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Abstract:
During last years a lot of improvements have been put on in order to develop many products by the introduction of computer-aided tools, to reduce the cost and time of the Design and Manufacturing process, and to have a faster and cheaper evaluation for different variants of the same product. Also, a great interaction has been happened between the custom-fit of products character-rized with the human body or part of it. Innovative computer-aided tools could support to realize custom-fit products with a strict interaction with human body and definitely improve people's life style, in particular of persons with disabilities. This research presented a specific-fit of the lower limb prosthesis, which can guide and support the user of prosthetic devices, it has been studied the history and improvement of prosthetics, the modular ones that mainly composed by commercial components, except for the socket that is highly customized and manufactured around the patient stump. All the product and process knowledge is strictly correlated to a specific set of parameters, which guides the whole prosthesis design process: the patient's characteristics. In particular, these data are necessary to select the appropriate standard components, to model a functional socket according to the patient's anatomy, and creates the 3D model of the socket. The proposed framework is centered on the digital model of the amputee and directly manages the experts' knowledge in order to guarantee a product of high quality, commercial 3D CAD system has been adopted to create a library of 3D parametric models to represent standard components and for final prosthesis assembly.

Keywords:
CAD – CAM Integrated System,
3D scanner,
Bio sculptor,
Bio Scanner,
Design,
Prosthetic Devices,
Powered Prosthesis.

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Introduction:
Prosthetics are vary in the type and design; they are customized based on the patient's specific needs. Some of these prosthetic devices are non-functional, serving only cosmetic purposes. Another type of prosthetics is the body powered prostheses that have mechanical hooks and controlled by cables or harness powered by body motions. A more conventional type is the myoelectric prosthetics, which are controlled by nerve signals generated in muscles around a user's residual limb and powered through electronics like batteries, microcontrollers and DC motors.
The limited functionalities of existing commercial prosthesis in a cost-effective manner by proposing the use of myoelectric control. However, most of works were limited because of using heavy materials like wood, and constructed plastics for the development of test prototypes which do not satisfy some of the important factors to be considered when developing Prosthesis, like a human- appearance in terms of size or proportion and weight. Also, sufficient autonomy of energy source to allow the prostheses work all day was not considered.
Although, the development in computer technology and its application is very fast. Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) have now been

introduced in prosthetics.

The philosophy is that if the best abilities of a designer are combined with the best abilities of the computer, the result will be unbelievable. The computer can keep the designer's memory, support his analytical and logical ability and take over repetitive routines. The designer will then supply creativity and experience to the design process, control it and organize the information about it. The following (economic) reasons for the use of

CAD Programs:

- Avoid work duplication.
- Simplify studying three dimensional geometries avoiding physical models.
- Simplify input of data for analyses and display of results.
- Simplify documentation of the product.
  - Store experience and information from previous designs.

HYPOTHESIS AND METHODOLOGIES

Deductive Approach

OVERVIEW AND BACKGROUND

Throughout history, there have been those who sought to help those affected by limb loss so they could live fuller lives.

The history of prosthetics is based on only a few fragments that have been able to uncover. Over time, advances allowed for the replacement of a simple wood or iron artificial leg with sophisticated devices that came closer to mimicking biological function.

Prosthetic Legs of Ancient History

The religion of ancient Egypt emphasized wholeness, and it was believed that a missing limb would continue to affect the deceased in the afterlife. Egyptian artificial limbs were made out of fiber and designed to help replace form more than function.

While no functional prosth-etic leg has been discovered from this time, we do have examples of prosthetic toes Figure (1). The big toe of the foot is not only required for balance but would have been necessary to wear traditional Egyptian sandals.

Figure (1) a wood and leather toe

The Middle Ages 500 – 1500 A.D

Prostheses didn't see a lot of advancement in this era of human history. Prosthesis could only be afforded by the wealthy, or otherwise created out of whatever materials were at hand.

