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Design and Evaluation of a Catheter Contact-Force Controller for Cardiac Ablation Therapy

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***Abstract*— *Goal:* Maintaining a constant contact force of an ablation catheter during cardiac catheter ablation therapy is clinically challenging due to inherent myocardial motion, often resulting in poor ablation of arrhythmogenic substrates. To enable a prescribed contact force to be applied during ablation, a catheter contact force controller (CCFC) was developed. *Methods:* The system includes a hand-held device attached to a commercial catheter and steerable sheath. A compact linear motor assembly attaches to an ablation catheter and autonomously controls its relative position within the shaft of the steerable sheath. A closed-loop control system is implemented within embedded electronics to enable real-time catheter-tissue contact force control. To evaluate the performance of the CCFC, a linear motion phantom was used to impose a series of physiological contact force profiles; lesion contact force was controlled at prescribed levels ranging from 15 to 40 g. *Results:* For a prescribed contact force of 25 g, the CCFC was able to regulate the contact force with a root mean squared error of 3.7 ± 0.7 g. The ability of the CCFC to retract the catheter upon sudden changes in tissue motion, which may have caused tissue damage, was also demonstrated. Finally, the device was able to regulate the contact force for a predetermined amount of time according to a force-time integral model. *Conclusion:* The developed CCFC is capable of regulating catheter-tissue contact force in a laboratory setting that mimics clinical ablation therapy. *Significance:* Catheter-tissue contact force control promises to improve the precision and success of ablation lesion delivery.**

***Index Terms*—Catheterization, force control, linear actuators, real-time systems, medical robotics, robot manipulators.**

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I. Introduction

Percutaneous radiofrequency (RF) catheter ablation is becoming the standard of care for a variety of cardiac arrhythmias. Cardiac interventionalists introduce ablation catheters into the heart and manipulate them until the distal tip contacts the targeted myocardium. Once reached, RF power is delivered to form ablation lesions that interrupt the electrical pathways responsible for the arrhythmia. For successful treatment it is important that these lesions are transmural, as superficial lesions leave areas of healthy myocardium that may result in conduction recurrence and ablation failure.

Catheter-tip-to-tissue contact force (CF) has been shown to be an indicator for assessing lesion development [1-5], and CF guidelines have been established to label a delivered lesion as effective [6-8]. Additional studies have shown that monitoring both the duration of the delivery and CF at a specific RF power can predict lesion volume [3, 6-11]. Conventionally described as a Force-Time Integral (FTI), the model may be used as a prospective quantitative tool to determine lesion volume under defined parameters. Unfortunately, this model is dependent on catheter stability and while used in the clinic as a guide, it has not been used as a quantitative metric that can predict lesion volume or transmurality. Finally, lesions delivered with excessive CF present a risk of deep tissue overheating, which may result in "steam pop", perforation and

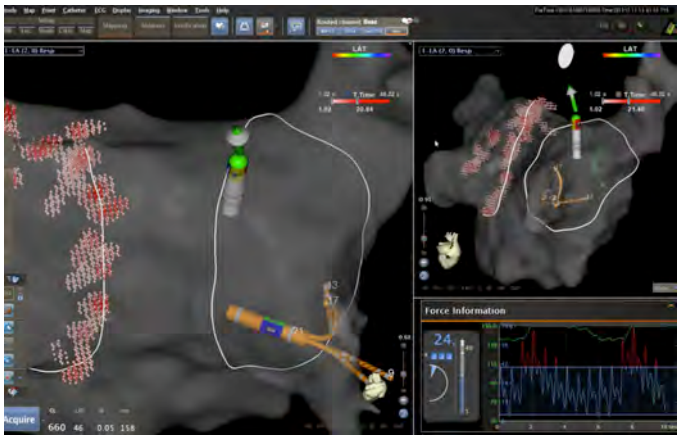

Fig. 1. Modern electromagnetic catheter tracking systems (*e.g.* CARTO, Biosense Webster Ltd., Yokneam, Israel) enable visual feedback of the real-time CF experienced on the tip of the catheter (e.g. 7.5F SmartTouch, Biosense Webster Ltd., Diamond Bar, CA, USA). The figure is a snapshot demonstrating catheter location in the rendered left atrium (white with green tip) and the CF as a function of time in the lower right hand corner. Note the variation in CF with cardiac and respiratory motion. Image courtesy of London Health Science Center.

injury outside the heart, including esophageal, pulmonary and phrenic nerve damage [2]. These potential risks often inhibit the interventionalist and cause them to deliver the lesion tentatively, with a lower level of CF to lessen the risk of injury. Clinically, CF information is often used as a guide to ensure catheter tip contact and confine the CF within acceptable ranges, but is ultimately limited by tissue motion, as seen in the CF profile in the lower right-hand corner of Fig. 1.

