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ORIGINAL CONTRIBUTION

Evaluation of efficacy of intradermal injection therapy vs derma roller application for administration of QR678 Neo® hair regrowth formulation for the treatment of Androgenetic Alopecia—A prospective study

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Abstract

Background: Non-surgical hair restoration is one of the most exciting and innovative fields in cosmetic surgery today. The addition of latest technique like derma roller seeks to achieve better results for delivering pharmaceutical solution for hair growth in comparison with topical administration.

Aim: We aim to compare intradermal injection vs. derma roller technique for administration of QR678Neo®hair regrowth therapy for the treatment of androgenetic alopecia (AGA) in male and female patients.

Method: A sum of 50 patients in the age range of 20–70 years with AGA were included and divided into 2 groups; Group A (intradermal) and Group B (derma roller). Intradermal injection of QR678Neo® formulation and derma roller with superficial application of QR678Neo® was given in each group. Assessment was done using hair pull test, global photographic assessment, video-microscopic assessment, and patient subjective assessment at baseline, 6 months, and 1 year.

Results: Significant diminution in hair fall was seen in both the groups. All the video-microscopic assessment factors were better in intradermal injection group compared to the derma roller group, but not significant. Erythema and pain were high in derma roller group in compare to intradermal.

Conclusion: Derma roller technique is more convenient and easy to perform, especially when the availability of a trained person to carry out intradermal injection is not feasible, it gives satisfactory results. It is also beneficial in needle phobic and apprehensive patients. Though the results are more efficacious with intradermal scalp injection technique, this study established satisfactory results with derma roller technique as well.

KEYWORDS
androgenetic alopecia, derma roller, hair regrowth therapy, intradermal application, QR678 Neo

1 | INTRODUCTION

Scalp hair is very important for looks in both men and women. For women, it is the crowning beauty of graciously flaunted femininity and for men, it is a conventional icon of masculinity.[1] The hair follicle has a role in epidermal homeostasis, skin tumorigenesis, and wound healing.[2] Hair loss is often distressing and may have a significant result on the individual's quality of life.[2]

Different types of hair fall conditions or alopecia encountered in clinical practice include non-cicatrical and cicatrical alopecia.[3,4] Non-cicatrical alopecia includes androgenetic alopecia, anagen effluvium, loose anagen syndrome, alopecia areata, telogen effluvium, traction alopecia, and trichotillomania. Cicatrical alopecia includes chronic lichen planopilaris, cutaneous lupus erythematosus, and central centrifugal cicatrical alopecia.[5]

Androgenetic alopecia is the commonest form of hair loss condition in both the genders. This could begin as early as puberty and around 50% of men get affected by 50 years of age and 40% of women by 70 years of age. Male pattern alopecia typically presents as receding frontal hairline, recession in bi-temporal region, and thinning on the crown. The severity is classified according to Norwood-Hamilton grade I-VII. Female pattern alopecia is widening of midline and hair loss on the top with the hairline retained and the severity is classified according to Ludwig's type I-III.[5]

Traditionally, management of alopecia aims at reducing dihydrotestosterone (DHT) and initiating hair follicles with the help of 5-alpha reductase (5AR) inhibitors including platelet-rich plasma (PRP), finasteride, and minoxidil. Additional treatments involve microneedling, laser therapy, mesotherapy, and hair transplant. All these treatment modalities have their specific selection criteria and varied success rates for hair loss.[6]

Derma roller application treatments have emerged as a suitable technique for increasing the permeability of the skin. It is a method that creates transdermal microchannels through the stratum corneum layer of skin to boost the permeability of skin for small-molecules, proteins, drugs, and vaccines.[7-10] Apart from the local drug delivery effect, derma roller causes micro wounds in the skin, which increases the micro blood circulation at the local level and induces the wound-healing process.[8] Using derma rollers also reduces trypanophobia (needle phobia) related to the use of hypodermic needles for intra-dermal delivery.[7,8]