Amputation procedures at this time were still primitive, and often performed by a barber or a ship's cook. A peg leg was a common replacement for survivors of war or battle. Scrap wood was easy to come by and could be fashioned into an artificial leg by any tradesman.

Knights who lost limbs could be fitted with iron artificial legs that wouldn't allow them to ride their horse, but otherwise provide little function.

Ambroise Paré (1510 – 1590): Father of the Modern Prosthetic Leg

Along with improving amputation techniques and survival rates during this time Ambroise Paré developed functional prosthetic limbs for all parts of the body. He used his understanding of anatomy to design prosthetics that mimic the function of biological limbs.

He was the first to develop an above-knee prosthetic with an adjustable harness and a hinge-knee with lock control – both of which are still used today. He also transitioned away from wood in favor of much lighter prosthetics made of leather, paper, and glue.

Prosthetic Legs of the 17th through 19th Centuries

Paré's advances opened up new thinking for amputation and prosthetics. Inventors would continue to advance the science of the prosthetic limb continually leading up to the modern day.

Pieter Verduyn was a Dutch surgeon who in 1696 invented a non-locking below-knee prosthetic. This device had external hinges and a leather thigh socket, which is similar in form and function to modern corset prosthetics.

James Potts

Londoner James Potts invented an above-knee prosthetic in 1800 with a calf and thigh socket made of wood, and a flexible foot attached with catgut tendons to a steel knee joint. This design was not only more articulate than precious prosthetics but was considered more aesthetically pleasing.

This design emigrated to the U.S. in 1839 and was the standard leading up to the U.S. Civil War.

Prosthetic Legs of The American Civil War

The American Civil War raged from 1861 to 1865, and the demand for prosthetics rose astronomically. This need ushered in an era of rapid growth in prosthetic leg technology in The United States with over 80 patents for prosthetic legs filed between 1861 and 1873 Figure (2).

J.E. Hanger and The Hanger Limb

James Edward Hanger (1843 – 1919) was an

American engineer who was the first amputee of The Civil War. He spent his convalescence designing a prosthetic leg, and would go on to patent his “Hanger Limb” and found the company that became Hanger Inc.

His original Hanger Limb was fashioned out of oak barrel staves and had articulated knee and ankle joints for better mobility.

Figure (2) the American Civil War Prosthetic **leg**

The Salem Leg Company

The Salem Leg Company produced articulated above-knee prosthetics and below knee prosthetics. They were officially recommended by the U.S. government for the army and their sales materials included testimonials from prominent war veterans.

2-6- The first powered prosthesis

It was a pneumatic hand patented in Germany in 1915, A drawing of an early pneumatic hand is shown in Figure (3), it shows a drawing of the first electric powered hand, These drawings were published in 1919.

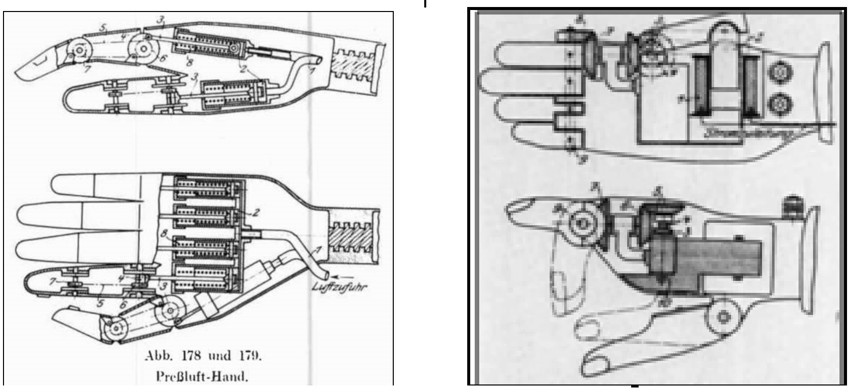

Figure (3). Early compressed-gas powered hand (Perhaps the first powered prosthesis component). From Ersatzglieder under Arbeitshilfen (Limb Substitutes and Work Aids) 1919

2-7- Modern Prosthetics

The World Wars necessitated new advancements in prosthetic technology. After World War I, the Surgeon General of the U.S. Army got the ball rolling on what would become the American Prosthetics and Orthotics Association. Despite this, there were no major advancements in prosthetics till post-World War II when the U.S. government provided funding to military companies to improve the form and function of prosthetics. This led to many of the modern materials used in prosthetics such as plastic, aluminum, and other composite materials.

