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Detection, Tracking and Related Costs of Ablation Catheters in the Treatment of Cardiac Arrhythmias

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1. Introduction

The adjective '*cardiac*' signifies '*related to the heart*' and it originates from the Greek word '*kardia*' meaning '*heart*'. The human heart is a muscular pump roughly the size of a fist. It pumps blood continuously through the circulatory system. The average human heart will beat at 72 beats per minute, and beat 2.5 billion times during a 66 year lifespan. Further, the heart pumps an average 5.2 liters of blood per minute. It weighs approximately 250 to 300 grams in females and 300 to 350 grams in males [1].

The heart's electrical system includes three parts (see Figure 1):

1. *S-A node* (sinoatrial node)– known as the heart's natural pacemaker, the S-A node has special cells that create the electricity that makes your heart beat.
2. *A-V node* (atrioventricular node)– the bridge between the atria and ventricles. Electrical signals pass from the atria down to the ventricles through the A-V node.
3. *His-Purkinje system*– carries the electrical signals throughout the ventricles via conduction pathways to make them contract.

Severe disorders of the heart rhythm can lead to sudden cardiac death (SCD), which is a sudden and unexpected death. Not to be confused with heart attacks which occur because of coronary artery blockage, sudden cardiac death happens when the electrical system of the heart becomes very irregular leading the heart to beat dangerously fast. At the outset of such a scenario, the greatest concern becomes blood flow to the brain being reduced, and unless treated rapidly patient death ensues.

In 2012, a review of the epidemiology of SCD was disseminated [3]. For brevity, we provide only a short summary of its highlights. In the United States alone, the incidence rate ranges

between 180,000 and 450,000 cases annually [3, 4]. These estimates vary owing to differences in SCD definitions and surveillance methods [3, 5]. Prospective studies using multiple centers within the United States [3, 6-7], Netherlands [3, 8], Ireland [3, 9] and China [3, 10] showed SCD rates ranging from 50 to 100 per 100,000 general populations. From these, it is clear that the overall burden in the population remains high. Improvements in primary and secondary prevention have resulted in substantial declines in overall coronary heart disease (CHD) mortality over the past 30 years [3, 11-12], whereas SCD rates specifically have declined to a lesser extent [3, 13-16]. SCD still accounts for 50% of all CHD deaths and up to 20% of all deaths [3, 17]. For some segments of the population, rates are not decreasing and may actually be increasing [3, 14, 18]. As such, SCD prevention represents a major opportunity to further reduce mortality from CHD [3].

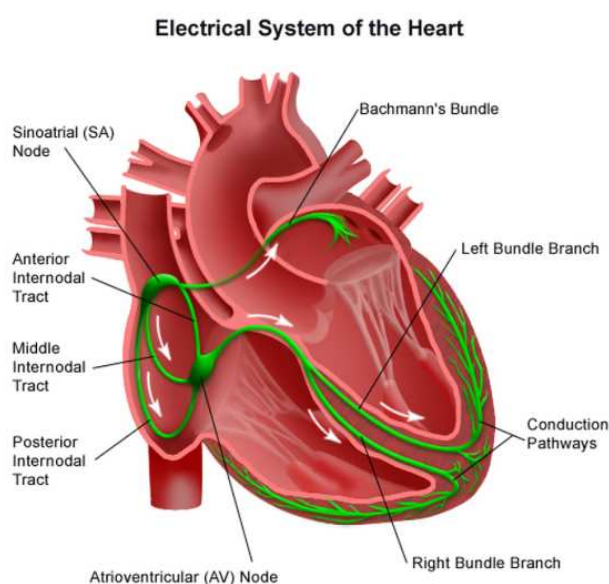


Figure 1. The electrical activity of the heart – image taken from [2].

i. Radiofrequency catheter ablation

Cardiac arrhythmias have been linked to SCD and the handling of these has been facilitated by the ability to definitively treat many patients with radiofrequency (RF) catheter ablation. Two very common arrhythmias treated are atrial fibrillation (AF) and ventricular tachycardia (VT). The first originates by impulses beginning and spreading through the atria, competing for a chance to travel through the AV node. The heart rhythm becomes disorganized, rapid, and irregular resulting in loss of coordinated atrial contraction. On the other hand, VT is a rapid rhythm originating from the lower chambers of the heart. It prevents the heart from filling adequately with blood, thereby less blood is able to pump through the body. VT is considered a more serious arrhythmia.

