EUSTACHIAN TUBE VENTILATION PLUG

FIELD

The present application generally relates to medical devices and, in particular, to an implantable eustachian tube ventilation plug for treating patulous dysfunction of eustachian tubes.

BACKGROUND

Referring to FIG. **1**, a brief overview of the anatomy of the human ear **10** is provided as context for the present disclosure. FIG. **1** is a cross-sectional view illustrating the external ear **12**, middle ear **14**, and inner ear **16**, as well as the eustachian tube (ET) **18** that connects the middle ear **14** to the nasopharynx **20**. The external ear **12** comprises the auricle **22** and external auditory canal **24**. The tympanic membrane **26** separates the external ear **12** from the middle ear **14** and vibrates with sound. These vibrations are transmitted through the middle ear **14** by three small bones called the ossicles. The ossicles include the malleus (hammer) **28,** incus (anvil) **30,** and stapes (stirrup) **32**. They transmit the vibrations into the inner ear **16** via the oval window (not shown). The vibration of the oval window then creates fluid waves in the cochlea **36**. The fluid waves are then converted into nerve signals that travel on the vestibulocochlear nerve **38** to the brain for processing.

The ET **18**, a narrow canal connecting the middle ear with the nasopharynx, is approximately 1.5 inches long in adults. The ET **18** has two segments: a bony segment **40** and cartilaginous segment **42**. The cartilaginous segment **42** runs from roughly the opening of the ET **18** into the nasopharynx **20** to the bony isthmus **44**. The bony segment **40** runs the rest of the length of the ET **18** into the middle ear **14**. The ET **18** acts as a pressure-equalizing valve for the middle ear **14**, which is normally filled with air. A properly functioning ET **18** remains closed in its resting state, opening periodically for brief periods of time (a fraction of a second) in response to swallowing or yawning. The ET **18** also serves to drain fluid and mucus from the middle ear. In addition, the ET **18** inhibits or blocks the transmission of sound from the nasopharynx **20** into the middle ear **14**, thereby insulating the middle ear **14** from the noises in the nasopharynx **20** such as breathing, swallowing, and speaking.

Blockage of the ET **18** isolates the middle ear space from the outside environment. The lining of the middle ear absorbs the trapped air and creates a negative pressure that pulls the eardrum inward, which can cause pain, pressure, and hearing loss. Long-term blockage of the

ET **18** can lead to the accumulation of fluid in the middle ear space, which further increases the pressure and hearing loss, resulting in serous otitis media. If the fluid becomes infected, acute otitis media may result.

In some cases, the valve of the ET **18** can fail to close properly, resulting in a condition known as Patulous Eustachian Tube. When the ET **18** remains open, sound can travel from the nasopharynx **20** to the middle ear **14**, resulting in patients being able to hear the sound of their own voice, breathing, or other bodily functions too loudly. Patulous ET can also cause a sense of fullness in the ears, ringing or buzzing in the ears (tinnitus), mild hearing loss, and frequent sniffing.

Current surgical treatments for patulous ET **18** include injecting fillers into the areas surrounding the ETs **18** to encourage them to remain closed; placing a shim, or small wedge device, in the ETs **18** to lessen symptoms; and reconstruction of the cartilaginous segment **42** of the ET **18**. Injections and shim placement have high one-year symptom recurrence rates. Reconstruction is an effective solution, but it inhibits the middle ear **14** from being ventilated, leading to additional surgeries and frequent middle ear infections. Thus, there is a need for an effective and permanent (e.g., >1 to 10+ year efficacy) treatment for patulous ET **18** that maintains proper ventilation of the middle ear **14**.

BRIEF SUMMARY

Patients with a patulous ET need a safe and effective solution to provide periodic pressure relief for the middle ear, and to block internal body sounds from traveling to the middle ear via the ET, without inhibiting middle ear ventilation. As described herein, an implantable ET ventilation plug performs these functions via multiple membranes that allow for the passage of air, but inhibit sound transmission due to the tortuous path of ventilating holes within the membranes.

Accordingly, certain embodiments provide a plug configured to be implanted into a Eustachian tube, the plug comprising: a tubular body defining a longitudinal axis and comprising a proximal end, a distal end, and a central lumen extending between the proximal end and the distal end; at least a first ventilation membrane and a second ventilation membrane, each ventilation membrane being positioned along the longitudinal axis of the tubular body and intersecting at least a portion of the central lumen; and a hook portion coupled to the tubular body, the hook portion configured to be positioned outside the Eustachian tube.

