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Inventor(s)	STEIN; Thomas et al.

METHODS FOR TREATMENT OF NASAL WALL INSUFFICIENCY, AS WELL AS PUNCTURE GUIDE, INSTRUMENT SET AND MEDICAL SYSTEMS THERFORE

Abstract

Provided herein is a method for treatment of nasal wall insufficiency, comprising: providing a puncture guide, the puncture guide comprising a stabilizing frame and a plurality of puncture passages; providing a bipolar radiofrequency probe having a piercing tip; introducing the puncture guide into the nasal passages of the patient; piercing the radiofrequency probe into nasal wall tissue through one of the plurality of puncture passages; energizing the radiofrequency probe for heating the nasal wall tissue; de-energizing the radiofrequency probe; removing the radiofrequency probe from the nasal wall tissue; repeating the above steps for sequentially pierce the radiofrequency probe through each of the plurality of puncture passages; and allowing the nasal wall tissue to cool. Further provided are a puncture guide for treatment of nasal wall insufficiency, comprising a stabilizing frame and a plurality of puncture passages; an instrument set for treatment of nasal wall insufficiency, comprising: a bipolar radiofrequency probe, the probe having a main body and an elongate shaft, the shaft having a piercing tip and first and second electrodes disposed near the distal end thereof, and a puncture guide; and a medical system for treatment of nasal wall insufficiency, the system comprising: a bipolar radiofrequency probe, the probe having a main body and an elongate shaft, the shaft having a piercing tip and first and second electrodes disposed near the distal end thereof; a puncture guide having a stabilizing frame and a plurality of puncture passages; and an electrosurgical generator.

Inventors: **STEIN; Thomas (Teltow, DE), HERZOG; Eva (Berlin, DE), SCHÜRSTEDT; Katica (Schönefeld, DE), WECHSLER; Wladislaw (Hamburg, DE), STOCKHAUSEN; Etienne Michael (Dallgow-Döberitz, DE), LAZZARI; Matteo (Hamburg, DE)**

Applicant: **OLYMPUS WINTER & IBE GMBH** (Hamburg, DE)

Family ID: **1000008447105**

Assignee: **OLYMPUS WINTER & IBE GMBH (Hamburg, DE)**

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Background/Summary

[0001] The present application claims benefit of the U.S. provisional application 63/551,391 filed on Feb. 8, 2024.

FIELD

[0002] The present disclosure relates to methods, puncture guides, instrument sets, and systems for treatment of nasal wall insufficiency. More particularly, the present disclosure relates to electrosurgical methods for treatment using a puncture guide, puncture guides, and instrument sets and systems including a puncture guide.

BACKGROUND

[0003] Nasal wall insufficiency is a common cause of obstructed nasal breathing in adult patients. Patients suffering from nasal wall insufficiency experience difficulties inhaling a sufficient volume of air when inhaling through the nose, caused by a dynamic collapse of the lateral nasal walls due to limited strength of cartilage tissue around the nasal passage. Classical treatments for nasal wall insufficiency include grafting, implants, and suture suspension.

[0004] Recently, electrosurgical therapy options have been proposed, wherein lesions are created in the affected tissue with the aim to increase the stiffness thereof. However, the proposed methods are complicated, and still involve surgery.

[0005] It would be attractive to provide methods, instrument sets, and systems for easy and effective treatment of nasal wall insufficiency.

SUMMARY

[0006] The present disclosure provides a method for treatment of nasal wall insufficiency, comprising: providing a puncture guide, the puncture guide comprising a stabilizing frame and a plurality of puncture passages; providing a bipolar radiofrequency probe having a piercing tip; introducing the puncture guide into the nasal passages of the patient; piercing the radiofrequency probe into nasal wall tissue through one of the plurality of puncture passages; energizing the radiofrequency probe for heating the nasal wall tissue; de-energizing the radiofrequency probe; removing the radiofrequency probe from the nasal wall tissue; repeating the previous steps for sequentially pierce the radiofrequency probe through each of the plurality of puncture passages; and allowing the nasal wall tissue to cool.

