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**EFFECTS OF OPEN-IRRIGATED RADIOFREQUENCY ABLATION CATHETER
DESIGN ON LESION FORMATION AND COMPLICATIONS: IN VITRO COMPARISON
OF SIX DIFFERENT DEVICES**

Running title: **In vitro comparison of open-irrigated catheters**

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ABSTRACT

Introduction - Open-irrigated radiofrequency ablation catheters with slight differences in tip architecture are widely used, although limited comparative data are available. The purpose of this study was to compare the lesion size and potential complications produced by commercially available open-irrigated catheters in an in vitro porcine heart model.

Methods and Results - Six catheters were tested (Biosense Webster Thermocool®, Boston Scientific Open irrigated™, St Jude CoolPath™, St Jude CoolPath Duo™, Biosense Webster Thermocool® SF, St Jude Cool Flex™) at 20 W and 35 W power-control, under two different blood flows (0.1 and 0.5 m/s) and at two target durations (30 and 60 s). A total of 601 lesions were made in 26 in vitro preparations. The tip temperature profile showed significant differences between the catheters ($p < 0.001$) with the Thermocool® SF registering the lowest. Only the surface diameter and the depth at maximum diameter of the lesion were influenced by the design of the ablation electrode. The lesion volume did not show significant differences between catheters for any power, application duration or blood flow condition. Char and pops occurred more often at 35 W with only slight differences between the catheters.

Conclusions - Tip design of the six different irrigated catheters does not affect the lesion total volume although a slight difference in lesion geometry in terms of surface diameter and depth at maximum diameter is present. The catheters show a slight different in vitro safety profile

Keywords: irrigated catheter, radiofrequency ablation, catheter ablation, lesion size, complications

INTRODUCTION

Radiofrequency (RF) catheter ablation is the therapy of choice for several cardiac arrhythmias. The aim of this technique is the creation of myocardial lesions of predictable size, minimizing the risk of complications.¹

Lesion size depends on the power delivered to the tissue, but this is limited by the risk of local thrombus formation. The development of thrombi is directly related to the temperature reached at the catheter tip during the application of RF. Various cooling catheter tip systems have been developed to prevent the occurrence of local thrombus formation, allowing greater power delivery and, as a result, improving catheter efficiency and safety in lesion creation.²⁻⁶

The two available methods for active electrode cooling to date are internal and external irrigation of the tip; the latter also called open irrigation. With the external system, fluid actively flows through holes arranged on the surface of the distal part of the electrode, reducing the overheating of the tissue-electrode interface.⁵ As compared with standard RF ablation catheters, active electrode cooling allows the creation of larger lesions at sites with reduced blood flow and affords a lower incidence of thrombus formation.^{4,6}

In recent years a number of different electrode architectures for open-irrigated catheters have been developed, varying the tip dimensions, temperature sensors location and the number, size or distribution of the irrigation ports on the tip surface. However, it is not known whether electrode architecture differences have an impact on lesion generation and the occurrence of adverse events.

The purpose of this study was to compare the lesion size and potential complications produced by six different commercially available open-irrigated RF ablation catheters in an in vitro porcine heart model.

METHODS

The study protocol was approved by the ethic and animal welfare committee of our institution and conformed to the regulation for the treatment of animals established by the *Guide for the Care and Use of Laboratory Animals* published by the U.S. National Institutes of Health (NIH Publication No. 85-23, revised 1996).

In vitro setup

Freshly excised porcine ventricles were mounted on a platform and placed in a lucid chamber filled with circulating heparinized blood (ACT>300) collected from the same animal and maintained at a temperature of 37° C. (Figure 1A) The left ventricle was isolated and opened through a longitudinal incision, exposing the endocardial surface and then immersed into the blood bath. A manipulator attached to the platform allowed placement of the ablation catheter perpendicular to the myocardial preparation. All catheters were tested with a stable tissue contact using a constant weight of 10 g. A pulsatile blood flow generated by a peristaltic pump (Masterflex® I/P, Cole-Parmer, Vernon Hills, IL) was directed at the ablation electrode-tissue interface through a plastic tube placed at a distance of 2 cm from the ablation electrode. The pump flow was set to obtain a mean flow velocity at the interface of either 0.1 or 0.5 m/s as measured by pulsed Doppler. RF energy was applied in the unipolar mode between the catheter tip electrode and an indifferent lead placed at the bottom of the chamber.

