Leadless pacemaker tine damage and fracture: novel complications of a novel device fixation mechanism

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BACKGROUND Leadless pacemakers represent a paradigm-changing advancement. However, they required innovative and novel device design, including the use of nitinol tines for fixation.

OBJECTIVE We aimed to understand the potential for fracture in the novel tine-based fixation mechanism.

METHODS A retrospective approach was used to search the MAUDE (Manufacturer and User Facility Device Experience) database for events related to Micra pacemaker tine fracture and damage. Review of each report was performed to ascertain frequency of tine fracture and damage.

RESULTS Of 4241 MAUDE reports (2104 Micra VR, 2167 Micra AV), 230 included the terms "fracture" or "tine," which yielded 7 tine fractures and 19 reports of tine damage. Overall, 2 (29%) of 7 tine fractures were noted during implantation, whereas 2 (29%) of 7 were discovered $\geq$1 week after implantation; 5 (71%) of 7 tine fracture reports described no associated patient signs or symptoms, and 4 (57%) of 7 described no change in pacing parameters. Tine damage occurred during implantation in 16 (84%) of 19, compared with 2 (11%) of 19 noted $\geq$1 week after implantation; 15 (79%) of 19 tine damage cases reported no associated signs or symptoms, and 7 (37%) of 19 described no changes in pacing parameters. Among all cases, there was 1 case of device embolization.

CONCLUSION The novel tine-based fixation mechanism appears susceptible to a novel failure mechanism—tine fracture and/or damage. Our analysis suggests these events may not always be associated with adverse signs or symptoms. Diligent attention at implantation, and future bench or clinical studies are needed to understand the rate, clinical impact, and mechanism of such failures, and role of surveillance.

KEYWORDS Leadless pacemaker; Failure; Complication; Tine fracture; MAUDE

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Introduction

While the advent of transvenous cardiac pacemaker systems was a revolutionary development for the treatment of bradyarrhythmias, short- and long-term limitations of transvenous hardware have been more and more limiting. Specifically, the long-term risks of vascular occlusion, infection, and malfunction represent the Achilles heel of transvenous pacing. The development of entirely self-contained, leadless pacemaker devices represented a welcome alternative to traditional transvenous pacing systems and an important paradigmatic and technological shift in the field.

The Micra leadless pacing system (Medtronic, Minneapolis, MN) is a self-contained pacemaker implanted directly in the right ventricle of the heart. Micra pacemakers have demonstrated comparable electrical performance and lower rates of major complications compared with traditional transvenous pacemakers.[1,2] Development of the device required innovation, including a novel fixation approach for an entirely leadless pulse generator and, over time, the ability to sense atrial activity.[3,4] Active fixation relies on 4 electrically inactive nitinol tines on the distal end of the device, which are loaded with the tines in a straight position in the delivery system prior to implantation, and self-expand into the ventricular myocardium assuming their default curved shape during the implantation procedure. This ensures low pacing thresholds and prevents device dislodgement.[4]

Despite relatively low rates of complications, adverse events of Micra pacemakers include, but are not limited to, cardiac perforation and effusion, venous access–related complications, micro-dislodgement and macro-dislodgment, and embolization.[5] However, the technology is relatively new, and an understanding of potential complications and risks continues to evolve with augmented and broadened experience. Two recent case reports describe episodes of the nitinol fixation tines fracturing and separating from the Micra

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KEY FINDINGS

- We searched the MAUDE (Manufacturer and User Facility Device Experience) database for reports of damage or fracture of nitinol tine fixation devices in the Micra VR and Micra AV leadless pacemakers.
- A total of 7 reports of tine fracture and 19 reports of tine damage were identified.
- The timing of the discovery of tine fractures varied in relation to the implantation procedure, while the majority of tine damage was discovered during the implantation procedure.
- Clinical signs and symptoms were reported in a minority of cases of both tine fracture (n = 2 of 7 [29%]) and tine damage (n = 4 of 19 [21%]).
- Changes in device pacing parameters were more commonly reported with tine fracture (n = 4 = 7 [57%]) compared with tine damage (n = 7 of 19 [37%]), but in both groups changes in device pacing parameters were not consistently associated with clinical signs or symptoms.
- No tine fracture reports described embolization of the device or the fractured tine; however, one tine damage report described embolization of the device to peripheral vasculature.

leadless pacemaker.[6,7] These cases represent the first reported complications of their kind. The purpose of the current study was to understand the potential scope of Micra tine fracture and/or malfunctions within the Manufacturer and User Facility Device Experience (MAUDE) database, and explore patterns that may explain the tine fractures, as well as clinical impact.

