Thomas Küffer ORCID iD: 0000-0003-3553-4945

Andreas Haeberlin ORCID iD: 0000-0002-9283-0110
Sven Knecht ORCID iD: 0000-0001-7122-021X
Laurent Roten ORCID iD: 0000-0002-0827-1329
Tobias Reichlin ORCID iD: 0000-0002-7197-8415

Validation of the accuracy of contact force measurement by contemporary force-sensing ablation catheters

Thomas Kueffer MSc[a], Andreas Haeberlin MD, PhD[a,b], Sven Knecht DSc[c], Samuel H Baldinger MD[a], Antonio Madaffari MD[a], Jens Seiler MD[a], Aline Mühl MSc[a], Hildegard Tanner MD[a], Laurent Roten MD[a], Tobias Reichlin MD[a]

[a] Department of Cardiology, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland

[b] ARTORG Center for Biomedical Engineering, University of Bern, Switzerland

[c] Department of Cardiology, University Hospital Basel, Basel, Switzerland

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Corresponding author

Prof. Dr. med. Tobias Reichlin, MD
Department of Cardiology, Inselspital – University Hospital Bern
Freiburgstrasse, CH-3010 Bern, Switzerland
Email: tobias.reichlin@insel.ch
Phone: +41 (0)31 634 00 50

Conflict of interest

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Abstract

Introduction: Contact force-sensing catheters are widely used for ablation of cardiac arrhythmias. They allow quantification of catheter-to-tissue contact, which is an important determinant for lesion formation and may reduce the risk of complications. The accuracy of these sensors may vary across the measurement range, catheter-to-tissue angle, and amongst manufacturers and we aim to compare the accuracy and reproducibility of four different force sensing ablation catheters.

Methods: A measurement setup containing a heated saline water bath with an integrated force measurement unit was constructed and validated. Subsequently, we investigated four different catheter models, each equipped with a unique measurement technology: Tacticath Quartz (Abbott), AcQBlate Force (Biotronik/Acutus), Stablepoint (Boston Scientific), and Smarttouch SF (Biosense Webster). For each model, the accuracy of three different catheters was measured within the range of 0-60 grams and at contact angles of 0°, 30°, 45°, 60°, and 90°.

Results: In total, 6685 measurements were performed using 4x3 catheters (median of 568, IQR 511-606 measurements per catheter). Over the entire measurement-range, the force measured by the catheters deviated from the real force by the following absolute mean values: Tacticath 1.29g ±0.99g, AcQBlate Force 2.87g ±2.37g, Stablepoint 1.38g ±1.29g, and Smarttouch 2.26g ±2.70g. For some models, significant under- and overestimation of >10g were observed at higher forces. Mean absolute errors of all models across the range of 10-40g were <3g.

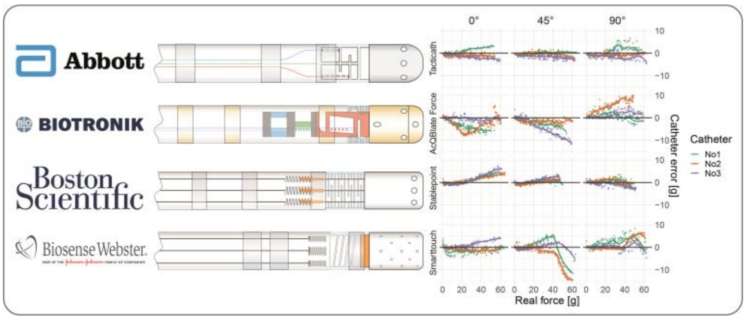
Conclusion: Contact measured by force-sensing catheters is accurate with 1-3g deviation within the range of 10g to 40g. Significant errors can occur at higher forces with potential clinical consequences.

Graphical Abstract

Schematic drawing of 4 commercially available contact force sensing catheters and validation of their accuracy of contact force measurement.

