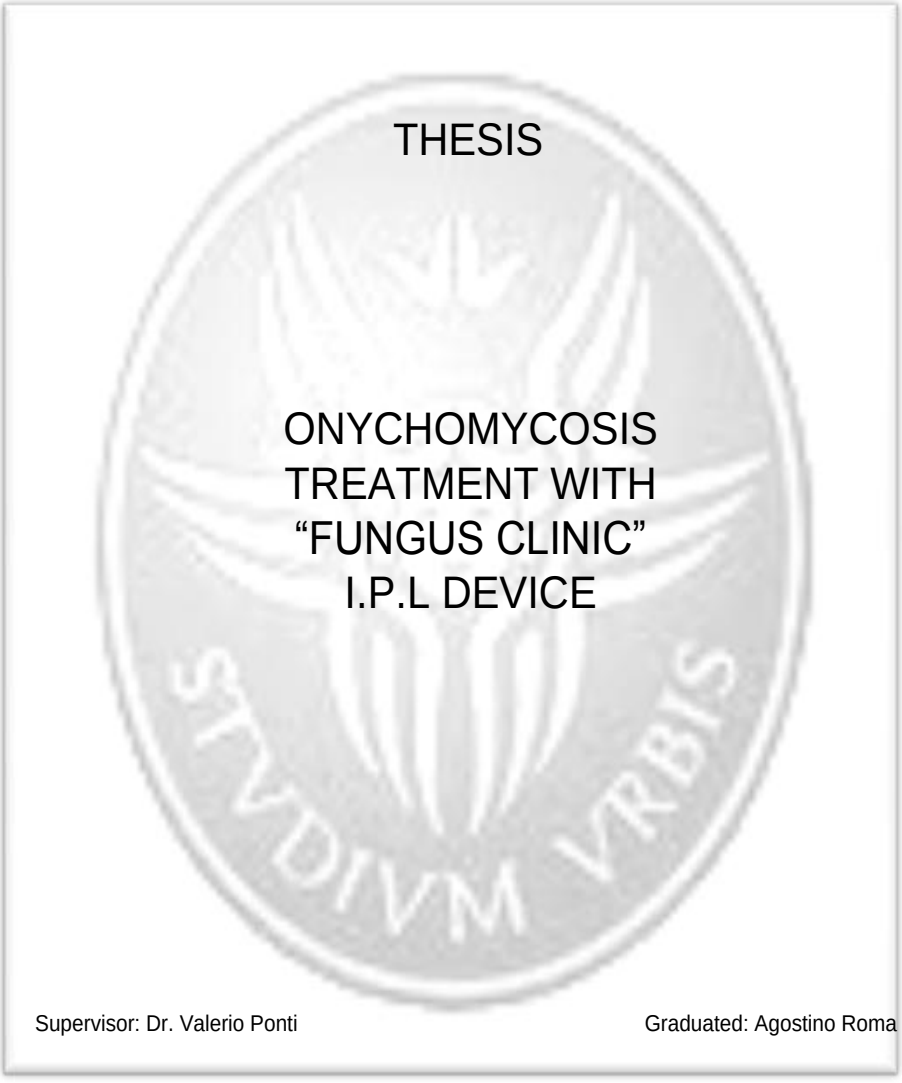
SAPIENZA
UNIVERSITÀ DI ROMA

Bsc Course in PODIATRY



THESIS

ONYCHOMYCOSIS
TREATMENT WITH
“FUNGUS CLINIC”
I.P.L DEVICE

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Graduated: Agostino Roma

Dean: Prof. Montesi Mauro

Academic year 2010 - 2011

CHAPTER 6

Description and use of machinery

Fungus clinic Pulsed Light (IPL Formatk Ltd. Israel)

In the previous chapter most common and traditional up-to-date Onychomycosis treatments were described.
Generally, these methods are considered:

- ✓ Poorly effective (vicious circle expectation-disappointment - expectation)
- ✓ Are not always compatible with the patient's health;
- ✓ Do not totally decisive;
- ✓ Old, not the result of new research.

For these reasons, in 2011 a new device was tested:
"Fungus Clinic" Intense pulsed light (IPL Formatk Ltd. - Israel).
An innovative method for the treatment of nails affected by Onychomycosis, based on the emission of a light beam of a specific range of wavelengths (530 nm - 1100 nm) and a pulse duration inferior than the TRT, which disables the fungus by thermal shock.
According to the principle of selective photo-thermolysis, the radiation absorbed by the target tissue is converted into thermal energy that causes disabling parasitic organism, since it destroys it and makes it unable to grow and / or reproduce. This treatment eliminates basically the pathogenic source in the nail. It is the organism itself that absorbs the photo - energy, leaving the surrounding tissue completely intact. The deactivation of the organism may result from a thermal destruction, by denaturation or partial denaturation of one or more molecules that form the fungus body, making it unable to grow and reproduce. The temperature in the region where the unwanted organism
resides must be sufficiently high to destroy it, but not high enough to cause injury to the surrounding environment. This can be achieved by irradiating the target organism for a period not greater than the thermal relaxation time of tissues (TRT), which is
the time that takes to disperse the heat in the environment.
Fungus clinic has developed an innovative non-invasive method

for the treatment of Onychomycosis and pigmented lesions based on IPL technology, using the correct spectrum of wavelengths combined with an appropriate pulse duration in respect of TRT, reaching the most effective and safe technique for the treatment of Onychomycosis.