The next advance in technology didn’t come until 1946 when researchers developed a suction sock for lower-limb amputees. Similar attachment technology is still in use today.

In the 1970s – around the time Fish Insurance was established – an inventor by the name of Ysidro M. Martinez (who was an amputee himself) developed a lower-limb prosthesis that focused on improving movement and reducing friction. It relieved pressure and made walking more comfortable, which improved the lives of many future patients.

The future of prosthetics

It may have taken thousands of years to get from a humble prosthetic toe to the functional devices we have today, but advancements are coming thick and fast. With 3D printing advancing and becoming more affordable, the possibility of anyone being able to easily design and print a prosthetic limb become a reality. New 3D scanning and body modeling technology enabled people to 3D scan their limbs and have prosthetics modeled after them, making for more natural fitting and appearance.

As well, there’s new state-of-the-art prosthetics which take in data on how the wearers walk. As a new piece of wearable tech known as ‘Shortcut’ could mean that wearers can use computers and smartphones with their prosthesis. It’s worn on the wrist of the hand that has the prosthetic and signals from the limb muscles are sent to the device, which translate to movement on a computer screen.

Even more impressive, researchers are developing a bionic limb which is controlled by thought. It attaches to an implant inserted directly into the bone, and nerve reassignment surgery then allows brain signals to directly control movement.

Computer Aided Design and Manufacturing

Definition of CAD

Computer-aided design (CAD) involves creating computer models defined by geometrical parameters. These models typically appear on a computer monitor as a three-dimensional representation of a part or a system of parts, which can be readily altered by changing relevant parameters. CAD systems enable designers to view objects under a wide variety of representations and to test these objects by simulating real-world conditions.

Definition of CAM

Computer-aided manufacturing (CAM) uses geometrical design data to control automated machinery. CAM systems are associated with computer numerical control (CNC) or direct numerical control (DNC) systems. These systems differ from older forms of numerical control (NC) in that geometrical data are encoded mechanically. Since both CAD and CAM use computer-based methods for encoding geometrical data, it is possible for the processes of design and manufacture to be highly integrated. Computer-aided design and manufacturing systems are commonly referred to as CAD/CAM.

Comparison between Conventional Methods of Shape Capture and Latest Methods of Shape Capture

The Conventional Method is based on patient's manual measurements, a prescription is made, measurements are taken and moulding and rectification are performed Figure (4).

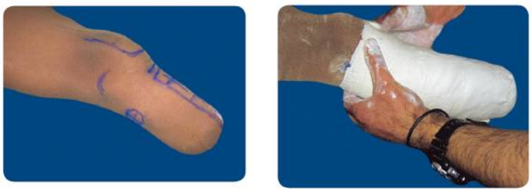

Figure (4) Conventional Methods of Shape Capture

Soft liner manufacture

Measure the plaster mould (Figure (5). Note the:

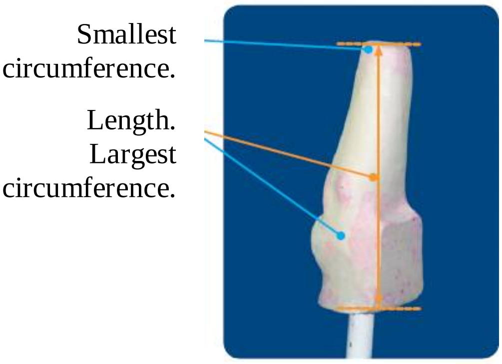

Figure (5) Soft Liner Manufacturing

- Draw a trapezoid on a sheet according to the measurements taken Figure (6).

