A Biomechanical Double Sac (Pericardium-Pebax) for Specially Shaped Artificial Ventricles: A Computerized Study to Evaluate Its Mechanical and Volumetric Properties

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Abstract: For original ovoid shaped artificial ventricles, a biomechanical double sac consisting of a biological sac (porcine pericardium) as the blood contact interface and a synthetic sac (Pebax 3533) as the mechanical support to assume systolic-diastolic dynamic constraints was conceived. The volumetric and mechanical properties were assessed with a three-dimensional modeling of Pebax sacs and computerized simulations of their systolic distortions for both right and left ventricular configurations. The stresses and strains of these sacs were represented as quantitative mappings for a maximum end-systolic state and were below the respective threshold values above which the Pebax material is jeopardized for permanent structure impairment. After fatigue tests applied on Pebax strips under the alleged working conditions of Pebax sacs, the material structure was unchanged and maintained its intrinsic mechanical properties. The theoretical maximum stroke volumes were 74.4 cm³ and 62.4 cm³ for the left and right ventricular configurations, respectively. With these mechanical and volumetric features, the biomechanical double sac concept was considered valid and could be provided for a consequent specific total artificial heart.

Key Words: Artificial heart—Pericardium—Biomaterials—Mechanical constraints.

The acknowledged needs for artificial hearts (left ventricular assist devices and total artificial hearts [TAHs]) are induced by the increases in the numbers of patients suffering from end-stage congestive heart failure refractory to medical treatment and by the lack of cardiac grafts for heart transplantations (1–3). However, their common use to satisfy such clinical needs has not yet been possible because of persistent problems despite recent progress. For example, thromboembolic events, infectious complications, anatomical mismatches, and mechanical failures have often been reported for current models and ascribed to their design and/or their biomaterials (4–8) so that it appeared to be appropriate to explore and perfect new designs and biomaterials to resolve these problems (9,10). For this purpose, a new design of artificial ventricles unique in their truncated ovoid shapes and biomechanical double sac was designed to produce, together with an electrohydraulic actuator, an orthotopic TAH with pulsed outputs. The biomechanical double sac has been designed with a biological sac (pericardial sac) (11) as the blood contact surface and a synthetic sac (Pebax 3533 sac) (Elf Atochem Inc., Paris, France) to resist the mechanical loads of pulsed cardiac cycles. The extremely new feature of this concept motivated a first feasibility approach, a computerized study to evaluate the volumetric properties of the double sacs and the mechanical properties of the synthetic part (Pebax sac) with consequent fatigue tests applied on Pebax strips and consecutive tensile tests of the constrained synthetic material.

MATERIALS AND METHODS

Description of the concept
The concept consists of an orthotopic TAH (Fig. 1) made in 1 piece with an external synthetic bag shaped like a truncated egg. This shape is provided
with a rigid shell configured like a hull and covering the inside of the bag only on the inferior part of this surface. On the shell 2 artificial ventricles (right and left) are supported with their respective actuators necessary to generate right and left pulsed outputs, respectively.

The shape and dimensions of the TAH and therefore of each ventricle, the bulkiness of the actuators having been taken into account, were determined through cardiovascular anatomical data obtained from 15 patients awaiting heart transplantation (12). Each artificial ventricle has a truncated ovoid shape (anterior apex and posterior truncated base) with the following geometric characteristics: the diameter of the posterior basis for blood inflow is 60 mm, the length from the posterior basis to the anterior apex is 60 mm, the width 20 mm from the posterior basis is 58 mm, and the width 50 mm from the posterior basis is 35 mm. Each ventricle has a superior orifice (22 mm diameter) for blood outflow; the right ventricle outflow orifice is more anterior than the left one. All these orifices should be fitted with bioprostheses, among which should be specific atrioventricular bioprostheses because of the large diameters of the inflow orifices.

The 3 following ventricular components were designed for each artificial ventricle: a biologically compatible blood contact surface (pericardial sac), a flexible mechanical interface with activating fluid (synthetic Pebax sac), and a rigid framework (rigid housing).

These 3 ventricular components are characterized by the previously described ventricular shape and dimensions as well as by their specific positions (Fig. 1). The pericardial sac is placed inside the Pebax sac, and both these sacs are separated from one another by a virtual space and constitute a biomechanical double sac in the rigid housing. For each ventricle, the pericardial sac and Pebax sac are fixed around the orifices of the rigid housing in a fashion to leave virtual space between these sacs. This space is to be occupied only by a thin liquid layer and is to allow sliding of each sac on the other for the double sac distortions during the cardiac cycle. The hydraulic activating fluid has been devised to operate on the biomechanical double sac to generate pulsed outputs.