While ideally the CF should be regulated within a prescribed range, interventionalists cannot respond fast enough to compensate for cardiac and respiratory motion [12]. Approaches to minimize myocardial motion during ablation, have been proposed, including high-frequency-jet ventilation [13]. None have successfully provided a motionless environment in all patients [14]. Kesner *et al.* [15] demonstrated CF control of catheters and instruments used for mitral valve repair, however, the implementation does not address problems associated with catheter ablation.

Commercial force-sensing ablation catheters enable the interventionalist to simultaneously monitor the CF in real-time while delivering the lesion, as illustrated in Fig. 1. Often these catheters are used together with steerable sheaths, whose added level of versatility and stability has increased clinical success [13, 16, 17]. The interventionalist typically manipulates the steerable sheath until the catheter is pointing at the target region, and then advances the catheter forward through the sheath until the desired level of CF is imparted onto the tissue.

In this manuscript, we introduce a tool that enables the delivery of effective RF lesions by autonomously regulating the CF of a force-sensing ablation catheter based only on the real-time CF measurements. The Catheter Contact-Force Controller (CCFC) is a hand-held, modular device that enables robotic control of the catheter within the sheath, which otherwise would be done manually by the interventionalist. The CCFC is an add-on tool compatible with commercially available, preexisting force-sensing ablation catheters and sheaths.

II. System Description

Incorporation of the CCFC replaces the manual manipulation of the catheter through the sheath. Rather than advancing the catheter forward until a sufficient CF level is reached, the interventionalist would engage the CCFC, which monitors the CF in real-time and updates the position of the catheter to maintain the CF experienced at the tip of the catheter at a desired level, despite motion of the target tissue. The CCFC system comprises a hand-held, compact, electromechanical device and an embedded system.

A. Hand-Held Device

The hand-held CCFC device, Fig. 2, is mechanically clamped to the distal end of the sheath handle (*i.e.* at the hemostatic seal and insertion point of the catheter). A catheter-locking adapter rigidly clamps the catheter shaft onto a precision linear actuator (LM2070-040, MICROMO, Clearwater, USA) traveling along a 12 mm diameter 134 mm long precision magnetic shaft. Movement of the actuator directly translates to movement of the catheter through the sheath. The adapter and actuator are mounted within an enclosure, which is designed to securely lock onto the sheath handle, while keeping the catheter concentrically mounted within the hemostatic seal. A set of hinges and latches enables easy clamping and removal of the CCFC. Both the adapter and enclosure were fabricated in polypropylene using additive manufacturing (Objet3D Pro, Stratasys Ltd., Rehovot, Israel).

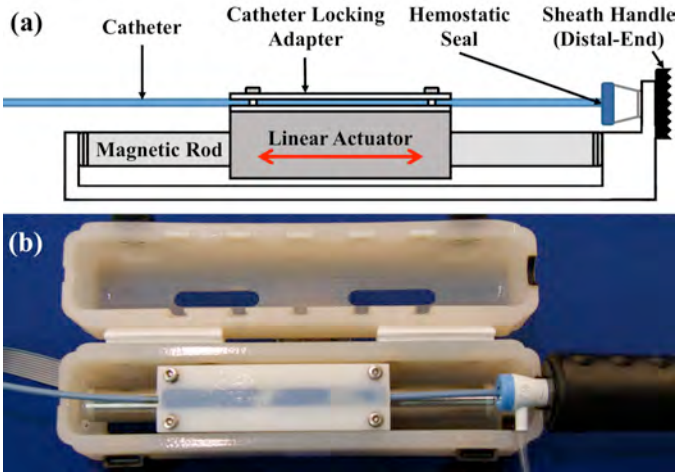

Fig. 2 Schematic side-view (a) and photograph top-view (b) of the electromechanical hand-held CCFC attached to a steerable sheath and force-sensing ablation catheter. Movement of the linear actuator along the fixed magnetic rod moves the catheter through the hemostatic seal of the sheath handle.