In certain embodiments, each of the first and second ventilation membranes comprises at least one hole.

In certain embodiments, the at least one hole of the first ventilation membrane is longitudinally or radially offset from the at least one hole of the second ventilation membrane.

In certain embodiments, the at least one hole of the first ventilation membrane and the at least one hole of the second ventilation membrane are configured to allow air flow between the proximal end and the distal end of the tubular body.

In certain embodiments, the at least one hole of the first ventilation membrane and the at least one hole of the second ventilation membrane are configured to allow fluid communication between the proximal end and the distal end of the tubular body.

In certain embodiments, the at least one hole of the first ventilation membrane and the at least one hole of the second ventilation membrane are configured to inhibit transmission of sound waves traveling between the proximal end and the distal end of the tubular body.

In certain embodiments, the at least one hole is about 0.1 mm to about 0.4 mm in diameter.

In certain embodiments, the tubular body is about 2 mm to about 5 mm in diameter and about 0.5 cm to about 10 cm in length.

In certain embodiments, the tubular body is tapered at the proximal end or the distal end.

In certain embodiments, the hook portion is about 0.25 cm to about 10 cm in length.

In certain embodiments, the hook portion is configured to be positioned in a subject's nasopharynx.

In certain embodiments, the at least two ventilation membranes comprise a rigid biocompatible material with a density greater than about 1 g/cm^3.

In certain embodiments, the first ventilation membrane is located proximate the proximal end of the tubular body and wherein the second ventilation membrane is located proximate the distal end of the tubular body.

In certain embodiments, the first and second ventilation membranes are positioned at least about 1 mm apart.

In certain embodiments, a portion of the central lumen between the first and second ventilation membranes comprises empty space.

In certain embodiments, the first and second ventilation membranes are configured to allow air to flow between the proximal end and the distal end of the tubular body.

In certain embodiments, the first and second ventilation membranes are configured to allow fluid communication between the proximal end and the distal end of the tubular body.

In certain embodiments, the first and second ventilation membranes are configured to inhibit transmission of sound waves traveling between the proximal end and the distal end of the tubular body.

In certain embodiments, the tubular body comprises at least one of polyetheretherketone, polycarbonate, and polysulfone.

In certain embodiments, the hook portion comprises stainless steel.

Other objects, features, and advantages of the present invention will be apparent to one of skill in the art from the following detailed description and figures.

BRIEF DESCRIPTION OF THE FIGURES

The present application can be understood by reference to the following drawings, wherein like reference numerals represent like elements. The drawings are merely exemplary to illustrate certain features that may be used singularly or in combination with other features and the present application should not be limited to the embodiments shown.

FIG. **1** is a cross-sectional view of a human ear depicting the inner, middle, and outer ear potions and the Eustachian tube connecting the middle ear with the nasopharynx.

FIG. **2A** is an isometric side view of an exemplary embodiment of a ventilation plug for implantation into the Eustachian tube.

FIG. **2B** is an isometric exploded view of another exemplary embodiment of a ventilation plug for implantation into the Eustachian tube.

FIG. **3** is a graph illustrating mean pressure data collected at various times during ventilation testing of a prototype of a ventilation plug for implantation into the Eustachian tube.

FIG. **4** is a graph illustrating sound pressure level data collected at various frequencies during sound testing of a prototype of a ventilation plug for implantation into the Eustachian tube.

DETAILED DESCRIPTION

The presently disclosed implantable medical device provides a safe and effective treatment for patients with patulous ET **18**. As illustrated by two embodiments of the device shown in FIGS. **2A** and **2B**, the device comprises an implantable ET ventilation plug **46A**,

46B. The plug **46A**, **46B** is configured to provide periodic pressure relief for the middle ear **14**, as well as to inhibit or block internal body sounds from traveling to the middle ear **14** via the ET **18**, without inhibiting middle ear ventilation. The implantable ET ventilation plug **46A**, **46B** comprises a tubular body **48A**, **48B** with a longitudinal axis, a proximal end **50A**, **50B**, a distal end **52A**, **52B**, and a central lumen **54A**, **54B** (the central lumen **54B** is shown as a stylized internal cylinder and is not drawn to scale) extending between the proximal end **50A**, **50B** and the distal end **52A**, **52B**. The tubular body **48A**, **48B** can be made from biocompatible plastic, including, but not limited to, polyetheretherketone, polycarbonate, and polysulfone. In an embodiment, the tubular body **48A**, **48B** can range from about 0.5 cm to about 10 cm in length and from about 2 mm to about 5 mm in diameter. In an embodiment, the tubular body **48A**, **48B** can be tapered at one or both of the proximal end **50A**, **50B** and the distal end **52A**, **52B** to facilitate placement in the ET **18**.

