Erchonia Laser Therapy in the Treatment of Onychomycosis

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Abstract

Lasers have been used for many extensively in many settings; there is a growing awareness amongst the public of Lasers and what they can do. This paper presents the results of an 18 month clinical study of the above mentioned device the Erchonia Lunula Laser for the treatment of onychomycosis. The study has been carried out on 320 patients both male and female with an average age of 40. The laser treatment consists of 4 treatments at weekly interval using the Lunula Laser manufactured by Erchonia. This is a laser that combines two different wavelengths of laser light - one at 405 nm for direct fungicidal activity and one at 635 nm to stimulate a natural immune response - to provide effective clearing of the nail bed; it is claimed, within three months. Unlike other lasers used for the treatment of this condition, the Lunula laser is reported to cause no pain to the patient treated and no temperature change to the area exposed to the lights. The follow up intervals were twelve weeks post final laser, twenty four week post final laser, fifty two weeks post final laser and finally at seventy six weeks post laser. Usual studies of this type normally conclude in fifty two weeks or less, however, it is the aim of the researchers to observe the nail up to seventy six weeks to ascertain the efficacy of the treatment. In the treatment there were no reports of side effects and the majority 91% of patients are happy with the treatment. It was the primary aim of this study to present laser as an effective treatment for onychomycosis with a good evidence base.

Key words: onychomycosis, fungal nail infection, Lunula Laser,

Introduction

Onychomycosis is a persistent nail infection of the nail bed, the nail matrix and or the nail plate, statistically it is the most common nail disorder in adults affecting up to 50% of patients presenting with nail disorders (Zaias et al 1996, Schlefman 1999, Ghannoum et al 2000). Fungal skin infections account for 33% of all skin infections (Zaias et al 1996, Schlefman 1999). Onychomycosis is caused by dermatophytes that colanise dead skin, nail and hair tissue and nondermatophyte moulds, Candida species rarely form part of this condition (Evans 1998). The most common dermatophytes seen in the mycology of onychomycosis are Trichophyton rubrum and Trichophyton mentagrophytes, Trichophyton rubrum is responsible for approximately 90% of all presentations (Zaias et al 1996, Schlefman 1999). The over all prevalence of onychomycosis in the general population ranges from 2 to 14%. The risk of infection increases with age and 15 to 20% of the population aged between 40 and 70, 32% of those between 60 and 70 and 48% of those over 70 (Schlefman 1999). Evidence suggests that the instance of onychomycosis in the population is on the rise (Schlefman 1999, Ghannoum et al 2000). There are several conditions that present visually in the same way as onychomycosis including lichen planus, nail trauma, atopic dermatitis and psoriasis.

There are many treatment options for onychomycosis; these include systemic antifungal agents, topical antifungal agents, mechanical debridement, chemical debridement, combinations of these treatments and palliative approaches. The treatment choice is dependent on the practitioners training, experience and other available modalities and interventions as well as cost (Gupta et al 2003)

The treatment of advanced onychomycosis is expensive due to the input needed from the clinician and is subject to high failure rates. Antimycotics prescribed for the treatment of onychomycosis are usually delivered over several months and have cure rates of 40 - 80%, Terbinafine, Fluconoazole and Intraconazole are among the more frequently used drugs (Gupta et al 1998, De Doncker et al 1996). These drugs however are associated with a number of common side effects such as headache, rash, gastrointestinal and endocrine disturbances (liver) (Gupta et al 1998, Scher 1999). The usual course of drug therapy is for three months unless a pulse dose is used. Patients have the inconvenience of frequent blood tests during drug therapy. Topical antifungal products are widely promoted on the television and other media, these products are available direct to the public without a prescription, they are safe to use and relatively cheap, these topical products are seldom effective (Ciclopirox 2000).

