A novel radiofrequency ablation catheter using contact force sensing: Toccata study

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OBJECTIVES The aim of this multicenter study was to evaluate the device- and procedure-related safety of a novel force-sensing radiofrequency (RF) ablation catheter capable of measuring the real-time contact force (CF) and to present CF data and its possible implications on patient safety.

BACKGROUND The clinical outcome of RF ablation for the treatment of cardiac arrhythmias may be affected by the CF between the catheter tip and the tissue. Insufficient CF may result in an ineffective lesion, whereas excessive CF may result in complications.

METHODS Seventy-seven patients (43 with right-sided supraventricular tachycardia [SVT] and 34 with atrial fibrillation [AF]) received percutaneous ablation with the novel studied catheter. The CF applied and safety events related to the procedure were reported.

RESULTS CF values at mapping ranged from 8 ± 8 to 60 ± 35 g and from 12 ± 10 to 39 ± 29 g in the SVT group and the LA group, respectively, showing a significant interinvestigator variability (P < .0001). High transient CFs (>100 g) were noted in 27 patients (79%) of the LA group. One device-related complication (tamponade, 3%) occurred in the AF group.

CONCLUSIONS Catheter ablation using real-time CF technology is safe for the treatment of SVT and AF. High CFs may occur during catheter manipulation and not just during ablation, suggesting that measuring CF may provide additional useful information to the operator for safe catheter manipulation. In the future, CF-sensing catheters may also increase the effectiveness of RF ablations by allowing better control of the RF lesion size.

KEYWORDS Ablation; Atrial fibrillation; Catheter ablation; Supraventricular tachycardia; Contact force

ABBREVIATIONS AF = atrial fibrillation; AVNRT = atrioventricular nodal reentry tachycardia; CF = contact force; LA = left atrium; PVs = pulmonary veins; PVI = pulmonary vein isolation; RA = right atrium; RF = radiofrequency; SAEs = serious adverse events; SVT = supraventricular tachycardia

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Introduction
Over the past 2 decades, percutaneous catheter ablation has become the most common treatment of recurrent supraventricular tachycardias (SVTs), such as atrioventricular nodal reentry tachycardia (AVNRT), accessory pathway Wolff–Parkinson–White syndrome, atrial flutter, and other atrial tachycardias. Radiofrequency (RF) catheter ablation of atrial fibrillation (AF) is increasingly commonly performed, and the various techniques for ablation in the left atrium (LA) include, at minimum, electrical isolation of the pulmonary veins (PVs).

Recent preclinical research has shown that the contact force (CF) between the catheter tip and the target tissue is a key factor to safe and effective lesion formation. Insufficient CF may result in an ineffective lesion, whereas excessive CF may result in complications such as heart wall perforation, steam pop, thrombus formation, or esophageal injury. Until now, the operator could assess the CF only indirectly, or with a force sensor available with a robotic system at the proximal end of a sheath. To allow continuous, accurate, and direct measurement of the CF between the catheter tip and the target tissue, a novel technology was developed that integrates a CF sensor at the distal tip of an RF open-irrigated catheter. The objective of this paper was to evaluate the clinical data of a novel CF-sensing open-irrigated tip RF ablation catheter in terms of both device-related and procedure-related safety up to 12 months post-procedure and to present CF data during the interventional procedure and its possible implications on patient safety. Knowledge of the CF may reduce commonly related complications.

Methods
Patients
This study enrolled 2 patient groups with atrial arrhythmias. The right-sided SVT group consisted of patients with confirmed right-sided SVT that included AVNRT, Wolff–Parkinson–White syndrome, atrial tachycardia, and isthmus-dependent atrial flutter. The AF group consisted of patients with confirmed paroxysmal AF. A total of 77 Caucasian patients were enrolled in the study: 43 in the right-sided SVT group and 34 in the AF group. All study patients were enrolled in the study: 43 in the right-sided SVT group and 34 in the AF group. All study patients signed an informed consent form and met all study entry criteria at screening. Study entry criteria for patients with confirmed paroxysmal AF. A total of 77 Caucasian patients were enrolled in the study: 43 in the right-sided SVT group and 34 in the AF group. All study patients signed an informed consent form and met all study entry criteria at screening. Study entry criteria for patients with confirmed paroxysmal AF included AVNRT, Wolff–Parkinson–White syndrome, atrial tachycardia, and isthmus-dependent atrial flutter.

