ORIGINAL ARTICLE

The efficacy in treatment of facial atrophic acne scars in Asians with a fractional radiofrequency microneedle system

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Abstract

Background Treatment of acne scars remains a challenge to dermatologists. Multiple modalities have been employed with variable results and adverse effects.

Objective To determine the efficacy and adverse effects of a fractional radiofrequency microneedle system (FRMS) on acne scars in Asians at 1-, 3- and 6-month follow-up visits after treatment.

Methods Thirty subjects with atrophic acne scars for more than 6 months were enrolled in the study. All volunteers were treated with a FRMS on affected areas. The subjects were treated for a total number of three treatment sessions at 1-month intervals. Subjective assessments were obtained at baseline, 1, 3 and 6 months after the last treatment session by self-evaluation and two blinded dermatologists. Objective evaluation using an ultraviolet A-light video camera was also performed. In addition, pain scores, immediate reactions, healing times and other adverse effects were evaluated.

Results Twenty-six subjects with skin phototypes III–V completed treatment protocol. The average mean scar age was 7 years (range: 0.5–15 years). At 6-month follow-up visit, the majority of the subjects (42.3%) reported a 26–50% improvement on their acne scars. Percent reduction in scar volume corresponded to clinical evaluation. Adverse reactions of the treatment included pain, immediate oedema/erythema, minimal scabbing and transient pigmentary alteration on treated areas. The average pain score was 5.6 of 10. Worsening of skin texture or new scar formation was not observed in any subjects.

Conclusion Fractional radiofrequency microneedle system is a safe and effective device for treating acne scars in Asians with minimal risk of downtime and adverse effects.

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Conflict of interest

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Introduction

Scars resulting from inflammatory acne are commonly seen in general adults. Dark-skinned individuals are at higher risk for developing postinflammatory pigmentary alteration and atrophic scars subsequent to severe inflammatory acne.[1] Many treatment options, such as topical retinoic acid application, chemical peeling, dermabrasion, scar revision/excision/subcision, punch grafting, skin rolling technique, fillers and ablative/non-ablative/fractional resurfacing with lasers/lights/plasma devices, have been used to improve acne scars, with varying levels of success and adverse effects.[2]

Radiofrequency (RF) technology has been used since 1920 when Bovie has been introduced as a high-frequency alternative current device to cut or coagulate tissue.[3] RF technology is currently used for a variety of medical purposes. For dermatologic conditions, RF technology has been used for tissue cutting, ablation, desiccation, coagulation, electrolysis and dermal heating. RF delivers volumetric heating to dermal structures resulting in tightening of skin without disruption of the epidermis.[4] Several studies have shown clinical applications of RF for treatments of excessive skin laxity, telangiectasia, unwanted hair and acne.[5]

In 2004, fractional photothermolysis (FP) devices have been developed to correct the drawbacks of both ablative resurfacing with its significant side-effects and non-ablative resurfacing with its limited effectiveness.[6] FP devices do this by leaving intact tissue bridges between multiple tiny areas of coagulation necrosis within the dermis after irradiation, resulting in rapid healing time as healing originates not only from stem cells in skin appendages but also from the epidermal stem cells between bridging areas. Recently, a novel fractional radiofrequency microneedle system (FRMS) has been introduced for the

purpose of treating acne scars. The acne scar improvement is thought to be a result of heat-induced collagen shrinkage, collagen neogenesis and stimulating remodelling.

The purpose of this study was to determine the efficacy and adverse effects of a FRMS on acne scars in Asians at 1-, 3- and 6-month posttreatment follow-ups.

Methods

Patient characteristics

Thirty subjects (15 females and 15 males) aged 22–45 years old (mean age 34) with facial atrophic acne scars more than 6 months and skin phototypes III–V were enrolled into the study. Study inclusion criteria included no active inflammatory acne for 6 months prior to study treatment and no topical or physical scar treatments within 12 months before entry to the study. Subjects who had a history of isotretinoin or hormonal use within 6 months before study treatment, history of keloid, history of filler injection on the treated area, concurrent skin inflammation/infection on the face, pregnancy or lactation were excluded.

