Assessment of penetrating thermal tissue damage/spread associated with PhotonBlade™, Valleylab™ Pencil, Valleylab™ EDGE™ Coated Pencil, PlasmaBlade® 3.0S and PlasmaBlade® 4.0 for intraoperative tissue dissection using the fresh extirpated porcine muscle model

Haydon E. Bennett[a], Scott D. Taylor[b], James H. Fugett II[a], Joshua L. Shrout[a]
Paul O. Davison[c], S. Eric Ryan[c] and James E. Coad [a]*

[a] Pathology Laboratory for Translational Medicine, West Virginia University, Department of Pathology, Mailstop 9203, 1 Medical Center Drive, Morgantown, WV 26506;
[b] Taylor Engineering, 605 Highland Ave., San Martin, CA 95046; and
[c] Invuity, Inc. 444 De Haro Street, San Francisco, CA 94107

ABSTRACT

Penetrating thermal tissue damage/spread is an important aspect of many electrosurgical devices and correlates with effective tissue cutting, hemostasis, preservation of adjacent critical structures and tissue healing. This study compared the thermal damage/spread associated with the PhotonBlade™, Valleylab™ Pencil, Valleylab™ EDGE™ Coated Pencil, PlasmaBlade® 3.0S and PlasmaBlade® 4.0, when performing a single pass dynamic tissue cut in fresh extirpated porcine longissimus muscle. These devices were used in a fashion that emulated their use in the clinical setting. Each device's thermal damage/spread, at Minimum, Median and Maximum power input settings, was assessed with nitroblue tetrazolium viability staining in the WVU Pathology Laboratory for Translational Medicine. The thermal damage/spread associated with the PhotonBlade™ was compared with the other devices tested based on the individual treatment results (*n=179 cuts combined*). In summary, the PhotonBlade™ overall demonstrated the least penetrating thermal tissue damage/spread, followed by the PlasmaBlade® 4.0, then Valleylab™ Pencil and PlasmaBlade® 3.0S and then Valleylab™ EDGE™ Coated Pencil in order of increasing thermal damage/spread depths.

Keywords: Electrosurgical devices, thermal tissue injury, lateral thermal spread, tissue dissection, tissue cutting, viability staining, histology, tissue analysis.

1. INTRODUCTION

Penetrating thermal tissue damage/spread is an important aspect of electrosurgical devices, which correlates with effective tissue hemostasis, preservation of adjacent critical structures, and tissue healing. This study's purpose was to compare the penetrating thermal tissue damage/spread associated with the PhotonBlade™ (*Figure 1; Invuity, San Francisco, CA*) with the Valleylab™ Force FX™ c electrosurgical generator (*Medtronic, Minneapolis, MN*), the Valleylab™ Pencil (*Figure 2; Medtronic-Covidien, Boulder, CO*) with the Valleylab™ Force FX™ c, Valleylab™ EDGE™ Coated Pencil (*Figure 3; Medtronic-Covidien, Boulder, CO*) with the Valleylab™ Force FX™ c, PlasmaBlade® 3.0S (*Figure 4; Medtronic, Minneapolis, MN*) with the PULSAR™ II electrosurgical generator (*Medtronic, Minneapolis, MN*), and PlasmaBlade® 4.0 (*Figure 5; Medtronic, Minneapolis, MN*) with the PULSAR™ II electrosurgical generator, when performing a single pass dynamic tissue cut treatment.

This study used the fresh extirpated porcine longissimus muscle model and nitroblue tetrazolium viability staining (*NBT staining*) to determine the penetrating thermal tissue damage/spread for each device. Each device was used in a fashion that emulated its intended use in the clinical setting.

*jcoad@hsc.wvu.edu; phone 304-685-6124

Energy-based Treatment of Tissue and Assessment IX, edited by Thomas P. Ryan, Proc. of SPIE
Vol. 10066, 100660J · © 2017 SPIE · CCC code: 1605-7422/17/$18 · doi: 10.1117/12.2252111

Figure 1: PhotonBlade.

Figure 2: Valleylab Pencil (*Model E2516H*).

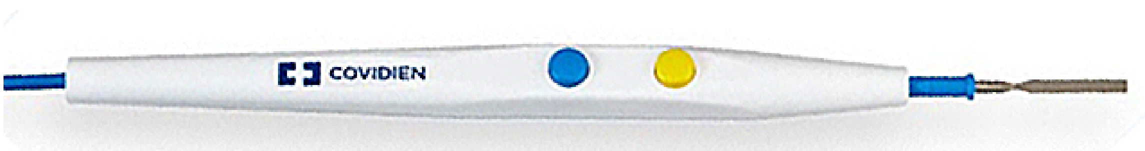

Figure 3: Valleylab EDGE Coated Pencil (*Model E2450H*).

Figure 4: PEAK PlasmaBlade (*Model 3.0S*).

Figure 5: PEAK PlasmaBlade (*Model 4.0*).

2. METHODOLOGY

2.1 Overview

This study's purpose was to compare the penetrating thermal tissue damage/spread associated with the PhotonBlade with the Valleylab Force FX c electrosurgical generator to that of the Valleylab Pencil with the Valleylab Force FX c, Valleylab EDGE Coated Pencil with the Valleylab Force FX c, PlasmaBlade 3.0S with the PULSAR II electrosurgical generator and PlasmaBlade 4.0 with the PULSAR II electrosurgical generator, when performing a single pass dynamic tissue cut treatment. This study used the fresh extirpated porcine longissimus muscle model and nitroblue tetrazolium viability staining (*NBT staining*) to determine the penetrating thermal tissue damage/spread for each device.

2.2 Treatment characterization

The dynamic tissue cut parameters used to assess the penetrating thermal tissue damage/spread associated with these devices emulated those anticipated for their clinical use. The PhotonBlade, Valleylab Pencil, and Valleylab EDGE Coated Pencil were evaluated using a Cut Mode power range of 20W (*minimum power setting*) to 50W (*maximum power setting*) with the Cut Mode, low waveform. A third power setting of 35W (*median power setting*) was evaluated as an intermediate setting between the minimum and maximum settings. The PlasmaBlade 3.0S and 4.0, when coupled with the specified Pulsar II generator, were evaluated using the Cut 6 (*20W*), Cut 7 (*35W*) and Cut 8 (*50W*) settings, representing comparable minimum, median and maximum device settings, respectively.

Practical speeds for fresh tissue cutting were selected to be 3 mm/second (*maximum tissue contact duration*), 5 mm/second (*intermediate tissue contact duration*) and 10 mm/second (*minimum tissue contact duration)* for the Maximum, Median and Minimum, respectively. These power input - cutting speed combinations allowed for complete assessment of the minimal to maximal penetrating thermal damage/spread anticipated to occur in the clinical setting. For standardization, the treatments were performed with a cutting depth of 5 mm and cut length of 15 mm using a robotic software-controlled treatment program. All treatments were performed with these devices vertically oriented.

