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Research Article

Adverse Clinical Events Associated with the Use of Anti-snoring Devices

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Abstract

Background: With the recent interest and growth of sleep medicine, oral devices are used increasingly to treat patients suffering from snoring and Obstructive Sleep Apnea (OSA). The main advantages of using removable oral devices to address snoring and OSA are the relative simplicity of the treatment and cost-effectiveness. Although promising, little is known about the risk of adverse outcomes associated with the use of removable oral devices for snoring and OSA. The objective of this study is to analyze the adverse events reported to the Manufacturer and User Facility Device Experience (MAUDE) database that are associated with the use of removable oral anti-snoring devices and actions taken by the manufacturer to address these events.

Methods: The study analyzed the MAUDE database of the United States Food and Drug Administration (FDA). Data were collected from reports pertaining to removable oral anti-snoring devices. The variables documented were "type of event," "signs and symptoms of the patient," "reporter occupation," and "type of adverse event."

Results: A total of 326 cases were recorded during the study period. The most common adverse events were malfunction, followed by injury, which affected 48.5% (158) and 48.2% (157) of the patients, respectively. Device breakage was documented in 22.2% (72)of patients. In 3.3% (11) of the cases, part of the oral device was swallowed by the patient during sleep, therefore posing a choking hazard. The most common patient problem was hypersensitivity/allergic reaction seen in 29.0% (95) of patients. 9.8% of these patients already had a known allergy to drugs, metal or other materials.

Conclusion: Taking a detailed health history of the patient could help prevent many of these adverse events.

Keywords: Obstructive Sleep Apnea; Snoring; Anti-snoring Devices

Introduction

Snoring is the noise that occurs during sleep when airflow becomes turbulent as it passes through a restricted throat, causing the tissues in the upper airway to vibrate [1]. Airflow limitations precede all forms of snoring including regular snoring and those with obstructive sleep apnea [2]. On inspiration, air travels by the tongue, the soft palate, the uvula and the tonsils [3]. When a person is awake, the muscles in the back of the throat tighten to hold these structures in place and prevent them from collapsing and vibrating. During sleep, the muscles that keep the upper airway open relaxes [3].

Snoring during sleep mainly occurs because the muscles that keep the upper airway open including the genioglossus, which controls the tongue become more relaxed and less active [4]. This relaxation makes the airway more prone to narrowing or

collapsing, leading to the vibration of throat tissues as you breathe in [4]. Not all individuals with snoring have clinically significant Obstructive Sleep Apnea (OSA); nevertheless, snoring is the earliest and most common symptom of OSA, occurring in 70-95% of patients with OSA [5]. The acute effects of these events include repeated drops in oxyhemoglobin saturation, cardiovascular perturbations and cortical arousals that fragment sleep [6]. The prevalence of OSA associated with accompanying daytime sleepiness is approximately 4 to 14% for adult men and 2 to 5% for adult women in the general population [7,8]. In fact, disease prevalence is higher in different population subsets, including overweight or obese people, those of a minority race and older individuals [9].

Continuous Positive Airway Pressure (CPAP) is the primary noninvasive treatment of choice for OSA since its introduction in early 1981 [7]. However, it is also associated with various challenges that drives noncompliance in patients such as nasal congestion, discomfort secondary to pressure sensation and air leak, mask intolerance due to skin inflammation and feelings of claustrophobia. Other alternatives include behavioral and surgical weight-loss therapies, positional therapy, pharmacologic therapies, pharyngeal and maxillomandibular surgeries and Oral Appliances (OA) [10]. OA therapy advances the mandible to modify posture and enlarge the airway [11]. OA therapy for the management of OSA is considered an effective, low-risk alternative to CPAP and demand for OA increases for those who cannot tolerate CPAP and refuse surgery. However, little is known about adverse events associated with the use of OA to treat OSA. The purpose of the current study is to describe the number and characteristics of adverse events associated with OA using the Manufacturer and User Facility Device Experience (MAUDE) database [12].

Methodology

Medical devices can be searched on the MAUDE database for adverse events using a unique product code. OA used for the treatment of OSA include three basic designs: mandibular re-positioners, tongue retaining devices and palatal lifting devices. All of these devices provide the same therapeutic goal of increasing the pharyngeal space to improve the patient's ability to exchange air. The increase in airway space decreases the air turbulence, which is a causative factor in snoring. These devices are classified according to the product codes below as used in the MAUDE reports.

