Importance Neocollagenesis can be achieved using a dermal rolling needle device, thereby reducing the appearance of acne scars.

Objective To determine the efficacy of a needling device for treatment of acne scars.

Design, Setting, and Participants We performed a single-center, rater-blinded, balanced (1:1), split-face, placebo-controlled, parallel-group randomized clinical trial at an urban academic institution. The study took place from November 30, 2009, through July 27, 2010. Twenty healthy adults (age range, 20-65 years) with acne scars on both sides of the face were enrolled. Fifteen individuals completed the study, and no enrolled participants were withdrawn for adverse effects.

Interventions For each participant, one side of the face was randomized for needling. Three needling treatments were performed at 2-week intervals.

Main Outcomes and Measures Two blinded dermatologists separately rated participants’ acne scars based on standard digital photographs obtained at baseline and at the 3-month and 6-month follow-up visits on the quantitative global scarring grading system.

Results Mean scar scores were significantly lower in the treatment group compared with baseline at 6 months (mean difference, 3.4; 95% CI, 0.2-6.5; \( P = .03 \)) and nominally but not significantly lower compared with baseline at 3 months (mean difference, 2.4; 95% CI, –0.01 to 4.8; \( P = .052 \)). In the control group, mean scar scores did not vary significantly from baseline at 3 months (mean difference, 1.0; 95% CI, –1.4 to 3.4; \( P = .96 \)) and at 6 months (mean difference, 0.4; 95% CI, –2.3 to 3.5; \( P > .99 \)). The needling procedure was not particularly painful, with a mean pain rating of 1.08 of 10. Participants perceived a 41% mean improvement in overall scar appearance on the treated side. No adverse events were reported.

Conclusions and Relevance After 3 needling treatments, there was improvement in the appearance of acne scars over time compared with the control group, with minimal pain reported.

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Author Affiliations: Department of Dermatology, Feinberg School of Medicine, Northwestern University, Chicago, Illinois (Alam, Han, Pongprutthipan, Disphanurat, Kakar, Nodzenski, Pace, Kim, Yoo, Poon, West); Department of Otolaryngology, Feinberg School of Medicine, Northwestern University, Chicago, Illinois (Alam); Department of Surgery, Feinberg School of Medicine, Northwestern University, Chicago, Illinois (Alam); Department of Medicine, Emory University School of Medicine, Atlanta, Georgia (Veledar); Center for Research and Grants, Baptist Health South Florida, Miami (Veledar).

Corresponding Author: Murad Alam, MD, MSCI, Department of Dermatology, Feinberg School of Medicine, Northwestern University, 676 N St Clair St, Ste 1600, Chicago, IL 60611 (m-alam@northwestern.edu).
Acne scarring has been associated with significant psychological consequences. Treatment of acne scarring remains a therapeutic challenge, with treatment approaches that include a range of possible options. In recent years, fractional laser resurfacing has been used successfully to reduce scars associated with acne. Nonablative and ablative lasers can be used to either remove or perforate skin in a fine pinpoint pattern, with resulting neocollagenesis; only a fraction of the skin is treated with each treatment, and a series of treatments are required to treat the entire affected surface.

It has been suggested that neocollagenesis and improvement of acne scars can also be achieved using needle rollers, which use a mechanical, macroscopic approach to induce small epidermal and dermal perforations. Needle rollers are cylindrical objects with a circumferential array of perpendicularly placed needles and a rotational axle affixed to a handle. Like paint rollers, such devices can be moved back and forth along the skin.

Needling as a possible treatment for acne scarring was introduced by Camirand and Doucet, who described use of a tattoo gun to abrade acne scars. Fernandes subsequently asserted that needling with a roller led to percutaneous collagen induction. Aust et al retrospectively reported needling used to treat various skin textural complaints, including scarring. In a prospective trial of rolling acne scars, Fabbrocini et al reported a benefit in patients treated with needle rollers. We describe the results of a randomized clinical trial to assess the degree of benefit of needle rollers for treatment of acne scars, including macular, rolling, ice pick, boxcar, and hypertrophic scars.

Methods

Study Design
This study was a single-center, rater-blinded, balanced (1:1), split-face, placebo-controlled, parallel-group randomized clinical trial. The study was approved by the Northwestern University Institutional Review Board, and written informed consent was obtained.