RF Ablation catheters

Six different commercially available open-irrigated catheters were tested: Thermocool® (Biosense Webster, Inc., Diamond Bar, CA), Blazer OI™ (Boston Scientific Corporation, Natick, MA), CoolPath™ (St. Jude Medical Inc., St. Paul, MN), CoolPath Duo™ (St. Jude

Medical Inc., St. Paul, MN), Thermocool® SF (Biosense Webster, Inc., Diamond Bar, CA), CoolFlex™ (St. Jude Medical Inc., St. Paul, MN). Technical specifications are summarized in Figure 2. All catheters contained a thermocouple embedded within the tip electrode for monitoring electrode temperature during ablation, although the exact position of the thermocouple inside the catheter tip is not reported in the technical specifications of the catheters. Besides, the Blazer OI™ catheter has a cooling chamber immediately before the irrigation ports at the base of the tip.

Ablation protocol

Endocardial lesions were created in power-control mode with a power of 20 W and 35 W using a Stockert 70 RF generator (Biosense Webster, Inc., Diamond Bar, CA). During each radiofrequency energy application, we continuously recorded the power delivered, the impedance, and the temperature at the tip electrode (PowerLab® 8/30 with LabChart® Pro software version 7, ADInstruments Pty. Ltd. Bella Vista, NSW, Australia). RF energy was delivered at target duration of 30 s or 60 s, and at two blood flows (0.1 and 0.5 m/s). A fixed saline irrigation rate of 13 ml/min was provided to all catheter designs through a peristaltic pump (Masterflex® I/P, Cole-Parmer, Vernon Hills, IL).

Immediately after each RF application, the catheter was examined for the presence of local thrombi and the endocardial surface was inspected for the presence of charring, disruption (“cratering”), or thrombus.

Lesion assessment

After the delivery of RF energy, the myocardium was cross-sectioned at the level of each lesion and stained with 1% triphenyltetrazolium chloride (TTC) at 37 °C for 20 minutes. Lesion volume was calculated as previously described by other authors.^{4, 6, 7} Briefly, as illustrated in Figure 1B, we measured the maximal depth (A), maximal diameter (B), depth

at the maximal diameter (C) and lesion surface diameter (D), for each lesion. Then, the lesion volume (LV) was estimated by assuming that the lesion shape was an oblate ellipsoid and subtracting the volume extending above the surface of the muscle according to the following formula: $LV = \left[0.75\pi \left(\frac{B}{2}\right)^2 (A - C) \right] - \left[0.25\pi \left(\frac{D}{2}\right)^2 (A - 2C) \right]$

Statistical analysis

Data are expressed as mean \pm SD. Tip-electrode impedance and temperature, and lesion measurements were compared within and between groups by ANOVA. Significant differences were further evaluated using Bonferroni's method for pairwise multiple comparisons. Data on safety profile are expressed as a percentage of RF applications that experienced a complication. A chi square test was used to compare the frequencies of the complications. A value of $p < 0.05$ was considered statistically significant.

RESULTS

A total of 601 lesions were performed in 26 in vitro swine heart preparations. There was no statistically significant difference in baseline impedance between the catheters used in this study (Table 1). No premature cutoffs of the RF delivery occurred due to impedance or temperature rises. An effective 20 W and 35 W powers were delivered in all applications, respectively.

Catheter tip temperature

The mean catheter tip temperature achieved during 30 and 60 s of RF application showed significant differences between the six studied catheters at 20 W and 35 W ($p < 0.001$ and $p < 0.001$ respectively) (Table 1). Indeed, the Thermocool® SF catheter consistently showed the lowest temperature at 20 W and 35 W ($p \leq 0.001$) being the only catheter that

did not show a significant difference on mean temperature between 20 W and 35 W power level. The CoolPath™ and CoolPath Duo™ showed the highest temperature ($p < 0.001$) at 20 W, whereas at 35 W most catheters with the exception of the Thermocool® and the Blazer OI™ showed similar high mean temperatures. At 20 W, the effect of blood flow (0.1 m/s vs. 0.5 m/s) on mean catheter temperature was different depending on the catheter tip characteristics: while no effect was detected on the Thermocool®, Blazer OI™ and CoolPath™, a paradoxical response with an increase in tip temperature with a higher flow was observed in the Thermocool® SF and CoolFlex™ ($p < 0.001$). This effect was not observed when a power of 35 W was used (Figure 3).

