# Chemical Peeling for Nail Disorders: Need for a Systematic Approach

Dear Sir,

We read with interest the right–left comparative study on nail peels in superficial nail abnormalities by Daulatabad *et al.*,[1] published recently in your esteemed journal. However, we wish to add a few comments hoping to enhance the understanding of the basic and clinical aspects of such a study.

Firstly, we appreciate the authors' admission regarding (a) the paucity of precedential clinical studies excepting the first-ever pioneer work, the prospective uncontrolled study by Banga and Patel[2] that evaluated the effect of glycolic acid (GA) 70% on rough/hyperkeratotic nails (published in JCAS itself), and (b) the unclear mechanism of action of chemical peels through the nail plate, a hard and relatively impermeable structure compared to the stratum corneum of the cutis. However, it is noteworthy that in this study, only 15 patients were evaluated compared to 31 patients evaluated in the pilot study by Banga and Patel (including 9 with hyperkeratotic nails).[1,2] There seems to be a paradox with respect to the comparative size of the cohort, stemming from the commentarial recommendations by the corresponding author of the study in question on the role of chemical peeling in nail disorders[3] published in the same issue of JCAS, in which the credible and innovative work of Banga and Patel was published.[2] The concerned author in this commentary had aptly suggested with the doubtless intent of constructive criticism that concrete conclusions regarding chemical peeling for nails can be derived only through well-controlled studies with a larger number of patients. However, this study, conducted almost 2 years after the commentary published in JCAS by the same esteemed author (the corresponding author of the study in question, as well as the author of the commentary on the study by Banga and Patel in which she offered excellent suggestions to improve upon their pilot protocol and provided significant and feasible propositions for future studies in this relatively unexplored arena of nail therapeutics to ensure generation of genuine and high-quality evidence) included only 17 patients with 15 evaluated in the final analysis. It is intriguing that the esteemed author highlighted 'small number of patients (31)' as a major constraint/limitation of the pilot study by Banga and Patel[3]; although the cohort of patients analysed in the study conducted by the author and her team was infact 50% smaller in size.[1] The total number of nails analyzed was 120 in the study by Daulatabad *et al.* (the study being discussed).[1] Although the 'number of nails' was not mentioned by Banga and Patel in their pilot study, logically (based on double the number of patients included) as well as factually (through personal communication from the second author - Dr Kalpana Patel), the number of nails included for analysis was a total of 317 (more than double of 150). Interestingly, the esteemed author in her commentary also stated that the study by Banga and Patel 'did not include any patients with trachyonychia'.[3] As a matter of fact, 22 of the 31 patients (71%) in the pilot study actually had trachyonychia, although these patients were referred to as having 'dry rough nails', which is the most consensual and recently accepted general term for this condition.[4]

Secondly, the esteemed author, once again offered a very pertinent suggestion of conducting 'well-controlled' and designed studies in future.[2] But regrettably, the three tenets of 'good study design' for an interventional study, namely 1) study population (large sample size and employing a statistically guided criterion for deciding sample size), 2) unambiguous definition of primary, secondary and other outcome measures, and most importantly 3) validation of measurement technique used for outcome determination[5] were not adhered to in the study being discussed. Given the small cohort of 15 patients (despite 120 nails being evaluated), and this being the second-ever study on a totally new therapeutic approach for superficial nail disorders, we believe that the following approach would have been better: 1) patients with the same clinical diagnosis (e.g. idiopathic trachyonychia only, or nail lichen planus only) should have been included instead of even smaller number of patients ($n$ ranging from 2 to 6) with four different diagnoses, and 2) evaluation of a single peeling agent with comparison against placebo or a favourable modality with some evidence for that condition, e.g. nail fold injection of triamcinolone for nail lichen planus, instead of comparison of two peeling agents. Although the authors of this study attempted to improve on the methodology of Banga and Patel[2] by including the Nail Surface Abnormality Index (NSI), a self-designed objective scoring system, this score was not validated. Validation of a measuring instrument (determined by statistical methods) is imperative for assessing its quality and practicability before employing it in a study. Only statistically established validation of a 'self-designed'

measuring instrument accords 'accuracy' to it; exemplified by the Onychomycosis Severity Index devised by Carney *et al.*[6] Accuracy subsumes reliability and validity and can be high only when both its components are also high. Precision represents the consistency of results yielded by the validated instrument on repeated use. Low precision is synonymous with imprecision in measurement and mandates larger sample size to reduce the errors.[6] Unfortunately in this study, validation of the self-designed instrument was not even considered clearly making NSI unreliable for the purpose it was designed for; the 'study-design' suffering further from a randomly decided small sample size. Further, it was disappointing to find no mention of the statistical tests applied, or the cut-off level of significance adopted in the study; the brass tacks of any study protocol. There is also no mention (at least) whether patients were allowed/enquired about use of other non-specific (e.g. biotin containing supplements) or specific therapy (topical/intralesional steroids for nail lichen planus). In the absence of validated scores for nail surface abnormalities, and the relative nonavailability of advanced tools, we propose the use of onychoscopy, a simple and handy tool for pre- and posttreatment evaluation of the nail surface.[7]

Thirdly, we believe that classifying the peeling agents used (GA, 70% [2 coats] and phenol, 8% plus trichloroacetic acid [TCA], 15%) as "medium-depth" peels, especially in context of nail peeling is inaccurate. The classification of peeling agents into superficial, medium-depth, and deep peels is based on the depth of penetration through the layers of the skin (not nail). The stark difference in the microanatomy of the nail plate and the skin need not be overemphasized. And although GA (70%) left for up to 15 min may qualify as a medium-depth peel for the skin (not nail), the croton oil-free low-concentration phenol (8%) combined with TCA (15%) is a modified phenol peel with ill-defined depth of penetration. In a recent comprehensive chapter addressing 'phenol peels and their modifications for the skin of color' authored by one of our authors (SS), pH-optimized (0.5) non-buffered hydroalcoholic combination solutions of low concentration phenol (typically 8%), TCA (usually 15%) and 1-2% of other hydroxy acids like mandelic, ferulic, phytic, salicylic etc. have been labeled as Croton oil-free Phenol Combination (CFPC) peels.[8] Multiple coats followed by sealing off with retinol cream with a leave-on time of 6–8 hours is the minimum essential standard protocol of this peel combination to classify as a medium-depth peel, that too for the 'skin' (not nail).[8] Thus, at least in future trials on nail peeling with a truly well-designed study protocol, we recommend simply stating the type and concentration of the peeling agent(s) used instead of using terms like superficial/medium/deep to extrapolate a classification suitable for the skin to its most impenetrable appendage, the nail.

Finally, the authors' conjecture about the deproteinating and denaturing effect of phenol limiting its deeper penetration is logical, but irrelevant for the concentration used in their study. When used as a skin peel, 88% phenol causes immediate coagulation of keratin that limits the penetration to the upper reticular dermis. Dilution of phenol makes it a strong keratolytic with sulphur bonds-disrupting activity enabling much deeper penetration.[9]

Thus, despite a commendable effort by the authors, we suggest caution in the interpretation of the study results. We propose that instead of a comparative study of two peeling agents, involving a small number of patients and an unvalidated scoring system, studies with larger cohort, placebo-controlled trial design, and a validated objective scoring system are warranted.

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## Conflicts of interest

There are no conflicts of interest.

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