about 40 cm^2). Many of the multi-day use patch manufacturers recommend using medical tape to secure the patch. For example, the patient instructions for the fentanyl Duragesic® patch recommends applying first aid tape at the edges or use of adhesive dressings as a patch overlay to prevent the problem of patches that do not stick to the skin properly (see www.duragesic.com).

[0005] Another approach to long term transdermal patches is the use of a relatively breathable backing layer to increase wear time. Success with these patches is limited as the increased breathability of the backing layer reduces drug flux requiring an increase in total patch area.

[0006] Therefore, there exists a need for transdermal compositions, devices and methods that address at least these shortcomings.

[0007] The foregoing examples of the related art and limitations related therewith are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the drawings.

SUMMARY

[0008] The following aspects and examples thereof described and illustrated below are meant to be exemplary and illustrative, not limiting in scope.

[0009] It is an object of the present disclosure to provide methods and compositions to effect long term or prolonged transdermal delivery of an active agent.

[0010] In examples, the transdermal patch comprises a first backing layer; an interfacing adhesive layer; a second backing layer comprised of a plurality of segments that are at least partially separated; an adhesive active agent layer comprising at least one active agent; and a release liner. In examples, the first backing layer is comprised of an elastic material. In examples, the second backing layer and the adhesive active agent layer together comprise a composite layer where the composite layer is comprised of a plurality of segments that are at least partially separated. In some examples, the plurality of segments are at least partially connected. In examples, at least the first backing layer and the interfacing adhesive layers are laminated. In some examples, the layers of the composite layer are laminated. In examples, the adhesive active agent layer is comprised of an adhesive matrix.

[0010a] In one aspect, the present disclosure refers to a transdermal patch, comprising: a first backing layer comprised of an elastic material; an interfacing adhesive layer; a composite layer comprising (i) a second backing layer and (ii) an adhesive active agent layer comprising at least one active agent, the composite layer comprising a plurality of segments that are at least partially separated; a contact adhesive layer; and a release liner; wherein the contact adhesive layer is positioned between the adhesive active agent layer and the release liner.

[0010b] In another aspect, the present disclosure refers to a transdermal patch, comprising: (a) a first backing layer comprised of an elastic material; (b) an interfacing adhesive layer; (c) a segmented composite layer comprised of: (i) a second backing layer, (ii) an adhesive active agent layer; and (iii) a contact adhesive layer; wherein the segmented composite layer is comprised of a plurality of segments that are at least partially separated, and (d) a removable release liner in contact with the contact adhesive layer.

[0010c] In yet another aspect, the present disclosure refers to a transdermal patch, comprising: (a) a first backing layer comprised of an elastic material; (b) an interfacing adhesive layer; (c) a segmented composite layer consisting of these layers: (i) a second backing layer comprised of an occlusive material, (ii) an adhesive active agent layer; (iii) a microporous membrane; and (iv) a contact adhesive layer; wherein the segmented composite layer is comprised of a plurality of segments that are at least partially separated, and (d) a removable release liner in contact with the contact adhesive layer.

[0011] In examples, the first backing layer is comprised of an elastic polymer film, a multi-directional elastic woven fabric, a multi-directional elastic nonwoven fabric, a stretchable polymer film, a stretchable woven fabric, or a stretchable nonwoven fabric. In examples, the polymer fabric or polymer film is comprised of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polyvinylchloride, polyethylene vinyl acetate or copolymers thereof, and polyurethanes. In some examples, the first backing layer has a thickness of about 0.2-50 mil.

It is claimed:

1. A transdermal patch, comprising:

a first backing layer comprised of an elastic material;

an interfacing adhesive layer;

a composite layer comprising (i) a second backing layer and (ii) an adhesive active agent layer comprising at least one active agent, the composite layer comprising a plurality of segments that are at least partially separated;

a contact adhesive layer; and

a release liner;

wherein the contact adhesive layer is positioned between the adhesive active agent layer and the release liner.

2. The transdermal patch of claim 1, wherein the plurality of segments of the composite layer are at least partially connected.

3. The transdermal patch of claim 1 or claim 2, wherein the first backing layer is comprised of an elastic polymer film, a multi-directional elastic woven fabric, a multi-directional elastic nonwoven fabric, a stretchable polymer film, a stretchable woven fabric, or a stretchable nonwoven fabric.

4. The transdermal patch of any one of claims 1 to 3, wherein the first backing layer is comprised of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polyvinylchloride, polyethylene vinyl acetate or copolymers thereof, and polyurethanes.