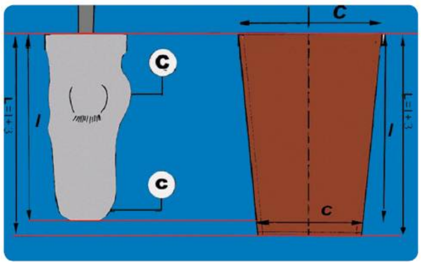

Figure (6) Soft Liner Manufacturing

- Apply glue on both skived sides and form a cone. Keep the trimmed distal side on the outside of the cone and leave it free of glue Figure (7).
  - Apply talcum powder inside the cone and on the plaster model.
  - Thermoforming is done using the vacuum pump, on a vertical suction hose.
  - Heat the EVA cone in the oven at 120°C.

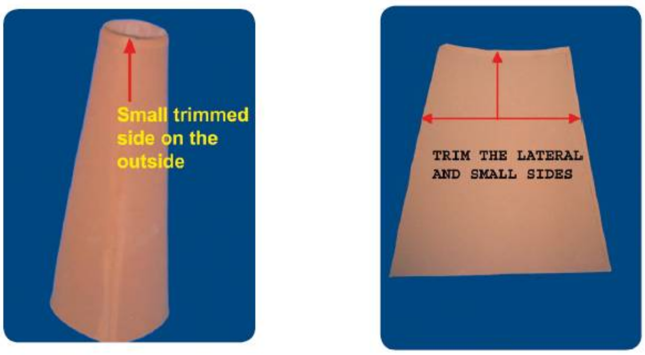

Figure (7) Soft Liner Manufacturing

- Pull the EVA cone over the plaster mould, keeping the glued line on the posterior side, until the;

- Trimmed distal side coincides with the tip of the plaster mould.
- Cover the mould with a plastic bag Figure (8), close it securely below the mould with an elastic strap and switch on the vacuum pump.

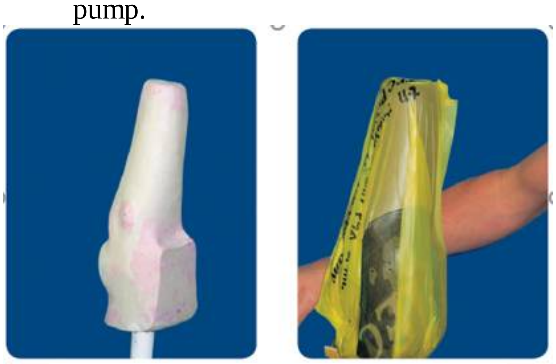

Figure (8) Soft Liner Manufacturing

- Allow the soft liner to cool down for few minutes.
  - Remove the plastic bag.
  - Apply glue to the trimmed edge and the cover cap.
  - Heat the cap in the oven and mould it on the socket.
  - Cut off the extra EVA and grind till smooth.
  - Add padding above the medial condyle and other areas if required.

Latest Methods of Shape Capture "Prosthetic CAD/CAM Soft wares"

In the following the description of the most diffused CAD/CAM prosthetic softwares available on market.

Infinity CAD systems: Auto Scanner & Auto Sculpt

A 3-D scanner is a device that identifies, analyzes, collects and draws/displays shapes or three-dimensional models of real-world environments or solid objects. A 3-D scanner enables the capture of geometric shapes and the recreation of the physical appearance of tangible objects, allowing them to be built and displayed on a computer device.

3D Scanner instantly acquires prosthetic 3D surfaces by gathering measurements made by smoothly sweeping a handheld laser scanning wand Figure (9). It is built on reflection technology. As a laser beam emitted through the handheld laser wand determines the scanning surface co-ordinate position. The computed points of data forms the 3D image of the scanned prosthetic shape, and cut the edge, laser reflection technology used in Auto Scanner, the collection of scanned surface data points will be hundreds of thousands per second, ensuring that the scanning process flows in fast reliable and accurate. The software uses various scientific formulas to calculate non-scanned data points; hence it forms a fine, high resolution 3D prosthetic image. Computer aided design software exclusively

Developed for modifying prosthetic 3D images. Using features of Auto Sculpt enables prosthetics to implement all necessary changes on the 3D Images according to the weight bearing specification of their patients.

