

**Report - Clinical Trial conducted by Dr Dinowitz
(Podiatrist - New York, USA in January/March
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Dear Mr. Johnston,

Allow me to utilize this method of e-mail to comment on my usage of the 12% Tinea cream and the 8% Nail lotion. My experience with the products has been nothing less than remarkable. As a practicing Podiatrist here in New York, USA for twenty five years there have been many, many products that have come and gone all with little success. Your AMYCOT® cream and lotion has proven its efficacy far beyond my hopes as a topical application. As per my study, at least 80% of the patients showed a 75% improvement on their fungal nails in 90 days, and those that I utilized your fungal cream for their tinea had 100% improvement in less than 30 days. Your product is safe, easy to use and a tremendous improvement over any fungal products I have used.

Dr Howard Dinowitz
2nd September 2006

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Onychomycosis of the toe nails has an estimated prevalence of more than 10% in the general population in countries such as Australia, the United States and the United Kingdom, making it the most common cause of abnormal nails. (1) Onychomycosis of the toenails has long plagued individuals. Some of the objective findings commonly identified are thickness, discoloration, dystrophic shaping and brittleness. Subjective symptoms that often present are pain, limitation of ambulation, malodor and unappealing esthetics.

Most products currently available are fungistatic and simply do not cure the disease. The available fungicidal products are at best a bit better. Patients abhor taking any additional oral medication. This class of medication comes with a plethora of side effects including liver toxicity.

This study was a ninety day assay that contained fifty individuals. Fifteen were diabetics; none of the participants had any immunosuppressant disorders or any system wide dermatologic disorders. None of the patients had Psoriasis. The ages of the patients ranged from 21 to 72 years of age.

The subjects were treated over a period of 90 days with a combination of 12% Amycot cream and 8% Amycot lotion. The cream or lotion was applied to the fungus nails twice daily for twelve weeks. Patients returned every four weeks. After observing nail changes, a rotary burr was used to slightly flatten, shape and clean any fungal debris. A scale of comparison, the Bonkelascale, was used to define the objective changes that were observed. The Bonkelascale utilizes comparative changes based on the criteria and findings used in twenty three years of clinical practice.

The Bonkelascale of clinical presentation of onychomycosis is as follows:

Class 4- indicates a thick, discolored and dystrophic nail with mal-odor and pain and limitation of ambulation. One or more.

Class 3- indicates a less thick, less discolored and less dystrophic nail with less mal-odor and less pain and less limitation of ambulation. One or more.

Class 2- indicates a discolored and dystrophic nail with a slight mal-odor with slight pain and slight limitation of ambulation. One or more.

Class 1- indicates a less discolored and less dystrophic nail with no mal-odor with no pain and no limitation of ambulation. One or more.

The results are as follows:

There were ten patients who started in class 4

6 improved to class 3

2 improved to class 2

2 remained unchanged

There were 26 patients who started in class 3

23 improved to class 2

1 improved to class 1

2 remained unchanged

There were 11 patients who started in class 2

10 improved to class 1

1 remained unchanged

There were 3 patients who started on class 1

2 appeared fully recovered

1 remained unchanged

In Summary:

With the utilization of the Bonkelascale it was made apparent that by topical application of either 12% Amycot cream or 8% Amycot lotion a qualitative and quantitative improvement of the onychomycotic nail took place.

In all classes studied, an average of 80% of the fungal nails applied with 12% Amycot cream or 8% Amycot lotion demonstrated an improvement of one full class. An average of 15% demonstrated an improvement of two full classes. A remainder of 5% demonstrated either full recovery or remained unchanged.

It is made clear that the utilization of 12% Amycot cream or 8% Amycot lotion significantly reduces the objective findings and subjective symptomatology of Onychomycosis of the toenails.

References:

(1) Ghannoum MA, Hajjeh, RA, Scher R, et al.

A large scale North American study of fungal infections isolated from nails: The frequency of Onychomycosis, fungal distribution and fungal susceptibility patterns.

Journal of American Academy of Dermatology 43:641, 2000

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