Methods

The MAUDE database is an online catalogue containing searchable, de-identified medical device reports voluntarily submitted to the Food and Drug Administration by both required and elective reporters. The database serves as a passive postmarket surveillance system that is frequently queried by researchers and medical professionals to identify device issues that may influence patient safety. MAUDE reports contain limited information, including the date of the event, the device, and a narrative description of the event; they also include an analysis on devices returned to the manufacturer if available.

This is a retrospective analysis of Micra VR and Micra AV MAUDE reports received by the Food and Drug Administration between June 9, 2016, and April 28, 2023. Micra VR and AV models use the same nitinol fixation mechanism. MAUDE reports were manually exported on June 4, 2023. We identified duplicate reports via search for identical report number or event description; duplicate event descriptions were reviewed, and only 1 report was included in the analysis if reports represented a single event.

Keyword searches for "fracture" and "tine" identified reports of interest, which were manually reviewed for descriptions of tine damage or tine fracture. A report was classified as tine fracture if it was reported that at least 1 tine was separated from the implantable pulse generator (IPG), or if the term "fracture" was used in the event description to describe a nitinol tine. Criteria for tine damage included descriptions of tines that were broken, damaged, bent, loose, or deformed. Reports of tine fracture and damage were reviewed for device model, timing of event relative to device implantation, patient signs and symptoms at time of detection, changes in pacing parameters, and device analysis from the manufacturer, if available. Patient signs and symptoms were defined as descriptions of clinical symptoms, changes in vital signs, or clinical events reported in the MAUDE reports. Changes in pacing parameters were defined as descriptions of rising pacing thresholds, changes in impedance, and pacing loss or failure described in the MAUDE reports.

The MAUDE database contains publicly available, de-identified data, and thus does not rise to the level of "human subjects research" under the Federal Common Rule, 45 CFR Part 46. Therefore, in accordance with University of Utah policies, this study did not require Institutional Review Board review. The research reported in this article was conducted in accordance with ethical standards and principles outlined in the Declaration of Helsinki, which were applied to this study involving nonhuman subjects medical research.

Results

A total of 4241 MAUDE database medical device reports were exported, including 2104 Micra VR model reports and 2167 Micra AV model reports. After excluding duplicates, keyword searches revealed a total of 230 reports including terms "fracture" or "tine." Manual review of these reports identified 7 tine fracture events and 19 reports of tine damage (Tables 1 and 2). Of the tine fracture reports, 2 (29%) of 7 occurred with the Micra VR model, while 5 (71%) of 7 were reported with the Micra AV model. Of the tine damage reports, 10 (53%) of 19 occurred with the Micra VR model, and 9 (47%) of 19 occurred with the Micra AV model.

Tine fracture reports

The 7 cases of tine fracture varied in the timing of the discovery of the event. Two (29%) of 7 cases of tine fracture were identified during the leadless pacemaker implantation procedure, whereas 2 (29%) of 7 of tine fractures were discovered a week or more after device implantation. An additional 3 (43%) of 7 of tine fracture reports did not specify the timing of the discovery of the fracture in relation to the implantation procedure (Figure 1); these include 2 reports describing tine fractures identified during later cardiac procedures. Only 2 (29%) of 7 cases of tine fracture described clinical signs or symptoms associated with the event, but 4 (57%) of 7 described changes in pacing parameters

Table 1 Fractured tine reports of Micra leadless pacemaker devices identified via MAUDE database review, including an abbreviated event description, the timing of the event in relation to device implantation, and patient signs or symptoms associated with the tine fracture

Case no.	MAUDE report no.	Model	Year	Event description	Timing of event	Associated signs/symptoms or changes in pacing parameters
1	9612164-2020-04355	Micra VR	2020	Tines came off IPG	During device implantation	No signs/symptoms/pacing changes reported
2	9612164-2021-00493	Micra AV	2021	Tine separated from IPG	Unclear (not specified)	Change in pacing parameters
3	9612164-2022-00581	Micra AV	2022	Tine separated from IPG during tensile test	During device implantation	Cardiac arrest
4	9612164-2022-02445	Micra VR	2022	Attachment arm fractured on x-ray	1 week postimplantation	Bradycardia, change in pacing parameters
5	9612164-2022-03072	Micra AV	2022	Tines fractured and separated from IPG	Unclear ("during a procedure for mitral valve")	Change in pacing parameters
6	9612164-2022-03313	Micra AV	2022	Tine separated from IPG	Unclear ("during an upgrade procedure")	No signs/symptoms/pacing changes reported
7	9612164-2022-03766	Micra AV	2022	Tine fracture and separation from IPG on fluoroscopy	2 months postimplantation	Change in pacing parameters

