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DEVICES

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Avoiding damage to transvenous leads—A comparison of electrocautery techniques and two insulated electrocautery blades

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Abstract

Background: Electrocautery (cautery) can damage transvenous cardiac device leads. The purpose of this study was to compare lead damage from an insulated cautery blade when used with several different techniques that included coagulation (COAG) versus cutting (CUT) mode, perpendicular active edge (active) versus parallel flat blade (flat) orientation (phase 1), and using one commercially available blade (PhotonBlade) versus another (PlasmaBlade) (phase 2).

Methods: In phase 1, lesions were delivered using combinations of: (1) COAG and CUT; (2) active and flat orientation; and (3) polyurethane, silicone, and copolymer insulation. In phase 2, lesions were delivered using combinations of: (1) PlasmaBlade and PhotonBlade, (2) four power output levels, and (3) eight different lead models. Lead damage was scored on an ordinal scale of 0 to 4.

Results: Phase 1: more leads were damaged using COAG than CUT (48% vs 2%, $P < 0.0001$). When using COAG, 74% of lesions using active orientation had damage versus 22% of lesions using flat orientation ($P = 0.0002$). COAG lesions to copolymer (61%) and polyurethane (68%) leads had greater damage than silicone (17%) ($P = 0.006$ and $P = 0.003$, respectively). Phase 2: 75% of treatments using PlasmaBlade had damage versus 40% of treatments with PhotonBlade ($P < 0.0001$). Higher power resulted in more damage. At the commonly used setting of CUT 20 W, damage occurred in 39% of treatments using PlasmaBlade versus 13% using PhotonBlade ($P = 0.0006$).

Conclusions: COAG resulted in more damage than CUT; this effect was greatest with the active edge, and with polyurethane or copolymer insulation. PhotonBlade was associated with less damage to leads than PlasmaBlade.

KEYWORDS

electrocautery, ICD, pacemaker, PhotonBlade, PlasmaBlade, transvenous lead

1 | INTRODUCTION

As the number of implanted cardiac rhythm management devices grows, reoperation for generator replacement and other device revisions is increasingly encountered. Electrocautery (cautery) is routinely used during these procedures to remove the pulse generator and to dissect the leads or to achieve hemostasis. However, cautery can generate heat that can cause inadvertent thermal damage to transvenous lead insulation, particularly when the outer insulation material is composed of polyurethane.[1,2]

The use of a cautery blade with an insulated coating that surrounds the blade except for an exposed edge has been advocated to reduce collateral damage to transvenous leads. PlasmaBlade (Medtronic, Minneapolis, MN, USA) is the most commonly used system that is powered by a proprietary electrosurgical generator. PlasmaBlade appears to reduce the incidence of lead damage compared to scissors and standard cautery.[3] PhotonBlade (Invuity, San Francisco, CA, USA) is an alternative insulated cautery blade that is compatible with any standard electrosurgical generator. The purpose of this study was to assess optimal cautery blade orientation and generator settings to

TABLE 1 Lead descriptions

	Manufacturers	Model number	Insulation materials
Phase 1	Boston Scientific	4469	Polyurethane
	St. Jude Medical	7120	Copolymer
	Medtronic	5054	Silicone
Phase 2	Medtronic	6947 DF4/DF1	Silicone
	Medtronic	5086	Silicone
	Boston Scientific	4593	Polyurethane
	Medtronic	4196	Polyurethane
	Medtronic	3830	Polyurethane
	St. Jude Medical	1056K	Polyurethane
	St. Jude Medical	1258T	Copolymer
	St. Jude Medical	2088TC	Copolymer

avoid lead damage using PhotonBlade (phase 1), as well as to compare lead damage occurring from cautery using PhotonBlade versus PlasmaBlade (phase 2).

2 | METHODS

2.1 | Lead selection

Transvenous pacing and defibrillator leads produced by all three major US lead manufacturers, Medtronic, Boston Scientific (Marlborough, MA, USA), and St. Jude Medical/Abbott (St. Paul, MN, USA), were included (Table 1). Leads were selected to represent a full spectrum of types, including conventional stylet-driven pacemaker and defibrillation leads, over-the-wire coronary vein leads, as well as three common insulation materials (polyurethane 55D [polyurethane], silicone rubber [silicone], and a silicone/polyurethane copolymer [copolymer]). Some leads were designed with more than one layer of insulation surrounding the conductors such as an inner layer of silicone and an outer layer of polyurethane.

