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Preferred Patterns of Diastolic Timed Vibrations for Pre-Hospitalization Treatment of Acute Coronary Ischemia

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Abstract— **This paper presents and evaluates preferred patterns of vibrations and active breaking techniques for the Diastolic Timed Vibrator (DTV). DTV uses low frequency mechanical vibrations applied to the chest to help in clot dissolution in pre-hospitalization treatment of acute coronary ischemia. In this work, we argue that random and ramp type vibration patterns increase the performance of the DTV method. Furthermore, we present results for various methods of vibration stopping aiming at reduction of vibration overspill into the systole of heart cycle of the patient.**

I. Introduction

According to the World Health Organization, the coronary heart disease (CHD) tops the list of leading causes of mortality worldwide [1]. Myocardial Infarction (MI) or heart attack occurs due to a profound reduction or interruption of blood supply (ischemia) to any part of the heart muscle tissue (myocardium). Major artery occlusion (thrombosis) usually occurs as a result of excessive accumulation of vulnerable atherosclerotic plaque made of white blood cells and lipids, in the artery limiting or even blocking artery blood flow. Studies show that myocardial cell death can occur within 20 minutes after the onset of ischemia [2]. A prolonged ischemia (lasting a minimum of 2 to 4 hours) causes acute MI, which eventually leads to death of all myocardial cells. Onset of acute MI often presents itself in the form of elevation in the ST portion of the ECG signal (ST Elevation MI or STEMI). Currently, there are two major reperfusion options available to STEMI patients: clot disrupting (anti thrombolitic) drugs, and angioplasty. In the latter option, the patient is required to be transferred to a cathlab in less than 90 minutes (door-to-balloon time) whereas in the former option the patient must receive treatment within less than 30 minutes (door-to-needle time) of the onset of MI.

Given the importance of starting the pre-hospitalization treatment of STEMI patients within the recommended time-frames, we propose a method that is safe and noninvasive, and thus could easily be used by the Emergency Medical Service (EMS) personnel and/or regular individuals to assist STEMI patients in starting pre-hospitalization treatment right after the onset of symptoms. Our approach can increase blood flow through the clotted coronary artery and penetration of clot disrupting drugs, which, in turn, would increase the survival rate of STEMI patients.

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II. Diastolic Timed Vibrations

We recently introduced the Diastolic Timed Vibrations (DTV) [3] [4]. It is a method consisting of applying low frequency mechanical vibrations to the chest of a STEMI patient during the diastole of the heart cycle, so as to help in rupturing and/or dissolving thrombus as well as improving Coronary Blood Flow (CBF) [5]. In the absence of clot-busting drugs during the door-to-needle period, DTV can be used as a standalone treatment method; but it can also complement thrombolytic drugs for improved reperfusion. Furthermore, the DTV can be used at hospitals where the STEMI patient is being prepared for the catheterization procedure.

Previous research suggests that diastolic timed mechanical vibrations at frequencies around 50 Hz improve CBF as well as left ventricular performance in subjects with either normal or impaired CBF [5]. Tension and spasm in the coronary arteries of STEMI patients can be relieved by application of low frequency vibrations to the chest wall since these vibrations can potentially help in vasodilating the arteries [6]. The process of vasodilation consists of relaxation of smooth muscle in the walls of the arteries and thus helping increase the blood flow.

Koiwa et al. [7] suggest that mechanical vibrations to the heart must be administered only during the diastole phase since these vibrations can facilitate myocardium relaxation leading to improved contraction strength. On the other hand, any vibrations during the systole phase of the already weakened heart of STEMI patients can display detrimental effects to the myocardium and hence, must be avoided. In order to stop vibrations during the systole, we extracted the QRS complex of the ECG signal by implementing a modified version of the Hamilton and Tompkins algorithm [8]. Therefore, our DTV apparatus can detect the start of systole by real time monitoring of patient's ECG and thus properly trigger vibrations. Additionally, this approach not only helps in rupturing chemical bonds in the thrombus but also increases turbulence leading to better mixture of thrombolytic agent and thrombus.

