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Review Article

Transdermal Patches: Design, Mechanisms and Therapeutic Uses

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ABSTRACT

Transdermal Drug Delivery System (TDDS) have emerged as an effective and patient-friendly approach for administering therapeutic agents to the skin, offering sustained drug release, improved bioavailability, and avoidance of first-pass metabolism. Herbal TDDS further enhance safety and tolerability by incorporating phytoconstituents with proven therapeutic benefits. These parameters of TDDS, alongside modern enhancement techniques such as iontophoresis, microneedles, electroporation, magnetophoretic, and ultrasound-mediated permeation. Special emphasis is placed on Boswellia serrata, an Ayurvedic medicinal plant known for its potent anti-inflammatory and analgesic properties due to the presence of Boswellia acids. Its extraction methods, phytochemical profile, pharmacological activities, and suitability for transdermal delivery are thoroughly discussed. The review also highlights the potential of Boswellia serrata-infused transdermal patches in managing chronic inflammatory disorders, particularly rheumatoid arthritis. Overall, herbal TDDS combining traditional knowledge and modern technology represent a promising avenue for safer and more effective therapeutic interventions.

Introduction

A transdermal patch is a medicated patch that is applied to the skin in order to administer a precise dosage of medication via the skin and into the bloodstream. "Transdermal Patches" or "Skin Patches" are other names for transdermal drug delivery systems (TDDS).[1] The FDA first authorised transdermal patch products in 1981. The capacity of the medications to enter the systemic circulation through the skin is a fundamental aspect of transdermal drug delivery. These medications have a low molecular weight (<600g/mol) and can penetrate the epidermis before entering the circulatory system through local blood vessels. For patient comfort and adhesive tendency, the medication must be physically and chemically stable, metabolised in the skin, and have a low daily dosage. There aren't many effective transdermal medications with these particular qualities.[2]One of the most suitable, traditional, simple, secure, and economical ways to give medication is through the transdermal route. Targeting a particular area of action and controlling the distribution rate are the primary goals of a transdermal medicine delivery system. Transdermal drug delivery devices are discrete, self-contained dosage forms that release medication into the systemic circulation at a regulated rate when applied to healthy skin. [3,4]

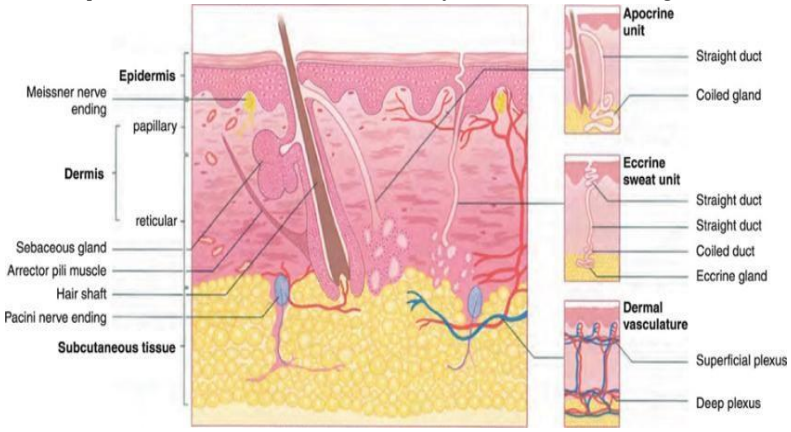

Fig 1: Structure of Human skin

A viable substitute for oral administration is the Transdermal Drug Delivery System (TDDS), which offers more consistent plasma drug concentration and improved patient compliance.

Traditional/Historical of *Boswellia serrata*

One of the oldest and most prized herbs in Ayurveda is *Boswellia serrata*. *Boswellia serrata* is regarded as a powerful herb in Ayurveda medicine for the treatment of ailments like respiratory problems, digestive issues, and arthritis. Osteoarthritis, rheumatoid arthritis, inflammatory bowel disease, and bronchial asthma can all be treated with a variety of pharmaceutical and nutraceutical formulations, from topical creams and ointments to capsules and tablets, thanks to the plant's anti-inflammatory, autoimmune, and pain-relieving qualities.[5]

Boswellia is frequently referred to as "Gajabjakshya" in Sanskrit, which implies that elephants like eating this herb. Three well-known ancient writings that form the foundation of traditional Ayurvedic medicine, which originated in India: The first basic medical texts were Charaka's Charaka

