Chapter 5
Medical Imaging-Aided Design of Personalized Devices

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Abstract Medical imaging comprises the different technologies and processes used to generate images of the human body (or any kind of biological systems) for clinical purposes, including diagnosis and surgical training, and medical studies, normally linked to anatomy and physiology.

There are several medical imaging technologies grouped in families, including radiology, nuclear medicine, endoscopy, thermography, high-precision digital photography, many kinds of microscopy, and ultrasound-based imaging. Recent advances on information and communication technologies have allowed product designers to tend bridges between the information obtained from the use of medical imaging tools and computer-aided design programs.

In short, the information obtained using some of these medical imaging can be almost directly converted in three-dimensional objects (replicating the geometries and structures of human body and biological systems) and can subsequently be used as input in CAD programs, for designing personalized medical devices adapted to the morphologies of such biostructures.

This chapter revises the most relevant of these medical imaging technologies for the development process of personalized medical devices and provides case studies linked to personalization based on high-precision photography, cardiac computed tomography, and nuclear magnetic resonance. Main support software for converting medical images into 3D CAD files is also discussed.

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Final manufacture of the personalized biodevices can be accomplished with help of several computer-aided manufacturing and solid free-form fabrication or additive manufacturing technologies, as described further on in several examples along the handbook.

5.1 The Advantages of Device Personalization

In conventional product development personalization is aimed at suiting consumers' unique tastes and hence improving marketability and final increase of enterprises' outcomes. Several strategies are typically followed, such as designs focused on parametric and modular products, on producing an important number of different accessories, on providing attachable external features (protecting cases, stickers…), and on final ergonomic adjustment to client upon acquisition, among other possibilities.

Impact of personalization and its influence on product design can be clearly appreciated in conventional industries, such as the automotive or the mobile phone sectors. Color, shape, size, and functionalities are day-by-day more personalized for making consumers feel special. In most cases such personalization is also linked to the concept of programmed obsolescence, as customers' tastes change (or are promoted to change) very rapidly and repairing conventional products is no longer "fashionable" or economically viable.

Novel design and manufacturing resources currently allow the cooperation of customers along the whole design process in several industrial sectors, such as furniture, transport, inner architecture and decoration, consumer electronics, toys, or jewelry. The use of CAD–CAE–CAM, together with rapid prototyping facilities, allows for such approaches, and unique part series are more and more frequent. The final cost is not so dramatic as it may appear, as these novel technologies are also evolving and several of them are available for less than 1,000 €. In fact with around 5,000 € for design, digitalization, and manufacturing resources, a very complete development workshop can be arranged.

In Biomedical Engineering, personalization is usually pursued for providing a remarkable solution for an especially unconventional and complex pathology, for promoting diagnostic or therapeutic capabilities of a device by a better adaptation to patient's morphology and for supplying enhanced technical helps designed by a more detailed application of ergonomic principles. In such a field personalization is in most cases a relevant need, not just a luxury, and its social impact justifies carrying out continued research for its promotion.

During last two decades, biodevice personalization has been greatly promoted by combining medical imaging technologies and the related outer/inner-corporal information, with computer-aided development tools. In short, the information obtained using some of these medical imaging can be almost directly converted in three-dimensional objects (replicating the geometries and structures of human body and biological systems) and can subsequently be used as input in CAD programs, for designing personalized medical devices adapted to the morphologies of such biostructures. Several procedures and applications are discussed in detail in the following sections. Solid free-form fabrication or additive manufacturing technologies (Chap. 10) help with final manufacture of personalized biodevices in a wide set of biomaterials for subsequent potential implantation.

5.2 Imaging Tools for Promoting Design Personalization

The advances seen in recent decades in different medical image capture systems (mainly, computed tomography (CT), Doppler echo scans, nuclear magnetic resonance (NMR) or magnetic resonance imaging (MRI), and positron emission tomography (PET), as well as more novel combinations PET/CT) have led to a remarkable increase in the diagnostic capabilities of these pieces of equipment as well in the reliability of the diagnoses made based on this information and the therapeutic decisions taken as a result (see referenced standards and associations).

Main differences between the different medical imaging (MI) technologies can be explained by means of the type of radiation they use, of the final precision and of their several application fields.

For example, nuclear magnetic resonance imaging uses nonionizing radiation, while computed tomography or positron emission tomography uses ionizing radiation. Normally NMR is more linked to obtaining images from soft tissues, while CT usually focuses on hard tissues (even though such conventional separation has blended in the last decade, in fact our case studies provided in next sections use NMR for designing a prosthesis adapted to bone and CT for designing a prosthesis adapted to muscle).

PET is more used as a diagnosis support tool in oncology and neurology, usually together with an additional result from more precise anatomical imaging. In fact PET scans are increasingly read alongside CT or magnetic resonance imaging (MRI) scans, with the combination (called “co-registration”) giving both anatomic and metabolic information (what the structure or organ is and what it is doing biochemically). More modern PET scanners are now commercially available with integrated high-end multi-detector-row CT scanners (so-called PET/CT).

CT and MRI scanners are able to generate multiple two-dimensional cross sections (called tomographs or “slices”) of tissue and further three-dimensional reconstructions. Early PET scanners had only a single ring of detectors; hence, the acquisition of data and subsequent reconstruction was restricted to a single transverse plane. More modern scanners now include multiple rings, essentially forming a cylinder of detectors.

