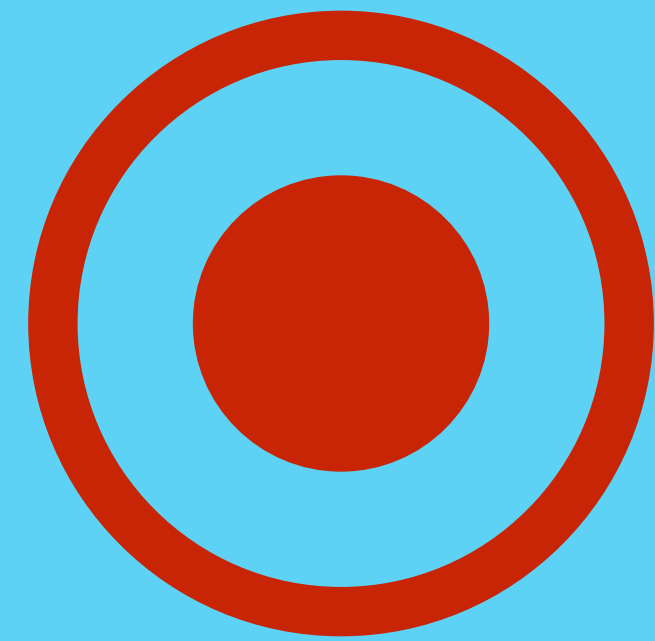**Q-CLEAR™**
COMPACT LASER SYSTEM

Optimal Laser Treatments for Fungal Nails
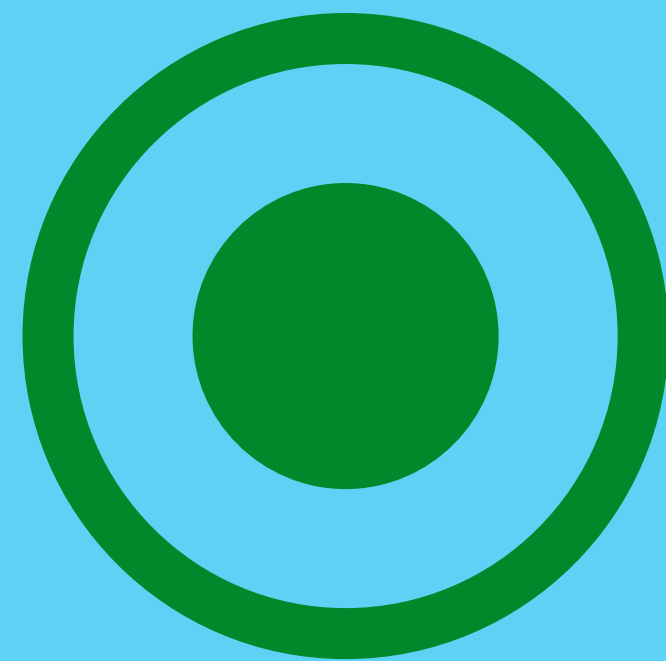
ALL LASERS ARE
not
CREATED EQUAL

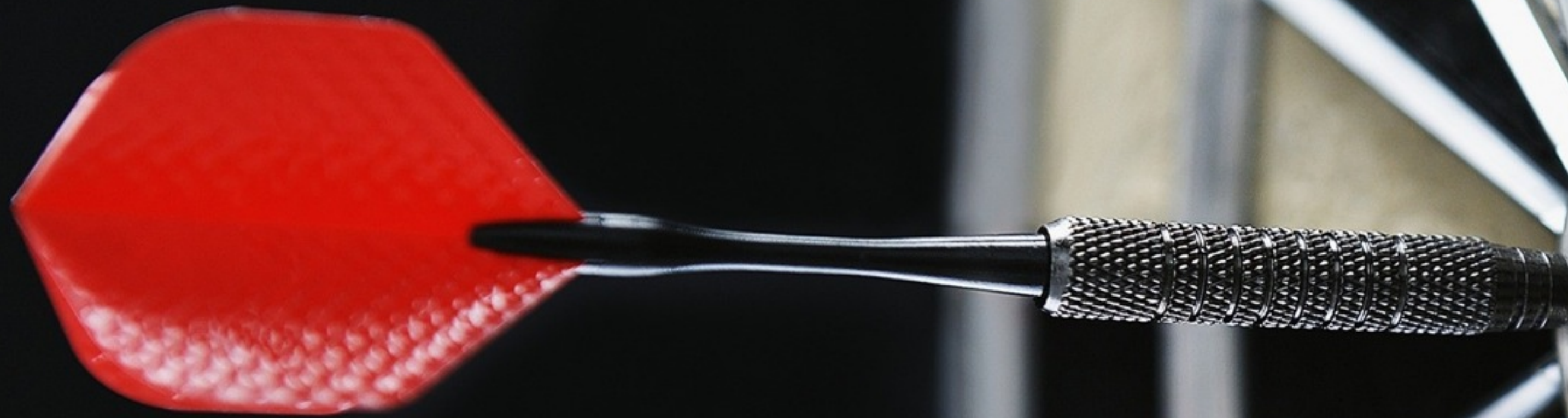# A TECHNOLOGY CHANGE IN THE STANDARD OF CARE

Light CAN target by:

- ⦿ Photo -Chemical
- ⦿ Photo -Mechanical

and/or

- ⦿ Photo -Thermal

Processes

TO
UNDERSTAND
HOW TO
TARGET

YOU HAVE TO
UNDERSTAND

THE **TARGET**

UNDERSTANDING THE TARGET

Morphology of the Fungi
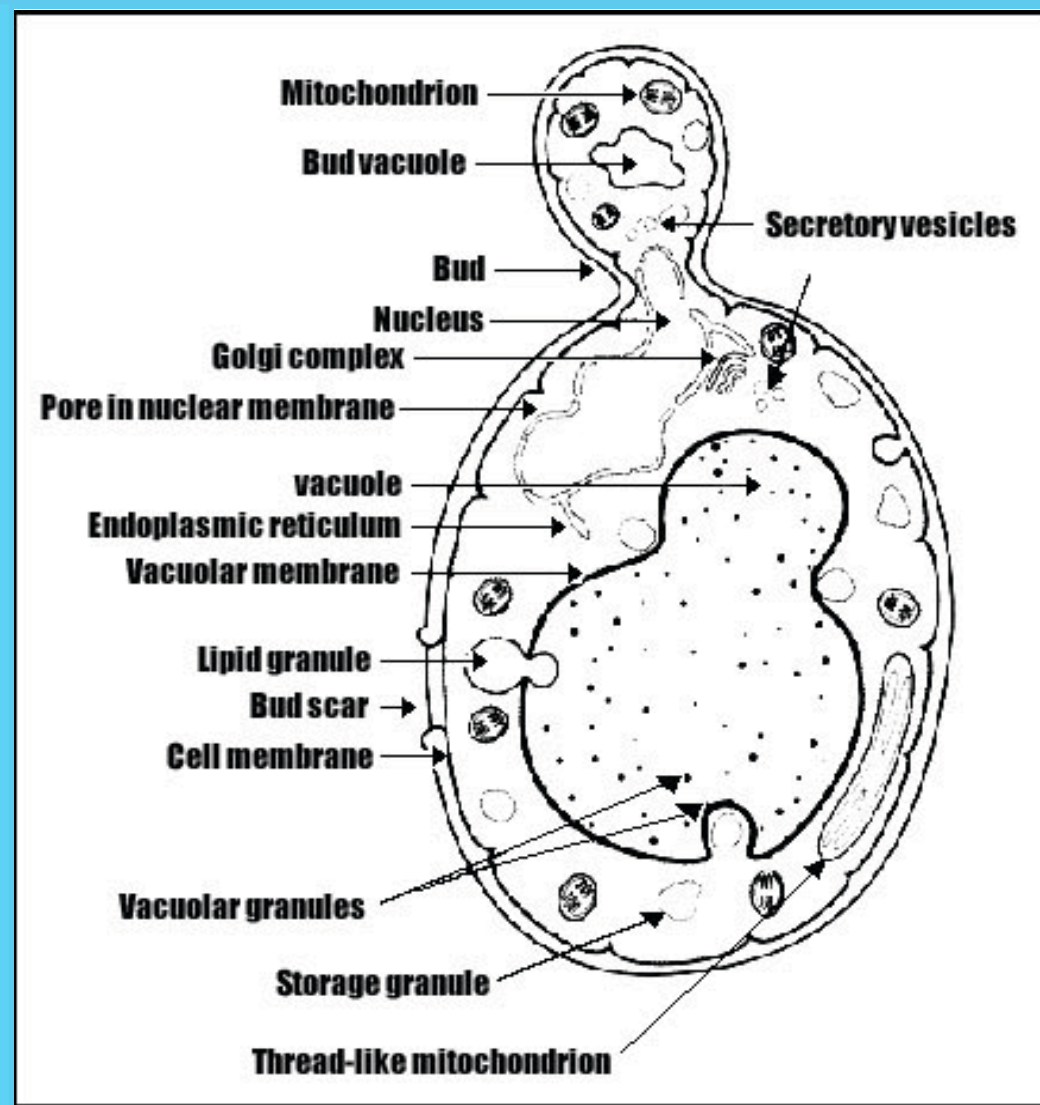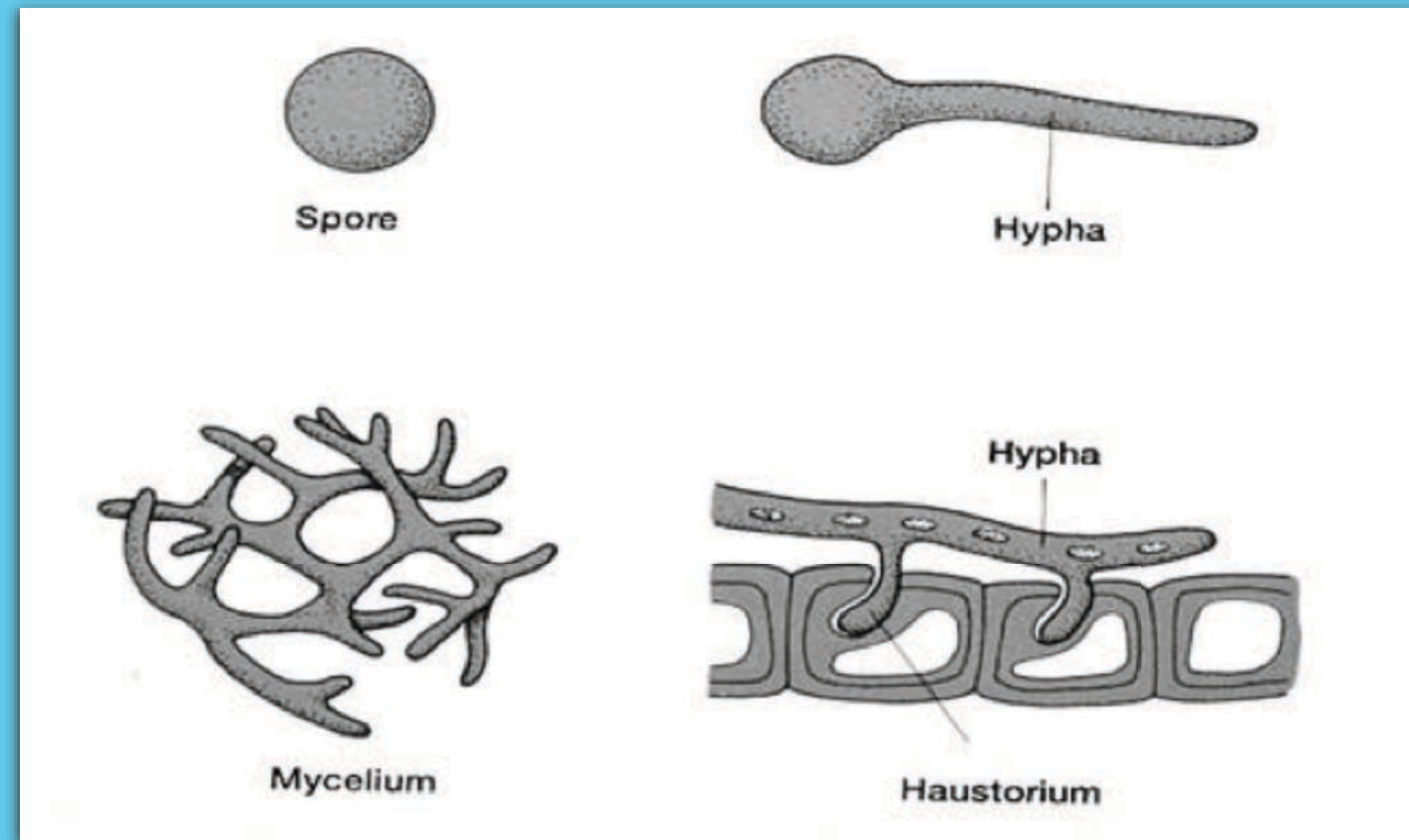
Outside It's Mostly Chitin

