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An Update on Various Penetration Techniques for Drug Delivery through Nails

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ABSTRACT: Fungal infections relating to the nails similar as onychomycosis, nail psoriasis involve the treatment with the aid of the oral remedy with the antifungal class of the medicines. Despite it's use the oral remedy was associated with the systemic side goods similar as hepatotoxicity and problems relating to the medicine's bioavailability. thus, transungual medicine delivery system came but held its own limitations and challenges. Cross linked keratin liaison of the nail plate conducting the expansive cling is responsible for hardness of the nail plate. To exclude the problems associated a number of mechanical and chemical approaches were deeply studied and analysed. Anyhow of employing the chemicals like penetration enhancers enhancing the flux across nails and weakening the integrity of nails, the topical permeability was still constricted due to its hedge parcels. new nail plate made up of mortal hair keratin was also delved as an indispensable model for studying flux across nail. Novel nail plate developed with the aid of keratin derived from human hair was also analysed as the reference model to study flux across nails. The best vehicle for antifungals is nail lacquers. Numerous studies are being conducted on the development of innovative penetration enhancers, water-based nail lacquers, and nail varnish containing antimycotic agents. Another treatment option for onychomycosis is patch-based administration, which consists of an occlusive backing layer and a pressure-sensitive adhesive matrix layer containing the active drug. In order to cure different skin infections, efforts are made to create devices that use a laser or germicidal light to improve penetration through the nail. Newer technologies show great promise and produce positive outcomes.

KEYWORDS: Oral, Transungual, Keratin, Topical, Penetration, Remedy, Flux, Nail lacquers, Antimycotic agents, Occlusive

I. INTRODUCTION

The nail unit, a flexible protective appendage located on the dorsal tips of the fingers and toes, is the largest and most intricate skin accessory organ. The nails' structure is made up of the keratinized squamous cells. The nail plate matrix, the nail bed, which is firmly attached to the distal phalanx plate, the hyponychium, which forms a common barrier at the physiological point of nail separation from the bed, and the eponychium which represent the underside of the proximal nail fold and is important for the production of cuticle, make up the mature nail organ automatically (1). Additionally, the nail unit has a robust vascular network to guarantee a sufficient blood flow. The growth of nail primordia begins at the tips of fingers and toes starting in the ninth week of pregnancy. There is no particular age for an individual to suffer from nail problems or to develop signs and symptoms. These conditions may vary largely from the common and non-lethal to subtly yet deadly. The most probable reason majority of nail deformities, followed by inflammatory or metabolic disorders relating to cancers or colour issues of nails is infections (2). It has proven difficult to treat nail problems since oral treatments have many drawbacks, such as low patient compliance, a high possibility of recurrence, serious side effects, and contraindication. Additionally, topical distribution in the treatment of nail diseases can be challenging in some cases, leading to complex nail structure with a complicated blockage and the difficulty to identify the best way to administer a medication to the nail bed (3).By using a nail drug delivery system to reach the appropriate therapeutic concentration of medication, these conditions can be healed. Human fingernails are not just defensive and cosmetic function, but they can also be thought of as an alternate medicine delivery method, particularly for nail conditions like psoriasis or onychomycosis. These nail conditions are common in the general population, especially in older and immunocompromised individuals (4). Topical treatments are constrained by their poor penetration rate through the nail plate, whereas oral treatments are associated with systemic adverse effects and medication interactions. Regarding the applied active medication must penetrate the thick keratinized nail plate and reach the deeper layers, the nail bed, and the nail matrix in order to effectively treat nail disease.The structure, functionality, and permeability of the human skin have been clarified by studies, but little is known about the nail, skin

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derivatives, and the characteristics of nail keratin. To treat not only topical nail illnesses but also to take into account the potential to reach systemic circulation and nearby target areas, the goal of this effort is to enhance our understanding of the physicochemical characteristics that affect medication absorption . This review aims to investigate the challenges associated with drug penetration through the nail plate and the improvement of antifungal drug bioavailability (5).

Parts of Nails

1.Nail matrix and lunula

The nail matrix, which is made up of germinative epithelial tissue whose cell division produces the nail plate, is hardly the living part of the nail apparatus. It is located near the proximal tip of nail beneath the skin (6). The nail bed (75–85%) and the matrix (15–25%) are the two groupings of tissues beneath the nail. The lunula, the apex of the matrix, is visible in some numerals. Sometimes it is totally hidden by the proximal nail's crease. About half of the area between the nail fold and the central crease of the distal interphalangeal joint is occupied by the proximal element (7).

