Rapid Prototyping in Biomedical Applications

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Abstract-- Rapid Prototyping (RP) is the term given to a set of processes that can quickly fabricate any given three-dimensional object into a model or prototype, directly from a CAD file via the additive deposition of individual cross-sectional layers of the part.

With increased competition from the global economy & the challenge of delivering new customized products more quickly than before, several technologies collectively known as Rapid Manufacturing (RM) have been developed.

Rapid manufacturing is a process that employs concept of RP to produce directly end-use items without molding, casting or machining. This is why RM is heralded as the next industrial revolution of digital age.

This paper focus on Biomedical application of different Rapid Prototyping & Rapid Manufacturing technologies & its advantages.

Index Terms—**Rapid Prototyping, Rapid Manufacturing, Biomedical applications, bio-compatible and bio-absorbent material, tissue engineering.**

I INTRODUCTION

Prototyping (RP) is two decade old technology to quickly produce tangible objects directly from a 3D CAD model and is being used to shorten and simplify the product development cycle for many applications including aerospace, automobile and home appliances etc., It involves adding material successively, in layers, to create a solid of a predefined shape. Over the years, RP has evolved from producing prototypes for form, fit and functional testing to producing final end products for functional use.

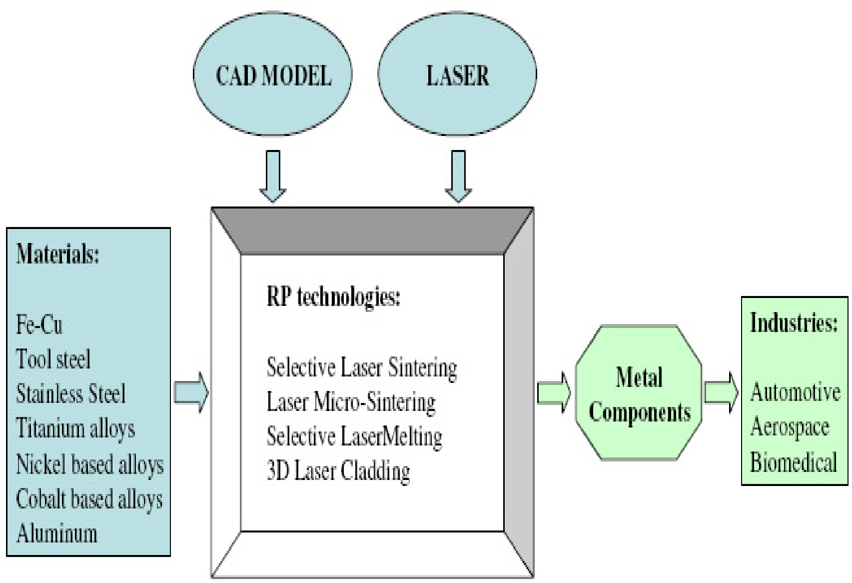


Fig.1- Schematic representation of Concept in RP technology

In the beginning, RP was mostly used for the fabrication of prototypes made from polymers as communication and inspection tools. The fabrication of conceptual and functional prototypes made from polymers is already well established in the market. Components made by RP techniques are no longer used only as visualization tools or for assembly testing. The next natural step for these techniques is to produce functional parts directly from metals and ceramics. This started the transition phase of rapid prototyping to rapid manufacturing. Nowadays, rapid manufacturing (RM), i.e. fabrication of end-use parts directly from RP machines, have been the subject of a lot of research.

Experts have envisioned the wide ranging advantages that exist when rapid manufacturing is implemented. The application of different RM technologies focus on the initial cost and time savings that are realized when tooling is eliminated. The current future trend is shifting towards RM, thus eliminating the need for most prototype tooling and production tooling. RM is the next frontier for researchers, publishers & users of advance technologies. Figure 1 represents concept of different RP technologies.