2.2 | Lead preparation and protocol

A chicken tissue model was used to simulate dissection of the transvenous leads. Grooves 1–2 cm deep were made in a chicken breast, with each lead placed inside of a groove. The chicken breast was placed on a grounding pad (Valleylab E7506, Covidien/Medtronic) for monopolar cautery. The chicken breast, lead, and grounding pad were placed in a tray on top of a balance (Ohaus CS5000, Parsippany, NJ, USA) and applied force was measured for each lesion. Contact was made for 3 seconds between the cautery blade, lead, and surrounding chicken tissue while delivering cautery. The chicken breast samples used were preselected to cover at least 90% of the conductive surface area of the grounding pad. All the samples used were consistent in weight (mean = 0.29 kg, SD = 0.028 kg). For each combination of test conditions, all lesions using both PhotonBlade and PlasmaBlade devices were delivered into the same piece of chicken breast.

TABLE 2 Phase 2 equivalent electrosurgical generator settings[4]

	PhotonBlade	PlasmaBlade
1	CUT Pure 20 W	CUT 6
2	CUT Pure 35 W	CUT 7
3	COAG Desiccate 35 W	COAG 5
4	COAG Fulgurate 40 W	COAG 8

2.2.1 | Phase 1 protocol

The first phase was conducted using PhotonBlade with a ValleyLab Force FX-C electrosurgical generator (Covidien/Medtronic). Lesions were delivered using combinations of the following:

1. Output modes: COAG 20 W and CUT 20 W.
2. Blade orientations: perpendicular active edge (active) and parallel flat blade (flat) (Figure 1).
3. Lead insulation materials: polyurethane, silicone, and copolymer.

Each combination was replicated using three separate but identical cautery blades, three times each, for a total of 108 treatments.

2.2.2 | Phase 2 protocol

The second phase was conducted using PhotonBlade and PlasmaBlade. PhotonBlade was used with a ValleyLab Force FX-C electrosurgical generator and PlasmaBlade was used with a PULSAR II generator (Medtronic) at comparable settings (Table 2).[4] Lesions were delivered using active orientation and combinations of the following:

1. PlasmaBlade and PhotonBlade.
2. Four power output levels expressed in PlasmaBlade setting and equivalent power in watts: CUT 6 (20 W), CUT 7 (35 W), COAG 5 (35 W), and COAG 8 (40 W).
3. Eight different lead models: two copolymer, two silicone, and four polyurethane.

Combinations were replicated using three separate cautery blades, three times each, for a total of 72 lesions per lead, except when using the Medtronic 5086 lead, which was too short to accommodate all lesions; therefore, 63 lesions were performed on this lead. A total of 567 lesions were delivered.

2.3 | Analysis of insulation damage

Each lead section was labeled with an alpha-numeric code corresponding to the lead, device, generator setting, and orientation, where applicable. Following testing, each lead section was cut and separated into individual containers for analysis.

Lead segments were examined by a board certified veterinary pathologist who was blinded to the treatment variables and who received the segments in a random order. Lead segments were assigned a damage score on an ordinal scale of 0 to 4 corresponding to no visual damage, minimal damage, moderate damage, minor insulation breach, and major insulation breach, respectively (Table 3). Leads

