Implantation of the Subcutaneous Implantable Cardioverter-Defibrillator
An Evaluation of 4 Implantation Techniques

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Background—Alternative techniques to the traditional 3-incision subcutaneous implantation of the subcutaneous implantable cardioverter-defibrillator may offer procedural and cosmetic advantages. We evaluate 4 different implant techniques of the subcutaneous implantable cardioverter-defibrillator.

Methods and Results—Patients implanted with subcutaneous implantable cardioverter-defibrillators from 2 hospitals between 2009 and 2016 were included. Four implantation techniques were used depending on physician preference and patient characteristics. The 2- and 3-incision techniques both place the pulse generator subcutaneously, but the 2-incision technique omits the superior parasternal incision for lead positioning. Submuscular implantation places the pulse generator underneath the serratus anterior muscle and subfascial implantation underneath the fascial layer on the anterior side of the serratus anterior muscle. Reported outcomes include perioperative parameters, defibrillation testing, and clinical follow-up. A total of 246 patients were included with a median age of 47 years and 37% female. Fifty-four patients were implanted with the 3-incision technique, 118 with the 2-incision technique, 38 with submuscular, and 37 with subfascial. Defibrillation test efficacy and shock lead impedance during testing did not differ among the groups; respectively, P=0.46 and P=0.18. The 2-incision technique resulted in the shortest procedure duration and time-to-hospital discharge compared with the other techniques (P<0.001). A total of 18 complications occurred, but there were no significant differences between the groups (P=0.21). All infections occurred in subcutaneous implants (3-incision, n=3; 2-incision, n=4). In the 2-incision group, there were no lead displacements.

Conclusions—The presented implantation techniques are feasible alternatives to the standard 3-incision subcutaneous implantation, and the 2-incision technique resulted in shortest procedure duration. (Circ Arrhythm Electrophysiol. 2017;10:e004663. DOI: 10.1161/CIRCEP.116.004663.)

Key Words: implantable cardioverter-defibrillator | implantation | implantation technique | subcutaneous implantable cardioverter-defibrillator | ventricular arrhythmia
Subpectoral implantation of conventional transvenous pacemakers and ICDs has been described in patients with low body mass indexes or prior noninfectious pocket complications. Subpectorally implanted leads were excluded.8-10

Herein, we provide a hands-on description of 4 implantation techniques of the S-ICD and subsequently evaluate these 4 techniques for periprocedural outcomes and clinical follow-up.

Methods

Study Design and Population
We conducted a retrospective cohort study between February 2009 and May 2016. Consecutive patients implanted with the S-ICD were included from 2 hospitals, the Academic Medical Center, Amsterdam, The Netherlands, and Mount Sinai Hospital, New York, United States. However, all patients participating in the ongoing PRAETORIAN trial (A Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter-Defibrillator Therapy; NCT01296022) at both centers were excluded.8 Physician preference and patient characteristics determined the implant technique used.

For example, in some patients with a slim posture, the pulse generator was implanted submuscular to reduce mechanical stress on the skin covering the pocket. The need for informed consent was waived by the institutional review boards because of the observational and retrospective nature of the study. Written permission from patients was obtained for the use of photographs presented in this article.

Hands-On Description of 4 Implantation Techniques
The 4 implantation techniques differed in how the pulse generator and the lead are implanted. Below we first describe 3 implantation techniques of the pulse generator and subsequently 2 methods to implant the lead. The techniques used for implantation of the pulse generator and lead can obviously be combined according to implanting physicians’ preference and experience.

WHAT IS KNOWN

• Alternative implant techniques to the standard 3-incision implantation of the subcutaneous implantable cardioverter-defibrillator may offer procedural and cosmetic advantages, but safety and outcomes data are lacking.
• The alternative implantation techniques include the 2-incision technique, which omits the superior para-sternal incision, and implantation of the pulse generator underneath the anterior fascia of, or entirely underneath, the serratus anterior muscle.

WHAT THE STUDY ADDS

• In this cohort, there were no differences between the 4 evaluated implantation techniques in clinical outcomes, such as shock efficacy and complications.
• In patients implanted with the 2-incision technique, there were no lead dislocations during prolonged follow-up, and the procedure duration was shorter than the other implant techniques used.
• Subfascial implantation of the pulse generator resulted in similar operative and cosmetic advantages but less postprocedural pain than submuscular implantation. Therefore, the use of the submuscular technique may be limited to patients prone to or with previous pocket complications.

