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ORIGINAL ARTICLE

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Baseline incision characteristics and early scar maturation indices following cardiac device implantation

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Abstract

Aims: Dermatologic evaluation for cardiac implantable electronic devices (CIEDs) has not been established. We sought to ascertain baseline wound scar features using quantifiable surgical tools and scar scales on post-CIED patients.

Methods: A single-center, prospective observational case-control study was performed where 92 study subjects (40 healthy volunteers and 52 post-CIED patients) completed the study. Durometer was used to quantify skin pliability before CIED placement, postprocedure, and 2 weeks postprocedure. Higher durometer readings signified reduced skin pliability. Durometer readings were compared to the patients' contralateral pectoral skin and to a healthy volunteer's cohort skin within the prepectoral region. Patient wounds were observed and graded using the Patient Observer Scar Assessment Scale (POSAS) and Manchester Scar Scale (MSS).

Results: Baseline pectoral skin pliability readings were similar in healthy volunteers and CIED patient population. In comparison to preprocedural measurements, surgical site skin pliability decreased in postprocedural and 2 weeks follow-up time points (*P*-value .004 and <.001, respectively). The increases in durometer readings were higher in the older population (age >75 over time, $P = .008$). POSAS evaluations showed on average a thin painless hypopigmented scar with moderate stiffness. MSS scar evaluation showed a palpable scar with slight contour differences and color mismatch and appeared to be slightly better in the African American population. There was no difference in scar characteristics with preprocedural use of antiplatelet or anticoagulation or staple closure or gender.

Conclusions: Serial measurements could be of value for development of new strategies for cosmesis and improved wound healing.

KEYWORDS

cardiac implantable devices, durometer measurements, incision characteristics, scar healing, skin thickness, wound complications

1 | INTRODUCTION

Cardiac implantable electronic devices (CIEDs) are frequently used with over 1.2 million pacemakers and 400 000 defibrillators implanted annually. The implantation of these devices, however, are accompanied with a risk of possible complications, such as wound infections, patient perceived nuisance issues related to visible scars, and pocket hematomas.[1,2] Wound healing and scar appearance are influenced by a number of factors including patient age, site of incision, direction of the incision, and the tension across the scar.[3] Of the various scar assessment tools currently available, the durometer is a well-validated instrument.[4] Durometers are handheld devices used to determine skin pliability by measuring the skin's compliance to a compressible pin within the device with readouts in standardized durometer units.[5] The objective of this study is to record and evaluate the process of early scar maturation during surgical wound healing following implantation of cardiac devices using objective and subjective scale assessments. To our knowledge, an objective assessment of wound healing post cardiac implantable device implants has not been systematically studied.

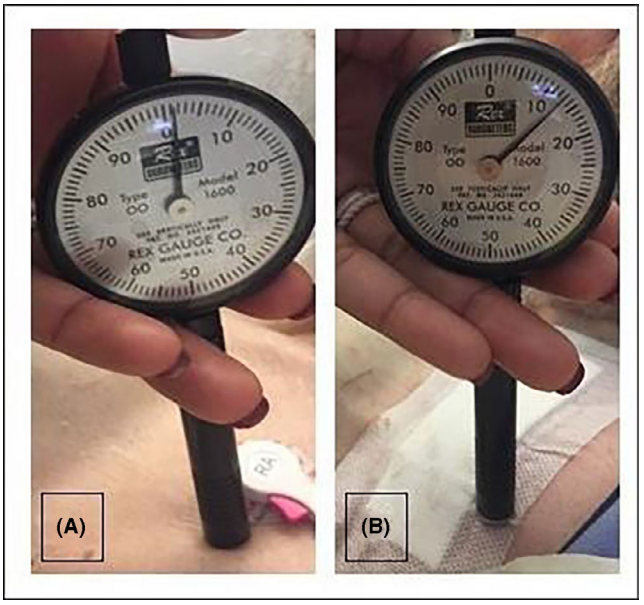


FIGURE 1 Skin pliability measurement method. A, Preprocedural skin thickness assessment in a patient. B, Postprocedural skin thickness assessment in a patient

2 | METHODS

This study was part of a prospective observational study, approved by the Institutional Review Board for Health Sciences Research at the University of Virginia (UVA). Written informed consent was obtained from all patients.

