Original paper

Evaluation of the effectiveness of combined podiatric therapy using essential oils in the topical treatment of toenail onychomycosis

Faustyna Kuros[1], Dominika L. Wcisło-Dziadecka[2]

[1]Department of Medicine and Health Sciences, Institute of Health, Academy of Applied Sciences, Nowy Targ, Poland
[2]Department of Practical Cosmetology and Skin Diagnostics, Faculty of Pharmaceutical Sciences in Sosnowiec, Medical University of Silesia in Katowice, Sosnowiec, Poland

Medical Studies
DOI: https://doi.org/10.5114/ms.2026.158798

Key words: essential oil, fungal infection, nail serum, onychomycosis, topical treatment.

Abstract

Introduction: Mycotic infections are difficult to treat and often require long-term therapeutic regimens. Many authors believe that topical therapy is at the forefront of nail disease treatment because of fewer side effects than combined therapy.
Aim of the research: The present study evaluated the efficacy of podiatric therapy using a blend of essential oils for the treatment of toenail onychomycosis and the quality of life of patients.
Material and methods: A randomised evaluation of the effectiveness of therapy on 40 patients with onychomycosis confirmed by mycological examination was conducted in a podiatry office. The participants were randomly assigned to groups I (experimental) and II (control). After cleaning the pathologically affected fragments of the nail plate, the patients in group I received topical serum with essential oils twice a day.
Results: A significant difference was observed in the effectiveness of the therapy after 5–6 months. Healthy nail growth was observed in 45.0% (n = 9) of Group I patients after 3–4 months of essential oil therapy. In Group II, the corresponding proportions increased over time but were lower than those in Group I at each follow-up visit (20.0%, n = 4). Quality of life scores increased from 2.00 to 5.50 (median) on a scale of 1 to 7 in Group I, and from 2.20 ±0.95 to 4.00 ±1.30 on a scale of 1 to 7 in Group II, respectively. Podiatric therapy improved nail appearance.
Conclusions: The use of essential oil-based serum in combination with nail milling constitutes a suitable topical treatment strategy and can be a safe additional therapy.

Introduction

Onychomycosis (OM) is a chronic infection of the nail apparatus (NA) caused by mycotic pathogens of various species, usually dermatophytes, moulds, and yeast. Dermatophytes such as *Trichophyton rubrum* and *Trichophyton mentagrophytes* are responsible for 90% of toenail infections worldwide. Infection usually involves the distal part of the bed, progressing proximally toward the matrix [1, 2]. Moulds, including *Fusarium*, *Aspergillus*, *Acremonium*, and *Scopulariopsis brevicaulis*, account for approximately 8% of infections, whereas *Candida albicans* accounts for 2% of cases [1, 3]. OM can be acquired as a result of peripheral vascular insufficiency, nail trauma, sports activity, or predisposition due to various genetic factors. Toenails are more commonly affected because of their slower growth. For most patients, OM poses a real medical risk, especially in those with diabetes and those undergoing immunosuppression or anticancer therapy [1, 4]. Moreover, it can lead to permanent damage to nail plates and other NA structures, resulting in reduced quality of life, discomfort, and social limitations. Failure to treat OM can cause local pain, secondary bacterial infections, and cellulitis. The disease often leads to the spread of infection to other parts of the body and its transmission to other people [2, 4, 5].

Mycotic infections are extremely difficult to treat and often require long-term therapeutic regimens because of the high recurrence rate, thick nail plate barrier, biofilm formation, drug-related interactions, and increased prevalence of species resistant to antimycotic medicines in certain ethnic groups [2–4, 6].

It appears from contemporary scientific reports and current publications in line with the tenets of evidence-based medicine (EBM) that, despite the availability of a number of both topical and oral drugs, alternative natural treatments for onychomycosis are still pursued [2, 5, 7]. Essential oils (EOs), which have been extracted and used by humans for centuries, are excellent "candidates" for the topical treatment of OM. Given the number of side effects of systemic treatment, there is an interest in the search for novel and alternative therapies to treat this dermatosis [8]. Many authors believe that topical therapy is at the forefront of the treatment of skin and nail diseases owing to greater tolerance by patients and fewer side effects compared to systemic or combined therapy. In addition, the emergence of resistant strains causes therapeutic failure, highlighting the importance of developing new and alternative treatments for OM [9–11].

Material and methods

The study comprised a randomised evaluation of the effectiveness of podiatric therapy involving the use of a commercially available cosmetic product (serum), applied in accordance with its intended purpose, and it was conducted in a podiatry office between

June 2021 and April 2024 on 40 patients with toenail onychomycosis. The study was conducted in compliance with the principles of the Declaration of Helsinki of the World Medical Association, Good Clinical Practice (GCP) guidelines, and applicable national regulations.

This study was approved by the relevant Bioethics Committee of the Silesian Medical University in Katowice. Because the study did not involve the use of a medicinal product or medical device outside its approved indication, and the intervention was part of routine podiatric practice, registration as a clinical trial in a public registry was not required.

The therapeutic effects observed in the clinical picture of NA and the efficacy of the applied methods were compared in terms of the type of pathogen, and the age and sex of the subject. In addition, the results included the number of applications with each therapy, an assessment of the subjects' quality of life before and after the therapies, and an assessment of the stage of onychomycosis and predispositions contributing to the disease. All study participants (patients) provided written informed consent before participating in the medical research experiment. In minor participants, consent was given in writing by the legal guardian or parent of the participant. Patients included in the research project (or their legal guardian or parent) were given an opportunity to review the final manuscript and provided written consent to publish.

Eligibility was based on physical examination and detailed patient history. An original questionnaire was used to assess the therapy. It consists of several parts concerning the type, location, and aetiopathogenesis of the disease, pain, as well as evaluation of the clinical picture of NA and the quality of patients' life before and after therapy. Inclusion criteria for the study included patients with any type of onychomycosis of the toenails with confirmed positive mycological examination (direct examination and culture test), and current absence of general and topical antibiotic therapy in the evaluated area. The exclusion criteria for the study were patients who were under 10 years of age, pregnant and breastfeeding women, hypersensitivity to essential oils, allergy to fragrances, mental illness or other ailments that could impair cooperation with a specialist, and no informed consent from the patient.

The study participants were randomly assigned to an experimental or control group (sequentially numbered). In both groups, fragments of infected nail plates and subungual NA hyperkeratoses were removed using a podiatric milling machine with a dust absorber, sterile tools (cuticle clippers, podiatric probe), and cutters made of the highest quality stainless steel (meeting international quality management standards ISO 9001:2008). In the applied procedure, a cemented carbide cutter with a standard cross-cut was used at intervals of 4–6 weeks with no interruption of the routine regimen applied toward the patient. This allowed the removal of large fragments of the infected nail in a short time, with no overheating of the nail plate. Following the initial preparation with the cemented carbide cutter, a steel ball cutter with cross-cutting and a slot cutter were used to clean the infected subungual keratosis precisely. The cleansing procedure was completed with a diamond cutter in the shape of a conical frustum to gently grind and smooth all the irregularities of the entire AP. In the experimental group, patients applied – to the nail bed and the cleaned nail plate – an antimycotic nail serum based on natural essential oils with INCI composition: *Melaleuca alternifolia* leaf oil, *Lavandula angustifolia* oil, *Thymus capitatus* herb oil, linalool, limonene, *Rosmarinus officinalis* leaf oil, *Eugenia caryophyllus* oil, 4-terpineol, geraniol, citronellol, eugenol, and isoeugenol. Using the included pipette, the serum was applied topically with 1-2 drops of the product twice a day (in the morning and evening). Study participants underwent clinical observation up to 4 times (after 3-4, 5-6, 7-8, and 9-10 months). Subsequently, the changes in the clinical picture of NA were assessed. In addition, the patients were asked to note any side effects that occurred during therapy. Data were collected using an original form, direct observation during follow-up visits, and evaluation of photographic documentation of the nails included in the study, to better monitor the course of the applied therapy.

