Chapter 25
The Application of an Integrated Product Development Process to the Design of Medical Equipment

Osiris Canciglieri Junior, Maria Lucia Miyake Okumura and Robert Ian Marr Young

Abstract With the research presented in this chapter we aim to investigate the importance of the concurrent engineering (CE) philosophy in the engineering-medical multidisciplinary environment for integrated product development process (IPDP) of medical equipment. We address the requirements of a health professional user as well as patient's needs. We have identified and contextualized the medical equipment lifecycle, the importance of CE in the IPDP of medical equipment and present propositions for the insertion of software tools that support product development phases. A discussion is included on the use of CE and IPDP oriented towards medical equipment conception and development, perspectives of engineering modular development and interface between Health and Engineering information areas for increasing technical, clinical and economic quality.

Keywords New product development · Virtual product creation · Concurrent engineering · Systems engineering · Product lifecycle management

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25.1 Introduction

Concurrent engineering (CE) has been increasingly used within the product development process (PDP) to support the searching for innovation, strategic alternatives and smart solutions to reduce the cost and lead-time. In this sense, the integrated product development process (IPDP) within a CE environment associated to the Health Technology could face the challenge of developing products that meet specific and customized conditions integrating multidisciplinary areas in the design phases.

Currently, most medical tools try to promote patient's quality of life through faster and more accurate diagnostics and less invasive screening and diagnostic tests, depend on high technology equipment. These medical equipment expose the close connections between engineering and medical areas since the new ideas planning must integrate the whole structure of the PDP. In this context, the research's objective present in this chapter, investigates the importance of the CE philosophy in the engineering-medical multidisciplinary environment for IPDP of medical equipment, addressing the requirements of the health professional user as well as the patient's needs. The methodology applied is theoretical with a qualitative approach and experimental nature. The study identifies and contextualizes the medical equipment life cycle, the importance of CE in the IPDP of medical equipment and presents propositions for the insertion of software tools that support the product development phases.

In the Sect. 25.2 medical equipment design oriented to IPDP is introduced. Its relationship to CE environment is described in Sect. 25.3. Discussion on the use of CE and IPDP is given in Sect. 25.4. Three cases studies are presented in Sect. 25.5 to illustrate the whole development process and the value of the proposed methodology. At the end, Sect. 25.6 presents final considerations on the use of CE and IPDP oriented for medical equipment conception and development, the perspectives of engineering modular development and the interface between Health and Engineering information areas seeking an increase in the technical, clinical and economic quality.

25.2 Medical Equipment Design Oriented to Integrated Product Development Process

This topic first contextualizes the medical devices as well as their definition, function and classification, and then addresses the process of developing new products targeted for medical area and its evolution/innovation. At the end, it is presented the importance of CE philosophy in the integrated development process of medical devices.

25.2.1 Medical Equipment and Classification

The Brazilian Health Surveillance Agency—ANVISA [1] defines medical equipment through the RDC 2/2010 Norm as "equipment or system, including its accessories and parts for medical use or application, dentistry or laboratory, used direct or indirectly for diagnostic, therapy and monitoring in the population health care, without using pharmacological, immunological or metabolic means to perform its main function in human beings, which may, however, be assisted by such means". WHO [2] considers a medical equipment as any instrument, apparatus, machine, implant, and similar applied to humans, according to the functions described as follows: (a) diagnosis, prevention, monitoring, treatment or alleviation of disease; (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; (c) investigation, replacement, modification, or support of the anatomy or of a physiological process; (d) supporting or sustaining life; (e) control of conception; (f) disinfection of medical devices; and (g) providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

The Food and Drug Administration has about 1,700 different types of generic medical devices classified and established, which are grouped in 16 specialties [3]. These devices are categorized into: pre-amendment devices, post-amendment devices, substantially equivalent devices, implanted devices, custom devices, investigation devices and transitional devices. Nevertheless, WHO [4] estimates around 10,000 types of medical devices available worldwide, not counting its variants. In 2008, this sector generated approximately US$210 billion employing over 1 million people in 27,000 companies located around the world. The projection for this sector is an economic growth of around 6 % per annum.

Classification of medical devices is related to the operational complexity degree of the equipment, the cost and time needed for training the health professional. According to Calil and Teixeira [5] this complexity can be: (a) low-easy operation, no need for skilled human resource and training; (b) medium-requires human resources with basic formation and equipment proper training; and (c) high-demands qualified and specialized technicians and specific training.

25.2.2 Development Process of Medical Equipment

The development of new products in the medical field is the result of technological advances enabling an improvement in people's lifetime since diagnoses and treatments of diseases are earlier and more efficiently detected. However, the reality of new ideas and technologies associated with health, in the proposed and developed products, presents a success probability of only one case out of a hundred [6].

The level of complexity in the development stages of medical equipment is increasing due to the demand for more accurate and effective examinations and therapies. The challenge lies especially in the technological mastery of several knowledge areas for the holistic design of the required concept.

25.2.3 Medical Equipment: Evaluation and Innovation

Currently, medical equipment is present in most clinical activities, such as the preventive tests, during treatment or monitoring, rehabilitation therapies and it is fundamental in the medical field, but its acquisition requires considerable investment because of its initial price, high cost of maintenance, and also by rapid technological obsolescence [7, 8]. This scenario led managers to adopt more systematic and rational health assessment processes for the acquisition of new equipment, while also considering safety, efficiency, quality and good manufacturing practices. Amongst the assessment processes, there is the health technology assessment (HTA) that started with the computer aided tomography advances aiming to absorb low cost new technologies and seeking for better cost-efficiency [9, 10]. Figure 25.1 illustrates the HTA behavior during the product life cycle and shows that HTA rate increases according to the medical equipment usage in function of time. It is noticed that there are a small number of users of medical

