# Very high-power short-duration ablation for treatment of cardiac arrythmias by the QDOT MICRO Catheter: The Fast and Furious study series

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**Abstract**

The QDOT MICROTM Catheter is a novel open-irrigated contact force-sensing single-tip radiofrequency ablation catheter. It incorporates six thermocouples at its tip and offers temperature-controlled and very high-power short-duration (vHPSD) ablation with 90 Watts for 4 seconds to improve safety and efficacy of catheter ablation procedures. The QDOT MICROTM Catheter was recently evaluated for pulmonary vein isolation and safety, efficacy and long-term follow-up found promising results. Although the QDOT MICROTM Catheter was mainly designed for pulmonary vein isolation its versatility to treat atrial fibrillation as well as other types of arrythmias was recently evaluated by the FAST and FURIOUS study series and other studies and will be presented in this article.

## Introduction

Catheter ablation is a safe and effective treatment strategy of cardiac arrhythmias and is increasingly performed world-wide. Beside the fact that cardiac arrhythmias are very versatile atrial fibrillation (AF) is the most common form which affects increasing numbers of patients.

Pulmonary vein isolation (PVI) by catheter ablation has shown high success rates for treatment of paroxysmal (PAF) and persistent AF (PersAF). Novel single-shot ablation devices implementing diverse energy sources (cryothermal, laser, pulse field ablation (PFA), radiofrequency (RF)) have shown excellent acute and long-term success rates with decreased procedure time compared to RF based 3D mapping and point-by-point PVI. Due to the fact that single-short devices are mainly designed for PVI they have several limitations concerning versatility, flexibility and adaptability to different anatomies.

Recently 3D mapping and point-by-point based catheter ablation achieved several improvements by implementing contact force (CF), ablation index (AI) or lesion size index (LSI)

guided RF ablation which have been shown to decrease procedure time, improving safety and patients outcome. Latest achievements are high-power short-duration (HP-SD) ablation with a maximum of 50W and very HPSD (vHPSD) ablation with maximum of 70-90W which have been introduced to clinical practice. In CF guided ablation procedures power is limited to 50W, while in a power-controlled ablation mode without CF sensing catheter power is limited to 70W. Although these concepts seem to be safe and effective, no real time temperature monitoring is possible because conventional catheters were utilized in those studies.

However, it has been shown that real-time subendocardial tissue temperature monitoring during RF energy delivery is a direct indicator of lesion formation but measurements by temperature sensors embedded in the catheter tip have been shown to be not an accurate indicator of actual tissue temperature.

# QDOT MICRO Catheter

To overcome those issues a novel ablation catheter was recently introduced. The QDOT MICRO$^{TM}$ Catheter (Biosense Webster, Inc. Diamond Bar, CA, USA) is an open-irrigated CF sensing single-tip catheter (**Figure 1)** . The QDOT MICRO$^{TM}$ Catheter incorporates three microelectrodes and six miniature thermocouples (1mm in diameter (3 proximal and 3 distal), at its tip for precise temperature monitoring. The thermocouples are embedded at distinct locations within the outer metal shell of the catheter, just 75 µm underneath the tip surface. The reason for this superficial location design was to obtain more accurate local temperature measurements from the catheter tip which is in direct contact with the tissue, in comparison to the conventional tip temperature measurements that is altered by the cooler parts of the tip that are not in touch with the tissue. It has been developed allowing for real-time catheter-to-tissue interface temperature measurements. Therefore, a real temperature-controlled catheter ablation with automatic adjustment of power and irrigation output based on real-time temperature measurement is achieved which allows for save and effective RF-lesion formation.

The QDOT MICRO$^{TM}$ Catheter offers two different ablation modes.

In QMODE (conventional temperature-controlled ablation mode with a maximum of 50W) the system adjusts 1) the irrigation flow rate and 2) power based on the measured temperature to stabilize the catheter tip temperature within the allowed temperature range avoiding over-heating and steam-pop. Lesions formation is guided by AI in the QMODE and is individualizable concerning power and ablation duration.

In QMODE+ (very high-power short-duration mode, vHPSD, 90W/4 seconds) only power is adapted to adjust the target temperature. The target temperature of the temperature-controlled ablation is usually 60°C based on the hottest surface thermocouple. The irrigation flow rate delays the energy application for a minimum of 2 seconds before and 4 seconds after each RF application. It is always possible to stop the lesion formation, however in QMODE+ it is only possible to ablate with 90W for a maximum of 4 seconds. The default irrigation setting is set at 2ml/min and 8 ml/min with a recommended CF working range 5 to 30g.