The medical community is also currently benefitting from the opportunity to exchange information from different medical image capture systems among centers and researchers. This is thanks to the “DICOM” (Digital Imaging and Communication in Medicine) standard and its generalized usage as a working format for different three-dimensional image reconstruction software, particularly with the introduction of version DICOM 3.0 in 1993.

Programs like “MIMICS” (Materialise NV) have also appeared (see the list provided below) which not only enable three-dimensional reconstruction to be performed from medical images but also basic operations on these images and their conversion to other formats accessible to “CAD–CAM” design and manufacturing programs.

As already explained in previous chapters, these CAD–CAM programs (Solid Edge, Catia, NX-8.0, Autodesk-Inventor, I-DEAS, Rhino, Solid Works, and others) comprise a wide range of computer tools that assist engineers, architects, and design professionals in their work. Simulations for in silico assessment of designs can also be performed with the help of CAE resources.

The power of these software packages quoted, and their being able to be used to handle information from medical imaging as a basis for the designs, means that currently the design of personalized prostheses can be performed in a question of hours while also making easier comparisons between alternative designs (Hieu 2002; Harrysson 2007).

Nonetheless, the use of personalized prostheses or implants has historically been something occasional and practically always the result of research projects between Academia and hospitals. This is basically due to the limits of cost and timeline problems that have prevented these personalized prostheses or implants, from competing with standard mass-produced designs.

However, the considerable industrial expansion experienced in recent years by a range of technologies called “rapid prototyping (RP) technologies,” normally based on high-speed computer numerical control machining or on additive manufacturing approaches (see Chap. 10), that enable schedules and costs to be reduced by manufacturing parts directly from geometric information stored in CAD–CAM program files, is presenting new opportunities for a personalized response to the development of implants and prostheses, the social impact of which could turn out to be highly positive (Schwarz 2005; Kucklick 2006).

Progressive linkage between CAD tools, MIMICS-like software, and CAM-assisted manufacturing is highly beneficial for the development of personalization in all kinds of products and industries and very special in the biomedical field. Main of such programs together with applications in the product development sector have been previously reviewed (Díaz Lantada and Lafont Morgado 2011) and are actualized further on, providing some examples of how the use of CT imaging is indeed versatile:

There are several software tools, 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 modeling 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 analyze format
- Biobuild, for converting volumetric imaging data to RP file formats
- Volume Graphics, for general purpose applications

Listed below are the main applications of computerized tomography (as a representative technology within the medical imaging sector), together with software for processing medical images and "CAD-CAE-CAM" tools, for optimizing product design and development activities:

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

These technological combinations provide novel ways of tackling more efficiently 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 nondestructive.

Next sections provide examples of biomimetic imaging-based designs, for comparing the use of high-precision photography, nuclear magnetic resonance imaging, and computed tomography, as input for constructing CAD files of personalized devices, as well as for comparatively discussing current limitations and main challenges.

5.3 Case Study: Biomimetic CAD Design of Skin

The use of mathematical models to generate biomimetic surfaces (see Chap. 6), especially thanks to the gradual employment of recursive and fractal models, often yields good approximations to the microtopography of living organisms, though it poses certain limitations when generating 3D CAD files for subsequent use in conducting simulations and obtaining physical prototypes using computer-aided engineering and manufacturing (CAE-CAM) tools. Said surfaces generated from mathematical models do, however, on occasion present excessive homogeneity or self-similarity, meaning that the imprecision of living organisms that are responsible for certain interesting properties cannot be adequately represented.

In this section we present a fast, low-cost, and efficient alternative method to yield biomimetic CAD files of the microtopography of human skin, files that can subsequently be used as an aid for simulating various interactions (mechanical, thermal, fluid, etc.) between the environment and the skin, as well as for the micromanufacturing of small specimens, whose texture resembles that of skin.

The process relies on the use of a high-resolution photographic camera to obtain images of the area being analyzed and on converting the resulting images into altitude matrixes, which are then used to obtain the CAD files that imitate the details of the original three-dimensional geometries. Using a similar process several microtopographies and microtextures of living organisms can be mimicked and further used for designing biodevices and implants with improved features.

The skin is the body's most extensive organ, forming the main barrier between internal organs and the external environment. It accounts for around 16 % of the body's weight. It has a surface area of some 2 m^2, and it varies in thickness between 0.5 mm at the eyelids and 4 mm at the heel. As the body's first line of defense, it is constantly exposed to potentially harmful environmental agents, including solid, liquid, and gaseous materials; sunlight; and microorganisms. Although the skin can be bruised, lacerated, burned, or infected, its unique properties allow it to engage in a constant cycle of healing, exfoliation, and cellular regeneration.

To fulfill its protective role, the skin is home to a permanent flora of microorganisms. There are relatively innocuous strains that protect the skin's surface from other, more virulent microorganisms. A thin layer of lipids covers the skin and contains oily bactericidal acids that protect against penetration by harmful microorganisms. The skin, thus, also doubles as an immunological barrier. It also has other important functions such as temperature regulation, somatosensation, and the synthesis of vitamin D.

There is a great amount of variation between the different body parts in terms of the skin's structure. This makes a description of the "normal skin" covering each body surface difficult. There are clear differences in the properties of skin, for example, the thickness of the layers, the distribution of sweat glands, and the amount and size of hair follicles. Nevertheless, skin does have certain structural properties that are common to all parts of the body.