Microneedling is a technique through which multiple tiny channels (needle size ranging from 1 mm to few mm) are created in a localized area. Microneedling is a secure and novel option which works as a supporting element for skin penetration of topical products and also facilitates the discharge of epidermal growth factors and platelet-derived growth factor at the local site by initiation of platelet and wound rejuvenation system. It further activates the stem cells in the hair bulge region, during wound-healing circumstances. As per certain animal studies, there is an up-regulation of hair growth-associated genes, B catenin, vascular endothelial growth factor, Wnt10 b, andWnt3a, as well.[7-11]

Both the techniques pave a way to effectively breach the stratum corneum and aid in the greater penetrating of medications into the dermis and the hair follicles.

Kapoor and Shome (2018) have invented a bioengineered, recombinant preparation called QR678Neo® which is a titrated mix of growth factors. In their study, the formulation was administered intradermally by microneedling or nappage system in both male and female type of hair loss. QR678 Neo® has previously confirmed successful clinical outcome in human trials and has received USA and Indian patent and is also approved for commercial use in India by Indian FDA.[12]

The previous studies proved its effectiveness in preventing loss of hair and stimulating new hair growth in comparison to PRP therapy. Also, the therapy has proved to be effective for hair loss treatment in female patients with hair loss caused by PCOS, in alopecia areata cases, and in post-cancer chemotherapy patients.[12-17]

However, there has been a notable debate in the literature about the better technique of drug delivery method for transport of the product into the deeper layers.[18-22] The aim of the present study is to evaluate the effectiveness of intradermal injection treatment vs derma roller technique for administration of QR678 Neo® hair regrowth solution for androgenetic alopecia in male and female patients.[12]

2 | MATERIAL AND METHODS

A comparative, prospective, single-blind research was carried out after approval from the Institutional Ethical committee review board at The Esthetic Clinics, India. A sum of 50 patients (25 males & 25 females), in the age range of 30–60 years, were selected. Patients were randomly separated into two groups of 25 patients each (Group A-Intradermal group and Group B-Derma roller group). Informed and written consent was signed by all the patients.

2.1 | Inclusion criteria

- Overall 50 participants (both male and female) with a history of androgenetic alopecia for period of minimum 6 months were selected for the study.
- Male patients having Norwood-Hamilton grade II-IV and female patients having Ludwig's type I-III were included.
- Participants who had not used topical application of minoxidil and /or oral finasteride in past 6 months.

2.2 | Exclusion criteria

- History of hair loss started within 6 months.
- Patients with severe medicine allergy and/or diagnosed with malignancy and autoimmune/ hematological disorders.
- Patients with other scalp disorder like seborrheic dermatitis, psoriasis, or alopecia areata.

All the medicines related to hair growth or applications had to be stopped six months prior to commencing the study and the

TABLE 1 Section 1 -Patient self-assessment questionnaire related to the efficacy of the treatment

Que. No.	Question	Possible Responses (On a scale of 0–5)
1.	Is the bald spot getting any better?	Strongly disagree >Strongly agree
2.	Is there any improvement in appearance?	Strongly disagree >Strongly agree
3.	Is there any improvement in growth of hair since start of the therapy?	Strongly disagree >Strongly agree
4.	Is the treatment effective?	Strongly disagree >Strongly agree
5.	Are you satisfied with the treatment?	Strongly disagree >Strongly agree

patients were not permitted to start any medications during the study period.

Patients had also been informed to have the same hairstyle and to avoid using hair color of any form throughout the study. Also, patients having systemic conditions underwent regular check-ups for the same.

2.3 | Intradermal injection and Microneedling technique for administration of QR678 Neo® into the intradermal scalp region

Participants were examined at the baseline, 6 months, and 1 year with usual global photographic and video-microscopic evaluation to assess the improvement in the situation of hair. At every visit, the scalp was cleaned with an alcohol swab. Approximately 1 ml solution of QR678Neo® was administered using intradermal technique in the scalp skin of patients from Group A. Approximately 60–70 small injections with 6 mm, 31G needle, were administered at a depth of 1–2 mm intradermally by nappage technique, covering the regions where hair thinning and alopecia were observed. Each injection was given in vertical and horizontal manner 1 cm apart in a grid pattern with amount of 0.02 ml at each site.

