external violence and suitable for pre-hospital applications, e.g. in ambulances and similar emergency vehicles.

These and other objects, which will appear from the following description, have now been achieved by an endotracheal tube shape modulating device which, according to one aspect of the present invention, comprises a proximal casing from which a rigid hollow member is extending in a forward caudal direction, a directing mechanism attached at the distal end of the rigid hollow member, and an operating handle extending from the casing, wherein the endotracheal tube shape modulating device has a sagittal relaxed state in which the projection of the directing mechanism in a sagittal plane is extending essentially along the longitudinal extension of the rigid hollow member in the same sagittal plane, and a sagittal compressed state in which the projection of the distal end of the directing mechanism in a sagittal plane is located ventrally relative the projection of the longitudinal extension of the rigid hollow member in the same sagittal plane; wherein the operating handle being pivotally connected to the casing such that the operating handle may pivot around a operating handle pivot axis relative the casing from a forward position in the sagittal relaxed state to a backward position in the sagittal compressed state, the distal end of the operating handle being closer to the proximal end of the casing in the backward position than in the forward position; the operating handle being mechanically connected to the directing mechanism by means of an upper directing wire, attached at its proximal end to an upper attachment point of the operating handle and at its distal end to a point on the ventral side of the directing mechanism, and a lower directing wire, attached at its proximal end to a lower attachment point of the operating handle and at its distal end to a point on the dorsal side of the directing mechanism, the operating handle pivot axis being located dorsally relative the upper attachment point and ventrally relative the lower attachment point; and the upper directing wire and the lower directing wire extending inside the rigid hollow member from the distal end of the casing through a singularity or plurality of passages selected from the group consisting of upper external passage, lower external passage and internal passage, the passages being located within the distal half of the rigid hollow member.
Advantages of such an endotracheal tube shape modulating device include, for example, an active user control of the return of the device from a sagittal compressed state to a sagittal relaxed state by actively pressing the operating handle forward. In addition, the wires communicating force between the operating handle and the directing mechanism are extending mainly on the inside of the rigid hollow member. Hence, the wires are hindered from scuffing the inside of a mounted endotracheal tube, which is advantageous from a safety perspective.

According to another aspect of the present invention, the endotracheal tube shape modulating device may comprise a left operating lever pivotally connected to the casing and arranged to pivot in a sagittal plane around a left operating lever pivot axis, and a right operating lever pivotally connected to the casing and arranged to pivot in a sagittal plane around a right operating lever pivot axis, wherein the left operating lever being mechanically connected to the directing mechanism by means of a left directing wire, attached at its proximal end to a left operating lever wire attachment point of the left operating lever and at its distal end to a point on the left side of the directing mechanism; the right operating lever being mechanically connected to the directing mechanism by means of a right directing wire, attached at its proximal end to a right operating lever wire attachment point of the right operating lever and at its distal end to a point on the right side of the directing mechanism; the left operating lever pivot axis and the right operating lever pivot axis being located ventrally relative the left operating lever wire attachment point and the right operating lever wire attachment point, respectively; the left directing wire and the right directing wire extending inside the rigid hollow member from the distal end of the casing through a singularity or plurality of passages selected from the group consisting of left external passage, right external passage and internal passage, the passages being located within the distal half of the rigid hollow member; and the endotracheal tube shape modulating device has a coronal relaxed state in which the projection of the directing mechanism in a coronal plane is extending essentially along the projection of the longitudinal extension of the rigid hollow member in the same coronal plane, and a coronal compressed state in which the projection of the distal end of the directing mechanism in a coronal plane is located laterally relative the projection of the longitudinal extension of the rigid hollow member in the same coronal plane.

Advantages of such an endotracheal tube shape modulating device include, for example, user control of the movement of the directing mechanism in both lateral directions, i.e. left and right, which may facilitate and reduce the time needed to install a thereon mounted endotracheal tube.

According to yet another aspect of the present invention, there is provided an endotracheal tube shape modulating device comprising a tube holder arranged to disengageably lock an endotracheal tube in relation to the rigid hollow member for
prevention of relative movement of the endotracheal tube in relation to the hollow member in a proximal or distal direction.

Further features of the invention and its embodiments are set forth in the appended claims.

**BRIEF DESCRIPTION OF THE DRAWINGS**

These and other aspects, features and advantages of which the invention is capable will be apparent and elucidated from the following description of non-limiting embodiments of the present invention, reference being made to the accompanying drawings, in which

Fig. 1 is a perspective view of an endotracheal tube shape modulating device 1000 in a coronal and sagittal relaxed state with a directing mechanism 600 comprising a first directing element 610 being pivotally movable in a coronal plane and a second directing element 620 being pivotally movable in a sagittal plane and a distal directing element 630 being pivotally movable in a sagittal plane, a rigid hollow member 400, a casing 100 from which an operating handle 200, a left operating lever 300 and a right operating lever 350 is extending and a spring element 700 for resiliently biasing the operating handle 200 toward a distal direction, according to an embodiment of the present invention;