The vHPSD strategy aims to create shallower but wider lesions in a very short time by reducing conductive heating and increasing resistive heating at the same time. Additionally, collateral tissue damage might be reduced.

The three microelectrodes at the catheter tip of the QDOT MICRO$^{TM}$ Catheter offer sharp potentials and a higher resolution during mapping. Previous analyses provided evidence for reduced RF ablation time and procedure duration while showing a good safety profile in comparison to conventional power-controlled ablation. Although the QDOT MICRO$^{TM}$ Catheter was mainly designed for PVI its versatility to treat other types of arrythmias was recently evaluated and will be presented in this article.

### Pulmonary vein isolation utilizing the QDOT MICRO$^{TM}$ Catheter

With the ability to perform temperature-controlled ablation in combination with vHPSD the QDOT MICRO$^{TM}$ Catheter is an ideal tool for thin-walled LA procedures especially for PVI (**Figure 2** ). The vHPSD strategy aims to create shallower but wider lesions in a very short time by reducing conductive heating and increasing resistive heating at the same time. Additionally, collateral tissue damage might be reduced. Utilizing conventional power-controlled moderate-power long-duration RF applications the "close – protocol" with an inter-lesion distance (ILD) of 6mm has been introduced and verified for PVI. Lesion formation of vHPSD applications creates wider but shallower lesions. To achieve continuous lesions, we recently adapted the close-protocol to an individualized and tighter "very close-protocol". Utilizing the "very close-protocol" an ILD of 3-4mm at anterior aspect and ILD of 5-6mm at the posterior aspect of the LA using vHPSD only is performed and safety, efficacy and follow-up in comparison to conventional CF sensing AI guided RF ablation has been shown in the FAST and FURIOUS AF and FAST and FURIOUS PVI studies.

FAST and FURIOUS PVI study was a prospective non-randomized trial which compared 50 AF patients (vHPSD group) treated by PVI with the QDOT MICRO$^{TM}$ Catheter in QMODE+ only vs 50 previous patients (control group) with conventional point by point RF 40W AI guided ablation by the THERMOCOOL SMARTTOUCH SOURROUND FLOW ablation catheter (Biosense Webster). For patients of the vHPSD group the QMODE+ was exclusively used for all procedures. No switch to QMODE was necessary to achieve PVI. No differences were observed between the groups concerning catheter maneuverability and catheter stability. Here a significantly reduced mean RF time of 352±81s (vHPSD) vs 1657±570 seconds (control, p<0.0001) was observed. Furthermore, the mean procedure duration was 59±13 (vHPSD) and 101±38 (control, p<0.0001) and the first pass isolation rate was 74% (vHPSD) and 76% (control, p=0.817). Severe adverse events were reported in 2% (vHPSD) and 6% (control, p=0.307) and the 12-month recurrence free survival was 78% (vHPSD) and 64% (control, p=0.142). In conclusion PVI solely utilizing vHPSD via a very close-protocol was shown to provide safe and effective PVI with a high rate of first-pass isolations. No steam pops and no catheter tip charring were detected. An esophageal temperature probe was utilized in all vHPSD patients. A temperature of >38.5°C was detected in 18 (36%) patients solely at the posterior part of the left PVs. The mean maximum oesophageal temperature was measured at 42±2 °C. No clinical apparent esophageal lesions and no atrio-oesophageal fistulas were found.

The QDOT-FAST trial was a first-in-human, prospective, multicenter, single-arm, clinical study of the QDOT MICRO$^{TM}$Catheter conducted in four European countries (Austria, Belgium, Czech Republic, and Italy). It evaluated the safety and short-term performance of the QDOT MICRO$^{TM}$ Catheter in QMODE+ for PVI in 52 PAF patients. The total procedure and fluoroscopy times were 105.2±24.7 min and 6.6±8.2 min, respectively. The total RF ablation time was 8.1 minutes. The longer procedure time compared to the FAST and FURIOUS PVI study might be explained by the fact that in only 78.8% of cases (41 of 52), PVI was achieved using the QMODE+ only.No severe adverse events occurred in this study.

