Muscle Usage and Workload Assessment of Cardiac Ablation Procedure with the Use of a Novel Catheter Torque Tool in a Pediatric Simulator

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Abstract

Background: Cardiac ablation catheters are small in diameter and pose ergonomic challenges that can affect catheter stability. Significant finger dexterity and strength are necessary to maneuver them safely. We evaluated a novel torque tool to reduce muscle activation when manipulating catheters and improve perceived workload of ablation tasks. The objective was to evaluate measurable success, user perception of workload, and muscle usage when completing a simulated ablation task with and without the use of a catheter torque tool.

Methods: Cardiology attendings and fellows were fitted with surface electromyographic (EMG) sensors on 6 key muscle groups in the left hand and forearm. A standard ablation catheter was inserted into a pediatric cardiac ablation simulator and subjects navigated the catheter tip to 6 specific electrophysiologic targets, including a 1-min simulated radiofrequency ablation lesion. Time to complete the task, number of attempts required to complete the lesion, and EMG activity normalized to percentage of maximum voluntary contraction were collected throughout the task. The task was completed 4 times, twice with and twice without the torque tool, in semi-randomized order. A NASA Task Load Index survey was completed by the participant at the conclusion of each task.

Results: Time to complete the task and number of attempts to create a lesion were not altered by the tool. Subjectively, participants reported a significant decrease in physical demand, effort, and frustration, and a significant increase in performance. Muscle activation was decreased in 4 of 6 muscle groups.

Conclusion: The catheter torque tool may improve the perceived workload of cardiac ablation procedures and reduce muscle fatigue caused by manipulating catheters. This may result in improved catheter stability and increased procedural safety

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Conflict of Interest Disclosure

Charles Berul, Bradley Clark, Justin Opfermann, and Paige Mass are co-inventors of the torque tool evaluated in this article.

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Keywords: Ablation; Electrophysiology; Muscle fatigue; Pediatrics; Workload.

Introduction

While ablation procedures in both adult and pediatric populations have high success rates and relatively low risk of significant complications [1,2,3], pediatric procedures pose additional technical challenges due to smaller size and unique congenital heart disease (CHD) [4]. Unintended catheter movement during ablation procedures can risk creating unwanted lesions or intracardiac injuries especially during ablations performed close to the compact atrioventricular (AV) node such as cases of septal accessory pathways or AV-nodal re-entrant tachycardia (AVNRT) [3, 5, 6]. The complication rate for catheter ablation procedures has been documented between 1 and 6% in adult patients [7,8,9] with more complex ablations resulting in higher complication rates. Likewise, infants, children, and patients with both repaired and unrepaired CHD may present as more complex cases due to the smaller distance between vital structures, unusual anatomy, and unpredictable location of the AV node in certain congenital heart lesions.

Poor ergonomics of current ablation catheters and ablation techniques create an additional potential risk due to operator muscle fatigue and catheter tip instability. Most electrophysiology and ablation catheters used in standard procedures are small in size (1–3 mm diameter) and require manual catheter manipulation several feet from the catheter tip. Lengthy ablation procedures that require multiple lesions may lead to an increase in operator muscle fatigue from repeated intense muscle usage. This can lead to a decline in performance throughout the procedure [10] and increase the risk of instability. Catheter stability has been directly correlated to the success of cardiac ablation procedures as well as the length of the procedure [11, 12].

Improved catheter stability and reduced operator fatigue has the potential to increase procedural efficacy, reduce anesthesia time, and decrease the risk of complications.

Some groups have attempted to improve catheter stability with remote navigation systems [13, 14]; however, increased procedure times and high start-up costs [15] have led to manual manipulation remaining the preferred method despite the risks of instability. We have previously described a novel catheter torque tool (Fig. 1) that securely attaches to the exterior of electrophysiology and ablation catheters ranging in size from 3 to 9 French. This tool is placed near the insertion point and provides a larger surface area and diameter for gripping the catheter, reducing the force necessary to torque the catheter and improving the translation of rotation applied without damaging the electrical integrity [16]. The tool is intended to be operated by the physicians left hand (though it can be used by either hand), while the right hand remains on the catheter handle as with typical catheter use (Fig. 2). The objective of this study is to evaluate usage of the catheter torque tool with regard to skeletal muscle fatigue and user experience during a simulated electrophysiology study and ablation procedure.

