

Comparação da eficácia do clobetasol em esmalte 0,05%, 1% e 8% no tratamento da psoríase ungueal: estudo piloto, prospectivo, controlado e randomizado

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Abstract: Background: Nail psoriasis may affect up to 90% of patients with psoriasis in the course of the disease throughout their lives and it is often a therapeutic challenge to dermatologists. Topical treatments described in the literature have demonstrated variable efficacy, and unsatisfactory results have been associated to inefficient penetration of the active ingredient into the nail plate and proximal nail fold. Recently the use of clobetasol on nail lacquer vehicle has been suggested, with satisfactory results and no side effects.

OBJECTIVE: To determine the efficacy and safety of clobetasol in nail lacquer vehicle in three concentrations (0.05%, 1% and 8%) in patients with nail psoriasis.

METHODS: Prospective, controlled, randomized pilot study in fifteen patients with nail bed and /or nail matrix psoriasis in both hands, subdivided into three groups: A(0.05% clobetasol nail lacquer), B(1% clobetasol nail lacquer) and C(8% clobetasol nail lacquer). All groups used clobetasol nail lacquer on the left hand and base coat nail lacquer as control on the right, twice a week for 16 weeks. Clinical evaluation was done by photographic records and the NAPSI score of both treated and control hands, as well as modified NAPSI score of the most affected nail of the treated hand.

RESULTS: Group C showed a statistically relevant clinical response compared to the other groups, reflected in the improvement of clinical parameters, of treated hand NAPSI score, when compared to the control hand, and modified NAPSI score of the most affected nail in the treated hand.

CONCLUSION: The 8% clobetasol nail lacquer was effective and safe, and it can be considered a good option of topical therapy in the treatment of nail psoriasis.

Keywords: Clobetasol; Nails; Products for nails and cuticles; Psoriasis; Therapeutics

Resumo: Fundamentos: A psoríase ungueal, de difícil manejo terapêutico, pode afetar até 90% dos portadores de psoríase no transcurso da doença, ao longo de suas vidas. Os tratamentos tópicos descritos na literatura têm eficácia variável, muitas vezes com resultados insatisfatórios causados pela ineficiência da penetração da substância ativa através da placa ungueal e dobra proximal. Recentemente tem sido proposto o uso do clobetasol em veículo esmalte, demonstrando resultados satisfatórios e ausência de efeitos colaterais. Objetivo: Determinar a eficácia e segurança do clobetasol em veículo esmalte em três concentrações (0,05%, 1% e 8%) nos pacientes com psoríase ungueal. Métodos: Estudo piloto, prospectivo, controlado e randomizado com quinze pacientes portadores de psoríase ungueal em ambas as mãos. Os pacientes foram subdivididos em três grupos: A (esmalte clobetasol 0,05%), B (esmalte de clobetasol 1%) e C (esmalte de clobetasol 8%). Os pacientes usaram esmalte de clobetasol na mão esquerda e esmalte base (sem medicação - controle) na direita, aplicando-os duas vezes por semana, por 16 semanas. Fez-se a avaliação clínica por registros fotográficos e pelos métodos: NAPSI da mão tratada e controle e NAPSI modificado da unha mais acometida da mão tratada. Resultados: O grupo C apresentou de forma estatisticamente significativa a resposta clínica mais relevante, refletida na melhora dos parâmetros clínicos, do NAPSI da mão tratada comparado ao da mão controle e do NAPSI modificado da unha mais acometida da mão tratada. Conclusões: Neste estudo piloto, o esmalte de clobetasol a 8% foi eficaz e seguro, mostrando-se uma boa opção de terapêutica tópica no tratamento da psoríase ungueal.

Palavras-chave: Clobetasol; Produtos para unhas e cutículas; Psoríase; Terapêutica; Unhas

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INTRODUCTION

Psoriasis is one of the most common skin diseases, with a universal distribution, affecting 1 to 2% of the population. It affects both sexes equally and can develop at any age, with incidence peaks during the second and fifth decades. Many hypothesis have been proposed but the etiology is yet unknown. It is known, however, that there is a polygenic inheritance associated with different histocompatibility antigens, and environmental factors are required for the disease to be expressed. Stress and mechanical trauma, causing the Köebner phenomenon, are the most important ones.

