Characteristics of Market Study for Niche Products:Surgery Implants

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Abstract **The project aims to achieve a market study in the sphere of biomechanics; the concerned products are niche ones, such as: surgery implants. Biomechanics is an interdisciplinary field and of linkage between Mechanics and Medicine, of great present interest in the world.**

Within biomechanics, mechanical modelling, on the basis of which the achievement of prosthesis and human skeleton implantation for the normal functions of the different apparatus of the human body is possible, is of a special importance.

Implants are objects realised of biocompatible materials, with the purpose of being introduced in the human body, where they will remain for a while in order to reconstruct bones or will be extracted after the fracture repair.

Keywords **niche, implants, biocompatible ,biomechanics.**

I..THE RELEVANCE OF THE THEMATIC AREA

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Within biomechanics, mechanical modelling, on the basis of which the achievement of prosthesis and human skeleton implantation for the normal functions of the different apparatus of the human body is possible, is of a special importance.

That is why the use of images resulted from computerised tomography processing in the purpose of projecting and achieving implants for the human skeleton is another research direction which is prioritizing at the national level.

Implants are objects realised of biocompatible materials, with the purpose of being introduced in the human body, where they will remain for a while in order to reconstruct bones or will be extracted after the fracture repair.

The advantage of the miniplates use and screws technique consists of obtaining a high degree of stability of the reconstructed bone area. Implantology has registered an important progress since the moment when titan osteointegration was demonstrated, titan implants having registered remarkable therapeutical results. For the subjects that have suffered different traumas, those with malformations

or with other affections of the osseous skeleton, prosthetic restorations by implants use have proved themselves to be extremely efficient, their superior qualities being both functional, and psychological. In national premiere, at the Centre for Modelling the Prosthetic Appliances and Operations on the Human Skeleton from the Polytechnic University of Timisoara CM-PICSU, through studies and research at international level standards, the first implants and osseous fixation appliances have been produced. It has been proven in this way that in our country products which are competitive with those existing abroad can be made. But, until now, no systematic study on the market of these niche products has been done. Such a study aims the achievement of the compatibility and competitivity level which is necessary for the full integration in the European research area.

II.THE IMPORTANCE OF THE PROPOSED THEME

In the technical education and especially in the high-tech fields, an extremely rapid development at the world level has been registered, that Romanian education and research are forced to keep up with; the increase in the volume of knowledge trend is even more accelerated in these fields, which raises special problems, requiring adaptation to requirements that are rather global, than local.

Biomechanics represents a new research field, of great interest for both medicine and top industries which aim at elaborating new materials and new technologies. It has a pronounced interdisciplinary character and has registered lately a special development. If the first biomechanics studies have occurred in the field of orthopaedics, more recent but of a special strength are the biomechanics studies in the field of stomatology.

A good cooperation and interdisciplinary in solving biomechanics problems between different categories of specialists: doctors, engineers can be noticed. A top institution in biomechanics is

The Centre for Modelling the Prosthetic Appliances and Operations on the Human Skeleton CM-PICSU, which is conceived to develop as a research - design - micro production unit that reunites more universities and hospitals from the country: the Polytechnic University Timisoara UPT through Mechanical Faculty - Mechanical Department, University of Medicine and Pharmacy Timisoara through: Municipal Clinical Hospital Timisoara SCMT - Clinic of Craniofacial Surgery

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CCOMF and Departmental Hospital Timisoara - Orthopaedic Hospital no.1 Timisoara COT, Technical University Cluj-Napoca UTCN trough: Department of Mechanisms and Fine Mechanics and Department of Mechanics and Software, Polytechnic University Bucuresti UPB through Mechanical Department, University of Craiova UC - Faculty of Medicine trough Clinic of Craniofacial Surgery CCOMFC, Central Military Hospital Bucuresti SMCB). Those working within this structure are high class specialists, who have a high potential of assimilating the last technologies in the field and of permanent adaptation to the market requirements. CMPICSU has succeeded to generate from its own funds (to which a financing through the National Research and Development Plan has also been added). The Laboratory for Implants Certification and Fixation Appliances that are Used in Osseous Surgery and Stomatology CIDUCOS.

A priority of the activity of CMPICSU is elaborating knowledge, transmitting them, bringing contributions in the prioritizing fields of science and technology of the beginning of the 21st century and the wide, flexible, interactive and continuous formation of specialists.

The proposed theme fits research orientation in the prioritizing directing lines of the European research, according to the Framework Program 7 of the European Union for the period 2007-2013 (PC7). The theme contributes to developing a dynamic and competitive social and economic environment, oriented towards the high technology fields and capable of meeting the long term strategic development requirements, in the context of the globalized economy. It contributes to realizing the transfer of science, technology and know-how, production and special services for the clients .In the same time, the theme stimulates the opening of the university and interaction with the economic, administrative and social environment at the local, national and global level, as well as to the permanent support for the cooperation and interinstitutional collaboration. On the basis of the analyses of data obtained within this study, the research and production activity will be oriented, so that the market requirements are satisfied to the highest degree. Through elaborating more efficient models, present engineering methods will be perfected and different biomechanics problems will be better solved.

