MEDICAL REVERSE ENGINEERING APPLICATIONS AND METHODS

L.C. Hieu¹,², J.V. Sloten³, L.T. Hung⁴, L. Khanh⁴, S.Soe¹, N. Zlatov⁴, L.T.Phuoc⁶ and P.D. Trung¹
¹ School of Engineering, University of Greenwich, Kent, UK, ² Cardiff School of Engineering, Cardiff University, Wales, UK, ³ Division of Biomechanics and Engineering Design, K.U.Leuven, Belgium, ⁴ Department of Information Technology, Hanoi University of Technology, Vietnam, ⁵ Departments of Medical Imaging and Neurosurgery, Central Army Hospital 108, Vietnam, ⁶ Biomedical Engineering Laboratory, University of Bologna, Italy

Abstract – Understanding, controlling and manipulation of patient data as well as shape, geometry and structure of the biomedical objects are important for developing Biomedical Engineering (BME) applications. Medical Reverse Engineering (MRE) is aimed to use the Reverse Engineering (RE) technology to reconstruct 3D models of the anatomical structures and biomedical objects for design and manufacturing of medical products as well as BME research and development. This paper presents the state of the art applications and methods about MRE. Different concepts and methodologies are provided to understand fundamentally the MRE processes and workflow. The key MRE applications are presented, including personalised implants for bone reconstruction, dental implants and simulations, surgical tools, medical training, vision science and optometry, orthopedics, ergonomics, orthosis, prosthesis, and tissue engineering. The current challenges as well as the hardware and software for MRE application development and research are discussed.

Keywords – Medical reverse engineering, Implant design and manufacture, Biomodelling

1. Introduction

The digital geometric data is very important for all engineering areas. It can be seen in the form of a certain 2D or 3D format, and not only used for design and manufacturing systems, but also for scientific and technological research and development processes, marketing and business, arts, film industry and televisions. Figure 1 presents the central activity of the digital geometric data in which it involves in many application areas; and the well-known examples and applications include (i) Design and Manufacturing: Computer Aided Design, Computer Aided Manufacturing, Computer Numerical Control & Computer Aided Engineering (CAD/CAM/CNC & CAE), (ii) 3D animation and simulations, (iii) 3D Art, Film and TV, and (iv) Medicine: Medical imaging and surgical planning.

In the area of Design and Manufacturing, 2D/3D digital geometric data, generally called 2D/3D data, is fundamentally an input for most of the state of the art production systems, from CAD/CAM/CNC to Micro & Nano Manufacturing. All the analysis and planning systems for product development and production are based on 2D/3D data, including Computed Aided Process Planning (CAPP), Computer Aided Inspection Planning (CAIPP) and Computer Aided Engineering (CAE).

It is clearly seen that the methods and technologies to reconstruct and manipulate 2D/3D data are crucial for many applications. There are two types of engineering, forward engineering (FE) and reverse engineering (RE). The definition of the terms FE and RE are well-documented; it is strongly dependent on the end-use applications and the field of study [1]. Generally, FE is the traditional process of moving from high-level abstractions and logical designs to the physical implementation of a system [2]. For new products or applications where the reference data is not necessary for 2D/3D geometrical modeling, FE principles are commonly used. However, in the cases, where we need to base on the reference data for 2D/3D geometrical modeling processes, or when we need to duplicate the objects for further development, the RE technology are the right option for implementation.
RE is generally defined as a process of analysing an object or existing system, including hardware and software, to identify its components and their interrelationships, and investigate how it works in order to redesign or produce a copy without access to the design from which it was originally produced [1]. In the area of 3D graphics and geometrical modelling, RE is used for reconstructing 3D models of an object in different geometrical formats from the available physical ones. Based on the end-use applications and technical requirements about data processing and accuracy of 3D models to be reconstructed, practically, RE can be divided into 3 groups: (i) Industrial RE, (ii) Artistic & Architectural RE, and (iii) MRE as presented in Table 1.

Since 1990s, RE has been playing an important role in medical product development and BME research, especially in the areas of design and manufacturing of personalised implants, surgical tools, medical training models, orthosis, prosthetics, and medical devices, where patient data in the form of CT/MRI images and 2D/3D formats are used for surgical planning and as the reference data for medical application development [4-15].