**Synthetic sac: Pebax sac**

Pebax or polyether block amides are thermoplastic elastomers. The structure of these products is made of a linear and regular sequence of rigid polyamide segments and flexible polyether segments. Their chemical formula is as follows:

\[
\text{HO} - \left[ \begin{array}{c} C - \text{PA} - C - \text{O} - \text{PE} - \text{O} \\ \| \\ O \end{array} \right]_n - \text{H}
\]

PA and PE represent the polyamide and polyether segments, respectively. Within the product range, Pebax 3533 is characterized by the following mechanical properties: Shore hardness, 33D; Modulus of elasticity in flexure, 12 mPa; tensile stress to breaking of a strip 1.8 mm thick, 30 mPa; and strain to breaking of a strip 1.8 mm thick, 670%.

**Biological sac: Pericardial sac**

The mechanical properties of the pericardiums, collected from Yucatan pigs and treated in a 0.6% glutaraldehyde buffered solution according to previous published methods (11) are the following: modulus of elasticity in flexure, 7 mPa with a flexible limit of distortion of 7–8% (reproducible values for all strips); tensile stress to breaking, from 16 to 25 mPa (mean 20.75 ± 3.7 mPa); and strain to breaking, from 25 to 50%. The ratio of the respective modulus of elasticity in flexure (Pebax/pericardium) was such that the flexible pericardium versus Pebax modulus of elasticity could be disregarded for stress evaluations by simulations of distortion as described in the text that follows.

**Computerized simulations of Pebax sac distortions**

The modeling of the Pebax sacs (left and right ventricular sacs) was performed with a mesh of elas-
tic quadrilateral shell elements (defined by 4 nodes) with the IDEAS MS 2.1 software (SDRC Inc., Cincinnati, OH, U.S.A.). The modeling parameters were as follows (Fig. 2): The previously mentioned intrinsic mechanical properties of Pebax (assigned to each quadrilateral shell element); the sac thickness, 1 mm; the reference geometrical states, the previously mentioned ventricular geometries (left and right) corresponding to end-diastolic states; the rigid geometry of the sac orifices modeled with fixed nodes; and the apex of the sacs modeled as either fixed with 4 fixed nodes or mobile with a modeled stop placed 10 mm from the reference position of the apex.

With these parameters the following 3 ventricular configurations were modeled: left ventricular Pebax sac with fixed apex; left ventricular Pebax sac with mobile apex; and right ventricular Pebax sac with mobile apex. A systolic distortion simulation of such a modeled Pebax sac was performed with a simulated depression applied to the internal wall of the sac that was progressively increased by successive increments of a 0.005 bars absolute value, simulating step by step the systolic distortion of the sac.

The volumes of the right and left ventricular sacs were evaluated for the reference geometric states (corresponding to the end-diastolic volumes) and for the maximum distorting states (corresponding to the end-systolic volumes). The resultant stresses and deformations of the Pebax material were evaluated with OPTRIS 4.2 software (Dynamic Software, Inc., Aix-en-Provence, France) for the obtained distorting at each value of applied depression over the 3 modeled ventricular configurations.

Fatigue tests of the Pebax 3533

Fatigue cycles were applied over Pebax strips meeting the ISOR 572 standard type 1 and fixed on a servohydraulic tension device (MTS 810) with a 2,500 N loading cell (MTS Inc., Minneapolis, MN, U.S.A.). Each cycle was to induce a 6% strain on the strips and then to loosen them. The frequency of the cycles was 2 Hz, and 3 series of cycles were performed: 1 million cycles, 1.3 million cycles, and 1.9 million cycles.

Assessment of the Pebax mechanical properties after fatigue tests

Pebax strips were then submitted to a continuous tension of 50 mm/min at 23°C on a device (Instron 4301) with a 500 N loading cell (High Wycombe, Bucks, England).

RESULTS

For each of the 3 modeled ventricular configurations, 2 geometric states were considered to express the results of the modeling of the Pebax sacs as well as their distortion simulation, the reference geometric state and the maximum distorting geometric state corresponding to the end-diastolic and end-systolic states of the sacs, respectively.

The volumes of the sacs were calculated for both of these states, allowing us to assess the end-diastolic and end-systolic volumes and to draw from them the theoretical maximum stroke volume of the 3 ventricular configurations (Table 1).

The stresses, strains, and thickness modifications of the Pebax material were the parameters used to estimate the effect of systolic distortion of the sacs.

