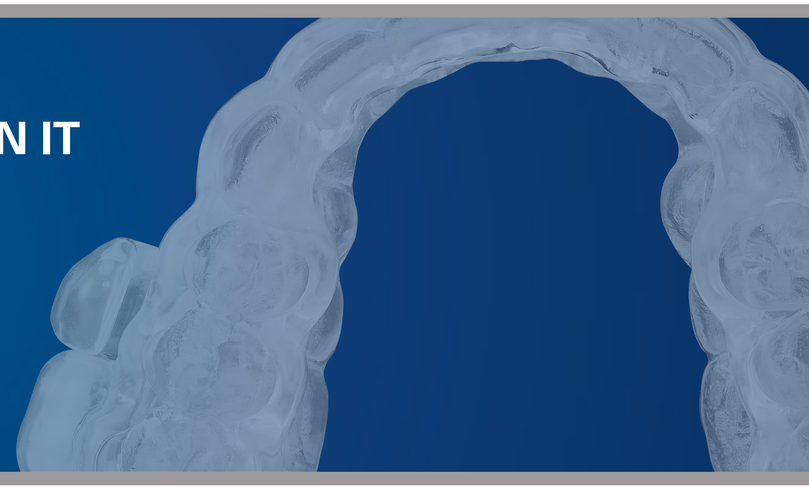
2023 AADSM Annual Meeting, ABSTRACT #011

OAT DEVICE DESIGNS ARE NOT THE SAME WHEN IT COMES TO PATIENT RISK AND SAFETY: AN FDA MAUDE DATABASE ANALYSIS

Rosemarie Rohatgi DMD D-ABDSM[1], Mark Murphy DDS D-ABDSM[2], Len Liptak MBA[3]
Edward Sall MD DDS MBA[4]

[1] San Diego Sleep Therapy
[2] Funktional Sleep and ProSomnus Sleep Technologies
[3] ProSomnus Sleep Technologies
[4] Advanced ENT Physicians of CNY and ProSomnus Sleep Technologies



Introduction: Are OAT device designs the same when it comes to patient risk and safety? There is a prevalent perception that all OAT devices are the same. Yet, logically, differences in OAT device designs (materials, structures, titration mechanisms, liners) should yield different performance profiles.

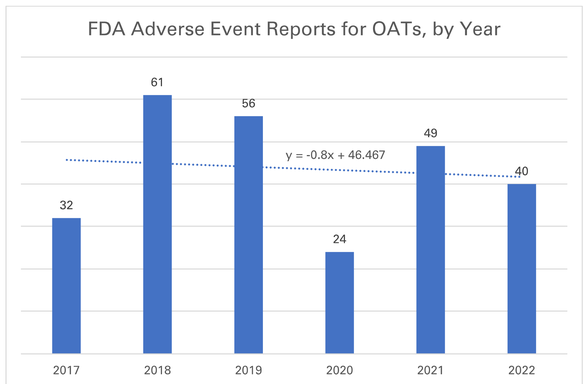
This investigation evaluates whether different OAT device designs are associated with differences in patient risk and safety, as objectively measured by FDA Adverse Event Reports (AERs). The FDA defines adverse events as undesirable experiences that should be reported when the outcome is death, life threatening, hospitalization, disability, required intervention, or a serious medical event. In other words, medically significant side effects.

Methods: The FDA MAUDE (**ma**nufacturer and end-**u**ser **d**evice **e**xperience) Database is a publicly available resource that indexes AERs. For this study, the MAUDE database was accessed on April 21, 2023.

Each AER specifies the associated OAT device. Each OAT device design was then characterized using publicly available information. Descriptive statistics were used.

Results, Overview:
262 adverse events have been reported to the FDA for OAT over the five-year period from 2017 and 2022.

This data shows that the count of AERs have declined slightly over this five-year period.