Subpectoral implantation refers to positioning the pulse generator underneath the SAM. The objective of this deeper position is to cover the pulse generator with muscle tissue to prevent pocket complications, such as erosion because of excessive mechanical stress and to improve the cosmetic result. The pocket incision is made in identical position as for a subcutaneous pocket, and the subcutaneous tissue is dissected down to the fascia. From there, the fascia between the third and fourth slip of the SAM is dissected in line with the muscle fiber direction toward the scapula (Figure 1). The submuscular pocket is created using blunt dissection. When the fascia between the muscle slips is dissected, attention should be paid to the long thoracic nerve. The SAM is innervated by the long thoracic nerve, which originates from the brachial plexus and travels inferiorly on the anterior surface of the muscle. Nerve and muscle integrity is critical for shoulder function. When the pulse generator and lead are inserted in the pocket, the muscle slips are sutured to close the submuscular pocket and subsequently the subcutaneous tissue and skin. Figure 2 presents an anatomic illustration of the submuscular pulse generator. We recommend to perform this technique initially under the supervision of an operator with experience in this anatomic location.

Traditional Subcutaneous Pocket
An incision is made along the inframammary crease, just above the anticipated position of the pulse generator, to avoid postprocedural mechanical stress on the wound. From the incision, the subcutaneous tissue must be dissected directly down to the muscular fascia. From there, the contour of the chest wall is followed to create the pocket, and hemostasis is ensured. The exact anatomic plane of the pocket depends on the size and position of the latissimus dorsi muscle: in patients with a more prominent latissimus dorsi, the muscle will partly cover the pulse generator. The inferior margin of the pulse generator is parallel to xiphoid or slightly more cranial and centered on the midaxillary line. When the pulse generator is inserted in the pocket, there is ideally some residual space in the pocket to reduce mechanical stress on the incision wound.

Submuscular Pocket
Submuscular implantation refers to positioning the pulse generator underneath the SAM. The objective of this deeper position is to cover the pulse generator with muscle tissue to prevent pocket complications, such as erosion because of excessive mechanical stress and to improve the cosmetic result. The pocket incision is made in identical position as for a subcutaneous pocket, and the subcutaneous tissue is dissected down to the fascia. From there, the fascia between the third and fourth slip of the SAM is dissected in line with the muscle fiber direction toward the scapula (Figure 1). The submuscular pocket is created using blunt dissection. When the fascia between the muscle slips is dissected, attention should be paid to the long thoracic nerve. The SAM is innervated by the long thoracic nerve, which originates from the brachial plexus and travels inferiorly on the anterior surface of the muscle. Nerve and muscle integrity is critical for shoulder function. When the pulse generator and lead are inserted in the pocket, the muscle slips are sutured to close the submuscular pocket and subsequently the subcutaneous tissue and skin. Figure 2 presents an anatomic illustration of the submuscular pulse generator. We recommend to perform this technique initially under the supervision of an operator with experience in this anatomic location.
Subfascial Pocket
Subfascial implantation positions the pulse generator underneath the fascial layer on the anterior side of the SAM. The fascial layer is ≈5 to 10 mm thick (Figure 3). For this implantation technique, the incision is also made in the inframammary crease. The subcutaneous tissue is dissected down to the fascia of the SAM. In similar direction as the cutaneous incision, the fascia is opened and with blunt dissection a pocket is formed (Figure 4). When the pulse generator has been placed in the subfascial pocket, the fascia, the subcutaneous tissue, and the skin are closed in 3 layers.

Traditional 3-Incision Lead Implantation
To implant the sensing and defibrillation lead of the S-ICD, an incision is made at the xiphoid and the tissue is dissected down to the fascia. Tunneling from the xiphoid incision to the lateral pocket is done with the electrode insertion tool (EIT). The electrode is sutured to the EIT and is pulled back through the tunnel to the xiphoid incision. A suture sleeve is placed over the electrode shaft 1 cm below the proximal sensing electrode and sutured to the fascia. Then a third incision is made at the manubrio-sternal junction 1 to 2 cm left from the midline. The EIT inserted at the xiphoid incision is tunneled to the super parasternal incision. To ensure adequate lead position and to avoid defibrillation test issues caused by high shock-lead impedance, the curvature of the sternum should be followed by forcing the tip of the EIT directly over the bone tissue of sternum. The lead is then pulled upwards from distal to proximal and fixated. Finally, both parasternal incisions are closed.