![FIG. 2. Shown is three-dimensional modeling of the synthetic (Pebax) sac for the right and left ventricular end-diastolic geometric reference states.](image)

**TABLE 1.** Calculated values of end-diastolic and end-systolic volumes and theoretic maximum stroke volumes for the various ventricular configurations

<table>
<thead>
<tr>
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<th>Left ventricular configuration with fixed apex</th>
<th>Left ventricular configuration with mobile apex</th>
<th>Right ventricular configuration with mobile apex</th>
</tr>
</thead>
<tbody>
<tr>
<td>End-diastolic volume</td>
<td>105.4 cm$^3$</td>
<td>105.4 cm$^3$</td>
<td>105.4 cm$^3$</td>
</tr>
<tr>
<td>End-systolic volume</td>
<td>46.7 cm$^3$</td>
<td>31 cm$^3$</td>
<td>43 cm$^3$</td>
</tr>
<tr>
<td>Stroke volume</td>
<td>58.7 cm$^3$</td>
<td>74.4 cm$^3$</td>
<td>62.4 cm$^3$</td>
</tr>
</tbody>
</table>
on the Pebax structure. For a distorting state corresponding to a given load, the calculated stress of each quadrilateral shell element was expressed in GPa and represented on the distorted sac modeling with a specific color referring to a colored value scale. Thus, the distribution of stresses on the Pebax sacs could be displayed for each obtained distorting state. In the same way as for a distorting state, the calculated strain and the calculated thickness of each quadrilateral shell element were expressed as a percentage (%) and in millimeters (mm), respectively, with their respective colored representations allowing for the display of the consequent distributions of strains and thickness on Pebax sacs. Figure 3 shows such distributions of stresses, strains, and thickness on Pebax sacs for the maximum distorting state of each of the 3 modeled ventricular configurations.

The thickness variations of the Pebax material were slight in any part of the Pebax sacs for the 3 modeled configurations. The calculated maximum thickness variations did not exceed 0.06 mm so that the thickness of the Pebax material remained in the 0.94–1.06 mm range.

The distributions of stresses and strains for the maximum distorting state of the left ventricular configuration with fixed apex showed a very focused area (red area on the apex [Fig. 3]) that was more stressed and strained than the rest of the configuration. For this area the calculated stress and strain were $2.37 \times 10^{-2}$ GPa and 13.7%, respectively. The rest of this configuration was slightly stressed and strained. The calculated stresses and strains for any part of this configuration except the focused apical area ranged in the $0.2 \times 10^{-3}$ to $1.4 \times 10^{-3}$ GPa interval and in the −1.2 to 6% interval, respectively.

For the left ventricular configuration with mobile apex, the distributions of stresses and strains were homogeneous, and the calculated values of stress and strain were also low for any part of the configuration and ranged in the 0.0 to $1.2 \times 10^{-3}$ GPa interval and the −1.3 to 5% interval, respectively.

For the right ventricular configuration with mobile apex, the distributions also showed a very focused area (red area on the posterior inflow orifice [Fig. 3]) that was more stressed and strained with calculated values of $1.81 \times 10^{-3}$ GPa stress and 10% strain. The rest of this configuration had slight stress and strain with calculated values ranging in the $0.14 \times 10^{-3}$ to $1.45 \times 10^{-3}$ GPa and −1.7 to 4.5% intervals, respectively.

A comparative study of tensile tests of Pebax material after fatigue tests and Pebax material free from fatigue tests revealed that the intrinsic mechanical properties of the material have not been modified under the alleged working conditions of the Pebax sacs, that is, stresses below 3 MPa and strains below 20% (Fig. 4).