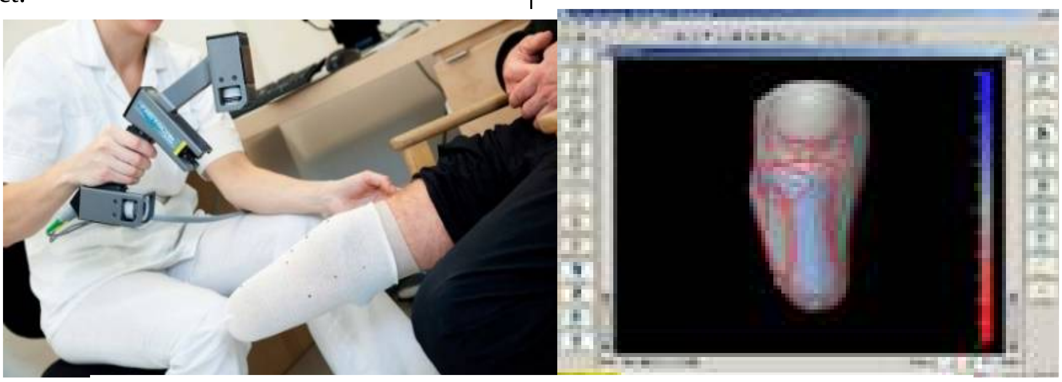

Figure (9). 3D surfaces by gathering measurements made by smoothly sweeping a handheld laser scanning wand

- **The following features demonstrate its ability:**

- Designer utilities enable Above Knee/ Below Knee/ AFO/ Spinal Jacket modifications.
- Curves creation and modifications for depressions and elevations.
- A pattern utility allows practitioners to create custom pattern shape libraries, Such patterns are reusable and can be applied to any other prosthetic 3-D images.
- Using utilities like volume/ area/ length, practitioners can change a prosthetic image global or segmental properties.
- An image smoothing feature allows fine resolution adjustments to the prosthetic image, In addition to the 3-D image view, horizontal and vertical cross section view options enable practitioners to view changes

from all angles.

- Modifications are restorable. Practitioners can undo changes or redo.
- practitioners make modifications at the desired surface of the prosthetic image.
- Apart from these utilities, AutoSculpt has many additional features that enable successful 3-D prosthetic image modification tool-kits, including coloring tools, visualization tools, ambient lighting, an orthographic camera, a headlight property, and other features.

Bio sculptor: Bio Scanner, Bio Shape Software & DSS Digital Socket System

Scan a patient in 10 seconds, Both patients and referral sources will be amazed by the efficiency, speed, and advanced technology of the Bio Scanner™. Since registration marks are not required, there is no preparatory work involved. You simply click and go. Change the mode to Optical Stylus and instantly place landmarks and alignment marks as you scan. Any portion of the body may be directly scanned for orthoses or prostheses. There is no size limitation. A miniature transmitter is placed on the body to accommodate for any movement. The Bio Scanner™ is able to image negative and positive models, allowing you to use the clinical techniques required for each patient.

The precision of the Bio Scanner™ is as impressive as its speed. Capture shapes to an accuracy of 0.178mm. To further improve quality, the software streamlines the final scan to equally distribute the scan sweeps.

The Bio Shape Manipulation Software is the most powerful CAD software available, Designed by Prosthetists and Orthotists, it was developed specifically for the clinician. Digital Socket System is the next generation of socket-by-numbers.

The following features demonstrate its ability:

- Test sockets will fit more precisely.
- Saving precious time.
- Template your personal socket design for your exclusive use.
- Receiving your virtual model for approval.