It always consists of three layers: the epidermis (outer layer), the dermis (internal layer), and the subcutaneous adipose layer (hypodermis). The basement membrane separates the first two layers, while the subcutaneous tissue, a layer of loose connective tissue and adipose tissue, connects the dermis to the body's underlying tissues (Simandl 2009).

The skin's functions depend greatly on the properties of its outermost layer, the epidermis, meaning that properly simulating its surface microtopography is necessary in order to conduct studies on the interactions between the environment and the human body. However, most recent studies on the computer-aided graphical generation of human skin have involved simulations of large areas of the human body, eschewing micrometrical details in almost every case, as this would have entailed time- and computer-intensive calculations.

Some researchers have focused on modeling wrinkles and the effects of aging (Boissieux et al. 2000; Yang and Zhang 2005; Zhuo et al. 2006) in an effort to enhance the appearance of animated characters in entertainment programs and in the videogame industry, as well as to simulate the effects of various cosmetic products.

Leading studies have resorted to generating wrinkles along vector fields so as to incorporate additional textures to surface meshes (Bando et al. 2002). In order to take into effect biomechanical aspects, recent research has resorted to using the boundary element method to simulate skin defects and to analyze their effect on other anatomical structures (Tang 2002), though detailed effects of the surface topography were omitted.

On occasion, physical prototypes have also been constructed to simulate the mechanical features of the epidermis, the dermis and subcutaneous fat. These models used polymeric materials of different rigidity and hardness to complement surgical training simulators, especially as these relate to devices for minimally invasive laparoscopic surgery (Munro et al. 1994).

In terms of the biomimetic design of anatomical elements, numerous researchers have resorted to the use of medical imaging tools (mainly computerized tomography and nuclear magnetic resonance), in combination with software to process said images (such as MIMICS, Materialise NV) and CAD programs. The availability of CAD files with the geometry of body structures, both muscular and bone tissues, has thus served to aid in the development of personalized implants (Kucklick 2006; Díaz Lantada et al. 2010b), especially when combined with rapid prototyping techniques (Winder and Bibb 2005; Kim 2008).

The accuracy of the aforementioned medical imaging systems, however, still does not allow for a faithful reproduction of the details associated with the surface microtopography of tissues, though new advances in micro-CT (see Chap. 14) technology are constantly yielding significant improvements (Shi et al. 2008; Guo et al. 2010).

The use of CAD-CAE-CAM (computer-aided design/engineering/manufacturing) tools is also applicable to tissue engineering, having given rise to a new field of study called computer-aided tissue engineering, a field that was initially associated with anatomical imaging, with modeling and simulation, and with surgery planning (Sun and Lal 2002).

This, in conjunction with new advances in biomanufacturing (see also Chap. 14) and associated biomaterials-based additive manufacturing tools (bioplotters), points to the manufacture of small body structures in the not-too-distant future (Mironov et al. 2009).

In any event, so as to profit from the advantages stemming from the increased accuracy of aided manufacturing systems aimed at producing artificial biostructures, we must continue to delve deeper into the biomimetic design of tissues and to improve aspects related to the generation of surface microtopographies, the effects of which are crucial to the proper operation of the tissues that we wish to mimic.

The biomimetic processes typically employed involve the use of mathematical models, such as fractals (Mandelbrot 1982), and can output surface textures to CAD files, which can be converted to formats that can be exported to CAE-CAM software.

These files in adequate formats can then be used, in conjunction with finite element analysis techniques, to conduct simulations as a prelude to the manufacture of physical prototypes (Díaz Lantada et al. 2010b, Biocoat), though imitating the desired topography is not always simple.

In this section an alternative low-cost approach is used, relying on the use of a high-resolution photographic camera to obtain images of the area being studied, and on the conversion of the resulting images into altitude matrixes, which can then yield the CAD files that imitate the details of the original three-dimensional geometries, in a process described below.

The skin surface photographed for present case study measures 9 mm × 6 mm, yielding 640 × 480 pixel images, meaning that the size of the details captured is on the order of 20 μm, which is sufficiently precise for the majority of micro-manufacturing techniques currently available (see Chap. 11), as well as for analyzing any kind of cutaneous pathology. The areas photographed correspond to two sections of fingerprint from the index finger and the back of the hand, in the area of the knuckles, of two 30-year-old researchers. This is done so as to determine the viability of the system when acquiring images of different parts of the body.

The images are processed using Adobe Photoshop to convert them to gray scale, followed by filtering to soften highlights. The images, saved in the .raw format, are then input to a program (courtesy of M.Sc. Eng. Alvaro Salmador) that converts the gray scale to an altitude scale. The program also converts the files into the .stl format for subsequent use in computer-aided design programs.

Different options are available for the CAD software used to convert from surface meshes, in .stl format, to conventional solid CAD pieces. Particularly important is the use of software specifically designed to handle .stl files (Materialise Magics, VisCAM, Solid View, MeshLab, among others) or the use of so-called mesh-to-solid programs, which transform .stl meshes into formats typically recognized by other CAD software. In our case, we used the CAD-CAE-CAM NX-8.0 software (Siemens PLM Solutions) to represent the .stl surfaces and the solid CAD pieces, with the final rendering.

Subsequent conversions to .iges format allows for an additional exchange of information with more specific calculation programs, such as Ansys or Abaqus, as well as with programs specifically designed for additive rapid prototyping with 3D Lightyear by 3D Systems.

