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EFFICACY AND TOLERABILITY OF 5% MINOXIDIL SOLUTION (CAREXIDIL®) IN MALE AND FEMALE ANDROGENETIC ALOPECIA: A 6-MONTH OPEN MULTICENTRIC STUDY

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Efficacy and tolerability of 5% minoxidil solution (Carexidil®) in male and female androgenetic alopecia: a 6-month open multicentric study

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***Aim*. The aim of the study was to evaluate efficacy and safety of 5% Carexidil solution®, applied twice a day on the scalp, on male and female androgenetic alopecia.**

***Methods*. The 6 month-study was performed in three Italian dermatological centers. Evaluation of efficacy was performed with subjective and objective methods, including operator and patient assessments, global photography and videodermoscopy.**

***Results*. Global photography revealed that after 6 months of treatment with 5% Carexidil solution®, androgenetic alopecia was improved in all 32 females and 16 males. Alopecia stopped to progress in 6 males. Scalp videodermoscopy confirmed the results. Some patients complained of increased hair greasiness, others complained of mild scalp itching. Two female patients developed contact sensitization to minoxidil, confirmed by patch test, 2 a mild malar-temporal hypertrichosis. All patients were satisfied by treatment and continued it after the end of the study.**

***Conclusions*. Our study confirms the data of the literature and the evidence coming from years of clinical experience, that twice a day topical application of 5% minoxidil solution, Carexidil ®, is effective in the treatment of male and female androgenetic alopecia, with evident efficacy already after 6 months.**

KEY WORDS: Alopecia - Minoxidil - Dermoscopy.

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Topical minoxidil is internationally accepted as one of the first choices for treatment of both male and female androgenetic alopecia (male and female pattern hair loss, MPHL, FPHL, baldness).[1-3] In Italy, minoxidil solution has been commercialized for the treatment of androgenetic alopecia for more than 20 years (the 2% concentration since 1988, the 5% concentration since 1995), but even if its safety profile and efficacy are well known, many dermatologists are still reluctant to prescribe it, or they utilize it incorrectly.

The aim of this open multicentric study, carried out in 3 Italian Dermatological Centers, was to evaluate the efficacy and tolerability of a 5% minoxidil solution, Carexidil®, applied to the scalp at a dosage of 1 ml twice daily for 6 months, in male and female androgenetic alopecia. Efficacy evaluation was based on subjective and objective methods. Subjective methods included patient and investigator evaluation, while objective methods included global photography and videodermoscopy.

The results of the study are useful guidelines regarding the correct use of 5% minoxidil lotion, including information to give to patients, expectations of efficacy after 6 months of treatment, and management of potential side effects.

Materials and methods

The study included male and female volunteers affected by mild to moderate forms of androgenetic

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alopecia according to the Ludwig (females) e Hamilton-Norwood (males) scales, aging from 18 to 65 years. Exclusion criteria included malignant neoplasms, severe systemic diseases, iron-deficiency, use of minoxidil or finasteride in the 6 months preceding the study, and known allergy towards one or more ingredients in the product. Each study participant signed an informed consent before taking part in the study.

Patients were instructed to apply 1 ml of Carexidil® solution twice daily to dry hair, pumping ten times with the dosage spout touching the scalp in areas affected by alopecia. Hair washing should be avoided in the 4 hours following the application of the solution.

Control visits were performed at baseline and after 4 and 6 months of Carexidil® treatment.

Evaluation of efficacy was performed at the 6-month visit and relied on qualitative and quantitative criteria, including investigator's clinical evaluation, patient's self-administered questionnaire and comparative evaluation of the global photographs. Subjective evaluations of treatment efficacy performed by operator and patients followed a 5-point scale (0 = worsening, 1 = unchanged, 2 = mild improvement, 3 = moderate improvement, 4 = marked improvement). Global photographs, standardized for distance, position and light exposure, were performed at baseline and at the 6 month control visit, and then compared using the following score: -1 = worsening, 0 = unchanged, 1= improvement. In two groups of patients (centers of Bologna and Genova), efficacy of Carexidil® solution was monitored with videodermoscopy performed at baseline and at the 6 month control visit, using Trichoscan (Dermoscope Fotofinder®, Campi Bisenzio, Firenze), at 20X e 70X magnification. Videodermoscopy permitted to count the total number of hairs and percentage of vellus hair (with diameter <40 μm) in a selected area of 1 cm in diameter.