The nail involvement is a frequent symptom in psoriasis and it is estimated that it is present in around 25 to 50% of the patients with the disease. 3 However, some authors suggest a rate of 80 to 90% of nail involvement throughout the course of the disease. ⁴ Among the clinical manifestations, cupuliform depressions and nail pitting or pits are the most common alterations. ^{4,5,6}

The correlation between arthopathic psoriasis and nail psoriasis is well known. Around 70% of the arthropathic patients present with the nail involvement commonly seen in psoriasis, which is usually present at the same time of the arthropathy, but can sometimes precede it. In arthropathic psoriasis there is diffuse inflammation in the extensor tendon enthesis of the distal interphalangeal articulation which, via contiguity, can sometimes spread to the point of involving the nail bed and matrix. So

When the nail involvement is the only clinical characteristic of the disease, the incidence seen on the literature is variable, on average up to 5%. In most cases the patients present with other lesions on the body besides the nails. ¹⁰ Nail psoriasis can be part of the clinical presentation throughout the course of the disease; it might relate to the severity of the disease or

be an isolated manifestation. ^{11,12} Nail abnormalities are more common on the fingernails than on the toenails, and usually more than one nail is involved.

The prevalence of onychomycosis is higher in psoriatic patients. Due to the epidemiologic variation in each region, the prevalence of the fungus species found can be: yeast, dermatophyte filamentous fungus and non dermatophyte filamentous fungus.^{3,13,14} Therefore, the direct mycological examination and the culture must be done before the start of the treatment with corticosteroids.

Throughout the course of the psoriasis, all nail structures might be involved. In decreasing order of frequency, the alterations are: pitting, onycholysis, chromonychia ("salmon-patch" or "oil" spots), subungual keratosis and splinter hemorrhages. The involvement of the skin around the nail apparatus is common. Nail dystrophy varies according to the site of the involvement, as seen on the chart below. (Table 1)

Acropustulosis is a severe and relapsing variant of nail psoriasis. ^{5,12} Nail psoriasis in childhood is rare and usually seen in the form of trachyonychia. Similarly to psoriatic lesions in other anatomic areas, nail psoriasis evolves in outbreaks, with periods of respite and spontaneous or treatment related remission.

Various therapeutic modalities have been used in the topical treatment of nail psoriasis, like topical corticosteroids, fluorouracil, calcipotriol, cyclosporine and tazarotene. Nonetheless, none of them has been absolutely satisfactory, both from the point of view of therapeutic response and dosing convenience. The corticosteroids and the vitamin D analogues remain the most commonly used topical therapies, with a good therapeutic response. 4.7.15,16,17

Class 1 corticosteroids (very high potency) have been used for a long time in vehicles like cream or gel, under occlusion, in specific physical abnormalities of

TABLE 1: Nail psoriasis: Clinical abnormalities according to involvement site

	*	<u> </u>		
NAIL MATRIX	NAIL BED	PERIONYCHIAL REGION	MATRIX / BED / PERIONYCHIAL REGION	
Pitting	Onycholysis	Psoriatic paronychia	 Acropustulosis 	
 Trachyonychia 	Subungual			
 Leukonychia 	keratosis			
Beau's lines	• "Oil" spots			
 Red spots on the lunula 	• "salmon- patch"			
	 Splinter hemorrhage 			

the nail matrix. The triamcinolone acetonide (5mg/ml) applied via intralesional infiltration to the proximal nail fold, aiming at reaching the matrix, has been shown to be effective, but adverse effects have been observed, such as intense pain during application and the possibility of nail matrix atrophy.¹⁸

The clobetasol propionate is the topical treatment modality most used in the United States of America for cutaneous psoriasis.¹⁹ It is also used in the treatment of nail psoriasis at a concentration of 0,05% in cream or gel vehicle, applied daily to the periungual area, over the matrix. However, the benefits are minimal, as the absorbance in this area is not good. Adverse effects with chronic use include the development of hypochromy, atrophy and telangectasias on the periungual area.²⁰

It is known that drugs incorporated to nail lacquer have a superior transungual penetration in relation to other vehicles, as seen in the treatment of onychomycosis. In 1999, Baran and Tosti showed, for the first time, the use of 8% clobetasol propionate in nail lacquer vehicle in the treatment of 45 patients with nail psoriasis. 21 Regaña et al. also discussed their experience with 10 patients.²²

In 2008, Regaña at al. performed a study with 15 patients with nail matrix and bed psoriasis using a combination of 8% clobetasol nail lacquer (during the weekends) and occlusive talcacitol cream on the other days, for a six - month period.²³ All patients had good therapeutic response, with clinical improvement directly correlated wih treatment duration, showing the efficacy and safety of the association between clobetasol nail lacquer and vitamin D analogue.

