

TONGUE IMPLANT

The present invention relates to a tongue implant.

As regards the obstructive sleep apnea syndrom (hereafter OSAS as used in the professional literature), recurrent breathing pauses arise during deep-sleep and rapid-eye-movement (REM) phases accompanied by muscular relaxation and thereby gravity-induced dropping of the tongue. In the extreme case the tongue then rests on the rear pharynx wall and closes the airpath in this region.

Such breathing pauses only come to an end when the oxygen depletion in the blood and the lack of oxygen causes sudden awakening until shallower sleep or complete awakening is attained within which the basic muscular tension rises again until the tongue withdraws from the rear pharynx wall and thus releases the breathing tract. Thereupon sleep slowly merges into a REM or a deeper phase until the above described process repeats.

OSAS must be treated because the regularly recurring oxygen depletions in the blood taking place during sleep may entail damage to the cardiac muscle, disease of the coronary vessels, cerebrovascular disease with more likely stroke and brain shrinkage as well high blood-pressure crises and a plurality of hormonal disorders, frequent awakening also possibly leading to lack of energy, fatigue and susceptibility to falling asleep during the day, presenting dangers in operating machinery or driving motor vehicles.

It is known to treat OSAS by generating a constant overpressure in the nose-pharynx spacer using a compressor outside the body and a tube and nose mask during the patient's sleep. Such overpressure treatment in the long run may cause expansion of the lung alveoli and may shorten their septa, (the so-called emphysema) and hence reduce the total pulmonary diffusion surface and provoke shortness of breath. Another drawback is that pulmonary overpressure entails raising the pumping output of the right heart ventricle in order to force the same quantity of blood against the increased opposing pressure in the lung. Muscle disease

of the right heart may ensue. Still another drawback is that wearing a mask during sleeping is bothersome.

Oral prostheses are known from the L. Grothe and H. Schneider book "Schlafapnoe- und kardiovaskuläre Erkrankungen" [Sleep apneic and cardiovascular diseases, Thieme publishers, 1996, which prior to sleeping must be inserted into the pharynx and serve the purpose to force the base of the tongue forward. However such prostheses promise success only for light cases of OSAS and because of complexity and inconvenience are tolerated only by a few percent of the patients.

Moreover surgical therapy is known in treating OSAS, consisting substantially in improving the air passage in the region of nose and of nose-pharynx. An attempt already has been made to shift the lower and the upper jaw or a sawed-out lower-jaw bone quadrangle in the chin zone together with the tongue muscles attached thereto in order to improve the air path. This attempt amounts to substantial surgery considerably stressing the patient but rarely offering satisfactory results because such intervention, just as the previously mentioned surgical therapy, is only an indirect treatment, and the dropping of the tongue and its resting against the rear pharynx wall and the entailed closure of the breathing duct are not basically averted.

Accordingly it is the object of the present invention to create a tongue implant for a novel implanting method whereby OSAS is effectively averted or is reduced and such patient difficulties as swallowing difficulties and sleep disorders shall be prevented.

The basic problem of the invention is solved by the disclosure of claim 1.

The basic concept of said disclosure is the creation of an implant designed to be directly implanted into the tongue, supporting the tongue base against dropping and thereby assuring an air passage even when the tongue, ie the tongue base, slackens. Implantation eliminates apposition or removal by patient. Furthermore it is inherently feasible to so design and configure the implant that swallowing shall be degraded insignificantly or not at all.

The implant of the invention meets two functions: a fastener element situated on and/or in the tissue to the side of the tongue is used to fasten and/or rest on the hyoid bone whereas a support element is used to basically support the tongue base, said support element running from the fastener element in the region of the tongue base at least partly perpendicularly to the tongue direction.

The support element may assume diverse shapes. One appropriate embodiment of the support element endows it with a curvature such that, in the implanted state, its concave side faces the pharynx. This shape favors the formation of an air passage between the tongue base and the rear pharynx wall.

Another appropriate embodiment of the support element is a strap design, the implanted strap substantially running perpendicularly to the tongue. In this embodiment the fastener element appropriately consists of a widening of the strap-shaped support element. Such widening appropriately may be in the form of two flat protrusions which, in the implanted state, will run on both sides of the implant as far as the region of the hyoid bone. The protrusions may rest on the hyoid bone and moreover they may be affixed to it by suitable means such as screws and may grow into.

In a further development of this embodiment, a third protrusion is configured between the former two and in the implanted state points toward the hyoid bone and in this manner can be implanted into a slit milled into the hyoid bone. Therein it may be fastened further by means of pins or it may grow-in in the manner known about implants.

When the fastener element consists of two flat protrusions, these may act like clamps in such a way that in the implanted state they shall at least partly clamp around the hyoid bone. This feature offers the advantage that no additional fasteners or steps are needed.