Methods

This study was approved by the Institutional Review Boards at Children's National Hospital, Nationwide Children's Hospital, and the Albert Einstein College of Medicine/Montefiore Medical Center. Healthy adult and pediatric cardiologists, including trainees, across three institutions volunteered to participate providing they had completed at least 1 week of an electrophysiology rotation demonstrating a basic clinical understanding of cardiac ablation procedures. A pediatric electrophysiology simulator designed to illuminate a bulb when catheter electrode contact is achieved with various targets within the vasculature [17] was set up on a benchtop. The participants were consented and given up to 5 min to become comfortable using the simulator, catheters, and novel torque tool.

After the introductory period, participants were outfitted with surface electromyography (EMG) sensors (Noraxon USA Inc., Scottsdale, AZ, USA) on the muscle belly of the left abductor pollicis, left brachioradialis, left flexor carpi radialis, left flexor carpi ulnaris, left extensor carpi ulnaris, and left extensor carpi radialis (Fig. 3). These muscles were selected due to their involvement in pinching and torquing movements of the left hand. Muscle usage of the right hand was not evaluated as this hand was not directly impacted by the torque tool. The participant was asked to squeeze a stress ball, fully flex the wrist, fully extend the wrist, and apply pressure with the thumb against a stationary object to collect a maximum voluntary contraction (MVC) for all the muscles under investigation. Surgical gloves were worn during the study to mimic clinical conditions. All participants torqued the catheter body with and without the torque tool using their left hand and used their right hand to manipulate the catheter handle.

The participants were asked to insert a catheter into the heart through a femoral approach and simulate typical 3-dimensional mapping of the right atrium and surrounding structures by deliberately touching the catheter tip to 6 targets within the vena cava and on the septal wall of the right atrium, avoiding the AV node, and in the order of: superior vena cava (SVC), inferior vena cava (IVC), fossa ovalis (FO), coronary sinus (CS), typical area of the slow pathway of the AV node, and the posteroseptal tricuspid valve annulus where a right posteroseptal accessory pathway could be located. After successfully reaching the 6 targets, they then simulated creating an ablation lesion either in the area of the slow pathway of the AV node or the posteroseptal accessory pathway by holding the catheter tip on the target for 1 min, again avoiding contact with the AV node. The task was completed a total of four times. A bidirectional D-F curve 7-French catheter (EZ Steer® NAV Bi-Directional, Biosense Webster Inc., Irvine, CA, USA) was used for two trials, whereas a unidirectional B-curve or a unidirectional F-curve 7-French catheter (NaviStar®, Biosense Webster Inc.) was used for another two trials. Each catheter was used once with the torque tool and once without. The choice of catheter, use of the torque tool, and the lesion location for the first trial were each determined by an independent coin toss. The catheter and lesion location remained the same for the first two trials and then switched for the last two trials. The torque tool conditions switched between the first and second trials and then followed the opposite pattern for the third and fourth trials. All potential starting conditions are shown in Table 1. The two catheters and alternating torque tool conditions were used to reduce learning curve bias in the results. Each participant completed paired trials with and without the tool under investigation to limit data bias that may result from limited catheter experience in some participants.

The time to successfully reach the 6 targets, total time to complete the entire task (mapping and lesion creation), and number of attempts to complete a 60-s simulated ablation lesion were recorded. At the conclusion of the task, participants completed the NASA Task Load Index questionnaire (TLX), which has been utilized to assess subjective mental demand, physical demand, temporal demand, performance, effort, and frustration [18], including in the assessment of medical devices [19].

EMG data was collected for the duration of the study. The MVC dataset was post-processed with an amplitude normalization to peak value and smoothed by a root mean squared algorithm (Myo Muscle, Noraxon). Peak values for each muscle group were identified as the maximum voluntary contraction. For each task, the EMG data was smoothed by root mean squared algorithm and normalized to percentage of MVC. Maximum muscle activation, mean activation, and the area under the curve, indicating the total work of the muscle, for each muscle group from each task were identified. A sample wave form of a filtered wave form both with and without the torque tool for the abductor pollicis is shown in Fig. 4.

Statistical analysis of the data was performed in Prism 9.3.1 (GraphPad, San Diego, USA). A Wilcoxon matched pairs signed rank test was used to compare the non-torque tool trials to the torque tool trials for all data collected. Any significant differences were defined as $p < 0.05$.

