MEDTRONIC CRYOFLEX™ SURGICAL ABLATION SYSTEM

VS.

ATRICURE® CRYOICE® SURGICAL ABLATION SYSTEM

An Objective, Intended-Use Comparison

Medtronic
Further, Together

OBJECTIVE

Compare the ablation performance of the Medtronic CryoFlex™ System (60SF3 probe) and the AtriCure® cryoICE® System (CRYO2 probe) in an objective, intended-use fashion in a well-controlled in vitro study.

BACKGROUND

The CryoFlex and cryoICE Systems have a label indication for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. There are some differences in the designs of the systems and their probes (Fig 1) which are promoted as advantageous for creating linear, transmural lesions.[1] Well-controlled, in vitro testing is a good means to compare the thermodynamic performance of these two cryo probes.

This intended-use testing was designed to objectively compare the capability of the systems to freeze to therapeutic temperatures through tissue. The target tissue temperature for immediate and irreversible cell death is -30° C.[2]

	Medtronic CryoFlex System	AtriCure cryoICE System
Cryogen	Argon Gas	Nitrous Oxide Gas
Probe Material	Stainless Steel	Aluminum
Probe Surface	Corrugated	Smooth

Figure 1: Key design differences between the Medtronic CryoFlex and AtriCure cryoICE Systems.

METHODS

Precisely sliced tissue samples (porcine) of 4, 6 and 8-mm ± 0.5-mm thicknesses were placed into a unique fixture designed to control human factor variables that could affect the performance of the probes (eg. tissue apposition, application force, etc). The fixture consisted of a platform with eight embedded thermal couples. The tissue was placed onto the platform so that the probes could be cantilevered to the tissue sample in a consistent fashion (Fig 2).

The systems were set up and operated as instructed in their technical manuals. Each cryoablation had a duration of two minutes, as recommended by the manufacturers. Five ablation runs were completed with each probe on each tissue thickness. Detailed temperature recordings from each of the eight thermal couples were taken every second and were collected into a database. More than 28,800 data points were collected during the testing.

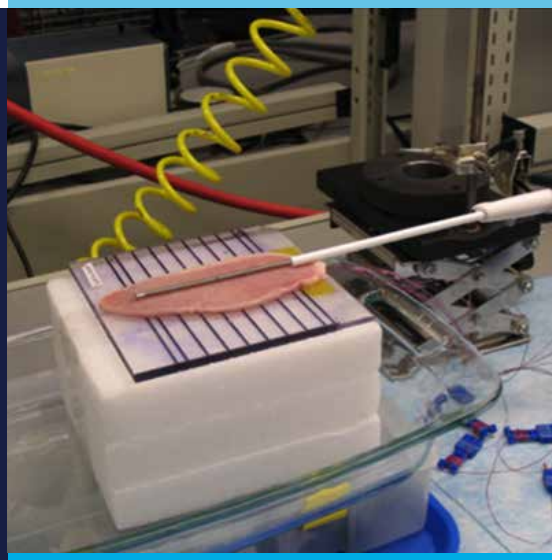

Figure 2: Test set-up

RESULTS[1]

In all of the tissue thicknesses tested, on average, the CryoFlex™ probe achieved -30° C or colder faster than the cryoICE® CRYO2 probe (Fig 3). In 4-mm thick tissue the CryoFlex probe achieved an average temperature of -91° C compared to -36° C achieved by the cryoICE System. In the 6-mm thick tissue, on average, the CryoFlex System readily achieved -70° C and the cryoICE CRYO2 probe only achieved -28° C, warmer than the target temperature. In the 8-mm thick tissue, on average, the CryoFlex probe achieved -41° C and the CryoICE probe only achieved -11° C, warmer than the target temperature. On average, the CryoFlex probe achieved a colder temperature in 8-mm thick tissue in two minutes (-41° C) than that achieved by the cryoICE probe in 4-mm thick tissue (-36° C). It was also observed that the temperature of the lesions created by the cryoICE System increased at a slightly accelerated rate immediately following the 2 minute ablation. On average, for the 8 thermal couples along the length of the probes, the CryoFlex System achieved the target temperature or colder for a significantly greater percentage of the ablation time than the cryoICE probe (Fig 4).

