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Akinori Sairaku

r.jrgw059@ybb.ne.jp

National Hospital Organization Higashihiroshima Medical Center

Yukihiro Fukuda

National Hospital Organization Higashihiroshima Medical Center

Yukiko Nakano

Hiroshima University Graduate School of Biomedical and Health Sciences

Article

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Posted Date: October 26th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-9759460/v1>

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Additional Declarations: No competing interests reported.

**Compression Performance of a Novel Leaf-Spring Pocket Compression Device: A Randomized
Crossover Evaluation**

Akinori Sairaku^{1,2}, Yukihiro Fukuda¹, Yukiko Nakano²

¹Department of Cardiology, National Hospital Organization Higashihiroshima Medical Center,
Higashihiroshima, Japan

²Department of Cardiovascular Medicine, Hiroshima University Graduate School of Biomedical and
Health Sciences, Hiroshima, Japan

Corresponding Author: Akinori Sairaku

Department of Cardiology, National Hospital Organization Higashihiroshima Medical Center

513 Jike, Saijo-cho, Higashihiroshima, Japan

E-mail: rjrgw059@ybb.ne.jp

Abstract

Pocket compression is routinely applied after cardiac implantable electronic device procedures to reduce hematoma formation, but conventional compression bandaging has important limitations, including positional instability of pressure and patient discomfort. We developed a novel leaf-spring pocket compression device designed to provide stable, localized compression. This study was conducted as a preparatory performance evaluation prior to a planned multicenter randomized controlled trial (jRCTs042250188). In this randomized crossover study, 33 healthy male volunteers underwent pressure assessment with both the leaf-spring device and conventional compression bandaging across six clinically relevant body positions. The target compression pressure range was predefined as 8–32 mmHg on physiological grounds. The number of body positions in which compression pressure fell within the target range was higher with the leaf-spring device than with conventional compression bandaging (5 [4–6] vs. 4 [3–5] per participant, $P=0.005$). Pressure variability across body positions was smaller with the leaf-spring device ($P<0.001$), and comfort scores were higher (5 [4–5] vs. 3 [2–4], $P<0.001$). No clinically significant skin complications were observed. These findings demonstrate that the leaf-spring device provided more stable and physiologically appropriate compression than conventional compression bandaging while improving comfort, supporting further clinical evaluation in patients undergoing cardiac device implantation.

Keywords: pacemaker implantation, pocket hematoma, compression bandaging, leaf-spring device

Introduction

Pocket hematoma remains a frequent early complication after transvenous pacemaker implantation and is a well-recognized risk factor for subsequent device infection [1]. Although local compression of the device pocket for 24–48 hours is routinely employed to reduce this risk [2], the conventional approach using gauze and elastic tape is inherently limited by positional variability in applied pressure, inconsistent compression, and patient discomfort [3].

To overcome these limitations, we developed a novel leaf-spring–based pocket compression device that delivers localized pressure through elastic force, without reliance on circumferential thoracic constriction. This design is intended to provide more stable and physiologically appropriate compression while improving tolerability.

Before patient-based clinical evaluation of a novel compression device, verification of basic compression performance under clinically relevant conditions is an important preparatory step in device development. The present study was therefore undertaken to characterize the fundamental

compression performance of this device by quantifying compression pressure across clinically relevant body positions and assessing user-reported comfort. This preparatory performance evaluation was conducted prior to a planned multicenter randomized controlled trial (jRCTs042250188) designed to assess the clinical efficacy and safety of the device.

Methods

Study Design and Participants

This investigator-initiated preparatory performance evaluation study was conducted at the National Hospital Organization Higashihiroshima Medical Center to evaluate a novel leaf-spring–based pocket compression device prior to its clinical application. Healthy male volunteers 18 years of age or older were eligible for enrollment. Exclusion criteria included allergy to adhesive materials or polyurethane, fragile skin, marked kyphosis, and body weight greater than 120 kg. The study protocol was approved by the institutional review board of the participating center (approval No. 2025-62), was registered in the UMIN Clinical Trials Registry (trial ID: UMIN000061249; registered on April 14, 2026), and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained

from all participants.