2.3 Test system justification

The fresh extirpated porcine longissimus muscle model was selected for this comparison study, as this tissue (*porcine longissimus muscle*) is clinically relevant (*similar*) in composition to human tissue anticipated to be dissected with the PhotonBlade. The porcine longissimus muscle also provided a tissue model of adequate size to allow for the emulation of clinical tissue dissection. The total number of tissue specimens and individual treatments used in this study was the minimum required to compare the penetrating thermal tissue damage/spread following treatment with the PhotonBlade, Valleylab Pencil, Valleylab EDGE Coated Pencil, PlasmaBlade 3.0S and PlasmaBlade 4.0 Surgery Systems.

2.4 Test system specification

This study utilized fresh domestic swine (*Sus, scrofa domesticus)* longissimus muscle obtained from an abattoir. The three swine were either male (*n=2*) or female (*n=1*) and without a minimum estimated live weight. Tissue specimens were not obtained from animals in poor health.

2.5 Institutional animal care and use committee (*IACUC*)

IACUC review and approval was not required for this study. The swine, from which the tissues were obtained, were euthanized as part of the work flow at the abattoir's facility and not solely sacrificed for this study. Prior to sacrifice, the living swine were not housed, cared for, or treated at West Virginia University. The Sponsor agreed that this study was required to assess the penetrating thermal tissue damage/spread characteristics of the PhotonBlade, Valleylab Pencil, Valleylab EDGE Coated Pencil, PlasmaBlade 3.0S and PlasmaBlade 4.0 Surgery Systems; this testing was scientifically necessary; and this testing was not an unnecessary duplication of previous investigations completed by the Sponsor.

2.6 Swine tissue collection and preparation

Immediate post-slaughter, non-cooled (*ambient temperature, fresh non-frozen*) porcine longissimus muscles were obtained from an abattoir. The porcine were euthanized at this facility, as part of their routine workflow, in accordance with West Virginia Department of Agriculture guidelines. The tissue was dissected from the carcass using non-thermal methods. The fresh tissues were trimmed of excess surrounding tissues and transported to the Pathology Laboratory for Translational Medicine (*PLTM*) for processing, treatment and subsequent NBT staining evaluation. Precautions were taken to ensure the specimens did not dry, become overly hydrated, heated, or frozen during transport to the laboratory. The fresh tissue specimens arrived in the Pathology Laboratory for Translational Medicine within 2 hours of sacrifice.

The tissues were further subdivided, as appropriate, into pieces to fit the testing robot. The sub-specimens were placed in individually labeled, thin-walled plastic bags and initially maintained at ambient temperature. When needed for treatment, the specimens were submerged in a 40 ± 2°C saline bath inside its plastic bag until the specimen's temperature was 37 ± 1℃.

2.7 Tissue treatments (*Figure 6*)

The PhotonBlade, Valleylab Pencil, Valleylab EDGE Coated Pencil, PlasmaBlade 3.0S, and PlasmaBlade 4.0 were used in the following fashion to thermally cut the tissue. The tissue sub-specimens were treated within 7.5 hours of the swine's euthanasia time. During the treatments, the warming plate temperature was set so that the tissue holder temperature was 37 ± 1°C.

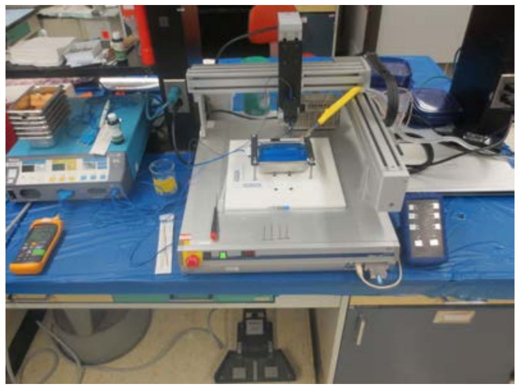

Figure 6: Overall Test System Layout.

The treatment procedure follows:

1. The prepared tissue sub-specimens were placed into tissue holder to constrain the tissue sample in a flat horizontal orientation. The tissue holder was then positioned on top of the warming plate and anchored to the robot stage, using threaded inserts and bar clamps.
2. Saline was lightly applied to the targeted treatment area to moisten the surface.
3. The appropriate software treatment program for the controller was selected.
4. Dynamic Cut Treatment:
    a. With the generator inactive, the controller software moved the device electrode down to contact the tissue surface until there was a just visually detectable tissue deflection.
    b. The software was reset with this "Home" position for the forthcoming treatment.
    c. The treatment program was started and device moved vertically upward to its highest vertical position and then descended to the "Home" position.
    d. Prior to reaching the "Home" position, the generator footswitch controller was activated.
    e. The device then descended the programmed amount into the tissue.
    f. Once it reached its full depth of penetration, the robotic stage moved the device vertically through the tissue for the programmed distance. Once the device completed its vertical travel, it rose out of the tissue and return to the maximum vertical stage position.
    g. The generator footswitch controller was inactivated once it was visually noted that the device was no longer in contact with the tissue.
5. The integrity of the electrode was visually inspected; the electrode was gently wiped with gauze to remove any tissue eschar buildup.
6. As tissue surface spacing permitted, additional treatments were made in this sub-specimen by returning to Step 2 above for next treatment.
7. If there was insufficient remaining surface area for additional treatments, the treated tissue specimen was removed from the holder and place in a clean, secure, labelled container with a saline-soaked gauze pad.

Following treatment, the tissue sub-specimens were maintained at room temperature in a plastic container for at least 2 hours but not more than 4 hours after completion of the treatments.

2.8 Treatment site dissection

Following the post-treatment acclimation period, each sub-specimen was re-oriented. For each cut treatment, a single perpendicular (*Figure 7*) tissue section (*red rectangle*) was taken from its approximate center. The perpendicular section was taken so to avoid the proximal and distal ends of the treatment pathway. The tissue blocks were taken so that they included the penetrating thermal tissue damage/spread region (*NBT-negative*) and a portion of adjacent viable tissue (*NBT-positive*). The tissue sections were frozen to -20ºC to -80ºC in OCT filled cryomolds.

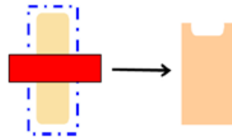

Figure 7: Diagram for sectioning the dynamic cut treatment sites.

2.9 NBT staining and evaluation

The frozen treatment site cross sections were cryosectioned at 10 microns onto labeled charge-coated slides. These slides were nitroblue tetrazolium (*NBT*) stained to assess for regions of thermal enzyme inactivation (*viability stain*).

