

Figure 1. Adverse event reporting from the MAUDE database for MAGEC rod usage until June 2019.

modes in spine surgery. Therefore, the objective of the current study is to search the Manufacturer and User Facility Device Experience (MAUDE) database, which is a voluntary reporting system of adverse events involving medical devices since 1993, to identify the trend and frequency of adverse events related to the usage of MAGEC rods and standard instrumentation in spine surgery.

Materials and Methods

The United States Food and Drug Administration (FDA) of the Department of Human Services runs the MAUDE database. Adverse events are defined as potential and actual product use errors and product quality problems. The database contains information on medical devices that may have malfunctioned or caused a death or a serious injury. These adverse events are reported by the manufacturer or a health-care professional (an operating room nurse or a surgeon). MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 Code of Federal Regulations 803.19. The FDA website was last accessed in June 2019, in preparation of data for this manuscript. The product code used was PGN (identifier for MAGEC rods), and all the categorial data based on event type were retrieved and analyzed to the date specified above. It is important to note that MAUDE data are not intended to be used either to evaluate absolute rates of adverse events (due to underreporting) or to compare adverse event occurrence rates between different devices (due to discrepancy in reporting between two devices). In addition to MAGEC rods, we also retrieved MAUDE data on the top 5 failure modes associated with standard instrumentation usage in spinal fusion; this does not include MAGEC rod failures, and may pertain to any possible diagnoses such as degenerative disc disease, spondylolisthesis, trauma, scoliosis, etc.

Results

A total of 163 incidences were recorded for MAGEC rod-related adverse events, until June 2019. Of these, 129 events were failure of noninvasive distraction mechanism, 24 were for rod fracture, and 10 for other medical complications such as infection, tissue necrosis, wear particles, etc., (Fig. 1). The top 5 failure modes associated with standard instrumentation usage in spinal fusion included pedicle screw breakage post surgery (n=336), set screw damage during surgery (n=257), rod breakage post surgery (n=175), interbody cage breakage during surgery (n=118), and pedicle screw breakage during surgery (n=75) (Fig. 2).

Discussion

The current study presents all the MAUDE reporting for adverse events related to the usage of MAGEC rods in growing children with scoliosis⁸). Rod fracture is a known problem with all growth sparring systems; however, the failure to noninvasively distract the spine is exclusive to MAGEC rods only^{9,10}). MAGEC rod's main benefit is that it allows for the noninvasive distraction of the growth rods. This benefit is realized by a drastic reduction in the number of consecutive surgeries, and in some cases, the possibility of reducing growth rod fracture and autofusion (caused due to gradual trauma to the spine via excessive distraction in traditional growth rod systems)¹¹⁻¹⁶). However, the failure of this attribute, noninvasive distraction mechanism, reduces the overall efficacy of the device with newer studies even questioning if there is a real quality-of-life difference with use of MAGEC rods¹⁷.

The results of the current study show that the most frequent clinical problem associated with the MAGEC rod is the failure of noninvasive distraction mechanism, which leads to invasive revision surgeries required to replace the device. These results also highlight the exponential increase

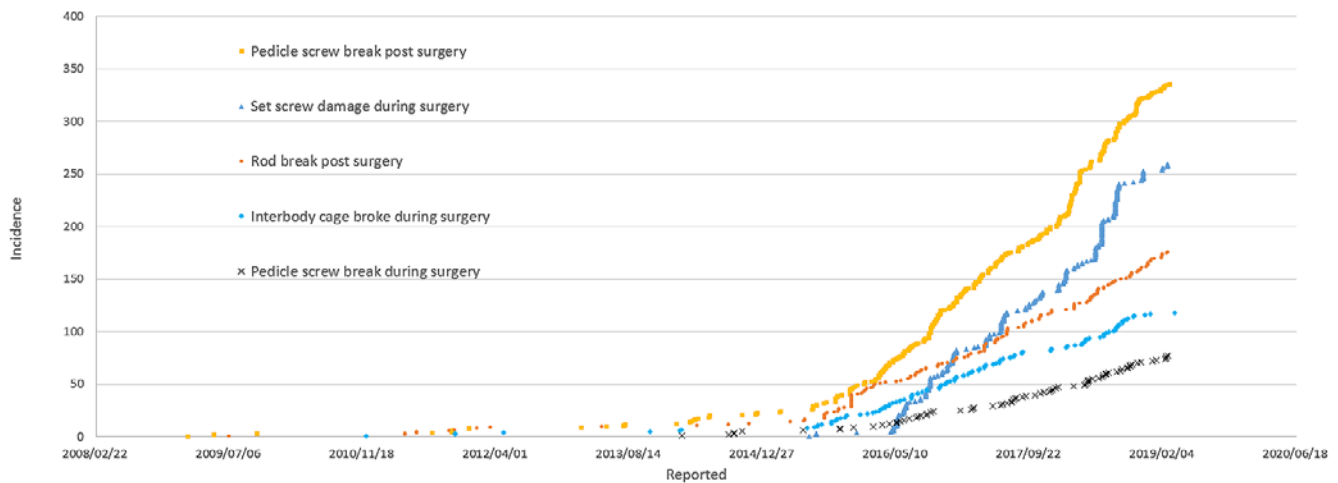


Figure 2. Adverse event reporting from the MAUDE database for the top 5 failure modes associated with standard instrumentation usage in spinal fusion until June 2019.

in such failure rates (Fig. 1). Furthermore, the MAUDE report on the top 5 failure modes associated with standard instrumentation usage in spinal fusion proves that such failures are substantially underreported.

Although the MAGEC rod has not completely replaced the traditional growth rod system, due to its unaffordability in underprivileged patients, it is still much more advantageous than its predecessor. The purpose of this study and many other clinical trials, or case series, is only to improve upon the existing noninvasive technology by thoroughly identifying the failure modes. In the case of MAGEC rods, it is the failure of its noninvasive distraction mechanism that needs attention. Further immediate research and development work should be undertaken to reduce these failure incidences in a clinical scenario. The limitation of the current study is that the patient demographics, surgical parameters, and the total number of surgeries performed (using MAGEC rods) in the United States within this period is unknown. The voluntary nature of such reporting also presents a challenge against excluding infrequently reported complications such as necrosis, which although is present in all cases (off-axis loading and wear), has only been reported 10 times in total. Despite these limitations, the type of adverse events and relatively high frequency of these events when compared to the top 5 failure modes associated with standard instrumentation usage in spinal fusion are a matter of great concern. In conclusion, the result of this study suggests a growing number of distraction mechanism failure associated with MAGEC rods. Better technical and clinical controls need to be set in place to avoid such adverse events, which leads to unplanned open surgeries. A higher distraction magnitude results in the generation of higher distraction forces, and this in combination with off-axis loading (exemplified by “growth marks”) result in wear and breakage of MAGEC rod’s components. Therefore, one method to reduce the propensity of such failures would be to apply minimum distraction at higher frequency, for example, 1.5-2.0 mm every month, instead of 4.5-6.0 mm every 3 months. This would

also reduce tissue trauma and its effects, such as autofusion¹¹⁻¹⁶. Other technical methods to reduce attrition could include ceramic coating at wear generating surfaces, also applicable for growth guidance techniques^{18,20}.

Conflicts of Interest: AA reports royalties from Paradigm Spine, Joimax, consultancy from Spinal Balance, and editorial board membership from Clinical Spine Surgery, Spine, outside the submitted work; the rest of the authors have nothing to disclose.

Author Contributions: Each co-author satisfied the 4 criteria as defined by ICMJE.

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