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DEVICES

Visual observation of extraction of a Micra leadless pacemaker from a human cadaver

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Abstract

Introduction: In this article we present the extraction of a Micra from a human cadaver implanted 3 years previously with both visual and X-ray imaging taken during the removal.

Methods: A Micra pacemaker was extracted from a human cadaver with endoscopy and fluoroscopy using a Micra delivery tool. Histological analysis was performed on slices from the tissue surrounding the Micra.

Results: The fully encapsulated Micra was easily retrieved with a maximum force of 1.9 pounds.

Conclusions: Even though the Micra was implanted almost 3 years previously, the snaring and extraction of the Micra was performed relatively easily and with minimal force required.

KEYWORDS
Micra, leadless pacemaker, extraction, human cadaver

1 | INTRODUCTION

The first Micra Transcatheter Pacemaker (Medtronic, PLC Galway Ireland) was implanted in December of 2013 as part of an IDE trial. Since then, over 150,000 leadless pacemakers (LP) have been implanted in patients worldwide. However, due to the 10-year longevity of these devices, few reports of device retrieval and extraction can be found in the literature. The most comprehensive review of Micra retrieval is the article by Dar et al. published in 2020 and contains 40 successful Micra retrievals (40 attempts) and 66 Nanostim (Abbott, Abbott Park, IL) retrievals (73 attempts).[1] The median time to retrieval was 45 days (1-95) for Micra and 256 days (1-1460) for Nanostim.

It is expected that after 10 years of being implanted, any LP will be fully encapsulated and difficult to remove. However, there is very little data on how long after implantation LPs can be successfully retrieved. The longest published implant time before successful retrieval is 4 years for Micra,[2] and 4 years for Nanostim.[1] There are only a small number of single center series and case reports of LP retrievals mostly within 1 year of implantation.[3–13]

In this case study, a Micra that had been implanted in August of 2018 was retrieved post-mortem under camera and fluoroscopy visualization in September of 2021.

2 | METHODS

Written informed consent was obtained from the donor participating in this study. The Anatomy Bequest Program Proposal Review Committee authorized access to the donor for purposes described in this article. Donor care and use policies provided by the Anatomy Bequest

ABBREVIATIONS: IDE, Investigational device exemption; LAO, Left Anterior Oblique; LP, Leadless Pacmaker; RAO, Right Anterior Oblique; RV, Right Ventricle.

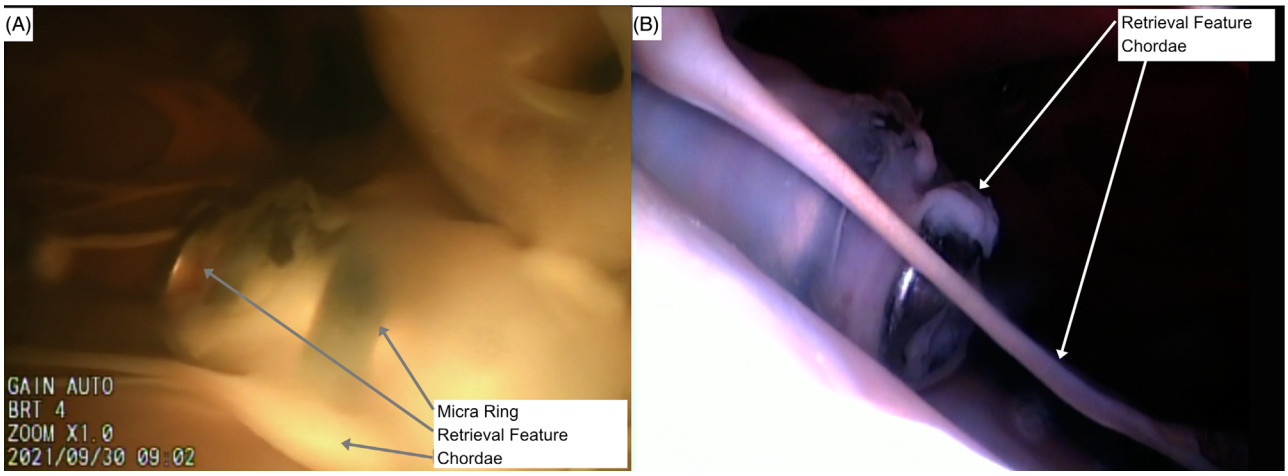

FIGURE 1 (A) View from the apex of the encapsulated Micra within the heart prior to any procedures. (B) View through the tricuspid valve of the Micra before any procedures [Color figure can be viewed at wileyonlinelibrary.com]

Program were followed. The cause of death was not listed in the medical history, and the procedure was performed 11 days after death.