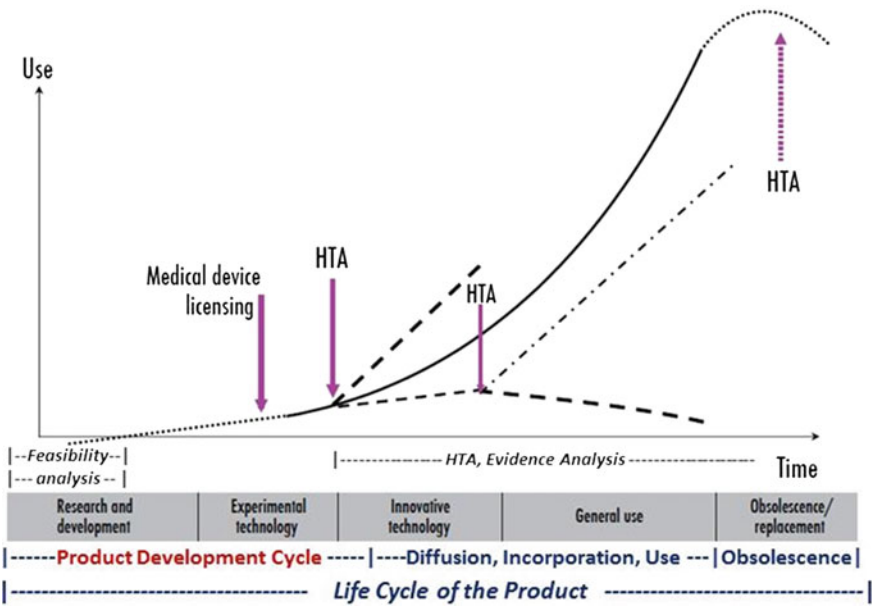

Fig. 25.1 Health technology assessment, diffusion of health technologies, feasibility analysis and evidence analysis in the research and product development. Based on [6, 8, 10, 19]

equipment with low rate of HTA during the product development cycle. However, this number of users can increase or decrease during the diffusion and incorporation of the product due to different obtained performance, shown in the figure by HTA rate forking which highlights the adherence of future users. Thus, as the analyses of the evidence is occurring and bringing good results, the rate of hypertension is likely to increase. This growth can be evidenced even in the stage of obsolescence of medical equipment. Therefore, it appears that the rate of assessment is low in launching products, it is advisable to do a deeper analysis of technical and economic feasibility since the beginning of the planning phase of the IPDP [6, 11].

Another assessment process is the evidence-based medicine (EBM), which uses tools of clinical epidemiology, statistics, scientific methodology and informatics to build knowledge and achieve higher performance applied to healthcare. The EBM objective is to provide information to support decision making in clinical practice. The Cochrane Center of Brazil provides a database of systematic review of SBE allowing information exchange free of charge worldwide. This database contains information on the COCHRANE analyzes occurrences from documented evidence provided during the practice of the process of medical care worldwide [12, 13]. Thus, medical device evaluation is related to technological innovation according to the formalities or requirements of the medical area, integrating new technologies, processes and organizational environments that result in the advancements on the medical field and contribute to the health of society [10, 14–18].

25.2.4 Concurrent Engineering in the Integrated Development

According to [20–23] the main features of CE are: (a) the emphasis on customer satisfaction; (b) the activities of multidisciplinary teams; (c) the autonomy of teams; (d) the simultaneous development; (e) the leadership to coordinate the entire process of product development; (f) the designs standardization; (g) the information sharing; (h) the use of computerized tools to streamline the processes; and (i) the management practices and instruments for quality assurance. The environment of CE ensures the product quality during the IPDP phases in the life cycle of health care products, leading to a reduced launch time and development costs since the CE environment allows the creation of the concept using various areas of knowledge, understanding more clearly the planning aspects throughout the IPDP phases [11, 24–26]. Decisions made at the beginning of the development cycle are responsible for approximately 80 % of the product final cost [27].

The development should be oriented to the design planning during the IPDP phases, using engineering systematic methods with interdisciplinary approaches, as well as providing flexibility to the integrated environment seeking the best alternatives to meet the needs of consumers. CE is a philosophy that must be applied to the IPDP taking into consideration the requirements of the users and also the

demands of the market through the use the tools, models, methods and concepts to identify the best alternative [28]. Therefore, the agents involved when using CE are known as the Seven Ts-Tasks, Teamwork, Techniques, Technology, Time, Tools and Talents [29]. Among these, the following resources stand out: quality function deployment (QFD), Computer-aided-design/Computer-aided-manufacturing (CAD/CAM), Design for Configuration, Design for Precision, Design for Aesthetics, design for safety/liability (DFS), design for life cycle (DFLC), design for manufacturing (DFM), design for assembly (DFA), design for reliability (DFR), Design for Use/Ergonomics/Human Factors, Universal Design, and so on [52, 53].

25.3 IPDP of Medical Equipment in a CE Environment

In the IPDP of medical equipment the users' values and demands and adverse external factors are included, which may relate directly or indirectly to the product development cycle, such as the discovery of new diseases or epidemiological changes, political and/or economic demands, or even demographical aspects. Nonetheless, these demands contribute to the medical field driving technological innovation and bringing new challenges in the search for solutions that can be deployed in the improvement of the functions of the medical equipment.

However, the improvement of the innovation performance lacks a conceptual framework that is able to describe the process as a whole and link knowledge with the skills and competencies necessary to control and strategically manage the product development cycle. A holistic framework would present reliability and a common language for advanced discussions and for information exchange by the teams involved in the process [32]. In this way, CE in IPDP promotes a robust involvement of multidisciplinary areas, which in this research are the engineering and the medicine, incorporating clinical, technical, operational and economic factors that ensure innovation or product evolution. It is worth mentioning that different areas influence the process, according to the competence granted in each IPDP phase, as illustrated in Fig. 25.2. The figure illustrates the PDP that consists of three stages: (a) pre-development; (b) development; and (c) post-development. In the initial stage process the medical field predominates, then decreasing during the IPDP phases and gradually attributing competence for the engineering area. Thus, after the stage of IPDP, the product should pass through the implementation, production and market launch process respectively. This period of post release is relevant because the information feedback from the market and especially the consumer's voice provides information that will serve as opportunities for improvement and product innovation [33]. This procedure also enables the improvement of product quality during the development cycle of the product.