[0007] The present inventors have discovered that electrosurgical heating of the nasal wall tissue while the tissue is stabilized by a frame of the puncture guide can achieve a stiffening effect on the nasal wall tissue, and can improve the strength of the nasal wall tissue to maintain a shape provided

by the stabilizing frame of the puncture guide.
[0008] The puncture guide may be left in the nasal passages of the patient until the method is completed. In some embodiments, the puncture guide is removed from the nasal passage of the patient about 2 minutes after de-energizing the radiofrequency probe for the last time. The nasal wall tissue may conform to a shape of the puncture guide during treatment, and may fully or partially maintain the amended shape after cooling.
[0009] In some embodiments, the puncture guide may be configured to be introduced into both nasal passages of the patient simultaneously. In other embodiments, the puncture guide may be configured to be introduced into the nasal passages of the patient one after the other.
[0010] Further provided herein is a puncture guide for treatment of nasal wall insufficiency, the puncture guide having a stabilizing frame and a plurality of puncture passages. The instrument set may be configured to allow application of the methods described above.
[0011] The frame of the puncture guide may include at least one hollow plug. The frame of the puncture guide may include a first hollow plug for introduction into the right nasal passage of a patient, and a second hollow plug for introduction into the left nasal passage of a patient. The frame of the puncture guide may include a tether between the first hollow plug and the second hollow plug.
[0012] The first hollow plug may comprise a first plurality of puncture passages. The second hollow plug may comprise a second plurality of puncture passages. The puncture guide may include a handle attached to the hollow plug or hollow plugs.
[0013] In some embodiments, the puncture guide may comprise a first guide plate and a first arm extending proximally from the first guide plate, a second guide plate and a second arm extending proximally from the second guide plate, and a plurality of puncture passages provided in the first guide plate. The puncture guide may further comprise a plurality of puncture passages provided in the second guide plate. The first and the second guide plates may have a curved shape. The first arm and the second arm may merge in a proximal elastic joint.
[0014] Also provided herein is an instrument set for treatment of nasal wall insufficiency, the instrument set comprising a bipolar radiofrequency probe, the probe having a main body and an elongate shaft, the shaft having a piercing tip and first and second electrodes disposed near the distal end thereof, and a puncture guide as described herein.
[0015] The present disclosure further provides a medical system for treatment of nasal wall insufficiency, the system comprising: a bipolar radiofrequency probe, the probe having a main body and an elongate shaft, the shaft having a piercing tip and first and second electrodes disposed near the distal end thereof, a puncture guide having a stabilizing frame and a plurality of puncture passages, and an electrosurgical generator.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0016] The subject of the disclosure is in the following further described at hand of exemplary drawings. The drawings, which are not necessarily drawn to scale, are provided for better understanding of the concepts disclosed herein, without the intention to limit the scope of disclosure.
[0017] In the drawings:
[0018] FIG. **1** shows steps of a method according to the present disclosure,
[0019] FIG. **2** shows a medical system according to the present disclosure,
[0020] FIG. **3** shows a bipolar radiofrequency probe,
[0021] FIGS. **4***a*-**4***c* show a puncture guide,
[0022] FIGS. **5***a*-**5***c* show a further puncture guide.

DETAILED DESCRIPTION

[0023] FIG. **1** shows an exemplary method **1** for treatment of nasal wall insufficiency. It will be appreciated that only the relevant steps of the procedure are explained in detail. Practitioners may add intermediate routine steps like administration of local anesthesia.

[0024] In step **10**, a puncture guide is provided. The puncture guide, examples of which will be described in more detail herein below, comprises a stabilizing frame and a plurality of puncture passages. The stabilizing frame may be shaped to define a desired geometry of a patient's nasal passage when the puncture guide is inserted into the patient's nasal passage.

[0025] In step **11**, a bipolar radiofrequency probe is provided. The radiofrequency probe may comprise a main body, serving as a handle, and an elongate shaft. The shaft of the radiofrequency may comprise a piercing tip. The radiofrequency probe may comprise first and second electrodes at a distal end thereof.

[0026] In step **12**, the puncture guide is introduced into the nasal passage of the patient. Introducing the puncture plug into the nasal passage of the patient may elastically push nasal wall tissue of the patient into a desired shape.

[0027] In step **13**, the radiofrequency probe is pierced through one of the puncture passages of the puncture guide into the nasal wall tissue. The radiofrequency probe may be inserted into the nasal wall tissue deep enough so that both first and second electrodes of the radiofrequency probes are completely buried in nasal tissue.

[0028] In step **14**, the radiofrequency probe is energized to heat the nasal wall tissue. For energizing, the radiofrequency probe is connected to an electrosurgical generator, and the electrosurgical generator is activated to provide electrosurgical energy to the radiofrequency probe. Heating the tissue can create a tissue lesion in the nasal wall tissue, which increases stiffness of the tissue.

[0029] After a desired lesion size has been created, the radiofrequency probe is de-energized in step **15**. Desirable lesion sizes may range between 5 mm and 15 mm in length, and 1.5 mm to 2.5 mm in width. A desired lesion size may be 11 mm in length and 2 mm in width. For de-energizing the radiofrequency probe, the electrosurgical generator may be deactivated.

