PERSONALISED MEDICAL PRODUCT DEVELOPMENT: METHODS, CHALLENGES AND OPPORTUNITIES

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Abstract: Personalised health care in general and personalised medical products in particular aim to provide the optimal diagnosis and treatment with the use of the right medicine, tools and devices to the right patient at the right time in order to meet well technical and clinical requirements as well as individual characteristics of each patient. It offers the increased effectiveness and better patient safety, and finally to obtain the best diagnosis and treatment quality. In this paper, the area of personalised medical product design and development is emphasised with the focus on design and manufacturing of implants, surgical tools, medical devices, orthotics and prostheses. State of the art technologies, methods and resources for developing personalised medical products are presented in which challenges and opportunities are addressed and discussed.

Keywords: Personalised health care, medical product development, implants, surgical tools, orthotics.

1. Introduction

Patient-specific diagnosis and treatments have been one of the most emerging research topics recently. The concept of Personalised Heath Care (PH) or Personalised Medicine (PM) was well documented [1, 2, 3]; it was firstly considered as a novel strategy to tailor medical treatment to the individual characteristics of each patient, with a main attention about the pharmaceutical area. However, the terms PH and PM are today widely used in different areas and medical applications. Especially, there have been a lot of efforts in development of personalised medical products and services for optimal diagnosis and treatment to meet well both clinical and technical requirements since the late 1990s [5-8]. With the advancement of design and manufacturing technologies in the last decades, more and more high-value added personalised medical products have been successfully developed, and brought in well-recognised benefits for patients. The high interest in PH is clearly shown in the recent funding calls from European Commission, under the FP7 work programmes in 2011 and 2012. PH is one of the main content of the Information and Communications Technologies - ICT call [4], especially the following ones: (i) Objective ICT-2011.5.1 - Personal Health Systems; (ii) Objective ICT-2011.5.5 - ICT for smart and personalised inclusion; and (iii) Objective ICT-2011.5.3 - Patient guidance services, safety and healthcare record information reuse. The term "personalised" and "patient-specific" as well as the related ones are used for different areas of application and research, including the following topics and key-words: (1) Patient guidance services for personalised management of health status; (2) Personalised web-based assistive and social computing solutions; (3) Patient-specific data and models of organs; (4) Personalised health systems; (5) Personalised digital media; (6) Personalised and predictive care; (7) Personalised prevention and research; (8) Personalisable solutions for learning and skills acquisition as well as Brain-Neural Computer Interfaces; (9) Personal health systems for remote management of diseases, treatment and rehabilitation; (10) Personal health records systems; (11) Personalised services and support; (12) Personalised instructional design; (13) Personalisation of educational technologies; and (14)
Systems for personalised interaction with users. The tendency for funding and investment in personalised products and services are clearly seen, in which personalised medical product design and development is one of the most interesting areas for the last decades, especially from the time when Rapid Prototyping (RP) and Rapid Manufacturing (RM) were successfully applied for development of implants, surgical tools and medical devices for diagnosis and treatment [5-11]. With the use of patient data for medical product development, implants, surgical tools and medical devices are able to be personalised to meet well specific requirements for the patient. The implants can be designed to fit exactly the defect window on the skull, or the titanium membrane can be designed and manufactured to fit well the geometry of the femur or tibia for treatment of the bone tumor [6]. Figure 1 presents typical 3D design and modelling for medical product development. The details about successful implementation of typical personalised medical products are presented in the next sections.

![Figure 1: 3D design and modelling for medical product development. (a) Design of a personalised implant for treatment of the skull defect. (b, c) 3D models of trabecular bone and a human heart for biomechanical simulation and tissue engineering applications. (d) A 3D model of a dental cast for development of the surgical guide. (e) A bone tumor on the skull and surgical tool for removing the tumor. (f) 3D models of the teeth for dental applications.](image)

Opportunities for PH in general and personalised medical products in particular lead to both technical and clinical challenges as well as issues related to investment and commercialisation of the research results. There is an emerging need for investigation of methodologies and technologies for robust, efficient and effective product development for medical applications in which the design and development team’s members, including MD or surgeons, radiologist, design and manufacturing engineers as well as patients, are normally not in the same place. The lack of high-skilled human resources in hospitals in product design and biomedical engineering, high costs for diagnosis and treatment, as well as limitation of the effective services for patients, could lead to limited applications of the personalised medical products. Taking advantages of the state of the art design and
The last 2 decades, implants to base 5, k with each other, are stressed and considered as providing the best solutions and to meet the specific requirements for customers or patients. In addition, collaborative design, intelligent database and expert systems could be useful for communication and collaboration among MD or surgeons, engineers and patients. This also helps the process of technology transfer to hospitals to be more convenient. Finally, the advancement in the areas of RP&M, micro and nano manufacturing and new material development add more values and minimise the development time for personalised products.