Statistical analysis

Statistical analysis was performed using R software, version 4.4.2. Comparisons before and after treatment were performed using the paired t-test or Wilcoxon test. Comparisons between study groups and dependency of treatment effectiveness on age, sex, and type of defect were verified using Student's *t*-test, Welch's *t*-test, Mann-Whitney U test, Pearson's χ^2 test, or Fisher's exact test, as appropriate. Normality of distribution was performed using the Shapiro-Wilk test and further verified with skewness and kurtosis. Variance homogeneity was assessed using Levene's test. All statistical calculations were performed at a significance level of a = 0.05.

Results

The study consisted of $N = 40$ patients with nail fungus randomly split into two study groups:

Group I (experimental) – patients treated with essential oil serum after cleaning the infected part of the nail ($N = 20$); Group II (control) – patients with infected nail cleaned but without essential oil treatment ($N = 20$). The proportions of females in the groups were 75.0% and 55.0%, respectively, with no difference between the groups ($p = 0.320$). Mean age was 48.00 ±11.52 years and 51.40 ±14.15 years, respectively, with no difference between groups ($p = 0.410$). Mycological results indicated dermatophytes as the most common group of pathogens responsible for nail fungi (60.0% and 55.0%, respectively, in both study groups). Detailed characteristics of the demographics and clinical assessment of the nails before therapy are presented in Table 1.

Table 1. Demographic characteristics clinical assessment of nails before therapy in both study groups

Variable	Group I (experimental)	Group II (control)	MD/RR (95% CI)	*P*-value
N	20 (100.0)	20 (100.0)	–	–
Sex				
Female	15 (75.0)	11 (55.0)	–	0.320
Male	5 (25.0)	9 (45.0)		
Age [years]	48.00 ±11.52	51.40 ±14.15	–3.40 (–11.66;4.86)	0.410
Education				
Primary	0 (0.0)	0 (0.0)	–	0.602
Vocational	7 (35.0)	9 (45.0)		
Secondary	2 (10.0)	3 (15.0)		
Post-secondary	0 (0.0)	1 (5.0)		
Higher	11 (55.0)	7 (35.0)		
Duration of symptoms [years]	2.00 (0.98;5.00)	8.00 (3.75;20.00)	–6.00 (–14.00;–2.00)	0.002
Occupation				
Cook	2 (10.0)	3 (15.0)	–	0.650
Salesman	2 (10.0)	2 (10.0)		
Teacher	1 (5.0)	2 (10.0)		
Accountant	3 (15.0)	0 (0.0)		
Babysitter	2 (10.0)	1 (5.0)		
Other	10 (50.0)	12 (60.0)		
Previous antifungal treatment	5 (25.0)	3 (15.0)	1.67 (0.46;6.06)	0.695
Chronic illnesses	6 (30.0)	9 (45.0)	0.67 (0.29;1.52)	0.514
Medications	3 (15.0)	4 (20.0)	0.75 (0.19;2.93)	> 0.999
Cosmetic treatments	13 (65.0)	8 (40.0)	1.62 (0.87;3.04)	0.205
Hybrid nail polish	11 (84.6)	7 (87.5)	0.97 (0.68;1.37)	> 0.999
Cosmetic pedicure	3 (23.1)	1 (12.5)	1.85 (0.23;14.85)	> 0.999
Pets	7 (35.0)	4 (20.0)	1.75 (0.61;5.05)	0.479
Travel to tropical countries	3 (15.0)	2 (10.0)	1.50 (0.28;8.04)	> 0.999
Public places	8 (40.0)	7 (35.0)	1.14 (0.51;2.55)	> 0.999
Gym	2 (25.0)	1 (14.3)	1.75 (0.20;15.41)	> 0.999
Hospital	1 (12.5)	0 (0.0)	–	> 0.999
Swimming pool	6 (75.0)	6 (85.7)	0.88 (0.53;1.44)	> 0.999
Sauna	2 (25.0)	3 (42.9)	0.58 (0.13;2.55)	0.608
Hotel	0 (0.0)	2 (28.6)	–	0.200
Predisposing factors				
Excessive sweating	6 (30.0)	7 (35.0)	0.86 (0.35;2.10)	> 0.999
Immune disorders	6 (30.0)	6 (30.0)	–	> 0.999
Mechanical damage to nails	13 (65.0)	16 (80.0)	0.81 (0.55;1.20)	0.479

Table 1. Cont.

Variable	Group I (experimental)	Group II (control)	MD/RR (95% CI)	*P*-value
Orthopaedic defects of fingers	9 (45.0)	8 (40.0)	1.12 (0.55;2.32)	> 0.999
Synthetic footwear	15 (75.0)	14 (70.0)	1.07 (0.73;1.57)	> 0.999
Insufficient foot hygiene	8 (40.0)	11 (55.0)	0.73 (0.37;1.42)	0.527
Garden work	4 (20.0)	3 (15.0)	1.33 (0.34;5.21)	> 0.999
Other	9 (45.0)	11 (55.0)	0.82 (0.44;1.53)	0.752
Fungal infection eliminated	0 (0.0)	(0.0)	–	–
Symptoms				
Pain when pressing in footwear	5 (25.0)	5 (25.0)	–	> 0.999
Unpleasant foot odour	7 (35.0)	8 (40.0)	0.87 (0.39;1.95)	> 0.999
Itchy skin	5 (25.0)	8 (40.0)	0.62 (0.25;1.58)	0.500
Redness and swelling of the nail fold	5 (25.0)	6 (30.0)	0.83 (0.30;2.29)	> 0.999
Discharge from under the nail plate	0 (0.0)	1 (5.0)	–	> 0.999
Slow nail growth	14 (70.0)	18 (90.0)	0.78 (0.56;1.07)	0.235
Other	0 (0.0)	(0.0)	–	–
Current treatments for fungal infection	0 (0.0)	(0.0)	–	–
Clinical features of infected nails				
Nail plate elevation	8 (40.0)	7 (35.0)	1.14 (0.51;2.55)	> 0.999
Subungual keratosis	15 (75.0)	13 (65.0)	1.15 (0.77;1.74)	0.730
Onycholysis	14 (70.0)	11 (55.0)	1.27 (0.78;2.08)	0.514
Crumbling of nail plates from the free edge	6 (30.0)	11 (55.0)	0.55 (0.25;1.19)	0.201
Long, yellow or brown areas of onycholysis	14 (70.0)	8 (40.0)	1.75 (0.95;3.22)	0.112
White, matt spots on the nail surface	4 (20.0)	11 (55.0)	0.36 (0.14;0.95)	0.05004
Black discolouration of the nail plate	3 (15.0)	6 (30.0)	0.50 (0.14;1.73)	0.451
Yellow-orange area of onycholysis in the central part of the nail (dermatophytoma)	6 (30.0)	3 (15.0)	2.00 (0.58;6.91)	0.451
Longitudinal nail grooves	14 (70.0)	12 (60.0)	1.17 (0.74;1.85)	0.740
Maceration and cracks in the skin in the third and fourth interdigital spaces	6 (30.0)	5 (25.0)	1.20 (0.44;3.30)	> 0.999
Inflammation of the nail folds (paronychia)	1 (5.0)	1 (5.0)	–	> 0.999
Exfoliative changes on the soles of the feet	9 (45.0)	12 (60.0)	0.75 (0.41;1.37)	0.527
Dissemination of vesicles and lumps on the skin of the feet	2 (10.0)	2 (10.0)	–	> 0.999
Affected nails				
Right foot				
Big toe	14 (70.0)	12 (60.0)	1.17 (0.74;1.85)	0.740
II toe	4 (20.0)	5 (25.0)	0.80 (0.25;2.55)	> 0.999

Table 1. Cont.

