Clinical Spotlight

Pacemaker Pocket Stabilization Utilizing a Novel Envelope and Three-Point Anchoring Technique

Naga Venkata K. Pothineni, Ramanan Kumareswaran, Robert D. Schaller

Abstract:

A 65-year-old man presented with chronic pain due to frequent movement of a dual chamber pacemaker (PPM) within the device pocket despite being secured to the underlying muscle. Due to chronic pain and possible indolent infection, the PPM was removed and a new device was implanted on the contralateral side via a persistent left superior vena cava. To prevent device movement, it was placed within a CanGaroo® Envelope (Aziyo Biologics Inc., Silver Spring, MD, USA), which was secured to the underlying muscle with a silk suture along three of its corners. The envelope, which becomes incorporated into the surrounding tissue forming a vascularized tissue pocket, should further reinforce device stability over time. The patient's left-sided symptoms abated immediately and he remains free of symptoms on the right side over a six-week follow-up period.

Pothineni NK, et al. Cureus. 2021 Feb 3;13(2):e13108.

Key Messages:

(courtesy of Robert Schaller, DO, Hospital of University of Pennsylvania)

- Frequent movement or rotation of a cardiac electronic implantable device pulse generator can result in chronic discomfort and/or lead displacement
- Device movement can be complex, including shifting in the pocket with positional changes or rotation of the device around multiple axes
- Contemporary securement solutions typically involve a single point suture option on the generator that may be inadequate or challenging to utilize depending on the lie of the generator
- The use of a biologic CIED envelope (CanGaroo® Envelope) facilitates multi-point suture fixation and provides a matrix for vascularized tissue ingrowth which becomes incorporated into the surrounding tissue, forming a vascularized tissue pocket that maintains the anchoring sutures in place and provides stabilization over time

Expert Editorial Opinion

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Implantation of cardiac implantable electronic devices (CIED), has increased significantly over the past several years. The indications for CIED implantation have changed based on recent clinical trials, especially in patients with heart failure. With expanded indications, patient age and accumulated comorbidities have increased over time.

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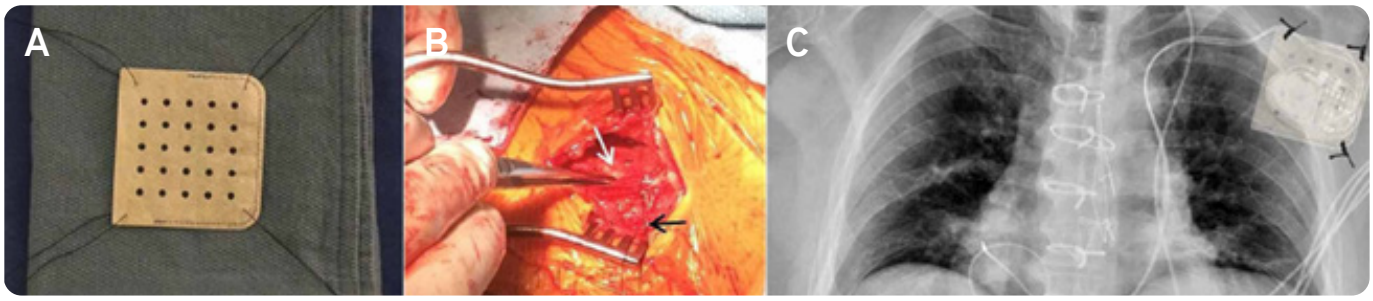

FIGURE 1: CanGaroo® pocket securement technique. (A) Silk sutures have been placed in all four corners of the envelope to demonstrate securement options. (B) The PPM has been placed in the CanGaroo® (white arrow) and a silk suture (black arrow) has been placed in one corner. (C) Anterior-posterior chest X-ray of a dual chamber PPM via a left persistent SVC with an image overlay of the CanGaroo pocket and anchoring sutures representative of a three point securement technique. | PPM, pacemaker; SVC, superior vena cava
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Expert Editorial Opinion

Cardiac Implanted Electrical Device Site Care: New Frontiers

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Implantation of cardiac implantable electronic devices (CIED), has increased significantly over the past several years.[2] The indications for CIED implantation have changed based on recent clinical trials, especially in patients with heart failure.[3] With expanded indications, patient age and accumulated comorbidities have increased over time.[4] In addition, with more common identification of the benefit of CIED therapy in young patients, there exists a separate cohort of young patients undergoing CIED implant who will require decades of CIED care.

Despite, long term experience with CIED implants, there remain issues with the implant and implant site. Studies have suggested the annual rate of infections remained constant until 2004, when a marked increase was observed, which coincided with an increase in the incidence of major comorbidities. This was associated with a marked increase in mortality and in-hospital financial charges.[4] Beyond infection, chronic issues at the surgical site remain an underappreciated problem. An 11-point post-operative pain prediction score has been developed which includes, lower body mass index, de novo implantation, hematoma development and younger age. Device site mobility and migration also remains a significant issue.[5] The most extreme form is known as Twiddler's syndrome with an estimated frequency of up to 7%.[6]

As such, there remains a need for novel CIED implant site technology that would allow for improved healing with both short and long term benefits along the dimension of infection, healing, pain and mobility. In this paper, Dr. Pothineni et al describe a novel technique for stabilization and anchoring a dual chamber pacemaker device. They describe a relatively rare but well documented concern which occurs in routine longitudinal device: chronic pain at the device site.[1] While infection is the most thought of complication, it is clear that other issues at the device site are common concerns for patients undergoing device implants. In fact, subclinical infection may be the nidus for chronic pain and inflammation. As such, a technique for patients such as this to allow for improved device stability and optimization of tissue healing at the surgical site is required.

> **"Beyond infection, chronic issues at the surgical site remain an underappreciated problem… As such, there remains a need for novel CIED implant site technology that would allow for improved healing with both short and long term benefits along the dimension of infection, healing, pain and mobility."**

The utilized device in the cited case report is CanGaroo Envelope. This material, which has been utilized in numerous surgical conditions is relatively novel to the CIED world. The biology is well described in the preclinical space: decellularized extracellular matrix supports proliferation functions by attracting stem cells, stimulating angiogenesis, and controlling immunomodulation to elicit an M2 regenerative response.[1] It is believed that fibrosis may be a nidus for bacteria colonization, and scar tissue severity has been associated with higher rates of related infection.[7,8] The purported benefit this technology offers might allow for the implanting physician to achieve all three aforementioned goals: reduced likelihood of infection, improved device stability and optimal tissue healing. Clinical data is required to confirm if the biology holds in this case. However the promise remains. As compared to an antibiotic impregnated synthetic pouch, the promise of regenerative biology might allow for undressed complications outside of infection. The "usability" the pouch form factor adds ability for device stabilization as described in this case. The authors have identified an innovative use of the pouch to maximize stability.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.
CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Material for the use only in countries with applicable health authority product registrations. This document is not for use or distribution in France.

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