In Group B patients, a derma roller with 1.5 mm needle size was passed (approximately 4–5 times) on the scalp in longitudinal, vertical, and diagonal manner, until little erythema was observed. Same amount of QR678Neo® (1 ml) was superficially poured drop by drop all over the scalp using insulin syringe and was rubbed with fingers all over the scalp skin specifically. A total of eight sessions were performed using the same techniques, at a gap of three weeks each, for both the groups.

2.4 | Scalp assessment and evaluations

2.4.1 | Hair pull test

It was carried out by an independent observer before initiation of each session to assess the improvement in hair fall. A bundle of approximately 50–60 hair was grasped between three fingers and was pulled against the base as near as to the scalp. Pulled out hair was then counted. Values were assessed at baseline, 6 months, and 1 year.

2.4.2 | Video-microscopic assessment

ProScope digital handheld camera was used, and video-microscopic pictures were clicked at the predetermined site on the center of the scalp, 20 cm posterior to glabella. The images were taken at baseline and at 1 year to evaluate hair counts per cm^2. The images were analyzed for hair density (cm^2), terminal hair count (cm^2), vellus hair count (cm^2), and shaft diameter (μm) using particular software (Trilogic company; Tricho. Science Version 1.5). Unpaired *t* test was used to assess the level of significance inside the group and amongst both the groups. GraphPad software was used, and results were calculated.

2.4.3 | Global photographic assessment

Normal clinical pictures of the vertex and the superior front region of the head were taken for the clinical assessment at baseline, 6 months, and 1 year. Two blinded dermatologist observers looked at the images and scored them on a scale of 0 to 10, with 0 indicating no hair development and 10 indicating absolute hair growth. The mean score was compared, and a graph was developed.

2.4.4 | Patient self-assessment

Patients were given a validated questionnaire with two parts to complete at the conclusion of the report (Tables 1 and 2). The concerns in section 1 were about the treatment's effectiveness, and they were to be scored on a scale of 0 to 5, with 0 indicating extreme disagreement and 5 indicating strong agreement. The second segment had four choices for adverse effects caused by the procedure, and patients were asked to choose the appropriate response by ticking the appropriate box (multiple selections were allowed).

3 | RESULTS

The research involved a total of 50 patients in the age range from 20 to 60 years. The table shows the demographic distribution of patients by age, gender, BMI, severity score, and category. (See Table 3) Female pattern hair loss type I-III is included, as per the Norwood-Hamilton Classification for Male Pattern Baldness Grades II-IV and Ludwig's classification (1977). All of the participants were allocated to one of two groups at random.

3.1 | Hair pull test

Every participant had a mean of total ten hairfall out before starting the procedure. After six months, all patients in the intradermal group had decreased hair loss, but only 60% of those in the derma roller group had reduced hair loss. At the one-year follow-up in our analysis, 10% of the findings in Group A remained unchanged (See Table 4).

3.2 | Video-microscopic assessment

The table indicates the baseline and final values for hair density (cm^2), vellus hair count (cm^2), terminal hair count (cm^2), and shaft diameter (m) before as well as after 1-year follow-up. The level of importance within the category was determined using an unpaired t test. It was discovered that all of the variables in Group A improved significantly (p-0.005), while the values in Group B were not meaningful ($p > 0.005$). Unpaired t test was also applied to measure intergroup impact. The correlation coefficient was 24, and the P value was important (See Table 5).