Fig. 2 is a perspective view of an endotracheal tube shape modulating device 1000 in a coronal relaxed and sagittal partly compressed state with a directing mechanism 600 comprising a first directing element 610 being pivotally movable in a coronal plane, around an axis C1 extending in a coronal plane, and in a sagittal plane, around an axis S1 extending in a sagittal plane, and a distal directing element 630 being pivotally movable in a sagittal plane, around an axis C2 extending in a coronal plane, and with a rigid hollow member 400 comprising a left external passage 410 from which a left directing wire 520 is extending to a fastening point at the left side of the first directing element 610 and a upper external passage 420 from which an upper directing wire is extending to a fastening point at the ventral side of the distal directing element 630, according to an embodiment of the present invention;

Fig. 3 is a perspective view of an endotracheal tube shape modulating device 1000 in a coronal relaxed and sagittal compressed state with a directing mechanism 600 comprising a first directing element 610 being pivotally movable in a sagittal plane and a distal directing element 630 being pivotally movable in a sagittal plane, and with a rigid hollow member 400 and an operating handle 200, according to an embodiment of the present invention;

Fig. 4 is a cut-through view of a casing 100 from the left side showing operating handle 200 comprising an upper attachment point 210, from which upper
directing wire 510 is extending in a distal direction, a lower attachment point 215, from
which lower directing wire 515 is extending in a distal direction, and operating handle
pivot axis 250, around which the operating handle 200 may pivot in a sagittal plane, a
left operating lever 300 comprising a left operating lever wire attachment point 320,
from which left directing wire 520 is extending in a distal direction, and left operating
lever pivot axis 310, around which left operating lever 300 may pivot in a sagittal plane,
according to an embodiment of the present invention;

Figs. 5A and 5B are perspective views of the proximal part of an endotracheal
tube shape modulating device 1000, in a coronal relaxed and sagittal partly compressed
state, comprising operating handle 200 with its operating handle pivot axis 250, upper
attachment point 210 of upper directing wire 510, lower attachment point 215 of lower
directing wire 515, left operating lever 300 with its left operating lever pivot axis 310,
left operating lever wire attachment point 320 of left directing wire 520, right operating
lever 350 with its right operating lever pivot axis 360, right operating lever wire
attachment point 375 of right directing wire 525 and spring element 700 forcing
operating handle 200 in a forward distal direction unless hindered by e.g. a user,
according to an embodiment of the invention;

Fig. 6 is a perspective view of the endotracheal tube shape modulating device
1000 of Figs. 5A and 5B in a sagittal fully compressed state, wherein operating handle
200 is pressed maximally backwards in the proximal direction, and in a compressed
coronal state, wherein left operating handle 300 is pressed forward in a distal direction,
according to an embodiment of the invention;

Figs. 7A and 7B are exploded views from the left side (A) and from the upper
ventral side (B) of the directing mechanism 600 of the endotracheal tube shape
modulating device 1000 of Fig. 2, comprising a lateral rigid hollow member bore 403
that coincides with a ventral two axis joint first bore 604 of a two axis joint 603 to allow
mounting of connecting pins 650 to enable a pivoting movement of the two axis joint
603 relative rigid hollow member 400, a first directing element 610 with a first directing
element proximal bore 614 extending in a sagittal plane that coincides with a two axis
joint second bore 605 to allow mounting of connecting pin 650 to enable a pivoting
movement of the first directing element 610 relative the two axis joint 603, and a distal
directing element 630 with a lateral distal directing element proximal bore 635 that
coincides with a lateral first directing element distal bore 615 to allow mounting of pin
650 to enable pivoting movement of the distal directing element 630 relative the first
directing element 610, according to an embodiment of the invention;

Fig. 8 is a perspective partly exploded view of the directing mechanism 600 of
the endotracheal tube shape modulating device 1000 of Fig. 1, comprising a ventral-
dorsal rigid hollow member bore 403 that coincides with a first directing element
proximal bore 614 (not shown) of a first directing element 610 to enable a pivoting
movement of the first directing element 610 relative the rigid hollow member 400, a second directing element 620 with a lateral second directing element proximal bore 624 that coincides with a first directing element distal bore 615 to enable a pivoting movement of the second directing element 620 relative the first directing element 610, a distal directing element 630 with a lateral distal directing element proximal bore 635 that coincides with a lateral second directing element distal bore 625 to enable a pivoting movement of the distal directing element 630 relative the second directing element 620, a left directing wire 520 attached at its distal end to the left side of the first directing element 610 and extending in a proximal direction through an internal passage 430 further within the rigid hollow member 400, and an upper directing wire 510 attached at its distal end to the ventral side of the distal directing element 630, according to an embodiment of the invention;

Figs. 9A and 9B are perspective views of the directing mechanism 600 of the endotracheal tube shape modulating device 1000 of Fig. 1 showing an axis SI extending in a ventral-dorsal direction around which axis the first directing element 610 is pivotally movable, an axis CI extending in a lateral direction around which axis the second directing element 620 is pivotally movable, and an axis C2 extending in a lateral direction around which axis the distal directing element 630 is pivotally movable, according to an embodiment of the invention;

Figs. 10A, 10B and 10C are perspective views of the directing mechanism 600 of the endotracheal tube shape modulating device 1000 of Fig. 1 in a coronal and sagittal relaxed state, according to an embodiment of the invention;