Results

Thirty-four cardiologists volunteered to participate in the study. Fifteen participants were experienced with catheter manipulation. This included electrophysiology attendings ($n = 8$), cardiac catheterization attendings ($n = 4$), and electrophysiology fellows ($n = 3$) who were finishing their first or second year of specialist training. Nineteen participants did not specialize in catheter manipulation including cardiology fellows ($n = 15$) and attendings of non-interventional specializations ($n = 4$). Table 2 describes participants' demographics in greater detail. Two participants (1 interventional and 1 non-interventional) withdrew from the study after one set of paired trials due to time constraints. All other participants completed two sets paired trials with and without the tool. The resulting 66 sets of paired trials were compared.

There was no significant difference in the time to reach the designated targets or total time to complete the task between the bare catheters and the catheters with the torque tool. Participants required an average of 1.6 attempts to complete the 60-s lesion both with the bare catheters and with the addition of the torque tool. These analyses held true when evaluated for the subgroup experienced with manipulating catheters. Interventional physicians did not have a significant difference in time or number of attempts between the bare catheter and with the use of the torque tool (Table 3).

Collectively, the participants reported a significant decrease in perceived physical demand ($p < 0.0001$), effort ($p = 0.0003$), and frustration ($p = 0.0008$) when using the torque tool, as well as a significant increase in perceived performance ($p = 0.0061$). There was no significant difference in mental or temporal demand. When evaluated for the subgroup experienced with manipulating catheters, they did not report a significant difference in mental demand, temporal demand, effort, frustration, or performance; however, they did report a significant decrease in physical demand ($p < 0.0001$) when using the catheter torque tool. It should be noted that frustration and performance were nearing significance (p [?] 0.08). The average scores on the NASA TLX for each metric are shown in Table 4.

One EMG dataset of an interventional cardiologist was found to be corrupt and excluded from analysis along with its paired trial. In the remaining 65 paired trials, there was a significant reduction in maximum muscle activation, mean muscle activation, and total muscle work for the left abductor pollicis ($p = 0.0011$, $p < 0.0001$, and $p = 0.0209$, respectively). Additionally, a significant reduction was seen in the mean muscle activation for the left brachioradialis, left flexor carpi ulnaris, and left extensor carpi radialis ($p = 0.0015$, $p = 0.0059$, and $p = 0.0003$, respectively) (Fig. 5). No significant differences in muscle activation were observed for the left flexor carpi radialis and left extensor carpi ulnaris. When evaluated for the interventional group only (28 paired trials), a significant difference was noted for the mean muscle activation in the left abductor pollicis ($p = 0.0221$) and the left brachioradialis ($p = 0.0041$).

Discussion

Participants were asked to simulate standard electrophysiology catheter movements by completing a short task in a challenging anatomical space produced by a pediatric size simulator. The study population included participants experienced with manipulating catheters as well as participants who do not regularly manipulate catheters. The addition of a novel torque tool resulted in reduced muscle activation with repeated movements and a subjective decrease in the task workload, including for participants who regularly manipulate catheters. There was no noticeable difference in measurable success as defined by time to complete the task with the use of the torque tool compared to the bare catheters. Likewise, participants were equally successful in their attempts to create a simulated 60-s ablation lesion. This held true for participants experienced with manipulating catheters. This suggests that the novel torque tool may be easier to use and preferred over bare catheters and does not add significant procedural time.

Based on self-reported scoring of the task workload, participants did not report a change in mental or temporal demand, indicating that the tool is not overly complex or difficult to use. Furthermore, reported reduction in physical demand, effort, and frustration and improvement in performance suggest that the torque tool improves the workload of electrophysiology and ablation procedures, even among participants highly experienced with manipulating catheters.

The left abductor pollicis was the primary muscle of interest given its heavy involvement in the pinching mechanics involved in torquing and manipulating catheters. The significant reduction in activation of this specific muscle suggests that the torque tool reduces not only the maximum activation required to grip and torque the catheter but also the overall work of the muscle when pinching and torquing catheters. This is further demonstrated by the significant reduction in the average activation of some of the other muscles recruited for pinching and torquing maneuvers. It should be noted that only one 60-s lesion was simulated in the study, while standard electrophysiology procedures often involve the creation of multiple lesions, culminating in the physician applying torquing and then isometrically holding the position many times throughout the procedure. This repeated muscle activity with limited rest between lesions may result in a rapid buildup of muscle fatigue [10]. As such, the significant reduction in muscle activation provided by the catheter torque tool may prove to be even greater in a real case compared to this simulation.