Keywords: Radiofrequency Ablation; Contact Force; Catheter Ablation; Force Sensing

Graphical abstract (Central Illustration):



Introduction

Radiofrequency ablation (RFA) is commonly used for the treatment of cardiac arrhythmias. In recent years, advancements in catheter manufacturing technologies allowed for more complex catheter designs, including the assessment of contact by force measurement at the catheter's tip. These catheters are widely used and have been demonstrated to be effective in complex ablation procedures including ablation of atrial fibrillation as well as ventricular arrhythmias.[1–5] The biophysics of RFA are well understood and lesion size is mainly a function of power, energy delivery time, catheter-to-tissue contact force per area, and stability[6]. This knowledge and the rise of force sensing catheters allowed the field to develop algorithms to predict lesion formation and –quality[7–12]. These novel algorithms are nowadays used in conjunction with conventional markers like tactile feedback, impedance drop, loss of pace capture, or electrogram amplitude attenuation[1,13]. For the algorithms to perform well, reliance on accurate cather-to-tissue contact force measurement is key. For some force sensing catheters, the accuracy of their sensors was externally validated previously[14]. Several latest generation models however have not been tested yet, including two catheter designs that newly gained CE mark approval in 2020 (Stablepoint, Boston Scientific; and AcQBlate Force, Biotronik/Acutus).

This study aimed to compare the four currently commercially available contact force-sensing ablation catheters regarding the accuracy of their contact force sensor measurements.

Materials & Methods

Measurement setup

We constructed and validated a bench setup that can assess the accuracy of the force sensors integrated in force sensing ablation catheters. The measurement system consists of an acrylic glass tank containing 0.9% saline solution heated to 37°C to emulate the electrical and thermal properties of the human body (Figure 1). It further offers a catheter fixation mechanism and a suspended platform on which a force can be applied. The force is redirected to the outside of the water bath onto a precision scale (resolution = 0.5g, FXN 3K-4N, Kern, Balingen, Germany), using low friction pulleys. The force pulls on a counterweight lying on the scale, consequently lifting the weight (Figure 1). After initial zeroing, the force applied to the platform can be read off directly from the scale. The surface of the platform consists of a slightly compressible polymeric foam, mimicking the flexibility of myocardial tissue. A custom-made catheter fixation mechanism allows holding the catheter at different angles from 0° to 90° against the platform. 0° is defined as perpendicular to the platform, such that the force is applied axially to the catheter (Z-axis), while 90° is defined as parallel to the platform, resulting in a force applied radially to the tip of the catheter (X- and Y-axis). The position of the catheter can be adjusted vertically to adjust the force exerted onto the platform. For simplicity reason, the terms “weight” and “force” are used interchangeably.

Validation of the measurement setup

The friction and the accuracy of the setup for measuring the force applied to the platform was validated with an empty tank by measuring standard weights, which were put on the platform. The results of the validation procedure can be found in the online supplement. A correction factor was used to account for friction in the measurement setup.

Ablation catheter models

Four ablation catheter models were investigated. Each model was used in conjunction with the corresponding equipment needed to read out the force sensor. Tacticath Quartz, Smarttouch, and Stablepoint must all be paired with a specific 3D mapping system while the AcQBlate Force can be used as a standalone solution. An overview of additional technical details can be found in table 1.

All four catheter models provide a force sensing tip, temperature measurement, irrigation, and catheter deflection. However, the force sensing technology is different for each model and described in the following section as well in Figure 2:

Tacticath™ Quartz (Abbott, Abbott Park, IL, USA):

A beam of light is emitted by the TactySys™ system and travels through three optical fibers towards the catheter’s tip into a complex, deformable 3-D structure incorporating three Fabry-Pérot interferometers made of two semi-reflective parallel surfaces. When a force is applied to the catheter tip, the flexible titanium-alloy structure deforms, changing its length and, therefore, the reflected interference pattern. By knowing the deformation characteristics, both the magnitude and orientation of the acting contact force can be computed.

AcQBlate® Force (Biotronik, Berlin, Germany):

The tip is suspended by a Z-Axis (In-axis to the catheter) sensor that is realized by a deformable parallelogram, sensitive to axial forces on the catheter. Additionally, separate X- and Y-Axis sensors are located more proximally along the shaft. They are sensitive to lateral forces only. One single optical fiber, incorporating a fiber Bragg grating (FBG) runs through the deformable sensors. At each sensor, a different wavelength is reflected. As soon as the catheter tip is exposed to a force, the fiber changes its length at the respective section, therefore shifting the reflected wavelength along the spectrum. Knowing the forces along all axes, the acting force vector can be calculated.

Stablepoint™ (Boston Scientific, Marlborough, MA, USA):

The tip is suspended by a machined precision spring, which can be compressed and bent. Three inductive sensors, comprising a ferromagnetic core and a coil are located in the proximal part of the catheter tip. The ferromagnetic cores are attached to the tip and move within the coils as the tip is deflected by an applied force. This results in a change of inductance of individual sensors. Knowing the rigidity of the spring, the axial and lateral forces acting on the tip can be calculated by Hooke's law.