B. Hybrid Control System

To maintain a prescribed CF between the tip of the catheter and a moving target we implemented a hybrid control system. Common closed-loop proportional-integral-derivative (PID) control algorithms are based on minimizing the error between the desired and actual inputs, and have been shown to be a viable solution in robotic catheter control systems [15, 18-20]. The CCFC uses a hybrid PID controller, a slight variation of a standard PID controller, whose control parameters change based on the error argument. The control signal *u(t)* is calculated as:

$$u(t) = \begin{cases} K_{P_A} e(t) + K_{I_A} \int_0^t e(\tau)d\tau + K_{D_A} \frac{d}{dt} e(t) & e(t) > F_T \\ K_{P_C} e(t) + K_{I_C} \int_0^t e(\tau)d\tau + K_{D_C} \frac{d}{dt} e(t) & 0 < e(t) \leq F_T \end{cases}$$

where the error *e(t)* is the difference between the desired and current contact forces, F_D and $F_C(t)$ respectively. The control parameters K_P, K_I and K_D generate a different control signal depending on the error measured in real time. If the error is larger than a predefined CF threshold, F_T, the control system is in an "aggressive" state indicated by K_{P_A}, K_{I_A}, K_{D_A}. When the error is lower than F_T the control system operates in a "conservative" state indicated by K_{P_C}, K_{I_C}, K_{D_C}. The CF threshold was empirically assigned to be 5g – a level that was observed to retain steady-state accuracy.

Tuning of the aggressive control parameters was achieved using the Tyrues-Luyben tuning method, as implemented by [21]. The conservative control parameters were manually tuned for a desired steady-state response; in the current implementation, the conservative control parameters were at least a factor of 4 smaller than the aggressive ones.

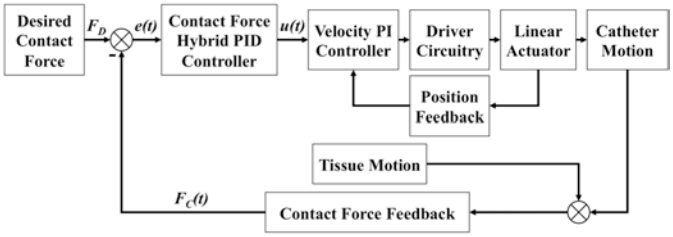

Fig. 3. Block diagram of the embedded system controlling the CCFC.

C. Electronic Hardware Design

The hybrid control system was implemented within an embedded electronic system, enabling real-time control of the linear actuator. A microcontroller development platform based on a Atmel SAM3X8E 84 MHz 32-bit ARM architecture (Due, Arduino LLC, Ivrea, Italy) generates a pulse-width modulated (PWM) control signal, based on the measured and desired contact force, which acts as input to the linear actuator controller and driver circuitry (MCLM-3003, MICROMO, Clearwater, USA). This daughter board is programmed with a native velocity proportional-integral (PI) controller that controls the speed of the motor based on the input PWM signal. Tuning of the PI controller was performed using the manufacturer's tuning software, before tuning the hybrid PID system. The update rate of the hybrid PID system was set to 1 kHz, which was the maximum rate of the linear actuator controller. Figure 3 is a block diagram of the designed embedded system.

D. Linear Motion Phantom

To evaluate the CCFC's ability to regulate CF on a moving target *in vitro*, a custom built linear motion phantom was developed (Fig. 4). The motion phantom was built to provide sinusoidal and physiologic motion profiles. A gear motor with a Hall effect encoder (37D Gearmotor, Pololu Electronics, Las Vegas, NV, USA) drives a lead screw mechanism providing linear motion to a carriage. A second PID control system within an embedded electronic system controls the motion stage: the circuit board assembly includes a microcontroller development platform (Due, Arduino LLC, Ivrea, Italy) and a DC motor driver daughter board (VNH5019 Driver Shield, Pololu Electronics, Las Vegas, NV, USA). A strain gauge capable of detecting force with 200-milligram resolution (S100, Strain Measurement Devices, Wallingford, CT, USA), coupled to a linear amplifier (CSG110, FUTEK Inc., Irvine, CA, USA), is mounted on the carriage and used to measure the CF of the tip of the catheter. A piece of silicone (Dragon Skin 30, Smooth-On Inc., Macungie, PA, USA) is positioned between the strain gauge and the tip of the catheter to mimic soft tissue compliance. A setscrew fixes the sheath firmly in place without hindering movement of the catheter housed within the sheath. Linear calibration, according to Hooke's law, was first performed to determine the relationship between the displacement of the tissue and the force measured by the strain gauge.