Samhita (C.B.C. 700); Susruta's Susruta Samhita (C.B.C. 600), which attempted to compile medical knowledge with a particular focus on surgery; and the two-volume work Ashtanga Samgraha and Ashtanga Hridaya (c. 130-200 A.D.), written by Vagbhata the Elder and Vagbhata the Younger, which summarised the eight parts of Ayurveda in both prose and verse. The antirheumatic properties of Gugguls, or tree gum resins, are described in the first two pillars of Ayurveda. [6]

Table 1: Ideal Properties of Transdermal Drug Delivery System [7]

S. NO.	Properties	Range
1	Shelf life	Should be up to 2.5 years
2	Patch size	Should be less than 40cm2
3	Dose frequency	Once a day, once a week
4	Packaging property	Should be easily removable from the release liner
5	Appearance	Should be clear or white colour
6	Skin reaction	Should be non-irritating
7	Release property	Should have consistent pharmacokinetics and pharmacodynamics over time

Fig 2: Transdermal Patch

How to Apply a Patch Step-by-Step

i) Different frameworks will have different Transdermal patch application points of interest.

ii) An important guide on how to apply a patch and safely remove and discard one can be found below.

iii) Clean up the area that will get the patch. The cycle must begin with flawless, dry hands.[8]

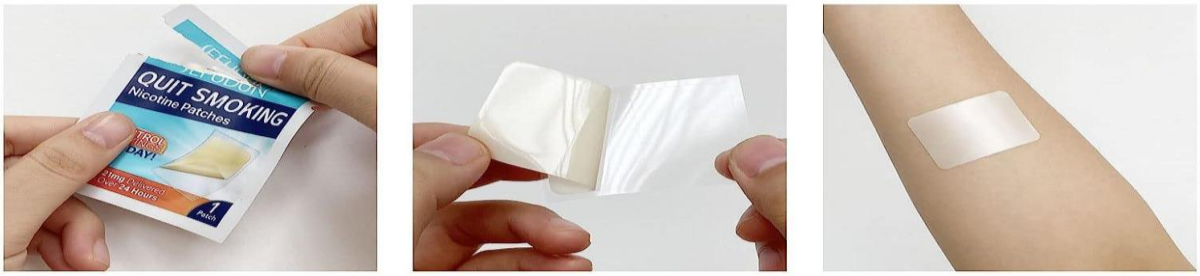

Fig 3: Step-by-Step Guide on Applying a Patch

The Fundamental Elements of a Transdermal Drug Delivery System include:

Polymer matrix/drug reservoir: The polymer matrix of TDDS controls the release of the drug. Polymers must be safe, chemically inert, and affordable. They must not deteriorate during storage. For example, cellulose derivatives, zein, gelatine, shellac, waxes, and gums; polyvinyl alcohol, polyvinyl chloride, polyethylene, polypropylene, polyacrylate, polyamide, polyurea, polyvinylpyrrolidone, polybutadiene, polyisobutylene, silicone rubber, nitrile, acrylonitrile, and neoprene.

Drug penetration and enhancers: For medications with suitable pharmacology and physical chemistry, the transdermal route is a very alluring choice. Drugs with a short half-life, a small therapeutic window, or substantial first-pass metabolism can benefit greatly from transdermal patches. Such as nitro-glycerine, fentanyl, etc.

Backing laminate: Backing laminates ought to be highly flexible or have a low modulus. Such as polyethene and vinyl.

Release linear: This shields the patch while it is being stored. Before using, the liner is taken out.[10]

Types of Transdermal Patches

Drug-in-adhesive single-layer: In this technique, the adhesive layer facilitates medication release and skin penetration in addition to helping to adhere the transdermal patch to the porous membrane. The Active Pharmaceutical Ingredients (API) and any additional excipients are included in a single layer of the single layer film.[11]

Multi-layer drug-in-adhesive: The multi-layer medications in the gummy layer are similar to the single-layer patch, but the various adhesive layers are utilised to release the medications in a controlled and prearranged manner. However, the drug's rapid release is handled by the single-layer system, while its controlled and prearranged release is handled by another layer.[12]

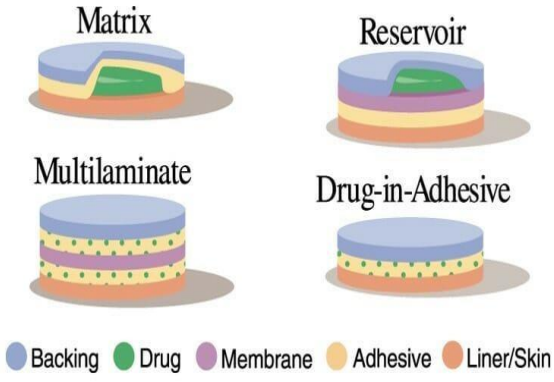

Fig 4: Types of Transdermal Patch

Reservoir: The active medicinal ingredient is contained in a different layer of the reservoir transdermal system. By inserting the drug as a solution or suspension into the liquid compartment that is divided by the semipermeable membrane and the adhesive layer, the API layer is separated. Between the skin and the release layer, there is a continuous layer of adhesive.[13]

