

Dermal Filler Medical Device Reporting (MDR)

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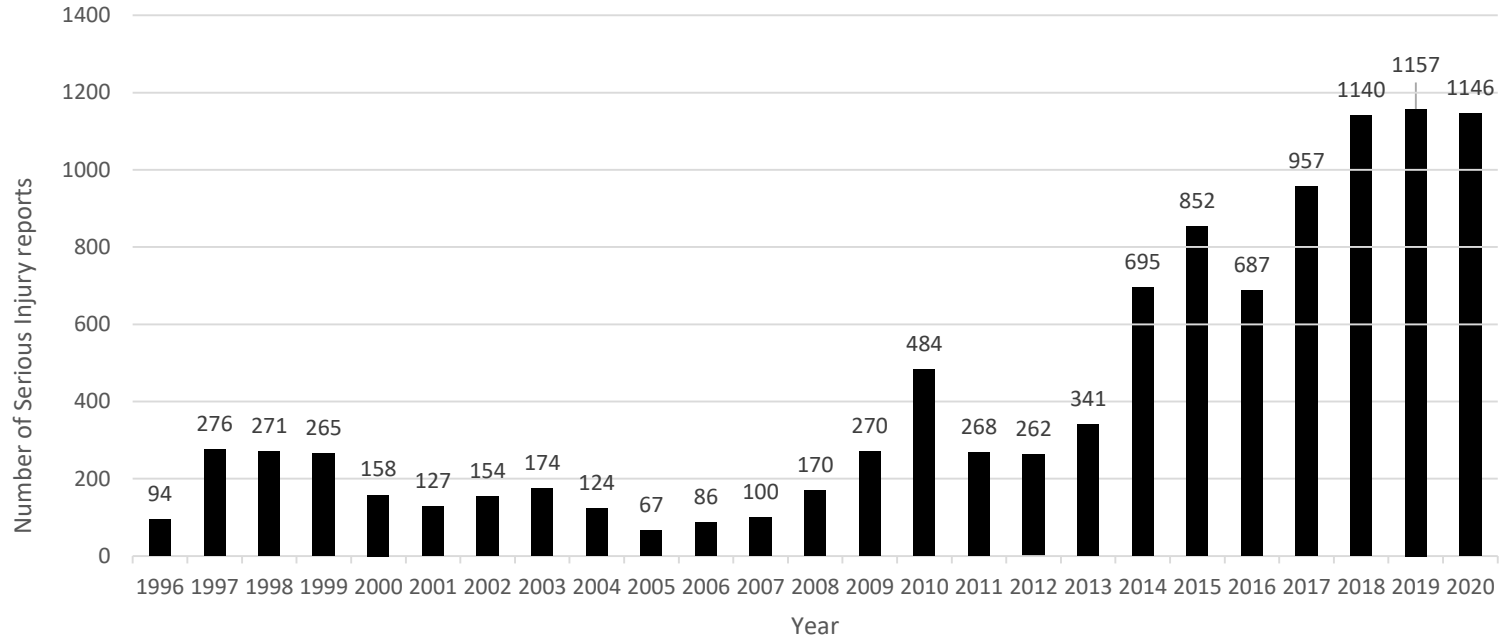
U.S. Food and Drug Administration

Medical Device Reports- Limitations

- The MDR system provides FDA with timely information on medical device performance from patients, providers, and manufacturers.
- While the MDR system is a valuable source of information, this passive surveillance system has limitations, including incomplete, inaccurate, untimely, unverified, or biased data in the reports.
- In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting, duplicate reporting of events, and the lack of information about the total number of devices.