Figs. 11A, 11B and 11C are exploded perspective views of the directing mechanism 600 of an endotracheal tube shape modulating device 1000 in which a first directing element 610 is pivotally movable around a lateral axis defined by a rigid hollow member bore 403 and a first directing element proximal bore 614, and a distal directing element 630 is pivotally movable around a lateral axis defined by a first directing element distal bore 615 and a distal directing element proximal bore 635, according to an embodiment of the invention;

Figs. 12A and 12B are perspective views of a mounted directing mechanism 600 of Figs. 11A, 11B and 11C in a sagittal compressed state, showing upper directing wire 510 attached at its distal end to the ventral side of distal directing element 630 and entering through an upper external passage 420 at the ventral side of rigid hollow member 400, according to an embodiment of the invention;

Fig. 13 is a perspective view of the directing mechanism 600 of Figs. 12A and 12B, showing a lower directing wire 515 attached at its distal end to the dorsal side of distal directing element 630 and entering through a lower external passage 425 at the dorsal side of rigid hollow member 400, according to an embodiment of the invention; and
Fig. 14 is a perspective view of the endotracheal tube shape modulating device 1000 of Fig. 2, showing its relation to the ventral, dorsal, lateral, proximal or cranial and distal or caudal directions, and to the sagittal, coronal and transverse planes, for illustrative purposes in order for the skilled person to clearly understand what may be understood by such directions and planes herein, according to one embodiment.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Embodiments of the present invention will be described in more detail below with reference to the accompanying drawings in order for those skilled in the art to be able to carry out the invention. The invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The embodiments do not limit the invention, but the invention is only limited by the appended patent claims. Furthermore, the terminology used in the detailed description of the particular embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention.

Embodiments of the present invention will now be described below with reference to Figs. 1 to 14. Reference to various parts of the drawings are done by numbers according to the table below.

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<thead>
<tr>
<th>#</th>
<th>part or parts</th>
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<tr>
<td>100</td>
<td>casing</td>
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<td>operating handle</td>
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<tr>
<td>210</td>
<td>upper attachment point</td>
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<tr>
<td>215</td>
<td>lower attachment point</td>
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The present endotracheal tube shape modulating device 1000 essentially comprise a proximal casing 100, a distal directing mechanism 600, a rigid hollow member 400 and means for communicating user exerted force from at least one pivotally movable handle or lever extending from the casing 100 to the directing mechanism 600. Such handles or levers may include an operating handle 200, a left operating lever 300 and a right operating lever 350. Means for communicating user exerted force include, for example, wires connected at one end to the part of handles or levers which is arranged within the casing 100, and at the other end to the outer surface of the distal directing mechanism 600. Preferably, at least a part of each of the wires is extending within the inside of the rigid hollow member 400. Examples of such wires include an upper directing wire 510, a lower directing wire 515, a left directing wire 520 and a right directing wire 525. A flexible endotracheal tube, such as e.g. a standard plastic endotracheal tube, may be mounted to partly or fully cover the distal directing mechanism 600 and the rigid hollow member 400. The shape of the rigid hollow member 400 may be such that it mimics the natural endotracheal pathway from the mouth to the tracheobroncial tree, such as e.g. slightly curved upwards in a ventral direction. This shape is translated to the endotracheal tube, in particular when the outer diameter of the distal directing mechanism 600 and the rigid hollow member 400 is equal to or slightly smaller than the inner diameter of the endotracheal tube, such as e.g. 30 to 100% or 50 to 90% thereof. In order to change the direction and/or shape of, most importantly for a facile introduction, the distal part of the endotracheal tube, the distal directing mechanism 600 may be additionally curved upwards, i.e. in a ventral
direction, by user controlled pulling of operating handle 200. Return of the operating handle 200 to a forward position may be accomplished by a resilient returning mechanism, such as e.g. spring element 700 or any other similar returning mechanism as well known in the art. The casing 100 may be designed, as known in the art, to allow a user to operate the present endotracheal tube shape modulating device 1000 with one hand only. For example, a user may rest the palm of one hand on a palm support surface 110 while simultaneously pulling operating handle 200 with one or several fingers with exception of the thumb, to curve the distal directing mechanism 600 upwards, i.e. in a ventral direction. The operating handle 200 may be further designed to allow a user to push it forward in a distal direction by use of e.g. the index finger, to aid the dorsal return of the distal directing mechanism 600. For example, the operating handle 200 may comprise a ring shaped element in which the index finger may be placed. While resting the palm of one hand on the palm support surface 110 and gently grabbing around the operating handle 200 with one or several fingers, the user's thumb may be used to push forward one of a left operating lever 300 and a right operating lever 350 to accomplish a left lateral and a right lateral movement, respectively, of the directing mechanism 600. The distal directing mechanism 600 may comprise at least two separate directing elements that are pivotally connected to each other and to the distal end of the rigid hollow member 400, to allow at least a ventral-dorsal movement of the directing mechanism 600 and optionally a lateral movement of the same.