III.THE ACTUAL KNOWLEDGE STAGE IN THE AREA RELATED TO THE SUBJECT PROPOSED

No rigorous market study on implants has been made in Romania until now.

Implants are objects made of biocompatible materials, with the purpose of being introduced in the human body, where they will remain for a while for bones reconstruction or will be extracted after the fracture repair. The advantage of the miniplates and screws use technique consists of obtaining a high degree of stability of the reconstructed part of the bone.

Implantology has registered an important progress since the moment when titan osteointegration was demonstrated, titan implants having registered remarkable therapeutical results. For the subjects that have suffered different traumas, those with malformations or with other affections of the osseous skeleton, prosthetic restorations by implants use have proved themselves to be extremely efficient, their superior qualities being both functional, and psychological.

Implants are done in accordance with the standards collection that is approved at national, European and world level, standards that include conceptions, conditions and technical and medical knowledge.

They may have untreated surfaces, treated by deposal of other substances, treated mechanically through sand-blasting.

The treatment of fractures in general aims to reconstruct completely and rapidly the functions of the skeleton and consists of uniting various anatomic forms, depending on the localization of the fracture. The rests of the bones are capable of taking over the tasks and the implant must substitute the lost extension properties. This loading is split between the bone and the implant, the latter one having to be ductile and adaptable at the surface of the bone. In accordance with the shape and the material that is used, there are more types of implants:

-*Implants made of biodegradable materials:* used for fixing the bones of the skull of the patients of different ages; have the big advantage that throughout a year, they may be assimilated by organism and eliminated. The principle that lays at the basis of this application is the decomposition of the biodegradable polymers in the human body in contact with the water.

- *Stabilizing implants, made of titan and biocompatible* non-oxidable steel: used for the severe traumas of the face skeleton which requires a big number of screws and plates; titan implants are preferred, because they have a high resistance to corrosion, because of the spontaneous formation of the thin layer of oxygen. Pure titan has a passive behaviour and does never causes toxic or allergic reactions. In the treatment of the fractures, the function of the implant is extended as much as it is necessary for the affected bone, so that to resist to the right functional loading.

The clamping through *plates* excludes the interfragmentary movement and achieves the inter-pressing of two surfaces, bone-bone or implant – bone. Implants that are used for the reconstruction of the skull are normalised; there are technical specifications for materials and dimensions. The systems of the different dimensions are symbolized with numbers and are used for the different areas of the skull. The system representation is indicated by the range of dimensions of the screws.

Screws are basic elements for the fixation of plates or of the similar appliances on the bone, in order to keep the osseous fragments united. For complicated situations, for the patients with severe deficiencies, special appliances for the fixation of the osseous fragments, called *fixation appliances* are used. *Fixation appliances* are very well

tolerated by patients and can be used for: all types of skulls with any kind of deficiencies; the cases when the treatment with implants of plate type has not given results; situations when a graft is necessary. They allow the correct multidirectional displacement on more levels, as well as correcting the implant position during the bone reconstruction period. They have various forms and dimensions, which are specific to the bones that are about to be implanted, and so have implants. Fixation appliances have a modulary construction, with more branches in different levels.

The dental implant has been conceived as a method of replacing a tooth or a group of teeth that are lacking on the jaws arches. Throughout the time, in order to assure a link as stable and lasting as possible between the surface of the implant and the bone, implants of various forms have been proposed and used, but the practice has shown that the treatment by the implant with the shape of a screw has the best results. The key of this success consists of the bigger contact surface between the implant and the osseous tissue, as well as in the fact that the surgery procedure is less traumatising than in the case of the use of the other types of implant. As a result, in present this type of implant is used at the largest scale.

The dental implant is a metallic body that is placed in the jaws osseous tissue and/or mandibulary. Once accepted, the implant takes over the function of the dental root. Accepting the implant requires the formation and consolidation of the link between the surface of the implant and the osseous tissue. All the other superstructures that are attached to the implant are part of the prosthetic work that will replace one or more teeth. In the case of modern implants, the superstructure is formed of the dental crown and the link between this one and the implant. In our country, implantology has overcome the pioneering stage, being successfully practiced by an increasing number of dentists.

The treatment by implants is complex and lasting, but disadvantages towards the classical alternative justify completely such an option. Presently, numerous patients have chosen the therapy by implants advantages: in the case of a lack of a tooth, the respective area is prosthesised; without affecting the neighbouring teeth. If more teeth are lacking, a fix prosthetic work may be sustained by the aid of a big number of implants.

The treatment by implants is a complex procedure, the use of technology of last generation and of good quality implants being compulsory for guaranteeing success. The cost of this type of treatment is bigger than that of the classical treatments. In the stomatological offices, the cost of an implant is of several hundreds euros. The cost of superstructures is added to this cost.