Lesion characteristics

Data on lesion characteristics are shown in Table 2. Only the surface diameter and the depth at maximum diameter of the lesion were influenced by the design of the ablation electrode either at 30 or at 60 s applications for a power of 20 W and at 30 s applications for a power of 35 W. At 20 W, after 30 s of RF application, the surface diameter was significantly smaller using the Thermocool® SF compared with the Thermocool® ($p < 0.001$), CoolPath™ ($p = 0.009$) and CoolFlex™ ($p = 0.015$). Moreover, after 60 s RF application, the Thermocool® SF continues to show the smaller surface diameter respect to all five tested catheters ($p < 0.001$), except for the CoolPath Duo™ ($p = 0.004$). This pattern changed when a power of 35 W was used. At 30 s application only the Boston OI™ showed a significant larger surface diameter compared with the CoolPath™ ($p = 0.022$), Thermocool® SF ($p = 0.004$), and CoolFlex™ ($p = 0.003$). At 60 s applications no significant differences between catheters were observed. By contrast, the depth at maximum diameter was significantly greater with the Thermocool® SF both at 30s and 60s RF application at 20 W compared to the rest of the catheters except the Thermocool® (Blazer OI™ $p < 0.001$ and $p < 0.001$, CoolPath™ $p = 0,039$ and $p = 0.01$,

CoolPath Duo™ $p=0.003$ and $p=0.024$, CoolFlex™ $p<0.001$ and $p=0.009$ at 30 s and 60 s, respectively). At 35 W, the Thermocool® showed the smallest depth at maximum diameter compared to the Blazer OI™ ($p=0.030$) and the CoolPath Duo™ ($p=0,039$) at 30 s application duration. At 60 s application duration, the depth at maximum diameter was not significantly different between the catheters.

Despite that the surface diameter and the depth at maximal diameter were affected by the catheter design, the total volume of the lesion induced by the six tested catheters did not show significant differences between catheters neither at any used RF power or application duration nor at different flow conditions (Figure 4).

Complications

The complications observed at the end of each RF application are shown in Table 2. Complications occurred more often when a power of 35 W was used. At a power of 20 W char was present in 7 out of 447 lesions (1,6%) and at a power of 35 W in 34 out of 154 lesions (22%). Char mostly occurred at low flow conditions (data not shown) and no significant differences were observed between the catheters. At 20 W pop was not observed in any application. On the contrary, at 35 W there was a substantial number of pops that mostly occurred at 60 s application duration. The rate of pops reached up to 80% of the 60 s applications for the CoolPath™ catheter and 73% for the Thermocool® SF. The rate of pops at 60 s application duration was significantly different between the catheters ($p=0.044$). Thrombus formation was observed only in the CoolPath™ catheter, being statistically different from the rest of the catheters (2 events, 3.1%, $p=0.037$); these 2 events occurred at 60 s applications, one at low and the other at high blood flow condition. For all catheters, the mean electrode temperature and impedance values at which the complication occurred were comparable to the values of RF applications free of complications.

DISCUSSION

Lesion volume

The main finding of this study is that the differences in the tip design of presently available open-irrigated RF ablation catheters do not affect to the lesion volume. This finding should likely be explained by the particular irrigation profile of each catheter. To the extent of our knowledge, this is the first time that the newest and most used commercially available open irrigated catheters are systematically compared in an in vitro study. Our results are in accordance with a previous work presented as an oral communication by Ikeda et al⁸ who compared three of the studied catheters (Thermocool®, CoolPath Duo™ and Thermocool® SF) and showed that they induced similar lesion size at 30 and 50 W.

Interestingly, at the two power setups used, lesion volume was nearly twice as big at 60 s compared to 30 s applications. Although it is generally assumed that the steady state for lesion formation is reached between 45 and 60 s,⁹ data in the literature comparing different application durations are scanty.¹⁰ Nevertheless, our results confirm previous findings and stress the importance of performing long applications in order to maximize lesion size.

