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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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Symbols

a_i	Coefficients of inter-species transfer function where $i=1$–5
F_{IL}	In-line force generated in the sternal *Pectoralis major*
F_T	Transverse force acting on the IPM/pectoral implant
k_r	Transverse stiffness coefficient of the rib cage
k_{t1}	Transverse stiffness coefficient of the *Pectoralis major*
k_{t2}	Transverse stiffness coefficient of the *Pectoralis minor*
L_f	Muscle fibre length
$L_{f,opt}$	Optimal muscle fibre length
L_m	Length of the sternal *Pectoralis major* along the estimated line of action
L_r	Characteristic length of the rib cage determined by the rib geometry and curvature
M_b	Body mass of subject
M_m	Mass of the entire *Pectoralis major*
n	Number of subjects
Q_{IL}	Uniformly distributed in-line force along the width of the *Pectoralis major* over the pectoral implant
t_m	Thickness of the sternal *Pectoralis major* at the location of the IPM/pectoral implant
$t_{m,cb}$	Thickness of the sternal *Pectoralis major* at crossbar of the buckle force transducer
t_{mu}	Thickness of the *Pectoralis minor* at the location of the IPM implant
V_m	Volume of the entire *Pectoralis major*
w_m	Width of the *Pectoralis major* over the IPM/pectoral implant
$w_{m,cb}$	Width of the *Pectoralis major* at the crossbar of the buckle transducer
ψ_1	Angle of attachment of the *Pectoralis major* at its origin
$\overline{\psi}_1$	Mean angle of attachment of the *Pectoralis major* at its origin for n subjects
ψ_2	Angle of attachment of the *Pectoralis major* at its insertion
$\overline{\psi}_2$	Mean angle of attachment of the *Pectoralis major* at its insertion for n subjects
ρ_m	Material density of *Pectoralis major*
σ_m	Axial stress in *Pectoralis major* during contraction
σ_{mu}	Axial stress in *Pectoralis minor* during contraction

Subscripts

B	Baboon
H	Human

relationship for in-line and transverse force of the *Pectoralis major* in baboons to humans. The proposed transfer function will provide the basis for the clinical quantification of mechanical forces on pacemaker implants by measuring the in-line force of *Pectoralis major* in patients using non- or minimally invasive methods such as electromyography.

2. Methods

2.1. Assessment of pectoral anatomy in baboon and human

After conclusion of a related study (de Vaal et al., 2010a), two Chacma baboons ($M_b=23.9\pm1.2$ kg) with pectoral sub-muscular implants of instrumented pacemakers (IPM) underwent imaging of the thoracic region with computed tomography (Aquilion 4, Toshiba Medical Systems, Zoetermeer, Netherlands) within two hours of euthanisation. Subsequently, the *Pmajor* was dissected and morphometric details were recorded as described by de Vaal et al. (2010a): length along the estimated line of action L_m, thickness and width at the crossbar of the buckle force transducer $t_{m,cb}$ and $w_{m,cb}$ and width over the IPM implant w_m. After excision, mass M_m and volume V_m of the muscle were recorded.

Using Mimics® (Materialise BV, Leuven, Belgium), the location of the IPM and surrounding musculoskeletal structures were reviewed in axial and sagittal cross-sectional views of baboon and human [Virtual Human Male (VHM), Visible Human Project, National Library of Medicine National Institutes of Health, Bethesda, MD, USA; (Garner and Pandy, 2000; Spitzer et al., 1996)] CT imaging data. In VHM images, the position of a pectoral sub-muscular pacemaker implant was estimated according to Brinker and Midei (2005). Comparative anterior–posterior and lateral measurements for baboon and human were obtained from axial views. A 3D representation of skeletal anatomy of one baboon with IPM implant was obtained by reconstruction from a CT image set using thresholding operations in Mimics®.

2.2. Simplified model of sub-muscular pectoral implant

A simplified representation of a sub-muscular pacemaker implant was proposed to facilitate the evaluation of influence of individual parameters on the mechanical loading on the implant. The representation was limited to the instance of the muscle contraction. This limitation was deemed sufficient for quasi-static loading, disregarding mass or damping effects, based on two assumptions. Firstly, the IPM was exposed to a load at rest, i.e. the muscle was compressed prior to contraction. Secondly, the effects of load rate and fibre orientation on the viscoelastic behaviour of passive muscle under compression (Van Loocke et al., 2008) can be neglected since, in our experiments, the muscle was active with increased stiffness compared to passive state and the compression acted in cross-fibre direction with lower stiffness and viscosity compared to the fibre direction. The muscle contraction was sustained for approximately 0.5 s only (de Vaal et al., 2010a) and the compression rate was similar to that for the contraction of a relaxed muscle to a maximum level of 200 s^{-1} (Wilkie, 1949). This value was considerably higher than the rate reported by Van Loocke et al. (2008) for which they reported that the reaction of passive muscle to compression was devoid of viscous effects for instantaneous loadings.

Fig. 1 illustrates a simplified physiological model: the IPM resting on *Pminor*, supported by rib cage, is compressed by the *Pmajor*. The mechanically equivalent model is illustrated in Fig. 2 indicating parameters considered to affect the normal force F_T in the two-dimensional case: in-line force F_{IL} generated in the *Pmajor*, material properties of the anatomical structures surrounding the IPM and angles of attachment of the *Pmajor* from the IPM location to origin and insertion of the muscle, ψ_1 and ψ_2, respectively. In the three-dimensional case, the interplay between width of the *Pmajor* over the implant, w_m, and the force uniformly distributed along this width, Q_{IL}, with

$$Q_{IL} = \frac{dF_{IL}}{dw_m} \tag{1}$$

was assumed to affect F_T due to the muscle contraction causing a concentrated muscle mass around the line of action. The IPM was considered to be a rigid structure. The transverse viscoelastic properties of *Pmajor* and *Pminor* (Van Loocke et al., 2008) were simplified as transverse stiffness k_{t1} and k_{t2}, respectively. The transverse stiffness of the rib cage (Viano and King, 2000) was simplified as transverse stiffness k_r.

The experimental measurement of in-line force F_{IL} and transverse force F_T of the *Pmajor sternum* in the baboon in a related study has been described in the supplement and in detail by de Vaal et al. (2010a).

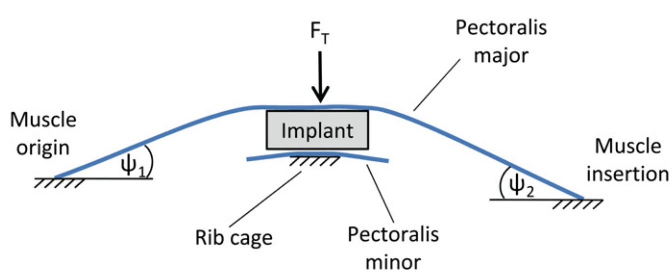

Fig. 1. Simplified physiological representation of a sub-muscular pectoral pacemaker implant situated between the *Pectoralis major* and the *Pectoralis minor* resting on the rib cage.