6.1 CHARACTERISTICS OF THE APPARATUS

The device "FUNGUS CLINIC" (IPL Formatk Ltd - Israel) generates:

- ✓ Light source filtered into a specific range of wavelengths;
- ✓ Photo-energy that is absorbed and converted into heat by all Dermatophytes: (Epidermophyton floccosum. Tricophyton rubrum 70% incidence, Tricophyton mentagrophytes 20% incidence);
- ✓ Irradiation of the infected area for a period not exceeding thermal relaxation time of the tissue (TRT);
- ✓ Damages only to the target and does not affect the surrounding tissue.

This technology uses flash lamps and benches of capacitors controlled by a computer that generates high intensity polychromatic pulsed light determined by the capacity and condensed by the electric pulse duration. Similar to the laser, the basic principle of the IPL devices is the selective thermal damage to the target.
The combination of wavelength, pulse duration, fluence and pulse intervals allows treating a broad spectrum of skin conditions.
The intense pulsed light technology is characterized by its capacity to storage energy and a special xenon lamp. The electrical energy stored in the battery of capacitors is passed, in the form of electrical excitation through the gas, contained in this lamp so that the light is emitted; the electric energy is converted, therefore into optical energy. The emission spectrum pulsed light varies from 500 to 1300 nm.
The distribution of light is not continuous but occurs through very

short pulses. Two parameters should be considered essential in the treatment of onychomycosis with IPL and are:

- wavelength;
- pulse duration.

Wavelengths in the spectrum

Target a specific part of the photo-spectrum and then directly to dermatological problem to treat.

Most of the dermatophytes responsible for onychomycosis are characterized by a color between yellow, orange, red and brown in the photo-spectrum, for this reason, an adequate spectrum of wavelengths has been chosen for the treatment of Onychomycosis with a source of light between 530 and 1100 nm.

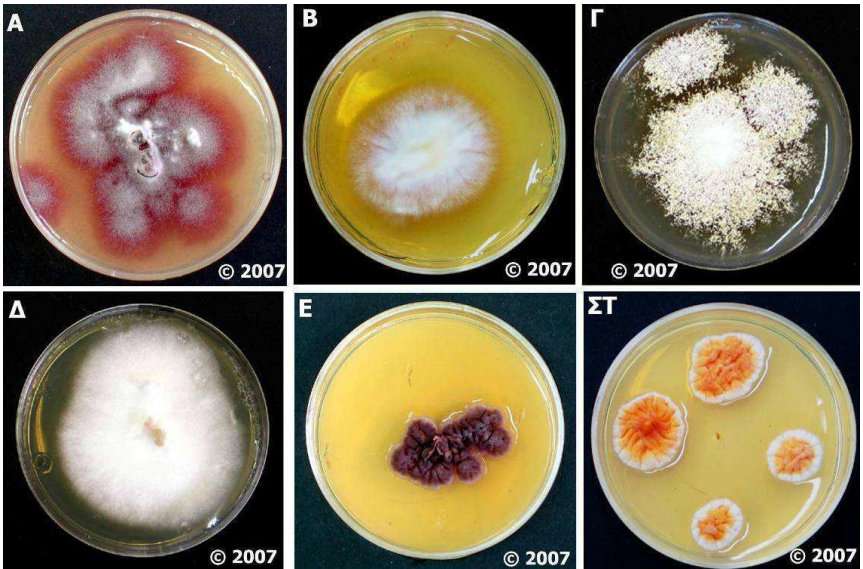
Pulse width or pulse duration

Derived from the time / energy; since biological tissue, is a fundamental physical parameter that helps us to optimize the result, increasing effectiveness and reducing damage or non-selective side effects. It is essential in the treatment because if the light radiation persists for a longer duration than TRT, the heat is conducted to the surrounding tissue and this can lead to a non - selective thermal injury of the tissue.

In other words must be considered in particular two parameters:

- The right wavelengths spectrum, in order to aim at the fungus-mode specification;
- The pulse width,

less than the TRT value , in order to prevent damage to surrounding tissues.



6.2 DESCRIPTION OF THE DEVICE

The apparatus consists of a body and a hand applicator.
Body:
Featuring a screen where it is possible to set the mode of working, the fluence, the clinical application.

Applicator F-SR:

- Purpose of application: Onychomycosis
- 3 modes: single pulse,
  Single or double every 2 sec,
  continuous pulse every 0.33 sec
- Fluence: up to 21.8 J/cm2;
- Wavelength: 530 - 1100 nm;
- Spot size: face 1.6 cm2;
- Security: proximity sensor;
- Pulse duration:
  - Single: from 3 to 10 milliseconds;
  - Double: 2 to 5 milliseconds;
  - Continuous: 1.1 to 3.3 milliseconds;
- Up to 50,000 shots

6.3 DESCRIPTION OF TREATMENT WITH IPL
PRELIMINARY PROCEDURE

Performing a nail fungus treatment:
- The first thing to do is pick a nail sample with the cutting nippers and gouge. Using sterile equipment, try to collect as much material as possible.
- Place the sample in sterile containers and immediately after introducing a minimum amount of physiological saline solution.
- Prepare the request to be sent to the laboratory, in which describes the type of examination to be done.
- The patient is asked to deliver the sample as soon as possible to the laboratory, and returning when ready;
- Cut the nail down and reduce it radically with the micro filer motor especially if dealing with thickened nails;
- Disinfect and dry the area to be treated carefully;
- Inform the patient about the number of treatments that may vary from 10 to 15, depending on the severity of the contamination and the patient's response. The treatment is carried out once every 7 days. It requires consistency and reliability for the success of the therapy. Finally, we inform the patient that the conclusion of the cycle of treatments will make a new cultural examination to verify the success of therapy.