The Anatomy Is Quite Complex

- **Anatomy and Morphology of Fungi**

- **Mycotic Chromophores**

- **Thermal relaxation of hyphae and mycelia**

- **Thermolytic susceptability of fungi**

- **Photomechanical effects on mycelia**

- **Spatial distribution of the infection – in 3D**

A Primary Offender

Trichophyton rubrum –T. rubrum
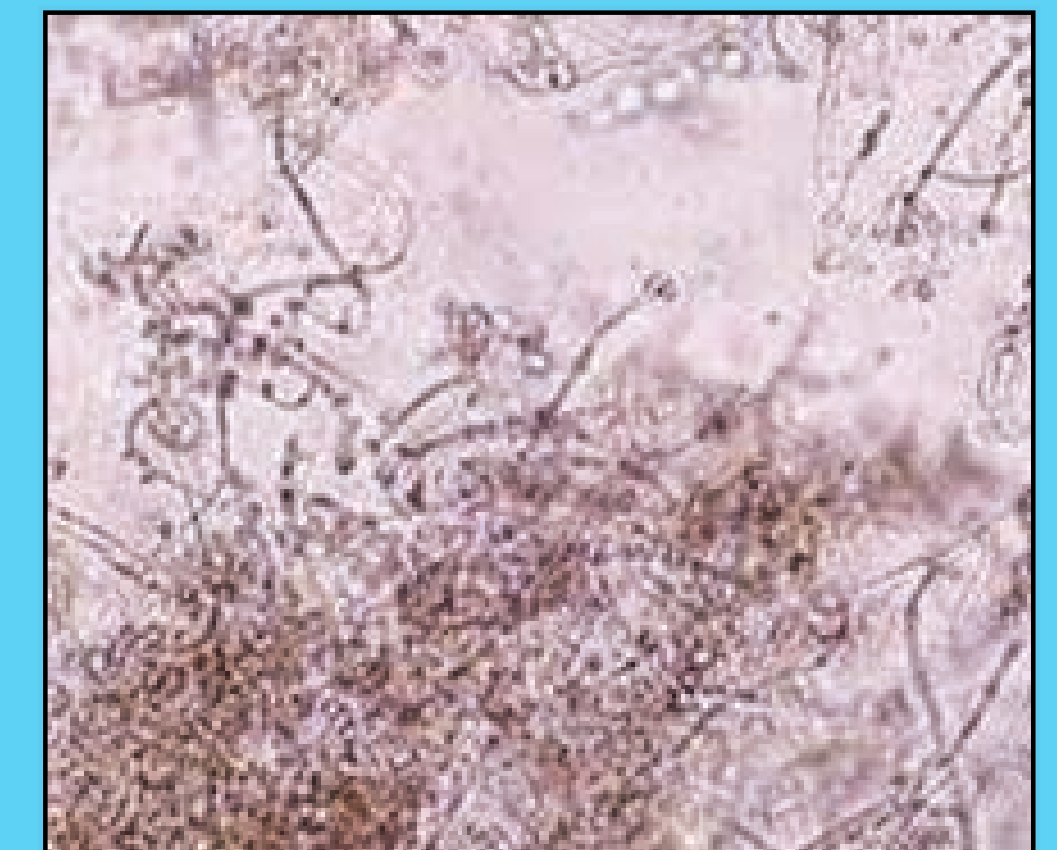
WHY USE LASERS TO KILL FUNGI?

You Don't Need a Laser to Kill Fungus

Many Other Treatments Can Work Just As Well

example:

Boiling Water Works Just Fine

(in the same way as some lasers)

TARGETING THE FUNGI

It's NOT Just

Targeting

It's Also...
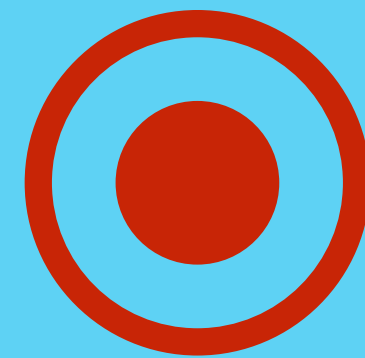
Anti-Targeting

Targeting
Fungus
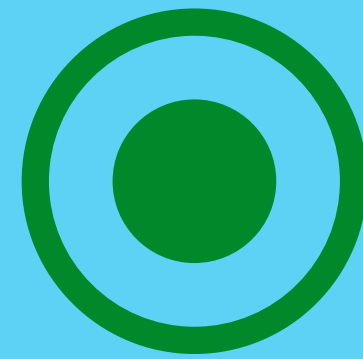
Anti-Targeting
Everything Else

That Really Matters!
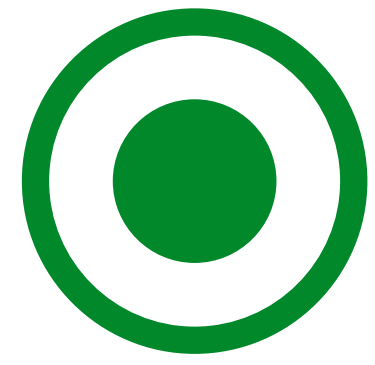
BUT, HOW DO YOU ANTI-TARGET?

what do you need to know?

A Clear Understanding of the
"Everything Else"

