


Evaluation of a novel mechanical compression device for hematoma prevention and wound cosmesis after CIED implantation

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Of note, Nishaki Mehta is the inventor of this novel device.

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Abstract

Background: An important complication of cardiac implantable electronic devices (CIED) implantation is the development of hematoma and device infection.

Objective: We aimed to evaluate a novel mechanical compression device for hematoma prevention and cosmetic outcomes following CIED implantation.

Methods: An open, prospective, randomized, single-center clinical trial was performed in patients undergoing CIED implantation. Patients were randomized to receive a novel mechanical compression device (PressRite, PR) or to receive the standard of care post device implantation. Skin pliability was measured with a calibrated durometer; the surgical site was evaluated using the Manchester Scar Scale (MSS) by a blinded plastic surgeon and the Patient and Observer Scar Scale (POSAS). Performance of PR was assessed through pressure measurements, standardized scar scales and tolerability.

Results: From the total of 114 patients evaluated for enrollment, 105 patients were eligible for analysis. Fifty-one patients were randomized to management group (PR) and 54 to the control group. No patients required early removal or experienced adverse effects from PR application. There were 11 hematomas (14.8% vs. 5.9% in the control and PR group respectively, $p = \text{NS}$). The control group had higher post procedure durometer readings in the surgical site when compared with the PR group (7.50 ± 3.45 vs. 5.37 ± 2.78 ; $p < .01$). There were lower MSS scores in the PR group after 2 weeks ($p = .03$).

Abbreviation: CAD, coronary artery disease; CIED, cardiovascular implantable electronic devices; CKD, chronic kidney disease; CRT, cardiac resynchronization therapy; DM, diabetes Mellitus; ERI, elective replacement indicator; HF, heart failure; HTN, hypertension; PressRite, novel mechanical compression device; UVA, University of Virginia.

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Conclusion: We have demonstrated the safety of PR application and removal. In addition, PR appears to improve postoperative skin pliability, which could facilitate wound healing.

1 | INTRODUCTION

Over 1.2 million pacemakers and 300,000 defibrillators are implanted annually worldwide, and this patient cohort requires generator change procedures every 8–10 years. As the population continues to age, these numbers continue to rise.¹ Up to 35% of patients undergoing cardiac implantable electronic devices (CIED) are prescribed antiplatelet and/or anticoagulant therapies, which can further increase the risk of hematoma.^{2,3} The development of hematoma is associated with up to 21-fold increase in risk of device infection, which is one of the most dreaded CIED complications.^{4–10}

Current strategies to reduce postoperative hematoma include variable practices including application of pressure dressing, sandbags or ice packs.¹¹ However, the impact of these strategies is nonuniform and ineffective such that they are not widely used. In addition, the cosmetic appearance of scars affect patient perception and quality of life.¹² There are currently no standardized tools to improve scar appearance post CIED implantation.

This study was designed to evaluate the efficacy and safety of a pneumatic transparent mechanical compression device (PressRite, PR) in comparison to the conventional strategies in patients undergoing cardiac device implantation.

2 | METHODS

An open, prospective, randomized, single-center clinical trial was performed in patients who underwent cardiac device implantation at the University of Virginia (UVA) Medical Center from January 2020 to May 2020. The University of Virginia Institutional Review Board approved this study. Written informed consent was obtained from all study subjects.

2.1 | Patient selection

One hundred and fourteen patients were assessed for eligibility and 112 patients were selected to for enrollment. The inclusion criteria were adult patients (> 18 years old) who were undergoing de novo CIED or generator change procedures and were able to consent for CIED implantation and randomization for the study. Exclusion criteria were a recent sternotomy, and any other chest, shoulder or abdominal surgery precluding the use of adhesive pads to secure the PR.