Variable	Group I (experimental)	Group II (control)	MD/RR (95% CI)	*P*-value
III toe	2 (10.0)	3 (15.0)	0.67 (0.12;3.57)	> 0.999
IV toe	4 (20.0)	5 (25.0)	0.80 (0.25;2.55)	> 0.999
V toe	6 (30.0)	7 (35.0)	0.86 (0.35;2.10)	> 0.999
Left foot				
Big toe	13 (65.0)	15 (75.0)	0.87 (0.58;1.30)	0.730
II toe	4 (20.0)	2 (10.0)	2.00 (0.41;9.71)	0.661
III toe	3 (15.0)	5 (25.0)	0.60 (0.17;2.18)	0.695
IV toe	2 (10.0)	6 (30.0)	0.33 (0.08;1.46)	0.235
V toe	4 (20.0)	8 (40.0)	0.50 (0.18;1.40)	0.301
Mycological results (aetiology)				
Dermatophytes	12 (60.0)	11 (55.0)	–	0.483
Yeasts and yeast-like fungi	2 (10.0)	1 (5.0)		
Moulds	4 (20.0)	2 (10.0)		
Mixed infections	2 (10.0)	6 (30.0)		
Identified pathogens				
Scopulariopsis brevicaulis	2 (10.0)	0 (0.0)	–	0.487
Trichophyton rubrum	8 (40.0)	11 (55.0)	0.73 (0.37;1.42)	0.527
Penicillum species	1 (5.0)	0 (0.0)	–	> 0.999
Trichophyton mentagrophytes	6 (30.0)	5 (25.0)	1.20 (0.44;3.30)	> 0.999
Candida species	1 (5.0)	3 (15.0)	0.33 (0.04;2.94)	0.605
Acremonium species	0 (0.0)	2 (10.0)	–	0.487
Fusarium oxysporum	2 (10.0)	2 (10.0)	–	> 0.999
Aspergillus spp	0 (0.0)	1 (5.0)	–	> 0.999
Candida albicans	1 (5.0)	1 (5.0)	–	> 0.999
Fusarium solani	0 (0.0)	1 (5.0)	–	> 0.999
Acremonium strictum	1 (5.0)	0 (0.0)	–	> 0.999
Fusarium species	0 (0.0)	1 (5.0)	–	> 0.999
Candida parapsilosis	0 (0.0)	1 (5.0)	–	> 0.999
Type of onychomycosis				
DSLO	18 (90.0)	14 (70.0)	–	0.390
PSO	0 (0.0)	1 (5.0)		
SWO	0 (0.0)	2 (10.0)		
EO	2 (10.0)	2 (10.0)		
TDO	0 (0.0)	1 (5.0)		

Categorical data are presented as n (%). Age is presented as mean ± standard deviation, and symptom duration is presented as median and interquartile range. MD – mean, or median difference (experimental vs. control); RR – relative risk (experimental vs. control); CI – confidence interval; DSLO – distal and lateral subungual onychomycosis, PSO – proximal subungual onychomycosis; SWO – superficial white onychomycosis, EO – endonyx onychomycosis, TDO – total dystrophic onychomycosis. Comparisons between groups were performed using Student's t-test (age), Mann-Whitney U test (duration of symptoms), and Pearson's c2 test or Fisher's exact test for categorical variables, as appropriate.

Table 2. Therapy characteristics and effectiveness in both study groups

Variable	Group I (experimental)	Group II (control)	MD/RR (95% CI)	*P*-value
Therapy duration				
3 months	0 (0.0)	0 (0.0)	–	> 0.999
4 months	1 (5.0)	1 (5.0)		
5 months	3 (15.0)	3 (15.0)		
> 5 months	16 (80.0)	16 (80.0)		
Therapy duration [months]	8.50 (6.75;10.00)	7.00 (6.00;9.00)	1.50 (0.00;2.00)	0.223
Number of procedures				
≤ 5	5 (25.0)	9 (45.0)	–	0.320
> 5	15 (75.0)	11 (55.0)		
Number of procedures				
≤ 4	5 (25.0)	3 (15.0)	–	0.695
> 4	15 (75.0)	17 (85.0)		
Number of procedures				
3	1 (5.0)	1 (5.0)	–	0.047
4	4 (20.0)	2 (10.0)		
5	0 (0.0)	6 (30.0)		
> 5	15 (75.0)	11 (55.0)		
Number of procedures	7.50 (5.50;9.00)	6.00 (5.00;8.25)	1.50 (–1.00;2.00)	0.402
Pain during procedure [1-4]*	1.00 (1.00;2.00)	1.00 (1.00;2.00)	0.00 (0.00;0.00)	> 0.999
Concerns during therapy				
I wasn't afraid of anything	10 (50.0)	10 (50.0)	–	> 0.999
I was worried that I might damage my nail	10 (50.0)	8 (40.0)	1.25 (0.63;2.50)	0.751
I was afraid that I would have to go to podiatry for the rest of my life	1 (5.0)	4 (20.0)	0.25 (0.03;2.05)	0.342
Because of the therapy, I had to choose the right footwear	2 (10.0)	4 (20.0)	0.50 (0.10;2.43)	0.661
The whole therapy was burdensome for me	1 (5.0)	0 (0.0)	–	> 0.999
Other	0 (0.0)	0 (0.0)	–	–
Stage of DSLO infection				
Before therapy	2.00 (1.75;3.00)	2.00 (1.75;3.00)	0.00 (0.00;1.00)	0.839
After therapy	0.50 (0.00;2.00)	2.00 (1.00;2.25)	–1.50 (–2.00;0.00)	0.051
Therapy effectiveness [1–3]**				
After 3–4 months	1.00 (1.00;2.00)	1.00 (1.00;1.00)	0.00 (0.00;1.00)	0.142
After 5–6 months***	2.00 (1.50;2.50)	1.00 (1.00;2.00)	1.00 (0.00;1.00)	0.026
After 7–8 months***	3.00 (1.50;3.00)	2.00 (1.75;3.00)	1.00 (0.00;1.00)	0.530
After 9–10 months***	2.50 ±0.71	2.33 ±0.82	0.17 (–0.66;1.00)	0.673

*Categorical data are presented as n (%). Numeric variables are presented as mean ± standard deviation (therapy effectiveness after 9–10 months) or median and interquartile range (other numeric variables) depending on normality. MD – mean or median difference (experimental vs. control); RR – relative risk (experimental vs. control); CI – confidence interval; DSLO – Distal and Lateral Subungual Onychomycosis. Comparisons of groups were performed using Student's t-test (therapy effectiveness after 9–10 months), Mann-Whitney U test (other numeric variables), and Pearson's c2 test or Fisher's exact test for categorical variables, as appropriate. *1, no pain, 4 meant excessive pain. **1 meant no improvement, 3 meant significant improvement. ***Based on n = 38 patients after 5–6 months, n = 27 patients after 7–8 months and n = 16 patients after 9–10 months.*

A significant difference was confirmed in the therapy effectiveness after 5–6 months. On a scale from 1 to 3 (1 = no improvement, 3 = significant improvement), therapy effectiveness was proven to be more effective in Group I (experimental) compared to Group II (control), with effectiveness of 2.00 vs. 1.00, MD = 1.00 CI95 [0.00;1.00], $p = 0.026$ (Table 2). Table 3 presents the patients' assessment of the nail picture after therapy. A visual summary of the nail picture assessments after each follow-up is shown in Figure 1. No significant difference was observed in the assessed nail picture between the 2 groups ($p > 0.05$). The proportion of patients who confirmed healthy growth of the nails was 70.0% in Group I (experimental) and 60.0% in Group II (control), with no difference between the groups ($p = 0.740$). A visual summary of the nail picture assessments after each follow-up is shown in Figure 2. Comparison of life quality assessment before and after treatment for both study groups is presented in Table 4. The outcomes reflecting changes in all the measured life quality assessment scales are shown in Figure 3. Effectiveness of treatment against selected predictors is presented in Table 5. The evolution of therapy effectiveness by sex in the study groups is shown in Figure 4. The duration of therapy was tested according to sex, age, and defect type in both study groups. No statistical dependency was observed ($p > 0.05$). One of the effects of podiatry therapy with essential oils is shown in Figures 5 A–D.