<u>"FUNGUS CLINIC" PROCEDUR (IPL)</u>

Iconography of the nail to be treated;
- Connect the F-SR applicator (530 - 1100 nm);
- Switch on the Fungus clinic device;
- Setting:
  Determination of fluence: 21,8 J/Cm²
- Pulse mode: Single
- Press the start button;
- Apply a thin layer of about 1-2 mm of gel Aquasonic

directly on the nail and the skin around the nail to be treated;

- Use protective eye-ware for the entire session by both the operator and patient;
- Use the applicator over each area three times giving a consecutive single pulse. Being the size of a toenail, greater than the spot of the prism; requires three series, each of three consecutive single pulses.

- First series, the probe is placed in a longitudinal way over the medial side of the nail;
- Second series: the applicator is placed longitudinally on the lateral side of the nail;
- Third series: the hand piece is placed transversely on the nail.

- Disinfect the applicator at the end of the treatment with instrumental disinfector solution

DURING AND AFTER TREATMENT

Prophylactic topic therapy in the treatment of Onychomycosis with I.P.L is an Integral and necessary part of the protocol for clinic Fungus Onychomycosis and contribute to achieve long-lasting result. Consist of the application of topical antifungal products that deactivating and inhibit the fungus spores from turning into an active fungus. Furthermore, it is very important to increase the prophylaxis in surrounding areas as they may be contaminated also. This should last for IPL therapy throughout the treatment and for three months afterwards.
The following topical products can be found in the form of creams, enamel, gel, emulsion, etc.

Active ingredient	**Generic name**
Ciclopirox Olamine 1%	Penlac, Cicloderm, Loprox
Terbinafine HCl 1%	Lamisil, Terbisil, Dermacil
Econazole Nitrate 1%	Spectazole, Pevaryl
Itraconazole 1%	Itraconazole Cream

Bifonazole 1%	Bifonazole Cream, Agispor, Keratospor, Comagis
Butenafine HCl 1%	Mentax
Ketaconazole 2%	Nizoril
Clotrimazole	Lotrimin
Naftifine HCl 1%	Naftin
Nystatin	Mycostatin
Oxiconazole	Oxistat

ADVATAGES OF IPL

- Versatility and economy;
- Purchase price proportionally inferior to R&D investments costs;
- The large spot size decreases the treatment time;
- It has a large capacitor bank that allows the delivery of energy by the lamp in the form of pulsed light;

DISADVATAGES OF IPL

- The large spot size decreases the ease of management and maneuverability;
- The weight of the hand piece;
- The range of wavelengths and fluence are often emitted by inconsistent pulse energy, in particular in the devices containing a small capacitor.
- The application of the gel and the direct contact of the hand piece with skin, hinder the observation of local immediate response. This makes it difficult to understand where the last pulse was made and then carefully to position where the next pulses should be done.

CONTRAINDICATIONS

- Patients with other diseases of the skin in the affected area;
- Severe diabetes;
- Ulcers or lesions in the treated area.
- Pregnancy
- Pacemaker
- Tumor
- Epilepsy
- Autoimmune Diseases
- Herpes

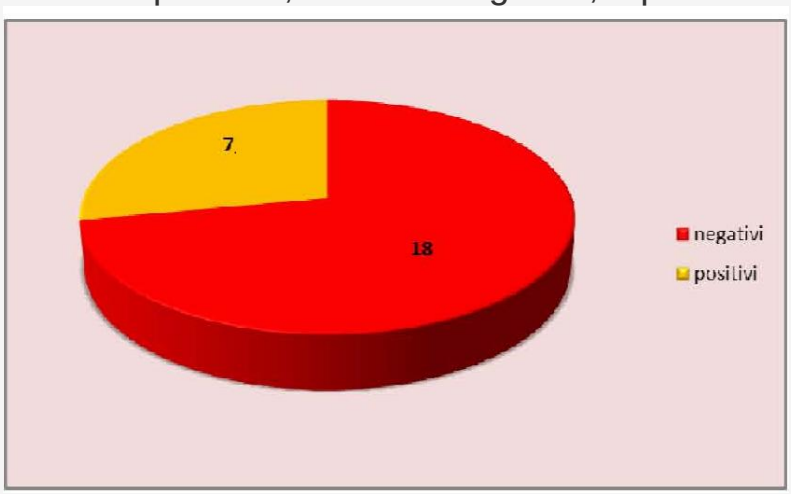
SIDE-EFFECTS

- In case of skin redness, rash or irritation
nail matrix, use a lenitive cream immediately after treatment.

