improve nasal airflow. Changing the nasal valve can be performed alone or together with other procedures (e.g., surgical procedures), such as those described above. Such methods and devices can lead to improved nasal airflow, increased volume of nasal airflow in patients with normal or reduced nasal airflow.

[0073] The internal nasal valve area is the narrowest portion of the nasal passage and thus functions as the primary regulator of airflow and resistance. The cross-sectional area of the internal nasal valve area is normally about 55-83 mm^2. As described by the Poiseuille law, airflow through the nose is proportional to the fourth power of the radius of the narrowest portion of the nasal passageway. Thus, changes as small as 1 mm in the size of the nasal valve have an exponential effect on airflow and resistance through the nasal cavity and the entire respiratory system.

[0074] Figs. 1 and 2A-C illustrate anatomical elements of a human nose. The lower lateral cartilage (LLC) includes an external component referred to as the lateral crus and an internal component referred to as the medial crus. The medial crus and septal nasal cartilage create a nasal septum that separates the left and right nostrils. Upper lateral cartilage lies between the lower lateral cartilages and the nasal bone. The left ULC is separated from the right ULC by the septal cartilage extending down the bridge of the nose. The opposing edges of the LLC and ULC may move relative to one another. Disposed between the opposing edges is an accessory nasal cartilage. The septal nasal cartilage and the ULC form an angle (Θ) called the nasal valve angle.

[0075] Fig. 2B illustrates a detailed cross-section of a segment of nose tissue in the area of the intersection of the ULC and the LLC. As shown in the detailed view of FIG. 2A, both inner and outer surfaces of the nasal cartilage are covered with soft tissue including mucosa, sub-mucosa and skin.

[0076] Fig. 2C illustrates a view of the nose as seen from the nostrils. Fig. 2 depicts the nasal valve 1 shown between the septum 2 and the Upper Lateral Cartilage 3. Fig. 2A also depicts the position of the turbinate 4.

[0077] The internal nasal valve area of the nasal airway passage can be visualized prior to and/or during any treatment by any suitable method, including but not limited to direct visualization, endoscopic visualization, visualization by the use of a

The internal shaft 328 can be moved relative to the electrode shaft 324 and may provide counter-traction and/or positioning. For example, when the electrode 322 is placed against a patient's upper lateral cartilage, the counter-traction element 328 may be pressed against the patient's nasal septum.

[0143] Fig. 11B depicts a device 450 similar to device 320 of Fig. 11A comprising an inter-nasal electrode 451 located at a distal end of a shaft 452 connected to a handle 454. The device 450 further comprises a counter-traction element 456 connected to a handle 458. Like the device 320 depicted in Fig. 11A, the connection 460 between the two handles 454, 458 is such that squeezing the two handles 454, 458 together causes the electrode 451 and the counter-traction element 456 to move away from each other, spreading the tissue they are contacting.

[0144] Fig. 12A depicts a device 330 comprising a single inter-nasal electrode 332 located at the end of a shaft 334. The shaft 334 is attached to a handle 336. The device 330 comprises another single inter-nasal electrode 338 attached to the end of a shaft 340. The shaft 340 is attached to a handle 342. The device comprises a connection 344 between the two handles 340, 342 that allows simultaneous deformation and treatment of both nostrils.

[0145] Fig. 12B depicts a device 470 similar to device 330 of Fig. 12A comprising a first inter-nasal electrode 472 located at a distal end of a shaft 474 connected to a handle 476. The device 470 comprises a second inter-nasal electrode 478 located at a distal end of a second shaft 480 connected to a second handle 482. The connection 484 between the two handles 476, 482 is such that squeezing the handles 476, 482 together causes the electrodes 472, 478 to move away from one another, spreading any tissue they may be in contact with. The device 470 comprises a ratcheting mechanism 475 between the two handles 476, 482 that allows the relative positions of the electrodes 472, 478 to be locked during treatment.

[0146] Fig. 13A depicts a side view of a device 350 also used for treating two nostrils comprising an inter-nasal electrode 352 attached to the end of a shaft 354. The shaft 354 is attached to a handle 356. As seen in the front view provided in Fig. 13B, the device 350 comprises a second inter-nasal electrode 358. The second inter-nasal

second shaft 400 is attached to a second handle 402. A connection 404 between the two handles 396, 402 may allow simultaneous deformation and treatment of the nostrils. Additional internal shafts 406, 408 comprise tissue-contacting surfaces and are attached to the handles 396,402. The internal shafts 406, 408 may be moved relative to each electrode shaft 394, 400 (shown in Fig. 15B) and may provide counter-traction and positioning.

[0150] Fig. 16 depicts a system 410 comprising a first device having an extra-nasal electrode 412 along a concave surface configured to positioned against an external surface of a patient's nose, the electrode 412 being attached to the end of a shaft 414. The shaft 414 is attached to a handle 416. A separate device 417 comprising an internal tissue mold 418 is attached to a shaft 420. The internal tissue mold is configured to be positioned inside the patient's nasal valve. The shaft 420 is attached to a handle 422. Each handle 422, 416 may be manipulated individually and may apply energy and deformation to create a desired tissue effect.

[0151] Fig. 17A depicts a side view of a device 430 comprising an extra-nasal electrode 431 attached to the end of a shaft 432. The shaft 432 is attached to a handle 434. The device 430 also comprises an internal tissue mold 436 attached to a shaft 438 which is attached to a handle 440. The handles 434, 440 are attached together and may be moved relative to each other to simultaneously deliver energy and deform tissue. Fig. 17B depicts a front view of the device 430.

