Proceedings of the 2020 Design of Medical Devices Conference
DMD2020
April 6, 7-9, 2020, Minneapolis, MN, USA

DMD2020-9039

A NOVEL TOOL FOR IMPROVED CONTROL AND MANEUVERABILITY IN PEDIATRIC CARDIAC CATHETER ABLATION PROCEDURES

Paige N. Mass [1] [a], Rohan N. Kumthekar [b], Charles I. Berul [a, b], Justin D. Opfermann [a]

[a] Sheikh Zayed Institute for Pediatric Surgical Innovation
Children's National Hospital
Washington, DC, USA

[b] Division of Cardiology
Children's National Hospital
Washington, DC, USA

ABSTRACT

Cardiac ablation catheters commonly used for the diagnosis and treatment of arrhythmias are small in diameter and require extensive finger grip and dexterity for safe maneuverability during procedures. This is especially important in the pediatric population where the cardiac structures are smaller and potentially more variable as a result of congenital anatomic anomalies. We developed a novel catheter grip accessory tool for improved control and maneuverability of cardiac ablation catheters. Mechanical testing of the tool demonstrated it could grip the catheter with an average force of 0.031 kN and transfer an average torque of 0.0392 N-m before slipping, both well above forces experienced in normal clinical use. During tensile testing, the tool fractured at an average force of 0.554 kN. At the point of failure, testing found that the electrical conduction and resistance of the catheter remained unchanged. In simulated use testing, the tool was able to translate torque more accurately to the catheter tip compared to manual manipulation of the catheter. This novel tool has the potential to reduce physician muscle exertion in ablation procedures and increase the safety profile when manipulating catheters within the heart.

Keywords: pediatric, arrhythmia, catheter ablation, congenital heart disease, torque tool.

1 BACKGROUND

Cardiac ablation procedures are used for the diagnosis and treatment of tachyarrhythmias not well controlled by anti-arrhythmic medication in adults and children.[1] Transvenous catheters, which provide diagnostic pacing information and deliver therapy, are inserted into the patient's vasculature by physicians specializing in cardiac electrophysiology. The catheters are steered from outside of the patient and the position within the heart is controlled by the physician pinching and twisting the catheter between their thumb and forefinger. Catheters inside the heart can be visualized by either fluoroscopy or electro-anatomic mapping. An ablation procedure attempts to restore a normal rhythm by identifying the source of the arrhythmia and creating a lesion to eliminate it. Multiple lesions are often necessary, requiring the physician to hold the catheter tip on a specific location for several minutes at a time. The catheters are small, ranging from 1-3 mm in diameter. Manipulating the catheters from outside the body requires the physician to pinch the catheter with excessive force and compensate their twisting motion when creating a lesion to account for slip between their thumb and forefinger. While ablation procedures are less common in pediatric patients than adults,[2] small stature and anatomical anomalies as a result of congenital heart disease can add further difficulty when manipulating ablation catheters in pediatric procedures.[3,4,5] Poor ergonomics and the extensive manual torque create undue stress and strain to the physician's forearm and fingers.

Additionally, poor ergonomics and muscle fatigue pose a danger to patients if the catheter slips when creating lesions. Catheter movement during ablation can risk creating unwanted lesions and damage to important heart structures such as cardiac valves [6] and the normal cardiac conduction system.[7] This is especially important for ablations occurring near the atrioventricular (AV) node where slight movement during ablation can cause inadvertent AV block. Unwanted catheter movement can result in the need for additional procedures and, in some cases, the placement of a pacemaker to supplement the damaged conduction system.

To improve catheter ergonomics, we have developed a catheter grip tool as an accessory to commercially available catheters. The grip tool is designed to affix to a catheter without crushing the internal electronics and creates a location of increased diameter for the physician to grip when manipulating the catheter. The increased diameter reduces the amount of force

[1] Contact author: pmass@childrensnational.org

between the fingers and thumb necessary to rotate the catheter and more precisely translates torque to the distal tip, eliminating the need to compensate for catheter slip when creating a lesion.

We hypothesize the use of a novel catheter grip tool will improve the safety profile of the ablation procedure by creating a more ergonomic environment and reducing physician muscle fatigue. In this work, we present the design, workflow, and first evaluation of the catheter grip tool. We quantify mechanical and electrical performance of the tool when used with a standard ablation catheter to demonstrate safety and efficacy for future clinical studies.

