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Medicated Naillacquer for the Treatment of Onychomycosis

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Abstract: *Nail conditions are primarily brought on by a fungal infection. Onychomycosis, sometimes called Tinea unguis or dermatophytes onychomycosis, is a fungal nail condition. Onychomycosis is brought on by dermatophytes, Candida, and non-dermatophytes moulds. The potency of medications decreases at the site of action when administered orally or systemically. Topical routes of delivery are employed to prevent this loss of medication potency. For a higher therapeutic effect, the medications must be absorbed into the nail unit and nail plate. By using a nail drug delivery system, oral toxicity of certain medications, such as anti-fungus, can be avoided, and pharmaceuticals have a longer contact time at the application site. Due to its localised effects, limited side effects, and potential for improvement, topical treatment will be extremely attractive in treating nail diseases.*
Hence in this review article we discussed about anatomy of nail, some disorders of nail and penetration enhancing methods, formulation and evaluation of nail lacquer. The drug delivery through nail plate are used in nail plate e.g. onychomycosis, green nail syndrome, paronychia and leukonychia. The nail disorders are mainly cause due to fungal or any microbial infection. The some formulations which are generally prescribed are Ciprofloxacin, Levofloxacin, Itraconazole, and Fluconazole. The some factors also affects the penetration power of nail are molecular size of drug, concentration of nail and vehicle used in formulation. In this review article we collect the information about nail anatomy, disorders of nail, drug penetration enhancing methods and treatment on the nail disorders, formulation and evaluation of nail lacquer.

Keywords: Nail Lacquer, Onychomycosis, Topical therapy, Fungal Infection

I. INTRODUCTION

Human nails can be used as a medicine delivery system in addition to its defensive and aesthetic functions, particularly in cases of nail illnesses like onychomycosis. When an active medication is applied, it penetrates the thick keratinized nail plate to reach deeper levels, including the nail matrix and nail bed. The qualities of the keratinized nail plate, the nail bed, and the nail matrix were poorly researched and understood, which led to less attention being paid to the ungual system. The fingernail is a crucial component of the body because it plays a significant role in defending the finger from various wounds and infections of the nails. The finger nail aids in the precise growth of the nail skin, protects the fingertip and tissue from injuries, but it has also been abused with numerous infections and diseases, including actual contaminations.

The human nails are highly susceptible to various diseases like Leuconychia, Onychauxis, and Onychatrophia etc. and may be infections cause due to bacteria, viruses or fungi. Sometimes this majorly leads to loss of appetite as well as psychological stress. There are many treatments on that disorders but mainly oral drugs and antifungal treatment is given. The some formulations which are generally prescribed are Ciprofloxacin, Levofloxacin, Itraconazole, and Fluconazole. The newly discovered techniques show that, we can developed the more effective drug by the other root of administration such as nail drug delivery system which is also known as Transungual drug delivery system. The physiochemical properties of nail shows that the nail behaves more like a hydrophilic membrane. Which results into the very typical drugs can penetrate that membrane to show there effect. The topical application of drug is mostly preferred

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because of localised action, very less or no adverse effects and drug interaction which make patient compatible to therapy and it is also have the low cost.

The nail lacquer system is also known as Film Forming System (FFS). FFS is mainly used for the topical and transdermal formulations. That FFS formulation is made from the volatile solvent, when we apply it on skin or nail the volatile solvent is get evaporated and the active ingredient form the layer on the nail or skin. The structure of film is like a polymer which releases the drug in the skin [1].

II. AIM AND OBJECTIVES

The importance of nail permeability to topical therapeutics has been realized, primarily in the treatment of Onychomycosis, which affects approximately 19% of the population. Onychomycosis though rarely life threatening, they can be very painful, uncomfortable and disfiguring for the sufferer and may produce serious physical and occupational limitations, psychological and emotional effects, and affect quality of life.

Known methods for the treatment fall into three categories:

1. Removal of all or part of the affected nails
2. Oral / systemic therapy
3. Topical/Ungual therapy.

Topical therapy is highly desirable due to its localized effects, which results in minimal adverse systemic events and possibly improved adherence. Recent advances in topical transfungal delivery have led to the development of antifungal nail lacquers. However, the effectiveness of topical therapies is limited by minimal drug permeability through the nail plate.

The objective of this review article is to gather all the information about nail anatomy, disorders of nail, drug penetration enhancing methods, treatment on the nail disorders and formulation and evaluation of nail lacquer.

