

A New Classification System for Grading the Severity of Onychomycosis

Onychomycosis Severity Index

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Objective: To establish and validate a new system to define the severity of onychomycosis. The Onychomycosis Severity Index (OSI) score is obtained by multiplying the score for the area of involvement (range, 0-5) by the score for the proximity of disease to the matrix (range, 1-5). Ten points are added for the presence of a longitudinal streak or a patch (dermatophytoma) or for greater than 2 mm of subungual hyperkeratosis. Mild onychomycosis corresponds to a score of 1 through 5; moderate, 6 through 15; and severe, 16 through 35.

Design: Consensus conference.

Setting: Teleconference.

Participants: The consensus group included 5 dermatologists, 1 dermatology resident with an interest in nail disorders, and a statistician. The meetings were held by closed teleconference.

Main Outcome Measures: Index reliability.

Results: The reliability of the OSI system was assessed in 2 steps. The first assessment included 37 dermatologists who scored 8 photographs of onychomycosis after being taught how to use the OSI. The scoring system showed very high reliability (Cronbach α =0.99 and intraclass correlation coefficient [ICC]=0.95). The second assessment entailed evaluation of 49 nails by 3 dermatologists, including an expert in the OSI. This assessment was conducted at the University of Alabama at Birmingham and at the Oregon Dermatology and Research Center, Portland. The scoring system showed very high reliabilities at both sites (Cronbach α =0.99 and ICC=0.96 at the University of Alabama at Birmingham, and Cronbach α =0.98 and ICC=0.93 at the Oregon Dermatology and Research Center).

Conclusion: The OSI is a new, simple, objective, reproducible numeric system to grade the severity of onychomycosis.

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ONYCHOMYCOSIS, A COMMON disease of the nail unit caused by dermatophytes, nondermatophyte molds, and yeasts, has a prevalence of approximately 2% to 13% worldwide.¹⁻⁸ Although many reports describe factors that predict a poor response to treatment, there is currently no system to clinically grade the severity of onychomycotic nail disease. Such a scale is necessary for clinical trial inclusion criteria, for clinician guidance in treatment choice, and for the prediction of therapeutic outcome. An example of the need for a grading system is the recent trial⁹ of ciclopirox olamine, 8%, in which mild to moderate disease was arbitrarily defined as 20% to 65% involvement of the nail plate. If a 20% area of involvement of the nail is considered mild, the clinician is left wondering how to define disease involving less than 20% of the nail. The boundary between mild and moderate disease is not clearly delineated. In ad-

dition, area alone does not necessarily predict disease severity. A nail with very limited involvement but significant thickness may have a poor prognosis.

A consensus conference was convened to develop an objective, reproducible numeric grading system describing the extent and involvement of distal subungual onychomycosis (DSO) that separates the nail involvement into a mild, moderate, or severe category. This new classification system could be an important tool for clinical trials, as a guide to treatment choice, and for the prediction of response to treatment.

METHODS

CONSENSUS GROUP

The consensus group consisted of 5 dermatologists (A.T., R.D., R.S., P.R., and B.E.) who are nail and onychomycosis specialists, 1 dermatology resident (C.C.) with a special inter-

Table 1. Poor Prognostic Factors

Patient Characteristic	Nail Characteristic	Organism
Immunosuppression	Subungual hyperkeratosis >2 mm	Nondermatophyte molds
Poor peripheral circulation	Significant lateral disease	Yeasts
Poorly controlled diabetes mellitus	Dermatophytoma (streak or patch) >50% Involvement Slow rate of nail growth Severe onycholysis Total dystrophic onychomycosis Matrix involvement	Mixed bacterial/fungal infections

est in nail disorders, and a statistician (J.D.), who met by closed teleconference and e-mail. A total of 6 teleconferences were held, each lasting approximately 90 minutes for a total of 9 hours.