The implantable ET ventilation plug **46A**, **46B** further includes at least two ventilation membranes **$56A_1$**, **$56A_2$** and **$56B_1$, $56B_2$**, respectively. In an embodiment, as shown in the exploded view of the implantable ET ventilation plug **46A** in FIG. **2A**, the ventilation membranes **$56A_1$**, **$56A_2$** can be positioned, or sandwiched, within a middle portion along the longitudinal axis of the tubular body **48A**. The ventilation membranes **$56A_1$**, **$56A_2$** can be about 1 mm in width and can be located about 1 mm or more apart from one another. The ventilation membranes **$56A_1$**, **$56A_2$** can intersect part or all of the central lumen **54A**. In another embodiment, as shown in FIG. **2B**, the ventilation membranes **$56B_1$, $56B_2$** can be positioned at the proximal **50A** and distal ends **50B** of the tubular body **48B**, intersecting part or all of the central lumen **54B.** The ventilation membranes **$56A_1$**, **$56A_2$** and **$56B_1$, $56B_2$** can be made from rigid, non-flexible biocompatible materials with a density greater than 1 g/cm^3, including, but not limited to, polyetheretherketone, polycarbonate, and polysulfone.

As shown in FIGS. **2A** and **2B**, the ventilation membranes **$56A_1$**, **$56A_2$** and **$56B_1$, $56B_2$** each comprise one or more ventilation holes **58A**, **58B**. In an embodiment, the ventilation holes can be about 0.1 mm to about 0.4 mm in diameter. Importantly, the ventilation holes **58A** in ventilation membrane **$56A_1$** are offset – either longitudinally, radially (e.g., between 0 and 360 degrees), or both longitudinally and radially – from the ventilation holes **58A** in ventilation membrane **$56A_2$.** Similarly, the ventilation holes **58B** in ventilation membrane **$56B_1$** are offset – either longitudinally, radially, or both longitudinally and radially – from the ventilation holes **58B** in ventilation membrane **$56B_2$.** The offsetting of ventilation holes in the paired membranes allows for airflow and fluid communication between the proximal and distal ends of the tubular body **48A**, **48B,** while at the same time inhibiting the transmission of sound

waves traveling between the proximal and distal ends of the tubular body **48A**, **48B** due to the torturous path that the sound waves would be required to take between the offset ventilation holes.

It should be noted that although multiple ventilation holes are described as being offset from one another, in certain embodiments only one ventilation hole is required to be offset in each pair of membranes. Further, it should be noted that although membrane pairs are described with respect to FIGS. **2A** and **2B**, more than two membranes can be used in certain embodiments of the ET ventilation plug, in which case some or all of the ventilation holes can be offset between the plurality of membranes. Finally, it should be noted that central lumen **54A**, **54B** between the plurality of membranes can be open or empty space in which air or fluid can freely flow. In other words, the ventilation holes **58A**, **58B** between ventilation membranes **56A$_1$**, **56A$_2$** and **56B$_1$, 56B$_2$**, respectively, are not connected by any additional tubing or internal structure (e.g., small tunnels within the tubular body **48A**, **48B**).

The implantable ET ventilation plug **46A**, **46B** further includes a hook portion **60A**, **60B** as shown in FIGS. 2A and 2B, respectively. The hook portion **60A**, **60B** can be coupled (e.g., via adhesive, soldering, or similar means) to the distal end **52A**, **52B** of the device and configured to be positioned outside a subject's ET **18**, such as in the nasopharynx **20**. The hook portion **60A**, **60B** serves to anchor the implantable ET ventilation plug **46A**, **46B** once it has been implanted. In an embodiment, the hook portion **60A**, **60B** can be made out of a moderately flexible, biocompatible material, including, but not limited to, thin stainless steel, such that it can be bent by standard medical instruments. In an embodiment, the hook portion **60A**, **60B** can range from about 0.25 cm to about 10 cm in length.

The present invention will be described in greater detail below by way of specific examples. The following examples are offered for illustrative purposes and are not intended to limit the invention in any manner. Those of skill in the art will readily recognize a variety of noncritical parameters which can be changed or modified to yield essentially the same results.

