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Hip prosthesis design. Market analysis, new perspectives and an innovative solution.

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Abstract

Life expectancy and quality raise have increased the request of better and customized solutions for patients. On the other side, while the health care market is continuously raising, the manufacturing industry, specially the automotive one, is facing a strongly negative trend under production and sales point of view. In this panorama, the development of biomedical devices represents a big chance for both patient's health care and manufacturing industry being an interesting opportunity for investments.
In order to design a new product, it is necessary to take into account the market needs and requests, especially when it is high-tech and involves human needs. Unfortunately, it often happens that the languages and research approaches of the parts involved in the market, supply and demand, are different which makes the communication more difficult, especially when Medicine and Engineering are involved. For example, requirements such as biocompatibility, life service or biological integration have to be translated in terms of material, manufacturing process or treatment. In order to correlate performance characteristics and design choice, tools like QFD (Quality Function Deployment) are available. In particular, they use results of market investigations on existing products and market requests to identify the improvement areas, to correlate them with design specifications so outlining the features of new products able to satisfy the market requests.
Within this approach, the present paper shows the results of a market analysis focused on hip prosthesis improvement. Therefore, using questionnaires sent to specialized physicians and medical centers, it was possible to collect information about pro and cons of existing devices identifying their criticalness' with particular attention to stem osteointegration. In fact, compiling a QFD table, it was possible to design new concepts of the prosthesis stem which are here described and their mechanical resistance was tested using FEM simulations.

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Keywords: hip prosthesis; stem; design; market analysis.

1. Introduction

The higher risk of diseases associated to factors like the patent's age or extreme activity behaviour (i.e. sports) and the progressive increment of life expectancy and the changes in life style have increased the request of medical treatment by the patients [1].

This represents a pulling element for the medical and industrial areas which are continuously searching for new and more performing solutions in several fields such as diagnostics, consumable equipments (surgical tools, prosthesis), therapy and rehabilitation [2-4].

Therefore, the biomedical sector has both a social and an economic role, especially for intensive research areas involved in the product development and manufacturing and in the services related with medicine.

Total Hip Replacement [THR] (Fig.1) is a surgical procedure that consists in the reconstruction of the hip joint, in particular the acetabulum is substituted by a cup

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fixed to the basin while the femur head is removed and replaced by a spherical head and a stem fixed in the femur.

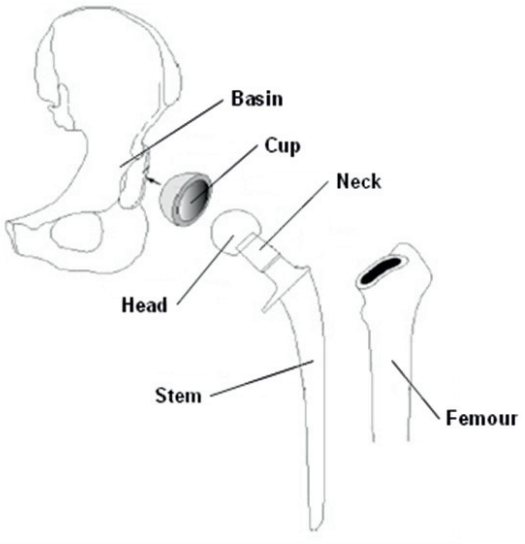

Fig. 1. Total Hip Replacement scheme [5]

Recent statistics referring to the period ranging from 1999-2005 on European Countries [6] show that THR implants have reached the number of hundreds-thousand per year with a continuously raising trend (i.e. +32,4% in Italy). This has pushed the actual market to offer a wide range of prosthesis differing in modularity [5], material [7] or stem anchorage system [7]. Besides this variety of solutions, the implants are still not reasonably failure-free reducing the implant life length. This has been shown in a recent research [8] which estimates the revision rate as 6% and 12% respectively in 5 and 10 years. Typical failure causes are stem or head rupture [9, 10], wear and consequent metallosis diseases [11], instability due to bone breaking, necrosis or stress shielding [12] and bacterial infections which forms a biofilm between the implant and the bone [13].

Therefore, because of the high requests of THR and the related unsolved problems, this topic represents an interesting filed for prosthetic devices and patient health care improvements. For this reason, the Authors are investigating the market and orthopaedics requests in order to identify the most important improvement areas. The research approach is similar to the one proposed in [14,15] where the collaboration with physicians has lead to the identification of new solutions for endoscopic devices.

In the present paper, results of the investigation are presented and the concept of an ideal prosthesis is outlined. Moreover, new solutions are identified and tested using FEM simulations in order to evaluated their mechanical resistance in static and dynamic working conditions.

2. Market requests and new product concept

In a preliminar phase of the research, medical books, scientific articles, meetings with phisicians, and lectures were used to understand the problem and investigate the market. The so collected information were merged in a questionaire which was sent to the main Italian ortopaedic associations. Data and opinions were collected with regard to:

- Type of adopted implants
- Fixing solutions (stem and cup)
- Geometries
- Materials
- Applications and risks associated to THR

The Results of the survey were elaborated using the QFD technique [16] highligting the needs (expressed as relative percentage) of market and design requirements (respectively *What* and *How* in the QFD matrix). Results are summarized in Table 1. It can be observed that the main characteristichs (covering the 92.3% of the market requests) of a THR prosthesis are represented by biological (47.3%) and geomeric-mechanical (45.0%) requirements. They can be satisfied improving the materials (23.8%), stem fixing (37.1%) and geometry (35.4%). Moreover, it can be noticed that the market requests mainly involve the stem of the prosthesis being the improvements of the cup mainly focused on wear reduction.

Table 1. DFQ most important THR prosthesis characteristics (WHAT) and design requirements (HOW). Relative importance is reported as cumulated percentage.

HOW (96.3%) / WHAT (92.3%)	Material (23.8%)	Stem Fixing (37.1%)	Geometry (35.4%)
Biologial Reqirements (47.3%)			
Biocompatibility (All)	X		
Chemical/Biological Inertness (All)	X		
Osteointegration (Stem)		X	
Press fit (Stem)		X	
Mechanical Requirements (45.0%)			
Wear resistance (Cup)	X		
Mechanical resistance (All)	X		X
Lower rigidity (Stem)	X		X
Modularity (All)			X
Customization (Stem)			X
Primary stability (Stem)			X

In order to satisfy the market requests within the model of Kaizen (continuous improvement) it was chosen to reuse and improve the actual solutions. This