2.2 | Randomization

After initial assessment for enrollment, a total of 112 patients were randomized using the UVA Online Collaborative Research Environ-

ment (OnCore) tool. Fifty-six patients were allocated in the PR group and 56 in the control group (Figure 1). Four patients in the PR group had their procedure canceled, delayed or postponed and one patient elected to withdraw from the study. Thus, fifty-one patients were included in the final analyses from which two patients did not receive the PR but were kept in the PR group based on the intention to treat analyses. In the control group, two patients had their procedures postponed and a total of 54 patients were included in the final analysis. The patients assigned to the management group had a PR applied over the medical bandage Primapore (Smith+ Nephew, Memphis, Tennessee) or Aquacel (ConvaTec, Bridgewater, NJ) over the surgical site for minimum of 2 hours.

The UVA electrophysiology group comprised of seven electrophysiologists as the time of the study. As reflective of national practice patterns and lack of guidelines in the absence of strong recommendations, the control group was permitted to have postoperative dressings at the discretion of the operator. Patients randomized to the control group received the regular standard of care that could either be 1) medical bandage Primapore or Aquacel over the surgical site or 2) conventional pressure dressing (stack of gauze with tape for compression) on top of medical bandage Primapore or Aquacel over the surgical site per physician's discretion.

2.3 | PressRite (PR) device description and application

PR is a modular biocompatible, transparent, lightweight, and durable pneumatic compression device that was designed to deliver sufficient pressure consistently over a 2–4 h application period and accommodate varying upper body anatomy, Table 1. (patent pending)

Device compression system is a modular assembly consisting of 1) Pneumatic compression system (transparent air inflation mecha-

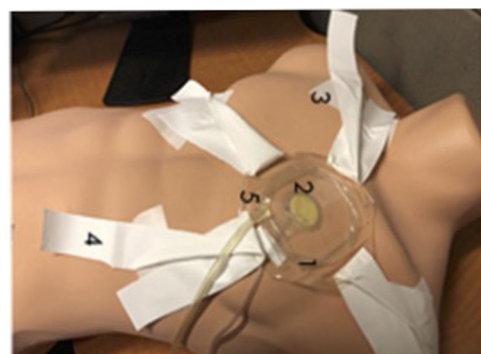


FIGURE 1 Enrollment process and allocation of patients [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Baseline characteristics, demographics and use of antiplatelets and anticoagulants

	Control (n = 54)	PR (n = 51)	p
Age (Mean ± SD)	65.35 ± 16.04	70.45 ± 14.07	.087
Female (%)	27.8%	35.3%	.40
White or Caucasian	64.8%	82.2%	.01*
African American	27.8%	11.8%	.01*
Left ventricular ejection fraction	0.48	0.43	.62
HTN	68.5%	70.6%	.81
DM	27.8%	21.6%	.46
CAD	42.6%	33.3%	.32
CKD	29.6%	25.5%	.63
Hematoma	14.8% (n = 8)	5.9% (n = 3)	.20 (Fisher's)
Use of antiplatelets, anticoagulants, and immunosuppression			
Antiplatelet	63.0%	43.1%	.04*
Anticoagulation	42.6%	58.8%	.09
Immunosuppression	3.7%	5.9%	.11
Hospitalization	18.5%	33.3%	.83
Device, manufacturer and type of procedure			
Single chamber pacemaker	3.8%	0%	.63
Dual chamber pacemaker	30.8%	39.2%	
Single chamber ICD	11.5%	5.9%	
Dual chamber ICD	21.2%	17.6%	
Biventricular ICD	30.8%	33.3%	
Subcutaneous ICD	1.9%	3.9%	
De Novo device implantation	61.5%	58.8%	.23
Generator change	30.8%	21.6%	
Upgrade	7.7%	17.6%	
Lead revision	0%	2%	
Medtronic	66.0%	60.8%	.87
Boston Scientific	22.0	23.5%	
St. Jude	12.0%	15.7%	

nism with inflatable bulb [Dyad Medical Sourcing, LLC (Bannockburn, IL)] with air release valve, custom made for this trial using medical grade thermoplastic polyurethane, shore 90A material), 2) Fixation mechanism (skin safe adhesive pads Stetrix (Tissue Management Solutions Bartlett, TN) with light weighted fabric slings which connect the compression system to the pads), 3) Pressure monitoring mechanism (pressure gauge with read-out scale, Varodem (The Compression Company Horn, Netherlands) (Figure 2, Supplemental video 1 18002833787). The compression system enables application of pressure up to 160 mmHg, additionally allowing complete surgical site inspection owing to transparent material. The pressure valve apparatus can be easily detached from the air inflation module after complete inflation and sealing the pressure valve.

