16

Enhancing Product Development through CT Images, Computer-Aided Design and Rapid Manufacturing: Present Capabilities, Main Applications and Challenges

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1. Introduction

1.1 Historical perspective of product development methodologies

It is difficult to find the origins of what we call "systematic design". To offer but one example, anyone studying the diagrams and sketches of Leonardo da Vinci can hardly fail to observe the depth of his analysis and how he systematically used variations to suggest possible solutions and be able to compare them (Taddei, Kaiser, König, 2006, Bautista, 2007).
Up to the Industrial revolution, product design and development work was essentially linked to art and craft and only with the gradual mechanization of processes halfway through the 19th Century did a need begin to emerge to optimize the use of materials and perform detailed studies on strength, stiffness, wear, friction, assembly and maintenance (Reuleaux, 1875).
However, it was not until the 20th Century that a systematic evaluation of these parameters was put forward as a way of gradually reaching an optimal solution. (Erkens, Wörgebauer).
Just before the Second World War a need was beginning to be noticed to rationalize product design processes but progress in this direction was hampered by the following factors:

- An absence of effective methods for representing abstract ideas.
- The widespread belief that design was an art and not a technical activity that could be carried out methodically and not just through creativity.

A large-scale use of systematic design methodologies would have to wait for these limitations to be overcome and for the introduction of a more widespread use of automation and the appearance of more modern data processing procedures.
Modern ideas on systematic development were given an enormous boost by relevant figures (Kesselring, 1951, 1954, Tschochner, 1954, Matousek, 1957 or Niemann, 1950, 1965, 1975), whose revolutionary ideas continue to suggest ways of solving and dealing with specific tasks related to machine and product design processes (Kaiser, König, 2006). During the 40s and the 50s Kesserling put forward a method based on successive approaches where each approach optimized different variables in line with technical and economic criteria. He also proposed several principles like "minimal production costs", "minimal weight and

volume", "minimal loss" and "optimal functionality and operability". On the other hand, in the 50s Tschochner emphasized the importance of four basic design factors: the principles of functionality, material, shape and size, similar to what Matousek would later do, but emphasizing the need to consider: the principles of functionality, material, manufacture and geometry. Niemann's approach designed in the 60s and 70s consisted in starting out design by defining a general outline for the product with the main sizes to be worked on in greater depth. To this end, the overall design continued to be divided into different parts that could be developed in parallel. The optimal solution was finally reached by a systematic variation of all the possible solutions.

These progressive approaches towards ever more systematic methodologies for product design were mainly performed by university lecturers who had learned the fundamentals of design and development during their practical class contacts with increasingly complex products. They realized that not only was it possible to apply more mathematical concepts, physical principles, information theory-based methods and systematic design, but that with the gradual increase in the division of work it was becoming indispensable. Their designs were evidently strongly influenced by the industries they worked for, but many of their principles suitably modified can be adapted to numerous cases of design in other sectors. The currently accepted principles for effectively carrying out new product development are based on the ideas of the foregoing authors, as well as on the series of design steps that subsequently set apart important researchers (Hansen, 1956, Wächtler, 1967 o Kuhlenkamp, 1971). In general terms, these researchers talk of "pre-studies", "defining the basic principle", "basic design" and "detailed design" as the main stages. They are also listed in "design guidelines" written by organizations like the "VDI – Verein Deutscher Ingenieure" or the "ISO – International Organization for Standardization" in reference to global testing and quality management.

1.2 Stages of a product's systematic development process

The outcomes of previous research, satisfactorily proven through numerous developed products, led to a slightly modified work structure (Roozenburg, Eeckels, 1995, Pahl, Beitz, 1996, Ulrich, Eppinger, 2007) which included: planning, conceptual design, basic engineering and detailed engineering, although a clear dividing line cannot always be set between these stages.

Defining objectives and planning.- This broadly consists of the strategic decision taken by a company, university or research centre as to which products or ideas must be developed to satisfy the new social needs, taking account of the scientific-technological and socio-economic circumstances of the time. To set about a product idea that will be successful the state of the market has to be fully understood and especially customers and their needs. Thus, market and customer requirements become the major stimuli for developing new products. However, these stimuli frequently have other origins, the most important of which are politics, the appearance of new technologies, processes, materials, discoveries or research results and environmental issues. Neither should the role played by internal stimuli be underestimated (arising in the company, university or technology centre itself) when it comes to making a decision about a new product. Among these internal stimuli are new ideas or outcomes related to research activity and the implementation of new means of production as well as production being made more rational and diversified. Depending on the stimuli mentioned, the main tasks to be included in the "defining objectives and planning" stage are:

- Situation analysis.- By carrying out an in-depth study of the company and its products, together with market analysis and other possible information sources, a thorough analysis can be reached of the starting out point.
- Drawing up search strategies.- By bearing in mind the companies' aims, strengths and weaknesses, as well as market gaps and needs, certain areas or promising fields can be discovered where ideas can be sought to be applied.
- Finding product ideas.- From the search in the chosen field for new applications, functions, principles of functionality, geometries, materials, energy management methods and other alternatives, a set of product ideas can be found.
- Choosing product ideas.- Depending on the company's aims and market needs, the set of ideas found are evaluated in order to choose the most attractive product idea.
- Defining the product to be developed.- By evaluating the different alternatives against a list of requirements a product proposal or definition is reached together with some initial objectives concerning costs, prices and schedules.

Conceptual design.- This is the stage where a decisive global principle is reached or a basis for reaching a satisfactory solution based on identifying crucial problems and choosing the right functional principles that in combination will attain the set objective. If this stage is to be properly tackled a series of prerequisites must be fulfilled linked to a correct conclusion of the previous stage. The objective must therefore be clearly stated and, in principle, be technically and financially viable. In addition, the designer must be informed of the needs of this conceptual design stage and the existence of possible solutions that allow proceeding directly to the design or basic engineering stage. The scope and depth required for the conceptual design stage must also be pre-established. Related to the above, the main tasks included in this stage are listed below:

- Abstraction for identifying basic problems.- The decisive designs and principles based on traditional methods cease to provide optimum responses in the face of scientific-technological advances concerning technologies, materials or procedures, which when used in combination usually provide the key to more effective new solutions. On the other hand, every industry, company or research centre has countless experiences, which, although valuable, can lead to prejudice and hinder the creative process. For this reason, particularly at the outset of a new product design, designers must make an effort of abstraction and distance themselves from the influences of conventional ideas and focus on analysing the list of requirements and setting out the fundamental problem or problems in an objective manner.
- Setting functional frameworks.- Having set out the basic problem to be solved, a global function must be obtained based on energy flows, mass and signals so that a relationship between the inputs to, and outputs from the plant, machine, part or object to be designed can be established. This global function can then be divided into less complex sub-functions and a lower level of abstraction, all of which can be individually dealt with to facilitate the search for solutions. Combining and relating these sub-functions leads to the so-called functional framework. It is advisable to draw up several functional frameworks depending on whether it is wished to optimize costs, functionalities, quality, development time or other factors.