Tolerability and cosmetic properties of Carexidil® solution were assessed at every follow-up visit with 3 questions that enquired about modality of application of the solution (0 = difficult to apply; 1 = easy to apply), hair greasiness (0 = increased, 1= stable), and tolerability of the solution on the scalp (0= optimal tolerability, 1= occasional scalp itching after application of the solution, 2= occasional scalp itching and erythema after application of the solution**,** 3= continuous scalp itching and erythema). Occurrence of any adverse event, related or not to the drug, was also recorded.

At the end of the 6 months study each patient was asked to express his/her degree of satisfaction about the treatment (highly satisfied, satisfied, unsatisfied) and his/her will to continue treatment with Carexidil® solution after the end of the study.

The study was approved by the ethical committees of the 3 hospitals.

Results

Seventy-five volunteers were enrolled, 54 of which concluded the 6-month study. They include 32 females and 22 males, with a mean age of 38.9 e 27 years respectively (female age range: 18-65, male age range: 18-56 years). According to severity of androgenetic alopecia patients were divided into the following groups: females: Ludwig I: 10 patients, Ludwig II: 17, Ludwig III: 5 patients; males: Hamilton II: 3 patients, Hamilton IIa: 4, Hamilton IIv: 3, Hamilton III: 2, Hamilton IIIa: 6, Hamilton IIIv: 4 patients (Tables I, II).

Females

Efficacy

Evaluation of global photographs taken at baseline and after 6 month of treatment with 5% Carexidil® solution revealed a clinical improvement in all 32 patients (Table I). Improvement was rated as moderate in 20 cases (62.5%) (Figure 1A, B) and marked in 12 (37.5%) (Figure 2A, B). Videodermoscopy performed in 25 of these patients revealed in all cases an improvement of the parameters typically evaluated in androgenetic alopecia: the total number of hairs/area of 1 cm diameter increased by 21,4% (mean number at baseline: 210,6, mean number at the end of the 6-month study: 255,8), and the percentage of vellus hair/area of 1 cm diameter decreased by 1.83% (mean percentage of vellus hair at baseline: 12,6%; at the end of the study: 10,3%) (Figure 3A, B).

Evaluation of efficacy, based on the questionnaire filled out by the investigator that rated the evolution of the alopecia with treatment, showed the following: unchanged in 7 patients, mild improvement in 5, moderate improvement in 12, marked improvement in 8. Evaluation of efficacy, based on the question-

TABLE I.—*Efficacy of 5% Carexidil® solution in male and female androgenetic alopecia for 6 months.*

Total N.	Global photography			VDS (1 cm diameter area)		Investigator's assessment					Patient's self assessment				
Females=32 Males=22	Worsening	Unchanged	Improvement	Total number of hairs	% vellus hairs	Worsening	Unchanged	Mild improvement	Moderate improvement	Great improvement	Worsening	Unchanged	Mild improvement	Moderate improvement	Great improvement
Females															
Ludwig I 10	-	-	10			-	2	2	-	6	-	-	1	5	7
Ludwig II 17	-	-	17			-	2	2	12	1	-	-	7	10	-
Ludwig III 5	-	-	5			-	3	1	-	1	-	-	2	2	1
Males															
Hamilton II 3	-	1	2			-	1	-	-	2	-	-	2	1	-
Hamilton IIa 3	-	1	1			-	-	2	1	-	-	-	2	1	-
Hamilton IIv 4	-	-	5			-	-	-	2	2	-	-	1	2	1
Hamilton III 2	-	2	-			-	1	1	-	-	-	-	1	-	1
Hamilton IIIa 6	-	1	5			-	1	3	1	1	-	-	2	3	1
Hamilton IIIv 4	-	1	3			-	2	1	-	1	-	-	2	2	-

TABLE II.—*Tolerability of 5% Carexidil® solution in male and female androgenetic alopecia for 6 months.*