PR was applied and removed by a trained operator. Pressure exerted to the surgical site was calibrated to 40 mmHg. Pressure readings were taken during 30-min sessions using sub-bandage pressure mea-

TABLE 2 Survey following PressRite removal

Surveyed questions	Mean ± SD
Pressure	2.16 ± 3.2
Pain	1.65 +/- 2.9
Itching	0.29 ± 0.8
Soreness	1.43 ± 2.8
Decreased mobility	0.83 ± 2.2
Discomfort	1.62 ± 2.7
Device removal	3.08 ± 3.3
Overall experience (0 to 10 being 10 the best possible experience)	7.6 ± 2.8

suring sensor (Kikuhime MediTrade, Soro, Denmark). Pressure transducer was calibrated prior each measurement. After device removal, patients were asked to complete a survey evaluating their experience and tolerability (Table 2).

2.4 | Implant site assessment

Postoperative survey: After removal of PR, the patient completed a postoperative survey that assessed different aspects of tolerance on a scale of 0–10.

Durometer Read-outs: Prior to the procedure, study investigators used Model 1600 Type OO Dial durometer (Rex Gauge, IL) to measure skin pliability at the surgical site (S) and contralateral site (CL) at the following time points: 1) preprocedure (baseline); 2) postprocedure within 24 h over the thinnest part of the dressing; 3) at the 2 week follow-up visit; and 4) at the 3 month follow-up visit. Three readings were obtained from the quadrant of interest and the average value was used for analysis. Higher durometer readouts correlate with higher skin tension and lower pliability. The durometer placement and read-out technique has been previously reported.¹³

Surgical Scar Evaluation: At the 2-week and 3-month follow-up period, the Manchester Scar Scale (MSS)¹⁴ and the Patient and Observer Assessment Scale (POSAS)¹⁵ was completed to assess wound healing. The physician component was evaluated by a blinded plastic surgeon. Owing to the COVID pandemic, follow up visits were transitioned to remote and patients were contacted up to 3 times to share their site follow up photographs when possible.¹⁶

2.5 | Endpoints of interest

The primary endpoint was the incidence of postoperative pocket hematoma in the group of patients using the hematoma prevention device versus controls. Secondary endpoints included durometer readings, POSAS and MSS scores, CIED revision, and CIED infection rates. Surgical site hematoma was analyzed according to the Bleeding Academic Research Consortium classification.¹⁷