[0152] Fig. 18 depicts a device 390 comprising pairs of bipolar electrodes 392 located at the distal end of a shaft 394. The electrodes may be similar to the electrodes described with respect to the electrode configuration of Fig. 8G in that they are non-penetrating. The shaft 394 is connected to a handle 398 which comprises a button configured to activate and deactivate the electrodes. As stated above, the device 380 may either comprise a generator or be connected to a remote generator.

[0153] Fig. 19A depicts the treatment element 502 of a treatment device (e.g., device 30). The treatment element 502 of the device comprises a monopolar electrode 504. A cross-section of the treatment element 502 is shown in Fig. 19B. It comprises an asymmetrical shape and has a convex surface where the electrode is positioned

configured to conform to only one of a patient's nostrils (for example, a patient's right nostril). More specifically, the convex surface is configured such that when inserted into the particular nostril, the convex surface would be located adjacent the upper lateral cartilage of the nasal valve of that nostril. The treatment element 502 further comprises a light 506 configured to illuminate the treatment area. For example an LED or a visible laser may be used. The visible laser may experience less diffusion in the tissue. Furthermore, the light 506 can be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location. Because the electrode 504 is not centered on the treatment element 502 of the device, a separate device having a mirror-image configuration may be required to treat the other nostril.

[0154] Fig. 20A depicts the treatment element 512 of a treatment device (e.g., device 30). The treatment element 512 of the device comprises two monopolar electrodes 514, 516 provided side-by-side on a convex surface of the treatment element. The cross section of the treatment element 512, shown in Fig. 20B, is configured to conform to the shape either nostril, depending on which side of the device (and accordingly, which of electrode 514 or 516) is placed in contact with the patient's nasal valve. Comprising two monopolar electrodes 514, 516 may allow the same treatment element 512 to be used for treatment in both nostrils, and each electrode may be activated separately depending on which side needs to be utilized. The treatment element 512 also comprises two lights 518, 520 (e.g., LEDs, lasers) configured to illuminate the treatment area for both nostrils. One or both of the lights 518, 520 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location.

[0155] Fig. 21A depicts a treatment element 522 of a treatment device (e.g., device 30). The tip 522 of the device comprises a monopolar electrode 524. The tip 522 comprises a symmetrical cross-section as shown in Fig. 21B. The tip 522 comprises a light 526 (e.g., LED) configured to illuminate the treatment area. The light 526 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The symmetrical tip allows the user to treat

square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 538 may increase distally along the length of the handle 538.

[0159] Figs. 22D and 22E depict side views of the device. As shown in Figs. 22D and 22E, the handle 538 of the device 530 may comprise an indentation or recess around the middle of the handle 538. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 540 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0160] In some embodiments, the shaft has a width or diameter of about 0.125 inches to about 0.25 inches. In some embodiments, the shaft is about 1.5 inches to about 4 inches long. In some embodiments, the shaft comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0161] Fig. 22G depicts a larger view of the distal tip 534 of the device 530. As shown best in Fig. 22G, the treatment element 532 comprises a generally elongate shape. The front of the treatment element 532 comprises a shallow, curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the treatment element comprises a concave shape. The shape of the front surface of the treatment element may be selected to conform to the nasal tissue. The back of the treatment element 532 also comprises a shallow curved surface. As best seen in Figs. 22D and 22E, the back surface varies in width along the length of the back surface of the treatment element 532. The back surface widens, moving distally along the tip until it is nearly in line with the proximal end of the electrode plate 532. The back surface then narrows towards the distal tip of the treatment element 532. This shape may maximize visualization of the area to be

treated, while, at the same time, providing sufficient rigidity for treatment. Other shapes are also possible. For example, the treatment element may comprise a generally spherical or cylindrical shape. In some embodiments, the treatment element comprises an angular shape (e.g., triangular, conical) which may allow for close conformation to the tissue structures. The treatment element 532 comprises a monopolar electrode plate 532. The monopolar electrode plate 532 can be in the shape of a rectangle having a curved or convex tissue-facing surface. Other shapes are also possible (e.g., square, circular, ovular, etc.). The electrode 532 may protrude slightly from the treatment element 535. This may allow the electrode to itself provide a convex shape configured to create a concavity in tissue to be treated.

[0162] In some embodiments, the treatment element has a width or diameter of about 0.25 inches to about 0.45 inches. In some embodiments, the treatment element is about 0.4 inches to about 0.5 inches long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0163] In some embodiments, the electrode has a width of about 0.15 inches to about 0.25 inches. In some embodiments, the electrode is about 0.2 inches to about 0.5 inches long. In some embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive.

embodiments, the kit includes a positioning element (e.g., a "cottle" device) configured to help a user locate the optimal treatment area.

[0167] In some embodiments, the shaft has a width or diameter or about 0.235 inches to about 0.25 inches. In some embodiments, the shaft is about 1.5 inches to about 4 inches long. In some embodiments, the shaft and/or handle comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0168] Figs. 23B and 23C depict side views of the device. As shown in Figs. 23B and 23C, the handle 560 of the device 550 may comprise an indentation or recess around the middle of the handle 560. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 562 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0169] Figs. 23D and 23E depict front and back views of the device. As shown in Figs. 23D and 23E, the handle 560 of the device generally comprises a rounded elongate shape. Other shapes are also possible. For example the device 550 may have a square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 560 may increase distally along the length of the handle 560.