Participant Selection
Participants were enrolled (N.K.) and data were collected from a university-based urban dermatology clinic, using approved postings, from the nearby university community. Inclusion criteria were as follows: age of 18 to 70 years, good general health, Global Acne Scarring Classification grades 2 through 4, and at least two 5 × 5-cm areas of acne scarring on the face (with at least 3 definable acne scars in each area). Exclusion criteria were as follows: history of keloids or hypertrophic scars, skin infection or active skin disease other than mild acne in or around the study areas, active systemic or local skin disease likely to alter wound healing, treatment within the last 6 months or pending treatment within the subsequent 6 months with injectable fillers or ablative or nonablative laser resurfacing to the study areas, medication with isotretinoin or other oral retinoids within the past 12 months, current treatment with anticoagulants or antithrombotics, or allergy to topical anesthetics (eg, lidocaine and prilocaine).

Study Procedures
At the screening and baseline visit (week 0), each participant’s medical history was recorded, and baseline standard (ie, anterior and 45° lateral view in a custom device that stabilizes the chin and forehead) digital photographs were obtained with a digital camera (Powershot G10; Canon). Participants were instructed to stop using any topical peeling medications and topical vitamin A treatments on their face 1 week before treatment and to keep this treatment discontinued until at least 4 weeks after their final treatment.

Three treatment visits were performed at 2-week intervals (ie, weeks 1, 3, and 5). At each of these visits, needling was performed on the study treatment area, and topical anesthetic was only massaged into the control area. Digital photographs and adverse events (eg, infection, prolonged erythema, prolonged edema, serosanguineous drainage, bleeding, ulceration, erosion, and pigmentation), including their duration, resolution, intensity, relationship to the study procedure, and any curative actions taken, were recorded before each treatment.

At 3 and 6 months after the first treatment, participants returned for follow-up visits. Digital photographs of the study areas were again obtained, any adverse events were recorded, and a participant satisfaction questionnaire was administered.

Needling Intervention
At each treatment visit, topical anesthetic (a 5% emulsion preparation that contained 2.5% each of lidocaine and prilocaine, AstraZeneca) was applied to the treatment area for 1 hour under occlusion. After the topical anesthetic was washed off, the skin was cleaned with chlorhexidine and needling treatment was administered (MTS Roller, CR10 [1.0 mm] or CR20 [2.0 mm]; Clinical Resolution Laboratory). The roller depth was determined by clinical evaluation of skin thickness and scar severity. Specifically, if scars appeared to be very fine and the participant had less sebaceous, fine skin, as was the case in some female participants, then a 1.0-mm device was used; otherwise, a 2.0-mm device was used. During each procedure, the device was rolled over the skin back and forth in each of 8 linear directions around the midpoint of the study treatment area (eg, north to south and back, northeast to southwest, east to west, southeast to northwest, and so on), such that the treatment area was traversed a total of 16 times, end to end. Pain level was recorded based on a 10-point visual analog scale after the procedure. Immediately after each treatment, gentle manual pressure with gauze was applied for 5 minutes to control pinpoint bleeding and serum secretion. The skin was soaked with saline swabs for an hour to facilitate hydration while the individuals were educated regarding the need for home care. For prophylaxis, participants with a history of herpes simplex virus were treated with oral antivirals (acyclovir, 400 mg 3 times a day for 5 days), and participants with an increased risk of bacterial infection as determined by the physician (eg, prior history of inflammatory acne or folliculitis) were treated with a topical antibiotic (eg, mupirocin).
were treated with an oral antibiotic (eg, cephalexin, 1 g 3 times a day for 5 days). For wound care, a bland emollient (Aquaphor Healing Ointment [Eucerin]; Beiersdorf Inc) was recommended for continual application at least twice daily for 7 days. Participants were instructed to avoid direct sun exposure and the use of any potentially irritating topical products (eg, glycolic acid–containing products, scrubs and foams, or topical retinoids) on their face for 1 week.

After the first treatment visit and before and after all subsequent treatment visits, the MTS Roller was cleaned thoroughly by repeated immersion in glutaraldehyde and/or ethyl alcohol. The device was then further cleaned by gas sterilization, stored in a closed package, and labeled with the participant’s name and the first treatment date on the box until the next treatment. This sterilization process was followed to ensure a high level of infection control in this research setting.

Outcomes
The primary outcome measure was the quantitative global scarring grading system, developed by Goodman and Baron.9 This system assesses scar appearance by counting the number of mild, moderate, severe, and hyperplastic lesions; an algorithm is then used to assign a specific point score based on the types and frequencies of the lesions observed, with higher scores indicating more scarring. Two blinded dermatologists (S.H. and M.P.) separately rated participants’ acne scars based on standard digital photographs obtained at baseline and at the 3-month and 6-month follow-up visits. Forced agreement was used to reconcile ratings.

