THE MEASUREMENT OF *IN VIVO* LOADING ON IMPLANTABLE PACEMAKER DEVICES: A FEASIBILITY STUDY

[1]Hamman de Vaal, [1]Jacques Scherman, [1]Peter Zilla, [2]James Neville, [2]Micah Litow, [1]Thomas Franz

[1]Chris Barnard Division of Cardiothoracic Surgery, University of Cape Town, South Africa
[2]Medtronic Inc., Minneapolis, MN, USA

INTRODUCTION

The aim of this study was to evaluate the feasibility of a measurement system for *in vivo* mechanical loadings on implanted pacemaker devices. Several emerging factors have increased mechanical demands for implanted devices: these include (generally more active) young patients [1-3], smaller, thinner devices [3-5], increased required longevity [6] and increased numbers of implants [5]. Additionally the recent advances in miniaturized technologies allowing video synchronized high bandwidth wireless force and acceleration data acquisition, has driven the support for this study.

METHODS

The novel *in vivo* measurement system comprised the following principal components (as shown in Figure 1):

1. Instrumented implantable pacemaker (IPM);
2. Wireless radio-frequency (RF) data logging set-up;
3. Synchronous video capture system.

The custom-made IPM (dimensions: 64x61x11mm) was equipped with 6 contact force sensors, 3-axis accelerometer, RF transceiver, and battery embedded in a medical grade epoxy cast resembling a typical commercial pacemaker housing. RF communication between the IPM and the data logging system at a maximum frequency of 1000 Hz (signal quality dependent) enabled remote activation of the IPM and wireless acquisition of IPM data. Physical activities of the subjects associated with loading events were recorded with synchronized video. The forces reported below were derived from the sum of individual sensor forces adjusted by the ratio of projected IPM surface area to total sensor surface area.

Following approval by the Institutional Review Boards, three Chacma baboons (implant weight: 24.2±2.0 kg) received one IPM implant in pectoral sub-muscular position. After allowing for wound healing and fibrous encapsulation for 9 weeks, *in vivo* forces were recorded in repeated sessions of 5-15 min daily for 5 days during animal activities associated with pre-feeding excitement at the holding facilities. Physiological range of motion movements of the arm ipsilateral to the implanted IPM were performed on the anaesthetized subjects. After device explant, the *Pectoralis major* muscles were excised and mass, volume and dimensions recorded.

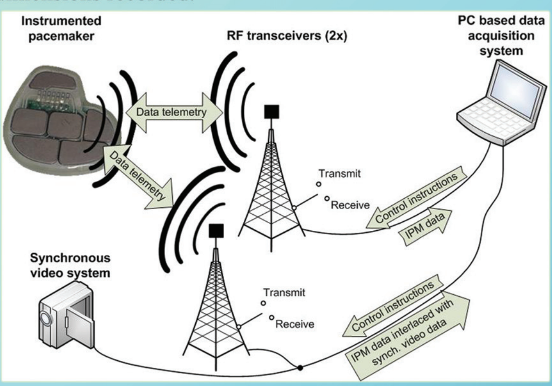

Figure 1: *High-level description of in vivo measurement system*

RESULTS AND DISCUSSION

All implants healed without complications. Remote IPM activation, force and acceleration measurements, and RF data transmission worked reliably and repeatedly in the indoor cage environment with transceiver distances up to 3m. Sensitivity, response time and sampling rate were sufficient to capture dynamic loading conditions. The muscle volume measured was 70, 120 and 135 cm^3 for implant 447, 449 and 575 respectively. Figure 2 illustrates the *in vivo* forces measured during conscious animal activities and Figure 3 shows the distribution of measured force events. The median force of implant 447 was 58.1% and 51.3% of those measured in implants 449 and 575. This agreed well with difference in volume of the Pectoralis major of 58.3% and 51.9% between implant 447 and implants 449 and 575, respectively. The maximum force measured did not follow this trend but association with a physical activity was confirmed. Performing range of motion arm movements on the anaesthetized subjects yielded the results shown in Figure 4. These results indicated the force peaks associated with extreme positions of the arm.

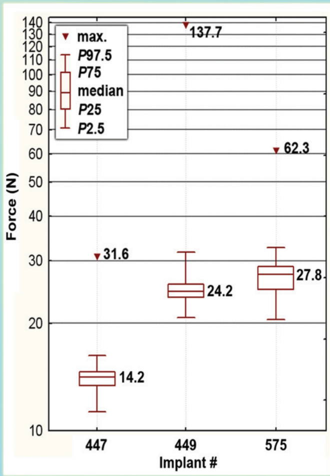

Figure 2: *Box plot of in vivo force (log scale) measured by pectoral sub-muscular implant, indicating percentile values.*

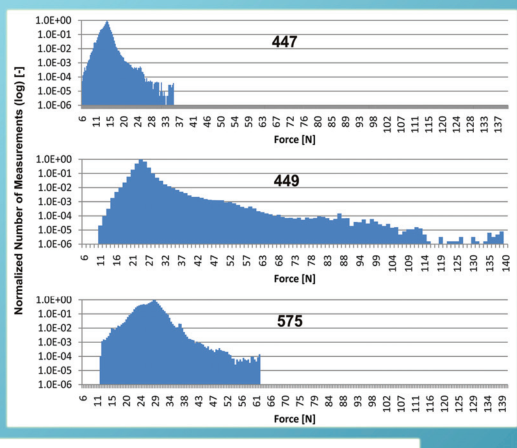

Figure 3: *Normalized histrograms of in vivo force measured by pectoral sub-muscular implant during conscious activities*

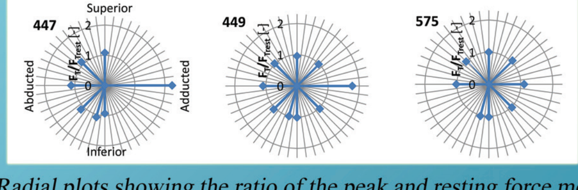

Figure 4: *Radial plots showing the ratio of the peak and resting force measured by pectoral sub-muscular implant in corresponding extreme arm positions*

CONCLUSION

The study demonstrated the feasibility of the developed *in vivo* measurement system. The measured forces correlated well with the volume of the *Pectoralis major* and with movements performed. The system offers potential for the investigation such as comparison of implant positions with respect to loading conditions, influence of external forces on implants and correlation of muscle-induced forces towards an animal-to-human *in vivo* loading transfer function.

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