According to one embodiment, the endotracheal tube shape modulating device 1000 may comprise a proximal casing 100 from which a rigid hollow member 400 is extending in a forward caudal direction, a directing mechanism 600 attached at the distal end of the rigid hollow member 400 and an operating handle 200 extending from the casing 100. The endotracheal tube shape modulating device 1000 may have a sagittal relaxed state in which the projection of the directing mechanism 600 in a sagittal plane is extending essentially along the longitudinal extension of the rigid hollow member 400 in the same sagittal plane. The endotracheal tube shape modulating device 1000 may further have a sagittal compressed state in which the projection of the distal end of the directing mechanism 600 in a sagittal plane is located ventrally relative the projection of the longitudinal extension of the rigid hollow member 400 in the same sagittal plane. An infinite number of sagittal compressed states exist in between the sagittal relaxed state and a sagittal maximally compressed state, the latter which represent a state in which the directing mechanism 600 is maximally turned upwards in a ventral direction. The operating handle 200 may be pivotally connected to the casing 100 such that the operating handle 200 may pivot around an operating handle pivot axis 250 relative the casing 100, from a forward position in the sagittal relaxed state to a backward position in the sagittal compressed state. The distal end of the operating handle 200 may be closer to the proximal end of the casing 100 in the backward
position than in the forward position. The operating handle 200 may be mechanically connected to the directing mechanism 600 by means of an upper directing wire 510. The upper directing wire 510 may be attached at its proximal end to an upper attachment point 210 of the operating handle 200 and at its distal end to a point on the ventral side of the directing mechanism 600. The operating handle 200 may be mechanically connected to the directing mechanism 600 by means of a lower directing wire 515, attached at its proximal end to a lower attachment point 215 of the operating handle 200 and at its distal end to a point on the dorsal side of the directing mechanism 600. The operating handle pivot axis 250 may be located dorsally relative the upper attachment point 210 and ventrally relative the lower attachment point 215. The upper directing wire 510 and the lower directing wire 515 may extend inside the rigid hollow member 400 from the distal end of the casing 100 through a singularity or plurality of passages selected from the group consisting of upper external passage 420, lower external passage 425 and internal passage 430. The passages may preferably be located within the distal half of the rigid hollow member 400, more preferable within the distal third or quarter of the same.

According to another embodiment, the endotracheal tube shape modulating device 1000 may comprise a left operating lever 300 pivotally connected to the casing 100 and arranged to pivot in a sagittal plane around a left operating lever pivot axis 310, and a right operating lever 350, pivotally connected to the casing 100 and arranged to pivot in a sagittal plane around a right operating lever pivot axis 360. The left operating lever 300 may be mechanically connected to the directing mechanism 600 by means of a left directing wire 520 attached at its proximal end to a left operating lever wire attachment point 320 of the left operating lever 300 and at its distal end to a point on the left side of the directing mechanism 600. The right operating lever 350 may be mechanically connected to the directing mechanism 600 by means of a right directing wire 525, attached at its proximal end to a right operating lever wire attachment point 375 of the right operating lever 350 and at its distal end to a point on the right side of the directing mechanism 600. The left operating lever pivot axis 310 and the right operating lever pivot axis 360 may be located ventrally relative the left operating lever wire attachment point 320 and the right operating lever wire attachment point 375, respectively. The left directing wire 520 and the right directing wire 525 may extend inside the rigid hollow member 400 from the distal end of the casing 100 through a singularity or plurality of passages selected from the group consisting of left external passage 410, right external passage 415 and an internal passage 430. The passages may preferably be located within the distal half of the rigid hollow member 400, more preferable within the distal third or quarter of the same. The endotracheal tube shape modulating device 1000 may have a coronal relaxed state in which the projection of the directing mechanism 600 in a coronal plane is extending essentially along the projection
of the longitudinal extension of the rigid hollow member 400 in the same coronal plane. The endotracheal tube shape modulating device 1000 may further have a coronal compressed state in which the projection of the distal end of the directing mechanism 600 in a coronal plane is located laterally relative the projection of the longitudinal extension of the rigid hollow member 400 in the same coronal plane. An infinite number of coronal compressed states exist in between the coronal relaxed state and a left coronal maximally compressed state, the latter which represent a state in which the directing mechanism 600 is maximally turned toward the left side. Further, an infinite number of coronal compressed states exist in between the coronal relaxed state and a right coronal maximally compressed state, the latter which represent a state in which the directing mechanism 600 is maximally turned toward the right side.

According to yet another embodiment, the directing mechanism 600 may comprise a first directing element 610, a distal directing element 630, an upper directing wire 510 and a lower directing wire 515. The first directing element 610 may be connected to the distal end of the rigid hollow member 400 with a link, as known in the art, which enables a pivoting movement of it around a lateral pivot axis. The distal directing element 610 may be connected to the distal end of the first directing element 610 with a link, as known in the art, which enables a pivoting movement of it around a lateral pivot axis. The distal end of the upper directing wire 510 may be connected to the ventral side of the distal directing element 630. The distal end of the lower directing wire 515 may be connected to the dorsal side of the distal directing element 630. The arrangement according to this embodiment enables active user control of the movement of the directing mechanism 600 in a ventral direction and in a dorsal direction.