Physicians not experienced with manipulating catheters are likely less skilled at maneuvering the catheters with smooth and relaxed movements. The reduction in muscle activation across all muscle groups evaluated was more prevalent when these participants were included in the analysis than when muscle usage was evaluated for participants experienced with manipulating catheters only. This may suggest the tool is more beneficial for physicians new to the specialty; however, the significant reduction in mean muscle activation for the abductor pollicis and brachioradialis seen in participants experienced with manipulating catheters suggests that all physicians may benefit from utilizing the torque tool.

The simulator setup used for this study is limited by a stationary, non-beating heart, providing a simpler environment than in clinical settings, making it difficult to fully assess catheter stability [16]. The consistent measured performance metrics and improved perception with and without the torque tool, along with the reduction in muscle usage, suggests that the catheter torque tool may improve catheter control in a clinical environment, which has additional cardiac and respiratory movements that affect catheter stability [11]. In more complex clinical settings, the reduction in muscle usage may be compounded in subsequent lesions, requiring physicians to hold catheters on lesion locations with more consistent contact. Improved catheter contact when creating lesions has been shown to produce more successful arrhythmia cures [20] and reduce the risk of complications, especially in pediatric populations and patients with complex anatomy and CHD [21]. Future work will be necessary to assess catheter stability and contact with the use of the novel torque tool in a clinical environment. Additionally, due to the short nature of this study, future work should be considered to evaluate the impact of using the novel torque tool when experienced physicians complete repetitive and/or more complex movements for an extended period of time as is typically experienced during cardiac ablation procedures.

The torque tool was not tested in conjunction with a long, steerable sheath, and future work may be of interest to compare performance differences between the two methods to improve catheter maneuverability and stability. Steerable sheaths have been shown to reduce procedure time for some procedures, though they do not appear to have an effect on procedural success and are noted to increase procedure cost [22].

Conclusion

Utilizing a torque tool during cardiac ablation results in a reduction in muscle activation and an overall improvement in user perception of performance as well as a reduction in frustration and physical demand. Operators may opt to use the device in procedures to increase catheter ergonomics, reduce workload, and improve the ability to maneuver catheters in difficult to reach locations. This could prove to be especially beneficial in challenging cases such as patients with complex anatomy, difficult to access arrhythmia sources, or smaller patient size. Furthermore, reductions in muscle activation and improved control and maneuverability of catheters may lead to an improvement in the safety profile of cardiac ablation procedures, reduce the chances of adverse events, and increase the success of cardiac ablation procedures.

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Figure 1: Catheter torque tool accessory designed with sliding sled to securely attach to cardiac ablation catheters ranging in size from 3-9 French and providing a larger surface area to grip and maneuver catheters. The tool is attached to a 7 French catheter as shown.