Two-Incision Lead Implantation
The 2-incision S-ICD implantation technique refers to a technique developed to insert the entire S-ICD system with just 2 incisions: 1 for the pocket and 1 at the xiphoid for lead insertion. The superior parasternal incision is omitted. The 2-incision technique was developed to reduce the infection risk by omitting the superior parasternal incision and to improve the cosmetic result. Lead insertion between the xiphoid and the pocket is identical. The difference is in the parasternal tunneling. Here, the EIT is covered by an 11-Fr peel-away sheath and then tunneled from the xiphoid incision in a cranial direction over the sternum. After tunneling, the sheath is advanced over the EIT. The EIT is then removed, and the hollow sheath remains in position. The electrode is inserted into the sheath and then peeled away, leaving the electrode in place. Finally, the lead is sutured with a sleeve to the fascia at the xiphoid to ensure adequate fixation, after which both the xiphoid and the pocket incision are closed. Also for the 2-incision technique, it is important to tunnel the lead directly on the sternal bone to avoid high shock-lead impedance, which reduces the effective defibrillation current.

Figure 2. Submuscular implantation of the pulse generator, underneath the serratus anterior muscle. A, Lateral view on the dissected serratus anterior muscle. The muscle slips are dissected in line with the fiber direction. B, The pulse generator of the subcutaneous implantable cardioverter-defibrillator (S-ICD) is placed underneath the muscle slips in the submuscular pocket. C, The slips of the muscle are sutured to close the submuscular pocket. D, The postoperative result of sub-serratus anterior muscle implantation of S-ICD pulse generator. Reproduced from Brouwer et al with permission of the publisher. Copyright © 2016 Elsevier.

Figure 3. Fascial layer detached from the serratus anterior muscle. A, The medial half of the fascial plane between the tweezers; B, the lateral half of the fascia between the tweezers.
Implantation of the S-ICD Periprocedural Outcomes and Clinical Follow-Up

All implanted devices were tested intraoperatively at the operator’s discretion, and success was defined as termination of ventricular fibrillation by the first shock at 65 J. Patients were routinely evaluated prior to discharge, 2 to 4 weeks and 2 months post-implant, and thereafter semiannually in the ICD clinic. Periprocedural outcomes include defibrillation test results, shock-lead impedance, procedure duration, and time to discharge. Subgroup analyses were performed for sex and obese versus nonobese patients regarding periprocedural outcomes. The reported clinical follow-up outcomes are device-related complications requiring surgical intervention, appropriate shocks (for ventricular tachycardia or ventricular fibrillation), and first shock conversion rate and inappropriate shocks (defined as shocks not for ventricular tachycardia or ventricular fibrillation).

Statistical Analysis

Continuous data were tested for normality and reported as means±standard deviation or medians with corresponding quartiles (25%, 75%) when appropriate and compared between groups using the Student’s t test or Mann–Whitney U test and ANOVA or Kruskal–Wallis for >2 groups. Jonckheere–Terpstra trend test was used to assess trend in procedure duration over time. Pairwise comparisons were calculated using Wilcoxon rank-sum test with Holm–Bonferroni correction for multiple testing. For discrete variables, percentages are calculated and compared with Fisher exact test. Estimated event-free (complications and inappropriate shocks) survival in the 4 groups was assessed by Kaplan–Meier analysis, and differences between strata were compared using the log-rank test. A 2-sided P value of <0.05 was considered to be statistically significant for all analyses. Statistical analysis was performed in R version 3.2.3 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient Characteristics

A total of 246 patients were included in this study, of which 35% (n=82) were implanted at Mount Sinai Hospital and 65% (n=154) at AMC hospital (Table 1). The median age was 47 years (interquartile range [IQR], 31–58), and 38% (n=90) were female. The majority of implants (68%, n=167) were for primary prevention of sudden cardiac death. Of the 4 implantation techniques used, the 3-incision technique with subcutaneous implantation of the pulse generator and submuscular implantation were used in both hospitals. The 2-incision technique with subcutaneous implantation of the pulse generator was solely used at AMC hospital, whereas the subfascial implantation technique of the pulse generator was only used in Mount Sinai Hospital. A total of 54 (22%) patients were implanted with the 3-incision technique, 118 (48%) with the 2-incision technique, 38 (15%) with submuscular, and 37 (15%) with subfascial. Table I in the Data Supplement presents the temporal distribution in the use of the 4 implant techniques.