2. Nail Bed

The bed of the nails is a very thin epithelium to which the nail plate adheres and slides during its development 8. The nail bed runs from the lunula distal margin to the hyponychium. A set of epidermal ridges that run the length of the skin extending to the lunula can be seen after the avulsion of the nail. A complementary series of ridges can be seen on the bottom of the plate of the nails, as a result, the nail was guided up the nail bed as if on tracks. The nail bed's tiny vessels are all aligned around the same axis. The nail bed is adorned with a low degree of proliferation and a keratin supplement that lacks the terminal separation keratins, K1 and K10, found in normal skin. The nail bed's dermis is scant, with slight fat, hard collagenous conformity to the underlying periosteum, and neither sebaceous nor follicular appendages are present. In-vivo magnification allows that near the nail bed's distal edge sweat ducts have been seen (8).

3. Hyponichium

The hyponychium is the area right beneath the free edge of the nail, where the nail plate starts to pull away from the nail bed. This space can create a crack between the hyponychium and an extended free nail. It's a hotspot for scabies, antigens, and various microbes, making it quite important in the context of surgery and the spread of infections. Essentially, it acts as a protective barrier around the nail bed (9).

4. Nail fold

The area around the nail plate, known as the proximal nail fold, has a layer of skin that extends to the top side. When the cuticle fails, it complicates the protective role of the proximal nail fold, showing that the first line of defence has been compromised. If you notice the cuticle growing back, it’s a good indication that the inflammation is starting to heal. It's quite common to experience inflammation in the nail folds and changes to the nail surface after a manicure, so it's best to steer clear of cuticle removal. (10).

5. Nail Plate

The nail plate is the most noticeable part of the nail structure. It’s a thin layer, measuring about 0.25 to 0.6 mm, made up of roughly 25 layers of dead, keratinized, and flattened cells that are tightly packed together. Essentially, the nail plate is a refined version of the stratum corneum, featuring a keratinized laminated structure that protects the nail matrix and bed. When examined using various techniques like silver staining, optical coherence tomography, ultrasound, and electron microscopy, you can clearly see this laminated shape. Although its physical characteristics suggest a bi-laminar structure, many believe it to be tri-laminar. The underside of this tri-laminar structure may have developed from materials that adhere closely to the nail bed, which could explain the increase in density and thickness as it grows outward. Additionally, it features linear ridges that align with the flatter ridges on the nail bed to which it is attached. Both the transverse and longitudinal axes of the nail plate are curved, allowing it to fit snugly at the lateral and proximal edges, providing a strong attachment and making the free edge quite functional. Interestingly, toenails tend to have more distinct features compared to fingernails. The lateral edges of the matrix and nail around the terminal phalanx of the big toe extend about halfway around it, giving the foot added strength. The upper surface of the nail plate is relatively flat, with a varying number of ridges that change as we age. The fold at the base of the nail, known as the lunula, serves as a reference point for measuring the growth rate of the nail plate (9).

6.Onychodermal Band

The distal edge of the nail bed, often referred to as the onychodermal band, has a distinct colour compared to the rest of the nail bed. Typically, this band measures about 1 to 1.5 mm and displays a darker pink or brown. Its colour or appearance can change due to various factors like disease or pressure, which can impact blood flow. The onychocorneal

band serves as the first line of defence, preventing foreign materials from getting under the nail plate. In simpler terms, the nail matrix is responsible for producing the nail plate, sitting on the nail bed and surrounded by the nail folds and the hyponychium (9).

II. NAIL DISEASES AND DISORDERS

The unusual appearance of the nail can be attributed to a variety of diseases and genetic conditions, such as congenital abnormalities, skin conditions that affect the nail bed, systemic diseases, decreased blood flow, local trauma, tumors of the nail fold or nail bed, infections of the nail fold or nail plate, and so on.

1.Paronychia Infections :- This disorder, which causes inflammation in the proximal and lateral nail folds, can be caused by bacteria, fungus, or some viruses. It could be either short-term or long-term. The bacteria can readily enter if this seal is torn or cracked. Chronic paronychia may be caused by an unpleasant reaction to an alkali or environmental irritant. The condition is exacerbated by nail fold swelling, which encourages the growth of common bacteria. Paronychia is an infection of the tissue encircling the sides and base of the nail as well as the proximal, lateral, and toenail folds.This condition may arise spontaneously or as a consequence of manipulation or trauma. Paronychia is among the most common hand infections. (11).