The cadaver was prepped for water perfusion to facilitate endoscopic visualization of the Micra retrieval by first removing the anterior chest wall. Briefly, warmed water was continuously pumped into the right jugular vein and exited through the pulmonary artery. This completely flushed the blood from the heart and attached vessels, giving a clear endoscopic view of the inside of the heart. A pressure head was applied to assure similar right heart pressure as in the living patient.

A Micra introducer was placed into the right atrium via the femoral vein using standard Micra cannulation and dilation techniques. Two steerable endoscopic cameras were introduced into the right heart – one via a port in the right atrial free wall and one via a port in the apex of the right ventricle (RV).

For the retrieval procedure, a 7 mm gooseneck snare (Onesnare, Merit Medical, Jordan UT) was placed into an empty Micra delivery tool, and the delivery tool was placed into the right atrium via the Micra introducer. The cup of the tool was guided over the retrieval feature at the proximal end of the Micra using fluoroscopy. The operator was blinded to the camera view during the actual snaring of the Micra. Then by zooming in with the fluoroscopy on the delivery tool cup, the snare was directed over and tightened onto the retrieval feature on the proximal end of the Micra.

The pull force during the extraction was measured using a Chatillon gauge (John Chatillon & Sons Inc, Largo FL) with a 2-pound sensor. To allow for force larger than 2 pounds, a second-class lever with a 4:1 ratio was used. The Micra was then slowly pulled into the cup while recording the maximum pull force.

The heart was then removed from the chest, and the RV opened to expose the implant location. A tissue block surrounding the implanted Micra was excised from the heart and immersed in 10% neutral buffered formalin solution. Once the tissue fixation was complete, the tissue block was sectioned across the middle of the body of the device (perpendicular to the long axis of the Micra), and through the tissue around the fixation tines and the electrode (parallel to the long axis of the device). Tissues were processed, paraffin-embedded, and sectioned at 4–6 um thick sections. Serial sections were stained with hematoxylin and eosin (H&E) and Masson's Trichrome.

3 | RESULTS

3.1 | Visualizing the existing Micra

Upon complete flushing of the heart with warm water, the Micra could be easily visualized inside the heart (Figure 1). The device was almost fully encapsulated, with a small portion of the retrieval feature remaining uncovered.

3.2 | Retrieval of existing Micra

The retrieval process began by engaging the tip of the delivery tool cup over the retrieval feature of the Micra (Figure 2). The snare loop (previously inserted into the delivery tool flush lumen) was then engaged around the retrieval feature of the Micra and secured. The Micra was then pulled into the cup with the snare using the cup as countertraction (Figure 3). The maximum retrieval force was 1.9 lbs. The only tissue adherent to the Micra was a ring of tissue contained in the waist of the retrieval feature.

3.3 | Examination of the opened right ventricle

When the right heart was opened to view the location of the implanted Micra, the encapsulation sock was found lying along the septum pointed laterally halfway between the apex and the tricuspid valve (Figure 4). The septum was generally quite smooth making implant in the true midseptum difficult.

