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Novel Haptic System for Palpation of Catheter Tissue Contact Force during Atrial Fibrillation Ablation

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Abstract— **We describe a novel haptic feedback system that enables operators to palpate catheter tissue contact force with the beating heart during radiofrequency ablation of cardiac arrhythmia in live swine. User haptic-motor reaction time with the haptic system was significantly shorter than visual-motor reaction times to simple on-off visual stimuli, even when compared to subjects staring at a visual display, which is not feasible while performing invasive cardiovascular procedures.**

I. Background

The most advanced technologies for treating dangerous arrhythmias, including atrial fibrillation (AF), require the delivery of radiofrequency ablation energy (RFA) via cardiac catheters to ablate diseased tissue and disconnect electrical pathways. Insufficient catheter: tissue contact leads to ineffective RFA while excessive force can cause heart perforation and death, particularly in inexperienced hands where complications occur in up to 6.29% of patients, with 1 in 238 deaths attributed to the procedure[1].

Anatomic mapping displays and fluoroscopic imaging of catheters have been complemented by visual displays of catheter tissue contact force (CF), but the addition of a force display has not been found to be superior to conventional systems in terms of success or complications[2], as optimal CF is not consistently maintained[3]. Operators are incapable of viewing, processing, and reacting to multiple visual displays simultaneously. Published data substantiates that haptic feedback improves attention, cognition, and performance[4]. Unfortunately, dampening characteristics of compliant cardiac catheters preclude tactile sensing of applied force and biophysical information.

II. Methods

We tested a patented Haptic System (HS) by interfacing it with a commercially available CF ablation system, TactiCath (St. Jude Medical, St. Paul, MN), during cardiac ablation in live swine. Real-time analog output voltage from TactiCath proportionate to applied CF was input to drive a haptic actuator in a proprietary haptic handle (HH) after processing in the HS. We hypothesized that blinded operators would identify time of tissue contact and variations in CF during RFA. The HH was composed of a sterilizable, industrial grade thermoplastic construct with polycarbonate meeting ISO 10993-1 and USP Class VI classification for medical device manufacturing. A single operator performed RFA of 30 sites in atria and ventricles in two anesthetized swine. Three physicians and two non-physicians *not* performing the procedure blinded to the visual display of CF reported when they palpated tissue contact and evaluated variable amplitude CF during catheter manipulation (n=15) and during RFA (n=15) holding the HH. The unblinded operator correlated tactile sensations with visual CF data.

We also used M-mode ultrasound to measure subject haptic-motor reaction time from time a catheter fitted with strain gauges impacted tissue to time of haptic response of a blinded operator holding the HH impacting the same tissue with an instrument using contralateral hand. We compared timing to historical controls reacting to a simple on-off visual display[5]. We hypothesized subjects using the HS would have shorter reaction times, less in duration than cardiac systole.

III. Results and Conclusion

Mean tactile reaction time for 2 subjects, 10 experiments each, was 185 msec (SD=32), which is statistically significantly less than visual: motor reaction time for controls; n=93; mean=321.8 msec (SD=38.6); $p < 0.0001$ (unpaired t-test) at 95% confidence level and less than normal ventricular systole time, defined as QTc interval[6]. Tissue contact and variations in CF amplitude were palpated by all subjects at all locations in the animal study. Pathologic evidence of RFA tissue necrosis was noted at times when CF was palpable with mean CF = 35.6 gm (range 20-40). The operator palpated variations in CF that consistently correlated with displayed CF values. There were no complications.

Operators using the HS can reliably palpate the presence of tissue contact and amplitude of forces at the tissue-catheter interface in real-time and react faster than to simple visual input. The HS is expected to free up attentional resources and enable physicians to better focus on fluoroscopic images, cardiac electrical data, and other visual information in the operating room arena while tactually confirming catheter opposition to tissue and the amount of applied force. The HS holds great promise to improve procedural success, reduce complications, and minimize fluoroscopic / operative times.

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