In this paper, the nature of MRE processes is presented. It provides the fundamental background about MRE as well as the state of the art applications. It is aimed at reviewing the latest development about MRE and presenting the methodologies for developing different medical

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Table 1: Three RE types based on the end-use applications and technical requirements

<table>
<thead>
<tr>
<th>RE types</th>
<th>Objectives and technical requirements</th>
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<tbody>
<tr>
<td>Industrial RE</td>
<td>Industrial RE is used to reconstruct 3D models of the physical objects for Engineering Design, CAD/CAM/CNC, Product Development, Quality Control and Dimensional Inspection. The typical object size is from 200x200x200 mm to 500x500x500 mm. The accuracy requirement for 3D models is normally high. The typical requirement is from ± 20 to ± 50 microns. In the area of Mold &amp; Tooling as well as micro-manufacturing, the accuracy requirement is up to (1 to 5) microns. For the applications such as the ship building and aeronautic industry, the accuracy requirement is quite flexible, depending on the size of the objects and their functions.</td>
</tr>
<tr>
<td>Artistic &amp; Architectural RE</td>
<td>Artistic &amp; Architectural RE is used for 3D geometrical modelling and control of the objects for artistic and architectural applications. The size of the objects normally varies from 10x10x10 mm to very big ones, including statues, architectural prototypes, houses and buildings. The accuracy requirement is normally low. The outside appearance, including the general shape and forms of the objects, are more concerned than the required accuracy.</td>
</tr>
<tr>
<td>Medical RE</td>
<td>When RE is used for medical application development and research, it is called Medical Reverse Engineering (MRE). It is normally involved in using patient data or biomedical objects to reconstruct 3D models of anatomical structures and objects of interest for development of different medical products, applications, and biomedical research. The accuracy requirement for MRE is dependent on the specific applications. For the personalised cranio-maxillofacial implants, biomodels and training models, the accuracy requirement is basically not high compared to Industrial RE, up to hundred(s) of microns. However, for the surgical tools and functional implants such as spine, hip and knee implants, the accuracy requirement is very high.</td>
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applications and implementing state of the art BME research.

2. Medical reverse engineering methods

The final target of all RE processes is to obtain 3D data representing the geometries of the objects of interest from which different applications are developed. There are two types of end-use data representation that are commonly used, especially in the areas of 3D Geometrical Modelling, Engineering Design and Product Development: (i) Polygons or Triangle Mesh and (ii) Non-Uniform Rational B-Spline (NURBS).

A polygon or triangle mesh includes vertices, edges and faces that define the shape of an object. The faces usually consist of triangles, quadrilaterals or other simple convex polygons. This type of data is the simplest way of representing the geometries of objects, appeared in most of the computer graphic systems; however, it is not an accurate representation of the geometries. NURBS surfaces are the ultimate output of the RE process that we would like to obtain for applications where accuracy requirements are high. NURBS are basically an accurate way to define a free-form curve and surfaces. NURBS are useful for a number of following reasons: (i) offer one common mathematical form for both standard analytical shapes and free form shapes; (ii) provide the flexibility to design a large variety of shapes; (iii) reduce the memory consumption when storing shapes; (iv) can be evaluated reasonably fast by numerically stable and accurate algorithms; (v) are invariant under affine as well as perspective transformations; and (vi) are generalizations of non-rational B-splines and non-rational and rational Bézier curves and surfaces [16].

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**Figure 2: MRE methods – Fundamental processes and information flows**

- **Impression casts**
  - **Physical objects**
  - **Patients**
  - **Biomedical objects or samples**

**Phase I**

**Data Acquisition (Contact & Non-Contact)**

**Phase II**

- **Point Clouds**
  - **Data Registrations**
  - **Data Filtering**
  - **Triangle Mesh Models**
  - **Triangle Mesh Optimisation**

**Phase III**

- **NURBS – CAD Geometrical Modelling**
  - **2D Profiles - Contours**

**Phase IV**

- **Biomedical Application Development & Research**

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Based on two types of end-use data representation, the fundamental MRE methods are presented as shown in Fig.2, in which the state of the art data processing chains for 3D geometrical reconstruction of the objects for medical application development and research are emphasised. There are 4 main phases: (i) Phase I - MRE inputs, (ii) Phase II - Data acquisition, (iii) Phase III - Data processing and analysis, and (iv) Phase IV - Biomedical Application Development & Research.