In this paper and presentation, methods, challenges and opportunities for personalised medical product development are emphasised and discussed. It is aimed to creatively develop innovative products to meet patient-specific clinical and technical constraints with high added values and cost-effectiveness for diagnosis and treatment. Breaking down the barriers and limitations for effective translation of knowledge into clinical practice is also the key objectives in the field of the study.

2. Personalised medical products - methods and applications

Personalised medical products have been commercially available for diagnosis and treatment in hospitals in recent years. Although big challenges still exist, there are many clinical cases which were successfully conducted for diagnosis and treatment. The typical personalised medical products and applications include: (i) Implants for bone reconstruction; (ii) Biomodels; (iii) Surgical tools and devices; (iv) Dental implants and dentures; (v) Ergonomics, orthotics and prostheses; (vi) Scaffolds for tissue engineering; and (vii) Patient-specific contact lens. The common approach for personalised medical product design and development is to base on patient data in the form of 3D models of anatomical structures to design products to meet both clinical and technical constraints. Designers need to collaborate with Medical Doctor (MD) or surgeons for surgical and treatment planning. The design is carefully evaluated and optimised before it is transferred to manufacturing processes for production. Medical Image Processing (MIP), simulation and 3D modelling tools are normally required for development teams, including MD or surgeons, radiologists, design and manufacturing engineers, to collaboratively work with each other, especially for the cases the team members are not in the same place.

- **Implants for bone reconstruction:** Personalised implants are commonly used for bone reconstructions in dental - cranio maxillofacial, orthopaedic and cosmetic surgery [5-7]. They are designed and manufactured to fit exactly the anatomy of patients and considered as the best treatment solutions for bone reconstruction, especially for the cases of large defects and fractures as well as big tumours on the skulls or other parts of skeletons such as femur or tibia. Temporary personalised implants are normally used for treatment of bone fractures in oral - maxillofacial and orthopaedic surgery such as orthopaedic plates and fixation tools.

The main advantages of personalised implants include (i) Short operation time and less requirement of high skills from surgeons, and (ii) Better cosmetic results compared to the ones fabricated by traditional manual methods [5-7, 10, 11]. With the advancement of MIP, CAD/CAM/CNC and RP&M in the last 2 decades, personalised implants can be designed and manufactured optimally. First of all, 3D models of anatomical structures need to be reconstructed from medical images such as CT/MRI. Depending on the complexity of implants and biomaterials to be used, optimal solutions for implant design and fabrication are applied [5, 8]. The most common biomaterials used for bone reconstruction are PMMA, HA (Hydroxy Apatite), CFRP (Carbon Fiber Reinforced Plastics), Bioceramics, HDPE (High Density Polyethylene), and Titanium. For the temporary implants for treatment of bone fracture and reconstruction, titanium alloys, stainless steels and CFRP are normally used.

- **Biomodels:** Biomodels are the physical models of anatomical structures. They have been used successfully for diagnosis, surgical planning and simulation in dental - cranio maxillofacial, orthopaedic and cosmetic surgery. The benefits and main applications of biomodels are well documented [5-10, 12, 13], including: (i) Enhancing the visualization of Region Of Interest (ROI) and anatomical features for better understanding of patient anatomy; (ii) Better communication in diagnosis, preoperative planning and consultancy among surgical team members, radiologists, and patients; (iii) Carrying out rehearsal procedures to improve surgeon’s skills and optimise preoperative procedures; and (iv) Prefabrication of custom-made implants and selection of an optimal donor site for...
**Surgical tools and devices:** Surgical tools and devices are very important for surgeons during the operation. Personalised surgical tools are used for enhancing surgeon’s skills, reducing the operation time, and increasing the accuracy and safety of the operation [7, 16, 17]. The most typical surgical tools include (i) Drilling guides for dental and spine surgery; (ii) Jigs to assist the process of removing tumours in bone reconstruction surgery; and (iii) Devices for determining the drilling angle for the implants in hip resurfacing arthroplasty (HRA) and total hip replacement surgery.

