Biomedical Impact in Implantable Devices-The Transcatheter Aortic Valve as an example

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Objective: To update the scientific community about the biomedical engineering involvement in the implantable devices chain. Moreover the transcatheter Aortic Valve (TAV) replacement, in the field of cardiac surgery, will be analyzed as an example of contemporary implantable technology.

Methods: A detailed literature review regarding biomedical engineers participating in the implantable medical product chain, starting from the design of the product till the final implantation technique.

Results: The scientific role of biomedical engineers has clearly been established. Certain parts of the product chain are implemented almost exclusively by experienced biomedical engineers such as the transcatheter aortic valve device. The successful professional should have a multidisciplinary knowledge, including medicine, in order to pursue the challenges for such intuitive technology. This clearly indicates that biomedical engineers are among the most appropriate scientists to accomplish such tasks.

Conclusions: The biomedical engineering involvement in medical implantable devices has been widely accepted by the scientific community, worldwide. Its important contribution, starting from the design and extended to the development, clinical trials, scientific support, education of other scientists (surgeons, cardiologists, technicians etc.), and even to sales, makes biomedical engineers a valuable player in the scientific arena. Notably, the sector of implantable devices is constantly raising, as emerging technologies continuously set up new targets.

1. Introduction

Each year millions of patients improve their quality of life through surgical procedures that involve implanted medical devices. The term implant is used for devices that replace or act as a fraction of the whole biological structure. Currently, implants are being used in many different parts of the body for various applications such as orthopedics, pacemakers, cardiovascular stents, defibrillators or neural prosthetics. While they can save or improve the quality of a patient’s life, they also pose some of the biggest engineering challenges which include design, prototyping, selection of materials, manufacturing and testing [1]. The biomedical engineering involvement in medical implantable devices is the most appropriate in such tasks starting from the design and extending to the
development, clinical trials, scientific support, education of other scientists (surgeons, cardiologists, technicians etc.), and even to sales. This conclusion makes biomedical engineers a valuable player in the scientific arena of implantable devices.

2. Methods

The contribution of biomedical engineer in the field of implantable devices is valuable, starting from the idea capturing to the education of other scientists for the proper positioning of the device. In this review will be discussed life-threatening diseases, in the field of contemporary cardiac surgery, such as aortic stenosis. The main focus of this paper is to analyze the biomedical impact throughout the product chain. Furthermore, essential features related to transcatheter heart valve such as hemodynamics and clinical trials will be discussed.

3. Heart Valves

The aortic valve is one of the four valves in the human heart and through which blood flows from the heart to the whole body. Aortic stenosis is the condition whereby the main valve leading from the heart to the rest of the body becomes tight, and it’s hard for the heart to eject blood into the circulation system for the rest of the body. At this stage aortic stenosis is generally caused by the calcification of the valve leaflets and with the deposition of the calcification the leaflets become immobilized. The symptoms related to aortic stenosis are often shortness of breath, chest pain, swelling of the legs, even syncope. Medical treatment for severe symptomatic aortic stenosis is not effective, and without aortic valve replacement, the rate of mortality is approximately 25 percent in 1 year and 50 percent in 2 years. Surgical replacement of the aortic valve markedly improves the symptoms of the patient and the patient’s long survival [2]. In normal patients, these operations carry a perioperative mortality of about 3 to 4 percent. However, according to recently published data of the European Society of Cardiology, 33 percent of all adults ≥75 years old with severe aortic stenosis do not undergo surgery even though it is the only successful treatment. The open surgery entails substantial risks for some patients with severe comorbidities such as advanced age, patients with previous history of open heart surgery etc., and for some considered as “high risk” patients [3]. To meet the medical needs of this population, a new technology has emerged over the past decade and is now being put into clinical practice: transcatheter aortic valve replacement (TAVR). This technology has significant impacts throughout the health care field with the creation of a new biotechnology industry around transcatheter valves, the creation of multidisciplinary “heart teams”, and the construction of hybrid procedure rooms with both cath lab and operating room capabilities.