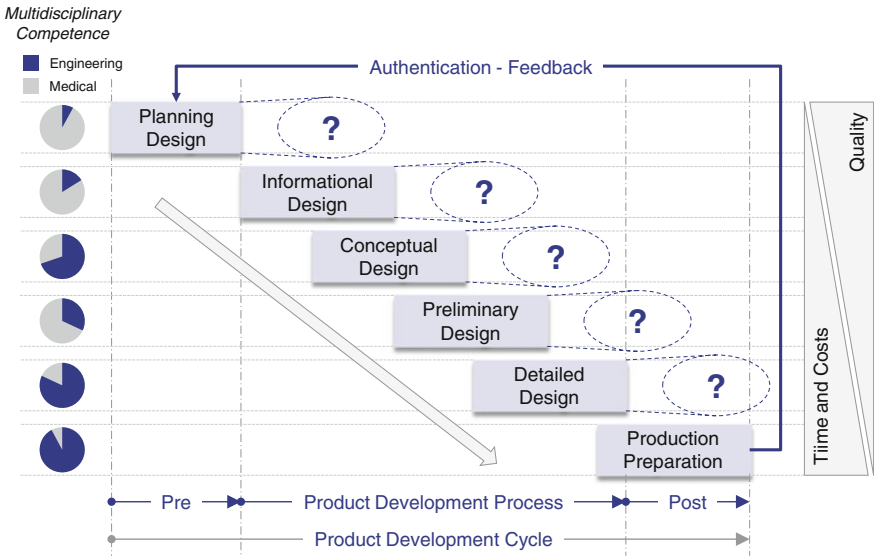

Fig. 25.2 Concurrent engineering in the integrated product development process of medical equipment

25.3.1 Medical Equipment Users

Medical equipment aims to meet the different expectations of their users. First, there are the health professionals who use or handle the equipment and need the knowledge about the equipment's operation and maintenance. Second, there are the patients who are the direct user of the equipment and are under the care of a health professional for diagnosis or treatment.

For the professional who handles the equipment, the requirements are primarily: practicality, comfort and flexibility of use, facilitating learning and ensuring the service quality to the patient, offering confidence in diagnostic procedures or treatment. From the patient point of view, the requirements focus on the comfort aspects while using the equipment and trusting in the procedures results. Health professionals seek to improve the patients' quality of life through the adequate examination procedure or treatment selection. In this context, the principles of Universal Design and Assistive Technology products provide the flexibility to meet the majority number of users and contribute to the mobility aspect of the patient with some limitation or disability [34]. Analogously, the conditions of equipment usage for the professional user such as ergonomics and usability must be considered [16, 17].

25.3.2 Pre-development Phase and Design Feasibility

The pre-development stage is the design planning, which consists of gathering relevant information from the medical area. According to [11, 24] this information is related to the design and product scope such as: (a) in the prognoses of the activities and their duration, deadlines, budgets; (b) in the definition of the responsible team; (c) in the resources needed to undertake the design; (d) in specifying the criteria and procedures for evaluating the quality; and (e) in the risk analysis and performance indicators selected for the design and product.

The Design Planning phase concentrates on the clinical information and techniques to investigate the user's need and market's demand and also to gather the first required characteristics of the product. CE investigates the user's requirements with a multidisciplinary view, identifying needs and creating opportunities for innovation and product evolution. Thus, issues of demands and market competitiveness are incorporated in the feasibility analysis that shows the design stability in the development cycle of the product.

25.3.3 IPDP Phases and Demand Factors

The design elaboration is a macro phase of Product Development and consists of the Informational Design, Conceptual Design, Preliminary and Detailed Design phases. These phases focus on the task set that is characterized by design scope, execution time, resources and risk prediction. The results of these phases respectively yield: design specifications, product conception, the technical and economic feasibility, and documentation. Some considerations for each design phase are:

1. **Informational Design Phase**: product design specifications, in which the needs of users are identified while considering different attributes: functional, ergonomic, safety, reliability, modularity, aesthetic and legal, among others [11]. This information comes from users of medical equipment. The activities of this phase include the survey and description of the tasks and actions that reveal the conditions and activity execution manner by the user [34–36].
2. **Conceptual Design Phase**: the objective is to establish the product functional structure contemplating the definition of the global function. During this phase the marketing planning has the task to monitor the market and identify the changes that may influence the development. Thus, the desirable characteristics of products is investigated considering the interactions with the users (health professional and patient), taking into account the balance of the technical qualities, ergonomic and aesthetic characteristics [37]. These features may be detailed by applying tools such as failure mode and effect analysis (FMEA) that identifies the most important component of the equipment or by using Value Analysis to determine the essential parts of the product.

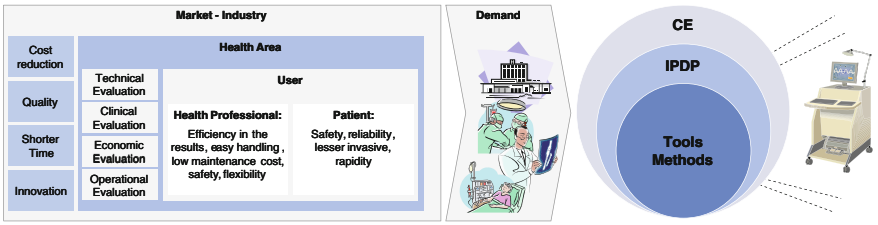

Fig. 25.3 Holistic view of medical equipment development

3. **Preliminary Design Phase**: the development team starts the design planning with updating and understanding the design specifications concerning the form, material, safety, ergonomics, manufacturing and others. At this stage, the prototype is elaborated by using resources such CAD/CAM environments that allow the three dimensions of design configuration to present practical, rapid and inexpensive solutions in the IPDP increasing product quality [38–40].
4. **Detailed Design Phase**: in this stage, the conceptual design is detailed and documented according to the engineering standards and the technical specifications of medical equipment. This detailed design is the basis for the manufacturing planning and the production line costs survey [41].

Each design phase requires strategic planning in order to find the best solutions considering the specificity of users and medical equipment. These specificities are obtained by using the design process support tools such as QFD, FMEA, Ergonomics and Usability, as illustrated conceptually in Fig. 25.3. In this context, the requirements for assembly process simplification, the reduction on the number of components, the parts standardization and the handling facilitation can be implemented using tools such as DFA, DFM, DFS, which leads to a reduction of time and costs for product manufacturing.

Therefore, during the phases of product development the more information and experiences are introduced, formalized and systematized in the processes, the higher will be the level of maturity of the IPDP, which will be reflected in the quality of the final product [42].