The Q-FFICIENCY trial was a prospective, multicenter (n=22), nonrandomized study that aimed to evaluate the safety and effectiveness of the QDOT MICRO$^{TM}$ Catheter in treating drug-refractory, symptomatic PAF patients (n=166) utilizing vHPSD only. The median procedural duration was 132 minutes and the median RF time was 8.0 minutes while the primary adverse event rate was 3.6%. The 12-month clinical success rate was 76.7%. Although the findings concerning safety and effectiveness were similar to the FAST and FURIOUS PVI study the procedure time was almost doubled which could be the consequence of its multicenter character with some centers unexperienced in QDOT MICRO$^{TM}$ Catheter procedures.

The POWER PLUS trial was a multicenter, randomized controlled trial, the authors compared procedural efficiency, efficacy, and safety of PVI using 90-W/4-second ablation to 35/50-W ablation. The procedural time was shorter in the 90-W group vs the 35/50-W group (median 70 (60, 80) minutes vs. median 75 (65, 88.3) minutes;$P = 0.009$). No major complications were observed in both groups with esophageal injury occurring in 1 patient per group.

A nonsignificant trend towards lower rates of first-pass isolation was seen in the 90-W group (83.9% vs 90%; $P = 0.0852$). However, no differences in 6-month outcomes were observed. The authors suggest to test a hybrid approach combining QMODE+ for anterior and QMODE for posteriore aspects of the LA in futures studies.

Although rare atrio-oesophageal fistula after catheter ablation of AF is a devastating and potentially lethal complication. The fact that vHPSD applications create shallower and wider lesions might be a factor for preventing atrio-oesophageal fistulas. A recent study of ninety consecutive patients treated by vHPSD based PVI underwent post-ablation oesophageal endoscopy. None of the 90 patients demonstrated oesophageal ulceration (0%) which might support the above motioned positive effect of the lesion formation in prevention of oesophageal lesions. Furthermore, no steam pop, cardiac tamponade, stroke, or fistula was reported in this study. Although the rate of clinical apparent stroke and TIA is reported to be low initial cerebral MRI data after QMODE+ based PVI showed silent cerebral lesions in 6/23 (26%) patients. Since coagulation on the catheter tip was detected at the end of the procedure suggesting this observation to being related to those events. Therefore, the RF generator software has been recently modified aiming to reduce the rate catheter

tip coagulation.

Recently, data on durability was assessed by cardiac MRI in 60 patients treated by vHPSD. Here complete PV encirclement was observed in 76.7% for RPVs, in 76.7% for LPVs, and in 66.7% for both PV pairs. These findings are promising and are in line with findings assessed in the FAST and FURIOUS PVI study. Here PVI durability assessed during redo-procedures was 75% (vHPSD) vs. 33% (control, $P < 0.001$). The FAST and FURIOUS REDO study is ongoing and will present data of PVI durability after initial vHPSD very close protocol based PVI.

The available data of the QDOT MICRO$^{TM}$ Catheter for PVI is promising. While demonstrating a good safety profile, the total ablation time, and procedural duration, were impressively low utilizing vHPSD. The retrospective peQasus study (clinical trials.gov: ID: NCT05710822, Very high-power short-duration ablation utilizing the QDOT MICRO$^{TM}$ Catheter for pulmonary vein isolation - A multicenter study) will evaluate safety and efficacy of the QDOT MICRO$^{TM}$ Catheter for PVI in multiple centers in Europe in a large group of >500 patients.

# QDOT MICRO$^{TM}$ Catheter for Cavotricuspid isthmus ablation

Beside the fact that QDOT MICRO$^{TM}$ Catheter QMODE+ based ablation for PVI has been evaluated in several trials and studies there is only limited data for catheter ablation of the cavotricuspid isthmus (CTI) in patients presenting with typical atrial flutter (AFL), (**Figure 3** ). The main concern about vHPSD is the lack of transmurality in regions with thicker tissue like the CTI. However, data utilizing 50W in studies by Kwon et al. and Yavin et al. reported a success rate for CTI block of 100%.

Schillaci et al. evaluated vHPSD ablation of the CTI in 28 consecutive patients (FAST) and compared the data to the last 30 consecutive patients who, previously, underwent CTI ablation by STSF guided by AI (control). For both groups an ILD of [?] 6 mm was aimed. The vHPSD ablation was as effective as AI-guided ablation in achieving acute CTI block (first pass rate: 89% vs 93%, $p = 0.59$), with a shorter RF time (88 +- 40 seconds vs 492 +- 269 seconds,$p < 0.001$) and similar procedure (30 +- 4 min vs 34 +- 10 min, $p = 0.5$) time was observed.