- Designing functional frameworks.- After establishing the different functional frameworks the principles of functionality for each of the sub-functions need to be sought. When they have been found, they should be properly interconnected to produce all the different possible functional frameworks that fulfil the global function. In line with the different preferences (cost, timeframe, quality and others) a table of choices can be made to choose the most suitable functional frameworks.
- Obtaining the decisive principle.- By taking the functional frameworks the different decisive principles to be evaluated can be obtained based on the different techno-economic criteria and preliminary calculations that can lead to the choice of the most adequate decisive principle (proposal for a preliminary solution or product concept) that can be worked on.

Basic engineering.- When the decisive principle has been arrived at it is time to specify the underlying ideas behind this preliminary proposal for a solution or product concept. During the basic engineering stage (also often called basic design) the design engineers have the task of defining the basic shapes and geometries that characterize the product, and must also choose the preliminary materials and appropriate manufacturing processes. It is at this stage when technical, technological and economic considerations become of vital importance. In other words the mission of this stage is to provide a definitive general outline of the product to be developed, on which an effective analysis can be performed concerning: function, duration, manufacture, assembly, functionality, costs and safety.

Unlike the conceptual design stage, the basic engineering stage is subject to numerous checks, which means the work of analysis and synthesis constantly alternate and complement each other. An enormous effort also needs to be made regarding the compilation of information to make it easier to evaluate solutions, identify errors and continuously optimize.

The complexity of this stage is also greater because many actions have to be performed simultaneously. Sub-tasks need to be repeated when high levels of information are reached and because any change in an area or sub-area has repercussions on all the rest. For these reasons, it is impossible to set a series of steps to be strictly adhered to that will ensure the basic engineering will come to a successful conclusion. However, the following approach may be followed in general terms:

- Choose the requirements that are crucially important in the basic engineering stage.
- Make scale drawings with the existing spatial constraints and evaluate the required free spaces.
- Draw up a basic outline to decide which components will be required to fulfil the main functions.
- A preliminary design of the parts and components that fulfil these main functions.
- Draw up a basic outline to decide which components will fulfil the remaining secondary functions.
- Draw up the preliminary designs of parts and components that fulfil these secondary functions.
- Evaluate the designs using both technical and economic criteria.
- Decide the overall preliminary design.
- Optimize the chosen design, eradicating any weak points that may have arisen during evaluation.
- Make proposals for improvement and checking if cost and quality objectives are met.

- Prepare a basic preliminary parts and documentation list for production and assembly. This documentation comprises the starting point for the detailed engineering stage.

During the basic engineering stage it is very useful to use check lists to ensure that when designing the different parts intended for the main product functions, all the various aspects have been taken into account. Of these aspects the most important are:

- Function.
- Principle of functionality.
- Design.
- Safety.
- Regulations.
- Ergonomics.
- Manufacturing.
- Quality control.
- Assembly.
- Transport.
- Operation.
- Fault detection.
- Recycling.
- Maintenance.
- Cost.
- Timescale.

Alongside this stage as part of the work to compare designs and check geometries and functionalities, it is very useful to produce prototypes that will aid decision-making and help reduce the number of design iterations and minimize both the timescales and costs associated with product development. Currently a distinction is made between virtual prototypes, the result of computer-aided design, simulation, calculation and manufacturing programs ("CAD-CAE-CAM" programs) and physical prototypes that coincide with the traditional concept of "original product sample for testing and checking".

The appearance of support "software" for engineering design work and its gradual incorporation into industry since the end of the 80s, together with growing operational and calculating capacity, have caused major changes to the way design processes are carried out. Information exchange has become easier enabling countless effects in combination to be taken into account using multivariable simulations and enabling forecasts to be made concerning the influence of parameters such as the material or the manufacturing process on the end quality of a part or product. All these "software" tools can be included in a set of computer tools for managing the life-cycle of a product or "PLM programs – Product Lifecycle Management" (Stark, 2004, Saaksvuori, 2008). These capabilities enable a company to effectively manage and develop their products and related services throughout their economic life. All companies also need to manage the communications and information with their customers ("CRM tools or programs – Customer Relationship Management"), with their suppliers (programs called "SCM – Supply Chain Management") and company resources (programs referred to as "ERP – Enterprise Resource Planning").

These three groups of software programs together with the PLM programs complete the four cornerstones of the information technology infrastructure that enable the main needs of a company to be addressed. More directly linked to product development in line with the approach taken here, PLM tools that include the following types of software programs come to the fore for performing tasks like:

- PPM - Product and Portfolio Management.- These are programs aimed at helping determine the optimal combination or sequence for the projects proposed for the company to successfully achieve it objectives in accordance with its economic and technological strategy and actual market requirements. These tools help analyse resources, costs, investment, production schedules and how one project affects another.
- CAD – Computer-Aided Design.- These programs support design engineers, architects and other design professionals in their work, which is to make their designs a reality. They usually have 2D and 3D drawing systems for creating files or have all the information on a product's geometry and its different parts, as well as its plans. Changes can be made, symmetries are included, scale designs and numerous operations that can help make changes to the design.
- CAE – Computer-Aided Engineering.- These computer programs allow simulating designs that have usually been made with CAD programs, and apply kinematic, dynamic, thermal or fluid mechanics considerations to the geometries designed and, above all, the chosen materials. They allow analysing how changes will affect the product or its parts and help optimize the number of prototypes or tests required.
- CAM – Computer-Aided Manufacturing.- These programs lend support to prototype manufacturing work and end products by converting the information on part geometry from a CAD program into a code that can be understood by numerical control, manufacturing or rapid prototyping machines. On occasions it has a similar mission to CAE programs, letting part quality be simulated according to the manufacturing process used as well as allowing a study on geometries and materials.
- PDM – Product Data Management.- These are programs focused on facilitating the records and paperwork of the processes to create modify and revise any of the parts of a product. The information stored ranges from specifications, CAD file diagrams, plans, manufacturing documents, assembly documents, tenders, test specifications and quality control, as well as financial reports.

In recent years the boundaries between these types of software are shrinking with the ever more frequent appearance of packs that combine different modules to provide a global response to all the aforementioned needs. As explained, these technologies can provide assistance at every product design stage as well as production start-up, market placement and after-sales services, up to the product's life-end. The benefits of using them become obvious at the basic engineering stage where their use is even more justified in the detailed engineering stage where the amount of information handled increases rapidly, as will be explained further on.

Regarding prototypes, the industrial importance acquired over the last decade by the so-called "manufacturing and rapid prototyping technologies" should be emphasized. These technologies enable physical parts to be directly obtained in a short time (hours or a few days) from the designs made with the help of a computer using "CAD-CAE-CAM" programs. They are of great help in optimizing design iterations, help the early detection of errors and speed up production start-up. They are usually either based on "Layer Manufacturing Technologies" (like Laser Stereolithography or Selective Laser Sintering) or on material elimination manufacturing processes (high speed numerical control machining). The different technologies available mean that prototypes can be obtained in a wide range of metal, ceramic and polymeric materials with remarkable precision (Freitag, Wohlers, 2003, Kucklick, 2006, Lafont, Lorenzo Yustos, Díaz Lantada, 2007, 2008).