The study protocol and informed consent documents were submitted and approved by the Ethical Committee on Research Involving Human Subjects, Faculty of Medicine Siriraj Hospital, Mahidol University, which conformed to the guidelines of the 1975 Declaration of Helsinki. Informed consent was obtained from each study subject before enrolment.

Treatment procedure

The treatment areas were cleaned with a mild cleanser and disinfected with 70% isopropyl alcohol. A topical mixture of lidocaine, 2.5% and prilocaine, 2.5% cream (a eutectic mixture of local anaesthetic, AstraZeneca LP, Wilmington, DE) was applied under occlusion to the treatment area for 1 h prior to each treatment. In all subjects, both entire cheek areas were treated with two consecutive passes of a FRMS (INTRAcel™, Jeisys Medical, Seoul, Korea). The subjects were treated for a total of three treatment sessions at 1 month intervals. The disposable handpiece of the device used consists of rows of 49 microneedle electrodes in a 1×1 cm^2 area. Each electrode was 1.5 mm in length, consisting of two parts. The proximal part of each electrode was covered with insulate. The distal part or tip of the electrodes that emitted RF waves was only 0.3 mm in length, uncovered by insulation. These microneedle electrodes emitted and directly delivered RF waves at the dermal level, while sparing the epidermis. Default treatment parameters available ranged from test level to level 5. In this study, all subjects were treated with level 3, operating at a voltage of 30 watts, radio wave of 80 ms and time of electrode existing on the skin of 330 milliseconds.

Identical treatment techniques were performed on all patients by a single physician (P.L.). The initial pass was made in an oblique pattern, followed by a second pass over the same area in a reverse oblique pattern. No posttreatment analgesic medications were required other than the application of cold gauzes to the treated sites for 15 min. When pain or burning sensations decreased, a layer of petroleum jelly was applied to the treated areas. None of the subjects had history of herpes infection. No prophylactic antibiotics, antiviral, or antifungal agents were prescribed for any subjects.

The subjects were instructed to cleanse the treated sites gently with only tap water postoperatively and apply white petroleum jelly to the treated area four times daily, and to avoid the use of any topical preparations or makeup on the face for 1 week. After the crusting completely exfoliated, subjects were instructed to avoid outdoor activities, to wear a broad-spectrum sunscreen with a sun protection factor of 50 and a protecting grade of ultraviolet light A (UVA) of 3+ for the duration of the study.

Treatment evaluations

Subjective evaluation Photographic documentation using identical camera settings, lighting and patient positioning was obtained at baseline and at 1, 3 and 6 months after final treatment. All digital photographs were shot with a facial photo fixture using a Canon PowerShot G9 standoff camera (OMNIA Imaging System, Canfield Scientific, Inc, Fairfield, NJ, USA). The fixture ensured a set distance and fixed angles between the patient and the camera. The imaging station provided preset camera angles for frontal through full profile together with the match pose image overlay for quick and accurate patient positioning. Flashlamps placed in fixed positions to the camera ensured even illumination of all parts of the face and the ability to examine subjects under controlled lighting.

Blinded clinical assessments of the treatment areas using comparative photographs were conducted by two independent, unbiased and board-certified dermatologists (W.M. and R.W.). The scar improvement at each follow-up visit was evaluated by showing two photographs (pre- and posttreatment) of each individual subject on a liquid crystal display (LCD) monitor. The two evaluators were blinded to the order of the photographs. The evaluators were then asked to perform two actions. First, they were asked to identify the photograph that showed better scar appearance as posttreatment photo. Second, the evaluators rated the difference in the severity of the acne scars in the two photographs using the following numeric responses: less than 25%, 25–50%, 51–75% and 76–100% difference in severity. In the case that the evaluators identified the pretreatment photo as having better scar appearance, the assessment was recorded as worse. When the evaluators identified the posttreatment photo as having better scar appearance, those quartile grading scales reflected an improvement in the scar. Adverse effects and recovery times were recorded at each follow-up visit. All subjects were also asked to rate the pain associated with treatment using a 10-point scale (0 = no pain

at all; 10 = the most severe pain) immediately after each treatment session.

The patients' overall satisfaction was also rated by the study subjects at each follow-up visit after completion of treatment, and the improvement of acne scars was graded into one of four categories: slightly better, fair, good and excellent, corresponding to the quartile grading scale mentioned previously.