Using routine light microscopy at 40x magnification (*Figures 9, 10, 11 and 12*), the presence of a grey-purple color change in the tissue was interpreted as having functional enzyme activity (*diaphoreses/NADPH; NBT-positive, viable*). The absence of a color change and preservation of native tissue coloration was interpreted as having non-functional enzyme activity (*NBT-negative, non-viable, thermal spread/damage region*). The depths were all measured perpendicular to the treatment site surfaces. A calibrated ocular micrometer was used to measure the NBT-negative (*tan*) tissue depths and widths when present. The maximal depth in each region was recorded to within ± 0.01 mm. The NBT-negative (*tan*) midline depth (*Midline*) and both lateral side width depths (*Width 1 and Width 2*) surrounding the treatment site were measured.

2.10 Data analysis

For each device, the Midline penetrating thermal tissue damage/spread depths will be reported as a unique parameter. The Width 1 and Width 2 penetrating thermal tissue damage/spread depths will be combined for the purpose of reporting the overall thermal spread/damage associated with the electrode sides. The penetrating thermal tissue damage/spread depths were summarized as the mean, standard deviation, median, minimum and maximum depth. For comparison purposes, the PhotonBlade was statistically compared to the Valleylab Pencil, Valleylab EDGE Coated Pencil, PlasmaBlade 3.0S, and PlasmaBlade 4.0. The device's penetrating thermal tissue damage/spread depths were compared using the non-parametric Wilcoxon Rank Sums method with alpha set at a 0.05 significance level.

3. STUDY RESULTS

For all five devices combined, one hundred and seventy-nine dynamic cut (*n=179*) were included in the study analysis. The included treatment sites were prepared from five fresh longissimus muscles that were obtained from three swine (*1 female and 2 male*). The approximate swine live weights were 250 ± 35.5 lbs. The NBT-negative thermal damage/spread depths were assessed and summarized in Tables 1 and 2. The thermal penetrations/damage depths, at minimal, median and maximum power inputs, are graphically shown by device in Figure 13.

3.1 PhotonBlade dynamic cut treatments

The mean PhotonBlade 20W at 10 mm/second dynamic cut midline thermal damage/spread depth was 0.11 ± 0.022 mm with lower and upper 95% confidence limits of 0.10 and 0.13 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.14 ± 0.048 mm with lower and upper 95% confidence limits of 0.12 and 0.16 mm, respectively.

The mean PhotonBlade 35W at 5 mm/second dynamic cut midline thermal damage/spread depth was 0.22 ± 0.039 mm with lower and upper 95% confidence limits of 0.19 and 0.25 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.37 ± 0.068 mm with lower and upper 95% confidence limits of 0.34 and 0.40 mm, respectively.

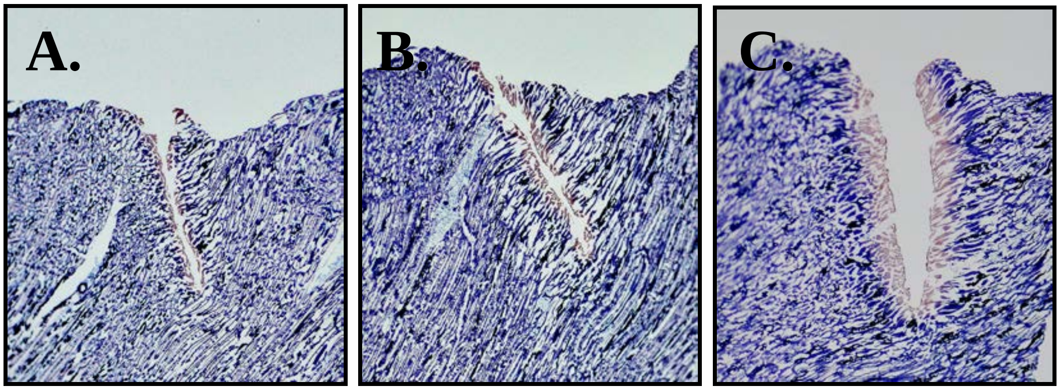

Figure 8. Representative NBT-stained PhotonBlade (*A*, *B and C*) dynamic longissimus muscle cut treatments (*taken at approximately 5x original magnification*). PhotonBlade Treatments: 20W at 10 mm/second (*A*), 35W at 5 mm/second (*B*) and 50W at 3 mm/second (*C*).

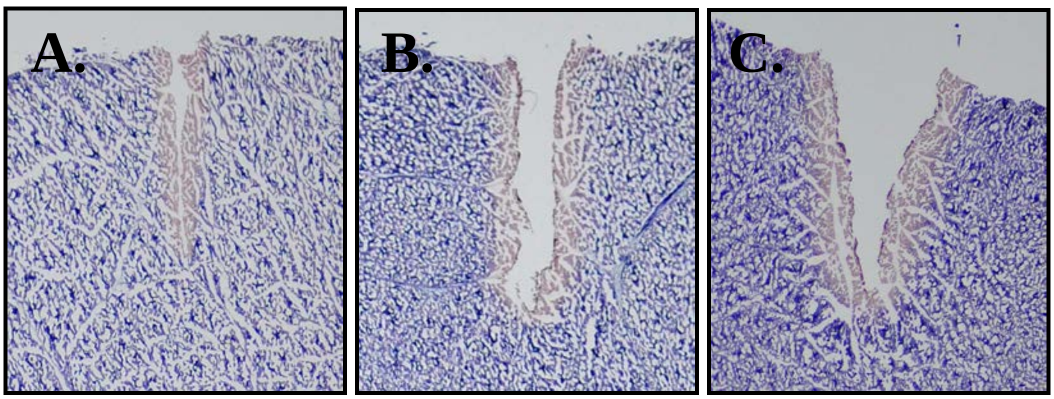

Figure 9. Representative NBT-stained Valleylab Pencil (*A*, *B and C*) dynamic longissimus muscle cut treatments (*taken at approximately 5x original magnification*). Valleylab Pencil Treatments: 20W at 10 mm/second (*A*), 35W at 5 mm/second (*B*) and 50W at 3 mm/second (*C*).

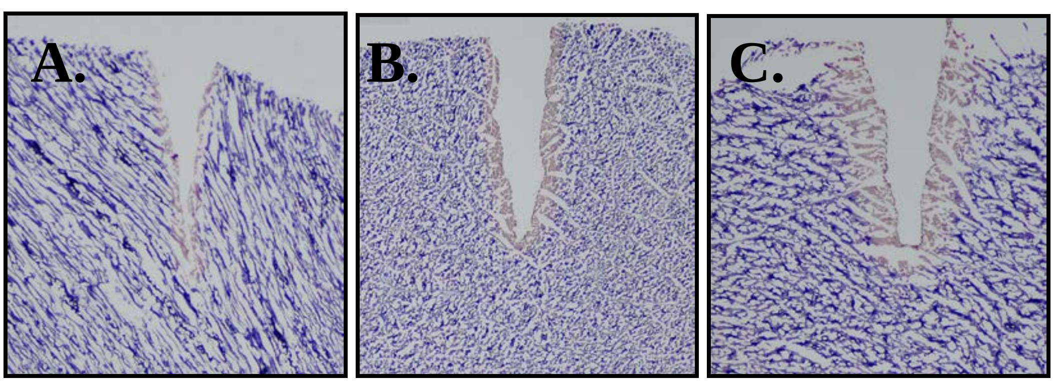

Figure 10. Representative NBT-stained Valleylab EDGE Coated Pencil (*A*, *B and C*) dynamic longissimus muscle cut treatments (*taken at approximately 5x original magnification*). Valleylab EDGE Coated Pencil Treatments: 20W at 10 mm/second (*A*), 35W at 5 mm/second (*B*) and 50W at 3 mm/second (*C*).

