Patient-Centered, Direct-Access Online Care for Management of Atopic Dermatitis
A Randomized Clinical Trial

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IMPORTANCE New models of health care delivery for dermatological care have the potential to increase access and improve patient-centered outcomes.

OBJECTIVE To compare effectiveness of a direct-access, online model for follow-up dermatologic care in pediatric and adult patients with atopic dermatitis with that of in-person office visits.

DESIGN, SETTING, AND PARTICIPANTS This was a 1-year, randomized controlled equivalency clinical trial in medically underserved areas, outpatient clinics, and the general community. Participants included children and adults with atopic dermatitis with access to the Internet, computers, and digital cameras.

INTERVENTIONS After an initial in-person visit, patients were randomized 1:1 to direct-access online or usual in-person care for follow-up management of atopic dermatitis. In the direct-access online group, patients captured and transmitted clinical images and history asynchronously to dermatologists online; dermatologists evaluated the clinical information, provided recommendations and education, and prescribed medications online asynchronously. In the in-person group, patients visited dermatologists in their offices for follow-up care.

MAIN OUTCOMES AND MEASURES Atopic dermatitis disease severity as assessed by patient-oriented eczema measure (POEM) and investigator global assessment (IGA).

RESULTS A total of 156 children and adults were randomized. Between baseline and 12 months, the mean (SD) within-group difference in POEM score in patients in the direct-access online group was −5.1 (5.48) (95% CI, −6.32 to −3.88); in the in-person group, the within-group difference was −4.86 (4.87) (95% CI, −6.27 to −3.46). The difference in the change in POEM scores between the 2 groups was 0.24 (6.59) (90% CI, −1.70 to 1.23), which was contained within the predetermined 2.5 equivalence margin. The percentage of patients achieving clearance or near-clearance of their disease (IGA score of 0 or 1) was 38.4% (95% CI, 27.7% to 49.3%) in the direct-access online group and 43.6% (95% CI, 32.6% to 54.6%) in the in-person group. The difference in the percent of patients achieving clearance or near-clearance between the 2 groups was 5.1% (90% CI, 1.7% to 8.6%), which was contained within the predetermined 10% equivalence margin.

CONCLUSIONS AND RELEVANCE The direct-access online model results in equivalent improvements in atopic dermatitis clinical outcomes as in-person care. Direct-access online care may represent an innovative model of delivering dermatological services to patients with chronic skin diseases.

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In the United States, there is an inadequate supply of dermatologists to meet the demand for dermatologic services.\textsuperscript{1-4} Lack of access to dermatologists is especially pronounced in rural and underserved communities.\textsuperscript{5,7} As a result, patients with chronic skin diseases, such as atopic dermatitis, who lack access to regular dermatologic care experience poor clinical outcomes and considerable impairment in quality of life.\textsuperscript{6}

Studies suggest that teledermatology presents an opportunity to improve access to dermatological specialist care.\textsuperscript{9,10} Store-and-forward teledermatology is defined as the practice of dermatology through digital capturing and transmission of clinical images and patient history followed by asynchronous evaluation of the clinical information by a dermatologist. The diagnostic accuracy and reliability of store-and-forward teledermatology have been studied and found to be relatively comparable with those of face-to-face care.\textsuperscript{11-12} However, few studies have examined clinical outcomes associated with store-and-forward teledermatology.\textsuperscript{13-16}

While store-and-forward telemedicine is increasingly used to provide underserved communities with access to dermatologic consultations, several limitations exist with traditional consultative teledermatology. In the consultative store-and-forward model, in order to engage in teledermatology, patients need to identify primary care providers (PCPs) with telemedicine capabilities in their community and travel to their office to be connected to a teledermatologist. All recommendations from the dermatologists are relayed to the patients through PCPs. That is, dermatologists serve as consultants in this practice model and have no direct patient contact. Thus, the traditional consultative model makes it difficult for patients to ask follow-up questions or have a dialogue with their dermatologists. A study\textsuperscript{17} has shown that patients are most concerned with the lack of direct contact with dermatologists in the traditional store-and-forward consultative model.