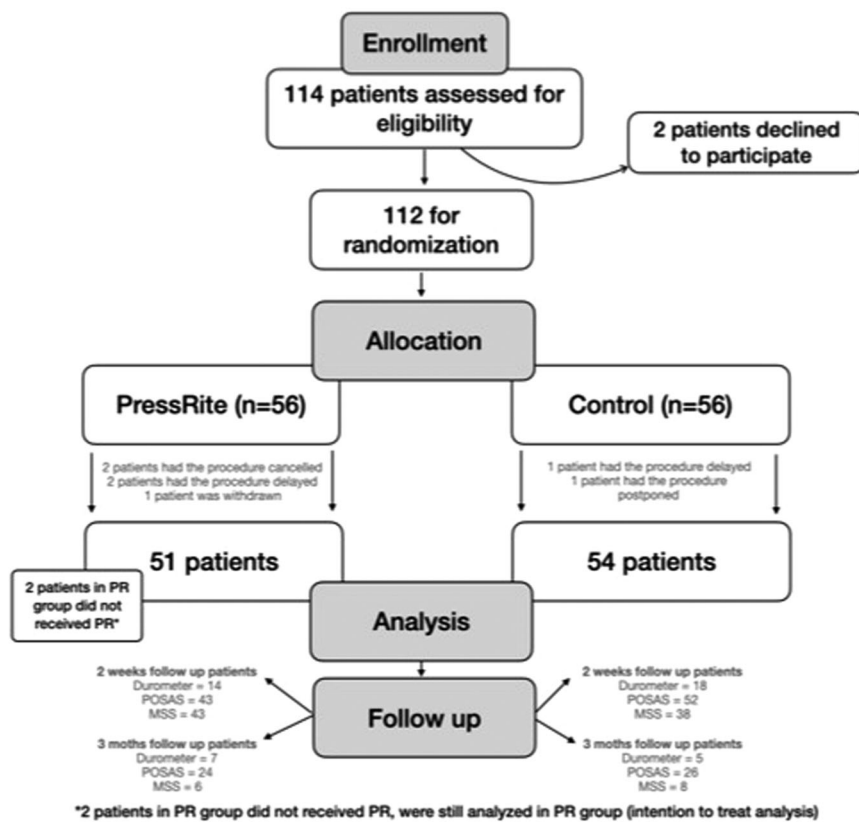


FIGURE 2 PressRite device on mannequin during staff training. Modular assembly – 1: Pneumatic compression device, 2: External pressure sensor between skin and device, 3: Adhesive landing pads, 4: Sling connecting pneumatic compression device to the landing pads and 5: Mechanism for inflation of the pneumatic compression device using an inflatable air bulb

2.6 | Data analysis

Quantitative data were expressed as the mean \pm standard deviation and median \pm percentiles. Comparisons between groups were performed using an unpaired Student's *t*-test (two-tailed) or U-Mann Whitney test (based on the distribution of the values). Comparisons of means from the same individual were performed using a paired Student's *t*-test. Categorical data were compared by Chi-Square test. One-way ANOVA was used to assess changes in durometer readings over time in both groups. *p* values of less than .05 were deemed to be significant. Data were analyzed according to the intention-to-treat model. SAS software was used for performing statistical analysis (Version 9.4, SAS Institute Inc.).

3 | RESULTS

3.1 | Study population

From the total of 114 patients initially screened, two patients declined to participate, and seven patients were removed from the study due to having the procedure canceled, delayed or postponed. Our final analysis was performed with 51 patients in the management group (PR) and 54 patients in the control group. Patient enrollment process is shown in Figure 1.

3.2 | Baseline characteristics

Patient characteristics, demographics, medication review, and procedural characteristics are shown in Table 1. The average age, gender, baseline comorbidities in both groups were similar. There were a higher number of Caucasian patients in the PR group (82.2%) compared with the control group (64.8%, $p = .01$). A higher number of patients in the control group were on antiplatelet agents (63.0% vs. 43.1%; $p = .04$). No differences were seen in the use of anticoagulant, or immunosuppressive medications. The distribution of the type of device, manufacturers and type of procedure (de novo vs. generator changes) was similar in both groups.

3.3 | PR application and post PR removal survey

The average pressure delivered by the PR was 34.68 mmHg. There were no instances of removing PR devices owing to patient intolerance (Table 2).

The patients in the PR group were surveyed to evaluate their tolerability and overall experience using this novel device. The mean score was 7.6 ± 2.8 . Pain, pressure, and discomfort levels were low and none of the studied subjects experienced major adverse events associated with PR use.

TABLE 3 Surgical site hematoma according to the Bleeding Academic Research Consortium

	Control	PR
Type 0 (no bleeding)	85.2% (46)	94.1% (48)
Type 1 (not actionable bleeding)	11.1% (6)	5.9% (3)
Type 2 (actionable bleeding)	3.7% (2)	0%
Type 3 (clinical, laboratory, and or imaging evidence of bleeding requiring specific action)	0%	0%
Type 4 (CABG-related bleeding)	0%	0%
Type 5 (fatal bleeding)	0%	0%
Total bleeding episodes	14.8% (8)	5.9% (3)

3.4 | Outcomes

There were eleven surgical site hematoma occurrences in the study. Eight were in the control group and three in the PR group (14.8% vs. 5.9%, $p = .27$) (Table 3).

Of the eight patients in the control group (8/54), three were on antiplatelet agents, three were on anticoagulation and two were on antiplatelet and anticoagulant agents. Six out of these eight patients underwent conservative management, while two of them had actionable bleeding (with testing of clotting time, platelet count, and hemoglobin). None of the patients underwent invasive management, transfusion, or device revision.