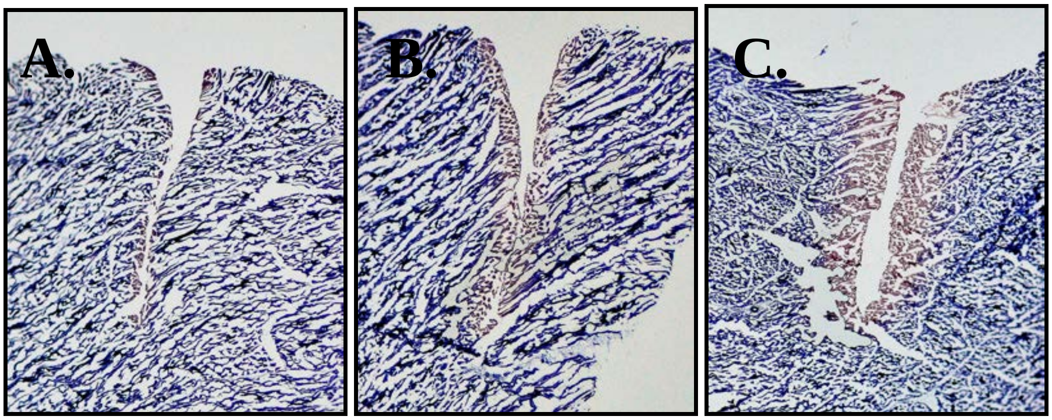

Figure 11. Representative NBT-stained PlasmaBlade 3.0S (*A, B and C*) dynamic longissimus muscle cut treatments (*taken at approximately 5x original magnification*). PlasmaBlade 3.0S Treatments: Cut 6 (*20W*) at 10 mm/second (*A*), Cut 7 (*35W*) at 5 mm/second (*B*) and Cut 8 (*50W*) at 3 mm/second (*C*).

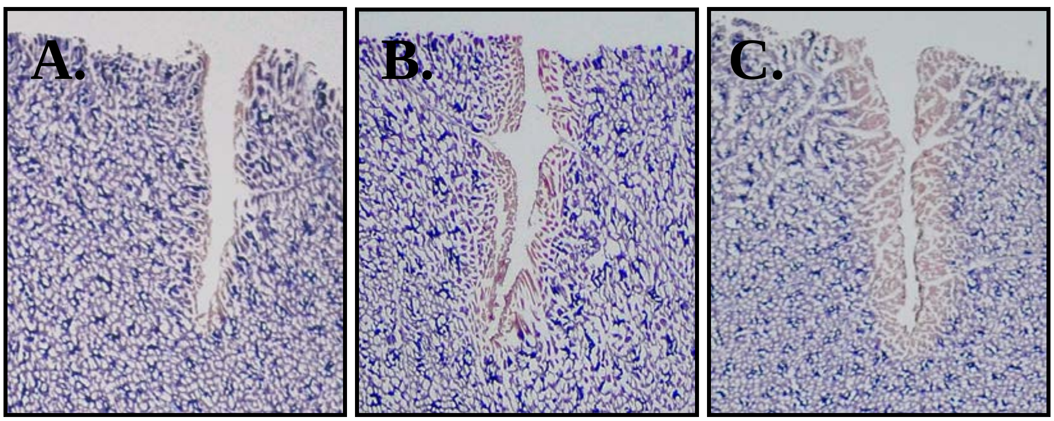

Figure 12. Representative NBT-stained PlasmaBlade 4.0 (*A, B and C*) dynamic longissimus muscle cut treatments (*taken at approximately 5x original magnification*). PlasmaBlade 4.0 Treatments: Cut 6 (*20W*) at 10 mm/second (*A*), Cut 7 (*35W*) at 5 mm/second (*B*) and Cut 8 (*50W*) at 3 mm/second (*C*).

The mean PhotonBlade 50W at 3 mm/second dynamic cut midline thermal damage/spread depth was 0.23 ± 0.035 mm with lower and upper 95% confidence limits of 0.20 and 0.25 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.54 ± 0.092 mm with lower and upper 95% confidence limits of 0.49 and 0.58 mm, respectively.

3.2 Valleylab Pencil dynamic cut treatments

The mean Valleylab Pencil 20W at 10 mm/second dynamic cut midline thermal damage/spread depth was 0.17 ± 0.059 mm with lower and upper 95% confidence limits of 0.13 and 0.20 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.40 ± 0.105 mm with lower and upper 95% confidence limits of 0.36 and 0.44 mm, respectively.

The mean Valleylab Pencil 35W at 5 mm/second dynamic cut midline thermal damage/spread depth was 0.28 ± 0.079 mm with lower and upper 95% confidence limits of 0.22 and 0.33 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.54 ± 0.109 mm with lower and upper 95% confidence limits of 0.49 and 0.58 mm, respectively.

The mean Valleylab Pencil 50W at 3 mm/second dynamic cut midline thermal damage/spread depth was 0.43 ± 0.078 mm with lower and upper 95% confidence limits of 0.39 and 0.48 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.80 ± 0.125 mm with lower and upper 95% confidence limits of 0.75 and 0.85 mm, respectively.

3.3 Valleylab EDGE Coated Pencil dynamic cut treatments

The mean Valleylab EDGE Coated Pencil 20W at 10 mm/second dynamic cut midline thermal damage/spread depth was 0.31 ± 0.072 mm with lower and upper 95% confidence limits of 0.27 and 0.35 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.43 ± 0.111 mm with lower and upper 95% confidence limits of 0.38 and 0.47 mm, respectively.

The mean Valleylab EDGE Coated Pencil 35W at 5 mm/second dynamic cut midline thermal damage/spread depth was 0.41 ± 0.087 mm with lower and upper 95% confidence limits of 0.36 and 0.46 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.69 ± 0.125 mm with lower and upper 95% confidence limits of 0.64 and 0.75 mm, respectively.

The mean Valleylab EDGE Coated Pencil 50W at 3 mm/second dynamic cut midline thermal damage/spread depth was 0.55 ± 0.124 mm with lower and upper 95% confidence limits of 0.47 and 0.62 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.97 ± 0.170 mm with lower and upper 95% confidence limits of 0.90 and 1.04 mm, respectively.

3.4 PlasmaBlade 3.0S dynamic cut treatments

The mean PlasmaBlade 3.0S Cut 6 at 10 mm/second dynamic cut midline thermal damage/spread depth was 0.19 ± 0.072 mm with lower and upper 95% confidence limits of 0.14 and 0.24 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.20 ± 0.056 mm with lower and upper 95% confidence limits of 0.18 and 0.23 mm, respectively.

