Non-Invasive Tool for Coronary Artery Diagnosis Using Signal Characteristic Analysis (CADSCAN®) and Iso-Surface Optimal Membrane-Adherent Compliant (ISOMAC®) Sensors

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Abstract –
CADSCAN® and acoustic ISOMAC® sensors combine state-of-the-art non-invasive acoustic sensing and proprietary Wavelet Transform algorithms with fast DSP core hardware to quickly detect and locate coronary arterial stenoses with near-pinpoint accuracy in real-time.

1 INTRODUCTION

This paper describes the efforts put forth in this purely non-invasive advanced technology. CADSCAN came into existence in 1997 at Diagnostic Devices, Inc. (DDI), pioneered by the husband and wife team of the Shertukdes.

The present system relates to early detection of blockages of the coronary arteries due to the formation of atherosclerotic plaque and, more particularly, and also early determination of the locations of such blockages in the coronary arteries to enable cardiologists to accurately perform the angiogram to repair the blockages before a catastrophic failure of the heart. Currently, invasive procedures, known as angiograms, are among the methods used for the diagnosis of the narrowing or blockage of the coronary arteries of the heart. In contrast, the CADSCAN® method is a ***non-invasive*** screening tool using ISOMAC® sensors [1].

2 BACKGROUND

Coronary artery disease generally refers to the buildup of cholesterol and other plaques in the interior layers of the arteries. As shown in Fig. 1, this slowly narrows the diameter of the arteries, thus restricting the flow of blood through the vessel. As a result, the tissues receive an insufficient blood supply. The plaque

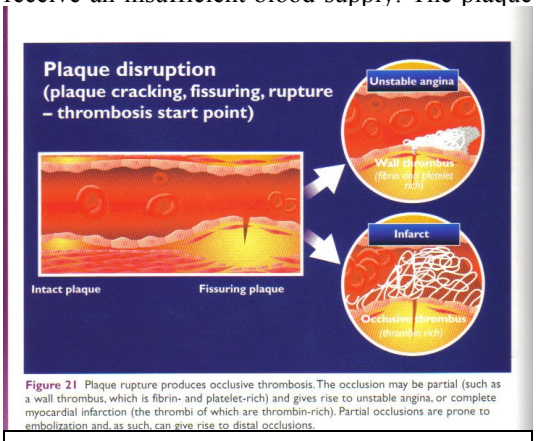


Fig. 1. Plaque disruption and crack in the wall of a coronary artery as shown in the left inset. Picture borrowed from Handbook of Dyslipidemia and Atherosclerosis by Prof. Jean-Charles Fruchart.

shown in the left inset, a crack may develop in the plaque and a blood clot may form - this is the mechanism of most heart attacks.

When this blockage occurs in an artery, it causes the blood to flow with more turbulence,

which generates high frequency sounds especially during the diastolic portion of the cardiovascular cycle, as shown in FIG. 3. This high frequency signal can be used as an admissible kernel for Wavelet Transform (WT) analysis in appropriate signal processing methodology. High frequency, spread spectrum signals that experience time and frequency scaling are difficult to decompose with narrowband analysis, such as Fourier transform, due to its sinusoidal kernel, which approximates the scaling effect with a Doppler shift. However, the WT uses a more general analysis kernel, or mother wavelet like the Morlet family of wavelets.

A necessary part of the intervention process also involves cardiac catheterization, which is invasive. This process is required before the actual angiogram and the subsequent angioplasty procedures are conducted. In a typical cardiac catheterization process a catheter is inserted extending from the groin area to the heart. At the end of this catheter are suitable sensors. In some cases there are active sensor heads, which emit a radio frequency signal of 1 MHz and project it towards the heart. These sensor heads are almost within 1" from the heart border. The projected signal is reflected of the arteries of the heart and can show the location of the occlusion. Angioplasty may be done. It is the object of the present device to provide a novel method for detecting and determining the position of the blockages in the coronary arteries of the heart. It is also an object to provide such a method, which can be readily, reliably and economically achieved. Another object is to provide novel apparatus to conduct the detection and location of the blockage in the coronary arteries. A further object is to provide such an apparatus, which may be fabricated from readily available components at a reasonable cost to enable its widespread use. This apparatus should be able to provide the detection of the stenoses in the coronary arteries and their location in relation to the reference origin, in this case considered as the base of the sternum as shown in FIG. 2.

CADSCAN® is a non-invasive device for detecting coronary artery disease. Normal biomedical signals like the systolic and diastolic motions of the heart are generally stationary. Coronary occlusions, however, create turbulence, related to the diastolic motion, making these signals non-stationary which can be detected acoustically. The acoustic signature of the turbulence can be studied using fractal analysis and wavelet transforms. The result is an estimation of an occlusion in the coronary arteries.