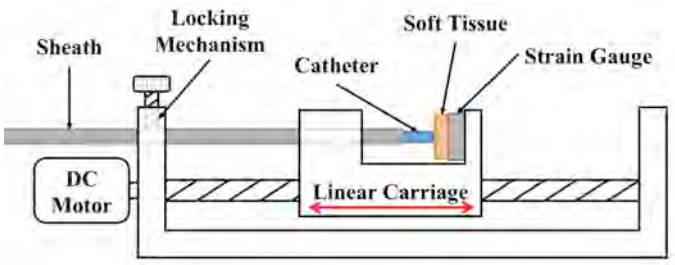

Fig. 4. Linear motion phantom with the catheter and sheath loaded, used to evaluate the CCFC. The linear motion imposed on the tip of the catheter simulates myocardial tissue motion.

The phantom was programmed to execute arbitrary sinusoidal and sine-sweep motion profiles and to replicate physiological motion. Contact force profiles were recorded by force-sensing ablation catheters during typical ablation procedures, similar to the profile illustrated in Fig. 1. These profiles, containing both high-frequency low-amplitude cardiac and low-frequency high-amplitude respiratory motion, were programmed into the motion phantom as position trajectories, using the linear calibration parameters.

The signal from the strain gauge, measured in real time, was used as the CF feedback signal of the CCFC control system (Fig. 3) and represent a surrogate of the CF signal that would be provided by a commercial force-sensing catheter.

III. System Evaluation

A. Linear Motion Phantom Evaluation

The linear motion phantom was first evaluated to ensure that the executed motion profiles mimic the physiological motion that results in contact force profiles similar to those measured clinically. The catheter was held fixed while the linear motion phantom imposed 16 different patient-specific motion profiles. The sheath was locked in place for half of the experiments. The real-time CF measurements provided by the strain gauge were recorded and compared to the corresponding CF profiles. No attempt was made to perfectly match the executed CF profiles to the corresponding patient profiles and the measured CF profiles were only inspected visually, ensuring the range of amplitudes and frequencies were within the physiologic range.

B. Catheter Contact-Force Controller Evaluation

Experiments were performed to evaluate the overall accuracy and dynamic performance of the CCFC. For these experiments, the CCFC was attached to the rear end of a commonly used steerable sheath (8F Agilis NxT, St. Jude Medical, Saint Paul, MN, USA) and CF sensing ablation catheter (7.5F SmartTouch, Biosense Webster Ltd., Diamond Bar, CA, USA) combination. Water was introduced via the sheath's side port to mimic the clinical setting and reduce the friction between the sheath and catheter. The sheath and catheter were inserted into the linear motion phantom as illustrated in Fig. 5.

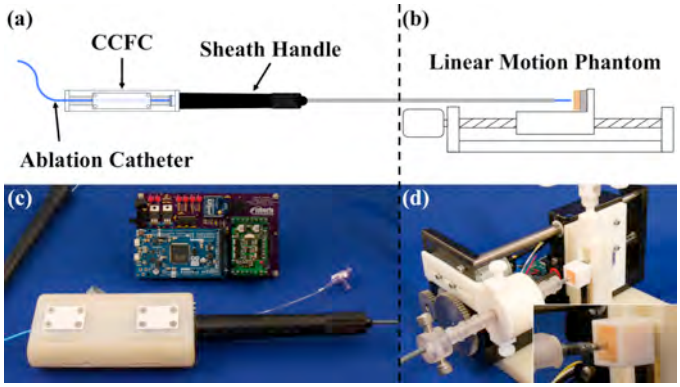

Fig. 5. Experimental setup to used to evaluate the performance of the CCFC. (a) line drawing (not to scale) showing the CCFC, sheath and catheter mounted with the linear motion phantom (b); photographs of the CCFC (c) and motion phantom (d) are also shown.

1) Step Response: The response of the CCFC control system to a step input (of 25 g) was first evaluated. The step response was then measured during 25 repeats and the rise time, overshoot, and peak level were characterized. During these experiments, the linear motion phantom was kept fixed.

2) Safety: It is important to ensure that the CCFC can respond to excessive, fast and sudden motions that may result in tissue perforation. The linear motion phantom was programmed to impose a bidirectional continuous sine sweep motion profile, sweeping from 0.1 Hz to 2.5 Hz with amplitude of 70 g peak-to-peak. This unlikely clinical scenario was selected following Fourier analysis of over 40 patient-specific CF profiles and determining that the maximum frequency component observed was 2.5 Hz. While the phantom executed the prescribed motion, the CCFC was engaged and attempted to regulate the CF to a desired reference of 25 g. The maximum error between the desired and actual contact force was measured. This experiment was repeated 10 times.