Micra VR refers to the MC1VR01 model transcatheter pacing system; Micra AV refers to the MC1AVR1 model transcatheter pacing system.
IPG = implantable pulse generator; MAUDE = Manufacturer and User Facility Device Experience.

associated with the tine fracture. This resulted in a total of 5 (71%) of 7 cases of tine fracture with either associated signs/symptoms or changes in pacing parameters, as 1 report described both a change in pacing parameters and patient signs/symptoms. The remaining 2 (29%) of 7 cases of tine fracture described no patient signs or symptoms, or changes in pacing parameters associated with the event (Table 1). In the 2 tine fracture cases describing clinical signs or symptoms, patients experienced cardiac arrest (n = 1) and bradycardia (n = 1). In the report describing cardiac arrest the tine fracture and cardiac arrest both occurred at the time of device implantation, with no cause for the cardiac arrest described, and no changes in pacing parameters reported. In the report describing bradycardia the patient experienced bradycardia 1 week after device implantation, with tine fracture discovered on radiography. An etiology for bradycardia was not provided, but the report noted an increase in pacing thresholds for the device. None of the 7 reports categorized as tine fractures described embolization of either the IPG or the fractured tine. The Micra devices that experienced tine fractures were returned to the manufacturer in 4 (57%) of 7 cases, while 3 (43%) of 7 were not available to the manufacturer. Of the devices that were returned to the manufacturer, none of the reports included an analysis or evaluation from the manufacturer.

Tine damage reports

The 19 cases of tine damage represented a variety of issues with the tines, including bent, broken, deformed, and loose tines, as well as tines that did not deploy properly and one that was hanging from the IPG (Table 2). Tine damage was discovered during the leadless pacemaker implantation procedure in 16 (84%) of 19 cases, whereas 2 (11%) of 19 tine damage events were discovered a week or more after device implantation. In addition, 1 (5%) of 19 cases of tine damage did not specify the timing of the damage in relation to implantation (Figure 1). A slim majority (n = 10 of 19 [53%]) of tine damage reports described neither patient signs or symptoms nor changes in pacing parameters associated with the tine damage (Table 2). The remaining 9 (47%) of 19 tine damage reports described either clinical signs/symptoms or changes in pacing parameters, which included 4 (21%) of 19 cases of tine damage associated with clinical signs or symptoms, and 7 (37%) of 19 cases describing changes in pacing parameters; 2 (11%) of 19 cases described both clinical signs or symptoms and changes in pacing parameters. In the 4 cases of tine damage with associated signs or symptoms, patients experienced complete atrioventricular block (n = 1), severe pain (n = 1), hypotension and tamponade (n = 1), and migration of the IPG to a vessel near the femoral vein (n = 1). In the cases of complete atrioventricular block, severe pain, and hypotension and tamponade, the tine damage as well as signs and symptoms were noted during the device implantation procedure; 2 of these cases described changes in pacing parameters at the time of implantation, while the other 2 did not report changes in pacing parameters. In contrast, in the 1 case of IPG migration, both device embolization and tine damage were discovered 2 weeks following device implantation; this represented the only case of device embolization among all 19 reports of tine damage. Of the Micra devices that experienced tine damage, 10 (53%) of 19 devices were returned to the manufacturer and 9 (47%) of 19 were not available to the manufacturer. Of the 10 devices that were returned, 3 reports included a device analysis from the manufacturer. These analyses were brief with 1 describing a bent fixation mechanism, 1 reporting 2 bent tines, and 1 describing no anomalies identified.