[0170] Fig. 23G depicts a larger view of the distal tip 556 of the device 550. As shown best in Fig. 23G, the treatment element 552 comprises a generally elongate shape. The front of the treatment element 552 comprises a shallow curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the treatment element comprises a concave shape. The shape of the front surface of the treatment element may be selected to conform to the nasal tissue. The back surface of the treatment element 552 comprises a

measurements taken by the thermocouple can be routed as feedback signals to a control unit (e.g., the control unit 42 described with respect to Fig. 3) and the control unit can use the temperature measurements to adjust the intensity of energy being delivered through the electrode. In some embodiments, thermocouples or other sensing devices may be used to measure multiple tissue and device parameters. For example, multiple thermocouples or thermistors may be used to measure a temperature at different locations along the treatment element. In some embodiments, one of the sensors may be configured to penetrate deeper into the tissue to take a measurement of a more interior section of tissue. For example, a device may have multiple sensors configured to measure a temperature at the mucosa, the cartilage, and/or the treatment element itself. As described above, in some embodiments, the sensors described herein are configured to take a measurement of a different parameter. For example, tissue impedance can be measured. These measurements can be used to adjust the intensity and/or duration of energy being delivered through the treatment element. This type of feedback may be useful from both an efficacy and a safety perspective.

[0172] In some embodiments, the treatment element has a width or diameter of about 0.25 inches to about 0.45 inches. In some embodiments, the treatment element is about 0.4 inches to about 0.5 inches long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0173] In some embodiments, the electrodes have a width or diameter of about 0.15 inches to about 0.25 inches. In some embodiments, the electrode is about 0.2

inches to about 0.5 inches long. In some embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0174] Energy applied to the tissue to be treated using any combination of the embodiments described in this application may be controlled by a variety of methods. In some embodiments, temperature or a combination of temperature and time may be used to control the amount of energy applied to the tissue. Tissue is particularly sensitive to temperature; so providing just enough energy to reach the target tissue may provide a specific tissue effect while minimizing damage resulting from energy causing excessive temperature readings. For example, a maximum temperature may be used to control the energy. In some embodiments, time at a specified maximum temperature may be used to control the energy. In some embodiments, thermocouples, such as those described above, are provided to monitor the temperature at the electrode and provide feedback to a control unit (e.g., control system 42 described with respect to Fig. 3). In some embodiments, tissue impedance may be used to control the energy. Impedance of tissue changes as it is affected by energy delivery. By determining the impedance reached when a tissue effect has been achieved, a maximum tissue impedance can be used to control energy applied.

[0175] In the embodiments described herein, energy may be produced and controlled via a generator that is either integrated into the electrode handpiece or as part of a separate assembly that delivers energy or control signals to the handpiece via a cable or other connection. In some embodiments, the generator is an RF energy source

material such as liquid nitrogen before, during, or after treatment. Using a material such as copper for the passive fins or other structure may advantageously provide high heat and electrical conductivity. In some embodiments, using metals with a high heat capacity in the device (e.g., in the energy delivery element, the re-shaping element, or both) may advantageously provide the ability to resist temperature change during energy delivery. In some embodiments, pre-cooling the electrode (e.g., by refrigeration, submersion, spraying with a cool substance like liquid nitrogen, etc.) may maintain a reduced temperature at the mucosa. Any combination of the cooling methods described herein may be used in conjunction with any of the energy delivery methods described herein (e.g., bipolar RF electrodes, arrays needles, plates, etc.). For example, Fig. 29 depicts an embodiment of a device 800 comprising a treatment element 802 comprising electrode needles 804 at its distal tip. The device 800 may be used in conjunction with a separate cooling device 810 which may comprise channels 812 or cavities to circulate air or fluid. The independent cooling device 810 may, in other embodiments, employ a different cooling mechanism.

[0196] In embodiments using laser energy to heat cartilage, it is possible to use a combination of two or more lasers whose beams converge at a location within the target tissue. This convergence may cause more heat at that junction as compared to locations where only a single beam is acting. The junction may be controlled manually or via computer control. Specific treatment may be provided.

[0197] In some embodiments, insulating material may be used to protect non-target tissue during energy delivery. For example, an electrode needle may be preferentially insulated on a portion of the needle that is in contact with non-target tissue. For another example, flat electrode blades may be insulated on a portion of the blade that is in contact with non-target tissue. Other configurations for heat isolation are also possible.

[0198] Any of the cooling mechanisms or combinations of the cooling mechanisms described herein may be used in conjunction with any of the devices or combinations of devices described herein, or the like.

achieve improvement in nasal airway. The electrodes may be activated while the tissue is deformed in the new shape to treat the tissue. The electrode may then be deactivated and the device may be removed from the nasal valve area.

[0216] Figs. 30A-30D depict a method for using a device 900 similar to those devices described above, including but not limited to Figs. 8A, 9B, 18, 22A-G, and 23A-G, to provide tissue re-shaping/molding and to impart energy to tissue near the nasal valve.

[0217] The method may include identifying a patient who desires to improve the airflow through their nasal passageways and/or who may benefit from an increase in a cross-sectional area of the opening of the nasal valve. The patient may be positioned either in an upright position (e.g., seated or standing) or be lying down. Local anesthesia may be applied to an area near or surrounding the tissue to be treated. General anesthesia may also be used.