Total n°	Lotion application		Hair greasiness			Scalp tolerability			Satisfaction			Adverse events	
	Easy	Difficult	Increased	Unchanged	Improved	Occasional itching	Occasional erythema and itching	Continuous erythema and itching	Very satisfied	Satisfied	Not satisfied	Telogen effluvium at the beginning of treatment	Localized hypertrichosis
Females=32	32	-	20*	12	27	3	-	2**	23	7	2**	1	2
Males=22	22	-	6	16	-	6	-	-	22	-	-	1	-

*Cause of study drop-out in 2 cases
**Cause of study drop-out in 2 cases

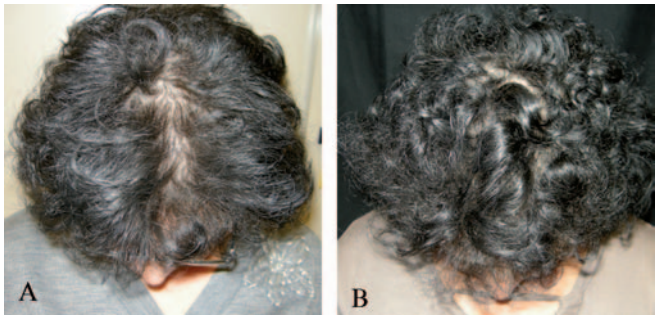

Figure 1.—Forty-two year old female with Ludwig I androgenetic alopecia before (A) and after (B) 6 months of use of Carexidil® solution.

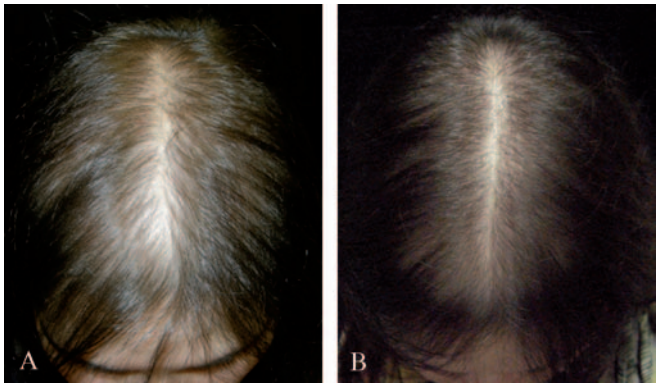

Figure 2.—Thirty-six year old female with Ludwig II androgenetic alopecia before (A) and after (B) 6 months of use of Carexidil® solution.

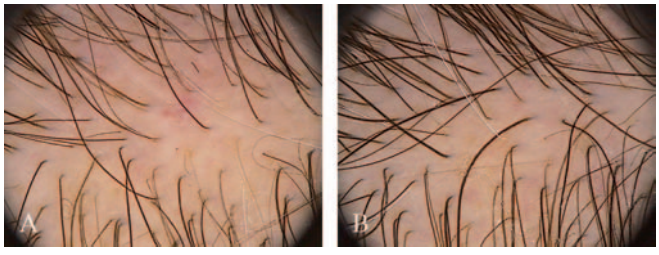

Figure 3.—Videodermoscopy the vertex area before (A) e after (B) treatment: increased thickness of the hair shafts and reduced number of empty follicles (increased hair density).

naire filled out by the patient revealed: mild improvement in 10 cases, moderate improvement in 15, marked improvement in 7 cases.

Tolerability

All 32 patients judged the solution easy to apply. Twenty of them reported an increased hair greasiness, which in 2 cases caused interruption of treatment. Tolerability of the solution on the scalp was defined 'optimal' by 27 patients. Three patients complained of occasional scalp itching after application of the solution, 2 reported continuous itching and scalp scaling. Patch tests with Carexidil® solution and propylene glycol were performed in all 5 patients and showed an allergic reaction to Carexidil® at 48 e 72 hours in 2 patients who subsequently interrupted treatment (Table II).

One patient complained of increased hair loss 3 weeks after beginning the treatment: the loss gradually subsided and 5% Carexidil® solution application was continued.

Two patients developed a mild hypertrichosis of the temporal (1) and malar (1) regions with the appearance of more pigmented thicker hair. Both patients were experiencing a marked improvement of androgenetic alopecia, confirmed by the global photographs and by the investigator's evaluation and continued 5% Carexidil® solution application. Twenty-three patients said that they were greatly satisfied by the product, 7 were satisfied. All 30 patients decided to continue treatment with 5% Carexidil® solution after the end of the study.

