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Rates of Vascular Occlusion Associated With Using Needles vs Cannulas for Filler Injection

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Key Points

Question

When injecting fillers, what is the risk of vascular occlusion with needles vs cannulas?

Findings

In this cohort study of 370 participating dermatologists, the risk of vascular occlusion appears exceedingly low (1 in 6410 syringes via needle and 1 in 40 882 via microcannula injector) when board-certified dermatologists inject skin fillers with needles or cannulas. Cannulas appear associated with lower occlusion risk, and most occlusions resolve without sequelae.

Meaning

When it is feasible and appropriate based on patient characteristics, anatomic location, and other clinical factors, dermatologists may consider using cannulas for filler injection to further minimize occlusion risk.

Abstract

Importance

Soft-tissue augmentation with skin fillers can be delivered with needles or microcannulas, but unwanted vascular occlusions are possible.

Objective

To determine whether filler-associated vascular occlusion events of the face occur more often with injections performed with needles than with microcannulas.

Design, Setting, and Participants

This retrospective cohort study included a random sample of board-certified dermatologists deemed eligible based on membership in relevant professional societies and attendance at relevant national professional meetings. Participants completed detailed forms in which they could enter deidentified data and volume statistics pertaining to patients undergoing filler procedures in their practices. Data were collected from August 2018 to August 2019.

Exposures

Injectable fillers approved by the US Food and Drug Administration delivered via needles or microcannulas.

Main Outcomes and Measures

The primary outcome measure was intravascular occlusion. Occlusion events were graded by severity (no sequelae, scar, and ocular injury or blindness).

Results

A total of 370 dermatologists (mean [SD] years in practice, 22.3 [11.1] years) participated and reported 1.7 million syringes injected. The risk of occlusion with any particular filler type using needle or cannula never exceeded 1 per 5000 syringes injected. Overall, 1 occlusion per 6410 per 1-mL syringe injections was observed with needles and 1 per 40 882 with cannulas ($P < .001$). Of the 370 participants, 106 (28.6%) reported at least 1 occlusion. Multivariate analysis found that injections with cannula had 77.1% lower odds of occlusion compared with needle injections. Participants injecting fillers for more than 5 years had 70.7% lower odds of occlusion than those who were less experienced. For each additional injection per week, the odds of occlusion decreased by 1%, and 85% of occlusions had no long-term sequelae. Nasolabial folds and lips were most likely to be occluded, with mean severity level of occlusions highest at the glabella.

Conclusions and Relevance

In this cohort study, filler injections with either needles or cannulas were associated with a very low risk of intravascular occlusion events. Moreover, the vast majority of such events were minor and resolved without scar or other injury. Injections with microcannulas were less often associated with occlusion events than injections with needles. Occlusion risk per syringe appeared de-

creased after the first few years of clinical practice and was also lower among those who more frequently inject fillers. Whether a needle or cannula is most appropriate for injection may depend on patient factors, anatomic site, and the type of defect being treated.

Introduction

Soft-tissue augmentation using prepackaged injectable skin fillers is an increasingly commonly performed procedure for correction of acne scars, traumatic injuries, HIV-associated lipoatrophy, age-related volume loss and rhytids, and other indications. Fillers, including hyaluronic acid derivatives, calcium hydroxylapatite, polymethylmethacrylate microspheres, and poly-L-lactic acid, are typically delivered through the epidermis and dermis into the subcutaneous tissue below the dermal-subcutaneous junction.[1,2,3] Filler delivery to the target site can be via a needle or through a disposable microcannula.