3) Patient-Specific Dynamic Response: To evaluate the overall performance of the CCFC versus manual intervention, the linear motion phantom was programed to execute 16 different patient motion profiles. Prior to any evaluation of the CCFC, a control experiment was performed whereby the phantom replicated each profile with the CCFC's disabled. This is representative of manual intervention, where the interventionalist contacts the catheter to moving myocardial tissue and holds the catheter still to deliver a lesion. The experiment was then repeated with the CCFC programmed to deliver 15 g, 25 g, and 40 g for the duration of the motion profile. Statistical analysis of the regulated CF profiles was performed to calculate mean, confidence interval, and root-mean-squared error (RMSE). Histograms of CF were also plotted for the "manual" and CCFC interventions. Note that for this study we use the term "manual" to refer to the CF profile representative of CF profiles recorded during clinical ablation procedures.

4) Force-Time Integral: This experiment was designed to demonstrate that the CCFC could be used not only to regulate the delivered force, but also to deliver lesions with prescribed FTI. The CCFC was programmed to deliver a prescribed FTI at a desired CF while the linear motion phantom imposed a patient motion profile. For each FTI/CF combination an expected duration can be calculated. The CCFC was programmed to calculate the FTI, and automatically retract the tip of the catheter back into the sheath once the desired FTI was reached. The generated CF profile and duration of catheter engagement was recorded and compared with expected values. This experiment was then repeated for various configurations of FTI and CF, which may be user-defined in a clinical setting. The tested FTI values were 500, 1000, and 1500 gs, where each was repeated with 25 and 40 g of CF. Each configuration was repeated 3 times.

IV. Results

A. Linear Motion Phantom

The linear motion phantom was able to replicate a range of patient-specific CF profiles. The profiles chosen to evaluate the CCFC are characteristic of typical cardiorespiratory patterns depicted in Fig. 6(a) as well as irregular profiles associated with patient motion or catheter instability depicted in Fig. 6(c). The generated CF curves, shown in Fig. 6(b, d), visually demonstrate a high level of similarity to the corresponding clinically acquired profiles (Fig. 6 a and c). These results demonstrate that the linear motion phantom is able to replicate cardiorespiratory forces that is typically encountered during catheter RF delivery and is appropriate to be used as a phantom for the CCFC's evaluation. Locking the sheath in place did not affect the results.

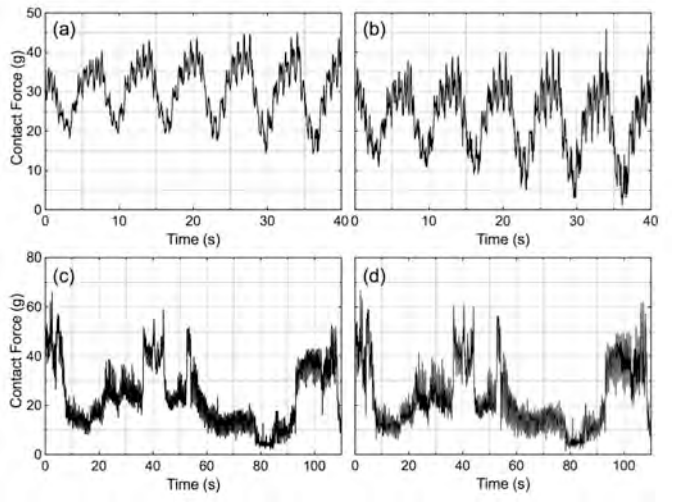

Fig. 6. Two representative patient CF profiles ((a) and (c)) and the corresponding CF profiles ((b) and (d), respectively) imposed on a fixed catheter tip by the linear motion phantom, executing the same patient profile. The motion profiles depicted in (b) and (d) are profile #13 and #3 in Fig. 8(d), respectively.

