Received: 12 May 2022 | Revised: 13 August 2022 | Accepted: 23 August 2022

DOI: 10.1111/jocd.15336

JCD Journal of Cosmetic Dermatology WILEY

LETTERS TO THE EDITOR

Evaluation of efficacy of derma roller sizes vs topical application for administration of QR678 Neo® hair regrowth formulation in the treatment of androgenetic alopecia

To The Editor,

Traditionally, pharmacologic treatment of alopecia targets at decreasing dihydrotestosterone (DHT) and stimulating hair follicles using 5-alpha reductase (5AR) inhibitors (finasteride) or minoxidil; however, new and experimental therapies are exploring inhibition of Janus kinase (JAK) and the use of platelet-rich plasma (PRP).[1]

Micro-needling with derma roller has emerged as a recent management strategy in androgenetic alopecia (AGA) cases. Its efficacy has been established by the authors recently.[2] It is a method that creates transdermal microchannels across the stratum corneum barrier layer of skin to increase the skin permeability of small-molecules, drugs, proteins, and vaccines.[3] Apart from the drug delivery effect, derma roller causes micro-wounds in the skin, which induces the wound healing process.[4]

Kapoor and Shome (2018) have prepared a bioengineered, recombinant formulation called QR678Neo®, which contains a combination of growth factors. Previous studies proved its effectiveness in preventing hair loss and stimulating new hair growth. QR678 Neo® has already demonstrated encouraging clinical results in human trials, has been patented by the United States FDA and Trademark Office and Indian Patent and Trademark Office, and has also secured Indian FDA approval for commercial use.[5]

There has been a notable debate in the literature about the better technique of drug delivery method for the transport of the product into deeper layers. The COVID-19 pandemic has resulted in a reduced influx of patients for cosmetic procedures as it has become difficult to carry out the injectables due to various restrictions both on the patients and on the doctors. Derma rollers (<0.5 mm) can be used by themselves given that proper instructions and protocol are provided to them. The lack of availability of the 1.5-mm derma roller during this time should also be noted. Topical application being the most patient-friendly method has its own drawbacks as proper penetration may not be possible in severe cases of alopecia. The aim of the current study was to evaluate the efficacy of the derma roller technique for the administration of QR678 Neo® hair regrowth solution in male and female patients with androgenetic alopecia by comparing the 1.5- and 0.5-mm derma roller groups to the topical application group.[5]

A prospective, comparative, single-blind study was carried out from June 2020 to May 2021 after obtaining approval from the review board of the Institutional Ethical Committee. A total of 75 patients (25 male and 25 female) in the age range of 20–60 years were selected for the study. All the patients resided in the suburban district of Mumbai and were presented with the diagnosis of androgenic alopecia. Male patients with Norwood Hamilton grades II-IV and female patients with Ludwig's types I-III were included. Patients were randomly divided into three groups of 25 patients each (Group A—1.5-mm derma roller group, Group B—0.5-mm derma roller group, and Group C—topical application group). Written informed consent was signed by all the participants.

Reduction in hair fall was noted in the patients of all the three groups by the end of 6 months, whereas the hair fall was reduced in just 70% in Group B compared with 60% of participants in Group C. In our study, 100% results were maintained in Group A at 1-year follow-up. Video microscopic assessment implies that the baseline and final values for hair density (cm^2), terminal hair count (cm^2), vellus hair count (cm^2), and shaft diameter (μm) at the beginning of the study and 1-year follow-up have been mentioned in Table 1. Unpaired *t*-test was carried out to find out the level of significance within the groups. It was noted that there was a significant improvement in all the parameters in Group A as $p < 0.005$ in Group A, whereas the baseline and final values in Group B were significant ($p < 0.005$). The baseline and final values in Group C were also found to be significant ($p < 0.005$). Also, intergroup significance was calculated using the unpaired *t*-test. There was a statistically significant result in all three groups (Table 1).

Global photographic assessment was performed with the help of subjective evaluation of the clinical photographs done by two blinded reviewers. Reviewers rated each photograph on a scale of 0 to +10, with 0 showing no improvement and 10 showing maximum improvement. The assessment was made at baseline, 6 months, and 1 year. Marked improvement was seen in Group A (mean-7), which was maintained for over 1 year (mean-8.1), whereas the mean score in Group B was 5.5 at 6 months and was further increased to 7.4 at the end of 1-year follow-up. Group C showed a mean score of 6.5 at baseline, which improved to 7.2 at year 1. It was also interesting to note that all individuals showed improvement in hair growth within Group A, B and C. No individual experienced any worsening with the therapy in any of the groups (Figures 1 and 2).