In the case of treatment of bone tumours, a surgical tool is used as a guide for removing the bone tumor. The implant is exactly designed and made; it is then implanted after the tumor is removed. In this way, in stead of using two operations, surgeons need only one operation for the treatment. The time for the operation as well as post treatment is therefore remarkably minimised.

In dentistry, personalised surgical tools are used for surgical positioning of orthodontic miniscrews and dental implants [18]. The surgical guides nowadays can be fabricated directly by RP. One of the most innovative personalised dental products is dental aligners for straightening the teeth. The software tools and RP processes developed by Align Technology, Inc. [33] allow design and fabricate a series of personalised aligners; and this dental service is today available worldwide.

**Figure 2: FEA of Hip Resurfacing Arthroplasty for development of personalised surgical tools.**

In hip replacement surgery, especially in HRA, the pre-operative and intra-operative planning, including selection of an implant from standard ones, measuring sizes of the femur head, and determining the implant (stem) angle, is currently based on 2D X-ray images, conventional tools and manual methods. This leads to a high risk in surgery and unstable treatment quality, which is much dependent on the experiences and skills of a surgeon. The errors from the current surgical techniques result in an incorrect implant angle, which could be the main reason of causing fractures of the femur and reducing the survivorship of an implant system. Moreover, the manual method tools are used for pre-and intra-operative planning without the support of the computer system, 3D medical imaging techniques, and personalised surgical aid tools, it also leads to longer operation time. Although the robotic and surgical planning systems are available for HRA, the drilling line for locating the implant is still defined geometrically and intra-operatively; the biomechanics aspects of the implant and bone structure are not fully considered. Figure 2 presents the stress and train distribution on the femur nec of HRA [34]. Personalised surgical tools for determining the optimal angle of the implant alignment is therefore neccessary and help enhancing the surgical skills, minimising the surgical time and improving biomechanic characteristics of the implants and bone structure that leads to better survivorship of an implant system.

**Dental implants and dentures:** A dental implant is a metal rod that is placed in the jawbone to hold a false tooth or teeth in place. Dental implants are usually made of titanium. After the implantation, the jawbone fuses with the titanium rod; and dentures, crowns or bridges can be screwed or clipped onto the implant. One dental implant can support one or more false teeth. Nowadays, software and tools are available for 3D surgical planning and simulation as well as design and development of personalised dental implants, dentures and protheses; the typical ones are SensAble™ Dental Lab and 3Shape's Smile Composer [36].

**Ergonomics, Orthotics & Prostheses:** Ergonomics is used in design to make products or services that meet the need of the users efficiently
and comfortably. Specifically, ergonomic design focuses on the compatibility of products or objects and environments with the humans using them. Human-centered design is the main aspects of ergonomics; therefore, it needs to be taken into account when design and development of personalised medical products such as innovative chairs and mattresses to support comfortably the spine of users, as well as orthotics and prostheses for rehabilitation and sports [19, 20]. Important human factors, such as vision, reach of envelope, operation strength and workloads as well as specific clinical requirements for the patients and users need to be taken into account during the product design and development process. There is an emerging research to develop novel ankle and foot orthotics for common disabling conditions which are cost-effective, high-speed to market, and personalised for form and function, such as the A-FOOTPRINT project funded by EC under FP7 programmes for the period 2009 - 2013. Disabling foot and ankle conditions affect approximately 200 million European citizens; and over €300 million per annum is spent treating many of these people withorthoses and splints [21]. Efforts have been made to develop orthotic devices such as personalised sports insoles for sporting activities to improve skeletal function, enhance the biomechanical performance of the users, and subsequently provide a more economical gait [24]. There have also been efforts to develop personalised innovative orthotics for treatment of Drop Foot which is an abnormal neuromuscular disorder that affects the patient's ability to raise their foot at the ankle [22, 23].