Not all PCPs are enthusiastic about consultative store-and-forward teledermatology owing to the increased workload related to implementing dermatologists’ recommendations without explicit accounting for these efforts. Furthermore, when patients have follow-up questions, not all PCPs receive timely and robust support from specialists in order to adequately address patient questions.

New models of specialty-care delivery are necessary to provide distance- and time-independent care to patients. One innovative health care–delivery model in dermatology involves direct-access online care, with which patients can communicate directly with dermatologists and receive timely recommendations to manage their skin diseases.\textsuperscript{18-20} This model may be especially suitable for managing chronic skin diseases, such as atopic dermatitis, for which regular follow-up care is necessary to control disease flares and maintain disease control.

We compared effectiveness of a direct-access, online model with that of an in-person model for follow-up management of pediatric and adult patients with atopic dermatitis in this 1-year, randomized controlled equivalency clinical trial. We tested the hypothesis that patients with atopic dermatitis managed through the direct-access online model have equivalent improvement in their disease severity as those managed in person, as measured by the patient-oriented eczema measure (POEM) and investigator global assessment (IGA).

### Methods

#### Study Design

In this randomized controlled equivalency clinical trial, we compared the effectiveness of a direct-access, asynchronous, online model for delivering follow-up dermatologic care for patients with atopic dermatitis with that of in-person office visits. We compared clinical outcomes between the 2 groups, where the participants were followed for 1 year. The study was approved by the University of California, Davis (UC Davis), institutional review board (243201).

We recruited 5 dermatologists from the UC Davis Department of Dermatology to participate in this study: 4 dermatologists providing clinical care to the study (either face-to-face or online depending on the patient randomization) and 1 dermatologist blinded to the randomization who performed IGA based on the digital photographs. The 4 dermatologists providing care to patients in person were also trained on how to provide care to patients online via the RelayHealth online telemedicine site, a website that provides asynchronous clinical connectivity between patients and physicians.

Owing to the nature of the intervention, the study staff, dermatologists, and participants could not be blinded to the group assignment during the course of the study. However, the rater responsible for performing the IGA assessment based on digital images was blinded to the randomization of the participants.

#### Patient Selection

We recruited pediatric and adult patients with atopic dermatitis from medically underserved clinics, general outpatient clinics, and the general community in the greater Sacramento area. Specifically, we recruited patients from federally qualified health centers, free clinics serving indigent patient populations, primary care network clinics affiliated with UC Davis, dermatology clinic at UC Davis, and the general community.

Regardless of race and sex, all children and adults were considered for the study if they met the following inclusion criteria: (1) met Hanifin\textsuperscript{21} criteria for diagnosis of atopic dermatitis; (2) were 4 years or older; (3) had Internet connection, a computer, and a digital camera; and (4) were able to have their skin imaged by themselves or by family members. The exclusion criteria included (1) patients who did not speak English or Spanish, (2) patients requiring systemic treatments (eg, cyclosporine, phototherapy), and (3) patients requiring regular laboratory monitoring.

#### Study Interventions

**Initial Visit for All Participants**

All participants had an initial in-office visit, where they provided written informed consent and were examined by dermatologists to confirm the diagnosis of atopic dermatitis and...
eligibility criteria. Patients were compensated for their participation. The study staff took baseline clinical photographs of the patient’s skin lesions. All participants also underwent baseline assessments of disease severity and quality of life using validated instruments. They were then randomized in a 1:1 ratio of the 2 arms of the study—the direct-access online group or in-person group.