In view of this data, the use of the 17-clobetasol propionate in nail lacquer has been shown to be efficient, although still little studied in the treatment of nail psoriasis. As this medication is not yet available for commercial use, compound formulas must be used.

This study aims at explaining and testing the efficacy and safety of clobetasol propionate in nail lacquer vehicle. Three different concentrations were used (0,05%, 1% and 8%), in psoriatic patients with nail abnormalities, aiming at observing the best response. It is expected that this study might provide better information about this new therapeutic option for typical psoriais nail dystrophies.

PATIENTS AND METHODS

Fifteen patients with nail psoriasis in both hands were selected from the Psoriasis outpatients clinic and the Nail Studies Center - Centro de Estudos da Unha (C.E.U) of the Instituto de Dermatologia Prof. Rubem David Azulay - Santa Casa da Misericórdia do Rio de Janeiro (7 men and 8 women, aged between 26 to 76 years, average of 48,7 years). Average duration of

the disease was around six years. The study was approved by the Ethics and Research Committee of the Santa Casa da Misericórdia do Rio de Janeiro.

Inclusion Criteria

Involvement of both hands ("nail" matrix and/or bed with psoriatic dystrophy); 18 years of age or older; absence of topical or systemic treatment and/or phototherapy for nail psoriasis for at least four weeks; signing of the Free and Explained Consent Form and the Image Authorization; negative direct mycological examination and culture for fungus and/or bacteria prior to the commencement of the study.

Exclusion Criteria

Topical or systemic treatment and/or phototherapy for nail psoriasis within the past 4 weeks; non-approval of the Consent Form and Image Authorization; positive direct mycological exam and culture for fungus and/or bacteria; clinical diagnosis of pustular or erythrodermic psoriasis; severe hepatic or renal insufficiency; pregnant or lactating women.

Assessment or the clinical efficacy

The patients were assessed at the beginning of the treatment and at every 4 weeks, for 16 weeks. The nail abnormalities on the treated hand, left hand (LH), control hand, right hand (RH), and the most involved nail of the LH of each patient were classified according to the "score" NAPSI (Nail psoriasis severity index) – a quantitative assessment of the clinical signs: pitting, subungual keratosis, onycholysis and Beau´s lines. 24,25 The modified NAPSI score of the most affected LH nail was also assessed. 26

Subungual keratosis was assessed by a pachymeter. Onycholysis, pitting and Beau's lines were observed through the progress of the nail plate surface involvement. The analysis was performed after dividing the nail surface into 8 spaces of 12,5%, according to the figure (Figure 1). At each clinical assessment the photographic registration was obtained.

The product Safety (clobetasol nail lacquer) was estimated by means of tolerability (continuation of the proposed treatment) and, clinically, by the observation and report of possible local side effects like burning sensation, pain, itch, atrophy.

The patient satisfaction level was obtained via a questionnaire related to the percentage of improvement achieved at the end of the treatment, under the patient's point of view: above 50% improvement – excellent treatment; between 20-50 % improvement - moderate; below 20% improvement - unsatisfactory.

The study factors were the clinical findings, the efficacy and the therapeutic safety.



FIGURE 1: Total surface area of the nail plate = 100%

Study Design

A pilot, experimental, prospective, controlled and randomized study.

The patients were evaluated at every four weeks until they completed four months of treatment (end of the proposed treatment); as such, the patients were seen at weeks 0, 4, 8, 12 and 16.

The patients received one (1) bottle of clobetasol nail lacquer for application on the LH and another one (1) containing colourless base coat, for use on the RH as a control to the contra lateral hand, and were oriented to apply both nail lacquers twice a week (Mondays and Thursdays), till the end of the follow up period.

The 15 bottles containing clobetasol for use on the LH (five at a concentration of 0,05%, five at a concentration of 1% and five at a concentration of 8%) were distributed randomically into three groups and, in addition, the label with concentrations stayed covered up so that neither the doctor nor the patient could not know the concentration used.

