Original Investigation

Multicenter Prospective Cohort Study of the Incidence of Adverse Events Associated With Cosmetic Dermatologic Procedures
Lasers, Energy Devices, and Injectable Neurotoxins and Fillers

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IMPORTANCE Common noninvasive to minimally invasive cosmetic dermatologic procedures are widely believed to be safe given the low incidence of reported adverse events, but reliable incidence data regarding adverse event rates are unavailable to date.

OBJECTIVE To assess the incidence of adverse events associated with noninvasive to minimally invasive cosmetic dermatologic procedures, including those involving laser and energy devices, as well as injectable neurotoxins and fillers.

DESIGN, SETTING, AND PARTICIPANTS A multicenter prospective cohort study (March 28, 2011, to December 30, 2011) of procedures performed using laser and energy devices, as well as injectable neurotoxins and soft-tissue augmentation materials, among 8 geographically dispersed US private and institutional dermatology outpatient clinical practices focused on cosmetic dermatology, with a total of 23 dermatologists. Participants represented a consecutive sample of 20,399 cosmetic procedures. Data acquisition was for 3 months (13 weeks) per center, with staggered start dates to account for seasonal variation.

EXPOSURES Web-based data collection daily at each center to record relevant procedures, by category type and subtype. Adverse events were detected by (1) initial observation by participating physicians or staff; (2) active ascertainment from patients, who were encouraged to self-report after their procedure; and (3) follow-up postprocedural phone calls to patients by staff, if appropriate. When adverse events were not observed by physicians but were suspected, follow-up visits were scheduled within 24 hours to characterize these events. Detailed information regarding each adverse event was entered into an online form.

MAIN OUTCOMES AND MEASURES The main outcome was the total incidence of procedure-related adverse events (total adverse events divided by total procedures performed), as verified by clinical examination.

RESULTS Forty-eight adverse events were reported, for a rate of 0.24% (95% CI, 0.18%-0.31%). Overall, 36 procedures resulted in at least 1 adverse event, for a rate of 0.18% (95% CI, 0.13%-0.25%). No serious adverse events were reported. Adverse events were infrequently associated with known risk factors.

CONCLUSIONS AND RELEVANCE Noninvasive to minimally invasive cosmetic dermatologic procedures, including energy, neurotoxin, and filler procedures, are safe when performed by experienced board-certified dermatologists. Adverse events occur in less than 1% of patients, and most of these are minor and transient.

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Cosmetic dermatology is a well-developed field that includes various procedures that are, individually, safe and effective. Combining these procedures may produce results comparable to those associated with more invasive cosmetic procedures.

Few studies report serious or frequent adverse events from cosmetic dermatologic interventions. Published data suggest that cosmetic dermatologic procedures are associated with a low rate of adverse events. However, adverse event intraprocedural or postprocedural incidence is in general not well described in the literature. Obstacles to collection of detailed adverse event data include a lack of a national or regional registry of procedures, the absence of public or private funding to support data gathering, and logistic and regulatory hurdles that complicate multicenter studies. Postmarketing safety data that are available tend to be fragmented, relevant to one or a few procedures, and usually derived from a single practice.

The objective of this study was to use a multicenter prospective cohort data collection strategy to characterize the incidence of adverse events associated with a subset of common cosmetic dermatologic procedures. Specifically, these included noninvasive to minimally invasive procedures in mon cosmetic dermatologic procedures. Specifically, these included noninvasive to minimally invasive procedures involving laser and energy devices, as well as injectable neurotoxins and fillers.

Methods

Study Design

Study procedures were performed under the authorization of the Northwestern University Institutional Review Board, which authorized data collection and managed transmittal of deidentified data across institutions to enable analysis. Consent was waived because no personal identifiers were collected.

This was a multicenter prospective cohort study of consecutive procedures performed using laser and energy devices, as well as injectable neurotoxins and soft-tissue augmentation materials, at geographically dispersed US private and institutional cosmetic dermatology outpatient centers. Most procedures were performed solely by board-certified dermatologists, but a few laser and energy device treatments were performed by mid-level clinicians, including physician assistants and nurse practitioners, under direct supervision of board-certified dermatologists who were present in the office at the time. In these cases where mid-level clinicians assisted with treatments, device settings and treatment protocols were predetermined in consultation with supervising board-certified dermatologists; in addition, all mid-level clinicians had previously received formal hands-on training, as well as classroom instruction, on the use of the specific devices they operated.