According to this study, a depth of 1.5 mm of microneedle tended to be more effective than that of 0.5 mm and the topical application in terms of improving terminal hair count and hair thickness.

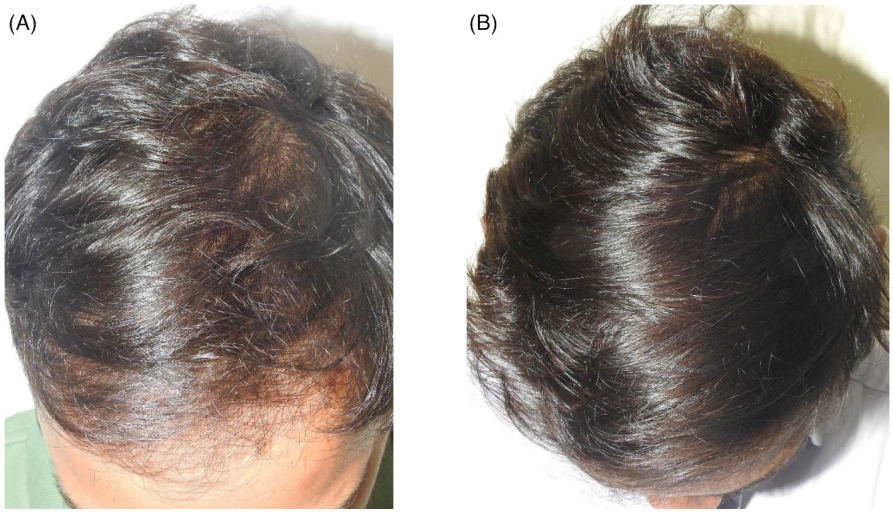

FIGURE 1 Group A Patient's clinical photographs: (A) Pretreatment image of participant with androgenetic alopecia. (B) Posttreatment image (after 8th session) with the use of 1.5-mm derma roller

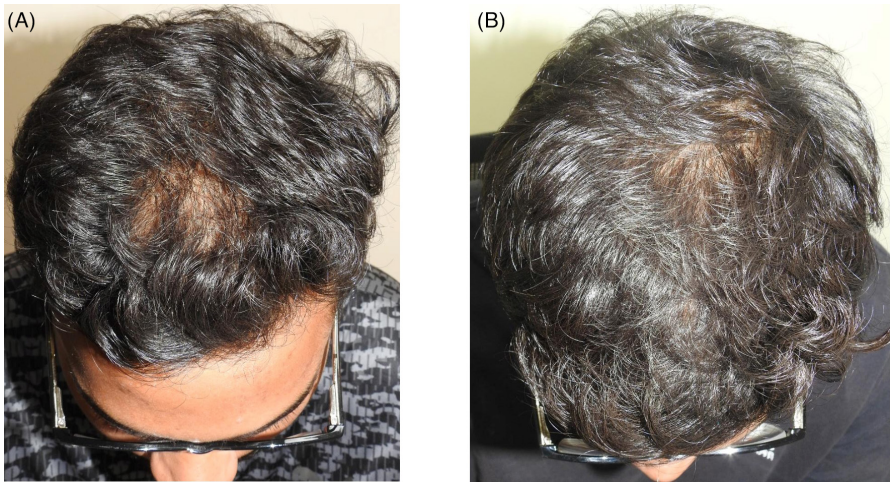

FIGURE 2 Group C Patient's clinical photographs: (A) Pretreatment image of participant with androgenetic alopecia. (B) Posttreatment image (after 8th session) with the use of the topical formulation

TABLE 1 Dermoscopic assessment: Hair growth parameters showing difference within and between derma roller groups A and B and Topical group C ($n = 75$)

		Group A		Group B		Group C			
Variables	Outcome	Mean + SD	Level of significance	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	65.13 ± 1.9	0.0001	24.4	24
	Final	82.50 ± 2.9		73.44 ± 2.6		68.44 ± 2.6		11.17	
Vellus hair count (cm^2)	Baseline	38.54 ± 3.1	0.0001	37.43 ± 2.8	0.0001	36.43 ± 2.7	0.0001	22.73	
	Final	20.43 ± 2.5		28.19 ± 3.2		24.19 ± 3.2		10.86	
Hair density (cm^2)	Baseline	176.5 ± 2.3	0.0001	175.2 ± 1.6	0.0001	173.1 ± 1.5	0.0001	37.05	
	Final	199.7 ± 2.0		182.5 ± 2.2		179.5 ± 2.1		13.41	
Shaft diameter (μm)	Baseline	30.21 ± 2.0	0.0001	29.70 ± 3.1	0.0001	28.70 ± 3.1	0.0001	21.34	
	Final	44.31 ± 2.6		34.0 ± 1.5		31.0 ± 1.5		8.2	

