






Responsiveness of the NAIL-Q Patient-Reported Outcome Measure

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Abstract

Background: Nail conditions account for ~10% of dermatological conditions and can significantly impact quality of life. The NAIL-Q is a patient-reported outcome measure that was developed to measure outcomes that matter to patients treated for any type of fingernail or toenail condition. The ability of the NAIL-Q to detect change (ie, responsiveness) has not yet been established.

Objective: To evaluate the responsiveness of the NAIL-Q in patients undergoing treatment for nail psoriasis, onychomycosis, brittle nails, and retronychia.

Methods: This prospective validation study included patients newly diagnosed at an urban dermatology clinic in the United States. Participants completed the NAIL-Q at baseline, 3, and 6 months. Responsiveness was evaluated by testing predefined hypotheses of the change score. Minimally important differences (MIDs) were calculated using anchor and distribution-based methods.

Results: Of 166 eligible participants, 142 completed a baseline assessment and 79 (56%) and 55 (39%) completed the 3 and 6 month follow-ups, respectively. Mean age of study participants was 56 years (standard deviation=19). Toenail conditions predominated (54%), with onychomycosis being the most common condition (54%). Hypothesis acceptance rates demonstrated validity of the change score for the Appearance 88% (15/17), Nail Symptoms 80% (16/20), and Outcome (treatment-related) 91% (10/11) scales. Effect sizes were moderate for Appearance, Nail Distress, and Outcome scales (0.6–0.7). MID values for the 3 scales ranged from 9 to 14.

Conclusions: The NAIL-Q demonstrated sufficient evidence of responsiveness in patients undergoing treatment for nail psoriasis, onychomycosis, brittle nails, or retronychia.

Keywords

nail disorders, patient-reported outcomes, validation, onychomycosis, nail psoriasis, quality of life

Introduction

Nail conditions are pervasive, affecting people of all ages and comprising ~10% of all dermatological conditions.^{1–5} Nail conditions can significantly reduce quality of life in patients due to their cosmetic appearance, symptoms (eg, pain), and impact on mobility.^{6–9} Treatments for nail conditions can include topical therapy, oral therapy (eg, terbinafine), intralesional therapy, or procedures such as chemical ablation and surgery. Nails are slow-growing, with fingernails and toenails growing at ~3.5 and 1.6 mm/month, respectively.¹⁰ Therefore, noticeable improvements can take substantial time to occur, even with effective treatment. Considering the length of time needed for nail conditions to resolve, it is important to understand outcomes that matter to patients, such as satisfaction with nail appearance, as these

can inform care and how to manage expectations over the course of treatment.

Patient-reported outcome measures (PROMs) are valuable tools for measuring outcomes from the patient

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perspective and are increasingly used in research and clinical care.^{11,12} Currently, 7 PROMs are used for the assessment of nail conditions¹³⁻¹⁹: 5 for onychomycosis (ie Onychomycosis-Specific Questionnaire, Health-Related Quality of Life measure for onychomycosis, ODSQ, NAILQoL, OnyCOE-t) and 2 for nail psoriasis (ie, NPQ10, NAPPQ-QOL). A review of the development and validation of these PROMs based on COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines²⁰ concluded that there is limited evidence supporting their validity, reliability, and responsiveness.^{21,22} In terms of content validity, currently available PROMs do not comprehensively measure nail appearance or a patient's satisfaction with the outcome of treatment. Nail-specific PROMs that focus on 1 diagnosis can also limit comparability across nail conditions and impede measurement in patients who may be experiencing multiple nail conditions at once.^{21,23}

The NAIL-Q²⁴ was developed to address limitations of existing PROMs for nail conditions.^{21,22} NAIL-Q used a concept-driven approach to design multiple independently functioning scales that can be used across nail conditions to measure outcomes related to appearance, nail-related distress, symptoms, function, nail strength, and treatment outcome. Evidence has been published for the content validity, reliability, and construct validity of each of the NAIL-Q scales. However, assessment of the responsiveness of NAIL-Q scales in a real-world setting was beyond the scope of its initial development.

Responsiveness (ie, ability to detect change) is an important property of a PROM, that is assessed in the same manner as construct validity by testing predefined hypotheses related to the change score between time points.^{20,25} It is important for a PROM to demonstrate responsiveness because PROMs are often used in clinical trials or in clinical practice to look at how conditions improve or worsen over time following an intervention.²⁶⁻²⁹ Establishing responsiveness and determining associated minimally important differences (MIDs), ensures that the change measured is valid and can be interpreted by the end user.