B. CCFC – Step Response

The response of the CCFC's control system to a 25 g step input is shown in Fig. 7. The following step response characteristics were calculated from the measurements: 38 ± 3 ms rise time, 3 ± 2 g overshoot, and peak of 29 ± 2 g; means and standard deviations of 25 repeats of the step response are reported. The negligible overshoot and oscillation indicate that the tuning method used to determine the control

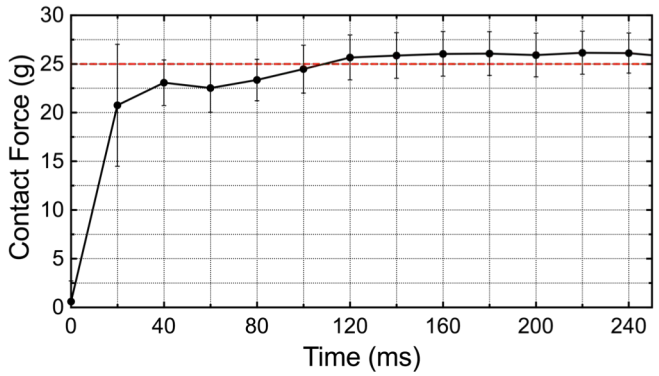

Fig. 7. Step response of the CCFC for a reference value of 25 g. At every time point, the mean and standard deviation are plotted.

parameters has resulted in a desired transient and steady state response.

C. CCFC – Safety

During the control of a 70 g peak-to-peak sine sweep from 0.1 Hz to 2.5 Hz, the maximum difference between the prescribed and measured CF was 15 ± 2 g, with all measured CF values being below 42 g. These results demonstrate that the CCFC is capable of reacting to sudden changes of tissue displacement that would otherwise result in large spikes of CF and potentially cause tissue damage.

D. CCFC – Patient-Specific Dynamic Response

The CCFC was able to significantly transform the CF profile on the catheter tip in comparison to manual intervention ($p<0.001$). Figure 8(a-c) depicts the distribution of measured CF for three motion profiles, representative of CFs measured during the delivery of different lesions; histograms are plotted for both manual and CCFC-controlled interventions, with a prescribed CF level of 25 g. The images in Fig. 8(d, manual) and Fig. 8(e, CCFC-controlled) are grey-scale representations of the CF histograms for all 16 motion profiles; they clearly demonstrate that when the CCFC is

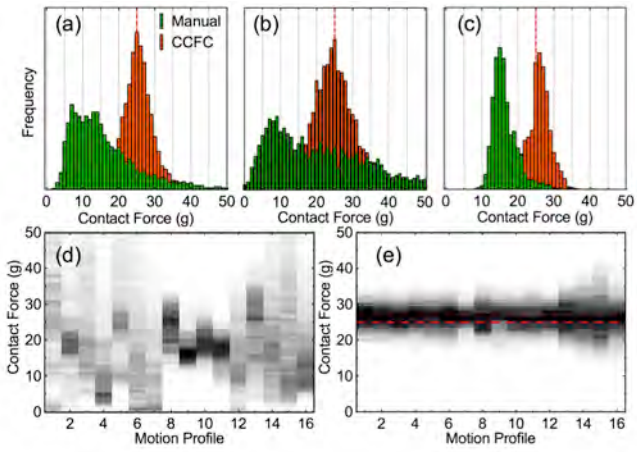

Fig. 8. Histograms (a)-(c) show the distribution of manual and CCFC-controlled CF for three unique motion profiles (16,15, and 9 from panel (d), respectively). The manual intervention histograms indicate that: (a) majority of lesion time was spent barely touching the tissue, (b) significant myocardial motion resulting in greatly fluctuation CF, and (c) a precise lesion was delivered but the force was not centered at the 25 g target. In each case CCFC-control brings the mean CF to the target. Histograms of manual (d) and CCFC-controlled (e) interventions, represented as grey scale values, show a significant difference in CF distribution for all 16 motion profiles.

TABLE I
PATIENT MOTION EXPERIMENTS

Prescribed CF (g)	15	25	40
5% Percentile	10.1 ± 1.2	19.7 ± 1.2	34.3 ± 1.2
95% Percentile	20.6 ± 1.3	31.1 ± 1.5	46.9 ± 1.7
Mean	**15.3 ± 0.1**	**25.4 ± 0.1**	**40.4 ± 0.1**
RMSE	**3.2 ± 0.6**	**3.4 ± 0.7**	**3.9 ± 0.8**

All measurements are presented in grams (g) of force. Mean and standard deviation of all 16 profiles are reported.