Dermal Filler Serious Injury MDRs: 1996-2020

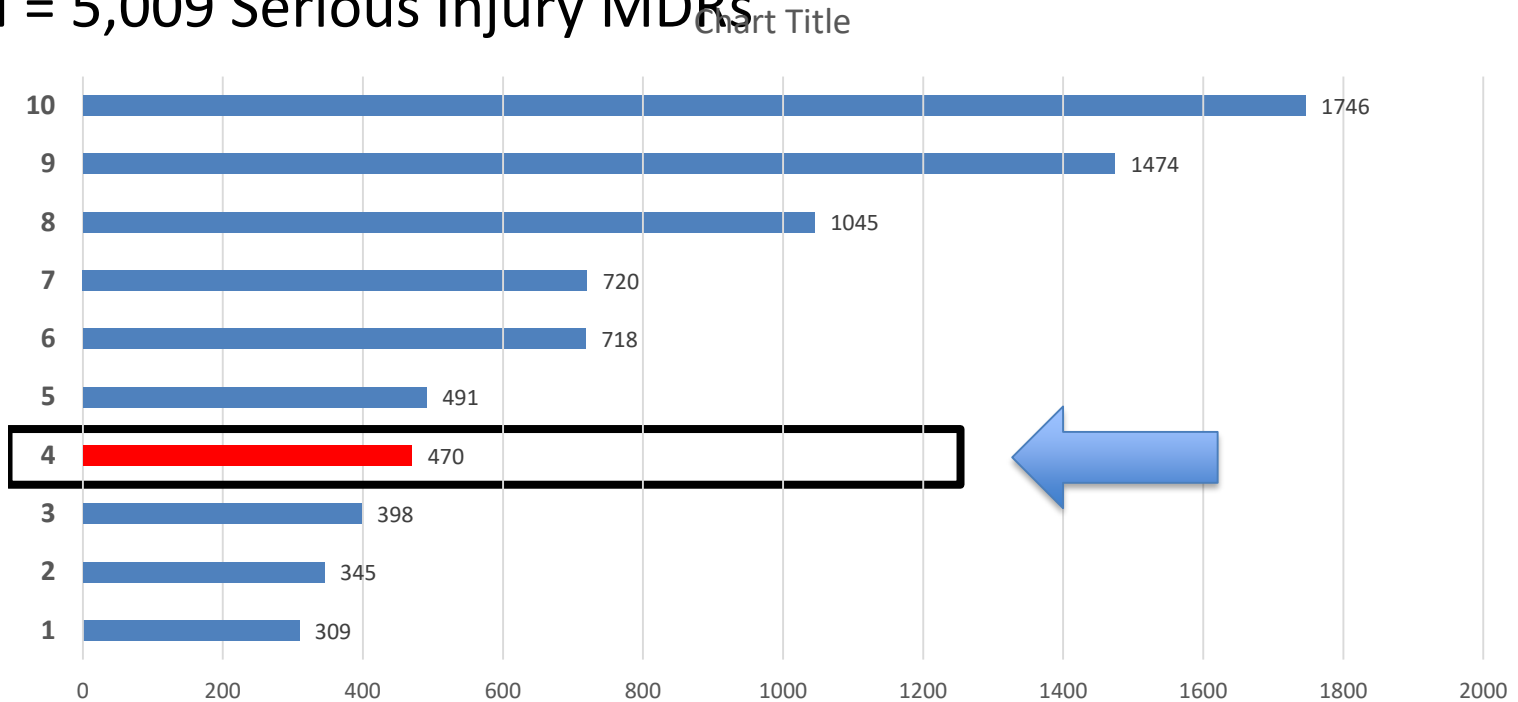
N=10,325



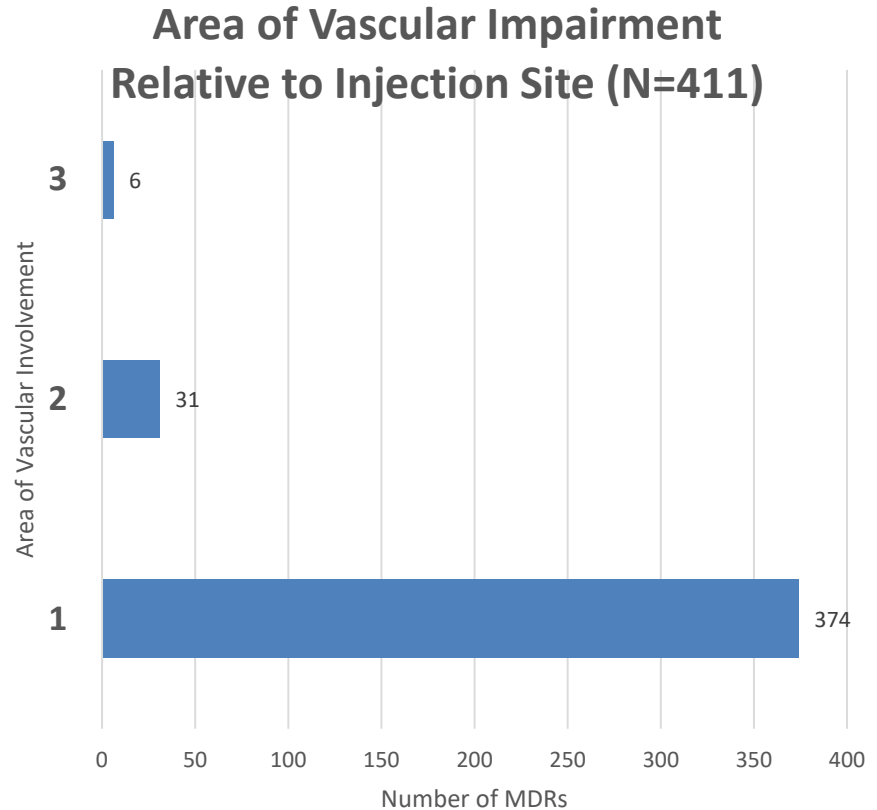
Serious Injury-An injury or illness that is life threatening, results in permanent impairment of a body function or structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or structure.

5 Year Data Search

- Dates: August 1, 2015 – August 1, 2020
- N = 5,009 Serious Injury MDRs

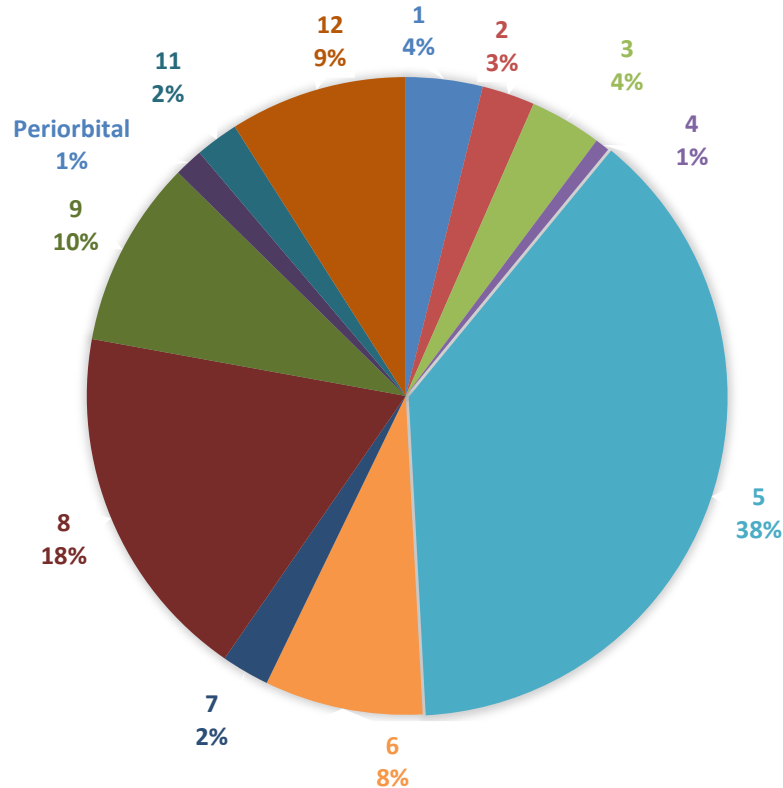


- Data extracted from 411 Dermal Filler MDRs identified as “Serious Injury” with associated patient problem code “Vascular System (Circulation), Impaired”
- 49% of MDRs originated outside of the United States
- This graph contains reports of uses that are not approved



Data extracted from 411 Dermal Filler MDRs identified as “Serious Injury” with associated patient problem code “Vascular System (Circulation), Impaired”.