Thirteen patients did not continue the trial. Reasons for dropout were personal and not related to treatment in seven cases. Two patients dropped out due to the development of allergic contact dermatitis due to minoxidil, and one patient decided to apply the solution only once daily for "practical" reasons.

Males

Efficacy

Evaluation of global photographs taken at baseline and after 6 month of treatment with 5% Carexidil® solution revealed a clinical improvement in 16 of 22 patients (72.7%) and stabilization of alopecia in 6 (27.3%) (Table I). Improvement of androgenetic alopecia was rated as moderate in 6 cases (Figure 4A, B) and marked in 10 (Figure 5A, B). Eight of the 10 patients who experienced a marked improvement had type "V" Hamilton-Norwood androgenetic alopecia in stages II and III, *i.e.* with prevalent involvement of the hair in the vertex area of the scalp.

Videodermoscopy, performed on 19 patients, revealed in all cases an improvement in the parameters typically evaluated in androgenetic alopecia: the total

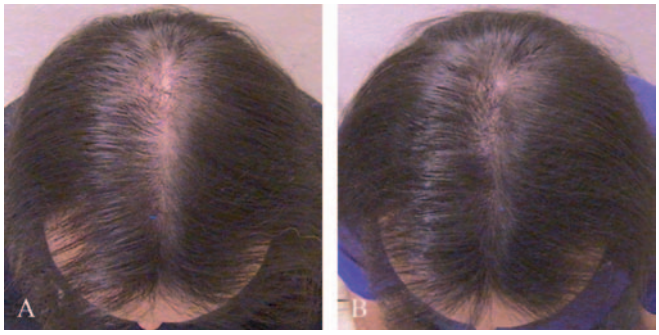

Figure 4.—Thirty year old male with Hamilton IIIv androgenetic alopecia before (A) and after (B) 6 months of use of Carexidil® solution.

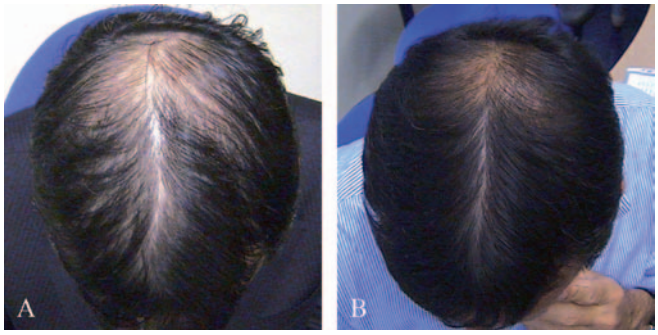

Figure 5.—Thirty-one year old male with Hamilton IIIv androgenetic alopecia before (A) and after (B) 6 months of use of Carexidil® solution.

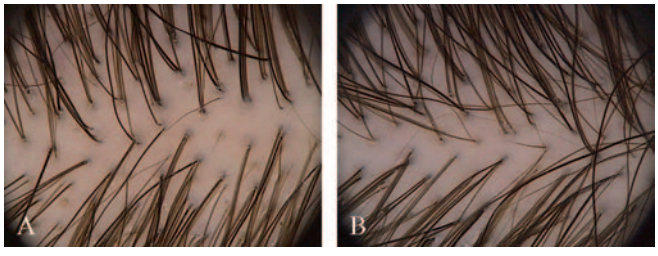

Figure 6.—Videodermoscopy the vertex area before (A) e after (B) treatment: increased thickness of the hair shafts and reduced number of empty follicles (increased hair density).

number of hairs in the 1 cm diameter area increased by 9,45% (mean number at baseline: 200,4, mean number at the end of the 6-month study: 219.3), and the percentage of vellus hair/area of 1 cm diameter decreased by 1.78% (mean percentage of vellus hair at baseline: 14,6%; at the end of the study: 12%) (Figure 6A, B).

Evaluation of efficacy based on the questionnaire filled out by the investigator showed the following: unchanged in 5 patients, mild improvement in 7, moderate improvement in 4, marked improvement in 6. Evaluation of efficacy, based on the questionnaire filled out by the patient revealed: mild improvement in 10 cases, moderate improvement in 9, marked improvement in 3 cases.