[0218] Optionally, a positioning element, like that described herein, may be used to measure a desired depth or angle of treatment. As described above, the positioning element may be inserted to the desired depth of treatment and rotated to a desired angle of treatment. Marks along the positioning element can indicate the desired depth. Marks along the base of the shaft of the positioning element can indicate the desired angle. The physician or other medical professional administering the treatment can then insert the treatment device to the desired location. The physician may also assess any other characteristics relevant to the treatment of the patient's nose that may influence the manner of treatment. In some embodiments, a re-shaping element may be used to manipulate the nasal tissue into a configuration allowing improved airflow; and treatment may be performed while such a re-shaping element is maintaining the desired configuration of the nasal tissue.

[0219] If the treatment device comprises a monopolar electrode or electrode needles, a ground pad may be attached to the patient. The ground pad may be attached at the patient's torso, for example the shoulder or abdomen. Other locations are also possible, such as the patient's buttocks. Preferably, the point of attachment is a large, fleshy area. After being attached, the ground pad may be plugged into a power source. If

What is Claimed is:

1. A device for treating a patient's nasal airway, the apparatus comprising:

an elongate shaft having a proximal end and a distal end;

a handle at the proximal end of the elongate shaft; and

an energy delivery element at the distal end of the elongate shaft, wherein the energy delivery element is sized to be inserted into a nose, is configured to deliver energy to tissues within the nose to reshape a region of the nose to a new conformation, and comprises a convex shape configured to create a concavity in nasal tissue.

2. The device of claim 1, wherein the energy delivery element comprises an electrode configured to deliver radiofrequency (RF) energy to the nasal tissue.

3. The device of claim 2, wherein the handle comprises a button configured to activate the electrode.

4. The device of claim 2, wherein the energy delivery element comprises one or more monopolar needles.

5. The device of claim 2, wherein the energy delivery element comprises a monopolar plate electrode.

6. The device of claim 5, further comprising a grounding pad.

7. The device of claim 2, wherein the energy delivery element comprises one or more bipolar electrode pairs.

8. The device of claim 7, wherein a first electrode surface of a bipolar electrode pair is positionable internal to the nose and a second electrode surface of a bipolar electrode pair is positionable external to the nose, so that the two electrode surfaces are positionable on opposite sides of the nasal tissue.

9. The device of claim 8, wherein the first electrode surface comprises one or more needles or a plate and the second electrode surface comprises one or more needles or a plate.

10. The device of claim 1, further comprising an adaptor coupled with the handle and configured to be connected to an energy source.

11. The device of claim 1, further comprising a control system coupled with the handle and configured to control the characteristics of energy applied to tissue.

12. The device of claim 1, further comprising a thermocouple coupled with the shaft or the energy delivery element and configured to measure a temperature near tissue to be treated.

13. The device of claim 1, wherein the energy delivery element comprises a re-shaping element having a shape configured to alter a conformation of a region of the nose to a new conformation.

14. The device of claim 1, further comprising a re-shaping element having a shape configured to alter a conformation of a region of the nose to a new conformation.

15. The device of claim 14, wherein the energy delivery element and the reshaping element are configured to be positioned on opposite sides of nasal tissue.

16. The device of claim 14, wherein the energy delivery element and the re-shaping element are both configured to be positioned within a single nostril of the nose.

17. A system for treating a patient's nasal airway, the system comprising:

a nasal airway treatment device, comprising:

an elongate shaft having a proximal end and a distal end;

a handle at the proximal end of the elongate shaft; and

an energy delivery element at the distal end of the elongate shaft, wherein the energy delivery element is sized to be inserted into a nose, is configured to deliver energy to tissues within the nose to reshape a region of the nose to a new conformation, and comprises a convex shape configured to create a concavity in nasal tissue; and

an energy source couplable with the handle of the nasal airway treatment device for providing energy to the energy delivery element.

18. The system of claim 17, further comprising a cooling mechanism coupled with the energy delivery element or the shaft for cooling the nasal tissue or nearby nasal tissue.

improve nasal airflow. Changing the nasal valve can be performed alone or together with other procedures (e.g., surgical procedures), such as those described above. Such methods and devices can lead to improved nasal airflow, increased volume of nasal airflow in patients with normal or reduced nasal airflow.

[0073] The internal nasal valve area is the narrowest portion of the nasal passage and thus functions as the primary regulator of airflow and resistance. The cross-sectional area of the internal nasal valve area is normally about 55-83 mm^2. As described by the Poiseuille law, airflow through the nose is proportional to the fourth power of the radius of the narrowest portion of the nasal passageway. Thus, changes as small as 1 mm in the size of the nasal valve have an exponential effect on airflow and resistance through the nasal cavity and the entire respiratory system.

[0074] Figs. 1 and 2A-C illustrate anatomical elements of a human nose. The lower lateral cartilage (LLC) includes an external component referred to as the lateral crus and an internal component referred to as the medial crus. The medial crus and septal nasal cartilage create a nasal septum that separates the left and right nostrils. Upper lateral cartilage lies between the lower lateral cartilages and the nasal bone. The left ULC is separated from the right ULC by the septal cartilage extending down the bridge of the nose. The opposing edges of the LLC and ULC may move relative to one another. Disposed between the opposing edges is an accessory nasal cartilage. The septal nasal cartilage and the ULC form an angle (Θ) called the nasal valve angle.

[0075] Fig. 2B illustrates a detailed cross-section of a segment of nose tissue in the area of the intersection of the ULC and the LLC. As shown in FIG. 2B, the detailed view of FIG. 2A, both inner and outer surfaces of the nasal cartilage are covered with soft tissue including mucosa, sub-mucosa and skin.

[0076] FIG. 2C illustrates a view of the nose as seen from the nostrils. FIG. 2C depicts the nasal valve 1 shown between the septum 2 and the Upper Lateral Cartilage 3. FIG. 2C also depicts the position of the turbinate 4.