According to yet another embodiment, the directing mechanism 600 may comprise a first directing element 610, a two axis joint 603 with two perpendicular connectable pivoting axis, a distal directing element 630, an upper directing wire 510, a lower directing wire 515, a left directing wire 520 and a right directing wire 525. One of the two perpendicular connectable pivoting axis of the two axis joint 603 may be connected to the distal end of the rigid hollow member 400 with a link, as known in the art, which enables a pivoting movement of it around a lateral or ventral-dorsal pivot axis. The first directing element may be connected to the other of the two perpendicular connectable pivoting axis of the two axis joint 603 with a link, as known in the art, which enables a pivoting movement of it around a lateral or ventral-dorsal pivot axis. The distal directing element 610 may be connected to the distal end of the first directing element 610 with a link, as known in the art, which enables a pivoting movement of it around a lateral pivot axis. The distal end of the upper directing wire 510 may be connected to the ventral side of the distal directing element 630. The distal end of the lower directing wire 515 may be connected to the dorsal side of the distal directing element 630. The distal end of the left directing wire 520 may be connected to the left
side of the distal directing element 630 or the first directing element 610. The distal end of the right directing wire 525 may be connected to the right side of the distal directing element 630 or the first directing element 610. The arrangement according to this embodiment enables active user control of the movement of the directing mechanism 600 in a ventral direction, in a dorsal direction, in a left lateral direction and in a right lateral direction.

According to yet another embodiment, the directing mechanism 600 may comprise a two axis joint 603 with two perpendicular connectable pivoting axis, a distal directing element 630, an upper directing wire 510, a lower directing wire 515, a left directing wire 520 and a right directing wire 525. One of the two perpendicular connectable pivoting axis of the two axis joint 603 may be connected to the distal end of the rigid hollow member 400 with a link, as known in the art, which enables a pivoting movement of it around a lateral or ventral-dorsal pivot axis. The distal directing element 630 may be connected to the other of the two perpendicular connectable pivoting axis of the two axis joint 603 with a link, as known in the art, which enables a pivoting movement of it around a lateral or ventral-dorsal pivot axis. The distal end of the upper directing wire 510 may be connected to the ventral side of the distal directing element 630. The distal end of the lower directing wire 515 may be connected to the dorsal side of the distal directing element 630. The distal end of the left directing wire 520 may be connected to the left side of the distal directing element 630. The distal end of the right directing wire 525 may be connected to the right side of the distal directing element 630. The arrangement according to this embodiment enables active user control of the movement of the directing mechanism 600 in a ventral direction, in a dorsal direction, in a left lateral direction and in a right lateral direction.

According to yet another embodiment, the directing mechanism 600 may comprise a first directing element 610, a two axis joint 603 with two perpendicular connectable pivoting axis, a distal directing element 630, an upper directing wire 510, a lower directing wire 515, a left directing wire 520 and a right directing wire 525. The first directing element 610 may be connected to the distal end of the rigid hollow member 400 with a link, as known in the art, which enables a pivoting movement of it around a lateral pivot axis. One of the two perpendicular connectable pivoting axis of the two axis joint 603 may be connected to the distal end of the first directing element 610 with a link, as known in the art, which enables a pivoting movement of it around a lateral or ventral-dorsal pivot axis. The distal directing element 630 may be connected to the other of the two perpendicular connectable pivoting axis of the two axis joint 603 with a link, as known in the art, which enables a pivoting movement of it around a lateral or ventral-dorsal pivot axis. The distal end of the upper directing wire 510 may be connected to the ventral side of the distal directing element 630. The distal end of the lower directing wire 515 may be connected to the dorsal side of the distal directing...
element 630. The distal end of the left directing wire 520 may be connected to the left side of the distal directing element 630. The distal end of the right directing wire 525 may be connected to the right side of the distal directing element 630. The arrangement according to this embodiment enables active user control of the movement of the directing mechanism 600 in a ventral direction, in a dorsal direction, in a left lateral direction and in a right lateral direction.

According to yet another embodiment, the directing mechanism 600 may comprise a first directing element 610, two two axis joints 603, each with two perpendicular connectable pivoting axis, a distal directing element 630, an upper directing wire 510, a lower directing wire 515, a left directing wire 520 and a right directing wire 525. The two two axis joints 603 may be arranged so that one of them is simultaneously pivotally connecting the distal end of rigid hollow member 400 and the proximal end of the first directing element 610, and the other the distal end of the first directing element 610 and the proximal end of the distal directing element 630. The distal end of the upper directing wire 510 may be connected to the ventral side of the distal directing element 630. The distal end of the lower directing wire 515 may be connected to the dorsal side of the distal directing element 630. The distal end of the left directing wire 520 may be connected to the left side of the distal directing element 630. The distal end of the right directing wire 525 may be connected to the right side of the distal directing element 630. The arrangement according to this embodiment enables active user control of the movement of the directing mechanism 600 in a ventral direction, in a dorsal direction, in a left lateral direction and in a right lateral direction.