The Psoriasis Area Severity Index was the model used by the group to develop a grading system.¹⁰ In selecting clinical features to assess, the group considered the biological progression of DSO. In DSO, infection first spreads from the skin to the distal free edge or the lateral nail folds. In early infection, the nail plate may appear normal, and the infection is limited to the stratum corneum of the nail bed and the hyponychium. Eventually, this often leads to thickening of the stratum corneum (subungual hyperkeratosis).¹¹ Then the infection may progress proximally along the rete ridges, appearing as streaks. As the nail plate becomes involved, its color may change to yellow, brown, or gray. Then the subungual hyperkeratosis progresses and the nail plate lifts, causing onycholysis. Over time, the nail plate begins to crumble and may become thickened.¹¹ In some cases, subungual hyperkeratosis is not a prominent feature; instead, patches, longitudinal streaks, or both are present, which are representative of dermatophytomas or fungal “abscesses.” Therefore, in severe cases of DSO, there are 2 subtypes: the first has prominent subungual hyperkeratosis (measured from the nail bed to the nail plate), and the second has fungal patches and/or streaks. These may occur concomitantly. Several characteristics have been associated with a poor response to treatment and are summarized in **Table 1**.¹²⁻¹⁷

The clinical features chosen for scoring in the Onychomycosis Severity Index (OSI) are the area of involvement, proximity of disease to the matrix, occurrence of dermatophytomas, and presence of severe subungual hyperkeratosis (>2 mm). In addition to the onychomycosis severity criteria in the literature (Table 1),¹²⁻¹⁷ more than 100 clinical photographs of diseased nails were examined to select easily identifiable features that represent the burden of disease and the likelihood of a poor treatment response, which is defined as the likelihood of a cure, the treatment length, and the patient’s perception of the disease. The area of involvement and the proximity of disease to the matrix are easily quantifiable and are clear measures of severity. The presence of a dermatophytoma and subungual hyperkeratosis are critical features because they represent the localized fungal burden in the nail.

DEFINITION OF FEATURES

Area of Involvement

Area of involvement is defined as the percentage of affected onychomycotic nail. It is measured using the boundaries of the lateral nail folds, proximal nail fold, and distal nail groove. In cases

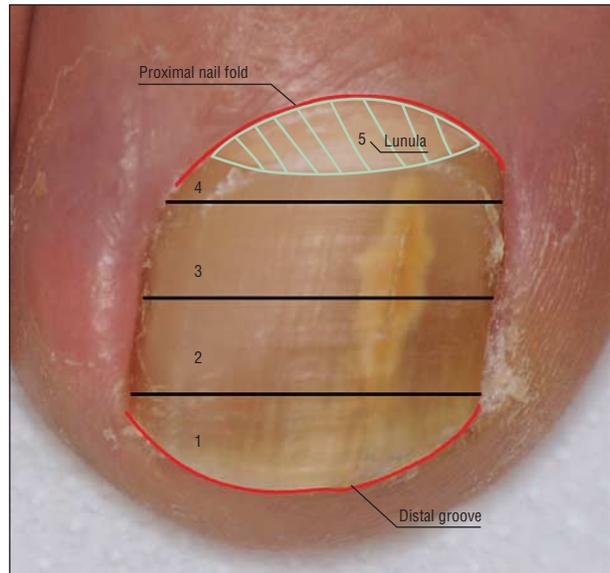


Figure 1. Proximity to matrix scoring. The nail is divided transversely into quarters. Involvement of the distal quarter is given a score of 1 (distal groove in red); if involvement extends to the first half of the nail, it is given a score of 2; the third quarter, a score of 3; and the proximal quarter, a score of 4. Involvement of the lunula (outlined in aqua) and the proximal nail fold (red) represents matrix involvement and is given a score of 5.

of long-term onycholysis, assessing the area of involvement can be particularly challenging because the nail bed disappears as the distal portion of the nail bed becomes keratinized and dermatoglyphics are present.¹⁸ In these instances, the distal groove should be approximated. In other situations, the patient or physician has cut the affected nail, and the area of involvement must be approximated from the distal groove. Although it may be difficult to determine the exact percentage of involvement, it is easier to determine a range of involvement by using a scale. One point is given if the disease involves 1% to 10% of the nail, 2 points for 11% to 25%, 3 points for 26% to 50%, 4 points for 51% to 75%, and 5 points for 76% or more of the nail. No points are awarded if no involvement is noted, and the nail is considered clinically cured. Involvement of 1% to 10% may occasionally indicate a “cure” if mycological analysis results are negative for fungus.¹⁵

