



*Photodisinfection  
for Toenail Fungus:  
Science and  
Treatment*



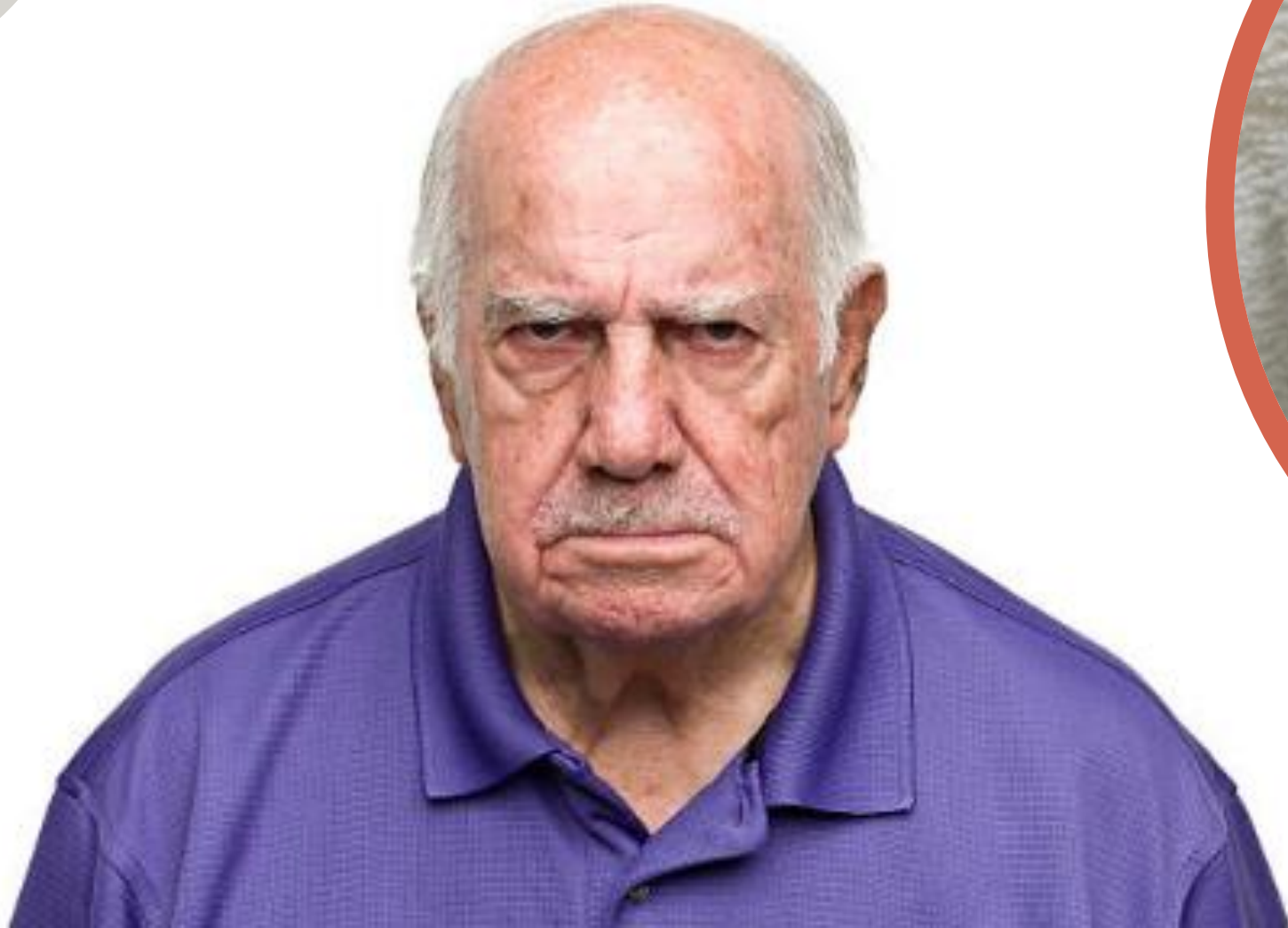
# Introductions

- Dana Molckovsky- registered pharmacist in Ontario. This presentation is confidential and is intended for educational purposes.