As mentioned earlier, the design process starts by converting the image of a photograph, expressed as a matrix with information on the colors (or the gray scale) for each coordinate pair (x, y) on the plane, into a matrix in which the colors or gray scale are replaced by data on the altitude of each point on the photograph.

To achieve this, the darkest pixels in the image are assigned a zero altitude, representing the bottom of the folds in the skin. The image's brightest pixels are assigned an altitude based on reference information and models (Boissieux et al. 2000; Jacobi et al. 2004; Yang and Zhang 2005) that provide different typical values for the height of wrinkles, depending on region of the body and age of the subject.

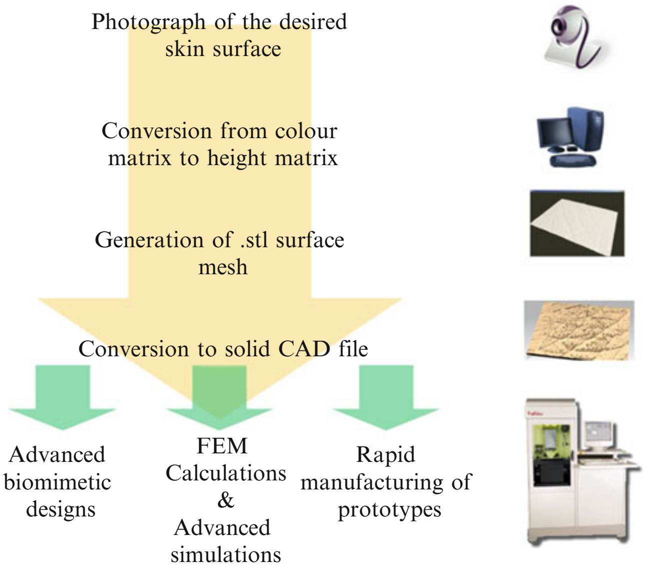


Fig. 5.1 Diagram of the design process and of associated potential post-processes

In our case we use a maximum difference of 160 μm for the fingerprints and of 240 μm for the folds in the back of the hand. Values between these maximum and minimum values are linearly interpolated, although the Maio algorithm used by some systems to display 3D images of fingerprints can also be used (Maio and Maltoni 1997). An additional scaling along the x- and y-axes contained in the plane of the original image may also be necessary to adapt the size of the meshed surface to the actual dimensions of the area photographed, which in this case was 9×6 mm^2.

Once the altitude matrix is obtained, it is converted into a .stl format surface mesh, which allows for subsequent processing by specific CAD software. Since surfaces with negligible thickness, like the intermediate meshes in .stl format, cannot be manufactured with the aid of RP technologies, nor do they allow for simulations based on the application of finite element analysis, they must first be converted into solid pieces with a nonzero thickness. The first step in this process can be achieved with the typical CAD tools used to automatically generate molds (core and cavity) from surfaces.

In the second step, the core can be cut at the desired distance to obtain the desired surface but with a certain thickness. Or a prismatic block can be used on which to imprint the wrinkled surface before finishing the process by combining the block and the cavity. The general outline for the design process, including possible simulation and computer-aided manufacturing activities, is detailed in Fig. 5.1.

Final rendering is shown in Fig. 5.2, after a brief additional explantation. Subsequent conversions to .iges format allows for an additional exchange of information with more specific calculation programs, such as Ansys or Abaqus, as well as with programs specifically designed for additive rapid prototyping with 3D

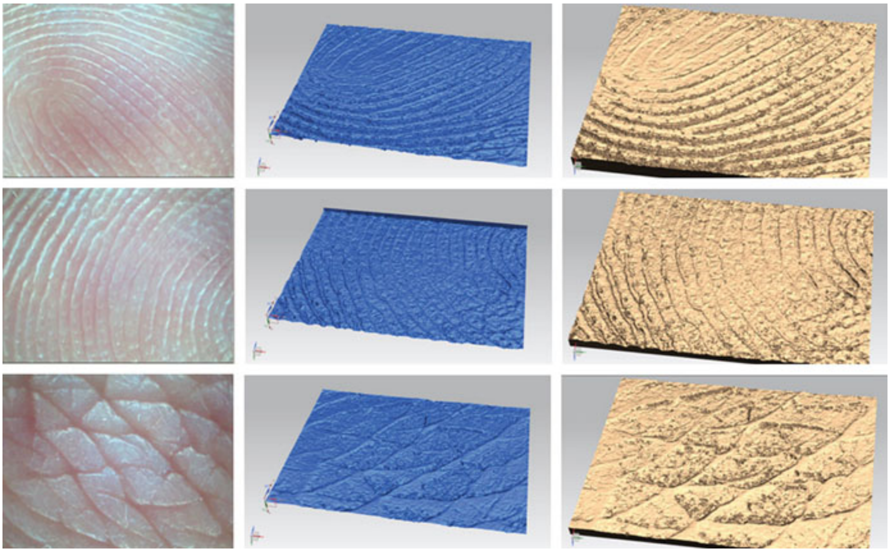


Fig. 5.2 Summary of results. Left column: original photographs (9 × 6 mm^2 each). *Center column*: associated surface meshes in .stl format. *Right column*: CAD files. *Top and center rows*: fingerprints. *Bottom row*: back of the hand, area of the knuckles (Image acquisition system and .stl format conversion courtesy of M.Sc. Eng. Alvaro Salmador)

Lightyear by 3D Systems and recent open access solutions linked to projects such as RepRap.