[0030] Then, in step **16**, the radiofrequency prove is removed from the nasal wall tissue by pulling the shaft of the probe through the puncture passage of the puncture guide.

[0031] The method then loops back to step **13**, where the radiofrequency probe is pierced through a next puncture passage of the puncture guide. Then, the probe is again energized to create another lesion close to the previously created lesion, and de-energized and removed.

[0032] The same may be repeated until the radiofrequency probe has been pierced through all puncture passages of the puncture guide. In this way, a predetermined number of lesions may be created in the nasal wall tissue of the patient. The predetermined number of lesions may be two lesions, three lesions, four lesions, of even more than four lesions.

[0033] After the radiofrequency probe has been pierced through all puncture passages of the puncture guide, in step **17** the radiofrequency probe is removed from the site, while the puncture guide is left in the nasal passage for a predetermined time span, while the nasal wall tissue of the patient is allowed to cool. When the nasal wall tissue of the patient cools down, cartilage in the nasal wall further stiffens, while maintaining a shape defined by the stabilizing frame of the puncture guide. Cooling of the nasal wall tissue may be assisted by external or internal application of a cooled fluid like air or water, or by external application of a cooling pad. The time span for cooling of the nasal wall tissue may be between 1 minute and 5 minutes. The time span for cooling of the nasal wall tissue may be about 2 minutes.

[0034] Finally, the puncture guide is removed from the nasal passage of the patient in step **18**.

[0035] FIG. **2** shows a medical system **100**, which can be used to perform a method as described above. The system **100** includes an electrosurgical generator **110**, a bipolar radiofrequency probe **120**, and a puncture guide **130**.

[0036] The electrosurgical generator **110** may be any suitable electrosurgical generator like from the ESG series offered by the present applicant. It is configured to provide the bipolar radiofrequency probe **120** with an electrosurgical therapy signal.
[0037] The bipolar radiofrequency probe **120** comprises a main body **150** and a rigid elongate shaft **160** extending distally therefrom. At the distal end, the shaft **160** comprises a piercing **161** for facilitating insertion of the shaft **160** into nasal wall tissue (not shown). In some embodiments, the shaft **160** may have a diameter of about 1 mm, and may have a length of about 40 mm to 100 mm, preferably of about 50mm to 60 mm.
[0038] Near the distal end, the shaft **160** comprises two electrodes **165**, **166**, which contact tissue (not shown) to couple the electrosurgical therapy signal into the tissue. In the shown embodiment, one of the electrodes **165** forms the piercing tip **161**.
[0039] The main body **150** is sized to enable easy and convenient handling of the radiofrequency probe **120**. Conductors (not shown) from the electrodes **165**, **166** run through the shaft **150** and are connected to conductors of a supply cable **180** inside of the main body.
[0040] The puncture guide **130** shown in FIG. **2** comprises two frustoconical plugs **201**, **202** linked by a tether **203**. The plugs **201**, **202** each have a hollow passage defined by a wall **204**, allowing a patient to breath normally when the puncture guide **130** is inserted into the patient's nose.
[0041] In the wall **204** of the plugs **201**, **202**, puncture passages **205** are provided. As can be seen from the cutaway section of the left plug **201**, the puncture passages run about parallel to a longitudinal axis of the plugs **201**, **202**, so that the radiofrequency probe **120** can be pierces through the puncture passage **205** into the nasal wall (not shown) of the patient in a shallow angle, without piercing though the nasal wall tissue. The term “about parallel” as used herein may encompass a small angular deviation between the puncture passages **205** and the longitudinal axis of the plugs **201**, **202**, which may be in the range of ±1°, ±2°, ±5°, or the like.
[0042] In the shown embodiment, each plug **201**, **202** comprises three puncture passages **205**, of which only on is visible in the breakout section of plug **201**, and two are visible on the outer surface of plug **202**. In other embodiments, puncture passages may be provided in a different number like two puncture passages per plug, four puncture passages per plug, or even more puncture passages per plug.
[0043] The wall **204** of the plugs **201**, **202** forms a stabilizing frame of the puncture guide **120**. The material of the wall **204** is selected to be sufficiently biocompatible so that the puncture guide **120** may safely be placed in the nose of a patient for a period ranging from a few minutes to about one hour. The material of the wall **204** may further be selected to provide sufficient stiffness so that nasal wall tissue of the patient may be pushed into and maintained in a desired shape during treatment. Applicable materials include surgical steel, biocompatible polymers, or the like. In case of polymers, the plugs **201**, **202** and the tether **203** may be integrally formed as one piece. In other embodiments, the plugs **201**, **202** and the tether **203** may be formed as separate parts and may be connected through any suitable means.
[0044] The bipolar radiofrequency probe **120** and the puncture guide **103** of the shown embodiment are designed as single-use instruments. The bipolar radiofrequency probe **120** and the puncture guide **130** may be provided as pre-confectioned instrument set, which is packed ready to use. A pre-confectioned instrument set may comprise a single radiofrequency probe and a single puncture guide. In some embodiments, a pre-confectioned instrument set may comprise a plurality of puncture guides, which may have different sizes to fit with different patient anatomies. In other embodiments, a pre-confectioned instrument set may comprise a plurality of radiofrequency probes having different shaft lengths, different shaft diameters, or both.
[0045] FIG. **3** shows the bipolar radiofrequency probe **120** in more detail. The probe **120** comprises a main body **150** with a rigid elongate shaft **160** extending distally therefrom. The shaft **160** is bent near the main body **150** to facilitate introduction of the probe into the puncture guide **130**.
[0046] At a distal end of the shaft **160**, the probe **120** comprises a pair of electrodes **165**, **165**