Smarttouch® SF (Johnson&Johnson, New Brunswick, NJ, USA):

The tip of the catheter is suspended by a machined precision spring. A magnetic transducer generates a small magnetic field in the distal part of the catheter. Three magnetic field sensors are located in the more proximal part of the catheter, distributed around the circumference. As forces are acting on the catheter tip, it moves slightly towards the sensors, changing the signal received by the sensor coils. By Hooke's law, the acting force and direction can be calculated from the three sensors and the known characteristics of the spring.

Measurement protocol

All catheters were fixed 18-20mm proximal to the tip to get an adequately low bending of the distal part while not compromising the force sensor tip by the clamping mechanism. Prior to the measurements, the catheters were submerged in the heated saline bath for five minutes, allowing for warm-up. The catheter was zeroed after each change of the contact angle. Measurements were taken repeatedly adjusting the exerted force in-between measurements until a minimum of 100 measurements at one specific angle was reached. During acquisition, equal distribution of the measurements across the full measurement range of 0g to 60g was ensured. Subsequently, the catheter was fixed at a different angle and the same protocol was repeated for all angles of 0°, 30°, 45°, 60°, and 90°. The error made by the catheter was calculated by subtracting the weight displayed on the scale (real force) from the contact force displayed on the catheter readout (measured force). A resulting negative value means that the catheter underestimates the real force; a positive value means the catheter overestimates the real force. We evaluated three catheters for each model to verify reproducibility and to quantify inter-catheter variability. For the Stablepoint catheter, measured-force values above 50g are not displayed at angles >45°.

Statistical analysis

Continuous variables are presented as mean ± standard deviation or as median and interquartile range as appropriate. Linear regression analysis was used to determine the measurement error due to friction. Spearman correlation coefficients were used to assess the correlation between measured force and real force. A local smoothing function (locally estimated scatterplot smoothing (LOESS)) was used for the interpretation of the measurement data (loess function, span = 0.3). Statistical analyses were made by using R 4.0.2 (R Core Team, Vienna, Austria).

Results

We acquired a total of 6685 measurements using 12 catheters, three for each of the 4 models. For each catheter, a median of 107 (IQR 100-128) measurements was taken at each of the five specific angles. The overall correlation between measured force and real force was high with $\rho_{Spearman} \geq 0.98$ for all models. The results of all measurements are displayed in Figure 3. The mean absolute error for each model, across the full range, was 1.29g ±0.99g for Tacticath, 2.87g ±2.37g for AcQBlate Force, 1.38g ±1.29g for Stablepoint, and 2.26g ±2.70g for Smarttouch. However, for some combinations of a catheter, angle, and applied force, overestimation and underestimation of the real force were higher with a maximum of 6.5g / -5.6g for Tacticath, 11g / -11.6 for AcQblate Force, 7.4g / -5.6g for Stablepoint, and 8.5 / -22.6g for Smarttouch.

In the clinical range of 10-40g, all catheters had a lower absolute mean error with 1.19g ±0.88g for Tacticath, 2.86g ±2.08g for AcQBlate Force, 1.02g ±0.77g for Stablepoint, and 1.52g ±1.17g for Smarttouch (figure 4).

In the high force range (>40g), overestimation of more than 10g was observed for the AcQblate Force catheter at 90°, while both Smarttouch and AcQblate Force underestimated forces by more than 10g at angles of 30° and 45°. The Stablepoint catheter overestimated higher contact forces at 0° and 30°. Finally, the Tacticath did not over- nor underestimate forces by more than 5g at all angles.

AcQBlate Force and Smarttouch showed a higher variance between individual catheters (figure 3, second and fourth row). Conclusively, when pooling the data of all three catheters for each model and fitting the data using a local estimate function (loess), the measurement errors of two models scatter more: The residual standard errors of these loess functions are numerically higher for AcQBlate Force (14.5g) and Smarttouch (14.0g), compared to Tacticath (12.3g) and Stablepoint (10.1g).