Besides PVI in the FAST and FURIOUS PVI study CTI block was achieved by Qmode+ only in 13 / 13 patients. In one patient with a repeat procedure the CTI was checked and was found to be durable blocked. Similar findings have been evaluated in the FAST and FURIOUS CTI study. Here complete CTI block using vHPSD ablation was achieved in all 15 patients. A median of 23 (20, 39) RF applications over a median RF ablation time of 92 (78, 154) seconds were applied and no periprocedural complications, no charring and no steam pops were observed.

The preliminary data show that vHPSD ablation might represent an effective and safe strategy to achieve bidirectional CTI block for the treatment of typical AFL.

### Ablation of atrial tachycardia by the QDOT MICRO$^{TM}$ Catheter

Although the QDOT MICRO$^{TM}$ Catheter was designed for atrial procedures data on the treatment of atrial tachycardia is limited to only one published case report.

Here a patient with perimitral atrial tachycardia with a critical isthmus on the anterior wall was treated by the QDOT MICRO$^{TM}$ Catheter utilizing QMODE+ only. An ablation of an anterior line was performed. After 10 vHPSD applications the atrial tachycardia terminated and the anterior line was completed with a total of 29 applications with an extremely low RF time of 116seconds. No periprocedural complications occurred. Interestingly the microelectrodes of the QDOT MICRO$^{TM}$ Catheter showed sharp and fragmented potentials at the area of the critical isthmus even though the standard electrodes showed no visible signals. This observation demonstrated the applicability of the microelectrodes for identifying potential targets for

catheter ablation. The combination of microelectrodes and vHPSD ablation seems to be an interesting option for mapping and ablation of atrial tachycardias (**Figure 4** ).

**Accessory pathway ablation**

Another case report has been recently published demonstrating the safety and efficacy of vHPSD ablation of a left lateral accessory pathway by a single 90W/4s RF application utilizing QDOT MICRO$^{TM}$Catheter. An immediate loss of pathway conduction was reported. Afterwards three bonus applications of vHPSD have been conducted. The 12-lead ECG confirmed absence of delta wave even after 12 months of follow-up.

**Ablation of premature ventricular contractions utilizing QMODE+**

Although vHPSD concepts have been evaluated for atrial procedures, data for ablation within the ventricles is very limited. Only one case report and one study for catheter ablation of PVC utilizing the QDOT MICRO$^{TM}$ Catheter have been published in humans up to date.

In the initial case report a patient with frequent monomorphic PVC originating from the right ventricular (RV) outflow tract (OT) (RVOT) received three-dimensional electroanatomic reconstruction of the right ventricle. The earliest activation was detected within the antero-lateral RVOT. At this area the microelectrodes detected early fragmented potentials which were not detectable on the standard bipolar electrode of the ablation catheter. A single vHPSD application of 4 s was performed resulting in an immediate loss of PVC. No periprocedural complications occurred and no recurrent PVC was reported during long-term follow-up.

After successful performing the above-mentioned case a pilot study for PVC treatment via QDOT MICRO$^{TM}$ Catheter was conducted. In the prospective single-center FAST and FURIOUS PVC study, we sought to investigate the efficacy, safety and clinical outcome of vHPSD ablation for the treatment of idiopathic PVCs originating from the right and left ventricular OTs. The data was compared to standard power-controlled ablation strategy using conventional contact-force sensing ablation catheters. In this study, twenty-four consecutive patients underwent PVC ablation utilizing vHPSD ablation (study group) and were compared with 24 consecutive patients previously treated with power-controlled ablation (control group). Each group included 12 patients with PVCs originating from the RVOT and 12 patients with PVCs originating from the left ventricular OT (LVOT). The acute endpoint of PVC elimination was achieved in all patients. In this study, vHPSD was used as the first approach and was switch to conventional QMODE after ineffectiveness. In 16/24 (67%) patients (study group) the acute endpoint was achieved by using vHPSD only (RVOT: 92%, LVOT 42%). The earliest activation found on the microelectrodes of the QDOT MICRO$^{TM}$ Catheter was significantly earlier than on the standard bipolar electrodes. The median RF delivery time was massively reduced utilizing vHPSD ($p<0.0001$). No difference was observed regarding procedure duration ($p=0.489$), follow-up ($p=0.712$) and severe adverse events (4%, study group, 8%, control group, $p=0.551$).

Although the FAST and FURIOUS PVC study was a single center non-randomized study it demonstrated the feasibility and safety of the QDOT MICRO$^{TM}$ Catheter for treatment of OVC originated from the RVOT and LVOT. In the thin walled RVOT the success rate of vHPSD was 92% while it was 42% for LVOT case. Therefore, it seems to be reasonable to consider vHPSD (QMODE+) for PVC originating from the RVOT (**Figure 5** ) and conventional QMODE for PVC originating from the LVOT.