The use of processing of images obtained by computerised tomography in the purpose of projecting and realizing implants for the human skeleton is a prioritising research direction at national level. In The Multiple Users Research Base –The Centre for Prosthetic Modelling of Surgery Interventions on the Human Skeleton (BCUM CMPICSU), an artificial Titan personalized mandibulary has been made in national premiere, implanted successfully by the medical collective of the basis. Research has also allowed the publication of the paper -Human Mandibulary - Imagistic and Biomechanical Studies-, which represents the first Romanian book of biomechanics that uses numerical modellings on the basis of the images acquisition and processing. As a concrete result of the research activity in this field, the first Romanian Case of surgery implants and the first osseous fixed appliance have been achieved, and homologated by The Ministry of Health in the year 2004. It has been distinguished with the third price at the ConRo 2004 -Made in Romania- Exhibition. Within CMPICSU, the different types of defects of the osseous skeleton can be analyzed on specialized installations, and surgery and mechanical methods of repair can be projected. Packs of programs specialized in the processing of images obtained through scintigraphy, tomography, serigraphy, cephalometry have already been realized here.

Dental implants made in the CIDUCOS laboratory have only costed 50-100 euro and are at least as performant as those obtained abroad. The quality of the products is guaranteed by applying some fabrication procedures that are imposed by the quality assurance systems.

In present, the CIDUCOS laboratory is accredited for making certain types of implants, such as those used in the cranial-facial surgery, oral-jaw-facial, orthopedics and dental implants.

In the field of surgery implants, both in hospitals, and in private clinics such imported products with a very high commercialization price are used.

The spreading of the use of surgery implants in our country, inexistent until now, of a study on this market makes this investigation very necessary.

The subject which we propose will make references to few publications from different areas, such as: marketing,consumer behaviour,psychology and sociology.

IV.ORIGINAL ASPECTS OF THE RESEARCH

. The analysis of the existing situation in CMPICSU and the CIDUCOS laboratory represents the starting point in the project; this requires first of all the marketing audit, so an analysis of the internal and external environment of the unit.

External audit will analyze the market, the competition and will also include the PEST analysis. The market will be analyzed by the means of the elements: size, increase trends, structure, capacity, marketing methods, access etc. competition represented by the enterprises that offer the same products/services or their substitutes of the consumers from the actual or potential markets will also be explored. The PEST analysis will include: the political factors, (governmental and international settlements, taxes, normative acts, general constraints and of the local authorities, etc.); the economic factors (inflation, acquisition costs, transport and sell costs, etc.); socio-cultural factors (population's average age, life style,

interest in health, the culture and education level, etc.); technological factors (inventions and innovations, the virtual reality systems, etc.). These factors can affect the unit, but are outside its control. Once identified, they will be analyzed in relationship with the unit in a certain order, having as a criterion the degree in which that can influence its activity.

Internal audit will regard the operational variables of marketing, analyzing the situation from the CIDUCOS laboratory: sales (total, by geographical area, by client, by product, by the way of selling-rates, cash etc.); market quotas; costs and profit; information and marketing research; the marketing mix: product, price, distribution, promotion, operations and necessary resources.

The results of the marketing audit will be materialized in the SWOT analysis; its aim will be to study the essential characteristics of the CIDUCOS laboratory that shape its identity and could advantage it in the future activities. It will include: the strengths (extremely well prepared stuff, low costs, etc.); weaknesses (the marketing is not developed accordingly etc.); opportunities (potential development of products to meet demand, entrance on other external and internal markets, the creation of new marks for gaining a favourable position on the market, etc.); threats (entrance of other competitors of the respective market, the decrease of the consumer's interest in the traditional products, the occurrence of internal and external normative acts, etc.).

Every unit wants to transform the threats in opportunities, by the efficient use of its available resources. That is why, the next step will be that of establishing: the marketing objectives (in which the direction for the future will be decided, the desired results) and the marketing strategies (the actions that will be undertaken for achieving them).

The proposed theme may have a substantial input to activity development of CIDUCOS by establishing some realistic marketing objectives and a bigger probability of achieving the general objectives derived from the mission of this laboratory; better coordination of the whole stuff's activity, the bigger probability of identifying future evolutions of markets and products , the increased capacity of facing changes, the more efficient communication between the actors from this market, the more efficient allocation of organizational resources in function of market opportunities and transformation of threats in opportunities by the efficient use of its available resources.

V.FESABILITY OF THE PROPOSED POTENTIAL CONTRIBUTIONS

A market study is an initiative that requires certain costs. The CIDUCOS Laboratory, taking advantage of the already created system of connections with other educational and research institutions from our country, has considered that could use this institutional advantage in the benefit of a market study. CIDUCOS also enters this project with already consolidated technical equipment, adding a few elements able to make the research team's work easier. The risk this research could face is an eventual lack of information about certain relevant indicators or in impossibilities of establishing some constructive research contacts with potential units, users of surgery implants. In this case, the solution is the achievement of a secondary analysis, starting from already published information. The research team has the experience in market studies and has accumulated both theoretical and operational knowledge.

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