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 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.

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1. Introduction

The higher risk of diseases associated to factors like the patient’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 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
fixed to the basin while the femur head is removed and replaced by a spherical head and a stem fixed in the femur.

![Diagram of Total Hip Replacement scheme](image)

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 preliminary phase of the research, medical books, scientific articles, meetings with physicians, and lectures were used to understand the problem and investigate the market. The so collected information were merged in a questionnaire which was sent to the main Italian orthopaedic 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] highlighting 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 characteristics (covering the 92.3% of the market requests) of a THR prosthesis are represented by biological (47.3%) and geometric-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%) | Material (23.8%) | Stem Fixing (37.1%) | Geometry (35.4%) |
|-------------|----------------|--------------------|-----------------|
| Biological Requirements (47.3%) |
| Biocompatibility (All) | X |
| Chemical/Biological Inertness (All) | X |
| Osteointegration (Stem) |
| Press fit (Stem) | X |
| Mechanical Requirements (45.0%) |
| Wear resistance (Cup) | X |
| Mechanical resistance (All) | X |
| Lower rigidity (Stem) | 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
approach is helpful in maintaining the advantages of the actual prosthesis and changing their lacks. In particular, the overall good biocompatibility and the acceptable wear resistance of the cup were maintained, while attention was focused on stem problems that can be grouped in stresses-distribution once the prosthesis in the bone. In fact, too concentrated stress can lead to osteolysis, local fracture, necrosis and, therefore, to the reduction of osteointegration and stability of the stem. Moreover, the high rigidity of actual stems causes an asymmetric distribution of forces on the patient’s legs during daylife activities leading to body disalignments.

Therefore, the idea at the base of the proposed concept consists of a new stem whose geometry improves both the mechanical and the stresses distribution requirements. In particular, its geometry:

- has hollow cavities which can contain fillers (i.e. bonechips, scaffold) or porous titanium [17,18] where the bone cells growth can be faster after the implantation.
- improves the osteointegration (as a consequence of the previous point)
- does not require cement for fixing (press-fit solution)
- reduces the rigidity to the implant
- is derived from actual solutions (main dimensions)
- can be customized according to patient scans

These characteristics are keypoints for the product improvement because it is expected that they will generate a strong connection between the stem and the ingrowth femour. In fact, traditional stems are fixed in the medullary cavity, therefore stresses are distributed along the cavity surface and the vascularization of the femour is reduced (2/3 of it comes from the medullary cavity). Within the ingrowth bone tissue of the new stem, stresses will be distributed on the whole femour section and the central vascularization will be imporved. This will lead to lower risks of localized peaks of stress, necrosis and instability. Moreover, customized prosthesis manufacturing represent a new opportunity for better meeting the patients needs and, thanks to the diffusion of rapid prototyping technologies, it has become economically sustainable [18-20]

In addition, in order to satisfy the other customer requirements, the new stem is:

- made of the same actually used materials (Ti alloys) which guarantee adequate biocompatibility, strength and lightweight
- modular, in order to be integrable with necks and heads available on the market
- mechanical resistant to daily life activities and withstands actual standards (ISO 7206).

3. Mechanical resistance

Before being implantable, a prosthetic device has to be certified according to actual standards (ISO 7206). The critical aspect of the proposed concept is that its resistant section is reduced in order to leave space for the fillers. Therefore, the mechanical resistance of the new stems in static an cyclic conditions will be investigated.

With regards to static resistance, the data reported in [21-23] were used to identify the maximum force acting on the hip joint, while ISO 7206 standard was used to verify the fatigue resistance. In particular, [22] reports the force measurements during daily life activities on 4 patients, showing that the maximum force (about 11.000kN) occurs when stumbling (Fig.2). Moreover, according to ISO 7026 (Fig.3 and Table 2), the prosthesis is tested in the worst working conditions. In fact, the stem is fixed on its distal end in order to reproduce a partial detachment condition. To pass the tests, 6 consecutive specimens have to safely reach the target having a maximum displacement equal to 5mm.

Fig. 2. Forces acting on hip joint during day life activities [21-23].

Fig. 3. ISO 7026 fatigue test. 1) sample 2) load 3) loading device 4) example of sample container 5) fixing media 6) metal plate 7) metallic head. CT and D are respectively the total and free lengths of the stem.
4. FEM model and new stem testing

From the conceptual idea of the new stem, different solutions were designed and tested. In order to verify their mechanical resistance, an FEM model was developed and used to simulate the effect of the applied loads according to the mechanical requirements described in Section 3.