III. LITRETURE SURVEY

01.	**Ghannoum MA et al, 2010**	The effectiveness of various Terbinafine hydrochloride nail solutions (TNS) formulations with/without dodecyl-2-N, N- dimethyl amino propionate hydrochloride (DDAIP HCI) was evaluated by Ghannoum MA et al in 2010. High antifungal effectiveness was shown by TNS prepared with and without DDAIP HCI and containing 1%, 5%, and 10% Terbinafine hydrochloride. The quantity of Terbinafine hydrochloride penetration into human nail plates was quantified by Venjnovic I et al. in 2010 using liquid formulations comprising enhance 5/15 hydrophobins A-C at a concentration of 0.1% (w/v). 10% (w/v) Terbinafine was present in 60% (v/v) ethanol/water without an enhancer in the reference solution that was utilised. After a 10- day permeation trial, all hydrophobins under test aided terbinafine permeation; nevertheless, one of them reached an exceptional enhancement factor of 13.05 in comparison to the reference.
02.	**Robert DT et al, 2010**	Provided the Onychomycosis treatment recommendations created for dermatologists by the British Association of Dermatologists. They provide evidence-based therapy recommendations, identify the strength of the evidence that was available at the time the recommendations were prepared, and provide a brief summary of epidemiological factors, diagnosis, and investigation.
03.	**R. P. Patel et al, 2009**	Drug absorption through a human nail, Today's cosmetic treatments include topical nail preparations including varnishes, enamel, and lacquers. It shields the nail plate, but more significantly, it adds colour and lustre to make them more beautiful. Solvents, film-forming agents, resins that help the film cling to the nail plate and give it shine, and plasticizers that provide the film flexibility and longevity are all components of basic nail varnish. Onychomycosis, nail psoriasis, yellow nail syndrome, paronychia, and many other nail conditions can be effectively treated using medicated nail lacquers

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04.	**S. Hadzidedic et al, 2010**	They created six formulations of nail lacquer containing 0.9% (w/v) fluconazole, Eudargit RS 100, and acetone for their article Characterization of antifungal nail lacquer formulations containing fluconazole. Ingredients like di-butyl phthalate, polyethylene glycol 400, or propylene glycol are present in the formulations as plasticizers at two distinct concentrations. We assessed the produced formulations' drying times, created film fineness, fluconazole test, and viscosity.
05.	**Tulli A. et al, 1988**	The challenges in treating onychomycosis with a novel formulation of tioconazole are principally brought on by the requirement of extended systemic therapy. So, by using an efficient local therapy, many of these issues might be prevented. The efficiency and tolerability of two topical ungual preparations-a 28% solution of tioconazole and a 2% tincture of miconazole-were compared in the current investigation. Both formulations' therapeutic effects and tolerability were deemed acceptable. Although the difference was not statistically significant, the tioconazole formulation did seem to be somewhat more effective.
06.	**R. Shireesh Kumar et al, 2010**	Low bioavailability of the nail plate limits the transungual transfer of ketoconazole from the nail lacquer for topical treatment of nail disease. They conducted several tests with permeation enhancers such cysteine, thioglycolic acid, urea, and hydrogen peroxide and discovered a rise in the permeability of the medicine ketoconazole when it was administered.
07.	**Sigurgeirsson B. et al, 2010**	Evaluated the effectiveness of Amorolfine nail polish for the prevention of onychomycosis during a three-year period. Amorolfine was shown to be safe and well tolerated throughout the research. with no adverse events associated with the medication.
08.	**Monti D. et al, 2010**	Examined the antimycotic performance of a brand-new, water- soluble nail polish that contains ciclopirox (CPX/sol. When Ciclopirox/sol nail lacquer is applied, it quickly penetrates the nail and provides levels of Ciclopirox that are high enough to prevent fungal development for a long time after lacquer dosage delivery.
09.	**Sudaxshina M. et al, 2010**	Evaluated the most recent studies on ungual drug delivery as well as the penetration and drug delivery of nail lacquers. Review the many elements that can impact how well a medicine can penetrate the nail plate and be absorbed.
10.	**Togni G. et al, 2010**	Investigated the 8% Ciclopirox nail lacquer (P-3051)'s in vitro antifungal activity and in vitro and in vivo nail permeability. Hydroxypropyl chitosan serves as the film-forming agent in P- 3051. When exposed to dermatophyte strains taken from clinical samples in experimental infections, P-3051 and the reference both exhibited the same protective efficacy.
11.	**Bohn M. et al, 2010**	Ciclopirox nail lacquer topical solution 8% was determined to have a favourable dermatopharmacology for the treatment of onychomycosis. The delivery mechanism for ciclopirox is a nail lacquer. Circopirox concentration in the residual lacquer layer reaches around 35% after volatile solvents in the lacquer evaporate, creating a strong concentration gradient for nail penetration.
12.	**Gupchup GV. et al, 2010**	He claimed that a strongly cross-linked keratin network with numerous disulfide connections makes up the majority of a nail. When used with keratolytic treatments, substances containing sulfhydryl groups can greatly improve medication penetration. These sulfhydryl substances are believed to weaken the disulfide bonds in the keratin matrix of the nail.
13.	**Tandel Amrutal et al, 2012**	Examined the transungual penetration of voriconazole nail lacquer against Trichophyton rubrum in their investigation. The goal of the study was to quantify how much voriconazole from permeation enhancer-containing nail lacquer formulation, permeated through the nail