On the other hand, three patients in the PR group (3/51) developed surgical site hematoma. The first case was a biventricular ICD generator change and was only on aspirin. The second case had a biventricular ICD generator change and was on warfarin monotherapy. The last INR check was 2.2 four days prior to the procedure. The third patient had a single chamber pacemaker generator change and was on aspirin and apixaban that was held 48 hours prior to the procedure. All three patients had conservative management. None of the bleeding episodes were higher than BARC 3 for both groups.

3.5 | Post-operative durometer readouts higher in the control group

The preprocedure durometer readings for the surgical and contralateral sites were similar for both groups. In the PR group, the preprocedure versus postprocedure durometer readings in the surgical and contralateral sites were not significantly different. (4.2 ± 2.2 vs. 4.8 ± 2.7 and 4.6 ± 2.1 vs. 5.3 ± 2.7 ; $p = \text{NS}$). The control group had higher post-procedure durometer readings in the surgical site when compared with the PR group (7.50 ± 3.45 vs. 5.37 ± 2.78 ; $p < .01$) (Figure 3).

3.6 | Surgical scar evaluation based on MSS scores better in the PR group

Significantly lower MSS scores were seen in the PR group after two weeks ($p = .03$, Figure 4). The POSAS scores were similar in both groups

at 2-weeks and 3-months follow-up. Representative scar images for both groups are shown in Table 4.

3.7 | Follow up data

A detailed chart review after one year of enrollment was performed showing that there were no device infections, lead extractions or revisions in the studied population. Three patients in the control group (1 STEMI and 2 cardiogenic shock) and six patients in the PR group died during follow up (1 NSTEMI, 2 cardiogenic shock, 1 VT/VF, 1 peritonitis, 1 unknown cause of death).

4 | DISCUSSION

In this randomized clinical trial, we demonstrated: 1) safety and reliability of PR application; 2) lower postoperative durometer readings over the surgical site in the treatment group compared with the control group; and 3) lower MSS scores in the treatment group after 2 weeks of follow-up.

The intervention in this study was designed to overcome the limitations of current mechanical compression devices, which are opaque, block visual access to the site and are not titratable for pressure application. In addition, most of the alternative solutions for mechanical compression are site specific. The modular assembly of PR device lends to universal site application as demonstrated in our study where we had left pectoral site, right pectoral site and left lateral site placements. Furthermore to our knowledge, there is no mechanical compression device for CIEDs with the ability to dynamically adjust pressure.

In addition, nurses and technicians were trained to place the PR on a mannequin in a short orientation session using a mannequin. The easy application and removal with minimal baseline training could translate to scalability. In this study, we have demonstrated the safety and tolerability of PR with no adverse events. No patients required early removal for discomfort and there were no adverse effects noted.

One of the study endpoints is based on assessment with a durometer, which is a well-validated hand-held instrument that measures the skin pliability by measuring the skin compliance to a compression pin with readouts in durometer units. It is highly reliable, reproducible, convenient and painless. Higher readouts signal reduced skin pliability which can occur with postoperative swelling and consequently with fibrosis.¹⁸⁻²⁰

We have previously demonstrated the usefulness of durometers for scar assessment in patients undergoing CIED implantation compared to control volunteers. Our baseline findings in control patients in this study are consistent with what we previously reported. In addition, we now show that the durometer readouts in the PR group were lower on the surgical site post operatively and similar to the contralateral site. This suggests adequate compression and dispersion of surgical swelling. This in turn could putatively reduce skin tension and permit better scar healing.