**Contact lens:** A contact lens is a corrective, cosmetic, or therapeutic lens usually placed on the cornea of the eye. It has been estimated that 125 million people use contact lenses worldwide, including 28 to 38 million in the United States and 13 million in Japan [37]. The types of lenses used and prescribed vary markedly between countries, with rigid lenses accounting for over 20% of currently-prescribed lenses in Japan, the Netherlands and Germany but less than 5% in Scandinavia. The commercially available contact lens is symmetrical and manufactured by the well-documented turning techniques. However, each person has a different eye shape and size. Recently, there has been interested in developing a new generation of personalised or patient-specific contact lenses that fit well the eye of individuals or groups of people. This leads to innovative design and development of ellipsoidal contact lens that has a complex shape, and it is not symmetrical. Personalised or patient-specific contact lenses are especially necessary for people who have special eyes or high astigmatism, in order to get more comfort and special clear vision. Both Rigid Gas Permeable (RGP) and soft contact lens are nowadays obtainable for peoples’ personalised needs.

**Scaffolds for tissue engineering applications:** Tissue engineering emerged in the early 1990s to address limitations of the tissue grafting and alloplastic tissue repair where the cells are taken from a patient, their number expanded and seeded on a scaffold. The appropriate chemical, biological, mechanical and electrical stimuli are applied and new tissues are generated and then implanted to help restore function in the patient [25-28]. Tissue engineering utilises porous biomaterial scaffolds to deliver biological factors that accelerate tissue healing. The ideal scaffolds should have an appropriate surface chemistry and microstructures to facilitate cellular attachment, proliferation and differentiation. Specifically, a tissue engineering scaffold needs to fulfill the following primary requirements, including (i) Correct anatomic shape and volume in which the anatomic shape which is defined geometrically by the tissue defect, (ii) Adequate mechanical support via relevant selection of constitutive parameters of linear and nonlinear elasticity, viscoelasticity and poroelasticity, and (iii) Enhancement of tissue regeneration through the biologic delivery [25, 26].

Patient data is therefore needed for design and development of the personalised scaffolds to meet the primary requirement of the anatomic shape and volume of the tissue defect to be repaired. Recent advancement in RP&M and 3D modelling as well as micro and nano manufacturing have made it possible to create scaffolds with controlled architecture [26-28]. The world’s first tissue-engineered whole organ transplant - using a windpipe made with the patient’s own stem cells was successfully implemented in 2008 using the tissue scaffold which was made of the fibrous protein collagen. The first synthetic windpipe transplant was successfully conducted in July 2011, based on the nanocomposite tracheal scaffold that is an exact replica of the patient’s own windpipe. Today, the personalised windpipe can be made within one week.

3. Challenges and opportunities

In the previous sections, typical personalised medical products and development methods were reviewed and presented. There are more and more high-value added personalised products are being developed to meet patient-specific requirements with the aim to improve the quality of diagnosis and treatment for patients. However, there are challenges that need to be overcome in order to make it possible for the wide applications in hospitals in both developed and developing countries. Figure 3 presents the most important factors and issues that
influence in the design and development of personalised medical products.
Most of personalised medical products need to use patient data as the starting point for product design and development. Normally, patient data are in the form of medical images such as Computerized Tomography (CT), Magnetic Resonance Imaging (MRI), Positron Emission Tomography/CT (PET/CT), and Optical Coherence Tomography (OCT), or point clouds that represents the geometry of the subjects acquired by RE techniques. In treatment of bone fracture and reconstruction, CT images provide the best quality for 3D modeling of bone structures and skeleton. Meanwhile, MRI images are useful for 3D reconstruction of soft tissues. In eye imaging and 3D reconstruction of the eye shapes, CT, MRI, OCT and RE are commonly used; the use of these techniques depend on the clinical constraints and required accuracy. There are many applications where the direct scanning and imaging is not possible; in these cases, the negative casts and molding techniques are applied such as the use of dental casts and rapid tooling for modeling the teeth, eye shapes and foot for development of surgical tools, dentures, contact lens and orthotics [22, 23].

![Figure 3](image_url)

**Figure 3: Key factors and issues in design and development of personalised medical products.**

There are 2 main types of data and formats used in personalised medical product development, including (i) 2D cross-sectional images in the form of the DICOM format for medical imaging techniques such as CT/MRI and PET-CT; and (ii) Point clouds in the form of the ASCII format for the RE techniques.