Discussion

In this study, we provide an industry-independent validation of the accuracy of contemporary contact force ablation catheters. This study extends the current knowledge about the accuracy of force sensing catheters by validating all four currently available models, two of which (Stablepoint and AcQBlate Force) had not been assessed before. Further, all catheters were tested on a measurement setup which was validated in-house and has a very high accuracy and reproducibility. The main findings of this study are:

First, the overall correlation between measured force and real force was excellent with $\rho_{Spearman}$ ≥0.98 for all models. Second, within the clinical range of 10g-40g the absolute measurement errors were low with mean errors of <3g. Third, at higher forces (>40g), the Smarttouch and the AcQBlate Force catheter showed significant underestimation or overestimation of the real force by more than 15g at some angles.

Clinical implications

Efficacy

Contact force is an important predictor of lesion formation and accurate estimation therefore is important to predict lesion size and ablation efficacy[6,13,15]. Regarding an effective and safe contact force during ablation procedures, there is a U-shaped relationship with too low contact forces being less effective and too high forces increasing the risk for complictions[1]. In clinical trials, different minimal contact forces have been proposed for effective ablation by multiple investigators of clinical trials and range from >6.5g (SMART-AF) to >10g (TOCCASTAR), and >20g (EFFICAS II)[2,3,16].

Safety

Contact force enacted on tissue is linked to the potential for complications like cardiac perforations. In an ex-vivo porcine study, minimal contact forces needed for perforation were ranging from 131g for the right atrium to 227g for the left ventricle[17]. In another study on human heart specimens, previously ablated tissue had a 2-fold reduced minimal force when compared to healthy tissue and the minimal force needed for perforation was as low as 38g[18]. An underestimation of high contact forces could therefore lead to an increased risk for perforations. Here, Smarttouch and AcQblate Force showed significant underestimation at 30° and 45°.

Combining the evidence for efficacy and safety, a range of 10g to 40g is generally considered appropriate for clinical ablation. The accuracy within this range was good for all models with a mean absolute error of <3g and should therefore not affect the estimation of lesion formation by much as long as forces are kept within this range.

Technical considerations

Accuracy

For clinical use, the error of force-sensing catheters ideally should be as low as possible and the accuracy should be independent of other parameters such as catheter-to-tissue angle. Bourier et al. found an overall mean error of 1.2g for the Tacticath catheter when measuring at different contact angles, with individual catheters, irrigation, and catheter deflection[14]. Irrigation and deflection did not have an influence on the accuracy of the sensor and therefore were not repeated here.

Further, the contact angle may influence the accuracy, as the individual sensors on each axis are strained differently. In that regard, we did not find a decreased accuracy for contact parallel to tissue, however, it seems that the Z-axis sensor of Stablepoint is too sensitive. For comparison, Bourier et al. found a decreased accuracy for the SmartTouch catheter at 90° of contact[19].

Impact of catheter orientation

Some important considerations regarding parallel-to-tissue contact remain: While the force acting on the very distal end of the catheter produces accurate results, even a slightly more proximal application of the force naturally results in a reduced deflection of the tip (law of leverage) and therefore in an underestimation of the true force. In addition, forces acting on even more proximal parts of the catheter cannot be measured at all. This limitation of the technology applies to all models and should be considered when the catheter is oriented parallel to the tissue as can be the case during ablation of the ridge on the left pulmonary veins.

Impact of force sensing technology

Regarding the force sensing technology implemented in each catheter model, no differences in measurement accuracy were observed between optical sensors (Tacticath & AcQBlate Force) and electromagnetic sensors (Stablepoint and SmartTouch). In addition, between the two models with increased scattering, one implements an optical sensor and the other an electromagnetic one which speaks against a class effect.

Limitations

Despite an extensive set of measurements, some limitations remain: First, with n=3 catheters for each model, the variability within one catheter model cannot be assessed reliably and it cannot be excluded that another catheter performs better or worse than described here. Measuring a greater number of catheters might reveal relevant differences in manufacturing. Second, we measured static contact force, while in-vivo contact force is dynamic. This might have an influence on the accuracy of the force sensor. Force peaks occurring during the contraction of the heart might not be detected, resulting in an underestimation of the force. However, given that contact force sampling rates are a multiple of the heart rate, verifying static force instead of dynamic force should not have a major impact on the clinical implications of our findings (Table 1).

Lastly, although we did allow a warm-up phase before the measurements, we did not systematically test factors, which could have an impact on the accuracy of the force sensors. Specifically, the influence of water absorption during a multiple-hour dwell time, repeated RF applications, and frequent deflection of the catheter cannot be excluded.