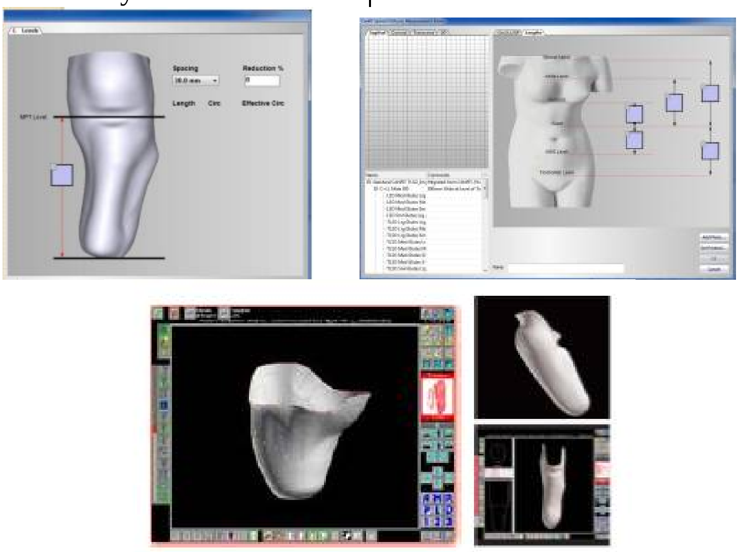

Figure (10) Bio Shape Software.

Rodin4D: Fast Scan 3D & Software

Easy to handle, fast, accurate, the Fast scan figure (11) no-contact 3D digitizer enables you to digitize freely and easily the most complex forms, with it you can:

- Digitize your patients in order to work directly on their form afterwards.
- Create accurate and realistic library forms.
- Digitize your plaster casts before destroying them.

Figure (11) Fast Scan 3D and Software.

3-3-2-4- Design TF and Design TT

Design TF is a software that allows the orthopedic technician to realize a transfemoral check socket using only some measurement taken from the residual limb. It creates a 3D model of the check socket in order to modify its shape.

Design TT is a system composed by a digital camera, which takes pictures of the residual limb and calculates circumferences and volume of the stump, then the software creates a 3D model of a transtibial to check socket and modify its shape.

Figure (12) Design TF and TT

ComfORTAC, Orten PIX & CAD Software

ComfORTAC acquires 360° trunk and lower limbs measurements by structured light projection. This system also enables morphological reference points to be recorded from their direct position on the patient. These reference points are used by our CAD software's for the design of orthopedic devices.

Orten PIX protocol is based on measurements only. The file is quickly computed in the desired shape and does not require further modification. This technique is quickly mastered, and the time saved is greatly maximized. This method is particularly adapted to Above the Knee prostheses, mattresses, seating and standing systems.

A transtibial socket is easy to design from the 3D modeling of the stump. In few clicks, you can apply compression and create build-up areas. The design of a cosmetic cover is also straightforward. It can be created as the symmetric of the healthy leg. In the case of leg orthosis, more tools (such as flexion) are available.