2 DEVICE DESIGN

Commercial torque devices that improve ergonomics and control of guide wires exist but are too small for use with cardiac ablation catheters and attach by compression between two pressure points. While this clamp mechanism is tolerated by a stainless-steel guide wire, the isolated compression in two points will pinch and deform an ablation catheter, potentially altering the radiofrequency energy being delivered. A novel design that radially distributes the compression force to prevent damage to the internal electronics is necessary for ablation catheters. The catheter grip tool we present in FIGURE 1 consists of a two-part base and a sliding sled to achieve this function.

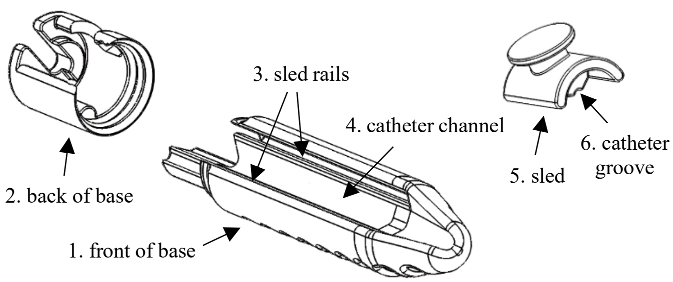

FIGURE 1: CAD drawing of a prototype catheter grip tool with key features identified.

2.1 Base. The base of the grip tool is designed in two pieces that securely snap together in the manufacturing process (FIGURE 1.1 and 1.2). There are two parallel rails (FIGURE 1.3) that allow the sled to slide forward and backward within the tool. A cut-out in the back of the base allows the sled to be pulled to the side, opening the tool for a catheter to be placed inside. The front of the base has a semi-circular catheter channel with a radius of 1.5 mm and is sloped at 3.33 degrees respective to the sled rails (FIGURE 1.4). The base has an outer diameter of 17 mm providing greater surface area for the physician to grip when manipulating the catheter.

2.2 Sled. The sled (FIGURE 1.5) is designed to ride in the base rails. The bottom of the sled has a catheter groove (FIGURE 1.6) that sits parallel to the catheter channel and is designed to radially distribute the compressive forces around the catheter body. The sloped features of the catheter channel and groove respective to the sled rails results in the channel and groove converging as the sled is advanced forward. This mechanism allows the tool to grip catheters ranging in size from 3-9 French.

Prototypes of the tool were 3D printed by digital light synthesis (DLS) using a biocompatible rigid polyurethane (Carbon Resin RPU 70, Carbon, Redwood City, CA), that has been tested by the manufacturer in accordance with ISO 10993-5 and ISO 10993-10 and determined to be suitable for prolonged tissue contact (more than 30 days) and short-term mucosal membrane contact (up to 24 hours).

2.3 Workflow. After the catheter has been inserted through a sheath into the vasculature and positioned within the endocardial space, the catheter grip tool is brought onto the surgical field in the open position (FIGURE 2A) with the catheter resting in the channel of the tool, approximately 2 to 6 inches distal to the vasculature access sheath. Once the tool is in place, it is fixed on the catheter by rotating the sled 90 degrees enclosing the catheter in the tool (FIGURE 2B) and sliding it forward until tight on the catheter (FIGURE 2C). Once secured, the tool can be used to steer the catheter with finer manipulation (FIGURE 2D).

After the source of the arrhythmia has been identified, the grip tool is used to maintain stable catheter tip position while radiofrequency energy is used to create a lesion. This process may be repeated for multiple lesions until a successful ablation is achieved. If necessary, the grip tool can be removed from the catheter and placed in a different location to advance the catheter deeper into the heart. The tool can also be placed on different catheters including diagnostic and catheterization catheters during the procedure and/or multiple tools can be used simultaneously and/or sequentially.

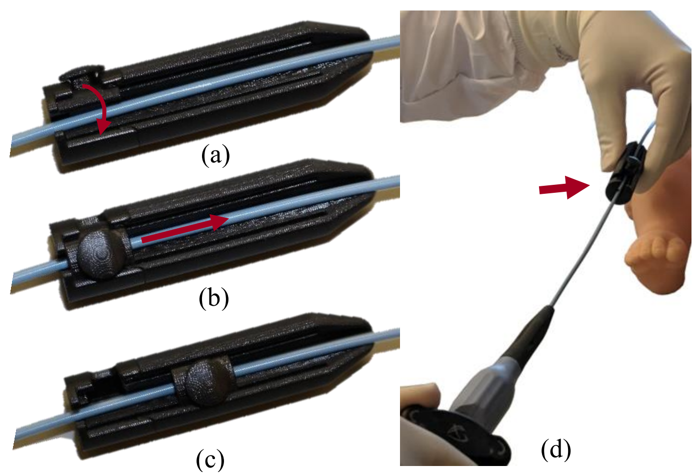

FIGURE 2: Catheter grip tool in the open state (a), in the closed state not advanced (b), in the closed stated advanced and locked on a catheter (c) and attached to a catheter slightly distally to femoral insertion site (d).