Ablation setup

A constant flow rate of 13 ml/min was used for all catheters in the study with the aim of comparing catheters under exactly the same irrigation conditions.¹¹ This flow rate is slightly different to the rate recommended for clinical use by each manufacturer and may not reflect the ideal flow to achieve individual tip performance. However, since the own manufacturers recommend adjusting the flow rate depending on tip temperature response and ablation conditions, it is unlikely that this parameter significantly affected the results.

Irrigation pattern effects

Ikeda et al⁸ reported that the Thermocool® SF catheter produces greater electrode-tissue interphase cooling with lower irrigation flow rates as compared with the Thermocool® and

the CoolPath Duo™. Although we did not measure this parameter, we actually found that the Thermocool® SF catheter showed the lowest temperature profile and that temperature was not affected by the power used. For the other catheters, the number and distribution of the holes around the electrode tip did not correlate with tip-temperature.

As a result of the superficial cooling effect, the highest tissue temperature during RF delivery in open-irrigated tip ablation occurs at the subendocardial surface.⁷ Therefore, the maximum lesion width is usually located intramurally, with less amount of necrosis at the epicardium. Based on this, the different irrigation patterns should affect the surface diameter. The depth at the maximum diameter, which corresponds to the “hottest point” produced by heat conduction, was also slightly different between catheters.

The influence of the irrigation ports arrangement is markedly evident when considering the effect of the blood flow on the tip temperature at 20 W applications. The catheters with lesser number of holes showed similar temperature at different blood flows. On the contrary, the catheters with more number of holes showed an increase in the tip temperature when the blood flow augmented. This finding could be explained by the fact that, although the cooling effect in these catheters is probably more homogeneous over the tip surface, the local fluid output per hole is lower and, as a result, the irrigating saline flow is not able to counteract the higher blood flow.

Complications

Although several studies have documented the safety of irrigated-tip catheters,⁴⁻⁶ catheter type, contact conditions and power settings play a role in the frequency of complications that occur during RF ablation.⁶ However, since this is an in vitro study and extrapolation of our data to clinical practice may be limited, the catheters showed only a slightly different safety profile despite the different irrigation patterns. This is consistent with a recent publication by Scaglione et al¹² who compared the Thermocool® and the Thermocool® SF

in a clinical setting showing that the risk of a specific complication was similar for the two catheters.

Study limitations

This study was performed in a porcine in vitro model in a standardized setup. Although an in vitro animal model is not directly comparable to the beating human heart, the use of trabeculated porcine endocardium, heparinized blood, and an electrode-tissue interface pulsatile flow perfusion accomplish a high degree of reproducible physiological conditions. Trabeculated tissue may vary electrode-tissue surface among applications affecting lesion size and may impair electrode irrigation varying electrode exposure to blood flow. The lack of statistical differences in baseline impedance suggests a similar contact surface of the ablation electrode tips.¹³ Likewise, the elevated number of lesions performed at each setting probably helped to minimize these limitations.

The effect of different catheter irrigation rates was not studied in this protocol. Different flow rates may affect lesion dimensions and the incidence of cratering or coagulum formation. However, Weiss et al¹¹ investigated the impact of different irrigation catheter flow rates on the development of lesions and showed differences only in the surface diameter but not in the lesion depth.

All experiments were performed in the perpendicular catheter contact and no data were collected on parallel-side contact. Data from the literature on this issue are controversial. While some authors showed consistently larger lesions in parallel contact as compared to perpendicular contact,¹⁴⁻¹⁶ others showed that catheter orientation did not play a role in lesion size.⁶

The high rate of pops during 60 s applications at 35 W limited the number of valid lesions to be measured. This probably reduced the statistical power to detect differences in the surface diameter and depth at maximum diameter observed at other settings.

CONCLUSIONS

The tip design of six different open-irrigated RF catheters did not affect total lesion volume, although a slight difference in lesion geometry was observed. The safety profile of the catheters was also slightly different, although the clinical significance of the complications is hard to elucidate.