TABLE 2 Section 2 -Patient self-assessment questionnaire regarding the adverse effects due to the procedure

Adverse Effect	Tick the appropriate Response(if noticed)
Itchy Scalp	
Uncomfortable Pain during Injection	
Unsteadiness during injection	
Increase in hairfall	

3.3 | Global photographic assessment

Two blinded observers analyzed the clinical images subjectively. Each photograph was scored on a scale of 0 to 10, with 0 suggesting no improvement and 10 indicating full improvement. The test took place at three separate times: at the beginning, six months, and one year later. (Table 6) Both the groups had a mean value of 4 at the start of the analysis. Group A showed significant progress (mean-7) that was sustained for over a year (mean-8.8), while Group B mean value was 5.5 at 6 months and improved to 6.7 after a year. Within Group A, it was also important to see that everyone improved their hair growth. Though, in Group B, 2 individuals (5%) showed no improvement at all. None of the individuals complained about any worsening during the therapy in both the groups. (Table 7, Figures 1 and 2).

3.4 | Patient self-assessment

In section A, a questionnaire was given to participants to assess the efficacy of the treatment and advised to grade it on a scale of 0–5. Higher agreement rate was given for the improvement in bald spots by Group A (mean = 4) in comparison to Group B (mean =2). Additional factors such as improvement in appearance (Group A = 4, Group B = 2.5), improvement in growth of hair (Group A = 5, Group B = 3), overall effectiveness of the treatment (Group A = 5, Group B = 3), and satisfaction with the treatment (Group A = 5, Group B = 3) were also higher in Group A (Figure 3).

One of the patients in Group A and 2 patients in Group B felt uncomfortable pain while performing the procedure. Itchy scalp was reported higher in Group B in comparison to Group A. While no other side effects were noted in patients of Group A, few patients ($N = 2$) in Group B reported erythema of scalp skin. None of the patients of any group reported hair fall post-therapy (Figure 4).

4 | DISCUSSION

Since puberty hair loss is the main prevalent source of hair loss in both men and women, it usually manifests as gradual thinning, miniaturization, and hair loss at the affected areas.[17] Individuals who are affected can develop psychological disorder as well as social impairment. In clinical practice, androgenetic alopecia (AGA) is

TABLE 3 Table depicting demographic distribution of patients according to age, gender, BMI, and severity score.

Group (N)	Gender (N)	Age range (years)	Norwood Grade	Ludwig Grade	N (%)	Age (mean years ±SD)	BMI (mean ± SD)
Group A (25)	Male–13 Female–12	20–70	II	I	9 (18.0%)	33.0 ± 1.8	24.80 ± 1.3
			III	II	10 (20.0%)	32.7 ± 1.6	22.23 ± 2.7
			IV	III	6 (12.0%)	34.2 ± 1.8	25.69 ± 2.2
Group B (25)	Male–12 Female–13		II	I	9 (18.0%)	33.7 ± 2.3	22.25 ± 1.8
			III	II	10 (20.0%)	32.8 ± 2.5	24.1 ± 1.85
			IV	III	6 (12.0%)	32.0 ± 1.9	23.0 ± 1.7

TABLE 4 Table depicting distribution in both groups on the basis of number of hair pulled

	Number of Hair Pulled			
Groups	**Baseline**	**6 Months**	**1 Year**	**δ**
Group A	10	3	0	10
Group B	10	4	3	7

single or with combination showed considerable results. Minoxidil 5% lotion (1 ml) when used daily twice is efficient in halting advancement and restoring AGA in men.[18-20] However, they may have severe side effects, such as headaches and a spike in body hair with minoxidil and loss of libido with finasteride.[21-24]

It is crucial in the management of the hair cycle and development. Once signal from mesenchyme-derived dermal papilla cells go into multipotent epidermal stem cells in the bulge zone, hair follicle restoration

TABLE 5 Dermoscopic assessment: Hair growth parameters showing difference within and between intradermal and derma roller groups (n = 50)