Participants in both the online and in-office comparison groups underwent a standardized training session consisting of instruction on specific image-capturing techniques to ensure that high-quality images would be taken with the correct lighting and focus. During this training session, the participants and their family members were taught how to take standardized global and representative, close-up lesional photographs. The global images were used to assess the body surface area of involvement of atopic dermatitis, whereas the close-up lesional images were used for morphologic examination (eg, erythema, induration, lichenification, impetiginization). For most participants, the global images were taken by the family members. However, for the participants wishing to take their own global images, they were taught how to take full-body images with the autotimer function on digital cameras. In addition, the participants in the direct-access online group were trained on how to access the direct-access online website for their dermatologic care. These patients had to demonstrate competence navigating the telemedicine site prior to conclusion of their first visit. All instructions on navigating the telemedicine site and capturing skin images were provided to patients both electronically and in hard copies.

**In-Person Group (Control Arm)**

The participants randomized to the in-office visits had 6 in-person visits with a dermatologist at 2-month intervals. Within 24 hours of each in-office visit with their dermatologists, these participants were asked to take photographs of their skin at home and submit the images to the study team via the same website. This was to ensure that the blinded rater was not able to distinguish the randomization assignment based on the photographic technique or the image quality. Study staff reviewed these clinical images to ensure adequate image quality for outcome assessment. If images were not adequate, the patient would be asked to retake and resubmit the images within 24 hours.

During the in-person visits, the participants received usual care from the study dermatologists, including evaluation of atopic dermatitis and discussion of treatment plan. At each of these in-person follow-up visits, the participants also completed the standardized assessments for disease severity and quality of life.

**Direct-Access Online Group (Intervention Arm)**

The participants randomized to the direct-access online group had 6 online visits with a dermatologist at 2-month intervals. During the online visits, the participant went to the secure online health care–delivery platform to submit all the necessary information for online visits and communicate with dermatologists asynchronously. For example, they completed a standardized questionnaire in which they reported their progress as well as any adverse events. Throughout the study, all participants had access to instructions on how to take pictures of their skin lesions, upload and transmit images and history, and other steps necessary to complete an online visit and view dermatologist recommendations.

After the patients completed the online visits, research staff reviewed the submitted visit information for completeness and ensured that the images were of high quality prior to forwarding them to the dermatologist. The dermatologists caring for the online participants evaluated the transmitted clinical information and digital photographs, made treatment recommendations or modifications, and prescribed medications electronically. The dermatologist had 3 business days to complete the online visit. If the patient had follow-up questions, he or she could communicate with dermatologists online asynchronously through the same telehealth platform (Figure 1).

**Outcome Instruments**

Baseline POEM and IGA scores were recorded at the initial office visit as well as at all follow-up visits. At each of the 6 subsequent online or in-person visits, all participants responded to the POEM questionnaire, a sensitive and validated patient-oriented disease severity measurement.22 POEM comprises 7 questions that assess the symptom morbidity of patients with atopic dermatitis during the week leading up to the questionnaire. The response to each question indicates the number of days the patient experienced a particular sign or symptom (no
days, 1-2 days, 3-4 days, 5-6 days, everyday) with a maximum score of 28 points. Higher scores denote greater symptom morbidity.

All participants also received baseline digital photographs taken at the initial visit. For each of the subsequent study visits, participants in both comparison groups took digital photographs of their skin lesions. A dermatologist blinded to the randomization rated each patient's atopic dermatitis severity using the IGA scale based on the photographs. The IGA scale is a validated disease outcome measurement for atopic dermatitis that is widely used in clinical trials and comprises a 6-point ordinal scale that ranges from 0 to 5 (0, clear; 1, almost clear; 2, mild disease; 3, moderate disease; 4, severe disease; 5, very severe disease).

**Statistical Analysis**

The power analysis and sample size calculation for this study were calculated based on the primary outcome measure—the POEM score. This is an equivalency trial comparing the effectiveness of 2 models of delivering follow-up dermatological care for atopic dermatitis. We aimed to establish upper and lower differences $\delta_L < \delta < \delta_U$, where $\delta_L$ and $\delta_U$ are a priori-specified values used to define equivalence. The null hypothesis $H_0: |\delta| > \delta_U$ is tested against the 2-sided alternative hypothesis $H_A: |\delta| \leq \delta_U$ at significance level $\alpha = .05$. With 156 participants who accounted for dropout rates up to 15%, this study has 80% power to test $\delta_U = 2.5$ as the a priori-determined equivalence limit for the POEM score.