2.Pseudomonas Bacterial Infection :-This can occur between an artificial nail layer and the nail plate, as well as between the nail bed and the nail plate. The traditional 'green' colouring of this illness type has caused many people to mistake it for mold. In actuality, mold is not a pathogen that affects humans. Iron compounds are the primary source of the discolouration, which is an infection-related side effect. Pseudomonas flourishes in moist conditions, feeding on germs and dead tissue on the nail plate while enabling it to grow. For this illness, an artificial coating will cause the nail plate to weaken and discolour. The deeper the germs have infiltrated the nail plate membranes, the finer the discolouration (12).

3.Nail Psoriasis :-The skin disorder psoriasis is typified by elevated red spots that are uncomfortable and inflammatory. The nail bed has a characteristic yellow-red nail discolouration that resembles a drop of blood or oil beneath the nail plate and causes skin thickening behind the nail, while the nail matrix exhibits pitting and deep transverse furrows. The nail loosened and cracked as a result of the loss of the nail plate's flexibility and hardness (13).

4.Tinea Unguis :-These nails have the characteristic of swelling, distorting, and eventually losing the nail plate. The defining feature of this kind of illness that affects the finger or toe nail is a thicker, deformed nail. This disease is more common in toenails than fingernails. Teenagers and adults encounter it more often than small children do (14).

5.Spoon Nails :-This condition makes it possible for the free edge of the nail to become spoon-shaped. Many youngsters are affected by it. In addition to cold contact resulting in blue-and-white fingertips from Raynaud's illness or other collagen vascular disorders, nail biting creates several transverse grooves on the nail plate. Leuconychia is one of the nail illnesses that can result in white stripes or streaks on the nail due to damage. Rough, brittle nails that frequently cut vertically or tear easily are signs of an illness called onychorrhexis. Atrophy of the nail plate is a sign of onychotrophia (15).

6.Onychatrophia :-The nail plate can shrink, become less shiny or sometimes even shed entirely due to nail degeneration. Same thing can happen to nails (16). A variety of reasons accounting for nail atropy includes the injury to the matrix or some major health issue. The youthful appearance of nails is lost, they initiate getting smaller or may completely wither away (17). The nail lacks the ability to regenerate its health and vitality-like muscles. Onychatrophia is the medicated term selectively used to indicate irreversible atrophic nail disease (18).

7. Onychogryphosis :-Due to their lack of hygiene or failure to clip nails, this is common among older individuals. It enables the nail plate to curl and become thicker, resulting in a ‘claw-shaped’ look. Nails that have become thicker can cause discomfort by pinching the skin. Subungual haemorrhage can occur due to excessive trauma, especially if you have diabetes or a peripheral vascular disorder (19).

8. Beu’s Nails :- Linear depressions and darker cell lines are observed horizontally on the nail plate (26). These lines can result from chemotherapy, injuries, illnesses, malnutrition, or any serious metabolic disorder. Beau's lines (20) are horizontal ridges or dents that appear on one or more of your fingernails or toenails. They signify that your nail growth

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was interrupted due to a condition, injury, or dermatological issue (21). If the root cause is dealt with, smooth, fresh nails will regrow (21)

III. FACTORS AFFECTING DRUG DELIVERY THROUGH NAILS

Physical and chemical traits of nails: Nails are formed by the complexing of keratin protein. Via the nail development plane, transverse linkages with keratin filaments occur. This kind of structure imparts toughness to the nail plate. In addition, numerous hydrogen and disulfide bonds act as electrostatic bridges linking keratin filaments together. These bonds ensure that the nail remains a reliable barrier. The nail's thicker section, which offers greater resistance to drug penetration, is made up of phospholipids that contribute to the nail's flexibility. The hydrophilic properties of the nail plate are due to lipids.