It has been suggested that injections with microcannulas may be relatively less likely than needle injections to cause dermal or subcutaneous lacerations of the microvasculature. This may possibly secondarily reduce posttreatment ecchymoses as well as the risk of filler-associated vascular occlusion,[4] commonly in the glabella, nasal dorsum, forehead, nasolabial folds, and periorbital region, though occlusion has been documented with injection to all areas of the face.[5,6,7,8,9,10,11] The most common sequela of vascular occlusion is skin necrosis, while the most devastating is injection-related visual compromise, including blindness. Stroke, another devastating event, has also been rarely reported.[11]

The hypothesis underlying the protective benefit of microcannulas is that their blunt tips generally avoid piercing vessel walls, thereby mitigating bleeding and the likelihood that filler will be introduced into a vessel lumen. Many other factors may also be associated with the risk of filler-associated vascular occlusion, including injection force, rate of injection, depth of injection, anatomic site, quantity injected, bore and length of the injection instrument used, operator experience, and operator technique.[12]

While there appears to be growing perception among many experts that use of microcannulas in preference to needles may be helpful in reducing the risk of intravascular injection in certain higher-risk conditions, data supporting this assertion are sparse. The benefits of cannulas have been enumerated, and they have been compared regarding effectiveness at particular anatomic sites,[13,14,15,16,17,18,19] but statistics regarding the degree of reduction of intravascular occlusion risk, if any, are not available. The aim of this study is to determine whether the estimated frequency of skin filler–associated vascular occlusion events of the face is greater with injections performed with needles than with microcannulas.

Methods

Study Type, Setting, and Participants

This is a retrospective cohort study of injection practices, injection volumes, and prior intravascular occlusion events. Study approval was obtained from the Western Institutional Review Board, and reporting is in accordance with Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines. Data collection was from American Board of Medical Specialties board-certified US dermatologists with a practice focus on skin filler[20] injectables. These dermatologists were identified from the registrant list of the 2018 Controversies and Conversations in Laser and Cosmetic Surgery symposium, as well as the membership rolls of the American Society for Dermatologic Surgery in July 2019. A random sample of these participants, selected via a web-based random number generator, was invited to participate. Participants were provided detailed forms in which they could enter deidentified data and volume statistics pertaining to the patients undergoing filler procedures in their practices, with this data obtained from their practice records. While the request and expectation was that data collection by participants would be based on electronic health record or electronic billing system (for those who did not use electronic health records) with queries resulting in precise capture of units injected, to ensure patient confidentiality and to avoid insurmountable HIPAA (Health Insurance Portability and Accountability Act) and institutional review board constraints, data collection was not audited.

Quantitative Variables

Variables collected included number of years in practice; number of years injecting fillers with needles and with microcannulas, respectively; number of 1-mL equivalents of filler injected per week per device type; and number of vascular occlusive events per device type. Responses were further stratified by type of filler material, anatomic site of injection, and severity of sequelae. Filler materials included hyaluronic acid, poly-L-lactic acid, polymethylmethacrylate, and calcium hydroxylapatite. Anatomic sites included forehead, temple, glabella, nose, lips, nasolabial fold, jawline, marionette lines, chin, and other facial sites. Severity levels were no long-term sequelae, occlusion associated with scar, and occlusion associated with ocular injury or blindness. Survey respondents retained their anonymity, and no attempts were made to identify them or contact them for further information.

Statistical Analysis

A total group sample size of 265 participants was deemed sufficient to achieve 90% power to detect a significant difference between 2 dependent means with an effect size of 0.2 at significance level of $\alpha = .05$. A univariate analysis, using χ^2 or Fisher exact tests depending on the expected frequency cell counts, was performed to identify the association between injection instrument and frequency of vascular occlusion for each filler type, between injection instrument and severity of vascular occlusion for each filler type, and between anatomic site and severity of vascular occlusion.

Multivariate logistic regression was performed to identify factors associated with vascular occlusion. Independent variables were filler type (hyaluronic acid, poly-L-lactic acid, other), injection instrument (cannula, needle), number of years practicing (≤5, >5), and number of injections per week. Number of years practicing was dichotomized into 5 or fewer and greater than 5 to reflect an approximate time frame for developing competency in filler injection. Subgroup analysis was

performed for each instrument type (needles vs cannulas). Statistical significance was defined as α less than .05. All statistical analyses were performed using SAS statistical software, version 9.4 (SAS Institute Inc).