CHAPTER 7

Experimental study

The study aimed to test the effectiveness of I.P.L for the treatment of Onychomycosis using "Fungus Clinic" device (Formatk Systems Ltd. - Israel). The study group consists of 25 patients with suspected Onychomycosis, presented themselves at the Italian Institute of podiatry - Rome (IPI). A first mycological culture examination was performed on each patient's nail sample to detect the fungi species. A cycle of 10 sessions of I.P.L - "Fungus Clinic" once a week and a final mycotic culture test for assessing the final
the effectiveness of the treatment itself, but only for those who tested positive. Of
these 25 patients, 18 were negative, 7 positive.



All were treated with IPL, although the sample study was concentrated on only 7 patients with positive result (colored in yellow in table below). This was done because all patients presented the clinical symptoms of Onychomycosis, and for this reason, the possibility of false negatives was taken under consideration.

7.1 MATERIALS AND METHODS

For the realization of the study, a multi-steps a protocol was followed:

- Collection of patients anamnesis data;
- Compilation of medical records;
- Iconography: carried out with an optical microscope camera;
- Sample collection and a mycological culture of the nail:

The kit used for collecting the sample consists of:
- Nippers
- A gouge No.2
- A sterile test tube

With the cutter has been cut portion of the nail to be examined, while with the gouge was carried out curettage of the nail bed trying to collect as much material as possible to send in the laboratory. The obtained material was placed inside of a sterile tube with the addition of saline.

The sample was sent to a specialized laboratory accompanied by specific request. Once we received back the results, treatment's sessions were started in both patients tested positive to Onychomycosis and in those with negative results, because of possible of false negatives.

- Treatment with "Fungus Clinic" IPL

After accommodate the patient, a photo of the infected nail was taken with an optical microscope camera, in order to compare it to results obtained during the course of treatment.
Afterwards, switching on the device and setting the parameters as following:

- Single mode pulse
- 21,8 J/Cm² energy fluence

Once, the parameters were set up, we pass to operative phase by pressing the "standby button" that switches from red color into green, at this moment the applicator is activated and ready to use.

Aquasonic gel was applied then on the nail.


Both patient and operator had to wear goggles.

Then we proceeded with the treatment with the e F-SR applicator.

9 consecutive single pulses were totally performed on the infected toenail in the following way:

- 3 flashes on the medial part of the nail; (Lengthwise)

- 3 flashes on the lateral portion; (Lengthwise)

- 3 flashes on the central portion. (Crosswise)

At the end, we proceeded with the cleaning of the hand probe (glass prism)
using some disinfectant wipes soaked with chlorhexidine.

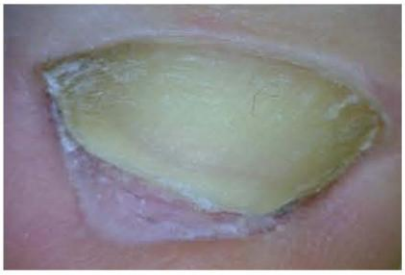
Collection of tissue sample for 2nd cultural examination:
A week after the final treatment, all patients tested positive for the first examination, have carried out the crop in order to verify the presence or absence of the fungus, in order to evaluate the effectiveness of the treatment after 10 sessions.

7.2 CASE REPORTS

Case study 1

1st Visit

1st Treatment



5th Treatment

10th Treatment

analisi cliniche e microbiologiche

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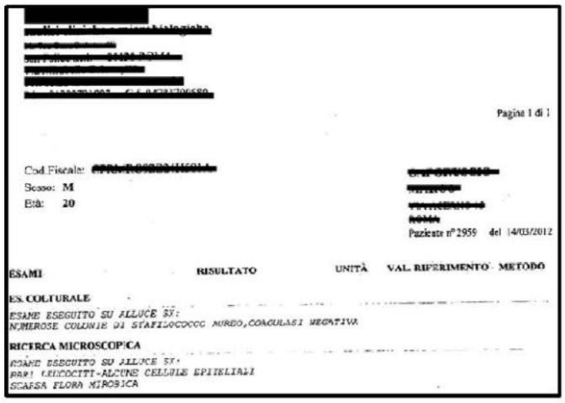
Cod.Fiscale: [redacted]
Sesso: M
Età: 19

[redacted]
ROMA
Paziente n°15147 del 23/12/2011

ESAMI	RISULTATO	UNITÀ	VAL. RIFERIMENTO	METODO
ES. COLTURALE				
CAMPIONE DI UNGHIA				
NUMEROSE COLONIE DI CANDIDA.				
NUMEROSE COLONIE DI STAFILOCOCCO ALBO.				
NUMEROSE COLONIE DI PROTEUS.				
RICERCA MICROSCOPICA				
CAMPIONE DI UNGHIA				
ALCUNI LEUCOCITI.				
NUMEROSE CELLULE SPITELIALI.				
NUMEROSE SPORE DI CANDIDA.				