[0077] The internal nasal valve area of the nasal airway passage can be visualized prior to and/or during any treatment by any suitable method, including but not limited to direct visualization, endoscopic visualization, visualization by the use of a

The internal shaft 328 can be moved relative to the electrode shaft 324 and may provide counter-traction and/or positioning. For example, when the electrode 322 is placed against a patient's upper lateral cartilage, the counter-traction element 328 may be pressed against the patient's nasal septum.

[0143] Fig. 11B depicts a device 450 similar to device 320 of Fig. 11A comprising an inter-nasal electrode 451 located at a distal end of a shaft 452 connected to a handle 454. The device 450 further comprises a counter-traction element 456 connected to a handle 458. Like the device 320 depicted in Fig. 11A, the connection 460 between the two handles 454, 458 is such that squeezing the two handles 454, 458 together causes the electrode 451 and the counter-traction element 456 to move away from each other, spreading the tissue they are contacting.

[0144] Fig. 12A depicts a device 330 comprising a single inter-nasal electrode 332 located at the end of a shaft 334. The shaft 334 is attached to a handle 336. The device 330 comprises another single inter-nasal electrode 338 attached to the end of a shaft 340. The shaft 340 is attached to a handle 342. The device comprises a connection 344 between the two handles 336, 342 that allows simultaneous deformation and treatment of both nostrils.

[0145] Fig. 12B depicts a device 470 similar to device 330 of Fig. 12A comprising a first inter-nasal electrode 472 located at a distal end of a shaft 474 connected to a handle 476. The device 470 comprises a second inter-nasal electrode 478 located at a distal end of a second shaft 480 connected to a second handle 482. The connection 484 between the two handles 476, 482 is such that squeezing the handles 476, 482 together causes the electrodes 472, 478 to move away from one another, spreading any tissue they may be in contact with. The device 470 comprises a ratcheting mechanism 475 between the two handles 476, 482 that allows the relative positions of the electrodes 472, 478 to be locked during treatment.

[0146] Fig. 13A depicts a side view of a device 350 also used for treating two nostrils comprising an inter-nasal electrode 352 attached to the end of a shaft 354. The shaft 354 is attached to a handle 356. As seen in the front view provided in Fig. 13B, the device 350 comprises a second inter-nasal electrode 358. The second inter-nasal

second shaft 400 is attached to a second handle 402. A connection 404 between the two handles 396, 402 may allow simultaneous deformation and treatment of the nostrils. Additional internal shafts 406, 408 comprise tissue-contacting surfaces and are attached to the handles 396,402. The internal shafts 406, 408 may be moved relative to each electrode shaft 394, 400 (shown in Fig. 15B) and may provide counter-traction and positioning.

[0150] Fig. 16 depicts a system 410 comprising a first device having an extra-nasal electrode 412 along a concave surface configured to positioned against an external surface of a patient's nose, the electrode 412 being attached to the end of a shaft 414. The shaft 414 is attached to a handle 416. A separate device 417 comprising an internal tissue mold 418 is attached to a shaft 420. The internal tissue mold is configured to be positioned inside the patient's nasal valve. The shaft 420 is attached to a handle 422. Each handle 422, 416 may be manipulated individually and may apply energy and deformation to create a desired tissue effect.

[0151] Fig. 17A depicts a side view of a device 430 comprising an extra-nasal electrode 431 attached to the end of a shaft 432. The shaft 432 is attached to a handle 434. The device 430 also comprises an internal tissue mold 436 attached to a shaft 438 which is attached to a handle 440. The handles 434, 440 are attached together and may be moved relative to each other to simultaneously deliver energy and deform tissue. Fig. 17B depicts a front view of the device 430.

[0152] Fig. 18 depicts a device 390 comprising pairs of bipolar electrodes 392 located at the distal end of a shaft 394. The electrodes may be similar to the electrodes described with respect to the electrode configuration of Fig. 8G in that they are non-penetrating. The shaft 394 is connected to a handle 398 which comprises a button 395 configured to activate and deactivate the electrodes. As stated above, the device 380 may either comprise a generator or be connected to a remote generator.

[0153] Fig. 19A depicts the treatment element 502 of a treatment device (e.g., device 30). The treatment element 502 of the device comprises a monopolar electrode 504. A cross-section of the treatment element 502 is shown in Fig. 19B. It comprises an asymmetrical shape and has a convex surface where the electrode is positioned

configured to conform to only one of a patient's nostrils (for example, a patient's right nostril). More specifically, the convex surface is configured such that when inserted into the particular nostril, the convex surface would be located adjacent the upper lateral cartilage of the nasal valve of that nostril. The treatment element 502 further comprises a light 507 configured to illuminate the treatment area. For example an LED or a visible laser may be used. The visible laser may experience less diffusion in the tissue. Furthermore, the light 507 can be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location. Because the electrode 504 is not centered on the treatment element 502 of the device, a separate device having a mirror-image configuration may be required to treat the other nostril.

[0154] Fig. 20A depicts the treatment element 512 of a treatment device (e.g., device 30). The treatment element 512 of the device comprises two monopolar electrodes 514, 516 provided side-by-side on a convex surface of the treatment element. The cross section of the treatment element 512, shown in Fig. 20B, is configured to conform to the shape either nostril, depending on which side of the device (and accordingly, which of electrode 514 or 516) is placed in contact with the patient's nasal valve. Comprising two monopolar electrodes 514, 516 may allow the same treatment element 512 to be used for treatment in both nostrils, and each electrode may be activated separately depending on which side needs to be utilized. The treatment element 512 also comprises two lights 518, 520 (e.g., LEDs, lasers) configured to illuminate the treatment area for both nostrils. One or both of the lights 518, 520 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The user can then use the light to properly position the device in the desired location.