The results of this study suggest that, from a clinical perspective, changing the electrode tip design of open-irrigated ablation catheters has no impact on the efficacy (lesion size), and only a minor influence on safety. However, it must be considered that efficacy and safety of ablation performed clinically also depend on factors like catheter shaft stiffness, torque and push abilities and operator's experience, which have not been evaluated in this study.

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Jose M Guerra: study design, data collection, data analysis/interpretation, critical revision of the article

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TABLE 1: Initial impedance and mean temperature for each analyzed catheter.

	<i>Power (W)</i>	Biosense Webster Thermocool®	Boston Scientific Blazer™ OI	St Jude CoolPath™	St Jude CoolPath Duo™	Biosense Webster Thermocool® SF	St Jude CoolFlex™	p
Initial impedance (Ω)	20 - 35	139 ± 18	142 ± 18	139 ± 21	143 ± 23	142 ± 17	142 ± 24	ns
Mean Temperature (°C)	20	33 ± 1	32 ± 2	39 ± 2	37 ± 3	30 ± 2	33 ± 2	<0.001
	35	42 ± 3	34 ± 2	43 ± 4	45 ± 6	29 ± 1	44 ± 4	<0.001

Values: Mean± SD

TABLE 2: Characteristics of the myocardial lesions and complications induced by the six analyzed RF catheters.

	Power (W)	Application duration (s)	Biosense Webster Thermocool®	Boston Scientific Blazer™ OI	St Jude CoolPath™	St Jude CoolPath Duo™	Biosense Webster Thermocool® SF	St Jude CoolFlex™	p
n	20		80	87	64	70	78	68	
	35		26	28	25	25	26	24	
Surface diameter (mm)	20	30	5.9 ± 0.8	5.3 ± 1.2	5.6 ± 0.9	5.2 ± 1.1	4.7 ± 1.0	5.5 ± 1.1	<0.001
		60	6.2 ± 1.1	6.0 ± 1.2	6.2 ± 1.1	5.9 ± 0.8	5.0 ± 1.1	6.2 ± 1.1	<0.001
	35	30	6.7 ± 1.2	8.0 ± 1.2	6.4 ± 1.1	6.6 ± 1.0	6.2 ± 1.1	6.1 ± 0.9	0.001
		60	8.3 ± 1.1	8.0 ± 0.8	6.9 ± 1.4	7.7 ± 1.0	8.0 ± 1.2	8.0 ± 1.0	ns