Figure 5.2 shows the main stages of the process for obtaining files of CAD solids from photographs of the skin through an intermediate mesh-conversion step in .stl format. The first rows show the process as applied to fingerprints, and the bottom row shows an example involving the surface topography of the back of the hand. This latter example can be directly applied to other parts of the human body or biological systems for promoting biomimetic biodevices.

The final thickness of the CAD files depends on the intended purpose of said files. If it is desired to conduct FEM-based simulations, it must be adapted to the thickness of the epidermis for fluid analyses, in which surface effects are dominant. The thickness of the dermis may have to be included too if the goal is to analyze mechanical stresses/strains and their effect on subcutaneous anatomical components. If the goal is to build prototypes, the minimum layer thickness attainable with the various technologies must be considered and the thickness adapted always depending on final application. Some of these possible applications include producing anatomical models for surgical training, manufacturing microtextures for studying contact phenomena, or, in the future, the biomanufacturing in the laboratory of small patches of skin for use in operations.

Figure 5.3 shows how the use of a filter to eliminate highlights can, on occasion, have a notable influence on the quality of the resulting surface mesh, since such

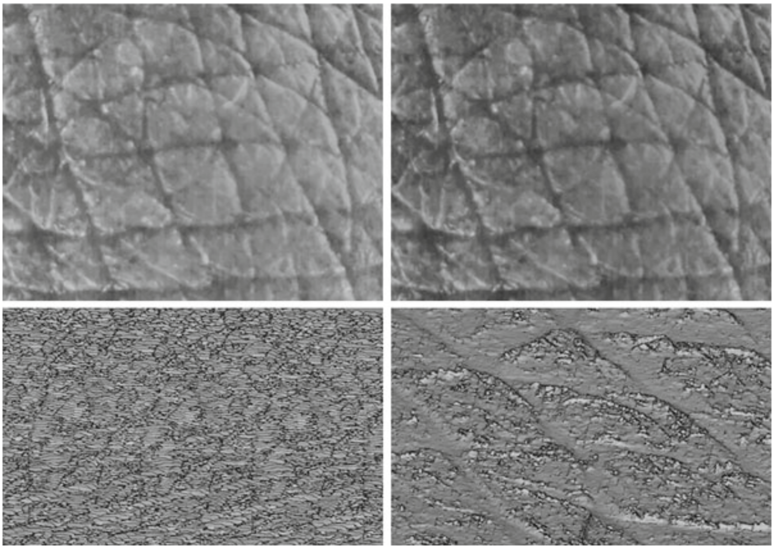


Fig. 5.3 Filtering effects: enhanced precision due to misleading effects stemming from highlights

filtering aids in reducing dramatic artificial height differences stemming from sudden changes in sharpness in the original photographs.

The 3D images shown help to demonstrate the simplicity and effectiveness of the process described. They also help to validate its applicability for producing biomimetic designs of skin from different parts of the human body. The process has been tested with skin from the fingerprints and from the back of the hand, but the extension to other areas of interest to the cosmetics industry, like the face, arms, and legs, is immediate.

The process has been validated on hairless parts, as in most of the studies referenced and based on optical acquisition systems (Jacobi et al. 2004), though it would be interesting to analyze its effects in depth with a view to the generation of .stl meshes and CAD files. It is important to note that for regions of skin measuring some 60 mm^2, reproductions with details on a scale of 20 µm were obtained, something that is nearly impossible to achieve using laser digitalization or medical imaging techniques, even if micro-CT is used.

Moreover, the process described is based on technologies that are much more accessible and innocuous to patients and as such has clear educational implications. One of the current limitations, however, is the appearance of edge effects for areas of skin larger than those described. This can be resolved by developing a movable pickup to acquire images, which could then be jointly connected and transformed into the associated surface meshes and CAD files.

Our process can also be utilized to analyze parameters such as the average rugosity and the depth of the wrinkles and to conduct additional studies on the influence of age or cutaneous pathologies on texture (Smalls et al. 2005) and the subsequent aspect of human skin, as well as in activities involving human recognition. It also has potential applications in veterinary medicine and zoology.

In terms of the rapid manufacture of complex surface microtextures, previous research has helped to validate the use of conventional rapid prototyping technologies to obtain biomimetic surface details on the order of 0.4–4 mm (Díaz Lantada et al. 2010a). Other manufacturing processes based on copying biological structures by using physical or chemical vapor-deposition methods to produce micro-scaffolds have attained details on a scale of tens of microns (Lakhtakia et al. 2009; Pulsifer et al. 2010).

In any case, there are multiple computer-aided manufacturing techniques that can utilize the information in CAD files to produce objects with biomimetic microtextures using multiple materials. A brief comparison of those technologies is included in Chaps. 10 and 11.

A similar method, based on processing high-resolution photographs, can be applied to a multitude of other biological organisms to mimic surface textures with which to achieve special visual or contact phenomena effects and apply them to surfaces on consumer products, as already employed by fabrics based on the morphology of shark skin (Speedo Fastskin), surfaces of components based on dolphin skin (Pavlov 2006), paints and lacquers that aid in achieving self-cleaning surfaces and based on the surface of lotus flower leaves (Barthlott and Neinhuis 1997), and other applications.