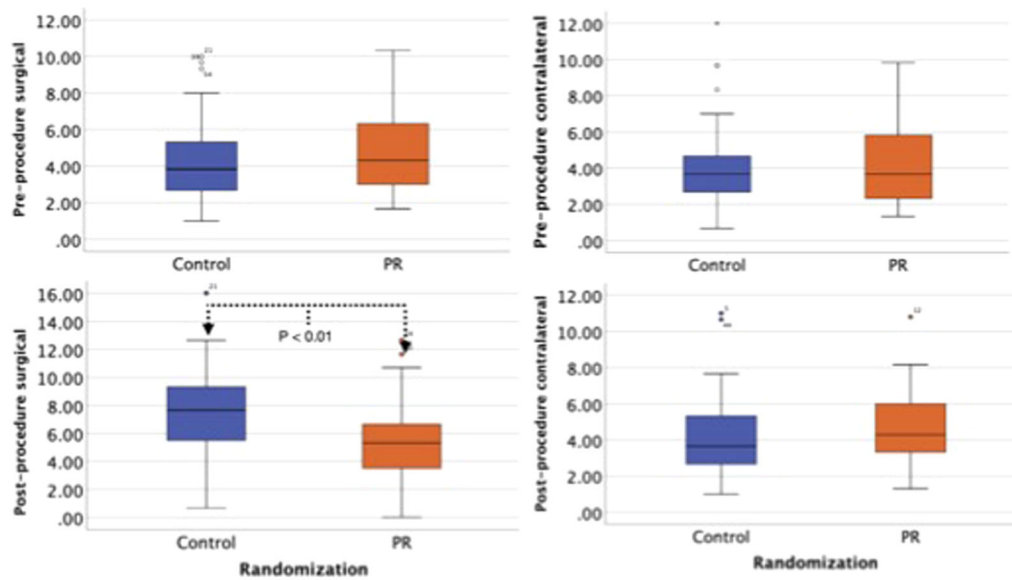


FIGURE 3 Preprocedural and postprocedural durometer readings in the surgical and contralateral sites [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]

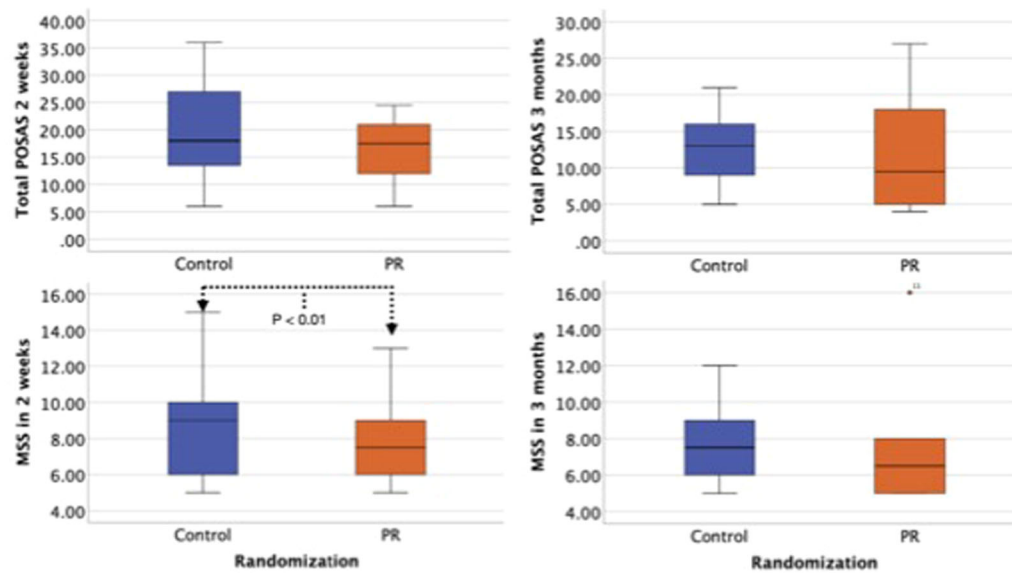


FIGURE 4 POSAS and MSS data in the PressRite and control groups at 2 weeks and 3 months [Color figure can be viewed at [wileyonlinelibrary.com](https://onlinelibrary.wiley.com)]

Given the low event rate of hematomas in this study, we did not find a discernible difference in the two groups; however, the PR group had a lower hematoma rate that did not meet statistical significance. Based on these findings, we believe additional studies with greater numbers of patients will help define clinical effectiveness.