According to yet another embodiment, the directing mechanism 600 may comprise a first directing element 610, having a first directing element proximal bore 614 and a first directing element distal bore 615, a second directing element 620, having a second directing element proximal bore 624 and a second directing element distal bore 625, and a distal directing element 630, having a distal directing element proximal bore 635. The first directing element 610 may be pivotally connected to the rigid hollow member 400 by a singularity or plurality of connecting pins 650, such as one connecting pin 650, which together are extending through the first directing element proximal bore 614 and the rigid hollow member bore 403 in a direction extending essentially from the ventral side to the dorsal side of the endotracheal tube shape modulating device 1000. The second directing element 620 may be pivotally connected to the first directing element 610 by a singularity or plurality of connecting pins 650, such as one connecting pin 650, which together are extending through the second directing element proximal bore 624 and the first directing element distal bore 615 in an essentially lateral direction of the endotracheal tube shape modulating device 1000. The distal directing element 630 may be pivotally connected to the second directing element 620 by a singularity or plurality of connecting pins 650, such as one connecting pin 650, which together are
extending through the distal directing element proximal bore 635 and the second
directing element distal bore 625 in an essentially lateral direction of the endotracheal
tube shape modulating device 1000. The distal end of each of the left directing wire 520
and the right directing wire 525 may be connected to the left and right side,
respectively, of either of the first directing element 610, the second directing element
620 and the distal directing element 630. The distal end of each of the upper directing
wire 510 and the lower directing wire 515 may be connected to the ventral and dorsal
side, respectively, of the distal directing element 630. The arrangement according to this
embodiment enables active user control of the movement of the directing mechanism
600 in a ventral direction, in a dorsal direction, in a left lateral direction and in a right
lateral direction.

According to yet another embodiment, the endotracheal tube shape modulating
device 1000 may comprise a tube holder arranged to disengageably lock an
endotracheal tube in relation to the rigid hollow member 400 for prevention of relative
movement of the endotracheal tube in relation to the hollow member 400 in a proximal
or distal direction. Devices known in the art for disengagably fasten an outer hollow
tubular element to a closed in inner element are well known in the art and may, after
optional well known appropriate modifications, be used as such a tube holder. For
example, such a tube holder may be a screw being screwed through the wall of the
endotracheal tube which, in a screwed-in state, engages with the outer surface of the
rigid hollow member 400 and which, in a screwed-out state, disengages from the outer
surface of the rigid hollow member 400. Advantages of a tube holder include, for
example, a minimized risk of unintentional relative movement between the endotracheal
tube and the endotracheal tube shape modulating device 1000. Such an unintentional
movement may aggravate the correct placement of the tube when the endotracheal tube
shape modulating device 1000-endotracheal tube unit is pushed forward into the patient.
The tube holder may typically be disengaged when the tube has been correctly placed to
allow removal of the endotracheal tube shape modulating device 1000 by a backward
movement of the same with one hand, while holding the tube with the other hand.

According to yet another embodiment, the directing mechanism 600 may
comprise a first directing element 610, having a first directing element proximal bore
614 and a first directing element distal bore 615 which may extend essentially in lateral
direction, a distal directing element 630, having a distal directing element proximal bore
635 which may extend essentially in lateral direction, and a two axis joint 603. The two
axis joint 603 may be pivotally connected to the rigid hollow member 400 by a
singularity or plurality of connecting pins 650, such as one connecting pin 650, which
together are extending through a two axis joint first bore 604 and a rigid hollow member
bore 403. The two axis joint first bore 604 may be essentially extending in a direction of
either a ventral-dorsal direction and a lateral direction. The first directing element 610
may be pivotally connected to the two axis joint 603 by a singularity or plurality of connecting pins 650, such as one connecting pin 650, which together are extending through the first directing element proximal bore 614 and a two axis joint second bore 605. The two axis joint second bore 605 may be extending in a direction essentially perpendicular to the direction of the two axis joint first bore 604. The distal directing element 630 may be pivotally connected to the first directing element 610 by a singularity or plurality of connecting pins 650, such as one connecting pin 650, which together are extending through the distal directing element proximal bore 635 and the first directing element distal bore 615. The distal end of each of the left directing wire 520 and the right directing wire 525 may be connected to the left and right side, respectively, of either of the first directing element 610 and the distal directing element 630. The distal end of each of the upper directing wire 510 and the lower directing wire 515 may be connected to the ventral and dorsal side, respectively, of the distal directing element 630. The arrangement according to this embodiment enables active user control of the movement of the directing mechanism 600 in a ventral direction, in a dorsal direction, in a left lateral direction and in a right lateral direction.

According to yet another embodiment, the endotracheal tube shape modulating device 1000 may comprise a suction device for removal of e.g. mucus or blood from the airways. Such a suction device may, for example, comprise a separate tube attached to the outer surface of the rigid hollow member 400. The distal opening of such tube may be arranged close to the distal end of an endotracheal tube when mounted on the endotracheal tube shape modulating device 1000, and the proximal opening connected to a suitable pump outside the patient for removal of internal fluids, like e.g. mucus or blood. Optionally, the rigid hollow member 400 may serve as a conduit for such fluids. For example, a suitable pump may be connected near the proximal end thereof via a separate opening, while proximal openings, such as e.g. one or several of the passages 410, 415, 420, 425 and 430, may serve as inlet for such fluids.