When working with 2D cross-sectional images, segmentation by threshold techniques is used to define the 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. 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 hard and soft tissues in patient data [29]. The accuracy related to data acquisition and processing is the most important issues and challenges that need to be taken into account for personalised medical product design and development. This is also important when considering the investment on the hardware and software as well as equipments. It is noted that the errors from the image segmentation and data processing could be up to 0.5 to 1 mm. For the applications that use the RE techniques for collection of patient data, the errors from data acquisition, registration and processing could be
more than 1 mm. Normally, patients, hospitals, product design and development centres or companies are normally not in the same places, they are geographically distributed. Therefore data transfer and communication during the product development process needs to be taken into account. CT/MRI data acquisition is commonly done in hospitals, then the data is sent to centres or companies via the internet for personalised medical product development. For dental applications, dental casting and rapid tooling techniques are used with help of the specialists at medical centres or hospitals. This could lead to difficulties and time-consuming. Tools and software for remote data management and viewing as well as collaborative design and communication could be the best solution; especially when the completed design needs to be evaluated and confirmed by MD or surgeons as well as patients before it is transferred to the prototyping and manufacturing phase.

The surgical planning as well as procedures for diagnosis and treatment are normally required for personalised medical product design and development [7]. The planning that is done by surgical teams or MD results in the clinical constraints. Of course, the technical specifications for the products also need to be considered as well. Since it is very common that MD or surgeons and designers are not in the same place. Designers need to be equipped a good knowledge and background in Biomedical Engineering. As mentioned above, it is also necessary to develop software and tools for collaborative design and treatment planning so that MD or surgeons as well as designers are able to work collaboratively, and transfer the design data conveniently and quickly for better communication and planning. In this way, the lead time for product design and development is minimised.

The other important issue that needs to be carefully considered is the design and manufacturing techniques to be applied for personalised medical product development. Since most of personalised medical products have complex shapes and require special materials. In addition, the products need to meet both clinical and technical constraints. The conventional and traditional design and manufacturing techniques cannot be straightforwardly applied. However, with the advancement in MIP, RE, CAD/CAM/CNC and RP as well as hydro-forming in the last decades, the optimal solutions for design and manufacturing of personalised medical products are successfully investigated [5-12, 22-26].

For products such as personalised implants, surgical tools and biomodels, design evaluation needs to be biomechanically evaluated and checked with MD or surgeons. This is practically time-consuming if the designer and MD or surgeons are not in the same place. It is similar to the case of surgical and treatment planning, software and tools for collaborative design, evaluation and simulation could be useful for design evaluation and check. To date, most of the MIP and 3D modeling for design and development of personalised implants and surgical tools do not support collaborative design, viewing and simulation. Stand-alone modules for viewing the design may be available, however, it is not convenient. In addition, the investment of the state of the art MIP, CAD and 3D modeling tools for MD or surgeons are not economically effective because of the high investment and maintenance cost.

Materials used for the products as well as the required accuracies decide the relevant manufacturing techniques to be used. In recent years, direct fabrication of implants and surgical tools in biocompatible metal using electron beam melting (EBM) technology is available [30]. Europe allowed the production of hip implant products which are fabricated directly from EBM technology as such the Arcam’s EBM® machines which were awarded the CE certification in January 2007. The U.S. implant manufacturers have recently received FDA’s clearance for products manufactured with the Arcam’s EBM® technology. There are about 30,000 orthopedic implants which have been produced by EBM worldwide, mostly in Europe; and about half have been implanted into patients. Moreover, a direct metal laser sintering (DMLS) from EOS GmbH can be used to produce the dental coping which is the main structure of a crown or bridge that is personalised to fit the patient [32]. It is noted that the cost of the medical products and treatment depend heavily on the design and manufacturing technologies to be used. With the use of 3-axis CNC milling for making personalised cranioplasty implants, the cost of treatment could be reduced up to 50% compared to the use of RP or 5 Axis CNC milling [6, 10].

Finally, development of personalised medical products needs to take into account carefully the end-use applications. Especially, this is important when considering about investment of the relevant hardware and software as well as necessary equipments. Personalised dental products may require specialised equipments and software. However, personalised products such as implants, surgical tools, orthotics and prostheses, the common advanced technologies such as CAD/CAM/CNC can be used if the relevant design and manufacturing methods are optimally applied. Of course, the key technologies such as RE and RP should play an important roles for personalised design and development of implants, surgical tools and guides, dental aligners, biomodels and dental copings [5, 32, 33].