A. DTV Architecture

Figure 1 shows the block diagram of the proposed system. A standard therapeutic massager (Human Touch HT-1280) is used to apply vibrations to the chest. Frequency and amplitude of vibrations are measured by means of a MEMS feedback accelerometer (Analog Devices ADXL278) installed on the inner wall of the massager head. A patient simulator (Fluke PS410) is used to generate reference

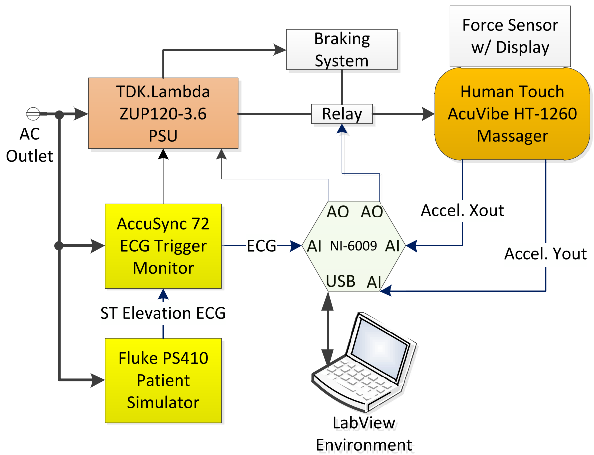

Fig. 1. Block diagram of the proposed DTV system.

ECG signals with ST Elevation for system validation. An ECG monitor (AccuSync 72) is used for acquisition of the ECG signal generated by the patient simulator. The analog ECG signal filtered and amplified by the ECG monitor is sampled by a data acquisition device (National Instruments USB-6009) and sent to a custom created LabVIEW Virtual Instrument (VI) for further processing and analysis. The VI analyzes the ECG signal and identifies the QRS complexes to determine onset and end of systole. The detected timings are used to trigger a relay embedded in the power circuit of the massager unit. Finally, a force sensor is used to determine the engagement force applied on the massager by the operator. The massager is powered with an external programmable DC power supply capable of generating a maximum voltage of 120V and controlled through the VI. An active braking system assists the motor in the massager to stop within the diastole so as to prevent any vibration spillage into the systole cycle.

B. Challenges

Determination of the most effective vibration frequency is of paramount importance. In order for the DTV to achieve the best possible outcome, the vibrations should be administered over frequencies between 40 Hz and 60 Hz as it is where the resonance frequency spectrum of myocardium falls [9]. However, various vibration patterns within this vicinity could result in different outcomes when vibrating the chest for clot dissolution. The optimum frequency range is also subject dependent and thus cannot be established a priori.

Furthermore, vibration spillage into the systole phase can have detrimental effects. It has been suggested that DTV must cease vibrating within 10 ms of the stop command [10]. Also, efficient starting of the motor should be implemented to ensure that the most of the diastole is covered by vibrations to help in heart muscle relaxation. To this end, various methods of efficient starting and stopping of the motor are presented and discussed in this paper.

III. Vibration Patterns

In order to maximize beneficial effects of DTV, we consider four possible patterns of frequency application. Figure 2 shows the massager drive voltage (proportional to the generated mechanical vibration frequency) and detected vibrations for the proposed patterns along with the ECG signal with ST elevation used to generate the trigger signal indicating the systole and diastole of the heart cycle. The results were obtained at 30 N force applied on the massager.

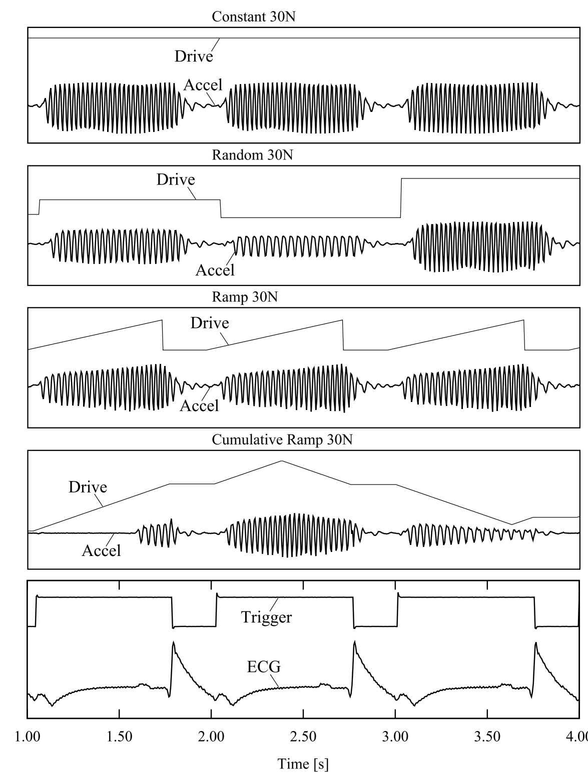

Fig. 2. Massager drive, induced mechanical vibrations (Accel), R trigger, and ECG (with ST elevation) for the four vibration patterns discussed.

