TREATMENT OPTIONS

- Home remedies
- Topical medication
- Systemic medications
- Surgery
- Pin point thermal laser therapy
- Non thermal laser therapy
• MOST COMMON DISEASE OF THE NAILS AND CONSTITUTES ABOUT HALF OF ALL NAIL ABNORMALITIES

• AFFECTS TOENAILS AND OR FINGERNAILS

• TOENAIL INFECTIONS ARE PARTICULARLY COMMON OCCURRING IN ABOUT 10% OF THE ADULT POPULATION

• A RECENT STUDY INDICATES THAT ONYCHOMYCOSIS IS THE SINGLE MOST DIFFICULT PROBLEM FOR PODIATIC AND DERMATOLOGICAL PHYSICIANS TO DIAGNOSE AND TREAT.


AFFECTS ON PATIENT

- Pain
- Mobility Limitations (difficulty walking)
- Footwear Limitations
- Psychosocial/Cosmetic Nuisance
- Cross Contamination
- Skin Infections (Tinea Pedis)
- Ingrown Nails/Wounds
Nail growth is continuous throughout life, approximately 0.5-1.2 mm/week. The longer the finger or toe, the more rapid the growth.

Toenails grow at 33%-50% the rate of fingernails.

Regeneration of a fingernail after avulsion is 160 days (4 months, 22.85 weeks).

40 days to emerge from the nail fold and another 120 days for growth to the fingertips.

Toenails take between 12-18 months to completely grow out.
WHY SHOULD TOENAILS REMAIN INTACT AND BE HEALTHY?

• Protects distal phalanx from trauma
• Aids in the appreciation of fine touch
• Used for scratching
• Aesthetic organ
• Provides structural integrity to the distal end of toe
TOPICAL FACTS

• TOPICAL ANTIFUNGALS, LASERS AND LIGHT SYSTEMS ARE RELATIVELY NON-INVASIVE TREATMENTS

• POOR NAIL PENETRATION WILL LIMIT IT’S EFFECTIVENESS

• ROUTE ENTRY INTO THE NAIL BED PLAYS A VITAL ROLE IN DETERMINING THE EFFICACY OF THE DRUG OR LASER

• NON THERMAL LASER (LUNULA) TREATS ENTIRE NAIL COMPLEX
  • NAIL PLATE
  • NAIL BED
  • GERMINAL MATRIX

• CHARACTERISTICS IN SOLUTIONS THAT INCREASE NAIL PENETRATION ARE VISCOS FLUIDS WITH LOW SURFACE TENSION (EFINACONAZOLE-JUBLIA, CLENAFIN)

• AGENTS THAT PENETRATE VIA THE TRANSLINGUAL ROUTE THROUGH THE SPACE BETWEEN THE NAIL BED AND PLATE ARE OPTIMAL.
TOPICAL MEDICATIONS OPTIONS AS ADJUNCTIVE TREATMENT

RESEARCH STUDIES FROM 1999-2015 SUGGEST THE FOLLOWING (7)

- **CICLOPIROX (PENLAC, LOPROX, CICLODAN)**
  - Lacquer base with poor nail penetration in studies
  - Reserved for mild cases
  - Dependant upon daily debridement
  - Mycological cure rates are 29%-54.3%
  - Complete cure rates range from 5.5%-8.5%

- **EFINACONAZOLE (JUBLIA, CLENAFIN)**
  - Broad spectrum of activity against non-dermatophytes and yeasts (T. rubrum, T. mentagrophytes, C. albicans)
  - Vehicle (fluorescein) can reach subungual spaces
  - Nail polish does not appear to affect the permeation giving patients options for cosmetic concealment (7).
  - 2013 double blinded CT over 52 weeks with 1655 participants suggested a 56% mycological cure rate for mild cases only (7)
TOPICAL MEDICATIONS OPTIONS AS ADJUNCTIVE TREATMENT