Product codes utilized in study:

LRK Anti-Snoring Device

LQZ Jaw Repositioning Device

PLC Upper and Lower sprint device

These three product codes represent all removable oral anti-snoring devices as described above in the introduction. Multiple variables were identified and studied during the time frame of January 2011 to August 2021:

- The reporter occupation, which comprised manufacturers, dentists, patients, consumers, users and other healthcare professionals
- The report number
- Date of the event
- Type of adverse events
- Event description

From the event description, we were able to derive information on signs and symptoms, duration of use and whether patients followed up with the dentist after the adverse event. We were also able to identify if the symptoms resolved after the patient stopped using the device.

Results

A total of 326 reports of adverse events were reported from 2011 to 2021. Fig. 1 shows annual results for the number of adverse events reported. Most adverse events, 50 were reported in 2018, followed by 45 in 2021.

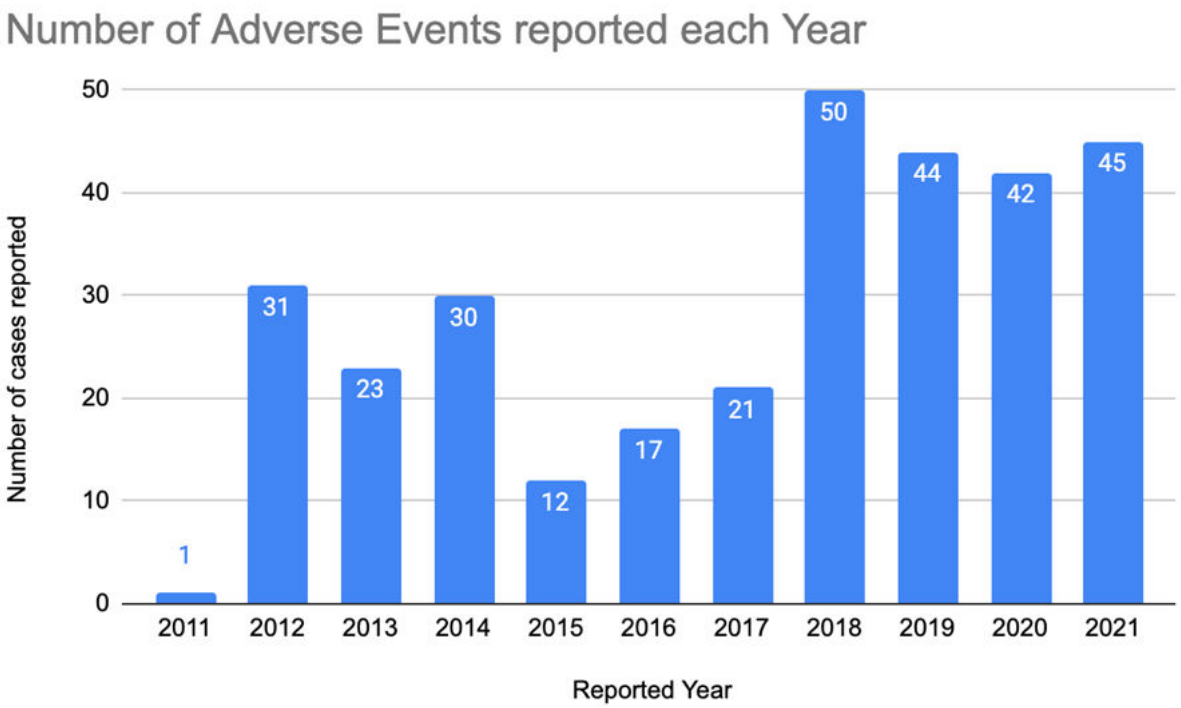

Figure 1: annual results for the number of adverse events reported.

Fig. 2 demonstrates the occupation of who is reporting the adverse event. It was found that in the majority of the cases, 45.7% of the cases, the dentists were the primary reporters. In 21.5% of the reports, no reporter occupation was mentioned. Only in 14.7% of the cases were adverse events reported by the patients, followed by the consumer, 12.0 %.