Authors in [19] provide an excellent review on the history and evolution of RF ablation. Catheter ablation with direct current from a standard external defibrillator began to supersede surgery in the 1980's. A shock was delivered between the distal catheter electrode and a

cutaneous surface electrode [19]. However, this high-voltage discharge was difficult to control and could cause tissue damage. As clinicians became more skilled and electrophysiological mapping improved, direct current (DC) ablation was used to treat cases of Wolff-Parkinson-White, ventricular tachycardia and atrial tachycardia [19, 20-25]. By the 1990's, radiofrequency energy had supplanted direct current [19, 26] since there was high incidence of complications associated with the high-energy discharge. In addition to this, RF ablation could be performed on conscious patients [19, 27-29].

Today, catheter ablation procedures are performed in an electrophysiology laboratory. RF electrode catheters are most commonly inserted percutaneously into the femoral veins and orientated within the heart to allow pacing stimulation and intracardiac electrical signal recording at key sites: such as the right atrium, right ventricle, the area of the His bundle or the coronary sinus [19, 30]. The efficacy of catheter ablation is highly dependent on accurate identification of the site of origin of the arrhythmia. Once this site has been identified, an ablation catheter (typically 7-11 French in size, see Figure 2) is positioned in direct contact with it and radiofrequency energy is delivered to ablate it. After one minute, a lesion of 5-mm depth is formed, which is enough to destroy the full thickness of the atrial myocardium in that location [19, 30].

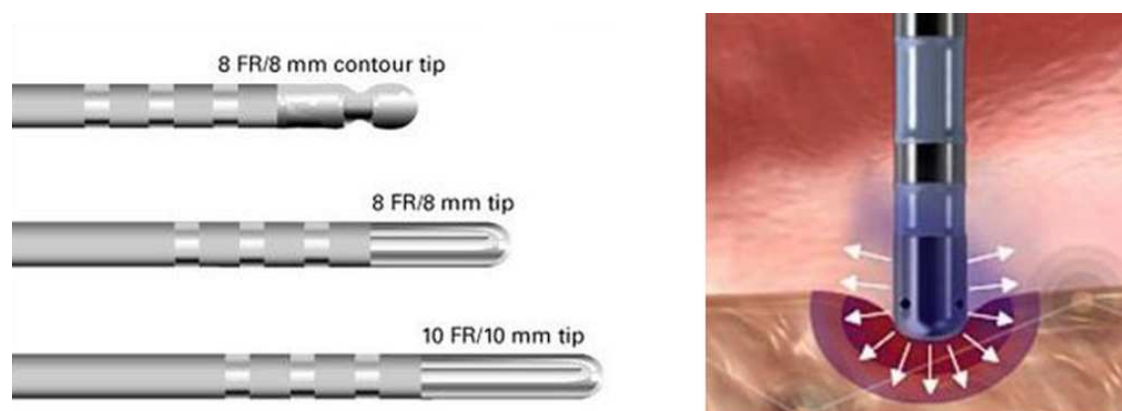


Figure 2. *Left*) Radiofrequency cardiac ablation catheters of different sizes - image taken from [36]. *Right*) The catheter tip delivers the bursts of high-energy waves that destroy the abnormal areas - image taken from [37].