[0155] Fig. 21A depicts a treatment element 522 of a treatment device (e.g., device 30). The tip 522 of the device comprises a monopolar electrode 524. The tip 522 comprises a symmetrical cross-section as shown in Fig. 21B. The tip 522 comprises a light 526 (e.g., LED) configured to illuminate the treatment area. The light 526 can also be situated such that light can be transmitted through the nasal tissue (including the skin) and can be visualized externally by the user. The symmetrical tip allows the user to treat

square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 538 may increase distally along the length of the handle 538.

[0159] Figs. 22D and 22E depict side views of the device. As shown in Figs. 22D and 22E, the handle 538 of the device 530 may comprise an indentation or recess around the middle of the handle 538. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 540 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0160] In some embodiments, the shaft has a width or diameter of about 3.175 millimeters (0.125 inches) to about 6.35 millimeters (0.25 inches). In some embodiments, the shaft is about 38.1 millimeters (1.5 inches) to about 101.6 millimeters (4 inches) long. In some embodiments, the shaft comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0161] Fig. 22G depicts a larger view of the distal tip 534 of the device 530. As shown best in Fig. 22G, the treatment element 532 comprises a generally elongate shape. The front of the treatment element 532 comprises a shallow, curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the treatment element comprises a concave shape. The shape of the front surface of the treatment element may be selected to conform to the nasal tissue. The back of the treatment element 532 also comprises a shallow curved surface. As best seen in Figs. 22D and 22E, the back surface varies in width along the length of the back surface of the treatment element 532. The back surface widens, moving distally along the tip until it is nearly in line with the proximal end of the electrode plate 532. The back surface then narrows towards the distal tip of the treatment element 532. This shape may maximize visualization of the area to be

treated, while, at the same time, providing sufficient rigidity for treatment. Other shapes are also possible. For example, the treatment element may comprise a generally spherical or cylindrical shape. In some embodiments, the treatment element comprises an angular shape (e.g., triangular, conical) which may allow for close conformation to the tissue structures. The treatment element 532 comprises a monopolar electrode plate 532. The monopolar electrode plate 532 can be in the shape of a rectangle having a curved or convex tissue-facing surface. Other shapes are also possible (e.g., square, circular, ovular, etc.). The electrode 532 may protrude slightly from the treatment element 535. This may allow the electrode to itself provide a convex shape configured to create a concavity in tissue to be treated.

[0162] In some embodiments, the treatment element has a width or diameter of about 6.35 millimeters (0.25 inches) to about 11.43 millimeters (0.45 inches). In some embodiments, the treatment element is about 10.16 millimeters (0.4 inches) to about 12.7 millimeters (0.5 inches) long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0163] In some embodiments, the electrode has a width of about 3.81 millimeters (0.15 inches) to about 6.35 millimeters (0.25 inches). In some embodiments, the electrode is about 5.08 millimeters (0.2 inches) to about 12.7 millimeters (0.5 inches) long. In some embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive.

embodiments, the kit includes a positioning element (e.g., a "cottle" device) configured to help a user locate the optimal treatment area.

[0167] In some embodiments, the shaft has a width or diameter of about 5.969 millimeters (0.235 inches) to about 6.35 millimeters (0.25 inches). In some embodiments, the shaft is about 38.1 millimeters (1.5 inches) to about 101.6 millimeters (4 inches) long. In some embodiments, the shaft and/or handle comprises a polymer such as polycarbonate or PEEK. In other embodiments, the shaft comprises stainless steel or other metals. The metals may be coated with an external and/or internal insulating coating (e.g., polyester, polyolefin, etc.). The handle may comprise the same material as the shaft, in some embodiments. In some embodiments, the shaft is rigid. This may allow a user of the device increased control over the deformation of nasal tissue. In some embodiments, the shaft comprises some amount of flexibility. This flexibility may allow a user adjust an angle of the distal tip by bending the distal end of the shaft.

[0168] Figs. 23B and 23C depict side views of the device. As shown in Figs. 23B and 23C, the handle 560 of the device 550 may comprise an indentation or recess around the middle of the handle 560. This may allow for enhanced grip and control when a user is holding the device. The indentation or recess may be near the input control or power button 562 to allow a user to easily activate and deactivate the device while holding it in a comfortable position.

[0169] Figs. 23D and 23E depict front and back views of the device. As shown in Figs. 23D and 23E, the handle 560 of the device generally comprises a rounded elongate shape. Other shapes are also possible. For example the device 550 may have a square shaped cross section. In some embodiments, a circumference (or width or cross-sectional area) of the handle 560 may increase distally along the length of the handle 560.