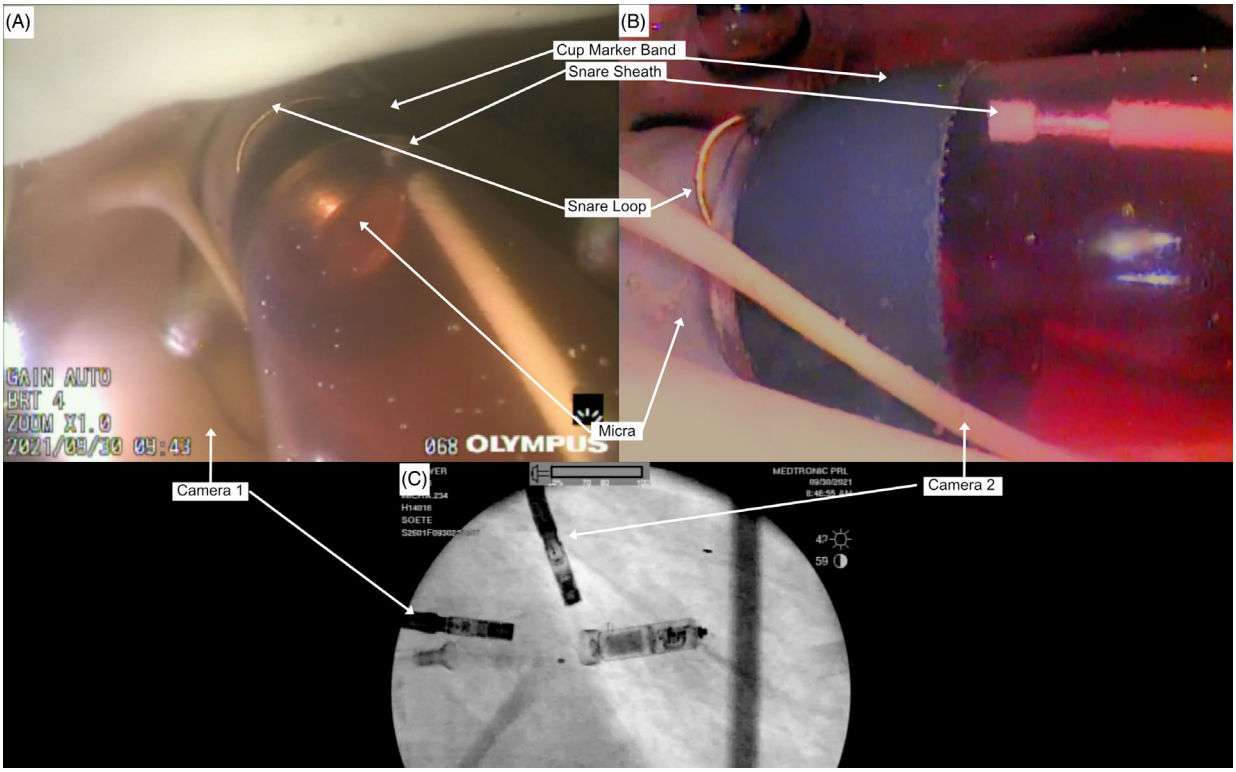

FIGURE 2 Alignment of the cup and placement of the snare. (A) Camera 1 took a view along the cup with the Micra retrieval feature seen through the cup. (B) Camera 2 took a view of cup tip over Micra retrieval feature. Also notice how the snare is guided directly over the retrieval feature with the cup in place. (C) An RAO X-ray image of the cup engaged over the Micra proximal end [Color figure can be viewed at wileyonlinelibrary.com]