Current ablation systems allow for temperature monitoring and control [31]. These are valuable tools during RF ablation procedures as they: (i) provide important information regarding the adequacy of tissue heating, (ii) minimize the development of coagulum, and (iii) maximize the lesion size. Newer technical modifications, such as a larger distal electrode and saline cooling of this electrode, have helped to minimize impedance rises and allow creation of larger and deeper lesions [19, 32-35].

ii. Radiation exposure

Catheter ablation is often a long procedure requiring fluoroscopy exposure. RF ablation usually can routinely be accomplished with <20 min of fluoroscopy for most arrhythmias [19]. In 2012, a task force led by prominent cardiologists defined guidelines and recommendations

for ablation procedural techniques, patient management and follow-up [38]. One concern raised was that an important complication of ablation is the delayed effect of the radiation received by the patients which yield [39] malignancy, and genetic abnormalities [40]. Many of the described studies in [38] demonstrated that catheter ablation of atrial fibrillation required significantly greater fluoroscopy duration and radiation exposure than simpler catheter ablation procedures. Thus, increasing availability and familiarity of electrophysiologists with 3D mapping systems [41] may significantly reduce fluoroscopy time. The task force recommendation is that this can only be achieved by an awareness of the importance of reducing fluoroscopy time, and therefore radiation exposure, by the operator. Although it is hypothesized that use of remote 3D navigation systems will reduce radiation exposure to patients and operators, this remained unproven until recently [38].

iii. 3D Mapping systems

An overview of cardiac mapping technologies is presented in [42]. The use of non-fluoroscopic techniques, using either magnetic or electrical fields for mapping of catheter position, has reduced fluoroscopy time and radiation dose to both patient and staff.

The common mapping technologies that combine 3D anatomy and electrophysiological data are: *CARTO* and *CARTOMerge* (Biosense Webster), *NavX* (St.Jude Medical), and *RPM* (Cardiac Pathways-Boston Scientific). Other technologies that provide continuous data of all electrophysiological events include *Ensite 3000* (St. Jude Medical) and *Basket* (Cardiac Pathways-EP Technologies) [43-44]. More sophisticated mapping technologies that involve the fusion of imaging modalities (i.e. using preoperative MRI/CT, to fluoroscopy) are also discussed [45]. Two sample visualizations of the above technologies are seen in Figure 3.

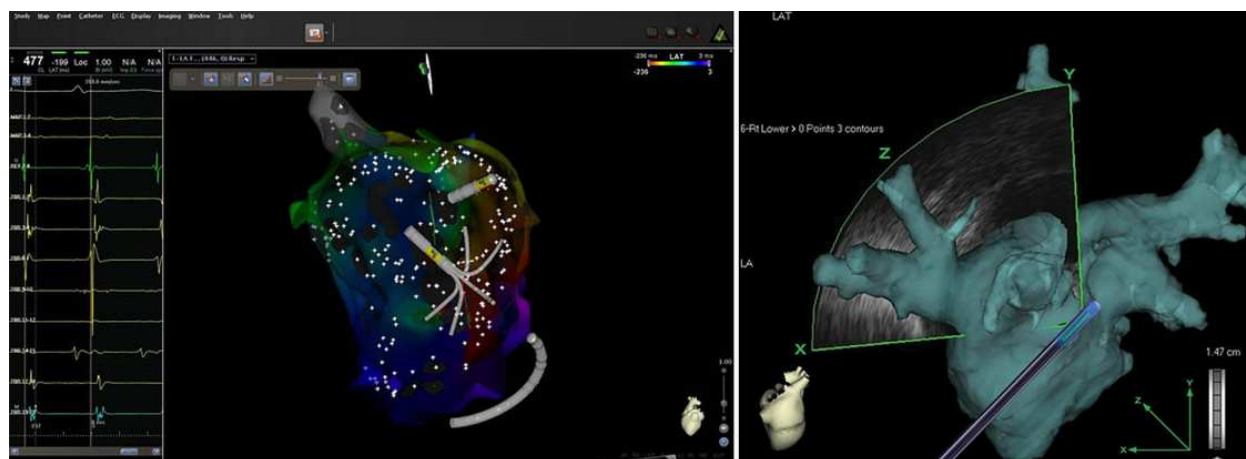


Figure 3. BioSense Webster has recently released (*left*) a multi-electrode mapping version of its 3D cardiac mapping system, and (*right*) a platform to merge ultrasound data of the heart [37].