Objective evaluation

Designated scars on both cheeks of the face were marked on every subject and mapped with a translucent sheet during the first visit to ensure the uniformity of the scar locations. Skin surface smoothness and volume of designated scars of each individual subject were objectively evaluated using an UVA video camera (VisioScan VC 98; Courage-Khazaka, Köln, Germany) with analysis software (Surface Evaluation of the Living Skin; Courage-Khazaka), as described previously.[7] The device consists of a handheld probe with a measuring area of 6 × 8 mm. An average value of two measurements on a representative area on each side of the face was obtained. In brief, this instrument measures the skin surface characteristics based on a graphic depiction of the living skin under UVA illumination and the electronic processing and evaluation of this image according to its clinical surface conditions. The surface evaluation of the Living Skin (SELS) software (developed by the Institute for Experimental Dermatology, Prof. Tronnier, University of Witten-Herdecke, Germany) was used to calculate skin smoothness from the average width and depth of acne scars and to determine scar volume based on the virtual amount of liquid needed in the measured area to fill the image to the average height of all scar peaks. The evaluation was done at baseline and 1, 3 and 6 months after the last treatment.

Statistical analysis

The Wilcoxon signed rank test was utilized to determine if there were any significant differences in the clinical improvement scores between the 1-, 3- and 6-month follow-up visits. Analyses of repeated measures, including repeated measures analysis of variance and multivariate analysis were performed to test the differences in the means of skin surface smoothness and scar volume over time (baseline, 1, 3 and 6 months after the final treatment). The statistical tests were two sided, and a probability value of <5% was considered statistically significant. The statistical analysis was performed using SPSS statistical analysis software version 18.0 (SPSS Inc., Chicago, IL, USA).

Results

Of the 30 patients enrolled, 26 (87%) completed treatment protocol. Four subjects were withdrawn from the study because they could not attend scheduled follow-up visits. The average mean scar age was 7 years (ranging from 0.5 to 15 years). Most subjects (96%) had skin phototypes IV–V.

Clinical improvement assessed by two blinded independent dermatologists is demonstrated in Figure 1. None of the subjects was assessed to have a worsened appearance of their scars after the FRMS treatments. The average improvement of the subjects' scars at the 1-month follow-up visit after the last treatment was graded as excellent in 0%, good in 4%, fair in 23% and slightly improved in 73%. At the 3-month follow-up visit, the average improvement was excellent in 2%, good in 13%, fair in 35% and slightly improved in 50% of the cases. At the 6-month follow-up visit, the improvement of the subjects' scars was judged as excellent in 8%, good in 23%, fair in 36.5% and slightly improved in 32.5%. Inter-rater agreement was tested using the kappa statistic at each follow-up visit. Weighted kappa statistics for inter-rater agreement at 1-, 3- and 6-month follow-up visits was 0.771, 0.759 and 0.852, respectively ($P < 0.001$), which meant that the two independent evaluators had very good strength of agreement. Most of the patients in this study had moderate to severe punched out atrophic and rolling acne scars. These type of scars responded best to FRMS treatment when compared with ice pick and hypertrophic acne scars.

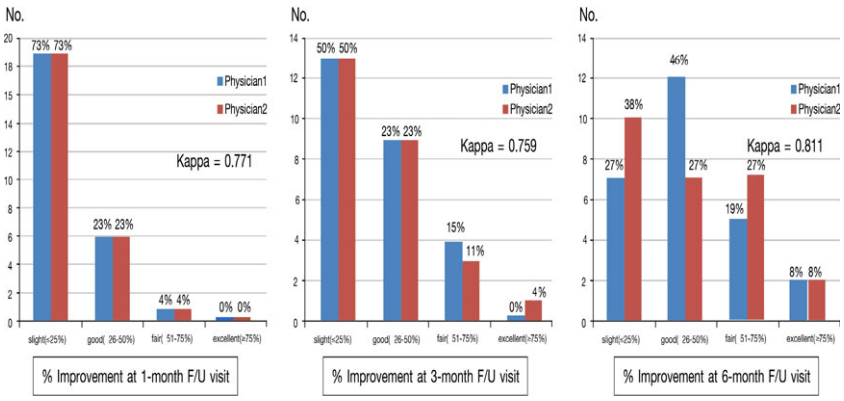

Figure 1 Overall scar improvement assessed by two blinded independent dermatologists at 1, 3 and 6 months after the third treatment.