RESEARCH STUDIES SUGGEST THE FOLLOWING

- TAVABOROLE (KERYDIN)
  - NEWER CLASS OF ANTIFUNGALS
  - PROTEIN SYNTHESIS INHIBITOR (EXHIBIT ANTIFUNGAL PROPERTIES)
  - 48 WEEK RANDOMIZED CT NEGATIVE MYCOLOGY WAS FOUND IN 31.1%-35.9%
  - TAVABOROLE WAS FOUND TO PENETRATE THE NAIL PLATE 250 TIMES GREATER THAN CICLOPIROX (3)
ARE TOPICAL MEDICATIONS ENOUGH TO CURE SEVERE FUNGAL MYCOTIC NAILS?
MR. C: TX#1 JULY 31, 2018 (BEFORE)
IMAGES PROVIDED BY FEET FOR LIFE MEDICAL FOOT CARE

- AGE: 53
- GENDER: MALE
- MEDICATION: NONE
- COMORBIDITIES: PSORIASIS, IBS
- ALLERGIES: NONE
- PREVIOUS TREATMENT: NONE
MR. C:  TX#4 SEPTEMBER 6, 2018 (AFTER)

6 WEEKS LATER
✓ NAIL DEBRIDEMENT
✓ LASER THERAPY
✓ HOME CARE REGIME
MR. P: TX#1 NOVEMBER 4TH, 2017 (BEFORE)
IMAGES PROVIDED BY FEET FOR LIFE MEDICAL FOOT CARE LTD.

- AGE : 43
- GENDER : MALE
- MEDICATION : NONE
- COMORBIDITIES : HYPERTENSION, COLITIS
- ALLERGIES : PENICILLIN
- PREVIOUS TREATMENT : NONE
MR. P - TX #4 MARCH 18TH, 2018  NOTE : NOT FOLLOWING HOME CARE PROTOCOL

(AFTER) FIVE MONTHS LATER

TREATMENT- NAIL DEBRIDEMENT AND LUNULA LASER X4 TREATMENTS IN FOUR CONSECUTIVE WEEKS
MR. P: TX#5 SEPTEMBER 17TH 2018 (10 MONTHS LATER)

✓ NAIL DEBRIDEMENT
✓ LASER THERAPY
✓ HOME CARE PROTOCOL
❖ SOMETIMES FORGETS HOME CARE PROTOCOL
• AGE: 65
• GENDER: FEMALE
• ALLERGIES: NONE
• MEDICATIONS: ATORVASTATIN CALCIUM, BEZAFIBRATE, CLOPIDOGREL BISULFATE, DOMPERIDONE, DULOXETINE, FUROSEMIDE, LEVOTHYROIDINE, METFORMIN, METOPROLOL, POTASSIUM, LANTUS, HUMALOG, RAMIPRIL, PANTOPRAZOLE, CEPHALEXIN.
• COMORBIDITIES: DIABETES, ARTERIAL DISEASE
• PREVIOUS TX: HOME CARE WET DRESSINGS
• TX: IRRIGATION, DEBRIDEMENT, LUNULA LASER 2X/WK, IODINE, SORB AG DRESSING
MS. O
AUGUST 22\textsuperscript{ND}, 2018

FOLLOWING DEBRIDEMENT

NO LASER APPLIED AS OF YET
MS. O
SEPTEMBER 23RD, 2018
(1 MONTH LATER)
NON THERMAL LUNULA
AND MED X LASER APPLIED
TWICE A WEEK FOR FOUR
WEEKS
Case study 1

- Male
- 55 years old
- Borderline diabetic
- No medication
- No allergies
- 10 year history OM left hallux nail
- 4 x Lunula treatments

Before treatments

6 weeks after 1st treatment
Case study 3

- Female
- 38 years old
- Thyroid condition
- Thyroxine medication
- No allergies
- At least 6 month history of OM both hallux nails
- No previous treatment
- 4 x Lunula treatments
Case study 4