The Fungal Environment

Understanding
The Environment

- Thermal Properties of Dermal Tissues

- Thermal Properties of the Nail Plate

- Regenerative Properties of the Dermis

- Regenerative Properties of the Nail Matrix

- Thermolytic Susceptability of the Dermis and Matrix

- Optical Properties of the Dermis, Matrix, and Nail Plate
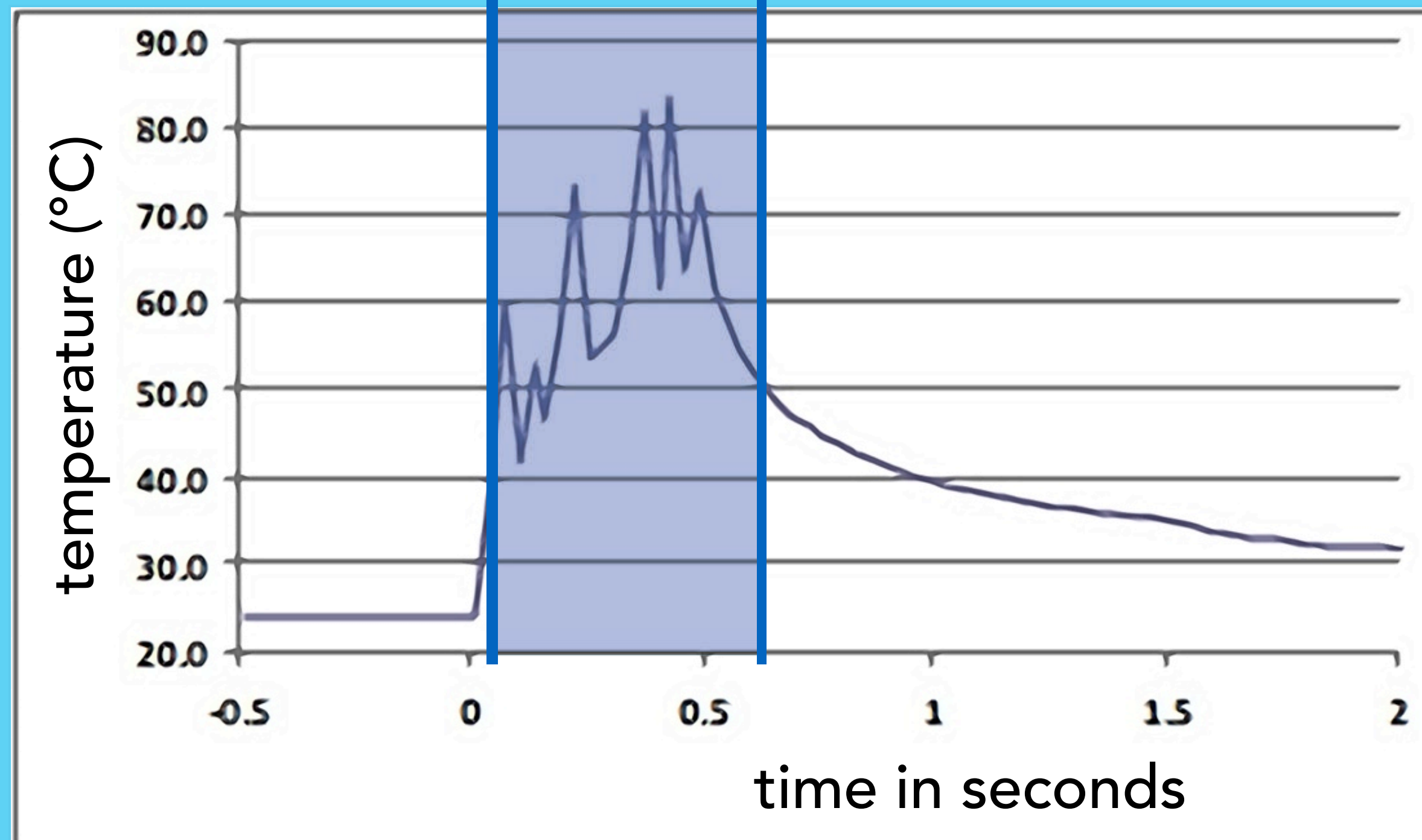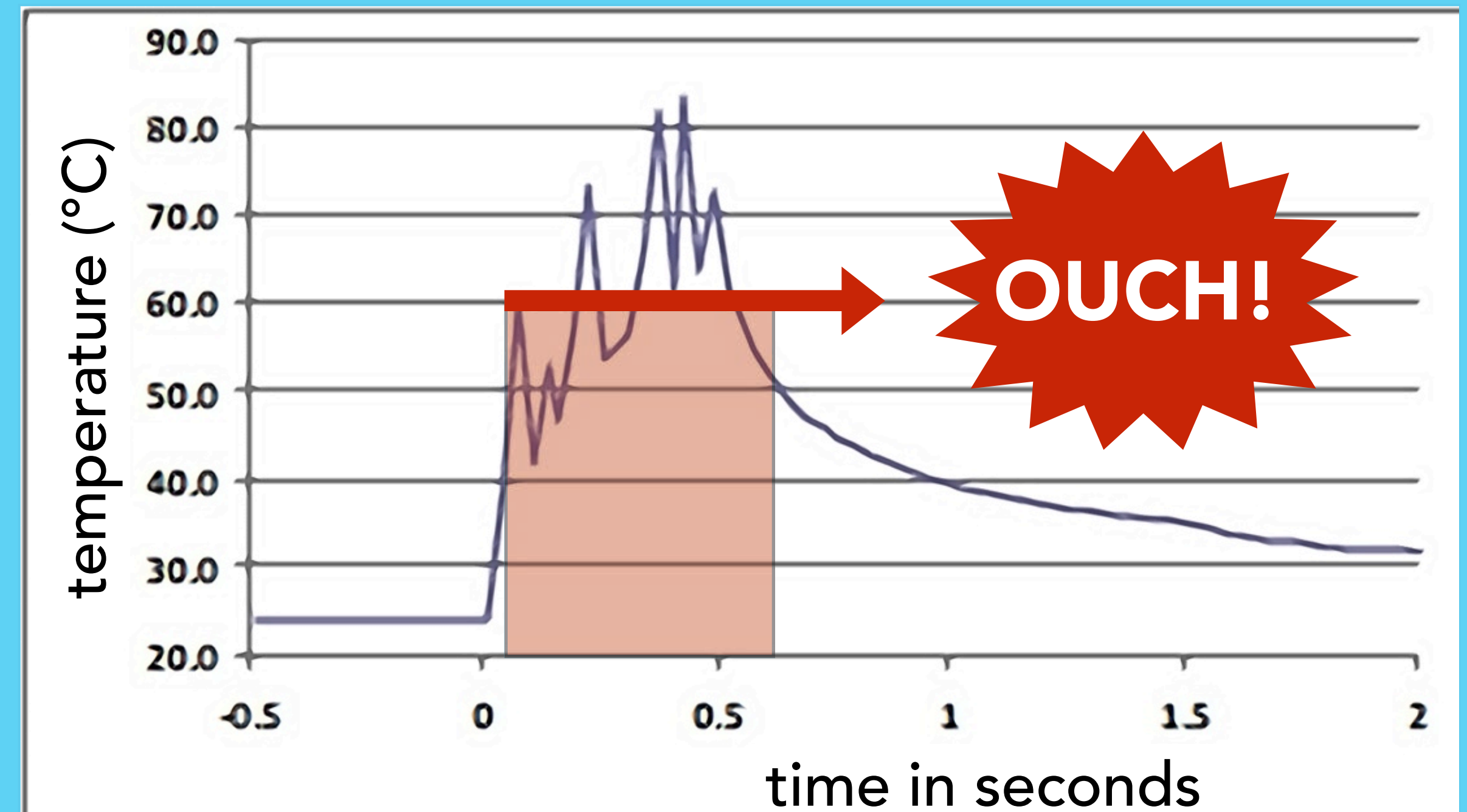
PROBLEMS WITH OTHER LASER PRODUCTS

Wrong Wavelength

- Can't Penetrate Nail Plate
- Lack of Fungal Chromophores

Wrong Pulse Format

- Long Pulses (ms duration) Lack Selective Energy Confinement
- Short Pulses (ns duration) ablate and cause plumes

Wrong Fluence

- Too Much causes pain and side-effects
- Too Little yields little efficacy

Wrong Peak Power

- Ablative or Thermal side-efects
- Reduced efficacy

Wrong Average Power

- Volumetric tissue heating
- Insufficient mycolytic effect

Wrong Spatial Properties

- Pinpoint overtreatment
- Poor coverage of treated areas

Wrong Treatment Protocol

Laser Fungal Thermolysis

0.5 s Duration

5 s Duration

Log Survival Fraction

Temperature (°C)

Reported
Arrhenius Model

Eact = 22 kcal/mole
T0 = 62°C
t_{Tx} = 500 ms

R = 0.96

$N(T, t_{pulse})/N_{INITIAL} = \exp[-K(T)t_{pulse}]; K(T) = \exp[E_{act}/k(T-T0)]$

Fungal Survival @ 0.5s

7% Survival of the Fungi

the "7% Solution"

THIS IS WHY
Multiple Treatments Are Necessary,
with other Lasers other than Q-Clear™

But May Still Be Ineffective!