Proximity of Disease to Matrix

The nail is divided transversely into quarters starting distally and extending proximally. As the leading edge of disease moves proximally, it is given a score of 1 through 4 depending on which quarter the leading edge extends to. If the proximal edge is in the distal quarter of the nail, a score of 1 is awarded; if it extends to the first half of the nail, a score of 2; the third quarter, a score of 3; and the proximal quarter, a score of 4. A score of 5 is assigned only if there is definitive matrix infection that includes lunula involvement or disappearance of the leading edge under the proximal nail fold (**Figure 1**). We believe that the proximity of infection to the nail matrix is a very important prognostic factor and is a critical component of the OSI. Matrix involvement is an indicator of a poor prognosis and merits a separate score.

The proximity of infection to the nail matrix becomes especially significant when only lateral disease is present. In some instances, lateral disease extending to the lunula may make up only 10% of the nail surface and would be scored as only 1 if proximity to the matrix were not taken into account. Using this measure of severity, the score becomes 5.



Figure 2. Examples of dermatophytoma. A, Yellow patch. Note that the borders of the patch are not contiguous with the distal edge. B, Large yellow patch. C, Yellow streaks.

Table 2. Onychomycosis Severity Index^a

Area of Involvement		Proximity of Disease to Matrix		Presence of Dermatophytoma or Subungual Hyperkeratosis >2 mm	
Affected Nail, %	No. of Points	Amount of Involvement From Distal Edge	No. of Points	Present	No. of Points
0	0	<1/4	1	No	0
1-10	1	1/4-1/2	2	Yes	10
11-25	2	>1/2-3/4	3		
26-50	3	>3/4	4		
51-75	4	Matrix involvement	5		
76-100	5				

^aThe Onychomycosis Severity Index is calculated as follows: the score for area of involvement is multiplied by the score for the proximity of disease to the matrix, and 10 points are added for the presence of a dermatophytoma or subungual hyperkeratosis of greater than 2 mm. A cumulative score of 0 indicates cured; 1 through 5, mild onychomycosis; 6 through 15, moderate onychomycosis; and 16 through 35, severe onychomycosis.

Longitudinal Streaking or Patch (Dermatophytoma)

A longitudinal streak is often near the lateral nail fold. Caution must be exercised not to confuse streaks with onycholysis; consequently, we defined the *longitudinal streak* as extending from the free edge of the nail to the proximal edge of the nail.

Dermatophytomas represent collections of fungal hyphae on histological examination, reminiscent of an aspergilloma.¹⁴ Penetration of antifungal drugs into dermatophytomas is considered limited. One study¹⁷ found that patients with a dermatophytoma were less likely to reach mycological cure when treated with oral terbinafine hydrochloride. A dermatophytoma may exist as a yellow, white, or orange longitudinal streak or as a white or yellow round patch. When evaluating a patch, the area must not be contiguous with the free edge of the nail, and a patch is not to be confused with onycholysis (**Figure 2A** and **B**). The presence of a patch or longitudinal streak is graded with 10 points, thereby pushing any nail with a dermatophytoma into the moderate or severe category depending on the area and length of involvement. More than 1 dermatophytoma may exist in the same nail; however, only 1 is graded, for a maximum of 10 points.

Subungual Hyperkeratosis

Subungual hyperkeratosis represents thickening of the stratum corneum in response to fungal infection, and the height is measured from the nail bed to the nail plate. This finding is considered a poor prognostic factor because antifungal therapy may have difficulty penetrating through the debris when it is greater than 2 mm thick, as stated in previous articles.^{12,13,15,16} The presence of subungual hyperkeratosis of greater than 2 mm is given a score of 10 points. If less than 2 mm of hyperkeratosis is present, no points are awarded. It is important that only the area

of debris and not the nail plate itself is measured when assessing subungual hyperkeratosis.

PERFORMING NAIL ASSESSMENT

To assess the nail, the score for the area of involvement (range, 0-5) is multiplied by the score for the proximity of disease to the matrix (range, 1-5), and 10 points are added if a longitudinal streak or a patch (dermatophytoma) is present or if there is greater than 2 mm of subungual hyperkeratosis (**Table 2**). If multiple streaks or both a streak and a patch are present, only 10 points are given. Because a longitudinal streak or a patch and subungual hyperkeratosis represent a high fungal burden, the presence of these features is scored only once. For example, if a dermatophytoma, a longitudinal streak, a patch, and greater than 2 mm of subungual hyperkeratosis are present, only 10 points are awarded. The maximum score for each nail is 35. Examples of OSI nail scores are illustrated in **Figure 3**.