The mean PlasmaBlade 3.0S Cut 7 at 5 mm/second dynamic cut midline thermal damage/spread depth was 0.29 ± 0.070 mm with lower and upper 95% confidence limits of 0.24 and 0.34 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.52 ± 0.116 mm with lower and upper 95% confidence limits of 0.47 and 0.58 mm, respectively.

The mean PlasmaBlade 3.0S Cut 8 at 3 mm/second dynamic cut midline thermal damage/spread depth was 0.43 ± 0.100 mm with lower and upper 95% confidence limits of 0.36 and 0.49 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.92 ± 0.151 mm with lower and upper 95% confidence limits of 0.85 and 0.99 mm, respectively.

3.5 PlasmaBlade 4.0 dynamic cut treatments

The mean PlasmaBlade 4.0 Cut 6 at 10 mm/second dynamic cut midline thermal damage/spread depth was 0.12 ± 0.025 mm with lower and upper 95% confidence limits of 0.10 and 0.14 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.14 ± 0.053 mm with lower and upper 95% confidence limits of 0.12 and 0.16 mm, respectively.

The mean PlasmaBlade 4.0 Cut 7 at 5 mm/second dynamic cut midline thermal damage/spread depth was 0.22 ± 0.051 mm with lower and upper 95% confidence limits of 0.19 and 0.25 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.47 ± 0.100 mm with lower and upper 95% confidence limits of 0.43 and 0.51 mm, respectively.

The mean PlasmaBlade 4.0 Cut 8 at 3 mm/second dynamic cut midline thermal damage/spread depth was 0.35 ± 0.080 mm with lower and upper 95% confidence limits of 0.30 and 0.40 mm, respectively. The mean lateral Width 1-2 thermal damage/spread depth was 0.68 ± 0.160 mm with lower and upper 95% confidence limits of 0.61 and 0.74 mm, respectively.

3.6 PhotonBlade versus Valleylab Pencil statistical comparisons

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 20W at 10 mm/second (*0.11 ± 0.022 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.018*) that with the Valleylab Pencil 20W at 10 mm/second (*0.17 ± 0.059 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.14 ± 0.048 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab Pencil (*0.40 ± 0.105 mm*).

Table 1. Mean NBT-negative thermal penetration/damage depths in millimeters.

	Mean ± Std Dev	**Median**	**Minimum**	**Maximum**	**Mean ± Std Dev**	**Median**	**Minimum**	**Maximum**	**p=**
	PhotonBlade Treatments				**Valleylab Pencil Treatments**				
Test Conditions:	20W at 10 mm/second (*n=10, 20*)*				20W at 10 mm/second (*n=14, 28*)*				
Midline Depths	0.11 ± 0.022	0.13	0.08	0.13	0.17 ± 0.059	0.13	0.10	0.25	0.018
Widths 1-2 Depths	0.14 ± 0.048	0.15	0.05	0.25	0.40 ± 0.105	0.38	0.18	0.75	< 0.001
Test Conditions:	35W at 5 mm/second (*n=11, 22*)*				35W at 5 mm/second (*n=12, 24*)*				
Midline Depths	0.22 ± 0.039	0.23	0.15	0.28	0.28 ± 0.079	0.27	0.10	0.43	0.011
Widths 1-2 Depths	0.37 ± 0.068	0.38	0.28	0.53	0.54 ± 0.109	0.55	0.25	0.70	< 0.001
Test Conditions:	50W at 3 mm/second (*n=10, 20*)*				50W at 3 mm/second (*n=13, 26*)*				
Midline Depths	0.23 ± 0.035	0.23	0.18	0.28	0.43 ± 0.078	0.43	0.30	0.55	< 0.001
Widths 1-2 Depths	0.54 ± 0.092	0.54	0.35	0.65	0.80 ± 0.125	0.75	0.63	1.03	< 0.001
	PhotonBlade Treatments				**Valleylab EDGE Coated Pencil Treatments**				
Test Conditions:	20W at 10 mm/second (*n=10, 20*)*				20W at 10 mm/second (*n=13, 26*)*				
Midline Depths	0.11 ± 0.022	0.13	0.08	0.13	0.31 ± 0.072	0.30	0.18	0.43	< 0.001
Widths 1-2 Depths	0.14 ± 0.048	0.15	0.05	0.25	0.43 ± 0.111	0.43	0.20	0.63	< 0.001
Test Conditions:	35W at 5 mm/second (*n=11, 22*)*				35W at 5 mm/second (*n=12, 24*)*				
Midline Depths	0.22 ± 0.039	0.23	0.15	0.28	0.41 ± 0.087	0.40	0.25	0.53	< 0.001
Widths 1-2 Depths	0.37 ± 0.068	0.38	0.28	0.53	0.69 ± 0.125	0.71	0.43	1.03	< 0.001
Test Conditions:	50W at 3 mm/second (*n=10, 20*)*				50W at 3 mm/second (*n=13, 26*)*				
Midline Depths	0.23 ± 0.035	0.23	0.18	0.28	0.55 ± 0.124	0.55	0.30	0.70	< 0.001
Widths 1-2 Depths	0.54 ± 0.092	0.54	0.35	0.65	0.97 ± 0.170	1.00	0.63	1.30	< 0.001

* (*n= midline depth measurements, lateral side depth measurements*)

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 35W at 5 mm/second (*0.22 ± 0.039 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.011*) that with the Valleylab Pencil 35W at 5 mm/second (*0.28 ± 0.079 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.37 ± 0.068 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab Pencil (*0.54 ± 0.109 mm*).

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 50W at 3 mm/second (*0.23 ± 0.035 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab Pencil 50W at 3 mm/second (*0.43 ± 0.078 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.54 ± 0.092 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab Pencil (*0.80 ± 0.125 mm*).

3.7 PhotonBlade versus Valleylab EDGE Coated Pencil statistical comparisons

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 20W at 10 mm/second (*0.11 ± 0.022 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil 20W at 10 mm/second (*0.31 ± 0.072 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.14 ±*

0.048 mm) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil (*0.43 ± 0.111 mm*).

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 35W at 5 mm/second (*0.22 ± 0.039 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil 35W at 5 mm/second (*0.41 ± 0.087 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.37 ± 0.068 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil (*0.69 ± 0.125 mm*).

Table 2. Mean NBT-negative thermal penetration/damage depths in millimeters.