Note: At These Durations, Skin Temperatures
In Excess of 50°C Can Be Quite **Painful**.

Designed to **Anti-Target** healthy dermis

and **Target** what doesn't belong there
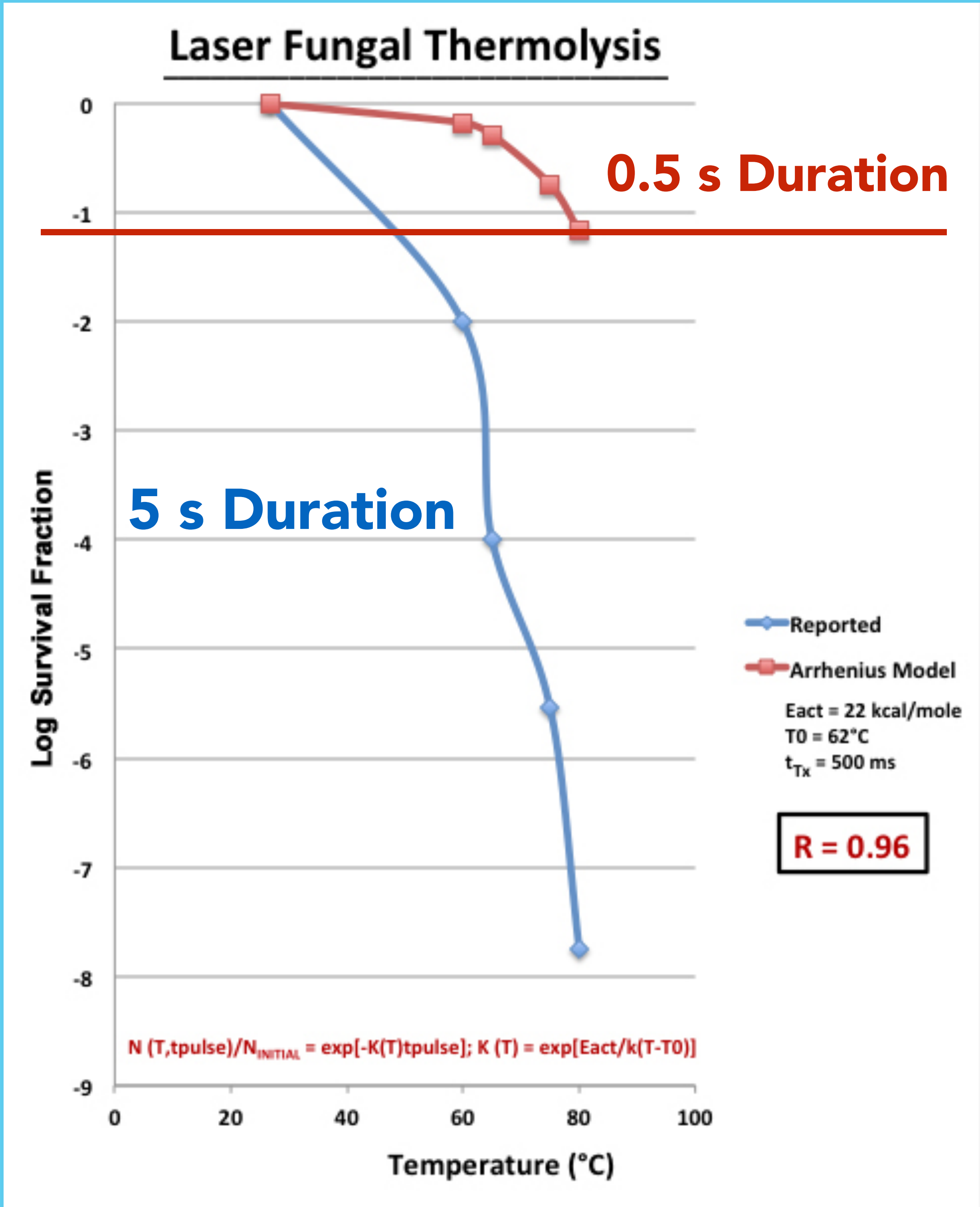
including fungus

Q-CLEAR™
COMPACT LASER SYSTEM

3.5mm

MAKING A
LASER
DEVICE

The Effect of Pulse Format

Time Dependence of Target and Tissue Temperatures

$T > T^*_{target}$

T_{target}

$T(t)$

$T < T^*_{tissue}$

T_{tissue}

t

$E(t)$

t
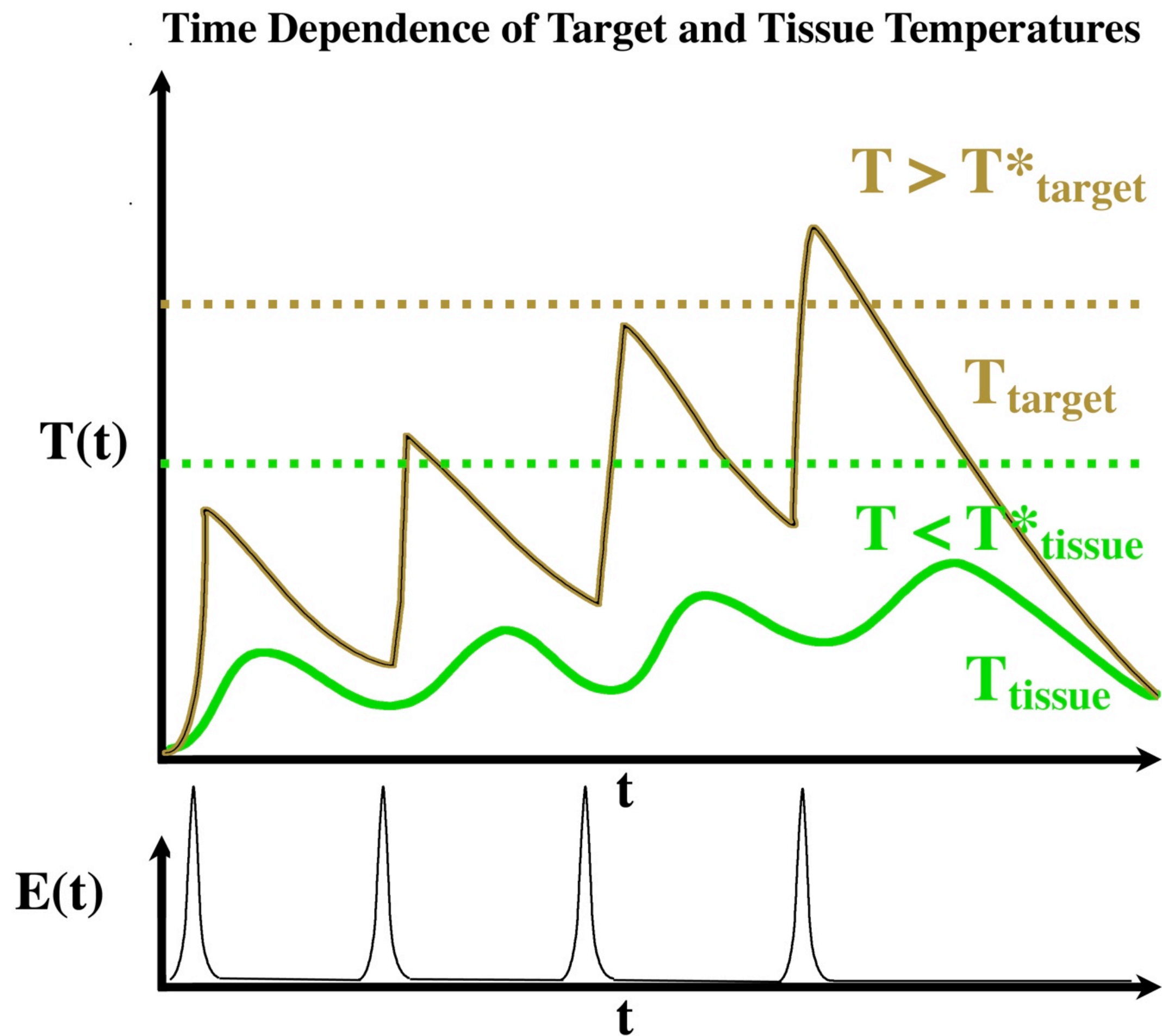
Figure : Schematic dependence of temperature increases in target and anti-targeted tissue as functions of time for a time-structured laser pulse format given by E(t), the time-dependent laser pulse energy. The dotted lines indicate the temperature levels sufficient to damage the target (T^*_{target}) and anti-target (T^*_{tissue}), respectively.