Video-microscopic Assessment							
		Group A		Group B			
Variables	**Outcome**	**Mean +SD**	**Level of significance**	**Mean +SD**	**Level of significance**	**T value**	**Df**
Terminal hair count (cm^2)	Baseline	65.42 ± 1.7	0.0001	66.23 ± 1.9	0.0001	25.40	24
	Final	82.50 ± 2.9		73.44 ± 2.6		11.19	
Vellus hair count (cm^2)	Baseline	38.54 ± 3.1	0.0001	37.43 ± 2.8	0.0001	22.73	
	Final	20.43 ± 2.5		28.19 ± 3.2		10.86	
Hair density (cm^2)	Baseline	176.5 ± 2.3	0.0001	175.2 ± 1.6	0.0001	38.05	
	Final	199.7 ± 2.0		182.5 ± 2.2		13.41	
Shaft diameter (μm)	Baseline	30.21±2.0	0.0001	29.70 ± 3.1	0.0001	21.49	
	Final	44.31 ± 2.6		24.0 ± 1.5		8.2	

TABLE 6 Global photographic assessment; patient showing improvement

	Group A			Group B		
Reviewer	**Baseline**	**6 Months**	**1 Year**	**Baseline**	**6 Months**	**1 Year**
Reviewer 1	4	6.5	8.75	4	5	6.5
Reviewer 2	4	7.5	9	4	6	7
Mean	4	7	8.8	4	5.5	6.7

TABLE 7 Global photographic assessment; patients showing no improvement and worsening

	No. of Patients showing no Improvement	**No. of Patients showing worsening**
Group A	0	0
Group B	2	0

the commonest variety of hair loss. In the vast majority of cases, a clinical diagnosis should be identified and the disorder treated medically.[17,18]

Adjunctive non-pharmacological treatment modalities such as counseling, cosmetic camouflage, and hair transplantation are essential dealings for some patients. There are limited non-surgical management possibilities for the treatment of androgenetic alopecia in male. Specifically, lotion minoxidil and tab. Finasteride when used

begins.[18] Free dihydrotestosterone (DHT) attaches to the androgen receptor on dermal papillary cells and causes follicular miniaturization through molecular signaling pathways. Inflammation, various gene transcription factors (stimulatory pathways like Wnt/-catenin, Shh, and STAT3, as well as the inhibitory pathways, growth factors, and stimulation of hair bulge stem cells have all been linked to the development of AGA. Since their primary goal is androgens, current traditional treatments (i.e., oral/topical finasteride and topical minoxidil) struggle to target any of the aforementioned pathways.[25,26]

Many new techniques have emerged as an adjuvant to hair regrowth therapy few of which is microneedling and derma roller. Microneedles are typically formed of polymers and are used to encapsulate and regulate the release of drugs through transdermal drug delivery. They can be utilized as a skin pretreatment when they are precisely implanted and withdrawn to create a micron-scaled pore on the surface of skin—the microchannels formed to function on a "poke and patch" concept.[27]

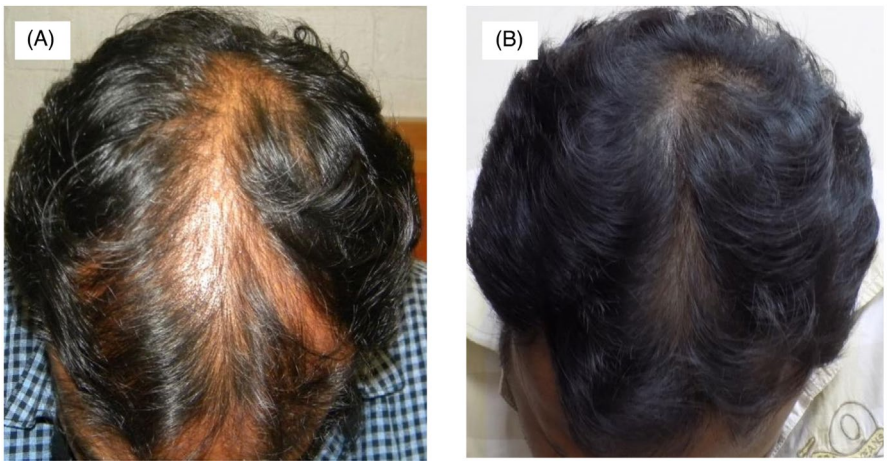

FIGURE 1 Group A Patient clinical photographs: (A) Pre-treatment. (B) After 8th session