Size of diffusing molecule: The larger the molecules, the less drugs penetrate into the nail plate. As molecular size increases, diffusion through the keratin meshwork will become more difficult. (22)

HLB value: When the lipophilicity of a substance increases, the permeability coefficient decreases up to a certain point. Beyond that point, further increases in lipophilicity lead to greater permeation. However, the permeability coefficient of pure alcohol will be approximately five times lower than that of diluted alcohols. Aqueous formulations cause nails to absorb water and swell, resulting in entrapment within the nail plate. The expansion of the keratin network leads to the formation of larger pores, which facilitates the diffusion of molecules. (22)

Degree of ionisation: Compared to their non-charged equivalents with permeability coefficients, ionic substances are less permeable to nail plates. (23)

Nature of vehicle: Because water hydrates the nail layer, it swells. Swelling increases the distance between keratin fibers, creating more pores for penetrating molecules to pass through, and ultimately increasing molecular penetration, assuming the nail plate or bed is a colloidal gel. By using a nonpolar solvent that doesn't wet the nail in place of water, drug absorption into the nail plate should be decreased. (24)

Presence of Dorsal layer: The best defense against medication penetration between the nail layer is an overlap of cells. When the layer is totally eliminated, as can be done by chemical etching and debridement with 30–40% phosphoric acid or by using the keratinolytic enzyme, drug permeability improves. (25)

Effect of nail constituents during binding: With a permeation index of roughly 5, keratin is thought to be positively and negatively charged at pH values below and above this. As a result, they can either bind or repel molecules based on their charge. Ionic chemicals may have a decreased nail permeability for this reason. Deep penetration is limited when a drug binds to keratin because it reduces permeant availability and the concentration gradient. (25)

Formulation effect: The permeability of weak acids and bases through nail plates is decreased by pH, which also affects the degree of ionization of these substances. It affects how soluble they are in preparation, how they partition into the nail layer, and how they interact with keratin. The solvent has an impact on the drug compartment on the nail plates, the solubility of the medications in the formulation, and the hydration of the nails. Permeability is increased by DMSO. (25)

IV. METHODOLOGIES FOR NAIL DRUG DELIVERY

Nail penetration can be accomplished by a variety of methods, such as mechanical (nail abrasion and avulsion), chemical (permeation boosters), and physical (iontophoresis, micro-needles, etc.).

1. Mechanical Approaches: Numerous mechanical techniques, such as nail abrasion and nail avulsion, have been investigated in studies to improve medicine transungal delivery and nail penetration. The abrasion process thins the nail plate and minimizes fungal debris if the nail is infected with fungi. Nail abrasion is the process of sanding the nail plate to thin it out or remove it completely. The severity will determine how much sand paper is needed. A high-speed hand piece can be used to sand the nail edges, which is required. Drills used by dentists are used to make tiny holes and encourage nail plate penetration. On the other hand, under local anesthetic, a nail avulsion entails the partial or total surgical removal of the injured nail plate. (26)

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2. Chemical Method: The diffusion of tolnaftate into the nails is explained by the combination of N-acetyl-l-cysteine and 2-mercaptoethanol. It has also been demonstrated that N-acetyl cysteine promotes the uptake of oxiconazole. Furthermore, other organic solvents that can help increase the drug's penetration through the nail include ethanol, propylene glycol, isopropanol, and polyethylene glycol. During transungual drug transport, organic solvents that come into direct contact with the nail plate might change the nail's hydration state and result in barrier resistance.(27)

3. Physical method: The small needles in microneedle-based medication delivery systems do not hurt and reveal the stratum corneum's pores. The etching process is an alternate technique that involves exposing environmental agents to substances like phosphoric acid that modify surfaces. As a result, there are more microsporocytes produced, the surface area and wettability increase, and the contact angle decreases. By providing the perfect surface for the bonding material, microporosities can improve the interpenetration and bonding of the drug delivery system and aid in the interdiffusion of the medicinal substance. The iontophoresis technique uses an electric field to move substances across a membrane. Using this method may cause the nails to absorb more medicine. The eight-fold distribution of glimeofulvin is facilitated by iontophoresis. (28)

Nail Lacquers for the delivery of drugs through nails:

People use nail polish or varnish to enhance and protect their fingernails or toenails. For a very long time, nail lacquer has been used as a cosmetic to strengthen and protect nails. Topical nail preparation techniques including lacquer, enamel, and varnish are necessary for modern beauty restoratives. It protects the nail plate while enhancing their colour and lustre. It also creates high tissue concentration and active chemicals to cure fungal nail disorders. More significantly, the medication for male patients is made of a film that allows it to pass through nails. It is colourless and non-glossy. (40) The drug is carefully distributed with polymer in the medication's polymer film, which might be considered a matrix type controlled release, because it is anticipated that the drug will spread in the film prior to manufacture. (29)

Working of a nail lacquer: Fick's law of diffusion states that because the medication is soluble in the polymer film, it acts over the unit area's plane surface.