Data acquisition occurred for 3 months (13 weeks) per center, with the start dates staggered over 6 months to minimize bias associated with seasonal variation in patient presentation. Data collection was accrued directly on the DermBase web-based interface described previously.¹

Participating Centers

Centers were selected to provide geographic diversity and to provide technique diversity, with efforts made to avoid recruiting multiple physicians trained at the same institutions. All treating physicians were board-certified dermatologists in practice for 5 years or more. Key nonphysician study personnel (R.K. and N.P.) identified by the lead physician at each center were trained on data acquisition and reporting by personnel at the coordinating center. Data pertaining to the numbers and types of cosmetic procedures performed, as well as detailed information about adverse events, were uploaded each working day to the DermBase site from each participating center.

Data Collection Forms

Two principal data evaluation forms were used. These were (1) the Weekly Questionnaire (closed weekly but with daily data entry in day-specific columns), which recorded the numbers of laser and energy device procedures, as well as injectable neurotoxin and filler procedures, by category type and subtype, and (2) an Adverse Event Reporting Form that included detailed clinical information, which was completed when any unexpected adverse event was reported.

Covariates collected for practices surveyed were practice type, practice setting (ie, urban, suburban, or rural), practice location (ie, geographic region), and the median physician years of experience. For all cases, covariates collected included the anatomic area receiving treatment, the type of treatment, and the specific device or drug used.

Additional covariates collected for patients with adverse events included sex, age, Fitzpatrick skin type, medical history, risk factors, and specific types of adverse events. Infection was assessed by clinical impression and by culture positivity, and during data analysis either was deemed sufficient to label the case as infected. Notably, this study was not designed to assess delayed adverse events associated with cosmetic procedures. Similarly, this study was not designed to detect the incidence of transient, self-limited, and spontaneously resolving erythema, edema, discomfort, or mild ecchymoses, events that are associated with normal postprocedural healing after minimally invasive cosmetic procedures.

Data Reporting and Collection Procedures and Controls

All sites were prospectively asked to track all complications actively for the duration of the study. Any adverse event initially observed or detected by participating physicians or their staff was reported. At the time of procedure performance, patients were also asked to be vigilant about potential adverse events for at least 1 month and to promptly report any unexpected results by phone to the office of the treating physician. To further ensure appropriate ascertainment of adverse events, treating physicians or their representatives were asked to contact patients by phone within 1 week of the procedure to query patients regarding any signs, symptoms, and events requiring medical care. Patients reporting adverse events were offered a clinic appointment within 24 hours. Follow-up visits were performed when patients reported adverse events or when physicians suspected adverse events. At such visits, an
appropriate history was elicited, and physical examinations were conducted to ascertain the signs and symptoms, as well as any patient reports of previous adverse events that had resolved before presentation. Follow-up visits were staffed by study physicians, with nonphysician extenders also seeing the patients in some cases.

Outcome Measures
The main outcome measure was the total incidence of procedure-related adverse events, as verified by clinical examination. Secondary outcomes included the rates of particular types of adverse events and the rates at which different procedures were associated with adverse events.

Statistical Analysis
All data were analyzed descriptively, with means, medians, and ranges for continuous measures and percentages for categorical variables. Overall adverse event rates were computed, and the rates were also computed by procedure type. In addition, it was determined what percentage of procedures resulted in at least 1 adverse event.

Results
For a 9-month period (39 weeks), from March 28, 2011, to December 30, 2011, each of 8 centers for cosmetic dermatology (23 physicians) in the United States (Table 1) prospectively collected data for 13 consecutive weeks. A total of 20 399 procedures were studied. Forty-eight adverse events were reported, for an adverse event rate of 0.24% (95% CI, 0.18%-0.31%). Reported adverse events occurred following 36 procedures; therefore, 0.18% (95% CI, 0.13%-0.25%) of procedures resulted in at least 1 adverse event. No serious adverse events were reported. Adverse events were uncommonly associated with known risk factors. Adverse events most commonly occurred after procedures on the cheeks, followed by nasolabial and eyelid procedures. Demographic and medical information of patients experiencing adverse events is summarized in Table 2 and Table 3, respectively. Overall adverse event incidence and rate by procedure type are summarized in Table 4, and Table 5 lists the frequencies of specific adverse events by procedure type.