25.3.4 Post-development Phase and the Introduction of the Equipment on the Market

In Post-development stage, preparations for production and implementation of marketing planning is made, including the elaboration of assembly documentation, clearance for tooling construction, factory floor preparation, implementation of the production line, among others [11, 34, 41]. Thus, this phase comprehends the evaluation of product performance, comparison and adjustments in the technical

specifications. Also, the after-sales follow up services is monitored and the learning and experiences documentation for the subsequent designs is produced, what serves as a feed-back for the IPDP with the positive results, discarding the negative ones [42].

Thus, this phase is the transition from the area of engineering to the medicine, which will introduce and incorporate the medical equipment on the market. It would make the products more safety, use and maintenance technical specifications relevant and produced regarding the language for the health professional user and associated with the clinical and technical validation that results in the product performance [15, 18, 30].

25.4 Discussion on the Use of CE and IPDP Oriented to Medical Equipment

The technological level of medical equipment is in a continuous advancement due to the integration of engineering and medicine areas that contributes to success of the IPDP. The IPDP is supported by the CE environment, which manages the product development phases simultaneously, according to the expertise of each product segment. These segments are explored in IPDP through the application of engineering tools with the goal of finding the best solution that can be implemented in a modular manner (Product Family) allowing the rationalization and optimization of the IPDP phases.

However, there is a need to develop models of tools specifically oriented for the medical area, which interacts properly between areas to absorb the demands of the market. “Getting the design right means exhaustively investigating the product’s functional requirements and the users’ needs and preferences” [43]. So, further detailed studies are necessary and possible adjustments in the methods and existing tools need to be investigated to achieve a higher level of reliability and efficiency of the medical equipment [30, 44].

This association between medicine and engineering also contributes to aspects of integration interfaces in medical equipment that needs to be compatible with each other. Therefore, in view of an overall plan of the CE-oriented medical equipment, as illustrated in Fig. 25.4, the gray arrows represent the development of equipment linked directly with the information and concepts in the medicine field, which are integrated with engineering tools in the IPDP. However, there is the possibility of using this part of this knowledge to develop other products related to this area, which are showed by the white arrows [45]. Moreover, there are opportunities for new product development in different fields [46].

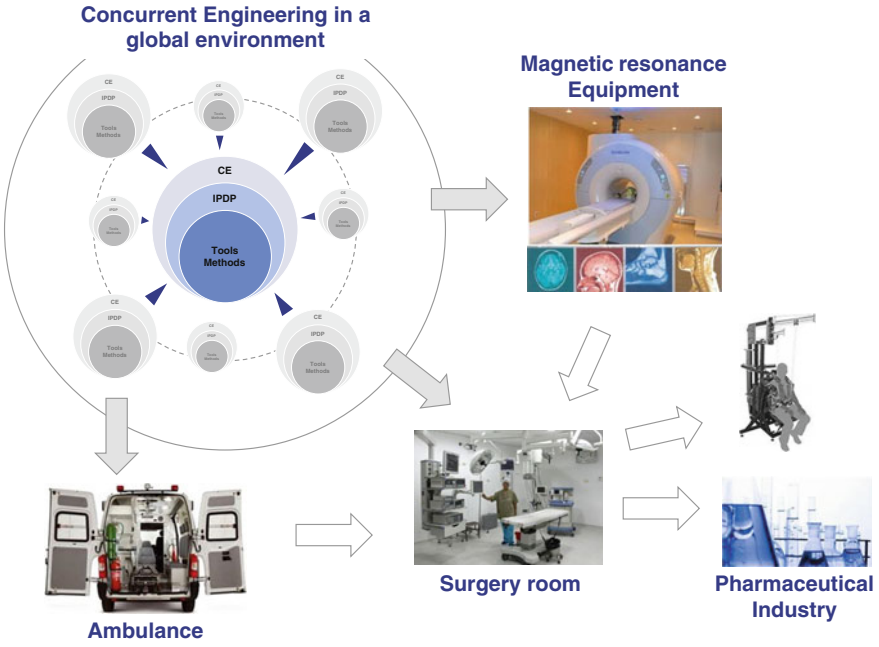

Fig. 25.4 The importance of CE in the global environment of medical equipment

25.4.1 CE and the Interfaces Between Medical Equipment

CE influences the design process through the correct dimensioning of the medical equipment conceptual structures that will be in activity jointly or in sequence of use. The IPDP structure must predict the equipment's joint activities or sequences for a good performance. In this type of interface, CE takes direct action on design activities since it allows a wide view on the operation and handling of the functions of a multi-functional equipment or even different equipment working simultaneously or sequentially in the same environment [25].

A quick and efficient operation between the equipment and/or within the same equipment depends on the professional user's decision and on the handling skill of these health processes. Thus, the user interface makes relevant the tasks and actions performed survey and the searching for interaction solutions that facilitate handling or rationalize the movements necessary to optimize the overall lead-time of their activity, safely and accurately.

The possibility of connection between medical equipment allows the appliance of auxiliary tools to complement the function or even to flexibly use different equipment, which can be selected by the professional user according to the necessity. This flexible characteristic aims to achieve adaptations and connections, which are designed in CE to develop the configuration of accessories of the equipment in the IPDP. This configuration requires a standardization of connection

parts targeting at the accessory use in different equipment or functions. Thus, in the CE environment the DFM/DFA/DFX tools can be applied with the universal principles aspect. That means considering the perspectives for the equipment easy assembly and disassembly, use and maintenance [30, 31]. The evolution of the product allows that the accessory with the highest frequency of use to be incorporated into the main unit, or even expand its functions to perform other activities in accordance with market trends.

The CE environment, because of its multi-disciplinary character, enables the interaction among distinct but correlated areas such as diagnostic medicine, rehabilitation medicine, adapted vehicles and pharmaceutical industry, among others. The proposed multidisciplinary environment for medical equipment becomes an important tool to extend the solutions, technically strengthening the IPDP and bringing improvement in technical, clinical and economic product quality.

The information, which is compatible and shared among areas, enables a deeper understanding of each field. Yet, few medical devices with the structure to encode and share information are available. Thus, there is a necessity to develop interfaces that allow compatibility among tools and methods from different areas so that, the equipment can fully concentrate the areas involved in IPDP adding clinical and technical value besides exchanging experiences, knowledge and practices [47].