- Male
- 25 years old
- General health good
- No medication
- No allergies
- At least 6 month history candida OM right hallux nail
- Previous topical treatments - various
- 3 x Lunula treatments

Before treatments

6
Months after 1st treatment
HOW DID WE DO IT?
ONTARIO PODORTHO NURSING ASSOCIATION
PROTOCOL

➢ ASSESSMENT-GATHERING SUBJECTIVE AND OBJECTIVE DATA
➢ IDENTIFY CO-MORBIDITIES THAT MAY INTERFERE WITH MICROVASCULAR STATUS TO NAIL MATRIX
➢ PREADORHERIAN SKIN AND NAIL INSPECTION-DETERMINE PATTERN OF INFECTION AND SEVERITY, POTENTIAL DIFFERENTIAL DIAGNOSIS THAT MAY INTERFERE WITH CURATIVE PROCESS I.E. TINEA PEDIS
➢ DETERMINE IF PATIENT RECEIVED A FORMAL DIAGNOSIS FROM EITHER PHYSICIAN OR PODIATRIST
➢ IDENTIFY PAST TREATMENTS AND EFFICACY
➢ DISCUSS TREATMENT RESULTS AND PATIENT GOALS
  ➢ CURE
  ➢ MAINTENANCE
➢ UNDERSTAND THE PATIENTS EXPECTATIONS- DO THEY EXPECT THIS TO BE CURED IN A WEEK? CAN YOU DELIVER?
➢ HELP PATIENT SET A REALISTIC GOAL- EDUCATE THEM ON THE DISEASE PROCESS, RATE OF NAIL GROWTH AND ALL TREATMENT OPTIONS INCLUDING YOUR DECIDED PROTOCOL
  ➢ WILL THEY ACHIEVE CURATIVE RESULTS OR MYCOLOGICAL RESULTS?
  ➢ IS THE CONDITION TO SEVER AND COMORBIDITIES MAY NOT ALLOW FOR COMPLETE CURE?
➢ CLEANSE AND DEBRIDE MYCOTIC/INFECTED NAIL(S)
➢ DELIVER NON-THERMAL LASER THERAPY TREATMENTS
➢ PROVIDE PATIENT EDUCATION ON HOME CARE PROTOCOL WITH CLEAR WRITTEN INSTRUCTIONS
ANTI-FUNGAL KIT

✓ ANTI FUNGAL FOOT FOAM (TOLNAFTATE)
✓ ANTI FUNGAL NAIL SPRAY (TOLNAFTATE)
✓ BIOSEN SOCK DETERGENT
✓ LUNULA LASER BROCHURE
✓ BROCHURES ON PRODUCTS
✓ PRESCRIPTION FOR JUBLIA
✓ INSTRUCTION SHEET
HOME CARE INSTRUCTIONS

1. BIOSEN ULTRASONIC CLEANSER-TO BE USED AS DETERGENT FOR HOSIERY AND LINENS IN WASHING MACHINE WEEKLY

2. ANTI-FUNGAL FOAM FOR FEET (TOLNAFTATE)

3. ANTI-FUNGAL NAIL SPRAY (TOLNAFTATE OR CLOTRIMAZOLE)

4. FOOTWEAR IN FREEZER FOR 48 HOURS

5. PHYSICIAN MAY PRESCRIBE A TOPICAL MEDICATION-PATIENT TO DECIDE IF THEY WISH TO USE IT

6. EXPLANATION OF THE LASER AND WHAT YOUR PATIENT CAN EXPECT

7. EXPECTATIONS PRACTITIONER HAS FOR THE PATIENT-SET A COMMITMENT TO CARE
LASER PROTOCOL

- LUNULA LASER #1
- LUNULA LASER #2 (2ND WEEK)
- LUNULA LASER #3 (3RD WEEK)
- DEBRIDE & LUNULA LASER #4 (4TH WEEK)
- FOLLOW UP AT 24 WEEKS (INSPECT APPEARANCE OF RE-GROWTH)
- POSSIBLE LASER 5,6,7,8
- RE-EVALUATE AT 12 MONTHS
WHAT IS THE **LUNULA** COLD LASER?