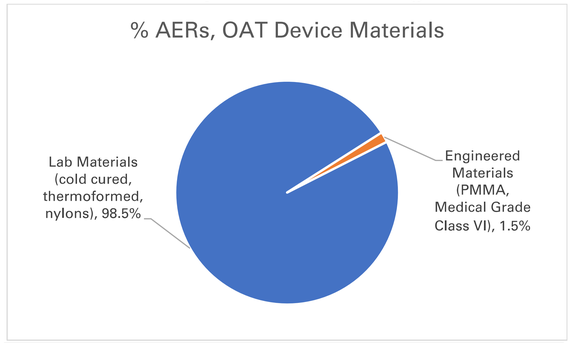
Results, Top 15 AER "Device" Problems from 2020 to 2022:

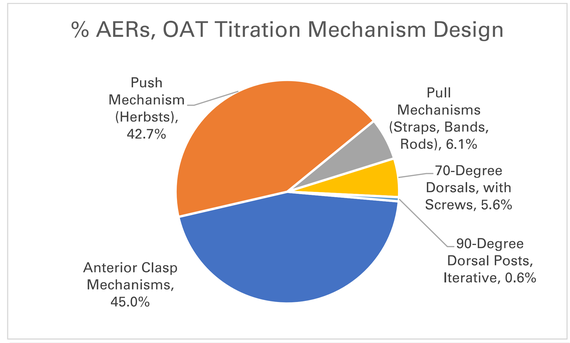
Device Problems	Count	Device Problems	Count	Device Problems	Count
Adverse Event Without Identified Problem	142	Patient-Device Incompatibility	22	Product Quality Problem	12
Break	65	Migration or Expulsion of Device	18	Material Separation	11
Insufficient Information	45	Patient Device Interaction Problem	18	Crack	10
Extrusion	25	Biocompatibility	15	Delamination	9
Detachment Of Device Component	22	Detachment of Device or Component	14	Material Integrity Problem	8

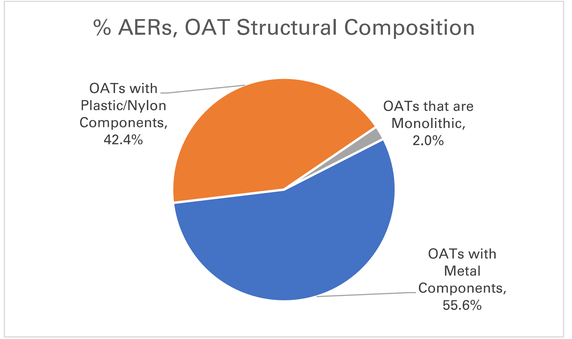
Results, Top 20 AER "Patient" Problems from 2020 to 2022:

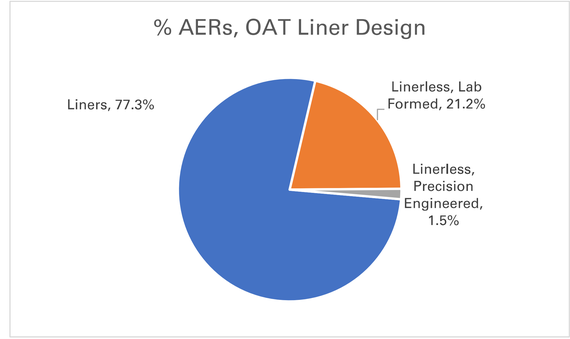
Device Problems	Count	Device Problems	Count	Device Problems	Count
No Known Impact Or Consequence To Patient	115	No Information	14	No Code Available	9
Hypersensitivity/Allergic reaction	91	Failure of Implant	13	Foreign Body In Patient	8
Reaction	57	Inflammation	12	Tooth Fracture	7
Pain	36	Erythema	11	Burning Sensation	7
Swelling	30	Rash	11	Tingling	6
Discomfort	17	Unspecified Infection	10	Numbness	6
No Consequences Or Impact To Patient	16	Irritation	9		

Results, AER % by OAT Device Design Characteristic:









Conclusions: OAT device designs are not the same when it comes to patient risk and safety.

Healthcare providers may wish to place more emphasis on OAT device materials, as materials seem more closely associated with AER "patient" problems and "device" problems.

Healthcare providers may consider placing less emphasis on dental side effects, as dental side effects comprise only 2.5% of AERs.

Healthcare providers may be able to reduce patient safety risks by selecting OAT device designs that are associated with lower frequencies of AERs: Precision Engineered Materials, Monolithic Structures, 90-Degree Iterative Titration Mechanisms and Precision Engineered Linerless designs.

Healthcare providers should have the freedom to prescribe non-mechanical hinge devices given the association between mechanical hinge style OAT device designs and the higher prevalence of AERs.

This investigation has limitations. The FDA database relies on reports from providers, manufacturers, and patients. It is also difficult to estimate AER frequencies by OAT device design without knowing unit volumes, however, based on public information, the lowest counts of AERs are associated with high volume OAT device designs.