A. Single Frequency

The first and most widely discussed pattern consists in application of vibrations at a single optimal frequency. Naya et al. [5] and Koiwa et al. [7] suggest that the frequency of 50Hz matches the resonance of the heart muscle and thus induces the highest amplitude of vibrations. Nevertheless, the optimal value of application frequency can vary between subjects and is very difficult to estimate in rudimentary conditions usually present in emergency situations. As shown in Fig. 2, the massager stops vibrating right at the R wave of the ECG signal and starts at the beginning of diastole. There is some overspill to the systole region, whose scale and impact will be discussed in the next section.

B. Random Frequency

In order to increase the probability of generating a correct excitation frequency, we propose to generate random frequencies from the preferred range. Usually, resonance frequency of the heart muscle falls within 40 to 60Hz.

Therefore, application of vibrations with frequency values randomly chosen from this range can be more beneficial than using a single frequency.

C. Frequency Sweep

Both random and single frequency approaches do not warrant that the optimum frequency for a given patient is reached. Therefore, given that the optimal frequency for most subjects lies between 40Hz and 60Hz, a linear sweep between those frequencies can be the most beneficial. As duration of the diastole, where the mechanical vibrations are applied is from 1.04s at 40 BPM to 165ms at 160 BPM [11], the vibration sweep could be too quick to be efficient. Therefore, we consider two possibilities: (a) Sweeping between the minimum and maximum frequencies within one diastole (ramp), (b) Partitioning the frequency sweep over multiple cycles (cumulative ramp). Finally, the frequency sweep can be beneficial in increasing the amplitude of vibrations, if a nonlinear resonance is induced in the heart muscle [12].

IV. Method

In our tests, we used a patient ECG simulator to generate ST Elevation patterns, which are supplied into the ECG trigger monitor. The ECG trigger monitor has been customized such that it generates a 5V train of square waves synchronized with the diastole of the heart cycle [8]. The trigger output generated by the ECG monitor was used for direct driving of the internal relay in the massaging unit. The target frequency and the pattern of vibrations are achieved by varying the input voltage to the massager. The analog control of the power supply allows for almost instantaneous responses from the power supply thus inducing minimal delay. The LabVIEW driven data acquisition card used to capture the ECG, trigger, and acceleration waveforms was also used to control the power supply output for frequency control and pattern generation.

The signals including ECG (1 lead), trigger, motor drive, and accelerometer signal were acquired by the LabView VI. The same VI was used to approximate the motor start and stop times. In order to provide a robust timing method, the acceleration signal was low pass filtered with 400 Hz cut-off frequency and its DC offset was removed. Then, signal was separated into the starting part, steady part, and stopping part. The steady amplitude was calculated as the mean amplitude of acceleration during the steady state. The starting time values were calculated from the rising edge of the driving signal to a point where the steady amplitude was achieved. For the stopping time, two exponential functions were fitted; one to peaks of the stopping signal and one to the valleys of the stopping signal. The obtained fitted functions were used to calculate the time delay after the falling edge of the trigger signal for which the vibration amplitude decreased by 1/e from the initial amplitude calculated for the steady state. This method allows to precisely indicate the stopping time, even when the 1/e point does not fall on one of the peaks.

As of now, the setup has been tested only on a test bench. We have not tested it on any human subject. More research is required to further verify the safety of the setup to allow tests on human subjects.

V. Results

A. Application Force

Application force is an important factor affecting the efficiency of transferring mechanical vibrations to the heart. In a real use, the application force level will depend on the subject's tolerance and will vary between 30 N and 50 N. The presented research evaluates the performance of the system for those application levels.

In the simplest case, with no active breaking system, the stop and start times are affected by the engagement force only. We measured average start and stop times of the massager running at 42 Hz. Obviously, the start time is the longest for 50N application force at 162 ms and shortest at no load at 110 ms. On the other hand, the breaking time is the longest at no load at 166 ms and shortest at highest application force at 44 ms. Figure 3 shows the vibration period versus the duration of diastole for various heart rate values, with and without application force. Vibrations are triggered to stop when the R wave is detected, which occurs a minimum of 40 ms before the mitral valve closure indicating the actual start of systole [10]. It can be seen that the elevated motor start time induces a delay that significantly reduces the useful time of application of vibrations. At 50 N, the start time of 162 ms leaves no space for vibrations for heart rates above 120 BPM.