[0170] Fig. 23G depicts a larger view of the distal tip 556 of the device 550. As shown best in Fig. 23G, the treatment element 552 comprises a generally elongate shape. The front of the treatment element 552 comprises a shallow curved surface, providing a convex shape configured to deform the nasal tissue and create a concavity therein. In some embodiments, the front of the treatment element comprises a concave shape. The shape of the front surface of the treatment element may be selected to conform to the nasal tissue. The back surface of the treatment element 552 comprises a

measurements taken by the thermocouple can be routed as feedback signals to a control unit (e.g., the control unit 42 described with respect to Fig. 3) and the control unit can use the temperature measurements to adjust the intensity of energy being delivered through the electrode. In some embodiments, thermocouples or other sensing devices may be used to measure multiple tissue and device parameters. For example, multiple thermocouples or thermistors may be used to measure a temperature at different locations along the treatment element. In some embodiments, one of the sensors may be configured to penetrate deeper into the tissue to take a measurement of a more interior section of tissue. For example, a device may have multiple sensors configured to measure a temperature at the mucosa, the cartilage, and/or the treatment element itself. As described above, in some embodiments, the sensors described herein are configured to take a measurement of a different parameter. For example, tissue impedance can be measured. These measurements can be used to adjust the intensity and/or duration of energy being delivered through the treatment element. This type of feedback may be useful from both an efficacy and a safety perspective.

[0172] In some embodiments, the treatment element has a width or diameter of about 6.35 millimeters (0.25 inches) to about 11.43 millimeters (0.45 inches). In some embodiments, the treatment element is about 10.16 millimeters (0.4 inches) to about 12.7 millimeters (0.5 inches) long. The treatment element can, in some embodiments, comprise a ceramic material (e.g., zirconium, alumina, silicon glass). Such ceramics may advantageously possess high dielectric strength and high temperature resistance. In some embodiments, the treatment element comprises polyimides or polyamides which may advantageously possess good dielectric strength and elasticity and be easy to manufacture. In some embodiments, the treatment element comprises thermoplastic polymers. Thermoplastic polymers may advantageously provide good dielectric strength and high elasticity. In some embodiments, the treatment element comprises thermoset polymers, which may advantageously provide good dielectric strength and good elasticity. In some embodiments, the treatment element comprises glass or ceramic infused polymers. Such polymers may advantageously provide good strength, good elasticity, and good dielectric strength.

[0173] In some embodiments, the electrodes have a width or diameter of about 3.81 millimeters (0.15 inches) to about 6.35 millimeters (0.25 inches). In some embodiments, the electrode is about 5.08 millimeters (0.2

inches) to about 12.7 millimeters (0.5 inches) long. In some embodiments, the treatment element comprises steel (e.g., stainless, carbon, alloy). Steel may advantageously provide high strength while being low in cost and minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise materials such as platinum, gold, or silver. Such materials may advantageously provide high conductivity while being minimally reactive. In some embodiments, the electrodes or energy delivery elements described herein comprise anodized aluminum. Anodized aluminum may advantageously be highly stiff and low in cost. In some embodiments, the electrodes or energy delivery elements described herein comprise titanium which may advantageously possess a high strength to weight ratio and be highly biocompatible. In some embodiments, the electrodes or energy delivery elements described herein comprise nickel titanium alloys. These alloys may advantageously provide high elasticity and be biocompatible. Other similar materials are also possible.

[0174] Energy applied to the tissue to be treated using any combination of the embodiments described in this application may be controlled by a variety of methods. In some embodiments, temperature or a combination of temperature and time may be used to control the amount of energy applied to the tissue. Tissue is particularly sensitive to temperature; so providing just enough energy to reach the target tissue may provide a specific tissue effect while minimizing damage resulting from energy causing excessive temperature readings. For example, a maximum temperature may be used to control the energy. In some embodiments, time at a specified maximum temperature may be used to control the energy. In some embodiments, thermocouples, such as those described above, are provided to monitor the temperature at the electrode and provide feedback to a control unit (e.g., control system 42 described with respect to Fig. 3). In some embodiments, tissue impedance may be used to control the energy. Impedance of tissue changes as it is affected by energy delivery. By determining the impedance reached when a tissue effect has been achieved, a maximum tissue impedance can be used to control energy applied.

[0175] In the embodiments described herein, energy may be produced and controlled via a generator that is either integrated into the electrode handpiece or as part of a separate assembly that delivers energy or control signals to the handpiece via a cable or other connection. In some embodiments, the generator is an RF energy source

material such as liquid nitrogen before, during, or after treatment. Using a material such as copper for the passive fins or other structure may advantageously provide high heat and electrical conductivity. In some embodiments, using metals with a high heat capacity in the device (e.g., in the energy delivery element, the re-shaping element, or both) may advantageously provide the ability to resist temperature change during energy delivery. In some embodiments, pre-cooling the electrode (e.g., by refrigeration, submersion, spraying with a cool substance like liquid nitrogen, etc.) may maintain a reduced temperature at the mucosa. Any combination of the cooling methods described herein may be used in conjunction with any of the energy delivery methods described herein (e.g., bipolar RF electrodes, arrays needles, plates, etc.). For example, Fig. 29 depicts an embodiment of a device 800 comprising a treatment element 802 comprising electrode needles 804 at its distal tip. The device 800 may be used in conjunction with a separate cooling device 810 which may comprise channels 815 or cavities to circulate air or fluid. The independent cooling device 810 may, in other embodiments, employ a different cooling mechanism.

[0196] In embodiments using laser energy to heat cartilage, it is possible to use a combination of two or more lasers whose beams converge at a location within the target tissue. This convergence may cause more heat at that junction as compared to locations where only a single beam is acting. The junction may be controlled manually or via computer control. Specific treatment may be provided.

[0197] In some embodiments, insulating material may be used to protect non-target tissue during energy delivery. For example, an electrode needle may be preferentially insulated on a portion of the needle that is in contact with non-target tissue. For another example, flat electrode blades may be insulated on a portion of the blade that is in contact with non-target tissue. Other configurations for heat isolation are also possible.