Compression Methods

The core component of the device is a steel leaf spring measuring 365 mm in length, 12 mm in width, 0.8 mm in thickness, and 55 mm in radius, with an adjuster attached to its anterior end. Circular front and rear pads are connected to the anterior and posterior ends of the spring, respectively. Each pad consists of a circular rubber disk 7 cm in diameter and 5 mm in thickness, lined on its inner surface with a polyurethane gel sheet of identical size and thickness. Together, these components constitute the main body of the device, which has a headphone-like configuration. An auxiliary woven elastic band, 15 mm in width and equipped with an adjustable buckle, is used to secure the device to the chest wall (Figure 1).

The compression bandage consisted of a pancake-shaped gauze pad, 8 cm in diameter, prepared from seven 10-by-10-cm gauze sheets, and 5-cm-wide adhesive tape.

Study Procedures

Participants were randomly assigned in a 1:1 ratio by sealed-envelope allocation to either a leaf-

spring–first sequence or a bandage–first sequence. Sealed envelopes were opened only after participant enrollment. In the leaf-spring–first sequence, pressure assessment was performed first with the leaf-spring device and then with the compression bandage. In the bandage–first sequence, the order was reversed. This crossover design was adopted to permit within-subject comparison while minimizing potential order-related bias, particularly in the subsequent comfort assessment (Figure 2).

For all measurements, participants lay supine with the upper body unclothed. The usual site of left infraclavicular pacemaker pocket creation was marked, and a pressure-sensor sheet (Palm Q®) was placed over the marked site with its center aligned to the presumed pocket center. For assessment with the leaf-spring device, the front pad was positioned over the sensor sheet, the device was mounted so that the chest wall was sandwiched between the front and rear pads, and the auxiliary elastic band was passed beneath both axillae and secured around the chest. For assessment with the compression bandage, the gauze pad was placed over the center of the sensor sheet and was firmly fixed from the shoulder to the chest wall with three strips of adhesive tape (Figure 2).

Pressure measurements were then obtained in six predefined body positions: supine, left lateral, right lateral, sitting, chest extension, and slouching. In each position, pressure was measured three times, and the mean value was used for analysis. After completion of both compression assessments, all participants completed a comfort questionnaire using a 5-point Likert scale ranging from 1 to 5, with 1 indicating extreme discomfort and 5 indicating no discomfort [4]. Skin findings, including redness,

were also evaluated. Because of the nature of the interventions, blinding of participants and investigators was not performed.

The target compression pressure range was defined as 8–32 mmHg on physiological grounds. The lower bound was derived from the mean inferior vena cava pressure of approximately 8 mmHg in the supine position, as reported in our previous study [4], representing the minimum pressure required to achieve venous hemostasis. The upper bound corresponds to the conventional capillary perfusion threshold of approximately 32 mmHg, above which sustained external pressure may compromise microcirculatory flow and increase the risk of tissue ischemia [5].

Outcome Measures

The study was designed to evaluate device performance characteristics rather than clinical outcomes such as pocket hematoma formation. Therefore, the predefined performance outcomes were pressure characteristics and participant-reported comfort. No important changes to the study protocol, predefined outcomes, or statistical analyses were made after study commencement.

Statistical Analysis

The target sample size was set at 30 participants; however, 33 participants were planned for inclusion to account for potential data loss or withdrawal. The sample size was determined pragmatically with reference to prior methodological guidance suggesting that 20 to 50 participants are generally sufficient for parametric analyses [6]. No interim analyses or stopping guidelines were prespecified because of the short-term exploratory nature of the study.

Continuous variables are presented as means $\pm$ standard deviations or medians with interquartile ranges, as appropriate.

Because all participants underwent both compression methods, comparisons between the leaf-spring device and compression bandage were performed using paired analyses: paired t-tests for normally distributed variables and the Wilcoxon signed-rank test for non-normally distributed variables.

To evaluate the effects of body position and compression method on pressure, a repeated-measures analysis of variance with both factors as within-subject variables was performed.

Inter-sequence comparisons were performed using the Student's t-test for normally distributed variables and the Mann–Whitney U test for non-normally distributed variables, as appropriate.

All statistical analyses were performed using JMP software (SAS Institute, Cary, NC). A two-sided P value of less than 0.05 was considered to indicate statistical significance.

No additional subgroup or sensitivity analyses were planned.

Results

Participants

Between February 1 and February 28, 2026, 33 healthy male volunteers were enrolled. Age, body weight, height, and body mass index were 34 ± 9 years, 68.6 ± 10.3 kg, 170.4 ± 5 cm, and 23.6 ± 2.9 kg/m², respectively. Baseline characteristics were well balanced between the leaf-spring–first sequence (N=17) and the bandage-first sequence (N=16), with no significant differences in age, body weight, height, or body mass index. All randomized participants completed the study protocol and were included in the final analysis. No participants were excluded after randomization. No missing data were observed.