The dropout rate for in-person follow-up visits for patients reporting adverse events by phone was 0.0%. All patients who reported adverse events came in for at least 1 postoperative management visit.
Discussion

This multicenter prospective study of a large cohort of consecutively performed cosmetic procedures demonstrates that adverse events are uncommon after minimally invasive and noninvasive laser, energy device, filler, and neurotoxin procedures. The adverse events per procedure, as well as the proportion of procedures associated with at least 1 adverse event, were less than 0.5%. Most adverse events were types that would be expected to resolve with treatment over weeks or months. Significantly, no serious adverse events were reported.

While all the constituent adverse event rates were low, the rates for fillers were slightly higher than those for energy devices and neurotoxins. However, this is to be expected because among noninvasive and minimally invasive procedures fillers are slightly more invasive than lasers and neurotoxins. The more viscous prepackaged injectable fillers (Perlane [Valeant/Galderma], Juvederm Ultra Plus [Allergan], and Radiesse [Merz Aesthetics]) were associated with margin-
However, because 2226 pulsed-dye treatments were delivered after ablative carbon dioxide resurfacing, and only 1 adequately performed. For instance, no adverse events were reported of specific procedures, particularly those that are less frequently performed. 

As with all studies of a range of procedures performed by several different physicians, this study is subject to bias associated with differences in technique and overall skill level. For instance, if viscous fillers are diluted by some physicians with lidocaine, the resulting slurry may be less prone to induce adverse events than carbon dioxide laser. An- other limitation is that, even when comparable numbers of related procedures are performed, a single case can potentially skew the relative adverse event rates given the low absolute adverse event rates. Within the subcategory of viscous pre-packaged fillers, while the 3 more viscous agents listed above are similar in the proportion of procedures associated with adverse events, the number of adverse events per procedure is higher for Radiesse because of a single case that was associated with 7 reported adverse events. Even including this case, the proportion of cases associated with at least 1 adverse event is actually somewhat lower for Radiesse than for the other 2 products. Finally, ascertainment of adverse events that occurred more than 1 month after a procedure was variable in frequency across centers because no protocol-based recommendation exists for this. However, because most adverse events associated with cosmetic dermatologic procedures likely manifest within 1 month, this was not considered a major cause of underreporting.

### Table 5. Frequencies of Specific Adverse Events by Procedure Type

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>No. (%) of 48 Overall Adverse Events</th>
<th>Procedure Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lump, nodule, beading</td>
<td>11 (22.9)</td>
<td>5 Juvederm Ultra, 1 Juvederm Ultra Plus, 2 Restylene, 2 Sculptra, 1 silicone</td>
</tr>
<tr>
<td>Hyperpigmentation</td>
<td>4 (8.3)</td>
<td>3 Nd:YAG, 1 intense pulsed light</td>
</tr>
<tr>
<td>Persistent purpura</td>
<td>4 (8.3)</td>
<td>1 Mid-infrared, 2 Juvederm Ultra, 1 Restylene</td>
</tr>
<tr>
<td>Ulceration</td>
<td>4 (8.3)</td>
<td>1 Pulsed-dye laser, 1 Nd:YAG, 1 Radiesse, 1 Restylene</td>
</tr>
<tr>
<td>Burn</td>
<td>3 (6.3)</td>
<td>1 Nd:YAG, 1 intense pulsed light, 1 invasive radiofrequency, 1 cryolipolysis</td>
</tr>
<tr>
<td>Granuloma</td>
<td>3 (6.3)</td>
<td>1 Juvederm Ultra Plus, 1 Radiesse, 1 silicone</td>
</tr>
<tr>
<td>Occlusion</td>
<td>2 (4.2)</td>
<td>1 Radiesse, 1 Restylene</td>
</tr>
<tr>
<td>Sign or symptom of infection</td>
<td>2 (4.2)</td>
<td>1 Radiesse, 1 Perlane</td>
</tr>
<tr>
<td>Necrosis</td>
<td>2 (4.2)</td>
<td>2 Radiesse</td>
</tr>
<tr>
<td>Persistent dysesthesia</td>
<td>1 (2.1)</td>
<td>1 Cryolipolysis</td>
</tr>
<tr>
<td>Persistent erythema</td>
<td>1 (2.1)</td>
<td>1 Fractional non-carbon dioxide</td>
</tr>
<tr>
<td>Abscess</td>
<td>1 (2.1)</td>
<td>1 Restylene</td>
</tr>
<tr>
<td>Altered smile</td>
<td>1 (2.1)</td>
<td>1 Radiesse</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>1 (2.1)</td>
<td>1 Radiesse</td>
</tr>
<tr>
<td>Filler migration</td>
<td>1 (2.1)</td>
<td>1 Juvederm Ultra Plus</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1 (2.1)</td>
<td>1 Botulinum toxin</td>
</tr>
<tr>
<td>Tyndall effect</td>
<td>1 (2.1)</td>
<td>1 Juvederm Ultra</td>
</tr>
<tr>
<td>Ptosis</td>
<td>1 (2.1)</td>
<td>1 Ptosis</td>
</tr>
<tr>
<td>Reticulate erythema</td>
<td>1 (2.1)</td>
<td>1 Restylene</td>
</tr>
<tr>
<td>Scarring</td>
<td>1 (2.1)</td>
<td>1 Radiesse</td>
</tr>
<tr>
<td>Texture irregularity</td>
<td>1 (2.1)</td>
<td>1 Restylene</td>
</tr>
<tr>
<td>Excessive bruising</td>
<td>1 (2.1)</td>
<td>1 Fractional non-carbon dioxide</td>
</tr>
<tr>
<td>Persistent edema</td>
<td>0</td>
<td>None</td>
</tr>
<tr>
<td>Serious adverse event</td>
<td>0</td>
<td>None</td>
</tr>
</tbody>
</table>