Mild nail involvement with onychomycosis is classified as a score of 5 or less; moderate, 6 through 15; and severe, 16 through 35. A baseline or clinically cured nail is classified as a score of 0. The scoring system allows for subtle variations in grading; if one clinician grades severity as 50% involvement and another grades it as 55%, multiplying the area of involvement by the proximity to the matrix will give the same overall score of mild, moderate, or severe.

RELIABILITY ASSESSMENT

A preliminary reproducibility assessment was performed by asking 15 dermatology residents, 1 dermatology research fellow, and 1 medical student to evaluate 8 onychomycotic nail photographs using the OSI. The photographs reviewed included



Figure 3. Examples of mild, moderate, and severe nail involvement scored using the Onychomycosis Severity Index system. A, This nail receives a score of 2 (for area of involvement) multiplied by 2 (for proximity of disease to the matrix) for a total of 4. No dermatophytomas or hyperkeratosis is present. This nail has mild involvement. B, This nail receives a score of 1 (for area) multiplied by 3 (for proximity of disease to the matrix) for a total of 3. This nail has mild involvement. C, The great nail receives a score of 3 (for area) multiplied by 4 (for proximity of disease to the matrix) for a total of 12. No dermatophytoma or hyperkeratosis is present. This nail has moderate involvement. D, The great nail receives a score of 1 (for area) multiplied by 5 (for proximity of disease to the matrix owing to matrix involvement) for a total of 5. A lateral streak is present for an additional score of 10. This nail receives a score of 15, which denotes severe involvement. E, The right great nail receives a score of 5 (for area) multiplied by 5 (for proximity of disease to the matrix owing to matrix involvement) for a total of 25. Thick subungual hyperkeratosis is present, for which we add 10 points for a total of 35. This nail has severe involvement.

the photographs in Figure 3. The physicians and students recorded their scores on a grading sheet. Each answer was reviewed and compared with the answers from the consensus group. Although some variation occurred within actual numeric scores, almost all nail scores corresponded to the consensus group's severity category. There were 15 errors among the 136 photographs graded by the 17 participants. All errors were related to misidentification of dermatophytomas, that is, nails were given an additional 10 points for the presence of a

dermatophytoma by the participants when the consensus panel had not. This was the most difficult area for physicians to score because there was a low threshold to score a nail as having a dermatophytoma. Therefore, the aim was to keep the grading of a dermatophytoma as simple as possible by dividing the features into 2 categories: patch or longitudinal streak.

Two assessments were performed to show the reliability of the scoring system. Reliability was assessed using the Cronbach α and the intraclass correlation coefficient (ICC). Values

for Cronbach α greater than 0.7 are generally considered a marker of high reliability, and ICC values of greater than 0.9 generally indicate excellent correlation.¹⁹ The first assessment included 37 dermatologists who were asked to evaluate 8 photographs of onychomycotic nails after being taught how to use the OSI with images of different nails. A standard OSI scoring sheet was provided to each physician, and the same 8 photographs were projected onto a screen for evaluation. The scores were recorded on the OSI scoring sheet. The pictured nails represented a wide range of severity (individual nails had mean scores of 2.1, 2.8, 6.8, 7.4, 8.4, 15.4, 28.6, and 31.5). The scoring system showed very high reliability across all the nails (Cronbach α =0.99 and ICC=0.95).