1st Lab Exam (Positive)



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Età: 20

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Paziente n°2959 del 14/03/2012

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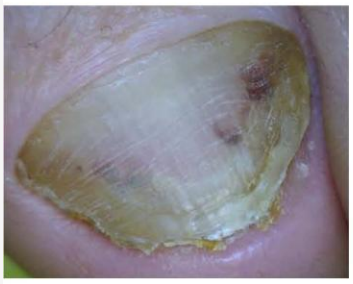
ES. COLTURALE				
ESAME ESEGUITO SU ALLUCE SX:				
NUMEROSE COLONIE DI STAFILOCOCCO AUREO,COAGULASI NEGATIVA				
RICERCA MICROSCOPICA				
ESAME ESEGUITO SU ALLUCE SX:				
RARI LEUCOCITI-ALCUNE CELLULE EPITELIALI				
SCARSA FLORA MICROBICA				

2nd Lab Exam (Negative)

After 3 month

Case study 2

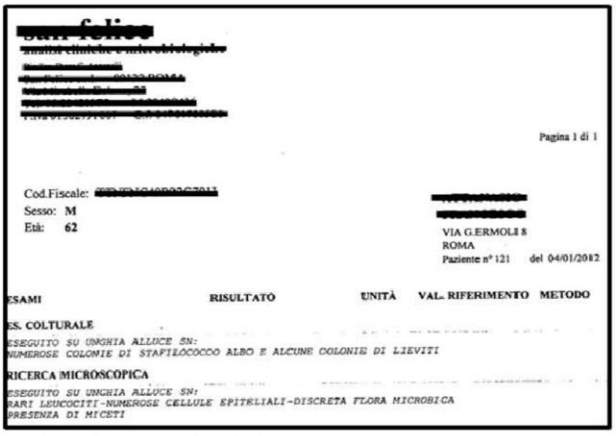
1st Visit



1st Treatment

5th Treatment

10th Treatment



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Sesso: M
Età: 62

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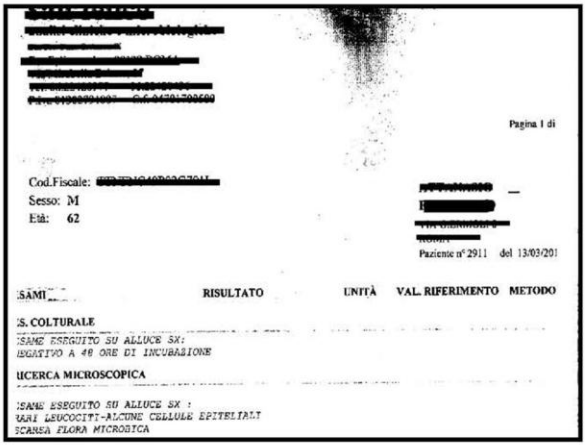
VIA G.ERMOLI 8
ROMA
Paziente n° 121 del 04/01/2012

ESAMI	RISULTATO	UNITÀ	VAL. RIFERIMENTO	METODO
ES. COLTURALE				
ESEGUITO SU UNGHIA ALLUCE SN: NUMEROSE COLONIE DI STAFILOCOCCO ALBO E ALCUNE COLONIE DI LIEVITI				
RICERCA MICROSCOPICA				
ESEGUITO SU UNGHIA ALLUCE SN: RARI LEUCOCITI-NUMEROSE CELLULE EPITELIALI-DISCRETA FLORA MICROBICA PRESENZA DI MICETI				

First Lab Exam (Positive)



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Età: 62

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S. COLTURALE				
SAME ESEGUITO SU ALLUCE SX: EGATIVO A 48 ORE DI INCUBAZIONE				
UCERCA MICROSCOPICA				
SAME ESEGUITO SU ALLUCE SX : ARI LEUCOCITI-ALCUNE CELLULE EPITELIALI CARSA FLORA MICROBICA				

Second Lab Exam (Negative)

After 3 months

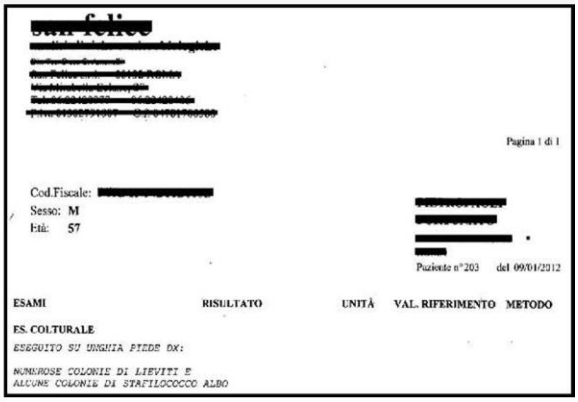
Case Study 3

1st Visit

1st Treatment

5th Treatment

10th Treatment



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Sesso: M
Età: 57

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Paziente n°203 del 09/01/2012

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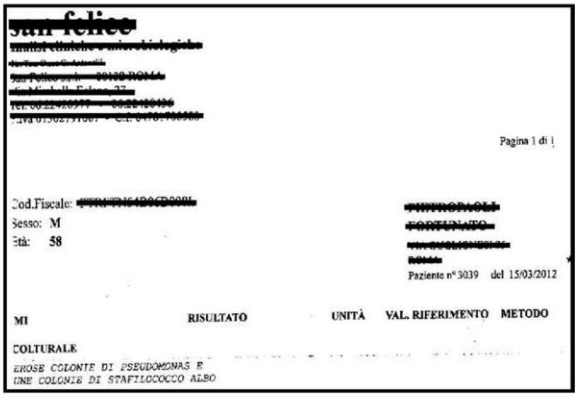
ES. COLTURALE				
ESEGUITO SU UNGHIA PIEDE DX:				
NUMEROSE COLONIE DI LIEVITI E ALCUNE COLONIE DI STAFILOCOCCO ALBO				