Periprocedural Outcomes

All 246 patients were successfully implanted. The median procedure duration was 68 minutes (IQR, 53–77) at AMC hospital and 95 minutes (IQR, 84–114) at Mount Sinai Hospital (P<0.001; Table 2). In both hospitals, there was a significant trend toward decreasing procedure duration over time to 52 minutes (IQR, 40–72) at AMC (P<0.001) and 89 minutes (IQR, 81–100) at Mount Sinai in 2015 (P=0.004). Pairwise comparison of implantation techniques demonstrated that the 2-incision technique with the pulse generator in the subcutaneous position was significantly shorter in procedure duration than the other 3 implantation techniques, which did not differ significantly from each other.

In 81% of patients, defibrillation threshold testing was performed. There was a significant decreasing trend over time in the number of patients tested (P<0.001). The test was successful at 65 J in 98% (n=194) of the patients tested. Of note, all 4 patients in whom the first defibrillation test was not successful at 65 J were in the 2-incision group, but this was not significantly different from that of the other groups (P=0.24). In 2 patients with a failed test, a second test at 65 J with reversed polarity was successful, and the third patient was successfully tested at 80 J reversed polarity. The fourth patient had failed tests at 80 J, for which both the lead and

the pulse generator were repositioned directly on the sternal bone below the subcutaneous fat and the pulse generator more toward posterior. This resulted in 2 successful tests at 65 J and lower shock impedances. The median shock impedance was 68 (IQR, 57–84) Ohms. Pairwise comparison of shock impedance for the 4 implantation techniques did not reveal significant differences between groups.

Pairwise comparison of the duration to hospital discharge demonstrated that the 2-incision technique with the pulse generator in subcutaneous position was significantly shorter in duration than the other 3 implantation techniques (against all 3, \( P < 0.001 \)). The 3-incision, the submuscular, and the subfascial implantation technique did not differ significantly from each other in hospitalization duration. The results were similar in the AMC subset of patients. Because of the retrospective nature of the study, pain scores were not available. However, anecdotally, patients implanted with the submuscular technique did seem to experience more postoperative surgical site discomfort.

The results did not change in a subgroup analysis stratified for obesity, except that higher shock impedance was observed in the obese subgroup (83 ohms versus 65 ohms in the nonobese subgroup; \( P < 0.001 \); Tables II and III in the Data Supplement). The subgroup analysis stratified for sex yielded similar results as the primary analysis (Tables IV and V in the Data Supplement).

### Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Subcutaneous 3-Incisions</th>
<th>Subcutaneous 2-Incisions</th>
<th>Submuscular</th>
<th>Subfascial</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>246</td>
<td>54</td>
<td>118</td>
<td>38</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>Implants Mt Sinai, %</td>
<td>88 (36)</td>
<td>23 (43)</td>
<td>0 (0)</td>
<td>29 (76)</td>
<td>37 (100)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Age, y, median [quartiles]</td>
<td>47 [31, 58]</td>
<td>48 [31, 60]</td>
<td>44 [26, 53]</td>
<td>51 [26, 66]</td>
<td>58 [44, 63]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Female, %</td>
<td>91 (37)</td>
<td>18 (33)</td>
<td>49 (42)</td>
<td>11 (29)</td>
<td>14 (38)</td>
<td>0.509</td>
</tr>
<tr>
<td>Weight, kg, median [quartiles]</td>
<td>78 [65, 90]</td>
<td>76 [65, 91]</td>
<td>78 [67, 91]</td>
<td>70 [60, 84]</td>
<td>80 [66, 94]</td>
<td>0.225</td>
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<tr>
<td>BMI ≥30, %</td>
<td>47 (19)</td>
<td>10 (19)</td>
<td>23 (20)</td>
<td>4 (11)</td>
<td>10 (28)</td>
<td>0.30</td>
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</table>