The model was developed in ALGOR environment (Fig.4), the hip prosthesis was modeled as a linear-elastic body made of annealed Ti6Al4V whose characteristics are reported in Table 3. In order to simplify the model, prosthesis stem, neck and head are modeled as a unique body. The stem distal end was fixed and the load applied according to ISO 7206 (Fig.3).

The model was used for either static and cyclic resistance simulations on different stem geometries. First, a commercially available stem (Fig.4) which has the required certifications for implantation was tested in order to check that the FE model was able to properly forecast its resistance. Then, this stem was used as reference to analyze three different designing solutions according to the previously described improvement concept. Being these stems hollow so to contain the fillers, they were tested considering severe stress concentration effects (Table 3 and Table 4). The tested geometries and simulation results are reported in Fig.5 and Table 4 in terms of stress distributions, static and fatigue safety coefficients ($\eta_s$ and $\eta_f$, respectively) and maximum displacement of the prosthesis. Since Stem#3 geometry is under patent procedure, it will be here shown only in terms of final results.

Fig.5 shows that the maximum stressed area (both for static and cyclic tests) is located between the free and the blocked part of the stem. Moreover, commercial stem results (Stem#0) are in agreement with its actual resistance. Stem#1 showed to be not suitable since it cannot withstand the maximum force ($\eta_s = 0.71$), while Stem#2 passes both static and cyclic tests, but its fatigue safety coefficient is too low ($\eta_f = 1.18$) for being considered for implantation. Nevertheless, its geometry can be improved so to increase the fatigue resistance. Stem#3 results are positive in all the tests ($\eta_s = 1.46$ and $\eta_f = 2.5$), especially if we consider that it has been tested in the worst conditions (stress concentration) and that its geometry has not been yet optimized. Therefore, Stem#2 and especially Stem#3 show to be suitable for prosthesis improvement according to the proposed concept.

Table 3. Annealed Ti6Al4V alloy characteristics

| Material       | Ti6Al4V          |
|----------------|------------------|
| Modulus of Elasticity | 113.8 GPa       |
| Tensile Strength   |                  |
| Yield             | 880 MPa          |
| Ultimate          | 950 MPa          |
| Fatigue Strength (1E+7 cycles) |          |
| Smooth surface    | 510 MPa          |
| Stress concentration ($K_t = 3.3$) | 240 MPa |

Table 4. Mechanical resistance test summary.

| Geometry | $\sigma_{max}$ [MPa] | $\eta_s$ | Cyclic Stress conc. | $\eta_f$ | Max Displ. |
|----------|----------------------|---------|---------------------|---------|------------|
| Stem #0  | 378                  | 2.32    | NO                  | 8.82    | 2.3 mm     |
| Stem #1  | 1.245                | 0.71    | -                   | -       | -          |
| Stem #2  | 672                  | 1.31    | YES                 | 1.18    | -          |
| Stem #3  | 602                  | 1.46    | YES                 | 2.5     | 4.4 mm     |
5. Conclusions and future works

Society is asking today for better or new medical solutions in terms of devices and treatments. In particular, aspects like the increment of life expectancy and the changes in life style, have increased the number of Total Hip Replacement even if the available solutions still present lacks in terms of performances which reduce their life and require prosthesis revision. This represents an opportunity for researchers and industries for both improving the patient health care and finding new attractive opportunities for business.

For this reason, in the present paper the results of a market analysis which outlined the actual requests and needs in terms of hip prosthesis are presented (QFD analysis). In particular, stem resulted to be the prosthesis market analysis which outlined the actual requests and attractive opportunities for business.

improving the patient health care and finding new aspects like the increment of life expectancy and the changes in life style, have increased the number of Total Hip Replacement even if the available solutions derived and tested using FEM simulations. The tests were performed in order to verify the mechanical resistance of the prosthesis during day life activities in terms of maximum load and fatigue resistance. As results, two of the proposed solutions passed the tests and show possibility of improvements. The best identified solution has been chosen to be patented.

Next work will be oriented to the experimental testing of the proposed solutions, in particular prototypes of the patented stem will be produced and mechanically tested according to ISO 7206 standard and data available in literature. Further, its biomedical requirements will be tested in terms of biocompatibility and osteointegration capability.

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