According to yet another embodiment, the endotracheal tube shape modulating device 1000 may comprise means for detection of a correct placement of the endotracheal tube in the tracheobroncial tree. Such means, such as e.g. carbon dioxide detectors and oxygen detectors, are known in the art.

According to yet another embodiment, the rigid hollow member 400 may be made of a material, as known in the art, which is essentially impossible to bend. Examples of such materials include, but is not limited to, metals like e.g. aluminum and stainless steel and suitable plastic or polymeric materials.

According to yet another embodiment, the rigid hollow member 400 may be made of a material, as known in the art, which makes it slightly bendable in a non-resilient fashion. Such a slightly bendable rigid hollow member 400 will
advantageously allow a user to pre-form the same according to the patient's personal anatomy for a more facile placement of the endotracheal tube.

According to yet another embodiment, the endotracheal tube shape modulating device 1000 may be designed and used for nasal placement of an endotracheal tube.

According to yet another embodiment, the endotracheal tube shape modulating device 1000 may comprise a removable cover or case. Such a removable cover or case may, for example, be made of a flexible material such as e.g. latex or a medically acceptable plastic or polymeric material. Preferable, the cover or case is design to tightly fit and cover at least the entire distal part of the endotracheal tube shape modulating device 1000, which is within the patient during use of the same. Such a cover or case will advantageously minimize the risk of exposing the patient to infectious microorganisms residing on an incompletely sterilized endotracheal tube shape modulating device 1000.

In the claims, the term "comprises/comprising" does not exclude the presence of other elements or steps. Furthermore, although individually listed, a plurality of means, elements or method steps may be implemented by e.g. a single unit or processor. Additionally, although individual features may be included in different claims, these may possibly advantageously be combined, and the inclusion in different claims does not imply that a combination of features is not feasible and/or advantageous. In addition, singular references do not exclude a plurality. The terms "a", "an", "first", "second" etc do not preclude a plurality. Reference signs in the claims are provided merely as a clarifying example and shall not be construed as limiting the scope of the claims in any way.
CLAIMS

1. An endotracheal tube shape modulating device (1000) comprising a proximal casing (100) from which a rigid hollow member (400) is extending in a forward caudal direction, a directing mechanism (600) attached at the distal end of said rigid hollow member (400), and an operating handle (200) extending from said casing (100), wherein said endotracheal tube shape modulating device (1000) has a sagittal relaxed state in which the projection of said directing mechanism (600) in a sagittal plane is extending essentially along the longitudinal extension of said rigid hollow member (400) in the same sagittal plane, and a sagittal compressed state in which the projection of the distal end of said directing mechanism (600) in a sagittal plane is located ventrally relative the projection of the longitudinal extension of said rigid hollow member (400) in the same sagittal plane; wherein said operating handle (200) being pivotally connected to said casing (100) such that said operating handle (200) may pivot around a operating handle pivot axis (250) relative said casing (100) from a forward position in said sagittal relaxed state to a backward position in said sagittal compressed state, the distal end of said operating handle (200) being closer to the proximal end of said casing (100) in said backward position than in said forward position;
said operating handle (200) being mechanically connected to said directing mechanism (600) by means of an upper directing wire (510), attached at its proximal end to an upper attachment point (210) of said operating handle (200) and at its distal end to a point on the ventral side of said directing mechanism (600), and a lower directing wire (515), attached at its proximal end to a lower attachment point (215) of said operating handle (200) and at its distal end to a point on the dorsal side of said directing mechanism (600), said operating handle pivot axis (250) being located dorsally relative said upper attachment point (210) and ventrally relative said lower attachment point (215); and
said upper directing wire (510) and said lower directing wire (515) extending inside said rigid hollow member (400) from the distal end of said casing (100) through a singularity or plurality of passages selected from the group consisting of upper external passage (420), lower external passage (425) and internal passage (430), said passages being located within the distal half of said rigid hollow member (400).
2. Endotracheal tube shape modulating device (1000) according to claim 1, further comprising a left operating lever (300) pivotally connected to said casing (100) and arranged to pivot in a sagittal plane around a left operating lever pivot axis (310), and a right operating lever (350) pivotally connected to said casing (100) and arranged to pivot in a sagittal plane around a right operating lever pivot axis (360), wherein said left operating lever (300) being mechanically connected to said directing mechanism (600) by means of a left directing wire (520), attached at its proximal end to a left operating lever wire attachment point (320) of said left operating lever (300) and at its distal end to a point on the left side of said directing mechanism (600); said right operating lever (350) being mechanically connected to said directing mechanism (600) by means of a right directing wire (525), attached at its proximal end to a right operating lever wire attachment point (375) of said right operating lever (350) and at its distal end to a point on the right side of said directing mechanism (600); said left operating lever pivot axis (310) and said right operating lever pivot axis (360) being located ventrally relative said left operating lever wire attachment point (320) and said right operating lever wire attachment point (375), respectively; said left directing wire (520) and said right directing wire (525) extending inside said rigid hollow member (400) from the distal end of said casing (100) through a singularity or plurality of passages selected from the group consisting of left external passage (410), right external passage (415) and internal passage (430), said passages being located within the distal half of said rigid hollow member (400); and said endotracheal tube shape modulating device (1000) has a coronal relaxed state in which the projection of said directing mechanism (600) in a coronal plane is extending essentially along the projection of the longitudinal extension of said rigid hollow member (400) in the same coronal plane, and a coronal compressed state in which the projection of the distal end of said directing mechanism (600) in a coronal plane is located laterally relative the projection of the longitudinal extension of said rigid hollow member (400) in the same coronal plane.