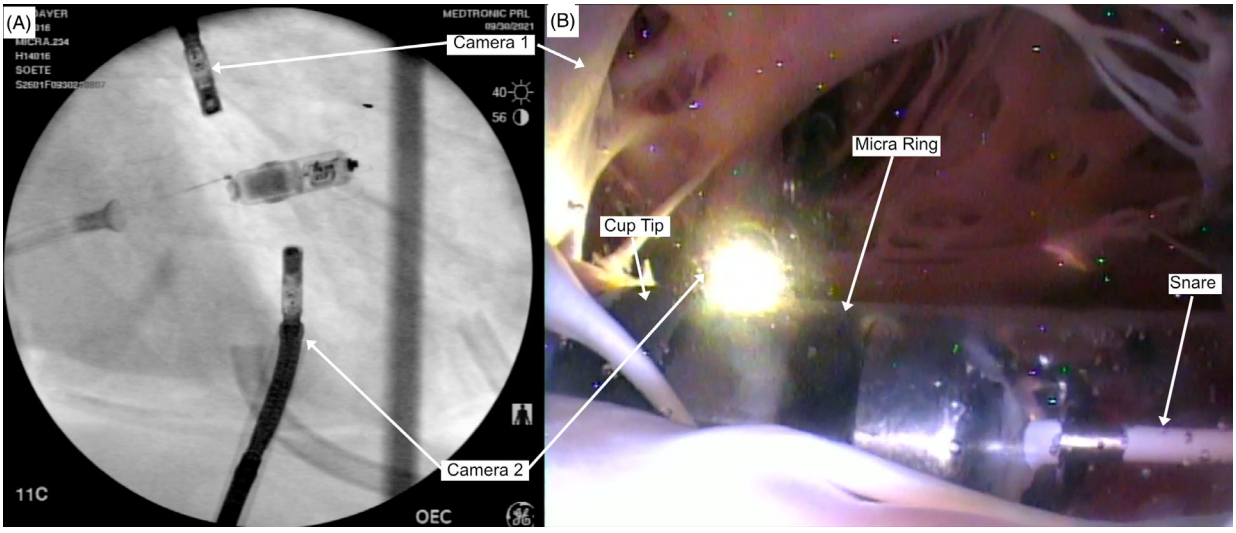

FIGURE 3 Pulling the Micra into the cup with the snare. (A) RAO X-ray view of the Micra with the two endoscope cameras. (B) Image from camera 1. Camera 2 is seen as the bright light. Note how the snare is tightly locked around the retrieval feature, and there is no tissue around the proximal Micra device [Color figure can be viewed at wileyonlinelibrary.com]

The encapsulation sock of the Micra was approximately 2.5 cm deep, which is the length of the Micra, indicating the encapsulation was left intact in the heart. It was possible to see the tine tracts and the electrode impression at the bottom of the encapsulation sock indicating the tissue was not adherent to the distal Micra features or materials.

3.4 | Histopathology of the tissue adjacent the Micra

From the Trichrome sections in Figure 5 you can see that the encapsulation of the Micra was mature, with little ongoing inflammation.

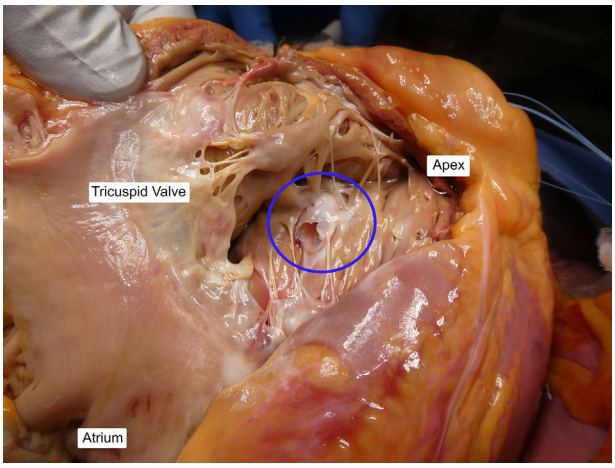

FIGURE 4 Image of opened right ventricle showing the encapsulation sock indicated by the blue circle. Note the location of the Micra in the anterior free wall septal groove while lying against the septum and some muscular trabeculae [Color figure can be viewed at wileyonlinelibrary.com]

In Section 5C you can see one tine was close to the epicardial fat, but did not penetrate into the pericardial space. While three of the four tines were visible in the tissue sections, no tine was visible on the epicardial surface of the heart prior to retrieval. At the Micra site, there was a localized rim of mature peridevice fibrosis at the myocardial interface and dense, mature encapsulation along the body at the interface with the RV lumen (Figure 5). The fibrosis contacting the device, including the electrode site and tine tracts, was composed of dense paucicellular collagen in parallel arrangement with the surface of the device. Inflammation at the device interface was rare. Inflammation was largely confined to the mid to outer peri-device fibrosis as low-density mononuclear infiltrates mainly located perivascularly. The peridevice fibrosis was overall well-demarcated ranging from an abrupt transition to normal myocardium to a variable thin rim of adjacent myocardial atrophy with interstitial fibrosis. Peridevice fibrosis at the electrode area ranged from ~0.3 to 0.9 mm thick and the luminal facing aspect of the Micra body encapsulation ranged from ~0.6 to 1.1 mm thick.

4 | DISCUSSION

This postmortem case provided a unique opportunity to study the retrieval of a Micra LP using both fluoroscopy and endoscopy to visualize the retrieval which had been implanted clinically 3 years prior.

While this retrieval was not performed on the beating heart, the technique presented of placing the cup over the device before attempting to snare the retrieval feature we believe simplifies the attachment of the snare. Snaring the retrieval feature within a closed space is much easier then attempting to snare the Micra beyond the cup with a 7 mm snare. With articulation and rotation, we have used this technique successfully in many animal retrievals with a beating heart. The snare is difficult to see, and we believe it is worth spending the time to bring at least the retrieval feature into the cup. In this study, only a few millimeters of the Micra was inside the cup, but we could then zoom in closely with the X-ray to orient the snare and attach it to the device. This limits the X-ray exposure significantly by minimizing the time spent with high magnification of the image.