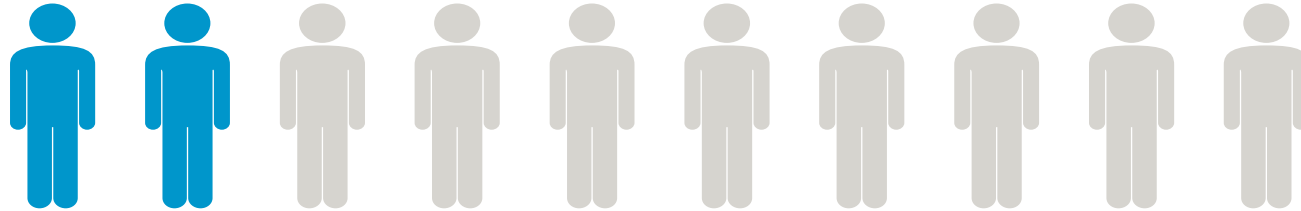




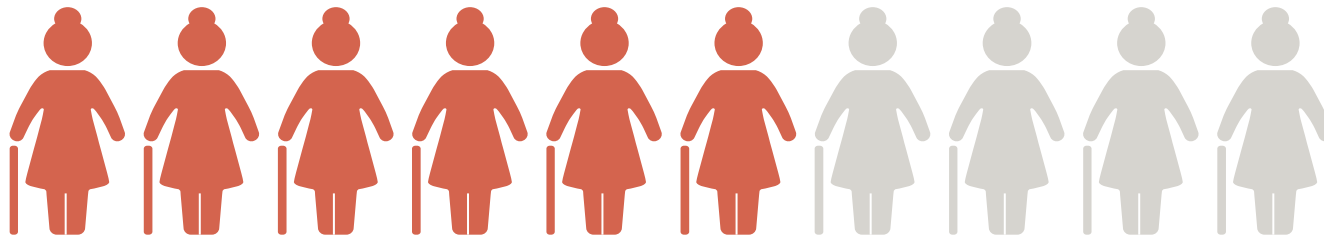
# Roger and his nasty toe



# Millions suffer from onychomycosis globally



10-20% of the general population



50% of seniors

It's unsightly, embarrassing and hard to treat

Bad smell, often painful

Contagious, can migrate

Embarrassing!