Matrix: The drug suspension and solution are contained in a semisolid matrix within the matrix system. The adhesive layer that surrounds the drug layer creates a semisolid matrix and is in charge of skin adhesion. Another name for it is a "Monolithic system."[14]

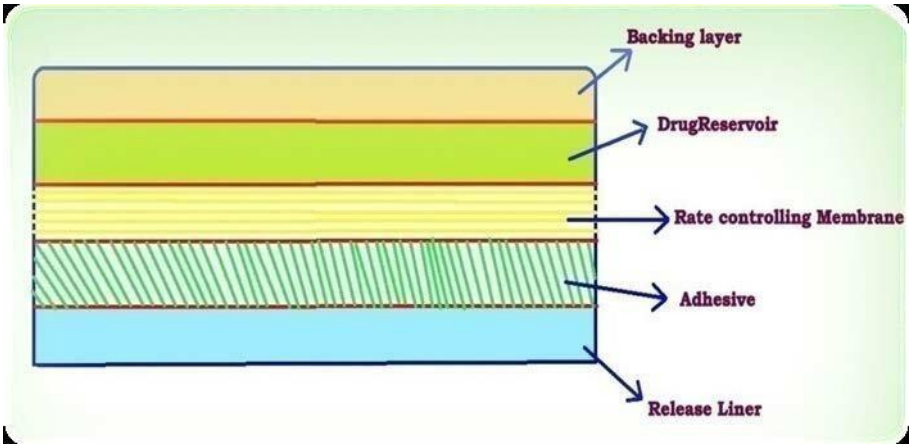

Fig 5: Different layers of Transdermal Patches

1. Modern Techniques of Transdermal Drug Delivery System

Iontophoresis: Using an electrode that stays in touch with the formulation to be delivered, current (a few milliamperes) is passed to the skin, restricted to a specific area. For instance, iontophoretic administration of lidocaine is thought to be a good method for the quick onset of anaesthesia.

Electroporation: To cause skin disruption, high-voltage pulses are applied. The creation of temporary pores during electroporation is thought to be the reason for the rise in skin permeability. The method was effectively applied to increase the skin permeability of molecules of varying sizes and lipophilicity.

Magnetophoretic: This technique applies a magnetic field as an external driving force to improve the diffusion of a diamagnetic solute across the skin. Exposure to a magnetic field may also cause structural changes that may increase permeability.

Ultrasounds: This method transfers ultrasonic energy from the system to the skin by combining a medication with a coupling agent. By rupturing the lipids in the stratum cornea, the medication can pass through the biological barrier.

Microoperation: To promote skin permeability and puncture only the stratum corneum, microneedles are applied to the skin. Microneedles are needles with a width of 10 to 20 µm.

Skin abrasion: These methods involve the direct removal or disruption of the skin's outer layers, which facilitates the easy penetration of medications applied topically.

Needle-less injection: This transdermal administration method uses a dependable energy source to launch liquid or solid particles through the skin's outer layers at supersonic speeds.

Microneedles: These devices were created as a way to intrusively administer medications to the skin. It has been demonstrated that solid microneedles can puncture the skin painlessly and increase skin permeability to a range of tiny chemicals. Numerous substances, including tiny molecules, DNA, proteins, and virus particles, have been dip-coated onto microneedles. [15]

Benefits of Transdermal Patches:

- It provides consistent medication penetration through the skin, resulting in consistent serum drug levels.
  It provides a steady plasma level, just as an intravenous infusion.
- The patch is simply removable if toxicity arises from TDDS.
- The ease with which medications can be applied makes it quite convenient.
- First pass metabolism is eliminated. [16]

Transdermal patches' drawbacks:

- Acute illnesses are not treated with it; only chronic illnesses are.
- TDDS cannot be used with ionic drugs.
- Dose dumping may occur.
- Compared to other drug delivery methods, transdermal patches are relatively costly. [17]

Transdermal patch components:

Liner: This protects the patch while it is being stored. Before using, the liner needs to be taken out. It is a component of primary packaging that prevents medication loss from the polymer-matrix.
Adhesive: This ingredient is used to attach the patch to the skin and hold its components together.