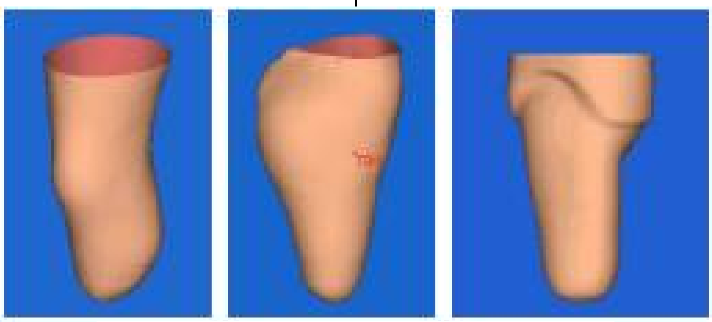

Figure (13) ComfORTAC and Orten PIX

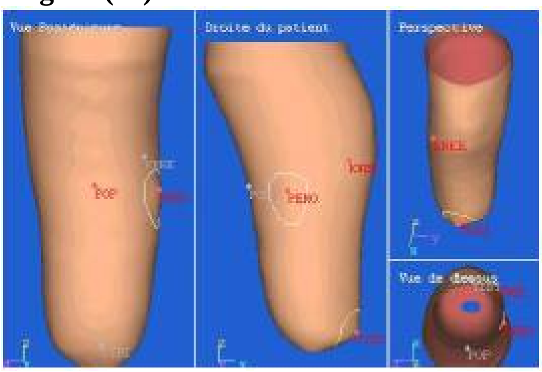

Figure (14) CAD Software

Confit P&O System

The Confit TM P&O CAD/CAM System provides an integrated suite of tools for acquiring shape data, designing and modifying shapes, and carving positive models. Tailored specifically for the prosthetics and orthotics industry, the components are designed to work effectively as a single unit.

Methods for Acquiring Patient Shape Data:

- Digital Input using Confit TM Laser Scanner: The hand-held, non-contact laser scanner digitizes 3-dimensional anatomical surface data with a level of accuracy comparable to traditional methods of clinical shape measurement. Any digitized shape can be imported into a general shape modification program. Measurements can also be extracted from digital files for use in the measurement-based design applications.
- Manual Measurement Input: The measurement-based design applications

accept standard clinical measurements. Once this data is entered, users have the option to scale a library shape to the measurement input provided. Extensive libraries of reference shapes , which contain typical corrective modifications are available. Custom shape libraries , which reflect your clinical experiences and preferences can also be established.

Designing and Modifying Shapes

- Digital Input: the design software for use with digitized shape data (actual 3D-cast or patient surface shape data) is the general shape modification program, Confit TM P&O Design.
- Manual Measurement Input: The design applications, which accept measurement-based shape data and provide convenient reference library shapes include Confit TM System II-AK Design and Confit TM System II-BK Design.

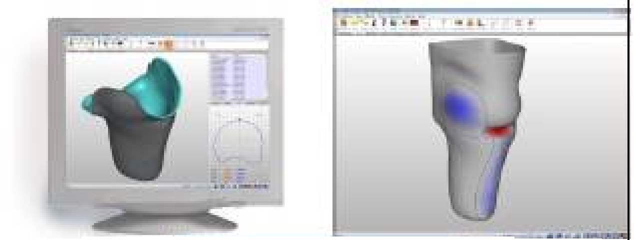

Figure (15) Confit-TM BK Design.

Results and discussions

- It has been concluded from the current study of using the CAD/ CAM software's that, it takes just minutes to have the patient measurements to start selecting the suitable parts for the patient.
- By using CAD software, prosthetists can design, develop and modify the prosthetic parts before starting manufacturing process.
- In order to model a functional socket according to the patient's anatomy, we can use the archived data.
- In the modification stage, we can avoid work duplication and wasting time by using archived data too.
- In the design stage, we can save time, effort and materials while using the CAD CAM software, as the traditional techniques take a lot of time and wasting time and materials.
- Designers can assure the product quality by using CAD Systems.

1- Conclusions

- ICT tools can support the specific phases of the product development process, but they do not offer any kind of assistance to the prosthetists.
- All the design process decisions and actions are taken on the base of the prosthetists experience and personal skills.
- In the case of residual limb, these systems derives the geometry of the check socket or the positive chalk from the external shape of the stump, also using libraries of standard models. Then, the realization of the positive model is guided with a CAM module, onto which the socket is thermoformed. This procedure is always linked to the production of a check socket , which is tested on the patient and then modified.
- Systems which can assist and guide the orthopedic technician during the design phases, could improve the development process and the product quality. In order to deal with the problem of representing the knowledge involved in a product development and in each single step.
- In this system the orthopedic technician is assisted in each single phase of the prosthesis design process, from the selection of the most appropriate components for the patient until the 3D modelling of the full prosthesis.

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