Retrospective analysis of the MAUDE database on dermal filler complications from 2014−2020

To the Editor: An estimated 1.6 million injectable soft-tissue filler injections were performed in 2019, a 78% increase since 2012.[1] Although filler treatments are considered safe, there are potential risks and complications. We investigated adverse events associated with filler procedures using the Manufacturer and User Facility Device Experience (MAUDE) database.

The MAUDE database was filtered for adverse events involving dermal fillers from January 2014 to December 2020. We used R version 4.0.5 (R Foundation) for data aggregation and statistical analysis. Adverse events were grouped into complication categories. Binomial test was used to compare the proportion of complication categories in 2014-2016 versus 2017-2020. Reports with no clinical symptoms or patient involvement were excluded.

A total of 5994 reports were identified. The top 5 complications were skin inflammation (16.0%), swelling (14.1%), infection (13.4%), pain (7.9%), and erythema (5.5%). There was a significant percent difference for the respective complications when comparing reports in 2014-2016 and 2017-2020 (Table I).

Skin necrosis accounted for 3.5% of adverse events. There was a significant percent increase from 2014-2016 to 2017-2020 (Table I). The 3 most commonly associated injection sites were nasolabial fold (20.8%), nose (15.6%), and cheek (14.9%) (Fig 1). Vision changes, which accounted for 1.5% of adverse events, included visual impairment (0.5%), loss of vision (0.4%), blurred vision (0.4%), and visual disturbances (0.2%). Vision changes also had a significant percent increase (0.94%; 95% CI, 0.31-1.25; $P = .001$). Top injection sites associated with vision changes were cheek (31.0%), nose (20.2%), and nasolabial fold (15.0%).

Our analysis demonstrates decreases in the proportion of common complications (swelling, pain, and erythema) reported in the MAUDE database. Decreases in reports of these types of adverse events may be due to improvements in filler technology or in patient education by media sources on expected side effects of fillers.[2,3]

Despite decreases in common complications, reports of complications that are of concern, like infection and necrosis, have increased. Infection with filler procedures is likely the result of technique.[4] This may indicate a need for continued emphasis on sterile technique. While rare, injection necrosis is a serious complication that results from injection into or near the vascular supply, causing vessel occlusion. A concerning sequela of vascular involvement is vision loss, which also increased in reports in the MAUDE database. Facial anatomy is highly vascular and may present challenges when performing injections. The top necrosis-associated injection sites in our study were nasolabial fold, nose, and cheek, which coincided with findings of previous studies.[5] Consequently, it is important to inject with caution in these locations.

The MAUDE database is a valuable source of information but does have several limitations. Submissions of adverse events can be self reported and not verified or confirmed by medical personnel. Event narratives were not standardized and had variable procedural data, which can influence complications. Thus, they may be incomplete, inaccurate, or biased.

Analysis of the MAUDE database suggests improvements in common complications and an increasing proportion of serious complications reported. As the popularity of dermal fillers continues

Table I. Top 10 complications from January 2014 to December 2020

Complication	%	Percent difference from 2014 to 2016 versus 2017 to 2020 (95% CI)	*P* value
Skin inflammation	16.0	3.05 (1.67-4.44)	<.001
Swelling	14.1	−4.14 (−5.46 to −2.81)	<.001
Infection	13.4	1.08 (0.53-1.62)	<.001
Pain	7.9	−2.38 (−3.43 to −1.35)	<.001
Erythema	5.5	−3.69 (−4.57 to −2.81)	<.001
Necrosis	3.5	0.85 (0.15-1.55)	.018
Skin discoloration	3.5	−0.48 (−1.19 to 0.23)	.19
Allergic reaction	3.4	0.94 (0.24-1.64)	.008
Blood pressure changes	3.4	5.65 (4.98-6.33)	<.001
Systemic symptoms	3.4	−1.29 (−1.99 to −0.59)	<.001

