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Knowledge-based design of lower limb prosthesis

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You're not disabled by the disabilities you have,

you are able by the abilities you have

(Oscar Pistorius)

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Abstract

During last years the development of many products has been improved by the introduction of computer-aided tools reducing the time and costs of the full development process, and allowing to evaluate in a faster and cheaper way different variants of the same product. Besides, a great attention has been put on custom-fit products characterized by a close interaction with the human body or part of it. Innovative computer-aided tools can help to realise custom-fit products with a strict interaction with human body and definitely improve people's quality of life, in particular of persons with disabilities.

The work presented in this thesis refers to this context and to a specific custom-fit product: the lower limb prosthesis. **Main objective** has been to realize an innovative knowledge-based framework, centred on the virtual models of the patient's body, which can guide and support the user during all the steps of the prosthesis design, suggesting rules and procedures for each task. Research activities have been organized into **four main phases** as follows.

First it has been studied the **State of the Art** of prosthesis, the modular ones, and of ICT tools for socket design available on the market. A modular prosthesis is mainly composed by commercial components, except for the socket that is highly customised and manufactured around the patient stump. This component is the interface between the stump and the mechanical part of the prosthesis and requires high level of customization in order to satisfy functional and comfort requirements.

Regarding known ICT tools we have verified that they can support some specific tasks of the product development process, but they do not offer any kind of assistance to the prosthetists. In fact, design process decisions and actions are taken on the base of technicians' experience and personal skills. Therefore, it is strategic to integrate within such systems specific domain knowledge, in order to obtain a valid and high quality final product, and to develop for this reason a design framework which can assist the technician during all the process.

The **second phase** consisted in **acquiring the knowledge** related to the **product and the traditional process** to manufacture modular lower limb prosthesis, reviewing specific literature and scientific publications and, above all, interviewing qualified orthopaedic technicians. This activity has been carried out in an orthopaedic laboratory, participating and following personally all the stages of the prosthesis manufacturing processes. All information has been formalized with IDEF0 diagrams, deriving all the implicit design rules and procedures. It has been highlighted that 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 in correlation to the patient's anatomy, and to correctly size the final prosthesis assembly. From this phase we have extrapolated:

- Patient parameters guiding the whole process;
- Selection procedures to choose the most appropriate standard components;
- Rules to correctly size the prosthesis;

- Rules and procedures to create the 3D model of the socket.

In the **third phase**, on the basis of previous analysis, we have reengineered the prosthesis design process and developed a **knowledge-base design framework**, which guides the technicians step by step providing for each activity specific knowledge and rules (e.g. dimensioning or selection rules for standard parts). The proposed framework is **centred on the digital model of the amputee** and directly manages the experts' knowledge in order to guarantee a product of high quality. Each activity is supported in direct way by the management of specific domain knowledge through virtual assistants, which provide procedures and/or suggestions to perform best choices and, when possible, execute them automatically (e.g., choosing components and materials, or sizing parts). It integrates ad hoc tools for domain technical knowledge management both of product and process, virtual modelling of components both standard (e.g. pylons and tubes, prosthetic feet, etc.) and custom-fit, and tools for behaviour simulation (e.g. by means of FE and multibody techniques) to investigate component-human body interaction.
In particular, the work developed in this thesis has been focused on modelling issues. The framework has been implemented using a commercial KBE system (Ruledesigner® Configurator). A commercial 3D CAD system (Solid Edge Siemens PLM Software) has been adopted to create a library of 3D parametric models to represent standard components and for final prosthesis assembly. The rules and procedures extrapolated for socket design have been embedded within a module, named Socket Modelling Assistant (SMA), specifically developed by V&K Research Group (University of Bergamo) for socket virtual modelling. SMA provides a set of virtual tools that permit to emulate the tasks traditionally performed by the technicians.
Last phase concerned the **validation and experimentation** of the framework. First we have tested and refined the procedures for standard components selection in collaboration with the involved orthopaedic laboratory. By means of the framework, we have set up prosthesis configuration for ten patients, five transfemoral and five transtibial and compared with those ones proposed by the prosthetics. Results have been considered satisfactory for most of the cases. It has been appreciated the possibility to generate rapidly alternative configurations. Secondly, procedures and rules for socket modelling have been tested creating the 3D model of the socket for two patients, one transfemoral and one transtibial. Together with the technicians, we mainly tested the efficacy of the shape manipulation tools that virtually emulate traditional procedures. Preliminary results have been considered positively by the laboratory technical staff but they envisaged the need of some modifications to make mentioned tools easier to use, especially, by a non computer-skilled end-user. Finally, for a better evaluation of socket model, we need to compare it with the real one manually realised.

Keywords: lower limb prosthesis, knowledge-based system, virtual prototyping, custom-fit products, digital human models.

Riassunto

Durante gli ultimi anni lo sviluppo di molti prodotti è migliorato grazie all'introduzione di strumenti assistiti dal calcolatore riducendo tempi e costi di tutto il processo di sviluppo, e permettendo di valutare in modo più rapido ed economico diverse varianti dello stesso prodotto. Inoltre, una grande attenzione è stata posta sui prodotti personalizzati caratterizzati da una stretta relazione con il corpo umano o parte di esso. Innovativi strumenti assistiti dal calcolatore possono contribuire alla realizzazione di prodotti personalizzati con forte legame con il corpo umano e sicuramente migliorare la qualità della vita delle persone, in particolare di persone disabili.

Il lavoro presentato in questa tesi fa riferimento a questo contesto ed ad uno specifico prodotto personalizzato: la protesi d'arto inferiore. **L'obiettivo principale** è stato realizzare un innovativo sistema basato sulla conoscenza, centrato sui modelli virtuali del corpo del paziente, che potesse guidare e supportare l'utente durante tutti i passaggi per la progettazione di una protesi. Le attività di ricerca sono state organizzate in **quattro fasi principali** come segue.

Per **prima cosa** è stato analizzato lo **Stato dell'Arte** dell'ultima generazione di questa tipologia di protesi, quelle modulari, e degli strumenti ICT per la progettazione dell'invaso disponibili sul mercato. Una protesi modulare è principalemte composta da componenti commerciali, eccezion fatta per l'invaso che è altamente personalizzato e realizzato sull base dell'arto residuo del paziente. Questo componente è l'interfaccia tra il moncone e la parte meccanica della protesi e richiede un alto livello di personalizzazione così da soddisfare requisiti funzionali e di comfort.

Per quanto riguarda gli strumenti ICT conosciuti abbiamo verificato che possono supportare alcune fasi del processo di sviluppo prodotto, ma non offrono alcun tipo di assistenza al tecnico. Tutte le decisioni e le azioni intraprese durante la progettazione sono scelte sulla base della loro esperienza e delle loro personali capacità. Quindi, sarebbe strategico integrare la conoscenza di dominio specifica in questo tipo di sistemi, così da ottenere un prodotto finale valido e di altà qualità, e sviluppare per questa ragione un ambiente di progettazione che assiste il tecnico durante tutto i processo.

La **seconda fase** ha riguardato **l'acquisizione della conoscenza** relatica al **prodotto** ed al **processo tradizionale** di fabbricazione di protesi modulari d'arto inferiore, studiando la letteratura e le pubblicazioni scientifiche del settore e, soprattutto, intervistando il personale altamente qualificato di un laboratorio ortopedico. Questa attività è stata svolta presso l'ortopedia, partecipando e seguendo personalmente tutte le fasi del processo di realizzazione delle protesi. Tutte le informazioni sono state formalizzate utilizzando diagrammi IDEF0, derivandone tutte le regole e le procedure implicite. Si è realizzato che tutta la conoscenza di prodotto e processo è strettamente correlata con uno specifico gruppo di parametri, che guidano l'intero processo di progettazione: le caratteristiche del paziente. In particolare questi dati sono necessari per selezionare i componenti standard più idonei,

per modellare un invaso funzionale in relazione all'anatomia del paziente, e per dimensionare correttamente l'assemblaggio finale della protesi. Da questa fase abbiamo ricavato:

- I parametri del paziente che guidano l'intero processo;
- Le procedure di selezione per scegliere i componenti standard più idonei;
- Le regole per dimensionare correttamente la protesi;
- Regole e procedure per creare il modello 3D dell'invaso.

Nella **terza fase**, sulla base dell'analisi precedente, è stato reingegnerizzato il processo di progettazione della protesi e sviluppato **un sistema basato sulla conoscenza**, che guida passo per passo i tecnici fornendo conoscenza e regole specifiche (per esempio le regole di dimensionamento e di selezione dei componenti standard). Il framework proposto è totalmente **centrato sul modello digitale dell'amputato** e gestisce direttamente la conoscenza degli esperti così da garantire un prodotto di alta qualità. Ogni attività è supportata direttamente dalla gestione della conoscenza di dominio specifica attraverso degli assistenti virtuali. Che forniscono procedure e/o suggerimenti per compiere la miglior scelta e, quando possibile, eseguirle automaticamemte (per esempio, scegliere i componenti ed i materiali, o dimensionare le parti). Integra strumenti ad hoc per la gestione della conoscenza tecnica di dominio sia di prodotto che di processo, per la modellazione di componenti sia standard (ad esempio piloni e tubi, piedi, etc.) che personalizzati, e strumenti per la simulazione del comportamento (ad es. tecniche di analisi ad elementi finiti o multi-body) per investigare l'interazione componenti-corpo umano.

In particolare il lavoro sviluppato in questa tesi ha riguardato la fase di modellazione. Il framework è stato implementato utilizzando un sistema KBE commerciale (Ruledesigner® Configurator). Un sistema commerciale CAD 3D (Solid Edge Siemens PLM Software) è stato adottato per realizzare una libreria di modelli 3D prametrici per rappresentare i componenti standard e per l'assemblaggio finale della protesi. Le regole e le procedure estrapolate per la progettazione dell'invaso sono state inserite all'interno di un modulo, chiamato Socket Modelling Assistant (Assistente di modellazione dell'invaso, abbreviato SMA), specificatamente sviluppato dal Gruppo di Ricerca VK (Università degli Studi di Bergamo) per la modellazione virtuale dell'invaso. Lo SMA fornisce un set di strumenti virtuali che permettono di emulare le attività tradizionali compiute dai tecnici.

L'**ultima** fase ha riguardato la **validazione** e la **sperimentazione** del framework. Per prima cosa abbiamo verificato e rifinito le procedure di selezione dei componenti in collaborazione con l'ortopedia conivolta nel progetto. In funzione del framework, abbiamo predisposto la configurazione della protesi per 10 pazienti, cinque transfemorali e 5 transtibiali, e le abbiamo comparate con quelle proposte dai tecnici. I risultati sono stati valutati buoni per la maggior parte dei casi. È stata apprezzata la possibilità di generare rapidamente configurazioni alternative. In secondo luogo, le procedure e le regole per la modellazione dell'invaso sono state verificate creando il modello 3D dell'invaso per due pazienti, un transfemorale ed un transtibiale. Insieme ai tecnici, abbiamo principalemte verificato l'efficacia degli strumenti di modellazione della forma che simulano virtualmente le procedure tradizionali. I risultati preliminari sono stati considerati positivi dallo staff tecnico dell'ortopedia ma hanno evidenziato il bisogno di alcune modifiche per rendere gli strumenti

menzionati di più facile utilizzo, in particola modo, da un non utilizzatore e non esperto di computer. In fine, per una migliore valutazione del modello dell'invaso, abbiamo bisogno di compararlo con i modelli reali realizzati a mano.

Parole chiave: protesi d'arto inferiore, sistema basato sulla conoscenza, prototipazione virtuale, prodotti personalizzati, modelli umani digitali.

Introduction

Current ICT tools for product development are focused on a specific task (e.g. geometric modelling, structural analysis, gait analysis) rather than on the full process. Moreover, when considering custom-fit products characterized by a strong dependence and interaction with the human body, they do not focus on user's morphology but at most they allow a simple adjustment of a standard solution. Various research projects highlighted how custom-fit products, such as helmets, motorcycle saddles or handicapped equipments, can strongly improve their quality thanks to innovative computer-aided tools. Anyway, the results obtained revealed some limits: both product and process strongly depend on skill and technical knowledge of involved technical staff. Therefore, there is a need of innovative design processes which can offer in a single framework tools for each different activity, specialize modelling and simulation procedures according to the specific product requirements, and support the operator with the knowledge required to develop the full product development process and the single activity.

This thesis work refers to this field and focuses the attention on the specific case of lower limb prosthesis. The development of such prosthesis is prevalently based on hand-made procedures: IT methods and tools play a partial role. A typical example of a custom-fit component of lower limb prosthesis is the socket, the component which needs a total custom-fit manufacturing. In fact, the socket is the most critical component and is shaped by the orthopaedic technician around the patient stump. S/he manually manipulates negative and positive plaster casts according to stump anatomy and on the base of his/her knowledge and experience.

In such a context, main objective of this PhD thesis has been to develop an innovative framework to design limb prosthesis centred on the virtual model of human body and able to manage the whole process and experts' knowledge in an integrated environment. We aimed at creating "automatic assistants" to provide the prosthetic with design rules and procedures to automatically select and virtually model prosthesis components.

To this end, following activities have been performed:

- Analysis of the State of the Art;
- Acquisition of the specific product and process knowledge;
- Identification of design rules and procedures both prosthesis components;
- Development of the new design framework based on a re-engineered prosthesis design process;
- Validation and experimentation of the system.

This PhD thesis has been developed under the framework of the I4BIO Project (Innovation for Bioengineering Project) co-funded by Fondazione Cariplo and University of Bergamo.

Knowledge acquisition, experimentation and validation of the framework has been realized with the collaboration of Ortopedia Panini in Milan, a high qualified orthopaedic laboratory. The medical knowledge and competence has been provided by Prof. Walter Albisetti of University of Milan and Dr. Omar De Bartolomeo.
The present thesis is organized according to the following contents:

Chapter 1 regards the State of the Art of lower limb amputees and prostheses. Lower limb amputations and causes are introduced and the post-surgical treatment are described, in particular, the different stages of rehabilitation process and the different typologies of prosthesis commonly used. Then, it is given a general overview about the ICT prosthetic tools available on market and the different techniques which can be used to acquire human morphological shapes.

Chapter 2 is centred on the knowledge acquisition and formalization phase. It is given a general description about the product knowledge, the components of a modular lower limb prosthesis, different typologies, characteristics and functions. Then, it is portrayed the acquisition and formalization of the traditional manufacturing process knowledge, using IDEF0 diagrams to better analyse and understand in detail all the procedures and rules applied.

Chapter 3 is dedicated to the description of the design rules and procedures extrapolated during the phase of knowledge acquisition. It will show that all the process is guided by some specific parameters: the patient characteristics. Then it will be given an explanation about the selection procedures of the standard components, both for transtibial and transfemoral prosthesis. Finally procedures and rules identified for the critical phase of the socket modelling will be described.

Chapter 4 will introduce the implemented new design process, using IDEF0 diagrams to show the new activities and better understand adopted mechanisms and procedures. The new design framework architecture is introduced. A short introduction on KBE systems will be given, and then the database of standard components will be portrayed in detail. Finally the architecture of the Socket Modelling Assistant (SMA), the ad-hoc tool developed for the socket modelling phase, will be explained.

Chapter 5 is dedicated to the experimentation phase. The system has been experimented in two different phases: first the procedure to select the standard components have been verified with the technical staff of the orthopaedic laboratory involved into this work; then we have considered the configuration of two test-cases: a transtibial and a transfemoral amputee. For both cases we have acquired the stump digital model and we have configured the virtual prosthesis model.

Chapter 1

State of the Art

In this work attention has been focused on two specific typologies of lower limb prosthesis: below knee prosthesis (also called “transtibial”) and above knee prosthesis (also called “transfemoral”), realised with the state of the art components in order to obtain the maximum comfort and usability for the amputees. These two types have been selected since they are the most common ones: according to the last ISTAT (Italian National Institute of Statistics) data [1], in 2005 in Italy there were about 3 millions of handicapped people, 250000 of lower limb amputations, and according to FIOTO (Italian Federation of Orthopaedic Technicians) every year there are 11000 new lower limb amputations, of which 1000 transtibial (TT) and 4000 transfemoral (TF) [2].

Last generation of modular components for this kind of prosthesis are: the liner, the socket, the lock, the knee (only for transfemoral), the tube or the double joint, and a foot, beyond a great variety of adapters. In Figure 1.1 it is visible a scheme of a modular TF prosthesis.

In particular the liner (see example in Figure 1.2) rolls onto the residual limb and is then inserted and locked into the socket. This is the last generation of suspension systems and can provide improved cosmetics, cushion the residual limb, reduce shear between the residual limb and the socket, and minimize pistoning of the residual limb in the socket. Heat buildup, sensitive skin problems, and decreased proprioception can be drawbacks of this suspension system.

Most of these products are standard components , which are chosen from commercial catalogues on the base of amputee characteristics, apart the liner , which can be both standard and custom fit, and the socket which is always manufactured expressly in relation to the specific anatomy of the patient. In particular the standard liner is normally well fitting on most of residual limbs, only a really small number of patients with particular and problematic

stump anatomy need a customized liner. While the socket has to be specifically designed for each patient, since it is the interface between the residual limb and the prosthesis. It must not only protect the residual limb, but also appropriately transmit the forces associated with standing and ambulation. Sockets are manufactured starting from a positive chalk cast. The cast can be manufactured following a fully hand-made procedure or partially based on digital tools, such as CAD/CAM systems.