An alternative technology is the intracardiac echocardiography (ICE) which has become the imaging modality of choice in many interventional settings primarily due to its flexibility and ease of use. The most commonly used ICE transducer is the *ACUNAV* (Siemens Medical Solution) which provides real-time visualization of structural anatomy. Another advantage of

such a transducer is that it delivers precise information about catheter position and adjacent structures. The first report of the various uses of ICE in atrial fibrillation is outlined in [42]. These include but are not limited to: (i) facilitating transseptal puncture, (ii) assisting catheter positioning prior to ablation, and (iii) identifying pulmonary vein structure. Also reported is the efficacy of ICE during the treatment of ventricular tachycardia [46]. Here, ICE is used to monitor catheter position and stability, and additionally is used to visualize the aortic cusp region. Lastly, registration between ICE and a 3D reconstruction of the left atria, performed using rotational fluoroscopy, is reported and shown to be an alternative technique to support atrial fibrillation ablation [47].

Robotic cardiac catheter ablation has been recently developed to eliminate potential errors in catheter manipulation. Also, the use of robots could systematically decrease clinician fatigue and fluoroscopy exposure. Some electrophysiologists agree that areas between mitral valves and pulmonary veins are typically difficult to reach and position correctly the mapping catheter. Robotics can thus provide more accuracy in these cases. Yet, initial studies show complications can occur at about the same rate as manual ablation. Currently there are two robotic systems – the *Stereotaxis Magnetic Navigation System* (Stereotaxis, Inc.) and the *Hansen Sensei Robotic Catheter System* (Hansen Medical). Both systems allow the physician to perform the mapping and ablation procedure while sitting in a control room remote from the patient [48]. Ongoing robotic developments use a magnetic tracking device to track the distal part of the ablation catheter in real time, and a master-slave robot-assisted system for actuation of a steerable catheter [49].

iv. Hospital induced costs

In 2013, an exhaustive study was released that evaluated the cost of special equipment chosen by physicians to perform cardiac ablations [50]. More specifically, the costs associated with the treatment of atrial fibrillation procedures were investigated. A synopsis of the relevant costs follows.

Cost of mapping technology: the 5-year cost for the mapping systems and maintenance is \$375,000 (Biosense Webster Carto 3) and \$495,000 (St. Jude EnSite Velocity). Phased array ICE catheters use standard ultrasound machines. The rotational ultrasound catheter (Ultra ICE, Boston Scientific, Natick, MA, USA) requires a special machine (iLab®) with a 5-year cost of \$131,400. Lastly, the 5-year cost ranged from \$33,000–\$67,000 for the traditional RF generators [50].

Cost of catheters: Catheters compatible with the St. Jude Ensite Velocity system ranged from \$1,500–\$1,900, and the special navigation catheters required by Carto 3 cost \$2,800–\$3,000. The lowest cost ICE catheter is the Boston Scientific Ultra ICE™ rotational catheter costing \$1,050. The most expensive are the phased-array catheters costing \$2,640–\$2,800. Although the rotational ICE catheter costs \$1,590 less than the phased array, it requires a separate ultrasound processor (iLab®); therefore, it takes 82.6 cases to begin saving on each rotational ICE catheter [50].

Cost of Robotic Systems: The manufacturer's list price for the Stereotaxis NIROBE Robotic magnetic navigation system (MNS) is \$2,875,000 with an annual maintenance contract of

\$104,000 per year for a total 6-year cost of \$3,395,000. Assuming 200 patient cases per year, the robotic MNS costs \$2,829 per case. It requires a disposable \$1,200/case ablation catheter advancement system and \$250/case circular mapping catheter drive. The system requires special catheters which cost \$3,590 including cables and irrigation tubing and can only utilize the Carto 3 mapping system. The lowest- and highest-cost scenarios for a MNS ablation are \$12,261 and \$15,464. These costs for MNS ablation are 84.7 and 133 % higher than the lowest-cost RF equipment [50].