Tolerability

All patients judged the solution easy to apply. Six reported increased hair greasiness. Six patients complained of occasional scalp itching after application of the solution. Patch tests with Carexidil® solution and propylene glycol performed in these 6 patients were negative and none of them interrupted treatment. Tolerability of the solution on the scalp was defined "optimal" by all (100%) patients who continued application of 5% Carexidil® solution until the end of the study.

One patient complained of increased hair loss at the beginning of treatment: hair loss gradually subsided and treatment was not interrupted.

Thirteen patients did not finish the trial. Reasons for dropout were personal and not related to treatment in 6 cases. Two patients interrupted treatment since they found it not very practical to apply the solution twice a day.

Discussion

Our study confirms the data in literature and evidence obtained over years of clinical practice that twice daily topical application of 5% minoxidil solution, Carexidil®, is effective in treating female and male androgenetic alopecia, with results already visible after 6 months.

Clinical improvement of androgenetic alopecia is evident in 100% of female patients, including those with severe forms. It should however be noted that mild forms of androgenetic alopecia respond better to treatment, with improvement already visible both clinically and by videodermoscopy after a few months of Carexidil® solution application.

Carexidil® solution is also effective also in males, with efficacy evident in 100% of the patients: after 6 months of treatment 2/3 of the patients showed improvement of androgenetic alopecia and 1/3 showed an arrest in the progression of the disease. Androgenetic alopecia with prevalent vertex involvement

(type "V" Hamilton-Norwood) responds better to treatment than other forms, followed by anterior type. It is in fact well known that fronto-parietal recession rarely responds positively to treatment, which usually only induces arrest of its progression.

An important evidence about 5% Carexidil® solution efficacy derives from the patients' evaluation of effectiveness: all patients, males and females, reported an improvement of their alopecia after 6 months of therapy. Patients' evaluation of efficacy was always better than that of the investigator, as has also been frequently reported by other studies on treatments for androgenetic alopecia. A possible explanation for this finding is the patients' great concern for their alopecia and their consequent great enthusiasm as soon as they see clinical improvement induced by treatment. All the patients that concluded our study wanted to continue 5% Carexidil® solution application at the end of the 6-month period, as a proof of their great appreciation and faith in the product. Another reason that explains prolongation of treatment after the end of the trial is the fact that at baseline we carefully explained to all patients that any treatment effect is maintained only if drug application is not interrupted. This is a very important issue to underline: at the present time there is no medical treatment for androgenetic alopecia that permits to maintain its benefit after interruption. If the treatment is effective it should not be stopped. In our experience, as soon as the patient experiences a clinical improvement he/she is very keen to continue Carexidil® solution application.

Only 3 of our patients interrupted Carexidil® application for practical reasons: 2 males completely stopped its use while a female patient decided to apply it only once daily. A recent study on female androgenetic alopecia has shown that a once daily topical application of 5% minoxidil vehicle in mousse is as effective as a twice daily applications of the 2% solution.[4] With time we will be able to evaluate if a once daily application of the 5% minoxidil solution is equally effective.

The use of 5% minoxidil solution Carexidil® is very easy: 10 pump sprays twice daily to dry scalp. All our patients reported easy and rapid application.

About half of our patients complained that their hair was more greasy and sticky after the use of the product. Propylene glycol, one of the components of the solution, may indeed sometimes dry and form a thin layer on the scalp and around the hair emergency. Propylene glycol may also cause scalp irritation:[5] about 16% of the patients in our study reported the occasional occurrence of scalp itching, but never so severe as to induce interruption of therapy. When a patient using minoxidil solution complains of scalp itching and/or erythema it is however always advisable to exclude allergic contact dermatitis. Allergic sensitization can be easily tested by carrying out a patch test on the forearm with the solution and propylene glycol, with readings at 48 and 72 hours.[6] Although in the literature propylene glycol is reported to be the cause of contact allergy to minoxidil solution,[7, 8] it is the active principle minoxidil that may indeed cause allergy in sensitized patients. Two of our patients had a positive patch test to minoxidil and therefore interrupted application of the solution. Other 9 patients were patch tested since they complained of scalp itching, but had a negative patch test and therefore continued application of 5% Carexidil® solution, as they were satisfied or greatly satisfied by treatment.