Diagnosis

<table>
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<tr>
<th></th>
<th>Ischemic CMP, %</th>
<th>Nonischemic CMP, %</th>
<th>Genetic arrhythmia syndromes, %</th>
<th>Congenital heart disease, %</th>
<th>Other, %</th>
<th>Primary prevention, %</th>
<th>Prior device</th>
<th>Kidney function</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>63 (26)</td>
<td>68 (28)</td>
<td>98 (40)</td>
<td>8 (3)</td>
<td>9 (4)</td>
<td>167 (68)</td>
<td>26 (11)</td>
<td>0.979</td>
</tr>
<tr>
<td>Normal</td>
<td>214 (87)</td>
<td>47 (87)</td>
<td>103 (87)</td>
<td>23 (19)</td>
<td>17 (14)</td>
<td>73 (89)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>29 (12)</td>
<td>6 (11)</td>
<td>13 (11)</td>
<td>6 (16)</td>
<td>2 (5)</td>
<td>30 (83)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td>3 (1)</td>
<td>1 (2)</td>
<td>2 (2)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>4 (11)</td>
<td></td>
<td></td>
</tr>
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</table>

BMI indicates body mass index; CMP, cardiomyopathy; and LVEF, left ventricular ejection fraction.

### Table 2. Periprocedural Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Subcutaneous 3-Incisions</th>
<th>Subcutaneous 2-Incisions</th>
<th>Submuscular</th>
<th>Subfascial</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>246</td>
<td>54</td>
<td>118</td>
<td>38</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>Discharge, median [quartiles]</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>1 [1, 2]</td>
<td>1 [1, 1]</td>
<td>0.004</td>
</tr>
<tr>
<td>DFT performed, %</td>
<td>194 (79)</td>
<td>47 (87)</td>
<td>108 (92)</td>
<td>32 (84)</td>
<td>7 (19)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DFT successful at 65 J, %</td>
<td>190 (98)</td>
<td>47 (100)</td>
<td>104 (96)</td>
<td>32 (100)</td>
<td>7 (100)</td>
<td>0.457</td>
</tr>
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</table>

DFT indicates defibrillation test.
Clinical Follow-Up
The median follow-up duration was 14 (quartiles 2, 42) months for the entire cohort (Table 3). Follow-up differed significantly over the 4 groups because they were introduced later on in time. During follow-up, 18 complications occurred, of which infections requiring system removal was the most common complication (n=7, 3%). All infections occurred in subcutaneous implants: 3 in the 3-incision group and 4 in the 2-incision group. Skin erosion occurred in 2 patients, both implanted subcutaneously. There was 1 lead dislocation, which occurred in the 3-incision group. This patient was implanted before the suture sleeve to secure the lead to the fascia at the xiphoid was introduced. There were no lead dislocations in the 2-incision group and no infections in the submuscular or subfascial groups.

There were no significant differences between the 4 implantation groups for appropriate or inappropriate shocks. However, there was a natural trend toward more shocks in the groups with longer follow-up duration.

Discussion
Evaluation of 4 different implantation techniques of the S-ICD system demonstrates that the 2-incision, submuscular, and subfascial approaches have similar clinical outcomes when compared with the 3-incision subcutaneous implantation technique (per the regulatory labels). The fact that these outcomes are not significantly different is important because other patient and physician factors can help to decide which implantation technique should be used. For patients, this includes an improved cosmetic result of lead implantation because 1 parasternal incision is omitted with the 2-incision technique and a less prominent position of the pulse generator with submuscular and subfascial implantation. For physicians, the 2-incision technique may reduce procedure time.

The first shock success rate during periprocedural defibrillation testing did not differ between the 4 implant techniques. All failed shocked occurred in the 2-incision group, though the difference did not reach statistical significance in this cohort of a total of 246 patients. A study with a larger sample size may bring more certainty regarding this issue. The higher overall rate of defibrillation test success of 98% may, in part, be explained by the fact that the median weight was 78 kg. Excessive subcutaneous fat tissue seems to be associated with failed defibrillation.