3 CADSCAN® SYSTEM

The CADSCAN system is composed of three parts:

1. Sensors – ISOMAC® sensors which are new and improved and provide iso-surface membrane deflection to obtain zero time difference of arrival (TDOA) between component elements as compared to other pvdf sensors (PADS) where the elements are stacked and are in a different spatial level [1].
2. A small handheld computer for signal processing and wavelet transformation to estimate the occlusion
3. Algorithms to remove signal noise (normal functioning of the heart), and to locate the coordinates of possible stenoses.

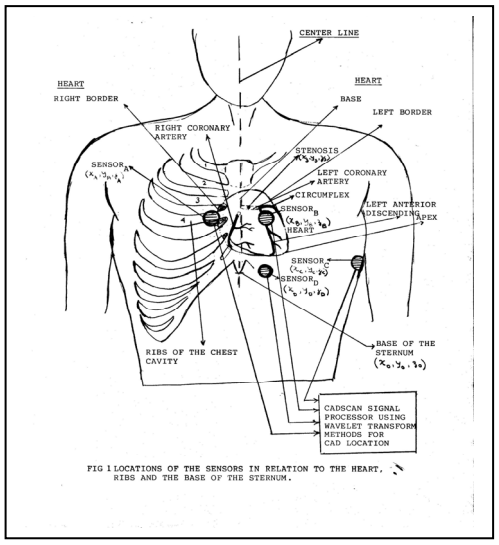
Fig. 2 contains a schematic indicating the location of the sensors in relation to the heart, ribs, and base of the sternum. Generally all the sensors are acoustic sensors like microphones or piezo-electric crystals. For calibration purposes an R-wave sensor was initially used as $sensor_D$.

The procedure is straightforward and simple. Data is collected from the sensors on the chest of the patient at four points as indicated in Fig. 2. A typical signal is shown in Fig. 3.

This non-invasive screening device can be used by office-based physicians, paramedics and general hospitals. CADSCAN® can non-invasively localize incipient faults due to narrowing or blockage in the coronary arteries of the heart with a very high degree of accuracy and it is the only such product existing in the market. There are presently 18 to 20 million angiograms performed worldwide per year at a cost of $63 Billion. In addition, the risk of a heart attack or death from this invasive procedure, in a patient who is stable and not in an emergency situation, is about 1 in 1000*. The CADSCAN® method, which is a non-invasive screening technique, will cost 10-20 times less to perform than an angiogram. This significant savings will unquestionably serve as an incentive to insurance companies, major service providers and to the US and foreign governments, especially in those countries practicing socialized medicine.

The diastolic part of the signal is utilized to assess the stenosis in the coronary arteries. The algorithms in the CADSCAN system perform wavelet transforms which provide both frequency and time domain analysis.

Fig. 2. Location of Sensors in Relation to the Heart, Ribs, and Base of the Sternum



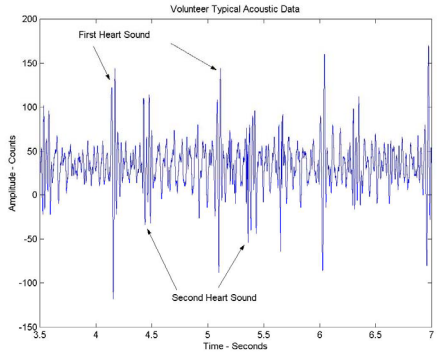


Fig. 3. A typical heart signal obtained with ISOMAC®

A scaling factor and translation parameters associated with the frequency of the turbulence and vibrations of the heart are applied to obtain estimates of the time delays for the pulse of sensors and the estimates of the transformed and scaled signals. These parameters are then evaluated to determine the estimated position of the occlusion in the coronary arteries of the heart.

Note that the system uses multiple combinations of sensors to detect the location of an occlusion. Any two sensor signals can be evaluated to obtain possible stenoses location. All combinations of sensor signals are exhausted and corresponding time difference of arrival of the signals are evaluated knowing the speed of sound in the medium inside the chest. Since this medium consists of tissue, bones and blood a typical value of the speed of sound in blood (water) is chosen as the closest known speed.

4 CORRELATION OF MEASUREMENTS WITH ANGIOGRAMS

This location of the stenoses in the coronary artery is estimated using suitable symbolic logic toolbox and the translation parameter 'b' at which the maximum of the wavelet coefficient function occurs. The algorithms generate a CADHOC number which corresponds to an angiogram occlusion reading as indicated in Table 1 below.

The results of the processing from the CADSCAN are then tabulated as shown in Table 2 and compared in the CROC as in Fig. 4. These results are compared with an existing angiogram report for the patient. CADSCAN® has been performed on 32 patients to date. Thirteen subjects were known to have coronary artery disease and seventeen patients were known not to have coronary artery disease. The location accuracy has been within 1.5 to 2.5 cms from the centroid of the stenoses. Further increase in the accuracy is possible with higher speed A/Ds and efficient DSP cores. Current efforts are directed to achieve these performance indices.