The method can also be carried out starting directly from SEM images of the surfaces of different animals and plants, depending on the desired degree of precision and without needing complex and expensive technologies (sometimes also needing specific installations and protected laboratories) such as nuclear magnetic resonance (NMR) and computed tomography (CT), whose application fields and levels of detail attainable are also discussed in next sections, providing also a couple of case studies.

This proposal also has applications in the field of tissue engineering, since it can aid in producing CAD files with geometries that imitate the surface characteristics of different fabrics for subsequent simulation of their behavior with the aid of FEM-CFD software, as has already been done with certain biomimetic surfaces (Pavlov 2006). It should prove interesting to use this type of file to assess the response | of tissues with different designs in terms of their surface texture and the response of different fluids so as to analyze their hydrophobic and impermeability characteristics.

Regarding the reproduction of biological structures, the proposed design method, with the help of high-precision additive manufacturing technologies, may well be an important complement to current bioreplication techniques, such as sol–gel, atomic layer deposition, PVD/CVD, or imprint lithography and casting, for several industrial applications (Pulsifier and Lakhtakia 2011). For large series of parts, soft-lithographic approaches and micro-replication techniques, such as micro hot-embossing and microinjection molding, may also be good choices (see Chaps. 11 and 12).

5.4 Case Study: Personalized Prosthesis Adapted to Hard Tissue

The case study detailed in this section as an example details the process for producing a customized hip prosthesis design from the helpful information of 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. More detailed information may be found in the references (Osuna 2008; Ojeda Díaz 2009; Ojeda Díaz et al. 2009).

Just as a brief revision, hip replacement is a surgical procedure in which the hip of the patient is replaced by a prosthetic hip. Such joint replacement orthopaedic surgery is generally conducted to relieve arthritis and related pain or to fix severe physical joint damage as part of hip fracture treatment. A total hip replacement (total hip arthroplasty) consists of replacing both the acetabulum and the femoral head, while hemi- (or half) arthroplasty generally only replaces the femoral head.

The prosthesis used in hip replacement consists of different parts, the acetabular cup, the femoral component, in which this case study focuses and the articular interface. The femoral component is designed to fit in the femur, normally by removing a part of the bone and shaping the remaining part to accept the prosthetic component.

There are two main types of femoral components, cemented, based on adhesive fixation between prosthesis and bone, and uncemented, based on friction for promoting stability. Final prosthesis-type selection depends on several factors, including age of the patient, mechanical strength of the bone, as assessed with the help of medical imaging, life expectancy, among others.

Even though the potential benefits of personalized femoral components for hip replacement is still controversial, it is clear that, if taking the geometry of patient's femur as design input for the femoral component, required bone adaptation (through boring, milling and cutting) during surgical intervention should be lower and lighter.

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. 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, for ad hoc design operations, after processing the images (Fig. 5.4) "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 valid format for a design program and this femoral zone can be used as the basis for a customized prosthesis design, as can be seen in Fig. 5.5.

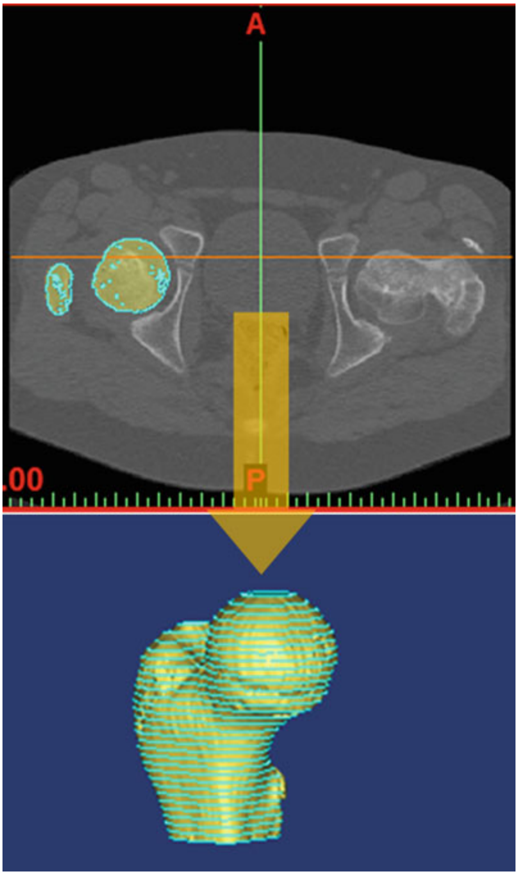


Fig. 5.4 3D reconstruction of femur based on the information from NMR images. Mimics software for computer-aided designs based on medical images

In this case it has been done by using a "surface through curves" command for obtaining external surface of the femoral component. Final solid part is obtained by closing such external surface with simple geometrical elements and accepting the automatic Solid Edge's proposal of "converting to solid." The CAD designs can further be converted into formats recognized by CAE programs, for verifying through FEM-based simulations that final biodevice will withstand service loads.

Similar developments are simple to carry out, especially when trying to adapt a design to a hard tissue, which is normally very well highlighted in CT/NMR medical images. Important applications include the design of all kind of bone prosthesis, as well as scaffolds for tissue engineering, whose biomimetic design is now promoted thanks to advanced in quality and precision of acquisition systems, as discussed in Chap. 14. Designs adapted to soft tissues are less common, as soft tissue density is normally more similar to that of surrounding fluids, cartilages and biostructures, In any case next section provides an interesting example linked to cardiovascular surgery.