Compression Pressure and Variability

Across all measurements, compression pressure was significantly lower with the leaf-spring device than with the compression bandage (12.7 ± 5.4 mmHg vs. 26.8 ± 12.9 mmHg; $P<0.001$; Figure 3). The number of body positions in which the compression pressure fell within the target range was higher

with the leaf-spring device (5 [4–6] vs. 4 [3–5] per participant; $P=0.005$; Figure 4).

Variability in compression pressure across body positions was smaller with the leaf-spring device than with the compression bandage ($P<0.001$; Figure 5).

Comfort and Sequence Effects

Comfort scores were higher with the leaf-spring device than with the compression bandage (5 [4–5] vs. 3 [2–4]; $P<0.001$; Figure 6).

No significant differences were observed between the leaf-spring–first and bandage–first sequences in overall compression pressure across positions (19.8 ± 12.1 mmHg vs. 19.6 ± 12.2 mmHg; $P=0.85$) or in comfort scores (4.5 [2–5] vs. 4 [3–5]; $P=0.62$).

No clinically significant skin complications were identified.

Discussion

Principal findings

In this preparatory performance evaluation study, a leaf-spring–based pocket compression device provided more consistent compression than conventional bandaging across a range of body positions. The device more frequently maintained pressures within the predefined target range, exhibited less variability with postural changes, and was associated with greater comfort. No clinically significant skin complications were observed.

Mechanistic Rationale

We previously developed a leaf-spring–based hemostatic device for femoral venous access sites following atrial fibrillation ablation. In a randomized clinical trial, that device suppressed rebleeding without increasing adverse events and was associated with higher patient comfort than conventional compression bandaging [4]. The present device shares the same fundamental mechanism, in which elastic force generated by a leaf spring provides sustained local compression.

Comparison with Existing Compression Strategies

Several clinical studies have evaluated newly developed pocket compression devices in comparison with conventional bandaging [3, 7-9]. These devices, as well as standard compression bandaging,

share a common structural concept: circumferential compression of the thorax to generate pressure at the pocket site. In contrast, the present device uses the elastic force of a leaf spring as the primary source of compression. This design allows localized and stable pressure to be applied to the pocket site without constricting the entire thorax. This distinction is likely to account for the ability of the device to achieve compression within a physiologically appropriate range while maintaining a high level of user comfort.

Limitations of Conventional Bandaging

Compression pressure during the application of a conventional bandage is known to vary substantially with body position [3]. In addition, the elastic properties of gauze and adhesive tape may diminish over time, leading to progressive loosening. To compensate for this anticipated reduction in pressure, bandages may be applied more tightly than necessary. This practice may explain the excessively high pressures observed under certain conditions, such as chest extension or lateral positioning. Together with the circumferential constriction of the thorax and the discomfort associated with removal of adhesive tape, these factors likely contributed to the lower comfort observed with conventional bandaging.

Limitations

This study has several limitations. First, the study was intentionally designed as a preparatory performance evaluation rather than a patient outcome study. Accordingly, both compression methods were applied to healthy volunteers under controlled conditions for a limited duration, and clinical outcomes such as pocket hematoma formation were not evaluated. Second, the sample size was relatively small.

Conclusions

In this preparatory performance evaluation study, a leaf-spring–based pocket compression device achieved stable and physiologically appropriate compression across a range of body positions while improving participant-reported comfort compared with conventional bandaging. These findings suggest that a mechanism based on localized elastic force, rather than circumferential thoracic constriction, may offer a more consistent and tolerable approach to pocket compression. A multicenter randomized controlled trial (jRCTs042250188) is currently under preparation to evaluate the clinical efficacy and safety of this device in patients undergoing cardiac device implantation.

Declaration of Generative AI and AI-Assisted Technologies in the Writing Process

Generative artificial intelligence (ChatGPT, OpenAI) was used for language editing only.

Funding

This study received no specific funding.

Declaration of Competing Interest

All authors declare no conflicts of interest.

Data availability statement

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Author contributions

A.S. conceived the study, collected and analyzed the data, and drafted the manuscript. Y.F. and Y.N. supervised the study. All authors reviewed the manuscript.

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Figure



1a



1b

Figure 1. Leaf-Spring–Based Pocket Compression Device Applied to a Mannequin.