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		plate. Utilising a modified Franz diffusion apparatus with phosphate buffer saline in the acceptor chamber and human cadaver nail plates that had been amputated, the permeability investigations were carried out on the nail plates. Thioglycolic acid, added at a concentration of 5%, increased the drug's permeability by 0.7 as the enhancement factor.
14.	**A N Merekar et al, 2012**	Created a medication-infused nail polish for pre-oral drug administration. The formulations were created using the model medication Enalapril Maleate and polymer Eudargit RL 100 at concentrations ranging from 1% to 5% (w/v) in the polymeric system. The glossiness, film formation, drying time, smoothness of flow, and non-volatile content of various lacquers were compared after that. The artificial membrane was used for the in vitro tests, which were conducted in solvent A (phosphate buffer, pH 7.4, and AR-grade methanol, in a 4:1 ratio). The results demonstrated that the nail lacquer formulation had a satisfactory drug release. Thus, the use of nail lacquers as a viable technique for hypertension medicine delivery is possible.

IV. ANATOMY OF HUMAN NAIL

The human nail plate consists of three layers: the dorsal and intermediate layer derived from the matrix and the ventral layer from nail bed. The intermediate layer is three - quarter of the whole nail thickness & consists of the soft keratin. The upper layer, dorsal, is only a few cell layer thick but consists of hard keratin, with relatively high sulphur content, mainly in the form of amino acids cysteine, which constitutes 94% by weight of nail. The upper layer of the nail mainly diffuses into and through the nail plate. The ventral layer consists of soft hyponychial in which many pathological changes occur. Thus, in the treatment of these nail diseases, an effective drug concentration in the ventral nail plate would be of great importance.

Nail growth is greatest in childhood and decrease slowly with aging. Due to pressure from posterior nail fold grows forward instead of upward. Nail growth is also affected by local disturbances in the nail fold or by abnormal keratinization of the nail plate. General or local factor may result in the development in the nail of thicken, ridging, pitting, discoloration, brittleness, splitting and even separation of nail from its bed (onycholysis). A transverse groove may result from severe illness. The changes in colour for a variety of reasons for instance white spots in the nail plate, which is seen 62% of normal people, is due to imperfect keratinization with retention of nuclear material.

Nail is a horn-like envelope covering a dorsal part of the terminal phalanges of fingers and toes in people, most non-human primates, and a couple of different vertebrates. Nails which are similar to claws, are found on numerous other animals. Fingernails and toenails made up of a tough protein called keratin, similar to animals' hooves and horns. The nail consists of the nail plate, nails matrix and nail bed below it, and grooves surrounding it. Importance of nails in disease diagnosis: the colour, appearance, shape and nature of the nails gives information about the general health and hygiene of a person.

Nails are inspected as an everyday practice by specialists to get a few pieces of information about fundamental infections. Just by taking a gander at nails we can recognize the cleanliness of an individual. The unusual nail might be congenital. The cause for changes in the nail extends from basic motivations to dangerous illnesses. Hence the study by a doctor is essential for diagnosis.