1st Lab Exam (Positive)



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Cod.Fiscale: [redacted]
Sesso: M
Età: 58

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Paziente n° 3039 del 15/03/2012

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COLTURALE				
ENOSE COLONIE DI PSEUDOMONAS E UNE COLONIE DI STAFILOCOCCO ALBO				

2nd Lab Exam (Negative)

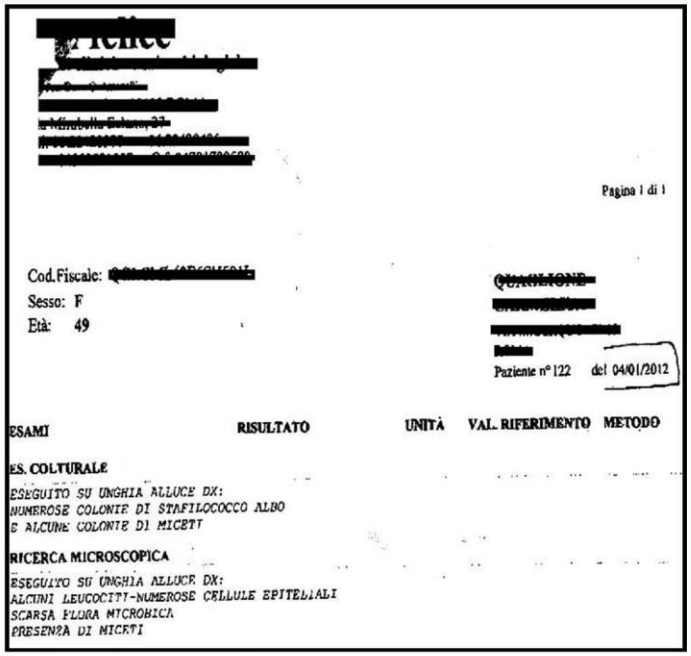
After 3 month

Case Study 4

1st Treatment

5th Treatment

10th Treatment



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Sesso: F
Età: 49

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Paziente n° 122 del 04/01/2012

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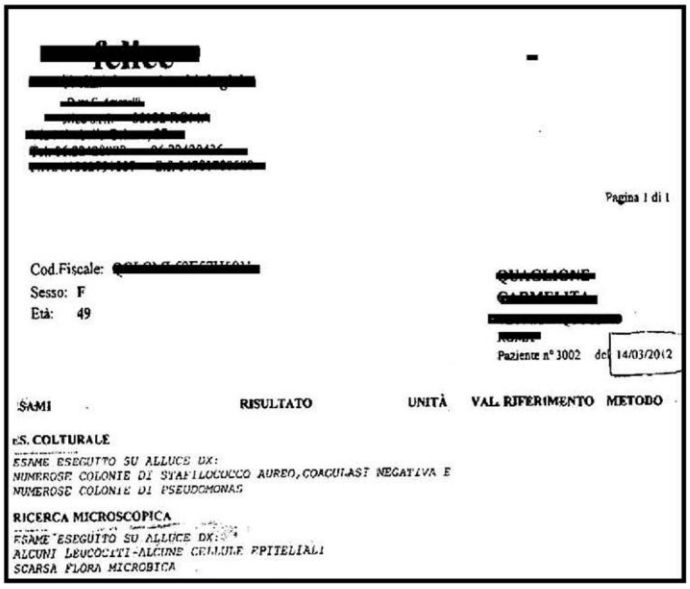
ES. COLTURALE
ESEGUITO SU UNGHIA ALLUCE DX:
NUMEROSE COLONIE DI STAFILOCOCCO ALBO
E ALCUNE COLONIE DI MICETI

RICERCA MICROSCOPICA
ESEGUITO SU UNGHIA ALLUCE DX:
ALCUNI LEUCOCITI-NUMEROSE CELLULE EPITELIALI
SCARSA FLORA MICROBICA
PRESENZA DI MICETI

1st Lab Exam (Positive)



Pagina 1 di 1

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Sesso: F
Età: 49

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Paziente n° 3002 del 14/03/2012

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ES. COLTURALE
ESAME ESEGUITO SU ALLUCE DX:
NUMEROSE COLONIE DI STAFILOCOCCO AUREO, COAGULASI NEGATIVA E
NUMEROSE COLONIE DI PSEUDOMONAS

RICERCA MICROSCOPICA
ESAME ESEGUITO SU ALLUCE DX:
ALCUNI LEUCOCITI-ALCUNE CELLULE EPITELIALI
SCARSA FLORA MICROBICA

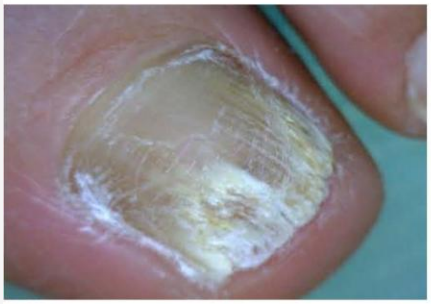
2nd Lab Exam (Negative)