spaced apart from each other along the longitudinal axis of the shaft **160**. The distal electrode **165** has a pointed tip suitable for piercing into tissue.
[0047] As can be seen from detail A of FIG. **3**, the shaft **160** of the probe **120** includes a conductive shaft tube **170**, which can be made from surgical steel or any other suitable metallic material. Within the conductive tube **170**, a center wire **171** runs along the shaft **160**. An inner insulator **173** isolates the center wire from the conductive tube. The conductive tube **170** is sufficiently rigid to avoid bending of the shaft **160**.
[0048] At the distal end of the shaft **160**, the center wire **171** projects from the conductive tube **170** and is connected to the distal electrode **165** by any suitable means like soldering or crimping. An insulating washer **175** isolates the distal electrode **165** from the conductive tube **170**.
[0049] An insulating sheath **176** covers a main part of the outside of the conductive tube **170**, leaving only a short distal portion uncovered. The uncovered portion of the conductive tube forms the proximal electrode **166**.
[0050] As shown in detail B of FIG. **3**, in the main body **150**, the conductive tube **170** and the center wire **171** are connected to respective wires of a supply cable **180**, which can be connected to a radiofrequency generator through a plug (generator and plug not shown in FIG. **3**). The main body **150** can be made from any suitable material like thermoplastic resin, and can be filled with potting (not shown) to secure the other components of the probe.
[0051] FIGS. **4***a* to **4***c* show a further embodiment of a puncture guide **300** to be part of an instrument set instead of puncture guide **120**.
[0052] Puncture guide **300** comprises two curved guide plates **301**, **302**, which can be moved between a closed position, shown in FIG. **4***a*, and an expanded position shown in FIG. **4***c*. FIG. **4***b* shows the puncture guide **300** in a sectional side view.
[0053] In the closed position, the guide plates **301**, **302** are brought into contact to form a plug similar to the plugs **201**, **202** shown in FIG. **2**. In the shown embodiment, each guide plate **301**, **302** comprises three puncture passages **305**. In the expanded position, the guide plates **301**, **302** are separated from each other.
[0054] Arms **310**, **311** are attached to the guide plates, and are connected by an elastic joint **315** at their other ends. The elastic joint **315** is configured to bias the guide plates **301**, **302** away from each other, so that the puncture guide **300** assumes the expanded position in absence of an external force.
[0055] In use, a surgeon can hold the puncture guide **300** at the arms **310**, **311** and compress the arms **310**, **311**, so that the puncture guide **300** assumes the closed position. The surgeon can then introduce the guide plates **301**, **302** into one nasal passage of the patient, and subsequently release pressure from the arms **310**, **311**, so that the guide plates **301**, **302** spread apart from each other and spread the nasal passage of the patient. In such spread position, the surgeon can then perform the treatment method as described above for the first nasal passage of the patient. Afterwards, the surgeon can remove the puncture guide **300** from the first nasal passage and repeat the procedure for the second nasal passage.
[0056] In use, only one of the guide plates **301**, **302** will abut the nasal wall of the patient, while the other one of the guide plates **301**, **302** will abut the nasal septum. Only the puncture passages in the guide plate contacting the nasal wall will be used during treatment.
[0057] FIGS. **5***a* to **5***c* show a further embodiment of a puncture guide. The puncture guide **400** again comprises first and second guide plates **401**, **402**, each guide plate **401**, **402** comprising three puncture passages **405**. Arms **410**, **411** attached to the guide plates **401**, **402** are connected through an elastic joint **415** at their other ends. FIG. **4***b* shows puncture guide **400** in a sectional side view.
[0058] Other than the arms **310**, **311** of puncture guide **300**, the arms **410**, **411** of puncture guide **400** are crossed between the guide plates **401**, **402** and the elastic joint **415**, so that the elastic joint **415** biases the puncture guide **400** into the closed position shown in FIG. **5***a*, and the puncture guide **400** can be brought into the expanded position shown in FIG. **5***c* by compressing the arms