However, there is not much difference observed between the values. Group B showed improvement in vellus hair count as compared to Group A. Moreover, Ro et al. showed that micro-needling with a depth of 0.5 mm appears to be more effective. On the contrary, Ak et al. and Faghihi G et al. reported that applying a derma roller of 1.5-mm-sized needles was efficient to improve hair growth in AGA.[6]

The topical application is more convenient and easier to perform than the derma roller technique and the scalp injection technique,

especially when the availability of a trained person to carry out intradermal injection is not feasible, it gives satisfactory results. Though the results are more efficacious with the intradermal scalp administration technique, the results of this study established satisfactory results with both sizes of the derma roller and topical application groups. The limitation of this study is that it caters to a specific demographic of a certain population; hence, generalization cannot be made. We recommend a similar study with a larger sample size. This study demonstrates encouraging and promising results using the dermaroller administration systems, as well as the topical administration of the QR678 Neo® for hair growth treatment and maintainence. This has the potential to be a game changer in clinical practices globally, especially in the post CoVID era, in cases where inaccessibility of mesotherapy/ inoffice administration may pose to be a deterrent for many patients. Snugly fitting in the borderline of minimally-invasive and non-invasive treatment modalities, the QR678 Neo® is an evidence based, technologically driven and scientific proven formulation-providing clinically perceptive and statistically significantresults in hair growth and hair rejuvenation.

KEYWORDS

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

CONFLICT OF INTERESTS

The authors have been awarded a patent from the United States Patent & Trademark Office (USPTO) and 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.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICAL APPROVAL

The current study received Ethical Clearance from the Institutional Review Board.

FINANCIAL DISCLOSURE

The research is not supported by any grant. None of the authors have a financial interest in any of the products, devices, or drugs mentioned in this article.

Debraj Shome MD, FRCS, FACS, MBA[1]
Harshal Tandel BDS[2]
Vaibhav Kumar MDS, FRSPH[3]
Rinky Kapoor MD[4]

[1]*Department of Facial Plastic Surgery & Facial Cosmetic Surgery & Director, The Esthetic Clinics, Mumbai, India*
[2]*Academic and Research Coordinator, The Esthetic Clinics, Mumbai, India*
[3]*Research Manager, The Esthetic Clinics, Mumbai, India*
[4]*Department of Dermatology, Cosmetic Dermatology & Dermato-Surgery & Director, The Esthetic Clinics, Mumbai, India*

Correspondence
Debraj Shome, MD, FRCS, FACS, MBA, Consultant Facial Plastic & Facial Cosmetic Surgeon, The Esthetic Clinics, Mumbai, India.
Email: debraj.shome@theestheticclinic.com

ORCID

Debraj Shome https://orcid.org/0000-0003-2163-1170
Vaibhav Kumar https://orcid.org/0000-0003-2166-1740

REFERENCES

1. Jones MC. Treatment options for androgenetic alopecia. *US Pharm*. 2018;43:12-16.
2. Yoo KH, Lee JW, Li K, Kim BJ, Kim MN. Photodynamic therapy with methyl 5-aminolevulinate acid might be ineffective in recalcitrant alopecia totalis regardless of using a microneedle roller to increase skin penetration. *Dermatol Surg*. 2010;36:618-622.
3. Park KY, Jang WS, Lim YY, et al. Safety evaluation of stamp type digital microneedle devices in hairless mice. *Ann Dermatol*. 2013;25:46-53.
4. Shome D, Kapoor R, Vadera S, Doshi K, Patel G, Mohammad Khan T. 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. *J Cosmet Dermatol*. 2021;20:3299-3307. doi:10.1111/jocd.14139
5. Kapoor R, Shome D, Vadera S, Kumar V. QR678 & QR678 neo hair growth formulations: a cellular toxicity & animal efficacy study. *Plast Reconstr Surg Glob Open*. 2020;8(8):e2843.
6. Faghihi G, Nabavinejad S, Mokhtari F, Naeini FF, Iraji F. Microneedling in androgenetic alopecia; comparing two different depth of microneedles. *J Cosm Dermat*. 2020;20(4):1241-1247.