5 EXPERIMENTAL DESIGN

SUMMARY

The CADSCAN® experiment was designed to test the hypothesis that the CADSCAN®

Table. 1
CADHOC # and Angiogram Occlusions

Angiogram-Lumen Diameter Stenosis (ALDS)	CADSCAN-Range of CADHOC #
5% < ALDS <= 20%	Approx = 0.55
ALDS < 40% not critically significant	Tending towards 0.55
40% <=ALDS<60%	0.5<CADHOC<0.55
60%<=ALDS<=80%	0.3<=CADHOC<=0.5
ALDS>80%	0.05<=CADHOC<0.1

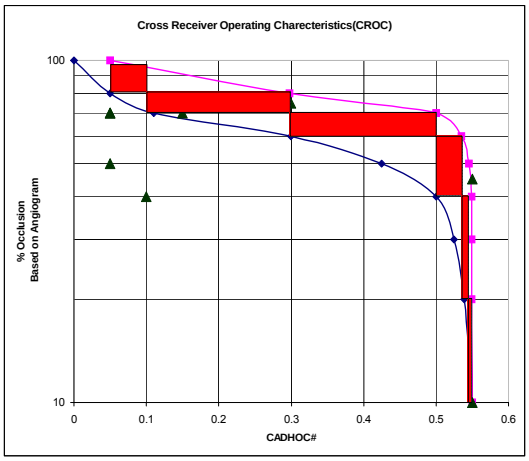


Fig. 4. Cross Receiver Operating Characteristics (CROC)

system could be used as a screening test to determine the existence of blockages in the coronary arteries. Angiography was used as a confirmatory test according to established medical protocols. Among the control group of 17 subjects with no presenting symptoms, CADSCAN® had no false positives; results were significant at the level of 3 standard deviations according to the Chi Square test. Among the test group of 11 cardiac patients, there were no false negatives; results were significant at the level of 2.5-2.75 standard deviations.

CONTROL GROUP

The control group of 17 subjects was selected on the basis of availability. All members of the control group had no current indication of coronary obstructions based on health history. They had no presenting symptoms and had not been seen or referred by a cardiologist. The group was composed of: 7 adults (2 women and 5 men), 7 teenagers (15-20 years of age), and 3 children (12-15 years old). Three of the five male adults had bypass surgery in the past but had no current symptoms of coronary artery obstruction.

TEST GROUP

The test group of 13 cardiac patients was selected on the basis of known heart disease; eleven of the patients were ongoing patients of the cardiologist and one was a new referral. The group included 4 women and 9 men. The members of this group were going to have angiograms performed regardless of the results of the CADSCAN®.

TEST PROCEDURE

The CADSCAN test was performed as a screening test; the angiogram was performed subsequently as a confirmatory test. The experiment used standard medical protocol, that is, patients who had symptoms of heart disease were given an EKG stress test. If indicated, the EKG was followed by a nuclear medicine study. If further indicated, this second test was followed by an angiogram. Consequently, members of the control group were not given further testing if the CADSCAN showed no evidence of coronary occlusion. All members of the test group were given angiograms subsequent to the CADSCAN.

The CADSCAN® tests were administered by Dr. H. Shertukde. Before administering the test, informed consent was obtained from the patients in the test group and the subjects in the control group. Additionally, patients in the test group were checked by the cardiologist. Testing required all patients to hold their breath for 16 seconds. The patient test tail of the experiment was blind in the sense that the testers know that the patients had heart disease, but they did not know what the specific diagnosis was. A constant testing protocol was maintained for all 30 cases; there was no change in the hypothesis.

Results

Table 2
Experimental Results

Type of	#	CADSCAN	ANGIO	EKG
Patient Positive	13	12(92.3%	GRAM 10	1
Negative	19	sensitivity) 19 (100%		16
Total	32	specificity)		

6 CONCLUSIONS

CADSCAN® is a relatively inexpensive screening device that is simple to operate and can be easily used in the physician's office. Its portability makes it a practical tool that can be used by emergency medical technicians to diagnose patients on their way to the hospital. The system is user friendly, in a comfortable and easy to use handheld form and the overall system is completely non-invasive. The results of the system CADSCAN® have been compared with the present "gold standard" and the results are encouraging.

ACKNOWLEDGEMENT

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[2] Shertukde et al., Utility patent application US PTO # 10/830,719 (provisional application serial number 60/464,777) and PCT application number PCT/US2004/012556 for "Apparatus and Method for Non-Invasive Diagnostics of Coronary Artery Disease."

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* Johns Hopkins White Papers 2002, Coronary Heart Disease