25.5 The Application of IPDP Concepts on the Development of Medical Equipment—3 Preliminaries Cases Studies

This topic presents three cases studies in order to illustrate the Development of Medical Equipment throughout of IPDP concepts. The first case study explores the design methodology for geometric modeling of customized prosthesis; the second is to show the design and development of a conceptual system and device for acquisition, conversion, transmission and processing of biomedical data; and the third to illustrate a methodology to determine a suitable implant for a single dental failure.

25.5.1 Design Methodology for Geometric Modeling of Customized Prosthesis

There is a substantial need for reconstructive or replacement surgery worldwide due to mainly car accidents, accidents at the work, radical sports, genetically-based malformation and pathological and degenerative illness. The current bone replacement methods use the selection of an approximate prosthesis from a preformed selection normally made out of metal, high density polyethylene or

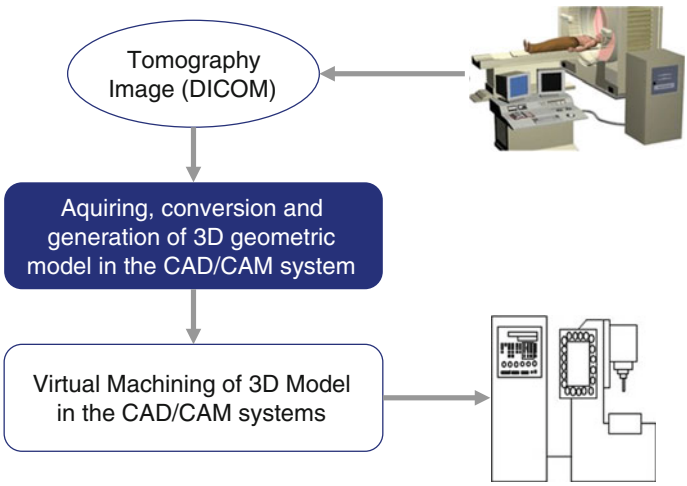

Fig. 25.5 Conception and manufacturing of prosthesis models

ceramics using the surgeon expertise or hand-making an appropriate prosthesis. It requires adjustments during the surgery process that increase substantially the surgery time and costs as well as can cause, in certain cases, traumas to the patient.

Canciglieri et al. have developed a methodology for modeling geometrically custom design prosthesis for surgical use through mathematical extrapolation of data from digital images obtained via tomography of individual patient's bones [48, 49]. Individually tailored prosthesis designed to fit particular patient requirements as accurately as possible should result in more successful reconstruction, enable better planning before surgery and consequently fewer complications during and after surgery. The methodology consists of two main functions as shown in Fig. 25.5. The first function, the focus of this research, is the acquirement and conversion of the tomography image to produce a 3D geometric model in CAD system (see Chap. 12), and the second one is the virtual machining of the 3D model generated in the first function.

To demonstrate the feasibility of virtual model creation, it was used part of a cow femur bone once it was easily purchased from a specialist supplier. The selected part allowed about 288 tomography cuts to be taken by a helicoidally tomography scan machine from General Electric Medical Systems, model HiSpeed CT. The cut analysis interval started at the CUT 100 and finished at the CUT 140. The procedures to obtain the cloud of points were: (a) removal of unwanted lines and imperfections due to the bone porosity; (b) removal of the internal edge; (c) edge detection techniques; (d) image preparation for Cartesian coordinate's acquisition; and (e) the acquisition of the Cartesian coordinates.

The data, after converted from pixels to mm, were imported into the CAD system and the repositioned planes were used in the loft command. The 40 cuts used for the reconstruction are shown in Figs. 25.6 and 25.7 is depicted the 3D solid model obtained after the appliance of the loft command in CAD system.

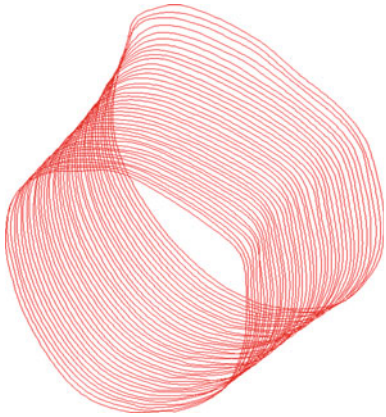

Fig. 25.6 Cuts positioned for the application of loft technique

Fig. 25.7 Application of loft command (to the parallel profiles)

To prove the dimensional results of the virtual model, the tomography femur was dimensioned. After the interval of interest was determined, three marks were made to prove the dimensioning (cuts 100, 120 and 140). The dimensioning was made through contact, at each mark, of the pointer of a 3-dimensional coordinates measure machine (DEA—Sirroco) with a certainty of 3 microns. The virtual model obtained by the methodology and the virtual models obtained by the 3-dimensional measure machine were compared at eight referential points to verify their accuracies. The results showed that, although there are some divergences points, for all three marks, the curves are very similar and overlap which effectively demonstrated the feasibility of the research's concepts. The curves are highlighted in contrasting colors: blue for the curve obtaining through the proposed methodology and red for the curve obtained through the three-dimensional machine, as illustrated in Fig. 25.8.

The authors proposed to continue the work since substantial extra research needed before these concepts could become a practical reality, such as further investigation of image processing techniques for conversion to 3D models using CAD/CAM systems.

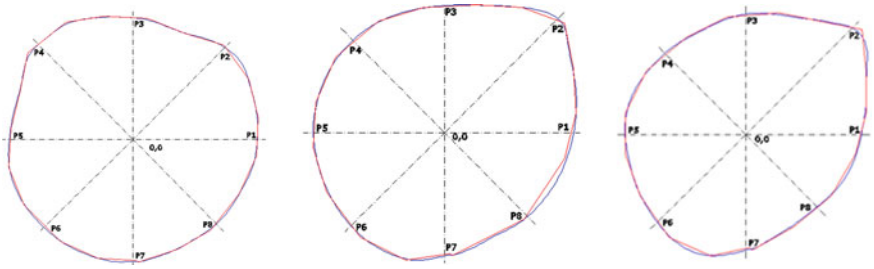

Fig. 25.8 Overlapped curves for the three sections respectively

25.5.2 Design and Development of a Conceptual System and Device for Acquisition, Conversion, Transmission and Processing of Biomedical Data

Biomedical data acquisition in real time has become more important in sports training and even in physical activities of everyday life as they can help the health or sport professionals supervise, monitoring and adjust the level and rhythm of the exercises. These data are usually acquired through specific equipment and are transferred manually to a computer to be analyzed allowing the adjustment in training to get the best performance. This system of data acquirement takes time, cost and can induce to errors since the data will be analyzed separately and not at the same time of the event/acquisition. In this way, there is a necessity for a system that is able to acquire the biomedical signals and send remotely to a computer where it will be analyzed in real time.