2.1 | Patient selection

Patients undergoing cardiac implantable device implantation procedures at UVA were screened for inclusion. Exclusion criteria included pediatric patients (under 18 years of age), pregnant patients, patients undergoing lead extraction, and implantable loop recorder implants. After the appropriate screening, informed consent was obtained. Device implantation and closure were performed based on physician's discretion.

2.2 | Implant site assessment

Prior to the procedure, study investigators used the Model 1600 Type OO Dial durometer (Rex Gauge) to measure skin pliability at three sites in the quadrant of the planned implantation and contralateral nonsurgical site (Figure 1). The durometer was placed perpendicular on the site of interest and the readout was in standard Shore durometer units based upon indentation of the mechanical pin. Higher durometer readings are suggestive of less pliability and more fibrosis. On the postprocedure day, durometer measurements were taken at the implant site and at the contralateral site. The measurement was obtained over the thinnest part of the Primapore dressing (Smith+Nephew) or Aquacel (ConvaTec). Management of the implant site was left to the discretion of the implanting physician. Routine 2 week shoulder restriction was advised. At the 2 week postprocedure visit, durometer measurements were repeated, surgical site was photographed to allow for scar evaluation using Manchester Scar Scale (MSS), and patient survey component of Patient and Observer Assessment Scale (POSAS) was completed. Clinical follow-up information was collected from chart review of medical records.

2.3 | Data analysis

Three durometer readings of each site obtained were averaged for each clinical assessment. An experienced plastic surgeon subsequently evaluated the surgical site photographs to complete POSAS and MSS 2 weeks postprocedure. These data were compared to those of 40 healthy volunteers, who served as controls. Control patients had durometer measurements obtained over left and right prepectoral regions with similar assessment as patients. Durometer readings obtained from healthy volunteers and patients were described as mean ± SD. Baseline durometer readings from healthy volunteers and CIED patients were compared using an unpaired two-tailed *t* test. Postprocedure and 2 week postprocedure durometer readings were compared to contralateral readings for their respective time point using a paired two-tailed *t* test. In the patient population, one-way ANOVA was used to assess change in durometer readout over study duration. Scar assessment results were

presented as descriptive measures of scar quality after CIED placement. Linear regression models to assess the impact of gender, race, age, and type of device on durometer, MSS, and POSAS readings were performed. SAS software was used for performing statistical analysis (Version 9.4 SAS Institute Inc.).

3 | RESULTS

3.1 | Demographics of the study subjects and control population

Fifty-two patients undergoing initial CIED placement were enrolled and successfully completed the study. The average age was 67 ± 14 years, 14 (26.9%) were female, and 38 (73.1%) were male. Their clinical demographics are listed in Table 1. Of the patients, 63.5% (n = 33) were elective outpatients. Eight patients were admitted with heart failure diagnosis but device procedures were performed when they were close to euvolemia. There was no difference in durometer readings in patients with heart failure versus the rest of the cohort. Forty-nine patients were alive at the end of the study. There were two noncardiac causes and one unidentified cause of death. Five patients had hematomas, which were conservatively managed with one patient requiring blood transfusion for venous access site bleeding during the procedure. There were no extractions during the follow-up period. One patient underwent device revision for threatened erosion 26 months following implantation. Another patient underwent dual chamber upgrade for symptomatic bradycardia. Staples were used in nine patients for closure. There was no difference in durometer readings in patients with heart failure versus the rest of the cohort. There was no difference in the durometer readings in patients on antiplatelet (35 patients) and anticoagulant (22 patients) agents or a combination of antiplatelet and anticoagulant regimen[10] compared to the rest of the cohort. Forty healthy volunteers with no known cardiac history were included as a control group. The average age was 21.9 ± 6.77 years, 16 (40%) were female, and 24 (60%) were male.