II RAPID PROTOTYPING TECHNOLOGY – AN OVERVIEW

Research in the rapid manufacturing of metallic components is relatively new, there are currently numerous different directions in RP technology development. These technologies can be grouped according to their fundamental material deposition working principles as seen in Figure2

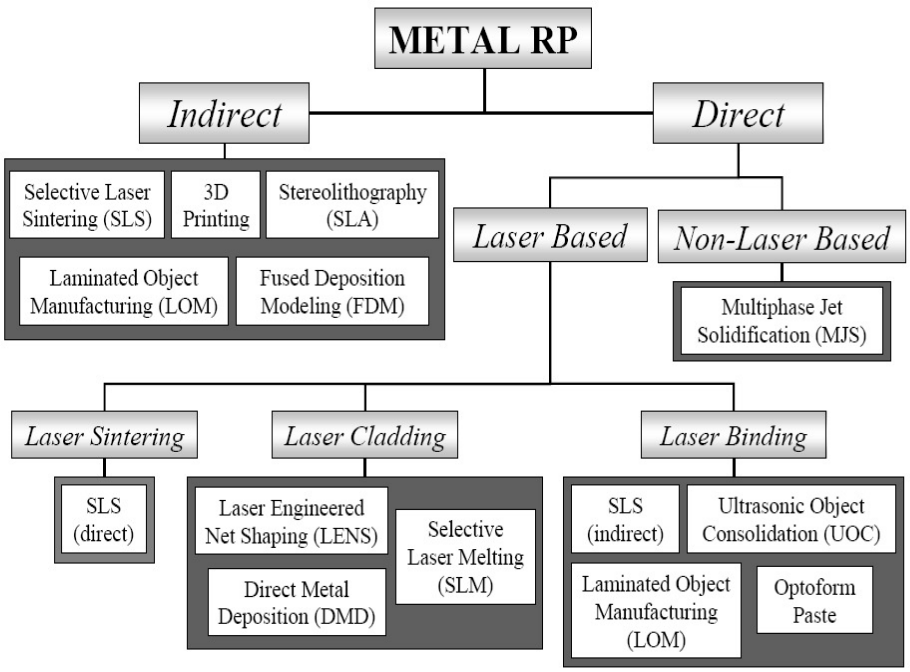


Fig.2-Classification of Rapid Manufacturing technologies

(A) Non-laser based technologies:
It involves the selective deposition of metal material. Currently, Multiphase Jet Solidification (MJS) is the only non-laser based technique being developed. It selectively deposits its preheated material through a nozzle.

(B) Laser based technologies:
It involves the use of a laser to selectively join the metallic material. As can be seen in Figure 2, this can be done through sintering, cladding, or binding.

1) Laser *sintering*
It involves the use of a high powered laser to selectively melt the surfaces of pure metallic powders in order to create the part. The part typically undergoes subsequent infiltration in order to create a fully dense part.

2) Laser *cladding*
It Uses an extremely high-powered laser, metal particles are completely melted and selectively deposited on a substrate.

3) Laser *binding*
It involves the use of a laser to bind a second phase in order to hold the metallic particles together. These parts are then required to undergo a debinding stage and a sintering stage

III. BIOMEDICAL APPLICATIONS OF RAPID PROTOTYPING

• Design and development of medical devices and instrumentation.

This is the field where applications of RP show the best results. It specially applies to hearing aids & other surgical aid tools. The STL files are created directly by scanning impressions of the inner ear. This will not only save labor in creating a patient-specific hearing aid, but will also provide a digital archive of that patient's hearing aid shell in case the original shell is lost. The demonstrated capability is to build 20 hearing aid shells in 90 minutes. More than 1,5 million shells have already been produced successfully by hearing aid manufacturers all over the world.

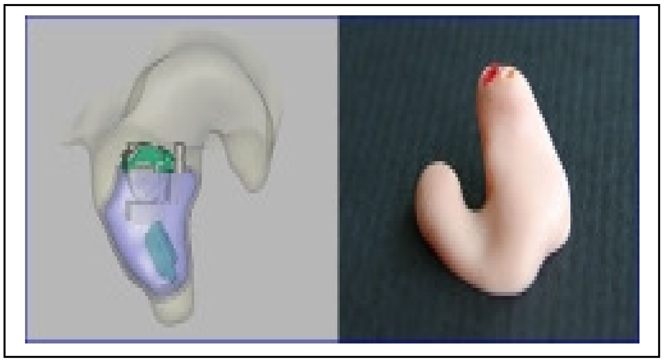


Fig: 3 Hearing shell

- **Medicines**

Rapid manufacturing technology can make pills with tightly-controlled time release profiles. For example, dosage forms can be produced to provide pulsed, monotonic, rapid, or constant release. Multiple drugs in the same pill can be synchronized with each other.
One use of this technique is to optimize dosage timing while providing precisely synchronized relief from side-effects with a second drug. It's also possible to isolate a toxic core within a non-toxic region of a pill. This can be helpful in lowering exposure of manufacturing personnel to harmful ingredients or in providing more effective drug release to a patient.
An expert system can be used to drive an additive fabrication process for producing small batches of pills with varying release profiles, sizes, internal architectures, active ingredient concentrations and other characteristics. This technique would be useful for optimizing dosages or in drug testing.
Fast-dissolving medication forms can be prepared as well as tiny pills for implanting at the root of a tooth or drug delivery devices for attaching to the outer surface of the eye. These complex devices would automatically deliver medicine directly to the organ.