- **CLASS 2**
- **LOW LEVEL LASER THERAPY**
- **DUAL DIODE, ROTATING COLLIMATED, MONOCHROMATIC, COHERENT BEAM**
  - 405NM VIOLET BEAM
  - 635NM RED BEAM
  - **INTENSITY: 17.5-25MW PER DIODE**
  - **DOSAGE: ~0.95 J/CM2 PER DIODE**
PEROXYNITRITE IS A COMPOUND THAT HAS POTENT ANTIMICROBIAL EFFECTS

- This compound is formed when nitric oxide (NO) reacts with reactive oxygen species (ROS).
- Lunula Laser by Erchonia is the only true low level laser with unique multiple diodes used to treat onychomycosis.
- 635 nm diode enhances mitochondrial energy producing (NO).
- 405 nm diode is the best producer of (ROS) providing antimicrobial, antibacterial, & antifungal effects.
- Cell destruction is triggered by the cytotoxic effects of peroxynitrite.
LUNULA MECHANISM

405nm
Damages fungus
— weakening immune defense

635nm
Improves immune response. Increases circulation enhancing immune system attack

Fungus is destroyed and the nail clears!
TREATMENT WITH LUNULA

• START WITH STANDARD 4 X TWELVE-MINUTE TREATMENTS
• PATIENTS SIMPLY INSERT FOOT
• CLINICIAN ACTIVATES THE DEVICE BY PRESSING START BUTTON
• PROVIDES A PATIENT WITH A COMFORTABLE, UNMANNED TREATMENT
WHAT CAN THE LUNULA BE USED FOR?

- ONYCHOMYCOSIS
- DAMAGED NAILS
- PSORIATIC NAILS
- SLOW GROWING NAILS
- Tinea pedis
- WOUND HEALING
- IMPROVING CIRCULATION
- COMPLICATIONS OF DIABETES
- POTENTIALLY MUCH MORE
ADDITIONAL BENEFITS OF LUNULA

DUE TO THE INCREASE IN BLOOD SUPPLY THE LUNULA MAY ALSO;

➢ IMPROVE CIRCULATION IN THE EXTREMITIES
➢ TREATS THE ENTIRE FOOT INCLUDING SKIN AND NAILS
➢ INCREASE RATE OF NAIL GROWTH
➢ INCREASE NUTRITION TO THE NAIL
➢ TREATS ENTIRE NAIL COMPLEX- NAIL PLATE, NAIL BED, GEMINAL MATRIX
➢ ASSIST WITH WOUND HEALING
➢ REGENERATES DAMAGED NAILS
➢ PAINLESS ENSURING PATIENT COMPLIANCE
➢ NO CHANCE OF LIVER TOXICITY
➢ DOES NOT INTERFERE WITH ANY SYSTEMIC MEDICATIONS
<table>
<thead>
<tr>
<th></th>
<th>Hot (Thermal)</th>
<th>Cold (Non-thermal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uses heat to destroy fungi spores</td>
<td>✓ Uses photochemistry to destroy fungal spores</td>
<td></td>
</tr>
<tr>
<td>One nail at a time</td>
<td>✓ All nails on the foot at the same time</td>
<td></td>
</tr>
<tr>
<td>Treatment takes 30 minutes per foot</td>
<td>✓ Treatment cycle is 12 minutes per foot</td>
<td></td>
</tr>
<tr>
<td>Uncomfortable, often painful</td>
<td>✓ No pain or discomfort felt</td>
<td></td>
</tr>
<tr>
<td>Hands on practitioner</td>
<td>✓ Hands free practitioner</td>
<td></td>
</tr>
<tr>
<td>Can cause burning of tissue, need to wear glasses</td>
<td>✓ No known side effects</td>
<td></td>
</tr>
<tr>
<td>One positive effect (specific to Onycho)</td>
<td>✓ Has several positive effects due to increase in blood flow</td>
<td></td>
</tr>
</tbody>
</table>
4 CONCERNS WITH USING THERMAL LASER