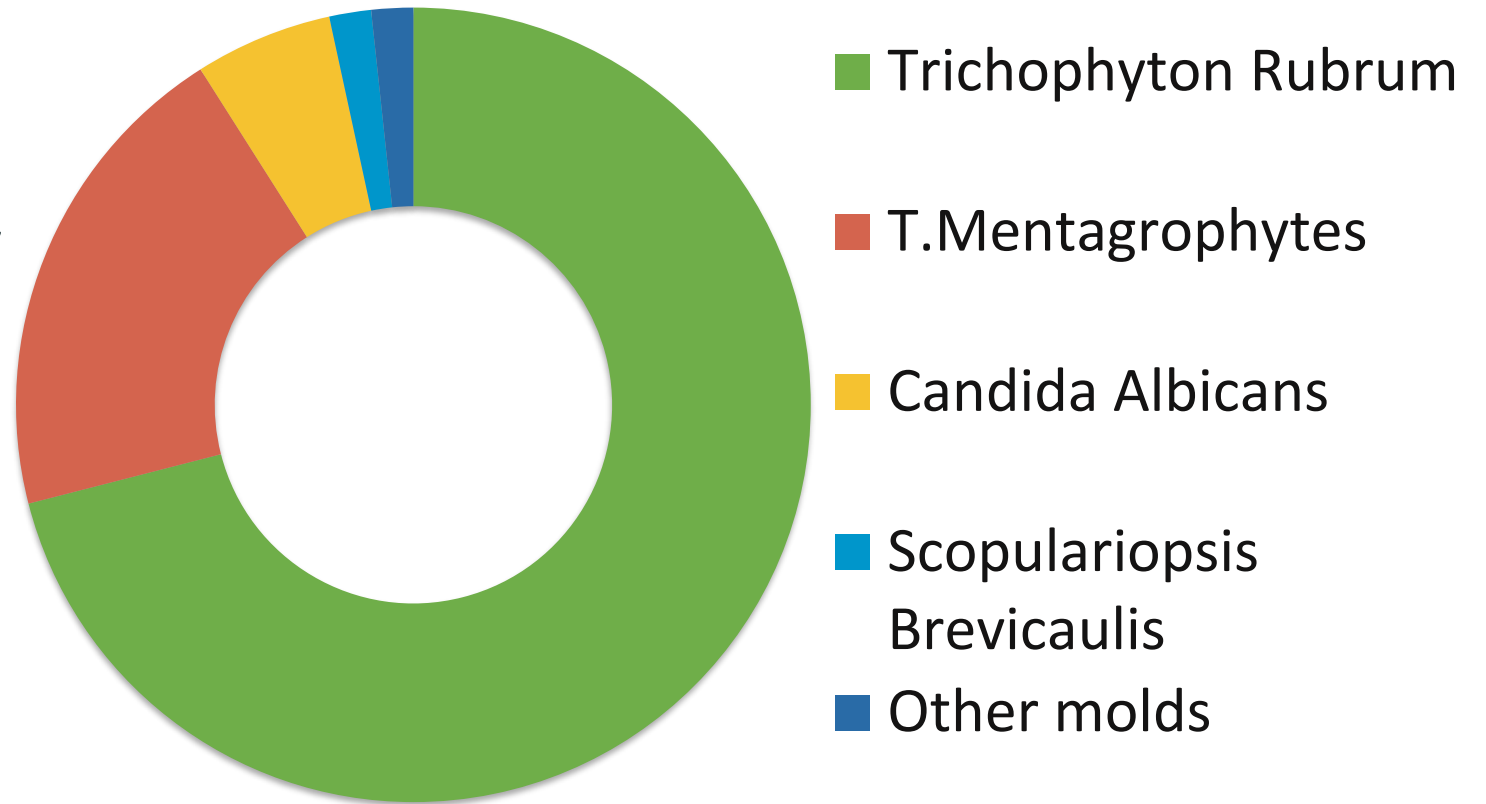
Secondary infections

# Causes of onychomycosis



Dermatophytes feed on keratin.

Under normal healthy conditions, this top skin layer is dry and not easily invaded by dermatophytes.



Dermatophytes



# Existing treatments for onychomycosis



**Low efficacy, costly, side effects, compliance issues**

<b>Medication</b>	<b>Efinaconazole</b>	<b>Terbinafine (oral)</b>	<b>Laser</b>
<b>Compliance</b>	Daily for 48 weeks	Daily over 12 weeks + blood tests	Varies with laser
<b>Side Effects</b>	Low	Liver toxicity scares many patients	Some burning sensation
<b>Efficacy</b>	15-18% complete cure	46% complete cure	Varies with brand
<b>Cost</b>	\$1000/course; regional dependence	\$50/course; regional dependence	~\$30-80,000