Membrane: The membrane controls the release of drugs from multi-layer patches and reservoirs. Materials like poly-2-hydroxyethylmethacrylate are commonly used to make it.
Drug: The active ingredient that comes into direct touch with the release liner is his, her, their, ettc
Polymer: The polymer needs to be chemically and biologically compatible with medications and additives like glue, plasticisers, and permeation enhancers.
Backing: It gives the patch flexibility and aesthetic appeal, protects it from the environment, and supports it. [18]

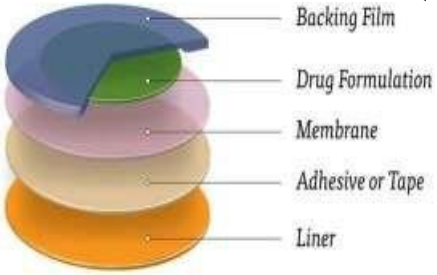

Fig 6: Components of the Transdermal patch

Factors Influencing Transdermal Patches

- ❖ Biological factors:
  - Skin pH
  - Skin moisture
  - Application site
  - Age and sex
  - Skin pathology
- ❖ Physicochemical variables
  - Partition coefficient
  - Molecular size and shape
  - Drug and concentration
  - Stability and half-life
  - Formulation factors
  - Release properties
  - Enhancement of Permeation [19]

Transdermal patch evaluation criteria include:

Physical appearance: To guarantee the transdermal patches' aesthetic appeal and physical integrity, their organoleptic qualities were assessed. It helps to verify consistency and appropriate formulation qualities, the patches were visually examined for colour, clarity, flexibility, and smoothness. These factors are crucial for evaluating the patches' overall quality and patient compliance.

Weight uniformity: Before testing, the produced patches are dried for four hours at 60°C. A predetermined patch area must be divided into various sections and weighed using a digital scale. The individual weights must be used to obtain the average weight and standard deviation values. [20]

Thickness uniformity: To verify the drug-prepared patch's thickness, the average thickness and standard deviation are calculated using a digital micrometre at various points on the patch.

Folding durability: A portion of the strip is cut and folded repeatedly in the same spot until it breaks. The value of folding endurance was determined by how many times the film could be folded without breaking. [21]

Content uniformity: Ten patches are chosen, and each patch's content is decided. Transdermal patches pass the content uniformity test if nine out of ten have content between 85% and 115% of the required value, and one has content between 75% and 125% of the stated value. However, an extra 20 patches are tested for drug content if the content of three patches falls between 75% and 125%. The transdermal patches pass the test if the range of these 20 patches is between 85% and 115%.

Moisture uptake

To maintain 84% relative humidity, the produced patches must be weighed separately and stored in a desiccator with a saturated potassium chloride solution. [22]

Drug content: A designated patch area must be dissolved in a suitable solvent in a predetermined volume. After that, the mixture must be filtered through a filter medium, and the drug content must be determined using the appropriate technology (UV or HPLC). Next, calculate the mean of three distinct samples.

Peel adhesion test: Peel adhesion in this test refers to the force needed to remove an adhesive layer from a test substrate. The variables that affected the peel adhesion properties were the molecular weight of the sticky polymer and the kind and quantity of additives. After applying a single tape to a stainless-steel plate or a preferred backing membrane, the tape is pulled from the substrate at an angle of 180°C, and the force used to remove the tape is measured. [23]

Transdermal Patches' Mode of Action: Transdermal patches work in a variety of ways, and the active medicinal ingredient travels through the skin from the patch to the circulatory system. A systemically active medication must have certain physicochemical characteristics that facilitate the drug's sorption through the epidermis and entry into the microcirculation in order to reach a target tissue. [24]