	Mean ± Std Dev	**Median**	**Minimum**	**Maximum**	**Mean ± Std Dev**	**Median**	**Minimum**	**Maximum**	**p=**
	PhotonBlade Treatments				**PlasmaBlade 3.0S Treatments**				
Test Conditions:	20W at 10 mm/second (*n=10, 20*)*				Cut 6 at 10 mm/second (*n=11, 22*)*				
Midline Depths	0.11 ± 0.022	0.13	0.08	0.13	0.19 ± 0.072	0.15	0.10	0.35	0.001
Widths 1-2 Depths	0.14 ± 0.048	0.15	0.05	0.25	0.20 ± 0.056	0.20	0.08	0.30	0.001
Test Conditions:	35W at 5 mm/second (*n=11, 22*)*				Cut 7 at 5 mm/second (*n=10, 20*)*				
Midline Depths	0.22 ± 0.039	0.23	0.15	0.28	0.29 ± 0.070	0.25	0.23	0.43	0.008
Widths 1-2 Depths	0.37 ± 0.068	0.38	0.28	0.53	0.52 ± 0.116	0.53	0.28	0.75	< 0.001
Test Conditions:	50W at 3 mm/second (*n=10, 20*)*				Cut 8 at 3 mm/second (*n=11, 22*)*				
Midline Depths	0.23 ± 0.035	0.23	0.18	0.28	0.43 ± 0.100	0.43	0.30	0.65	< 0.001
Widths 1-2 Depths	0.54 ± 0.092	0.54	0.35	0.65	0.92 ± 0.151	0.95	0.63	1.15	< 0.001
	PhotonBlade Treatments				**PlasmaBlade 4.0 Treatments**				
Test Conditions:	20W at 10 mm/second (*n=10, 20*)*				Cut 6 at 10 mm/second (*n=13, 26*)*				
Midline Depths	0.11 ± 0.022	0.13	0.08	0.13	0.12 ± 0.025	0.13	0.05	0.13	0.315
Widths 1-2 Depths	0.14 ± 0.048	0.15	0.05	0.25	0.14 ± 0.053	0.13	0.08	0.28	0.582
Test Conditions:	35W at 5 mm/second (*n=11, 22*)*				Cut 7 at 5 mm/second (*n=13, 26*)*				
Midline Depths	0.22 ± 0.039	0.23	0.15	0.28	0.22 ± 0.051	0.25	0.13	0.28	0.789
Widths 1-2 Depths	0.37 ± 0.068	0.38	0.28	0.53	0.47 ± 0.100	0.45	0.30	0.68	< 0.001
Test Conditions:	50W at 3 mm/second (*n=10, 20*)*				Cut 8 at 3 mm/second (*n=13, 26*)*				
Midline Depths	0.23 ± 0.035	0.23	0.18	0.28	0.35 ± 0.080	0.38	0.20	0.48	0.001
Widths 1-2 Depths	0.54 ± 0.092	0.54	0.35	0.65	0.68 ± 0.160	0.63	0.45	1.00	0.006

* (*n= midline depth measurements, lateral side depth measurements*)

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 50W at 3 mm/second (*0.23 ± 0.035 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil 50W at 3 mm/second (*0.55 ± 0.027 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.54 ± 0.092 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil (*0.97 ± 0.170 mm*).

3.8 PhotonBlade versus PlasmaBlade 3.0S statistical comparisons

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 20W at 10 mm/second (*0.11 ± 0.022 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.001*) that with the PlasmaBlade 3.0S Cut 6 at 10 mm/second (*0.19 ± 0.072 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.14 ± 0.048 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.001*) that with the PlasmaBlade 3.0S (*0.20 ± 0.056 mm*).

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 35W at 5 mm/second (*0.22 ± 0.039 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.008*) that with the PlasmaBlade 3.0S Cut 7 at 5 mm/second

(*0.29 ± 0.070 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.37 ± 0.068 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the PlasmaBlade 3.0S (*0.52 ± 0.116 mm*).

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 50W at 3 mm/second (*0.23 ± 0.035 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the PlasmaBlade 3.0S Cut 8 at 3 mm/second (*0.43 ± 0.100 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.54 ± 0.092 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the PlasmaBlade 3.0S (*0.92 ± 0.151 mm*).

3.9 PhotonBlade versus PlasmaBlade 4.0 statistical comparisons

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 20W at 10 mm/second (*0.11 ± 0.022 mm*) was not significantly different than (*Wilcoxon Rank Sums p=0.315*) that with the PlasmaBlade 4.0 Cut 6 at 10 mm/second (*0.12 ± 0.025 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.14 ± 0.048 mm*) was not significantly different than (*Wilcoxon Rank Sums p=0.582*) that with the PlasmaBlade 4.0 (*0.14 ± 0.053 mm*).

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 35W at 5 mm/second (*0.22 ± 0.039 mm*) was not significantly different than (*Wilcoxon Rank Sums p=0.789*) that with the PlasmaBlade 4.0 Cut 7 at 5 mm/second (*0.22 ± 0.051 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.37 ± 0.068 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the PlasmaBlade 4.0 (*0.47 ± 0.100 mm*).

The mean dynamic cut midline thermal damage/spread depth with the PhotonBlade 50W at 3 mm/second (*0.23 ± 0.035 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.001*) that with the PlasmaBlade 4.0 Cut 8 at 3 mm/second (*0.35 ± 0.080 mm*). The mean lateral Width 1-2 thermal damage/spread depth with the PhotonBlade (*0.54 ± 0.092 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.006*) that with the PlasmaBlade 4.0 (*0.68 ± 0.160 mm*).

4. CONCLUSIONS

Penetrating thermal tissue damage/spread is an important aspect of electrosurgical devices and correlates with effective tissue hemostasis, preservation of adjacent critical structures, and tissue healing. This study's purpose was to compare the penetrating thermal tissue damage/spread associated with the PhotonBlade with the Valleylab Force FX c electrosurgical generator, the Valleylab Pencil with the Valleylab Force FX c, Valleylab EDGE Coated Pencil with the Valleylab Force FX c, PlasmaBlade 3.0S with the PULSAR II electrosurgical generator, and PlasmaBlade 4.0 with the PULSAR II electrosurgical generator, when performing a single pass dynamic tissue cut treatment in the fresh extirpated porcine longissimus muscle. Each device was used in a fashion that emulated its intended use in the clinical setting.

For all five devices combined, this study utilized one hundred and seventy-nine dynamic cut treatments (*n=179*) in the study analysis. The fresh *ex vivo* porcine longissimus muscles underwent single dynamic cut treatments in the West Virginia University Pathology Laboratory for Translational Medicine. Each device's associated penetrating thermal tissue damage/spread, at Minimum, Median and Maximum power input settings, was assessed with nitroblue tetrazolium viability staining (*NBT staining*).

The penetrating thermal tissue damage/spread associated with the PhotonBlade was compared with those of the Predicate/Control Articles based on the following comparisons (*Figure 13*):

Cut Minimum: PhotonBlade 20W vs. Valleylab Pencil 20W, Valleylab EDGE Coated Pencil 20W, PlasmaBlade 3.0S Cut 6, and PlasmaBlade 4.0 Cut 6 penetrating thermal tissue damage/spread; single dynamic pass 10 mm/second cut treatments.