2.1 Phase I - MRE inputs

There exists an interactive nature of the information processing and implementation steps of MRE. The input for MRE is crucial for data acquisition to develop medical applications and research. It determines not only the techniques and methods for data acquisition, but also data processing and analysis. It controls the required accuracy level from which 3D models are constructed for further medical application development. Depending on the end-use applications, different types of inputs for MRE are selected to meet not only the technical requirements, but also clinical constraints as shown in Fig. 3.

![Figure 3: The end-use applications determine MRE inputs](image)

The state of the art end-use applications of MRE include personalised implants for bone reconstruction, dental implants and simulations, surgical tools, medical training, vision science and optometry, orthopedics, ergonomics, orthosis, prosthesis, and tissue engineering. Table 2 presents the typical MRE’s end-use applications as well as the MRE inputs and related raw data types which are outputted from the data acquisition process. The MRE inputs can be patients or physical objects or impression casts as well as biological and medical samples from which the geometrical information of the object of interest and study is captured and collected for development of medical applications and research.

2.2 Phase II- Data acquisition

There are different techniques for MRE data acquisition. They are classified into two main groups: Contact and Non-contact. Contact methods use sensing devices with mechanical arms, Coordinate Measurement Machines (CMM) and Computer Numerical Control (CNC) machines, to digitise a surface. With non-contact methods, 2D cross-sectional images and point clouds that represent the geometry of an object are captured by projecting energy sources (light, sound or magnetic fields) onto an object; then either the transmitted or the reflected energy is observed. The geometrical data of an object are finally calculated by using triangulation, time of flight, wave-interference information and image processing algorithms. There is no contact between the RE hardware and an object during the data acquisition process.

<table>
<thead>
<tr>
<th>Applications</th>
<th>Examples</th>
<th>MRE inputs &amp; Data type</th>
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<tbody>
<tr>
<td>Personalised implants</td>
<td>-Implants for bone reconstructions for patients with skull defects due to traffic accidents or bone tumors -Implants for cosmetic cranio-maxillofacial surgery</td>
<td>- Patients - Data type: CT or MRI images</td>
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</table>
Medical Reverse Engineering Applications and Methods

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</tr>
</thead>
<tbody>
<tr>
<td><strong>Dental implants &amp; simulation</strong></td>
<td>- Implants: (i) Implants for bone reconstruction of the mandible, (ii) Dental implants for tooth reconstruction and replacement - Simulation: Simulation of an implant position on 2D &amp; 3D models, identification of the mandibular canal, calculation of the bone density, &amp; surgical planning</td>
<td>- Patients - Impression casts - Data type: CT or MRI images, Point clouds</td>
</tr>
<tr>
<td><strong>Surgical tools</strong></td>
<td>- Drilling guides for dental and spine surgery - The jigs to assist the process of removing tumors in bone reconstruction surgery</td>
<td>- Patients - Impression casts - Data type: CT or MRI images, Point clouds</td>
</tr>
<tr>
<td><strong>Surgical training &amp; simulation</strong></td>
<td>- Medical training models for surgeons and Medical Doctors to enhance surgical skills as well as to learn &amp; practice physical examination, general medical procedures, and clinical skills - Virtual 3D models for medical simulation, biomedical analysis and study</td>
<td>- Patients - Biomedical objects - Impression casts - Data type: CT or MRI images, Point clouds</td>
</tr>
<tr>
<td><strong>Vision science &amp; Optometry</strong></td>
<td>- Development of the contact lens - Simulation and study of the contact lens and eye shape</td>
<td>- Patients - Impression casts - Data type: CT or MRI images, Point clouds</td>
</tr>
<tr>
<td><strong>Orthopeadics</strong></td>
<td>- Development of hip and knee implants as well as the surgical tools such as orthopeadic plates, fixation tools and screws - 3D models for biomedical analysis and study</td>
<td>- Patients - Biomedical objects - Impression casts - Data type: CT or MRI images, Point clouds</td>
</tr>
<tr>
<td><strong>Ergonomics, Orthosis &amp; Prosthesis</strong></td>
<td>- Design &amp; manufacturing of personalised orthosis and ergonomic products such as chairs and car seats, shoes, and sport products - Design &amp; manufacturing of personalised prosthesis</td>
<td>- Patients - Biomedical objects - Impression casts - Data type: CT or MRI images, Point clouds</td>
</tr>
<tr>
<td><strong>Tissue Engineering</strong></td>
<td>- Design &amp; manufacturing of tissue engineering scaffolds - 3D modeling of bone structures for biomedical analysis and study</td>
<td>- Patients - Biomedical objects - Data type: CT or MRI images, Point clouds</td>
</tr>
</tbody>
</table>