**DISCUSSION**

Polyurethane, as well as pelletane, silastic, and silicone, are biomaterials of reference and the most used ones as blood interfaces (sacs, diaphragms) in current artificial ventricles. Even though there have been some improvements made to the designs and/or structures of the sacs and diaphragms to improve their performance (7,13), complications (thromboembolism, infection, and calcification) and even failures of artificial heart implantation have been associated with the very nature of the biomaterials used (5,8) and their impairment after use (4–8,14,15). The concept of the biomechanical double sac was developed as a solution for these problems, a biological support (pericardial sac) to improve ventricular hemocompatibility and a mechanical support (Pebax 3533 synthetic sac) to sustain the mechanical constraints of the pulsed cardiac cycle inherent in the proposed TAH functioning. The biological support guaranteed by the pericardial sac, the feasibility of which has already been proven (11), allowed us to choose a synthetic material for the mechanical support according to mechanical criteria only without considering the proven intrinsic hemocompatibility of this material. Therefore, other materials such as polyurethane, pelletane, silastic, and silicone, and in particular Pebax materials, already known and tested, could have been chosen for this application. However, this radically new concept required a study to evaluate the mechanical and volumetric properties determined by the original shape and materials. More important than the study of the distortion mode of the sac, known as a factor influencing intraventricular flows and therefore the hemocompatibility (16,17) of the sac, was the assessment of the influence of the original ventricular configuration upon the respective maximum distorting and subsequent stresses as well as upon the residual end-systolic volumes and thus the maximum theoretical stroke volumes. To simulate such systolic distortions, it was necessary to use a technical mean that was a simulated homogeneous pressure differential applied on each side of the modeled Pebax sacs. This simulated load was applied only on modeled Pebax sacs that were considered to be more rigid and consequently more stressed than pericardial sacs and thus considered as restraining factors of the biomechanical double sac distortion. The distributions of stresses and strains on maximally distorted Pebax sacs could be obtained for the 3 modeled ventricular configurations.
FIG. 3. Shown are the distributions of stresses, strains, and thickness deformations of the Pebax material for the maximal end-systolic distorting state of the 3 modeled ventricular configurations. The value scales of these parameters are expressed in GPa, in percentages (%), and in millimeters (mm), respectively.
configurations with a quantitative evaluation of so distributed stresses and strains. In this way the most stressed and strained areas could be identified as being on the modeled fixed apex of the left ventricular configuration and on a restricted section of the right ventricular configuration inflow orifice. However, the stresses and strains recorded for these very focused critical areas remained below the maximal stress and strain capable of causing permanent modifications of the Pebax structure (3 MPa stress and 20% strain, respectively). Except for these focused areas, the distorted Pebax sacs were slightly stressed, and the calculated strains did not exceed 6% elsewhere on the distorted sacs for the 3 modeled ventricular configurations. The tensile tests on Pebax strips after material fatigue cycles did not show modifications of the Pebax structure for the considered ventricular applications and their alleged working conditions. Consequently, the mechanical feasibility of Pebax sacs was confirmed for the studied ventricular applications as a result of the absence of the modification of intrinsic mechanical properties during the assumed working conditions of these sacs (Fig. 4). This mechanical feasibility should be validated through resistance tests on Pebax sac prototypes, especially because the fatigue tests on the Pebax strips were of short duration and on biomechanical double sac prototypes in further extended contact with blood because such blood contacts with corollary physicochemical reactions on biological tissues can interfere with the mechanical properties of the pericardium and virtual space and consequently the double sac.

Another purpose of this study was to determine the volumetric capabilities of the biomechanical double sac. The calculated end-diastolic volume for the reference state of the ventricular configurations corresponded to the measured end-diastolic volume of the pericardial sacs (11), the measured volume validating the calculated volume with values of 110 cm$^3$ and 105.4 cm$^3$, respectively. Minimal end-systolic volumes were calculated for the maximum distorting of the ventricular configurations, allowing us to deduct the theoretical maximum stroke volume from each of these ventricular configurations. The differences between these volumes were the result of the dynamic and geometric factors pertaining to each of the ventricular configurations. The simulated mobility of the left ventricular apex permitted an increase in the theoretical maximum stroke volume from 58.7 cm$^3$ to 74.4 cm$^3$ (Table 1); the ventricular apex motion was a technical means to simulate ventricular apex mobility and could not exceed 10 mm or the maximal distortions were no longer realistic.
On the other hand, the geometric properties of both the left and right ventricles related to their ejection orifice have determined, with identical dynamic factors, theoretical maximum stroke volumes of 74.4 cm³ and 62.4 cm³, respectively (Table 1). Such volumes have been considered to be hemodynamically acceptable compared to the stroke volumes of currently available artificial ventricles. Furthermore, the 16% relative difference between the theoretical maximum stroke volumes of both right and left ventricles and consequently the maximum outputs of both right and left ventricles was also estimated as being hemodynamically acceptable compared to the relative differences of left and right ventricular outputs observed with other TAHs, which can vary between 5 and 30% (18–20). Thus, the design of these original artificial ventricles appeared to be compatible with assumed good hemodynamic performances of the consequent TAH.

CONCLUSION

This computerized study was a first approach, the purpose of which was to estimate the feasibility and realism of the concept before producing prototypes. This study has been conclusive and profitable allowing us to evaluate the mechanical and volumetric properties of artificial ventricles. With the recorded data, we have just demonstrated that the biomechanical double sac and the underlying TAH concept appear to be a realistic and promising solution for artificial hearts, the expected clinical use of which still remains very limited because of unsolved problems. This first study should lead to other ones to validate the obtained results and to estimate the expected advantages with this original TAH.

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REFERENCES


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