Maximum diameter (mm)	20	30	8.3 ± 0.9	8.4 ± 1.8	8.3 ± 1.1	8.1 ± 1.3	8.0 ± 1.6	8.0 ± 1.5	ns
		60	10.1 ± 1.6	10.1 ± 1.7	10.7 ± 1.5	10.4 ± 1.5	9.9 ± 1.8	10.5 ± 2.1	ns
	35	30	11.2 ± 1.0	11.3 ± 1.4	11.7 ± 1.0	11.6 ± 1.8	11.6 ± 0.8	11.1 ± 1.2	ns
		60	13.5 ± 1.7	12.5 ± 2.1	13.1 ± 2.4	14.1 ± 0.8	12.9 ± 1.7	13.3 ± 1.9	ns
Depth max. diameter (mm)	20	30	1.4 ± 0.3	1.2 ± 0.3	1.3 ± 0.3	1.3 ± 0.3	1.5 ± 0.3	1.2 ± 0.3	<0.001
		60	1.7 ± 0.4	1.6 ± 0.3	1.6 ± 0.5	1.6 ± 0.4	1.9 ± 0.3	1.6 ± 0.4	0.001
	35	30	1.4 ± 0.2	1.8 ± 0.5	1.6 ± 0.4	1.8 ± 0.4	1.8 ± 0.2	1.7 ± 0.3	0.016
		60	2.2 ± 0.4	2.0 ± 0.5	2.4 ± 0.6	2.2 ± 0.4	2.6 ± 0.4	2.2 ± 0.8	ns
Maximum depth (mm)	20	30	4.0 ± 0.7	4.0 ± 0.8	4.0 ± 0.6	4.1 ± 0.8	4.0 ± 0.8	3.7 ± 0.8	ns
		60	5.4 ± 0.9	5.2 ± 0.8	5.3 ± 0.89	5.5 ± 0.8	5.4 ± 0.8	5.3 ± 0.7	ns
	35	30	5.9 ± 0.7	6.2 ± 0.6	6.1 ± 0.8	6.1 ± 0.7	6.3 ± 0.5	6.3 ± 1.0	ns
		60	7.2 ± 0.8	6.5 ± 1.2	8.1 ± 0.8	7.3 ± 0.7	7.0 ± 0.3	7.2 ± 1.1	ns
Volume (mm³)	20	30	99.3 ± 32.9	116.7 ± 66.2	101.4 ± 31.1	109.6 ± 52.2	97.1 ± 51.9	97.0 ± 57.4	ns
		60	218.4 ± 89.3	215.1 ± 98.3	242.6 ± 84.4	243.9 ± 91.0	209.5 ± 103.1	236.5 ± 103.4	ns
	35	30	309.4 ± 74.0	306.6 ± 114.3	351.6 ± 96.3	326.9 ± 107.1	336.1 ± 32.5	315.3 ± 72.4	ns
		60	502.0 ± 143.5	416.7 ± 229.6	561.3 ± 231.6	569.0 ± 142.7	417.5 ± 131.4	500.3 ± 179.7	ns
Char	20	30-60	0 (0%)	2 (2.4%)	3 (4.6%)	1 (1.4%)	1 (1.3%)	0 (0%)	ns
		30	1 (8%)	4 (29%)	4 (40%)	4 (40%)	0 (0%)	3 (30%)	0.054
	35	60	6 (43%)	4 (29%)	1 (7%)	4 (27%)	1 (7%)	2 (14%)	ns
Pop	20	30-60	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	ns
		30	0 (0%)	1 (7%)	1 (10%)	0 (0%)	1 (10%)	1 (10%)	ns
	35	60	4 (29%)	6 (43%)	12 (80%)	8 (53%)	11 (73%)	6 (43%)	0.044
Thrombus	20	30-60	0 (0%)	0 (0%)	2 (3.1%)	0 (0%)	0 (0%)	0 (0%)	0.037
	35	30-60	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	ns