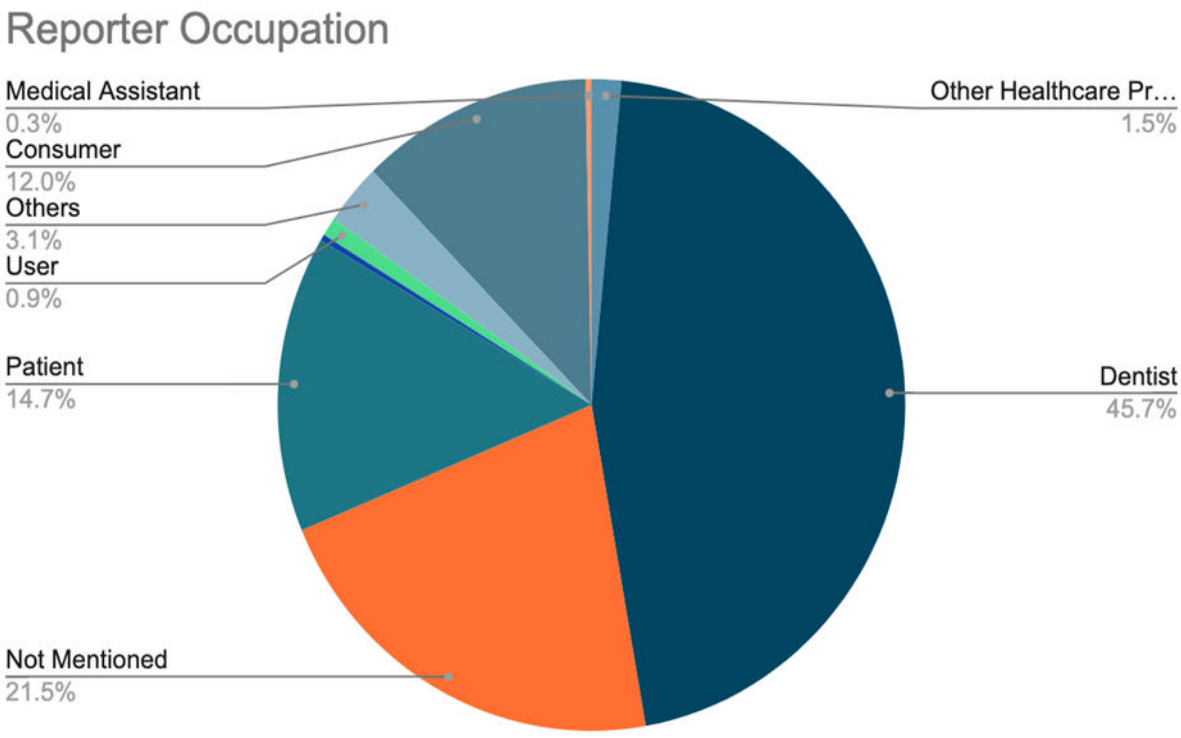

Figure 2: demonstrates the occupation.

Fig. 3 shows the signs and symptoms reported. Hypersensitivity/allergic reaction was the most commonly reported symptom and was mentioned in 25.2% of the total reports. Many patients reported other intra-oral symptoms ranging from swelling and redness of lips and gums, blisters, fissured tongue and fungal reaction at the back of the throat. Device breakage was the second most common symptom reported by 24.5% of the patients. In multiple cases, it was observed that the patient presented with more than one symptom.

