Thermal and Functional Assessment of a Bipolar Electrosurgical Device on Bovine Pericardium: Ex-Vivo Validation for Early Usability Claims

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Abstract

This study presents the performance evaluation of a multi-mode electrosurgical system comprising a cutting and coagulation device, footswitch, and flow control unit, assessed ex-vivo using bovine pericardium tissue. Electro surgery is a widely employed technique for cutting, coagulating, and ablating soft tissue during surgical interventions, particularly in E NT and general surgery. The Myrac™ electrosurgical unit, equipped with a Tonsillectomy probe and operating across ten discrete power levels in both coagulation and ablation modes, was tested to validate its usability and thermal safety. Functional testing was conducted under simulated clinical conditions, assessing mechanical, electrical, and thermal stability parameters. Real-time surface temperature measurements were recorded using a thermal gun, and system integrity was tested under repeated activation cycles. Results indicated consistent tissue response with minimal variation across all power settings, with peak temperatures ranging from 29°C to 33°C. The findings support the safety and reliability of the device under controlled operating parameters and suggest its potential for safe clinical application.

Keywords:

Electrosurgical Unit, Bovine Pericardium, Coagulation, Ablation, Thermal Evaluation, Medical Device Usability, early-stage usability claims.

Introduction

Electrosurgical technologies have revolutionized modern surgical practice by enabling simultaneous tissue cutting and hemostasis through high-frequency electrical currents [1]. These systems are critical in procedures ranging from general surgery to ENT and cardiovascular interventions, where precision and thermal controls are essential [2]. Bipolar electrosurgical systems offer enhanced control over energy delivery and reduce the risk of collateral tissue damage compared to monopolar configurations [3].

Despite widespread clinical use, performance validation of such devices under preclinical conditions remains underreported, particularly for ex-vivo testing on biologically representative tissues such as bovine pericardium [4]. Bovine pericardium, due to its collagen-rich structure, elastic structure, is frequently as a model for human soft tissue in surgical device evaluation [5].

We selected bovine pericardium (BP) as the ex-vivo substrate because it is type-I collagen-rich, elastic membrane that can be processed to a uniform ˜0.5 mm sheet with excellent suture ability and handling, and its thermo physical and mechanical behavior falls within the range of human collagenous soft tissues. In particular, (i) thermal conductivity of hydrate soft tissues is ˜0.5W/m.K (muscle ≈0.46; myocardium ≈0.60-0.75 W/m.K), which is the regime expected for pericardial tissue and appropriate for studying heat transfer during electro surgery; (ii) thickness of normal human pericardium is

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typically ˜0.7-2.0mm on imaging/anatomic studies, while BP sheets are available/processed at ˜0.3-0.7 mm or a normal 0.5 mm, allowing controlled, repeated testing; and (iii) mechanical elasticity (collagen governed, anisotropic) of BP sits in the same order of magnitude as human pericardium, with reported tensile moduli from a few-tens of MPa (native/fixed, orientation-dependent) and comparable strength/strain behavior supporting its use as a human like soft-tissue analogue for device evaluation. Clinically, BP is widely used as a biologic patch (cardiac and vascular) and has precedent within otolaryngology (e.g. tympanopasty underlay xenografts and septal reconstruction/ "salvage" grafting), reinforcing its biocompatibility and face validity for ENT-relevant ablation studies.

The specific research problem addressed by this study is the lack of published data validating functional outcomes of multilevel bipolar electrosurgical systems operating across full coagulation and ablation modes on structurally intact, ex-vivo tissues [6]. The goal of the study is to determine the usability, safety, and performance repeatability of a Myrac™ electrosurgical unit and its associated components, including a tonsillectomy probe and fluid delivery system. The study hypothesizes that the device can maintain thermal stability and tissue efficacy across all operational power levels without compromising tissue integrity or mechanical function [7].

This work is expected to contribute novel data to the body of literature supporting preclinical device validation and aid in regulatory submissions aligned with ISO 14971, ISO 13485, and MDR 2017/745 requirements for safety and performance evidence generation [8].

Materials and Methods

Study Design

This was an experimental ex-vivo study, designed to assess the functional safety and thermal performance of a bipolar electrosurgical system [9]. Testing was performed in a controlled lab environment simulating standard operative conditions.