3 PERFORMANCE TESTING

3.1 Grip Strength. To demonstrate that the grip tool would not slip when pushing the catheter into or pulling it out of the body, the grip strength of the tool must exceed the observed forces during catheterization. To quantify grip strength, the tool was attached to a standard 7 French catheter (Biosense Webster, Diamond Bar, CA) and an axial force was applied to the tool. The average grip strength was defined as the maximum force prior to slip between the tool and catheter when the axial force was applied (N=10). Prior to testing, three cardiac electrophysiologists familiar with the tool were asked to place the tool on a catheter and tighten it to the point where they felt it was secure enough to use during a procedure. The distance each physician advanced the sled was measured and averaged to determine a standard sled position for testing. On an Instron 5965 Series Machine (Instron, Norwood, MA) with a 5kN loadcell and manual grips, the catheter was placed in the lower grip at the spot where it exits at the tip of the tool, and the tool was placed in the upper grip. To replicate the catheter being removed from the body, the catheter grip tool was pulled with a constant, positive displacement of 100 mm/min until the first drop in force was observed (FIGURE 3). The tool began to slip at an average force of 0.031 ± 0.00696 kN. This grip strength is approximately 10 times greater than the peak force needed to insert a catheter into a vessel [8], indicating that the torque tool will not slip when used during catheterization.

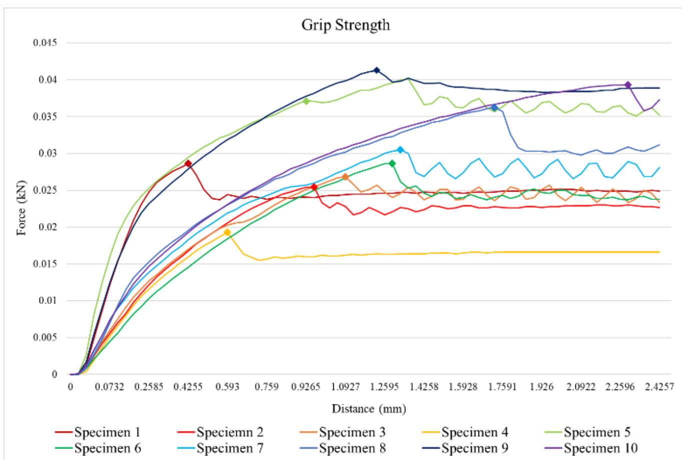

FIGURE 3: Graph of force (kN) over displacement (mm) for the catheter grip tool attached to a standard 7 French ablation catheter (N=10) with grip strength before slippage identified.

3.2 Slip Torque. Additionally, the tool was tested to determine the torque the tool could withstand before allowing the catheter to slip (N=10). The Instron was set up with a 450N/5N-m load cell with a manual chuck lower grip and manual upper grip. The tool was placed on the catheter with the sled advanced to the standard distance previously determined. The catheter was then clamped in the lower chuck grip, and the tool was clamped in the upper manual grip. The Instron was used to rotate the tool clockwise at 5.00 rev/minute while the catheter remained stationary to simulate a user twisting the catheter in the heart. The slip torque was defined as the maximum torque prior to the first observed drop in torque (first slip) (FIGURE 4). The average slip torque was 0.0392 ± 0.00642 N-m and occurred at an average rotation of 32 ± 12°. This slip torque is nearly 5 times greater than the max torque exhibited when rotating a catheter within a vessel [8], indicating that the grip tool will not slip under normal clinical conditions.