Conclusion

The catheter-to-tissue contact force measured by force-sensing ablation catheters is accurate with an absolute mean error of <3g in a clinical range of 10g to 40g for all four currently available force-sensing ablation catheters. Some combinations of model and angle may be prone to significant errors at higher forces with >10g of overestimation and >15g of underestimation of true contact force, which may be clinically relevant.

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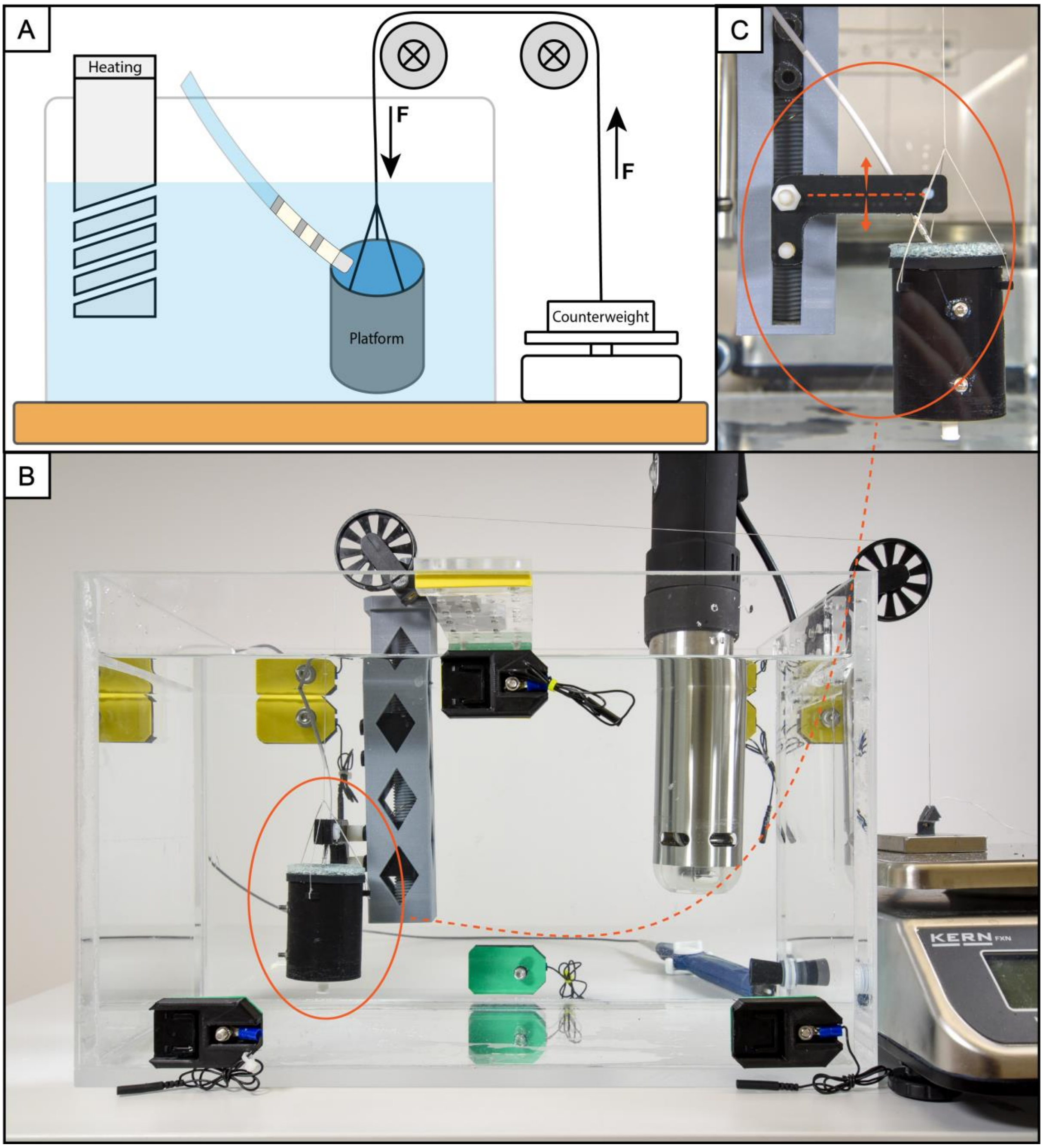

Figure 1: Bench-top set-up to measure forces acting on an ablation catheter.