TABLE 1 Baseline patient demographics and device characteristics, POSAS, and MSS evaluations.

Age	67.23 ± 14.58
Sex (female)	14
Race (African American)	9
Preprocedure creatinine	1.21 ± 0.47
Immunosuppression use	4
Generator change procedures	11
Staples	9
Device hematoma	5
Device revision	1
DM	20
HTN	52
Antiplatelets	20
NOAC	7
Warfarin	16
MSS	8 ± 2
POSAS	18 ± 9
Death	3

Abbreviations: DM, Diabetes; HTN, hypertension; MSS, Manchester Scar Scale; NOAC, new oral anticoagulant agent; POSAS, Patient Observer Scar Assessment Scale.

3.2 | Durometer readings in patients and healthy volunteers were similar

Preoperative readings in patients at both surgical and contralateral sites were 5.4 ± 2.6 and 5.6 ± 3.1, respectively. As shown in Figure 2, these were comparable to readings in healthy controls (5.6 ± 0.6 and 5.6 ± 0.5, P = NS).

3.3 | Postprocedure skin pliability at the surgical and contralateral sites was higher than preprocedure readings

Durometer readings increased postoperatively for both the surgical and contralateral sites. At the surgical sites, the mean durometer reading 1 day postprocedure was 7.5 ± 4, which was significantly higher than the preoperative mean durometer reading (5.4 ± 2.6; P = .0031). Similarly, skin pliability of the contralateral site (durometer reading of 5.6 ± 3.1) was also higher on the postoperative day relative to the preoperative measurement (7.3 ± 3.2; P = .0004).

3.4 | Two week durometer readings were significantly higher for the surgical site

While surgical site and nonsurgical site durometer readings were similar at the preoperative and immediate postoperative assessments,

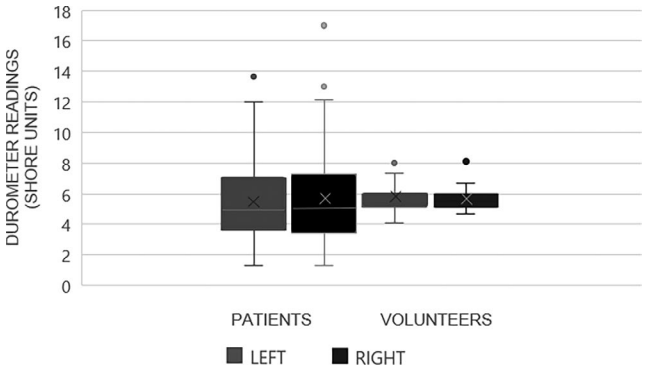


FIGURE 2 Baseline skin pliability (Shore units). There was no difference between skin pliability in healthy controls and patients in both left and right sites, all $P > .05$