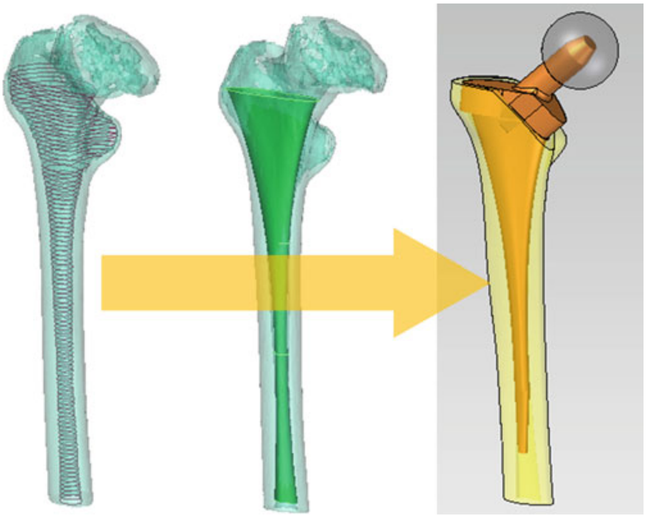


Fig. 5.5 Example of personalized prosthesis designed from the information of CT images. Mimics combined with solid edge as software support tools

5.5 Case Study: Personalized Prosthesis Adapted to Soft Tissue

Previous chapter provided some brief notes on cardiovascular surgery and on the use of annuloplasty rings for mechanically supporting the cardiac tissue of the left atrioventricular union and reducing the problem of mitral valve insufficiency.

The large number of alternative designs for annuloplasty rings (at least 20 models are extensively used) chosen according to the patient, their pathology, and the cardiologist or heart surgeon's experience shows that the design of these rings is a problem that is not yet solved. In fact, on most occasions various models and sizes of these implants are set out on the operating table, so that the most suitable one can be chosen, by direct inspection during the operation itself, thereby increasing the number of decisions to be made and the schedule of the operation.

Although the use of personalized annuloplasty rings, manufactured for each patient according to the size and morphology of their valve complex, could be very beneficial for the treatment of mitral insufficiency, this possibility has been limited for reasons of deadlines and costs, as well as for design and manufacturing difficulties. This section attempts to explain a possible alternative, which thanks to the state of current technology may lead to the treatment of mitral insufficiency using personalized annuloplasty rings.

In order to begin the personalized design procedure, we need inner information of patient's heart morphology; what has been managed with the help of a Philips helicoidal CT with 64 detectors (Fig. 5.6 shows some examples of the kind of graphical information obtainable).

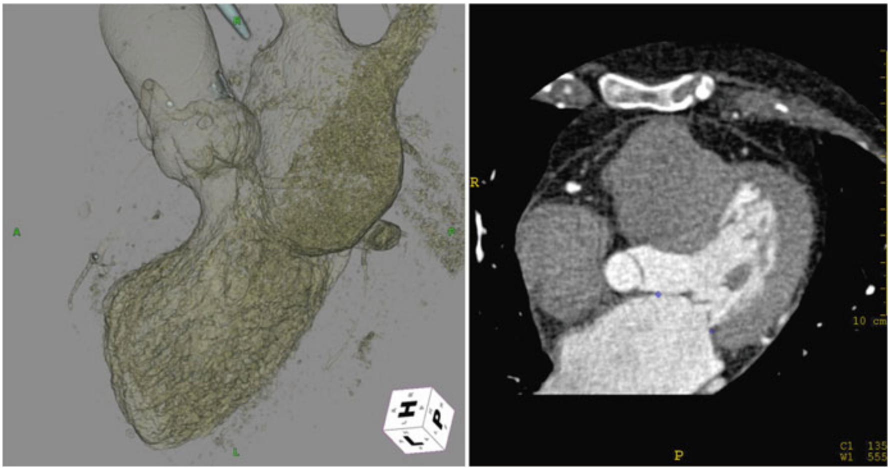


Fig. 5.6 Image of the left atrioventricular union, where mitral valve is place (*left*) and slice showing the leaflet insertion points marked in *blue* (*right*) (Courtesy of Raquel del Valle – Lennox Hill Heart and Vascular Institute NY)