*a Thirteen adverse events were associated with the following lasers and energy devices: 1 pulsed-dye laser, 5 Nd:YAG, 2 fractional non-carbon dioxide, 1 mid-infrared, 2 intense pulsed light, 1 invasive radiofrequency, and 1 cryolipolysis. Thirty-five adverse events were associated with the following neurotoxins and fillers: 2 botulinum toxin, 8 Juvederm Ultra (Allergan), 3 Juvederm Ultra Plus (Allergan), 9 Radiesse (Merz Aesthetics), 8 Restylene (Valeant/Galderma), 1 Perlane (Valeant/Galderma), 2 Sculptra (Valeant/Galderma), and 2 silicone.
Significantly, this study only studied the safety of cosmetic procedures performed by board-certified dermatologists. Other providers, possibly with less training in specific procedures and more limited understanding of facial anatomy, skin physiology, and wound healing, may perform these procedures with variable safety.

Caveats aside, a notable finding of this study was that similar but not identical proprietary substances had similar adverse event rates. Not only were viscous prepackaged fillers similar with regard to adverse event rates but so also were the less viscous fillers and the neurotoxins.

Prior investigations of adverse events associated with cosmetic dermatology procedures have been less extensive. Safety studies that provide incidence data regarding adverse events tend to be limited to those performed for initial Food and Drug Administration drug or device approval. In some cases, follow-on studies have been performed that pool the results of pivotal trials or reenroll willing participants for a longer duration to improve generalizability or assess long-term safety.\(^1\)\(^-\)\(^3\)

Few adverse event incidence data are available to describe cosmetic procedure safety in routine clinical practice as treatment strategies and approaches evolve beyond those studied in controlled populations for regulatory approval. Most reviews and discussions of adverse events have focused on the manifestation and management of adverse events and have not attempted to estimate their incidences.\(^4\)\(^-\)\(^7\) Adverse event studies that include a denominator signifying the total number of cases performed tend to be multyear retrospective cohort studies of a single, busy physician, with the attendant recall and reporting bias. For particular drugs or devices, consensus recommendations are often developed by reviewing the results of a few major centers several years after regulatory approval, but these tend to focus on evolving refinements in technique designed to maximize safety and effectiveness, rather than estimation of adverse event rates per se.\(^8\)

Adverse event data for cutaneous lasers and energy devices are fragmented because of the many dozens if not hundreds of different devices in this category, and each tends to be studied separately.\(^9\) The present study is novel in that it entailed (1) active ascertainment of adverse events to minimize underreporting, (2) a prospective design to minimize recall bias, and (3) multicenter data collection to reduce bias associated with differences in physician technique.