The above discussion and presentation is about the most influencing factors and issues, including the
common challenges and opportunities, that need to be carefully considered when development of personalised medical products, especially for investment of software and equipments. Special considerations should be paid to innovative and creative development of advanced RP and fabrication technologies as well as biomaterials. The key factors and issues in design and development of personalised medical products shown in Figure 3 also imply the multi-disciplinary research and development as well as close collaborations among engineering, medicine, software development, and material science.

Although personalised medical products are useful for diagnosis and treatment and have been successfully applied in hospitals for many clinical cases. They are not commonly available in hospitals, even in developed countries, there are still limited clinical cases conducted in the last decades [8]. The following are the key challenges that need to be overcome; and these are also the opportunities for further research and development.

- **Complex design, 3D modeling and MIP:** There are limited human resources in hospitals that can do the medical product design and development. The design is normally done by product design centres or companies working in the areas related to Biomedical Engineering. Most of personalised medical products are required to meet both clinical and technical constraints, and high skills of design, 3D modeling and MIP are normally needed. Although advanced modeling tools and software are available, there are still challenges and difficulties, especially designers need to have a good background in both engineering and medicine. Intelligent design database and expert systems to support MD or surgeons and designers could be good options.

- **Multi-disciplinary collaboration and translation of knowledge into clinical practice:** As mentioned above, most of personalised medical product design and development require multi-disciplinary collaborations among MD or surgeons, radiologists, design and manufacturing engineers. The design and manufacturing processes involve in the multi-disciplinary collaboration among different experts which are normally not in the same office and organisation. Therefore, it may lead to time-consuming or miscommunication. Software and tools for effective and efficient collaborative design and communication should be necessary.

- **High cost of personalised medical products:** Since the products need to be designed and developed for personalised diagnosis and treatment. It cost more compared to the products of mass production. In addition, investment for hardware and software for personalised medical product design and development is quite expensive. The state of the art MIP software and modelling tools cost from 20,000 to 50,000 USD. The RP machines that can be used for medical applications are from 50,000 to 200,000 USD. Moreover, complex design and 3D modelling as well as the need of multidisciplinary collaboration also add more cost to the final product. The high cost is one of the big challenges that limit the wide application of personalised medical products in diagnosis and treatment. Investigation of cost-effective methods with the use of evidence-based practice and knowledge-based product development may be useful for personalised medical products [21]. Advantages of collaborative design and mass-customisation may also need to be taken into account for development of the optimal design and manufacturing systems for individual or groups of personalised medical products.

4. **Conclusions**

Personalised health care in general and personalised medical products in particular aim to provide the optimal diagnosis and treatment with the use of the right medicine, tools and devices to the right patient at the right time in order to meet well technical and clinical requirements as well as individual characteristics of each patient. In this paper and presentation, the methods and typical personalised medical products that have been conducted successfully for diagnosis and treatment were reviewed and presented. The most important factors and issues that play an important role in design and development of personalised medical products were also discussed. Although the presentation is more emphasised on the specific products or groups of products and applications, the paper is aimed to generalise challenges and opportunities for research and development of medical products for PH from which suggestions for further investigation on design and manufacturing methods as well as software and tools for personalised product design and development are made and summarised.

It would be helpful if there are innovative tools and methods for collaborative design and communication for multidisciplinary product design and development team to work together effectively and efficiently, including MD or surgeons, radiologists, design and manufacturing engineers and patients. Especially, there is a strong need for tools and technologies that allow collaborative design, simulation and evaluation of the developed personalised products. In combination with the intelligent design database or expert systems to support MD or surgeons and designers, challenges about complex design and multidisciplinary collaborations could be solved. Finally, methodologies for mass-customisation, concurrent engineering and collaborative design could be useful.
and applicable for development of optimal design and manufacturing systems for individual or groups of personalised medical products; in this way, the cost of the products could be minimised. Finally, in order to be convenient for translation of knowledge into clinical practice, there is a need of better and more efficient ways and working environments to help hospitals and product design centres or companies to work collaboratively and efficiently. A robust decision support and information management tools as well as intelligent database and expert systems could be useful; and they should also be integrated into the personalised medical product design and development systems.

5. Bibliography


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