Depending on the objective and the similarity to the end product, the physical prototypes are usually divided into the three following levels:

- Level "A" prototypes (commonly called "A-samples").- These are demonstration prototypes for analysing shapes, geometries and other more subjective aspects (like aesthetics, visual impact or ergonomics) related to the product under development.
- Level "B" prototypes (commonly called "B-samples").- These are functional prototypes intended for checking the behaviour of different product parts and their functionalities. Although they are generally made of non-final materials, these tests are usually performed with limits on certain applications.
- Level "C" prototypes (commonly called "C-samples").- These are prototypes with similar materials and behaviour to the end product although the manufacturing methods used to obtain them do not coincide with the methods used in production. These level "C" prototypes are usually manufactured for final checks, to prepare production start-up and for obtaining official approval as part of the detailed engineering stage which will be dealt with further on.

However, the end of the basic engineering stage and the beginning of the detailed engineering stage cannot be precisely delimited as there is always some overlap that is to the benefit of the overall process.

Detailed engineering.- Once the final basic design has been obtained, work must be begun on the requirements of the shape, properties, size and tolerances of the different parts. The final choice of manufacturing and assembly must also be done as well as final cost evaluation.

The outcome of this stage is the definitive technical specifications of the product: a list of functionalities, production plans and the specifications including the instructions for assembly, disassembly and operation.

Based on this information or technical documentation, production start-up can be undertaken as well as the placing of the product on the market. According to the above, detailed engineering work can be divided into the following:

- Finalizing the end design.- The different parts are fully defined by means of plans or 3D geometry CAD files, and materials, tolerances, adjustments and other details are specified.
- Parts integration.- By means of full comprehensive plans or CAD assembly files which define the product as a whole.
- Finalizing paperwork.- For an unambiguous definition of the product and be able to launch production.
- Final checks.- As to compliance with general regulations and company standards. Precision of size and tolerances, the availability of standard or catalogue parts and other checks.

The basic and detailed engineering stages can often be brought together in one single design stage with a global focus where the level of detail is gradually added. The ever more generalized use of CAD-CAE-CAM technologies and the already mentioned PLM tools has promoted this gradual fusion between stages, which also simplifies any information exchange between the agents involved in product design.

In this chapter we will concentrate on the advantages and novel possibilities that CT imaging technologies have helped to introduce into the area of product design and development. We will analyse in the following sections the novel possibilities of CT-aided product development, as a complement to the aforementioned "CAD-CAE-CAM" and rapid prototyping tools, and the implications of computed tomography in all the stages of product lifecycle. The main application fields and some case studies will be provided, so as to give a wider panorama of the related advantages.

2. New possibilities: CT-aided product development

The remarkable advances of the last decades in the different systems of medical image acquisition (mainly computerized tomography, Doppler echography, magnetic resonance and positron emission tomography) have considerably increased the diagnostic capability of these systems as well as the reliability of the diagnoses based on these data and the ensuing decisions made regarding the therapy to be applied.

Computerized Axial Tomography (CAT- Scan) resulted from the research of two teams. One team led by Dr. Alan McLeod Cormack (who disclosed the theoretical formulation in 1962, 1963 and 1964) and the other by the engineer Godfrey Newbold Hounsfield (who built the first prototype in 1971), for which they received the Nobel Prize for Medicine in 1979.

The conventional CAT provides axial planes of the body by way of sections of a quality that is often higher than anatomical slices. This is achieved by using the simultaneous rotation of the tube producing the ray beam and the corona detectors. A computer calculates the dose absorbed at the different points of the slice during the rotational motion of the whole system, which displays an image on a screen.

Since the first TAC images in 1976, different generations have appeared in the search for ever faster processing speeds and better image quality while attempting to obtain reconstructions on other different axial planes that are of an acceptable quality, with a larger number of detectors and shorter study times.

Thanks to the important advances in hardware during these years a new computerized tomography (CT) has been developed, helical CT (HCT), which uses the continuous rotation of the detector and the X-ray source in combination with the continuous movement of the examination table. With this method of examination 100% of the time is put to use. Moreover, with this system, data capture is not slice by slice as in axial CT, but results in the entire volume being captured so that slices can be reconstructed in all three dimensions of space. Combining this new hardware with the progress in software for processing the images taken enables more efficient diagnoses to be made from the more realistic and exact reconstructions achieved with 3D textures and images. An HCT 64 detector model was used for this work due to its having the precision required for subsequent customized design.

In fact, medical circles are now benefiting from the ability to exchange information from different medical image acquisition systems between centres and researchers. This is due to the "DICOM" (Digital Imaging and Communication in Medicine) standard having been set up and its now generalized use as a working format for a range of three-dimensional image reconstruction software, particularly since the introduction of version DICOM 3.0 in 1993.

As an additional development tool, "Mimics" (Materialise NV) and similar programs have also appeared which not only perform three-dimensional reconstruction from medical images but also carry out simple operations on these reconstructions and convert them to other formats that can be accessed by "CAD-CAE-CAM" computer-aided design, engineering and manufacturing programs. These "CAD-CAE-CAM" programs (Solid Edge, Catia, NX-5, I-DEAS, Rhino, Solid Works and others) form a wide range of computer tools that are at the service of engineers, architects and design professionals, as has previously been explained regarding modern product development methodologies. The power of these software packages together with their ability to manage information from medical images as a basis for design, means that at present, customized designs, specially for the medical device industry, can be designed in a matter of hours, while comparing alternative designs is also made easier (Hieu, 2002, Harryson, 2007).

However, the use of customized designs, products, prostheses or implants has been historically sporadic, practically always the fruit of research projects. This is basically due to problems of cost and timescale which have always prevented these customized products, prostheses and implants from competing with standard mass-produced designs.

Nonetheless, in recent years "rapid prototyping" has also led to reduced timescales and costs by manufacturing parts directly from the information on their geometry stored in the files of "CAD-CAE-CAM" programs or Mimics and to the advent of new capabilities for a customized response in the product development industry, with a social impact that is likely to be highly positive (Schwarz, 2005, Kucklick, 2006).

There are several softwares, for handling the information obtained from medical imaging technologies, and enabling computer-aided design, engineering and prototyping tasks. They are usually referred to as "Mimics-like" programs (due to the relevance of Mimics (Materialise NV). Among such programs, due to their industrial impact and quality of results, it is important to mention at least:

- Mimics (Materialise NV), for general purpose applications.
- Simplant (Materialise NV), especially oriented to Odontology.
- Surgiguide (Materialise NV), especially oriented to Odontology.
- 3D Doctor, for bone modelling from CT scan and soft tissue from MRI.
- Analyze (Mayo Clinic), for handling images from MR, CT and PET.
- MRIcro Software, for converting medical images to SPM friendly Analyze format.
- Biobuild, for converting volumetric imaging data to rapid prototyping file formats.
- Volume Graphics, for general purpose applications.