Case Study 5

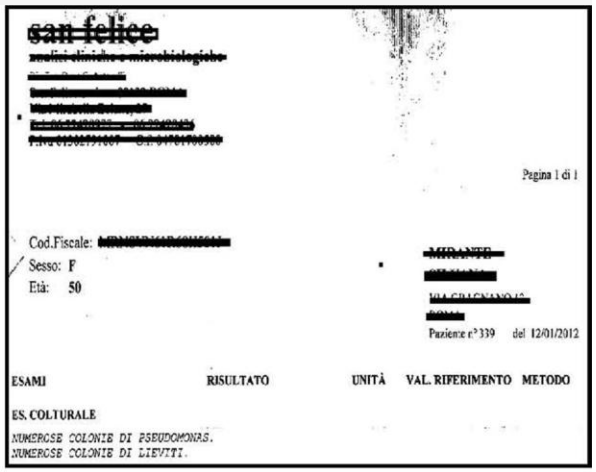
1st Visit

1st Treatment

5th Treatment



10th Treatment



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Pagina 1 di 1

Cod.Fiscale:

Sesso: F

Età: 50

Paziente n° 339 del 12/01/2012

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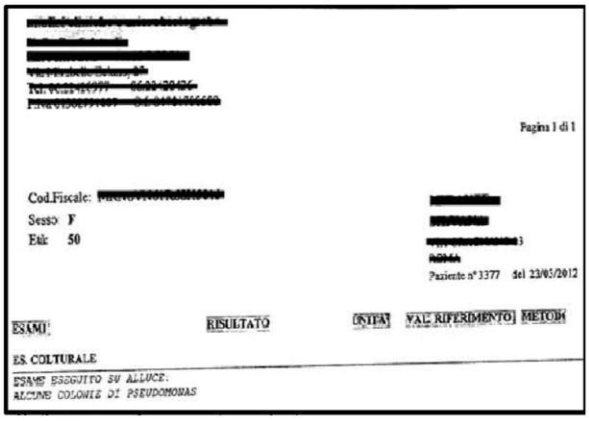
ES. COLTURALE				
NUMEROSE COLONIE DI PSEUDOMONAS.				
NUMEROSE COLONIE DI LIEVITI.				

1st Lab Exam (positive)



Pagina 1 di 1

Cod.Fiscale:

Sesso: F

Età: 50

Paziente n° 3377 del 23/05/2012

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ES. COLTURALE				
ESAME ESEGUITO SU ALUCE:				
ALCUNE COLONIE DI PSEUDOMONAS				

2nd Lab Exam (Negative)

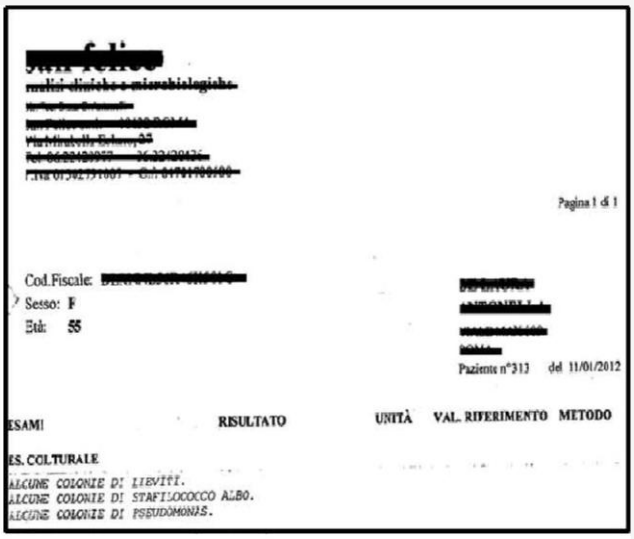
After 3 month

Case study 6

1st Treatment

5th Treatment

10th Treatment



Pagina 1 di 1

Cod.Fiscale: [redacted]
Sesso: F
Età: 55

Paziente n°313 del 11/01/2012

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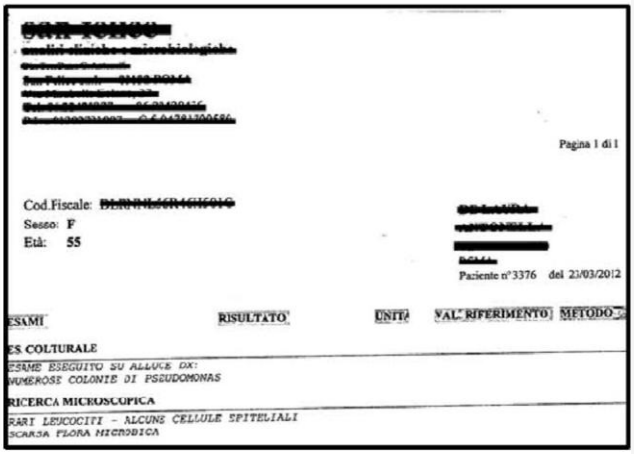
ES. COLTURALE				
ALCUNE COLONIE DI LIEVITI.				
ALCUNE COLONIE DI STAFILOCOCCO ALBO.				
ALCUNE COLONIE DI PSEUDOMONAS.				