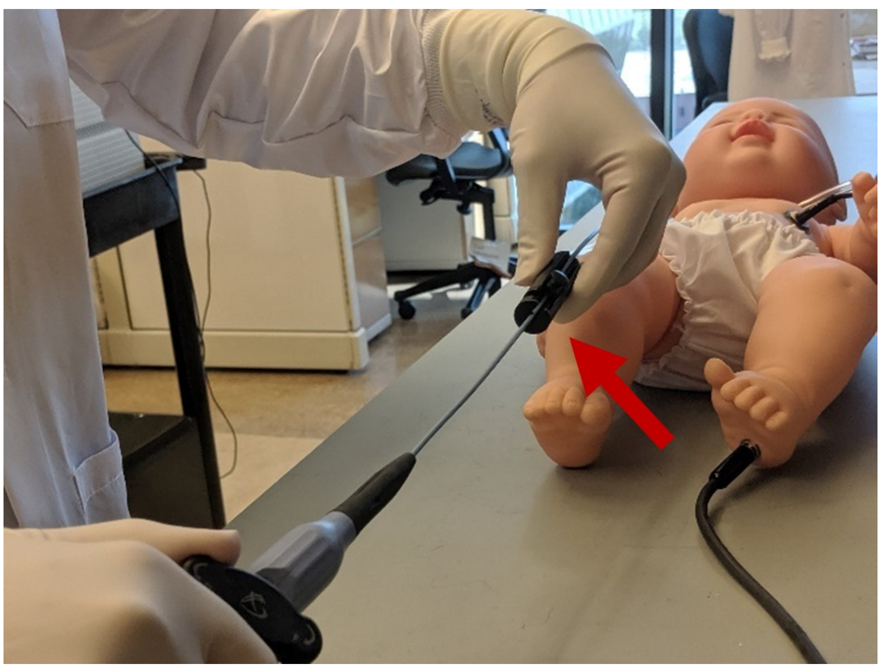

Figure 2: Participant is shown manipulating a catheter with the use of the torque tool through a femoral approach in the pediatric simulator.

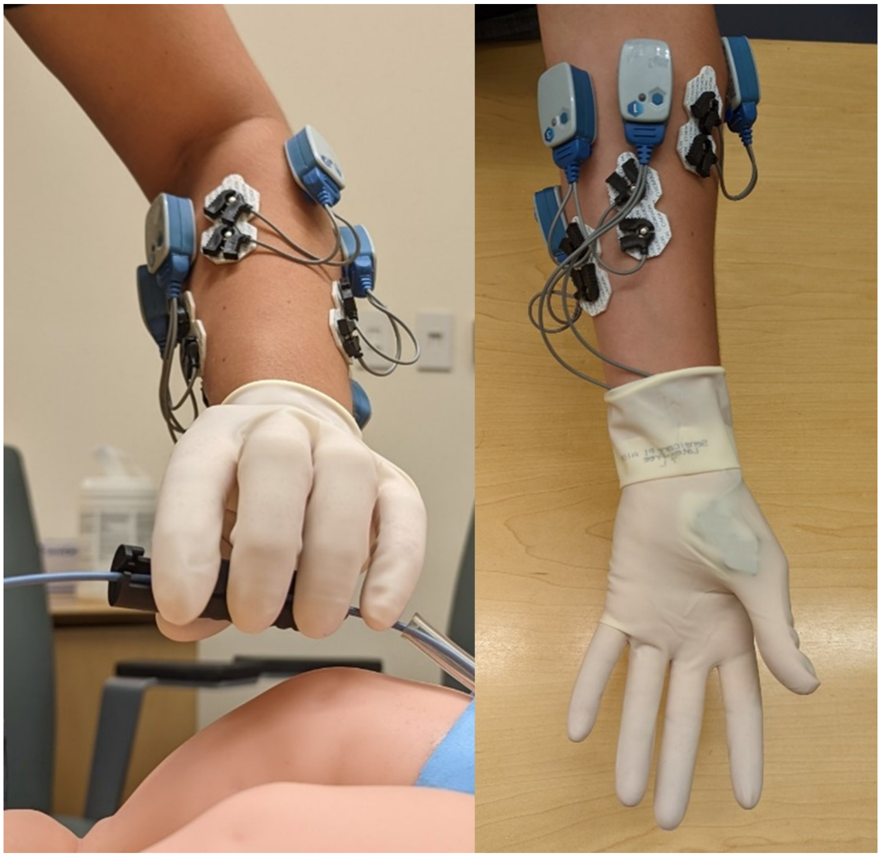

Figure 3: Electromyography sensors on the left forearm while manipulating the catheter torque tool (a) and close-up view with abductor pollicis sensor visible under the glove.

	Task 1 (coin flip)	Task 2	Task 3	Task 4
Catheter	bidirectional (heads)	bidirectional	unidirectional	unidirectional
	unidirectional (tails)	unidirectional	bidirectional	bidirectional
Torque Tool	without (heads)	with	with	without
	with (tails)	without	without	with
Lesion Location	slow pathway (heads)	slow pathway	accessory pathway	accessory pathway
	accessory pathway (tails)	accessory pathway	slow pathway	slow pathway

Table 1: Possible starting conditions are shown under task 1 and determined by coin flip. The resulting conditions for tasks 2-4 are shown in italics and are pre-determined by the coin flip in task 1.