Listed below are the main applications of computerized tomography, together with software for processing medical images and "CAD-CAE-CAM" tools, for optimizing product design and development activities:

- Personalized and special designs (Bibb, 2000, Chang, 2003, Díaz Lantada, 2010).
- Reverse engineering, modular developments and design optimization (Flisch, 1999, Vasilash, 2009).
- Object reconstruction (Effenberger, 2008, Vasilash, 2009).
- Prototyping and trials (Flisch, 1999, Effenberger, 2008).
- Inspection of inner details and defects during manufacturing processes (Losano, 1999, Effenberger, 2008).
- Inspection of inner details and crack propagation during service life (Losano, 1999, Effenberger, 2008).
- Multipurpose non-destructive evaluations (Losano, 1999, Effenberger, 2008).

These technological combinations provide novel ways of tackling the design process, but also for validating manufacturing processes and verifying service life. It is very important to mention that the whole process is economical and non-destructive. In addition CT allows inner details and defects to be registered, which proves to be a great advantage when compared with other monitoring processes, such as three-dimensional laser reconstructions or surface ultrasound-based examination technologies.

Figure 1 includes a schematic description of the main applications of computerized tomography for product design and development, taking into account the whole lifecycle, from the design stage to the end of product life or replacement by novel products. The different typical formats conventionally used are also included in the diagram, taking into account the related studies and software for design, calculation or manufacturing.

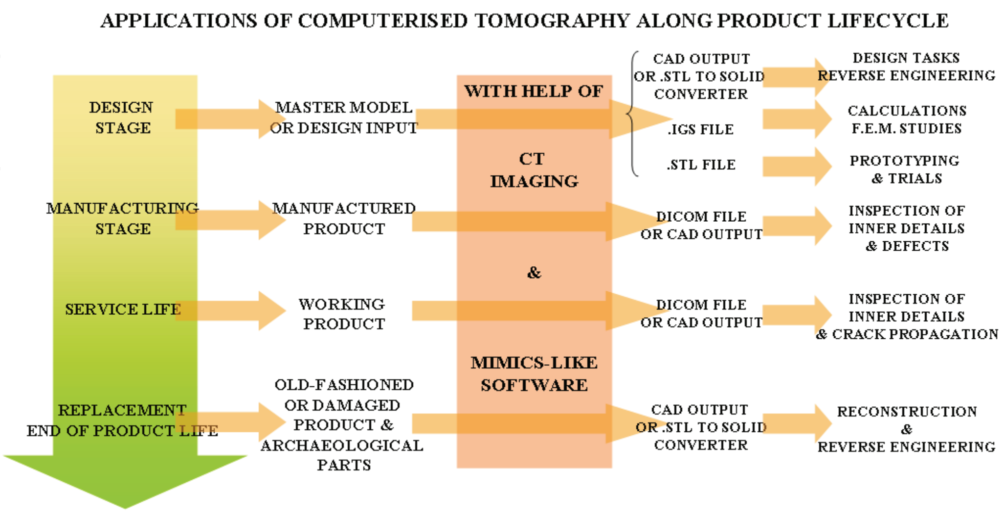

Fig. 1. Schematic review of applications of computerized tomography for product lifecycle.

The combined use of such technologies is of recent appearance; in fact, the main evolution has been registered in the last decade, as Figure 2 shows. The Figure represents the evolution of “ISI Web of Knowledge”-indexed publications related to the use of computed tomography for promoting product development activities, such as design, calculations or engineering and prototyping.

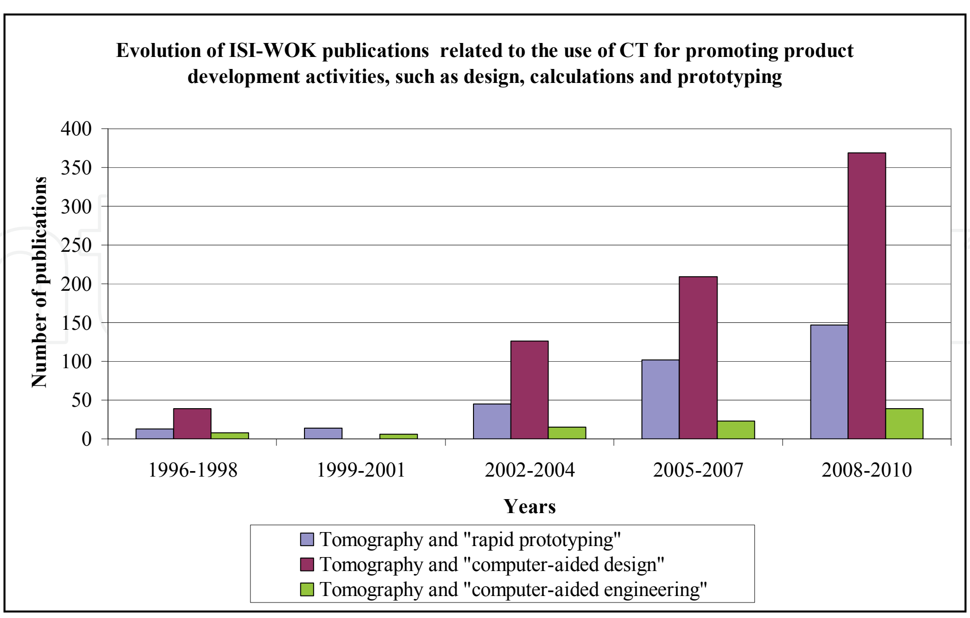

Fig. 2. Evolution of ISI – Web of Knowledge publications including the combination of “tomography” with “rapid prototyping”, with “computer-aided design” and with “computer-aided engineering”.

All these novel possibilities and applications can be included or described under the terms "CT-aided engineering" or "CT-aided product development". The main application fields of these technological combinations focusing on product development are discussed further on in the following section.

3. Main application fields

The first approximations, around 15 to 20 years ago, linked to using computed tomography as a support tool for product design and development correspond to the industry of personalized medical prosthesis and devices, as well as to some studies linked to the prototyping of human body structures for subsequent surgical planning and training tasks. As the main applications of computed tomography imaging have always been within the medical field, it is normal that the first experiences connected to CT-aided product development would be related to the development of medical devices or surgical support tools. However, during the last decade, the application fields have greatly expanded and there are examples of remarkable CT-aided product design and development case studies in sectors such as the plastics processing industry (Reinhart, Losano, 1999), the automotive sector (Vasilash, 2009), the medical device area (Bibb, 2000, Díaz Lantada, 2010), with especial growth in dentistry and oral surgery (Chang, 2003) and other industries (Filsch, 1999). There are even application experiences related to archaeology and art (Vasilash, 2009), including remarkable teaching consequences and proposals.
For a more detailed analysis regarding the main application fields of CT in product development, searches of the main scientific publications related to ["tomography" and "rapid prototyping"], ["tomography" and "computer-aided design"] and ["tomography" and "computer-aided engineering"] were carried out. Such mentioned searches were done in September 2010 using the capabilities of ISI – Web of Knowledge databases and the main results are shown in Figures 3, 4 and 5. Of course, computed tomography is not the only imaging technology of application for promoting product development activities and we have to mention other possibilities, such as obtaining information from laser digitization or