Panel A shows a schematic drawing of the setup. The platform is suspended in a heated saline bath. The force applied by the catheter to the platform is redirected by two low-friction pulleys and measured by the scale, which is placed outside the water bath. Panel B shows the implementation with a water tank and heating, the measurement platform and the catheter fixation mechanism, the low friction pulleys, and the scale. Panel C shows a close-up view of the platform and the catheter fixation mechanism. The clamp can hold the catheter at different angles and is displaceable in the vertical axis to adjust the force applied to the platform.

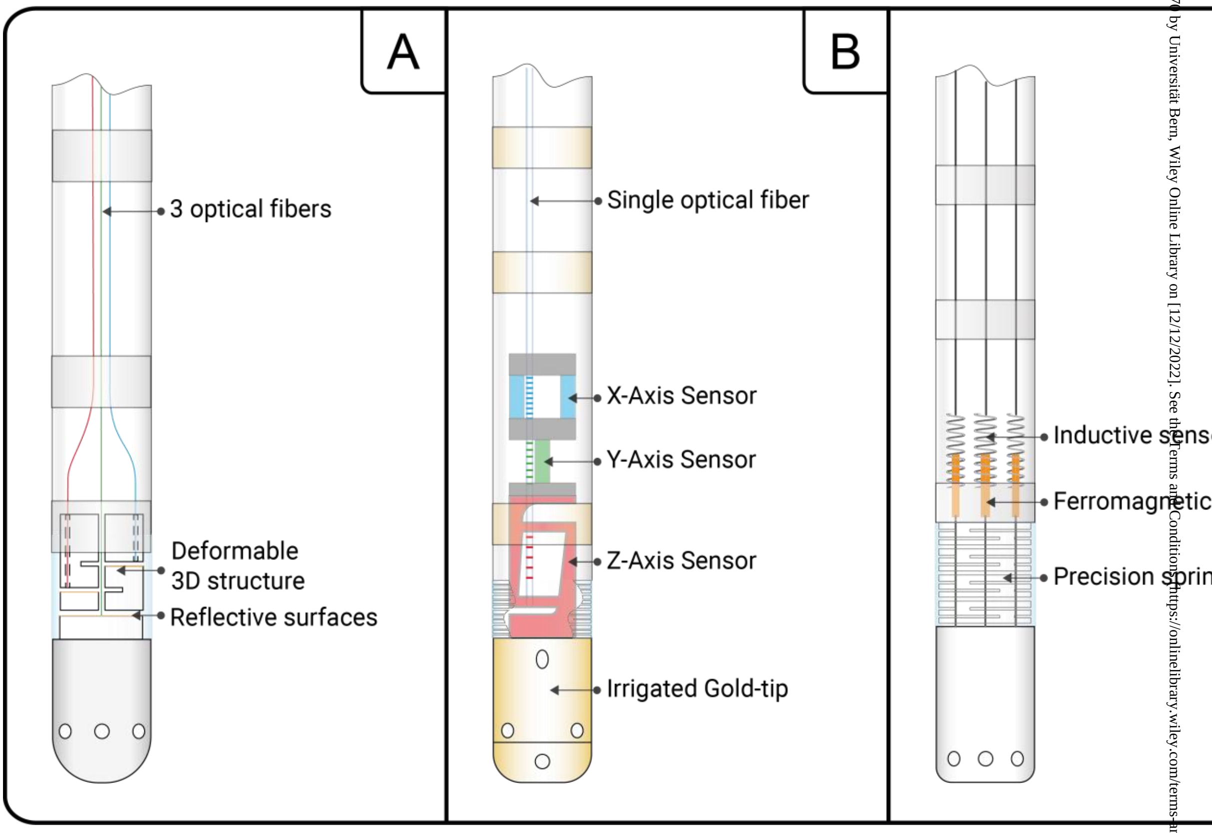

Figure 2: Force sensing technology overview

Schematic drawing of commercially available contact force sensing catheters and their implemented measurement technology. All catheters incorporate a 3-axis force sensor allowing for precise quantification of catheter-to-tissue contact during cardiac ablation interventions. Panel A: Tacticath™ Quartz (Abbott, Abbott Park, IL, USA), Panel B: AcQBlate® Force (Biotronik, Berlin, Germany), Panel C: Stablepoint™ (Boston Scientific, Marlborough, MA, USA), Panel D: Smarttouch® SF (Johnson&Johnson, New Brunswick, NJ, USA). For additional details see methods section and table 1.