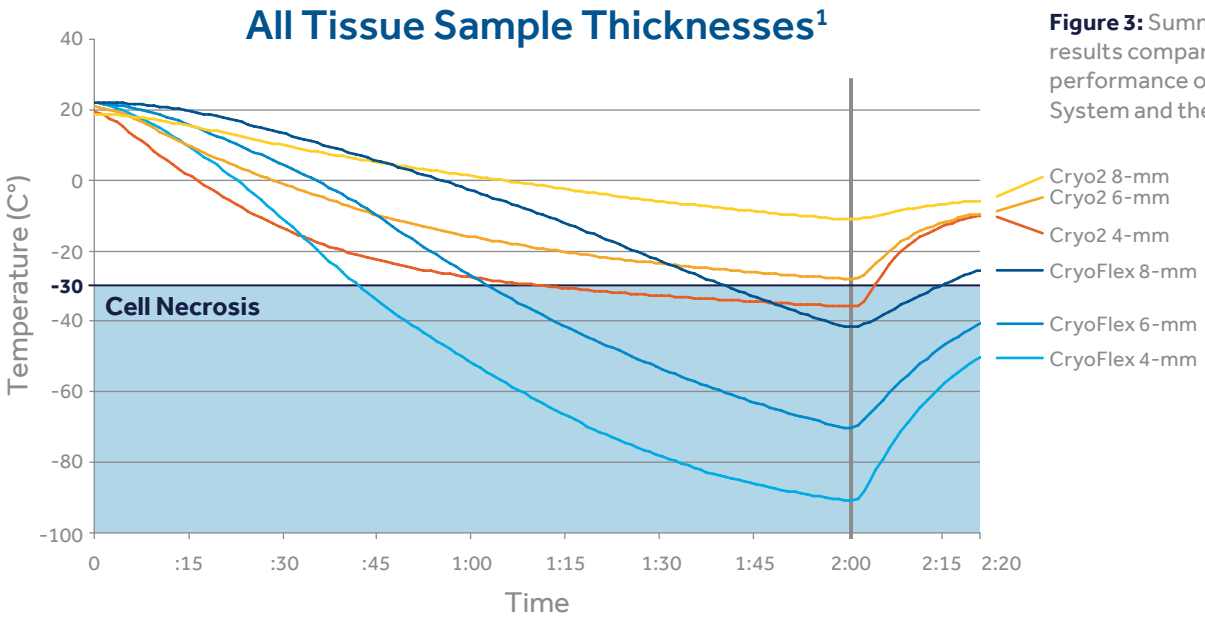

Figure 3: Summary of the in vitro testing results comparing the time/temperature performance of the Medtronic CryoFlex System and the AtriCure cryoICE System.