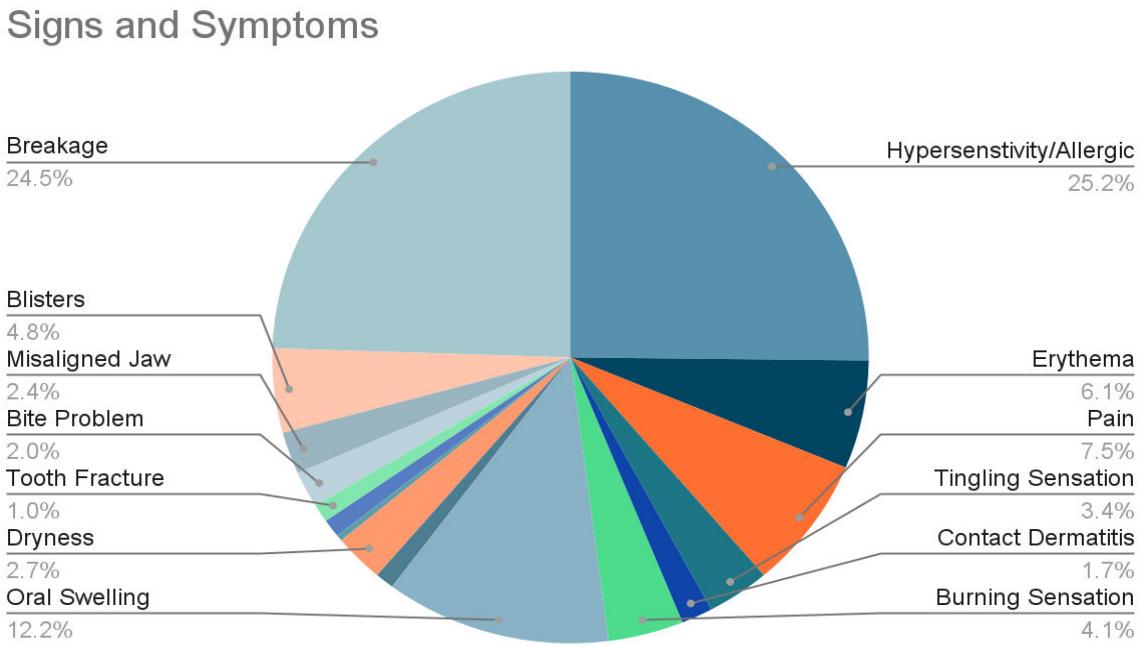

Figure 3: The signs and symptoms reported.

Fig. 4 shows the different categories of adverse events reported with the use of a removable oral anti-snoring device. Malfunction (problem with the use of the device) was found to be the most common adverse event reported in 48.5% (158 patients) of the cases, followed very closely by Injury reported in 48.2% (157). In only 3.4% of the cases, no answer was provided for the type of adverse event.

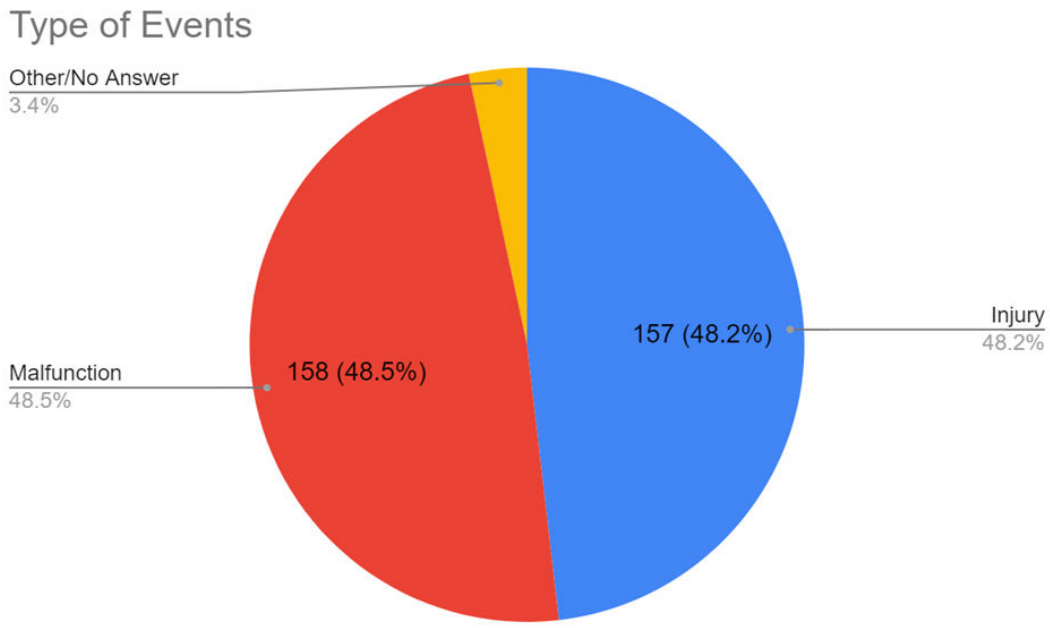

Figure 4: The different categories of adverse events.