Discussion

Onychomycosis (OM) is the most common nail disorder, occurring worldwide with a prevalence of 5.5% and accounting for 50% of all nail disorders seen in clinical practice [9, 11]. Although the number of invasive mycotic infections is steadily increasing worldwide, few clinical studies have investigated the efficacy of topical therapies using essential oils (EOs). The choice of EO treatment requires ethical, evidence-based decision-making and consideration of patients' individual needs, the extent of quality-of-life discomfort, and aesthetic goals [4, 10, 12]. Scientific evidence underpinning EBM conducted *in vitro* has proven that EOs are of great interest in global research and a viable option for alternative treatment of OM [8, 9, 12, 13]. Topical treatment is often the first choice in mild to moderate cases because of the lower risk of systemic side effects and drug-related interactions; however, their efficacy is limited to the presence of hyperkeratosis, which interferes with their absorption at the nail plate level. It is worth noting that the NA plate is an aggregate of very dense keratinised tissue, which provides low permeability for diffusing substances. The penetration of a topical antimycotic drug through the nail plate requires a carrier that is specifically formulated for transungual administration. Some studies have shown efficacy in enhancing transungual penetration using mechanical methods such as nail abrasion, physical techniques such as UV light, carbon dioxide laser, iontophoresis, sonophoresis, or photodynamic therapy, or when chemical penetration aids are used, for example, keratolytic enzymes, urea, mercaptans, sulphides, and hydrogen peroxides [10, 14]. In light of the articles reviewed, it can be concluded that studies on EOs and their penetration present promising data; however, these were gathered mainly from preclinical studies. Interventional studies to date have shown that, compared to other therapies, EOs

Table 3. Assessment of nail picture after the therapy in both study groups

Variable	After 3–4 months		After 5–6 months*		After 7–8 months*		After 9–10 months*	
	Group I	Group II	Group I	Group II	Group I	Group II	Group I	Group II
Does the nail plate adhere to the nail placental? (yes)	4 (20.0)	4 (20.0)	9 (47.4)	8 (42.1)	9 (60.0)	8 (66.7)	7 (70.0)	5 (83.3)
Are there any pathological masses under the nail plate? (yes)	17 (85.0)	15 (75.0)	11 (57.9)	11 (57.9)	8 (53.3)	7 (58.3)	1 (10.0)	3 (50.0)
Are any stains visible on nail plate? (yes)	12 (60.0)	17 (85.0)	10 (52.6)	14 (73.7)	7 (46.7)	5 (41.7)	3 (30.0)	2 (33.3)
Is the structure of the nails smooth? (yes)	2 (10.0)	1 (5.0)	5 (26.3)	4 (21.1)	4 (26.7)	4 (33.3)	5 (50.0)	2 (33.3)
Is the skin around the nails properly coloured and unchanged? (yes)	12 (60.0)	11 (55.0)	16 (84.2)	11 (57.9)	13 (86.7)	9 (75.0)	9 (90.0)	5 (83.3)
Does the nail plate grow back healthy? (yes)	9 (45.0)	4 (20.0)	13 (68.4)	7 (38.9)	11 (73.3)	8 (66.7)	8 (80.0)	4 (66.7)

*Data presented as n (%). *Based on n = 38 patients after 5–6 months, 27 patients after 7–8 months, and 16 patients after 9–10 month.*

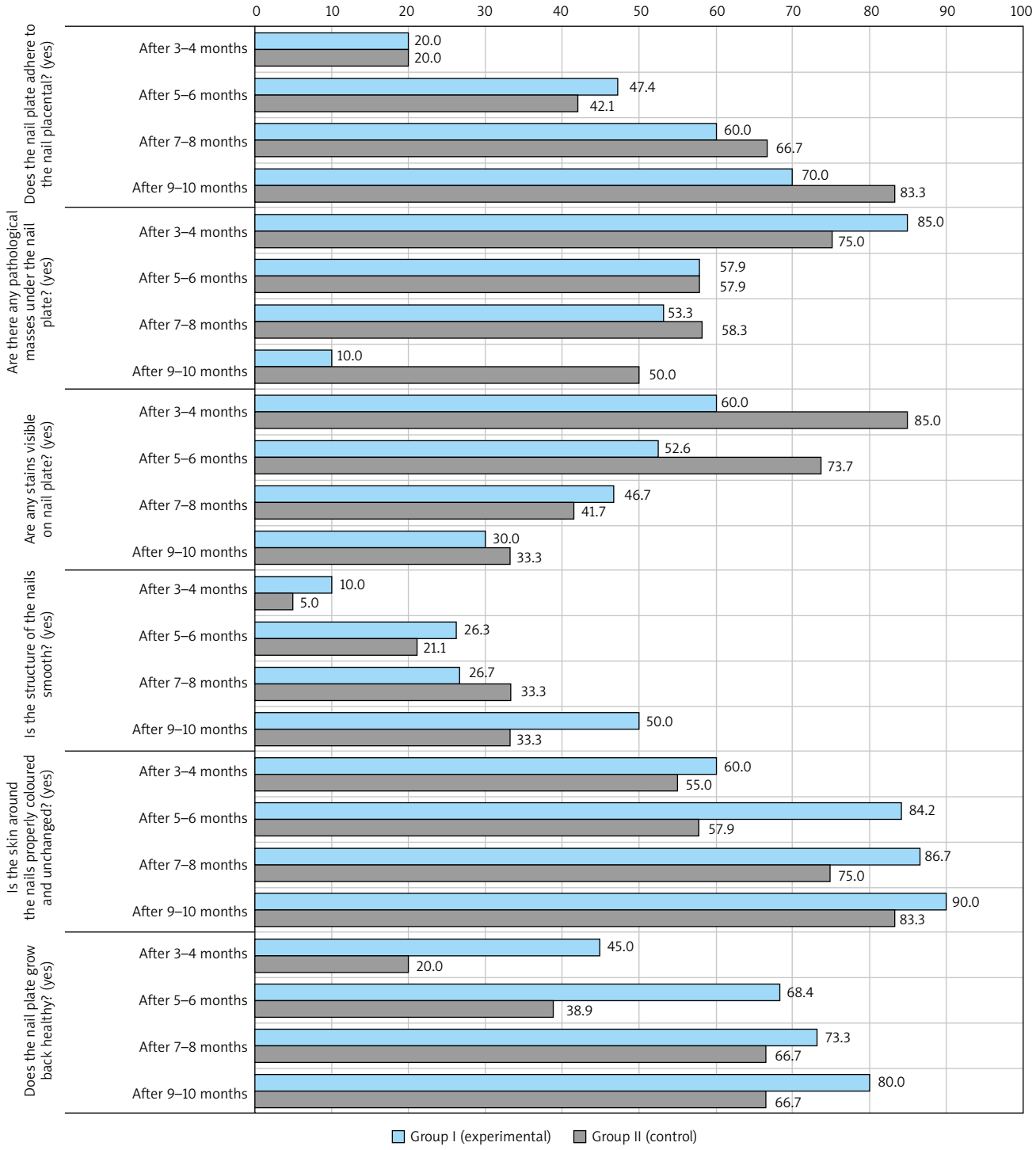

Figure 1. Assessment of nail picture after the therapy in both study groups, expressed as proportion of patients in respective group

Figure 2. Assessment of nail picture at last follow-up after the therapy, in both study groups, expressed as proportion of patients in respective group

have proven to be as effective as conventional therapies such as terbinafine, ketoconazole, and clotrimazole. However, most of the identified studies have a low level of evidence because they are preclinical, pointing to the need for experimental studies that can safely constitute the basis for application in clinical practice, as well as contribute to the care of patients affected by OM. One limitation is the small number of existing reviews on natural (non-pharmacological) treatment options for OM [4, 8, 15, 16].