This course of action is established by**:**

$$J=D\ dc/dx$$

where D is the drug's diffusion coefficient in the film and dc/dx is the drug's concentration gradient over the dx diffusion pathway.

The diffusion path's thickness increases over time. The medicine's absorption is enhanced by the higher concentration in the lacquer as the film surface adjacent to the nail surface becomes more concentrated with the drug. Nail lacquer-based medications are a special kind of medication. In 1992, a clear, colourless liquid formulation containing ethanol, butyl acetate, ethyl acetate, glycerol triacetate, eudragit RL 100, and the antifungal amorolfine 5% was initially offered for sale. Nail lacquer, which is used once or twice a week for up to six months on infected nail plates and nine to twelve months on toenails, was approved by the FDA in 1999. For up to 48 weeks, fungal infections and other conditions can be cured topically with nail lacquer, a colorless, transparent liquid with an antifungal ingredient. After cleaning the film with alcohol, the nail lacquer is reapplied every seven days.

Merits of Nail Lacquers:

1. It can be difficult to remove nail polish by washing or rubbing the nail.
2. For protection that lasts for a week, just one application of lacquer is needed.
3. The proper lacquer preparation can optimize both production and diffusion rate.
4. As simple to use as an oral dosage form, the formulation
5. little or non-existent negative systemic impacts

Demerits of Nail Lacquers:

1. Rashes brought on by side effects, which usually show up as erythema of the proximal nail fold. Shape change, irritation, ingrown toenails.
2. Discoloration - another adverse impact of nail lacquer are all associated with nail problems.

Absorption through the nails:

The nail plate, which is between 0.25 and 0.6 mm thick, is around 100 times thicker than the stratum corneum. The nature of the nail plate resembles a concentration more than the layers. Because hydration can alter the hydrogel's real pore size and, in turn, the transungual transport, hydrated nail plates behave like a hydrogel with a higher ionic strength than polar and semi-polar alcohols. Additionally, the nail is first strengthened by keratin, which is mostly joined by disulphides. Short hydrophilic molecules have a better chance of penetrating the nail. Many pharmacological substances cannot diffuse through the nail at therapeutic concentrations due to their high lipophilia. Compared to aqueous systems, lipophilic vehicles—like nail lacquer—are more suited for topical treatment on the nail due to their higher adhesion. After a 400-hour lag time, the nail plate penetrates with first-order kinetics. The membranes mostly control the length of permeation due to their great penetrability, which is then controlled by the matrix.

Comparison of topical nail lacquers to the oral antifungals:

From the ventral to the dorsal side of the nail plate, antifungal drugs such as fluconazole or itraconazole are applied until the targeted area is systemically reached. However, when applied to the dorsal side of the nail plate, nail lacquer penetrates the thickness of the nail plate and reaches the ventral side of the nail bed. Topical application increases the drug's bioavailability at the targeted location by preventing first-pass digestion. Additionally, the topical approach provides sustained and regulated drug release through depot building without any adverse systemic effects. As a result, topical treatment has a higher bioavailability and activates faster than oral drug. Topical medication distribution through the nail is also known as transungual drug delivery.

V. CONCLUSION

Despite recent significant advancements in our knowledge of topical transungual delivery and nail permeability properties, many things remain unclear, such as the distinct fine microstructure of the nail plate, a structural mathematical model for forecasting nail delivery, and drugkeratin binding characteristics. Nail disorders are prevalent, can be incapacitating, and affect a patient's capacity to move around and carry out daily tasks. The majority of the time, a physical examination is sufficient to confirm the diagnosis. Accurate histological assessments are made possible by appropriate biopsy procedures. By raising the likelihood that the created product will be effective, the creation of new human nail performance testing models will give formulators methods for creating topical formulations. Topical therapy along with physical or chemical augmentation techniques could be the therapeutic approach used to treat nail fungal infections. Furthermore, extra care must be taken to prevent the nail infection from returning. Clinicians are treating nail diseases and enhancing patient care with the use of new formulations and treatments. But we think there is room for improvement, particularly with regard to cars that are frequently ineffective in the nail. By using systemic medicines that interact more with the patient's other medications, a constructive method of treating nail diseases from the outside rather than the inside can be provided.

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