Adversarial Events Associated with Orbital Floor Implants: A National Perspective

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Introduction

- Orbital floor injuries had an incidence of 11.3 per 100,000 people in 2017. An increase of 47% from the previous decade.[1]
- Surgical approaches are indicated when there is loss of visual acuity along with enophthalmos >2mm, retrobulbar hematoma, nerve incarceration, periorbital fat entrapment, and fractures encompassing over one-half of the orbital floor.[2, 3]
- Orbital floor implants (OFIs) are a common reconstructive surgical method utilizing materials such as titanium mesh, or more recently, patient-specific implants.[4]
- Post-operative complications include hyperesthesia, diplopia, intra-orbital hematoma, and enophthalmos.[5]
- The majority of OFI literature focuses on efficacy of treatment, but there is a lack of data surrounding complications associated with implantation.
- Using the national Manufacturer and User Device Experience (MAUDE) database, we sought to characterize post-surgical complications.
- We seek to improve physician counseling, prediction of complications, and improve patient outcomes.

Methods and Materials

Database Background: The MAUDE database is a collection of adverse events developed by the Food and Drug Administration (FDA). All cases of adverse events must be reported to the database, which includes patient and device related complications.

Data Collection: "Orbital Floor Implant" was the search term used to query the database. All reports between Jan 2011 and Jan 2023 were analyzed. Adverse events, treatment, treatment type, and treatment complications were collected.

Statistical Analysis: Descriptive statistics were used to characterize patient and device related problems and outcomes using RStudio (Version 2022.02.3, RStudio PBC)

Results

Table 1. Adverse event characteristics

Characteristic	(n,%)
Device company (44)	
Synthes	28 (63.64)
Stryker	4 (9.09)
Biomet	6 (13.64)
Other	6 (13.64)
Time since placement (21)	
Intraoperative	**15 (71.43)**
< 1 month	1 (4.76)
1 to < 6 months	2 (9.52)
6 months to <1 year	1 (4.76)
1+ years	2 (9.52)
Device Problem (42)	
Physical defect (deformation, fracture, etc.)	**15 (35.71)**
Delamination	5 (11.90)
Migration	**7 (16.67)**
Patient-device incompatibility	5 (11.90)
Expiration	2 (4.76)
None	5 (11.90)
Other	4 (9.52)
Patient problem (38)	
Enophthalmos	4 (10.53)
Diplopia	2 (5.26)
Infectious/inflammatory process	**7 (18.42)**
Retained foreign body	5 (13.16)
Pain	3 (7.89)
No impact to patient	7 (18.42)
Other	4 (10.53)
Event Type (44)	
Injury	31 (70.45)
Malfunction	13 (29.55)
Delayed primary surgery (39)	10 (25.64)
Treatment complication (31)	6 (19.35)

Results

Figure 1. Incidence Of OFI adverse reports by year. Adverse events were most frequently reported in 2015 (n=10)

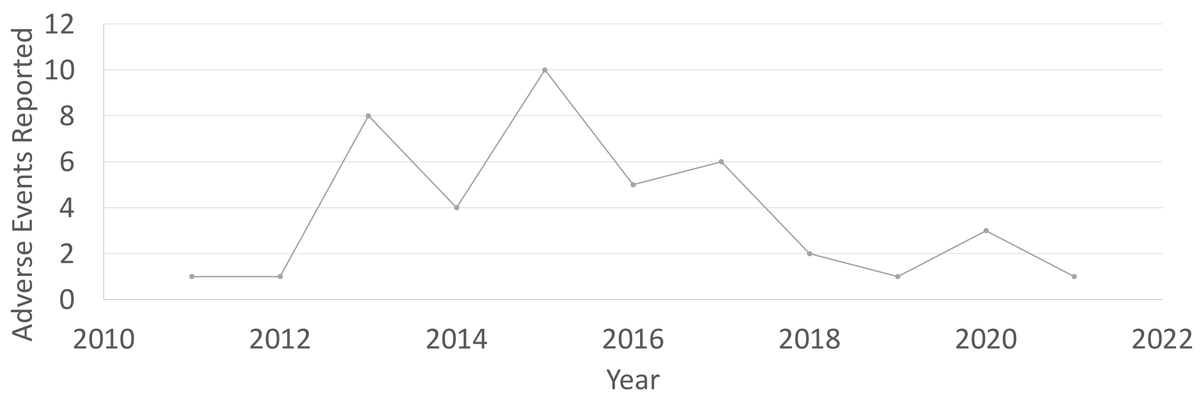


Figure 2. Characteristics of treatment options. Reoperation with implant removal and replacement was the most common intervention (n=14)