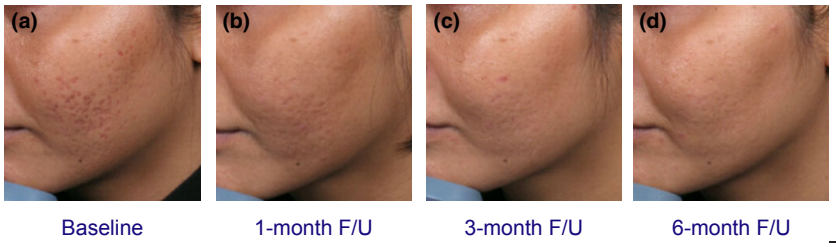

Figure 2 Patient's left profile at baseline (a), 1 month (b), 3 months (c) and 6 months after the third treatment (d).

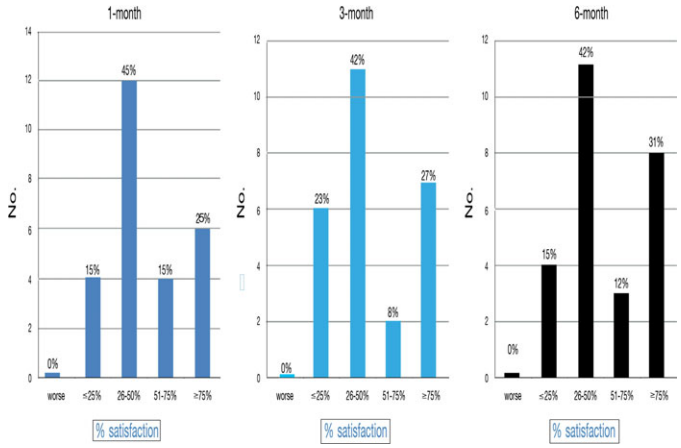

Figure 3 Overall subject satisfaction at 1 month, 3 months and 6 months after third treatment.

For subjects' evaluations, at 1-, 3- and 6-month follow-up visit, the majority of the subjects (45%, 42% and 42% respectively) reported having 26–50% satisfaction. Subjects had reported improvement of acne scars since the 1-month follow-up visit after the third treatment. At the 6-month follow-up visit, 85% of the subjects rated themselves as having at least 26–50% satisfaction in their acne scar improvement. None of the subjects assessed themselves as having had no improvement or having worsened (Figs. 2 and 3).

Objective evaluation assessed by the Visioscan VC 98 (Courage-Khazaka) at 1-month follow-up visit demonstrated statistically significant improvements of the skin surface roughness ($P = 0.012$) and scar volume ($P = 0.03$), compared with the baseline measurement. However, no further improvements of either skin surface roughness or scar volume at the 3- and 6-month follow-ups was found when compared with the 1-month follow-up visit value (Fig. 4).

Adverse reactions

All subjects stated that treatment-related pain was moderate (the average pain score was 5.6 of 10). The adverse reactions found in this study were demonstrated in Table 1. Immediate erythema at the treated area was observed in all subjects and persisted for 3–10 days. Oedema also occurred within a short period after receiving RF pulse in all subjects and resolved in 1–3 days. Twelve subjects (46%) reported the occurrence of thin scabs, which disappeared in 2–7 days. Transient mild postinflammatory hyperpigmentation (PIH) was experienced in

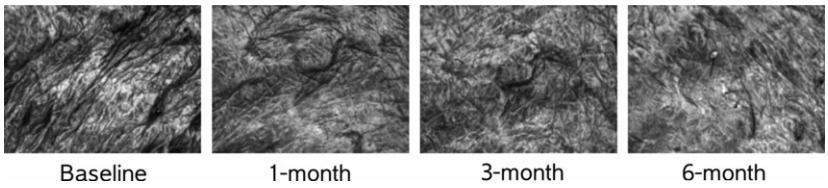

Figure 4 Images from Visioscan VC 98 at baseline, 1 month, 3 months and 6 months after last treatment. There were improvements of skin surface roughness and scar volume at 1 month after treatment with fractional radiofrequency microneedle system (FRMS). However, no further improvements after 3-month post-FRMS treatment were observed.