Discussion

We report a systematic analysis to understand a series of new issues with a novel pacemaker fixation mechanism. The tine-based fixation mechanism developed for the Micra leadless

Table 2 Damaged tine reports of Micra leadless pacemaker devices identified via MAUDE database review, including an abbreviated event description, the timing of the event in relation to device implantation, and patient signs or symptoms associated with the tine damage

Case no.	MAUDE Report no.	Model	Year	Event description	Timing of event	Associated signs/symptoms or changes in pacing parameters
1	9612164-2017-01067	Micra VR	2017	"Broken tine" (bent on manufacturer analysis)	Unclear (noted during valve surgery)	No signs/symptoms/pacing changes reported
2	9612164-2018-00892	Micra VR	2018	2 tines were bent	During device implantation	Change in pacing parameters
3	9612164-2020-01611	Micra VR	2020	1 tine did not deploy and remained inside catheter	During device implantation	No signs/symptoms/pacing changes reported
4	9612164-2020-04053	Micra VR	2020	Tines opened unevenly	During device implantation	Change in pacing parameters
5	9612164-2021-01202	Micra VR	2021	Tines broken on x-ray	7 mo postimplantation	Change in pacing parameters
6	9612164-2021-01811	Micra VR	2021	Tines damaged during removal	During device implantation	Complete AV block
7	9612164-2021-02899	Micra VR	2021	Tines stuck and bent outward	During device implantation	No signs/symptoms/pacing changes reported
8	9612164-2021-04499	Micra VR	2021	Tines of device bent	During device implantation	Change in pacing parameters
9	9612164-2022-02447	Micra AV	2022	Tine "was hanging" from IPG	During device implantation	Hypotension, tamponade, change in pacing parameters
10	9612164-2022-02746	Micra VR	2022	Tines deformed	During device implantation	Severe pain, change in pacing parameters
11	9612164-2022-02929	Micra AV	2022	Tines opened too wide	During device implantation	Change in pacing parameters
12	9612164-2022-03563	Micra AV	2022	Tines "noted to be flared"	During device implantation	No signs/symptoms/pacing changes reported
13	9612164-2022-04173	Micra AV	2022	Tine "became loose" from IPG	During device implantation	No signs/symptoms/pacing changes reported
14	9612164-2022-04481	Micra AV	2022	Tines were bent	During device implantation	No signs/symptoms/pacing changes reported
15	9612164-2022-04710	Micra AV	2022	Tine "was deformed"	During device implantation	No signs/symptoms/pacing changes reported
16	9612164-2022-04884	Micra VR	2022	Tines more spread out than usual	During device implantation	No signs/symptoms/pacing changes reported
17	9612164-2023-00599	Micra AV	2023	Tine "was deformed"	2 weeks postimplantation	IPG migrated to "near the femoral vein"
18	9612164-2023-00793	Micra AV	2023	Tines did not return to normal state	During device implantation	No signs/symptoms/pacing changes reported
19	9612164-2023-01158	Micra AV	2023	Tines "were possibly damaged"	During device implantation	No signs/symptoms/pacing changes reported

Micra VR refers to the MC1VR01 model transcatheter pacing system; Micra AV refers to the MC1AVR1 model transcatheter pacing system.
IPG = implantable pulse generator; MAUDE = Manufacturer and User Facility Device Experience.

pacemaker represents a novel system, and tine fracture and damage theoretically have potential to cause pacemaker dysfunction and adverse complications. Our analysis revealed a total of 7 reports of Micra tine fractures and 19 reports of tine damage. A complete understanding of the scope of this problem would require detailed knowledge of implantation volumes worldwide. Estimates of U.S. implantations are up to 100,000 in 2023 (including both models).[8] However, the MAUDE database includes reports submitted from practitioners globally, and data on international implantations are even more limited; it has been reported that nearly 200,000 patients globally have been implanted with Micra devices.[9] Based on these numbers, our analysis suggests the incidence of tine fracture or damage could be as low as 0.01% (26 of 200,000)—a relatively rare phenomenon with the novel tine-based fixation mechanism developed for the Micra devices. This calculation provides only a rough estimate of the rate of known tine fracture or damage and is susceptible to error, as the MAUDE database relies on voluntary reports and therefore may underestimate the true incidence if a significant number of tine fracture or damage events either have not been identified or have not been reported to the database.