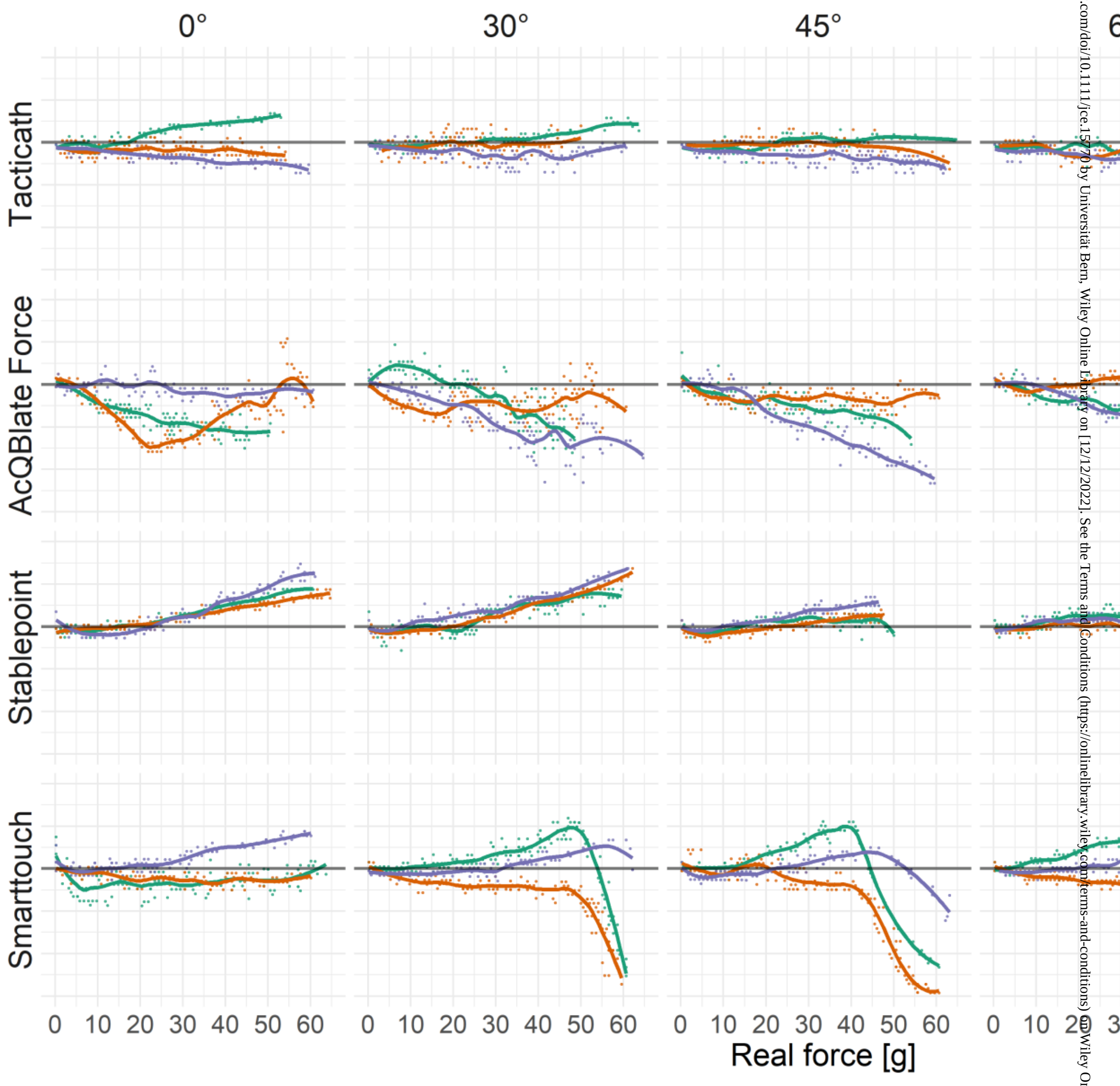

Figure 3: Measurement errors at different contact angles

Measurement errors of four commercially available contact force sensing catheters across their measurement range. Each row shows the results for different catheter models. Different catheter-to-tissue angles are displayed in columns (0° equals perpendicular to tissue, 90° equals parallel to tissue). The x-axis of each graph shows the real force exerted on the tissue and the y-axis the measurement error made by the catheter. Points above the black line in each graph mean the catheter overestimates the force and points below the black line mean the catheter underestimates the force. Different colors indicate different catheters. A local smoothing function was used for easier interpretation of the measurement data (loess function, span = 0.3). For the Stablepoint™ catheter, measured-force values above 50g are not displayed at angles >45°.