The device, which has a headphone-like configuration, is applied to the upper thorax, with the main body clamping the chest wall and the front pad positioned over the left infraclavicular region to deliver localized compression. An auxiliary elastic band encircling the thorax serves to stabilize the device and prevent cranial displacement (Panel A, anterior view; Panel B, lateral view).

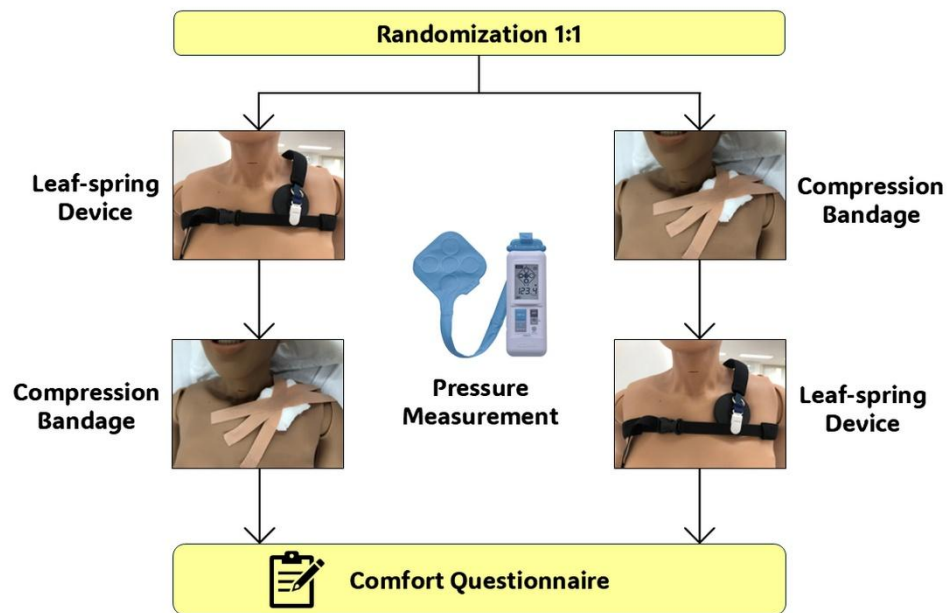


Figure 2. Study Flow Diagram.

Participants were randomly assigned in a 1:1 ratio to either the leaf-spring–first sequence followed by compression bandaging or the reverse sequence. Compression pressure was measured using a portable pressure-sensing system (Palm Q[®]), as shown in the center panel. After completion of both compression assessments, all participants completed a comfort questionnaire.

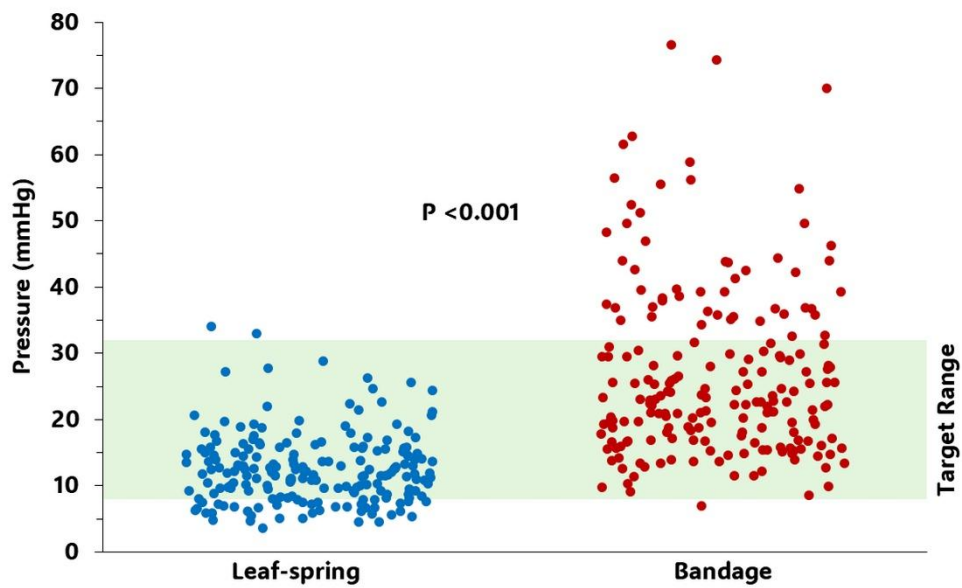


Figure 3. Distribution of All Measured Compression Pressures.