With respect to surgical scar assessment, the MSS and POSAS scales have been previously demonstrated to have high reliability and validity.²¹⁻²⁴ The MSS score in the present study provided a signal for effectiveness of treatment at 2 weeks; however, more definitive

assessment was affected by high dropout rates during the COVID pandemic because the in hospital /in clinic follow up visits were not possible.

As our population continues to age and the need for CIED implants grows, the utility of a reliable, safe, and easily applied mechanical compression device could offer advantages to reduce risk of hematomas and putatively improve wound healing metrics. This represents an exploratory feasibility pilot trial with encouraging results that justify larger multicenter trials to validate concept observations.

TABLE 4 Representative images of surgical scars in the PressRite and control groups at 2 weeks and 3 months

Images	Durometer readout surgical site	MSS at 2 weeks and 3 months	Total POSAS at 2 weeks and 3 months
PressRite 2 weeks 	8	Color - 4 Matte - 1 Contour - 1 Distortion - 2 Texture - 3	11
PressRite 3 months 	4	Color - 1 Matte - 1 Contour - 1 Distortion - 1 Texture - 1	6
Control 2 weeks 	7	Color - 2 Matte - 1 Contour - 2 Distortion - 2 Texture - 2	14
Control 3 months 	4	Color - 1 Matte - 1 Contour - 1 Distortion - 1 Texture -	12

4.1 | Limitations

This represents a small-randomized clinical trial in a single center. The COVID-19 pandemic disrupted a planned systematic follow-up. A larger study with multicenter participation could expand on the real-life applicability of PR. Validation in other institutions would add scientific rigor to our initial observations.

5 | CONCLUSION

This study was a feasibility pilot trial to evaluate the PressRite device. It showed that the PR is a safe and well-tolerated pneumatic compression device that reduces the incidence of surgical site hematomas and attenuates swelling with improved wound healing in patients undergoing CIED procedures.