Cut Median: PhotonBlade 35W vs. Valleylab Pencil 35W, Valleylab EDGE Coated Pencil 35W, PlasmaBlade 3.0S Cut 7, and PlasmaBlade 4.0 Cut 7 penetrating thermal tissue damage/spread; single dynamic pass 5 mm/second cut treatments.

Cut Maximum: PhotonBlade 50W vs. Valleylab Pencil 50W, Valleylab EDGE Coated Pencil 50W, PlasmaBlade 3.0S Cut 8, and PlasmaBlade 4.0 Cut 8 penetrating thermal tissue damage/spread; single dynamic pass 3 mm/second cut treatments.

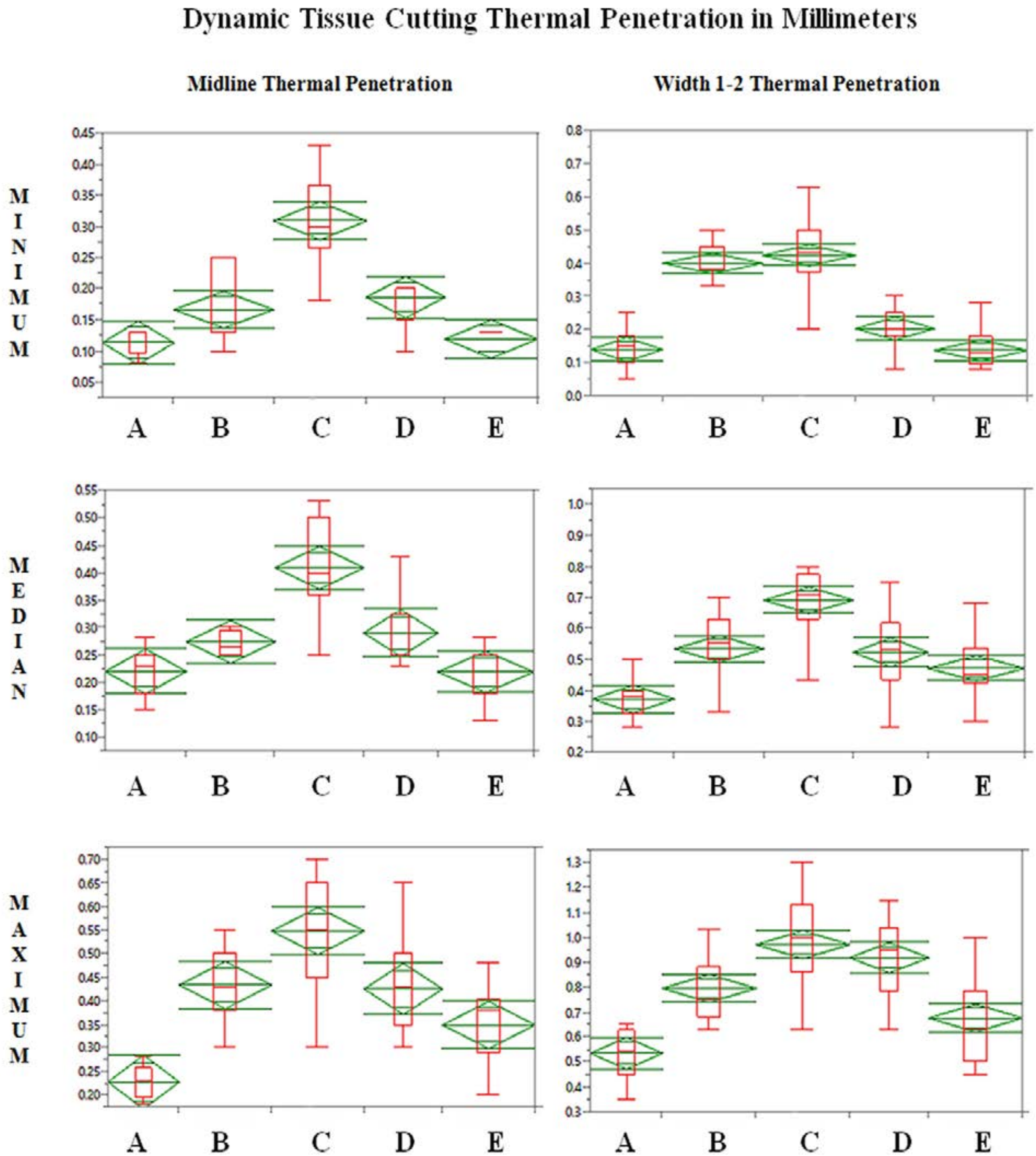

Figure 13. Graphical pictorials of the dynamic cutting NBT-negative thermal penetrations by device at Minimum, Median and Maximum power input settings. Device Identifiers: **A.** PhotonBlade with the Valleylab Force FX c electrosurgical generator; **B.** Valleylab Pencil with the Valleylab Force FX c; **C.** Valleylab EDGE Coated Pencil with the Valleylab Force FX c; **D.** PlasmaBlade 3.0S with the PULSAR II electrosurgical generator; and **E.** PlasmaBlade 4.0 with the PULSAR II electrosurgical generator. Green median diamonds, redline box quartiles and green bar 95% confidence intervals are displayed.

Based on the individual treatment results, the following themes were identified (*see above Study Results section for details*):

Dynamic Cut Minimum Power Setting: Dynamic tissue cutting with the PhotonBlade, at its minimum power setting (*20W at 10 mm/second*), demonstrated significantly less midline and lateral side thermal damage/spread than the Valleylab Pencil, Valleylab EDGE Coated Pencil and PlasmaBlade 3.0S. Similar midline and lateral side thermal damage/spread was identified between the PhotonBlade and PlasmaBlade 4.0.

1. The mean midline thermal damage/spread depth with the PhotonBlade 20W at 10 mm/second (*0.11 ± 0.022 mm*) was less than (*Wilcoxon Rank Sums p=0.018*) that with the Valleylab Pencil 20W at 10 mm/second (*0.17 ± 0.059 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.14 ± 0.048 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab Pencil (*0.40 ± 0.105 mm*).
2. The mean midline thermal damage/spread depth with the PhotonBlade 20W at 10 mm/second (*0.11 ± 0.022 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil 20W at 10 mm/second (*0.31 ± 0.072 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.14 ± 0.048 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil (*0.43 ± 0.111 mm*).
3. The mean midline thermal damage/spread depth with the PhotonBlade 20W at 10 mm/second (*0.11 ± 0.022 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.001*) that with the PlasmaBlade 3.0S Cut 6 at 10 mm/second (*0.19 ± 0.072 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.14 ± 0.048 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.001*) that with the PlasmaBlade 3.0S (*0.20 ± 0.056 mm*).
4. The mean midline thermal damage/spread depth with the PhotonBlade 20W at 10 mm/second (*0.11 ± 0.022 mm*) was similar to (*Wilcoxon Rank Sums p=0.315*) that with the PlasmaBlade 4.0 Cut 6 at 10 mm/second (*0.12 ± 0.025 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.14 ± 0.048 mm*) was similar to (*Wilcoxon Rank Sums p=0.582*) that with the PlasmaBlade 4.0 (*0.14 ± 0.053 mm*).

Dynamic Cut Median Power Setting: Dynamic tissue cutting with the PhotonBlade, at its median power setting (*35W at 5 mm/second*), demonstrated significantly less midline and lateral side thermal damage/spread than the Valleylab Pencil, Valleylab EDGE Coated Pencil and PlasmaBlade 3.0S. The PhotonBlade showed similar midline and significantly less lateral thermal damage/spread than the PlasmaBlade 4.0.

1. The mean midline thermal damage/spread depth with the PhotonBlade 35W at 5 mm/second (*0.22 ± 0.039 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.011*) that with the Valleylab Pencil 35W at 5 mm/second (*0.28 ± 0.079 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.37 ± 0.068 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab Pencil (*0.54 ± 0.109 mm*).
2. The mean midline thermal damage/spread depth with the PhotonBlade 35W at 5 mm/second (*0.22 ± 0.039 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil 35W at 5 mm/second (*0.41 ± 0.087 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.37 ± 0.068 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the Valleylab EDGE Coated Pencil (*0.69 ± 0.125 mm*).
3. The mean midline thermal damage/spread depth with the PhotonBlade 35W at 5 mm/second (*0.22 ± 0.039 mm*) was significantly less than (*Wilcoxon Rank Sums p=0.008*) that with the PlasmaBlade 3.0S Cut 7 at 5 mm/second (*0.29 ± 0.070 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.37 ± 0.068 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the PlasmaBlade 3.0S (*0.52 ± 0.116 mm*).
4. The mean midline thermal damage/spread depth with the PhotonBlade 35W at 5 mm/second (*0.22 ± 0.039 mm*) was similar to (*Wilcoxon Rank Sums p=0.789*) that with the PlasmaBlade 4.0 Cut 7 at 5 mm/second (*0.22 ± 0.051 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.37 ± 0.068 mm*) was significantly less than (*Wilcoxon Rank Sums p<0.001*) that with the PlasmaBlade 4.0 (*0.47 ± 0.100 mm*).

Dynamic Cut Maximum Power Setting: Dynamic tissue cutting with the PhotonBlade, at its maximum power setting (*50W at 3 mm/second*), demonstrated significantly less midline and lateral side thermal damage/spread than the Valleylab Pencil, Valleylab EDGE Coated Pencil, PlasmaBlade 3.0S and PlasmaBlade 4.0.

1. The mean midline thermal damage/spread depth with the PhotonBlade 50W at 3 mm/second (*0.23 ± 0.035 mm*) was significantly less than (*Wilcoxon Rank Sums $p<0.001$*) that with the Valleylab Pencil 50W at 3 mm/second (*0.43 ± 0.078 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.54 ± 0.092 mm*) was significantly less than (*Wilcoxon Rank Sums $p<0.001$*) that with the Valleylab Pencil (*0.80 ± 0.125 mm*).
2. The mean midline thermal damage/spread depth with the PhotonBlade 50W at 3 mm/second (*0.23 ± 0.035 mm*) was significantly less than (*Wilcoxon Rank Sums $p<0.001$*) that with the Valleylab EDGE Coated Pencil 50W at 3 mm/second (*0.55 ± 0.027 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.54 ± 0.092 mm*) was significantly less than (*Wilcoxon Rank Sums $p<0.001$*) that with the Valleylab EDGE Coated Pencil (*0.97 ± 0.170 mm*).
3. The mean midline thermal damage/spread depth with the PhotonBlade 50W at 3 mm/second (*0.23 ± 0.035 mm*) was significantly less than (*Wilcoxon Rank Sums $p<0.001$*) that with the PlasmaBlade 3.0S Cut 8 at 3 mm/second (*0.43 ± 0.100 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.54 ± 0.092 mm*) was significantly less than (*Wilcoxon Rank Sums $p<0.001$*) that with the PlasmaBlade 3.0S (*0.92 ± 0.151 mm*).
4. The mean midline thermal damage/spread depth with the PhotonBlade 50W at 3 mm/second (*0.23 ± 0.035 mm*) was significantly less than (*Wilcoxon Rank Sums $p=0.001$*) that with the PlasmaBlade 4.0 Cut 8 at 3 mm/second (*0.35 ± 0.080 mm*). The mean lateral thermal damage/spread depth with the PhotonBlade (*0.54 ± 0.092 mm*) was significantly less than (*Wilcoxon Rank Sums $p=0.006$*) that with the PlasmaBlade 4.0 (*0.68 ± 0.160 mm*).

5. SUMMARY

In summary, the PhotonBlade demonstrated the least penetrating thermal tissue damage/spread, followed by the PlasmaBlade 4.0, then Valleylab Pencil and PlasmaBlade 3.0S and then Valleylab EDGE Coated Pencil in order of increasing thermal damage/spread depths.

ACKNOWLEDGEMENT

The authors acknowledge Invuity, Inc. for their support of this study.

REFERENCES

[1] Coad JE, Bischof JC. Histologic differences between cryothermic and hyperthermic therapies. Proc. SPIE 4954, 27-36 (2003).

[2] Coad JE. Thermal Fixation: A central outcome of hyperthermic therapies. Proc. SPIE 5698, 15-22 (2005).

[3] Thomsen SL, Coad JE. Developing clinically successful biomedical devices by understanding the pathophysiology of the target tissue: insights from over 25 years at the microscope. Proc. SPIE 6440, 1-15 (2007).

[4] Person B, Vivas DA, Ruiz D, Talcott M, Coad JE, Wexner SD. Comparison of four energy-based vascular sealing and cutting instruments: A porcine model. *Surgical Endoscopy*. 2008; 22:534-8.

[5] Godwin BL, Coad JE. Healing Responses Following Cryothermic and Hyperthermic Tissue Ablation. Proc. SPIE 7181, 1-9 (2009).

[6] Coad JE. Practical pathology perspectives for minimally invasive hyperthermic medical devices. Proc. SPIE 7901, 1-12 (2011).

[7] Livengood RH, Vos JA, Coad JE. Hyperthermic tissue sealing devices: A proposed histopathologic protocol for standardizing the evaluation of thermally sealed vessels. Proc. SPIE 7901, 1-9 (2011).

[8] Grisez BT, Jones RM, Coad JE. Evolution of pathology techniques for evaluating energy-based tissue effects. Proc. SPIE 8584, 1-9 (2013).

[9] Jones RM, Grisez BT, Thomas AC, Livengood RH, Coad JE. Tissue sealing device associated thermal spread: A comparison of histologic methods for detecting adventitial collagen denaturation. Proc. SPIE 8584, 1-7 (2013).

[10] Beatty CJ, Thomsen SL, Vos JA, Coad J. Practical pathology for thermal tissue applications. Proc. SPIE 9326, 1-7 (2015).