Lasers have been used in medical settings for a considerable time. Lasers used however in the treatment of onychomycosis have not, nor have they undergone any rigorous examination. There has to date been no significant clinical trial carried out on a large demographic to support the claims made by manufacturers of laser devices claiming market advantage with their products. It is the intention of this study to produce good quality information from research that will support or deny the use of laser in the treatment of onychomycosis to inform best practice.

This study is presented using simple statistics expressed as a percentage, the figures shown are as the authors and other clinicians understand. P values etc will be calculated and extensive statistical analysis made at the end of this study. But in this the primary report the authors have kept it simple and basted their finding in clinical evidence based practice.

Methods

This clinical study relies on all subjects having a positive mycology, therefore there is no need for a control group as all patients received active laser. 320 patients or 2320 toes were subject to laser irradiation at 405nm and 635nm for twelve minutes at weekly intervals for four weeks.

Inclusion criteria

Participation in this study is reliant on the following:-

* onychomycosis present in at least one great toenail.
* Disease involvement in the great toenail(s) with onychomycosis of at least 10%.
* Spikes of disease extending to the nail matrix in the affected great toenail(s).
* Proximal subungual onychomycosis.
* Distal subungual onychomycosis.
* White superficial onychomycosis.
* Patient is willing and able to refrain from using other (non-study) treatments (traditional or alternative) for his or her toenail onychomycosis throughout study participation.
* Patient has not used other treatments for at least 6 months prior to participation in the study.
* Patient is willing and able to refrain from the nail cosmetics such as clear and/or colour nail lacquers throughout study.
* Male or female. 18 years of age or older.

A copy of the study protocols is available on request.

Exclusion criteria

Patients who have used oral antifungal medicines within 3 months prior to the administration of the first laser treatment are excluded from this study as are patients who are unable to abstain from the use of nail cosmetics. Other exclusions are nevoid subungual formation, psoriasis of the nail plate, atopic dermatitis and lichen planus.

Treatment procedure

 This treatment has two principle aims, 1.) to restore the affected nails to health within the 18 month course of this study, and 2.), to eradicate the fungus from the nail and related area within the four week treatment protocol.

As this wa a positive mycology study only patients who test positive for onychomycosis and meet the inclusion criteria were offered treatment. Samples were collected and cultured in the normal way. Patients were treated in groups dependent on the percentage nail inclusion. The graph below show the average percentage amount of total nail infected at the time of treatment in the 320 patients. All patients were given a diary to fill in ever week noting any adverse response to treatment along with any visual changes to the nail. No support products were given and all subjects had to refrain from using any nail cosmetics for the duration of the laser active stage in the study. Subjects were discharged to follow-up groups one the present on twelve consecutive weeks with clear nails.

Graph showing % nail inclusion

All patients were treated as outlined below at each of their four visits.

1. The foot to be treated was cleansed using a clinell wipe.
2. Nails were clipped and reduced using a bur where necessary.
3. The foot was cleansed to remove any debris and dust.
4. The forefoot was photographed using a high resolution digital camera. These photos were taken from a fixed position that was repeatable throughout the study. Measurements were taken from the pictures by an independent lab using digital measures.

It is important to note that no chemicals were used to pre soften thickened nails as the researchers wanted to remove any possibility of interference from outside sources.

This was a four week protocol where the laser was administered on the same day each week for 12 minutes. All laser units were programmed to deliver constant therapy for this time and then turn off.

After the pre-treatment was complete the laser therapy was administered using the Lunula LaserTM (Erchonia FX-405™). This is a double-headed laser with a dual-diode omitting a light wavelength of 635 nm and 405 nm covering both the ultraviolet and infrared light spectrums. The device is mains powered and stands on the floor. The treatment area of the unit is aseptically cleaned after each patient is treated. The diagram show the, 1.) laser diodes, 2.) the magnetic catch for closing the unit, 3.) the heel plate which is also the door to the unit and 4.) the aperture into which the forefoot sits for the 12 minute treatment.