At the end of the treatment the nail lacquers were uncovered and the effectiveness was verified through clinical analysis of the photographic records (on weeks zero and 16) and the comparison of the results from the NAPSI on the treated hand and modified NAPSI of the most involved nail of the treated hand among the groups A (clobetasol nail lacquer 0,05%), B (clobetasol nail lacquer 1%) and C (clobetasol nail lacquer 8%) versus control hand (right hand) before and after treatment. 25,26

Statistical Analysis

The tests used were: ANOVA of Kruskal-Wallis, Wilcoxon signed-ranked test and Mann-Whitney test. The statistical analysis was processed using the statistical software SAS® System.

RESULTS

On the initial sample, in a total of 15 patients, the most commonly found clinical signs of nail psoriasis were: pitting, onycholysis, subungual keratosis, salmon spots, hemorrhagic striates and complaints of pain. (Table 2)

The analysis of the modified NAPSI of the most affected LH nail, by total sample and by treatment groups, showed significant improvement of the modified NAPSI on the total group of an average of 7.7 points (p = 0.0001), which corresponds, on average, to 51.5% (p = 0.0001). On the individual groups (A, B and C) this improvement was non-significant at the 5% level. However, it can be said that there is a statistical tendency to improvement and, probably, with a bigger sample and a longer duration, this improvement is significant. In conclusion, the establishment of treatment appears to be worthwhile (Table 3).

When analyzing the Napsi variation 25 of the most involved nail of the LH from the general sample and by groups, we observed a significant improvement of the NAPSI of the most involved nail of the LH on the total group of an average of 1 point (p = 0.030).

On the individual groups this improvement was not significant at the 5% level. However, there is a tendency to improvement and, probably, with a bigger sample and for a longer duration this improvement is significant, particularly for the groups B and C. (Table 4)

Therefore, when comparing tables 3 and 4 statistically, there is the suggestion that, for this sample, the MODIFIED NAPSI²⁶ is more sensitive than the NAPSI.²⁵

The progress of the NAPSI on the control hand (RH) did not show any significant improvement from the start to the end of the treatment on either the total sample or the individual groups (Table 5).

When checking for a significant difference of the absolute delta (points) and the relative delta (%) among the three treatment groups: A (0,05% clobetasol), B (1% clobetasol) and C (8% clobetasol), we observed that there was no significant change, at the 5% level, of the relative deltas (%) of the NAPSI among the three nail lacquer groups. However, we observed that, by the variation of the NAPSI on the treated hand (LH), the group C (LH) showed an improvement of 39% more than that of the A and B groups (Table 6).

Adverse effects like atrophy, hypochromy, periungual telangectasia, local pain and hypersensitivity to the medication, as well as patient satisfaction were also registered. In this study there were no reports of adverse effects.

In terms of the perception (or satisfaction) of improvement by the patients: five reported excellent results, four moderate, three non-satisfactory and three patients did not answer this question.

After the photographic analysis, an important improvement was observed on most patients on the

0

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Variable	Category	Total		Group A	Group B	Group (
		N.	%	n	n	n
Sex	masculine	7	46,7	2	3	2
	feminine	8	53,3	3	2	3
Subungual keratosis	neg	5	33,3	2	3	0
	+	7	46,7	3	0	4
	++	2	13,3	0	1	1
	+++	1	6,7	0	1	0
Onycholysis	neg	2	13,3	1	0	1
	+	2	13,3	1	1	0
	++	2	13,3	2	0	0
	+++	9	60,0	1	4	4
Salmon - patch	neg	3	20,0	1	0	2
	+	5	33,3	3	1	1
	++	3	20,0	0	3	0
	+++	4	26,7	1	1	2
Pitting	neg	1	6,7	0	1	0
	+	4	26,7	1	1	2
	++	6	40,0	3	2	1
	+++	4	26,7	1	1	2
Splinters	neg	8	53,3	3	2	3
	+	6	40,0	2	2	2
	++	1	6.7	0	1	0

0,0

53,3 46,7

0

8

TABLE 2: Description of the clinical variables of the total sample of 15 patients

group C (8% clobetasol) (Figures 2, 3 and 4).