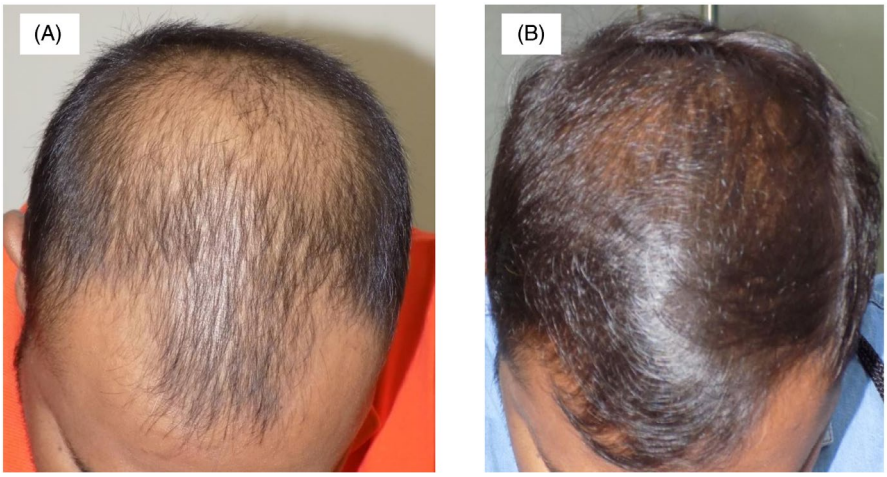

FIGURE 2 Group B Patient clinical photographs

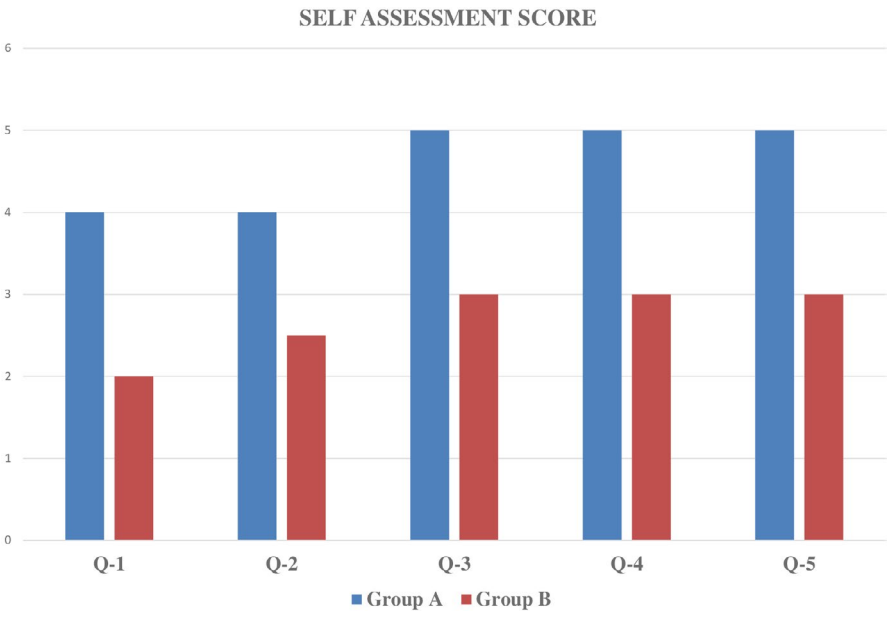

FIGURE 3 Patient self-assessment questionnaire: section 1

The "scrape and repair" method, in which tiny projections are scraped over the skin to produce micro-abrasions, is a variant of a standard accurate microneedle technique. Within a patch, the medication is applied to complex small projections. The microneedle patch is made up of a matrix of sturdy microneedles that generate a grid of micropores from which drugs can be distributed to the skin for local or systemic diffusion. A study was done by Faghihi et al., comparing two various depths of microneedles in the management of