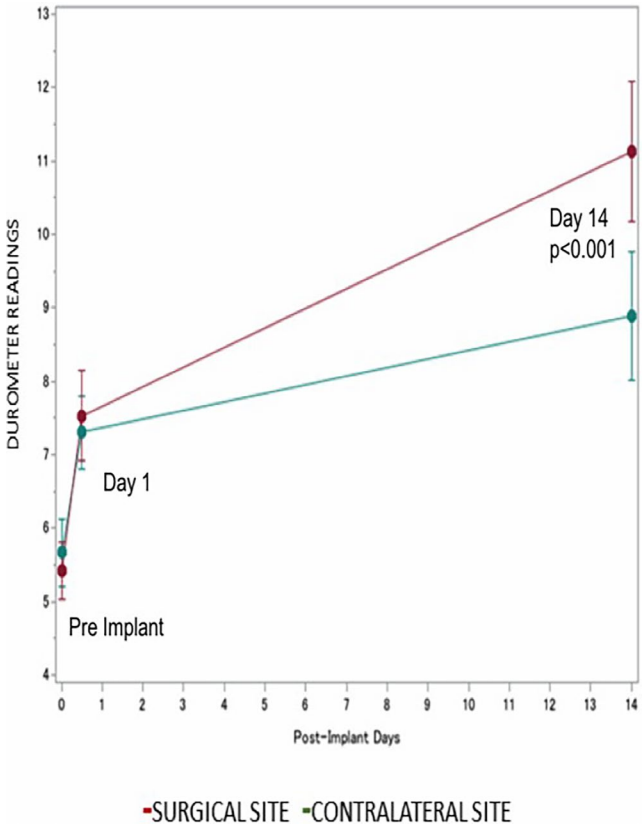


FIGURE 3 Skin pliability changes during early scar maturation—Durometer readings (Shore Units) over the study duration. There was significant increase in skin pliability in surgical site during 14 d postimplantation. At 1-d postimplantation, skin pliability was higher than preimplantation, $P = .0031$. At 14 d postimplantation, durometer readings were significantly higher than 1-d postimplantation. Skin pliability of contralateral site increased significantly from preimplantation to 1-d postimplantation, $P = .0004$. In contrast, durometer readings of contralateral site were similar between 1-d postimplantation and 14 d postimplantation. At 14 d postimplantation, skin pliability was higher at the surgical site compared with the contralateral side ($P < .001$).

2 week durometer readings were significantly higher on the surgical side compared with the nonsurgical side ($P < .001$). The mean durometer readings with standard deviation bars for all three time points are shown in Figure 3.

3.5 | Patients over 75 years of age had higher durometer readings than patients under 75 years of age

The linear trends for durometer readings including means and standard error bars in patients younger than and patients over 75 years are shown in Figure 4 for both the nonsurgical (contralateral) side (A) and surgical side (B). Based on a linear mixed regression model, on the nonsurgical side, durometer readings were higher overall in patients over 75 years of age, ($P = .008$). The interaction term for time and age was not statistically significant ($P = .34$). Other covariates,

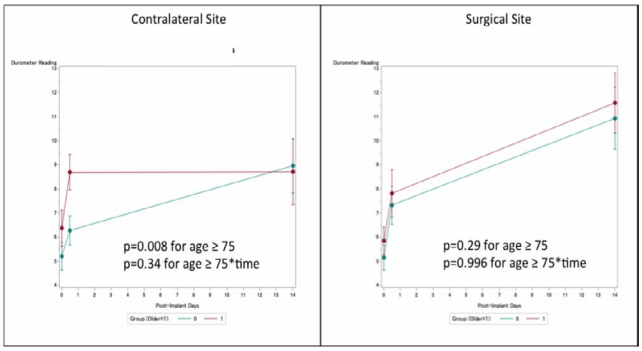


FIGURE 4 Age group comparison in patient cohort—Durometer readings (Shore units) during early scar formation. A, Durometer readings in contralateral site during 14 d postimplantation. In patient population older than 75 y old, durometer readings were higher than in younger population, $P = .008$. B: Durometer readings in surgical site during 14 d postimplantation. There was no significant difference in skin pliability of surgical site between age groups in patient cohort, $P > .05$.

such as sex, race, and type of device, were not significantly associated with higher durometer readings ($P = .008$).