• Great improvements to the fields of prosthetics and implantation

- **Dental restorations:**

Numerous rapid manufacturing approaches to the fabrication of dental restorations are commercially available or under development. These range from using a model generated by RP methods for casting dental materials, to the direct fabrication of the dental restorations themselves.
Direct metal laser sintering (DMLS) technology to fabricate the metal framework of a bridge with up to six teeth from a specially-developed cobalt-chrome alloy. The building time of an individual crown works out to only three minutes. This contrasts sharply with the manual process which permits a trained technician to make only about ten crowns in an entire workday.

Fig.4 –bridge by DMLS

It's no longer necessary for technicians to mount, embed, cast, de-flask or spend much time cleaning the molded product. The frameworks emerge from the machine at full density and ready to be veneered with ceramic after very little finishing. The slight roughness of the sintered parts also works to good advantage in this application improving the adhesion of the ceramic.

Another good example is the ability of Three Dimensional Printing to accurately match tooth color.

The SLM process is also ideal for the efficient production of individual medical implants made of materials such as Ti or TiAl6V4. The material of the finished SLM component is biocompatible and features the necessary mechanical properties as specified by national and international standards. With the help of SLM, the production time for individual implants can be reduced to a matter of hours rather than weeks, as compared to conventional manufacturing processes.
In addition, the given geometric freedom can be used to produce implants with new functionalities such as hollow structures, graded porosity and adapted rigidity or surface structure.
The SLM process is in commercial use for the series production of dental restorations made of cobalt-chromium and gold dental alloys.

- **Custom implants:**

RP techniques are very useful in making prostheses and implants for years. The ability to quickly fit prosthesis to a patient's unique proportions is a great advantage.
The techniques are also used for making hip sockets, knee joints and spinal implants. Both the release of and the improvement of the properties of used materials have had a significant influence on the quality of prostheses and implants made by RP.
One interesting example is maxillofacial prostheses of an ear which is obtained by creating a wax cast by laser sintering of a plaster cast of existing ear.
Due to RP technologies it is very easy to manufacture custom implants. The made model could be used as a negative or a master model of the custom implant.

Fig 5: Titanium hip implant made by Laser Engineered Net Shaping

• Planning and explaining complex surgical operations.

This is very important role of RP technologies in medicine which enable presurgery planning. The use of 3D medical models helps the surgeon to plan and perform complex surgical procedures and simulations and gives him an opportunity to study the bony structures of the patient before the surgery, to increase surgical precision, to reduce time of procedures and risk during surgery as well as costs (thus making surgery more efficient).
The possibility to mark different structures in different colors (due to segmentation technique) in a 3D physical model can be very useful for surgery planning and better understanding of the problem as well as for teaching purpose. This is especially important in cancer surgery where tumor tissue can be clearly distinguished from healthy tissue by different color. Surgical planning is most often done with stereolithography (SLA) where the made model has high accuracy, transparency but limited number of colors and 3DP (for more colored models, presentation of FEA results).

Recently PR modeling technique was used for the separation of Siamese twins who was borned by the attaching of the skull portion as shown below.

RP modeling for surgical planning to separate Siamese twins.
(Courtesy, Biomedical Modeling, Inc.)

Fig 6: RP modeling for surgical planning

The software translates the patient's anatomy (CT or MRI data) into full 3D models or rapid prototyping data within minutes. It is a very significant discovery in medicine and the first step on the way to making other complex human organs.

IV CASE STUDY– Jaw implant by Rapid Manufacturing

A study carried out by the doctors Michel Janssens and Jules Poukens, the Belgian company Materialise and the AZM Universidad-Hospital in the Netherlands, respectively, has clearly demonstrated that the use of technologies of rapid manufacturing that would allow a surgery of implant faster, careful and better planned than that which is possible with conventional techniques. This study is carried out within the framework European project called custom-fit , that shows the latest developments made in implants.
The success of case is based on the data of the patient, cost and complexity involved, the need for exact images for a correct diagnosis and their suitability for the autonomous diagnosis of doctors.