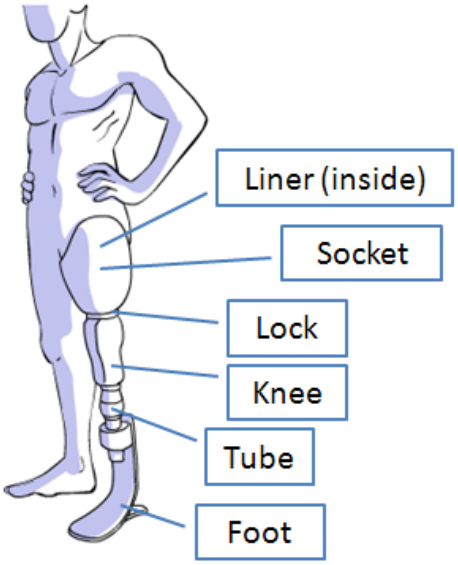

Figure 1.1: Scheme of main components of modular TF lower limb prosthesis.

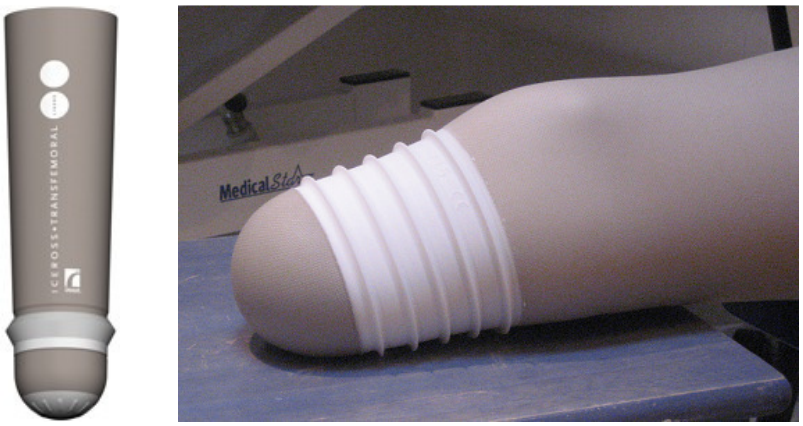

Figure 1.2: Example of last generation liners by Össur: liner with 1 silicone membrane (left) and with 5 silicone membranes worn by patient (right).

Since the aim of this work was to develop an innovative framework to design lower limb prosthesis using ICT tools, we have studied the actual tools available on market to identify their principal characteristics. In the following we are going to describe the lower limb

amputation and its principal causes, the post-surgical management and the ICT tools available on market for prosthesis design.

1.1 – Lower limb amputation and causes

Lower-extremity amputation is one of the oldest known surgically performed procedures [3-5]. The original surgical principles as described by Hippocrates remain true today. Refinements of surgical technique such as haemostasis, anaesthesia, and improved perioperative conditions have occurred, but only relatively small technical improvements have been made.

Today amputation is still often viewed as a failure of treatment. The responsibility for performing an amputation may even fall on the most junior member of the surgical team. Whatever the reason for performing an extremity amputation, it should not be viewed as a failure of treatment. Amputation can be the treatment of choice for severe trauma, vascular disease, and tumours. Patients and family members must be aware of their options and have realistic expectations of surgical outcomes in order to make informed decisions regarding amputation.

Amputation surgery is an ancient procedure dating back to prehistoric times. Neolithic humans are known to have survived traumatic, ritualistic, and punitive rather than therapeutic amputations. Cave-wall hand imprints have been found that demonstrate the loss of digits. Unearthed mummies have been found buried with cosmetic replacements for amputated extremities.

The earliest literature discussing amputation is the Babylonian code of Hammurabi, inscribed on black stone, from 1700 BCE, which can be found in the Louvre. In 385 BCE, Plato's Symposium mentions therapeutic amputation of the hand and the foot. Hippocrates provided the earliest description of therapeutic amputation in De Articularis for vascular gangrene. Hippocrates describes amputation at the edge of the ischemic tissue, with the wound left open to allow healing by secondary intent.

The main risks described in the early history of amputation surgery were haemorrhage, shock, and sepsis. Before the discovery of anaesthesia, the procedure itself was quite difficult. The patient would be held down by a number of assistants and be given alcohol (usually rum). The patient would essentially be awake and aware during the procedure.

One of the greatest difficulties for a person undergoing amputation surgery is overcoming the psychological stigma that society associates with the loss of a limb. Persons who have undergone amputations are often viewed as incomplete individuals. Following the removal of a diseased limb and the application of an appropriate prosthesis, the patient can resume being an active member of society and maintaining an independent lifestyle.

Although a diseased limb can be removed quite readily, resolving the problem of the extremity, the care does not end there. The surgery must be performed well to ensure that the patient is able to wear a prosthesis comfortably. Knee joint salvage enhances rehabilitative efforts and decreases the energy expenditure required for ambulation [6].

The patient must learn to walk with a prosthesis, apply and remove the prosthesis, care for the prosthesis, monitor the skin and the presence of any pressure points, ambulate on difficult terrain, and use the commode at night. Because of the complexity of these issues, the treatment team should include the surgeon, the primary care physician, a physical therapist, a prosthetist, and a social worker [7-8].
Lower-extremity amputations may be performed for the following reasons [3-5]:

- Peripheral vascular disease (PVD) : most amputations performed are for ischemic disease, primarily in elderly persons with diabetes mellitus. These patients often experience peripheral neuropathy that progresses to trophic ulcers and subsequent gangrene and osteomyelitis.
- Trauma: severe open fractures with popliteal artery and posterior tibial nerve injuries can be treated with current techniques; however, treatment is at a high cost, and multiple surgeries are required. The result is often a leg that is painful, non-functional, and less efficient than a prosthesis.
- Tumours: Amputation is performed less frequently with the advent of advanced limb-salvage techniques.
- Infections: Treatment of sepsis with vasoconstrictor agents may at times lead to vessel occlusion and subsequent extremity necrosis, necessitating amputation. At other times, eradication of infection from many difficult sources necessitates removal of the affected digit or limbs.
- Congenital limb deficiency: Amputations for congenital limb deficiencies are performed primarily in the paediatric population because of failure of partial or complete formation of a portion of the limb. Congenital extremity deficiencies have been classified as longitudinal, transverse, or intercalary. Radial or tibial deficiencies are referred to as preaxial, and ulnar and fibular deficiencies are referred to as postaxial.

Amputation of the lower extremity is often the treatment of choice for an unreconstructable or a functionally unsatisfactory limb. Amputation must be performed with great care and be considered a reconstructive procedure.
The higher the level of a lower-limb amputation, the greater the energy expenditure that is required for walking. See Figure 1.3 to view the levels of amputation [9]. As the level of the amputation moves proximally, the walking speed of the individual decreases, and the oxygen consumption increases.
For most people who have undergone below knee amputations, the energy cost for walking is not much greater than that required for persons who have not undergone amputations. For those who have undergone above knee amputations, the energy required is 50-65% greater than that required for those who have not undergone amputations.

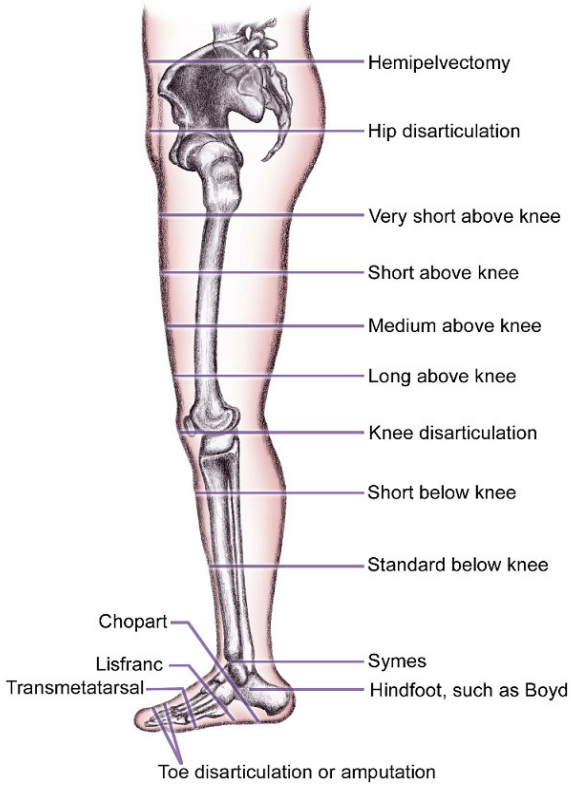

Figure 1.3: Levels of lower limb amputation.

Among major amputations in the lower limb, the transtibial (below-knee) amputation is the most common. Many series report a ratio of at least two transtibial amputations to every transfemoral (above-knee) one [10]. It is important to note that it is the most proximal level in the lower limb at which near-normal function is available to a wide spectrum of lower-limb amputees. This is because energy consumption for the transtibial amputee, due to preservation of the knee joint, is far less than for amputees with a transfemoral level (see examples of amputees in Figure 1.4). The relative ease of transtibial vs. transfemoral gait is borne out by several studies of prosthesis usage. Combined data from 13 studies from 1943 through 1983 [10] showed an average transtibial prosthesis usage rate of 73.5%. In contrast, analysis of four studies covering the same period disclosed that transfemoral prosthesis usage averaged only 26.5%. Most of the patients in these studies had peripheral vascular disease. Another detailed study was made of 25 unilateral transtibial amputees who were all under the age of 45 years at the time of amputation for trauma [10]. They were reviewed 2½ years following surgery as regards their function and life-style. Eighty-four percent wore their prostheses more than 13 hours a day, 72% could walk a mile if necessary, and 84% drove automobiles. Sports were played by 72%. The most notable finding was that 84% of these unilateral transtibial amputees regarded themselves as minimally or nondisabled.

Another singular advantage of transtibial over transfemoral amputation is markedly reduced perioperative mortality [10]. The combined mortality of three studies for transtibial amputation was 9.5% as compared with 29.7% for transfemoral amputation. Virtually the

same findings were reported by Sarmiento and Warren [11], who noted a fall in mortality rate from 24% to 10% that was directly related to the reversal of their transtibial-to-transfemoral ratio from 1:2 to 2:1.

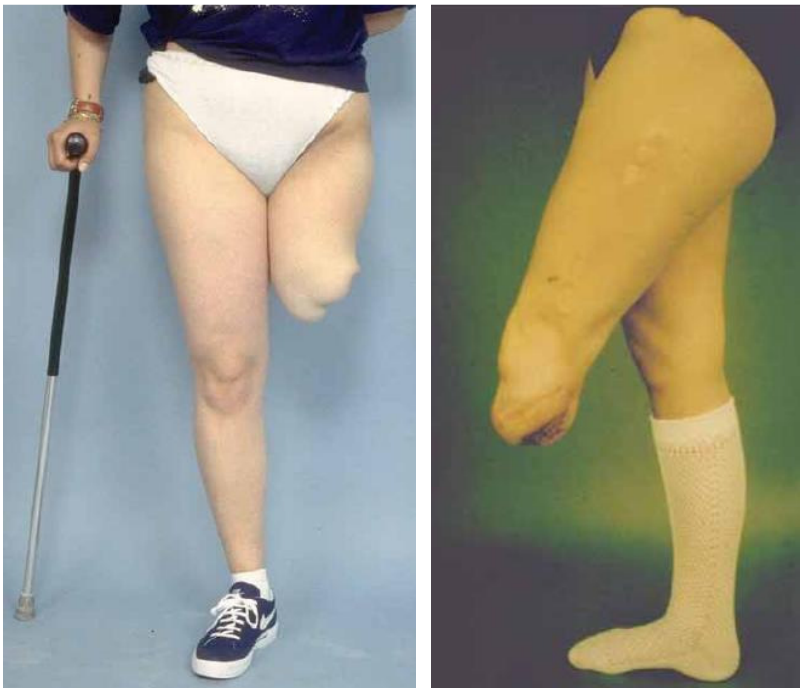

Figure 1.4: Examples of lower limb amputees: transfemoral (left) and transtibial (right).

For many years, transfemoral amputations were preferred to transtibial ones because it was felt that primary healing is easier to obtain at the thigh level. Healing at that level, however, is far from certain. Boontje [12], in a series of 171 amputations, noted a 28% failure of transfemoral healing as compared with 35% for transtibial cases.

It was long taught that diabetics should have a primary amputation at the transfemoral level because of their supposed inability to heal at more distal levels. Data were combined from four series that compared the healing rate of transtibial amputations in diabetics with that in patients with purely ischemic disease. Of 194 diabetic patients, 92% healed their wounds. In contrast, only 75% of 188 patients with purely ischemic disease healed. Two additional series of 100 diabetics each reported transtibial healing rates of 99% and 90%, respectively. These studies strongly suggest that the notion that diabetics do best with a primary transfemoral amputation for foot lesions should be discarded.

In ischemic conditions, unilateral transtibial amputation may be followed by loss of the opposite limb with progression of vascular disease. One study of 80 patients noted an interval of 23 months, on average, between transtibial amputations. The risk of contra lateral limb loss is 10% per year. With sufficient longevity, therefore, transtibial amputees often face the prospect of opposite lower-limb loss. The chances of ambulation as a bilateral transtibial amputee therefore become a major concern. Pooled data on 137 patients showed that 77% of bilateral transtibial amputees were able to attain functional ambulation.

In summary, the importance of preserving the knee joint cannot be overemphasized. It allows younger patients to continue a vigorous life-style and elderly patients the opportunity to walk as opposed to wheelchair confinement. In view of the high risk of later contra lateral amputation, every effort should be made to preserve at least a transtibial level at the first amputation.
The aim of amputation surgery is a well-healed, sensate, functional end organ that will interface well with a prosthesis. Selection of length is based on etiologic factors and on clinical and laboratory evaluation. As much length as possible should be preserved, compatible with disease eradication and good prosthetic function. Meticulous management of tissues will lead to preservation of the length obtained at surgery. Myodesis is advocated in cases in which local dysvascularity is not a problem. Postoperative rigid dressings are strongly recommended because of local protection of the wound and the prevention of edema and knee flexion contractures. Early mobilization prevents deconditioning, thereby allowing early discharge to an outpatient status. Early prosthetic weight bearing has great value in selected cases if closely monitored. Optimal amputee management is best achieved through a team approach beginning even before surgery.

1.2 – Post-surgical management

When amputation of a limb is being considered, it is important to inform the patient about future rehabilitation [13]. An early visit by the prosthetist can also be helpful. The prosthetist can give specific informations about prosthetic options and rehabilitation and can show various types of prostheses to the patient. The prosthetist can also suggest preprosthetic management with rigid dressings, elastic bandaging, or prosthetic shrinkers to speed the maturation of the residual limb. When then the amputee is ready for prosthetic fitting, additional orientation information can be explained about the different stages of the rehabilitation process, including how long the preparatory prosthesis will be used and when the evaluation for a definitive prosthesis will occur.