EXAMPLES

Example 1 – Ventilation Testing

To test the ventilation capacity of a prototype ventilation plug in accordance with the present disclosure, a tube (simulating the ET) was set up with the prototype ventilation plug sealed onto one end of the tube and a motorized plunger to shrink the tube's volume on the other end of the tube. A Honeywell ASDX pressure transducer was fixed into the tube. The

end of the ventilation plug that extended from the tube and was open to external air was sealed with putty. The tube's volume was shrunk to increase the pressure gradient across the prototype ventilation plug to 500 Pascal (Pa). This volume was held for 5 seconds, then returned to baseline. A decrease of less than 100 Pa during this 5 second hold was used to indicate a good seal. The putty was then removed from the protruding end of the prototype ventilation plug, and the volume of the tube shrunk back to that which previously created the pressure gradient of 500 Pa with the sealed tube. However, as the device was open to air at this point, some of the pressure dissipated immediately, resulting in a roughly 300 Pa max gradient, as illustrated by the graph shown in FIG. **3**. The volume was held for 5 seconds. The volume was then returned to baseline and held for 5 seconds. This process was repeated at least 5 times. Approximately 1 teaspoon of ketchup was evenly spread across the end of the device that was open to external air to simulate mucus. The data shown in FIG. **3** suggests that ventilation with a mucus-coated device is slightly slower than that of a device that is not coated with mucus, but the simulated mucous-coated device still ventilated the middle ear sufficiently.

Example 2 – Sound Testing

To test the sound blocking capacity of a prototype ventilation plug in accordance with the present disclosure, a buzzer was inserted on one side of a silicone patulous ET model based upon studies by Janzen-Senn et. al. [Janzen-Senn I, Schuon RA, Tavassol F, Lenarz T, Paasche G (2020) Dimensions and position of the Eustachian tube in Humans. PLoS ONE 15(5): e0232655. https://doi.org/10.1371/journal.pone.0232655] and Yoshida et. al. [Haruo Yoshida, Toshimitsu Kobayashi, Kenji Takasaki, Haruo Takahashi,Hideki Ishimaru, Minoru Morikawa & Kuniaki Hayashi (2004) Imaging of the patulous eustachian tube: high-resolution CT evaluation with multiplanar reconstruction technique, Acta Oto-Laryngologica, 124:8, 918-923, DOI: 10.1080/00016480410017422]. Sound pressure level was measured in decibels (dB) with a Brüel & Kjær Hand-held Analyzer Type 2250-L. As illustrated by the graph shown in FIG. **4**, the dB level of the buzzer sound at the opening of the model was first measured with a small ~2 cm square foam piece placed a few cm into the model ET, then with and without a prototype ventilation plug inserted deep and shallow into the silicone model. Insertion was performed with a needle driver and the hook was clamped into the silicone with the needle driver. This test demonstrated that, when properly placed, the ventilation plug prototype device can block sound with about 76% of the efficiency of a foam shim across 0.25 kilohertz to 4 kilohertz.

Although at least one embodiment of an eustachian tube ventilation plug has described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the spirit or scope of this disclosure. All directional references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present disclosure, and do not create limitations, particularly as to the position, orientation, or use of the disclosure. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and can include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in detail or structure can be made without departing from the spirit of the disclosure as defined in the appended claims.

Various embodiments are described herein to various apparatuses, systems, and/or methods. Numerous specific details are set forth to provide a thorough understanding of the overall structure, function, manufacture, and use of the embodiments as described in the specification and illustrated in the accompanying drawings. It will be understood by those skilled in the art, however, that the embodiments may be practiced without such specific details. In other instances, well-known operations, components, and elements have not been described in detail so as not to obscure the embodiments described in the specification. Those of ordinary skill in the art will understand that the embodiments described and illustrated herein are non-limiting examples, and thus it can be appreciated that the specific structural and functional details disclosed herein may be representative and do not necessarily limit the scope of the embodiments, the scope of which is defined solely by the appended claims.

Reference throughout the specification to “various embodiments,” “some embodiments,” “one embodiment,” or “an embodiment”, or the like, means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases “in various embodiments,” “in some embodiments,” “in one embodiment,” or “in an embodiment”, or the like, in places throughout the specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. Thus, the particular features, structures, or

characteristics illustrated or described in connection with one embodiment may be combined, in whole or in part, with the features structures, or characteristics of one or more other embodiments without limitation given that such combination is not illogical or non-functional.