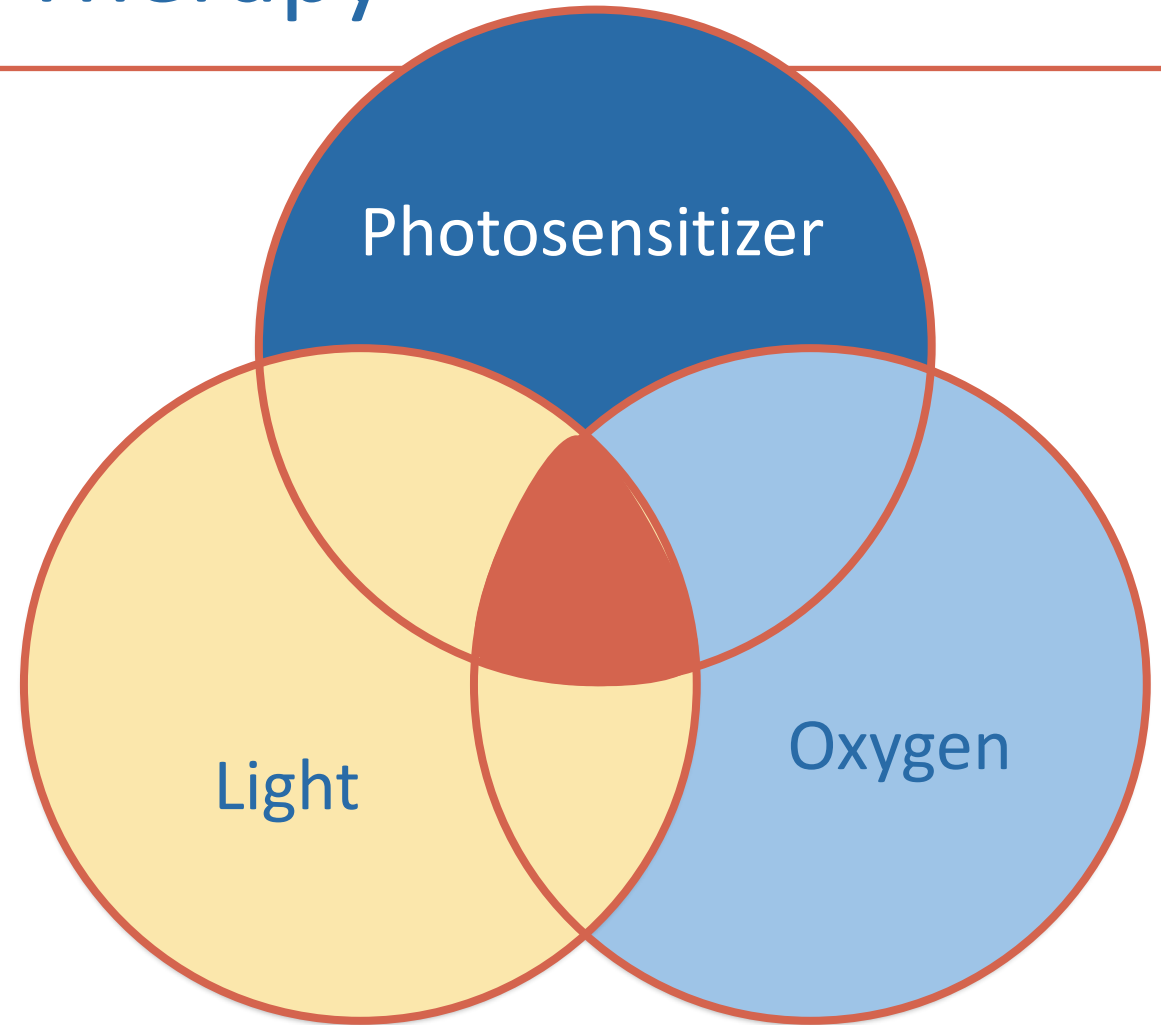


# PDT: Photodisinfection Therapy

Combines a light-sensitive compound and a light source to destroy abnormal cells.

## Uses

Photodisinfection is used in the US and Europe in the treatment of localized cancers and acne.



# Vision



## Work with nature

- Control microorganisms and pathogenic germs
- Protect normal cells.

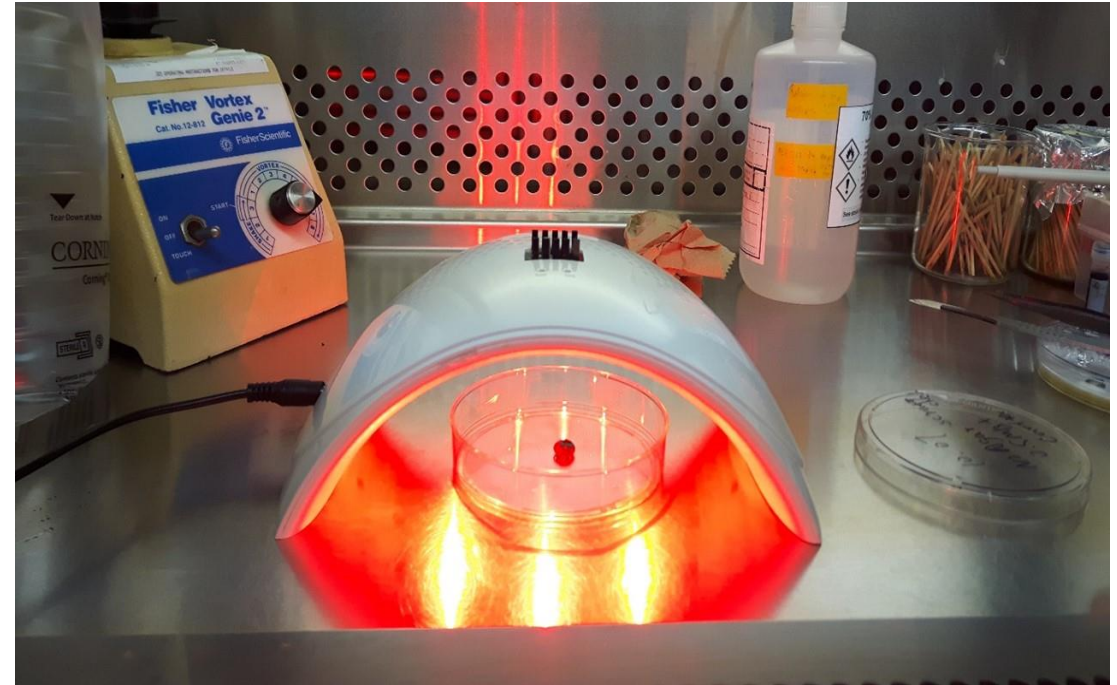
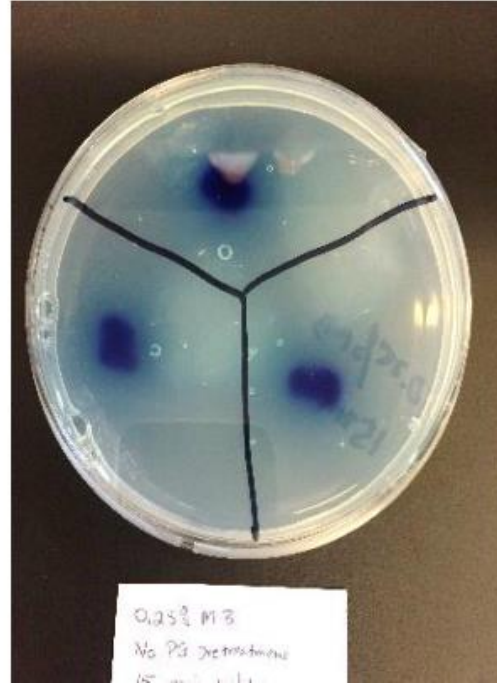
## Achieve