While this retrieval was performed with a Micra delivery tool and snare to allow counter traction, the pull-out force was only 1.9 pounds which is within the forces measured in lead extraction literature.[14–15] This may be why other LPs have been retrieved after multiple years without counter traction.

While the current retrieval at 3 years is at the longer end of published retrievals, it is not extraordinary. The longest implant time before a successful LP retrieval is 4 years.[1–2] However, Grubman et al. published on multiple retrievals including one device that was successfully retrieved at 406 days, but two devices could not be retrieved at 259 and 229 days.[5] The first failure was due to x-ray malfunction, but in the second case the Micra could not be removed with just tension. Villegas et al. described three Nanostim devices that were successfully removed at 983, 1048, and 1070 days.[7] At Mayo Clinic in Rochester, MN, eight Nanostim devices were retrieved between 480 and 615 days, and one device was left in when the retrieval feature on the device detached.[9] Curnis et al.,[8] removed a Micra using the Micra delivery system and snare after 29 months, and Lakkireddy et al.,[6] described 47 of 53 LP retrieval attempts being successful between 0.2 and 4 years after implant. Therefore, the current retrieval is not the longest implant time, but it is the first to be captured with direct visualization.

One of the key elements to predicting the ease of retrieval is the amount of encapsulation on the Micra, particularly around the retrieval feature. Given the smooth body and flexible tines, the device will slide easily out of the encapsulation if the encapsulation does not continue over the retrieval feature. In this patient, the retrieval feature was mostly exposed allowing the snare to engage the retrieval feature, while requiring minimal tearing of the encapsulation tissue.

Once the retrieval feature is fully encapsulated, the retrieval may become more difficult. If the encapsulation precludes placing the snare over the body of the device, then the retrieval will not be possible. It is not clear how often this will happen, but based on the successful retrievals beyond 1 year to date, this may be somewhat rare. In this cadaver, the retrieval feature had some encapsulation, but it was not extensive or complete. However, tightening the snare into the waist was not difficult. In a more mature encapsulation (say at 10 years) it may not be possible to cut through the encapsulation on the body and tighten the snare into the waist. There is just not enough experience with long term implants of Micra to know what will happen.

Using the Micra tool to retrieve the device provided two advantages. First, by placing the cup over the retrieval feature, the snare was constrained making attachment of the snare to the retrieval feature much easier. Second, the cup provided counter traction in the event the encapsulation layer was very strong.

The Micra came out without any tissue attached to the tines or device body. This has also been seen in other retrievals. The Micra