4. Design of Transcatheter Aortic Valves

Both the Edwards SAPIEN valve and the Medtronic CoreValve are designed to function through a mechanism similar to a normally functioning human tricuspid aortic valve. However, while both are trileaflet in design with a metallic framework for support, their construction as well as preparation and delivery have significant differences. The integrated Edwards SAPIEN XT transcatheter heart valve system is comprised of bovine pericardium which is individually matched for flexibility and strength. The valve tissue is affixed to a stainless steel frame with cobalt-chromium alloy. This frame design allows the valve to be compressed down further than the older generation of Edwards SAPIEN valve during delivery and catheter implantation (the first generation used stainless steel frame), so the procedure can be performed in patients with smaller femoral arteries [4]. In contrast to the Sapien valve, the CoreValve is a self-expanding valve with a nitinol frame. Although the first generation of the CoreValve (first implanted in humans in 2004) was made from bovine pericardium with an intra-annular valve function similar to that of the Sapien valve, the current generation CoreValve is made from porcine pericardium. The choice of nitinol as opposed to stainless steel gives the CoreValve
system the ability to be loaded onto a catheter delivery system that does not require a balloon and enables the valve to be gradually deployed in stages.

5. Delivery System

Prior to delivery, the Edwards SAPIEN XT valve is tightly compressed using a crimping mechanism onto a balloon catheter. A catheter is a long, thin, flexible tube that is able to guide the new valve through the artery and place it in the correct position. Furthermore, aortic balloon valvuloplasty is performed, and thereafter the Sapien transcatheter heart valve system is advanced up the aorta and placed across the native aortic valve. The balloon with the attached valve is then rapidly inflated and deflated, expanding and releasing the Sapien valve. The newly functioning valve is passively secured to the underlying native leaflets and to the aortic annulus as a result of this delivery. In contrast to the SAPIEN valve, the CoreValve is deployable via self-expansion without the aid of a balloon catheter. The stent is initially crimped and placed in a sheath before being deployed at the treatment site. This is possible due to nitinol’s shape memory property that allows the stent to be expanded to its predetermined shape by allowing blood to come into contact with it. Neither of the techniques requires the removal of the native heart but is pushed to the walls of the heart by the artificial valve. The catheter can be inserted into the body from one of several locations such as transfemoral, transapical and transaortic approach.

6. Clinical Trials with TAVR

The safety and effectiveness of the implantable valves has been studied in more than 50,000 patients. The PARTNER Trial was enrolled between 2007 and 2009 and the results were dramatically positive of the transcatheter valve. Up to date, the PATHNER II trial randomized 560 patients who were eligible for surgery to transfemoral approach using the new Sapien XT or transfemoral using the original Sapien device. Mean age of the patients was 84 years old and they followed for a minimum of 1 year. Data at 30 days revealed that mortality (Sapien 5.1%, Sapien XT 3.5 %) and appearance stroke (Sapien 3% and Sapien XT 3.2%) were similar between groups. The primary end point in 1 year did not differ between groups (Sapien 34.7%, Sapien XT 33.9%).

7. Results

The scientific role of biomedical engineers has clearly been well established. Since the day of the first pacemakers, implantable devices have undergone a major transformation. Certain parts of the product chain are implemented almost exclusively by experienced biomedical engineers such as the transcatheter aortic device. The successful professional should have prior experience with transcatheter heart valves which includes extensive knowledge of the various access routes as well as anatomy and physiology of the cardiovascular system. To obtain the best outcome for the patient, there must be a true collaboration between surgeons, cardiologists, technicians etc., not only in evaluation of the patient but in the procedure itself. Transcatheter aortic valve implantation represents a promising, new technology that aims to replace the high risk surgical heart valve replacement. However, there remain significant difficulties to be overcome. One of the major drawbacks is the issue of paravalvular leaks which is possible due to the valve not being in the correct position. Valve design may also have a positive contribution in resolving this issue. Paravalvular leakage greatly reduces the efficiency of the valve. Another issue that should be examined is the incidence of a stroke. Stroke is a major concern in transcatheter aortic valves as its incidence is higher in patients receiving this method than those surgically or medically treated as observed in the PARTNER study. Another issue is the increased incidence in permanent pacemaker placement for patients getting the CoreValve, as the ability to reposition if needed as well as issues of alternative access in patients whose femoral anatomy
cannot accommodate the large sizes required for the transfemoral approach. Lastly, as modifications and improvements are made to the design, the medical field must continue to adapt and develop in response to this technology [5].

8. Conclusions

One of the fastest growing fields of technology, a field of astounding recent achievements and even more ambitious hopes is the biomedical engineering. In rapidly growing field of science, the successful professional should have a multidisciplinary knowledge in biological and health sciences as well as the ability to communicate with life sciences professionals, physicians in order to pursue the challenges for such intuitive technology. Biomedical engineers are having a key role in the chain of implantable devices in general, and more specifically, the transcatheter aortic valves. To fulfill the project they need to cooperate with cardiologists, cardiac surgeons, anesthesiologists, image specialists, nurses and technicians. As the sector of implantable devices expands, the biomedical engineering role will be greater and most valuable in the scientific arena.

9. References

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