Efficacy • Safety • Ease of use





# Modifying the existing science





# What ToeFX looks like



Single-use disposable applicators



Light source designed to fit the parabola of the foot





Approved by Health Canada Nov 2020

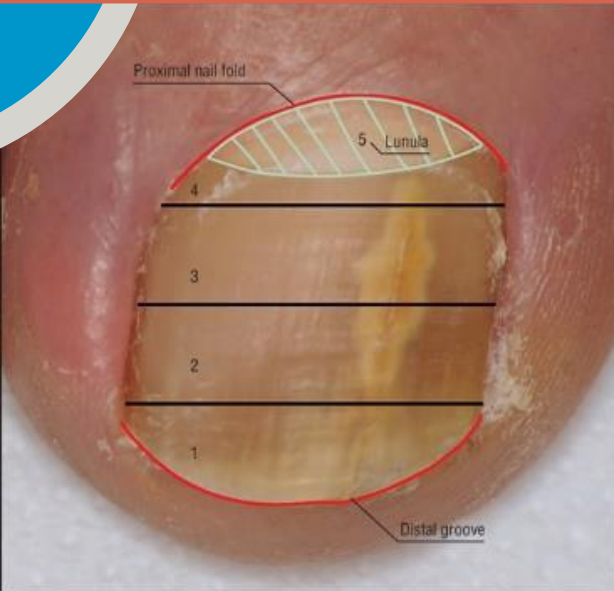


- Class 2 medical device
- 6-month clinical trial with 20 patients (29 toes)
- Evolved from existing photodisinfection technology





# OSI - severity scoring



## Criteria:

- Total area
- Proximity to the matrix
- Thickness

## OSI Score

Mild =  $\leq 5$

Moderate = 6 - 15

Severe = 16 - 35





# Results: 97% of patients responded

Improvement in clear nail		6 months of ToeFX
50-100%	<b>Excellent</b> (near or total elimination of fungus) <b>or very good results</b>	<b>76% of patients</b>
30-50%	Good	21% of patients
<30%	No or poor response	3% of patients

**Preventive sessions very important!**



# Safe and painless for the patient

- No side effect were recorded
- No known contraindications
- Selective, only attacking fungus cells – healthy cells untouched
- Contraindication with G6PD
- Caution with Diabetes