1.2.1 – Prosthesis stages

There are four generic post-surgical stages [13]: postoperative, initial, preparatory and definitive or special-purpose prostheses. Although progression through all four levels may be desirable, only selected amputees will receive the postoperative or initial prostheses, which are directly molded on the residual limb. Most amputees will have preparatory and definitive prostheses, and a much smaller number will receive special-purpose prostheses for showering or for swimming and other sports. In detail these different types of prostheses:

1. Postoperative prosthesis: postoperative prostheses are, by definition, provided within 24 hours of amputation. These are often referred to by various acronyms including immediate postsurgical fitting (IPSF) and immediate postoperative

prosthesis (IPOP). Although technically feasible for virtually any amputation, postoperative fittings are currently most commonly prescribed for the younger, healthier individual undergoing amputation due to tumor, trauma, or infection. Its use in the elderly or dysvascular individual is controversial but can be successful when meticulous technique and close supervision are available;

2. Initial prosthesis: the initial prosthesis (see example in Figure 1.5) is sometimes used in lieu of a postsurgical fitting and is provided as soon as the sutures are removed. This is sometimes referred to as an early postsurgical fitting (EPSF). Due to the usual rapid atrophy of the residual limb, the EPSF is generally directly molded on the residual limb by using plaster of paris or fiberglass bandages. An alternative is to use a weight-bearing rigid dressing. Such devices are used during the acute phase of healing, generally from 1 to 4 weeks after amputation, until the suture line is stable and the skin can tolerate the stresses of more intimate fitting. Postoperative and initial prostheses are most commonly used in rehabilitation units or in hospitals with very active amputee programs;

3. Preparatory prosthesis: preparatory prostheses (see example in Figure 1.5) are used during the first few months of the patient rehabilitation to ease the transition into a definitive device. They are also used in marginal cases to assess ambulatory or rehabilitation potential and help clarify details of the prosthetic prescription. The preparatory prosthesis accelerates rehabilitation by allowing ambulation before the residual limb has completely matured. Preparatory prostheses may be applied within a few days following suture or staple removal, and limited gait training is started at that point. Originally, the preparatory prosthesis was a very rudimentary design containing only primitive components. The modern preparatory limb, however, usually incorporates definitive-quality endoskeletal componentry but lacks the protective and cosmetic outer finishing to reduce the cost. It allows the therapist and prosthetist to work together to optimize alignment as the amputee gait pattern matures. Different types of knee mechanisms or other components can be tested to see whether individual patient function is improved. Preparatory prostheses are generally used for a period of 3 to 6 months following the date of amputation, but that time can vary depending on the speed of maturation of the residual limb and on other factors such as weight gain, weight loss, or health problems. The new amputee may begin by wearing one thin prosthetic sock in the preparatory prosthesis; after 3 months, he may be wearing ten plies of prosthetic socks to compensate for atrophy. When the number of plies of prosthetic socks the patient must wear remains stable over several weeks, it is usually an indication that the definitive prosthesis can be prescribed;

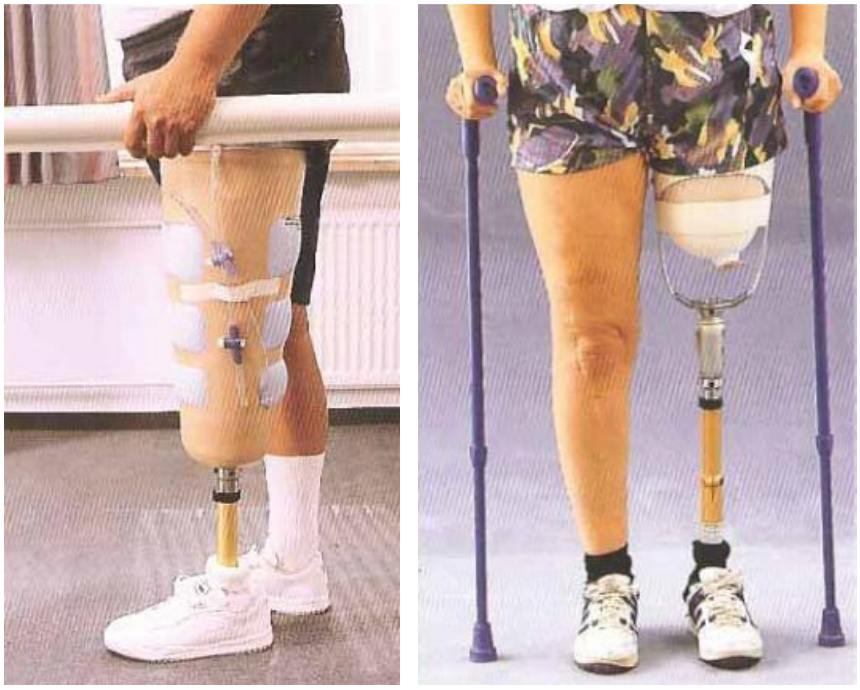

Figure 1.5: Examples of initial (left) and preparatory (right) lower limb prostheses.

4. Definitive prosthesis: the definitive prosthesis is not prescribed until the patients residual limb has stabilized to ensure that the fit of the new prosthesis will last as long as possible. The definitive prescription is based primarily upon the experience the patient had when using the preparatory prosthesis. The information learned during those months will demonstrate to the clinic team the patient need for a lightweight design, special types of feet or suspension, or any special weight-bearing problems that may arise. There are mainly two kinds of definitive prosthesis: a traditional and a modular prosthesis (see examples in Figure 1.6). The first type has rigid parts with the main function to support the bodyweight and aesthetically substitute a limb, they are usually made of wood or millwork resins. The second type has a supporting structure , which is tubular and modular, and it can have an external aesthetic soft cover. The use of modular prostheses in the last years is quickly increased, due to their extensive adaptability to different types of amputees and to the possibility to substitute each single module of the prosthesis maintaining all the others. For this reason the use and the manufacturing of traditional prosthesis is slowly disappearing.

   Unfortunately a definitive prosthesis is not a permanent prosthesis since any mechanical device will wear out, particularly one that is used during every waking hour. The average life span for a definitive prosthesis is from 3 to 5 years. Most are replaced due to changes in the amputee residual limb from atrophy, weight gain, or weight loss. Substantial changes in the amputee life-style or activities may also dictate a change in the prosthetic prescription. Overall physical condition is also a

factor since the more debilitated individual generally requires a very lightweight and stable.

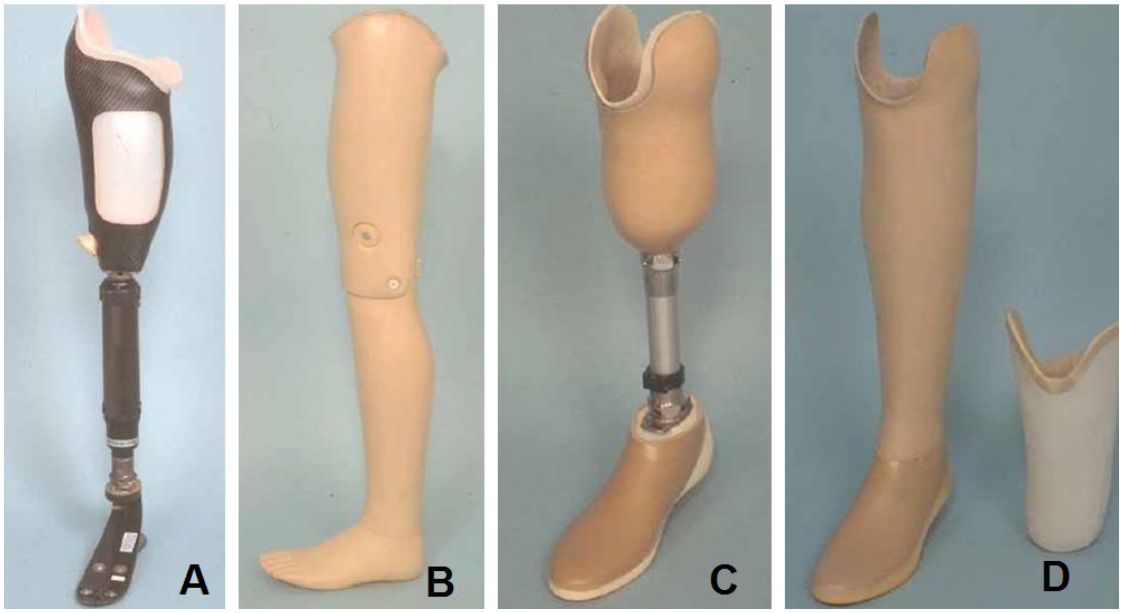

Figure 1.6: Examples of modular (A) and traditional (B) definitive transfemoral prosthesis; examples of modular (C) and traditional (D) definitive transtibial prosthesis.

A certain number of patients will require special-use prostheses (see examples in Figure 1.7) designed specifically for such activities as showering, swimming, or skiing. It is most economical if special-use devices are prescribed at the same time as a definitive replacement is necessary since both can be fabricated from the same positive model. Most require specialized alignment. For example, swimming prostheses are made waterproof and aligned so that the patient can walk without a shoe. In some cases the foot can be plantar-flexed and have a swim fin attached. Snow skiing prostheses require an increase in dorsiflexion at the ankle and may incorporate additional knee support or auxiliary suspension. Special-use prostheses can be valuable to the amputee who wishes to expand his activities and participate in a full range of sports and recreational pursuits. There are sports-related amputee organizations in every major city in the country, with the greatest participation in golf and snow skiing.

Figure 1.7: Examples of special-use prosthesis for running (left) or skiing (right).

For the purpose of this work the attention has been focused on the definitive prostheses; in fact, while the procedures to manufacture/assemble postoperative, initial and preparatory prostheses are quite simple, fast and standardized since they are temporary prostheses whose components have a short useful life or they are reused for different amputees, the process to realize a definitive prosthesis is more elaborate and time-consuming since they have to be perfectly custom-fit on patients and they have a mean life of 3-5 years. While the special-use prostheses are manufactured only for a quite small number of amputees compared to the production of definitive prostheses.

1.2.2 – Prosthesis types

The prosthetist of today is a highly skilled individual who must meet significant educational and professional standards prior to obtaining board certification. The prosthetists role in the rehabilitation team has become more significant as a result. In the period following World War II, prostheses were relatively simple, and prescriptions were therefore extremely specific, with the prosthetist given little attitude in exercising clinical judgement. Given the complexity of today components, many of the details regarding prosthetic configuration are now based on clinical results observed by the prosthetist.
The modular type of lower limb prosthesis, nowadays most diffused than traditional one, is principally composed as previously said by (see scheme in Figure 1.8): a socket, a knee (only for transfemoral patients), a tube, a foot and different typologies of locks and joints to assemble the various modules.

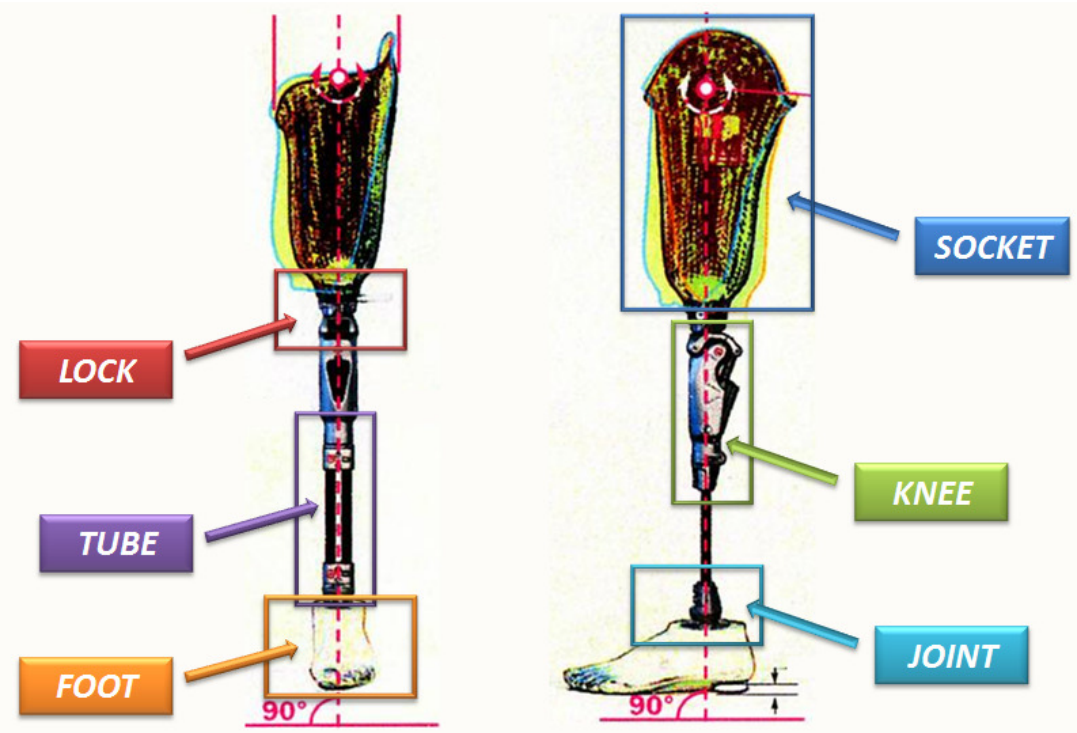

Figure 1.8: Scheme of a modular transfemoral prosthesis, frontal (left) and lateral (right) views.

It is also important to highlight that during this study we have considered the manufacturing process of prostheses for amputees who wear a liner between the stump and the socket, in particular an hypobaric liner, since this system normally helps most of patients to avoid skin problems, improve cosmetics, cushion the residual limb and reduce shear between the stump and the socket. And among the different typologies of sockets, we have considered the Total Surface Bearing (TSB) socket for transtibial amputees, and the Ischial-Containment, or CAT-CAM (Contoured Anterior Trochanteric-Controlled Alignment Method), socket for transfemoral ones. The TSB type distributes more equally the pressure throughout the transtibial residual limb [14] and the body weight is borne by the entire surface of the residual limb [15]. The CAT-CAM socket contains more residual limb volume and this permits a wide distribution of forces [16]. The ischial tuberosity is contained in the socket, resulting in a bony lock; this containment provides a stable mechanism to control mediolateral and rotational stability [16]. Both types have been chosen since they ensure a high level of comfort and adaptability for most of patients, in good health or with some pathologies, and for any shape or length of the stump. In Figure 1.9A, it is possible to see a sketch of CAT-CAM socket and its horizontal section to show the homogeneous pressure distribution of a stump inside this kind of socket. In Figure 1.9B, there is a sketch of TSB socket.

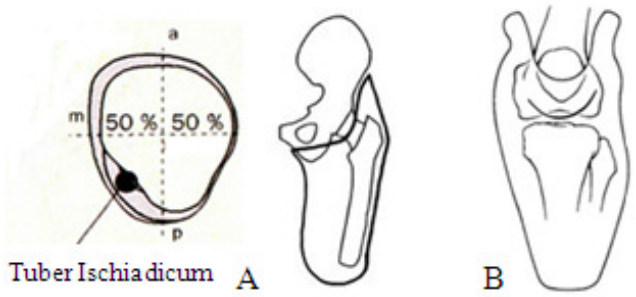

Figure 1.9: Sketch of CAT-CAM socket (A) and TSB (B) socket.

In Figure 1.10 there are some real examples of definitive CAT-CAM and TSB sockets, ready to be worn by amputees.

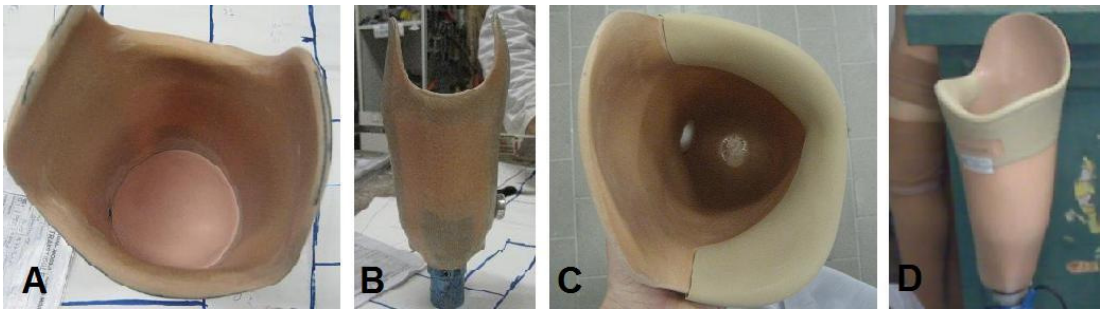

Figure 1.10: Top (A) and frontal (B) view of a definitive TSB socket; top (C) and frontal (D) view of a definitive CAT-CAM socket.

1.3 – ICT tools for prosthesis design

As said most of components are selected from catalogues, while the socket is totally custom-fit on patient's residual limb. In Italy the vast majority of prosthetists are small businessmen or employees of small businesses and the design and manufacture of a socket is almost a hand-made activity carried out by skilled technician. The technician makes an evaluation of the amputee considering his/her general health conditions and performing some manual measurements on the stump. The technician creates a stump negative plaster cast manipulating plaster patches directly on patient's residual limb, and then from it, s/he realizes the positive model. The positive plaster is manually modified by adding and removing chalk in specific zones and according to stump measurements and patient characteristic. After this, a thermoformable check socket is manufactured directly on the modified positive model and, then, tested on the amputee. Other necessary modifications are marked on the positive model to realize a more comfortable and well fitting final socket. Finally, the definitive socket is realized and all the prosthesis components are assembled for the final static set-up. Besides the residual limb undergoes continuous changes during the passing of time, and on average at least every two years the amputee needs a new socket. In regards to CAD/CAM systems, the procedure for transtibial and transfemoral is slightly different, but the output is always the 3D model of positive cast for the CAM system to produce the physical

prototype of the positive cast. On the market we can find some commercial CAD/CAM softwares (for further detail see [17-22]) , which can assist the orthopaedic technicians in some steps of the development process. Figure 1.11 lists some of these systems.

COMPANY	SYSTEM	
BioSculptor	Acquisition Tech.	Laser scanner with 2 cameras, a miniature transmitter for the body and scan-through-glass technology, or manual measurements
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	AK: starting from a library of templates -> external shape of the socket
		AK/BK: using oblique, transverse and circumferential measurements -> automatic generation of the check socket
infinity CAD systems	Acquisition Tech.	Laser reflection scanner with 1 or 2 cameras
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	BK: proximal brim and shape utilities help to transform areas anywhere on the acquired shape -> external shape of the socket
		AK: standard shapes from a library, tools to change volume, length, circumferences -> model of the socket
Orten	Acquisition Tech.	Structured light projection, digital camera or manual measurements
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	BK: on the geometry of the residual limb in defined areas you can apply compression or create build-up areas -> external shape of the socket
		AK: the desired shape is created using a protocol based on manual measurements -> positive model of the socket
ÖSSUR	Acquisition Tech.	Digital camera or manual measurements
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	BK: calculate circumferences and volume of the stump and allows to modify the acquired shape -> positive model of the socket
		AK: measurements taken from the residual limb -> model of the check socket
RODIN4D	Acquisition Tech.	Laser scanner with 1 camera
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	AK/BK: starting from a shapes library, adding check measurements, checking volume and circumferences -> positive model of the socket
VORUM RESEARCH CORPORATION	Acquisition Tech.	Manual measurements and an appropriate proximal brim
	Acquired Data	External shape of AK and BK residual limb
	Stump/Socket Modelling	AK/BK: fitting an appropriate brim to the patient, and taking circumferential measurements, supported by a variety of socket styles -> model of the socket

Figure 1.11: Some CAD/CAM prosthetic systems available on the market (AK=Above Knee, BK=Below Knee).