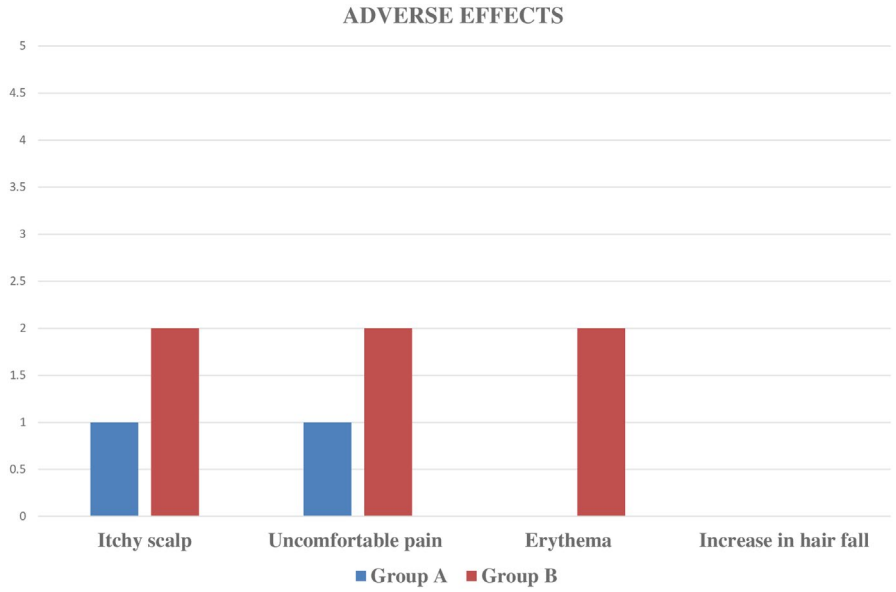

FIGURE 4 Patient self-assessment questionnaire: section 2

androgenic alopecia. In a study by Ro et al., 0.5 mm length needle for microneedling was found to be much successful than 0.3 mm depth. Another choice is to use a roller with microneedles that pierce the stratum corneum as the roller turns on the skin. Derma rollers, which are widely available, are used for skin pore opening therapies based on this concept.[22-25]

Derma rollers used were comprised of 192 titanium alloy-coated needles that are positioned in a roller of total of 24 rows, 8 needles each. Derma rollers exist in a range of sizes, range from 0.5 mm to 3 mm, 1.5 mm being the most typical size for AGA patients. The derma roller is moved across the scalp in a sequential, multidirectional motion with fierce pressure before pinpoint bleeding points are clear.[24,25]

According to Jha AK et al., using a 1.5 mm depth of derma roller was successful in increasing hair development in AGA patients.[23,24] In our study also, we have used derma roller with 1.5 mm needle size.

Microneedling induces hair regrowth through a variety of mechanisms[22,23,24,28,29]:

1. Platelet stimulation and skin wound healing enhance the discharge of platelet-derived growth factor and epidermal growth factors.
2. Stimulation of stem cells in the bulge area of hair during wound healing triggered by a derma roller.
3. over-expression of hair growth-associated genes, vascular endothelial growth factor, B catenin, Wnt10 b, and Wnt3a (wingless-related integration site; protein coding)

The QR678 hair growth factor formulation, developed by Kapoor and Shome, is a bioengineered, recombinant formulation (QR678 in this study) containing a mixture of growth factors. This invention was given the name QR 678 to represent a "Fast Response to a Disorder that Previously Had No Solution," in this case, alopecia. The formulation is administered into the scalp's intradermal layer and can help to reduce hair loss and promote hair growth.[12]

This formulation contains the growth factors in specific doses, as well as vitamins, nutrients, amino acids, nucleic acids, in a soluble medium.[12] In this review, this prescription formulation is designed for intradermal injection into the scalp, as described above.