Cost of The Medtronic Arctic Front® cryoballoon cost is \$6,500. The costs of a cryoballoon ablation with focal cryoablation touch-up for the lowest- or highest-cost scenarios is similar to that for the balloon-only ablation, but requires the addition of a Freezor® MAX focal cryoablation catheter for \$3,095. The lowest cost estimate requires repeated removal of the cryoballoon and insertion of the focal ablation catheter through the same sheath. The highest-cost estimate assumes the addition of a variable-diameter circular mapping catheter used independently of the cryoballoon through a steerable sheath. The total lowest and highest costs of \$15,942 and \$22,284 were 140 % and 236 % higher than the lowest-cost RF ablation [50].

The conclusions of the study [50] are that hospitals and clinicians have many choices of ablation equipment. These equipment costs ranged from \$6,637 to \$22,284 per case. In the end, the development of more expensive technologies should demonstrate an increase in the efficiency of cardiac ablation procedures as well as positive patient outcomes.

2. Detection and tracking of cardiac ablation catheters

There are several reasons as to why detecting and tracking the position of ablation catheters relative to the patient anatomy is important. They are related to interventional guidance aspects: (i) accounting for heart motion compensation, (ii) easing positioning & navigation during cardiac ablation, (iii) planning the ablation procedure by (iv) registration to preoperative data such as CT and MRI. To achieve detection and tracking, there are two primary options available: (a) hardware solutions that include mechanical and optical systems or the previously mentioned mapping systems, and (b) software and image-based solutions that make use of intraoperative images such as X-ray fluoroscopy.

We observe notable differences when comparing mapping systems with image-based solutions. First, although mapping solutions are expensive, they provide high accuracy and robustness and their clinical usage is getting popular. However, there is a notable learning curve for clinicians to get used to this technology. As for image-guided solutions, these require dealing with high data variation and involve the acquisition of a large amount of X-ray images. Their usage is still very limited since there is a high performance requirement for a practical clinical solution.

Whether using mapping systems or conventional RF ablation techniques, clinicians still rely on X-ray images to position and guide catheters. Thus, exploiting X-ray image information is crucial for providing additional information to clinicians during cardiac ablation procedures.

Hence, there has been a trend lately of researchers investigating image-based solutions since these would also provide inexpensive and simple assistance to clinicians and could alleviate some of the burdens involved with the commercially available expensive technologies. We have identified three recent works that focus on the detection and tracking aspects of catheters visible in X-ray images [51-53].

These works address some of the inherent properties associated with the acquisition of X-ray images: (i) low quality and characterized by low signal to noise ratios, (ii) the non-rigid catheters visible in them have foreshortening artifacts due to X-ray projection principles, (iii) catheters may be occluded or overlapped by other catheters or background artifacts, and (iv) specifically during real-time fluoroscopic guidance, one can also observe motion blur artifacts.

i. Detection of catheters

The goal of any algorithm is to find all potential catheter electrode candidates in the X-ray images. The key is to perform these detections without the requirement of user interactivity or algorithm re-initialization. Once candidate electrodes are estimated these need to be subsequently filtered to remove false positives (outliers).

In current research practice, the ‘blob detector’ formulation is used to detect electrodes. We recall that electrodes appearances are not always the same in X-ray images due to foreshortening and projective effects. They can appear larger or smaller and their shape can change from rectangular → elliptical → circular over consecutive frames. It should be noted that for an individual X-ray image, the appearance of the electrodes belonging to the same catheter are very similar: if one of them appears as a circle it is very likely that the others share the same appearance. The candidate electrodes are obtained from a blobness measure influenced by non-maximum suppression. This blobness measure is implicitly greater than one since we are using a scale-space approach to detect electrodes at different scales. In other words, a catheter tip electrode will appear larger than the other electrodes.

Authors in [51, 53] investigated different methods that yield different performances both w.r.t. the detection rate and execution time. These approaches are based respectively on the usage of a “laplacian of gaussian” (LoG) and a “difference of gaussian” (DoG). The (LoG) blob detector [54] is a non-separable linear filter capable of finding blob-like structures while having low responses to edge-like structures. For each X-ray image it is necessary to run three linear filters and to evaluate the blobness measure:

$$Blobness_{LoG}(x, y, t_0) = t_0(L_{xx}L_{yy} - L_{xy}^2) \quad (1)$$

where L_{xx} , L_{yy} , L_{xy} are respectively the convolution of the X-ray image $I(x,y)$ with G_{xx} , G_{yy} , G_{xy} being the second derivatives of the gaussian filter and $t_0 = \sigma^2$ is used for normalization purposes equal to the variance of the gaussian filter.