We first introduce the acquisition techniques of human body shapes and then some of most known prosthetic CAD/CAM systems.

1.3.1 – Acquisition of human morphological shapes

Human morphological shapes are in general definition of shapes/structures of internal and external parts of the human body. For the acquisition of these shapes there are different methodologies in different sectors. For this reason we have classified them in:

1. *Acquisition of internal morphological geometries*
2. *Acquisition of external morphological geometries*

In the following we will describe the most diffused techniques available nowadays on market.

a. Acquisition of internal morphological geometries

In medical sector these techniques are called biomedical imaging or diagnostic imaging, terms used to identify the general process , which allows to observe part o fan organism not externally visible. The first imaging technique, the radiography technique, was born at the end of the 19th century, when the German physicist Wilhelm Conrad Röntgen discovered X-rays and it was suddenly understood the possibility to use these rays to obtain human body images (the radiographies). Ever since more sophisticated techniques have been invented, , which allow to study anatomy and different biochemical and physiological processes at the base of human organism functioning. In the '70s a big evolution in diagnostic imaging has been represented by introduction of tomographic techniques. These techniques provide images of human organism sections and allow to 3-dimensionally reconstruct and visualize organs and apparatus, by support of modern computers. The principal techniques nowadays available for imaging acquisition of an organism, such as human body, are:

a) Traditional and computerized radiography
b) Computed tomography
c) Single Photon and Positron Emission Computerized Tomography
d) Magnetic resonance
e) Ecography

In the following we will see in detail the characteristics of these techniques.

a) Traditional and computerized radiography

Traditional radiography is the first invented biomedical imaging technique, and still in use. Radiography is based on X-rays and the barrier effect due to interaction between matter and radiation.

- *Traditional radiography*

It was born at the beginning of the 20th century, few years after the discovery of the X-rays, and until the '50s it was the only diagnostic imaging technique. X-ray images are obtained

generating a X-ray beam and let it go through the patient's body. During the '30s the Italian radiologist Alessandro Vallebona proposed a method to represent a single layer of the human body on a radiographic film: this exam is called stratrigraphy. From the middle of the '80s, it has been supplanted by new computerized technologies (see example in Figure 1.12).

- *Computerized radiography*

In medicine Computerized Radiography (CR) is the equipment , which allows to obtain digital medical images by X-ray, using specific memory phosphors, which are deleted and reused for many times. This technique was born during the '80s. Absorbing an X-photon, phosphor is excited for a medium/long time, memorizing the photon position. This information is read illuminating phosphor by a red/infrared laser ray. The light, which goes out from the phosphor, is collected by a photo-multiplicator, and a computer collects its informations and shows on a monitor the X-ray image , which has generated the signal. This image can be printed, stored in a hard disk, recorded on a CD/DVD or elaborated. In fact this system has not the same resolution as the traditional one, but since computers can improve images thanks to processing image algorithm, this system can provide better images [23].

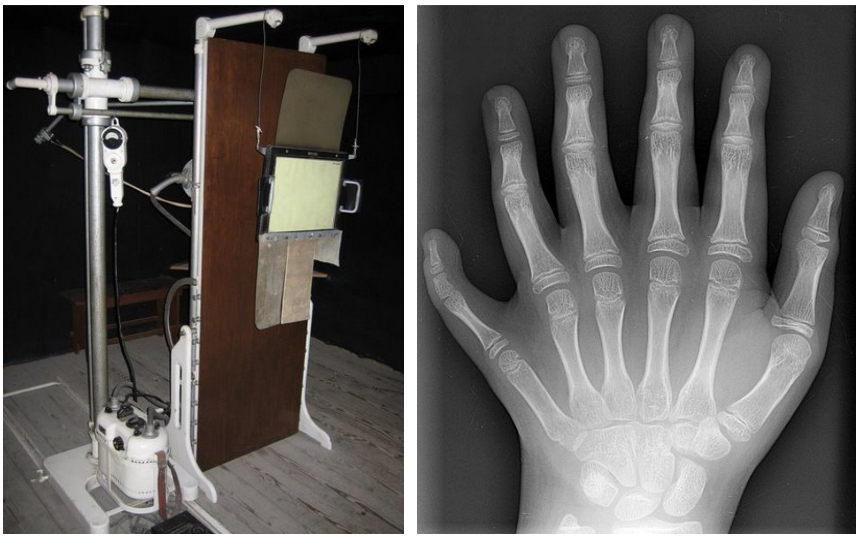

Figure 1.12: Equipment for traditional radiology (left) and an example of computerized radiology of a left hand affected by polydactyly (right).

b) Computed tomography

Computed Tomography (CT) is a diagnostic imaging method , which uses X-ray, and reproduces patient human body sections and 3-dimensional processing (see example in Figure 1.13).

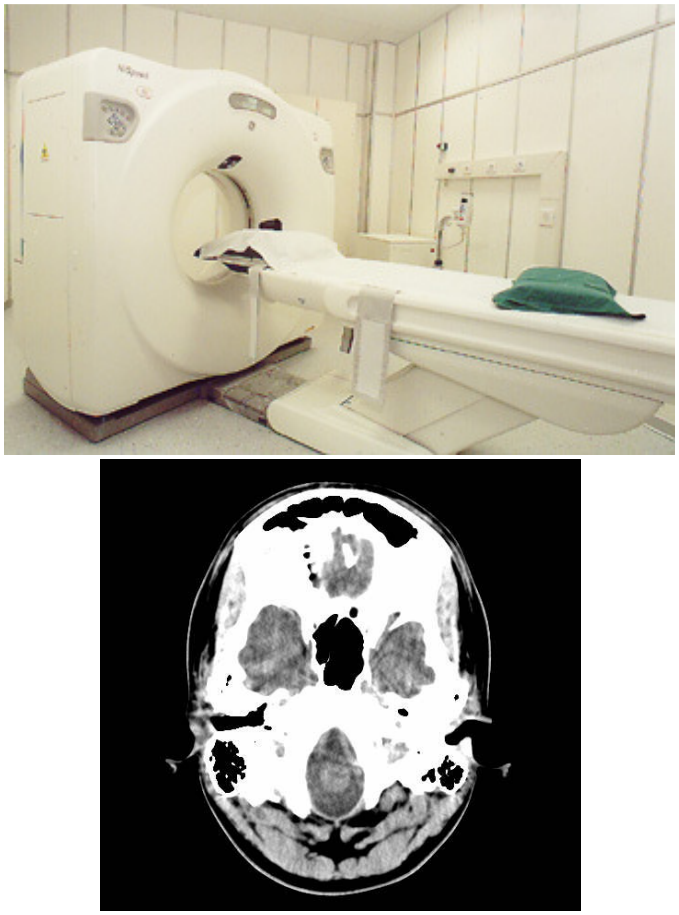

Figure 1.13: Example of CT machine (left) and example of CT cranium image (right).

For this procedure it is necessary a computer, this is the reason of the adjective “computed”. It is also well known as Computed Axial Tomography (CAT), but the adjective "axial" is not anymore appropriate, since the last generation of this technology doesn’t acquire only on one axial plane, transversal, but it has been adopted a spiral acquisition technique, which obtains more images in a single acquisition. This circular methodology at the base of the CT functioning was invented by the English engineer Godfrey N. Hounsfield and the South-African physicist Allan M. Cormack, who were medicine Nobel in 1979.

The image is created by CT measuring the fading effect of X-ray , which goes through the human body. This varies proportionally to the electronic density of crossed tissues. Since the obtained images are digital, the human body is divided in volume elements (voxel), to each of them it corresponds a single image element (pixel), on the base of a grey scale. A voxel with higher density has a lighter grey (see scale in Figure 1.14). TC methodology obtains better results than traditional radiology regards to diagnostic imaging of soft tissues. Unfortunately radiation dose for the patient is quite high compared to traditional radiology. For this reason it has to be adopted only if strictly necessary, in particular for children. The TC exam can be improved using a contrast liquid by intravenous injection, which better identifies structures with same density.

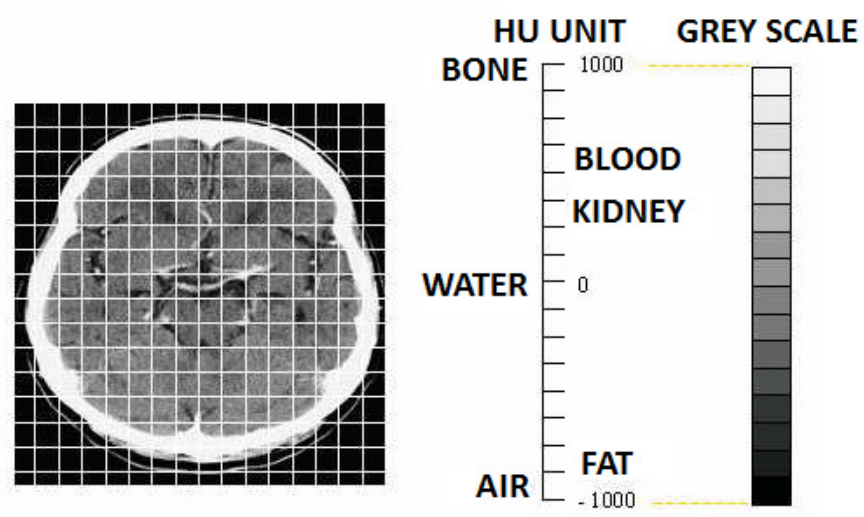

Figure 1.14: Hounsfield grey scale relative to principal human body organs.

The emitter of X-ray beam rotates around the patient and the detector, at the other side, collects the image of the patient's body section; the patient is lying on a couch , which slides in precise and determined way inside a tunnel, showing a different body section at each rotation. The sequence and of images and the angle of acquisition are processed by a computer, which shows the results on a monitor. The results are consecutive sequences of sections, with a determined thickness: all the sections can be processed by a 3-dimensional rendering software to obtain tomographic images in any spatial plane or 3-dimensional. These images can be stored in an hard disk, recorded on a CD/DVD or printed on a film.

In unidirectional continuous rotation TC machines, emitter and detector are installed on a rotational ring. This method allows a continuous acquisition of images: while the couch slides on a plane, the scanning planes moves spirally around the patient, obtaining a spiral scanning. Normal spiral TC machine complete a rotation in more or less one second, and acquire the whole body in 40-60 seconds (see schemes in Figure 1.15) [24].

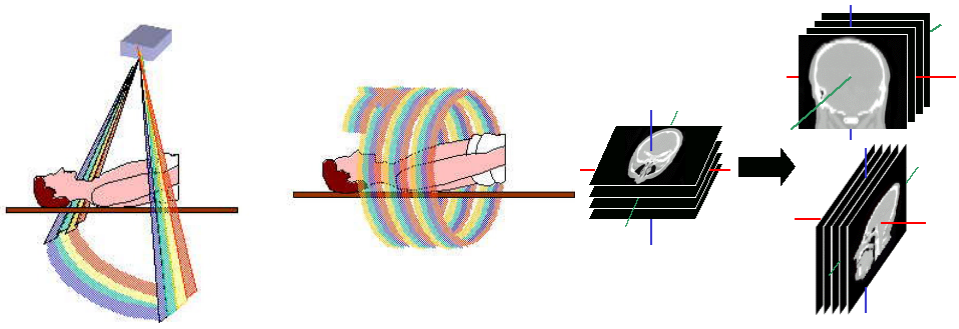

Figure 1.15: Functioning scheme of traditional CT machine (left), of spiral CT machine (centre), and examples of TC images (right).

c) Single Photon and Positron Emission Computerized Tomography

Single Photon Emission Computerized Tomography (SPECT) and Positron Emission Tomography (PET) are diagnostic techniques of the tomography technique category: they give images of bi-dimensional sections of the human organism by adopting mathematical algorithm, such as CT. SPECT and PET are emissive techniques: this means that it is possible to detect outside the organism the distribution of a radioactive substance (radiotracer), administered in small quantities, normally through intravenous way. The distribution measure of the radiotracer inside the organism gives informations about the organ in exam. Therefore radiations of emission tomography, which come out the patient's body, are detected after giving radiotracer; while CT gives structural images highlighting a pathological region due to variation of tissue density, emission tomography gives functional images highlighting a pathological region such as a region with anomalous undertaking of radiotracer, due to an alteration of the tissue function. SPECT and PET are anyway different for the type of emission and the radiation detection equipment. SPECT and PET have also different clinical applications in neurology, cardiology and oncology diagnostic.

○ *Single Photon Emission Computerized Tomography*

SPECT makes use of radioactive isotope , which emit gamma radiation, electromagnetic radiations, such as light and radio waves, but with higher energy and frequency. The detector system, the SPECT tomograph, (see example in Figure 1.16) is constituted by a rotating detector around the patient to register emitted radiations in the different angular directions (see scheme in Figure 1.17). Anytime gamma camera emits a radiation, it is produced an impulse. Impulses are digitalized and all the information are registered and stored in a computer. For the many positions of the gamma camera around patient during SPECT exam, it is created an image of the radioactive tracer distribution (scintigrafic image). Scintifigrafic images are mot tomographic images, therefore the single scintigrafic images are elaborated by mathematical algorithms , which creates the images of the radiotracer distribution on axial section planes (perpendicular to the human body). The axial sections can be re-elaborated by a computer and re-organized in sagittal, coronal o other desired direction. For faster exams, there are SPECT tomographs with multiple head, constituted by 2 or 3 rotating gamma camera, which detect simultaneously radioactivity in different angular positions. The SPECT technical characteristics are lower than PET ones and other tomographic techniques (CT and MR). For example, the recognition capability to identify small parts (technical spatial resolution) is about 7-8 mm in SPECT, 4-5 mm in PET and less than 1 mm in CT and MR [25].

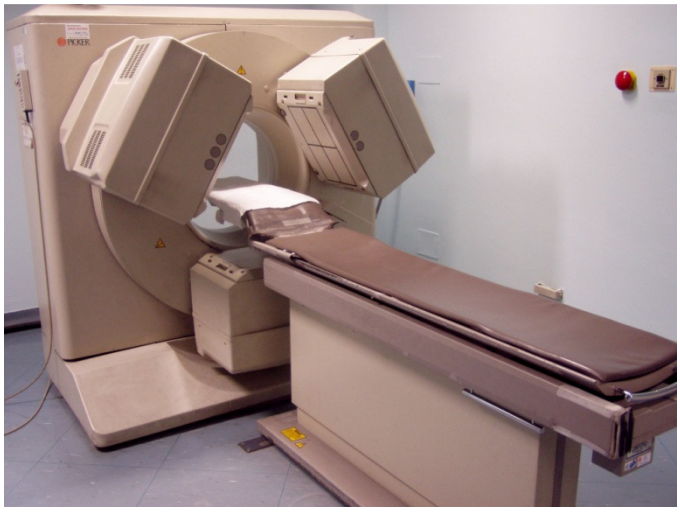

Figure 1.16: Example of SPECT tomograph.

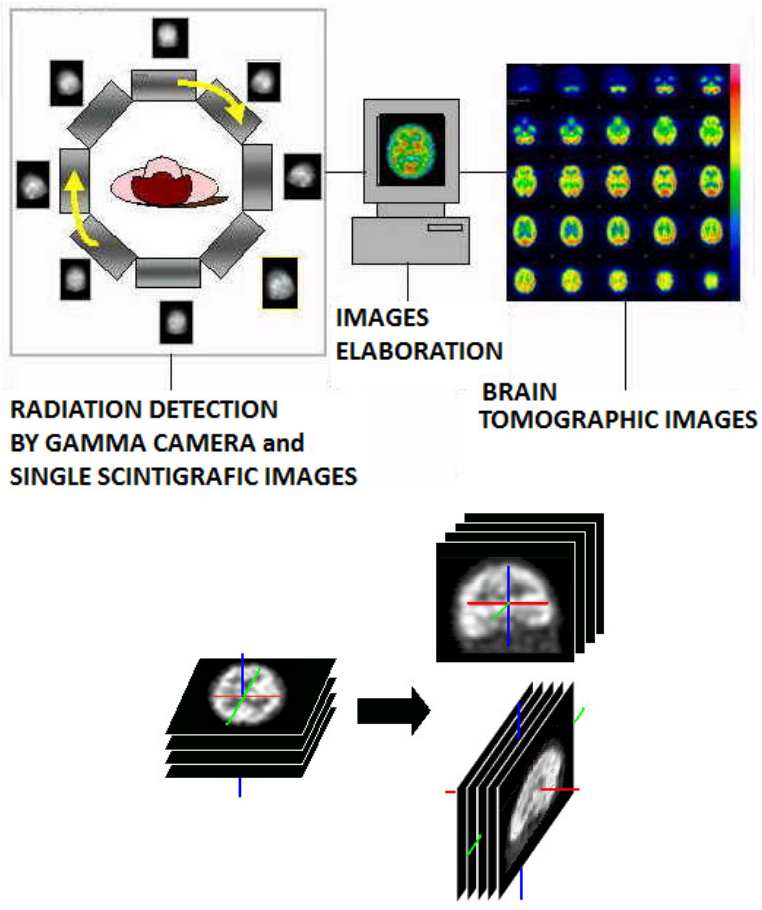

Figure 1.17: Scheme of SPECT image creation (left) and coronal and sagittal sections derived from SPECT axial sections (right).

