- CONFIDENTIAL -

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

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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:

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 compressive 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. After device explant, the *Pectoralis major* muscles were excised and mass, volume and dimensions recorded.

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. Figure 1 illustrates the *in-vivo* forces measured during animal activities. 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* (see Table 1) 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.

Table 1: Properties of *Pectoralis major* for different implants

Implant #	447	449	575
Mass *Pectoralis major* (g)	82	125	149
Volume *Pectoralis major* (cm^3)	70	120	135

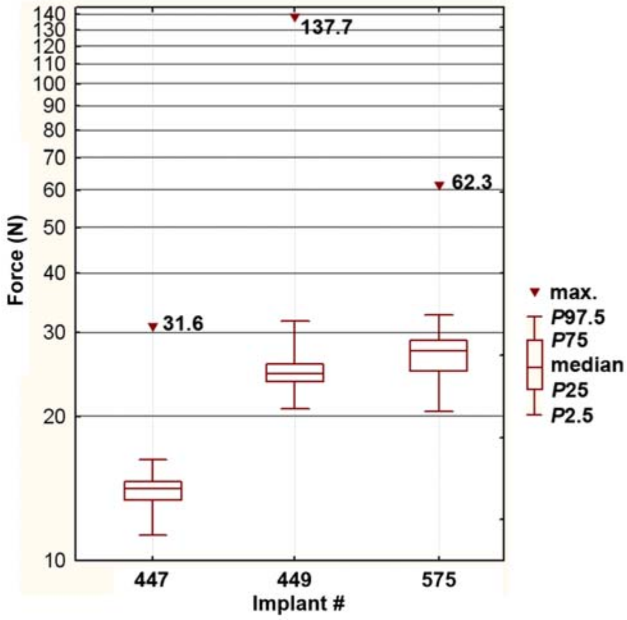

Figure 1: Box plot of *in vivo* force (log scale) measured by pectoral sub-muscular implant, indicating percentile values.

CONCLUSIONS

The study demonstrated the feasibility of the developed *in vivo* measurement system. The measured forces correlated well with the volume of the *Pectoralis major*. 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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