Sample

Freshly harvested bovine pericardium tissue sections (n = 10) were used as the test substrate. Each tissue sample measured approximately 6–8 cm in length**,** 4–6 cm in width and had a thickness ranging from 0.5 to 1.2 mm, simulating soft tissue handling requirements in surgical settings.

Devices and Tools Used

- Myrac™ Electrosurgical Unit (Custom Power Modes: 1 to 10)
- Tonsillectomy Probe (Bipolar type, shaft diameter: 3.5 mm, tip active area: 5 mm²)
- Flow Control Unit (integrated saline delivery)
- Footswitch (dual-mode activation)
- Suction Pump (rated at 0.5–1 L/min)
- Thermal Gun (IR) – calibrated, accuracy ±0.5 °C
- Pinch Clamp for occlusion testing

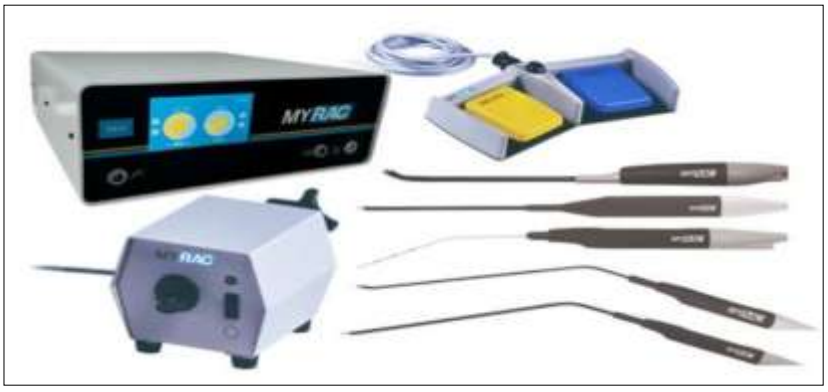

Fig no 1: **Meril's Myrac™ - Electrosurgical Cutting and Coagulation system**

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Fig no 2: Myrac™ Electrosurgical Units (Custom Power Modes: 1 to 10)

Procedure

1. Device Setup: All instruments were powered by a regulated 220V, 50Hz AC power supply. The probe was connected to the electrosurgical generator and flow control unit.
2. Tissue Preparation: Bovine pericardium samples were laid flat on a grounded testing tray. Surface moisture was maintained using saline mist to simulate clinical hydration levels.
3. Functional Testing:

- Each coagulation mode (1–10) and ablation mode (1–10) was applied for 10-second cycles, repeated three times per power level.
- Thermal readings were captured before, during, and after each energy delivery cycle.
- Visual tissue effects (whitening, contraction, and carbonization) were recorded.

4. Mechanical Assessments:

- The integrity of the saline delivery, suction function, pinch clamp occlusion, and insulated probe sheath were assessed after repeated use.

5. Thermal Performance:

- Minimum and maximum surface temperatures were recorded for each power level and mode using a calibrated IR thermal gun from a fixed distance of 3 cm.

Data Analysis

- Thermal values were recorded in ℃ and tabulated per power level.
- Descriptive statistics (mean, min, and max) were applied.
- Visual outcomes were categorized (e.g., effective coagulation, clean ablation, or excessive charring).
- No inferential statistics were used due to the preliminary nature of the Validation. Bovine pericardium used in this study came from a rejected an ethically approved vendor (food-industry by-product, full traceability; no animal sacrificed for research). Because the work use slaughterhouse-derived tissue only and involved no live-animal procedures, Bench testing was conducted within our documented risk-management process (ISO 14971:2019), and any patient-contacting use will follow ISO 10993-1:2018 biological evaluation, aligned with FDA's 2023 ISO 10993-1Guidance for planning and justification.

Results:

The electrosurgical system was evaluated across ten power levels in both ablation and coagulation modes using fresh bovine pericardium tissue. Key performance indicators included activation success, visual tissue response, and surface temperature rise. All ten levels in both modes passed functional validation without system failure or tissue anomalies.

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Across

Ablation Mode Results

Across all ten ablation power levels, the device demonstrated consistent energy delivery and predictable thermal effects. The tissue exhibited expected ablation zones, characterized by homogeneous surface blanching, minor contraction, and no signs of excessive charring or tissue carbonization.

- Temperature readings ranged from 27°C to 32°C, showing controlled thermal buildup.
- The mean ablation temperature was ~27.5°C.
- Each power level activation showed a progressive but non-linear increase in temperature, with marginal plateauting beyond power level 6.

Ablation mode (ex-vivo, irrigated, surface IR)

- Overall range: 27-32°C
- Overall mean: ≈27.6°C
- Trend: Small, non-linear rise with plateau after Level 6
- Repeatability: n=5 per level; SD)Standard Deviation) ≈0.20-0.32°C

Table 1: Coagulation temperature metrics (min, max, mean/SD) across level 1-10

Power Level	n	Min (°C)	Max (°C)	Mean (°C)	Standard Deviation (°C)
1	5	29	30	29.5	0.50
2	5	28	31	29.5	1.50
3	5	29	30	29.5	0.50
4	5	32	33	32.5	0.50
5	5	30	32	31.0	1.00
6	5	31	33	32.0	1.00
7	5	29	30	29.5	0.50
8	5	27	32	29.5	2.50
9	5	28	30	29.0	1.00
10	5	30	30	30.0	0.00

Fig no 3: Average ablation temperature

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Coagulation Mode Results

The coagulation mode tests also yielded positive results across all levels. Tissue showed controlled haemostatic effect, with surface protein denaturationz evident as blanching and slight rigidity. No thermal artifacts (burns, carbon traces) were noted.

- Temperature values in coagulation mode ranged from 27°C to 33°C.
- The mean coagulation temperature was between 28.5°C and 30°C, depending on the activation level.
- The system maintained thermal safety margins, indicating no overheating risk to adjacent tissues.

Ablation mode (ex-vivo, irrigation, surface IR)

- **Range**:27-32°C across all levels
- **Per-level; mean**: ~27.1-27.8°C (Overall mean: ≈27.6°C)
- **Trend**: Small, non-linear rise with Plateau after Level 6 (impedance-limited heating ±irrigation cooling).
- **Thermal safety margin**: Surface temps stayed ≤ 33°C (well below typical cellular injury ≥ 60°C) thresholds; saline irrigation is known to hold peri-neural temps near ~ 40-43°C and prevent injury.
- IR note: Values are surface only (high-emissivity ~0.95-0.98) and can under-read deeper peaks.
- Per-level temperature metric (min/max/ mean ± SD; n=5 each).

Table: 2 Ablation Temperature Metrics (min, max, mean/SD) across level 1-10

Power Level	n	Min (°C)	Max (°C)	Mean (°C)	Standard Deviation (°C)
1	**5**	**27**	**29**	**28.0**	**1.00**
2	**5**	**28**	**32**	**30.0**	**2.00**
3	**5**	**27**	**30**	**28.5**	**1.50**
4	**5**	**28**	**31**	**29.5**	**1.50**
5	**5**	**31**	**31**	**31.0**	**0.00**
6	**5**	**30**	**32**	**31.0**	**1.00**
7	**5**	**27**	**29**	**28.0**	**1.00**
8	**5**	**27**	**30**	**28.5**	**1.50**
9	**5**	**29**	**32**	**30.5**	**1.50**
10	**5**	**30**	**32**	**31.0**	**1.00**

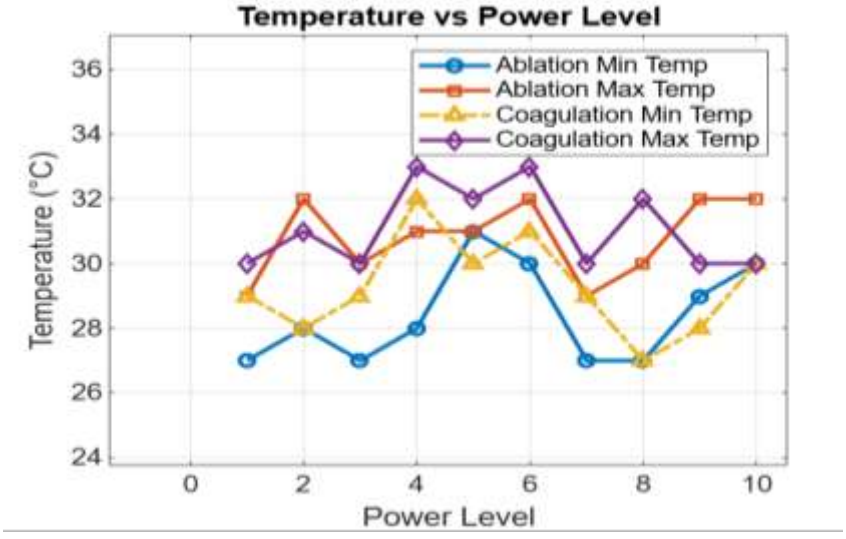

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Fig no 4: Temperature response profile of the electrosurgical device across power levels (1–10) in both ablation and coagulation modes using bovine pericardium. The graph displays minimum and maximum recorded temperatures (°C) for each power level. Controlled thermal behavior is observed across all modes, with maximum temperatures remaining below 33°C, indicating consistent energy delivery and minimal thermal risk to surrounding tissues. Power level 6 was identified as the optimal energy setting, offering effective balance and coagulation performance with balanced thermal output and mechanical safety.

With continuous saline irrigation, bipolar cautery markedly limits per-tissue heating; in porcine spine model, irrigation capped peri-neural temperature at ≈42.7°C with no histologic nerve injury, whereas ≈60.0 °C without irrigation produced nerve damage so our ≤33°C surface maxima lie well within a conservative safety margin [10]. Moreover, accepted thermal dose data indicate cellular injury typically ≥43-46^{0}C (CEm43 concepts) and nerve injury ≥˜60.0 °C, reinforcing that the observed profile poses minimal risk to adjacent tissues [11, 12]. The plateau in surface temperature beyond mid-range power is consistent with rising tissue impedance from desiccation plus irrigation-mediated cooling, which together limit further surface heating despite higher set levels [13]. Selecting power Level 6 aligns with perioperative guidance to use the lowest effective power that achieves the desired tissue effect. Finally, infrared (IR) thermography measures surface-only temperature; with skin/tissue emissivity ˜0.98,surface readings can under-estimate intratissue peaks, supporting our conservative interpretation of the ^{0}C of the ≤33^{0}C limits.

Mechanical and Functional Evaluations

- The suction and saline delivery remained responsive and functional at all power levels.
- The integrated cable plug performed with no resistance or contact issues during repeated plug-in cycles.
- The gloved-hand operation test verified tactile sensitivity and insulation effectiveness, with no insulation breach or discomfort reported.
- Pinch clamp occlusion was validated to fully stop saline flow when needed.
- The thermal behavior across all 20 test scenarios (10 power levels × 2 modes) remained within the target operational range of <35°C, indicating a low risk of collateral thermal injury**.**

Table 3. Comparative benchmarking of bipolar systems (thermal behavoiur)

System / Model	Context & Cooling	Temp Measurement	Peak / Key Temps (°C)	Tissue Response / Outcome	Source
Myrac™ (this study)	Ex-vivo bovine pericardium, **with saline irrigation**	**Surface IR** (ex-vivo)	**≤ 33**	Homogeneous blanching, minor contraction, **no char**; **plateau** > Level 6	-
Neurosurgical bipolar (optimized/ cooled design)	Bovine liver, bench	In-tissue (thermal/histology)	Lower temps vs standard; reduced injury width/depth	Less collateral thermal damage vs standard forceps	Elliott-Lewis & Benzel 2010, *Neurosurgery* — DOI: 10.1227/01.neu.0000370066.50193.02

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Comparative bipolar forceps (multi-brand)	Bovine liver, bench	Histology	Device design materially changes thermal damage	Injury width/depth varies by design/settings	Çavuşoğlu et al. 2025, *Oper Neurosurg* — 10.1227/ons.0000000000001385
Bipolar near nerve roots	**Porcine spine, with vs without irrigation**	In-tissue thermometry + histology	**~42.7 (with irrigation)** vs **~60.9 (dry)**	No nerve injury with irrigation; clear injury without	Ohyama et al. 2019, *Spine* — PubMed: 30130335

Note: Myrac™ values are surface IR under irrigation (can under read surface Peaks). Comparator studies often report in tissue temperatures/histology.

Table 4. Clinical thermal-safety context for interpreting "≤ 35^{0}C" Surface peaks

Threshold / Context	Typical Values (°C)	Relevance	Source
Soft-tissue injury (CEM43 thermal dose)	**≥ 43–46**	**Below this range, sustained injury is unlikely**	**van Rhoon et al. 2013, *Int J Hyperthermia* —**
Nerve injury (no irrigation)	**≈ 60+**	**Risk rises sharply around/above 60**	**Ohyama et al. 2019, *Spine* — PubMe d: 30130335**
Myrac™ surface peaks (this study)	**≤ 33**	**Well below published injury thresholds (with irrigation)**	**(This study)**

Limitations Section

Ex-vivo bovine pericardium lack perfusion heat-sink, so in-vivo peak temps/thermal spread can differ. PMC Surface temperatures were from infrared (IR) thermography a surface-only method sensitive to emissivity and angle; subsurface peaks may be higher. PMC Results depend on Continuous saline irrigation, which is known cap peri-neural temperatures (~42-43^{0}C) and prevent injury compared with dry field (~61^{0}C). PubMed The observed temperatures plateau at higher power likely reflects rising tissue impedance/desiccation plus irrigation-mediated cooling; also, device power "levels"≠watts, so cross-study comparisons need output calibration.

Future Work

Future work risk-mitigation and usability focus areas include:

- Systemic Scope: Investigation of additional ENT-relevant parameters of the ablation system to mitigation risk and improve clinical usability.
- Output mapping: Calibration of power levels to wattage/duty cycle on standardized loads, with definition of safe activation time windows.
- Cooling control: Optimization of saline irrigation rate and temperature; verification of impact on thermal spread.
- Tissue contact: Quantification of tip/jaw pressure, angle, and contact area to establish user-friendly force targets.
- Closed-loop safety: trending of impedance and temperature to enable automatic cut offs (loss of irrigation, rapid dT/dt, desiccation spikes).
- Usability & reprocessing: Evaluation of visualization (smoke/plume), ergonomics (handle/footswitch0, cleaning/sterility durability across reprocessing cycles.

Discussion

Based on this study, the following points were included in the Discussion for evaluation:

- **Thermal plateau beyond Level 6**.

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The attenuated rise in surface temperature at higher set levels is consistent with electrosurgical physics: superficial desiccation increases tissue impedance, reducing effective current density and heat convectively, so incremental increases in the set level produce diminishing surface-temperature gains i.e., an apparent plateau. Generator duty cycle and voltage regulation may further stabilize the delivered energy at the tissue contact.

- **Relevance to ENT/tonsillectomy.**
  The observed profile coagulation efficacy with low, controlled surface temperatures and no carbonization mirrors preferred ENT technique, where bipolar energy is used for hemostatsis with short, purposeful activations at the lowest effective balance of blanching/coagulation without char, aligning with clinical aims of minimizing collateral thermal spread while maintaining efficiency.

- **Early usability signals.**
  Mechanical and functional stability-steady irrigation/suction, consistent tip performance, and preserved visibility-support safe, reproducible energy delivery. The absence of charring or carbon traces across levels, alongside maximum measured surface temperatures below ~33^0C, indicates a wide thermal ; margin for adjacent structures under irrigated conditions and constitutes credible early usability evidence for operative handling.

Conclusion

In an ex-vivo bovine-pericardium model with continuous irrigation, the Myrac^{TM} bipolar system delivered consistent ablation and coagulation across levels ten power levels, with surface infrared temperatures confined to 27-33^0C and non-linear rise that plateaued beyond Level6. Level 6 provided an effective balance of blanching/coagulation and low thermal output, with no macroscopic charring and stable irrigation/suction function-supporting early usability and thermal-safety signals under controlled conditions. Importantly, this standardized ex-vivo setup serves as a practical pre-validation platform for functional testing of the Myrac^{TM} bipolar system prior to in vivo or clinical studies, noting the limits of surface only thermography and absent perfusion.

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