3.6 | Patient perception and surgical scar scale evaluation at follow-up

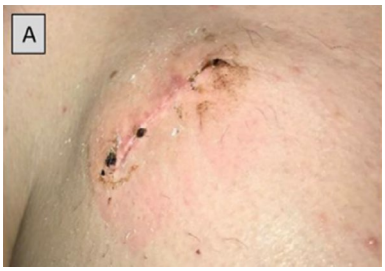
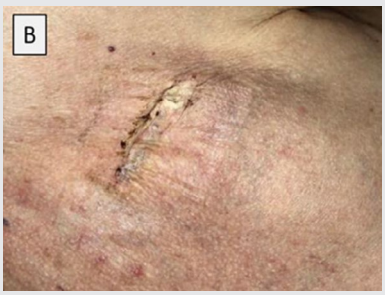
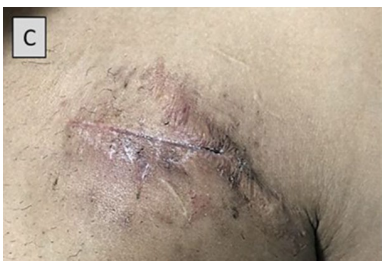
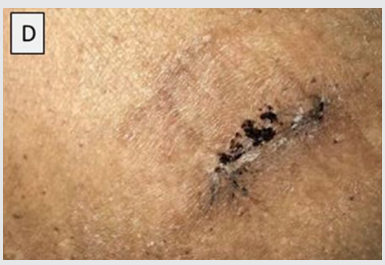
The POSAS and MSS values of all CIED patients were adjudicated by a blinded plastic surgeon (Table 1). The mean total POSAS and MSS scores were 20 ± 8.5 and 9.2 ± 2.5, respectively. At 2 weeks, the POSAS evaluations most often showed a thin painless hypopigmented scar but had moderate stiffness. The 2 week MSS scar evaluation most often showed a palpable matte scar with distortion and slight color mismatch. There was no correlation with gender, antiplatelet, anticoagulation regimen, hematoma, or type of device closure with the MSS and POSAS scores. Patients of African American race had a trend for better scar healing by MSS after adjustment for age ($P = .06$). Representative scars are shown in Table 2.

4 | DISCUSSION

4.1 | Our study identified the following major findings

Healthy control infraclavicular skin thickness and patient preprocedure readings were equivalent showing no difference in these subject populations. Durometer readings at the surgical site were higher postprocedure as early as 1 day after CIED placement and persisted until the 2 week time point. POSAS and MSS were able to quantify scar characteristics for post-CIED wounds showing stiff scars with mild contour differences but otherwise thin hypopigmented scars without pruritus or discomfort. To our knowledge, there have been

TABLE 2 Representative photographs—scars with the corresponding MSS and POSAS scores. (A) MSS—7, POSAS—13. (B) MSS—6, POSAS—14. (C) MSS—11, POSAS– 57. (D) MSS—5, POSAS—4

	MSS	POSASObserver Component	POSAS Patient Component
	Color—2 Matte—1 Contour—1 Distortion—1 Texture—2	Vascularization—2 Pigmentation—1 Thickness—2 Relief—2	Painful—2 Itching—0 Color—2 Stiff—2 Thick—0 Irregular—0
	Color—1 Matte—1 Contour—1 Distortion—1 Texture—2	Vascularization—1 Pigmentation—3 Thickness—1 Relief—1	Painful—1 Itching—2 Color—1 Stiff—2 Thick—1 Irregular—1
	Color—3 Shiny—2 Contour—2 Distortion—2 Texture—2	Vascularization—2 Pigmentation—5 Thickness—2 Relief—2	Painful—8 Itching—10 Color—7 Stiff—9 Thick—10 Irregular—2
	Color—1 Matte—1 Contour—1 Distortion—1 Texture—1	Vascularization—1 Pigmentation—1 Thickness—1 Relief—1	Painful—0 Itching—0 Color—0 Stiff—0 Thick—0 Irregular—0

Abbreviations: MSS, Manchester Scar Scale; POSAS, Patient Observer Scar Assessment Scale.

no studies to evaluate wounds after initial CIED implantation in the acute postoperative phase.