An important potential concern with the 2-incision technique that may limit broader adoption is the risk of lead dislocation. Therefore, it is important to emphasize that in the current analysis, there were no lead dislocations in the 2-incision technique group. Another concern may be that adequate parasternal lead positioning may be more difficult and less reliable with the 2-incision technique, but no difference was seen during periprocedural defibrillation testing or in clinical outcomes, such as inappropriate shocks. However, a reduction in the number of infections by the 2-incision technique could not be demonstrated in the current cohort.

The rationale for submuscular implantation of the pulse generator was to prevent pocket complications in patients with a slim posture because the relatively larger size of the (first-generation S-ICD) pulse generator may result in excessive mechanical stress on the wound bed. This, in turn, may delay healing of the incision wound. A second reason to introduce this technique was to improve the esthetic appeal because the muscle forces the pulse generator against the chest wall. However, an important downside of submuscular implantation is that our anecdotal experience suggests that patients experience more postprocedural pain. Because of the retrospective nature of this analysis and the absence of systematic post-implantation pain scores, this could not be objectivized.

The postprocedural pain concerns in patients implanted submuscularly, combined with the introduction of a thinner profile pulse generator, resulted in the introduction of the subfascial implantation technique. This technique offers the same operative and cosmetic advantages as submuscular implantation, while minimizing postprocedural pain. Although the number of patients and the follow-up duration in this cohort is limited, the experience, to date, is encouraging. From an implanters

Table 3. Clinical Follow-Up

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Subcutaneous 3-Incisions</th>
<th>Subcutaneous 2-Incisions</th>
<th>Submuscular</th>
<th>Subfascial</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate shock, %</td>
<td>22 (9)</td>
<td>6 (11)</td>
<td>11 (9)</td>
<td>3 (8)</td>
<td>2 (5)</td>
<td>0.867</td>
</tr>
<tr>
<td>Inappropriate shock, %</td>
<td>24 (10)</td>
<td>9 (17)</td>
<td>13 (11)</td>
<td>1 (3)</td>
<td>1 (3)</td>
<td>0.059</td>
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<tr>
<td>Days follow-up, mean (SD)</td>
<td>433 (73, 1208)</td>
<td>1797 (153, 2182)</td>
<td>776 (248, 1220)</td>
<td>268 (76, 373)</td>
<td>40 (18, 66)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total complications, %</td>
<td>18 (7)</td>
<td>6 (11)</td>
<td>9 (8)</td>
<td>3 (8)</td>
<td>0 (0)</td>
<td>0.208</td>
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<tr>
<td>Infections, %</td>
<td>7 (3)</td>
<td>3 (6)</td>
<td>4 (3)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Lead dislocation, %</td>
<td>1 (0)</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Device dislocation, %</td>
<td>2 (1)</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>0 (0)</td>
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<tr>
<td>Hematoma, %</td>
<td>1 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1 (3)</td>
<td>0 (0)</td>
<td></td>
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<tr>
<td>Erosion, %</td>
<td>2 (1)</td>
<td>1 (2)</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td></td>
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<tr>
<td>DFT failure, %</td>
<td>1 (0)</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
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<tr>
<td>Inappropriate shocks, %</td>
<td>2 (1)</td>
<td>1 (2)</td>
<td>2 (2)</td>
<td>1 (3)</td>
<td>0 (0)</td>
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</tr>
<tr>
<td>Device failure, %</td>
<td>2 (1)</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td>1 (3)</td>
<td>0 (0)</td>
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DFT indicates defibrillation test.
implantation. These alternative techniques may enhance the
esthetic appeal of the S-ICD. The 2-incision technique
resulted in shortest procedure duration.

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N, Grace AA, Olde Nordkamp LR, Burke MC; IDE and EFFORTLESS
investigators. The learning curve associated with the introduction of the

Conclusion
The presented surgical techniques are feasible alternatives
to the standard 3-incision technique for subcutaneous ICD

standpoint, the subfascial implantation technique can guide
implanters to find the correct anatomic location of the pulse
generator. Particularly, in obese patients, the use of anatomic
landmarks can be more challenging, and therefore, finding fas-
cial layer covering the serratus anterior helps to position
the pulse generator correctly. The significantly higher shock imped-
ance found in the subgroup with obese patients underscores
the importance of finding the correct anatomic location because a
higher shock impedance with similar device output reduces the
effective current available for defibrillation as represented in
Ohm’s law, where current is voltage divided by resistance.