The (DoG) blob detector [55] is an approximation of the “laplacian of gaussian” filter and is based only on the usage of gaussian filters that are linearly separable. A scale-space representation of the image is obtained by filtering the image with a gaussian kernel using increasing

variances. The difference between two neighboring scale-space images is taken and this latter result is used as a blobness measure. The mathematical formulation for the 2D gaussian filter is:

$$G(u, v, t_0) = \frac{1}{\sqrt{2\pi t_0}} e^{-(u^2+v^2)/(2t_0)} \quad (2)$$

and the blobness measure becomes:

$$Blobness_{D_0G}(x, y, t_0) = I(x, y) * G(x, y, kt_0) - I(x, y) * G(x, y, t_0) \quad (3)$$

This detector has a significant response in correspondence to edge-like features in the image and thus yields more outliers (i.e. higher false positives) when compared to the LoG detector. False positive candidate electrodes exist. To eliminate these, a Top-Hat filter is implemented which discards candidates that do not fulfill spatial and geometric constraint characteristics of an electrode. Since we are looking for “quasi circular” candidates mimicking electrodes, a structuring element with a circular diameter of 15 pixels is used. This immediately removes the majority of outliers. Second, since an electrode is metallic (and thus radiopaque), it appears as a very dark cluster in the X-ray image. Thus, candidate electrodes appearing as a bright cluster are rejected. From this, the blobness measure can be used to distinguish between catheter tips and other electrodes (tip-electrodes have a stronger measure as they are larger in size). For the sake of brevity, we direct readers to [51, 53] for additional details on the various outlier removal methods. Figure 4 and Figure 5 show intermediate and final results of image-based catheter detection solutions. The accuracy of the techniques is well above 95% when compared to ground-truth data.

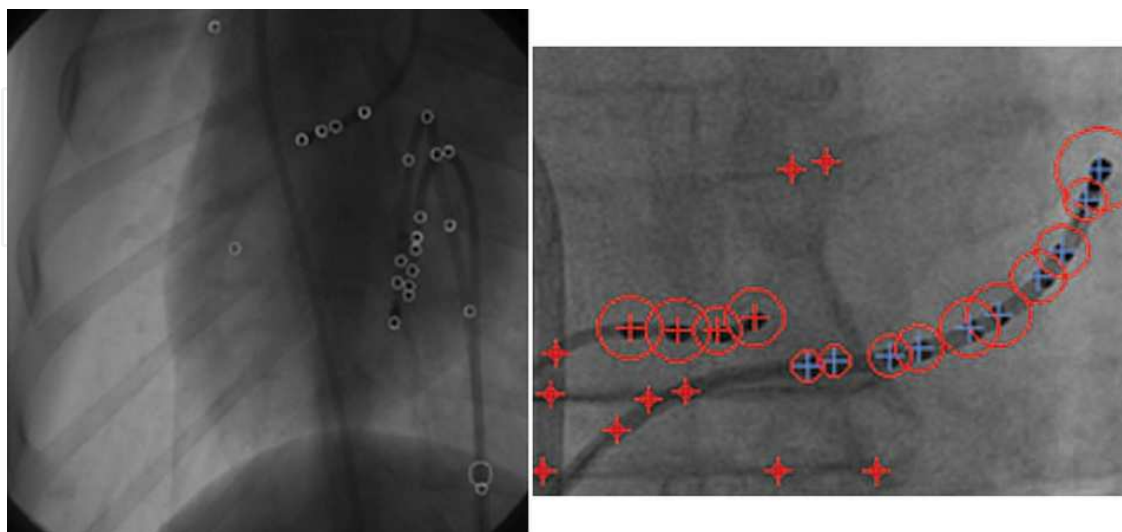


Figure 4. Examples of blob detections in X-ray images of dog (*left*) and patient (*right*). Images taken respectively from [51] and [53].