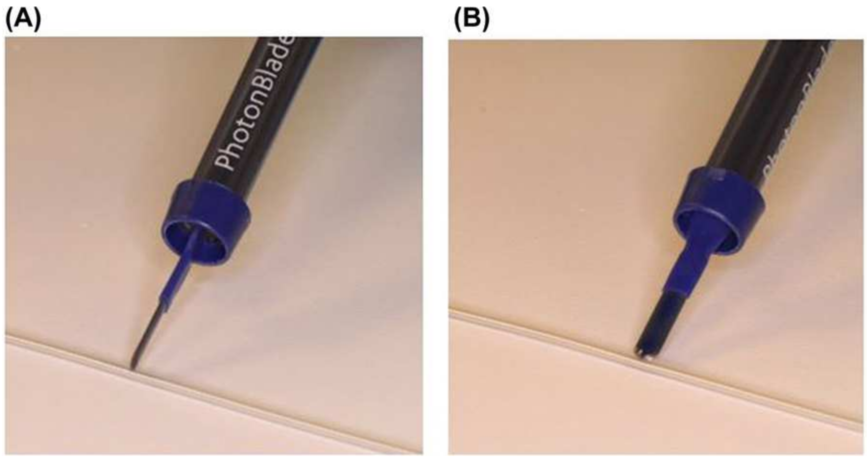
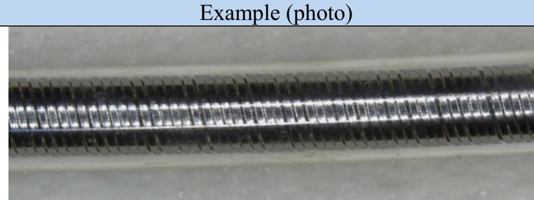
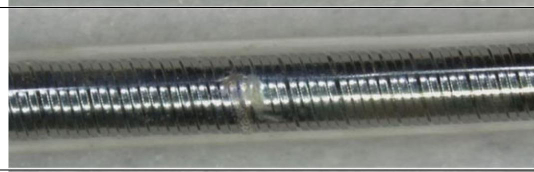
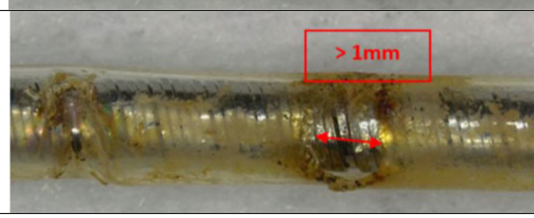


FIGURE 1 Blade orientations. Panel (A), perpendicular active edge (active) blade orientation; Panel (B), parallel flat blade (flat) orientation [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Lead damage scoring

Rating	Description	Example (photo)
0	No visual damage: no visual damage to the lead insulation.	
1	Minimal damage: damage is not visible to the naked eye, but may be seen under a microscope.	
2	Moderate damage: damage to the insulation layer(s) is obvious to the naked eye. No exposure of the metal conductor.	
3	Minor insulation breach: disruption of insulation material to the metal conductor, up to 1-mm wide.	
4	Major insulation breach: complete disruption of insulation material to the metal conductor, more than 1-mm wide.	

with two layers of insulation were only considered breached when the metal conductors became exposed.

2.4 | Statistical analysis

Cochran-Mantel-Haenszel statistics were used to test hypotheses of no partial association between the cautery blade type and lead damage when stratifying by a third variable such as insulation material or blade orientation or output setting. Additional measures of association included likelihood ratio χ^2 statistics, Fisher's exact test, and relative risk when 2×2 contingency table analysis was employed. The difference in unadjusted means was tested using the parametric Student's t test or the nonparametric Wilcoxon rank sum tests depending on the distribution of the data. Pairwise comparisons of the difference

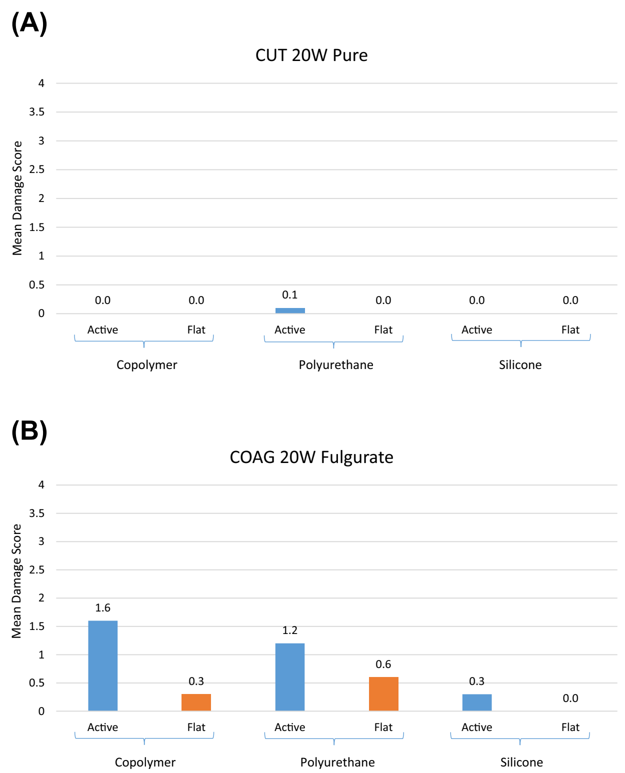


FIGURE 2 Phase 1 Mean damage scores by generator output setting. Panel (A), CUT 20 W pure; Panel (B), COAG 20 W fulgurate [Color figure can be viewed at wileyonlinelibrary.com]

in multiple group means were accomplished using the Tukey-Kramer honestly significant difference (HSD) test. The statistical significance level was set at 0.05. However, exact probabilities were computed in most comparisons. All analyses were performed using JMP 13.0 statistical software (SAS Institute, Inc., Cary, NC, USA).