Fig. 5 shows the different types of adverse events seen in patients. 7 patients reported a misaligned jaw. 6 patients reported the device getting swallowed and bite problems, respectively. 4 patients reported burns in their oral cavity. 3 reported tooth fractures, followed by 1 patient who was diagnosed with sleep apnea.

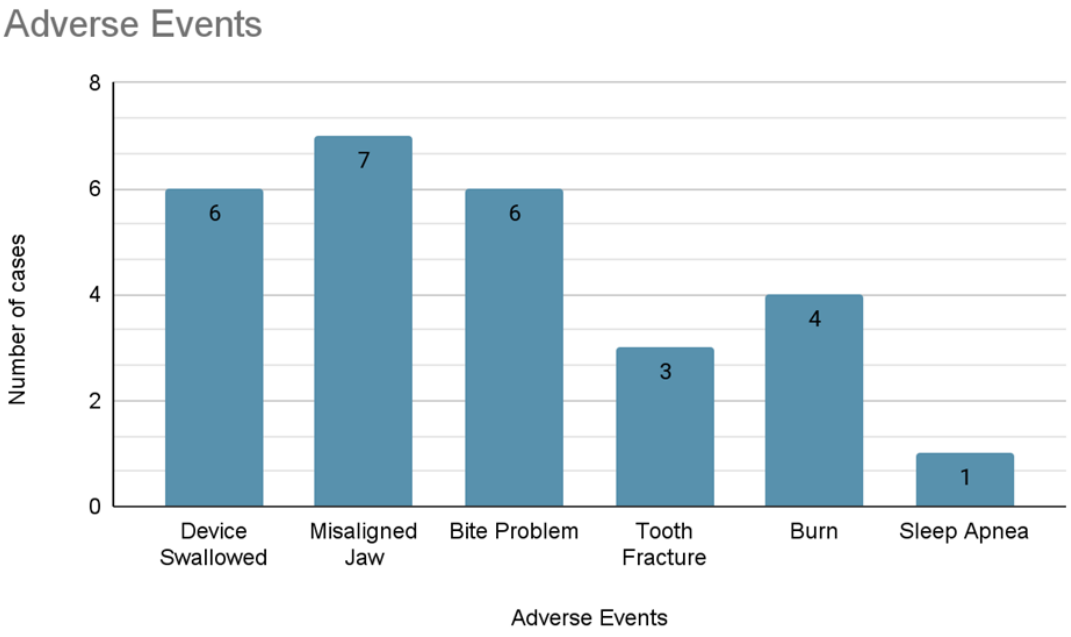

Figure 5: The different types of adverse events seen in patients.

1.8% patients reported symptoms within the first hour of usage. 5.4% patients reported symptoms within the first 24 hours of usage. The majority of the cases were reported within 1 day to 1 week, which was 25% of the total reported cases. 17.9% of patients reported symptoms between 1 week to 1 month. 19.6% patients reported having adverse events between 1 to 3 months and 3 to 6 months, respectively. 3.6% of the reported cases showed symptoms between 6 months to 1 year. 7.1% patients reported symptoms after more than 1 year of device usage (Fig. 6).