In the process, studies are carried out with conventional method & Rapid Manufacturing method whose common flow diagram is detailed in Figure 7A.
This case study explains the steps followed for a jaw implant.

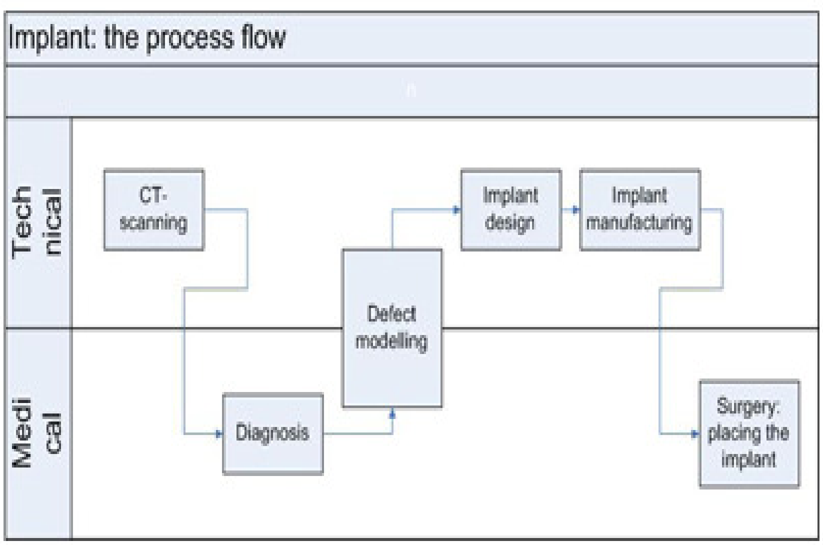


Fig 7A: Diagram of flow of process

Fig 7B: The Infected Patient

To make a thorough diagnosis, the patient was scanned through computerized tomography (CT). Figure 7C shows the images of the jaw using the Mimics, images-based CT software. The objective was to obtain a scanned image of the damaged bone (Yellow color indicating damaged portion) .

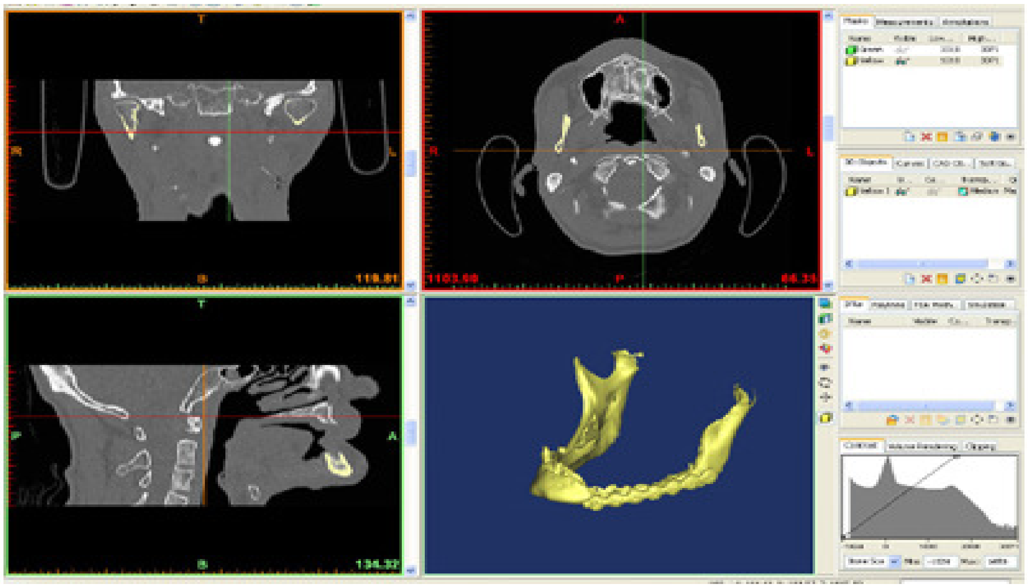


Fig 7C: CT computation of jaw

The geometric aspect of the problem was undertaken to carry out a detailed planning of the intervention. In the case of the jaw, the images clearly show the infection of the bone. With this display, the surgeon planned the details for jaw implant. Digital imaging was used to design the two guides of court that is perfectly consistent to the jaw (see Figure 7D).