- *Proton Emission Computerized Tomography*

PET makes use of radiotracers , which emits positrons (particles with same electron mass, but positive electric charge). The radioactive isotopes used to radioactivate PET radiotracers have 3 principal characteristics (which are the difference from SPECT isotopes):

- They decay together with the positron emission;
- They quickly decay, in few minutes. That's why it is necessary to have also a cyclotron (a particle accelerator machine used to produce radioactive isotopes) to use a PET. This is one of the reason why PET is more expensive and less diffused;
- PET isotopes are the radioactive correspondence of natural composites of matter (carbon, oxygen, nitrogen). Theoretically it is possible to mark an infinitive number of composites present in an organism to have radiotracers for different functions. The availability of physiological radiotracers is a positive characteristic for PET, in particular compared to SPECT.

A positron, emitted during radioactive core decay after radiotracer giving, covers a short distance (almost about few mm) and after to have released all its energy, meets a matter electron. Interaction between positron and electron creates the so called "annihilation", where their mass disappear to generate two electromagnetic radiations, emitted 180° one from the other one. A PET tomograph (see example in Figure 1.18) is constituted by very small thousands detectors rings (around few mm for each detector), which allow to detect annihilation radiations , which goes out the human body, simultaneously, in many angular positions (see scheme in Figure 1.19). The radiation detection creates electrical impulses , which are digitalized and recorded on a computer. Such as SPECT, PET data are elaborated by algorithms to obtain radioactivity images (radiotracer distribution) in body sections. PET systems and detection techniques have had a great evolution in the last years, now images have a technical spatial resolution of 4-5 mm [26].

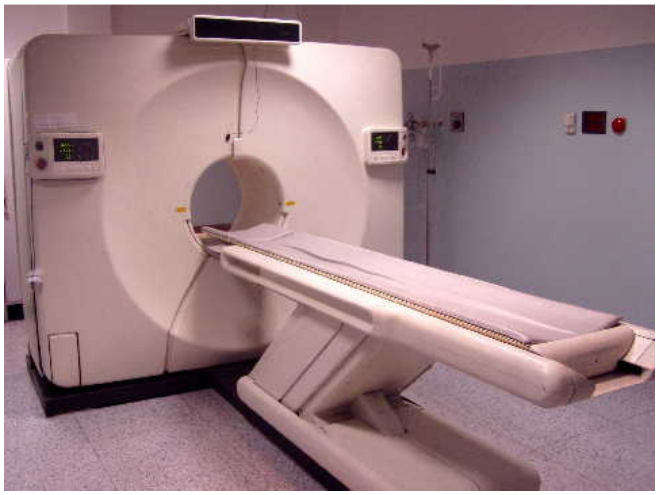

Figure 1.18: Example of PET tomograph.

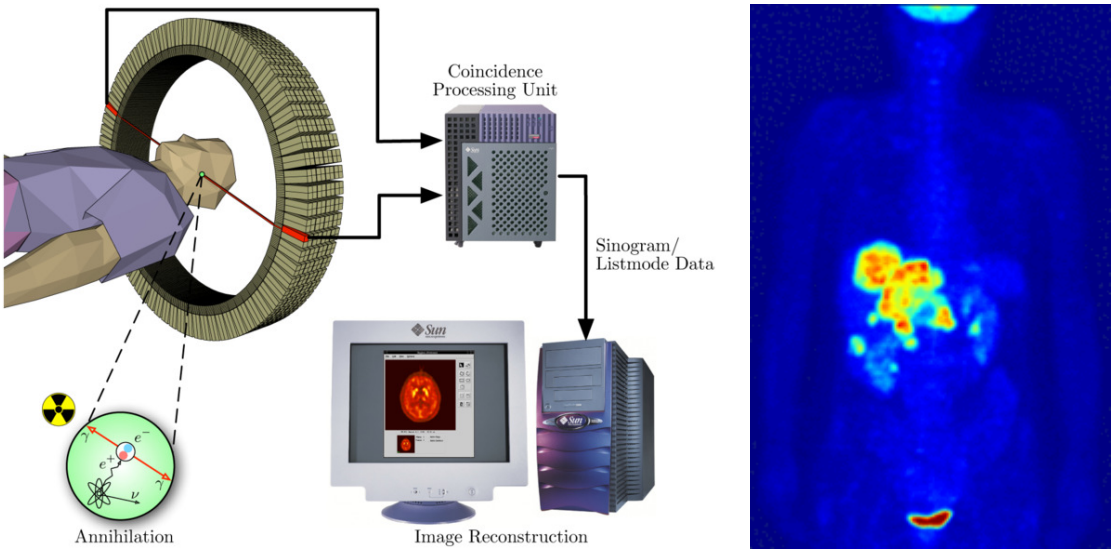

Figure 1.19: Scheme of PET process acquisition (left) and example of Maximum Intensity Projection (MIPS) of a total body acquisition (right).

d) Magnetic resonance

Magnetic Resonance Imaging (MRI) or Magnetic Resonance Tomography (MRT) or simply Magnetic Resonance (MR) is a diagnostic imaging technique, based on the physical principle of nuclear magnetic resonance. In fact the density signal in MR is given by the atomic core of the examined element. MR is generally considered not noxious for patients.
The functioning principle is based on processing patients to a strong static magnetic field. The magnetic field intensity can vary from tenths of Tesla, for small machines, to 3 Tesla for last generation of MR machines (see example in Figure 1.20). In this static field, the proton spins inside tissues are aligned to the force directions; in this way tissues acquire a small magnetization. The aligned protons show a procession in the magnetic field direction, which has a typical frequency. If to the patient it is applied a rotating magnetic field at this frequency and sufficient energy, it is possible to rotate protons magnetization of a determined angle (called flip angle) on the base of the images which are requested. Giving energy to this frequency is the phenomenon, the resonance, which gives the name to the method. After the impulse, protons come back to the magnetic field alignment, and this is called relaxation. This relaxation happens in two determined time constants: the first one, called T1, is the rapidity of protons to come back to the original alignment; the second one, called T2, is the rapidity of destruction of tissue magnetization.

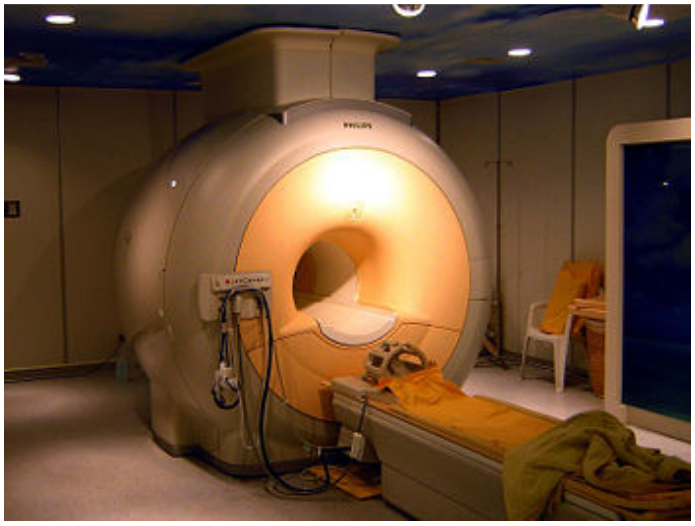

Figure 1.20: Example of MR machine.

During an MR exam patient cannot wear metal objects; in particular it has to be known if patient has metal chips into his/her body due to previous operations/accidents. This because a strong magnetic field such as MR one can move these metal objects and causes harms to the patient tissues. Until few times ago prosthesis, vascular clips, stent or other chirurgical apparatus were an obstacle to execute an MR exam, anyway after the '90s these objects are made with material compatible with MR. While pacemakers are still dangerous. The patient lies on a couch , which slides through a big ring. An MR image can look similar to a CT image (see example in Figure 1.21), but in MR case bones are dark. The technical spatial resolution is quite low, but information discovered with this system are different from the others; in fact tissues are differentiated on the base of their biochemical composition, e.g. there is difference between tissue of liver and spleen, or between healthy and diseased tissue. The scanning time is rather long compared to other techniques [24].

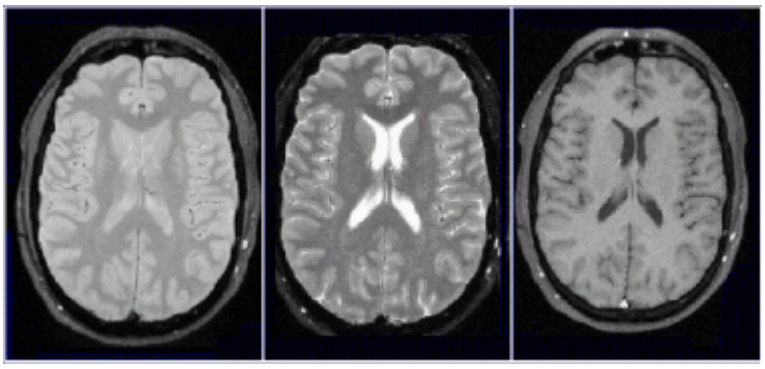

Figure 1.21: Example of MR images of a brain.

e) Ecography

Ecography or ultrasonography is a medical diagnostic system , which doesn't use X-ray, but ultrasounds and it is based on the principle of echo emission and transmission of ultrasound waves. This technique is generally used in internist, chirurgical and radiological sectors. Nowadays this method is considered base and filter compared to other more complex imaging techniques, such as CT or MR. Ecography is operator-dependently, since are required good skills of manual ability and observation, beyond clinical experience. Ultrasound implemented in this method are between 1 and 20 MHz. The frequency is selected keeping into consideration that higher frequencies have a higher resolution, but penetrate less into the human tissue. These waves are generated by piezoceramic crystal inserted into a probe in direct contact with the patient skin and interpolation of a specific gel (which deletes air between probe and skin, allowing ultrasounds to penetrate into the tissue); the same probe captures the return signal, which is elaborated bya computer and shown on a monitor. Quite diffuse are also the real-time probes, where ultrasounds are produced and collected in a single sequence in different directions, by probe mechanical or electronic modulations. The reflected percentage of the ultrasound wave brings informations about impedance difference between two tissues, and it is calculated in this way:

$$R = \frac{(Z_1 - Z_2)^2}{(Z_1 + Z_2)^2} \qquad (1.1)$$

Where R is the impedance difference, and Z_1 and Z_1 are respectively the impedance of each tissue. The high impedance difference between bone and tissue prevents to see behind bones. Air and gas areas (small Z) create shadows, due to their total reflection. The time spent from a wave to go, reflect and return is given by a computer, which calculates echo deepness. Basically an ecography device is constituted by 3 components:

1) A probe , which transmits and receive a signal;
2) An electronic system , which guides the transducer, generates the transmission impulse, receive return echo to the probe and elaborates the signal;
3) A visualization system, such as a monitor.

In the following it will described the available scanning system and the elaboration methods [24].

Scanning systems are characterized by image shape derived from the transducer. Scanning systems available are:

- *Linear scanning*: image shape is rectangular and transducer are linear (see example in Figure 1.22);
- *Sectorial scanning*: image shape is sectorial and transducer are mechanical sectorial with single, annular o array crystal;
- *Convex scanning*: image shape is a trunk cone and transducer are convex.

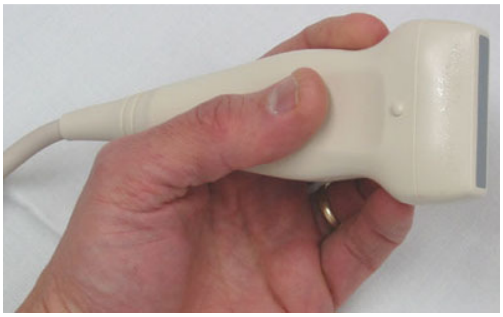

Figure 1.22: Example of linear scanning device.

There are different elaboration methods due to the probe output signal. Normally they are:

- *Amplitude modulation*: each echo is represented by a peak whose amplitude corresponds to the echo intensity;
- *Brightness modulation*: each echo is represented by a light point whose grey tone is proportional to echo intensity;
- *Real-time mode*: waves are emitted and collected in different directions in sequence, in order to have an image on all the observation field;
- *Motion-scan mode*: it is a brightness modulation but cadenced;
- *Doppler mode*: when a wave is reflected on an object in motion, the reflected part changes frequency in relation to the object speed (Doppler effect). A computer knowing the frequency difference can calculate the object speed, while deepness is known. Informations about speed and frequency are represented with different colours on a monitor (see example in Figure 1.23);

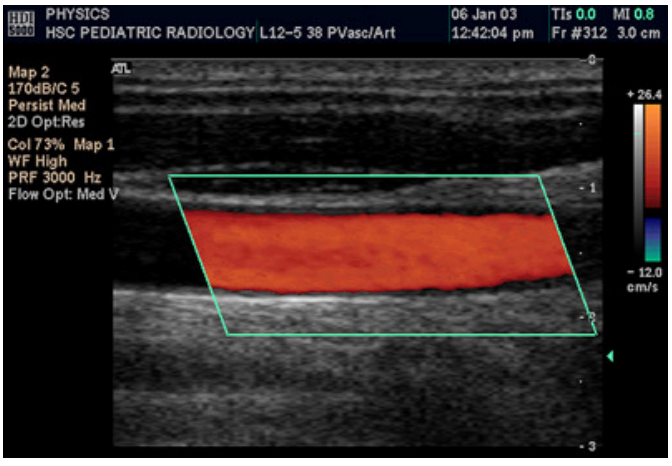

Figure 1.23: Example of carotid coloured doppler.

- *3D mode*: the last generation of ecography device allows the 3-dimensional rendering, based on the acquisition of a tissue volume. In this way it is clearly represented an object aspect (see example in Figure 1.24). Adding the "real time" option, it is possible also to see the object movements;

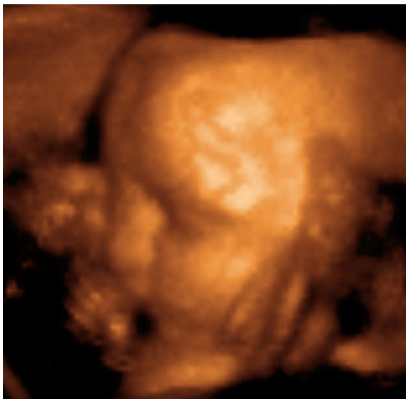

Figure 1.24: 3D ecography of a 29-weekns human fetus.

b. Acquisition of external morphological geometries

Beyond diagnostic imaging to examinate internal human parts, there are instruments to acquire external parts. These techniques measure and acquire external surface images of the human body allowing accurate and repeatable acquisitions [27]. They are characterized by capability to acquire complex shapes with high fidelity, without direct contact with the human body and quite short times (few seconds). Born for research reason in ergonomic and anthropometric study, subsequently applied in other sectors for special purpose, these system are evolved for resolution and scanning time, but not for size and easy usability. Even if these techniques are still not very diffused, there are different systems available on market. Principal types are:

a) Structured light system
b) Laser scanner system
c) Stereophotogrammetry

a) Structured light system

This technology uses the structured light projected and reflected on an object. In this system acquisition of anthropometric measures is based on Moiré effect, which uses projection of light beams organized in a regular scheme. From deformation of these light beams, which are reflected from the body, it is possible to reconstruct shape and measures of the body itself [28]. These systems are quite quick since this technology acquires contemporarily more points of a geometry or the whole field. This characteristic allows to acquire objects in motion (motion capture). This technology adopts traditional halogen lamps , which have no collateral effect and no psychological impact. The only problem is that object with particular curves or in small dimensions cannot very well be acquired and /or can lose details. Hardware components of this system are usually (see scheme in Figure 1.25):

1) A projector , which projects structured light patterns on objects;
2) A digital camera to acquire images of the illuminated objects.

Both devices are guided by a software module on a computer.