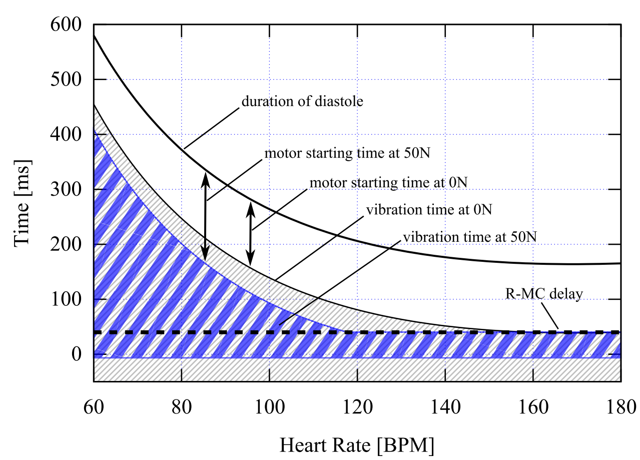

Fig. 3. Timing of vibrations versus duration of diastole measured from aortic valve closure to mitral valve closure (MC) for various heart rates. R-MC delay shows the time between the peak of R-wave and MC.

B. Active breaking

Breaking time of the massager defines the amount of vibrations that are still applied to the chest of the patient after the stop trigger was received. Currently, R-wave detection generates the trigger signal, which means that the motor has at least 40 ms to stop before the onset of systole [10]. Another research is currently performed to improve prediction of the QRS complex to provide an earlier trigger signal [8].

TABLE I

AVERAGE STOP TIMES WITH THE ACTIVE BREAKING METHODS.

Method	Average Stop Time [ms]	Standard Deviation [ms]
Open circuit	54.7	45.6
Short circuit	48.3	14.7
68μF capacitor	44.6	18.0
28Ω resistor	37.5	20.9
Inverted drive	11.7	0.31

In order to further reduce the breaking time of the massager, several active breaking methods were evaluated. A fast double pole double throw relay (Tyco Electronics V23105) was used to engage the breaking system with the ECG trigger signal. We considered the following active stopping methods (Table I):

- Short circuiting the motor: the trigger signal disconnects the drive voltage and short circuits the motor coil to quickly dissipate the accumulated magnetic energy.
- Resistive load: in order to avoid excessive discharge currents, instead of short circuiting the motor, a resistive load is connected to the motor coil.
- Capacitive load: a capacitor is connected to the motor coil to form an LC oscillating circuit to invert the voltage applied on the motor.
- Inverted supply: the drive signal is briefly applied in the opposite direction to induce a stopping torque in the motor. The duration of the inverted pulse is controlled in a feedback loop using the accelerometer to ensure that the motor does not start spinning in reverse.

VI. DISCUSSION

The presented work discusses the two major aspects impacting the proper operation of a Diastolic Timed Vibrator: vibration patterns and vibration timing. The effectiveness of the applied vibrations relies on the application of the optimal frequency, whose value depends on the physique of the subject. In order to ensure that the vibrator generates the optimum vibration frequency, we implemented a randomized drive and two variants of a sweep drive. While the sweep methods ensure that the optimum frequency is applied at least momentarily, the random method provides longer application time at each frequency, but does not guarantee that the optimum frequency for a given patient is used.

Furthermore, vibration timings were evaluated. In order to prevent overspill of vibrations into the systole, the motor must be stopped just before its onset (Mitral Valve closure). The length of the diastole for male subjects can be approximated using a formula proposed by Weissler et al. [11]. The duration of diastole can be as short as 170 ms in some individuals at heart rate of 150 BPM. As a result, the motor must be able to effectively vibrate during this period and cease all motion just before the onset of the systole. Based on the results obtained from the active braking system (Table I) we are able to stop the unloaded motor (worst case scenario) in less than 12 ms. Considering that the application force on the massager can further dampen motor vibrations and further improve the stop time, we believe that the massager can be effectively stopped well before the onset of systole when triggered by the R-wave.

VII. CONCLUSIONS

The presented work discusses the major challenges in improving effectiveness of Diastolic Timed Vibrations as a pre-hospitalization method of treatment of acute coronary ischemia. We presented various vibration patterns that help ensure that the optimal frequency of vibrations for a given patient is applied. Furthermore, we evaluated the timing of the vibrator at various application forces, with multiple active breaking methods. We found that the stopping times can be sufficiently low at high application forces in order to prevent vibration spill into the systole. The starting times can be excessively high which becomes an issue at higher heart rates. We will work on improving the starting time of the vibrator by using voltage boosting systems and prediction of the onset of diastole.

Our next goal is to determine the best possible approach for detecting perceived vibrations by the heart and the coronary arteries. This objective requires further extensive research which would potentially include in-vitro testing and experiments on animal subjects.

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