The support element may be in the form of a strip which in the implanted state is concavely bent toward the rear pharynx wall and of which the ends, in the implanted state, shall rest against the rear pharynx wall and/or against the lateral pharynx tissue and thereby

shall constitute the support element. Said strip appropriately shall be made of a flexible material. As a result, swallowing shall be degraded only little, while on the other hand the concave flexure of the trip-shaped support element provides a blocking effect so that, despite high flexibility advantageous for swallowing, comparatively large clogging forces are absorbed by the support element and in this manner the tongue base is prevented from settling down.

The support element also may be made of a flexible material when assuming other designs, the flexibility being selected in such manner by the expert that on one hand tongue displacement, especially during swallowing, shall not be hampered significantly or at all, while on the other hand the flexibility shall not be excessive and entail loss of the supporting effect.

Advantageously both the support element and the fastener elements may consist of the patient's body material. This patient body material may be removed from the patient. Illustratively appropriately shaped rib cartilage may be used. Another applicable embodiment uses a preformed cultivated blank as the patient-body material. This blank may be from the start in the shape of the desired implant, or it may be processed to assume such a shape.

All the above embodiments require that the implant have a rough surface, in particular protrusions and/or outwardly open ducts. These ducts moreover may be used in such a way for healing incorporation that for instance they are combined into a common outlet at the lower implant end and then are connected to a suction source for instance with a suction drain, whereby not only shall blood and wound secretions be evacuated, but also tissue surrounding the implant at least partly shall be sucked into the ducts in order to cause intimate healing incorporation. Furthermore x-ray opaquing media may be injected as needed subsequently into the ducts to check on implant seating or find implant tears which shall be detected by the leakage of said opaquing media.

Basically the protrusions and/or recesses may be arbitrary. In one suitable embodiment, said protrusions and/or recesses are composed of a tissue enclosing the implant.

The tissue used appropriately shall be known to offer good healing incorporation, freedom from resorption and infrequent foreign-body reactions.

In another embodiment of the invention, the implant comprises an elastic core enclosed by a soft material. The core is dimensionally stabilizing, and the soft material improves the transition to the surrounding tissue. Silicones are appropriate for the elastic core. However the core or even the entire implant may also be made from an implantation-compatible metal.

The invention is further elucidated below in relation to embodiments shown in the drawing.

Fig. 1 is a topview of an embodiment of an implant of the invention,

Fig. 2 is a rear view of the implant of Fig. 1,

Fig. 3 is a front view of the implant of Fig. 1,

Fig. 4 is a perspective of the implant of Fig. 1 in combination with a hyoid bone,

Fig. 5 shows a second embodiment of the invention,

Fig. 6 shows a third embodiment of the invention,

Fig. 7 shows a fourth embodiment of the invention,

Fig. 8 is a schematic section of a human head and elucidates the installation of the implant of Fig. 5 at the hyoid bone,

Fig. 9 is a perspective of another embodiment of the invention,

Fig. 10 elucidates the position of the implant of Fig. 9 in the base of the tongue,

Fig. 11 is diagrammatical section of the implant of Fig. 9 in the base of the tongue, and

Fig. 12 shows an embodiment similar to that of Fig. 5.

Fig. 1 shows a topview of an implant of the invention comprising a curved support element 2 and a fastener element in the form of two lateral protrusions 4 and 6. This implant is implanted in such manner that the concave side of the support element points toward the pharynx.

Fig. 2 is a rear view of the implant of Fig. 1, a dashed line indicating a hyoid bone. A further protrusion 8 is situated between the two protrusions 4 and 6 and, like the overall implant, is substantially flat and shall be inserted into a slit 12, indicated in dashed lines, which is milled into the hyoid bone 10.

Fig. 3 shows a front view of the implants of Figs. 1 and 2.

Fig. 4 is a perspective of the implant of Figs. 1 through 3, the hyoid bone being denoted by dashed lines as in Fig. 2. Again as in Fig. 2, it is clear that the lateral protrusions 4 and 6 rest on the hyoid bone, whereas the central protrusion 8 enters a slit milled into the hyoid bone 10.

Fig. 5 shows another embodiment of the invention similar to that of Fig. 2, and substantially coincident with it. Identical or corresponding parts are denoted by the same reference numerals. The difference over the embodiment of Fig. 2 is that the central protrusion 8 of Fig. 2 is absent, whereas the protrusions 4 and 6 are fitted with additional beaks 14 and 16 which, in the implanted state, at least in part tightly enclose the hyoid bone in order to improve the support offered already by the support elements 4 and 6.

Fig. 6 shows the lower part of another embodiment of the invention which is similar to that of Fig. 1 through 4. Identical or corresponding parts are denoted by the same reference numerals. The differences are that the lateral protrusions 4 and 6 and also the central protrusion 8 are elongated to be able to enclose the neighboring portions of the hyoid bone 10 in the implanted state.