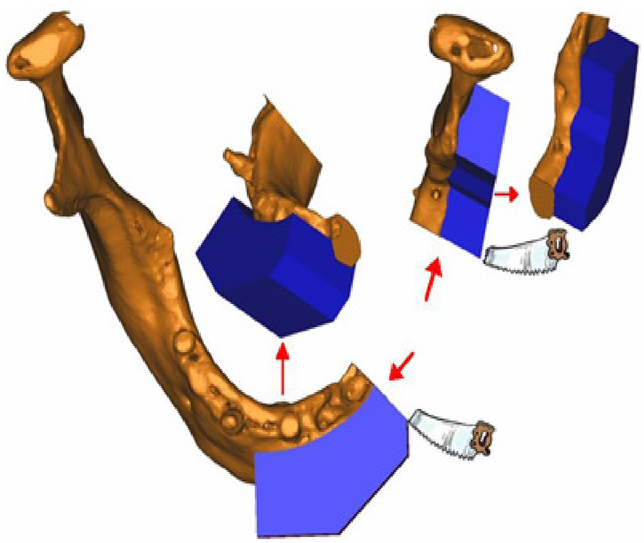


Fig 7D: Jaw Guides Designed according to Planning

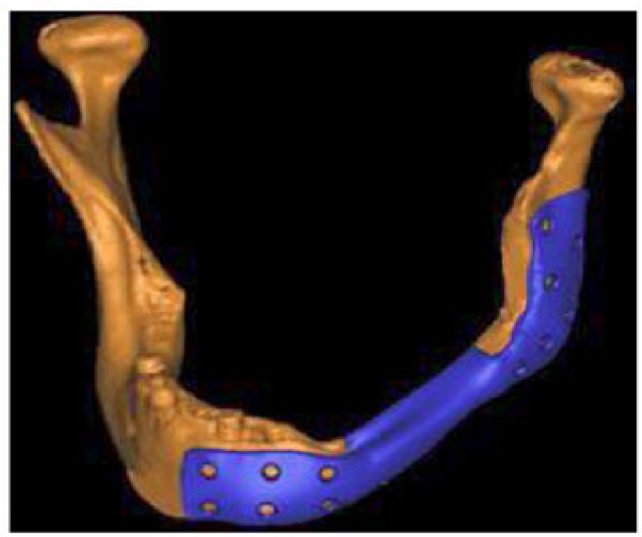


Fig 7E: The implant designed

It was possible to design implants personalized based on the default shown in the scanned image (Figure 7E). To compensate for the possibility of slack in the design it is clarified to remove greater amount of bone. It takes a considerable time from the scan to own surgery.

The design of the implant demand to work easily with the scanned data. The resulting models of Mimics are models transferred to a standard language of triangulation (STL) file that require to be converted to models in three dimensions, which is a process slow and difficult.

To avoid this problem the design was made using the software 3Matic, which embodies the design of the model directly in STL files.

The results have shown that the usual design in CAD of the mandibular implant takes 3 times as much as the design in 3Matic. For its manufacture, materials of implants required to strictly comply with medical regulations. At present, the most commonly used material for implants is titanium. This is not the material easy to process nor the most economical. Mandibular implant was initially carried out using a milling machine whose processing requirements is time consuming to commit the design and generates waste. At the same time, was created a model of the jaw in ABS using RM technologies to perform the surgery & facilitates the surgeons.

This new technique may improve the patient's life. The potential surprises during the operation is that the recovery time can be significantly reduced. Planning, design and manufacturing times are significantly reduced.
Finally, implants studied have better mechanical properties and other anatomical as nerves and veins elements.
The objective now is to improve the accuracy of CT scanners and the development of materials to make them both bio-compatible and bio-absorbent. In the future, it should be possible to improve the materials in such a way that made specifically for the patient and they can be replaced by natural bone after a period of time.