This study aimed to evaluate the responsiveness of the NAIL-Q in patients undergoing treatment in 4 nail conditions (ie, psoriasis, onychomycosis, brittle nails, and retronychia), and to establish estimates of the MIDs using anchor and distribution-based methods for each NAIL-Q scale.

Materials and Methods

This prospective validation study was conducted at the Dermatology Clinic at Weill Cornell Medicine in New York City, NY, USA. Data collection was performed online using Research Electronic Data Capture software (REDCap; Vanderbilt University, Nashville, TN, USA).³⁰ Ethics approvals were obtained from Weill Cornell Medicine and the Hamilton Integrated Research Ethics Board at McMaster University (#14622). Each participant was presented with a

digital informed consent form and given the choice to take part in the study or decline. Informed consent was confirmed electronically at the start of the survey and at each follow-up assessment.

Measures

NAIL-Q (<https://qportfolio.org/nail-q/>) includes 7 independently functioning scales, of which 4 are applicable to both fingernails and toenails. The common scales measure satisfaction with nail appearance (10 items), frequency of nail-related distress (7 items), concern with nail symptoms (6 items), and satisfaction with the outcome of treatment (7 items). Scales specific to fingers or toes include Fingernail Function (6 items; frequency of interference), Toenail Function (5 items; frequency of interference), and Fingernail Strength (4 items; concern). Most scales use the past week recall period. Exceptions include the Appearance scale that uses the timeframe of "now," and the Outcome scale that uses the "most recent" treatment. Instructions in the Appearance scale tell participants to answer based on their worst nail if more than 1 is affected. To score a scale, the raw scores are added together and Rasch-transformed on to a scale from 0 (worst) to 100 (best) using the look-up tables provided by the developers. Missing data were imputed using the mean, if at least 50% of the items within a scale were completed.

EQ-5D-5L is a generic utility measure of HRQL that has been applied in nail condition research.^{31,32} Each question rates severity based on 5 levels within 5 domains: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression. A higher score represents a better outcome for the global score, and ratings are based on "today".

Participants

Participants aged ≥ 18 years with nail psoriasis, onychomycosis, brittle nails, or retronychia were recruited at the Dermatology Clinic at Weill Cornell Medicine. Baseline data collection occurred between March 2023 and March 2025. Patients were not included if they did not speak or read English and/or had a cognitive or developmental delay that would impair self-report questionnaire completion. Participants were recruited through in-person and telehealth clinic visits, with follow-up surveys sent via an email invitation that contained secure survey links.

Data Collection

Participants completed the NAIL-Q at baseline prior to initiation of treatment and 3 and 6 months posttreatment. Demographics were collected at baseline and clinical information were collected at all 3 timepoints as needed. Demographic information included age, gender, race, education attainment, marital status, employment status, and

household income. Clinical data included the type of nail condition, severity of the condition (ie, resolved, mild, moderate, severe, very severe), length of time the condition had been present, the number and location for nails that were affected, lost, lifted, or missing, and the severity (none, mild, moderate, severe, very severe) of specific symptoms for each condition (eg, pitting, color, splitting, thickening). For each scale, anchor questions were asked at 3 and 6 months to measure the magnitude and importance of any change. More specifically, participants were asked 2 questions. The first question asked the direction of change (eg, equally as, or more or less satisfied with how the nails look now than 3 months ago) since the last assessment. For participants who responded more or less to the direction of change, the second question asked the importance and magnitude of that change, that is, “small decrease/increase, that is not important to me,” “small decrease/increase, that is important to me,” “moderate decrease/increase, that is important to me,” or “large decrease/increase, that is important to me.”

Analysis

Responsiveness validation. Predefined hypotheses were assessed for each scale based on the change score [time point 2 (T2)–time point 1 (T1); Supplement 1]. According to COSMIN guidelines, an acceptance of 75% or more of a priori hypotheses is considered sufficient evidence to indicate responsiveness of a scale.²⁰ One-way *T*-tests were used to test hypotheses regarding negative and positive change scores. For 1-way tests, a minimum sample of 25 was required to detect a standard effect size (ES; $d=0.5$) with 80% power. Tests of hypotheses assessing no difference from zero were examined using a 2-way independent *T*-test, with a minimum sample size of 33 required to detect a standard ES ($d=0.5$) with 80% power (https://www.statskingdom.com/32test_power_t_z.html). Correlations of normally distributed variables were assessed using Pearson’s correlation coefficient. When nonnormality of data was present or if data were not interval-level, Spearman’s correlations were used. As per COSMIN criteria,²⁰ coefficients were interpreted as follows: <0.3 dissimilar constructs, 0.3 to 0.5 dissimilar but related constructs, ≥ 0.5 similar constructs. Statistical significance was considered $P < .05$.