Study device—CF ablation catheter system
The CF ablation catheter system (TactiCath Set; Endosense SA, Geneva, Switzerland) consists of (1) an RF ablation catheter (the CF catheter: TactiCath), (2) a base station as a signal processing and displaying unit, and (3) a splitter interfacing between the catheter, the base station, and the RF ablation generator available in the electrophysiology laboratory (Figure 1). The CF catheter is an isodiametric 7 French, steerable, RF ablation catheter with saline open irrigation (6 holes at the distal tip) that integrates a CF sensor at the distal tip to measure the force (amplitude and direction) of the contact between the catheter tip electrode and the tissue. The sensor stiffens the catheter distal part, making it compatible with 8.5 French introducers and straight or steerable sheaths.

The CF sensor is a triaxial force sensor located between the second and third electrodes and has a resolution and sensitivity of about 1 g in a bench test. The sensor is able to measure the lateral and axial forces individually, and the forces are calculated every 100 milliseconds and displayed continuously. The catheter force reference (“no electrode–tissue contact”) is set when the catheter is floating in the heart chamber and is to be verified during the procedure.

Study procedure
The study was approved by each study center’s independent Ethics Committee.

After completion of the baseline evaluation, patients underwent the procedure following standard clinical practice guidelines. The catheter was evaluated and the CF continuously recorded during the entire interventional procedure including the standard treatment schemes of electrophysiologic mapping and ablation. The CF between the catheter tip and the heart wall was evaluated during a dedicated CF mapping phase and during ablation.

During CF mapping, the investigator was blinded to the force sensor value to minimize bias on the force being applied. The objective of this test was to assess the CF the investigator would apply during standard catheter mapping and RF ablation procedures. For the right-sided SVT group, the 6 CF mapping sites in the right atrium (RA) were the
superior, mid, and inferior free walls; the cavo-tricuspid isthmus area; the RA septum; and the RA appendage. For the AF group, the 6 CF mapping sites in the LA were the roof, the posterior wall, the anterior wall, the septum, the LA appendage, and the anterior atrioventricular ring. The investigator was to apply a self-assessed “good” CF level at respective CF mapping sites for 15 seconds based on intracardiac electrograms, catheter motion on fluoroscopy, or 3D mapping perception.

During the ablation phase, the force sensor value was available for the investigator, who performed a standard RF ablation procedure. The RF power settings followed the standards of the laboratory, ranging from 15 to 40 W for the AF group and from 15 to 50 W for the right-sided SVT group. Other RF application parameters, such as duration and type (point by point or dragging), also followed individual laboratory standards. The irrigation flow was ≥17 mL/min during RF ablation. The occurrence of any audible pops was recorded, and the presence of charring was assessed. In addition, in the AF group, the CF applied was assessed for each patient and per investigator.

All CF mapping and RF ablation records were reviewed by an independent third party and classified as valid or not valid for CF analysis. Valid records were those with stable CF for 15 consecutive seconds.

During the entire procedure with the catheter inserted into a heart chamber, high CF events were defined as ≥100 g for over 200 milliseconds and counted per patient from the AF group.

**Statistical methods**

This trial was specifically designed to assess safety in terms of the incidence of procedure- or device-related serious adverse events (SAEs) in comparison with literature data on specifically designed safety studies with comparable devices. The literature values on the incidence of procedure- or device-related SAEs for patients with right-sided SVT was estimated at 11.4%, with an upper confidence limit of 21.2%.11–14 For patients with AF, the literature values were estimated at 16.8%, with an upper confidence limit of 30.2%.1,9 Procedure- or device-related SAE incidence rates below these levels were considered to confirm the safety of the study device when used for the respective study indications. All SAEs were validated by an independent Data Safety Monitoring Board.

All statistical analyses were performed with patients as units of measurements. Any patient who withdrew from the study was analyzed up to the day of withdrawal. Statistical analyses were performed by using SAS software (version 9, Cary, NC, USA). Statistical analyses on CF data were based on analysis of variance tests.