Laser Pulse Duration

IS CRITICAL

Laser Temporal Format

IS CRITICAL

OTHERWISE

Unwanted Side Effects

(Pain, Burns, Bleeding, Tissue Spatter)

OR   **No Effect**

Optimizing The Laser Therapy

- Laser Wavelength
- Laser Temporal Characteristics
- Laser Fluences
- Defining Optimal Treatment Protocols

Q-CLEAR™
COMPACT LASER SYSTEM

3.5mm
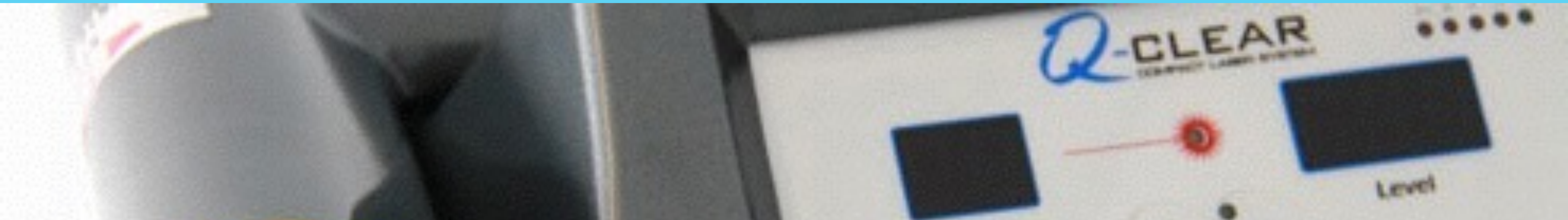
Clinical
RESULTS

Q-CLEAR™
COMPACT LASER SYSTEM

Before

After

1

3/16/10 3.0 J/cm2, 5mm spot size, 5 Htz

12/16/10 No treatment

Q-CLEAR™ COMPACT LASER SYSTEM

2

After

Before

3/11/10 1.8 J/cm2, 5 mm spot size, 1 Htz

10/19/10 11.8 J/cm2, 2.5 mm spot size, 5 Htz

Level

Q-CLEAR™
COMPACT LASER SYSTEM

4

Before

After

11/8/10 No treatment

3/25/10 5.2 J/cm2, 3.5 mm spot size, 5 Htz

Q-CLEAR
COMPACT LASER SYSTEM

Level

Q-CLEAR™ COMPACT LASER SYSTEM

5
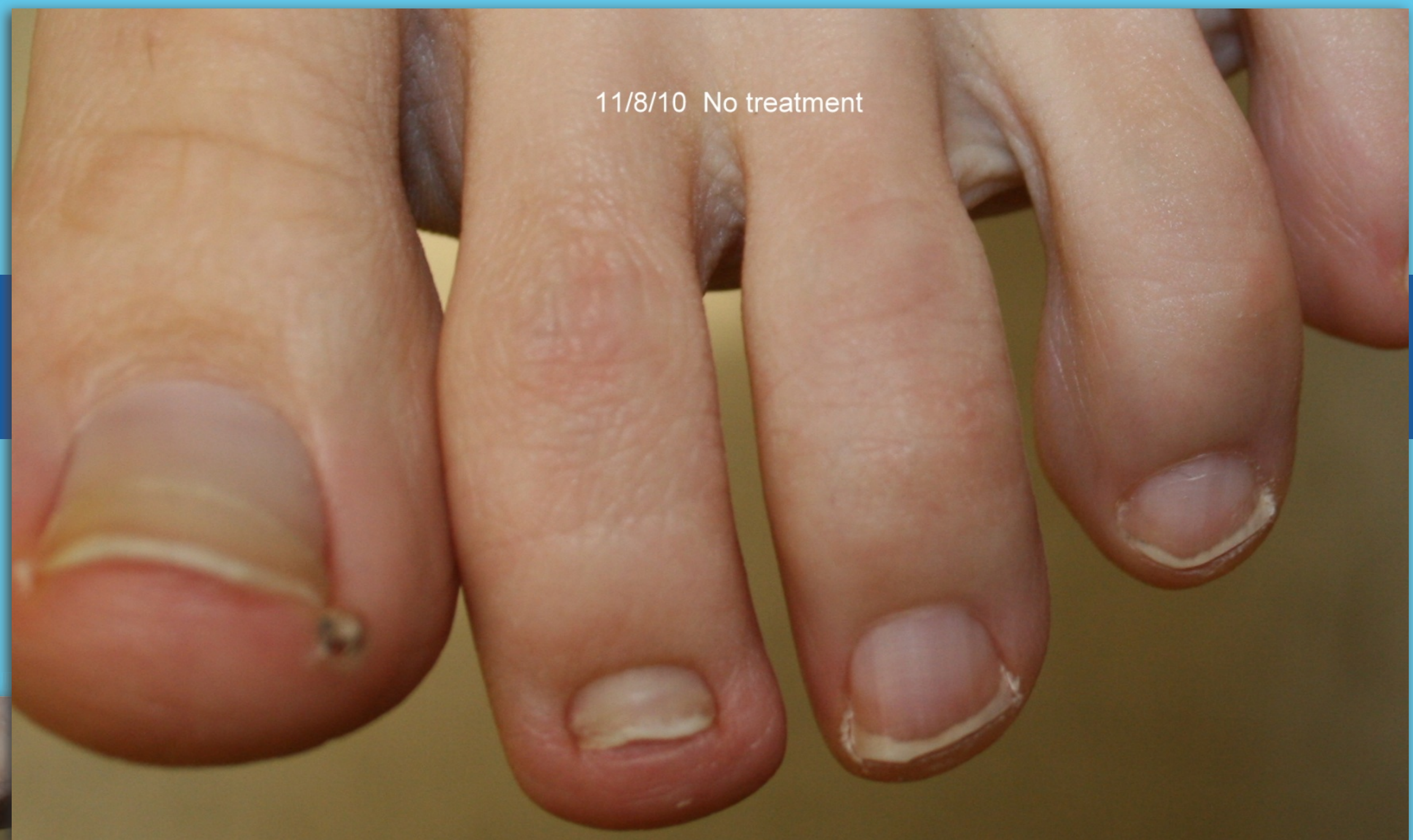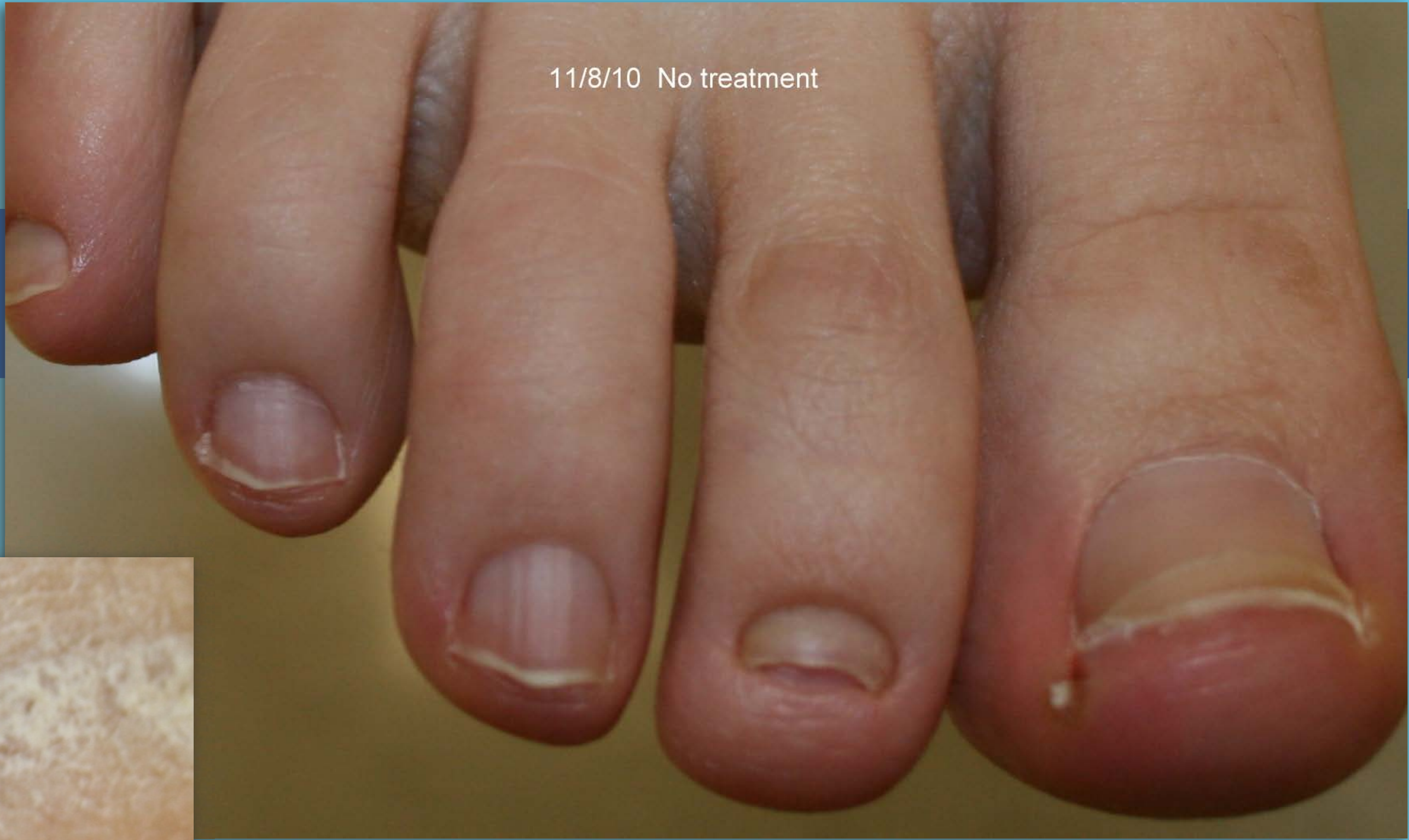
After

Before

5/26/20 11.8 J/cm2, 2.5mm spot size, 3 Hz

9/3/2010 11.8 J/cm2, 2.5mm spot size, 3 Hz

Q-CLEAR™
COMPACT LASER SYSTEM

6

After

Before

6/15/10 11.8 J/cm2, 2.5mm spot size, 3 Hz

9/15/10 11.8 J/cm2, 2.5mm spot size, 3 Hz

Q-CLEAR™
COMPACT LASER SYSTEM

SUMMARY OF
Clinical
STUDY

SUMMARY OF CLINICAL STUDY

Retrospective study of N=100

- Randomly selected from > 400 treated cases
- Blind graded for nail plate clearance
- Subjects ranged from 3-12 months post Tx

Significant Improvement in > 95% of Subjects

- 0% Pain
- 0% Adverse Side Effects
- 100% Patient Satisfaction

Implication: Essentially all Fungi are killed in a single treatment!

MYCOLOGY

Eradication of nail fungal infections

"On 2 month follow-up 125 patients or 95.42% showed mycological cure (negative microscopy and culture). There was no treatment failure (proximal extension of the lesion during treatment) or other materially adverse side-effect noted.

Clinical cure is associated with the alteration of percentages of disease free nail We find a change of >76% as excellent response, 51-75% as very good response, 26-50 as good response 6-25% as moderate response and >5% as low response to treatment."

Reference: Dr. K. Kalokasidis, et al., Procedings EADV 2013 – published, October 2013.