In their effectiveness studies, Alessandrini *et al.* (2020) demonstrated the efficacy and tolerability of a nail oil composed of vitamin E and essential oils of lime, oregano, and tea trees in the treatment of OM. Twenty patients with mild-to-moderate distal toenail onychomycosis caused by *T. rubrum* (14/20), *T. interdigitalis* (3/20), *Fusarium* sp. (2/20), and *Scopulariopsis bevicaulis* (1/20), confirmed by mycological examination, were recommended to apply oil once daily to the lesions. Periodic evaluation of treatment efficacy was carried out using standardised photography and mycological examination (KOH + culture) of the target nail at baseline (T0). Seventeen of the 20 patients were evaluated after 3 months (T1) of therapy, after 6 months (T2) of therapy, and after 6 months of observation (T3). Fourteen of the 20 patients completed the study. Of the 6 patients who resigned from the study, 4 discontinued treatment before the scheduled time, as their pathological nails were completely healed. In 7 out of the 14 patients (50%), toenail onychomycosis was completely healed, while 6 patients showed significant improvement (42.8%) (Figure 3), and one remained stable (7.1%). After a 6-month follow-up, 11 patients showed complete recovery from OM (78.5%), 2 showed significant improvement, and 1 remained stable. Eleven patients also reported a significant improvement in NA after 3 months of therapy. All patients were very satisfied with the treatment, no side effects were reported, and it was proven that the topical antimycotic oil used had a positive effect on the appearance of the toenail plates [17].

Goyal *et al.* (2024) attempted to develop a herbal alternative in the form of an EO-based nail polish (tea tree, frankincense, thyme, oregano, lemon, clary sage, eucalyptus, clove, geranium, ylang ylang, bergamot, lavender, rosemary, and cedar oils). The selection of EOs and the preparation of their blends (EOBs) were based on their antimycotic activity (minimum inhibitory concentration [MIC] and zone of inhibition [ZOI]) and their physiological effects on various pathological parameters of toenail onychomycosis. Different batches of nail polish (N1-N5) were prepared by varying the concentrations of the polymer and film-forming agent, and their formulation properties (drying time, occurrence of white spots, and film texture) were evaluated. The optimal batch of nail polish was filled with the screened EOB and evaluated for various properties and antimycotic activity. The F4 formulation showed minimal MIC among different batches and higher EOB (4.3 cm) compared to the commercially available formulation (3.5 cm), indicating better antimycotic activity. According to the authors, the development of this herbal mixture opens new possibilities for the treatment of OM. Additional studies and clinical analyses are required to confirm its clinical safety and efficacy [18].

Similar to several other effectiveness studies evaluating the efficacy of EOs in the treatment of onychomycosis, the study by Alessandrini *et al.* [17] had small sample sizes, was non-randomised, and had no con-

Table 4. Comparison of life quality assessment before and after treatment, for both study groups

Variable	Group I (experimental)				Group II (control)			
	Before	After	MD (95% CI)	*P*-value	Before	After	MD (95% CI)	*P*-value
Feeling of embarrassment due to state of nails [1–4] (1 – lowest, 4 – highest)	4.00 (3.00; 4.00)	1.00 (1.00; 2.25)	–3.00 (–2.50; –1.50)	< 0.001	3.15 ±0.81	2.25 ±0.79	–0.90 (–1.35; –0.45)	0.001
Worries about untidy appearance of nails [1–4] (1 – lowest, 4 – highest)	3.60 ±0.60	1.75 ±0.85	–1.85 (–2.31; –1.39)	< 0.001	3.65 ±0.59	2.45 ±0.76	–1.20 (–1.59; –0.81)	< 0.001
Worries that other people notice my nail problems [1–4] (1 – lowest, 4 – highest)	2.95 ±0.60	1.70 ±0.80	–1.25 (–1.70; –0.80)	< 0.001	3.00 ±0.56	2.35 ±0.81	–0.65 (–0.96; –0.34)	< 0.001
Worries that my deformation of nails is contagious and could spread [1–4] (1 – lowest, 4 – highest)	3.00 (3.00; 3.00)	1.50 (1.00; 2.25)	–1.50 (–2.00; –1.50)	0.001	3.00 (2.00; 3.25)	2.00 (1.00; 2.25)	–1.00 (–2.00; –1.00)	0.005
I rarely use open-nail type of shoes [1–4] (1 – not agree, 4 – highly agree)	2.45 ±0.94	1.65 ±0.81	–0.80 (–1.32; –0.28)	0.004	2.55 ±1.05	1.90 ±0.91	–0.65 (–1.00; –0.30)	0.001
Nails shortening is troublesome [1–4] (1 – lowest, 4 – highest)	2.30 ±1.03	1.35 ±0.49	–0.95 (–1.39; –0.51)	< 0.001	3.00 (2.00; 4.00)	2.00 (1.00; 3.00)	–1.00 (–1.00; –1.00)	0.002
Nails' impact on social life [1–4] (1 – highest, 4 – lowest)	2.50 ±0.95	3.45 ±0.76	0.95 (0.46; 1.44)	0.001	2.80 ±0.83	3.30 ±0.73	0.50 (0.22; 0.78)	0.002
Life quality [1–7] (1 – very poor, 7 – excellent)	2.00 (1.00; 2.25)	5.50 (3.00; 7.00)	3.50 (2.50; 5.00)	< 0.001	2.20 ±0.95	4.00 ±1.30	1.80 (1.15; 2.45)	< 0.001

Data are presented as mean±standard deviation or median and interquartile range, depending on the normality of the distribution. MD – mean or median difference (after vs. before); CI – confidence interval. Comparisons before and after performing the paired t-test or Wilcoxon test, as appropriate.

trol groups. Our study used randomisation, showing greater efficacy of therapy in the experimental group compared to the control group, with efficacy of 2.00 vs. 1.00 (MD = 1.00 CI95 [0.00;1.00], $p = 0.026$). A significant difference was observed in the effectiveness of therapy after 5–6 months. Mycological results also indicated that dermatophytes were the most common group of pathogens responsible for onychomycosis (60.0% and 55.0% in both study groups, respectively). Our intervention duration was shorter, i.e. between 3 and 10 months. During this period, we evaluated the effect of therapy on clinical characteristics and treatment efficacy, as well as nail pictures after therapy at the last follow-up in both study groups. Almost half of the patients (47.4%) confirmed adhesion of the nail plate to the NA bed 5–6 months after therapy with EOs and 70.0% after 9–10 months. The corresponding proportions in the control group were 42.1% and 83.3%, respectively. The reduction in pathological masses (nail bed hyperkeratosis) was similar to that in the experimental group after 5–6 months and 7–8 months (57.9% and 58.3%, respectively) and weaker after 9–10 months (50.0%), and the reduction of spots in the control group was similar to that in the experimental group after 9–10 months (33.3%). The above data indicate the therapeutic efficacy in both study groups. A statistically significant difference was observed in the percentage of patients who had normal nail colour after therapy, which was 36% higher in the experimental group than in the control group (95.0% vs. 70.0%, RR = 1.36, 95% CI [1.00;1.84], $p = 0.091$). The percentage of patients confirmed to have healthy nail growth was 70.0% in the experimental group and 60.0% in the control group, with no significant difference between the groups ($p = 0.740$). Together, these improvements led to holistic and sustainable improvement in the quality of life of all subjects following therapy.