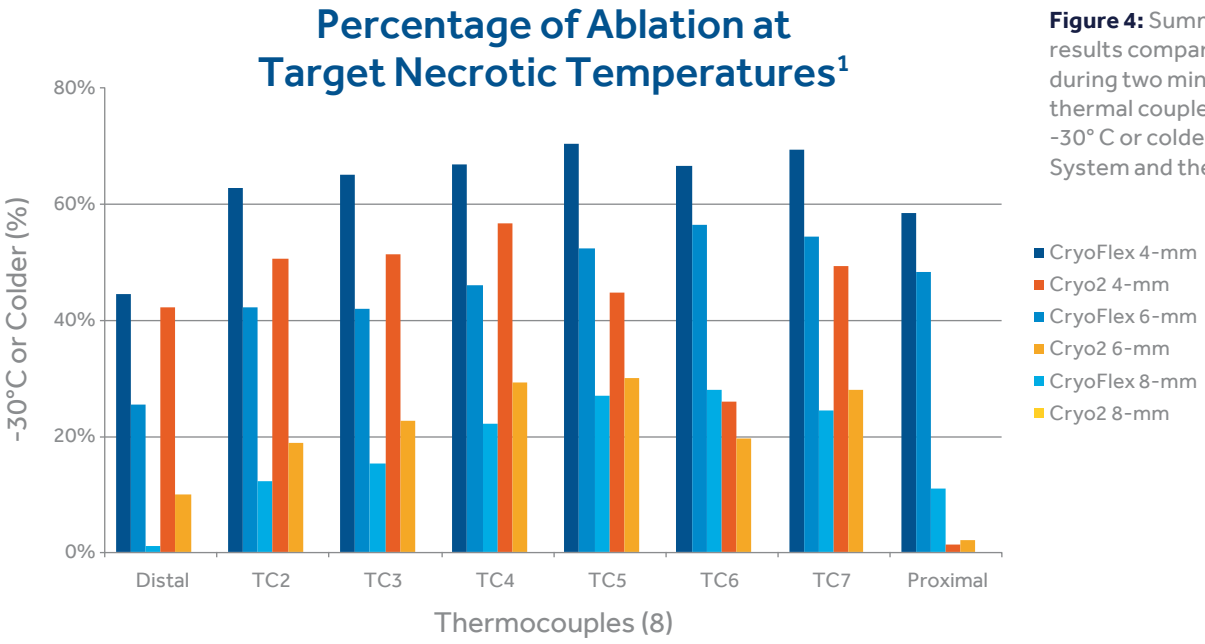

Figure 4: Summary of the in vitro testing results comparing the percentage of time during two minute ablations that each thermal couple recorded temperatures of -30° C or colder on the Medtronic CryoFlex System and the AtriCure cryoICE System.

1. Visit medtronicMICS.com for complete details of the in vitro testing on porcine tissue. Results may not be indicative of clinical performance.

CONCLUSION[1]

Based on performance achieving lethal cell temperatures -30° C or colder through tissue samples of 4, 6 and 8-mm thick, the Medtronic CryoFlex™ Surgical Ablation System created deeper lesions faster than the AtriCure cryoICE™ System. In all of the tissue thicknesses tested, the Medtronic CryoFlex System achieved linear, transmural temperatures far colder than the target temperature of -30° C. The AtriCure cryoICE System failed to achieve the target temperature through the 6 and 8-mm thicknesses, but achieved the target temperature with a margin of only 6° C through the 4-mm thickness.

For more information, contact your local Medtronic Surgical Ablation Products Representative.
U.S. Customer Service: 1 (800) 328-1357. Some products may not be available in all geographies.

The CryoFlex™ Surgical Ablation System

Indications for Use: is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The CryoFlex 7-cm, 10-cm, and 10-S probes plus the CryoFlex Clamp and CryoFlex Surgical Ablation Console freeze target tissue and block the electrical conduction pathways by creating an inflammatory response and cryonecrosis.

Contraindications: The CryoFlex Surgical Ablation Probe is not designed for use inside a beating heart.

Adverse Effects: Potential adverse effects with this device are similar to other cardiac surgery procedures and may include the following: bleeding; re-operation; extension of extracorporeal bypass; heart rhythm disturbances (atrial and/or ventricular); pericardial effusion; pericarditis; cardiac tamponade; pleural effusion; mediastinitis; conduction disturbances (SA/AV node); acute ischemic myocardial event; thrombus formation; low cardiac output; stroke; renal, gastrointestinal or respiratory complications; sepsis; adjacent structural damage; and death.

Cryoablation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. It is unknown whether Cryoablation with the CryoFlex Surgical Ablation Probe will have such an effect, but as in all such procedures, care should be taken to minimize unnecessary contact with coronary vessels during Cryoablation.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. See Instructions for Use for a complete list of warnings, precautions, and contraindications.

References:

1. Visit medtronicMICS.com for complete details of the in vitro testing on porcine tissue. Results may not be indicative of clinical performance.
2. Investigation into cardiomyocite response to cryoblation, Snyder et al., 16th Annual Boston Symposium on Atrial Fibrillation January 13-15, 2011 Poster Presentation.

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