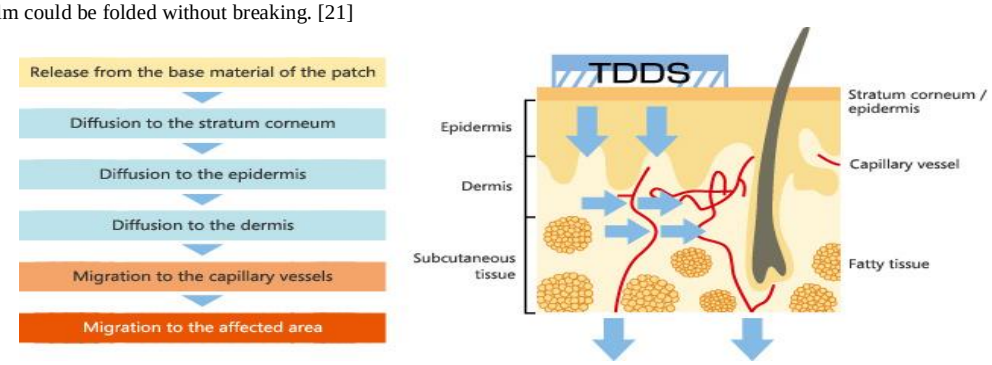

Fig 7: Mechanism of action of Transdermal Patches

Different Types of Herbal and Functional Patches

Several patches can aid with weight loss, quitting smoking, relieving stress and boosting sexuality, detoxing, improving sleep, delaying menopause, and more[22,23].

Slim herbal patch: Slim patches are made entirely of natural herbs and processed using transdermal technology to create a soft patch. It has a faint herbal scent and is delicate and silky. It is the all-natural method of long-term weight loss. The weight loss patch burns fat and gets rid of hunger.

Anti-rheumatic herbal patch: One of the most prevalent inflammatory diseases in underdeveloped nations, rheumatic disease has afflicted people for ages. Boswellia serrata, Curcuma longa, and Trichoderma indicum are the primary components of anti-rheumatic herbal patches, which are used to treat various skin conditions and have antirheumatic and anti-inflammatory properties. Trichoderma indicum and Boswellia serrata chloroform extract are used to create transdermal patches with antirheumatic properties

Anti-smoking patch: This patch is a cutting-edge termination aid that helps people safely and naturally stop smoking without increasing their body's nicotine intake. Zero nicotine patches, with their exclusive blend of chemicals, provide the best opportunity to finally kick the habit. They provide the body with a dose of nicotine by being applied to the skin.

Adverse Effect

Skin-related

a) skin irritation (burning, itching, redness)
b) Allergy reaction at the application site: contact dermatitis
c) Peeling or dry skin
d) If the adhesive is too strong, blistering
e) Hyperpigmentation with long-term use [23]

Systemic side effects

A. Cardiovascular

- Low blood pressure
- Fast/slow heart rate
- Dizziness or fainting

B. Central Nervous System

- Headache
- Drowsiness or sedation
- Confusion in elderly patients

C. Gastrointestinal

- Nausea and vomiting
- Constipation [24]

Marketed products

The Transdermal product market has been seeing a notable increase in trend, which is probably going to continue in the future [29,30]. Approximately 16 active ingredients are authorised for usage in TDDS products worldwide, and over 35 TDDS products are licensed for sale in the United States [31,32}.

Table 2: Some examples of Marketed products of TDDS [28]

Product Name	Drug	Manufacturer	Indication
Alora	Estradiol	Thera tech	Postmenstrual syndrome
Andro derma	Testosterone	Thera tech	Hypogonadism in males
Deponit	Nitro-glycerine	Schwara-pharma	Angina pectoris
Captapres-TTS	clonidine	Alza/Boehinger Ingelheim	Hypertension

Fig 8: Marketed Product of TDDS

One of the most prevalent inflammatory diseases in underdeveloped nations, rheumatoid arthritis has afflicted people throughout history. One of the main models of rheumatic diseases and a frequent source of disability is rheumatoid arthritis (RA). RA is characterised by joint deterioration, granuloma development, and extravascular inflammation. Lack of compliance is a significant issue with medication therapy in older RA patients. Thus, transdermal administration provides a more effective delivery method and has been shown to improve patient compliance.

Future of transdermal patches

Iontophoresis, microneedles, electroporation, sonophoresis, and other non-invasive technologies are being used in "active" transdermal delivery systems to improve drug delivery through the skin, as are difficult drug candidates like actives with low potency and low penetration flux. However, the creation of active patches has been linked to a great deal of misplaced optimism, with commercial, technical, and customer problems impeding early commercial success. [24]

Conclusion

Herbal transdermal patches are a new medicine delivery method that avoids first-pass metabolism and delivers phytoconstituents in a controlled and sustained manner. To obtain the best mechanical strength and permeation, their formulation primarily relies on the choice of appropriate polymers, plasticisers, penetration enhancers, and standardised herbal extracts. To guarantee quality and performance, evaluation metrics such as thickness, tensile strength, medication content homogeneity, moisture analysis, and in vitro diffusion studies are crucial. Despite their benefits, there are still issues with phytochemical stability, unpredictability, and regulatory standardisation. To establish herbal transdermal patches as dependable medicinal systems, more research focused on system validation and optimisation is needed.

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