Given that this was an early pilot trial, we considered it appropriate to consider acne scars collectively, not separately, by various morphologic subtypes (eg, rolling, boxcar, ice pick, and so on). Therefore, we did not record data pertaining to the different types of acne scars, and we did not power our study for subgroup analysis.

Secondary outcome measures included tolerability of each treatment as assessed by participant-reported pain on a visual analog scale. Participant-reported or investigator-observed adverse events, such as infection, prolonged erythema, prolonged edema, serosanguineous drainage, bleeding, erosions, ulcerations, hyperpigmentation, and hypopigmentation, were recorded at each treatment visit and at the 3-month follow-up. Participant satisfaction was assessed with a questionnaire administered at the 6-month follow-up.

Sample Size
The sample size of 20 participants would have had 80% power to detect an effect size between 2 time points of 0.89, where effect size is defined as the mean difference between time points divided by the time point–specific SD.

Randomization
Randomly generated 1’s and 2’s were sealed separately in opaque envelopes (N.K.) and used to assign the leftmost labeled acne scar area on a given participant to the treatment arm (1) or the control arm (2), with the contralateral side then receiving the remaining assignment.

Blinding
Given that the control arm was easily distinguished by visual and tactile cues from the treatment arm during treatment, participants and the treating dermatologist (M.A.) were not blinded. The 2 dermatologist raters of photographs (S.H. and M.P.) did not participate in randomization or treatment and therefore were able to be blinded regarding assignment.

Statistical Analysis
Changes in mean scar scores from baseline to 3 and 6 months, respectively, were computed for the treatment and control arms. Repeated-measures analysis of variance with pairwise comparisons with Sidak adjustment were performed to test whether the scar score varied on treatment type, time, or the interaction between the two. Means were also computed for pain scores, and repeated-measures analysis of variance was used to test whether pain scores varied on time. The Wilcoxon signed rank test was used to assess whether the difference in overall acne scar appearance was associated with treatment type.

Results
The study took place from November 30, 2009, through July 27, 2010. Twenty individuals consented, and 5 dropped out before the first treatment. The remaining 15 completed all treatments and are analyzed. The mean age of analyzed participants was 33.7 years (range, 20-65 years), 9 were men, 3 had received prior treatment for acne scars, and Fitzpatrick skin types ranged from I to V (1 participant had type I, 4 participants had type II, 6 participants had type III, 3 participants had type IV, and 1 participant had type V).

Scar scores were lower in the treatment group compared with baseline at 3 and 6 months (Figure 1). In the control group, mean scar scores did not vary significantly from baseline at 3 months (mean difference, 1.0, 95% CI, −1.4 to 3.4; \( P = .96 \)) and at 6 months (mean difference, 0.4, 95% CI, −2.8 to 3.5; \( P = .99 \)).
However, in the needling group, scar scores were significantly lower at 6 months compared with baseline (mean difference, 3.4; 95% CI, 0.2–6.5; \( P = .03 \)) (Figure 2). At 3 months compared with baseline, the reduction in scar score in the needling group was nonsignificant (mean difference, 2.4; 95% CI, −0.01 to 4.8; \( P = .052 \)) (Figure 3).

The needling procedure was not particularly painful. The mean pain rating was 1.08 of 10. Pain ratings increased slightly over time (\( P = .01 \)), with week 4 pain ratings (mean, 1.75; 95% CI, 0.90–2.60) significantly higher than week 2 (mean, 0.78; 95% CI, 0.40–1.20) and week 0 (mean, 0.71; 95% CI, 0.40–1.00).

Participants perceived a 41% mean improvement in overall scar appearance on the treated side. When asked to estimate the discomfort experienced during and in the days after their procedure, participants commonly reported no discomfort. Most participants were very satisfied with their procedure, replied yes when asked if they would do this procedure again to treat additional scars, and said they would recommend needling to their friends.

No adverse events were reported. Mild transient erythema and edema, which were not classified as adverse events and hence not formally tracked, were routinely observed by the investigator (M.A.) and reported by participants after treatments.

**Discussion**

This study reveals some improvement in acne scars after a series of 3 treatments of needling. There is a statistically significant improvement in such scars in the treatment group from baseline to 6 months and no significant improvement during this period in the control group. Pain associated with the treatment is mild, ranging from 1 to 2 on a standard 10-point visual analog scale. Adverse events were not observed.

We believe this is the first randomized clinical trial to assess scar outcomes after needling. In addition, unlike prior studies on acne scars, this study did not limit the types of acne scars assessed but rather included the complete range of different acne scar types.