**Results**

**Right-sided SVT group**

After diagnostic CF mapping, RF ablation was determined as contraindicated in 1 patient with AVNRT but with atypical atrioventricular node anatomy, and thus the patient was not ablated with the study device. A total of 42 patients (27 patients with atrial flutter, 13 patients with AVNRT, and 2 patients with Wolff–Parkinson–White syndrome) underwent the full study procedure and were evaluated at 7-day follow-up. During the further study follow-up, 3 patients withdrew consent. Patient characteristics are described in Table 1. A mean of 10 ± 9 ablations were delivered per patient, over an average of 10 ± 14 minutes RF time.

**Safety (procedure to 7-day postprocedure)**

No device-related SAEs occurred. One patient (2%) experienced a procedure-related SAE (95% confidence interval = 0%–12%). The SAE was a sinus bradycardia, followed by pacemaker implantation in a patient treated for atrial flutter with the study device and with a standard ablation catheter for concomitant RA arrhythmias. Audible popping during the procedure was recorded for 7 patients (16%). No clotting or char formation was observed. No other SAEs occurred within the 7-day follow-up period.

**Safety (up to 12-month postprocedure)**

During the 12-month study duration, 4 patients (9%) experienced SAEs related to arrhythmia recurrences (2 atrial flutter and 2 AVNRT). Other cardiac or noncardiac SAEs unrelated to the procedure were experienced by 7 patients (16%), and 1 patient (2%) died as a result of a lung tumor. Three of 42 patients (7%) had a second ablation procedure to treat arrhythmia recurrence by using nonstudy ablation catheters. No SAEs related to these repeat procedures were reported.

**The AF group**

In the AF group, 3 patients withdrew consent: 2 before the end of the 3-month follow-up period and 1 before the end of study. Patient characteristics are described in Table 1. A mean of 44 ± 17 ablations was delivered per patient, over an average of 38 ± 14 minutes RF time.

### Table 1 Baseline patient characteristics in right SVT and AF groups

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Right SVT</th>
<th>AF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>Mean ± standard deviation</td>
<td>56.9 ± 13.3</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>21–77</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td>Male</td>
<td>29 (67)</td>
</tr>
<tr>
<td>Cardiovascular history, n (%)</td>
<td>Cardiac disorders</td>
<td>14 (33)</td>
</tr>
<tr>
<td></td>
<td>Secondary arrhythmia</td>
<td>6 (14)</td>
</tr>
<tr>
<td></td>
<td>Coronary artery disease</td>
<td>4 (9)</td>
</tr>
<tr>
<td></td>
<td>Heart failure</td>
<td>1 (2)</td>
</tr>
<tr>
<td></td>
<td>Valvular disease</td>
<td>2 (5)</td>
</tr>
<tr>
<td></td>
<td>Other cardiac disorder</td>
<td>2 (5)</td>
</tr>
<tr>
<td></td>
<td>Vascular disorders</td>
<td>22 (51)</td>
</tr>
<tr>
<td></td>
<td>Hypertension</td>
<td>20 (47)</td>
</tr>
<tr>
<td>Left atrium diameter (mm)</td>
<td>Mean ± standard deviation</td>
<td>41.5 ± 4.2</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>34–51</td>
</tr>
</tbody>
</table>

AF = atrial fibrillation; SVT = supraventricular tachycardia.
Safety (procedure to 3 months)
Four of 34 patients (12%) experienced a device- or procedure-related SAE (95% confidence interval = 3%–27%). During blinded CF mapping and after complete pulmonary vein isolation (PVI), 1 patient (3%) experienced a tamponade requiring pericardiocentesis and fully recovered. A second patient (3%) experienced sinus bradycardia and recovered within 6 days. A third patient (3%) experienced groin bleeding, which was resolved after 2 days. A fourth patient (3%) experienced a stroke. The stroke was adjudicated by the Data Safety Monitoring Board as not related to the use of the study device but favored by a difficult transeptal puncture under the condition of low anticoagulation. Audible popping during the procedure was recorded in 4 patients (12%) or 0.3% of all RF applications. No clotting or char formation was observed.