1st Lab Exam (Positive)



Pagina 1 di 1

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Paziente n°3376 del 23/03/2012

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ES COLTURALE				
ESAME ESEGUITO SU ALLUCE DX:				
NUMEROSE COLONIE DI PSEUDOMONAS				
RICERCA MICROSCOPICA				
RARI LEUCOCITI - ALCUNE CELLULE SPITELIALI				
SCARSA FLORA MICROBICA				

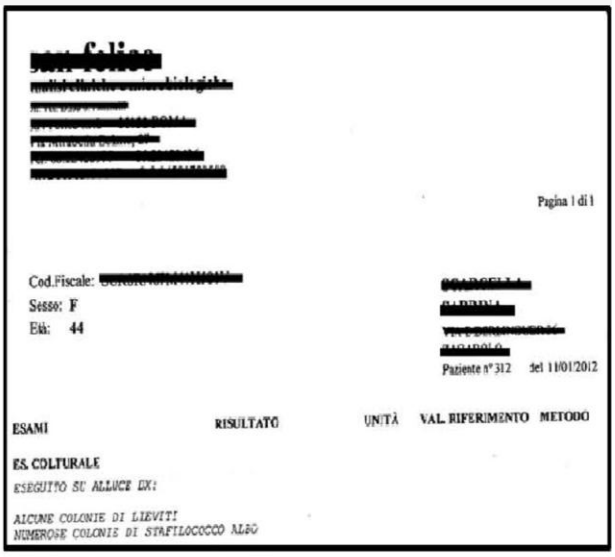
2nd Lab Exam (Negtive)

Case study 7

1st Treatment

5th Treatment

10th Treatment



Pagina 1 di 1

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Età: 44

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Paziente n°312 del 11/01/2012

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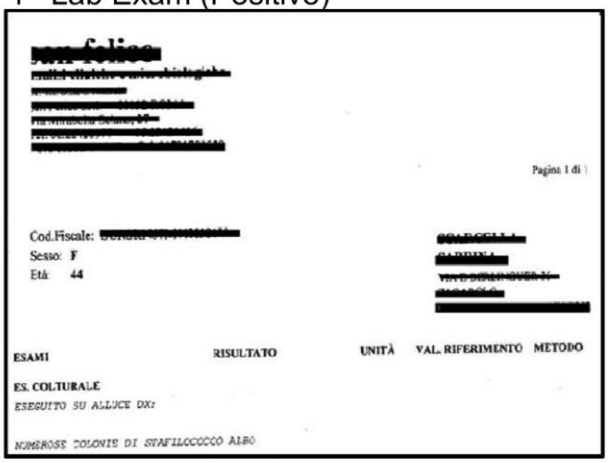
ES. COLTURALE				
ESEGUITO SU ALLUCE DX:				
ALCUNE COLONIE DI LIEVITI				
NUMEROSE COLONIE DI STAFILOCOCCO ALBO				

1st Lab Exam (Positive)



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Cod.Fiscale: [redacted]
Sesso: F
Età: 44

[redacted]

ESAMI	RISULTATO	UNITÀ	VAL. RIFERIMENTO	METODO
ES. COLTURALE				
ESEGUITO SU ALLUCE DX:				
NUMEROSE COLONIE DI STAFILOCOCCO ALBO				

2nd Lab Exam (Negative)

7.3 CONCLUSIONS

The Onychomycosis in general and particularly those of dermatophytes,
constitute one of the most common nail diseases.
Although not representing a severe disease, in terms of morbidity and
mortality, is often a source of suffering for these patients, which sometimes find hard to accept their nail's alteration or deformation.
From our study, emerged important results, claiming the effectiveness of Fungus Clinic IPL device (Formatk Systems Ltd. Israel) in the treatment of Onychomycosis.
The culture analysis performed at the end of treatment, carried out in the same laboratory where it was first done, shows that none of the patients treated presented any longer an active Onychomycosis, which demonstrate the validity of the technology.

patient	1st lab exam	2nd lab exam
C.M	Numerous colonies of Candida yeast, of Staphylococcus. Register of Proteus	Numerous colonies of Staphylococcus. Coagulase negative.
B.F	Numerous colonies of staphylococcus register and some yeasts, the presence of fungi	Negative, low microbial flora
Q. C	Numerous colonies of staphylococcus register, some colonies of fungi.	Numerous colonies of staphylococcus aureus, poor microbial flora.
P. F	Numerous colonies of yeast and some colonies of Staphylococcus	Large colonies of Pseudomonas and some colonies of Staphylococcus
L. A	Some yeasts, Staphylococcus Albo, of Pseudomonas	Large colonies of Pseudomas, poor microbial flora
M. S	Large colonies of Pseudomanas, Large colonies of yeast	Some colonies of Pseudomonas
S. S	Some colonies of yeast, many colonies of Staphylococcus	Large colonies of Staphylococcus Register

Furthermore, our study found that while an objective examination of the nail presents all the characteristics of Onychomycosis, the laboratory test of the collected samples will not give in the vast majority of cases, positivity for the fungus, not allowing then to make a complete diagnosis.
Nevertheless, we performed the "Fungus Clinic" therapy achieving very good results especially with regard to the clinical appearance of the nail.
All patients recruited for the study, were treated, even those who had a negative culture response to Onychomycosis at the beginning; in all patients we have noticed an overall improvement from the initial situation.
Although the study sample cannot be considered statistically large enough,
we can affirm that Onychomycosis treatment with "Fungus Clinic" (Formatk Systems Ltd. Israel) IPL device is an effective, fast and well tolerated by the patients. We carried out excellent results and patient's totally satisfaction.
Personally I hope this could become a pilot study for the official start for the recognition of a new technique, highly effective in the treatment of Onychomycosis.

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