It will be appreciated that the terms “proximal” and “distal” may be used throughout the specification with reference to a clinician manipulating one end of an instrument used to treat a patient. The term “proximal” refers to the portion of the instrument closest to the clinician and the term “distal” refers to the portion located furthest from the clinician. It will be further appreciated that for conciseness and clarity, spatial terms such as “vertical,” “horizontal,” “up,” and “down” may be used herein with respect to the illustrated embodiments. However, surgical instruments may be used in many orientations and positions, and these terms are not intended to be limiting and absolute.

The terms “about” and “approximately” may be used throughout the specification when referring to a measurable value or range, such as an amount, a distance, a temporal duration, and the like. The terms “about” and “approximately” are meant to encompass a suitable dimensional tolerance that allows the part or collection of components to function for its intended purpose as described herein. For example, the terms “about” and “approximately” are meant to encompass variations of ±20% or ±10%, in certain embodiments ±5%, in certain embodiments ±1%, in certain embodiments ±0.1% from the specified value, as such variations are appropriate in accordance with the present disclosure.

Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

CLAIMS

WHAT IS CLAIMED IS:

1. A plug configured to be implanted into a Eustachian tube, the plug comprising:

a tubular body defining a longitudinal axis and comprising a proximal end, a distal end, and a central lumen extending between the proximal end and the distal end;

at least a first ventilation membrane and a second ventilation membrane, each ventilation membrane being positioned along the longitudinal axis of the tubular body and intersecting at least a portion of the central lumen; and

a hook portion coupled to the tubular body, the hook portion configured to be positioned outside the Eustachian tube.

2. The plug of claim 1, wherein each of the first and second ventilation membranes comprises at least one hole.

3. The plug of claim 2, wherein the at least one hole of the first ventilation membrane is longitudinally or radially offset from the at least one hole of the second ventilation membrane.

4. The plug of claim 3, wherein the at least one hole of the first ventilation membrane and the at least one hole of the second ventilation membrane are configured to allow air flow between the proximal end and the distal end of the tubular body.

5. The plug of claim 3, wherein the at least one hole of the first ventilation membrane and the at least one hole of the second ventilation membrane are configured to allow fluid communication between the proximal end and the distal end of the tubular body.

6. The plug of claim 3, wherein the at least one hole of the first ventilation membrane and the at least one hole of the second ventilation membrane are configured to inhibit transmission of sound waves traveling between the proximal end and the distal end of the tubular body.

7. The plug of claim 2, wherein the at least one hole is about 0.1 mm to about 0.4 mm in diameter.

8. The plug of claim 1, wherein the tubular body is about 2 mm to about 5 mm in diameter and about 0.5 cm to about 10 cm in length.

9. The plug of claim 1, wherein the tubular body is tapered at the proximal end or the distal end.

10. The plug of claim 1, wherein the hook portion is about 0.25 cm to about 10 cm in length.

11. The plug of claim 1, wherein the hook portion is configured to be positioned in a subject's nasopharynx.

12. The plug of claim 1, wherein the at least two ventilation membranes comprise a rigid biocompatible material with a density greater than about 1 g/cm^3.

13. The plug of claim 1, wherein the first ventilation membrane is located proximate the proximal end of the tubular body and wherein the second ventilation membrane is located proximate the distal end of the tubular body.

14. The plug of claim 1, wherein the first and second ventilation membranes are positioned at least about 1 mm apart.

15. The plug of claim 1, wherein a portion of the central lumen between the first and second ventilation membranes comprises empty space.

16. The plug of claim 1, wherein the first and second ventilation membranes are configured to allow air to flow between the proximal end and the distal end of the tubular body.

17. The plug of claim 1, wherein the first and second ventilation membranes are configured to allow fluid communication between the proximal end and the distal end of the tubular body.

18. The plug of claim 1, wherein the first and second ventilation membranes are configured to inhibit transmission of sound waves traveling between the proximal end and the distal end of the tubular body.

19. The plug of claim 1, wherein the tubular body comprises at least one of polyetheretherketone, polycarbonate, and polysulfone.

20. The plug of claim 1, wherein the hook portion comprises stainless steel.

ABSTRACT

A plug configured to be implanted into a Eustachian tube includes a tubular body defining a longitudinal axis and comprising a proximal end, a distal end, and a central lumen extending between the proximal end and the distal end. The plug further includes at least a first ventilation membrane and a second ventilation membrane, each ventilation membrane being positioned along the longitudinal axis of the tubular body and intersecting at least a portion of the central lumen. The plug further includes a hook portion coupled to the tubular body, the hook portion configured to be positioned outside the Eustachian tube.