

Summary

[6] In one aspect, a drug delivery device is provided, including a body that has a wall bounding a reservoir defined within the body, the wall having at least one preformed through-hole disposed therein and having a water-permeable portion, the body including an elastic portion; a drug formulation which includes a drug, the drug formulation being disposed within the reservoir; and at least one restraining plug closing off an opening of the body and contacting the elastic portion of the body, the opening being in fluid communication with the reservoir, wherein the water-permeable portion of the wall is configured to permit water to enter the drug delivery device and contact the drug formulation located in the reservoir, wherein release of the drug from the device is controlled by (i) release of the drug through the at least one preformed through-hole in the wall, and (ii) release of the drug through the transient formation of one or more microchannels between the elastic portion of the body and the at least one restraining plug, extending to the opening, upon the generation within the reservoir of a hydrostatic pressure effective to form the one or more microchannels.

[7] In another aspect, a drug delivery device is provided, including a tubular body that has a wall bounding a reservoir defined within the body, the wall having a water-permeable portion and an elastic portion having at least one preformed release port disposed therein; a drug formulation which includes a drug, the drug formulation being disposed within the reservoir, wherein the water-permeable portion of the wall permits water to enter the drug delivery device and contact the drug formulation located in the reservoir; and at least one restraining plug secured within the reservoir in contact with the elastic portion of the body and adjacent the at least one preformed release port, such that the at least one restraining plug controls release of the drug from the device, via the at least one preformed release port, by the transient formation of one or more microchannels between the elastic portion of the body and the at least one restraining plug, extending to the at least one preformed release port, upon the generation of a hydrostatic pressure within the reservoir effective to form the one or more microchannels.

[8] Disclosed herein are methods of administering a drug to a patient using one of the above-described devices, including inserting the drug delivery device into a lumen or body cavity of a patient; and permitting water influx into the reservoir to develop a pressure in the reservoir effective to cause the drug to flow from the reservoir and out of the device and into the lumen or body cavity.

[9] Disclosed herein is a method of treating a patient in need of treatment for neurogenic detrusor overactivity (NDO) resulting from a spinal cord injury (SCI), including locally administering an effective amount of trospium into the urinary bladder of the patient continuously over a treatment period of 30 to 60 days.

[10] Disclosed herein is a method of treating a patient in need of treatment for idiopathic overactive bladder (iOAB) and urinary incontinence, including locally administering an effective amount of trospium into the urinary bladder of the patient continuously over a treatment period of 30 to 60 days.

Brief Description of the Drawings

[11] Referring now to the drawings, which are meant to be exemplary and not limiting, and wherein like elements are numbered alike. The detailed description is set forth with reference to the accompanying drawings illustrating examples of the disclosure, in which use of the same reference numerals indicates similar or identical items. Certain embodiments of the present disclosure may include elements, components, and/or configurations other than those illustrated in the drawings, and some of the elements, components, and/or configurations illustrated in the drawings may not be present in certain embodiments.

[12] FIG. 1A is a cross-sectional side view of one embodiment of an elastic portion of a device containing a restraining end plug.

[13] FIG. 1B is a cross-sectional end view of the embodiment of FIG. 1A.

[14] FIG. 1C is a cross-sectional side view of the device of FIG. 1A when the reservoir is not under an osmotic pressure.

[15] FIG. 1D is a cross-sectional side view of the device of FIG. 1A when the reservoir is under an osmotic pressure.

[16] FIG. 2 is a cross-sectional side view of one embodiment of a device having a preformed sidewall orifice and two restraining end plugs.

[17] FIG. 3A is a plan view of one embodiment of a device having a preformed sidewall orifice and two restraining end plugs.

[18] FIG. 3B is a cross-sectional magnified view of one of the end plugs of FIG. 3A.

CLAIMS

1. A drug delivery device comprising:
 - a body that comprises a wall bounding a reservoir defined within the body, the wall having at least one preformed through-hole disposed therein and comprising a water-permeable portion, the body comprising an elastic portion;
 - a drug formulation which comprises a drug, the drug formulation being disposed within the reservoir; and
 - at least one restraining plug closing off an opening of the body and contacting the elastic portion of the body, the opening being in fluid communication with the reservoir,
 - wherein the water-permeable portion of the wall is configured to permit water to enter the drug delivery device and contact the drug formulation located in the reservoir,
 - wherein release of the drug from the device is controlled by (i) release of the drug through the at least one preformed through-hole in the wall, and (ii) release of the drug through the transient formation of one or more microchannels between the elastic portion of the body and the at least one restraining plug, extending to the opening, upon the generation within the reservoir of a hydrostatic pressure effective to form the one or more microchannels.
2. The drug delivery device of claim 1, wherein release of the drug through the at least one preformed through-hole is osmotically driven.
3. The drug delivery device of claim 1, wherein:
 - the at least one restraining plug has an outer diameter,
 - the elastic portion of the body defines an opening having an inner diameter, and
 - the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 3 percent.
4. The drug delivery device of claim 3, wherein the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 5 percent, at least 10 percent, at least 15 percent, at least 20 percent, or at least 25 percent.