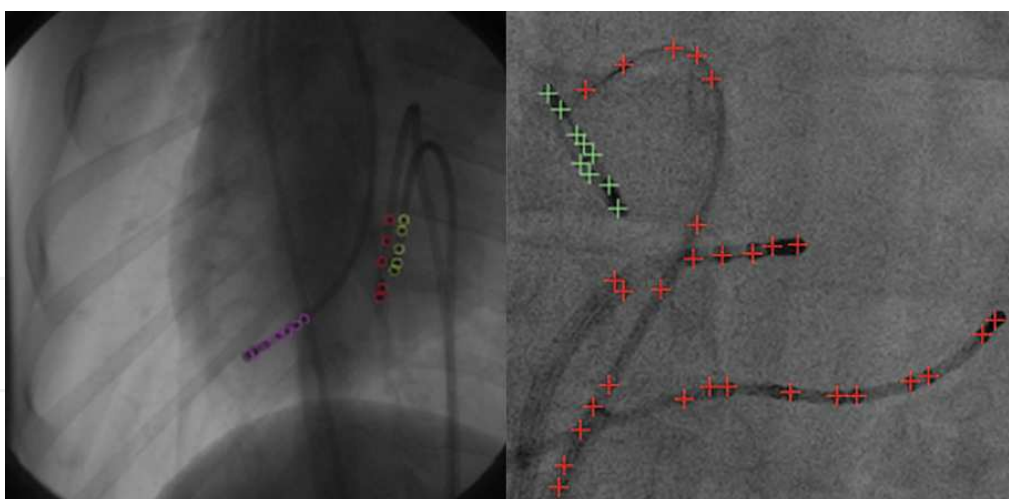


Figure 5. Example images of complete catheter detections in dog (*left*) and patient (*right*), after outlier removal. The different color coding implies detections of different catheter types. Images taken respectively from [51] and [53].

ii. Tracking of catheters

Initial solutions for tracking catheters in X-ray are presented in [52, 53]. In clinical practice, X-ray fluoroscopy images are acquired at about 15 frames per second depending on the system settings. Thus, developing image-based solutions that track at the rate of several images per second would be considered as an acceptable efficiency. The accuracy requirements depend on the specific application, and millimeter accuracy is roughly comparable with the currently available mapping navigation systems, while others [56, 57] have found 2-mm accuracy to be sufficient. Since the clinician needs to position the ablation catheter on heart tissue as it performs the burning, the most vital information to be tracked accurately is the catheter tip electrode. A very low false positive rate is also important to reduce any risk of inaccurate or insufficient treatment [52]. As seen in Figure 4-5, it is common practice that more than one catheter is used simultaneously; therefore, the ability to track multiple catheters is also an important requirement satisfied by image-based tracking solutions. For example, tracking the coronary sinus (CS) catheter can be used for transseptal puncture guidance [52, 58] and respiratory motion correction [52, 59]. There are several studies on the feasibility and significance of such a method for fluoroscopic-based guidance and mapping. Philips Healthcare has a product called the *EP navigator* that requires a user operator to indicate the position of the ablation catheter on the X-ray image ('point tagging'). It was evaluated during a catheter ablation [60], while the authors in [61] found it feasible to use their automatic catheter tracking method in a clinical environment.

In [52], authors introduce an efficient and robust method for multiple catheter detection and tracking. The proposed technique exploits the clinical setup knowledge to provide search constraints and boost both speed and accuracy. The method involves user input only in the beginning of the case, and runs fully automatically for the rest of the intervention. The method is based on a computationally efficient geodesic framework to trace the sheath and to find one or multiple catheter tips. The method was validated on 1107 fluoroscopic images taken from

four patients from different clinics, demonstrating robust multiple catheters tracking at 10 images/s. The complete details of the algorithm are found in [52]. Figure 6 shows intermediate and final results of catheter detection.

