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Patient-specific prediction of intrinsic mechanical loadings on sub-muscular pectoral pacemaker implants based on an inter-species transfer function

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ABSTRACT

With the steady technological development enabling reduced device dimensions and new patient populations, detailed data on mechanical *in vivo* loads become increasingly important to ensure reliability of implantable medical devices. Based on an intra-species correlation of in-line and transverse force of the *Pectoralis major* established previously for the Chacma baboon (de Vaal et al., 2010a), a simplified physiological model and a mechanical equivalent model were developed for a sub-muscular pectoral device implant considering *Pectoralis major*, *Pectoralis minor* and rib cage. By assessing the morphometric and mechanical parameters of these musculo-skeletal structures and the associated model parameters, the intra-species correlation was shown to exhibit (a) robustness for a larger intra-species subject population and (b) linear scale variance allowing application for humans under consideration of the inter-species difference of the attachment angles of *Pectoralis major*. The transfer function provides a basis for the prediction of patient-specific maximum mechanical loadings on a sub-muscular pectoral cardiac pacemaker implant through non- or minimal invasive measurements on the patient.

1. Introduction

Significant clinical benefits compared to pharmacological treatment (Cleland et al., 2005) as well as the reduction of the mortality in high-risk patient populations (Maisel et al., 2006) have been reported for implantable pulse generators (i.e. pacemakers) and implantable cardioverter defibrillators. New technologies allowing for smaller devices (Furman, 2002; Shmulewitz et al., 2006) and clinical progress have lead to a higher feasibility of implantable cardiac rhythm management in younger patients (Antretter et al., 2003; Furman, 2002).

The pectoral region has been the most common implant position for cardiac pacemakers due to fewer complications compared to the abdominal implants (Kron et al., 2001). The sub-cutaneous and sub/intra-muscular positions have been used for pectoral implants. For both, the pacemaker is placed in a tissue pocket either between the skin layer and the sternal *Pectoralis major* (*Pmajor*) for sub-cutaneous placement, or between the sternal *Pmajor* and the *Pectoralis minor* (*Pminor*)/rib cage for sub/intra-muscular placement (Kistler et al., 2004).

Smaller implant structures combined with different levels and patterns of physical activity of the recipients bring upon altered demands for structural integrity and reliability of the devices. While structural reliability of pacemaker leads has been studied extensively (Baxter and McCulloch, 2001; Fortescue et al., 2004; Hauser et al., 2007), research towards the mechanical *in vivo* conditions of the pacemaker structure is scarce. The availability of such data, and in particular maximum levels of mechanical loadings, is however important if not crucial for the mechanical design of implants with reduced size while ensuring reliability. We have, therefore, recently demonstrated for the first time the feasibility of a system to assess *in vivo* mechanical forces on implanted pacemakers and established in the non-human primate model an intra-species correlation between the force of the sternal *Pmajor* in line of its action and the transverse reaction force on a pectoral implant in sub-muscular position (de Vaal et al., 2010a, 2010b).

The current study was concerned with the development of a transfer function, which entails the extension of an intra-species

Abbreviations: CT, Computed tomography; IPM, Instrumented pacemaker; MLR, Multiple linear regression; PCSA, Physiological cross-sectional area; *Pmajor*, *Pectoralis major*; *Pminor*, *Pectoralis minor*; VHM, Virtual Human Male (Spitzer et al., 1996)

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