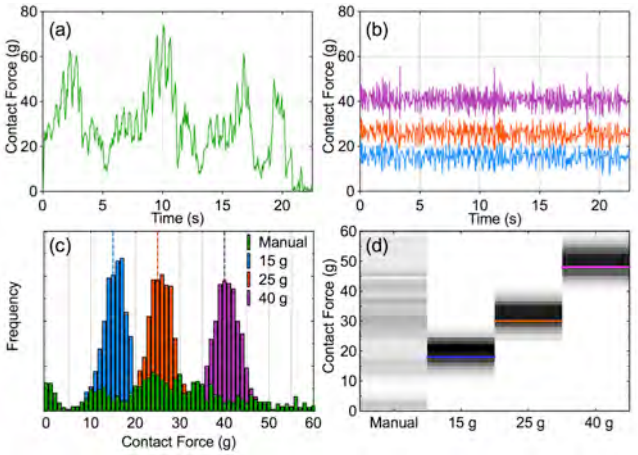

Fig. 9. (a) original CF profile (green), while the CCFC was disabled. (b) illustrates the generated CF profile while the CCFC was engaged to deliver 15 g (blue), 25 g (orange) and 40 g (purple). Histogram (c) and grey-scale representation (d) illustrate the CF distribution between manual and CCFC intervention at various desired CF levels. The motion profile depicted here is profile #1 from Fig. 8(d).

engaged the prescribed mean force is achieved for all motion profiles.

Similar performance was achieved regardless of the magnitude of the prescribed CF. Illustrated in Fig. 9, are the results for one representative experiment where the CCFC was programmed to deliver a CF of three clinically relevant levels – 15, 25, and 40 g. Consistently similar force distributions, were achieved regardless of the prescribed CF value. Detailed performance metrics – averaged over all tested motion profiles – are shown in Table I for the three prescribed CF levels.

E. CCFC – Force-Time Integral

For all experiments performed to demonstrate that the CCFC could achieve a target FTI, the CCFC successfully engaged the catheter with a desired CF until a target FTI was reached. The results obtained with each configuration of FTI and CF are presented in Table II. A representative experiment is illustrated in Fig. 10. The lesion delivery time was within 480 ± 199 ms of the expected duration. This is indicative of a regulated CF profile throughout the delivery, as excessive CF would result in short lesion delivery times and low CF levels would result in the opposite.

TABLE II
FORCE-TIME INTEGRAL EXPERIMENTS

Desired		Expected	Measured		
FTI (gs)	CF (g)	Duration (s)	FTI (gs)	CF (g)	Duration (s)
500	25	20	500	25.7 ± 3.0	19.49 ± 0.01
	40	12.5	500	40.7 ± 3.5	12.29 ± 0.01
1000	25	40	1000	25.4 ± 3.1	39.36 ± 0.04
	40	25	999	40.4 ± 3.4	24.71 ± 0.01
1500	25	60	1500	25.3 ± 3.0	59.27 ± 0.06
	40	37.5	1499	40.4 ± 3.4	36.99 ± 0.22

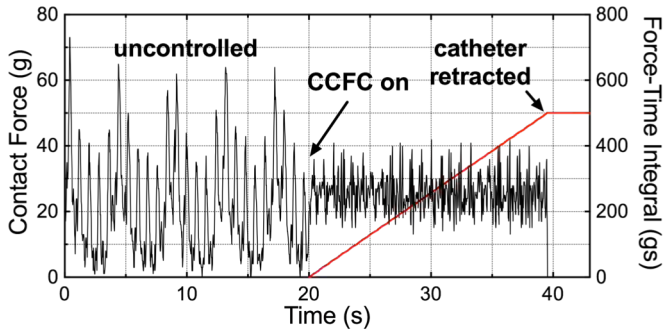

Fig. 10 Interval 0-20 s, the catheter was in contact with the phantom while the CCFC was disabled. Interval 20-39.5 s, the CCFC was engaged to deliver 500 gs at 25 g. Interval 39.5-45 s, the tip of the catheter retracted into the sheath once the desired FTI (red) had been reached. The motion profile depicted here is profile #15 from Fig. 8(d).

With each configuration of desired CF and FTI a similar profile was generated with an expected and predicable deviation.

V. Discussion

We have presented a novel and easy to use tool that regulates the CF imparted by standard ablation catheters on moving tissue regardless of the type of motion imposed. The compact hand-held device is used with commercially available force-sensing ablation catheters and steerable sheaths, which are widely used in modern electrophysiology suites. The presented CCFC utilizes the same tools and information available to the interventionalist but grants the ability to regulate CF and FTI.