Results

The study duration was August 2018 to August 2019. Of 600 participants invited, 418 agreed to participate, and 370 participants provided data regarding their filler injection volumes and history of intravascular occlusions, which were analyzed. Of the 370 participants, 106 (28.6%) reported at least 1 vascular occlusion secondary to filler injection.

Table 1 summarizes data on occlusions by the type of filler and by each instrument type. Table 2 summarizes information regarding cases of multiple occlusions per injector per instrument type. Table 3 summarizes the frequency of occlusions per anatomic site of injection. Table 4 summarizes the distribution of the severity of occlusions by filler type, injection instrument, and anatomic site of injection.

Multivariate analysis results for factors associated with overall vascular occlusion found that injections of poly-L-lactic acid had 74.8% decreased odds of vascular occlusion compared with injections of hyaluronic acid derivatives. Injections with cannula had 77.1% lower odds of occlusion compared with needle injections. Participants injecting for more than 5 years had 70.7% lower odds of occlusion compared with those less experienced. For each additional injection per week, the odds of vascular occlusion decreased by 1%. Multivariate analysis for factors associated with vascular occlusion with needle injections found that poly-L-lactic acid was associated with 72.5% lower odds of occlusion than hyaluronic acid and that each additional needle injection per week decreased the odds of occlusion by 3%. Multivariate analysis for factors associated with vascular occlusion with cannulas found no significant associations, including no association with filler type, years of experience injecting with cannulas, or number of cannula injections per week.

Post-hoc analysis detected no difference in the frequency of needle injections performed by those practicing 5 or fewer years vs those practicing more than 5 years (average percentage of total injections using needles, 75% vs 72%; average percentage using cannulas, 25% vs 28%; $P = .86$). Similarly, no difference was found in the frequency distribution of anatomic sites injected by those practicing 5 or fewer years as vs those practicing more than 5 years.

Discussion

This study measured the likelihood of vascular occlusion associated with filler injections, as reported by US dermatologists during the preceding 10 years (or for as long as they had been in clinical practice). As expected, the total risk of occlusion per syringe of filler injected was very low with either cannulas or needles. However, approximately one-third of injectors reported experiencing at least 1 occlusion. Injections with cannulas were more than 6 times less likely to cause occlusions than injections with needles, with 1 occlusion per 6410 per 1-mL syringe injections using needles and 1 per 40882 using cannulas.

The vast majority of injections were of hyaluronic acid products, so most occlusions, even those with cannulas, were also with hyaluronic acid. For the same reason, individual injectors were more likely to experience more than 1 occlusion with hyaluronic acid fillers rather than other fillers. Twenty injectors experienced 2 occlusions each with needle-injected hyaluronic acid filler and reported 2 occlusions, with 3 reporting a maximum of 5 occlusions; in contrast, only 2 (one-tenth as many) injectors experienced 2 occlusions with cannula-injected hyaluronic acid products, and only 1 reported a maximum of 3. During facial treatment with hyaluronic acid, the nasolabial folds and lips were most likely to be occluded, accounting for almost half of facial occlusions with hyaluronic acid, and the temple, jawline, and chin were least likely, with no incidence of occlusion with cannula in the latter 2 areas.

In general, the difference between the data for hyaluronic acid compared with other fillers is likely not a real difference, but rather an outcome of the reality that hyaluronic acid is injected more frequently. One notable exception may be the markedly lower reported rate of occlusion with poly-L-lactic acid, which is likely real and attributable to the lower viscosity of this substance, essentially a very dilute aqueous solution. Unlike the other fillers studied, which exert their effect immediately by directly occupying space in the subcutis, poly-L-lactic acid is a biostimulatory product that works indirectly, over a period of months, by stimulating collagenesis. Importantly, hyaluronic acid fillers also differ from others in that hyaluronic acids can be fully, specifically, and rapidly reversed by the enzyme hyaluronidase.[21] While it is beyond the scope of this investigation, it is likely that a major reason for the popularity of hyaluronic acid fillers is the availability of this safety feature, which may beneficially affect recovery after occlusion with HAs.