The goal of most studies available in medical databases is to find a safer and more effective method for topical treatment of OM. According to Goyal *et al.*, one of the main limitations of topical OM treatment is the effective delivery of drugs through the nail, which poses a significant challenge for therapeutic substances [17]. To date, researchers in their studies have not focused on the mechanical removal of pathologically altered nail plate fragments and cleaning of the keratinised NA bed to enhance the penetration of antimycotic substances, which in turn could positively affect the clinical picture of NA, not only in the experimental group but also in the control group. This finding is particularly relevant to the study population and was positively evaluated in the control group despite the fact that the therapy showed greater efficacy with EO-based sera. The method of mechanically cleaning NA using podiatric milling cutters may be an attractive choice for patients seeking treatment with fewer

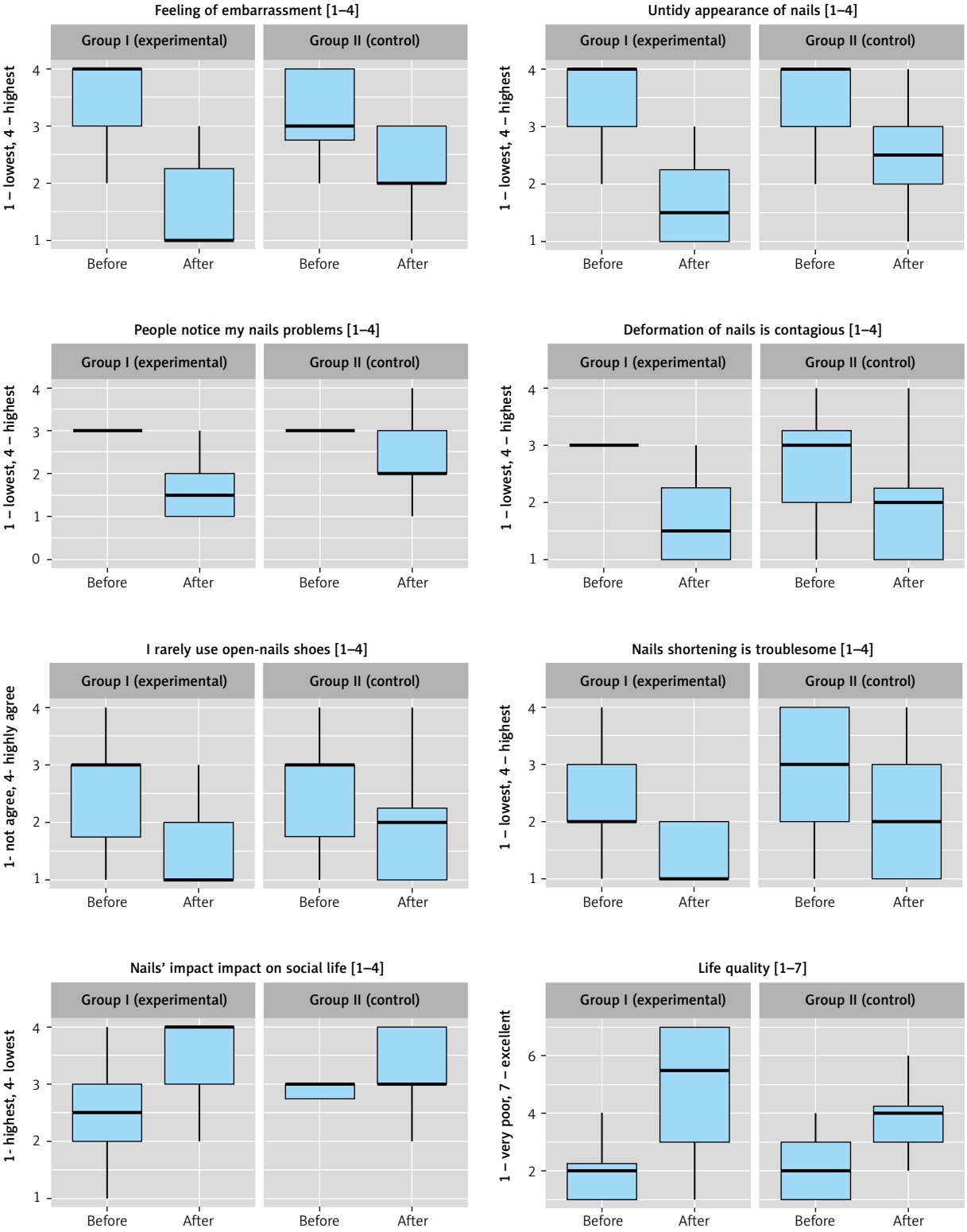

Figure 3. Boxplot charts presenting the distribution of life quality assessment scales before and after treatment, in both study groups

Table 5. Effectiveness of treatment against selected predictors

Variable	Effectiveness against sex				Effectiveness against age				Effectiveness against defect type			
	Females	Males	MD (95% CI)	*P*-value	Age < Me (49 years)	Age ≥ Me (49 years)	MD (95% CI)	*P*-value	Dermatophytes	Other pathogens	MD (95% CI)	*P*-value
Therapy effectiveness [1–3]* – Group I (experimental)												
3–4 m	1.67 ±0.72	1.00 ±0.00	0.67 (0.27; 1.07)	0.003	1.50 ±0.71	1.50 ±0.71	0.00 (–0.66; 0.66)	> 0.999	1.00 (1.00; 2.00)	1.00 (1.00; 2.00)	0.00 (–1.00; 1.00)	0.965
5–6 m	2.00 (2.00; 3.00)	2.00 (1.00; 2.00)	0.00 (0.00; 1.00)	0.178	2.00 (1.00; 2.00)	2.00 (2.00; 3.00)	0.00 (–1.00; 0.00)	0.234	2.00 (1.00; 2.00)	2.00 (2.00; 3.00)	0.00 (–1.00; 0.00)	0.068
7–8 m	3.00 (3.00; 3.00)	2.00 (1.00; 2.00)	1.00 (0.00; 2.00)	0.026	2.00 (1.00; 3.00)	3.00 (2.50; 3.00)	–1.00 (–2.00; 0.00)	0.226	2.00 (1.00; 3.00)	3.00 (3.00; 3.00)	–1.00 (–2.00; 0.00)	0.052
9–10 m	3.00 (3.00; 3.00)	2.00 (2.00; 2.00)	1.00 (–1.00; 1.00)	0.068	2.00 (2.00; 3.00)	3.00 (3.00; 3.00)	–1.00 (–2.00; 0.00)	0.232	2.00 (2.00; 3.00)	3.00 (3.00; 3.00)	–1.00 (–2.00; 0.00)	0.232
Therapy effectiveness [1–3]* – Group II (control)												
3–4 m	1.00 (1.00; 1.00)	1.00 (1.00; 1.00)	0.00 (0.00; 0.00)	0.870	1.00 (1.00; 1.25)	1.00 (1.00; 1.00)	0.00 (0.00; 0.00)	0.697	1.00 (1.00; 1.00)	1.00 (1.00; 2.00)	0.00 (–1.00; 0.00)	0.019
5–6 m	1.50 (1.00; 2.00)	1.00 (1.00; 2.00)	0.50 (0.00; 1.00)	0.850	2.00 (1.00; 2.00)	1.00 (1.00; 2.00)	1.00 (0.00; 1.00)	0.294	1.00 (1.00; 2.00)	2.00 (1.00; 2.00)	–1.00 (–1.00; 0.00)	0.294
7–8 m	2.00 (2.00; 3.00)	2.00 (1.00; 2.50)	0.00 (–1.00; 2.00)	0.299	3.00 (2.00; 3.00)	2.00 (1.00; 2.00)	1.00 (0.00; 2.00)	0.069	1.86 ±0.69	2.40 ±0.89	–0.54 (–1.56; 0.47)	0.261
9–10 m	3.00 ±0.00	2.00 ±0.82	1.00 (–0.70; 2.70)	0.178	3.00*	2.20 ±0.84	–	–	2.00 ±0.82	3.00 ±0.00	–1.00 (–2.70; 0.70)	0.178