**Conclusion:**

The QDOT MICRO$^{TM}$ Catheter offers vHPSD (90W/4s, QMODE+) as well as conventional temperature-controlled (QMODE, AI guided) ablation and showed safety and efficacy for PVI in a several studies. Beside those promising observations its ability to treat also other types of arrythmias including typical common type atrial flutter, macro-reentrant atrial tachycardia, supraventricular tachycardia with accessory pathway as well as PVCs was recently evaluated by preliminary case reports and studies (FAST and FURIOUS studies). Although the results are promising further multicenter evaluations are necessary to draw final conclusions.

**References:**

**Figures**

*Figure 1: QDOT MICRO$^{TM}$ Catheter*

Picture of the QDOT MICRO$^{TM}$ Catheter tip showing micro-electrode at the tip. The black arrows highlight one micro-electrode, the contact force sensor and the 56 irrigation holes at the catheter tip.

*Figure 2: QDOT MICRO$^{TM}$ Catheter during PVI in QMODE+*

A: Three-dimensional electroanatomic reconstruction (CARTO 3, UNIVIEW module, Biosense Webster) of the left atrium in PA view and B: superior view. Please note the circle depicted through red-black tags created by radiofrequency ablation utilizing the QDOT MICRO$^{TM}$Catheter in the QMODE+ ablation mode. The data of the current application is depicted in C: and shows the biophysics parameters of a very-high power short duration ablation by 90 W/4 s. The parameters of power (W) Impedance ($\Omega$), temperature (°C) and contact force (g) are shown. Right upper corner depicts the bulls eye view with temperature measurements of the QDOT MICRO$^{TM}$ Catheter tip.

*Figure 3: QDOT MICRO$^{TM}$ Catheter during CTI-ablation in QMODE+*

A: Three-dimensional electroanatomic reconstruction (CARTO 3, UNIVIEW module, Biosense Webster) of the right atrium in LAO and RAO during catheter ablation at the cavotricuspid isthmus (CTI) for the treatment of typical common type atrial flutter. Please note the white-red tags created by radiofrequency ablation utilizing the QDOT MICRO$^{TM}$ Catheter in the QMODE+ ablation mode.

*Figure 4: QDOT MICRO$^{TM}$ Catheter for ablation of atrial tachycardia by QMODE+*

A**:** Electroanatomic map of the left atrium utilizing CARTO 3, V7 (Biosense Webster). Left side, left anterior oblique, LAO) view. A local activation time map with evidence of a peri-mitral atrial tachycardia, suggesting the critical isthmus at the anterior wall. Coppery area – zone of slow or no conduction (Coherent module, Biosense Webster).

B: voltage map with evidence of a large scar area on the anterior and posterior wall. The bipolar voltage reference interval was set between 0.05 mV and 0.35 mV.

C: QDOT MICRO$^{TM}$ Catheter in QMODE+ and ablation at the anterior wall at the moment of atrial tachycardia termination Left side, right anterior oblique (RAO) view; right side, LAO view. Note the ablation catheter in the anterior wall during delivery of a very high-power short-duration application of 90 W/4 s. The contact force was 18 g and the distance from the previous application was 5.3 mm. The "bullseye" in the left upper corner indicates the temperature of the ablation catheter tip.

D: Final lesion set up with an anterior line depicted by red dots with white points.

*Figure 5: QDOT MICRO$^{TM}$ Catheter for mapping and ablation of premature ventricular contractions*

A**:** Electroanatomic map of the right ventricle utilizing CARTO 3, V7 (Biosense Webster). Left side, left anterior oblique, LAO) view. Earliest activation of the frequent monomorphic premature ventricular contraction (PVC, red pin within red area (Coherent module, Biosense Webster) was found at the antero-septal right ventricular outflow tract (RVOT). Final lesion with 3 very high-power short-duration application of 90 W/4 s depicted by red dots with white points.

B: Surface and intracardiac electrocardiograms with the QDOT MICRO$^{TM}$ Catheter at the location of earliest activation of the PVC within RVOT. Please note the potentials on the micro-electrodes (pointed out by black arrows). Abl d = distal electrodes on the map catheter.

Abl p = proximal electrodes on the map catheter. Abl u1-u2, Abl u2-u3, Abl u1-u3 = micro-electrodes. Speed 25 mm/s.