Values are expressed as Mean ± SD or occurrences (percentage of the total)

Figure 1: A) In vitro setup. B) Lesion measurements performed: maximal depth (A), maximal diameter (B), depth at the maximal diameter (C) and lesion surface diameter (D).

Figure 2: Technical characteristics of the six irrigated RF ablation catheters included in the study

Figure 3: Mean catheter tip temperature during the RF applications at the two tested powers and blood flow conditions. Bars represent: ± 1 SEM.

Figure 4: Graphical representation to scale of the lesions created by each tested catheter at 20 and 35 W and at 30 and 60 s application duration. Values represent mean lesion volume (mm^3) \pm 1 SEM. No significant differences were found. Note the large dispersion of lesions at 35 W 60 s, probably due to the limited number of lesions valid to be measured as a result of the high incidence of pops.

Figure 1:

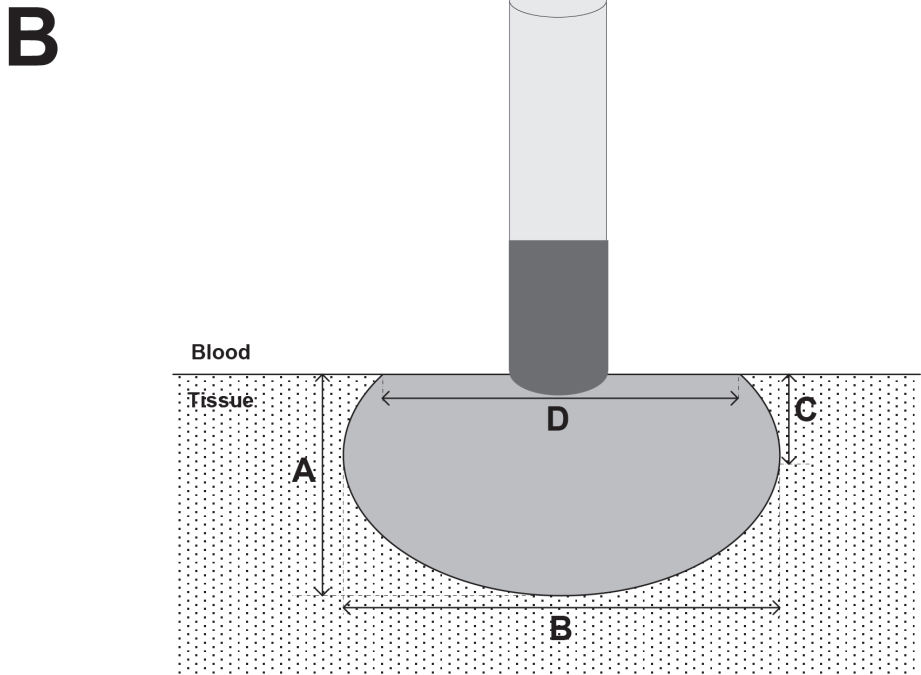
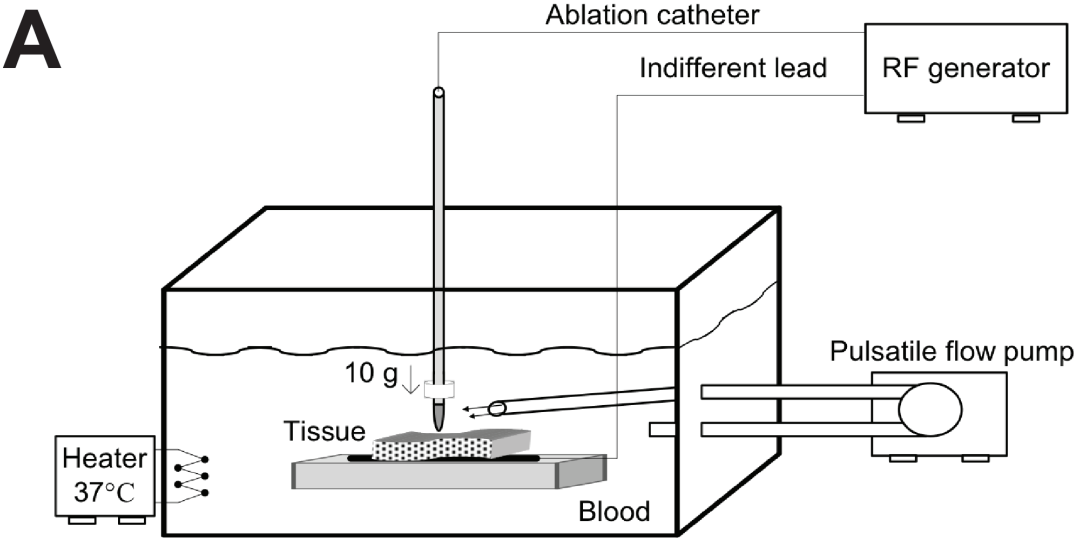
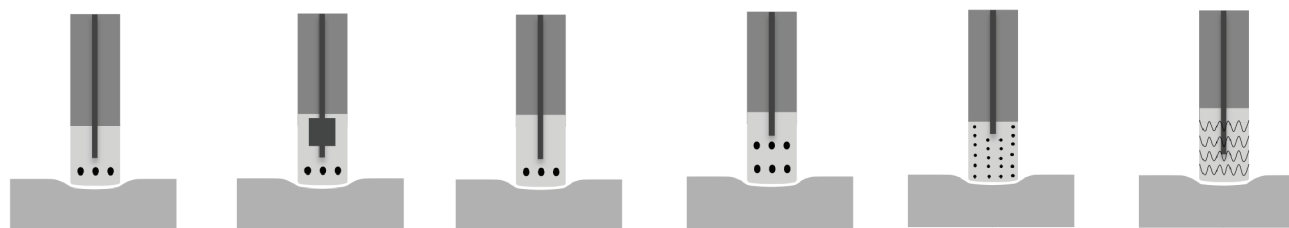


Figure 2:



Biosense Webster Thermocool® **Boston Scientific Blazer™ OI** **St Jude CoolPath™** **St Jude CoolPath Duo™** **Biosense Webster Thermocool® SF** **St Jude CoolFlex™**