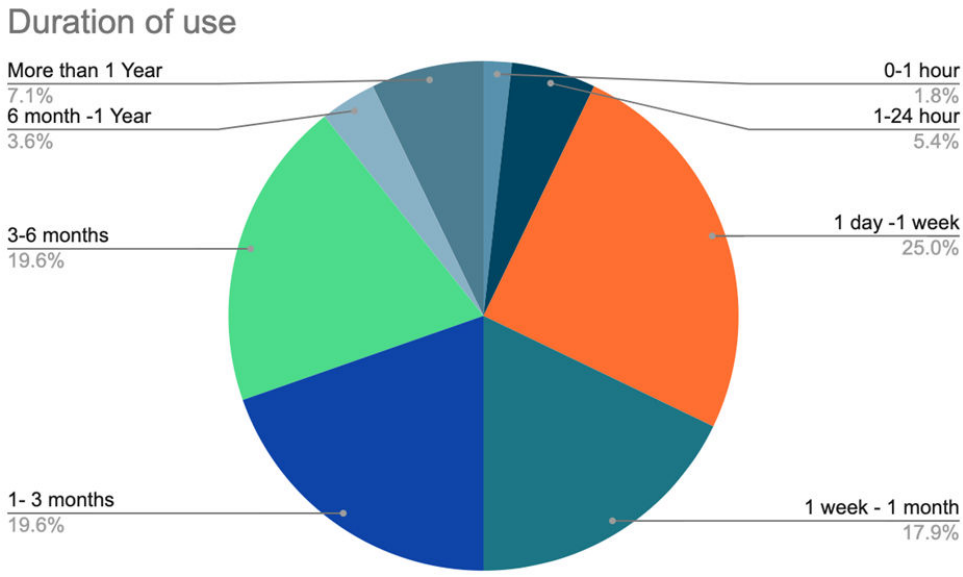

Figure 6: Duration of the device usage.

Out of the 326 cases, data for only 305 cases were available in the MAUDE reports. Out of this, 127 cases were available for evaluation by the manufacturer. Of the 127 cases available, the manufacturer was able to evaluate only 82 devices. For the rest of the cases, the data was either not available or the device was not returned to the manufacturer (Fig. 7).

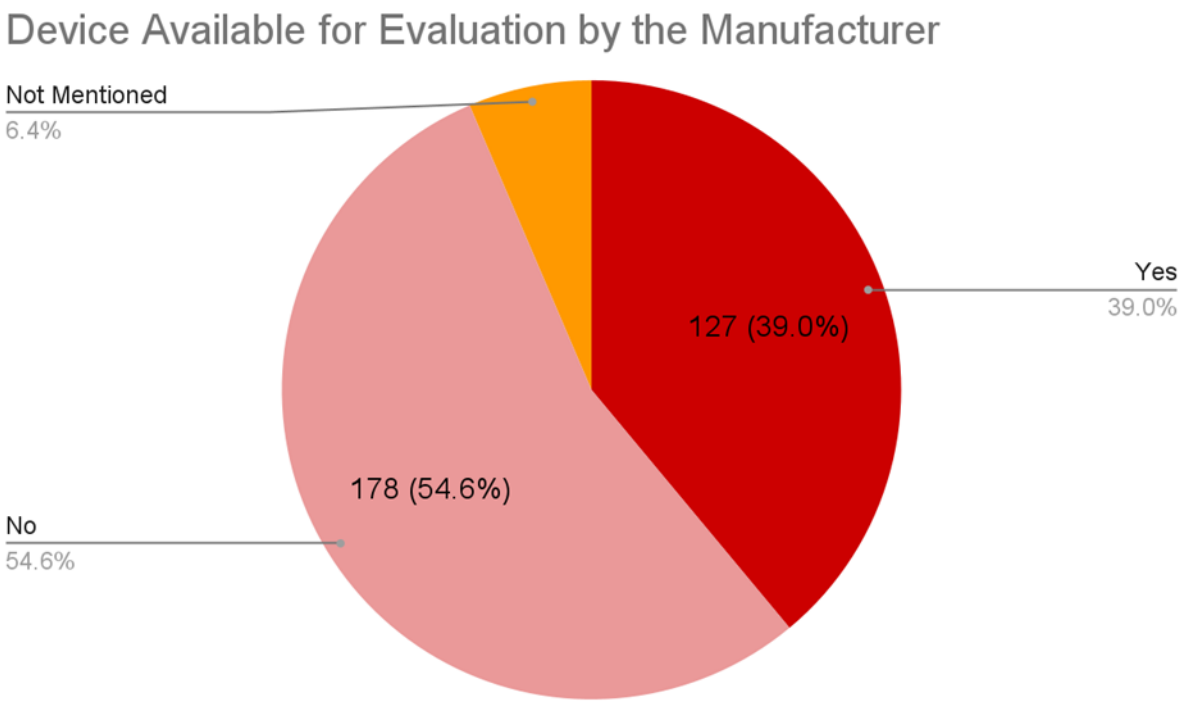

Figure 7: Reports regarding devices were available to evaluate by the manufacture.