5. The drug delivery device of claim 1, wherein the body further comprises an inelastic portion.
6. The drug delivery device of claim 1, wherein the at least one restraining plug is secured within the opening in the elastic portion of the body with an adhesive.
7. The drug delivery device of claim 1, wherein the drug formulation is in a solid form.
8. The drug delivery device of claim 7, wherein the device is configured to permit, *in vivo*, water to diffuse through the water-permeable portion of the wall and into the reservoir to solubilize the solid drug formulation.
9. The drug delivery device of claim 1, wherein the drug comprises tropium or another antimuscarinic agent.
10. The drug delivery device of claim 1, further comprising an osmotic agent.
11. The drug delivery device of claim 10, wherein the osmotic agent is a component of the drug formulation.
12. The drug delivery device of claim 1, wherein the at least one restraining plug is substantially cylindrical.
13. The drug delivery device of claim 1, wherein the at least one restraining plug comprises a wedged, tapered, angled, or rounded surface.
14. The drug delivery device of claim 1, wherein the Shore durometer of the elastic portion of the body is from about 40A to about 60A, and the Shore durometer of the at least one restraining plug is from about 70A to about 100A.

15. The drug delivery device of claim 1, wherein the Shore durometer of the elastic portion of the body is from about 45A to about 55A, and the Shore durometer of the at least one restraining plug is from about 75A to about 85A.
16. The drug delivery device of claim 1, wherein the Shore durometer of the elastic portion of the body is about 50A, and the Shore durometer of the at least one restraining plug is about 80A.
17. The drug delivery device of claim 1, wherein the device is elastically deformable between a relatively straightened shape suitable for insertion through a lumen into a body cavity of a patient and a retention shape suited to retain the device within the body cavity.
18. The drug delivery device of claim 1, wherein the body is formed from an elastomeric tube.
19. The drug delivery device of claim 1, wherein the elastic portion of the body is formed from a water-permeable material.
20. The drug delivery device of claim 1, wherein the one or more microchannels are not preformed orifices.
21. The drug delivery device of claim 1, wherein the at least one restraining plug has a parylene coating.
22. A drug delivery device comprising:
 - a tubular body that comprises a wall bounding a reservoir defined within the body, the wall comprising a water-permeable portion and an elastic portion having at least one preformed release port disposed therein;
 - a drug formulation which comprises a drug, the drug formulation being disposed within the reservoir, wherein the water-permeable portion of the wall permits water to enter the drug delivery device and contact the drug formulation located in the reservoir; and

at least one restraining plug secured within the reservoir in contact with the elastic portion of the body and adjacent the at least one preformed release port, such that the at least one restraining plug controls release of the drug from the device, via the at least one preformed release port, by the transient formation of one or more microchannels between the elastic portion of the body and the at least one restraining plug, extending to the at least one preformed release port, upon the generation of a hydrostatic pressure within the reservoir effective to form the one or more microchannels.

23. The drug delivery device of claim 22, wherein the at least one preformed release port comprises a through-hole or a slit disposed in the wall.

24. The drug delivery device of claim 22, wherein:
the at least one restraining plug has an outer diameter,
the elastic portion of the body has an inner diameter, and
the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 3 percent.

25. The drug delivery device of claim 22, wherein the outer diameter of the restraining plug exceeds the inner diameter of the elastic portion of the body by at least 5 percent, at least 10 percent, at least 15 percent, at least 20 percent, or at least 25 percent.

26. The drug delivery device of claim 22, wherein the body further comprises an inelastic portion.

27. The drug delivery device of claim 22, wherein the at least one restraining plug is secured within the elastic portion of the body with an adhesive.

28. The drug delivery device of claim 22, wherein the drug formulation is in a solid form.

29. The drug delivery device of claim 28, wherein the device is configured to permit, *in vivo*, water to diffuse through the water-permeable portion of the wall and into the reservoir to solubilize the solid drug formulation.
30. The drug delivery device of claim 22, wherein the drug comprises trospium or another antimuscarinic agent.
31. The drug delivery device of claim 22, further comprising an osmotic agent.
32. The drug delivery device of claim 31, wherein the osmotic agent is a component of the drug formulation.
33. The drug delivery device of claim 22, wherein the at least one restraining plug is substantially cylindrical.
34. The drug delivery device of claim 22, wherein the Shore durometer of the elastic portion of the body is from about 40A to about 60A, and the Shore durometer of the at least one restraining plug is from about 70A to about 100A.
35. The drug delivery device of claim 22, wherein the Shore durometer of the elastic portion of the body is from about 45A to about 55A, and the Shore durometer of the at least one restraining plug is from about 75A to about 85A.
36. The drug delivery device of claim 22, wherein the Shore durometer of the elastic portion of the body is about 50A, and the Shore durometer of the at least one restraining plug is about 80A.
37. The drug delivery device of claim 22, wherein the device is elastically deformable between a relatively straightened shape suitable for insertion through a lumen into a body cavity of a patient and a retention shape suited to retain the device within the body cavity.

38. The drug delivery device of claim 22, wherein the elastic portion of the body is formed from a water-permeable material.
39. The drug delivery device of claim 22, wherein the one or more microchannels are not preformed orifices.
40. The drug delivery device of claim 22, wherein the at least one restraining plug has a parylene coating.
41. The drug delivery device of claim 22, further comprising at least one preformed through-hole disposed in the wall of the body, wherein release of the drug from the device is further controlled by release of the drug through the at least one preformed through-hole in the wall.
42. The drug delivery device of claim 41, wherein release of the drug through the at least one preformed through-hole is osmotically driven.