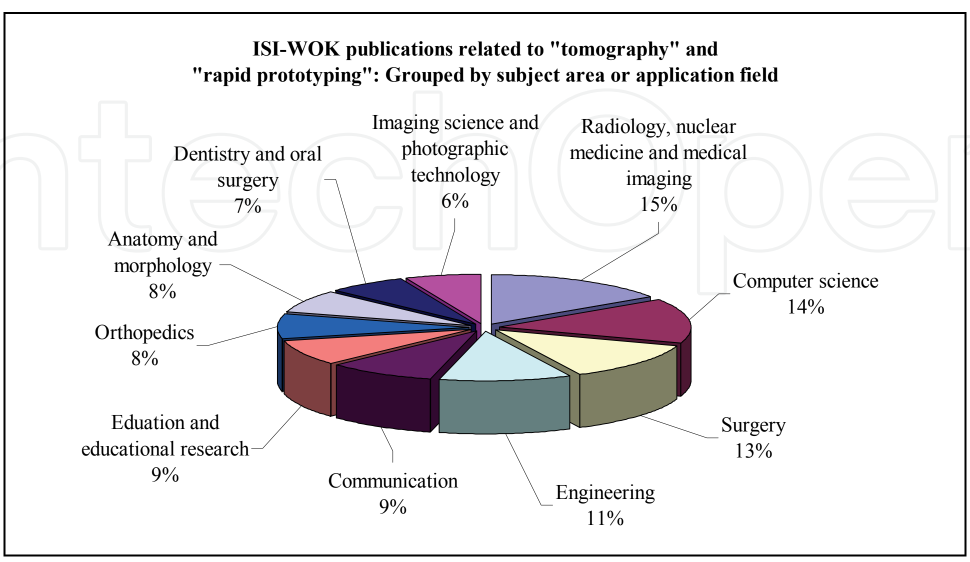

Fig. 3. ISI – Web of Knowledge publications with main topics "tomography" and "rapid prototyping" grouped by subject area or application field.

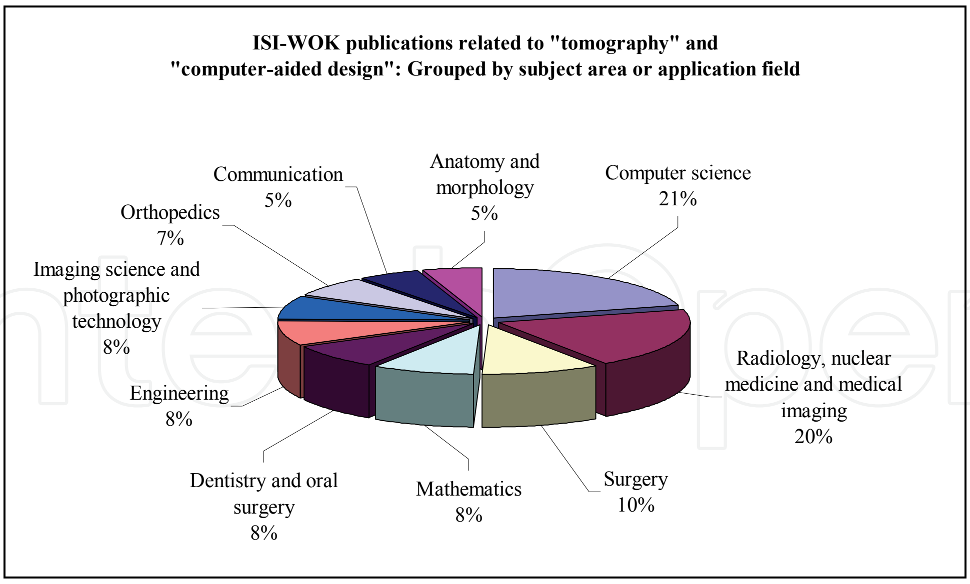

Fig. 4. ISI – Web of Knowledge publications with main topics "tomography" and "computer-aided design" grouped by subject area or application field.

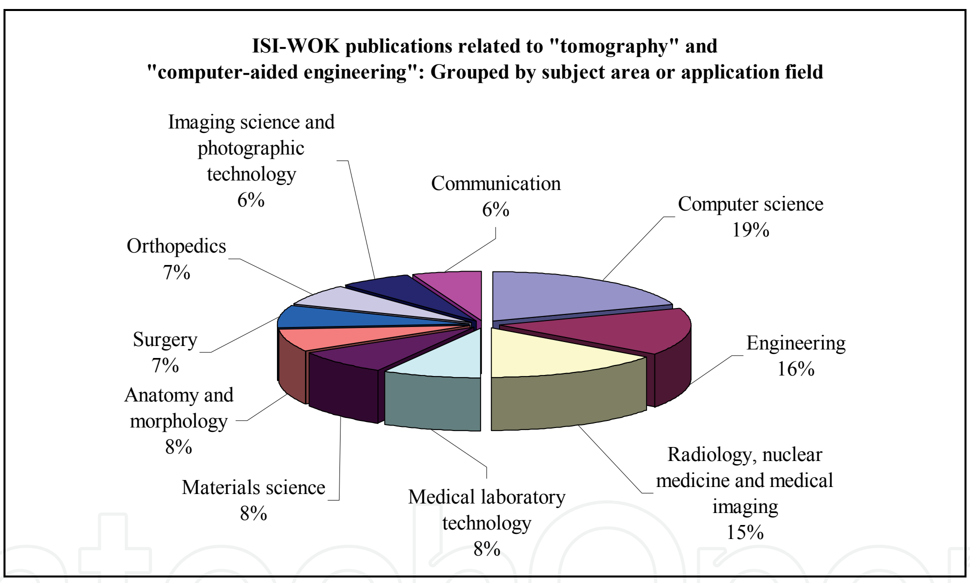

Fig. 5. ISI – Web of Knowledge publications with main topics "tomography" and "computer-aided engineering" grouped by subject area or application field.

using information from nuclear magnetic resonances and even positron emission tomography. A more detailed comparison between the capabilities of these technologies is included in the section regarding "Challenges and Future Trends".

Medical applications are most relevant according to all statistics, covering around 45 to 65% of applications, when considering surgery, orthopaedics, dentistry, radiology and anatomy together. Engineering studies (mainly related with product development, computer science and materials science) cover around 25 to 39% of applications of tomography combined with rapid prototyping, computer-aided design and computer-aided engineering, which is also an important number. Among medical applications there are several examples of publications regarding fields such as surgical training, medical device development,

development of diagnostic models and even development of models for teaching activities. Among engineering applications, the most important advances based on CT-aided processes correspond to the automotive and aeronautic industries.