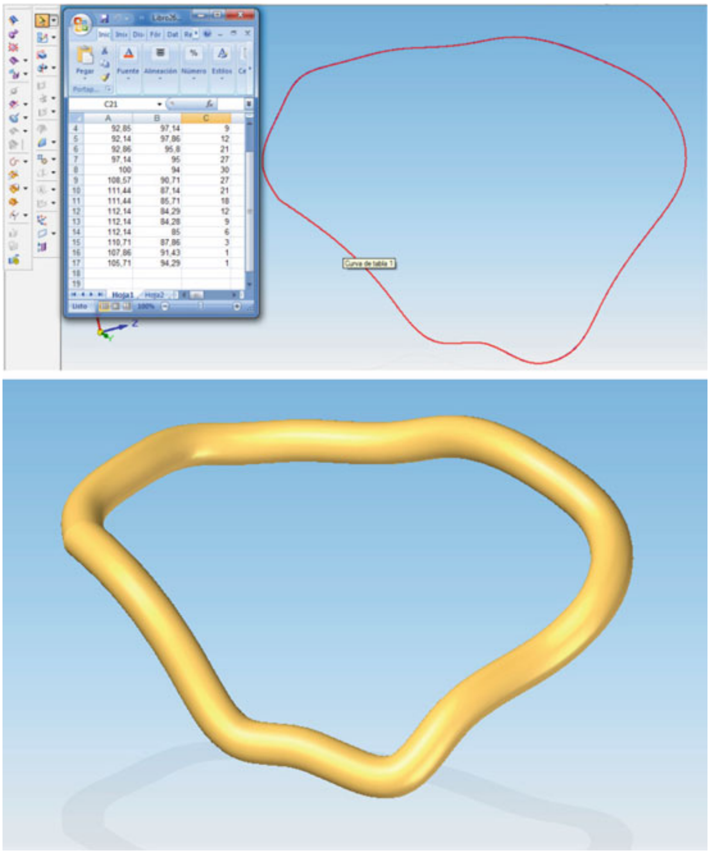
Main problem for this personalized procedure is that the density of the mitral ring (fibrous tissue) is very similar to that of the auricular and ventricular myocardium and that of the valve leaflets, which means it is not identified as a separate structure by any of the imaging techniques currently available for clinical evaluation. In fact, the main advances linked to the development of personalized prostheses have been traditionally linked to bone structures, since bone tissue density is very different from surrounding biostructures and tissues and can thus be more easily identified for subsequent computer-aided design tasks.

In this study we have to resort to the use of an alternative way for assessing the morphology of mitral valve by measuring “slice by slice.” Using the Philips TC software, the valve leaflets insertion points can be located “slice by slice” (as marked in Fig. 5.6 in blue) and in consequence obtain a three-dimensional form of the patient’s mitral annulus.

However, such software does not include output format for CAD programs so the Cartesian coordinates of the mentioned insertion points have to be written down, as provided by the Philips software, for subsequent introduction in the CAD program. Such introduction can be directly done by constructing points with the associated CAD command or by importing the coordinates directly from an Excel file.

Once the 3D location of the insertion points is clear, a spline can be constructed as basis for the solid ring, either “point by point” or “through table.” After the mentioned spline (Fig. 5.7 upper image), adapted to the form of patient’s mitral valve, is obtained, a point of the spline is selected and a reference plane, normal to the spline and containing such point, is constructed.

A 2.5-mm circumference contained in the reference plane and with center on the intersection point between plane and spline is then drafted. By using the “sweep”



	A	B	C
4	92,85	97,14	9
5	92,14	97,86	12
6	92,86	95,8	21
7	97,14	95	27
8	100	94	30
9	108,57	90,71	27
10	111,44	87,14	21
11	111,44	85,71	18
12	112,14	84,29	12
13	112,14	84,28	9
14	112,14	85	6
15	110,71	87,86	3
16	107,86	91,43	1
17	105,71	94,29	1
18			
19			

Fig. 5.7 Annuloplasty ring for mitral valve insufficiency: personalized design with the help of MI and computer-aided design resources

command, the circle is made to follow the whole spline, hence leading to final solid annuloplasty ring of Fig. 5.7. Additional details of the whole design process, here just summarized for providing an outline of case study, can be found by consulting the reference section (Díaz Lantada et al. 2010b).

This biodevice has been again designed with the help of Solid Edge, whose "spline" command allows the easy introduction of points by their (x, y, z) 3D coordinates, just as contained in an Excel table. Such connection with MS Excel is especially noteworthy, as already remarked in Chap. 4, and simplifies designs based on splines and 3D curves. Other CAD resources, even when capable of importing coordinates from tables, do not always provide such a direct process.

Future in vitro and in vivo trials will provide additional validation to the proposed methodology; however, we believe that combination of medical imaging technologies with designs programs constitutes a powerful tool for virtual validation and design optimization, before carrying out more time and cost expensive trials, as those analyzed in Chap. 15.

5.6 Main Conclusions and Future Research

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, has enabled the development of more complex geometries and products.

The additional possibility of using the information obtained from medical imaging (MI) technologies 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), whose applications in Biomedical Engineering are highly relevant.

This chapter has tried to cover some of the most important applications for such combination of medical imaging and design technologies, including some case studies related to successful developments of biodevices and prostheses, so as to analyze 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 “MI-aided product development” or even “MI-aided engineering.”

Main present challenges for improving the end quality and industrial impact of such developments are linked to further increasing MI precision (although some remarkable recent advances on micro-CT are commented on Chap. 14) and usability, probably by means of augmented reality, simplifying the connection between medical imaging equipments and CAD resources and producing easier to acquire equipments, whose current cost is typically above 100,000–200,000 €.

Regarding such costs of digitization equipment, laser scanners, and CCD (charge coupled device) film digitizers are much more economic (around 1,000–60,000 €) 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 noninvasive in-service verifications.

New trends in the medical imaging industry are trying also to mount different technologies, for combining their respective advantages, in one machine (CT + PET, CT + SPEC-single photon emission tomography…) and regarding biodevice development process 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 and their final impact on biomedical science and health.

Standards and Associations Related to Medical Imaging

- DICOM standard – Digital Imaging and Communications in Medicine: Strategic Document (http://medical.nema.org).
- Medical Imaging and Technology Alliance (www.medicalimaging.org).
- NEMA – The Association of Electrical and Medical Imaging Equipment Manufacturers (www.nema.org).

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