Participant Experience			Number of Participants	Percentage Female
Non-Interventional Cardiologists	1st Year Fellow		4	25%
	2nd Year Fellow		2	100%
	3rd Year Fellow		7	57%
	4th Year Fellow (non-invasive)		2	50%
	Non-Invasive Attending		4	25%
	Total Non-Interventional		19	47%
Interventional Cardiologists	EP Fellow		3	0%
	Cath Attending	¡ 5 years	1	100%
		5-10 years	1	0%
		¿ 10 years	2	50%
	EP Attending	¡ 5 years	3	0%
		5-10 years	2	50%
		¿ 10 years	3	33%
	Total Interventional		15	27%
Total Participants			34	35%

Table 2: Breakdown of participants demographics. Nineteen participants were non-invasive cardiologists including four 1st year fellows, two 2nd year fellows, seven 3rd year fellows, two 4th year fellows specializing in non-invasive cardiology and 4 cardiology attendings of non-invasive specializations. Fifteen participants were interventional cardiologists, including three 4th and 5th year pediatric or adult electrophysiology attendings, 4 cardiac catheterization attendings and 7 pediatric or adult electrophysiology attendings.

	Time to Reach Targets (sec)	Time to Complete Task (sec)	Attempts to Complete Lesion
All Participants (66 paired trials)			
Bare Catheter	148.1 ± 113.7	225 ± 122.4	1.59 ± 0.91
Torque Tool	149 ± 131.8	232.5 ± 139.3	1.59 ± 1.07
p Value	0.82	0.55	¿1.0
Interventional Participants (29 pair trials)			
Bare Catheter	91.6 ± 52.08	161.4 ± 50.85	1.48 ± 0.74
Torque Tool	89.9 ± 39.19	171.2 ± 45.64	1.59 ± 1.05
p Value	0.85	0.16	0.62

Table 3: Time to reach targets in seconds, time to complete the full task in seconds and number of attempts to complete the 60-second lesion are reported for all participants and for the subgroup of interventional participants. Neither group showed a significant difference in any of the values when the torque tool was used.

	Mental Demand	Physical Demand	Temporal Demand	Performance	Effort	Frustration
All Participants' Trials (66 paired trials)						
Bare Catheter	10.2	12.21	9.35	14.67	13.23	10.35
	± 4.7	± 3.88	± 4.56	± 4.38	± 4.09	± 5.45
Torque Tool	10.04	9.64	9.15	15.99	11.33	8.55
	± 4.63	± 3.81	± 4.2	± 3.7	± 4.31	± 5.45
p Value	0.76	¡0.0	0.82	0.01	0.0	0.0
Interventional Participants' Trials (29 paired trials)						
Bare Catheter	8.03	10.12	10.12	16.6	11.19	7.74
	± 3.83	± 3.39	± 3.39	± 2.74	± 4.36	± 4.84
Torque Tool	8	8.05	8.05	17.38	10.26	6.21
	± 4.01	± 3.31	± 3.31	± 2.49	± 4.29	± 4.98
p Value	0.94	¡0.0	0.75	0.08	0.3	0.08

Table 4: Average and standard deviation of self-reported scoring on the NASA Task Load Index for mental demand, physical demand, temporal demand, performance, effort, and frustration for the task completed with the bare catheter and with the addition of the novel torque tool. Significant differences are shown by italicized p values. Data is reported for all participants (n = 34, 66 paired trials) and interventional participants (n = 15, 29 paired trials.