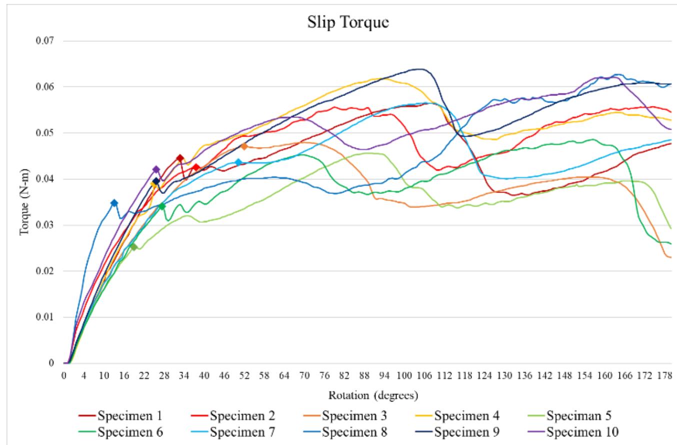

FIGURE 4: Graph of torque (N-m) over rotation (degrees) for the catheter grip tool attached to a standard 7 French ablation catheter (N=10) with slip torque before the first drop identified.

3.3 Catheter Performance at Maximum Grip Strength. The tool was tested to demonstrate that at maximum grip strength, the tool would fracture prior to damaging the internal electronics of the catheter (N=10). To measure electrical performance of the catheter, a function generator (Tektronix, Beaverton, OR) simulating an ablation waveform was used to deliver a radiofrequency signal to the tip of the catheter, and the signal was recorded using LabVIEW (National Instruments, Austin, TX). The Instron was set up with a 5 kN load cell, lower chuck grip, and upper compression plate. The catheter grip tool was loosely placed on the catheter and the tip of the tool was secured in the chuck. A sleeve was placed over the catheter grip tool and the compression plate was advanced at 10 mm/min, pushing the sled forward and tightening the tool on the catheter. Electrical resistance of the catheter was recorded at every 5 mm of displacement, while the simulated ablation waveform was recorded continuously.

In this experiment, the sled experienced failure at an average force of 0.554 ± .0972 kN, which was approximately 1.75 times greater than the force that can be generated by a human,[9] while the average electrical resistance was 4.21 ± 0.26 ohms at the start of the test and 4.20 ± 0.24 ohms at the end of the test (FIGURE 5). A t-Test assuming equal variance was performed on the starting and finishing values of resistance and no statically significant difference was observed ($p = 0.465$). The same statistical test was performed with the average starting and ending amplitudes of the simulated ablation waveform (7.807 ± 0.56 V and 7.805 ± 0.56 V) with no significant difference observed ($p = 0.497$). These results indicate that catheter performance remains unchanged under maximum grip strength.

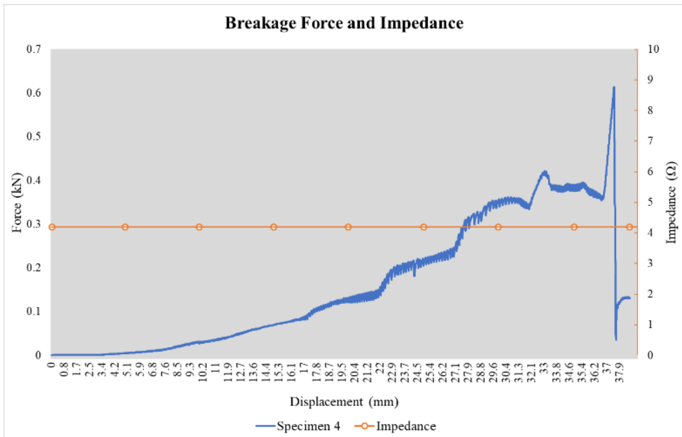

FIGURE 5: Representative graph of force (kN) and resistance (ohms) over displacement (mm) for the catheter grip tool attached to a standard 7 French ablation catheter until breakage for a single trial.

3.4 Simulated Use Testing. To demonstrate whether the catheter grip tool could successfully rotate the catheter as well or better than manual finger rotation, a study was designed to measure the angle of rotation of the catheter tip when a specified angle of rotation was applied (N=5). The catheter was inserted through a 2 ft piece of rubber tubing until the tip the catheter emerged from the distal end of the tube – mimicking femoral venous access to the heart. The tip of the catheter was locked in the deflected state at 0° of rotation. The catheter was rotated to 90° and 180° using both manual finger pinch rotation and by using the catheter grip tool to rotate the catheter. The degree of deflection at the tip from the zero point was measured using a protractor placed behind the tip. When rotating the catheter with the catheter grip tool, the tool was able to translate 100% of the rotation to the catheter tip for both 90 degrees and 180 degrees of rotation. When rotating the catheter with finger pinch, only 60% of the rotation was translated to the tip when 90 degrees of rotation was applied and 86% when 180 degrees of rotation was applied (TABLE 1). Statistical analysis with two sample t-Test showed rotation with the grip tool was significantly more accurate than finger pinch rotation for both 90 degrees and 180 degrees of rotation ($p < 0.01$).