The second assessment entailed evaluation of 49 onychomycotic nails of patients by 3 people: an expert in the OSI scoring system (P.R. and B.E.) and 2 other dermatologists who were taught how to use the OSI. The expert and 2 randomly selected physicians were then asked to evaluate the same patient nail and record their score on the standard OSI scoring sheet. The physicians were blind to the scores assigned to the nail by the other evaluators. This assessment was conducted at 2 different sites: the University of Alabama at Birmingham (34 patients) and the Oregon Dermatology and Research Center (24 patients). The nails from both sites represented a wide range of severity (both sites had patients with mean severity scores ranging from 1 to 35; patients at the University of Alabama at Birmingham had a mean [SD] score of 15.6 [10.6], and patients at the Oregon Dermatology and Research Center had a mean score of 17.5 [10.3]). The scoring system showed very high reliabilities at both sites (Cronbach α =0.99 and ICC=0.96 at the University of Alabama at Birmingham; Cronbach α =0.98 and ICC=0.93 at the Oregon Dermatology and Research Center).

COMMENT

The OSI is a simple tool consisting of grading the percentage of nail plate involvement, proximity of infection to the matrix, degree of subungual hyperkeratosis, and presence of a dermatophytoma. The OSI showed high statistical reliability across dermatology experts in nail diseases and dermatologists who were not experts in nail disease performing as observers of photographed nails and live patient nails, indicating that it is easily learned and provides consistent results. In general, a nail with a low OSI score would be more likely to respond favorably to conventional therapy, whereas a nail with a high OSI score would be more difficult to treat. Likewise, moderate nail involvement scored as 6 would be easier to treat than moderate nail involvement scored as 15, and severe nail involvement scored as 16 would be easier to treat than severe nail involvement scored as 35.

Two previous scoring systems have been developed. The first system, by Sergeev et al,¹⁶ scored severity on the basis of the clinical form of onychomycosis, length of infection, degree of subungual hyperkeratosis, and rate of nail growth as predicted by age. Scores for each category were used in an equation that calculated a final numeric grade. The second system, by Baran et al,¹² took into account 10 different clinical-, patient-, and organism-centered criteria that were weighted by prognostic implication. It did not define mild, moderate, and severe involvement, but instead was used to predict treatment response, and a higher score suggested a worse prognosis. However, neither of these systems has been validated.

Limitations of our study are that the OSI does not account for several published factors correlating with a poor prognosis, such as the patient's immune status, the organism, and the rate of nail growth. Some variation was seen between observers and, in most instances, involved scoring of the gray hyperpigmentation lining the proximal edge of the infection (Figure 2A). Whether this hyperpigmentation represents active infection or an inflammatory reaction to the infection is debatable because no study looking at this phenomenon currently exists, to our knowledge. The OSI was developed by analyzing photographs of diseased nails; however, it is intended to be used clinically. The interobserver variability in grading nail severity is likely due, in part, to evaluating a photograph of the nail.

By providing a standardized method for evaluating onychomycosis, the OSI provides an objective measurement of disease severity that may have a significant effect on future drug development and research studies. In clinical practice, this tool provides a quick and easy assessment of onychomycosis severity that may be tracked throughout a patient's treatment course. It allows for quick documentation and may be used in place of photographs. Further evidence-based study is needed to properly correlate nail disease severity with response to treatment.

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The Best of the Best

Top-Accessed Article: Herbal Therapy in Dermatology

Bedi MK, Shenefelt PD. Herbal therapy in dermatology. *Arch Dermatol.* 2002;138(2):232-242.

In this article, Bedi and Shenefelt present a comprehensive review of evidence-based uses of herbs in dermatology. Consumers are increasingly interested in therapy or because of the belief that natural treatments lead to fewer adverse effects. By disease, the authors list the herbal treatments that have been studied in humans and animals, effective doses, hypothesized mechanism of action, and potential adverse effects. In a second section, they review cutaneous and systemic adverse effects, including fatalities, that can occur with the use of herbal treatments for dermatologic diseases as well as drug-herb interactions.

Unfortunately, Bedi and Shenefelt's excellent review article cannot serve as an herbal treatment formulary because herbal treatments are considered to be dietary supplements, not drugs, by the Food and Drug Administration and therefore are not regulated or standardized. This lack of regulation puts the practitioner in the difficult position of knowing what may be effective without knowing where to send the patient to get it. In the analysis of various herbal products, not only has the active ingredient been found to be absent in some brands, but, in some cases, the product itself has been found to be adulterated with prescription medications or heavy metals. In the end, the article serves as a caveat against choosing natural over pharmaceutical treatment.

From August 2009 through August 2010, this article was viewed 2325 times on the *Archives of Dermatology* Web site.

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