4. Case studies: CT applications in product development

This section provides a couple of case studies, linked to the development of several prosthetic devices, regarding the use of computed tomography for enhancing personalized product developments. Traditionally, references of CT application to the design of personalized devices have been more linked to source images from hard tissues, but novel advances on quality and precision of the CT equipment also provide remarkable possibilities for designing prostheses adapted to soft tissues. Both approaches are compared further on, showing the design process of a hip prosthesis (including an evaluation of its influence on the patient's femoral structure) and explaining the development of a prosthesis adapted to cardiac tissue.

4.1 Design of personalized prosthesis adapted to hard tissue

The case study set out in this subchapter as an example details the process for producing a customized hip prosthesis design from the information from medical images. The aim was to produce a non-cemented prosthesis where the metal part is pressure-mounted inside the femur and must therefore be made to fit the available space. The design was made in the Machine Engineering Division of Universidad Politécnica de Madrid (www.upm.es) with the aid of the available CAD-CAE-CAM technologies. More detailed information may be found in the references (Osuna, 2008, Ojeda, 2009).

The usual procedure for carrying out a customized examination with a view to using a prosthetic device usually begins either by taking a computerized tomography - CT or a nuclear magnetic resonance - MRI / NMRI of the patient needing the prosthesis. Then, with the aid of .dicom or .dcm (Digital Communications in Medicine) format, the information from the CT or MRI can be transferred to a program such as "Mimics", so that it can be displayed in 3D, as Figure 6 shows. These programs usually include modules that allow selecting part of the patient's bone geometry and storing it in .stl or .igs formats that can be read by other CAD programs after processing the images "slice by slice". Having selected the relevant part of the patient's femur (in this example, the internal cavity to which the metal part of a customized prosthesis must be adapted) this three-dimensional geometry can be transferred to a format that is valid for a design program and this femoral zone can be used as the basis for a customized prosthesis design, as can be seen in Figure 7 (Ojeda, Osuna, Lafont, Díaz Lantada, 2009).

Fig. 6. 3D reconstruction of hip joint based on the information from CT images.

Mimics software for computer-aided designs based on medical images.

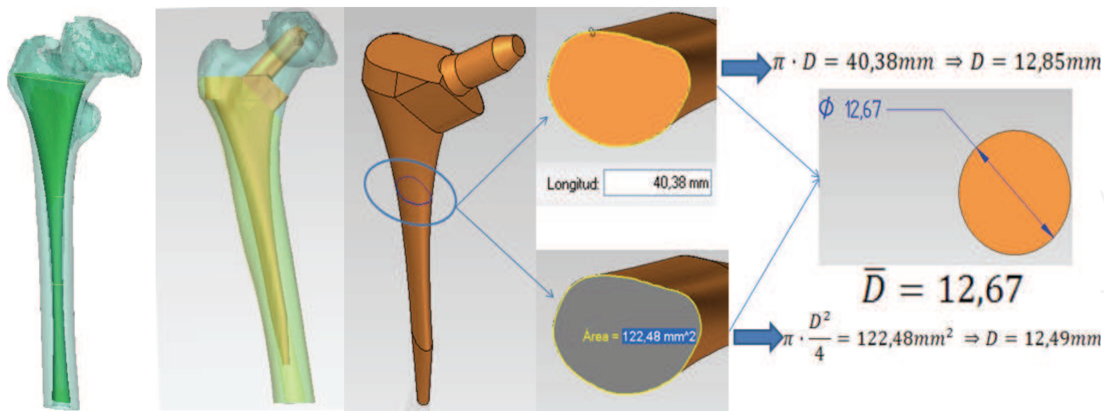

Fig. 7. Example of personalized prosthesis designed from the information of CT images.

4.2 Mechanical studies of body structures regarding the development of prostheses

Taking the designs produced by CAD programs, geometries can be converted into files that are recognized by CAE programs, that is, computer–aided calculation to which the finite elements method can be applied as a simulation tool for verifying that the designs are adequate for the in-service loads to be borne by the final product.

Until just a few years ago, this conversion was not always direct and the use of .igs or .stl formats led to some loss of information. However, the most widely-used CAD design programs are becoming more and more flexible in saving files and using different formats that are compatible with other CAD and CAE programs with FEM capabilities (Catia, NX-6, Solid Works, Rhino, Ansys, Nastran…). In fact, some programs like "Mimics" with the ability to reconstruct the information from medical images in 3D, cannot only transfer files to other design programs (and rapid prototyping machines) through their use of .stl format, but are also beginning to include specific outputs for finite element calculation and simulation programs.

In this study we have taken the relevant part of the patient's femur, from previous case study, and used a ".slt to solid" converter, so as to obtain a .igs file, for subsequent FEM calculations with the help of CAE programs. After introducing the geometry in such programs, material properties can be applied, the part can be meshed for optimizing calculations and loads and boundary conditions can be applied, so as to obtain a systematic study.

Figure 8 shows an example of how a patient's femur behaves, when the attached prosthesis receives a load from the acetabulum (2000 N is the value usually chosen for critical situations) and where the metal part is pressure-mounted inside the femur. The simulations were performed with FEM software taking an initial CAD design and allow us to study the stresses induced to a patient's femur, during loading of the prosthesis in conventional daily-life activities, so as to analyse the convenience of a prosthetic solution.

By using different contact models, the in-service behaviour of the implant and its effects on the surrounding tissue (bone in this case) can be reproduced. Some studies examine the influence of active prostheses on the geometry of soft tissues (Díaz Lantada, 2009). These studies are anyway essential for evaluating any harm that may be caused to the receptor organism by the designed implants.

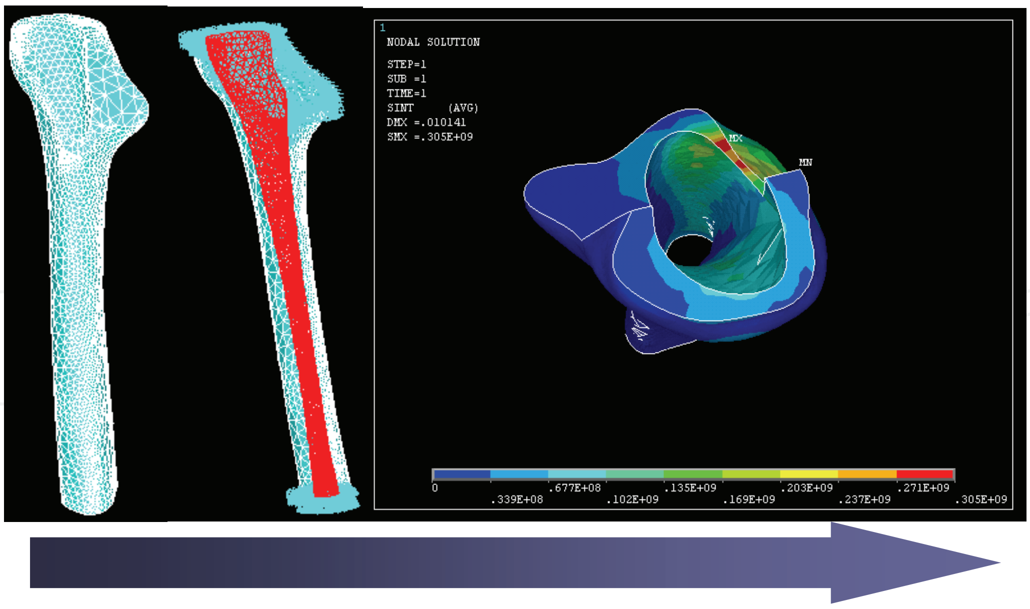

Fig. 8. Example of mechanical FEM study based on the information from CT images.