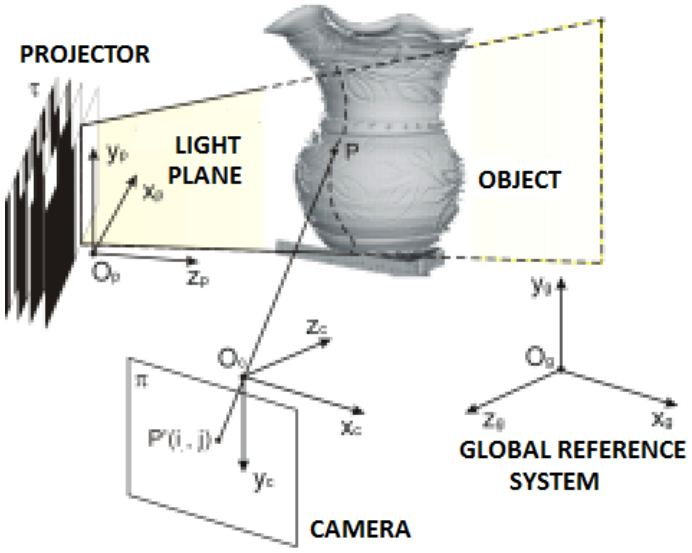

Figure 1.25: Scheme of a structured light system.

b) Laser scanner system

Scanner systems uses the most diffused laser nowadays available on market. Also these systems project light with determined characteristics and make use of its reflection on examined objects. In particular 3D laser scanning exploits the principle of triangulation [29]. An emitter explores field and position of each reflected ray, which is detected by a sensor , which indicates the position of an object into the space (see scheme in Figure 1.26). Differently from a structured light system, digitalization is done point by point and it is slower. For a quicker acquisition, laser can be substituted by a laser light beam , which acquires the whole section profile. For an all-accomplished acquisition it is necessary to do more acquisitions from different angulations. Generally these systems are composed by more than one laser, light sensors and a motion capture system.

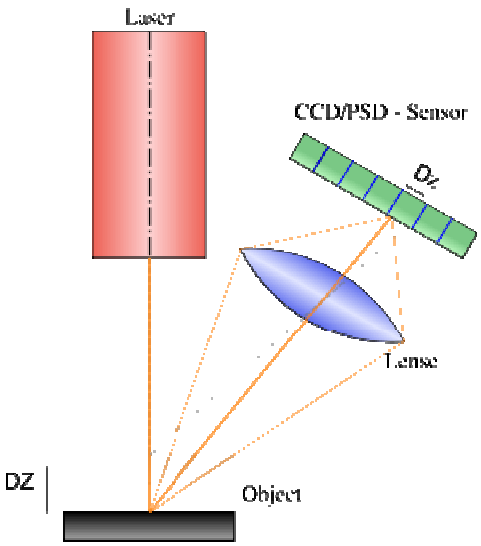

Figure 1.26: Scheme of a laser scanner system.

c) Stereophotogrammetry

This technology uses image-processing techniques, combined with geometric modelling techniques for digitalization of the human body (see general scheme in Figure 1.27). Starting from profiles of a figure edges obtained photographing a subject at different angles, it is possible to reconstruct with specific algorithm a 3D geometry [30]. Last generation of this technology allows to reconstruct the whole surface of a scanned human body and can be used for many different applications, and different positions.

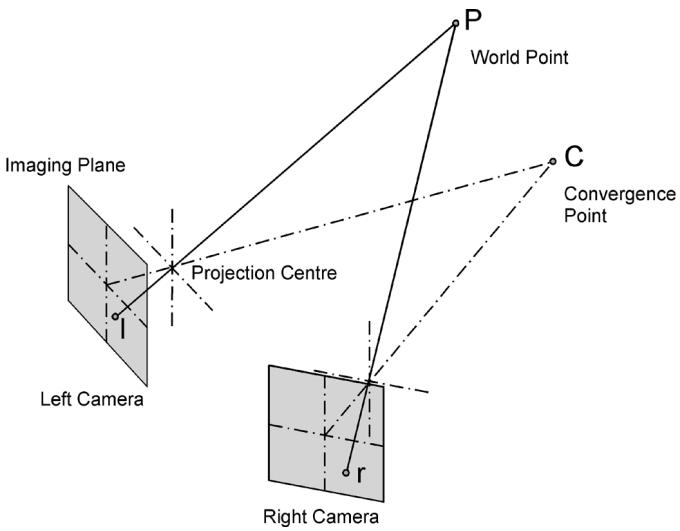

Figure 1.27: Scheme of a photogrammetry system.

1.3.2 – Prosthetic CAD/CAM softwares

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

1. *Infinity CAD systems: AutoScanner & AutoSculpt* [18]

   AutoScanner instantly acquires prosthetic 3-D surfaces by gathering measurements made by smoothly sweeping a handheld laser scanning wand. Practitioners can scan AK's / BK's / AFO's / Body Jackets / Head / Hands. AutoScanner is built on reflection technology. A laser beam emitted through the handheld laser wand determines the scanning surface coordinate position. The computed points of data (point cloud) form a 3-D image of the scanned prosthetic shape. Thanks to the cutting edge, laser reflection technology used in AutoScanner, the collection of scanned surface data points will be hundreds of thousands per second, ensuring that the scanning process is fast reliable and accurate. AutoScanner software uses various scientific formulas to calculate non-scanned data points, hence it forms a fine, high resolution 3-D prosthetic image. AutoSculpt is computer aided design software exclusively developed for modifying prosthetic 3-D images. User-friendly features of AutoSculpt enable prosthetist/practitioners to implement all necessary changes to their 3-D images according to the weight bearing specification of their patients. AutoSculpt prosthetic modification software has state-of-the-art features , which enable practitioners to modify their patients' residual limb 3-D images accurately and efficiently. 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
- Area creation, modification and transformation.
- Global and segment volume modifications.
- General utilities to make changes to resolution. End cap utilities, slice addition and subtractions.
- Volume reissue feature to change circumferential volume.
- BK design tools, with A-P, M-L modification
- AK, spinal jacket, AFO – Design library, Foot, Insole modification
- 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.
- Anterior/ Posterior/ Medial/ Lateral views and freehand rotate options of help 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.

An example in Figure 1.28.

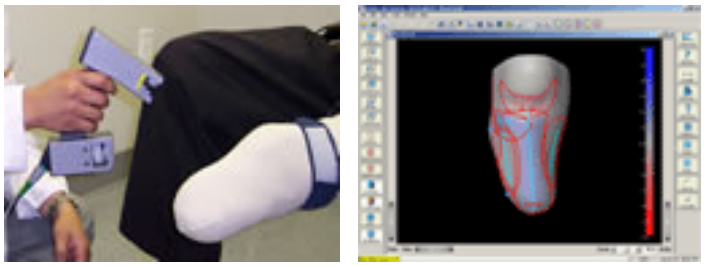

Figure 1.28: AutoScanner (left) and AutoSculpt (right).

2. *Biosculptor: BioScanner, BioShape Software & DSS Digital Socket System* [17]

   Scan a patient in 10 seconds. Both patients and referral sources will be amazed by the efficiency, speed, and advanced technology of the BioScanner™. 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 BioScanner™ is able to image negative and positive models, allowing you to use the clinical techniques required for each patient. With scan-through-glass technology, you may position the body horizontally for a TLSO or utilize a weight bearing table for AFOs or foot orthotics. The BioScanner™ automatically corrects the refraction. The precision of the BioScanner™ 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. You receive the most accurate scan available without added processing time. The BioShape Manipulation Software is the most powerful CAD software available for O&P. Designed by Prosthetists and Orthotists, it was developed specifically for the clinician. With BioShape, you are able to modify upper and lower extremity prostheses, spinal orthoses, lower and upper extremity orthoses, pediatric shapes, cranial helmets, liners and face masks. It seamlessly integrates with all of the Biosculptor® products.

DSS™ Digital Socket System is the next generation of socket-by-numbers. Our unique software utilizes oblique, transverse and circumferential measurements, we use the crucial anatomical data. This means your test sockets will fit more precisely, saving precious time. We can also template your personal socket design for your exclusive use. Plus, you may receive your virtual model for approval. Now, you can provide CAD/CAM test sockets to your patients with no investment. An example in Figure 1.29 and 1.30.

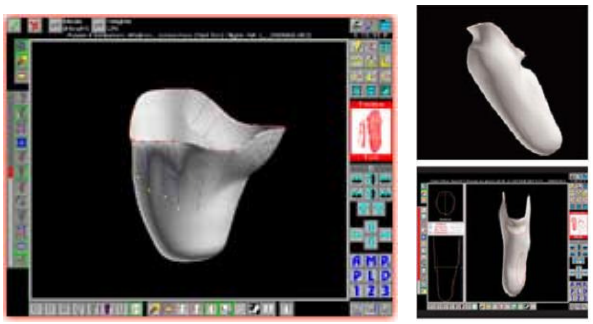

Figure 1.29: BioShape Software.

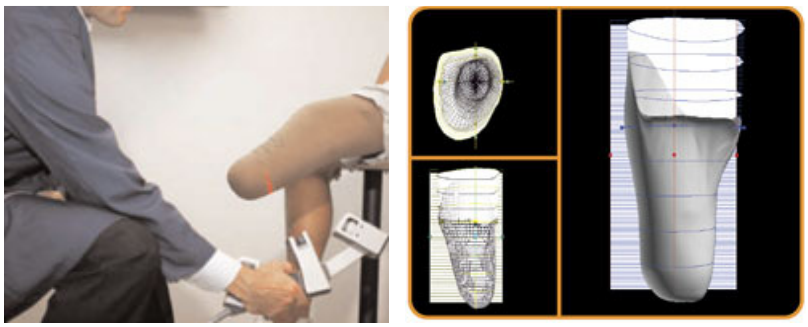

Figure 1.30: BioScanner (left) and DSS (right).

3. *Rodin4D: FastScan 3D & Software* [21]

Easy to handle, fast, accurate, the Fastscan no-contact 3D digitizer enables you to digitize freely and easily the most complex forms. Indispensable for the realisation of non-symmetrical forms, with it you can:

1. digitize your patients in order to work directly on their form afterwards
2. create accurate and realistic library forms
3. digitize your plaster casts before destroying them

Rodin4D now enables you to add control measurements on your 3D shape. In order to have better control of the measurements on your shape, a list is available allowing

you to add various measurements. These measurements are displayed at the top left of the 3D scene and are modified dynamically during your rectification.

- 3D Line : allows you to measure a linear distance between 2 points on the shape.
- Perimeter on section : measures the circumference from 3 points on the shape.
- Partial volume : measures the volume of the section of the selected form. The unit of measurement for partial volume is now dm3.
  An example in Figure 1.31.

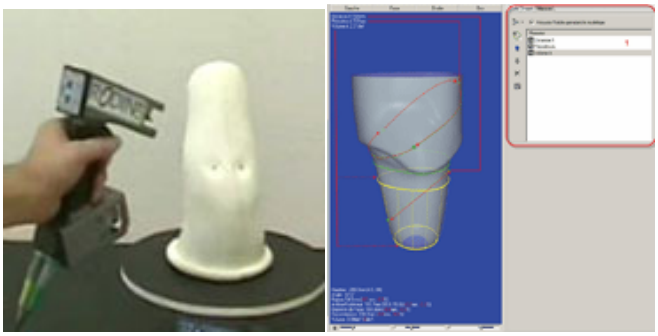

Figure 1.31: FastScan 3D (left) and Software (right).

4. *Össur: Design TF and Design TT* [19]

Design TF is a software with allowes the orthopedic technician to realize a transfemoral check socket using only some measurement taken from the residual limb. The software creates a 3D model of the check socket and allowes also the technician to modify its shape. All the data are then sent by email to Össur , which realizes the socket.
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, and a software, which using these data creates a 3D model of a transtibial check socket and allowes also the technician to modify its shape. All the data are then sent by email to Össur , which realizes the socket. An example in Figure 1.32.

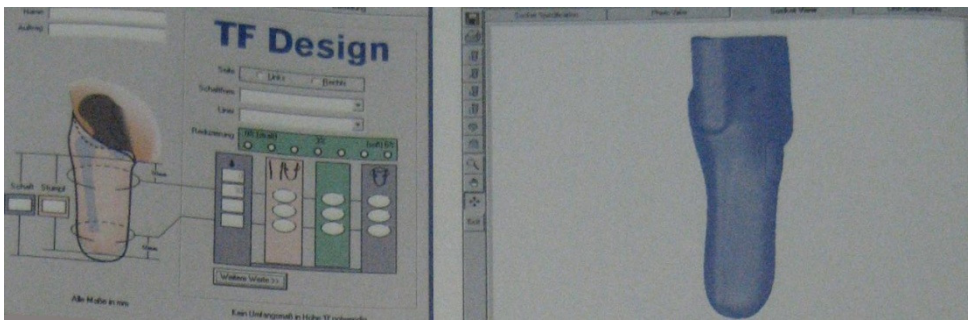

Figure 1.32: Design TF (left) and Design TT (right).

5. *Orten: ComfORTAC, Orten PIX & CAD Software* [20]

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 softwares for the design of orthopedic devices. Another OrtenPIX 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. Examples in Figure 1.33 and 1.34.

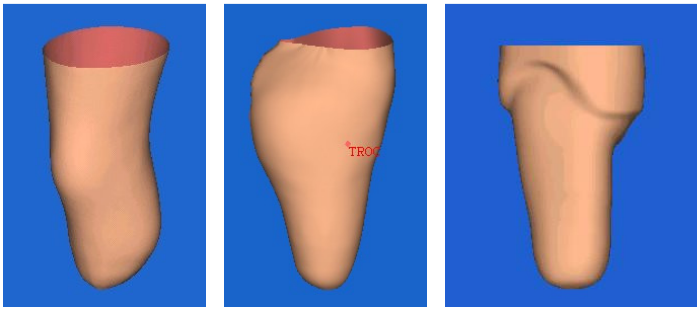

Figure 1.33: ComfORTAC (left and centre) and Orten PIX (right).

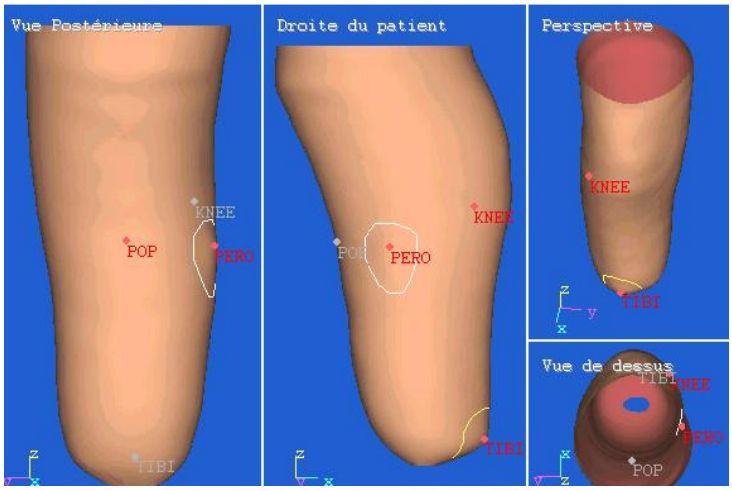

Figure 1.34: CAD Software.

6. *Vorum: Canfit P&O System* [22]

The CanfitTM 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 most effectively as a single unit. A flexible configuration of hardware and software enables you to assemble a system , which meets your specific requirements and budget.

1. Methods for Acquiring Patient Shape Data:

- Digital Input using CanfitTM 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;

2. Designing and Modifying Shapes: CanfitTM design applications are automated shape processing programs , which enable shape data to be stored, modified and easily retrieved. The CanfitTM suite of design tools are the most flexible and powerful available. A combination of large area and regional modifications and overlays, based on individual design and casting techniques, offer ultimate versatility in generating custom modifications:

- 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, CanfitTM P&O Design;
- Manual Measurement Input: The design applications, which accept measurement-based shape data and provide convenient reference library shapes include CanfitTM System II-AK Design and CanfitTM System II-BK Design;

3. Design below knee sockets in minutes with the Canfit-XTM System II - BK Design software. Designed specifically for the prosthetics field, this CAD/CAM program provides strict attention to detail and is easy and economical to operate. Socket data can be obtained by fitting an appropriate proximal brim

to the patient and taking a series of circumferential measurements or by taking measurements only. Since no cast is required, you eliminate the use of plaster in the design process. This also means that no digitizing is necessary, saving valuable time and money. Conveniently, the intimately fit proximal brim is used as a check socket during the measurement procedure. The measurement data entered into the design program generates a fully modified BK socket and displays it on the computer screen. This shape may be carved "as is," or further changed via interactive on-screen modification. Whatever your choice, it is extremely simple to achieve success, and most importantly, consistency in your sockets with this CAD/CAM software. The Canfit-XTM BK Design software may easily be used in conjunction with a central fabrication facility and an associated carver. The CANFIT-PLUSTM Remote Communications program transmits your designed socket data via modem or internet/e-mail to the manufacturing facility. Examples in Figure 1.35.

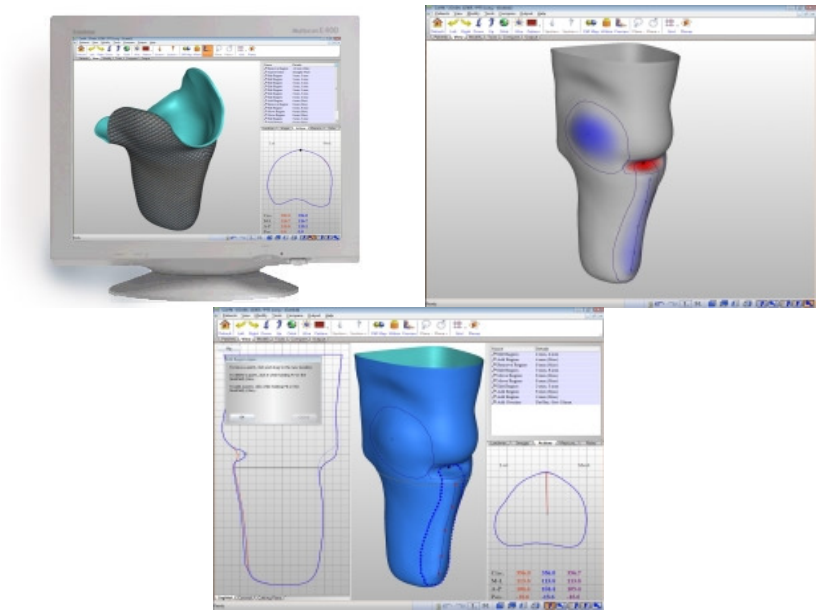

Figure 1.35: Canfit-XTM BK Design.