Responsiveness indicators

Group level. Paired *T*-tests were used to assess change between timepoints. Kazis ES and the standard response means (SRM) were calculated as indicators of responsiveness.^{33–35} Cohen’s criteria were used to assess the ratio of ES/SRM, with values interpreted as follows: 0.2 small, 0.5 medium, and 0.8 large.³⁵

Individual level. The significance of change at the individual level was calculated as (T2–T1 score)/standard

error (SE)_{diff}, where $SE_{diff} = \sqrt{(SE_{T1}^2 + SE_{T2}^2)}$. Values were interpreted as follows: significant worsening ≤ 1.96 , nonsignificant worsening -1.95 to 0 , no change $= 0$, nonsignificant improvement 0 to $+1.95$, and significant improvement $\geq +1.96$.³⁶

Minimally important differences. Both distribution and anchor-based MID values were calculated. Anchor-based MID values were guided by Devji’s criteria³⁷ and utilized the 2-staged anchor questions described above, which asked about the direction of change, followed by the magnitude and importance of the change. MID values were considered the mean absolute value of the change score based on the subgroup of participants who reported a small, but important change. The distribution-based MID was calculated as $0.5 \times$ standard deviation (SD_{change}) and $0.5 \times$ SRM.³⁸

Results

Of 166 eligible patients, 142 patients completed the baseline survey, resulting in 163 baseline assessments. There were 19 participants who had both their fingernails and toenails affected and completed separate assessments for the 2 locations (Supplement 2). Exclusion of cases was due to lack of consent ($n=3$) and not completing at least 1 NAIL-Q scale ($n=21$). Follow-up survey rates were 56% ($n=79$), and 39% ($n=55$) for 3 and 6 months, respectively. Given that assessments between all 3 timepoints used had a 3 month gap, the data for change between 3 months and baseline, and between 3 and 6 months were stacked resulting in 152 pairs of assessments (fingers and toes) for analysis.

At baseline, participant age ranged from 18 to 89 years (mean=56, $SD=19$) and most were female (68%). Toenail conditions predominated (54%), with 32% having a fingernail condition and 14% having both. Onychomycosis was the most common diagnosed condition (39%) and mainly affected toenails (54%). Brittle nails were the second most common condition (15.6%), more frequently affecting fingernails (36%). Prior to diagnosis, condition duration was between 1 and 10 years for 54% of toenail and 38% of fingernail conditions (Supplements 3 and 4).

Responsiveness Validation

Hypothesis testing was completed for the Appearance, Nail Distress, Nail Symptoms, and Outcome scales (see Supplement 1). The 3 location-specific NAIL-Q scales were excluded due to insufficient sample size. Hypothesis acceptance rates were as follows: Appearance 88% (15/17), Nail Symptoms 80% (16/20), and Outcome 91% (10/11). The Nail Distress scale only had 58% (11/19) of tested hypotheses accepted, not meeting the 75% threshold. Detailed hypothesis testing results are presented in Supplements 5 and 6.

Responsiveness Indicators

Group level. For group-level analyses, only participants who reported improvement were included due to the small sample of participants who reported worsening. Participants who improved showed statistically significant increases in scores ($P < .001$), with mean changes of 6 to 15 points across the scales (Supplements 7). ES were moderate for the Appearance, Nail Distress, and Outcome scales (0.6-0.7), with smaller ES observed for the Nail Symptoms scale (0.3).

Individual level. For the 152 assessment pairs, self-reported change in condition was as follows: 64.5% ($n=100$) improved, 27.1% ($n=42$) did not change, and 5.8% ($n=9$) worsened. For individual level change by scale, the percent that experienced significant change ranged from 56-77% (Supplement 8).

Minimally Important Differences

Mean change scores are displayed by the reported magnitude of change in the anchor question in Supplement 9. MID values, based on a small but important difference, were as follows: 9 points (Appearance), 14 points (Nail Symptoms), and 11 points (Outcome) (Supplement 7).

Discussion

This study used a hypothesis-based approach to assess the validity of the change scores for NAIL-Q scales and provided estimates of MID. The Appearance, Nail Symptoms, and Outcome scales evidenced responsiveness in a group of patients treated for a range of nail conditions. These findings mean that these scales can be applied in longitudinal studies to detect change within these constructs, and that the change scores produced by these tools are valid.³⁹ Both the Appearance and Nail Symptoms scales can be used pre- and posttreatment. The Outcome scale is only applicable to patients posttreatment but could be used to measure change in satisfaction over the course of a treatment, or after a change in treatment. The findings in this study add to the existing evidence for the validity and reliability of the NAIL-Q including the properties of content validity, construct validity, internal consistency, measurement invariance, and test-retest reliability.²⁴