Each point represents an individual pressure measurement obtained with the leaf-spring device or compression bandaging. The light green shaded area indicates the predefined target compression pressure range (8–32 mmHg).

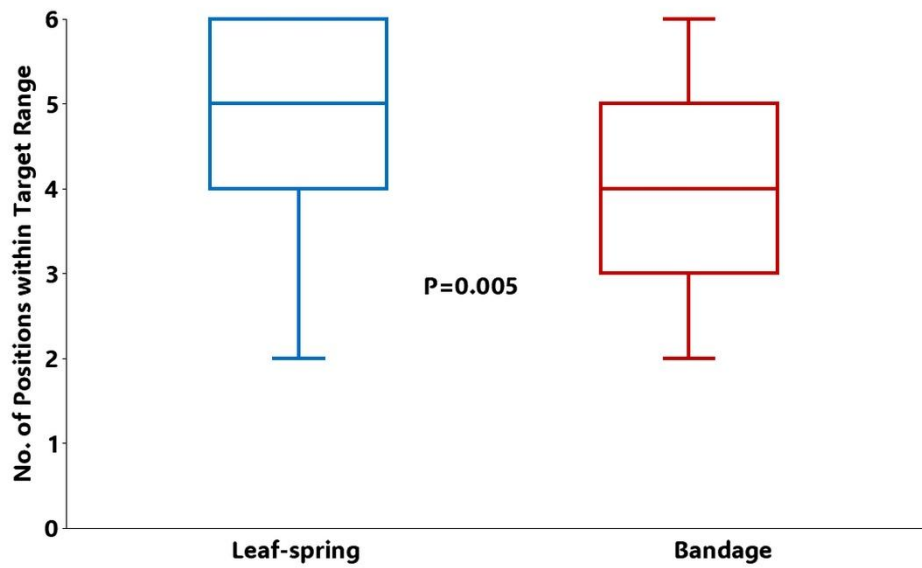


Figure 4. Number of Body Positions within the Target Compression Pressure Range per Participant.

The number of body positions (out of six) in which the measured compression pressure fell within the predefined target range (8–32 mmHg) is shown for each compression method. Boxes indicate medians and interquartile ranges.



Figure 5. Compression Pressure According to Body Position.

Compression pressures measured with the leaf-spring device and compression bandaging are shown across six body positions: supine, left lateral, right lateral, sitting, chest extension, and slouching.

Points indicate mean values. Error bars represent standard deviations, shown in the positive direction for compression bandaging and in the negative direction for the leaf-spring device.

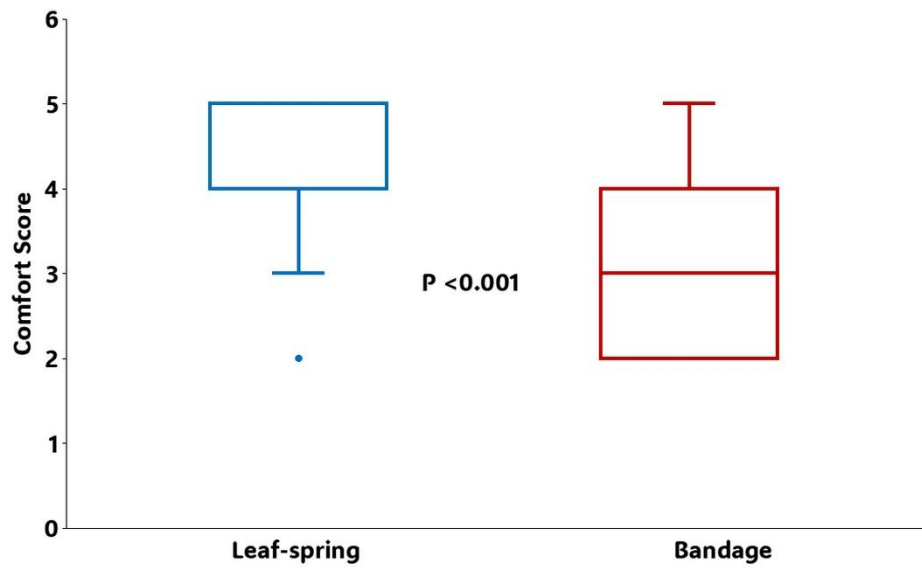


Figure 6. Participant-Reported Comfort Scores.

Comfort scores for the leaf-spring device and compression bandaging are shown. Boxes indicate medians and interquartile ranges.