Table 1 Adverse reactions after treatment with an fractional radiofrequency microneedle system in Asian subjects

Adverse reactions	No. of affected patients/ total No. of patients (%)	Duration
Pain	26/26 (100.00)	<30 min
Immediate erythema	26/26 (100.00)	3–10 days
Oedema	26/26 (100.00)	1–3 days
Burning sensation	24/26 (92.31)	1–3 days
Scabs	12/26 (46.15)	2–7 days
Hyperpigmentation	1/26 (3.85)	30 days

one patient (3.85%) and subsided spontaneously within 1 month without any recurrences after the remaining treatment sessions. Worsening of skin texture, new scar formation, wound infection, or contact dermatitis was not observed in any subjects.

Interestingly, beside the improvement of acne scars, 33% of subjects described experiencing improvement of facial contour and facial skin tightness at 6 months after three FRMS treatments (Fig. 5).

Discussion

The RF system has seen increased popularity in the fields of surgery, cardiology, ophthalmology, orthopaedics, oncology and dermatology. A variety of applications have been utilized such as tissue electrodesiccation and electrocoagulation,[8] aberrant cardiac electroconductive ablation,[9] hyperopia correction,[10] joint capsular tightening in arthroscopic knee surgery,[11] elimination saphenous varicose vein reflux[12] and hepatic cancer ablation.[13] Theoretically, the RF's mechanisms of action include delivering uniform heat at controlled depth to the dermal layers, resulting in immediate collagen shrinkage and subsequent collagen remodelling.[14] For FRMS, Hantash and colleagues studied the wound healing response of postfractional RF treatment.[15] They found that dermal tissue temperature at 72°C generated a RF thermal zone (RFTZ) pattern in the reticular dermis. There were zones of denatured collagen separated by zones of spared dermis. RFTZs were observed for 4 weeks post treatment and then replaced by new dermal tissue by 10 weeks post treatment, with consistent increases in HSP47 expression. Reticular dermal volume, cellularity, hyaluronic acid and elastin content were also increased. Reverse transcription polymerase chain reaction studies demonstrated an abrupt rise in IL-1beta, TNF-alpha and MMP-13 whereas MMP-1, HSP72, HSP47 and TGF-beta levels rose by 2 days post treatment. A marked induction of tropoelastin, fibrillin, as well as procollagens 1 and 3 by 4 weeks post treatment was also observed. In addition, Hantash and colleagues's study also demonstrated evidence of neocollagenesis and neoelastogenesis following fractional RF treatment on human skin. The columns of minute thermal zone pattern in the dermis after treatment with FRMS resulted in tissue remodelling and regeneration as evidenced by clinical improvement of scar and skin texture and confirmed by the results of the image analysis using an ultraviolet A-light video camera. Improvement of skin tightness has also been described after fractional dermal coagulation by FRMS. Collagen shrinkage and remodelling induced by fractional dermal coagulation were thought to be the fundamental factor leading to clinically observed improvement of atrophic scars and skin tightening.

This study also demonstrated that FRMS efficiently improved acne scars with minimal drawbacks in subjects with skin phototypes IV–V. Forty-six per cent of all subjects developed some scabs that fell off in 2–7 days, and 4% of all subjects developed transient PIH, which completely resolved in a month. Although the efficacy of this FRMS could not be compared to conventional ablative resurfacing, after three treatments with this FRMS in this study, all subjects rated themselves as having at least 25–50% overall satisfaction, whereas unbiased physicians graded 82% of subjects as having at least 25–50% improvement in scar conditions at a 6-month follow-up visit. However, the improvement of acne scars from FRMS was superior than fractional carbon dioxide (CO_2) and fractional Erbium:YAG (Er:YAG) lasers.

Manuskiatti and colleagues[16] compared the efficacy and safety of fractional CO_2 and fractional Er:YAG lasers systems for treatment of atrophic acne scars in dark-skinned patients. They found that 25% of the Er:YAG and CO_2 sites were assessed to have more than 25% improvement of the scar appearance at 1-month follow-up visit. At 3 months after the last treatment, 30% and 40% of Er:YAG and CO_2 sites, respectively, were rated to have more than 50% improvement. At the 6-month follow-up, the appearance of the scars judged as having more than 50% improvement noted in 55% and 65% of Er:YAG and CO_2 sites respectively. When comparing with fractional CO_2 and Er:YAG lasers, FRMS provides comparable results.