Therefore, in obese patients, the use of fluoroscopy may be
considered for 2 reasons. First, to ensure adequate positioning
of the lead directly on the sternum bone to avoid high shock-lead
impedances, which reduce the effective current. Second, to posi-
tion the pulse generator in optimal lateral position to have the defi-
brillation current go through the heart and avoid current shunting
to the anterior aspect of the chest wall. As mentioned previously,
the correct position of the S-ICD system is crucial for optimal
device function. For implanters new to the procedure, we advise
to first familiarize with the labeled 3-incision technique to obtain
skills and comfort with the procedure because there is an evident
learning curve with respect to device-related complications.9

This study has several important limitations. First, this
was a nonrandomized and retrospective study representing
the experience at 2 centers to which all associated limitations
apply. Therefore, the analyses presented here should be con-
sidered exploratory. Moreover, there were differences in base-
line characteristics and follow-up duration between groups.
Second, our cohort may be underpowered to detect small but
important differences in outcomes. Third, we cannot exclude
hospital bias because of differences, such as the implant tech-
niques used, local experience, and the healthcare systems in
which both hospitals operate. Finally, the techniques were
sequentially introduced in this cohort: 3-incision in 2009;
2-incision in 2010; submuscular in 2013; and subfascial in
2015. A previous publication describing the learning curve and
the effects of experience did not find an effect of implanters
experience on procedure duration in a cohort comprising
almost 900 patients (P=0.80).2 The shortening of the procedure
duration observed in the multivariable model of that study was
primarily explained by implant year (significant) and indepen-
dent of experience of the individual implanters (not significant
in the model). Therefore, the direction of bias would result in
shorter procedure durations for the later introduced implant
technique, but we actually observe longer implant durations in
the submuscular and subfascial implant techniques which may be
associated with their higher technical complexity. 
Implantation of the Subcutaneous Implantable Cardioverter-Defibrillator: An Evaluation of 4 Implantation Techniques


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Supplemental Table 1: temporal differences in use of implant techniques.

<table>
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<tr>
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<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>14</td>
<td>25</td>
<td>19</td>
<td>23</td>
<td>36</td>
<td>42</td>
<td>74</td>
<td>14</td>
</tr>
<tr>
<td><strong>Subcutaneous 3 (%)</strong></td>
<td>14 (100)</td>
<td>17 (68)</td>
<td>0 (0)</td>
<td>3 (13)</td>
<td>5 (14)</td>
<td>4 (10)</td>
<td>11 (15)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Subcutaneous 2 (%)</strong></td>
<td>0 (0)</td>
<td>8 (32)</td>
<td>19 (100)</td>
<td>20 (87)</td>
<td>20 (56)</td>
<td>20 (48)</td>
<td>25 (34)</td>
<td>6 (43)</td>
</tr>
<tr>
<td><strong>Submuscular (%)</strong></td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>11 (31)</td>
<td>18 (43)</td>
<td>9 (12)</td>
<td>0 (0)</td>
</tr>
<tr>
<td><strong>Subfascial (%)</strong></td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>29 (39)</td>
<td>8 (57)</td>
</tr>
</tbody>
</table>
### Supplemental Table 2: peri-procedural outcomes for obese (BMI ≥30) patients

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Subcutaneous three-incisions</th>
<th>Subcutaneous two-incisions</th>
<th>Submuscular</th>
<th>Subfascial</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>47</td>
<td>10</td>
<td>23</td>
<td>4</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Duration (median [IQR])</td>
<td>80 [68, 94]</td>
<td>89 [79, 107]</td>
<td>69 [60, 76]</td>
<td>86 [79, 97]</td>
<td>86 [81, 97]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge (median [IQR])</td>
<td>1 [1, 1]</td>
<td>1 [1, 2]</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>0.05</td>
</tr>
<tr>
<td>DFT Performed (%)</td>
<td>37 (79)</td>
<td>8 (80)</td>
<td>23 (100)</td>
<td>4 (100)</td>
<td>2 (20)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DFT Successful at 65J (%)</td>
<td>36 (97)</td>
<td>8 (100)</td>
<td>22 (96)</td>
<td>4 (100)</td>
<td>2 (100)</td>
<td>0.89</td>
</tr>
<tr>
<td>Shock impedance (median [IQR])</td>
<td>83 [69, 102]</td>
<td>100 [64, 157]</td>
<td>83 [74, 96]</td>
<td>92 [77, 98]</td>
<td>NA</td>
<td>0.47</td>
</tr>
</tbody>
</table>