*Data are presented as mean ± standard deviation or median and interquartile range depending on normality. There were 38 patients after 5–6 months, 27 patients after 7–8 months and 16 patients after 9–10 months. MD – mean or median difference (females vs. males, age < Me vs. age ≥ Me, Dermatophytes vs. other pathogens); CI – confidence interval; Me – median; m – months after therapy. Comparisons were performed using Student's t-test, Welch's t-test, or Mann-Whitney U test, as appropriate. *1, no improvement, 3 meant significant improvement. **No standard deviation due to n = 1 patient.*

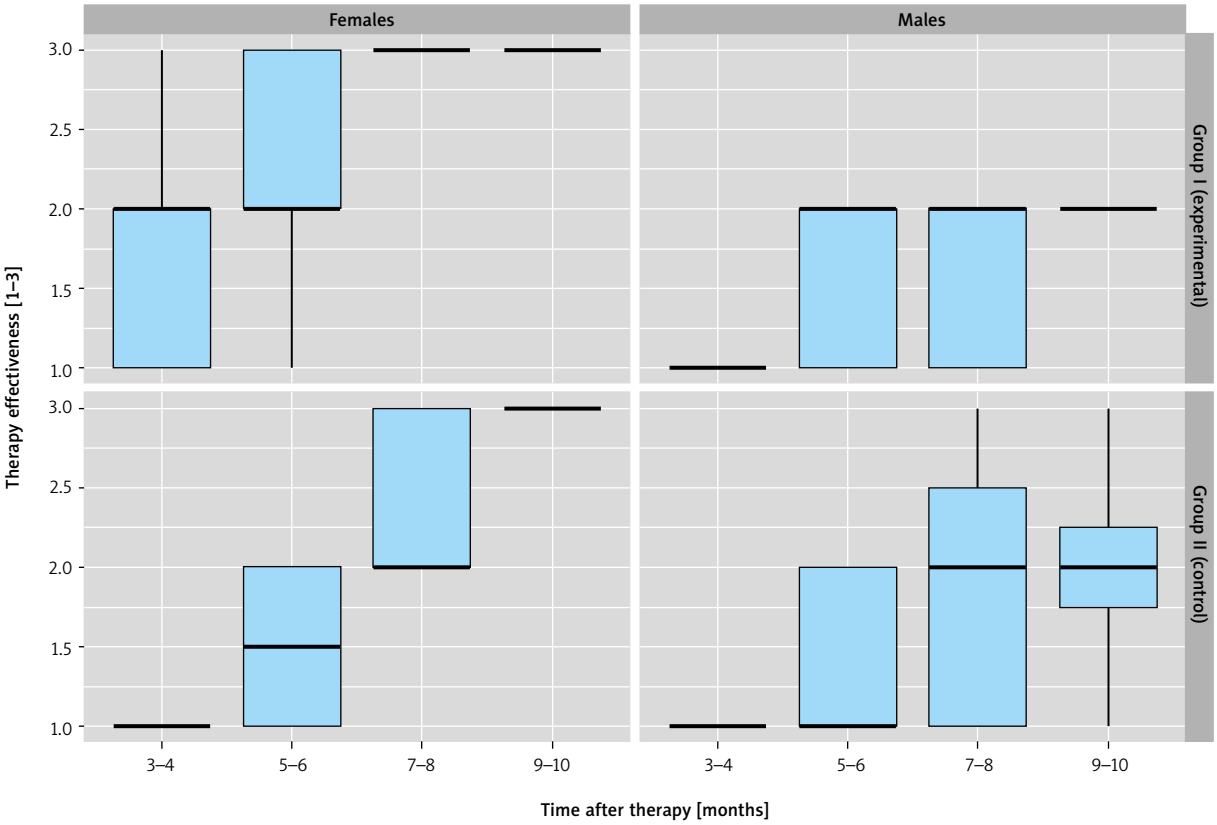

Figure 4. Boxplot chart presenting the distribution of therapy effectiveness assessment in scale from 1 to 3 in sex and subgroups and in split patients with essential oils – Group I and patients without essential oils – Group II

side effects, those taking multiple medicines, or those who are resistant or intolerant to synthetic antimycotic treatment or have allergies to EOs, which has not been previously reported and expands the existing published therapeutic effects.

Interestingly, the distal and lateral subungual onychomycosis (DSLO) stages after therapy were not significantly different ($p = 0.051$), but this was very close to the limit of significance and the statement that a statistically significantly lower stage was observed in the experimental group with EOs than in the control group. It is suggested that with a larger sample size and greater randomisation, a significant result would be possible; therefore, it is worth continuing to study this type of therapy to optimise treatment strategies.

In our study, as well as that of Alessandrini *et al.* [17] and Goyal *et al.* [18], a different mixture of EOs was used, and discrepancies in testing methodology and other variables highlight the difficulty of obtaining comparable and reproducible results using different standards. To date, no comprehensive studies have been conducted that examined all components of a given oil and, as a result, the extent to which the components of the tested formulations (serum and polish) contributed to the antimicrobial activity observed in other studies [13].

The results of our study are consistent with the results of other studies, confirming the effectiveness of essential oils based on previous *in vitro* and preclinical studies, and testifying to the positive therapeutic effect.

Conclusions

Our study suggests that the aetiological agent and type of onychomycosis have a significant impact on the effectiveness of topical therapy for this disease. The duration of therapy is affected by the type of mycotic species, number of infected nails, and stage of the disease. The choice of topical therapy in the treatment of OM should be tailored to individual patient characteristics, comorbidities, and preferences, so that doctors can optimise the treatment results, patient satisfaction, and safety. The use of essential oils after mechanical cleaning of infected nails is well tolerated; moreover, this method may be particularly useful in immunocompromised, diabetic, and elderly patients with chronic pathologies. Podiatric therapy should be considered a key component in the comprehensive treatment of OM. Further clinically relevant studies with larger, more diverse patient profiles and longer study periods are required to verify our preliminary findings, confirm the durability of the ther-