The analysis was based on the intention-to-treat population, which includes all randomized patients. In this longitudinal study, we measured POEM and IGA scores at baseline and the subsequent 6 follow-up visits. We examined the differences in the change in POEM scores from baseline to 12 months between the direct-access online group and the in-person group and compared them against the equivalence margin. We also compared differences in the proportion of patients achieving IGA scores of 0 or 1 at 12 months between the 2 comparison arms. We tested these proportions against predetermined equivalence margin of 10%. Sensitivity analyses were performed using repeated measures analysis of variance (ANOVA) approach for POEM and a generalized estimating equations (GEE) approach for IGA scores between the 2 comparison groups. All statistical analyses were performed using STATA statistical software (version 13; StataCorp Inc).

**Results**

A total of 156 children and adults with atopic dermatitis were randomized to receive follow-up care via either a direct-access online model or in-person visits over a 12-month period. Demographic information of the study population is provided in the Table. Patients submitted, on average, 8.7 and 8.2 photographs per visit in the direct-access group and in-person group, respectively. The staff requested reimaging in 6.3% and 6.6% of the online and in-person visits, respectively. No significant differences existed in the number of submitted photographs or requests for reimaging between the 2 arms ($P = .89$). Patients in both the direct-access online and in-person groups showed significant improvement in atopic dermatitis disease severity as measured with POEM over the 12-month study period (Figure 2A). Specifically, in the direct-access online group, patients’ POEM scores improved from a mean (SD) baseline of 13.04 (5.32) to 7.94 (4.55) at 12 months. This represented a within-group difference of $-5.1$ (5.48) (95% CI, $-6.32$ to $-3.88$) for the direct-access online arm. In the in-person group, the patients’ POEM scores improved from a baseline of 12.71 (5.58) to 7.85 (4.44) at 12 months. This represented a
within-group difference of -4.86 (4.87) (95% CI, -6.27 to -3.46) for the in-person arm.

To compare the differences in the change of POEM scores between the direct-access online group and the in-person group, we applied the predetermined equivalence margin of δ = 2.5 and 90% CIs typically used for equivalency trials. The mean (SD) difference in the change in POEM scores between the 2 groups was 0.24 (6.59) (90% CI, -1.70 to 1.23). Because the 90% CI is contained entirely within the equivalence margins of -2.5 to 2.5, the 2 interventions are equivalent in POEM assessment.

Patients in both the direct-access online and in-person groups showed significant improvement in atopic dermatitis disease activity as measured with IGA over the 12-month study period (Figure 3A). In particular, in the direct-access online group, patients’ IGA scores improved from a baseline median of 3 (IQR, 2-3) to a median IGA score of 2 (IQR, 1-2) at 12 months. The percentage of patients achieving IGA scores of 0 or 1 was 38.4% (95% CI, 27.7%-49.3%) in the direct-access online group. In the in-person group, patients’ IGA scores also improved from a baseline median of 3 (IQR, 2-3) to a median IGA score of 2 (IQR, 1-2) at 12 months. The percentage of patients achieving IGA scores of 0 or 1 was 43.6% (95% CI, 32.6%-54.6%) in the in-person group (Figure 4).