At the 3-month follow-up, none of the patients showed evidence of severe or moderate PV stenosis. PV stenosis was mild in 4 patients (12%).

Safety (up to 12-month postprocedure)
During the 12-month follow-up period, 9 patients (26%) experienced SAEs related to recurrences. Of these, 6 patients had a second ablation procedure, 2 patients required an electrical cardioversion, and 1 patient received antiarrhythmic therapy.

One additional patient had a second ablation procedure related to a non-SAE arrhythmia recurrence. All second ablation procedures were performed with a nonstudy ablation catheter, and no SAEs related to these procedures occurred. In 2 of the 7 patients who had a reintervention, all PVs were isolated; 1 of the 2 patients underwent ablation for atrial tachycardia.

Six patients had other cardiac or noncardiac SAEs unrelated to the procedure. No deaths occurred in the AF group.

CF analysis
CF mapping
For the CF mapping phase, 727 records (76%) from 42 patients in the right-sided SVT group were classified as valid for CF analysis. Differences in forces applied during CF mapping in the RA between the 17 investigators were statistically significant ($P < .0001$), with mean values ranging from 8 ± 8 to 60 ± 35 g (Figure 2). The CF applied at the septum and the appendage was statistically significantly higher than at other RA sites ($P < .0001$ and $P = .0046$, respectively).

In the AF group (32 patients), 529 records (90%) were classified as valid for CF analysis. Differences in forces applied during CF mapping in the LA between the 12 investigators were statistically significant ($P < .0001$), with mean values ranging from 12 to 39 g (Table 2). Compared with the CF applied at other LA sites, the CF applied at the septum was statistically significantly higher ($P < .0001$) and the CF applied at the appendage was statistically significantly lower ($P < .0001$).

Discussion
This is the first clinical study measuring CF in real time during mapping and RF ablation of right-sided SVTs and AF. Knowledge of the CF during the interventional procedure may reduce commonly related complications and increase patient safety.

The safety profile of the CF catheter when used by the experienced investigators in this study was comparable to that of conventional irrigated RF catheters. The incidence of device- or procedure-related SAEs among study patients with right-sided SVT was 2%, well below the prespecified safety rate of 11.4%. The incidence of device- or procedure-related SAEs among study patients with right-sided SVT was 2%, well below the prespecified safety rate of 11.4%.

CF ablation
In the AF group (34 patients), the total number of PV ablations was 1458. Seventy-one percent of the RF ablation records were classified as valid and analyzed. In all patients, PVI was successfully performed with the study device and CF recorded in real time. The CFs achieved for PVI by the 12 investigators are presented in Figure 3. A high variability was seen in the forces applied for PVI, both between investigators ($P < .0001$) and for individual investigators (coefficient of variability = 72.1).

Analysis indicated that the differences in CF between PV sites were statistically significant ($P < .0001$). On average, the highest force was applied at the right septal inferior position. The lowest forces during RF ablation of the PVs were applied at the left anterior inferior ridge and in the right septal superior position.

The high CF events during the entire procedure are shown in Figure 4. Six patients had more than 40 events. Patient 31 experienced tamponade and had more than 40 high-CF events. The cumulative duration of all these high-CF events for this patient was just less than 40 seconds. Figure 5 shows a CF trace versus procedure time for this patient (31) at the suspected time of the tamponade. Within the first 5 seconds of catheter manipulation, the CF study device recorded a single high transient force event of 137 g followed by an immediate decrease in CF.
related SAEs among patients with AF was 12%, which was below the prespecified safety rate of 16.8%. Thus, the safety of the CF catheter for RF ablation was confirmed in both groups.

There was high variability in CF during mapping and ablation between investigators and for individual investigators (see Figures 2 and 3) and between the different RF ablation sites. This high variability underscores the importance of measuring CF. Measuring CF during RF ablation will allow the operator to better control CF and hence, the RF lesion size based on the CF by selecting the optimal RF power and duration of RF application, for example, by decreasing RF power and/or RF duration at sites with high CF and by increasing RF power and/or RF duration at sites with low CF. Measuring CF during RF ablation will help prevent excessive CF, decreasing the risk of steam pop and cardiac perforation and the risk of injury, such as esophageal injury (atrialesophageal fistula) and phrenic nerve palsy, to noncardiac structures (collateral damage). Hence, measuring CF may lead to increased patient safety.