More important, although acne scars are notoriously difficult to rate in a standardized manner, the rating scale used by the blinded raters in this study incorporated information about scar type and number. Mild, moderate, severe, and hyperplastic scars were included, as were macular, erythematous, and pigmented scars; atrophic scars with shallow and deep bases; punched-out scars; linear scars; and troughed or rolling scars. For each major scar type, the total count was characterized by a numerical score. Inherent in the structure of the scale was the possibility that future ratings could be better or worse than past ratings. As such, the scale used differed from improvement scales, which only allow for positive changes or lack of change.

Intraoperative pain was very low but increased on the treatment side over time. This finding may suggest an inflammatory process, which may have been triggered by early treatments and increased over time with subsequent closely spaced treatments to eventually yield the desired clinical result. Differences in reported pain perception may be associated with participant characteristics and the specific pain regimen used.

Because improvement on the treated sides was better at 6 months than after 3 months, there is some evidence that needling provides more than a transient benefit for acne scars. It remains unclear how many treatments would be optimal and to what extent, if any, more than 3 treatments might have resulted in greater cumulative benefit.

As with many studies of this type, participant satisfaction was high. Participants reported an approximately 40% reduction in acne scarring on the treated side, with this being significantly higher than the 22% improvement based on measurements by blinded dermatologist raters. Participant satisfaction may have been affected by a placebo effect, as well as a desire to please the investigator, optimism, and cognitive dissonance associated with the mild discomfort and inconvenience associated with the treatment.

We found 2 randomized controlled studies of nonablative fractional laser for treatment of acne scars with meth-
ods similar to those of the current study. In a split-face study of a nonablative 1540-nm laser, participants were randomized to receive either 3-monthly treatments with laser or no treatment. On a scar scale from 0 (absent) to 10 (worst possible), at 12 weeks after treatment, the mean blinded rater score of the treated sides was 4.5 vs 6.5 for the untreated sides, and half of the participants judged their scars to be moderately or significantly improved. In a randomized split-face study of a nonablative 1550-nm fractional laser vs a 10,600-mm fractional carbon dioxide laser that entailed one treatment with each laser, clinical assessment by blinded raters was measured on a scale of 1 to 4 (1 indicating <25% improvement; 2, 26%-50%; 3, 51%-75%; and 4, >75%) and patient satisfaction on a word scale (very satisfied, satisfied, slightly satisfied, and unsatisfied). Three months after treatment, the mean improvement on the nonablative fractional side was 2.0, and most participants were slightly satisfied. Although direct comparison of these 2 fractional laser studies to the current study is complicated by differences in the scales used to assess results, in these studies and the current one, modest to significant improvements were detected by both participants and blinded raters.

Limitations of this study included the loss of power associated with participant dropouts. It is possible that more definitive results may have been obtained regarding change after treatment at 3 months and overall difference between the treatment and control arms had dropouts been fewer. However, despite this problem, the treatment arm was found to be associated with a significant improvement in scarring at 6 months compared with baseline. In addition, because some participants with finer scars and skin received treatment with 1.0-mm rollers, which would have penetrated less deeply than 2.0-mm rollers, these participants may have benefited to a lesser extent from neocollagenesis induced by the associated mechanical injury. Had all participants received treatment with 2.0-mm rollers, it is possible the mean overall improvement may have been greater. We would expect that the results seen at the end of the study would be due to long-term skin remodeling and

Figure 3. Clinical Response in a Representative Female Participant

Acne scars at baseline (A) and 3 months (B) for the control side. Compared with baseline (C), acne scar reduction can be seen at 3 months (D) for the needling side.
not transient edema or erythema: the latter could be expected to resolve in a few days to weeks at the most, and in our study outcomes were assessed at 3 and 6 months after treatment.

Conclusions

Needling may be a useful therapy for treatment of acne scars. This treatment resembles a macroscopic, nonthermal version of so-called fractional nonablative laser resurfacing. Potential indications for needling may include use as a stand-alone therapy by patients and physicians who either prefer needling or do not have access to laser therapy or adjuvant use as a supplementary treatment in combination with fractional laser treatments. The latter use may be more practical in the short term, given the well-established role of fractional laser as an effective modality for acne scar therapy. With regard to safety, one theoretic advantage of needling compared with fractional laser is there is probably a lesser risk of pigmentation changes in patients with Fitzpatrick skin type III or greater. Currently, the volume of data and studies on the effects of needling for acne scars is far less than that for fractional laser treatment. Side-to-side studies of needling and fractional nonablative laser for acne scarring are entirely lacking, so no strong assertions can be made regarding their relative benefits. Further studies are needed to better understand the diameter of needles, as well as the density (eg, surface area) and depth (eg, depth in millimeters) of needling treatments, that are optimal for treatment of acne scarring.

REFERENCES