However, the finding that the rate of tine fracture and damage appears rare is consistent with early testing of the Micra fixation mechanism in animal models over 6 to 91 weeks, which showed no tine fractures, no dislodgements, and a high safety factor against dislodgement.[4] Subsequent studies in humans also showed no evidence of tine fracture or damage, including the pivotal prospective Micra transcatheter pacing study, which reported no episodes of mechanical integrity issues, device connection issues, device lead damage, or device dislocation in over 700 patients, as well as postapproval registry analysis, which did not describe any

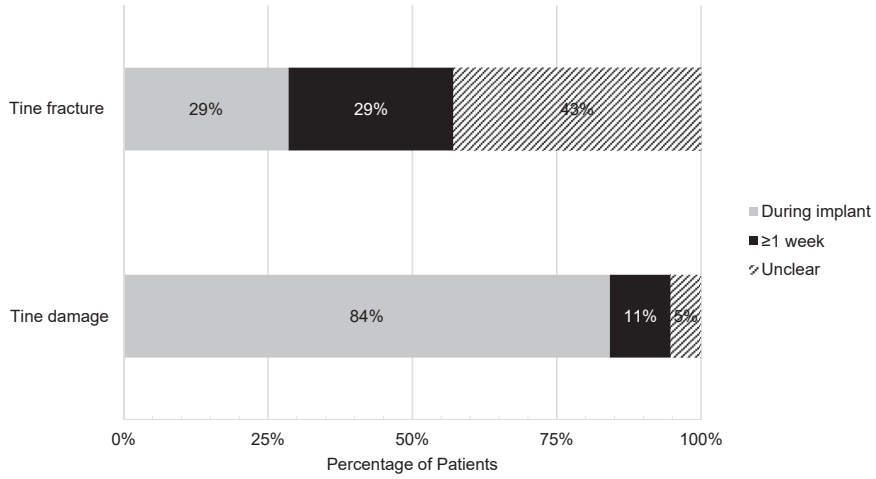

Figure 1 Timing of the discovery of tine fractures (n = 7) and tine damage (n = 19) in relation to implantation procedure of Micra leadless pacemakers. Reports of tine fracture or damage occurring during the implantation procedure are designated as "during implantation." There were no reports of tine fracture or damage within 1 week of the implantation procedure. Tine fractures and damage occurring >1 week postimplantation are designated as such. Several reports did not specify how much time had elapsed from implantation to tine fracture or damage; these reports were categorized as "unclear."

events of tine fracture or damage.[2,10] Prior reports of tine fracture are limited to 2 case reports.[6,7] Our analysis expands the number of known cases of tine fracture and damage, but the true incidence of tine fracture and damage is unknown, and cannot be accurately estimated using retrospective passive surveillance data, such as those from the MAUDE database. Furthermore, it is difficult to know the true incidence of tine fracture or damage, as our analysis suggests that neither patient signs and symptoms nor clinically significant device dysfunction are consistently associated with tine fracture or damage, and surveillance imaging is not routinely performed either in the clinical trials or clinical practice.

The nitinol tines of the Micra device are responsible for fixing the device to the heart wall and keeping the electrode in close proximity to the myocardium. Thus, tine fracture or damage can theoretically cause not only alterations in pacing parameters and symptoms of pacing failure, but also device dislodgement and embolization that could result in harmful complications. The findings of our study identified that a majority of reports of tine fracture and damage did not describe associated patient signs or symptoms or clinically significant device dysfunction (Tables 1 and 2). The low rates of reported clinical signs and symptoms associated with tine fracture and damage suggest that patients may be asymptomatic at the time of discovery of tine damage, but may also represent an oversight during the event reporting process in which patient symptoms were not described. If patients truly were asymptomatic with tine fracture and damage, it is likely in part due to the requirement that at least 2 tines be visualized as fixed during the implantation procedure and underscores the importance of the pull-and-hold test during implantation—to ensure that multiple tines are engaged. Early studies of the Micra tine-based fixation mechanism described that 2 engaged tines provide 15 times the holding force required to prevent dislodgement, accentuating the redundancy in the fixation mechanism.[4] Our study suggests that this redundancy appears to be relatively effective in preventing clinically significant complications, though it remains early in the expected lifespan of these novel devices. The data also indicate symptoms and changes in pacer parameters are inconsistent indicators and cannot be relied on to ascertain tine fracture or damage, as patients may not have associated signs, symptoms, or changes in pacer measurements. Thus, there may be additional cases of tine fracture or damage that are unrecognized, and understanding the true prevalence of these events may require surveillance imaging of the tines to accurately define.