Based on regression analysis, during the first 5 years in practice, the relative risk of occlusion is approximately twice as high per syringe injected. Importantly, even after adjusting for the number of years of experience injecting filler, the frequency of procedures performed, as measured by average number of injections per week, still influenced the odds of occlusion. Each incremental syringe injected per week reduced the relative risk of occlusion per syringe. It is not surprising that more years of experience and more syringes per week each independently reduced relative risk of occlusion given the extensive surgical literature showing that more experienced surgeons and those who perform a procedure more often tend to have fewer complications. On the other hand, the decrease in relative risk per incremental syringe per week injected is modest, which confirms that even less busy injectors can safely deliver filler. Furthermore, sensitivity analysis performed by using 10 years rather than 5 years as the cutoff for the years of experience variable in the regression model showed that there was no longer a statistically significant effect of years of experience on odds of occlusion, which suggests that the odds of occlusion are elevated only very early in dermatologists' careers.

Interestingly, the experience benefit is seen for filler injections in general, and needle injections in particular, but not for cannula injections. It may be hypothesized that cannula injections are less operator-dependent and that the learning curve for mitigating occlusion risk is shorter for cannulas than for needles.

Reassuringly, the vast majority of occlusions were of low severity level, with no sequelae. For filler types for which occlusions were reported with both needles and cannulas, there were no substantial differences in the level of occlusion severity based on instrument type. Of the anatomic sites at which occlusions were commonly reported, the nasolabial folds and the glabella had the most occlusions of severity levels higher than 1. The mean severity level of occlusions was highest at the glabella.

In this analysis, number of syringes per occlusion was the primary metric to define incidence. This was used because of the underlying assumption that the quantity injected (and the associated quantity of needle sticks and injections) is the most granular unit for assessing risk. Because some patients may receive multiple syringes, and repeat treatments, physicians may be able to use the syringe-level data provided to estimate patients' aggregate risk per treatment or over the course of several treatments.

Limitations and Strengths

Limitations of this study include its specificity for board-certified dermatologists and dermatologic surgeons. The results are thus not generalizable to physicians in other specialties, nor nonphysician injectors, each of whom may have different rates of occlusion. The results may also be less generalizable to the subset of cosmetic dermatologists who are high-volume filler injectors, as they comprised a smaller subset of the sample; based on the data, and given the association between number of injections and likelihood of occlusion, such high-volume injectors would be expected to all have experienced multiple occlusions despite their greater experience, and thus likely greater injection skill. Similarly, the results may not be generalizable to very low-volume injectors, who may have less injection experience and possibly be less interested in joining groups that focus on filler education.

In addition, while participants were asked to provide data based on medical records, data collection was retrospective and subject to data-entry errors, data-extraction errors, and errors in reporting, including misclassification, inadvertent omission, and loss of data associated with changes in medical records procedures. We asked for equivalents injected per week and not per year to avoid the situation in which the only participants who would provide data were those able to easily access their medical records by year. By asking for data for a typical week, we expected we would potentially avoid omitting many willing respondents and introducing selection bias. Because physicians work different numbers of weeks per year, the process of extrapolation could have affected the accuracy of the results. We did not include a specific category just for blindness because we were concerned that a request to elicit this information may have made potential respondents reluctant to respond to the survey or to provide complete or accurate information about blindness events. The likelihood of an occlusion event may have been a function of the treating dermatologist, as patients treated by the same dermatologist cannot be considered statistically independent and neither can the injections and occlusion events.