3. Endotracheal tube shape modulating device (1000) according to any one of the preceding claims, further comprising a tube holder arranged to disengageably lock an endotracheal tube in relation to said rigid hollow member (400) for prevention of
relative movement of said endotracheal tube in relation to said hollow member (400) in a proximal or distal direction.

4. Endotracheal tube shape modulating device (1000) according to any one of the preceding claims, wherein said directing mechanism (600) comprises a first directing element (610) and a distal directing element (630), said distal directing element (630) being pivotally connected at its proximal end for enabling pivoting movement in a sagittal plane.

5. Endotracheal tube shape modulating device (1000) according to claim 4, wherein said first directing element (610) being pivotally connected to the distal end of said rigid hollow member (400) for enabling pivoting movement in a sagittal plane.

6. Endotracheal tube shape modulating device (1000) according to claim 4, further comprising one or two two axis joints (603) pivotally connected to the distal end of said rigid hollow member (400) or to the distal end of said first directing element (610), for enabling pivoting movement in a sagittal plane.

7. Endotracheal tube shape modulating device (1000) according to any one of claims 4 to 6, further comprising a second directing element (620) being pivotally connected at both of its proximal end and distal end.

8. Endotracheal tube shape modulating device (1000) according to any one of claims 2 or 3, wherein said directing mechanism (600) comprises a first directing element (610) having a first directing element proximal bore (614) and a first directing element distal bore (615), a second directing element (620) having a second directing element proximal bore (624) and a second directing element distal bore (625), and a distal directing element (630) having a distal directing element proximal bore (635), wherein said first directing element (610) is pivotally connected to said rigid hollow member (400) by a singularity or plurality of connecting pins (650), which together are extending through said first directing element proximal bore (614) and a rigid hollow member bore (403) in a direction extending essentially from the ventral side to the dorsal side of said endotracheal tube shape modulating device (1000);
said second directing element (620) being pivotally connected to said first directing element (610) by a singularity or plurality of connecting pins (650), which together are extending through said second directing element proximal bore (624) and said first directing element distal bore (615) in an essentially lateral direction of said endotracheal tube shape modulating device (1000);
said distal directing element (630) being pivotally connected to said second directing element (620) by a singularity or plurality of connecting pins (650), which together are extending through said distal directing element proximal bore (635) and said second directing element distal bore (625) in an essentially lateral direction of said endotracheal tube shape modulating device (1000);

the distal end of each of said left directing wire (520) and said right directing wire (525) being connected to the left and right side, respectively, of either of said first directing element (610), said second directing element (620) and said distal directing element (630); and
the distal end of each of said upper directing wire (510) and said lower directing wire (515) being connected to the ventral and dorsal side, respectively, of said distal directing element (630).

9. Endotracheal tube shape modulating device (1000) according to any one of claims 2 or 3, wherein said directing mechanism (600) comprises a first directing element (610) having a first directing element proximal bore (614) and a first directing element distal bore (615), a distal directing element (630) having a distal directing element proximal bore (635), and a two axis joint (603), wherein
said two axis joint (603) being pivotally connected to said rigid hollow member (400) by a singularity or plurality of connecting pins (650), which together are extending through a two axis joint first bore (604) and a rigid hollow member bore (403);
said first directing element (610) being pivotally connected to said two axis joint (603) by a singularity or plurality of connecting pins (650), which together are extending through said first directing element proximal bore (614) and a two axis joint second bore (605);
said distal directing element (630) being pivotally connected to said first directing element (610) by a singularity or plurality of connecting pins (650), which together are extending through said distal directing element proximal bore (635) and said first directing element distal bore (615);
the distal end of each of said left directing wire (520) and said right directing wire (525) being connected to the left and right side, respectively, of either of said first directing element (610) and said distal directing element (630); and
the distal end of each of said upper directing wire (510) and said lower directing wire (515) being connected to the ventral and dorsal side, respectively, of said distal directing element (630).

10. Endotracheal tube shape modulating device (1000) according to claim 9, wherein said two axis joint first bore (604) is essentially extending in a direction of either a ventral-dorsal direction and a lateral direction;
said two axis joint second bore (605) is extending in a direction essentially perpendicular to the direction of said two axis joint first bore (604); and
the direction of said distal directing element proximal bore (635) and said first directing element distal bore (615) is extending essentially in lateral direction.
INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2014/050101

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61 M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE, DK, FI, NO classes as above

Electronic database consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, PAJ, WPI data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:
  "A" document defining the general state of the art which is not considered to be of particular relevance
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X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

& document member of the same patent family

Date of the actual completion of the international search 23-05-2014

Date of mailing of the international search report 26-05-2014

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