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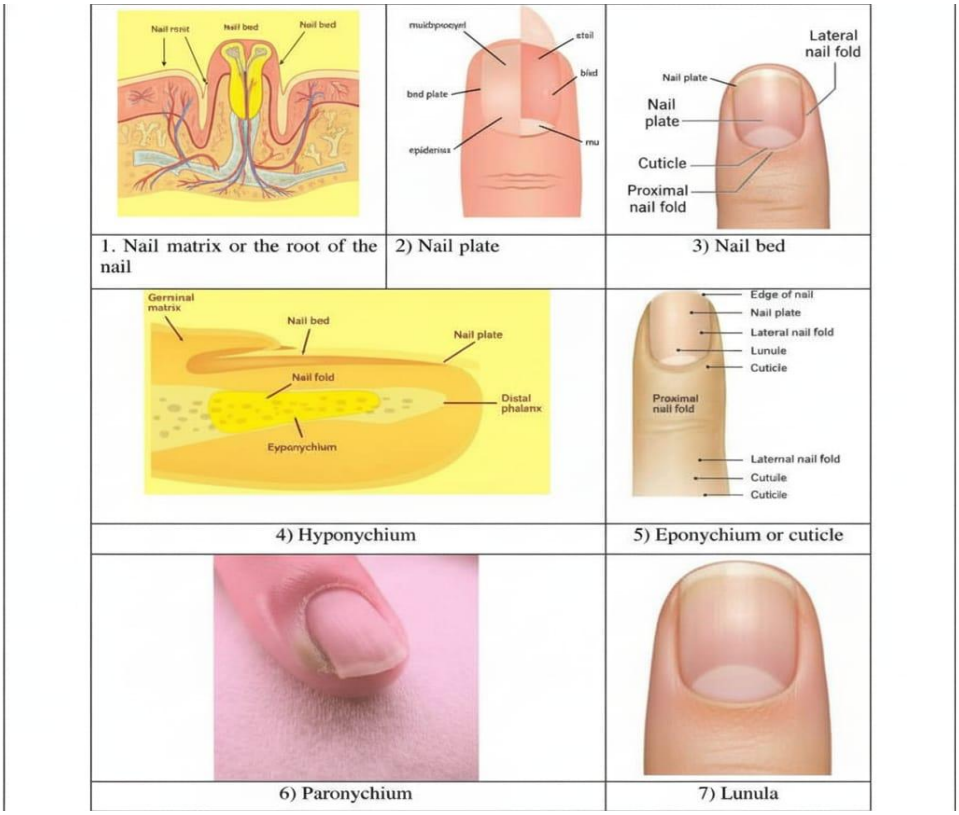

Fig 1. Anatomy of Human Nail

NAIL SKIN:

The epidermis of the nail has been substantially modified to resemble a scale. The nail consists of the nail matrix, nail bed, and nail plate. Only the deeper, live layer of epidermis may be found in the nail bed, which appears pink due to the dermis's visible capillary network. The cells that develop into the nail plate are produced by the matrix. The fingertip's form dictates whether the nail plate is flat, rounded, or angular, while the size, length, and thickness of the matrix define the nail plate's breadth and thickness. As long as the matrix obtains nutrients and is in a healthy state, it will continue to expand. The lunula, the white, half-moon-shaped base of the visible nail, is the component of the matrix that is visible. The thumb has the biggest lunula, but the little finger sometimes lacks one. The skin layer underneath the nail plate is called the nail bed. It is made up of two different types of tissue: the superficial epidermis, which lies just below the nail plate and moves with the plate, and the deeper dermis, which is the living tissue attached to the bone and includes capillaries and glands. [20]

The epithelium beneath the nail plate at the intersection of the free edge and the skin of the fingertip is called the hyponychium, often referred to as the quick. The nail bed is safeguarded by the seal it creates. The hyponychium and nail plate are sealed together by the onychodermal band. It may be identified by its glassy, greyish hue (in fair-skinned persons) and is located right under the free edge, in that area of the nail where the nail bed stops. [19] The eponychium is the end of the proximal fold that folds back upon itself to shed an epidermal layer of skin on to the newly formed nail plate. It is a small band of epithelium that runs from the posterior nail wall on to the base of the nail. The cuticle and eponychium work together to provide a seal of protection. The eponychium should not be touched, although the cubical of the nail plate contains live cells and is frequently removed during manicure. The perionyx is the eponychium's protruding edge that covers the proximal strip in lunala [19, 20].