Despite known risk of hematomas, device erosions, and psychological concerns, there is currently no standard process for wound healing assessment after cardiac device implantation aside from manual palpation and visual assessment.[6,7,8,9,10] The durometer applies a vertically directed indentation load on the scar to measure tissue firmness. It has been reported throughout the literature that the durometer is a highly reliable, convenient, and painless method of measuring skin pliability with increasing numbers reflecting reduced skin pliability.[11,12,13]

Although the healthy volunteers were younger, the durometer readings were comparable to patient baseline readings and each patient served as their own control with measurements from their contralateral site. These baseline values were similar to those in the study evaluating anterior chest wall skin thickness in nonscar regions of patients with keloid scars prior to surgical excision and radiation therapy (5.5 ± 1.6).[14] For follow-up, we utilized the 2 week time point, as we are a tertiary referral center. Patients are often discharged to their local clinics after the 2 week follow-up. Also, in the light of the recent COVID-19 epidemic, virtual visits were performed for a subset of our population where durometer readings were not obtainable. [15]

The follow-up readings are consistent with other studies that have shown increased durometer readings for subacute to chronic wounds.[14,16] Interestingly, the durometer values increased from preprocedure to postprocedure for both sites. While this is an intriguing observation for the contralateral site, we can speculate that being in fasting for the procedure could reflect on reduced skin pliability which improves with hydration during and following

the procedure and then normalizes to values at the 2 week follow-up. Another mechanistic explanation would be that fluid administration during the procedure with inability to recalibrate in a short time span with recumbent patient position could contribute to higher levels. This is supported by using the control site for each patient as the contralateral infraclavicular site, which also registered higher postoperative values and supports the edema hypothesis. Whether it is one of these mechanisms would be best understood by a preprocedure measurement when the patient is not fasting.

While the surgical site values followed a similar trajectory, the surgical site values were significantly higher at the 2 week time point suggestive of independent scar healing mechanisms. Consistent with prior studies, we noted that older age correlated with higher durometer readings.[17] Of the available surgical scales, the POSAS and MSS scar scales were selected for their demonstrated interobserver reliability and validity across multiple scar evaluation studies.[16,18]

The POSAS has been demonstrated to accurately capture the patient experience and is the most widely used assessment of patient satisfaction with scar quality.[19,20] There was no significant correlation with the type of closure, use of antiplatelet, or anticoagulation regimen. We had very few hematomas, which were minor. Surprisingly, AA patients had a lower MSS score but this could be from the young African Americans (AA) population in our cohort. This has not been previously reported.

Given the significant volume of CIED growth and need for generator change procedures, the implications of scar development and healing are of importance in this population. From a clinical standpoint, this represents a proof of concept trial to demonstrate ease and reliability of scar assessment in the CIED population. To routinely utilize these techniques would be burdensome to a busy clinic workflow. But these assessment mechanisms could be of value for the role of early detection of pocket hematomas, pocket infections, or threatened erosions. In addition, as surgical techniques evolve for CIED implantations and with the advent of pocket scaffolds/antibiotic pouches, systematic scar assessment would be a promising modality to ascertain efficacy of new technologies. We would recommend establishing baseline metrics for a given patient population, as our experience in Virginia may not mirror other sites.

4.2 | Limitations

This was a small prospective study but larger numbers in a more diverse setting could add further value. Also to understand the increase in durometer readings in bilateral sites, obtaining outpatient preprocedure values would assist in elucidating the mechanism for this observation. This was not possible given the different clinic sites where coordination was not possible for this study. But a larger study could address this limitation. Validation in other institutions would add scientific rigor to our initial observations.

5 | CONCLUSION

This study was a feasibility pilot trial to establish baseline objective and scale-based wound assessment after cardiac device implantation. These baseline values could be beneficial in determining how to optimize wound healing in this population. Early detection of elevated durometer values concerning for wound complications could allow for early identification of abnormal wound healing, pocket hematomas, or infections.

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CONFLICT OF INTEREST

The authors declare no conflict of interest for this manuscript. Dr Mehta has received honoraria from Medtronic and Abbott Medical. Dr Mason is a consultant for Medtronic and receives research support from Medtronic, Boston Scientific, and Cook. Dr. Haines has received honoraria from Biosense Webster, Farapulse, and Sagentia, and is a consultant for Affera, Boston Scientific, Integer, Medtronic, Philips Healthcare, and Zoll corporations. Dr Bilchick has NIH and AHA research grants and industry grants from Medtronic and Siemens Healthineers.

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