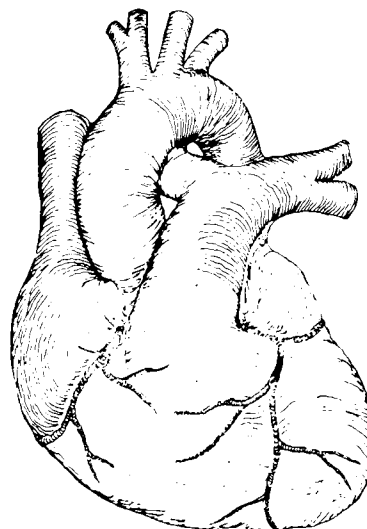


Developmental Rationale:

A Nonpulsatile Artificial Heart



ABSTRACT

The concept of a nonpulsatile artificial heart is discussed. The approach used in this investigation embodies the principle of a constrained force vortex to propel the blood. This novel approach eliminates the need for the direct contact of blood with impellers and also alleviates the constrictive and mechanical forces on blood cells resulting from high levels of shear and turbulence as well as direct impaction. By eliminating the direct contact of blood with these mechanical forces and with the use of atraumatic and nonthrombogenic low temperature isotropic carbon as the material of construction, a largely atraumatic pump is made possible. The use of force vortices enables the investigators to retain the high efficiency of a centrifugal impeller pump without encountering the traumatic effects of direct impeller contact. The result is a high efficient, atraumatic, nonpulsatile blood pump. The possible effects of nonpulsatile flow in the body are reviewed. Pump optimization is discussed. Finally, implantation of the artificial heart pump into animals on an experimental basis is discussed briefly.

By
Edson H. Rafferty, B.S.M.E.,
Harold D. Kletschka, M.D.
and
Douglas A. Olsen, Ph.D.

Bio-Medicus, Inc.
15308 Minnetonka Industrial Road
Minnetonka Industrial Park
Minnetonka, Minnesota 55343

Part One

INTRODUCTION

The scourge of heart disease is well recognized. Extensive research and clinical efforts have been expended in an attempt to cope with the problem. Open heart surgical techniques have been developed. Methods have been devised to facilitate replacement of diseased and injured valves. Various surgical approaches such as revascularization procedures¹⁻³ and coronary endarterectomy^{4,5} have been successfully utilized in the treatment of coronary occlusive disease.

Despite these energetic endeavors and achievements, heart disease remains the leading cause of disability and death.⁶ The inadequacy of present methods of dealing with heart disease suggests a more aggressive approach, namely, complete replacement of diseased hearts. Promising results have been achieved utilizing cardiac homografts.⁷⁻¹⁴ These, however, impose unsolved immunologic and immunosuppressive drug toxicity problems.

Assuming that these difficulties will eventually be overcome, formidable obstacles will still exist with respect to the application of this approach for clinical use involving human subjects. Inability to develop an adequate bank of healthy hearts would appear to

severely restrict its usefulness. In addition, a transplanted heart would be subject to the same disease states as the heart it replaced.

In view of such considerations, attempts have been made to fashion an artificial heart which can successfully assist or supplant the functions of the normal heart. This approach has resulted in the introduction of a host of ingenious devices to serve as artificial hearts.¹⁵⁻²⁸

Most of these devices were intended to mimic the cycle of the natural heart and delivered a **pulsatile** blood flow. None of the devices developed and tested to date can serve as a permanent substitute heart. Each unit studied has disadvantages peculiar to the given design that makes it unsuitable as an artificial heart. One unsolved limiting factor, common to all of the pulsatile devices, is the low efficiency of the pumping system.

A completely implantable artificial heart will not be feasible until highly efficient pumps are developed that can minimize power requirements. On the other hand, as discussed below, **nonpulsatile** artificial hearts are highly efficient and, because of their design, can utilize available nonthrombogenic construction materials.

To Be Continued