1.4 – 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 their experience and personal skills. Some of these systems are used only by the company , which produces them to develop different prosthetic components. 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 realisation 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. However they don't consider the possibility to use the systems to analyse and optimise the product such as CAE tools for FEA and multibody analysis. At this regard in literature we can find various experience related to the use of FEM/FEA tools for the analysis of the behaviour of prosthetic components [31-35] adopting different models for the materials (linear and not linear), simulating different situations However, these kind of tools are still less diffused within orthopaedic laboratories, especially small and medium ones. Therefore, it is strategic to integrate domain specific knowledge, in order to obtain a valid and high quality final product.

A system, which can assist and guide the orthopaedic 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, it seems that the winning methods are those based on the KBE approach. There are several applications in the context of Automatic Design realized with this kind of approach and tools [36-39] especially in the automotive and aeronautics sectors. However, no examples of similar applications can be found in the field of interest.

In the next chapters we first describe the work done to acquire and formalize the knowledge of the traditional process to manufacture modular lower limb prosthesis and of all modular prosthesis components, and then we introduce an innovative environment to design lower limb prosthesis, in which it is possible to manage all the process activities in an integrated environment, guided and supported in an automatic or semi-automatic way by experts' knowledge. In this system the orthopaedic 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.

Chapter 2

Knowledge acquisition and formalization

The tacit knowledge related to the product and the traditional process to manufacture modular lower limb prosthesis has been acquired reviewing specific literature, scientific publications [10, 13, 23, 40-47] and, above all, interviewing qualified technical staff of an orthopaedic laboratory and participating personally to socket manufacturing processes. It has been highlighted that all the product and process knowledge is strictly correlated to a specific set of parameters , which guides the whole prosthesis design process: the patient characteristics. In the following it will be described first all the prosthesis components knowledge acquisition and formalization, and then it will be analysed the traditional process followed by the technicians highlighting design rules and procedures , which have been derived for a correct prosthesis realisation. Knowledge formalization has been carried out with natural language, IDEF0 [48-50].

2.1 – Product knowledge

All the different typologies of the main components have been analyzed and formalized using mind maps [51-52]. A mind map is a diagram used to represent words, ideas, tasks, or other items linked to and arranged around a central key word or idea. Mind maps are used to generate, visualize, structure, and classify ideas, and as an aid to studying and organizing information, solving problems, making decisions, and writing. In Figure 2.1, it is possible to see an example of mind map with all components and their different typologies of a lower limb prosthesis.

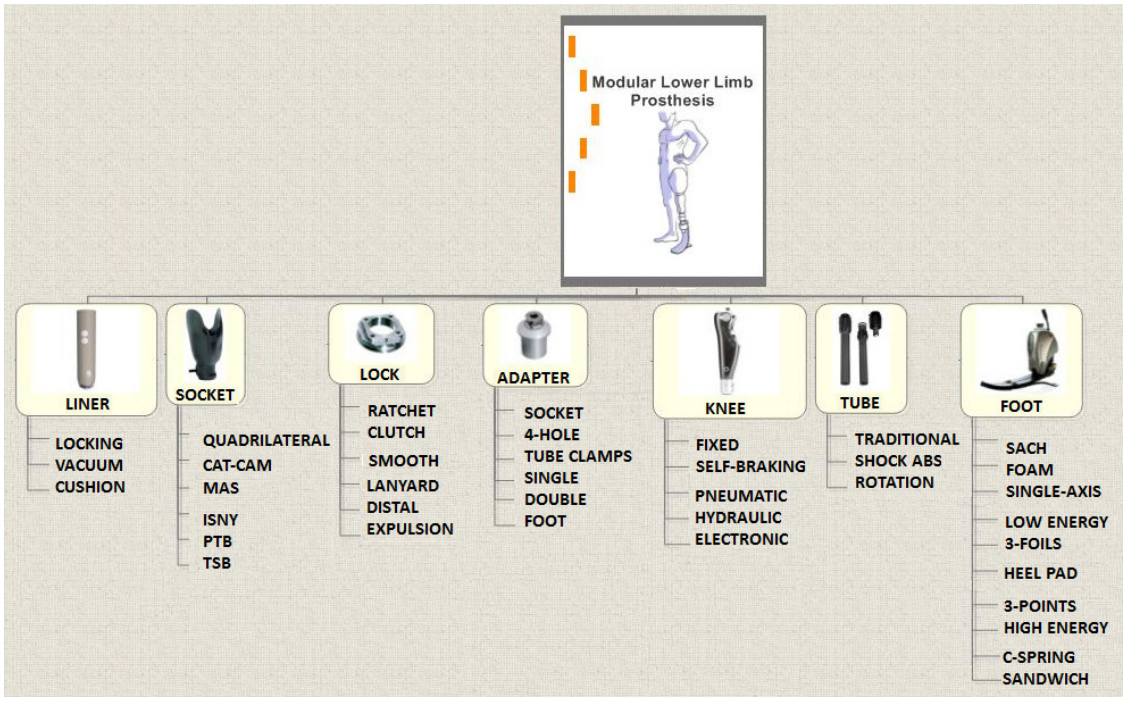

Figure 2.1: Mind map of modular lower limb prosthesis components.

In this mind map each main component (liner, socket, lock, adapter, knee, pylon/tube and foot) has been subdivided in a list of the most diffused typologies of the component itself. In the following we are going to see more in detail the functionalities of each component and the principal different typologies of all these modular components nowadays available. All these components, except the socket, are commercially available and selected from catalogues on the base of amputee characteristics, while, as said, the socket has to be specifically designed for each patient.

1. The liner

The liner is as an alternative suspension system to more conventional methods. It functions as the interface between the skin and the inner socket wall to protect the residual limb and to provide greater comfort to transtibial and transfemoral amputees while wearing their prosthesis. Liner can provide improved cosmetics, cushion the residual limb, reduce shear between the residual limb and the socket, and minimize pistoning of the residual limb in the socket. Heat buildup, skin problems, and decreased proprioception can be drawbacks of this suspension system. Examples of the last generation of liners is shown in Figure 2.2.

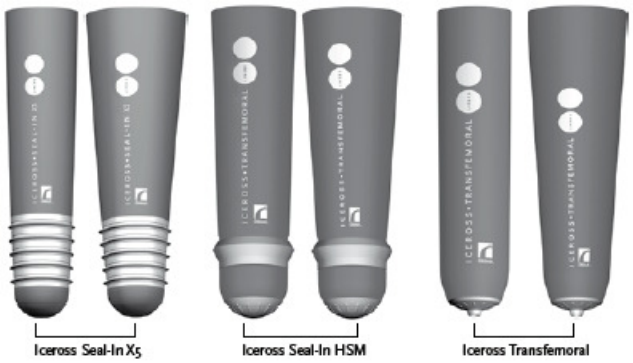

Figure 2.2: Different typologies of liners by Össur.

For a patient it is necessary to select the appropriate liner size. This can be done measuring the stump circumference, 4cm just over the stump top, and detract 2 to the circumference value (see scheme in Figure 2.3), and selecting the appropriate shape, which can be generally cylindrical or conical. For other particular stump shapes it is recommended a custom-fit liner, even if they are so rare that normally are only few exceptions.

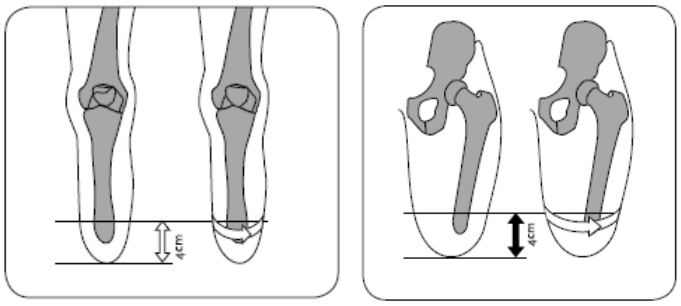

Figure 2.3: Scheme to correctly measure the stump to select a liner size: for TF (left) and TT (right) amputees.

On the base of stump length, stump shape and socket typology, it can be chosen a liner: "with locking system", which is a metal hub inserted into the socket bottom, suggested for short stumps, with particular bony protuberances; "with membrane", which has a silicon membrane between the liner and the inner socket surface guaranteeing an hypobaric suspension, suggested for patients with good mobility and without particular problems with the stump; "with cushion", which has a soft, extra thick distal pad improving user comfort and skin protection and guaranteeing a vacuum suspension, suggested for irregular stump tops and sensitive skins. In Figure 2.4 a simple scheme with these 3 different liner typologies.

Figure 2.4: Scheme of principal liner typologies: with locking system (left), with membrane (centre) and with cushion (right).

On the base of the patient prosthesis use, it is possible to have a liner with a global fabric reinforcement (Figure 2.5-B) or just on the top (Figure 2.5-A), and choosing between three liner materials: traditional silicone, silicone with soothing matters for sensitive skin (Figure 5-C), and silicone with elastomers for a better comfort (Figure 5-D).

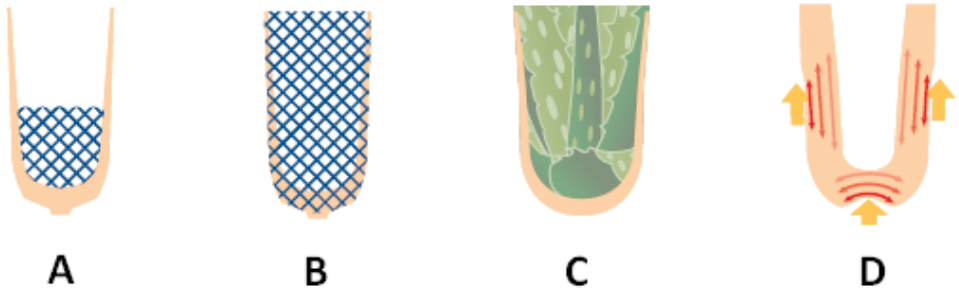

Figure 2.5: Scheme of liner extra properties.

On the base of all the data acquired on the different liner typologies and properties, it has been elaborated a preliminary scheme to select the most appropriate liner on the base of patient parameters, shown in Figure 2.8. In detail we have divided the parameters in this way:

- *Stump type*: TF are above knee amputees and TT are below knee amputees;
- *Stump amputation/stability*: unstable (relative recent amputation, generally less than 2 years) and stable (relative old amputation, more than 2-3 years);
- *Stump tonicity*: divided in 4 levels of muscles tonicity: low (muscles are atrophied), normal (muscles are only partially atrophied), good (muscles are still tonic) and very good (muscles are very tonic, due to previous sport activity);
- *Stump shape*: the morphological shape of the residual limb divided in cylindrical, conical and no-standard;
- *Stump protuberances*: where bony protuberances are located on the stump, all around the residual limb or only on the top;

- *Stump skin*: divided in sensitive (quite sensitive skin, possible problems of reddening and irritations), normal (normal skin with no particular problem) and scratches (presence of scars or scratches which can expose the stump to irritations and pain);

- *Stump dimension/length*: divided in:
  - *For TF amputee*: it is measured the distance between the stump top and the knee joint of the contralateral lower limb (see Figure 2.6):
    - *Short stump = distance is more than 12 cm*;
    - *Normal stump = distance is between 9 and 12 cm*;
    - *Long stump = distance is between 6 and 9 cm*;

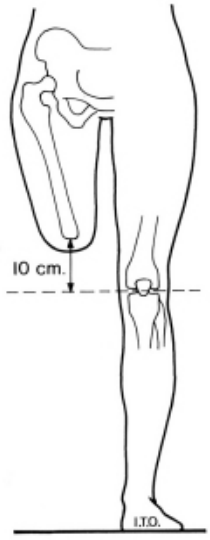

Figure 2.6: Evaluation of TF stump length (image courtesy of Tecnica Ortopedica Internazionale).

  - *For TT amputee*: it is measured the distance between the stump top and the knee joint of the residual limb (see Figure 2.7):
    - *Short stump = distance is between 4 and 11 cm*;
    - *Normal stump = distance is between 11 and 14 cm*;
    - *Long stump = distance is more than 14 cm*;

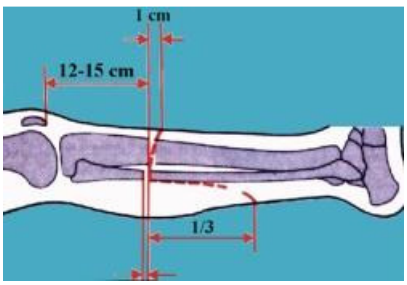

Figure 2.7: Evaluation of TT stump length (image courtesy of Tecnica Ortopedica Internazionale)

- *Patient activity/life style*: divided in 4 levels in accordance with the Healthcare Common Procedure Coding System (HCPCS), which is a set of health care procedure codes based on the American Medical Association's Current Procedural Terminology (CPT); in particular Level II codes are alphanumeric and primarily include non-physician services such as ambulance services and prosthetic devices, these last type of codes, called "K-code", are maintained by the US Centers for Medicare and Medicaid Services (CMS), for further details see [53]. Similar classification is used also in Europe, such as the classification correspondent to the profiling questionnaires of the German National Health Insurance (for further details see the German Federal Ministry of Health [54]), and the correlated classification used by important components manufacturer, see for example Otto Bock Mobis (Mobility-system) [55]. In summary the 4 levels used in Figure 2.8 can be described as:

    - *Low*: the patient has the ability or the potential to use the prosthesis for transfer purposes and to move at minimal speed on level floors. The amount of time and the distance that he/she can walk are seriously limited due to his/her condition;

    - *Normal*: the patient has the ability or the potential to move slowly with the prosthesis and can negotiate low environmental obstacles like curbs, single stairs or uneven ground. The amount of time and the distance that he/she can walk are limited due to his/her condition;

    - *Intense*: the patient has the ability or the potential to move with the prosthesis with variable cadence and can simultaneously negotiate most environmental barriers. He/she also has the ability to move about open areas and can undertake occupational, therapeutic and other activities that do not expose the prosthesis to above-average mechanical demands. This also includes those patients who have an increased need for security due to secondary conditions (additional handicaps, special living circumstances) in connection with medium to high mobility activities. In comparison to healthy individuals, the amount of time and the distance that he/she can walk are limited only in non-essential ways;

    - *Very intense*: The patient has the ability to move with the prosthesis in a manner similar to the unrestricted outdoor walker. The amount of time and the distance that he/she can walk are unlimited. Moreover, due to the high functional demands, the prosthesis can sustain a high degree o shock, tension and torsion;

Figure 2.8: Scheme of liner selection on the base of patient parameters.

For the purpose of this work we have identified the hypobaric liner as the most comfortable and adaptable liner typology for most of patients. This typology is also available in the most diffused shapes (cylindrical and conical), it can have a global reinforcement or only at the top, and it is made in normal or sensitive silicone to better satisfy different patients' skins.

2. The socket

The socket, as already said, is the component totally custom-fit on the patient's anatomy. It is an almost rigid "vase", made in wood, synthetic resin or carbon, that the amputee has to wear on his/her stump, and to which are assembled all the other components. In the following we are going to see the most diffused typologies of socket shapes.

- *For TF amputees*:

- Quadrilateral: it is the most traditional socket shape, most diffused from the '60s and then slowly substituted from the CAT-CAM from the '80s. It is still nowadays used by patients accustomed from the total contact between stump and socket, without liner, aboveall seniors and who has skin problems. It gives a particolar sensation of control on the prosthesis. It is suggested for long and tonic stumps. This socket has 4 sides with irregular edge and different heights, which basically compress the stump. In Figure 2.9 a scheme of an horizontal section of a quadrilateral socket;

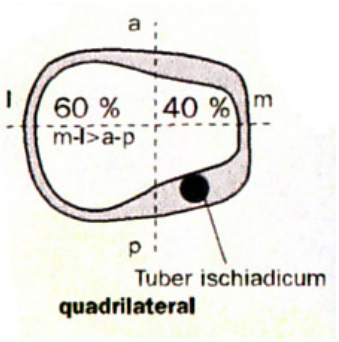

Figure 2.9: Scheme of an horizontal section of a quadrilateral socket [13].