DISCUSSION

Pain

Many therapeutic modalities have been used in the treatment of nail psoriasis; however, none has been fully satisfactory both from the point of view of efficacy and dosing convenience.

yes

no

Corticosteroids and vitamin D analogues are still the most quoted topic therapies in the literature, with good therapeutic response. 4,15,16,17

The use of clobetasol in nail lacquer, described in the literature, showed effective transungual penetration, reduction of both matrix and nail bed abnormalities, highlighting the absence of side effects observed when it is used as clobetasol cream. ^{21,22,23} It is supposed that a high concentration of clobetasol in nail lacquer vehicle (8%) have a better efficacy than the concentration of clobetasol in cream/gel/ointment usually found on the market (0,05%).

Currently, with the advent of adequate vehicles for transungual penetration and the possibility of therapeutic association with corticosteroids it is fair to say that the management of the psoriatic nail has changed dramatically. According to the literature review and the results from this pilot study it was found that the nail lacquer can still be considered an important vehicle for topical treatment of the psoriatic nail. The nail lacquer is a solution to avoid the adverse effects caused by the use of intralesional corticosteroids or corticosteroids in cream or gel applied to the skin, such as atrophy, hypochromy, telangectasia and bone reabsorption – effects still not reported with the use of this vehicle. Clobetasol in gel or cream applied to the nail fold seems to improve only the nail matrix disorders; however, the clobetasol in nail lacquer vehicle was able to improve the lesions on both the nail matrix and bed.

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On the studied population, the treatment with clobetasol nail lacquer at different concentrations (0,05%; 1%; and 8%) applied twice a week for 16 weeks was well tolerated and efficient, since the medication was used continuously and no adverse effects were observed. Besides, most patients rated the results as excellent or moderate.

TABLE 3: Analysis of the variation of the modified NAPSI of the most involved nail of the treated hand (LH), on the total sample, and by treatment group

Group	NAPSI	n	Average	SD/SE	Median	p- value ^a
All	Before	15	14,3	5,6	14	
	After	15	6,6	4,3	7	
	Delta (points)	15	7,7	1,3	7	0,0001
	Delta (%)	15	51,5	7,2	53,8	0,0001
A	Before	5	13,4	4,0	14	
	After	5	5,6	3,9	5	
	Delta (points)	5	7,8	2,7	11	0,12
	Delta (%)	5	52,9	17,7	57,9	0,12
В	Before	5	13,8	6,1	11	
	After	5	6,0	2,2	7	
	Delta (points)	5	7,8	3,0	4	0,062
	Delta (%)	5	49,2	12,5	36,4	0,062
C	Before	5	15,6	7,3	15	
	After	5	8,2	6,2	6	
	Delta (points)	5	7,4	1,2	7	0,062
	Delta (%)	5	52,3	8,1	53,8	0,062

SD: standard deviation; SE: standard error only for the deltas.

TABLE 4: Analysis of the variation of the NAPSI of the most involved nail from the left hand (LH), on the total sample and by groups

Group	NAPSI	n	Average	SD/SE	Median	p- value a
All	Before	15	3,3	1,0	3	
	After	15	2,2	1,7	2	
	Delta (points)	15	1,1	0,4	1	0,030
	Delta (%)	15	31,7	11,8	50	0,039
A	Before	5	3,4	1,3	4	
	After	5	2,8	2,5	2	
	Delta (points)	5	0,6	1,2	1	0,68
	Delta (%)	5	11,0	30,8	50	0,81
В	Before	5	3,4	0,5	3	
	After	5	1,6	0,9	1	
	Delta (points)	5	1,8	0,5	2	0,12
	Delta (%)	5	51,7	13,5	66,7	0,12
C	Before	5	3,2	1,3	3	
	After	5	2,2	1,3	2	
	Delta (points)	5	1,0	0,3	1	0,12
	Delta (%)	5	32,3	11,7	25	0,12

SD: standard deviation; SE: standard error only for the deltas.