• PRACTITIONERS BODY MECHANICS
• TIME MANAGEMENT FACTOR
• POTENTIAL INJURY TO PATIENT
• EXPOSURE TO LASER PLUMES CONTAINING
  • CARCINOGENS
  • VIRUSES
  • BACTERIA
  • FUNGAL SPORES
  • CANCER CELLS
  • TOXIC GASES
Katrina Waller-Podiatrist-United Kingdom

- Bought Lunula in 2014
- Took cultures to test for mycology before and after treatments
- Post treatment cultures showed negative
- Thought she had a faulty batch of cultures until one came back positive
- Purchased a second unit and opened a new clinic

Leaving behind the soldiers & sailors boots

In 2007, Gosport’s Royal Military Hospital Haslar was scheduled for closure. Experienced Podiatrist Katrina Waller’s role rehabilitating service personnel and getting them back on their feet was moving on. Rather than return to the NHS, Katrina felt the time was right to move on herself and set up her own practice.

Compleet Feet was established. 40 miles North from Gosport in Alton. The practice, quickly expanded with Katrina taking a course in non-surgical aesthetic procedures, which in turn led to the purchase of an NiyAG thermal laser.

Combining Katrina’s aesthetic and podiatry expertise meant the obvious application was in treating Onychomycosis (tine nail fungal infection), she explain what happened next.

Desperately seeking effective treatment

At the time Compleet Feet was one of the first in the UK to use a laser to treat fungal infections. Although I had done my research, I never expected there to be so much demand. I had people coming to me from as far away as Cornwall and Guernsey. People were desperate to get their nails sorted, That was when I realized just how significant the market is for an effective treatment. The infection seems to have a huge psychological and physical impact on people. It is uncomfortable and ugly. That’s why people do things because their feet hurt or they are embarrassed about the appearance.

I had more and more people coming through my door but the thermal laser had its problems:
- It is painful
- A cooler unit is essential to keep the pain just about manageable
- And the complexity of the treatment reduces the efficacy. The necessary cooling may even prevent the treated area getting hot enough to weaken and ultimately kill the fungus.

I wasn’t getting the clinical cure I expected. Some patients needed as many as twelve treatments to get the clinical cure and that wasn’t good enough. I found out about, and researched Lunula. Most significant were the clinical trials by Robert Sullivan of the Midleton Clinic. He approached his study with scientific rigor and his results were really convincing – and are worth reading.

Too good to be true

I bought my Lunula laser in January 2014. I couldn’t get over how easy it was to use. I take samples from each patient and use cultures to test for mycology before and after treatment. They were all coming back negative – which means any infection has been cleared. I thought I had a faulty batch of cultures until one came back positive. Actually they were fine – the Lunula was giving me these incredible results. I’m not hooked on the hot laser since, I was so impressed that I bought my second Lunula in May and opened a new clinic in Brighton.
WHEN YOUR PATIENT HAS COMPLETED YOUR PROTOCOL DO YOU STOP TREATING THIS PATIENT ALL TOGETHER?

IN A STUDY CONDUCTED BY; JENNA N. QUELLER AND NEAL BHATIA PUBLISHED IN THE JOURNAL OF FUNGI AUGUST 19TH, 2015 CONCLUDED THAT IN ORDER TO TREAT THE ENTIRE DISEASE THE PRACTITIONER MUST OPTIMIZE TOPICAL AGENTS AS SUSTAINED THERAPY AFTER INITIAL CLEARANCE TO REDUCE RE-OCCURRENCE OR RE-INFECTION.
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