Data collection was not audited, and it is possible that some or many participants may have provided information based solely on recall or estimation, which may have resulted in overestimation of the number of syringes injected and underestimation of the number of occlusive events. Recall

bias may have resulted in some incidents of occlusion being forgotten or overlooked, leading to underreporting with consequent underestimation of occlusion risk. It is also possible that some minor occlusion events may have been undetected or not identified as a problem by patients, who may not have reported these to their injector nor presented to the office for evaluation. On the other hand, diagnosed or reported occlusion events are typically unusually worrisome and quite memorable for the injector, hence recall bias may be less of a factor than for some less salient events. Because the exact dates of occlusion events were not elicited in order to maintain patient confidentiality and to avoid collection of patient identifiers, it is possible that a disproportionate number of needle-associated occlusion events occurred relatively early in the 10-year window examined, before increased awareness of the risk of ocular injury due to occlusion had resulted in improved injection methods with both needles and fillers.

Strengths of this study included the large cohort, which comprised more than 7000 person-years of experience and more than 1.5 million syringes of filler injected, as well as the diversity of experience levels among the participants. This suggests that the result may be generalizable for dermatologists who inject filler, although less so for cosmetic dermatologists who are high-volume injectors, as they comprised a smaller subset of the sample.

Conclusions

Overall, the study findings are useful in that they provide quantitative estimates of the risk of intravascular occlusion after injection of common prepackaged fillers. Cannulas appear to be less likely to be associated with occlusions than needles. Further research, including longitudinal prospective studies, are required to validate the findings obtained, including the degree of difference. Additionally, future studies may compare injectors with similar levels of experience and injection volumes but different number of occlusions to identify any technique differences that may be protective against occlusion. But based on the data analyzed, it appears that both types of instruments are safe, with occlusions occurring in, on average, fewer than 1 per 5000 syringes when injections are performed by dermatologists. Furthermore, most occlusions that do manifest subsequently remit completely without even a scar. While increased cannula use may further help mitigate the incidence of occlusive events, certain indications, anatomic locations, and patient needs may favor needle injection. Only the treating physician, after taking into account specific patient factors, can determine whether a needle or a cannula is most appropriate.

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Figures and Tables

Table 1.

Occlusions by Filler and Injection Instrument Type Among Participants

Filler and instrument	Total No. of syringes injected in past 10 y	Total No. of occlusions in the past 10 y	No. of syringes per occlusion	*P* value	Total No. of participants who reported occlusions
All fillers[a]					
Needle	1 128 192	176	6410	<.001	103
Cannula	531 466	13	40 882		9
Hyaluronic acid					
Needle	927 841	162	5727	<.001	95
Cannula	420 281	12	35 023		8
Poly-L-lactic acid					
Needle	82 593	4	20 648	.31	2
Cannula	39 550	0	NA		0
Polymethylmethacrylate					
Needle	24 034	0	NA	.38	0
Cannula	14 647	1	14 647		1
Calcium hydroxyapatite					
Needle	64 399	10	6440	.01	10
Cannula	40 118	0	NA		0

Abbreviation: NA, not applicable.

[a]Categories listed do not add up to the amount under All fillers because reports of nontemporary injectable fillers (eg, autologous fat) are excluded.

Table 2.

Incidence of Multiple Occlusions Per Injector, Filler Type, and Instrument Type

Filler, instrument, and No. of occlusions	Severity level frequency, No. (%)[a]				No. of injectors[c]
	No sequelae	Scar	Eye injury	Mean severity level[b]	
Hyaluronic acid					
Needle, 2 occlusions	33 (82.5)	7 (17.5)	0	1.18	20
Needle, 3 occlusions	37 (94.9)	2 (5.1)	0	1.05	13
Needle, 4 occlusions	10 (83.3)	2 (16.7)	0	1.17	3
Needle, 5 occlusions	11 (73.3)	3 (20.0)	1 (6.7)	1.33	3
Cannula, 2 occlusions	3 (75.0)	0	1 (25.0)	1.50	2
Cannula, 3 occlusions	3 (100)	0	0	1.00	1
Poly-L-lactic acid					
Needle, 3 occlusions	2 (66.7)	0	1 (33.3)	1.67	1

[a]Percentages are divided within rows, so rows total to 100%.