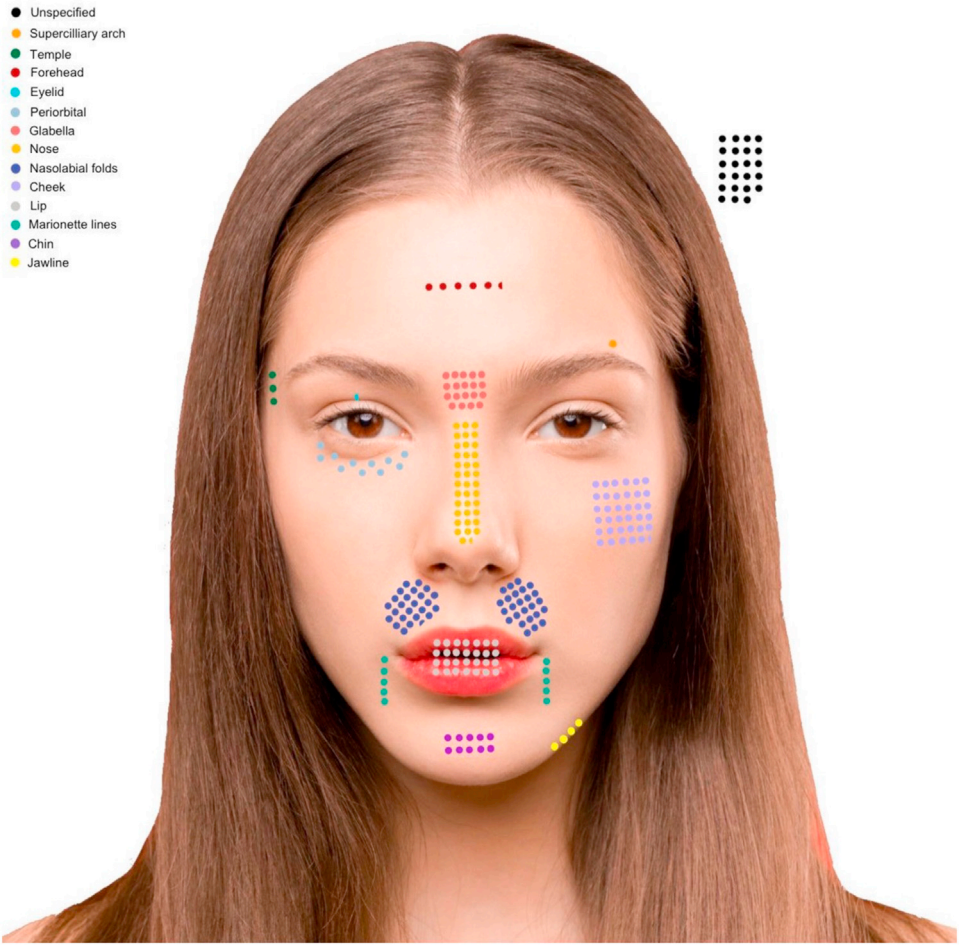

Fig 1. Injection site location for each report of necrosis from filler in 475 patients. Each dot represents 2 counts.

to grow, it is important for providers to understand possible adverse events to better counsel patients and improve safety management.

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Conflicts of interest

None disclosed.

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Impact of electronic prescribing on issued and filled opioid prescriptions following Mohs micrographic surgery

To the Editor: The Pennsylvania Department of Health implemented the Electronic Prescribing of Controlled Substances (EPCS) directive to help mitigate the ever-rising opioid epidemic. The EPCS mandates electronic prescriptions for Schedule II-V controlled substances, rendering paper prescriptions obsolete.[1] This order was intended to reduce medication errors, unnecessary opioid prescriptions, and forgery. The impact of electronic prescribing on the number of opioids prescribed and filled after dermatologic surgery is unknown. This study compares opioid prescribing and filling patterns before and after the EPCS implementation on October 24, 2019.

This was a retrospective chart review of patients aged ≥18 years undergoing single-site Mohs micrographic surgery at the University of Pennsylvania. Opioid prescription rates were compared before (from August 20, 2019, to October 24, 2019; "preintervention") and after the EPCS implementation (from October 25, 2019, to December 29, 2019; "postintervention"). The Prescription Drug Monitoring Program was used to connect patients' surgical encounters to filled opioid scripts.

Preintervention and postintervention opioid prescription rates (OPRs; number of prescriptions issued per number of surgical visits completed) and patient opioid fill rates (POFRs; number of prescriptions filled per number of prescriptions written) were compared using Pearson χ^2 test. "Incomplete" results (n = 6, patients unable to be identified within the Prescription Drug Monitoring Program) were excluded from primary POFR analysis but were considered in a separate sensitivity analysis (Supplementary Material, available via Mendeley at https://10.17632/vh84635837.1).

A total of 904 surgical encounters met the inclusion criteria (Table I). Overall, 19.3% (175/904) of patients received postoperative opioid prescriptions; 55.0% (93/169) of these were filled. Preintervention and postintervention OPRs were 20.4% (103/505) and 18.0% (72/399), respectively (absolute decrease = 2.4%; percent decrease = 11.8%; P = .374) (Fig 1). Preintervention and postintervention POFRs were 62.6% (62/99) and 44.3% (31/70), respectively (absolute decrease = 18.3%; percent decrease = 29.2%; P = .018) (Fig 1). In both periods, an average of 12 pills per patient were filled and the most common opioid prescribed was acetaminophen-codeine 300 mg−30 mg (preintervention: 61.2%, 63/103; postintervention: 59.7%, 43/72). The limitations of this study include lack of corresponding patient-reported pain levels and single tertiary center setting.

Table I. Patient demographics and surgical characteristics

	Preintervention n = 505 (%)	Postintervention n = 399 (%)
Sex		
Male	306 (60.6%)	254 (63.7%)
Female	199 (39.4%)	145 (36.3%)
Age, y		
Mean, median, range	68, 70, 28-97	66, 67, 26-98
Diagnosis		
Basal cell carcinoma	196 (38.8%)	150 (37.6%)
Squamous cell carcinoma	193 (38.2%)	156 (39.1%)
Melanoma	89 (17.6%)	73 (18.3%)
Other	27 (5.35%)	20 (5.0%)
Lesion location		
Head and neck	370 (73.3%)	316 (79.2%)
Trunk	58 (11.5%)	32 (8.0%)
Extremities	46 (9.1%)	27 (6.8%)
Hands and feet	28 (5.5%)	20 (5.0%)
Genitalia	3 (0.6%)	4 (1.0%)
Reconstruction type		
Linear closure	271 (53.7%)	210 (52.6%)
Flaps	95 (18.8%)	90 (22.6%)
Grafts	63 (12.5%)	39 (9.8%)
Second intention	43 (8.5%)	37 (9.3%)
Referral to surgical subspecialty	26 (5.2%)	20 (5.0%)
Wedge repair	5 (1.0%)	2 (0.5%)
Other	2 (0.4%)	1 (0.3%)
Multiple surgical sites	54 (10.7%)	46 (11.5%)

The EPCS implementation did not appear to alter physicians' prescribing patterns, in contrast to emergency medicine studies.[2] Previous dermatologic surgery studies have demonstrated OPRs ranging from 11.7% to 58%.[3] Anagolously, this study's significant POFR reduction from 62.6% to 44.3% is especially noteworthy as rates are lower than current reports of 81%.[4]

The EPCS implementation likely contributed to decreased POFR in multiple ways. First, electronic prescribing eliminates the paper prescription, which