Since most of medical applications are involved with complex geometries and shapes of the anatomical structures or biomedical objects, the contact techniques are less used compared to the non-contact ones for MRE data acquisition. However, for the applications which require a high accuracy, the contact techniques have to be used, such as the ones in which the impression casts of the interested objects are used as the MRE inputs. Table 3 presents the advantages and disadvantages of the contact and non-contact techniques [1]. Depending on the end-use applications and required accuracy, the relevant data acquisition techniques are selected.

Table 3: Advantages and disadvantages of the contact and non-contact techniques

<table>
<thead>
<tr>
<th>Technique</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
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<tbody>
<tr>
<td>Contact</td>
<td>(i) High accuracy; (ii) Low-costs; (iii) Ability to measure deep slots and pockets; and (iv) Insensitivity to colour or transparency.</td>
<td>(i) Slow data collection; and (ii) Distortion of soft objects by the probe.</td>
</tr>
<tr>
<td>Non-contact</td>
<td>(i) No physical contact; (ii) Fast digitizing of substantial volumes; (iii) Good accuracy and resolution for common applications; (iv) Ability to detect colours; and (v) Ability to scan highly detailed objects where mechanical touch probes may be too large to accomplish the task</td>
<td>(i) Possible limitations for coloured or transparent or reflective surfaces; and (ii) lower accuracy.</td>
</tr>
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</table>

The outputs of the MRE data acquisition process can be two following types: (i) Point clouds, and (ii) 2D slice images. These are then the inputs for the whole MRE data processing steps and further...
medical application development and research. When the laser and structured light are used as the projecting energy source, the output of the MRE data acquisition process is in the form of Point Clouds. When CT and MRI techniques are used, the output is in the form of 2D slice images.

2.3 Phase III- MRE data processing

Based on two types of raw data outputted from the data acquisition process, including point clouds and 2D slice images, different data processing approaches and workflow are used to obtain the right 3D models of the anatomical structures or objects of interest for medical application development and research as shown in Fig.2.

2.3.1 Point clouds as the input for MRE data processing

It is normally required to scan the object in different views in order to capture the entire geometry or the area of interest. Therefore, data registration is needed to combine, align or merge the point clouds from multiple scans so that all point clouds in the series are arrange in their proper orientation to on another in a common co-ordinate system.

In addition, a certain amount of error is always introduced into the scan data, and points may be placed in undesirable regions or overlapped. This is because points that have been scanned more than once when scanning complex shapes. Moreover, when the point cloud registration is applied, the aligned scan data normally contains overlapping points. Therefore, data optimisation is then required. In this step, the following common RE operations are used: (i) Noise and point redundancy reduction, and (ii) Sampling points. The sampling function is used to minimize number of points in the point cloud data so that it is easier to work with and make the data well-structured. Finally, the optimised point cloud data is finally triangulated to create 3D triangle mesh or polygon models of the object. 3D triangle mesh models are then optimised, manipulated and controlled or converted into 3D NURBS CAD models to meet the requirements from the end-use applications.

2.3.2 Slice images as the input for MRE data processing

For CT/MRI scanners, the images are normally stored in the form of DICOM format. However, with the applications that use MicroCT imaging systems, different data formats such as BMP or PNG can be used, the image resolutions achievable with these micro-CT systems extend into the range of light microscopy, down to one or a few microns [3].

Specialized image processing tools and packages are required to do image processing for 3D data reconstruction of the hard and soft tissues or objects of interest. There are two basic steps for 3D reconstruction from 2D slice images, including (i) Image segmentation, and (ii) Region of Interest (ROI) growing. Segmentation by threshold techniques is used to define ROI that presents the object for 3D reconstruction; it is based on the grey-scale value of image pixels. The object can be defined based on one lower threshold, or based on a lower and a higher threshold [1]. In the former case, the segmentation object will contain all pixels in the images with a value higher than or equal to the threshold value. In the latter case, the pixel value must be in between both threshold values to be part of the segmentation object. The region growing technique provides the capacity to split the segmentation into separate objects; it is useful for the separation of anatomical structures, especially bone and soft tissues.