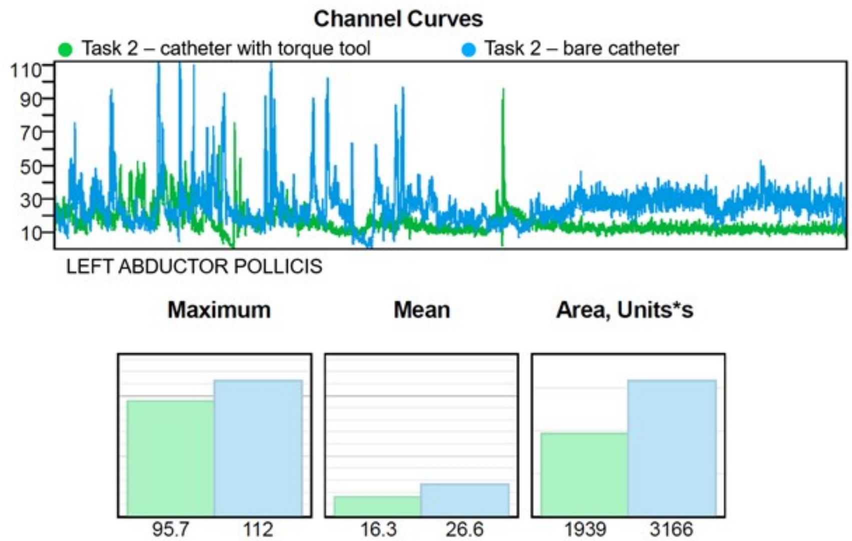

Figure 4: Electromyography signal from the left abductor pollicis during two trails, one with the torque tool (green) and one with the bare catheter (blue). The curve is smoothed by root mean squared algorithm normalized to the maximum voluntary contraction for that participant. Maximum muscle activation, mean muscle activation and area under the curve as a percentage of MVC are shown for both trails.

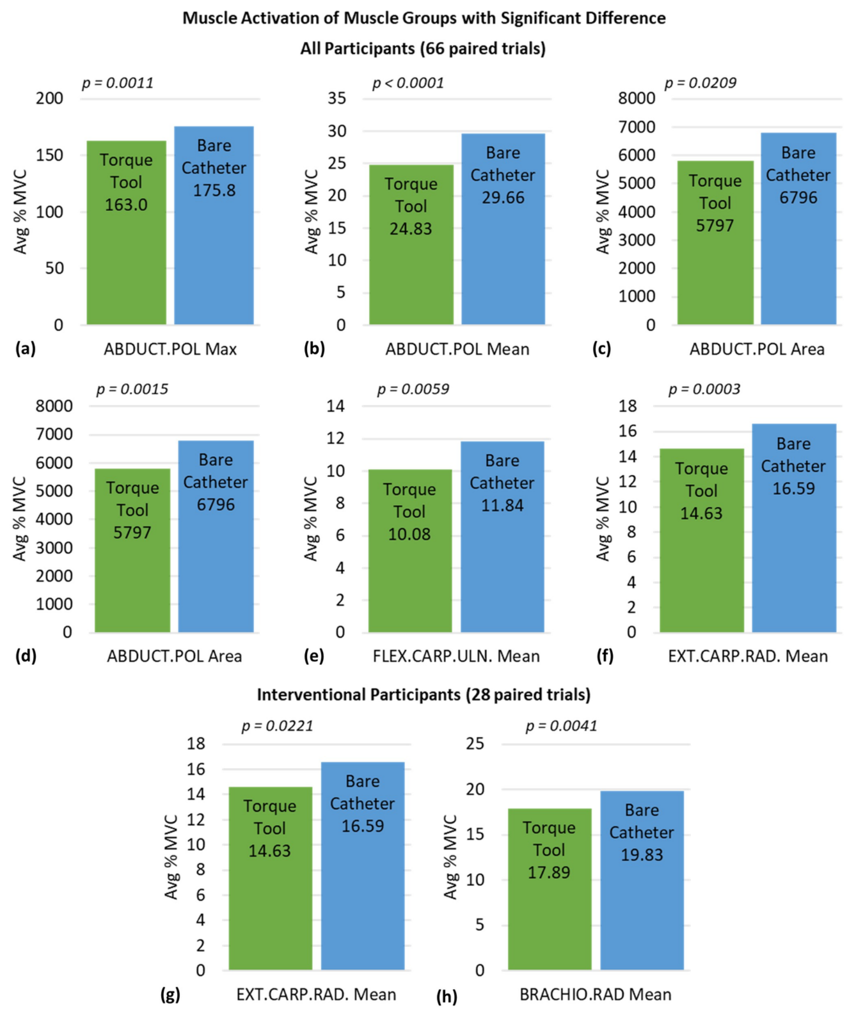

Figure 5: Average muscle activation for all participants (n = 34, 66 paired trials) as a percentage of MVC for maximum (a), mean (b) and area (c) in the left abductor pollicis and mean for the left brachioradialis (d), left flexor carpi ulnaris (e) and left extensor carpi radialis (f) for the bare catheter and with the torque tool. Additionally, average muscle activation for interventional participants (n =14, 28 paired trials) as a percentage of MVC for mean in the left abductor pollicis (g) and left brachioradialis (h). Muscle activity is significantly reduced with the torque tool.