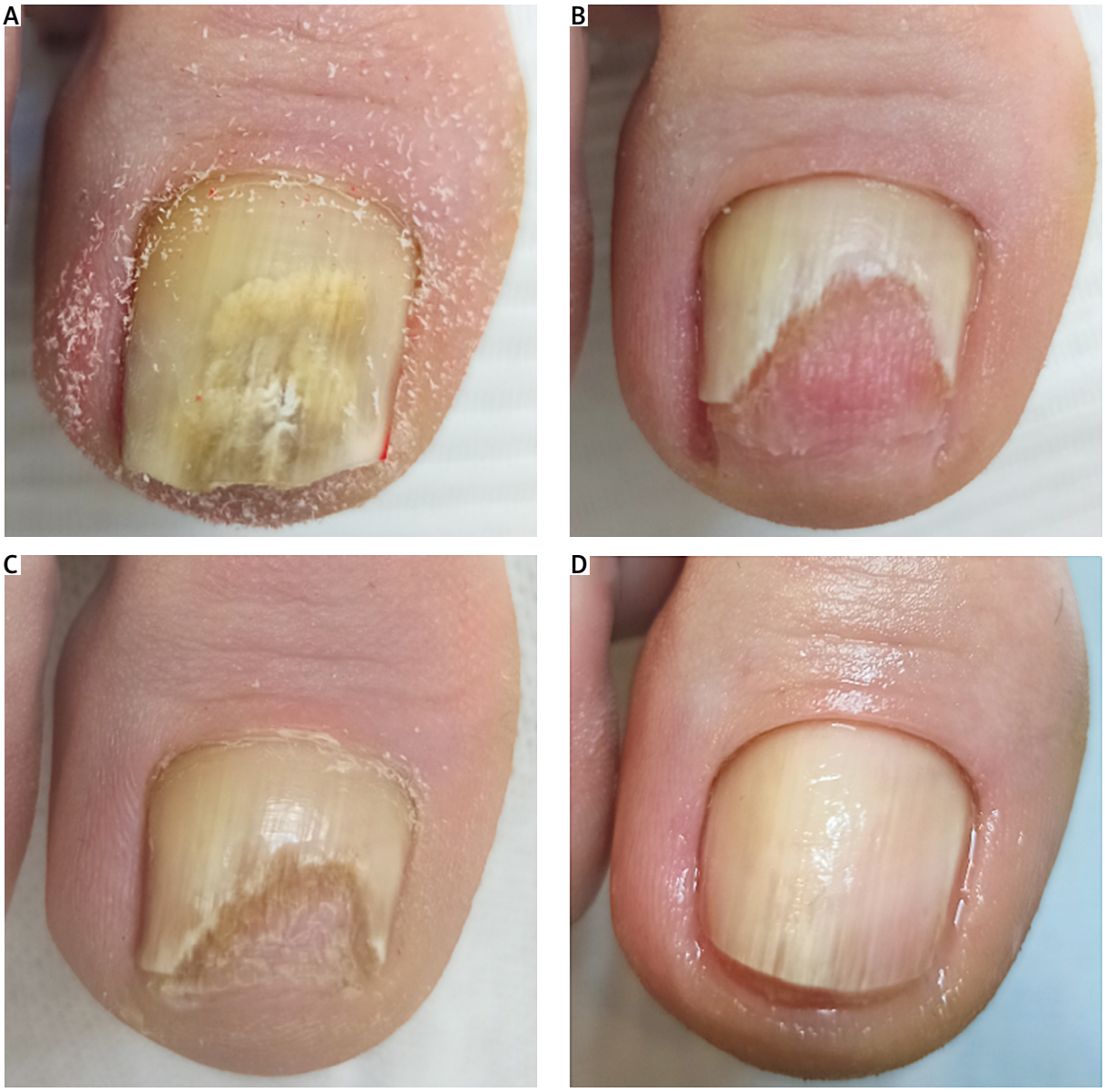

Figure 5. Course of therapy for Scopulariopsis brevicaulis mould infection in a 49-year-old woman. **A** – Initial condition before therapy – visible mycotic lesions persisting for 10 years, **B** – mechanical cleaning of the nail plate. **C** – Picture during therapy with regular use of an essential oil-based serum. **D** – The final effect after 10 months of therapy – a marked improvement in the nail condition and complete cessation of mycotic lesions

apy, and compare the effectiveness of the described therapy with that of other modalities *in vivo*.

Funding

No external funding.

Ethical approval

Bioethics Committee of the Silesian Medical University in Katowice under Resolution No. PCN/0022/KB1/43/21 (date of approval: 18 May 2021).

Conflict of interest

The authors declare no conflict of interest.

References

1. Haneke E, Stovbyr G. Post-Traumatic Single-Digit Onychomycosis. J Fungi. 2023; 9: 313.
2. Adin SN, Gupta I, Ali A, Aqil M, Mujeeb M, Sultana Y. Investigation on utility of some novel terpenes on transungual delivery of fluconazole for the management of onychomycosis. J Cosmet Dermatol. 2022; 21: 5103-5110.

3. Axler E, Lipner SR. Antifungal selection for the treatment of onychomycosis: patient considerations and outcomes. Infect Drug Resist. 2024; 17: 819-843.
4. Yousefian F, Smythe C, Han H, Elewski BE, Nestor M. Treatment options for onychomycosis: efficacy, side effects, adherence, financial considerations, and ethics. J Clin Aesthet Dermatol. 2024; 17: 24-33.
5. Sayed K, Khaled M, Gad A, Elbendary A. Combined fractional CO2 laser with topical tioconazole versus Q-switched Nd-YAG laser in the treatment of onychomycosis; a randomized comparative trial. Lasers Med Sci. 2024; 39: 274.
6. Chanyachailert P, Leeyaphan C, Bunyaratavej S. Cutaneous fungal infections caused by dermatophytes and non-dermatophytes: an updated comprehensive review of epidemiology, clinical presentations, and diagnostic testing. J Fungi. 2023; 9(6): 669.
7. Pandit B, Elewski B, Vlahovic TC. Concealing meets healing in the treatment of toenail onychomycosis: a review of concurrent nail polish use with topical efinaconazole 10% solution. J Clin Aesthet Dermatol. 2024; 17: 38-42.
8. Rodríguez JV, Pérez-Pico AM, Mingorance-Álvarez E, Mayordomo Acevedo R. Meta-analysis of the antifungal activities of three essential oils as alternative therapies in dermatophytosis infections. J Appl Microbiol. 2022; 133: 241-253.
9. Álvarez EM, Rodríguez JV, López Ripado O, Mayordomo R. Antifungal activity of tea tree (Melaleuca alternifolia Cheel) essential oils against the main onychomycosis--causing dermatophytes. J Fungi. 2024; 10: 675.
10. Gupta I, Adin SN, Aqil M, Mujeeb M, Sultana Y. Investigation on utility of some novel terpenes on transungual delivery of terbinafine for the management of onychomycosis. Dermatol Pract Concept. 2022; 12: e2022202.
11. Lee DK, Lipner SR. Optimal diagnosis and management of common nail disorders. Ann Med. 2022; 54: 694-712.
12. Sattayakhom A, Wichit S, Koomhin P. The effects of essential oils on the nervous system: a scoping review. Molecules. 2023; 28: 3771.
13. de Sousa DP, Damasceno ROS, Amorati R, Elshabrawy HA, de Castro RD, Bezerra DP, Nunes VRV, Gomes RC, Lima TC. Essential oils: chemistry and pharmacological activities. Biomolecules. 2023; 13: 1144.
14. Kozłowska-Geller M. Treatment of ingrown nail using CO2 laser – four-year own experience. Medical Studies. 2016; 32: 255-262.
15. Buck DS, Nidorf DM, Addino JG. Comparison of two topical preparations for the treatment of onychomycosis: melaleuca alternifolia (tea tree) oil and clotrimazole. J Fam Pract. 1994; 38: 601-605.
16. Ribeiro TB, Lira JAC, Oliveira RA, Bezerra SMG, Machado RS, Nogueira LT. Use of essential oils in onychomycosis: an integrative review. Braz J Enterostomal Ther. 2021; 19: e1321.
17. Alessandrini A, Starace M, Bruni F, Piraccini BM. An open study to evaluate effectiveness and tolerability of a nail oil composed of vitamin E and essential oils in mild to moderate distal subungual onychomycosis. Skin Appendage Disord. 2020; 6: 14-18.
18. Goyal R, Goyal A, Khan AA, Fatima S, Singh T, Malik DS. Formulation and evaluation of herbal essential oil based nail lacquer for management of onychomycosis. J Mycol Med. 2024; 34: 101515.

Address for correspondence

Faustyna Kuros
Academy of Applied Sciences
Nowy Targ, Poland
E-mail: faustyna.kuros@interia.pl

Received: 6.06.2025
Accepted: 18.07.2025
Online publication: 22.01.2025