The outputs of the image segmentation and ROI growing are 3D triangle mesh models or 2D contours of the ROI or anatomical structures. The same with the case of Point Clouds as the input for data processing, 3D triangle mesh models are finally optimised, manipulated and controlled or converted into 3D NURBS CAD models to meet the requirements from the end-use applications.

2.4 Phase IV- biomedical application development & research

The resulting 3D triangle mesh models can be directly used for applications such as Rapid Prototyping, 3D graphics and animations, Surgical Planning, and Structure or Biomechanics Analysis. However, for the applications that require high accuracy for graphic representation or further complex geometrical modeling and design, these triangle mesh models are used as the reference to create CAD entities (points, curves and primitives) and constructing NURBS CAD models which are again used as the reference for medical product development and research in which CAD/CAM/CNC/CAE systems are used.

3. Results

More than 75 medical applications and clinical cases have been conducted since 2001 [4-15]. Figures 4 and 5 presents the typical ones, including personalised implants, dental implants and simulations, surgical tools, surgical training and simulation, vision science & optometry, orthopeadics, ergonomics, orthosis, prosthesis and tissue engineering. The following are the brief description about the typical MRE applications that are shown in Fig.4.
Figure 4: Typical MRE applications, including personalised implants, dental implants and simulations, surgical tools, surgical training and simulation, vision science and optometry, orthopedics, ergonomics, orthosis, and tissue engineering.

- Fig.4 (1-3): 3D CAD models of the head constructed with the use of structured light RE scanner for data acquisition. These 3D NURBS models were used as the reference for development of the custom-made helmet and design of the cradle for MRI scanners.

- Fig.4 (4): 3D NURBS model of the knee which was constructed from CT and MRI data for Biomechanics analysis and simulation.

- Fig.4 (5): 3D NURBS models of the ear casts constructed from Point Clouds which were collected by laser scanning of the ear casts. These models were then used for design and manufacturing of the hearing aid devices.

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• Fig.4 (6): 3D models of the defect skull and a personalised cranioplasty implant [11-15]. The CT images of the patient were used for 3D skull reconstruction. 3D data of the defect skull was used for designing the personalised implant which fits well to the defect window. The implant was then prototyped by Rapid Prototyping, from which the mold was made for fabricating the biomaterial implant. Since the implant was fabricated before the operation, and the surgical plan was well prepared; the operation time was remarkably reduced to maximum of 2 hours for the most of the cranioplasty surgery. Figure 5 (8) presents the patient before and after the operation with the use of a personalised implant.

• Fig.4 (7): 3D triangle model of the human heart constructed from CT images. This 3D model was used for Biomechanics study as well as development of the artificial heart prototype for medical training.

• Fig.4 (8-9): 3D models of the elbow and foots which were constructed from laser scanning of the impression casts and CT images. These models were used to develop the personalised orthosis devices [5-8]. The orthosis device for the bone fracture treatment and elbow rehabilitation is shown in Fig.4 (9).

• Fig.4 (10): New generation of the chair and car seats with the lumbar supports developed, optimised and virtually tested based on the 3D models of the human body which were reconstructed from structured light scanning.

• Fig.4 (11): A patient with the bone tumor on the skull was treated by using a single-step operation based on MRE. 3D models of the skull and bone tumor were reconstructed from CT images. The jig was then designed and used as the guide to remove the tumor. At the same time, the personalised implant was designed and made to fit exactly the defect cavity created after the tumor was removed. In this way, we need only one single-step operation, instead of using two

Figure 5: MRE applications – Typical prototypes and clinical cases. (1-3): Prototypes of the implants and Biomodels for bone reconstruction and orthopedics surgery. (4): The medical training model for keyhole surgery. (5): The standard cranioplasty implants. (6-7): Custom-made orthosis devices developed from 3D models of the elbow and foot. (8): A patient before and after operation with the use of a personalised implant.
operations in which one operation is used for removing the tumor, and the second operation is conducted after 2 or 4 months from the first one for treatment of the defect cavity.

Figure 4 (11, left) presents 3D models of the skull with a bone tumor and the jig for removing the tumor. The personalised implant was designed to fit well to the defect cavity is shown in Fig. 4 (11, right).

- **Fig.4 (12):** 3D model of the human head, including both hard and soft tissues, constructed from CT and MRI images. It is used for testing the medical devices as well as developing the medical training models.