4

3

2

1

Diagram showing the laser unit used

Unlike other lasers applications used for the treatment of onychomycosis no reports of any pain were made by any of the 320 patient (2320 toes) (see findings from patients diary section below for qualification of this statement on page 5).

Treatment reviews points

It is important to remember that was an 18 month study. 18 months was chosen in order to evaluate the long term effects of the treatments and to chart any recurrence rate. It should be further noted that a recurrence after a clear nail is presented is not evidence of treatment failure as environmental factors must be taken into account. All patients on this study were issued with a “*Maintaining Your Foot Health*” leaflet.

Follow up measurements were taken at 12 week post final (forth) laser as well as at 24, 36 (samples taken for mycology), 48, 52, 64 and 76 weeks

Results

The following graphs shows the finding. Please notr that the graph stops once the cohort shown reached 0%:-

Graph 1

Of the 80 patients shown in Graph 1, 72 or 90% were discharged by week 48 as they presented with clear nails which remained clear for 12 weeks, by week 52 all will were discharged to follow-up groups.

Graph 2

Of the 70 patients shown in Graph 2, 61 or just over 87% of patients were discharged from the study due to clear presentation at 48 weeks, the remaining were discharge to follow-up by week 64.

Graph 3

Of the 110 patients in Graph 3, 88, or just over 80% had been discharged from the study to follow-up by week 48, as they presented with clear nails, the remaining were discharge to follow-up by week 64.

Graph 4

Of the 40 patients in Graph 4 all were discharged from the study by week 64 as they presented with clear nails which remained clear in keeping with the protocol.

Graph 5

Of the group represent by Graph 5, only 4 patients remained unresolved at the end on 76 weeks, 75% of patients had clear nails that they were happy with. Blood and tissue analysis were carried out on samples taken from the nail matrix and it was noted that there was a lack of fat cells at the matrix. This is due to the 635nm laser which is FDA approved for the treatment of fat cells.

Findings from patient’s diary’s

Adverse reactions from the notes of the 320 participants involved to date

* Tingling sensation during treatment was reported by 29 patients, all however said that this was slight and the common consent was that it felt like a vibration in the forefoot. Investigation of this showed that I was caused by the height of the chair upon which the patient was sitting.
* 4 patients felt numbness to the forefoot for the same resion mentioned above.

The total of adverse events was, based on the above was reduced to 0.

Of the patients involved in this study 201 were women and 119 were men. 72 patients reported using nail cosmetics during the treatment stage of the study.

Types of Onychomycosis

Onychomycosis may be classified into several types: distal subungual, white superficial, proximal subungual, endonyx, and total dystrophic.

Distal subungual onychomycosis, was the most common type seen in this study, this involves the nail bed and subsequently the nail plate. White superficial onychomycosis was seen as superficial white patches with distinct edges on the surface of the nail plate. Proximal subungual onychomycosis is a result of the fungal organism entering via the cuticle and the ventral aspect of the proximal nail fold. In endonyx onychomycosis, fungal organisms invade the nail plate without resulting nail bed hyperkeratosis, onycholysis, or nail bed inflammatory changes. In total dystrophic onychomycosis, complete dystrophy of the nail plate occurs; these changes may be primary or secondary.

Results

All of the above graphs and results are predicated on four laser treatments over 4 weeks with these results processed as per the findings up to and including week 76.

Graph 1 above shows the progression of the 20% infected nail group. There were 80 patients in this group, by week 52 all of these patients had been discharged and therefore one can conclude that over 52 weeks with four laser applications a success rate of 100% was achieved.

Graph 2 shows results from the second treatment group with 40% nail inclusion. There were 70 patients in this group, by week 52 all of these patients had been discharged and therefore one can conclude that over 52 weeks with four laser applications a success rate of 100% was achieved.

Graph 3 is the result drawn from the third group with 60% nail inclusion There were 110 patients in this group, by week 64 all of these patients had been discharged and therefore one can conclude that over 64 weeks with four laser applications a success rate of 100% was achieved.