**Conclusions**

To our knowledge, this study is the first large multicenter prospective cohort study that estimates adverse event rates associated with major categories of cosmetic dermatologic procedures, including laser and energy device procedures, as well as injectable fillers and neurotoxins. In the hands of well-trained dermatologists, these procedures are safe, with aggregate adverse event rates of well under 1%. Moreover, most adverse events are minor and rapidly remitting, and serious adverse events were not seen. Patients seeking such procedures can be reassured that, at least in the hands of trained board-certified dermatologists, they pose minimal risk.

**ARTICLE INFORMATION**

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**Author Contributions:** Dr Alam had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Alam.

**Acquisition, analysis, or interpretation of data:** All authors.

**Drafting of the manuscript:** Alam, Kakar, Ibrahim, Arndt, Cox, Chotzen, Kilmer, Silva, Weinkle.

**Critical revision of the manuscript for important intellectual content:** All authors.

**Obtained funding:** Alam.

**Study supervision:** Alam.

**Conflict of Interest Disclosures:** Dr Alam is employed at Northwestern University and has been a consultant for Amway and Leo Pharma, both unrelated to this research. Northwestern University has a clinical trials unit that receives grants from many corporate and governmental entities to perform clinical research; Dr Alam has been principal investigator on studies funded in part by Allergan, Bioform, Medicis, and Ulthera. In all cases, grants and gifts in kind have been provided to Northwestern University and not to Dr Alam directly, and Dr Alam has not received any salary support from these grants. Dr Alam receives royalties (~$5000 per year) from Elsevier for technical books he has edited. No other disclosures were reported.

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**Role of the Funder/Sponsor:** The funding source had a role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.
Correction: This article was corrected on December 4, 2014, to fix an error in Table 4.

REFERENCES

NOTABLE NOTES

Jonathan Hutchinson
The Greatest Syphilographer of All Time
Ismael Maatouk, MD; Roy Moutran, MD

Jonathan Hutchinson is recognized as the foremost British syphilologist of the 19th century. His interest in syphilis began early in his career, in 1849, when he described 2 cases of keratitis associated with congenital syphilis (CS).1 He realized later that very little had been written about CS.1

In 1861, Hutchinson wrote an article on deafness accompanying CS, particularly the upper incisors, in patients with CS.1 Hutchinson’s observation had been greeted with expressions of incredulity, so he decided to publish details of 13 cases followed later by details of 70 cases.1 At the same time, he published the results of his studies of the association between CS and interstitial keratitis. The old term strumous corneitis, which implied a connection with tuberculosis, was abandoned as meaningless in this context. Hutchinson’s conclusion was a new idea, and for many years it was not accepted.1

In 1863, Hutchinson wrote an article on deafness accompanying CS, but he characterized it more fully in his Clinical Memoir (1863); it affects older children or adults and is eventually bilateral. Thus, “Hutchinson’s triad” was complete and became a password in the profession, and at 35 years of age, Hutchinson became the specialist in the “great imitator” as he named the disease. In 1876, he stated that syphilis was “a disease which could affect the skin and internal organs.”1 In 1879 he described how syphilis could mimic a multitude of skin, eye, and neurological disorders.1 In 1887, 18 years before Treponema pallidum was discovered, Hutchinson stated that syphilis depends on a “living and specific microbe.”1

Hutchinson advocated mercury for the treatment of early syphilis; unlike many of his contemporaries, he believed that treatment should be started immediately after the diagnosis was made.1 He often combined iodoside with mercury in cases of late syphilis. Hutchinson was doubtful of the value of organic arsenicals introduced by Ehrlich in 1906.2

Hutchinson’s study of individual case histories is shown in the first edition of his book Syphilis1 dedicated to Fournier. (The second edition, largely rewritten, appeared in 1903.)1

It was probably his interest in syphilis that led him into the field of dermatology, ophthalmology, and surgery.2 Hutchinson’s interest in museums arose from his ideas of objective teaching. At the British Medical Association meeting in 1868, he suggested that an annual exhibition of models be arranged to mark the year’s progress. From this suggestion has arisen the system of scientific exhibit that is now a part of medical conventions.

By his death in 1913, at the age of 85 he had been appointed as the chair of every important medical society in England. He had reached the top in ophthalmology, dermatology, and surgery, and history will probably pronounce him the greatest syphilographer of all time.

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