The exact mechanism of action of minoxidil is not known, but it is likely that its positive effect on hair growth is due to its ability to open the adenosine-sensitive potassium channels of the cell membrane and to increase VEGF (Vascular Endothelial Growth Factor) synthesis by dermal papilla cells.[9]

Minoxidil concentrations suggested for the treatment of androgenetic alopecia are 5% for males and 2% for females. The rationale for the use of a higher concentration of minoxidil solution in females derives from a study that showed that application of 5% minoxidil in women with androgenetic alopecia is more effective that that of 2% and devoid of side effects if the dose of 60 mg a day is not exceeded.[10] In a subsequent study, 5% minoxidil solution resulted more effective than the 2% in female androgenetic alopecia, but more often associated with scalp itching and hypertrichosis of the face.[11] Two of our female patients developed a mild malar or temporal hypertrichosis during treatment with 5% minoxidil solution. None of them interrupted treatment since their alopecia subjectively and objectively improved through treatment and they were not bothered by the mild hypertrichosis. Once a day application of 5% minoxidil lotion is a possible option for these patients in order to maintain the positive effect on scalp hair and obtain a gradual disappearance of the hypertrichosis.

Increased hair loss after a few weeks from the beginning of minoxidil application is a rare but well-

known occurrence. It is usually worrisome for the patient, who is waiting for improvements and is on the contrary experiencing increased hair loss! Telogen effluvium after starting minoxidil treatment was first described in 1989,[11] and is considered a good prognostic factor, because it is an indicator of reentering anagen of hair follicles.

Studies on effectiveness of drugs in androgenetic alopecia usually have a 12-month duration.[4, 11, 13] Nonetheless, in clinical practice after 6 months it is already possible to assess treatment effectiveness, as well as tolerability and easy use. A control visit 6 months after the beginning of treatment is also advisable to increase patients' compliance to therapy.

Conclusions

Androgenetic alopecia has a strong psychological impact on the quality of life of both males and females [14, 15] and dermatologists can really be of great help to these patients, prescribing the best treatment, explaining outcome expectations, and following the patient over time in order to assess therapy effectiveness.

Riassunto

Minoxidil 5% (Carexidil®) soluzione cutanea per il trattamento dell'alopecia androgenetica maschile e femminile: studio clinico multicentrico in aperto

Obiettivo. Scopo del nostro studio è stato valutare l'efficacia e la tollerabilità di Carexidil® (minoxidil 5%) in soluzione cutanea, applicato 2 volte al dì sul cuoio capelluto, nell'alopecia androgenetica maschile e femminile.

Metodi. Lo studio è stato effettuato in aperto in 3 centri dermatologici, per una durata di 6 mesi. La valutazione dell'efficacia è stata fatta sia in modo soggettivo, attraverso il giudizio dell'operatore e del paziente, che in modo oggettivo, con lo studio delle fotografie globali e della videodermatoscopia.

Risultati. La valutazione delle fotografie globali ha rivelato un miglioramento clinico in tutte le 32 pazienti femmine e in 16 dei 22 pazienti maschi, ed una stabilizzazione dell'alopecia androgenetica nei rimanenti 6 maschi. La videodermatoscopia ha confermato questi dati. Alcuni pazienti hanno riferito un'aumentata untuosità dei capelli, altri la comparsa di modesto prurito dopo l'uso della soluzione. Due pazienti femmine hanno avuto una sensibilizzazione allergica (causa di drop-out) confermata dal patch test e 2 una lieve ipertricosi della regione temporale o malare. Tutti i pazienti hanno detto di essere molto soddisfatti dal prodotto ed hanno continuato l'utilizzo della soluzione cutanea dopo la fine dello studio.

Conclusioni. Il nostro studio conferma i dati della letteratura e l'evidenza di anni di pratica clinica, e cioè che l'applicazione locale 2 volte al giorno del minoxidil 5% in soluzione cutanea, Carexidil®, è efficace per il trattamento dell'alopecia androgenetica maschile e femminile, con risultati evidenti già dopo 6 mesi di trattamento.

PAROLE CHIAVE: Alopecia - Minoxidil - Videodermatoscopia.

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