All Subjects 3-12 months Post Tx

Histogram

Histogram of Count (y-axis, 0 to 20) versus percentage clearance categories (x-axis):
- Up To 10: 6
- 10 To 20: 8
- 20 To 30: 8
- 30 To 40: 14
- 40 To 50: 11
- 50 To 60: 8
- 60 To 70: 8
- 70 To 80: 5
- 80 To 90: 11
- 90 To 100: 21
- More: 0
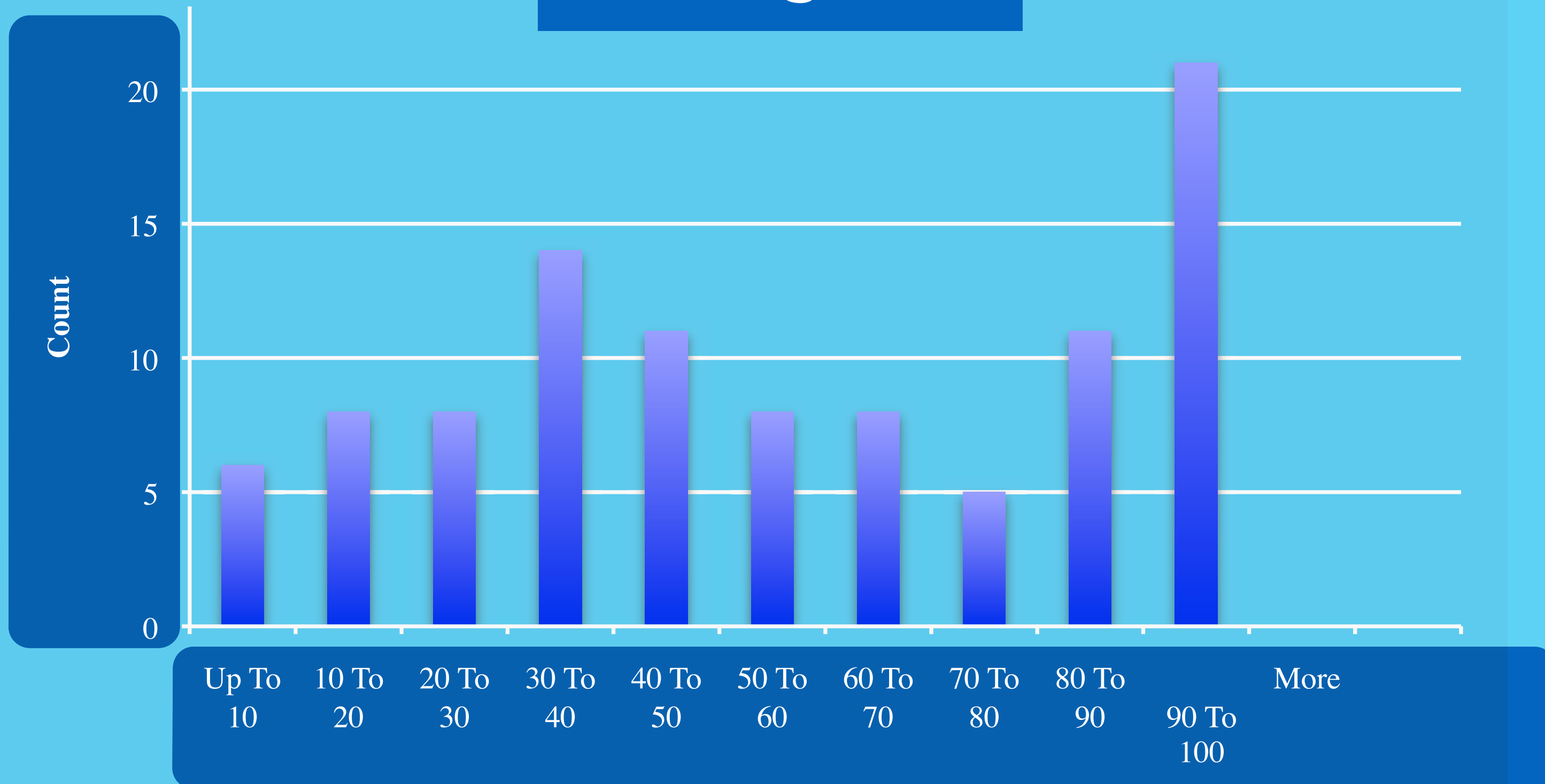
All Subjects: Distribution of percentage clearance following Q-Clear™ laser treatment of initially dystrophic nail area (independent of position of dystrophy on the nail plate) for all study subjects at study end. At study end, subjects ranged from 2.8 to 12 months post entry (initial Tx). Note: Due to the metric used, all subjects entering the study (by definition) begin at 0% clearance.

Table 6. Response to Treatment by: gender, age group, onychomycosis severity and fungal type, clinical extent, & location

All Patients	Patient/Derma tophyte/Nail Group	Excellent response (>75%)	Very good response (50-74)	Good response (25-49)	Moderate response (10-24%)	Low Response (>9%)	No Response (0%)
By Gender	Female	10 (10.6%)	44 (46.8%)	25 (26.6%)	10 (10.6%)	0 (0.0%)	5 (5.3%)
	Male	2 (5.4%)	9 (24.3%)	16 (43.2%)	9 (24.3%)	0 (0.0%)	1 (2.7%)
By Age Range	<30 y.o	3 (15.0%)	4 (20.0%)	10 (50.0%)	2 (10.0%)	0 (0.0%)	1 (5.0%)
	30-60	9 (10.5%)	37 (43.0%)	24 (27.9%)	13 (15.1%)	0 (0.0%)	3 (3.5%)
	60>	0 (0.0%)	12 (50.0%)	6 (25.0%)	4 (16.7%)	0 (0.0%)	2 (8.3%)
By Severity	Mild	3 (50.0%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Moderate	5 (13.5%)	23 (62.2%)	9 (24.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Severe	4 (4.5%)	28 (31.8%)	31 (35.2%)	19 (21.6%)	0 (0.0%)	6 (6.8%)
By Fungal Type	Dermatophytes	10 (9.3%)	51 (47.2%)	38 (35.2%)	8 (7.4%)	0 (0.0%)	1 (0.9%)
	Candida	1 (5.3%)	1 (5.3%)	3 (15.8%)	10 (52.6%)	0 (0.0%)	4 (21.1%)
	Non-dermatophytes	1 (25.0%)	1 (25.0%)	0 (0.0%)	1	0 (0.0%)	1 (25.0%)
	Trich. Rubrum	9 (9.4%)	48 (50.0%)	35 (36.5%)	4 (4.2%)	0 (0.0%)	0 (0.0%)
By Clinical Extent of Infection	Distal subungual	9 (7.3%)	50 (40.7%)	40 (32.5%)	18 (14.6%)	0 (0.0%)	6 (4.9%)
	Proximal subungual	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Superficial white	1 (50.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)
	Dystrophic type	2 (4.3%)	14 (29.8%)	17 (36.2%)	11 (23.4%)	0 (0.0%)	3 (6.4%)
	Lateral Edge	2 (4.3%)	5 (38.5%)	5 (38.5%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
By Location	Hand	0 (0.0%)	1 (9.1%)	3 (27.3%)	6 (54.5%)	0 (0.0%)	1 (9.1%)
	Feet	9 (9.9%)	38 (41.8%)	27 (29.7%)	14 (15.4%)	0 (0.0%)	3 ()3.3%

Q-CLEAR™
COMPACT LASER SYSTEM

Thank you