The integrated engineering system and a reduced size device developed by Boothroyd et al. [27] allows biomedical data acquisition operating in an integrated way: the biomedical signals are acquired by sensors and transmitted to a computer where the information is analyzed and converted into interpretative charts in real time.

The research is focused in three biomedical signals: oximetry, pedometrics and body temperature that can provide important information of how the body is responding to the training or exercises. Figure 25.9 shows the developed system for data acquisition, transmission and interpretation. The biomedical signals, in the pulse, oximeter were acquired by red and infrared light and converted into analogical and distinct electric impulses through two sensors/light receptors which were put in the index finger tip. The corporal temperature is easily obtained by the contact of the human skin with the sensor, put in the hand palm which uses the electric conductivity variation (ohmic resistance) to generate a distinct and analogical electric signal. The pedometry information was acquired by an electric switch placed inside the shoes, in contact with the sole of the foot and based in the electric switch on/off.

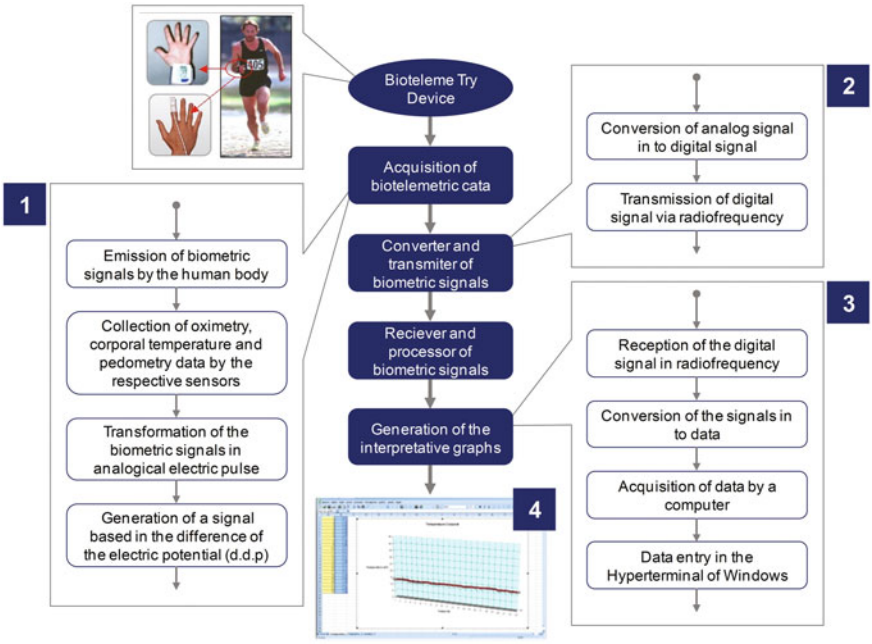

Fig. 25.9 Developed system for data acquisition, transmission and interpretation

The data obtained were analogical and needed to be converted into digital using a proper circuit (A/D) which was inside a micro controller for the radio frequency transmission (RF). As there were four distinct signals to be transmitted, they were serialized and transmitted orderly with milliseconds between them. The same process can be executed by a micro controller programmable with FLASH memory, through encoding lines. The signals enters the remote computer via serial door and can be observed, in real time, through the hyperterminal of Microsoft Windows which generates a document in text format with all the data. This document is loaded through a Macro developed by Microsoft Excel that generates a worksheet and from there, it was converted into interpretative charts. These charts can be divided in: Pulse oxymetry, showing the cardiac frequency and blood oxygenation rate in function of time; Pedometrics showing the distance and walking rhythm of the individual in function of time; and the Corporal temperature in function of time.

To validate the research, the system was applied to 5 volunteers. Tests were realized in a physiotherapy clinic with acclimatized environment using a motorized treadmill with a pre-adjusted distance of 50 m and medical supervision. From the data acquired it was possible to reach two distinct displays of interpretative charts: the first showing the relation between the pace length and the leg length,

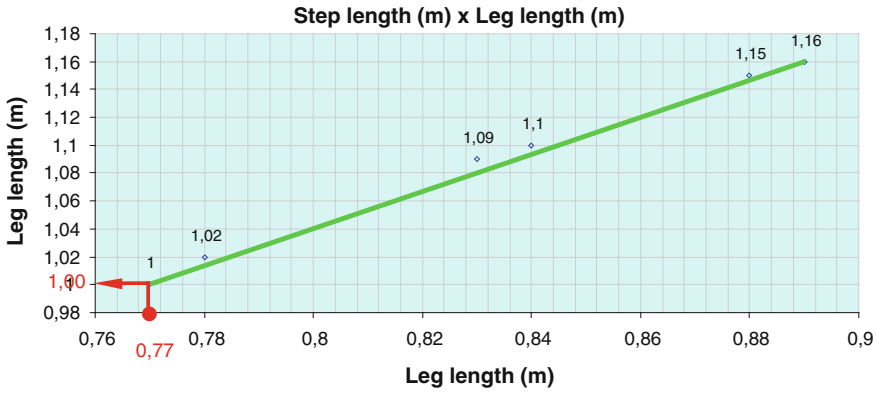

Fig. 25.10 Example of the relation between the pace length and the leg length

exemplified in Fig. 25.10; and the second showing the variation of temperature, the walked distance, number of paces, time between paces, and the oxymetry presented in Fig. 25.11.