[b]Mean severity level is defined as the numerical average when values are assigned as follows: 1, no long-term sequelae; 2, scar; 3, ocular injury or blindness.

[c]Injectors with multiple occlusions were classified by the total number of occlusions per injector per filler and instrument type (eg, if an injector had 3 occlusions from hyaluronic acid filler injected with a needle during the past 10 years, they would be listed as 3 occlusions but not also as 2 occlusions).

Table 3.

Mean Number of Occlusions and Occlusions Per Syringe for Hyaluronic Acid Filler by Anatomic Site and Instrument Type

Instrument[a]	Nasolabial fold		Lips		Cheek		Nose	
	No. (%) of occlusions[b]	Occlusions per syringe, %	No. (%) of occlusions[b]	Occlusions per syringe, %	No. (%) of occlusions[b]	Occlusions per syringe, %	No. (%) of occlusions[b]	Occlusion per syringe,
Needle	39 (24.1)	0.0042	31 (19.1)	0.0033	21 (13.0)	0.0023	18 (11.1)	0.0019
Cannula	2 (16.7)	0.0005	3 (25.0)	0.0007	1 (8.3)	0.0002	2 (16.7)	0.0005
Instrument[a]	**Marionette lines[b]**		**Jawline[b]**		**Chin[b]**		**Temple[b]**	
Needle	4 (2.5)	0.0004	3 (1.9)	0.0003	3 (1.9)	0.0003	1 (0.6)	0.0001
Cannula	0	0	0	0	0	0	1 (8.3)	0.0002

Abbreviation: NA, not applicable.

[a]Percentages are divided within rows, so rows total to 100%.

[b]Percentage of all occlusions with hyaluronic acid filler using the designated instrument (needle or cannula).

Table 4.

Occlusion Severity Level by Filler, Injection Instrument Type, and Anatomic Site

Characteristic	Severity level frequency, No. (%)[a]				*P* value[b]
	No sequelae	Scar	Eye injury	Mean severity level	
Filler					
Hyaluronic acid					
Needle	139 (85.8)	22 (13.6)	1 (0.6)	1.15	.02
Cannula	11 (91.7)	0	1 (8.3)	1.17	
Poly-L-lactic acid					
Needle	3 (75.0)	0	1 (25.0)	1.50	NA
Cannula	NA	NA	NA		
Polymethylmethacrylate					
Needle	NA	NA	NA		NA
Cannula	1 (100)	0	0	1.00	
Calcium hydroxyapatite					
Needle	7 (70.0)	3 (30)	0	1.30	NA
Cannula	NA	NA	NA		
All fillers					
Needle	149 (84.7)	25 (14.2)	2 (1.1)	1.16	.07
Cannula	12 (92.3)	0	1 (7.7)	1.15	
Anatomic site					
Nasolabial fold	40 (85.1)	7 (14.9)	0	1.10	
Lips	33 (97.1)	0	1 (2.9)	1.06	
Cheek	20 (83.3)	4 (16.7)	0	1.18	
Nose	17 (81.0)	3 (14.3)	1 (4.8)	1.15	
Glabella	12 (63.2)	7 (36.8)	0 (0)	1.37	
Forehead	12 (85.7)	1 (7.1)	1 (7.1)	1.23	.03
Marionette lines	4 (100)	0	0	1.00	
Jawline	1 (33.3)	2 (66.7)	0	1.67	
Chin	2 (66.7)	1 (33.3)	0	1.33	
Temple	5 (100)	0	0	1.00	
Other parts of face	15 (100)	0	0	1.00	

Abbreviation: NA, not applicable.

[a]Percentages are divided within rows, so rows total to 100%.

[b]Differences in severity level frequency between needles and cannulas for each filler type and across anatomic sites.