A pilot study by Kapoor and Shome (2018) proves the efficacy and safety of intradermal injection of QR678 Neo® in 1000 patients in preventing loss of hair and improving hair growth. Considerable decrease in hair fall was noted in 83% of the participants. Treatment was well tolerated by all patients.[13-17]

In a comparative study, QR678 Neo® intradermal injection has been proven to be more effective in comparison to PRP. Also, it has proven its effectiveness in chemotherapy-induced alopecia and female pattern hair loss related to PCOS. A comparitive study of QR678 Neo® with minoxidil and finasteride found that in advanced Alopecia, QR678 Neo® may be more effective when given in combination with topical minoxidil and oral finasteride. All these studies have mentioned use of intradermal injection technique to deliver the formulation, and it showed a significant amount of benefit in all the parameters.[12-16]

In a study by Dhurat et al., total 100 patients with grade III vertex or IV AGA were included into two groups. They were randomly divided; one group was treated with weekly microneedling with minoxidil 5% solution twice daily; another group was treated only with minoxidil 5% lotion. Following baseline photographs, hair was cut to maintain the same length of hair in everyone. Hair count was evaluated at fixed area (marked with tattoo) at baseline and at the end (week 12). The progress was assessed by 7-point scale. This study described derma roller group was statistically better than other group in initiating growth in men with AGA. It emphasized microneedling as a harmless and a promising tool in hair stimulation and also is helpful to cure hair loss resistant to minoxidil.[19]

Kumar M et al. performed another analysis that involved 68 men having Norwood-Hamilton grade III and IV AGA. Following randomization, one party received microneedling weekly and topical minoxidil 5% solution twice a day, while the other received

only minoxidil 5% solution daily twice. Before treatment (baseline) and after treatment (end), global photographs and Trichoscopic images were taken from a fixed target location. Hair count and patient self-assessment for growth of hair were the two principal efficacy criteria evaluated. While the response obtained was not cosmetically significant this study found that the microneedling combined with topical minoxidil was preferable over single topical minoxidil in terms of increased hair count and patient satisfaction.[30]

The outcome of our study indicates that the derma roller is a safe and a promising adjunct for greater scalp penetration of the QR678 formulation, leading to hair enhancement in both male and female AGA and is valuable for the treatment of hair loss refractory to conventional therapy. This procedure is minimally invasive, comfortable, and easy to perform at home, as compared to intradermal injection. Although both the methods have shown efficacy in hair regrowth, our study showed that results for hair growth are slightly better with intradermal therapy. Intradermal QR678 Neo® is better in terms of less pain, itchiness, and erythema in contrast to patients with derma roller and superficial application of QR678 Neo® (60%). Furthermore, issues regarding derma roller viz; variation in size of needles, regularity, interval, and end point of the procedure also need to be answered.

We encourage that microneedling method should be provided to those patients who are apprehensive about the pricking of repeated needles on the scalp. It can also be suggested for patients with AGA in combination with the current therapeutic modalities for quicker hair regrowth and improved patient compliance.

5 | CONCLUSION

Derma roller technique is more convenient and easy to perform, especially when the availability of a trained person to carry out intradermal injection is not feasible, it gives satisfactory results. Also, for self-use or usage in salons etc, where the patients are more sensitive to the needle prick and fear of blood, derma roller can be of great benefit. Though the results are more efficacious with intradermal scalp injection technique, the results of this study established satisfactory results with derma roller technique as well. The derma roller and mesotherapy used in this pilot study have emerged as a unique clinical modality for hair growth in people with AGA. Further research with a greater sample size and adequate follow-up review is recommended.

CONFLICT OF INTEREST

The authors have been awarded a patent from the United States Patent & Trademark Office (USPTO) & from the Indian Patent Office administered by the Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM) for the invented hair formulation, used in this study.

ETHICAL APPROVAL

The study was approved from the Institutional Ethical committee review board, The Esthetic Clinics, India

AUTHOR CONTRIBUTIONS

Dr. Debraj Shome: Research project: Conception, Execution, Manuscript: Review and Critique. Dr. Rinky Kapoor: Manuscript: Review and Critique. Dr. Sapna Vadera: Manuscript: Review and Critique. Dr. Komal Doshi: Research project: Organization, Manuscript: Writing of the first draft. Dr Ghanshyam Patel: Statistical analysis. Dr. Temoor Khan: Manuscript: Writing of the first draft.

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