Associated patient signs or symptoms were reported in a minority of events of tine fracture and damage. Among reports of both tine fracture and damage, 6 cases (2 tine fracture cases and 4 tine damage cases) described signs or symptoms associated with the tine issue. These clinical events included cardiac arrest, bradycardia, complete atrioventricular block, hypotension and tamponade, severe pain, and device embolization, with each of these signs or symptoms associated with 1 case of tine fracture or damage. Overall, there was no common sign or symptom that was consistent among cases describing tine issues. Reports from MAUDE provide limited details, making it impossible to determine the causality between the clinical events and the tine fracture or damage. In addition, the finding that 57% of reports of tine fracture and 37% of reports of tine damage describe changes in pacing parameters, with only a small subset of these reports describing clinical symptoms, indicates some patients may have subclinical changes in pacing parameters that may only be identified on device interrogation. A higher proportion of the tine fracture reports described associated changes in pacing parameters compared with tine damage reports, implying that tine fracture may have a higher probability of disrupting the interface between the device electrode and the myocardium to an extent that impacts the function of the pacemaker but may not alter function enough to elicit clinically meaningful signs or symptoms. However, it is possible that additional cases of tine fracture and damage

caused disruptions in pacing parameters that were not described in the MAUDE reports. These findings reiterate that clinical symptoms and changes in pacing parameters may be unreliable indicators of tine issues. However, if these signs or symptoms, or changes in device pacing parameters are encountered in a patient with a Micra device in the clinical environment, tine fracture or damage is a possible explanation to consider.

Overall, a minority of cases of tine fracture and a majority of cases of tine damage were discovered during device implantation (Figure 1). It is reassuring that these issues were discovered during the implantation procedure when they might be addressed immediately. In contrast, cases in which tine fracture or damage where discovered a week or more after device implantation are more concerning, as this suggests the tine issue either did not exist at the time of the implantation procedure or the tine issue was not identified with imaging or device interrogation during the implantation procedure. Furthermore, clinical management in this setting is less clear, and may be complicated with longer dwell time of the device.

It was not possible to discern the cause of tine fracture or damage from the MAUDE reports, as specific data elements that might shed light were not available (eg deployment attempts, number of tines engaged at implantation). The available manufacturer analyses were limited in scope and did not provide insight into the cause of tine fracture or damage. Possible contributing factors to tine fracture and damage may include direct damage to the tines during implantation, manufacturer defects, operator errors during device manipulation, or durability of the nitinol tines. Hu and colleagues[7] speculated that the location of the Micra device in their case report may have placed extra stress on the tines during the cardiac cycle, which may have contributed to tine fracture. Whether specific device implantation locations, or the angle at which the device is implanted within the right ventricle contribute to undue stress on the nitinol tines cannot be definitively answered with data from the MAUDE database, as the location of implantation is not consistently reported.

Overall, device complication rates of the Micra leadless pacemaker remain lower than traditional transvenous pacing systems.[5] However, tine fracture and damage represent novel and poorly understood complications of the new fixation mechanism employed by the device. It will be important to continue to monitor device complications moving forward to better understand the prevalence of tine issues and the durability of the nitinol tines as the Micra device is implanted into a growing number of patients. Furthermore, the discrepant reports of events from Micra AV vs Micra VR requires attention; this may be play of chance in reporting and sampling of the newer device, or there may be subtle hardware differences that are contributing. Additional clinical and bench testing may shed light on mechanisms and risk factors for such events.

Several limitations should be considered when discussing our results. Despite Food and Drug Administration recommendations, adverse events in clinical practice may not be routinely reported and included in the MAUDE database, which could result in significant selection bias and an underestimate of the number of device complications. In addition, reports in the MAUDE database are provided by physicians, the manufacturer, and other stakeholders, who frequently provide only short descriptions that lack patient demographics, information about physician experience with the implantation procedure, and the number of deployments, and do not use consistent terminology to describe device issues. Micra tine fracture and damage are seemingly rare phenomenon, making systemic assessment difficult; thus, the MAUDE database presents an opportunity to assess these events in a limited capacity. Larger registry data from clinical practice are needed to identify the true incidence and prevalence of tine fracture and damage. Nonetheless, this analysis provides insight into a rare but novel and potentially consequential finding with the novel Micra pacemaker fixation mechanism.

Conclusion

Tine fracture and damage is a rarely reported phenomenon with the novel tine-based fixation mechanism developed for the Micra leadless pacing system but is now recognized. Tine fracture and damage appear to be only loosely associated with clinically significant device dysfunction and patient symptoms, and is inconsistently associated with changes in the device's pacing parameters. Additional research is needed to better understand the realities of tine durability and its clinical implications.

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