The results showed that the developed system and device is able to obtain the information in a practical and reliable way, presenting normal standards values and not presenting significant errors. Therefore, the integrated engineering system

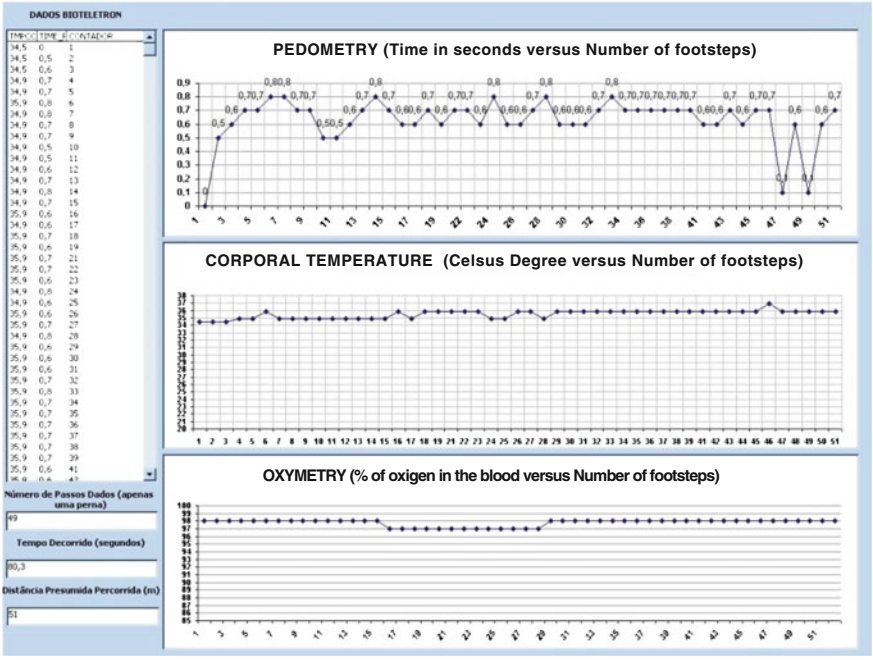

Fig. 25.11 Example of the displays presented by the device

developed to acquire, convert, transmit and process the biomedical data proved to be reliable and accurate and able to incorporate different concepts into a unique device. Further researches can be done as modifications and innovations can be implemented with the evolution of resources and tools, such as software and hardware, graphic interface or even the device miniaturization aiming the user's comfort.

25.5.3 Methodology to Determine a Suitable Implant for a Single Dental Failure

The multidisciplinary approach to achieve technological solutions in health care has improved surgical processes applying concepts of product engineering, especially in the medicine and dentistry areas. The use of CE concepts in dentistry improves the results since different points of view converge to a solution that is more reliable. Dental implant is a multivariable process that depends on the surgeon dentist expertise in most of the time. Some existing computer systems help with the visualization of CT images, but do not provide enough information for planning the dental implant process and do not support the process of selecting the implants that suits the patient best [50, 51]. In this context, a conceptual system is proposed based on techniques of medical and dental implant image processing which is able to provide support to the surgeon's decision making to define the single implant that best suits the patient [52, 53].

The dental implant selection is a simultaneous and interdependent analysis process that includes aspects as bone structure, nerves positioning, geometry of the mouth and teeth. For single implants placed between teeth, it is necessary to check the space available for inserting the implant. Figure 25.12 presents the conceptual methodological approach for determining the single dental implant, whose mark ("?") presents the necessary investigation to build an informational structure that provides support to the process.

The proposed system is divided in two parts:

(a) the product model where the requirements and specifications of all necessary information are defined to support the design system oriented on to single dental implant process; and
(b) the design system oriented to single dental implant process where the inference mechanisms for conversion, translation and sharing information between representations are defined.

The concept of inference mechanisms which are specialized systems elements capable of searching the necessary rules to evaluate and ordain logically the heuristic process of inference was used for the development of design system oriented to the process of single dental implant (DOSDI). The mechanisms for definition of the region of interest and geometric modeling of the symmetry axis and the

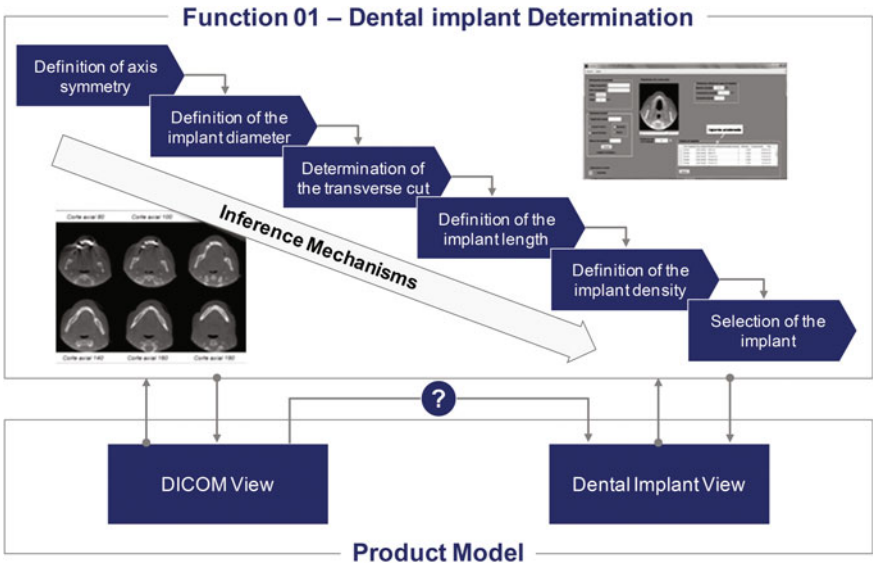

Fig. 25.12 Methodological proposal to determine a suitable implant for a single dental implant

mechanism of defining the implant diameter are responsible for the geometrical definition of the implant.

These mechanisms are intended to select the region of interest and the geometric modeling of the symmetry axis where the insertion of the dental implant occurs allowing the conversion of the axial cuts into transverse cut of this region. The definition of the region of interest is made by the oral facial dentist surgeon through observation/analysis, identifying the image that presents in detail the gaps between two teeth. The system intervenes and performs the geometric modeling of the dental arch from this image. From the region of interest is extracted only the bone information from processing these images using as segregation parameter, the Hounsfield Scale. As a result, the information of the bone geometry and the failure surrounding teeth is obtained, permitting a geometric analysis of the dental arch. Figure 25.13 illustrates a case study of a partial edentulous with a single failure in the canine region.