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REFERENCES

- Cabell CH, Heidenreich PA, Chu VH, et al. Increasing rates of cardiac device infections among Medicare beneficiaries: 1990–1999. *Am Heart J*. 2004;147:582–586. <https://doi.org/10.1016/j.ahj.2003.06.005>. PMID: 15077071.
- Mond HG, Proclemer A. The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009 – a World Society of Arrhythmia's project. *Pacing Clin Electrophysiol*. 2011;34:1013–1027. <https://doi.org/10.1111/j.1540-8159.2011.03150.x>. Epub 2011 Jun 27. PMID: 21707667.
- Perez AA, Woo FW, Tsang DC, Carrillo RG. Transvenous lead extractions: current approaches and future trends. *Arrhythm Electrophysiol Rev*. 2018;7:210–217. <https://doi.org/10.15420/aer.2018.33.2>.
- Greenspon AJ, Patel JD, Lau E, et al. 16-year trends in the infection burden for pacemakers and implantable cardioverter-defibrillators in the United States 1993 to 2008. *J Am Coll Cardiol*. 2011;58:1001–1006. <https://doi.org/10.1016/j.jacc.2011.04.033>. PMID: 21867833.
- Tarakji KG, Ellis CR, Defaye P, Kennergren C. Cardiac implantable electronic device infection in patients at risk. *Arrhythm Electrophysiol Rev*. 2016;5:65–71. <https://doi.org/10.15420/aer.2015.27.2>. PMID: 27403296; PMCID: PMC4939310.
- Voigt A, Shalaby A, Saba S. Continued rise in rates of cardiovascular implantable electronic device infections in the United States: temporal trends and causative insights. *Pacing Clin Electrophysiol*. 2010;33:414–419. <https://doi.org/10.1111/j.1540-8159.2009.02569.x>. Epub 2009 Sep 30. PMID: 19793359.
- Sohail MR, Henrikson CA, Braid-Forbes MJ, Forbes KF, Lerner DJ. Mortality and cost associated with cardiovascular implantable electronic device infections. *Arch Intern Med*. 2011;171:1821–1828. <https://doi.org/10.1001/archinternmed.2011.441>. Epub 2011 Sep 12. PMID: 21911623.
- Song J, Tark A, Larson EL. The relationship between pocket hematoma and risk of wound infection among patients with a cardiovascular implantable electronic device: an integrative review. *Heart Lung*. 2020;49:92–98. <https://doi.org/10.1016/j.hrtlng.2019.09.009>. Epub 2019 Oct 10. PMID: 31607409.
- Sadeghi H, Alizadehdiz A, Fazelifar A, Emkanjoo Z, Haghjoo M. New insights into predictors of cardiac implantable electronic device infection. *Tex Heart Inst J*. 2018;45:128–135.
- Essebag V, Verma A, Healey JS, et al. Clinically significant pocket hematoma increases long-term risk of device infection: bRUISE CONTROL INFECTION Study. *J Am Coll Cardiol*. 2016;67:1300–1308. <https://doi.org/10.1016/j.jacc.2016.01.009>. PMID: 26988951.
- Mehta NK, Doerr K, Skipper A, Rojas-Pena E, Dixon S, Haines DE. Current strategies to minimize postoperative hematoma formation in patients undergoing cardiac implantable electronic device implantation: a review. *Heart Rhythm*. 2021;18:641–650. <https://doi.org/10.1016/j.hrthm.2020.11.017>. Epub 2020 Nov 23. PMID: 33242669.
- Gandhi T, Crawford T, Riddell J. Cardiovascular implantable electronic device associated infections. *Infect Dis Clin*. 2012;26: 57–76.
- Mehta NK, Morgaenko K, Haines D, et al. Baseline incision characteristics and early scar maturation indices following cardiac device implantation. *J Arrhythm*. 2021;37:400–406. <https://doi.org/10.1002/joa3.12464>. PMID: 33850582; PMCID: PMC8021997.
- Beausang E, Floyd H, Dunn KW, Orton CI, Ferguson MW. A new quantitative scale for clinical scar assessment. *Plast Reconstr Surg*. 1998;102:1954–1961. <https://doi.org/10.1097/00006534-199811000-00022>. PMID: 9810991.
- Draaijers LJ, Tempelman FR, Botman YA, et al. The patient and observer scar assessment scale: a reliable and feasible tool for scar evaluation. *Plast Reconstr Surg*. 2004;113:1960–1965. <https://doi.org/10.1097/01.prs.0000122207.28773.56>. discussion 1966–7. PMID: 15253184.
- Monaghesh E, Hajizadeh A. The role of telehealth during COVID-19 outbreak: a systematic review based on current evidence. *BMC Public Health*. 2020;20:1193. PMID: 32738884.
- Mehran R, Rao SV, Bhatt DL, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. *Circulation*. 2011;123:2736–2747. <https://doi.org/10.1161/CIRCULATIONAHA.110.009449>. PMID: 21670242.
- Cuaderes E, Khan MM, Azzarello J, Lamb W. Reliability and limitations of the durometer and pressureStat to measure plantar foot characteristics in native Americans with diabetes. *J Nurs Meas*. 2009;17:3–18.
- Choh CTP, Wall ML, Brown MD, Nicholson A, Simms H. Use of durometry in assessment of venous disease. *Phlebology*. 2010;25:94–99.
- Moon KW, Song R, Kim JH, Lee E, Lee E, Song Y. The correlation between durometer score and modified Rodnan skin score in systemic sclerosis. *Rheumatol Int*. 2012;32:2465–2470.
- van der Wal M, Bloemen M, Verhaegen P, et al. Objective color measurements: clinimetric performance of three devices on normal skin and scar tissue. *J Burn Care Res*. 2013;34:e187–94.
- Beausang E, Floyd H, Dunn KW, Orton C, Ferguson M. A new quantitative scale for clinical scar assessment. *Plast Reconstr Surg*. 1998;102:1954–1961.
- Draaijers LJ, Tempelman FRH, Botman YAM, et al. The Patient and observer scar assessment scale: a reliable and feasible tool for scar evaluation. *Plast Reconstr Surg*. 2004;113:1960–1965.
- Van De Kar AL, Corion LUM, Smeulders MJC, Draaijers L, Horst C, Zuljen P. Reliable and feasible evaluation of linear scars by the patient and observer scar assessment scale. *Plast Reconstr Surg*. 2005;116:514–522.

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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