5. The transdermal patch of claim 1, wherein the first backing layer has a thickness of about 0.2-50 mil.

6. The transdermal patch of any one of claims 1 to 5, wherein the interfacing adhesive layer is comprised of one or more polymers selected from selected from acrylates, acrylate copolymers, polyisobutylene, silicone, polystyrene butyl rubber, polyethylene vinyl acetate and copolymers thereof, and plasticized polymers.

7. The transdermal patch of any one of claims 1 to 6, wherein the second backing layer is comprised of a material selected from an occlusive material and a breathable material.

8. The transdermal patch of any one of claims 1 to 7, wherein the second backing layer is comprised of one or more polymers selected from polyesters, polyethylenes, polypropylenes, polystyrenes, polyvinylchloride, and a polyethylene terephthalate/ethylene vinyl acetate laminate.

9. The transdermal patch of any one of claims 1-8, wherein the composite layer further comprises a tie layer positioned distal to the adhesive active agent layer.

10. The transdermal patch of claim 9, wherein the tie layer is a rate-controlling membrane that controls the rate of active agent release.

11. The transdermal patch of claim 9 or 10, wherein the tie layer is comprised of a porous polymer membrane material.

12. The transdermal patch of any one of claims 1-11, wherein the composite layer further comprises the contact adhesive layer positioned between the adhesive active agent layer and the release liner.

13. The transdermal patch of any one of claims 3-12, where each segment of the composite layer has a size of about 2-40 cm^2.

14. The transdermal patch of any one of claims 1-13, wherein the interfacing adhesive layer comprises a first adhesive layer adjacent the first backing layer and a second adhesive layer adjacent the second backing layer.

15. The transdermal patch of any one of claims 1-14, wherein at least the first backing layer and the release liner are sized to extend about 0.5-1.0 cm beyond the perimeter of the composite adhesive layer.

16. The transdermal patch of any one of claims 1-15, wherein the release liner is comprised of a material selected from a silicone coated material, a fluorocarbon coated material, and a fluorosilicone coated material.

17. The transdermal patch of any one of claims 1-16, wherein at least the first backing layer and the interfacing adhesive layers are laminated together.

18. The transdermal patch of any one of claims 1-17, further comprising:

a tie layer positioned between the adhesive active agent layer and the contact adhesive layer;

wherein at least the adhesive active agent layer, the tie layer, and the contact adhesive layer are laminated together.

19. The transdermal patch of claim 18, wherein at least the second backing layer, the adhesive active agent layer, the tie layer, and the contact adhesive layer are laminated together to form the composite layer.

20. The transdermal patch of any one of claims 1-19, wherein the adhesive active agent layer is comprised of an adhesive matrix.

21. A transdermal patch, comprising:

(a) a first backing layer comprised of an elastic material;

(b) an interfacing adhesive layer;

(c) a segmented composite layer comprised of:

(i) a second backing layer,

(ii) an adhesive active agent layer; and

(iii) a contact adhesive layer;

wherein the segmented composite layer is comprised of a plurality of segments that are at

least partially separated, and

(d) a removable release liner in contact with the contact adhesive layer.

22. A transdermal patch, comprising:

(a) a first backing layer comprised of an elastic material;

(b) an interfacing adhesive layer;

(c) a segmented composite layer consisting of these layers:

(i) a second backing layer comprised of an occlusive material,

(ii) an adhesive active agent layer;

(iii) a microporous membrane; and

(iv) a contact adhesive layer;

wherein the segmented composite layer is comprised of a plurality of segments that are at least partially separated, and

(d) a removable release liner in contact with the contact adhesive layer.

23. The transdermal patch of claim 21 or claim 22, wherein the second backing layer is a laminate comprising a polyester layer.

24. The transdermal patch of claim 21 or claim 22, wherein the segmented composite layer further comprises a tie layer positioned between the adhesive active agent layer and the contact adhesive layer.

25. The transdermal patch of claim 24, wherein the tie layer is a microporous membrane.

26. The transdermal patch of claim 25, wherein the microporous membrane is a polypropylene microporous membrane.

27. The transdermal patch of claim 21 or claim 22, wherein the second backing layer and the adhesive active agent layer are laminated.

28. The transdermal patch of claim 21 or claim 22, wherein the adhesive active agent layer, the contact adhesive layer, or both are comprised of an acrylic adhesive.