410, **411**.
[0059] In use, a surgeon can hold the puncture guide **400** at the arms **410**, **411** without compressing the arms **410**, **411**, so that the puncture guide **400** is in the closed position, and introduce the guide plates **401**, **402** into one nasal passage of the patient. The surgeon can then carefully push the arms **410**, **411** towards each other so that the guide plates **401**, **402** move away from each other and spread the nasal passage of the patient. In such spread position, the surgeon can then perform the treatment method as described above for the first nasal passage of the patient. Afterwards, the surgeon can remove the puncture guide **400** from the first nasal passage and repeat the procedure for the second nasal passage.

Claims

1. A method for treatment of nasal wall insufficiency, comprising: a) providing a puncture guide, the puncture guide comprising a stabilizing frame and a plurality of puncture passages, b) providing a bipolar radiofrequency probe having a piercing tip, c) introducing the puncture guide into the nasal passages of the patient, d) piercing the radiofrequency probe into nasal wall tissue through one of the plurality of puncture passages, e) energizing the radiofrequency probe for heating the nasal wall tissue, f) de-energizing the radiofrequency probe, g) removing the radiofrequency probe from the nasal wall tissue, h) repeating steps d) to g) for sequentially pierce the radiofrequency probe through each of the plurality of puncture passages, i) allowing the nasal wall tissue to cool.
2. The method of claim 1, wherein the puncture guide is left in the nasal passages of the patient until the method is completed.
3. The method of claim 1, wherein the puncture guide is removed from the nasal passage of the patient about 2 minutes after de-energizing the radiofrequency probe for the last time.
4. The method of claim 1, wherein the nasal wall tissue conforms to a shape of the puncture guide during treatment.
5. The method of claim 4, wherein the nasal wall tissue fully or partially maintains the amended shape after cooling.
6. The method of claim 1, wherein the puncture guide is configured to be introduced into both nasal passages of the patient simultaneously.
7. The method of claim 1, wherein the puncture guide is configured to be introduced into the nasal passages of the patient one after the other.
8. A puncture guide for treatment of nasal wall insufficiency, comprising a stabilizing frame and a plurality of puncture passages.
9. The puncture guide of claim 8, wherein the frame of the puncture guide includes at least one hollow plug.
10. The puncture guide of claim 9, wherein the frame of the puncture guide includes a first hollow plug for introduction into the right nasal passage of a patient, and a second hollow plug for introduction into the left nasal passage of a patient.
11. The puncture guide of claim 10, wherein the frame of the puncture guide includes a tether between the first hollow plug and the second hollow plug.
12. The puncture guide of claim 10, wherein the first hollow plug comprises a first plurality of puncture passages, and the second hollow plug comprises a second plurality of puncture passages.
13. The puncture guide of claim 9, wherein the puncture guide includes a handle attached to the hollow plug.
14. The puncture guide of claim 8, wherein the puncture guide comprises: a first guide plate and a first arm extending proximally from the first guide plate, a second guide plate and a second arm extending proximally from the second guide plate, and a plurality of puncture passages provided in the first guide plate.

15. The puncture guide of claim 14, wherein the puncture guide further comprises a plurality of puncture passages provided in the second guide plate.
16. The puncture guide of claim 14, wherein the first and second guide plates are curved.
17. The puncture guide of claim 14, wherein the first arm and the second arm merge in a proximal elastic joint.
18. An instrument set for treatment of nasal wall insufficiency, comprising: a bipolar radiofrequency probe, the probe having a main body and an elongate shaft, the shaft having a piercing tip and first and second electrodes disposed near the distal end thereof, and the puncture guide of claim 8.
19. A medical system for treatment of nasal wall insufficiency, the system comprising: a bipolar radiofrequency probe, the probe having a main body and an elongate shaft, the shaft having a piercing tip and first and second electrodes disposed near the distal end thereof, a puncture guide having a stabilizing frame and a plurality of puncture passages, and an electrosurgical generator.