V RECENT AND FUTURE TRENDS

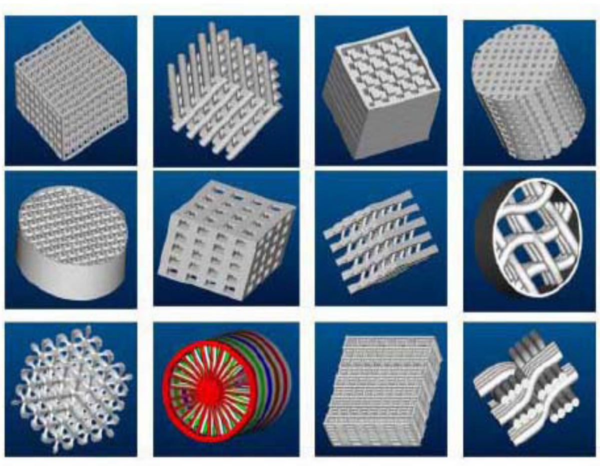
• Design and manufacturing biocompatible and bioactive implants and tissue engineering.

Further development in RP in tissue engineering requires the design of new materials, optimal scaffold design and the input of such kind of knowledge of cell physiology that would make it possible in the future to print whole replacement organs or whole bodies by machines.

RP technologies gave significant contribution in the field of tissue engineering through the use of biomaterials including the direct manufacture of bioactive implants. Tissue engineering is a combination of living cells and a support structure called scaffolds. RP systems like fused deposition modeling (FDM), 3D printing (3-DP) and selective laser sintering (SLS) have been proved to be convenient for making porous structures for use in tissue engineering. In this field it is essential to be able to fabricate three-dimensional scaffolds of various geometric shapes, in order to repair defects caused by accidents, surgery, or birth. FDM, SLS and 3DP can be used to fabricate a functional scaffold directly but RP systems can also be used for manufacturing a sacrificial mould to fabricate tissue-engineering scaffolds.

As the powders are subjected to low compaction forces during their deposition to form new layers, SLS-fabricated objects are usually porous. This interconnected porosity is a key property requirement in biomedical applications, including artificial bones and tissue engineering scaffolds.

Figure shows some of the complex 3D Scaffold designs.



The nature and extent of this interconnected porosity can be tailored and controlled effectively to meet different application criteria through material selection and physical design, and owing to the additive nature of the SLS process, control over internal structure is possible. The porosity also offers an opportunity during post processing to introduce additional materials into the object to alter material composition as well as help to control part stability. Polymethyl methacrylate coated calcium phosphate powders have been successfully processed via SLS and subsequent post processing enables to produce strong porous structures.

Materials:

There are varieties of materials which can be used for medical applications of RP.

Which material should be selected depends on the purpose of made model (planning procedures, implants, prostheses, surgical tools, tissue scaffold …), demanded properties of material for concrete application and the possibilities of the chosen RP technique. Materials must show biological compatibility.

RP medical materials include:

• Photosensitive resins for medical application (STL)
• Metals (stainless steel, titanium, Cobalt Chromium alloys, other)
•Advanced bioceramic materials (Alumnia,Zirconia, Calcium phosphate-based bioceramics, porous ceramics) **for LOM**
•Polycaprolactone(PCL)scaffolds,polymer-ceramic composite scaffold made of polypropylene-tricalcium phosphate (PP-TCP). PCL and PCL-hydroxyapatite (HA) **for FDM**
•PLGA, starch-based polymer **for 3DP**
•Polyetheretherketone-hydroxyapatite (PEEK-HA), PCL scaffolds in tissue engineering **for (SLS)**
•Bone cement: new calcium phosphate powder binders (mixture of tetracalcium phosphate (TTCP) and beta – tricalcium phosphate (TCP)), Polymethyl methacrylate (PMMA) material, other polymer calcium phosphate cement composites for bone substitutes and implants & many other biocompatible materials.

VI CONCLUSION

RP technology can make significant impact in the field of biomedical engineering and surgery.

Physical models enable correct identification of bone abnormality, intuitive understanding of the anatomical issues for a surgeon, implant designers and patients as well.

A precise RP model facilitates the pre-operative planning of am optimal surgical approach and enables selection of correct or appropriate implants.

In the UK, RPT has been used to help plan treatment in more than 20 patients; however, the cost of the modeling process is currently a significant limitation to its use. Surgical procedures continue to be more effective day by day with reduced risk and expense to both the patient and the hospital.

This could help minimize the problem of long waiting list and congestion in 'big' hospitals by reducing referral cases.

RP is showing magical outputs in all sectors of biomedical area from devices, implants to surgery.

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