# **Clinical paper**

Medtronic provides the following synopsis of a clinical publication involving Emprint<sup>™</sup> SX ablation platform.

- **TITLE** Navigation Improves Tumor Ablation Performance: Results From a Novel Liver Tumor Simulator Study
- AUTHORS Ian M. Kratzke, Ryan S. Goss, Sharif Razzaque, et al.
- JOURNAL Kratzke IM, Goss RS, Razzaque S, Shih A, Steele PL, Nurczyk KM, Gerber DA. Navigation Improves Tumor Ablation Performance: Results From a Novel Liver Tumor Simulator Study. Am Surg. 2022 Jan 31:31348221075748. doi: 10.1177/00031348221075748. Epub ahead of print. PMID: 35098720.

#### **BACKGROUND AND AIMS**

The Emprint<sup>™</sup> SX ablation platform produces three-dimensional (3-D) electromagnetic spatial antenna tracking with real-time ultrasound imaging to assist with accurate antenna placement during microwave ablation (MWA) procedures. The Emprint<sup>™</sup> SX ablation platform also allows the user to visualize the virtual ablation zone in 3-D for assessment of potential ablation zone coverage prior to energy activation. This study utilizes a preclinical simulator to evaluate the ablation efficacy and targeting efficiency outcomes of hepatic tumor ablations using the Emprint SX<sup>™</sup> navigation system (NAV), compared to using Emprint<sup>™</sup> ablation system with the standard ultrasound guidance technique (STD).

#### **STUDY DESIGN**

Fifteen participants were recruited for the study and divided into 2 groups: novice (N, n=9) and intermediate and expert (I+E, n=6) groups. The N group (all surgical residents) reported an average of 3 years of clinical experience, while the I+E group (3 surgical residents and 3 faculty members) reported an average of 11.2 years. All participants performed simulated hepatic tumor ablations using a tumor ablation simulator via 2 modes: 1) STD to emulate the two-dimensional ultrasound image and 2) NAV to provide an augmented reality view of the ultrasound scan and antenna positions in 3-D space. A total of 281 simulated tumor ablations were performed. Primary outcome was the percentage of under-ablation of tumors. Secondary outcomes included percentage of over-ablation of tumors, total trial time, time to locate tumor within liver parenchyma, and number of attempts at antenna placement prior to ablation.

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### **KEY POINTS**

- Mean under-ablation volume is 16.3% (SEM ±12.9) less with NAV vs. STD mode (p<0.001).
- Mean over-ablation volume is 14.0% (±8.2) higher with STD mode (p<0.001).
- NAV mode had a mean total trial time of 26.3 (24.1) seconds faster than STD (p=0.002).
- NAV mode participants took more time to locate the tumor by 6.6 (±9.8) seconds compared with STD trials (p=0.010).
- NAV trials had a mean of 1.3 (±1.0) fewer attempts at antenna placement compared to STD (p<0.001).
- Novices using NAV showed a larger mean improvement in performance, as seen in a decrease in both under-ablation (p=0.018) and over-ablation percentages (p=0.018).
- Novices using NAV performed significantly better than the I+E group using the STD approach in both under-ablation (-10.2%, p=0.003) and over-ablation (-10.9%, p=0.002).

## CONCLUSION

Emprint<sup>™</sup> SX navigation system improves tumor ablation efficacy and efficiency compared to standard ultrasound guidance in a simulated benchtop environment.

#### DISCLAIMER

Medtronic provided funding, resources, and authorship support for this study.

### **\*\*THIS CONCLUDES THE CLINICAL SYNOPSIS OF THIS PUBLICATION\*\***