To compare differences in the percentage of patients achieving IGA scores of 0 or 1 between the direct-access online group and the in-person group, we applied the predeter-

minded equivalence margin of 10%. That is, if the differences in the percentage of patients achieving IGA scores of 0 or 1 at 12 months was 10% or less, we deemed the 2 interventions to be equivalent. The difference in the percentage of patients achieving scores of 0 or 1 between the 2 groups is 5.1% (90% CI, 1.7%-8.6%). Because the 90% CI is contained entirely within the equivalence margins of -10% to 10%, the direct-access online model is equivalent to an in-person model for follow-up care of atopic dermatitis (Figure 3B). Sensitivity analyses were performed using a repeated-measures ANOVA approach for POEM and GEE approach for IGA scores.
Discussion

We evaluated a patient-centered, direct-access online model for delivering follow-up care for patients with atopic dermatitis. In this randomized controlled equivalency clinical trial, we found that patients whose disease was managed through the direct-access online model achieved equivalent improvements in atopic dermatitis disease severity compared with those whose disease was managed through the usual, in-person visits. The study finding of equivalence in managing atopic dermatitis is primarily limited to a population with relatively moderate disease based on POEM and IGA assessments.

Skin diseases account for 30% of all physician office visits. Chronic skin diseases are associated with markedly decreased quality of life and financial consequences. Many patients with chronic skin diseases, such as atopic dermatitis or psoriasis, desire expedient and convenient access to dermatologists for long-term management of their skin diseases.

While evidence supports diagnostic accuracy and reliability of asynchronous teledermatology, teledermatology has not been as widely adopted as previously expected. Real-world challenges of implementing and disseminating traditional consultative asynchronous teledermatology include a lack of direct communication between patients and dermatologists and inconsistent support from PCPs for the existing consultative teledermatology models. To be responsive to patient needs and to address challenges associated with consultative asynchronous teledermatology, it is valuable to evaluate novel technology-enabled specialty-care delivery models. Few studies to date have examined the effect of direct-access online models on clinical outcomes in dermatology.

The strengths of this study include its equivalency testing, randomized controlled equivalency design, and consistent follow-up with low dropout rate throughout the study. The equivalency study designs enabled investigators to test for and declare whether equivalence truly exists when comparing various interventions. Furthermore, a large proportion of the patients were recruited from underserved communities, which enabled us to evaluate the direct-access online model among populations with relatively greater health care needs and fewer technological resources.

The direct-access online model affords direct, versatile, and expedient clinical interactions for both patients and dermatologists. In this online model for follow-up care, patients no longer need to travel to a primary care facility with telemedicine capabilities in order to engage dermatologists. Instead, they are able to upload clinical images and medical history online and obtain asynchronous evaluation and recommendations from dermatologists directly. However, it is also important to understand potential limitations with direct-access online models. Appropriate patient selection, disease selection, and availability of in-person safeguards are important considerations.

This patient-centered direct-access online specialty-care delivery model can be applied to other chronic conditions for which regular access to specialists is critical to patient outcomes, such as psoriasis and wound management. For example, patients with psoriasis require long-term, regular care to maintain disease control, and this model has the potential to improve access and outcomes for this patient population. Patients with chronic wounds, such as those with diabetic foot ulcers and venous leg ulcers, cannot travel easily. This online model can encourage patients with chronic wounds to increase engagement in their wound management with online specialist support.

The findings need to be interpreted in the context of the study design. This study population comprised children and adults with a mean age in the late 20s. While this generally reflects the demographic of the population with atopic dermatitis, computer fluency of this study population may differ from that of patients with other chronic skin diseases. Furthermore, studies beyond a 1-year duration are necessary to determine the persistence of the effects of these health care delivery models.

Conclusions

Health services delivery in dermatology is an exciting and evolving field. With the changing health care environment and a growing demand for dermatologic services, technology-enabled health care delivery models have the potential to increase access and improve outcomes. Critical examination of existing teledermatology models and determination of barriers to dissemination serve as the foundation for designing novel health care delivery models. The direct-access online model provides a patient-centered approach to addressing dermatological care, and it may afford dermatologists flexible work models. As with any novel health services delivery models, comparative effectiveness studies investigating health outcomes are critical to evaluate these new models in an evidence-based approach.
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REFERENCES