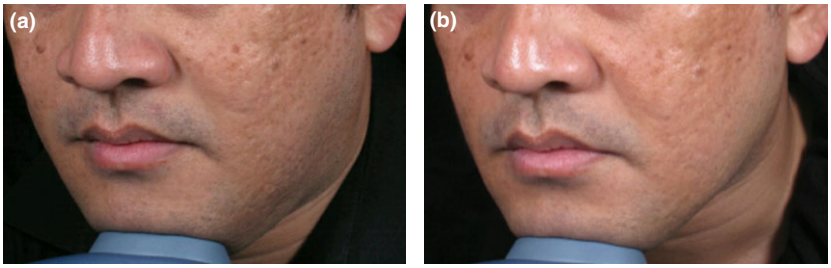

Figure 5 Additional improvement of facial contour and facial skin tightness: baseline (a) and 6 months after three fractional radiofrequency microneedle system (FRMS) treatments (b).

The observation from this study was consistent with the finding of a recent study by Peterson *et al.*[17] which reported a 68.2% improvement of acne scarring after 3 months of five treatments using a combining fractional 915 nm diode laser with RF along with a fractionated RF handpiece in subjects with Fitzpatrick skin types II–V. In their study, no episodes of PIH or infections were observed. Subjects with dark skin phototypes have limited options for improvement of acne scars because of greater incidence of PIH. PIH is a major adverse effect of ablative laser resurfacing or dermabrasion performed on dark-skinned subjects. In Fitzpatrick skin phototype IV, PIH occurs in as high as 80% of patients and can last for 3–9 months.[18] If this adverse reaction persists, it may cause psychological problems in the affected patients. For fractional CO_2 ablative laser treatment, Manuskiatti *et al.*[19] reported that more than 90% of the subjects experienced PIH. However, from this study, only one subject (4%) developed PIH after the first treatment. In addition, this PIH was transient and completely and spontaneously cleared in a month. This subject did not experience any relapse of PIH after the rest of the treatment sessions. The advantage of this FRMS over the fractional ablative systems was the lower risk of PIH, which may result from lesser epidermal injury during procedures.

Yeung *et al.*[20] studied the efficacy of combined fractional RF and fractional laser treatment for acne scars in Asians. The fractional RF system used in this study was needleless. All subjects received up to five treatments at 1-month interval. At 1 and 3 months after the last treatment, 43.8% and 52.6% of patients, respectively, showed >25% improvement of their acne scars. Therefore, the improvement of acne scars from fractional needleless RF was comparable with FRMS at higher number of treatment sessions. The incidence of PIH found in Yeung's study was 6.5% which was higher than this study (3.85%).

In addition, it was found that 33.3% of subjects reported improvement of facial contour and facial skin tightness, which is consistent with the study of Lee *et al.*,[21] who tested a fractional bipolar RF system on 26 Korean women. They found that fractional bipolar RF treatments produced moderate (26–50%) and significant incremental improvements in degree of smoothness and tightness 6 weeks after the third session from baseline. That study was limited by the relatively small subject collection, yet significant clinical improvements were noticed.

In conclusion, the fractional RF microneedle system demonstrated effectiveness in treating facial atrophic acne scars in dark-skinned types with minimal risk of adverse effects and downtime.

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Author contributions

Dr. Wanitphakdeedecha had full access to all the data in the study and takes responsibility for the integrity of data and the accuracy of the data analysis; Drs. Wanitphakdeedecha and Manuskiatti contributed to study concept and design; Drs. Limtanyakul and Vejjabhinanta acquired the data; Drs. Wanitphakdeedecha and Vejjabhinanta analyzed and interpreted the data; Dr. Vejjabhinanta drafted the manuscript; Dr. Manuskiatti critically revised the manuscript for important intellectual content; Dr. Vejjabhinanta involved in statistical analysis; Dr. Wanitphakdeedecha provided administrative, technical and material support; and Dr. Wanitphakdeedecha supervised the study.

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