# Case Study-Female, 49, Severe (OSI=26)



80% – March 2, 2020



31% – June 8, 2020



0% – Sept 14, 2020

KOH test negative





# Case Study- Female, 39, Moderate (OSI=6)



31% – March 19, 2020



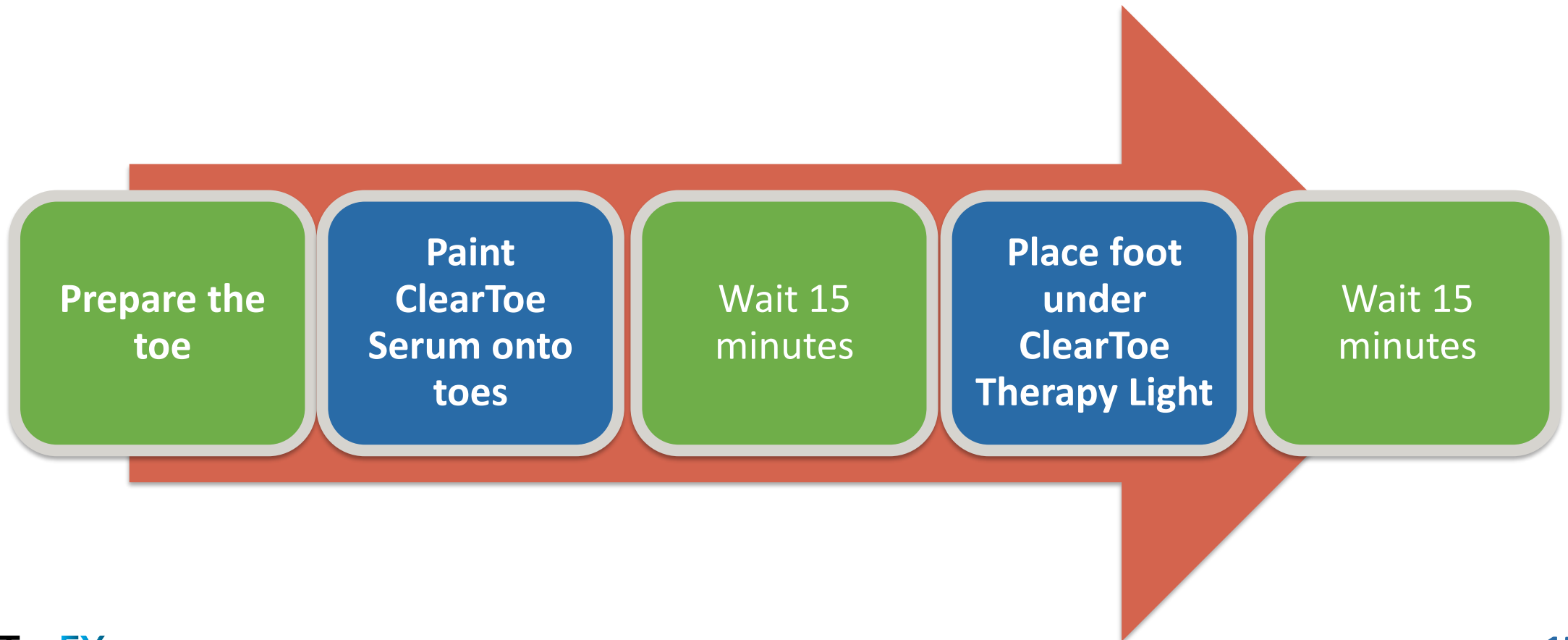
8% – June 25, 2020



0% – Sept 24 2020

KOH test negative

# ToeFX Treatment Regimen



# Tips for your practice

## Efficacy

Cover the nail

## Compliance: bi-weekly

Send reminders

## Seniors

Manage expectations;  
nails grow slower







## Roger: toe-taly happy

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*I am so grateful and excited that I can see the white of my nails. Can't remember when was the last time I did. I actually have toenails now!*

Kerry, 64, ToeFX patient



# A typical starting point







T0 Trichophyton rubrum



T1



T2



T4



T5



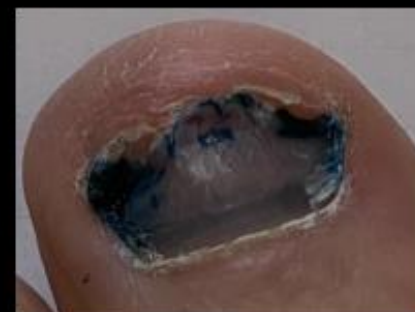
T6



T7



T8




T9



T10

# Debridement is Key

Podiatry Burs Carbide Burs RT515LSQ TIAN CARBIDE CUTTER LARGE CONE BUR



RT515LSQ TIAN CARBIDE


Model: RT515\_LSQ\_TIAN  
Manufactured by: Rotatool

\$50.00

Quantity:

[Add to Cart](#)

RT505NEM CARBIDE SMALL





Model: RT505NEM  
Manufactured by: Rotatool

\$40.00

Quantity:

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Podiatry Burs Carbide Burs RT501NEQ BALL BUR 2.1MM



RT501NEQ BA

Model: RT501NEQ  
Manufactured by: R

\$20.00

Quantity:

[Add to Cart](#)

# New study results



**Collaboration with Tannis Sorge, RN**  
**Tannis has 27 years of experience as a**  
**foot care nurse and educator.**

**The problem: most antifungal studies**  
**exclude severe patients!**



# Re-infection: the elephant in the room



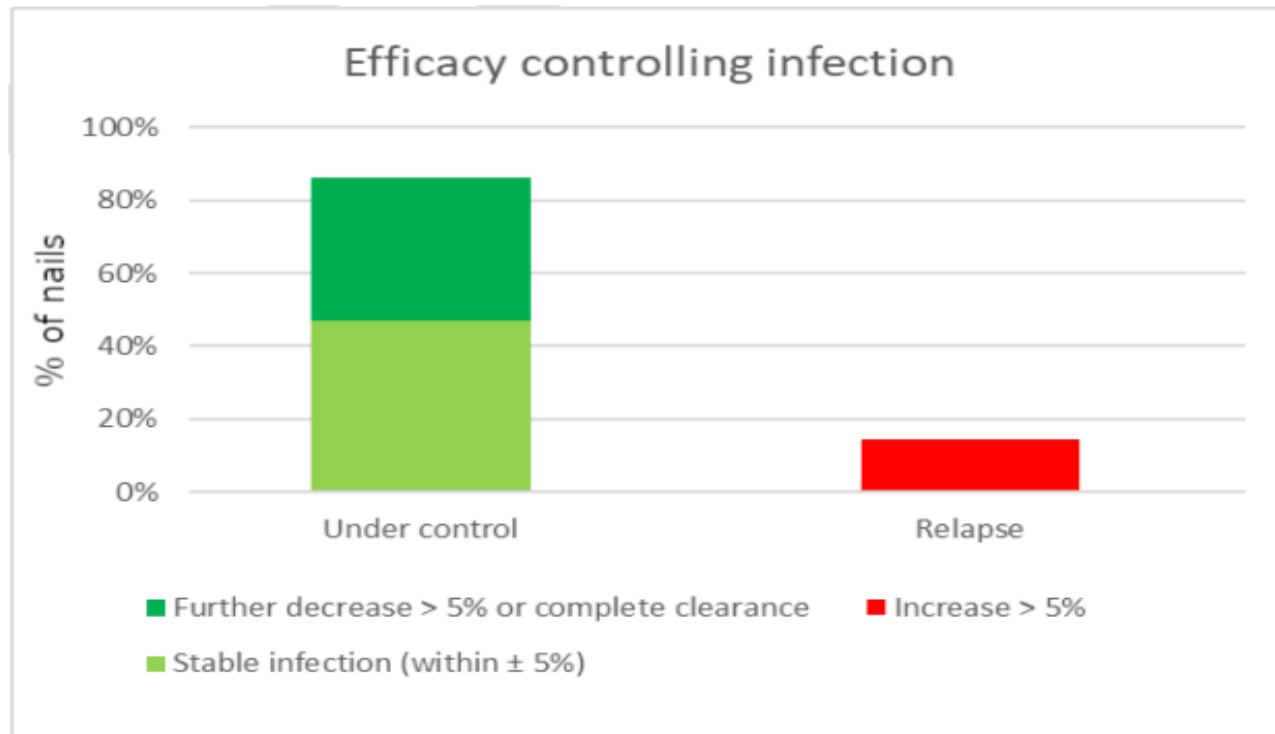
- Every clinician knows that fungus patients tend to re-infect
- Relapse rate is estimated from 20-50% --> probably more because it's not well-studied

# ToeFX studied the elephant in the room.



- **ToeFX sponsored a 1-year study of a maintenance treatment protocol for prevention of relapse.**
- **Sites in BC and in ON**
- **56 toenails**

# Photodisinfection keeps the fungus at bay



- **Treat the patient every 6-8 weeks after an initial regimen of ToeFX**
- **86% of patients experienced no relapse**
- **Patients either improved or stayed the same**



# ToeFX Treatment Regimen