Graph 4 shows the results of the fourth cohort with 80% nail inclusion. All of these patients had at least 61% inclusion. There were 40 patients in this group, by week 64 all of these patients had been discharged and therefore one can conclude that over 64 weeks with four laser applications a success rate of 100% was achieved.

Graph 5 is the result of the fifth cohort with 100% nail inclusion. 16 of these patient were discharged to follow-up by week 76. 4 patients had not resolved. There were 20 patients in this group, by week 76 16 of these had been discharged to follow-up and therefore one can conclude that over 76 weeks with four laser applications a success rate of 76% was achieved.

From the above results from this study it is possible to say that this type of cold laser (Lunula Laser manufactured by Erchonia) with a duel light frequency is 96% effective over 76 week on onychomycosis once the protocol is followed

Discussion

Dermatophytes cause infections of the skin, hair and nails due to their ability to obtain nutrients from keratinised material. The organisms colonise the keratinised tissues and inflammation is caused by the host response to the metabolic by-products. They are usually restricted to the non-living cornified layer of the epidermis because of their inability to penetrate viable tissue of an immunocompetent host. Invasion does elicit a host response ranging from mild to severe. Acid protenases, elastase, keratinase and other proteinases reportedly act as virulence factors (Rosenberg and Gallin 1999).

Dermatophytes are transmitted by direct contact with infected host (human or animal) or by direct or indirect contact with infected exfoliated skin or hair in clothing, combs, hair brushes, theatre seats, caps, furniture, bed linens, shoes, socks, towels, hotel rugs, sauna, bathhouse, and locker room floors (Ajello and Getz 1954). Depending on the species the organism may be viable in the environment for up to 15 months. There is an increased susceptibility to infection when there is a pre-existing injury to the skin such as scars, burns, excessive temperature and humidity.

Increasingly Onychomycosis is being viewed as a more cosmetic problem as people become ever more conscious of their appearance. Fungi from the nails may happen before secondary bacterial infections such as cellulitis, idiopathic reactions and chronic urticarial. Infected toenails may act as a reservoir for fungi facilitating their transmission to other parts of the body and potentially to others.

Clinical diagnosis of Onychomycosis is based on physical examination, microscopy and culture of nail specimens. Factors such as diabetes, hyperhidrosis, nail trauma, poor peripheral circulation; can contribute to the condition. Differential diagnosis for onychomycosis, as mentioned earlier, should be considered so as to allow the clinician to choose the most appropriate treatment.

It has been found to date, in this study, that 4 treatments for nails up to 60% inclusion has a satisfactory outcome and that nails with over 60% benefit from further pain free treatments. The author of this study would agree with a comment made by Dr Kerry Zang, one of the lead developers of this laser system, *Unlike other treatment modalities, such as systemic anti-fungal agents or repeated Class IV lasers, the Lunula cold laser system can be utilized as many times as necessary to resolve the problem and can be utilized without fear of any side effects or adverse reactions (Zang 2013).*

Conclusion

Lunula laser has performed consistently throughout this study. The authors of this study report agree with Dr Kerry Zang when he says, *I believe that the Lunula laser system stimulates the production of peroxynitrite which interacts with the lipid portions of the cell membrane as well as  DNA and other protein components of the invading micro-organisms which is cytotoxic to and inactivates the mycosis. The patient’s general medical condition influences the rate of nail growth and the effects the risks for re-infection. Depending on the patients general condition will determine the number of treatments necessary to cytotoxic to the mycosis present.*

Authors Note.

Protocols within research allow us to view specific outcomes, these protocols must be kept for the research to be valid. What we learn from this process it also valuable. I would make the following comments as a result of this study:-

* Nails need to be aggressively debrided.
* Patience is necessary as we are all different and we all respond to an intervention in a different way.
* In some instances other treatments may be necessary, again based on patience and experience.
* Management of the expectations of both the clinician and patient are needed.

For further information and advise please contact rsullivan@erchoniaeurope.com