Vascular Events by Anatomic Location of Injection



The Nose is associated with the highest number of Distant Vascular Impairment Events

The Lips are associated with the highest number of Local Vascular Events

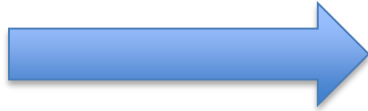
Serious Injuries Related to Vision

- A search was conducted of all 5,009 Dermal Filler MDRs labeled as “Serious Injury” for reports associated with vision related patient problem codes.

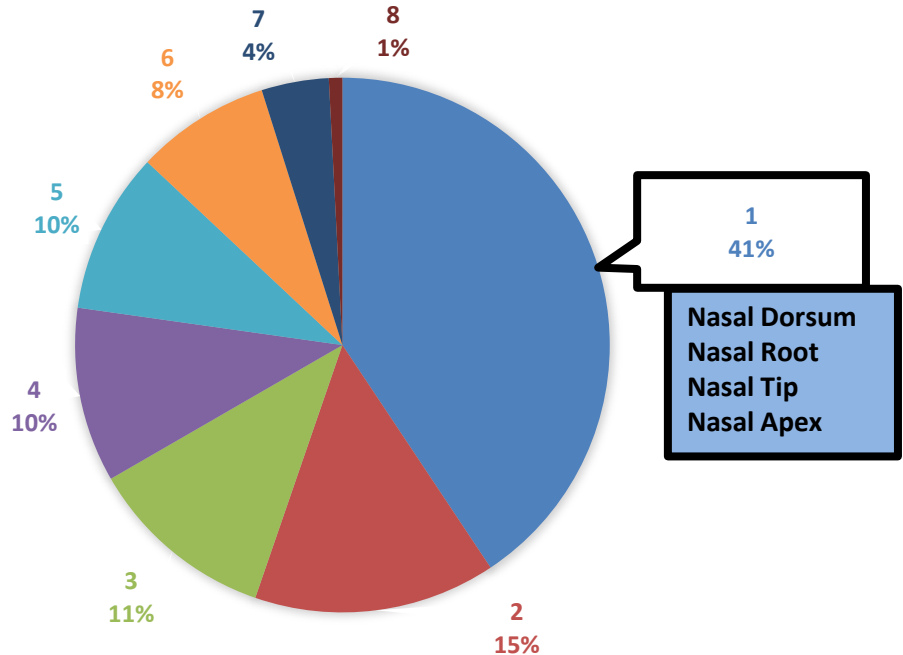
Vision Related Patient

Problem Codes

Optical Nerve Damage
Vision, Loss Of
Retina, Damage To
Eye Injury
Blurred Vision
Vision, Impaired
Visual Disturbances
Intraocular Pressure Rise
Corneal Edema
Corneal Ulcer
Ptosis