The Nail Distress scale did not meet the COSMIN 75% threshold with only 12/21 hypotheses accepted. Even though the Nail Distress scale did not meet the threshold to evidence responsiveness, 77% of participants experienced significant change at the individual level. Furthermore, at the group level, those who reported improvement had a significant increase in scores for the scale, with a mean change of 13, and a medium ES of 0.7. These findings suggests that the NAIL-Q Distress scale does detect improvement in scores over time with treatment, even though the threshold of acceptance of hypotheses

was not met. Hypothesis testing of the Nail Distress scale may have been influenced by several factors. Concealment behaviors, such as wearing shoes or nail polish to cover the nails, can reduce perceived distress, especially during colder months when it is easier to cover affected nails. Patients may also adapt their behaviors (changing footwear or physical activity) to minimize distress.⁴⁰ Additionally, distress levels may vary by nail condition. For example, onychomycosis primarily affects toenails, which are easy to conceal by wearing shoes, while brittle nails typically affect fingernails, which are hard to conceal.^{41,42} Small sample size by condition limited subgroup analysis, so potential effects by conditions could not be assessed. Also, predefined hypotheses related to the correlation with EQ-5D-5L may have been overestimated as the anxiety and depression subscale may capture more severe psychological symptoms than the Nail Distress scale. The nonsignificant correlation between the EQ-5D-5L anxiety/depression and NAIL-Q Nail Distress change scores ($P = .529$), suggests that these instruments measure different constructs. Further research is warranted to assess the responsiveness of the NAIL-Q Nail Distress scale focusing on conditions where nail-related distress is highly important to patients, with consideration for concealment practices.

Overall, this study reported distribution-based MID that ranged between 9 to 14 points and were similar to the observed anchor-based MID, apart from Nail Distress and Nail Symptoms scales where distribution MID were 11 and 8 points lower, respectively, than the anchor-based estimates. The ES for all scales were large, with only the Symptom scale having an ES below 0.5.³⁵ The large MID values we found suggest that changes in nail conditions that are important to patients may occur sooner than 3 months after treatment is initiated. It is important to note that distribution-based methods are limited as they only consider the variability in the scores and do not consider the patient perspective regarding change.³⁷ The precision of anchor-based estimates from this study was also limited by the sample size, as few participants reported a small difference that was important to them. To meet the precision criteria described by Devji et al, the ratio between the confidence interval width and MID estimate needs to be $<25\%$, or the calculation should have a sample size of at least 150 patients, neither of which was met by this study.³⁷ Therefore, the values presented here should be interpreted with caution. However, it is recommended that multiple methods be used to calculate MID values and then values can be triangulated across methods and studies.³⁸ The values in our study could be combined with future published work to inform a more generalized MID estimate. Further research could incorporate MID objectives into large prospective studies to allow calculations of more precise estimates for target groups.

This study has limitations. First, the study included only 4 nail conditions, potentially limiting generalizability. Follow-up periods for assessing MID may differ by condition due to the growth rate of nails and responsiveness of conditions to different treatments. Lost to follow-up resulted

in smaller sample sizes for most hypotheses limiting power to detect differences, though rates were consistent with similar validation studies of nail conditions. Lastly, insufficient sample size for the Fingernail and Toenail Function scales, as well as the lack of participants reporting deterioration (6%) in their condition, prevented comprehensive analysis of all NAIL-Q scales.

Conclusion

The NAIL-Q has been shown to be valid and reliable in past studies. This study provides evidence of the responsiveness of the NAIL-Q Appearance, Nail Symptoms, and Outcome scales. These scales could be utilized within clinical trials of nail treatments to look at improvement in these constructs over time, and in clinical practice to monitor improvement or deterioration in conditions over time. As the field continues to recognize the importance of patient-centered care, instruments like the NAIL-Q can play an increasingly vital role in optimizing treatment outcomes and advancing a fuller understanding of nail disorder management.

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Not applicable.

Data Availability Statement

Written consent to share data publicly was not obtained from participants, therefore, the research data is not available to share.

Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Drs Anne F. Klassen, Shari R. Lipner, and Maureen O'Malley are co-developers of the NAIL-Q and receive a share of any license revenues as royalties based on their institutions' inventor sharing policy. Dr Anne F. Klassen is an owner of EVENTUM Research, which provides consulting services to the pharmaceutical industry.

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Ethical Considerations

Ethics board approval was obtained from the Hamilton Integrated Research Ethics Board at McMaster University and Weill Cornell Medicine.

Consent to Participate


All research participants provided written informed consent prior to survey completion.

Consent for Publication

Not applicable.

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Supplemental Material

Supplemental material for this article is available online.

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