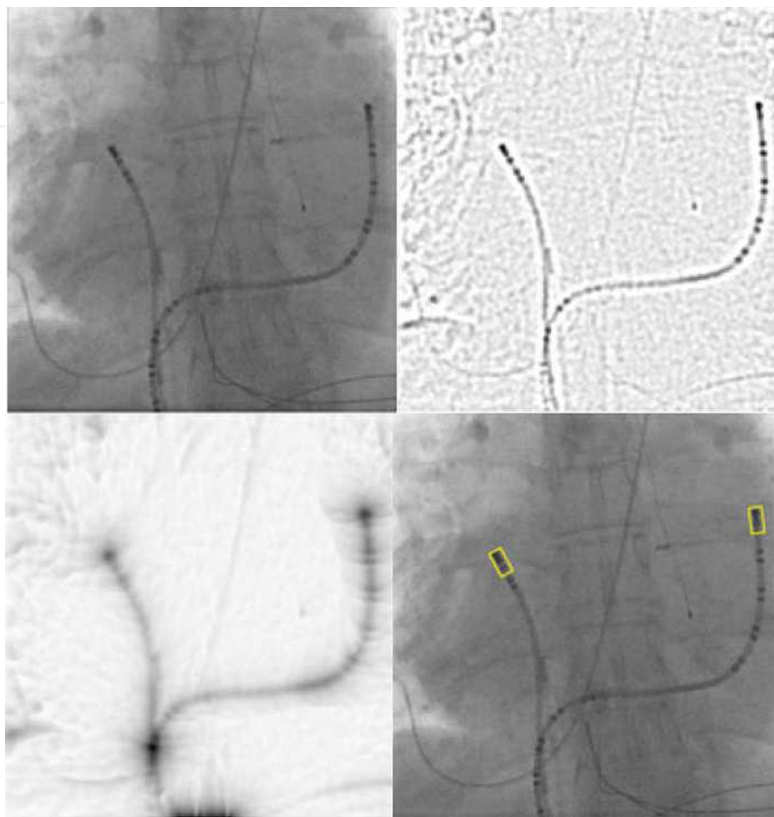


Figure 6. The original X-ray image with preprocessing (*top-row*) followed by geodesics properties computation. Final tip electrodes boxed in yellow (*bottom-row*).

Lastly, as an alternative tracking solution, authors in [53] develop a template-based approach. Tracking methods are initialized using the basic detection algorithm of LoG or DoG. This detection is used to create a customized 2D catheter model comprising a connected graph which gives information about the initial shape and orientation of the catheter. In subsequent X-ray image frames, the tracking methods use the same blob detection method and a modified catheter detection method that uses the customized model of the catheter being used during intervention [53]. Incorporating the customized model may allow successful tracking in cases where some catheter electrodes are overlapped with other dense objects or are outside the field of view. The current implementation requires manual detection of failed tracking, at which point the operator can restart with the basic detection algorithm [53].

iii. Future trends

There is room to investigate the above methods under various clinical conditions and different C-arm fluoroscopy devices. The variety in image quality in clinical cases is due to the variability in patient size, the variability in the image content with the presence of additional or implanted

devices that were not used in our animal experiment. These must be accounted for when improving results [62]. Ultimately, achieving automatic detections and tracking can simplify 3D reconstruction of electrodes using single or multi-view approaches [63-64].

3. Conclusions

In summary, this chapter presented the latest findings involving the detection and tracking of cardiac ablation catheters. Several commercial 3D mapping systems provide non-fluoroscopic catheters with magnetic tips. These are detected and tracked in real-time using custom hardware and are used in everyday practice in luminary hospitals. Conventional RF ablation is still a requirement in many hospitals worldwide that cannot afford the expensive 3D mapping technologies. The advantages of image-based tracking technologies are many including being inexpensive and practical. With the advent of real-time computing capabilities, speed is a non-issue. However, researchers must continue to focus their efforts on developing mature algorithms for robust tracking – with the right catheter models. The keys for robustness against large data variation from fluoroscopic sequences involve considering machine learning approaches and obtaining large data sets for training and quantitative evaluation.

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