	Average Recorded Degree of Tip Rotation	
	Finger Pinch Rotation	Catheter Grip Tool Rotation
90° rotation	54° ± 6.5	90° ± 0
180° rotation	155° ± 7.1	180° ± 0

TABLE 1: Average distal tip rotation when a catheter was rotated 90 degrees and 180 degrees using manual finger pinch and the catheter grip tool.

4 CONCLUSION

We successfully developed a catheter grip tool and presented workflow for use to provide improved control and maneuverability in pediatric cardiac ablation procedures. The tool can grip catheters with forces in excess of clinical conditions without damaging the internal electronics of the catheter. Our data demonstrates that the tool performance exceeds normal use conditions, while the output signal and resistance of the catheter are not altered prior to tool failure. In a simulated use study, the tool was able to more accurately translate torque than manual finger manipulation of the catheter. We demonstrated first evaluation of tool safety and propose this tool can improve the safety profile of ablation procedures by creating a more ergonomic environment and reducing physician muscle fatigue. In an upcoming pre-clinical study, we will address the impact of the tool on muscle fatigue in simulated use.

ACKNOWLEDGEMENTS

Our team would like to thank Medical Murray for design for manufacturing assistance.

REFERENCES

[1] Berul CI. "Catheter Ablation in Patients with Congenital Heart Disease." In: Zipes D, Jalife J, eds. Cardiac Electrophysiology from Cell to Bedside, 6th edition. Elsevier, 2014;127:1285-94.

[2] Clark BC, Berul CI. "Diagnosis and management of arrhythmias throughout life in congenital heart disease." *Expert Review Cardiovascular Therapy* 2016;14:301-320.

[3] Kugler JD, Danford DA, Houston KA, Felix G; Pediatric Radiofrequency Ablation Registry of the Pediatric Electrophysiology Society. "Pediatric radiofrequency catheter ablation registry success, fluoroscopy time, and complication rate for supraventricular tachycardia: comparison of early and recent eras," Journal of Cardiovascular Electrophysiology, vol. 13, no. 11, Apr. 2002.

[4] Van Hare GF, Javitz H, Carmelli D, Saul JP, Tanel RE, Fischbach PS, Kanter RJ, Schaffer M, Dunnigan A, Colan S, Serwer G. "Prospective assessment after pediatric cardiac ablation: demographics, medical profiles, and initial outcomes," Journal of Cardiovascular Electrophysiology, vol. 15, no. 7, Jul. 2004.

[5] Pilcher, Thomas A, and Elizabeth V Saarel. "Anatomic Challenges In Pediatric Catheter Ablation." Journal of Atrial Fibrillation, vol. 7, no. 11, Sept. 2014.

[6] Van Hare, GF, Colan SD, Javitz H, Carmelli D, Knilans T, Schaffer M, Kugler J, Byrum CJ, Saul JP; Participating Members of the Pediatric Electrophysiology Society. "Prospective Assessment after Pediatric Cardiac Ablation: Fate of Intracardiac Structure and Function, as Assessed by Serial Echocardiography." American Heart Journal, vol. 153, no. 5, 2007.

[7] Friedman, Richard A., Walsh EP, Silka MJ, Calkins H, Stevenson WG, Rhodes LA, Deal BJ, Wolff GS, Demaso DR, Hanisch D, Van Hare GF. "NASPE Expert Consensus Conference: Radiofrequency Catheter Ablation in Children with and without Congenital Heart Disease. Report of the

Writing Committee." Pacing and Clinical Electrophysiology, vol. 25, no. 6, June 2002.
[8] Rafii-Tari, Hedyeh, Payne CJ, Bicknell C, Kwok KW, Cheshire NJW3, Riga C, Yang GZ. "Objective Assessment of Endovascular Navigation Skills with Force Sensing." Annals of Biomedical Engineering, vol. 45, no. 5, 2017, pp. 1315–1327., doi:10.1007/s10439-017-1791-y.
[9] Peebles, Laura, and Beverley Norris. "Filling 'Gaps' in Strength Data for Design." Applied Ergonomics, vol. 34, no. 1, 2003, pp. 73–88., doi:10.1016/s0003-6870(02)00073-x.