3 | RESULTS

3.1 | Phase 1

Findings are shown in Figure 2. Significant damage was limited to leads coated with polyurethane and copolymer. Among all leads, a greater proportion was damaged using COAG compared to CUT (48% vs 2%, $P < 0.0001$) (Table 4). The mean damage score was 0.67 for COAG and 0.02 for CUT. When stratified by orientation, 74% of lesions using COAG and active orientation had damage compared with 22% of lesions using COAG and flat orientation ($P = 0.0002$). When COAG lesions were stratified by lead insulation material, both the copolymer (61%) and polyurethane (68%) lead insulations had significantly more damage than the silicone (17%) lead insulation ($P = 0.006$ and $P = 0.003$, respectively). Only a single CUT lesion was associated with damage, and this occurred using active orientation on a polyurethane lead. All other CUT lesions demonstrated no damage and therefore there was no significant difference seen by insulation type or orientation. Mean applied force was 0.14 ± 0.11 N. Applied force was found to be homogeneous across all damage scores.

3.2 | Phase 2

Seventy-five percent of treatments using PlasmaBlade had damage versus 40% of treatments using PhotonBlade ($P < 0.0001$) (Figure 3). The mean damage score was 1.64 for PlasmaBlade versus 0.78 for PhotonBlade. Regardless of device, 74% of treatments to copolymer leads resulted in damage versus 61% for polyurethane and 35% for silicone ($P < 0.0001$). Higher power resulted in more damage (Table 5). At the commonly used setting of CUT 20 W/CUT 6, damage occurred in 39% of treatments using PlasmaBlade versus 13% of treatments using PhotonBlade ($P = 0.0006$). Mean applied force was 0.32 ± 0.17 N. Applied force was found to be homogeneous across all damage scores and between the two systems.

4 | DISCUSSION

The aims of this two-phased study were: (1) to determine the effect of cautery mode, blade orientation, and lead insulation material on damage to transvenous leads during cautery with PhotonBlade, and (2) to compare damage to transvenous leads associated with cautery using PhotonBlade and PlasmaBlade.

4.1 | Treatment effects of electrocautery mode, blade orientation, and lead insulation material

The current study is consistent with prior data based on standard cautery versus PlasmaBlade that showed more damage occurring with: higher power, active compared to flat orientation, and polyurethane and copolymer lead insulation compared to silicone.[5,6]

In the present study, CUT waveform consistently resulted in less damage to all insulation materials in both blade orientations. In the prior study by Weisberg et al.,[5] when using PlasmaBlade, COAG mode resulted in damage to the copolymer lead in both orientations, while CUT resulted in damage to the copolymer and polyurethane leads only in the perpendicular (active) orientation. Thus, CUT waveform was previously associated with more damage than COAG to some insulation materials using active-blade orientation compared to the present study where CUT waveform consistently resulted in less damage to all insulation materials in both orientations. This may be due in part to differences in applied force between the studies, since a damage score of 1 can occur due to mechanical as well as thermal damage to leads.

4.2 | Frequency of lead damage as a function of device used

Damage was more frequent and deeper using PlasmaBlade compared to PhotonBlade regardless of lead insulation type. Damage was also greater with higher power output.

A prior study of 10 different transvenous leads showed that application of cautery by PlasmaBlade was associated with less damage to leads than standard cautery.[5] This is likely due to enamel blade

TABLE 4 Distribution of damage scores for CUT 20 W pure and COAG 20 W fulgurate

	Damage rating; *n* (%)			
Output	No damage 0	Minimal damage 1	Moderate damage 2	Total
CUT 20 W pure	53 (98.1%)	1 (1.9%)	0 (0.0%)	54
COAG 20 W Fulgurate	28 (51.9%)	16 (29.6%)	10 (18.5%)	54