### Supplemental Table 3: peri-procedural outcomes for non-obese (BMI <30) patients

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Subcutaneous three-incisions</th>
<th>Subcutaneous two-incisions</th>
<th>Submuscular</th>
<th>Subfascial</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>197</td>
<td>43</td>
<td>94</td>
<td>34</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Duration (median [IQR])</td>
<td>78 [60, 100]</td>
<td>105 [91, 124]</td>
<td>67 [54, 77]</td>
<td>91 [69, 107]</td>
<td>91 [81, 101]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge (median [IQR])</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>1 [1, 2]</td>
<td>1 [1, 1]</td>
<td>0.01</td>
</tr>
<tr>
<td>DFT Performed (%)</td>
<td>155 (79)</td>
<td>38 (88)</td>
<td>84 (89)</td>
<td>28 (82)</td>
<td>5 (19)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DFT Successful at 65J (%)</td>
<td>152 (98)</td>
<td>38 (100)</td>
<td>81 (96)</td>
<td>28 (100)</td>
<td>5 (100)</td>
<td>0.46</td>
</tr>
<tr>
<td>Shock impedance (median [IQR])</td>
<td>65 [57, 82]</td>
<td>68 [52, 88]</td>
<td>63 [57, 77]</td>
<td>77 [63, 90]</td>
<td>58 [55, 60]</td>
<td>0.77</td>
</tr>
</tbody>
</table>
### Supplemental Table 4: peri-procedural outcomes for male patients

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Subcutaneous three-incisions</th>
<th>Subcutaneous two-incisions</th>
<th>Submuscular</th>
<th>Subfascial</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>155</td>
<td>36</td>
<td>69</td>
<td>27</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Duration (median [IQR])</td>
<td>78 [60, 104]</td>
<td>105 [77, 120]</td>
<td>61 [50, 74]</td>
<td>91 [72, 113]</td>
<td>90 [81, 103]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge (median [IQR])</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>1 [1, 2]</td>
<td>1 [1, 1]</td>
<td>0.07</td>
</tr>
<tr>
<td>DFT Performed (%)</td>
<td>120 (77)</td>
<td>32 (89)</td>
<td>63 (91)</td>
<td>23 (86)</td>
<td>2 (9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DFT Successful at 65J (%)</td>
<td>116 (97)</td>
<td>32 (100)</td>
<td>59 (94)</td>
<td>23 (100)</td>
<td>2 (100)</td>
<td>0.29</td>
</tr>
<tr>
<td>Shock impedance (median [IQR])</td>
<td>65 [57, 83]</td>
<td>63 [51, 85]</td>
<td>64 [59, 75]</td>
<td>80 [63, 93]</td>
<td>NA</td>
<td>0.97</td>
</tr>
</tbody>
</table>

### Supplemental Table 5: peri-procedural outcomes for female patients

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Subcutaneous three-incisions</th>
<th>Subcutaneous two-incisions</th>
<th>Submuscular</th>
<th>Subfascial</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>92</td>
<td>18</td>
<td>49</td>
<td>11</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Duration (median [IQR])</td>
<td>79 [67, 93]</td>
<td>94 [88, 107]</td>
<td>75 [62, 82]</td>
<td>82 [48, 96]</td>
<td>89 [81, 98]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discharge (median [IQR])</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>1 [1, 1]</td>
<td>1 [1, 2]</td>
<td>1 [1, 2]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DFT Performed (%)</td>
<td>74 (80)</td>
<td>15 (83)</td>
<td>45 (92)</td>
<td>9 (82)</td>
<td>5 (36)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DFT Successful at 65J (%)</td>
<td>74 (100)</td>
<td>15 (100)</td>
<td>45 (100)</td>
<td>9 (100)</td>
<td>5 (100)</td>
<td>1</td>
</tr>
</tbody>
</table>