Discussion

In recent years, dental devices have assumed an increasingly important role in the treatment of snoring and OSA, particularly in its milder form [13]. While there is growing literature demonstrating the efficacy of these devices in the treatment of snoring, there are some potential adverse events that need to be considered when prescribing this treatment modality or advertising when selling this over the counter.

In the current study, between 2011-2021, we found that the year with the most adverse events reported was 2018 and there has been a steady decline since then. According to our findings in Fig. 4, the most commonly reported adverse event (48.5%) was device malfunction.

As reported in our study, the most common sign and symptom was hypersensitivity/ allergic reaction (25.2%). The use of oral appliances has the potential risk of undesirable side effects. Reported frequencies of side effects vary greatly, potentially related to differences in device design. After assessing the MAUDE-reported history, it was found that many patients had a known allergy to materials used for manufacturing oral devices. Methyl methacrylate acrylic is a common substance used for the fabrication of oral appliances.

In our study, amongst the metals, nickel was found to be most frequently allergenic. Previous research has also reported allergic reaction to methyl methacrylate in an OA [14]. Another key finding in our study, as seen in Fig. 5, is that patients reported physical side effects while using the device, varying from bite problems, jaw pain, inability to close the jaw, dislocation and misaligned jaw within a few weeks of using the appliance. Follow up with the manufacturer found that the patient had an existing dental condition and it may be exacerbated by the use of oral devices. Tooth movements are another side effect that is seen after a long period of use of OA's for OSA [15,16]. These devices use the patient's dentition and alveolar ridges for retention - this exerts reciprocal forces on the dentofacial structures. Therefore, changes in facial height and jaw relationship have been noted as early as 6 months after the MAD's use [17].

The development of these problems is not surprising, given the significant forces applied to the teeth and temporomandibular joint in repositioning the mandible. The key is that there should be regular and routine monitoring by an oral health professional or a sleep clinician in order to identify adverse events early and address them rapidly. Appliance breakage is a relatively common phenomenon in dental sleep medicine and one of the major concerns is the risk of ingestion or inhalation of the fragments. In the current study, we found that 79 (24.5%) patients reported device breakage during use. Some devices are more prone to breakage than others.

As the duration of use of a medical device like an OA increases, the risk of adverse events increase due to longer exposure. However, delayed detection may be associated with preventable harm and even death [18]. A notable finding in our study was that the duration of use, which was a reportable parameter, was only documented 16.3% of the time. Another key finding in our study was that the nature and extent of the side effects were found to be related to the duration of usage, as seen in Fig. 6. From a total of 326 patient cases, only 53 (16.25%) mentioned the duration the device was used.

Treatment of snoring or OSA promotes a healthier heart function, body and mind [10,19]. It has been found that patients with untreated OSA have higher rates of health care use, including more frequent and longer hospitalizations and higher healthcare costs. Furthermore, OSA has been associated with higher rates of unintentional injury, including motor vehicle collisions and work-related injuries [20]. OA is a relatively reversible modality of treatment for OSA and should be considered as one of the conservative treatment approaches. However, prescribers must be aware of possible adverse events associated with the use of OA for OSA and regularly monitor their patients to ensure early identification and management of an adverse event.

In a database study there are some limitations that must be considered when reviewing the results. Firstly, the MAUDE database is not well known in the dental profession which may have contributed to underreporting. Additionally, the database permits free text and this means that different reporters may have defined adverse events differently which could lead to miscounting events. Finally, only 45% of reports were from dental professionals and the other reports were lodged by patients and other healthcare professionals. This could mean that there were errors in reporting.

Conclusion

The early identification, management and reporting of side effects is essential to maximize treatment adherence and the clinical effectiveness of oral appliances. Taking a detailed patient history and use of inert material for the manufacturing of these appliances can help to prevent some of the side effects. Despite the known risk of adverse events, the use of OA for treating OSA remains a relatively safe, conservative and reversible treatment modality.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Acknowledgement

None.

Data Availability Statement

Not applicable.

Ethical Statement

The project did not meet the definition of human subject research under the purview of the IRB according to federal regulations and therefore, was exempt.

Informed Consent Statement

Informed consent was taken for this study.

Authors' Contributions

All authors contributed equally to this paper.

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