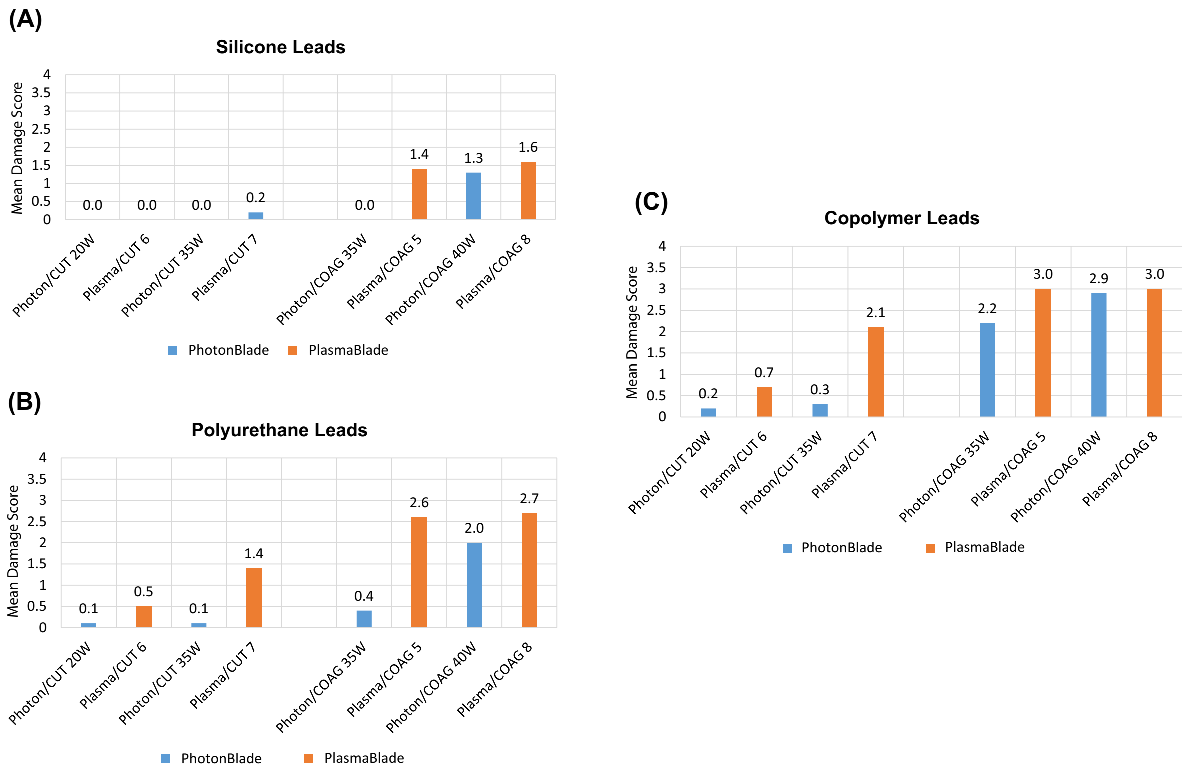


FIGURE 3 Phase 2 Mean damage scores by lead insulation material. Panel (A), silicone; Panel (B), polyurethane; Panel (C), copolymer [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 5 Rates of damage by device for matched settings

		Treatments resulting in damage; *n* (%)			
PhotonBlade output	PlasmaBlade output	PhotonBlade	PlasmaBlade	Risk ratio for lead damage	*P* value
CUT 20 W pure	CUT 6	8 (12.7%)[a]	28 (38.9%)	3.1	0.0006
CUT 35 W pure	CUT 7	7 (9.7%)	50 (69.4%)	7.1	< 0.0001
COAG 35 W desiccate	COAG 5	33 (45.8%)	68 (94.4%)	2.1	< 0.0001
COAG 40 W fulgurate	COAG 8	64 (88.8%)	71 (98.6%)	1.1	0.016

[a]There were 63 lesions made for this treatment condition. All other treatment conditions had 72 lesions.

insulation that limits exposure of active cautery to a small exposed active edge. The mechanism of reduced lead damage observed using PhotonBlade compared to PlasmaBlade in the present study requires further investigation and may be due to differences in the contact area and geometry of the active electrode surface. This could affect the current density, the amount of heat produced, and the dispersion of heat during electrocautery. In addition, there may be differences in the output waveforms and duty cycles of the two electrosurgical generators, which partially determine heat production even when controlling for equivalent power output settings. The relative contributions of these differences in the cautery blades versus the electrosurgical generators could not be independently assessed in these experiments because each cautery blade could only be paired with its own generator and not with the opposite.