4.3 Design of a personalized prosthesis adapted to soft tissue

The major advances in customized prosthesis design have traditionally been linked to bone structures, since bone tissue density is easily identifiable, making it easier to produce the associated design more easily than for soft structures and tissue. Bone tissue appears as a very distinct white on the Hounsfield Scale, which is an important advantage when processing information from medical imaging tools, with programs like "Mimics" and those previously mentioned. However, in soft organs the difference in density between tissues is very small and does not let the different structures be identified separately, which is an enormous barrier to customized design work. This is the case with cardiac prostheses and in particular, regarding mitral annuloplasty rings, shown here as an example of application (Díaz Lantada, 2010).

In these cases, due to the similar densities of soft tissue, surrounding cloth and blood, some reference points need to be found in the medical images that will help the three-dimensional reconstruction of the target zone of the organ or soft tissue. In the example shown, cardiac CT images were used to identify in each "slice" the points of insertion of the valve leaflets in the patient's mitral ring (marked in blue in Figure 9). These points were inserted through their Cartesian coordinates in a CAD program, in order to get an idea of the three-dimensional morphology of the patient's mitral ring, to which the prosthetic annuloplasty ring is to be adapted, as well as for design tasks, as can be seen in Figure 10. Such prosthetic rings provide additional stiffness to the structure of a patient's mitral valve and help to reduce the degree of mitral insufficiency. There are several models and sizes in the market, as no design has yet proved to be especially beneficial, so personalization may well be a promising solution. The proposed design was also carried out in the Machine Engineering Division of Universidad Politécnica de Madrid (www.upm.es), with the aid of the available CAD-CAE-CAM technologies.

Further information on the complete design process of prostheses adapted to soft tissue and the customized design methodology proposed may be found in the references cited. Whatever the case, the information from medical imaging technologies combined with rapid prototyping technologies, are not only enormously useful in planning surgical work

(Binder, 2000, Gilon, 2002, Mottl-Link, 2008, Kim, 2008), but also have considerable advantages when rapid customized implants are required.

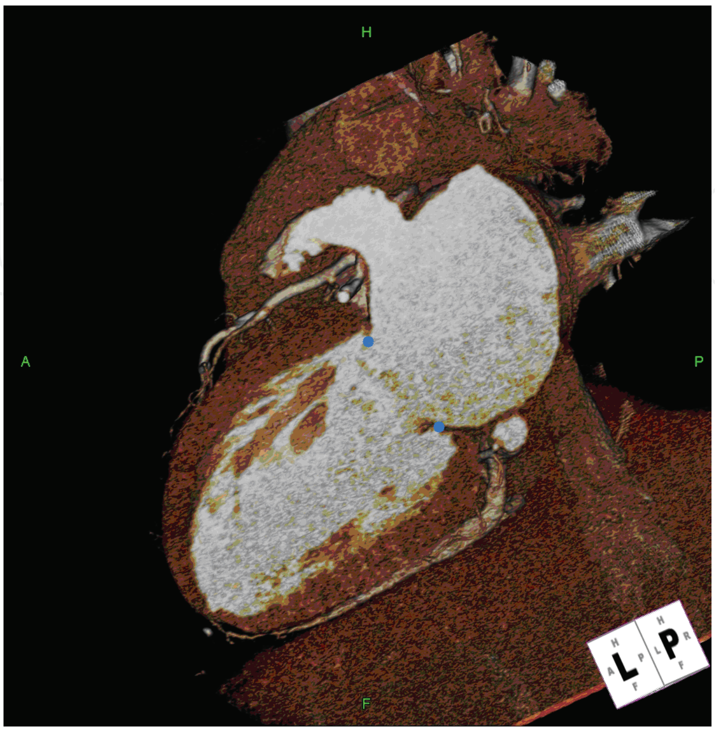

Fig. 9. Cardiac CT reconstruction of left atrium and ventricle, connected via mitral valve (Image courtesy of Raquel del Valle – Lennox Hill Heart and Vascular Institute NY).

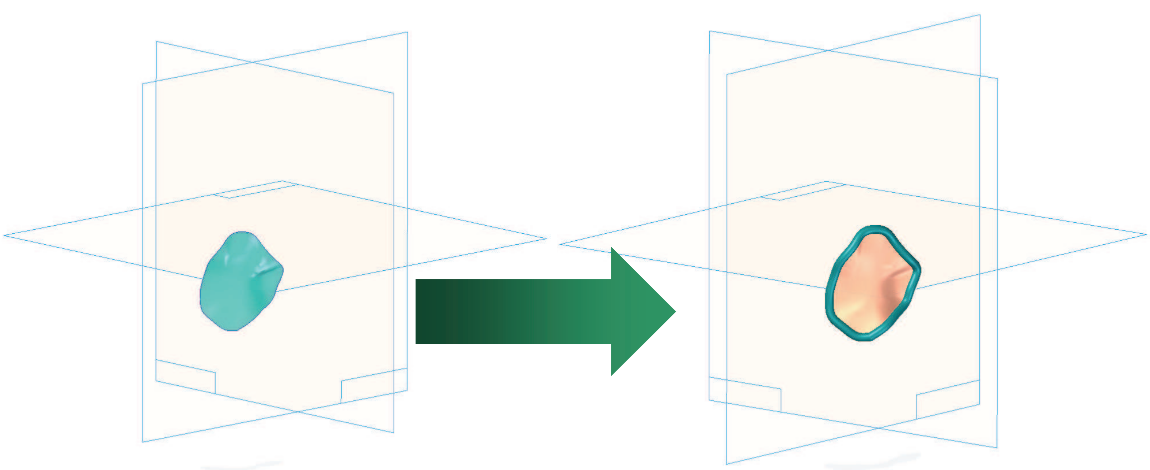

Fig. 10. Reconstruction of mitral valve section of a patient with mitral insufficiency and design of personalized annuloplasty ring, based on the information of cardiac CT images.

From the first solid models manufactured by layer manufacturing technologies, other rapid prototyping technologies denominated as "second stage" can be used to produce moulds by rapid-form copying. These moulds can be manufactured in numerous materials such as, silicones, ceramics, ceramics with a metal load and others, and allow casting stronger materials inside them than the original models. They enable prototypes to be produced for meeting the in-service specifications.