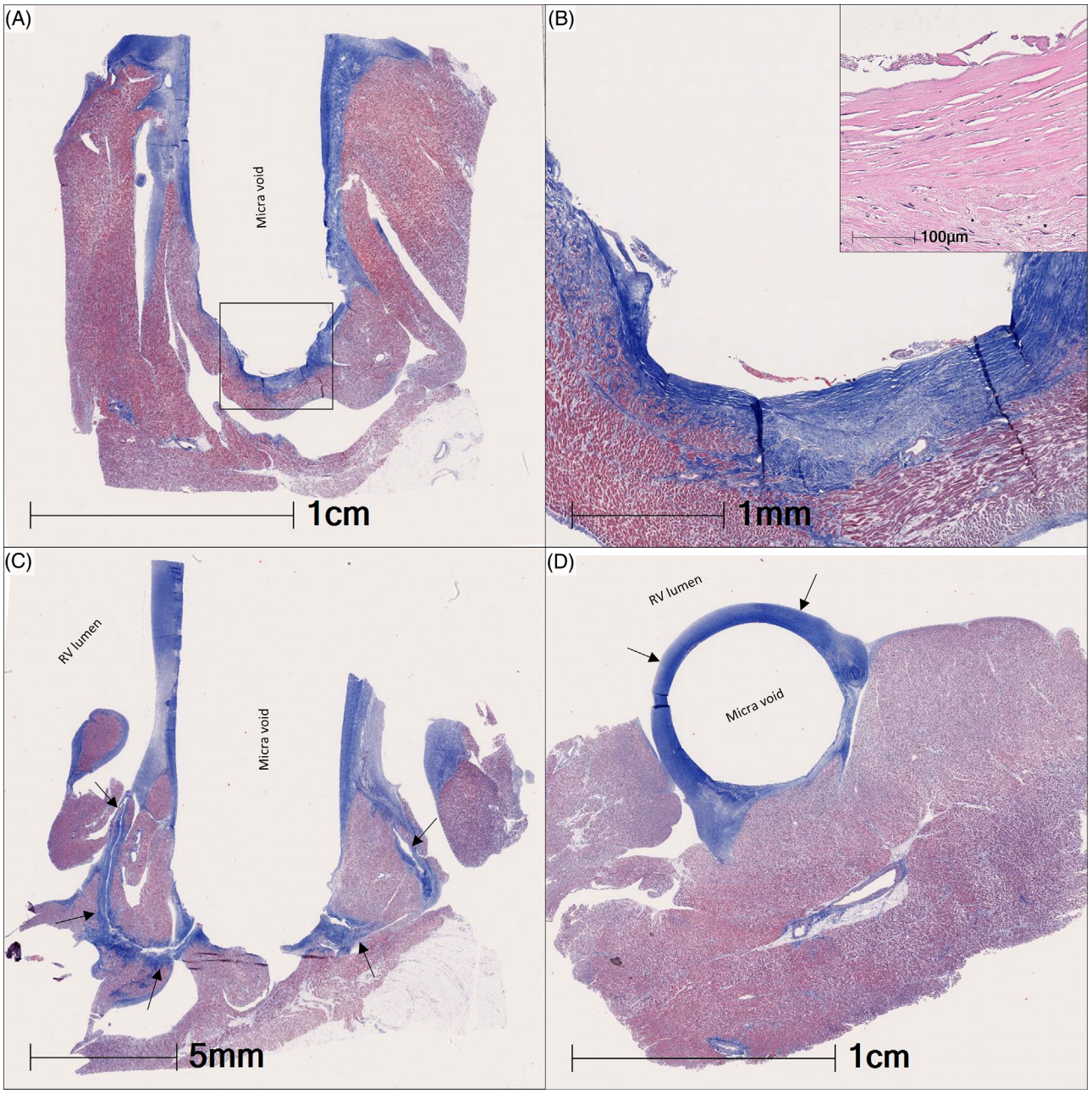

FIGURE 5 Micra site histopathology. (A) Micra implant site with electrode contact site (boxed), longitudinal section. Localized rim of peridevice fibrosis (blue staining) in the RV myocardium (red staining tissue). (B) Higher magnification of the electrode-contacting peridevice fibrosis with adjacent myocardium. (C) Longitudinal section of micra site with two opposite tine tracts (one incomplete) engaging the myocardium (arrows) with localized peri-tine fibrosis. (D) Cross-sectional view of a portion of the device encapsulation (arrow) of the Micra body and its continuation with the adjacent endocardium. All Masson's trichrome stain [Color figure can be viewed at wileyonlinelibrary.com]

design is such that the body is rigid, smooth, and isodiametric. In addition, the tines are flexible and smooth. This design minimizes any tissue attachment to the device. The only non-isodiametric section of the device is the retrieval feature in which there is often tissue ingrowth. However, if the snare can be guided over the body or retrieval feature, the snare can generally be tightened around the retrieval groove even in the presence of fibrous tissue.

In this patient, the Micra was implanted in the anterior free wall septal groove. This is likely due to the very smooth septum in this patient. The trabeculae were restricted to the anterior and inferior free wall septal grooves which made implanting the Micra in the mid septum difficult. While it is known the tines can penetrate the free wall into the pericardial space when implanted in the free wall septal groove, in this patient no tines were visible on the epicardial surface of the heart before retrieval.

From the histology of the tissue around the Micra, it was observed that the inflammation was minimal, and the fibrotic encapsulation was mature. It also showed that the tissue was only minimally disrupted by

the removal of the device before the heart was fixed. The tine tracts tended to create more widespread fibrosis, but even around the tines the fibrosis was mature with minimal inflammation.

5 | CONCLUSION

In this study, the Micra leadless pacemaker was able to be retrieved using existing tools without excessive force and without injury to the surrounding tissue.

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AUTHOR CONTRIBUTIONS

Matthew Bonner: Data collection, article creation, and editing. Kathryn Hilpisch: Data collection, article review, and final approval. Megan Harris: Data analysis, article review, and final approval. Kent Wika: Data collection, article review, and final approval. Mary Lauren Mesich: Pathology and histology analysis, article review, and final approval. Troy White: Article review and final approval.

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