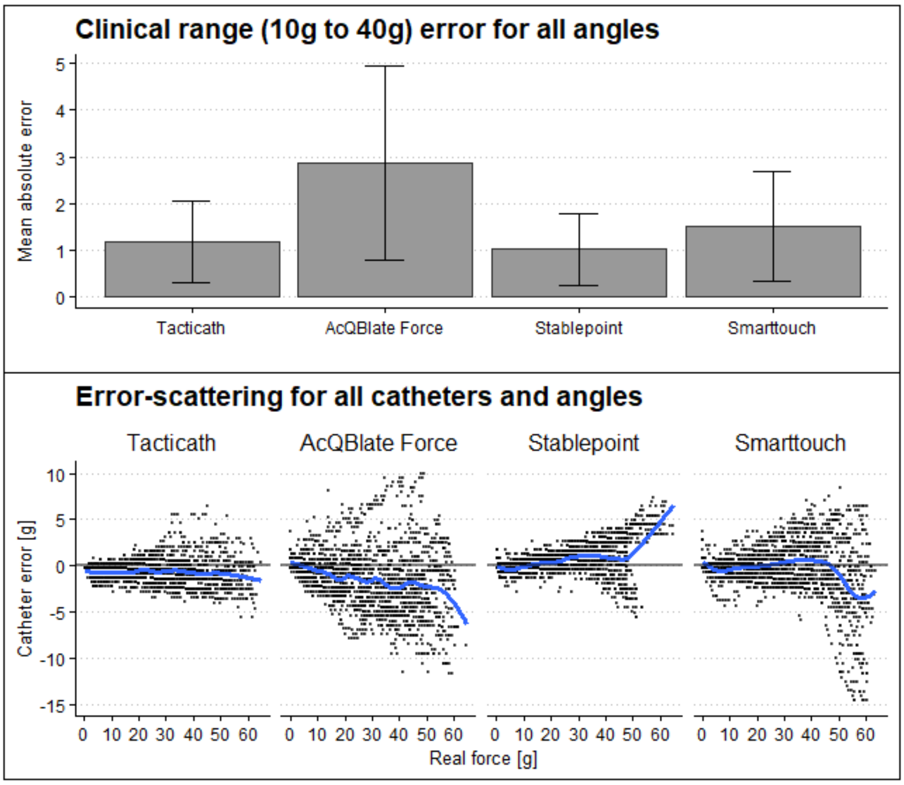

Figure 4: Mean measurement errors and scattering

Mean absolute errors within a clinical range of 10-40g for all catheter models, regardless of catheter-to-tissue contact angle (Upper Panel). All catheters have a mean error of <3g. Scattering of measurement errors for all three catheters per model combined, for all angles (Lower Panel)

	Tacticath™	AcQBlate® Force	Stablepoint™	Smarttouch® SF
Measurement Principle	Optical	Optical	Inductive	Magnetic
Catheter Size	$8\,F$	$8\,F$	$7.5\,F$	$8\,F$
Recommended Sheath	$8.5\,F$	$8.5\,F$	$8.5\,F$	$8.5\,F$
Tip length	$3.5\,mm$	$3.5\,mm$	$4\,mm$	$3.5\,mm$
Recommended Irrigation	$\leq 30W: 17\frac{ml}{min}$ $> 30W: 30\frac{ml}{min}$	$\leq 30W: 8\frac{ml}{min}$ $> 30W: 15\frac{ml}{min}$	$\leq 30W: 17\frac{ml}{min}$ $> 30W: 30\frac{ml}{min}$	$\leq 30W: 8\frac{ml}{min}$ $> 30W: 15\frac{ml}{min}$
Measurement range	Not specified	0g – 60g	0g – 50g	Not specified
Compatibility	Ensite	Standalone	Rhythmia	Carto
Force: vector display	Angle of 0 to 90°	Angle of 0 to 90°	Angle of 0 to 90°	Full 3D vector
Sampling rate	50 Hz	Unknown	20 Hz	10 Hz
Smoothed graph / number	Yes	Planned	Yes, customizable	Yes, customizable
Stability indication	Yes, highly customizable	No	Yes, customizable	Yes, customizable
Non-deflectable tip-length	18 mm	24 mm	21 mm	17 mm

Table 1: Overview of all four currently available force-sensing catheters.