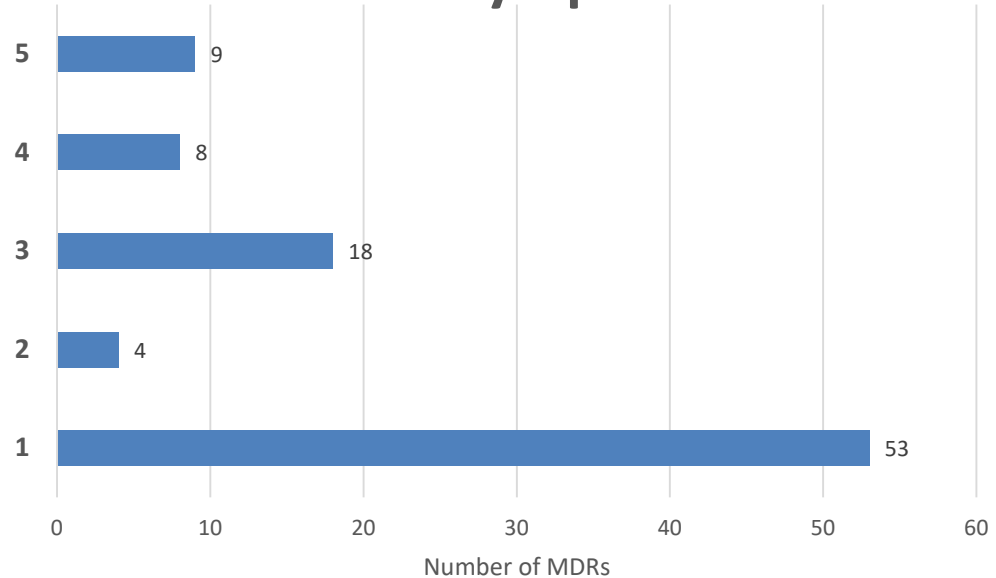
VISION-RELATED MDRs BY ANATOMIC LOCATION OF INJECTION (N=92)



Data was extracted from 92 MDRs for Dermal Filler with patient problem codes associated with visual impairment

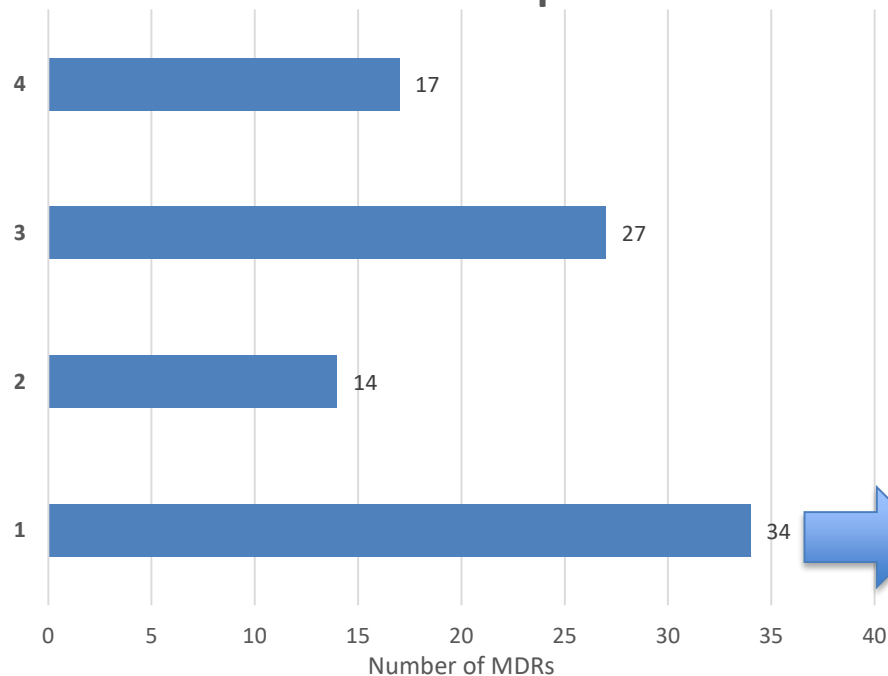
- 58% of patients had immediate onset of visual impairment
- Most Common Symptoms
 - Blurred vision
 - Pain
 - Partial or total blindness
 - Headache
 - Dizziness
- Eye(s) Affected
 - Unilateral N=68
 - Bilateral N=2
 - Unknown N=22

Onset of Visual Symptoms



Data was extracted from 92 MDRs for Dermal Fillers with patient problem codes associated with visual impairment

Clinical Course of Visual Impairment



14 patients with unresolved or permanent changes in vision were injected in the **Nose**

Of the 92 vision-related MDRs, there were 17 reports (17/92, 18.5%) of patients who also experienced neurological symptoms.

The most commonly reported symptoms

- drowsiness
- non-reactive pupil
- absent light reflex
- facial drooping
- paralysis