Tip length (mm)	3.5	4	4	4	3.5	4
Tip diameter (F)	7.5	7	7	7	7.5	7
Number irrigation holes	6	6	6	12	56	Laser-cut tip 4 holes on distal tip
Diameter irrigation holes (mm)	0.016	0.016	*	0.015	0.0035	---

* Non reported

Figure 3:

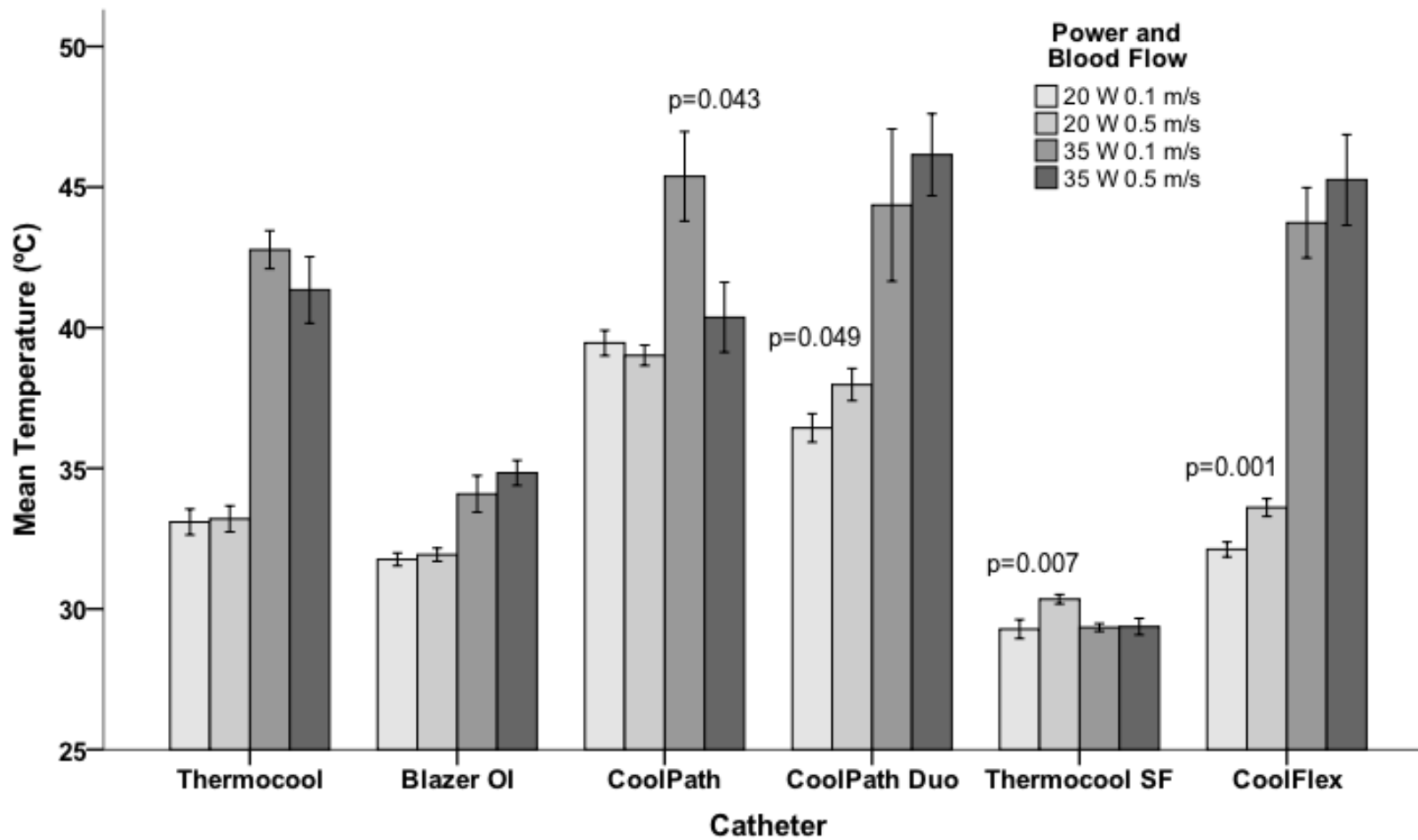


Figure 4:

