

# Clinical Performance Evaluation of Multi-hour Sustained Acoustic Medicine Treatment with 2.5% Diclofenac Coupling Patch



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## ABSTRACT

The study evaluates 2.5% diclofenac ultrasound coupling gel to deliver Low-Intensity Continuous Ultrasound (LICUS) through the Sustained Acoustic Medicine (SAM) treatment system. LICUS therapy has demonstrated effectiveness in treating soft tissue injuries and relieving musculoskeletal pain by triggering various healing processes.

**PURPOSE:** Investigate how the addition of 2.5% diclofenac sodium to standard aqueous SAM gel affects ultrasound coupling and diathermic properties during a prolonged SAM treatment.

**METHODS:** In a two-phase study, we examined acoustic and diathermic changes in bovine tissue during a 4-hour SAM stimulation at depths of 1 cm, 2cm, and 5cm with both aqueous gel and 2.5% diclofenac gel. Subsequently, we recorded the SAM heating treatment profiles in 54 healthy adults, comparing the use of diclofenac gel and standard gel during SAM treatment on the forearm and calf.

**RESULTS:** 2.5% diclofenac sodium significantly enhances coupling gel density, acoustic impedance, and signal propagation without adversely affecting diathermic profiles at various depths. The diclofenac gel sustains therapeutic ultrasound intensity for a longer duration compared to the aqueous gel. Importantly, there were no significant differences in diathermic effects observed.

**CONCLUSION:** Incorporating 2.5% diclofenac sodium into ultrasound gel improves ultrasound signal coupling into deep tissue, prolongs deep tissue heating, and does not negatively impact the diathermic profile during SAM treatment.

## BACKGROUND

- Sustained Acoustic Medicine (SAM) delivers low-intensity continuous ultrasound at 0.132 W/cm<sup>2</sup> for up to 4 hours delivering 18,7200 joules of energy.
- SAM therapy aids in healing soft tissue injuries and relieving musculoskeletal pain by enhancing diathermic and mechanotransductive properties.
- Diclofenac is an FDA-approved NSAID used to offer analgesic and anti-inflammatory effects.
- Recent research shows SAM with 2.5% diclofenac sodium gel reduces pain and improves outcomes for osteoarthritis patients and musculoskeletal injuries unresponsive to physical therapy.



Figure 1: FDA-cleared SAM device (model sam-12, ZetrOZ Systems LLC, Trumbull, CT)

## METHODS

### Clinical Procedure

- Subjects: n = 54 (26 males, 28 females, average age = 28, average BMI 25.8)
- Temperatures were recorded during treatment on the skin's surface, both at the treatment site and a control site.
- Participants were randomly assigned to one of four groups; Ultrasound Gel on forearm(14), Ultrasound Gel on calf(14), Diclofenac Gel on forearm(13), & Diclofenac Gel on calf (13).

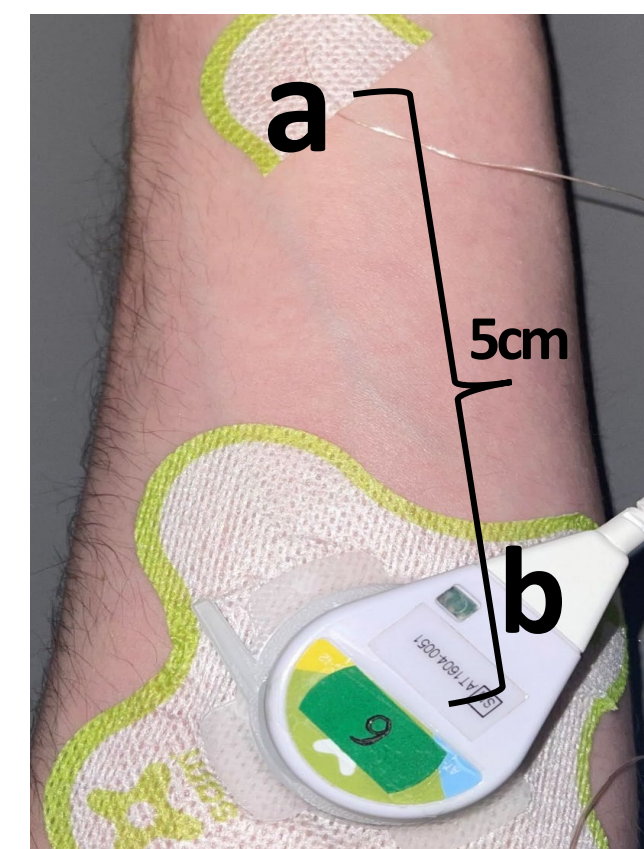


Figure 2: (a) control site (b) treatment site

### Laboratory Procedure

- Bovine muscle tissue was used to assess diathermic effects of SAM with and without 2.5% Diclofenac Gel at varying tissue depths.
- Intensity measurements were collected for ultrasound gel with and without 2.5% Diclofenac gel at increasing depths of bovine tissue using a hydrophone.

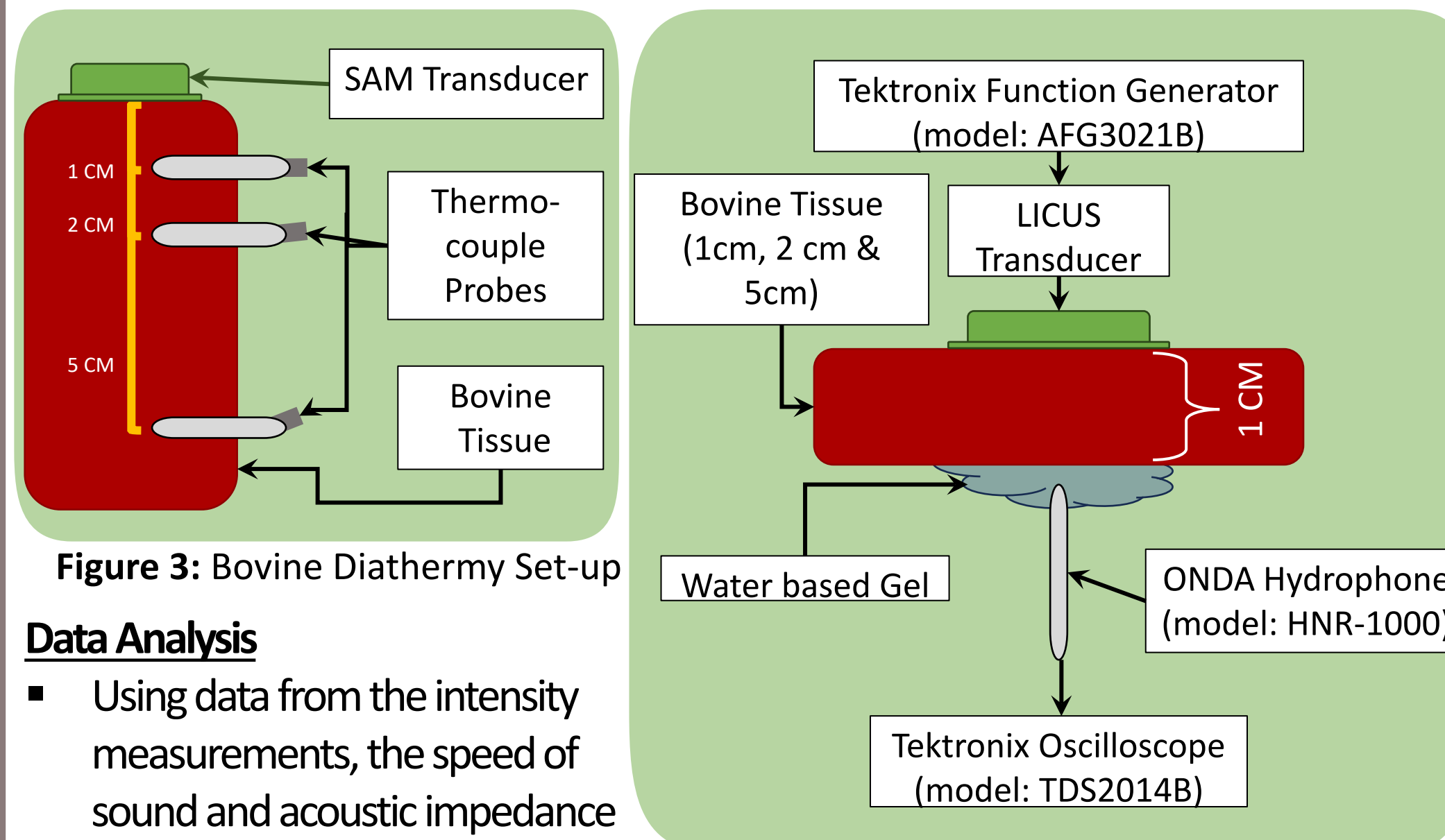


Figure 3: Bovine Diathermy Set-up

Figure 4: Intensity Measurement Set-up

### Data Analysis

- Using data from the intensity measurements, the speed of sound and acoustic impedance was calculated for both coupling gels.
- Speed of Sound =  $\frac{\text{distance (meters)}}{\text{time delay (seconds)}}$
- Acoustic Impedance =  $\text{density} \left(\frac{\text{kg}}{\text{m}^3}\right) * \text{speed of sound} \left(\frac{\text{m}}{\text{s}}\right)$

## CONCLUSION

- Incorporating 2.5% diclofenac into the ultrasound gel offered notable benefits including: increased acoustic impedance, improved ultrasound signal transmission to deeper tissue, and extended deep tissue heating.
- These findings highlight the potential of 2.5% diclofenac coupling gel as an effective long-duration ultrasound agent, optimizing therapy by enhancing signal penetration and sustaining deep tissue heating.

## RESULTS

### Calculated values of Speed of Sound and Acoustic Impedance

	Standard Ultrasound Gel	2.5% Diclofenac Gel	P-Value (n=5)
Density (g/mL)	1.02	1.06	0.0001
Speed of Sound (c) (mph)	1512.64±2.39	1513.24±2.24	0.6944
Acoustic Impedance (Z) (Mpa*s/m <sup>3</sup> )	1.54±0.002	1.60±0.002	0.0001

### SAM Ultrasound VS 2.5% Diclofenac Intensity at Different Depths

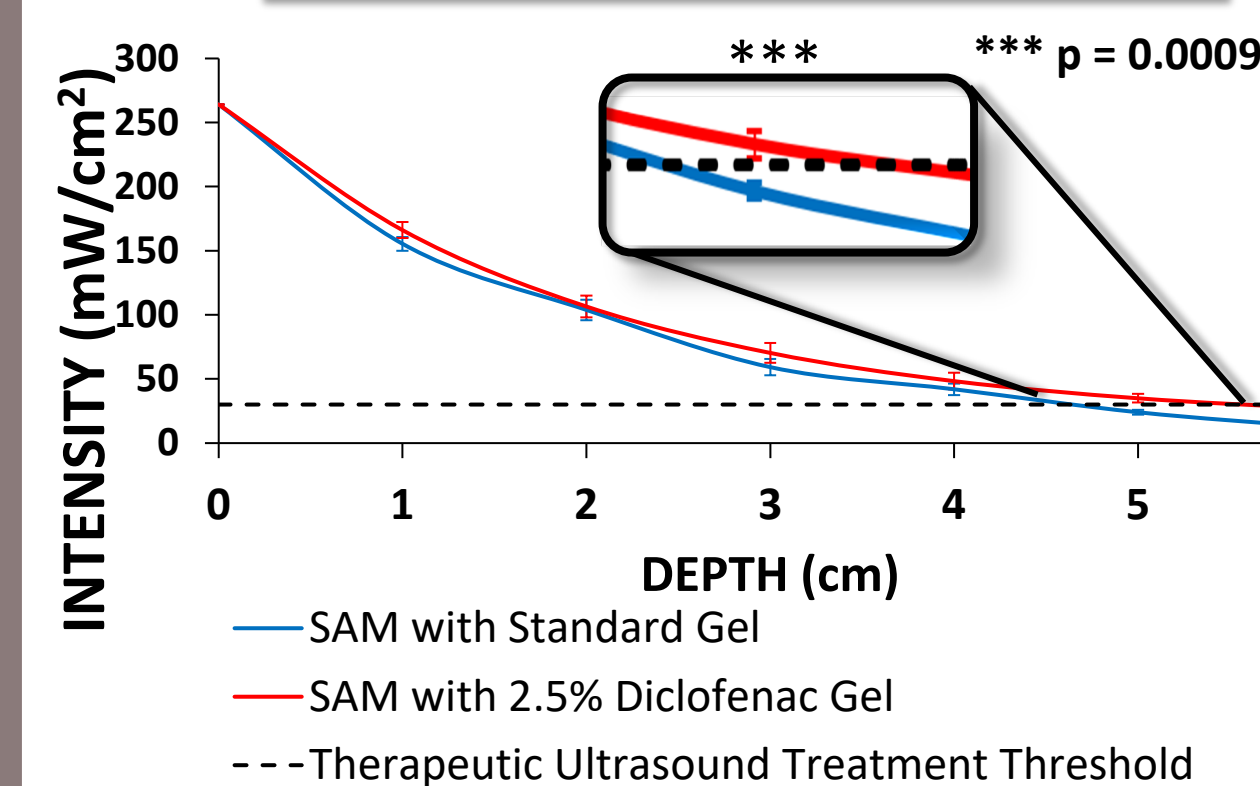


Figure 5: The SAM device achieves the therapeutic ultrasound threshold (30 mW/cm<sup>2</sup>) until about 4.5 cm with standard gel and 5.5 cm with diclofenac gel. The addition of 2.5% diclofenac significantly improves ultrasound propagation by approximately 1 cm, and acoustic intensity decreases with depth.

### AVERAGE TEMPERATURES AFTER 4 HOURS OF SAM STIMULATION ON CALF AND FOREARM

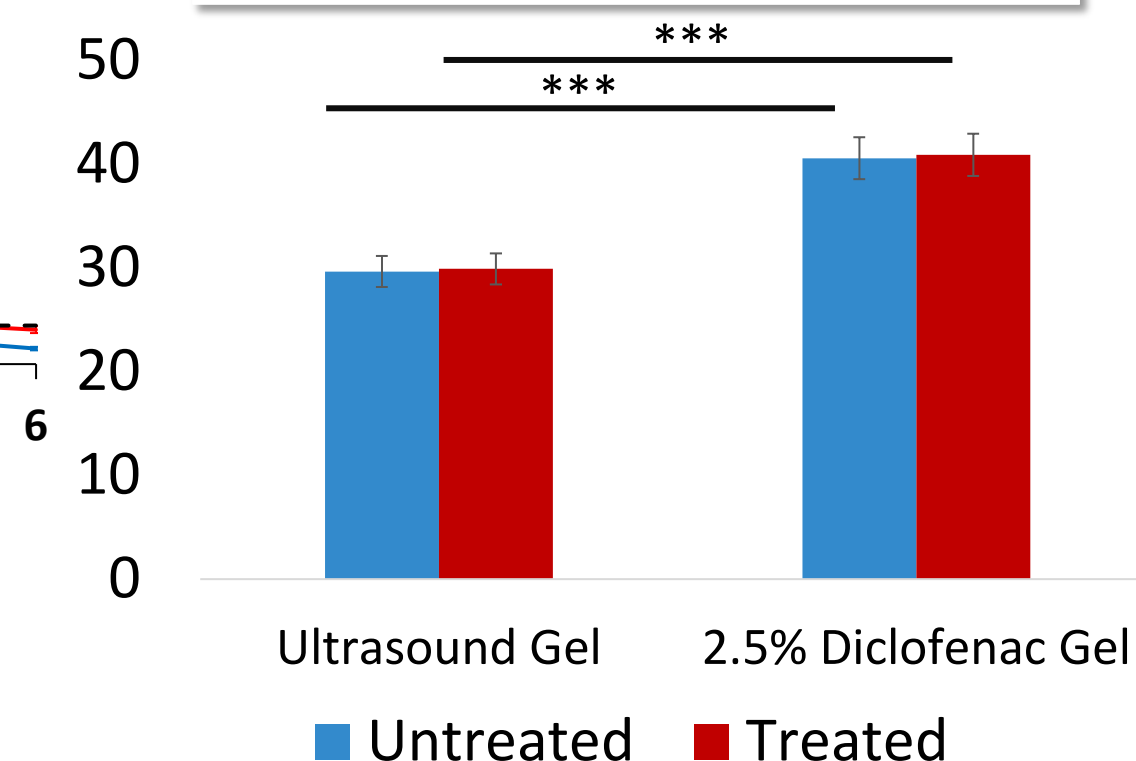


Figure 6: The presence of 2.5% diclofenac did not significantly affect surface temperature change after treatment at both locations, calf & forearm.

NOTE: \*\*\* = p < 0.0001

### Deep Tissue Diathermy Data on Bovine Muscle Tissue at Different Depths using Standard and 2.5% Diclofenac Ultrasound Gel (n = 5)

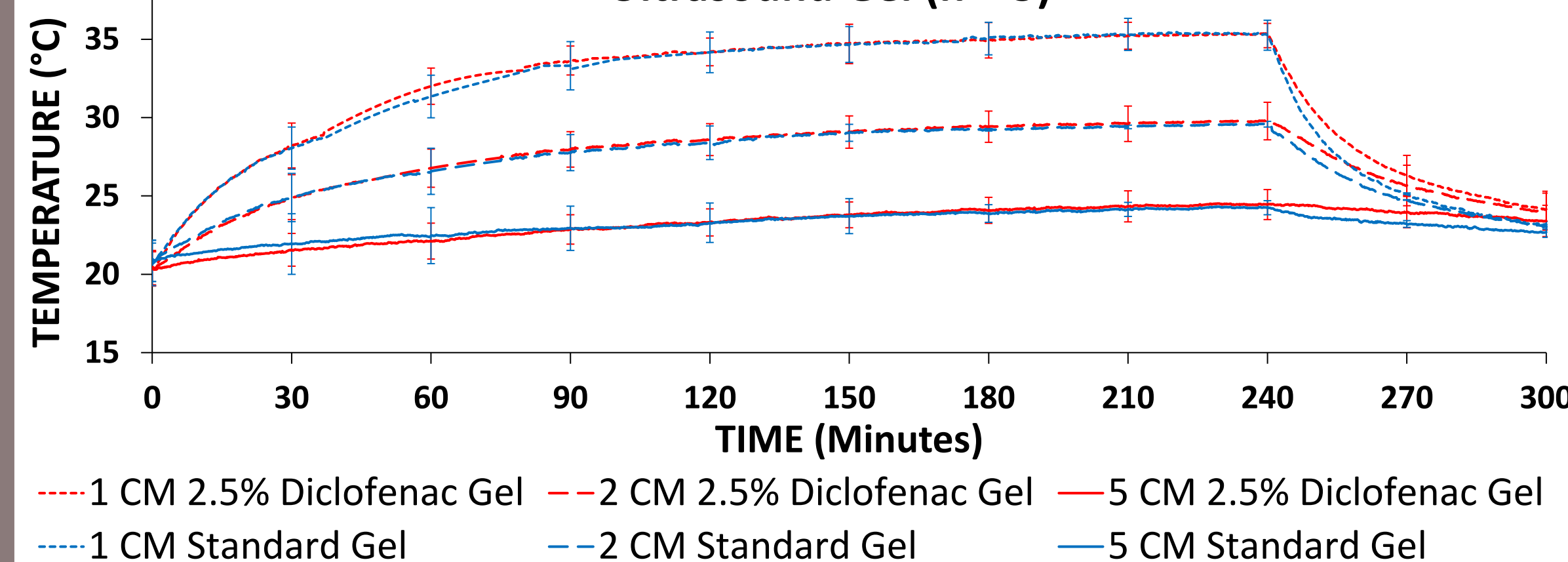


Figure 7: No significant differences in diathermic profiles were observed between SAM coupling patches without and with 2.5% diclofenac across all depths(1 CM, 2 CM & 5 CM)

## ACKNOWLEDGEMENT

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