direct application, can be limited by poor patient compliance when repeated doses are required, or poor efficacy due to challenges in delivering a drug to more distal sinus and ear anatomies.

[0006] Another challenge with topical drug delivery is presented when the nasal condition involves treatment of mucosal tissue. Most mucosal epithelial tissues are covered with a glycoprotein rich mucus layer. This mucus layer is a dynamic layer that generally works to clear contaminants from the respiratory system. It typically has a transit and turnover time of approximately 15-20 minutes. A locally delivered drug must pass through this mucus layer and be taken up by the mucosal epithelium before it is moved away from the target tissue site.

[0007] Accordingly, for certain nasal, otic, and throat conditions, it may be desirable to treat distal anatomies by distributing high concentrations of drugs with reduced dosing frequency evenly across treated sites and in the absence of a permanent implant for applications where mechanical support is not necessary. Regarding nasal conditions, it may be useful to have treatments that can both deliver drugs and dilate target sites such as the paranasal sinuses and/or deliver drugs to multiple sites with a single device. When mucosal tissues are affected, it would be desirable to have topical treatments where drugs can be delivered and taken up by tissue before they are cleared from the site by mucociliary flow.

SUMMARY

[0008] Described herein are expandable devices coated with a therapeutic agent (drug) that may be physically transferred to the tissue site of interest upon expansion. After therapeutic agent transfer, the expandable device may be collapsed and removed. The drug coating may be formulated to be transferred with a single expansion, or when multiple expansions with a single device are performed, partially transferred with each expansion. The drug coating transferred to the tissue may act as an in situ sustained release depot that enables maintenance of a therapeutic level of locally delivered drug for a desired time frame (e.g., days, weeks, or months). Some variations of the drug coating are formulated for rapid delivery through the mucous layer of tissue. For example, these formulations may include one or more mucolytic, mucoadhesive, or penetration enhancing agents to hasten drug delivery. In other variations, the expandable device may be combined with an implantable device, such as a stent or scaffold.

[0008a] In one aspect, there is provided an expandable device for treating a nasal, an otic, or a throat condition comprising a drug coating on an external surface thereof, and having a low-profile configuration and an expanded configuration,

wherein the drug coating comprises a corticosteroid and an excipient, the excipient comprising poly(vinyl pyrrolidone), a polysorbate, a poly(ethylene glycol), or a combination thereof.

[0009] Described herein is a method of treating a nasal, otic, or throat condition that may comprise providing an expandable device comprising a drug coating on an external surface thereof and having a low-profile configuration and an expanded configuration, delivering the

[0018] With respect to excipients, the drug coating may comprise at least one of a poly(ethylene glycol); poly(vinyl pyrrolidone); phospholipids; fatty acids; sodium dodecyl sulfate; polysorbates; pluronics; cyclodextrins such as hydroxypropyl-beta-cyclodextrin; sucrose fatty acid monoester; alkyl glycosides such as decyl maltoside and octyl maltoside; oleic acid; sorbitan trioleate; sorbital; mannitol; pectin; trehalose; tributyl citrate; triethyl citrate; glycerol monooleate; thymol; and shellac. In other variations, the drug coating may comprise at least one of a low molecular weight poly(ethylene glycol), glycerol, fatty acids, sebacates, fatty alcohols, lipids, lecithin, oils such as vegetable oils, glycol esters, and propylene glycol. In other variations, the drug coating may comprise at least one of a chitosan, collagen, elastin, silk, silk-elastin, alginate, cellulose, cellulosics such as hydroxypropyl cellulose, hydroxypropyl methylcellulose, methylcellulose, ethylcellulose, dextran, polyalkoanates, hyaluronic acid, gelatin, gellan, carrageenan, polylactide, poly(lactide-co-glycolide), poly(L- lactide-co-ca prolactone), polyglycolide, polyhydroxybutyrate, polyhydroxyvalerate, poly(ethylene glycol), polydioxanone, polyglactin, poly(E-caprolactone), polyglyconate, poly(glycolide-co-trimethylene carbonate), poly(sebacic acid), poly(ester urethane), poly(ester urethane) urea, cross-linked poly(ethylene glycol) (PEG), polyNIPAAM, PEG-poly(lactic acid) (PEG-PLA) block copolymers, and poloxamers.