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The cutaneous fold that covers the sides and proximal end of the nail is known as the nail wall(vallum unguis). The nail groove or fold (sulcus matrices unguis) is the cutaneous slits in which the lateral margins are lodged. The lateral margin (Margo lateralis) is located on each side of the nail under the nail wall. The border tissue around the nail is called the paronychium, and a paronychia is an infection there.[20]

ROLE OF NAIL:

The distal phalanx, the fingertip, and the surrounding tissue are all capable of being protected from injury by a healthy (finger) nail. By applying counter pressure to the finger's mash, it also aids in improving the fine, precise motions of the distal fingers. Even while the nail itself lacks nerve endings, it serves as a counterforce when the tip of the finger contacts an item, increasing the sensitivity of the fingertip. Finally, the nail serves as a tool, enabling what is known as a "extended precision grip" (for example, taking out a splinter in one's finger) [20, 21].

V. VARIOUS DRUGS USED IN TREATMENT

Sr. No	Drugs	Formulation	Brand names	Manufacturer
1.	Ciclopiroxamine(8%)	Topical Solution	Onylac®	Cipla (Mumbai, India)
2.	Ciclopiroxamine(8%)	Nail Lacquer	Penlac®	Dermil Laboratories (Misissaguga, Canada)
3.	Ciclopirox	Nail Lacquer	Loprax ®	Avents Pharma Ltd (Mumbai, India)
4.	Ciclopirox(8%)	Nail Lacquer	Ciclopoli ®	Polichem SA (Pazzallo, Switzerland)
5.	Amorolfine(5%)	Nail Lacquer	Loceryl ®	Roche Laboratories (Basel, Australia)
6.	Amorolfine(5%)	Nail Lacquer	Curanil ®	Galderma (Lausanne, Switzerland)
7.	Econazole(5%)	Nail Lacquer	Econil ®	Macrochem Corp. (Lexington, MA)
8.	Urea(40%)	Nail Film	Umecta ®	Jsj Pharmaceuticals (Charleston, SC)
9.	Ciclopirox	Solution(8%), Topical Solution(0.77%)	Loprax ®	Medicis Pharmaceutical Inc. (Melville, NY)
10.	Ciclopirox	Cream(1%)	Loprax ®	Sanofis-Aventis (Paris, France)
11.	Ciclopirox Olamine	Cream(0.77%)	Fougra ®	Fougera Pharmaceutical Inc. (Melville, NY)
12.	Sertoconazole Nitrate	Nail Patch	Zalain ®	Labtec GmbH (Langefield, Germany)
13.	Salicylic Acid	Nail Paint	Phytex ®	Pharmax Healthcare Ltd (Bexley, UK)
14.	Methyl Undecenoate	Nail Paint	Monphytol ®	LAB (UK)
15.	Ticonazole	Topical Solution	Trosyl ®	Pfizer Ltd. (Tadworth, Uk)
16.	Sertoconazole Nitrate(2%)	Cream	Ertaczo ®	OrthoNeutrogena (Los Angeles,CA)
17.	Tazarotene(0.1%)	Gel	Tazora ®	Allergen Inc, (Irvin, CA)
18.	Tazarotene	Cream	Avage ®	Allergen Inc, (Irvin, CA)

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VI. MARKETED FORMULATION

LOCERYL NAIL LACQUER Loceryl Nail Lacquer belongs to a group of medicines called antifungals. It kills a wide variety of fungi that cause nail infections.	
2. TOZORAC Tazorac is used to treat acne. Tazarotene (Tazorac) is also used to treat psoriasis (a skin disease in which red, scaly patches form on some areas of the body)	
3. ERTACZO Ertaczo (sertaconazole) is used to treat athlete's foot (tinea pedis) between the toes in adults and children 12 years and older who have healthy immune systems.	

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4. LOPROX This medication is used to treat fungal skin infections such as athlete's foot, jock itch, and ringworm.	
5. PENLAC NAIL LACQURE Penlac is an antifungal medicine that prevents fungus from growing on your skin. Penlac nail lacquer is used to treat fungal infections of the toenails and fingernails.	

VII. CONCLUSION

Transungual delivery is one of the major challenges and emerging areas of drug delivery for research scientists and clinicians to target and cure. An in-depth understanding of nail barrier properties and structure is necessary before treating and diagnosing nail disorders. There is a need for the development of effective in vitro models which can mimic the human nails better as compared to the currently used in vitro models. More research and development is required for establishing and correlating an animal nail disease model especially with actual in vivo human nail conditions.

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