PR Novel Hematoma Prevention Device

Nolan Shoukri[1], Steven Pearl[2], Nishaki Mehta[3]

[1]Oakland University William Beaumont School of Medicine, Rochester Hills, MI
[2]Emergency Medicine, Ascension Providence Rochester Hospital, Rochester, MI
[3]Cardiovascular Medicine, Corewell Health William Beaumont University Hospital, Royal Oak, MI

Introduction

- Hematomas are a common complication in cardiac internal electronic device (CIED) placement procedures, they occur in up to 20-25% of CIED implants.
- Previous RCT tested a novel hematoma compression device (PR) and showed good tolerability, decreased hematoma formation from 15% to 6%, and wound improvement.
- Based on feedback collected from the nurses, physicians, allied health professionals during the randomized control trial, iteration of the PR was done (Gen 2 PR).
- This study evaluated 1) bench testing of the Gen 2 PR device and 2) healthy volunteer testing of Gen 2 PR device.

Aims and Objectives

This study evaluated:

- 1) Bench testing of the Gen 2 PR device
- 2) Healthy volunteer testing of Gen 2 PR device

Methods

Benchmark testing:

- The device was evaluated on left pectoral positions for 2-hours intervals on mannequins
- Test was done to evaluate the performance of the embedded pressure sensor.
- The device and pressure sensors were examined every 10 minutes and the pressures, strap tension and surface of contact were recorded.

Healthy volunteer testing:

- The device was evaluated on left pectoral, right pectoral and left lower chest for 2-hours intervals at each location on healthy volunteers. **(Figure 1)**
- The volunteers and device were evaluated every 30 minutes to check the embedded sensor and the external pressure sensor.
- We obtained a post device removal survey after every test.
- Pictures were taken of the de-identified testing site prior to device placement and afterwards.
- Photographs were analyzed with the MSS and POSAS scar scales by a wound care specialist that was blinded. **(Figure 1)**
- Statistical analysis was done via R statistical program on the data collected.

Figures/Tables

Figure 1: Mannequin diagram showing PR placement sites (red circle). The blue text boxes shows average pain experienced at those sites during healthy volunteer testing along with the average MSS and POSAS (patient/observer) scores experiences at those sites.

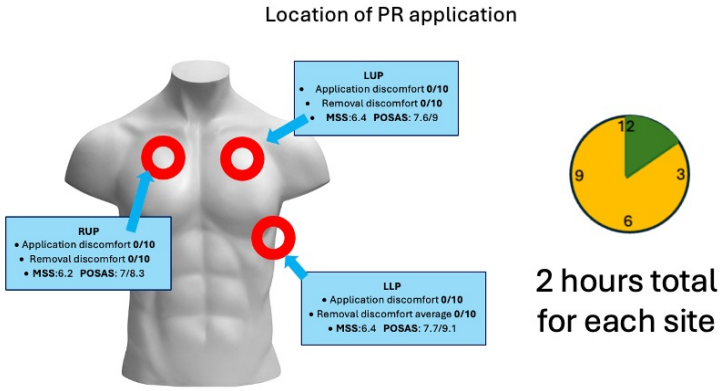
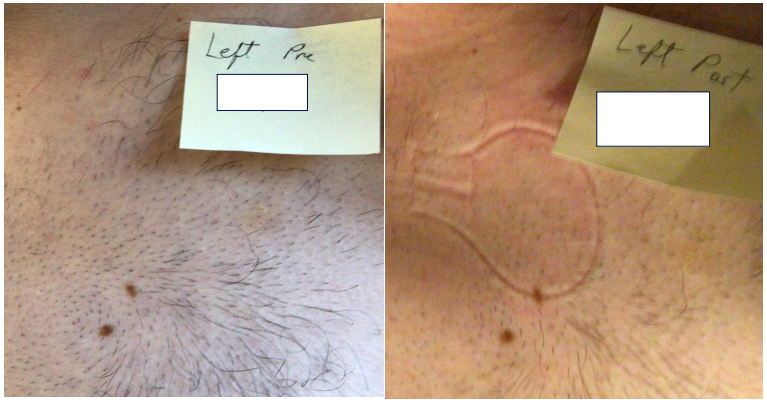


Figure 2: Showing pre- and post-device placement skin changes.



Results

Mannequin Testing Results:

- Device showed no evidence of wear and tear.
- 39/39 pressure checks were within the adequate pressure range.
- The pressure release valve functioned as expected in the higher bound of the pressure interval.
- The estimated contact surface based on the device contact indicator was about 52% on average for all testing.

Human Volunteer Testing:

- There were three males (33%) with seven volunteers being of Caucasian race (77.7%), one volunteer of Hispanic origin (11.1%), with an overall average age of 63.6 years..
- All tests satisfactorily completed without concern for integrity.
- The embedded pressure sensor demonstrated adequate pressure 100% of the time.
- Volunteers overall expressed that the device had very minimal discomfort and issues throughout the 2-hour testing and would be willing to use the device again in the future.
- There was no significant difference in sites prior to and following device placement and scar assessment scale scores between location of device placement. **(Figure 2)**

Discussion

- Overall, the Gen 2 PR device performed well in providing adequate pressure without significant side effects to users.
- Analysis of patients in our practice showed 56% of patients were on some type of blood thinner excluding aspirin alone.
- Hematoma has been identified by physicians and staff as a common complication following CIED placement procedures
- As more patients are on blood thinners, the importance of hematoma prevention increases.

Conclusion

Gen 2 PR device might be a safe and reliable way to reduce hematoma formation and prevent anticoagulation interruption peri-operatively.

References

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