While contact force measurement (at the tip of an ablation catheter) has been available to electrophysiologists for some time, it has been used primarily as a visual guide to determine if adequate contact has been made or if there is a risk of tissue perforation. The CCFC has been demonstrated to control the force at the tip of the catheter to within a few grams of a prescribed force level.

The CF profiles, recorded during clinical ablation procedures, used to impart clinically relevant motion for evaluating the CCFC and shown in Fig. 8 demonstrate some of the problems associated with ablation delivery. For example, profile #16 (Fig. 8(a)) represents a lesion where negligible force existed between the catheter tip and the wall during most of the time RF power was being delivered; when the CCFC was engaged the mean CF was increased to 25 g, as prescribed. Similarly, the scenario depicted in Fig. 8(b) demonstrates large variations in contact force (manual) due to motion, which is corrected via the use of the CCFC, reducing the RMSE (about 25 g) from 15.1 to 5.5 g. Even when a tight distribution of forces is achieved manually, as in Fig. 8(c), the mean CF may not be at a level sufficiently high for the delivery of a transmural lesion – use of the CCFC in this case shifts the distribution of CF from being centered about 15 g to being centered about 25 g. Consistently narrow, and symmetric, distributions of CF were also achieved for different prescribed CF levels (Fig. 9, Table I).

Successful control of CF over the duration of lesion "delivery" also enabled control of FTI. Automatic engagement and retraction of the catheter for specified FTI at a desired CF has the potential to become a fundamental and powerful tool in the electrophysiology suite. While FTI has been proposed as a useful measure in predicting lesion transmurality and volume, without a device like the CCFC FTI cannot be easily used as a metric clinically or in preclinical studies aimed at optimizing lesion delivery parameters.

The study evaluating the performance of the CCFC under conditions of rapidly varying motion have also demonstrated that use of the CCFC clinically has potential to minimize tissue damage due to excessive force. The CCFC was able to compensate for changes in CF as fast as 700 g/s and maintain CF within 15 g of the prescribed values. These results are significant because they indicate that using the CCFC, forces able to perforate tissue [22] would never be achieved.

The CCFC was designed as a hand-held device that would enable the interventionalist to engage it at any point during a complete ablation procedure, but is free to perform all other tasks as is done under current clinical practice. The CCFC can easily be removed from the catheter/sheath assembly to ensure optimal catheter steerability and be re-clamped when a target location has been reached, just prior to RF power delivery. The device is versatile and can be used as a stand-alone CF control aid or can be incorporated with catheter robotic navigation systems for further improvements in position and force control. Ongoing *in vitro* and *in vivo* studies aim to demonstrate the full effectiveness of the CCFC in controlling lesion volume.

VI. Limitations

Despite the extremely promising results, it is important to note that the study is limited by the fact that the motion of an *in vitro* dynamic phantom was used as a surrogate for contact force measured at the catheter tip during CCFC evaluation; the limitation is manifested in two ways. First, using a strain gauge positioned behind tissue-simulating silicone to provide CF measurements introduced damping of the CF that would have been measured at the tip of the catheter (i.e. at the interface of the catheter and silicone). Implementation of the CCFC with a force-sensing catheter would require re-tuning of the control parameters to account for the different dynamics. Second, for the phantom based experiments, the acquired CF data were implemented as linear motion profiles with the catheter placed perpendicular to the surface of the tissue. This experimental design assumed that the catheter was oriented the same way during acquisition of the clinical data. If clinically, the catheter tip was oriented at an oblique angle, larger motion profiles would correspond to the measured forces. It is likely however that the true characteristics of myocardial tissue motion will contain the same frequency components as the profiles used in this study, which ultimately does not affect the implemented control system of the CCFC.

All CF profiles used to evaluate the CCFC were acquired from patients undergoing pulmonary vein isolation ablation therapy and may not be representative of the CF profiles measured during ablation therapies of the left ventricle.

During left ventricular ablation procedures CF may change more rapidly due to systolic motion. The safety experiments performed as part of the present study contained CF waveforms with high changes of CF, larger than would be expected in ventricular ablations, and these preliminary tests provide confidence that the CCFC will be able to control force even during ventricular ablations.

VII. Conclusions

This study represents the first demonstration of contact force control using a versatile hand-held catheter contact force controller, which can be coupled to any force-sensing ablation catheter/steerable sheath combination. The demonstrated control of contact force under varying motion conditions is promising and suggests that – when implemented in combination with a force-sensing catheter – the CCFC can deliver prescribed ablation lesions.

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