5. Challenges and future trends

5.1 Quality, precision and cost of equipment

A limiting aspect for using computed tomography for promoting product development activities, in different industries not directly linked to the medical sector, has traditionally been the cost of medical imaging equipment and the surrounding installations needed. To overcome such limitations, some enterprises now offer imaging and prototyping services, including the possibility of carrying out CT scans and subsequently providing a CAD file with the geometry of the desired part of the product. Outsourcing such medical imaging and format conversion tasks is a remarkable solution for research teams or small enterprises, that might need the help of computed tomography (or other imaging technologies), without having the possibility of acquiring their own equipment. Regarding the costs of digitization equipment, laser scanners and CCD (charge coupled device) film digitizers are more economic (around 1000 – 60000 €) than CT scanners or NMR equipment (from 150,000 even up to 500,000 €). However, laser and optical systems do not allow the reproduction of inner details, so important not only for personalized design processes, but also for non-invasive in-service verifications. New trends in the medical imaging industry are trying to mount different technologies, for combining their respective advantages, in one machine (CT+PET, CT+SPEC…) and regarding product development enhancement, perhaps it would be very positive to combine in one machine the fastness of laser scans with the capabilities of reproducing inner details of computed tomography. Such advances, together with an increase in precision and more competitive prices will help to spread the industrial applications of these technologies.

5.2 Normalization and standardization of formats

An aspect requiring additional dedication, to simplify the tasks of designers and to promote the information exchange regarding 3D designs, is the development and decision to use a common universal file format for computer-aided design activities and another one for computer-aided manufacturing and rapid prototyping processes (if possible, the same one). Nowadays there are several formats for CAD programs (.par, .prt, .asm, .cat, .obj, .3ds, .iges, .step…), as well as numerous alternatives for information exchange and subsequent rapid prototyping (.stl, .ply, .vrml, .iges, .step…). Format conversions suffered by a part, throughout the design, calculation and manufacturing process, entail information and quality loss. Furthermore, the possibility of using different CAD-CAE-CAM tools, for profiting from their respective advantages, is limited due to incompatibilities. Previous attempts at standardization have been carried out by private and military initiatives (.iges) or have appeared as an answer to proposals from international organisms such as ISO (.step format was a consequence of ISO10303 Standard), although the initial objectives have not yet been achieved. However, in other areas there are remarkable examples of collaboration, as happens in document processing (with the use of .pdf) and in the medical sector (with the DICOM standard for medical imaging). Once these limitations have been tackled, the advantages of the combined use of computed tomography with CAD tools and rapid prototyping will become evident. Such homogenization would also imply a cost reduction for teaching centres, due to the need for fewer software licenses, and the distribution of teaching resources would also be more adequate.

5.3 Promotion tasks: Teaching issues and collaboration between researchers

To promote the industrial expansion of CT-aided product development and CT-aided engineering, and facilitate their use for the development of new devices in several fields, it is very important for universities, research centres and major sector companies to collaborate and exchange information in respect of the scientific-technological progress in these materials and their applications. It is an inherent mission of teachers and researchers to focus attention on these new fields of study and on the importance of examining them together in a coordinated manner and to look on other researchers as companions and never as rivals. Cooperation among technology branch and health branch teachers in the preparation and teaching of courses related to these subjects is also important. It is in this respect that the participation of departments from different universities is very positive as they can make their laboratories and research centres available to students. It is interesting to consider ways to exchange information and enhance teaching, like those listed below:

- It would be highly beneficial to set up a specific forum on medical imaging and its industrial applications, beyond the medical sector, with a specific section devoted to engineering and product design and development, where researchers, universities and companies can get in productive contact.
- Congresses and scientific meetings are very useful instruments for bringing together the main researchers in an area of knowledge, particularly when this is done according to a fixed schedule to discuss specific topics, and it would be very positive to arrange regular international meetings on CT-aided product development and CT-aided engineering, possibly also including topics linked to alternative technologies, such as nuclear magnetic resonance or laser digitization.
- To encourage the use of these technologies in Industry it is important to make known the advantages expected from their use. Therein lies one of the basic benefits of carrying out research work in the University, since the discoveries made encourage changing and gradually updating the syllabuses of the related subjects. This helps to promote and maintain students' interest and to increase the transfer of knowledge arising from research to Society as a whole.

5.4 Reverse Engineering: Related risks

We cannot finish the chapter without warning about the risks derived from the misuse of these combinations of technologies, especially regarding industrial piracy and the usurpation of intellectual property rights. Of course computed tomography, combined with computer-aided design and rapid prototyping, can give new life to old or damaged parts and products no longer available and promote restoration activities (for example for the classic automotive industry), as well as archaeological processes and modular design activities. However, it has also led to the appearance of pirate companies that plainly copy the designs of products from all kinds of industries (automotion, entertainment, household, furniture…) and start up production directly, without having invested in the development process. It is therefore always advisable to protect novel developments by means of patents, not just as a very positive advantage related with marketing activities and negotiation processes, but also as a way of being protected against the risks of reverse engineering. For a powerful protection, patents should provide a description, as detailed as possible, of the novel developments and be written with the help of specialized lawyer's offices.

6. Conclusions

Several technological advances during the last two decades have promoted novel approaches to product design and development. The generalized use of computer-aided design and simulation tools, together with the advances in materials science and manufacturing technologies (especially rapid manufacturing technologies or "layer manufacturing technologies"), has enabled the development of more complex geometries and products. The additional possibility of using the information obtained from CT images as input for computer-aided design and for computer-aided engineering programs has opened up new horizons for carrying out personalized and ergonomic designs, as well as for promoting all kinds of tasks linked to product design and reverse engineering (reconstruction of damaged products, reproduction of delicate parts and studies related to inner non-visible geometries, among others).

This chapter has tried to cover some of the most important applications for such combination of CT imaging, design and manufacturing technologies, including industrial design, automotive engineering, aeronautics, bioengineering, archaeology and even teaching or art. Some case studies related to successful developments have been explained in detail, so as to analyse the most common procedures and in order to provide advice for conventional difficulties. It is important to note that the impact of combining information from medical imaging technologies with the advantages of novel design and manufacturing tools is so remarkable and its applications so widespread, that we can speak of "CT-aided product development" or even "CT-aided engineering". The main present challenges for improving the end-quality and industrial impact of such developments have been also discussed, together with some analytical reflections on the most important risks derived from these novel capabilities, especially concerning the limits between reverse engineering and plagiarism. Current remarkable study and research trends have also been analysed, with the hope of promoting collaboration among universities, research centres and enterprises.

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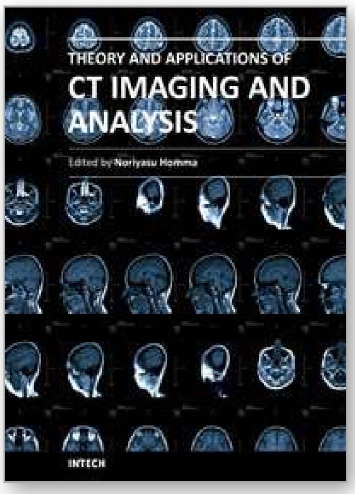

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