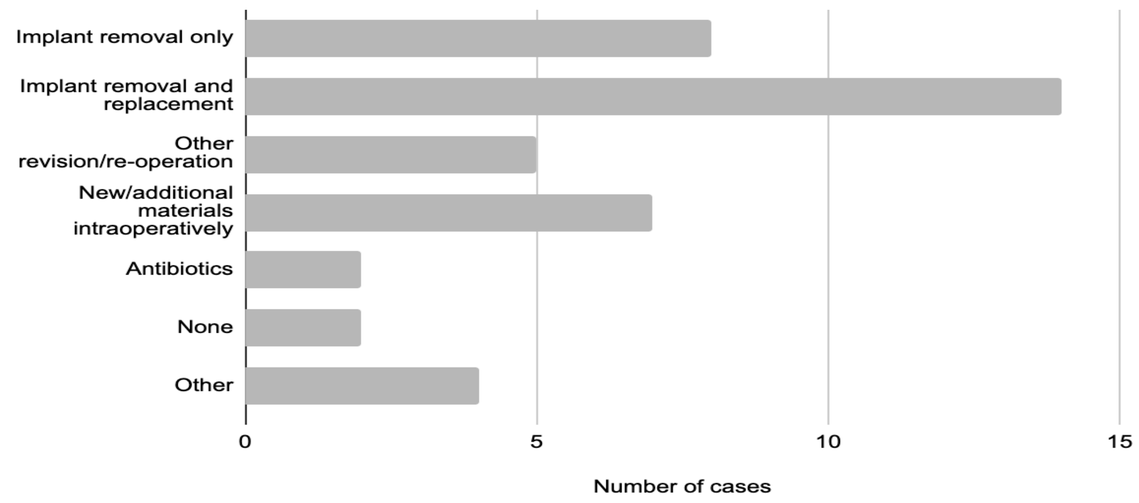
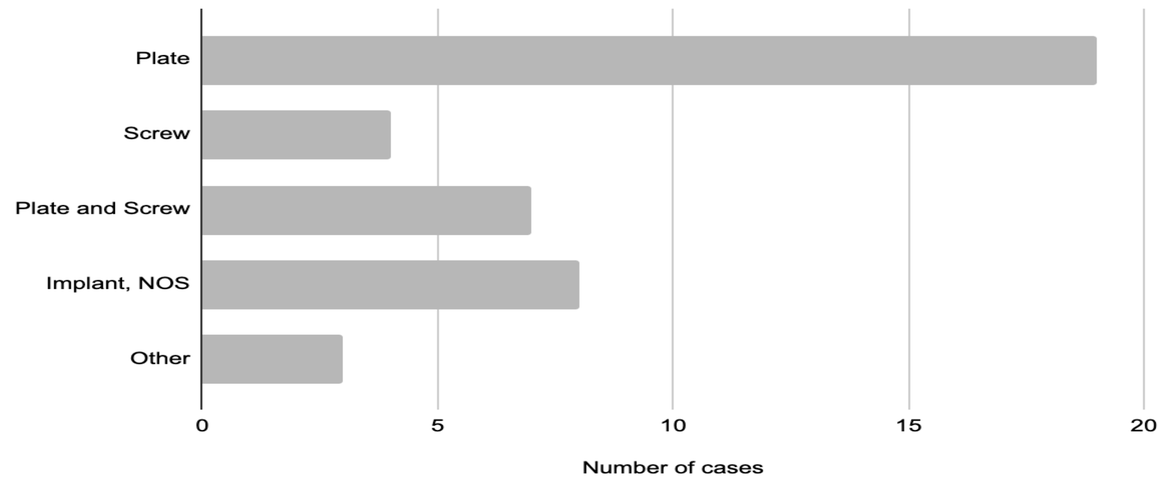


Figure 3. Frequency of part removal. Orbital floor plate removal was the most common (n=19)



Discussion

- Infectious and inflammatory processes were the leading cause of complications
- The MAUDE database did not report on timeline in which adverse events occurred postoperatively
- Adverse events primarily occurred intraoperatively
- Understanding common complications and their rates can help clinicians weight risks and benefits of surgical intervention
- Timeline of postoperative complications is important to report on to ensure proper postoperative follow-up
- Self-reporting is a limitation of the MAUDE database

Conclusions

Adverse events associated with OFIs were primarily caused by infectious/ inflammatory processes, device migration, and physical defects such as device fracture or malformation. Additionally, our findings showed that a majority of these complications occurred intraoperatively. More work must be done to study complications with surgical intervention of orbital floor fractures using OFIs to help improve clinician understanding and patient outcomes.

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