[0019] During manufacturing, the expandable device, e.g., a balloon, may be coated with a drug coating formulation by methods such as spray coating, pipette or syringe coating, or dip coating. Spray coating may achieve improved tissue uptake and drug delivery uniformity. For improved coating adhesion, the expandable device may be cleaned with a solvent and dried prior to coating. In addition, plasma treatment with an inert gas, such as argon or oxygen, after cleaning may increase the cleaning and wettability of the expandable device surface leading to increased coating adhesion and release of the coating upon contact with mucus at the mucosal tissue site. In some variations, the manufacturing method may include cleaning the balloon surface and/or treating the balloon with plasma, inflating the balloon, spray coating the balloon with a drug coating formulation, drying the balloon coating at room temperature or elevated temperature, and re-folding the balloon. In other variations, the manufacturing method may include cleaning the balloon surface and/or treating the balloon with plasma, inflating the balloon, spray coating the balloon with a drug coating formulation, exposing the coated balloon to a solvent vapor (solvent vapor annealing), and re-folding the balloon.

[0019a] In one aspect, there is provided a method of manufacturing an expandable device for treating a nasal, an otic, or a throat condition comprising:

inflating the expandable device, wherein the expandable device comprises a balloon;
coating the balloon with a drug formulation comprising a corticosteroid and an excipient, , the excipient comprising poly(vinyl pyrrolidone), a polysorbate, a poly(ethylene glycol), or a combination thereof;
exposing the coated balloon to a solvent vapor; and
sterilizing the coated balloon.

CLAIMS

What is claimed is:

1. An expandable device for treating a nasal, an otic, or a throat condition comprising a drug coating on an external surface thereof, and having a low-profile configuration and an expanded configuration,

   wherein the drug coating comprises a corticosteroid and an excipient, the excipient comprising poly(vinyl pyrrolidone), a polysorbate, a poly(ethylene glycol), or a combination thereof.

2. The expandable device of claim 1, wherein the corticosteroid comprises mometasone furoate or pharmaceutically acceptable salts, solvates, hydrates, esters, free bases, enantiomers, racemates, polymorphs, amorphous, or crystalline forms thereof.

3. The expandable device of claim 1, wherein the drug coating comprises the crystalline form of mometasone furoate in an amount ranging from 25% to 75%.

4. The expandable device of claim 1, wherein the drug coating comprises a plurality of coating layers.

5. The expandable device of claim 2, wherein the drug coating comprises mometasone furoate, a polysorbate, and a poly(ethylene glycol).

6. The expandable device of claim 1, wherein the expandable device is an inflatable balloon.

7. The expandable device of claim 6, wherein the inflatable balloon is compliant, semi-compliant, or non-compliant.

8. The expandable device of claim 7, wherein the inflatable balloon is folded, pleated, or wrapped in the low-profile configuration.

9. The expandable device of claim 1, wherein the drug coating comprises a corticosteroid to excipient ratio ranging from 3:1 to 1:3.

10. The expandable device of claim 1, wherein the corticosteroid in the drug coating has a dose density ranging from 100 $\mu g/cm^2$ to 600 $\mu g/cm^2$.

11. The expandable device of claim 1, wherein the target tissue site is a paranasal sinus, a sinus ostium, an inferior turbinate, a middle turbinate, a superior turbinate, a nasal cavity, the osteomeatal complex, the nasopharynx, adenoid tissue, a Eustachian tube, the trachea, or a combination thereof.

12. The expandable device of claim 11, wherein the paranasal sinus is a maxillary sinus, a frontal sinus, an ethmoidal sinus, or a sphenoidal sinus.

13. The expandable device of claim 1, wherein the nasal condition is selected from the group consisting of post-surgical inflammation, turbinate hypertrophy, rhinosinusitis, and rhinitis; wherein the otic condition is selected from the group consisting of post-surgical inflammation, otitis media, Meniere's disease, Eustachian tube dysfunction, and tinnitus; and wherein the throat condition is selected from the group consisting of post-surgical pain, esophageal cancer, esophageal stenosis, subglottic stenosis, tracheal stenosis, chronic laryngitis, tonsillitis, and epiglottitis.

14. A method of manufacturing an expandable device for treating a nasal, an otic, or a throat condition comprising:

inflating the expandable device, wherein the expandable device comprises a balloon;

coating the balloon with a drug formulation comprising a corticosteroid and an excipient, , the excipient comprising poly(vinyl pyrrolidone), a polysorbate, a poly(ethylene glycol), or a combination thereof;

exposing the coated balloon to a solvent vapor; and

sterilizing the coated balloon.

15. The method of claim 14, wherein sterilization comprises subjecting the coated balloon to electron beam irradiation.