Fig. 7 shows an embodiment similar to that of Figs. 1 through 4. Identical or corresponding parts are denoted by the same reference numerals. The difference is that the central protrusion has been omitted and instead feet 18 and 20 are present which support the implant, when implanted, underneath or at the thyroid cartilage of the larynx.

Fig. 8 details the implant installation of Fig. 6. It clearly shows that the protrusions 4 and 6 clamp the hyoid bone 10.

Fig. 9 is a perspective of an embodiment of a basically different design of the invention. The support element is in the form of bent strip 22 which shall be implanted in such manner that, in the implanted state, the bend shall be concave toward the rear pharynx wall. The length of the strip 22 is selected in such a way that the ends 24 and 26, in the implanted state, rest against the rear pharynx wall or sideways against and/or in the tissue and in this manner constitute the support element.

This design is clarified by means of Figs. 10 and 11 diagrammatically showing the implant of Fig. 9 in its implanted state.

Fig. 10 is a topview of a patient's tongue 28 and its adjacent portions and with an implant of Fig. 9 in this tongue 28. It will be noted that the concave side of the implant points toward the rear pharynx wall 30. The strip 22 is made of a flexible material. In other words, the strip 22 blocks the base of the tongue from collapsing toward the rear pharynx wall 30, the support forces being transmitted through the ends 24 and 26 to the sideways tissues. This embodiment offers the particular advantage that thanks to the said flexibility in conjunction with the bending of the strip 24, swallowing shall not be hampered.

Fig. 11 shows a section of a patient's head in the zone of the tongue 28 receiving at its base the said strip 22.

Fig. 12 shows an embodiment similar to that of Fig. 5. Identical or corresponding parts are denoted by the same reference numerals. The difference of this latter embodiment is that ducts 34 are present in the support element 2 and branch out and lead to apertures 36 and are combined in a duct 38 with a common outlet 40 which can be hooked-up to a suction-drain evacuating not only blood and wound secretions but also allowing to suck at least in part implant-enclosing tissue into the apertures 36 in order to thereby cause intimate healing incorporation.



CLAIMS

1. A tongue implant, comprising a fastener element (4, 6, 8) to be affixed to and/or to rest on the hyoid bone (10) or at and/or in the tissue situated to the side of the tongue, further comprising a support element (2) running from the fastening element (4, 6, 8) into the region of the tongue base and at least partly perpendicularly to the direction of the tongue (28).

2. Implant as claimed in claim 1, characterized in that the support element (2) is curved in such manner that, in its implanted state, its concave side faces the rear pharynx wall (30).

3. Implant as claimed in claim 1, characterized in that the support element (2) is in the form of a strap and when implanted runs essentially perpendicularly to the tongue (28).

4. Implant as claimed in claim 3, characterized in that the fastener element consists of a widening of the foot of the strap-shaped support element.

5. Implant as claimed in claim 4, characterized in that the fastener element consists of two flat protrusions (4, 6) which, in the implanted state, run on both sides of the implant as far as into the region of the hyoid bone (10).

6. Implant as claimed in claim 5, characterized in that a third protrusion (8) is situated between the two protrusions (4, 6) and, in the implanted state, points toward the hyoid bone (10) and thereby can be implanted into a slit (12) milled into the hyoid bone (10).



7. Implant as claimed in claim 5, characterized in that the two protrusions (4, 6) form clamps in such a way that, in the implanted state, they shall at last partly clamp the hyoid bone (10).

5 8. Implant as claimed in claim 1, characterized in that the support element is in the form of a strip (22) which, in the implanted state, is concavely bent toward the rear pharynx wall (30) and of which the ends (24, 26), in the implanted state, rest sideways on and/or in the tissue and in this manner constitute the support element.

10 9. Implant as claimed in claim 8, characterized in that the strip (22) is made of a flexible material.

10. Implant as claimed in claim 1, characterized in that the support element (2) is made of a flexible material.

15 11. Implant as claimed in claim 1, characterized in that the support element (2) and the fastener element are made of the patient's bodily material.

20 12. Implant as claimed in claim 11, characterized in that the patient's bodily material is removed from said patient's body.

13. Implant as claimed in claim 11, characterized in that the patient's bodily material consists of a preformed, cultivated blank



14. Implant as claimed in one of the above claims, characterized in that the implant comprises a rough surface, in particular protrusions and/or recesses and/or outwardly open ducts.

5 15. Implant as claimed in claim 14, characterized in that the protrusions and/or recesses are formed by a tissue enclosing the implant.

16. Implant as claimed in one of the above claims, characterized in that externally accessible ducts are present in the implant.

10 17. Implant as claimed in one of the above claims, characterized in that the implant comprises an elastic core enclosed by a soft material.