[0198] Any of the cooling mechanisms or combinations of the cooling mechanisms described herein may be used in conjunction with any of the devices or combinations of devices described herein, or the like.

achieve improvement in nasal airway. The electrodes may be activated while the tissue is deformed in the new shape to treat the tissue. The electrode may then be deactivated and the device may be removed from the nasal valve area.

[0216] FIGS. 30A-30D depict a method for using a device 800 similar to those devices described above, including but not limited to Figs. 8A, 9B, 18, 22A-G, and 23A-G, to provide tissue re-shaping/molding and to impart energy to tissue near the nasal valve.

[0217] The method may include identifying a patient who desires to improve the airflow through their nasal passageways and/or who may benefit from an increase in a cross-sectional area of the opening of the nasal valve. The patient may be positioned either in an upright position (e.g., seated or standing) or be lying down. Local anesthesia may be applied to an area near or surrounding the tissue to be treated. General anesthesia may also be used.

[0218] Optionally, a positioning element, like that described herein, may be used to measure a desired depth or angle of treatment. As described above, the positioning element may be inserted to the desired depth of treatment and rotated to a desired angle of treatment. Marks along the positioning element can indicate the desired depth. Marks along the base of the shaft of the positioning element can indicate the desired angle. The physician or other medical professional administering the treatment can then insert the treatment device to the desired location. The physician may also assess any other characteristics relevant to the treatment of the patient's nose that may influence the manner of treatment. In some embodiments, a re-shaping element may be used to manipulate the nasal tissue into a configuration allowing improved airflow; and treatment may be performed while such a re-shaping element is maintaining the desired configuration of the nasal tissue.

[0219] If the treatment device comprises a monopolar electrode or electrode needles, a ground pad may be attached to the patient. The ground pad may be attached at the patient's torso, for example the shoulder or abdomen. Other locations are also possible, such as the patient's buttocks. Preferably, the point of attachment is a large, fleshy area. After being attached, the ground pad may be plugged into a power source. If

What is claimed is:

1. A device for treating a patient's nasal airway, the apparatus comprising:

an elongate shaft having a proximal end and a distal end;

a handle at the proximal end of the elongate shaft; and

a fixed-size elongate treatment element, having a larger diameter than the elongate shaft, extending from the distal end of the elongate shaft, having a front surface and a back surface along a length of the treatment element, wherein the front surface comprises a shallow convex shape configured to mechanically press laterally against a nasal tissue to be treated to reshape a region of the nose to a new conformation; and

at least one electrode disposed on the front surface of the elongate treatment element configured to deliver radiofrequency (RF) energy to the nasal tissue to be treated.

2. The device of claim 1, wherein the back surface narrows distally along the length of the treatment element from approximately the distal end of the at least one electrode to the distal tip of the treatment element.

3. The device of claim 2, wherein the multiple electrodes are arranged both vertically and horizontally within the electrode array.

4. The device of claim 1, wherein one of the at least one electrodes is a monopolar needle.

5. The device of claim 1, wherein the at least one electrode comprises an electrode array comprising multiple electrodes.

6. The device of claim 5, wherein energy may be selectively delivered between a certain set of electrodes of the electrode array.

7. The device of claim 5, wherein the electrode array comprises one or more bipolar electrode pairs.

8. The device of claim 1, further comprising an external re-shaping element extending from the handle, wherein the treatment element is positionable internal to the nose and the external re-shaping element is positionable external to the nose, so that the external re-shaping element and the treatment element are positionable on opposite sides of the nasal tissue.

9. The device of claim 8, wherein the at least one electrode comprises one or more needles or a plate and the external re-shaping element further comprises one or more electrode needles or an electrode plate.

10. The device of claim 1, further comprising an adaptor coupled with the handle and configured to be connected to an energy source.

11. The device of claim 1, further comprising a control system coupled with the handle and configured to control the characteristics of energy applied to tissue.

12. The device of claim 1, further comprising a thermocouple coupled with the shaft or the energy delivery element and configured to measure a temperature near tissue to be treated.

13. The device of claim 1, wherein the energy delivery element comprises a re-shaping element having a shape configured to alter a conformation of a region of the nose to a new conformation.

14. The device of claim 1, further comprising a re-shaping element having a shallow, curved shape configured to alter a conformation of a region of the nose to a new conformation.

15. The device of claim 14, wherein the treatment element and the reshaping element are configured to be positioned on opposite sides of nasal tissue, and the shallow, curved shape is concave.

16. The device of claim 14, wherein the treatment element and the re-shaping element are both configured to be positioned within a single nostril of the nose, and the shallow, curved shape is convex.

17. A system for treating a patient's nasal airway, the system comprising:

a nasal airway treatment device, comprising:

an elongate shaft having a proximal end and a distal end;

a handle at the proximal end of the elongate shaft; and

an elongate, fixed-size treatment element having a larger diameter than the elongate shaft extending vertically from the distal end of the elongate shaft in a direction along a longitudinal axis of the shaft and handle, wherein the treatment element is sized to be inserted into a nasal airway or to be delivered external to a nose and configured to reshape a region of the nose to a new conformation, the treatment element comprising an at least one electrode configured to deliver energy to the nasal tissue disposed on a front surface of the treatment element configured to mechanically press laterally against a nasal tissue to be treated; and

an energy source couplable with the handle for providing energy to the at least one electrode.

18. The system of claim 17, further comprising a cooling mechanism coupled with the energy delivery element or the shaft for cooling the nasal tissue or nearby nasal tissue.