The geometrical analysis detects the geometrical center through the intersection of two reference lines that are based on the inner edge of the teeth failure neighbors (Fig. 25.14). This geometric center is used as a reference generating a symmetry line to the neighboring teeth which allows the extraction of the insertion center and the implant diameter as showed in Fig. 25.15.

The system delineates failure's axis of symmetry and together with the dentist it generates an accurate axis, relying only on images with an uncertainty grade of 0.25 mm, which is considered insignificant in the implantology area. The system defines the implant diameter, Table 25.1, based on the bone thickness obtained by

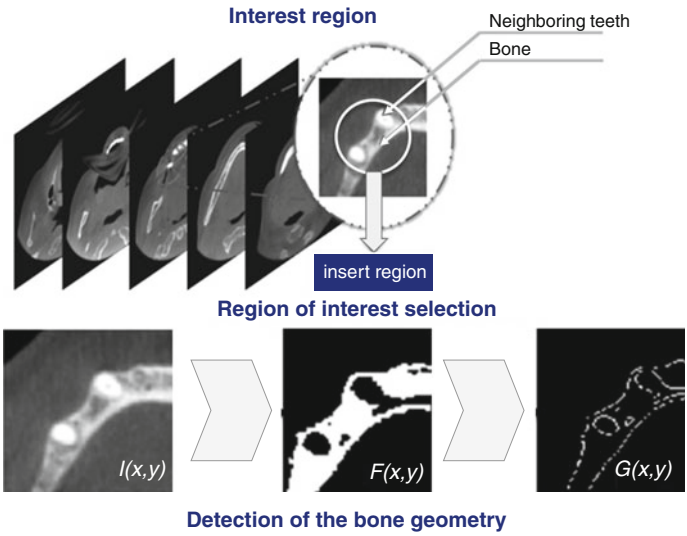

Fig. 25.13 Structure of the function of dental implant determination

Fig. 25.14 Symmetry axis construction in the dental arch

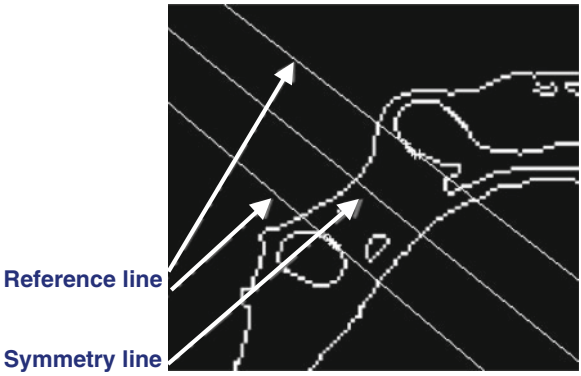

Fig. 25.15 Identification of the insertion point in the dental arch

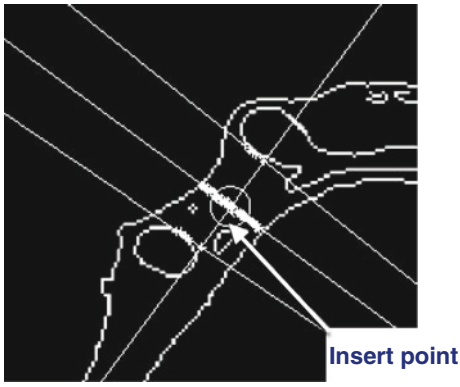

Table 25.1 Example of implant models obtained through the system

Implant body type	Implant body model	Bone density	Implant body diameter (mm)
CONE MORSE	TITA MAX CM	2	3.5
CONE MORSE	TITA MAX CM	2	3.5
CONE MORSE	TITA MAX CM	2	3.5
CONE MORSE	TITA MAX CM	2	3.75
CONE MORSE	TITA MAX CM	2	3.75
CONE MORSE	TITA MAX CM	2	3.75
CONE MORSE	TITA MAX CM	2	4.0
CONE MORSE	TITA MAX CM	2	4.0
CONE MORSE	TITA MAX CM	2	4.0
HEXAGONO INTERNO	TITA MAX IIPLUS	2	3.75
HEXAGONO INTERNO	TITA MAX IIPLUS	2	3.75
HEXAGONO INTERNO	TITA MAX IIPLUS	2	3.75

geometric modeling. For this specific case of study, it returned a selection of 12 models of dental implant that meet the design requirements delegating to the surgeon the identification of the most likely implant to be used. Since the number of implants offered by the manufacturer used in the research is approximately 150, the options were decreased by 92 % with the system turning the dental implant process more reliable.

The authors suggest for further researches the study of dental implant process in total edentulous with the construction of a guide mask and the identification of the insertion's depth as well as the drilling and threading rotation process.

25.6 Final Considerations

This study is a conceptual view on the CE philosophy importance in multidisciplinary engineering-medicine environment for IPDP of medical equipment. The level of complexity in the development of medical equipment requires the mastery of several technological areas of knowledge for the holistic design of the required product concept. The CE environment ensures the IPDP of products is oriented on health as it gives a wide view, understanding more clearly the planning aspects throughout the product life cycle.

To improve the innovation performance, it is necessary to develop a conceptual framework that is able to describe the IPDP process connecting the knowledge with the skills and competencies necessary to control and strategically manage the development cycle. So that, each design phase requires strategic planning to seek

the best solutions once it should consider the specificity of users and medical equipment. Indeed, if during the phases of product development more information and experiences are introduced, formalized and systematized in the processes, higher will be the IPDP level of maturity, which will reflect in the quality of the final product.

It is worth noting that it is necessary further studies to develop models of tools specifically oriented to medical area, which would interact properly between the medicine-engineering fields absorbing the demands of the users and the market tendencies [15]. An additional important topic is the interface development that allows compatibility among tools and methods from different fields, so that, the equipment could fully attend the requirements of the IPDP involved areas [54].

CE environment gives a comprehensive view of IPDP and enables the interaction of distinct areas due to its multidisciplinary characteristic once it takes in consideration the users' demands and desires as well as the market tendencies for high technological equipment with lesser invasive procedures and better technical, clinical and economic quality [30, 55]. Therefore, CE in the IPDP of medical equipment contributes for medicine and engineering areas evolution since it conducts the technological and clinical innovation and brings new challenges in the searching for solutions to contemporary health issues [56].

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