The high variability in intra-investigator CF illustrates that investigators, even during a careful ablation procedure, do not have tight control over CF. Again, this high variability underscores the importance of measuring CF for increased patient safety.

The CF measurements at 6 RA and 6 LA sites showed statistically significant differences in CF between investigators and between the different RF ablation sites. The applied forces varied statistically significantly depending on the accessibility of the ablation site, with lower forces applied to the left anterior inferior ridge, a predominant site of reconduction. It has been commonly thought that perforation occurred during ablation, but perforation may actually occur during catheter manipulation at any time of the procedure. For example, in 1 patient who experienced tamponade, a high transient force event was recorded during catheter manipulation and not during ablation. This high force of 137 g was followed by an immediate decrease in CF. A high force followed by a sudden decrease in force is indicative of the CF pattern found at and immediately after perforation of the myocardium. The tamponade experienced by this patient may have been the result of this sudden high force.

Shah et al suggested that it may be prudent to avoid a CF exceeding 100 g during catheter manipulation and ablation and that the CF should be lower in the vicinity of recently ablated sites as the myocardium is structurally weakened at those sites. Knowledge of the CF during the entire interventional procedure may increase understanding of the safety aspects in RF ablation. Recording high-CF values, even of short duration, may help the operator avoid a high-risk situation and be more vigilant for possible effusion.

Measuring CF during mapping within scarred regions will allow the operator to determine whether low electrogram amplitude is due to scarring or poor catheter contact.

Finally, the use of a catheter providing CF information may be an interesting tool for training electrophysiologist fellows to ensure less variability in manipulations and to avoid excessive CFs.

<table>
<thead>
<tr>
<th>Investigator identification number</th>
<th>CF statistic</th>
<th>Records, n</th>
<th>Mean (g)</th>
<th>SD (g)</th>
<th>Min–Max (g)</th>
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<tbody>
<tr>
<td>18</td>
<td>12</td>
<td>12</td>
<td>12</td>
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<td>12</td>
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<td>20</td>
<td>2–123</td>
</tr>
</tbody>
</table>

\( CF = \) average contact force; Max = maximum; Min = minimum; SD = standard deviation.

Table 2 Distribution of contact force by investigator for records collected during mapping in the left atrium.

The CF measurements at 6 RA and 6 LA sites showed statistically significant differences in CF between investigators and between the different RF ablation sites. The applied forces varied statistically significantly depending on the accessibility of the ablation site, with lower forces applied to the left anterior inferior ridge, a predominant site of reconduction. It has been commonly thought that perforation occurred during ablation, but perforation may actually occur during catheter manipulation at any time of the procedure. For example, in 1 patient who experienced tamponade, a high transient force event was recorded during catheter manipulation and not during ablation. This high force of 137 g was followed by an immediate decrease in CF. A high force followed by a sudden decrease in force is indicative of the CF pattern found at and immediately after perforation of the myocardium. The tamponade experienced by this patient may have been the result of this sudden high force.

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Measuring CF during mapping within scarred regions will allow the operator to determine whether low electrogram amplitude is due to scarring or poor catheter contact.

Finally, the use of a catheter providing CF information may be an interesting tool for training electrophysiologist fellows to ensure less variability in manipulations and to avoid excessive CFs.
This was the first study that used a direct CF catheter for RF ablation in humans. Randomized controlled studies are needed to assess whether catheter ablation with optimized CF and/or RF power improves long-term clinical outcome.

Conclusions
In conclusion, the CF catheter is as safe as conventional irrigated RF catheters. Assessment of CF showed marked inter- and intrainvestigator variability. High CF values may occur during manipulation and not just during ablation. This suggests that the ability to measure CF may provide additional useful information to the operator for safe catheter manipulation. In the future, CF-sensing catheters may increase the safety and effectiveness of RF ablation procedures by preventing the use of inappropriately high CF and by allowing better control of the RF lesion size.

Acknowledgments
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