- **Fig.4 (13):** Surgical training models developed from CT/MRI images. This was a project funded by European Union: PRIMACORPS, CRAF-99-70074, “Cost effective, realistic surgical trainer for hands-on endoscopic procedures through application of Rapid Prototyping, CAD/CAM technology and a novel material”.

- **Fig.4 (14):** New generation of contact lens was developed based on analysing 120 eye shapes of European people. The eye casts were done and used as the MRE input for reconstructing 3D eye shapes based on laser scanning. Mean geometries of the eye groups were computed for designing a new generation of the ellipsoidal contact lens. Menicon, a Japan’s first and largest contact lens manufacturer, is planning to manufacture 4 new types of ellipsoidal contact lens based on the reconstructed data sets of the eye shapes and their mean geometries.

- **Fig.4 (15):** 3D models of the teeth with the root canal constructed based on the laser scanning and micro-CT images for developing the tooth prototypes that mimic the real teeth for surgical training.

- **Fig.4 (16):** 3D model of the trabecular bone structure and its FEA simulation constructed from micro-CT images.

- **Fig.4 (17):** 3D model of the dental cast and the drilling guide for dental surgery based on laser scanning. The 3D models of the dental casts can also be used for not only developing the artificial tooth, but also the crown, orthodontic treatment devices, and dental bridges.

- **Fig.4 (18):** Application of MRE for treatment of Hip Resurfacing Arthroplasty (HRA). 3D models of the femur are reconstructed from CT data of the patient. They are used for developing the drilling guide and FEA simulation in order to obtain the optimal angle for the implant, from which the fracture of the femur head is reduced, and the length of the implant age is increased [9-10].

### 4. Discussion and conclusion

Related to MRE applications about design and manufacturing of biomodels, personalised implants, surgical tools as well as medical devices [11-15], although the benefits are well recognised, the number of clinical cases is still limited and the technology has not been widely applied for diagnosis and treatment due to difficulties of technology transfer to hospitals. The main reasons that lead to these difficulties are as follows [4]: (i) the complexity of the design, (ii) challenges about multi-disciplinary collaboration & communication, and (iii) high cost of technology and investment.

In order to develop successfully MRE applications, both technical and clinical constraints must be well defined. In addition, the optimal selection of the hardware and software for implementation is also important. There are typically three groups of currently available commercial hardware for MRE applications: (i) Non-contact scanners based on the structured light and laser source, (ii) Medical CT or MRI scanners, and (iii) Specialized instruments, including CMM and micro-CT systems. Depending on the accuracy level required for the applications, and MRE inputs or objects to be based on for data acquisition are determined, and the hardware is optimally selected.

There is no single software that can fulfill and satisfy completely the requirements in data processing and geometrical modelling works [1]. The selection of the software therefore depends on the end-use application, especially the complexity of the geometrical modelling processes and data exchange among the packages. The following are the typical software and tools that are necessary for implementation of MRE applications, including (i) Medical Image Processing (MIP), (ii) Rapid Prototyping (RP), (iii) Finite Element Analysis and simulation (FEA), (iv) Reverse Engineering & Dimensional Inspection, (v) Freeform Modelling, (vi) CAD/CAM, and (v) Dental CAD/CAM.

- **MIP:** These are the packages which are specifically developed for medical image processing, including MRI and CT data. Normally, they provide basic tools for image processing such as image segmentation, ROI growing, 3D reconstruction of the anatomical structures. Most of these package provides the common tools for surgical planning, especially the ones for dental surgery. A few packages allow simple geometrical modelling operations for implant design and
With the rapid development of both hardware and software, more and more medical applications are developed based on RE and its related ones. However, most of the MRE applications require high skills of design and geometrical modelling as well as medical image processing. In order to be successful, there is a need for a close multidisciplinary collaboration among professionals from different areas, including design and manufacturing, material sciences, biomedical engineering, and medicine.

Understanding well the data processing and information flows of MRE is crucial for successful development of the end-use applications as well as reducing the investment costs about both hardware and software. The paper presented fundamental concepts and backgrounds about MRE as well as the approaches for development and implementation of MRE applications. Finally, the potentials and benefits of applying the RE technology for medical application development and research are clearly shown with the introduction of the state of the art applications and clinical cases, including personalised implants for bone reconstruction, dental implants and simulations, surgical tools, medical training, vision science and optometry, orthopedics, ergonomics, orthosis, prosthesis, and tissue engineering.

References