When comparing the NAPSI score with the modified NAPSI we concluded that the latter is simpler and easier to use than the former, this way facilitating the analysis of the data related to the improvement of the nail psoriasis after the treatment. 7,25,26

It is important to report that the statistical analysis of the study suggests that a higher number of studied patients, coupled with a longer duration of the study can present even more significant results of the parameters assessed (NAPSI and modified NAPSI of

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TABLE 5: Analysis of the variation of the NAPSI on the control hand (RH) on the total sample and by treatment group

Group	NAPSI	n	Average	SD/SE	Median	p- value "
All	Before	15	10,2	5,0	8	
	After	15	10,0	6,0	9	
	Delta (points)	15	0,2	1,6	0	0.98
	Delta (%)	15	-33,6	42,2	0	0.99
A	Before	5	8,6	5,0	8	
	After	5	6,8	5,0	6	
	Delta (points)	5	1,8	4,0	2	0,75
	Delta (%)	5	-82,5	130,4	25	0,87
В	Before	5	9,8	3,3	8	
	After	5	10,6	3,7	10	
	Delta (points)	5	-0,8	2,6	-2	0,56
	Delta (%)	5	-18,9	22,1	-25	0,43
C	Before	5	12,2	6,6	9	
	After	5	12,6	8,0	12	
	Delta (points)	5	-0,4	1,4	0	0,99
	Delta (%)	5	0,5	15,2	0	0,99

SD: standard deviation; SE: standard error only for the deltas.

TABLE 6: Analysis of the relative delta (%) of the NAPSI amongst the groups

Relative Delta	Group	Average	SE	Median	p- value ^a
Modified NAPSI LH (more involved nail)	A	52,9	17,7	57,9	0,84
,	В	49,2	12,5	36,4	
	C	52,3	8,1	53,8	
NAPSI on the LH(treated hand) (more involved nail)	A	11,0	30,8	50	0,46
	В	51,7	13,5	66,7	
	C	32,3	11,7	25	
NAPSI - LH (treated hand)					
	A	13,4	24,3	-18,2	0,24
	В	-9,5	24,3	6,7	
	C	41,0	20,2	38,9	

EP: Standard error /

the most affected nails on the treated hands), with higher efficacy on the groups B and C. Nevertheless, the treatment time of any nail dystrophy depends on the time the nail takes to grow in each individual, thus being a longstanding treatment; since psoriasis is a chronic and relapsing disease, it is understandable that its treatment requires some duration.

The nail involvement in psoriasis is difficult to manage and the response to the proposed treatments is slow. Therefore, although there are a number of therapeutic alternatives with good response to medications used topically, systemically, intralesionally, by radiation, or in combination, there is still a paucity of studies that elucidate standardized therapeutic regimens in relation to the most adequate, efficient, safe and ideal option for the patient. Besides, even if there are studies reporting the use of systemic therapies for the treatment of nail psoriasis, like ciclosporine, retinoids and biologicals with excellent results, these drugs are rarely indicated for clinical cases of isolated

a test of the de Wilcoxon signaled points

a ANOVA from Kruskal Wallis



FIGURE 2: Patient from the C group (8% clobetasol nail lacquer): at the start (week zero) oil spots. hemorrhagic splinters, pitting and onychorrhexis are noted: after 16 weeks an improvement of all these abnormalities can be seen



FIGURE 4 - Patient from the C group (8% clobetasol nail lacquer) – after 4 months, an improvement of the trachyonychia, pitting, onycholysis is observed (detail of the 1st finger of the left hand before and after treatment)





FIGURE 3: Patient from the C group (8% clobetasol nail lacguer) - after 4 months, an improvement of the trachyonychia is observed (detail of the 2nd, 3rd and 4th fingers of the left hand - treated)



nail psoriasis. 27,28,29

The indication for systemic treatment in isolated nail psoriasis is not a routine, and there are a few cases that need this type of conduct. Unless the patient does not respond to long term local treatment, has a severe level of involvement, or has the acropustulosis variant, the local treatment is preferred.

CONCLUSION

According to the observations from this pilot study, we concluded that the clobetasol nail lacquer is

considered a safe therapeutic option in all the three concentrations tested. However, clinically and statistically, the clobetasol nail lacquer at a concentration of 8% (group C) was more efficient than the other concentrations on the resolution and improvement of the parameters both on the nail matrix and bed. Thus, the 8% clobetasol nail lacquer is an efficient and safe therapeutic option in the treatment of nail psoriasis.

The limitations of this study were the lack of double blind testing and the small number of patients. Taking into consideration these factors and the short study period and follow up time, we suggest that more studies are performed in order to corroborate these results. \square

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