Overall frequency of lead damage observed with both insulated blades was higher in the present study compared to the frequency of damage previously seen with PlasmaBlade. This may reflect higher power output used in the present study: PlasmaBlade settings up to CUT level 7 (35 W) and COAG level 8 (40 W). The highest settings tested in the prior study with PlasmaBlade were CUT level 5 (20 W) and COAG level 4 (30 W). At the commonly used setting of CUT 20 W/CUT 6, damage in this study occurred in 39% of treatments with PlasmaBlade versus 13% of treatments with PhotonBlade.

4.3 | Clinical implications

Electrocautery is routinely utilized during implantation of transvenous cardiac devices. When performing subsequent generator replacements or addition or replacement of transvenous leads, the leads are often adherent to the device generator and require dissection from thick fibrous sheaths in the device pocket. This can be technically difficult and exposes lead insulation to the risk of mechanical or thermal disruption. In one large study using a healthcare claims database, the incidence of lead damage following generator replacement was 0.46% for pacemaker replacement, 1.27% for implantable cardioverter-defibrillator replacement, and 1.94% for cardiac resynchronization therapy defibrillator replacement procedures. Procedures required to repair or revise leads were associated with increased inpatient hospitalization costs (mean $19 959 for pacemaker, $24 885 for implantable cardioverter-defibrillator, and $46 229 for cardiac resynchronization therapy defibrillator).[2] In another study based on a Danish registry, 0.9% of patients undergoing generator replacement required lead related reintervention,[7] while in the REPLACE registry there was a 1.0% incidence of reoperation resulting from lead dislodgement or lead malfunction in patients undergoing generator replacement without planned lead addition.[1]

PlasmaBlade is frequently used during replacement of cardiac implanted electronic devices as an approach to reduce the incidence of these complications. In one retrospective study of 611 patients, PlasmaBlade was associated with no damaged leads compared to 5.7% using conventional cautery and scissors, as well as shorter hospital stay and shorter procedure time, though it should be noted that the conventional cautery group had a much smaller sample size, a higher rate of lead damage compared to other literature, and the use of a historical control group resulted in procedures that were not performed contemporaneously.[3]

The findings of the current study confirm that operators must be aware of the risk of lead insulation damage when performing cautery in the vicinity of chronic transvenous leads, particularly with higher power output. PhotonBlade represents an alternative to PlasmaBlade that appears to be safer on transvenous lead insulation. When using PhotonBlade, CUT waveform should be selected when possible to minimize damage. If contact between PhotonBlade and a transvenous lead is unavoidable during electrosurgical dissection, brief contact should be limited to the insulated flat surface of the blade and not the active edge. Lower power output settings should be utilized given high rates of damage that were seen at higher power output, and special care should be taken near copolymer- and polyurethane- insulated leads that are most susceptible to thermal damage.

4.4 | Limitations

This study assessed damage to transvenous leads, but not the effectiveness of cautery using these two systems. For the leads containing more than one layer of insulation surrounding the conductors, damage scores may have been lower compared to a comparable lead with a single layer of insulation. The impact of insulation damage on electrical conductor integrity was not studied because lesions were delivered to sequential segments along each lead body to reduce the number of leads required. During delivery of some lesions at higher power outputs, glowing of the metal conductor was seen as well as arcing between lesion sites and this may have contributed to insulation damage. Lesions from both electrosurgical systems were present on each lead suggesting that any effects of this observation should impact both experimental groups similarly. The incidence of damage was nominally higher using CUT 20 W with PhotonBlade in phase 2 compared to phase 1. This may have been due to small sample size in phase 1 or higher mean applied force in phase 2. Finally, Invuity provided supplies, research support, and collaboration in study design; however, the cautery treatments, data collection, and analyses were performed by the authors who are not employees of the company.

5 | CONCLUSIONS

Following cautery applied to insulated transvenous leads using PhotonBlade, COAG mode was associated with more damage than CUT, and this effect was greatest when contact occurred using the active edge of the cautery blade, and when the lead insulation material consisted of polyurethane or copolymer. When compared to PlasmaBlade, the use of PhotonBlade was associated with less damage. At the commonly used setting of CUT 20 W, damage occurred in 39% of treatments using PlasmaBlade versus 13% of treatments with PhotonBlade. Additional studies are needed to evaluate differences in clinical endpoints, such as procedure times and complication rates using these two electrocautery systems.

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