- *Ischium containment socket or CAT*-CAM: this is the most diffused socket fom the '80s, and still nowadays for dynamic patients with the liner. It is particularly suggested to amputees with angiopathies and aboveall who has scars or use a bypass. It is also very goog for short and not very tonic stumps, but also for very sportive people. It has a particolar shape , which englobes ischium (not compressed), wrapes all muscles and the trochanter, that's why also called CAT-CAM (Contoured Anterior Trochanteric Controlled Alignment Method). The pressure is uniform on the stump, and also on top. In Figure 2.10 a scheme of an horizontal section of a CAT-CAM socket;

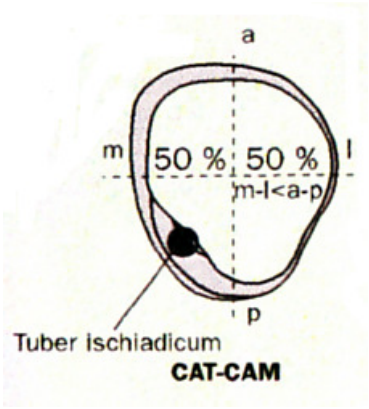

Figure 2.10: Scheme of an horizontal section of a CAT-CAM socket [13].

- *Flexible or ISNY*: this is not a traditional socket, designed in the '80 by Kristinsson of Iceland and then exported to the U.S.A., and so called ISNY (Iceland-Swedish-New York). It is indicated only for stable stump, normal and long, and who has great need of. It has an internal flexible thermoplastic part sustained by and external rigid or semi-rigid structure. The flexible part gives a good sensation of prosthesis control and reduces the internal temperature, and it is quite more comfortable than traditional socket. In Figure 2.11 some examples of flexible sockets;

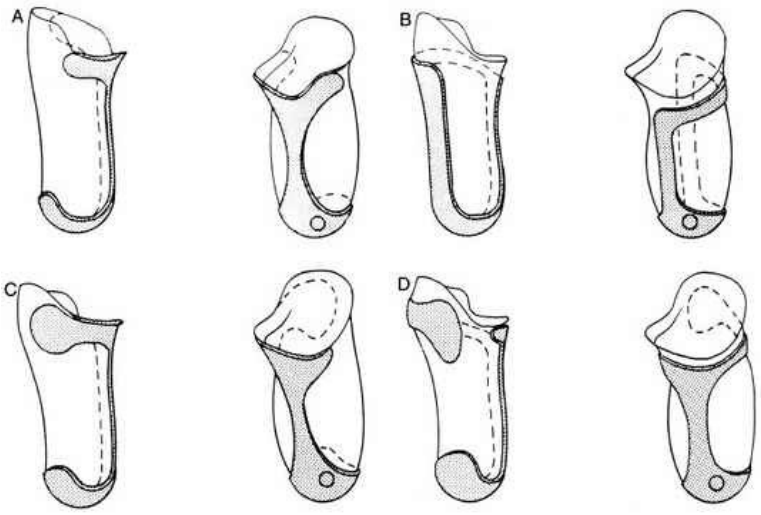

Figure 2.11: Examples of TF flexible sockets [13].

- *MAS*: this is the last generation of TF socket, not still very diffused, it is a kind of evolution of the CAT-CAM socket. It was ideated at the end of the '90s by Marlo Ortiz Vazquez, and so called MAS design or Marlo Anatomical Socket. It is indicated for dynamic amputees, with very tonic stumps. Compared to a traditional ischium containment socket, the back part reduced, leaving free all the buttock, better containing ischium and giving to the amputee more mobility freedom. Excluding in this way all the buttock weight, all the force distribution is directed to the lateral and

frontal side without any problem. For this socket it is necessary a totally perfect coupling between socket and stump. In Figure 2.12 an example of MAS socket;

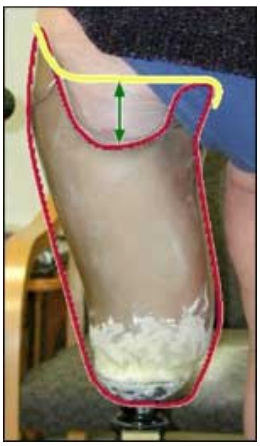

Figure 2.12: Examples of MAS socket [44].

- *For TT amputees*:

- *PTB*: Patellar Tendon Bearing has been the most diffused TT socket until the end of the '90s. This socket has higher pressure distribution areas to support socket itself and more comfortable area with protuberances and difficult blood circulation. It is not appropriate for sensitive skin. It has also two other subtypologies (see examples in Figure 2.13):

    - *Supracondylar Suprapatellar Suspension (SCSP)*: this is a PTB socket but it has also higher medial, lateral and frontal walls , which cover all the patella. Good for patients with very short stumps but slim. Aesthetically more visible but gives a great stability;

    - *Supracondylar Suspension (SC)*: similar to the SCSP but frontally leaves visible part of the patella. Appropriate for patient with good cruciate ligaments conditions, it permits a good knee flexion. Aesthetically less visible;

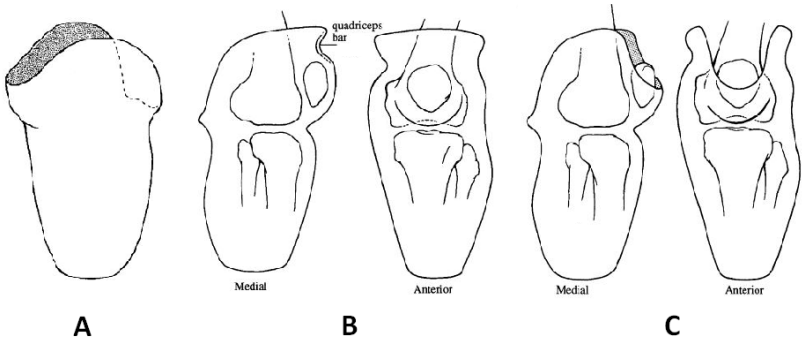

Figure 2.13: Examples of PTB (A), SCSP (B) and SC (C) sockets [13].

- *TSB*: Total Surface Bearing doesn't create areas with more or less pressure, but distributes them on all stump surface. The use with a liner helps the pressure distribution in these type of socket;

- *Flexible or ISNY*: as in the case of the TF socket, this typology is available also for TT socket, with an internal flexible thermoplastic part sustained by and external rigid or semi-rigid structure. The rigid or semi-rigid structure covers only the parts where it is necessary to have support. Good for patients very sportive, it is very light and, in case of anatomical changes, it is possible to substitute only the external structure (see examples in Figure 2.14).

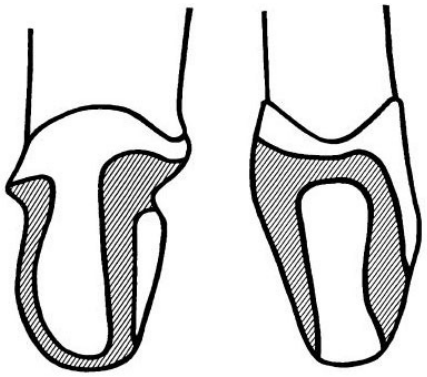

Figure 2.14: Examples of TT flexible socket [13].

		SOCKET								
		TYPOLOGY								
		TRANSFEMORAL				TRANSTIBIAL				
		QUAD.	CAT-CAM	ISNY	MAS	PTB	PTB-SCSP	PTB-SC	TSB	ISNY
AMPUTATION	Unstable									
	Stable									
TONICITY	Low									
	Normale									
	Good									
	Very good									
SHAPE	Standard									
	No-standard									
SKIN	Sensitive									
	Normal									
	Scratches									
STUMP DIMENSION	> 12 cm									
	9 - 12 cm									
	6 - 9 cm									
	4 - 11 cm									
	11 - 14 cm									
	> 14 cm									
WEIGHT	< 75 kg									
	75 ÷ 100 kg									
	100 ÷ 125 kg									
	> 125 kg									
ACTIVITY	Low									
	Normal									
	Intense									
	Very intense									
PATHOLOGIES	Yes									
	No									

Figure 2.15: Scheme of socket selection on the base of patient parameters

Similarly to the liner study, on the base of all the data acquired on the different socket typologies and properties, it has been elaborated a preliminary scheme to select the most appropriate socket on the base of patient parameters, shown in Figure 2.15. For all these parameters it has been previously done a detailed explanation, apart for:

- *Patient weight*: divided in 4 levels of weight less than 75 kg, between 75 and 100 kg, between 100 and 125 kg, and more than 100 kg;. For the use of this table see explanation previously given for the similar liner table;
- *Patient pathologies*: it is considered the presence or not of pathologies , which can influence the patient mobility or quality of life.

Even if most of all socket shapes just analyzed are still used by amputees, due in particular to the great psychological difficulties for amputee to change their habits and move to new technologies or possible improvements, it is consolidated by prosthetists that the best choice for above knee amputees is the CAT-CAM socket, while for below knee amputees is the TSB socket. It has been confirmed also at the last ISPO (International Society for Prosthetics and Orthotics) World Congress [56].

3. The lock

The lock is the device , which fixes the liner to the socket. In relation to the liner selected, the principal typology of lock are (see all examples in Figure 2.16):

- *For locking liners*:

- *Ratchet pin*: for moderate and highly active amputees with bony residual limbs who prefer the security of stepping into the prosthesis to don the socket. The ratchet pin makes an audible clicking sound when it engages, which many amputees find reassuring;
- *Clutch pin*: for amputees of all activity levels who have fleshy residual limbs. The patient dons the prosthesis by winding into the socket rather than pushing or stepping into it;
- *Smooth pin*: for moderate and highly active amputees with bony residual limbs who prefer the security of stepping into the prosthesis to don the socket. The lock is silent when it engages, but provides a secure suspension along the entire length of the socket;
- *Lanyard*: for new amputees or low to moderately active amputees with fleshy residual limb who prefer to be pulled into the socket to don the prosthesis. This suspension system allows the user to apply their prosthesis while sitting down;

- *For cushion liners*:

- *Distal valve*: for new for amputees of all activity levels that cannot tolerate a distal attachment or prefer suction suspension to a mechanical method. Used in conjunction with a suspension sleeve, this suspension system allows the user to apply their prosthesis while sitting down;

    - *For membrane liners*:

- *Expulsion valve*: for amputees who use hypobaric liners, also called liners with membranes.

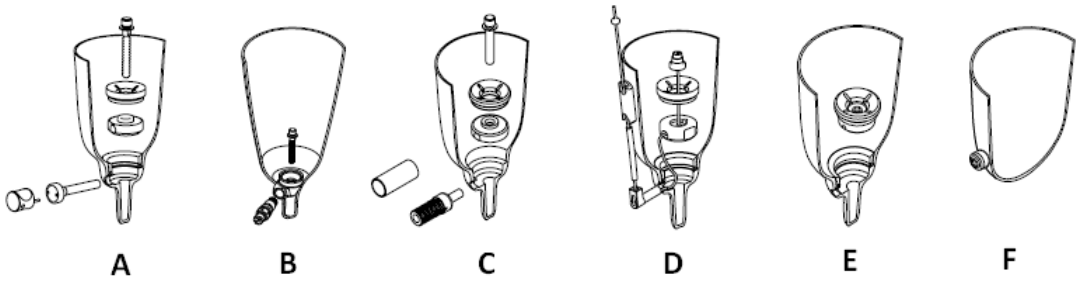

Figure 2.16: Examples of locks: ratchet pin (A), clutch pin (B), smooth pin (C), lanyard (D), distal valve (E), and expulsion valve (F) [19].

4. The knee

The knee is a modular component only for above knee amputees, since obviously the below knee ones have still their anatomical knee. For their centre of rotation they are divided into (see example in Figure 2.17):

- *Monocentric*: in this type the knee has only one rotation joint, therefore in the flexion phase of pendulating it is necessary to flex more the knee to avoid the foot dragging on the floor. The stability of this type is guaranteed by braking elements;

- *Polycentric*: in this type the knee there are more than one rotation joint, in this way polycentric articulations execute contemporary a movement of rotation and translation. The centre of rotation moves into the space in relation to the flexion angle and to the disposition of the articulation axes, determining cinematic and its intrinsic stability.

Figure 2.17: Examples of monocentric knee by Otto Bock (left) and polycentric knee by Össur (right).

Instead for their functioning knees can be divided into:

- *Fixed*: this knee doesn't flex during deambulation and it can be unlocked only to sit down. It is suggested only for patients who don't have a great mobility and needs the highest stability;
- *Self-braking or friction*: this knees works with a friction system , which prevents the knee flexion under load, while pendulating phase has a longer duration. It has a great stability in static phase, while it has the friction help during the deambulation;
- *Pneumatic*: during walking this knee avoids an elevated flexion and permits soft deambulation. It has a high stability in static position, and a more physiological walking;
- *Hydraulic*: this knee exploits the principle of liquid movement from one to another chamber, and solves the problem of walking arrhythmia, and brakes automatically. It is appropriate for dynamic people, who also walks on irregular surfaces and stairs ;
- *Electronic*: it is totally controlled by microchips with hydraulic functioning. It gives to the patient comfort and security. It is adapted to the patient deambulation and it can have also a remote control to switch deambulation type (see example in Figure 2.18).

Figure 2.18: Examples of electronic knee by Otto Bock.

5. The tube

The tube also called pylon is the component which connects the knee to the foot for TF amputees and the socket to the foot for TT amputees (see examples in Figure 2.19). It is connected to the other components by clamps or other adapters. It is possible to have a tube with rotation adapter or shock-absorbing system.

Figure2.19: Examples of tubes.

6. The foot

The appropriate foot choice is strictly correlated to the patient characteristics, and only for TF amputees also from the knee selection. Nowadays there are really many types of prosthetic feet, different for supported load, weight, flexibility, mobility and material. In particular the last generation of carbon feet has largely improved the functionalities and properties of this component. In the following we have tried to select the principal typologies, first we are going to see the most diffused rigid feet:

- *SACH*: the most used foot until the '90s, which stands for Solid Ankle Cushion Hill or rather not articulated ankle, central rigid part and flexible anterior part. This foot allows moderate dorsal and plantar flexion. It is an out-of-date technology used only by senior patients (see examples in Figure 2.20);

- *Distributed foam*: this is the rigid foot most diffused, it is divided in two parts, anterior part and heel bone. It is comfortable, and the heel impact is pleasantly dampened. It permits easy forward rollover (see examples in Figure 2.20);

Figure 2.20: Examples of SACH (left) and distributed foam foot (right) by Otto Bock.

In the category of dynamic feet, there are really a lot of typologies, the principal functioning properties are :

- *With elastic buffer*: it is a multiaxial foot, which means adaptable to irregular floors, with an elastic buffer at the ankle articulation;

- *With "S" spring*: it has a spring under the ankle with an "S" shape, generally made in plastic or carbon fiber. It allows an harmonic walking and a good compensation on irregular floors;

- *With "C" spring*: it has a spring under the ankle with a "C" shape and another basic spring, both dynamically connected by a ring. This system allows a dynamic and comfortable deambulation. It also stores and releases energy during walking;

- *Carbon fiber*: this is a general indication for feet made of carbon fiber. This type of feet are all very light, easy adaptable to irregular floors and can store and release energy during walking, reducing the load to the contralateral limb. They are the last generation of prosthetic feet, and are suggested to most of patients (see different examples in Figure 2.21);

Figure 2.21: Examples of different carbon feet by Össur.

- *Electronic*: the electronic foot, or better an ankle controlled by a microchip, is not at all diffused, due to the high cost of purchase and maintenance and to the great performance of the other carbon feet at quite cheaper price (see example in Figure 2.22);

Figure 2.22: Example of electronic foot by Össur.

7. The adapters

There are really many adapters, used to connect all the different components of a modular prosthesis. Even if different manufacturers produce different families of adapters, we have elaborated a list of the most common adapters used for TF and TT prosthesis. In particular we have to say that, differently from the other components, they are selected only for their material on the base of the patient weight, beyond their adaptability to the already selected components which have to be assembled:

- *Aluminium or stainless steel ada*pter: for patients until 100kg;
- *Titanium or carbon adapter*: for patients until 166kg.

For their type of use they can be mainly divided in:

- *Socket adapter*: used to connect the socket to the knee for TF amputees and to the tube clamp for TT amputees, the most diffused are: 4-Hole Socket Adapter (1), Male Pyramid Insert Prong (2), Female Pyramid Insert Prong (3), 4-Prong Socket (4) and 3-Prong Socket Adapter (5), see examples in Figure 2.23;

Figure 2.23: Examples of socket adapters [19].

- *4-hole adapter*: used to connect the 4-hole socket adapter to the knee, the most diffused are: 4-Hole Male Pyramid (1) and 4-Hole Female Pyramid (2), see examples in Figure 2.24;

Figure 2.24: Examples of 4-hole adapter [19].

- *Tube clamps*: used to connect the tube to the knee, to the foot or to the socket, the most diffused are: Male Pyramid Tube Clamp (1), Female Pyramid Tube Clamp (2), and 4-Hole Tube Clamp (3), see examples in Figure 2.25;

Figure 2.25: Examples of tube clamps [19].

- *Single adapter*: used to replace socket Male and Female Pyramid Insert Prong when it is necessary a higher adapter, most diffused are: Short Male Single Adapter Short (1), Long Male Single Adapter (2), and Female Single Adapter (3), see examples in Figure 2.26;

Figure 2.26: Examples of single adapters [19].

- *Double adapter*: used to substitute the tube when the distance between socket and foot is too small, most diffused are: Female Double Adapter (1) and Male Double Adapter (2), see examples in Figure 2.27;

Figure 2.27: Examples of double adapters [19].

- *Foot adapter*: used to connect the tube clamps or double adapters to the foot, most diffused are: Rigid Foot Adapter (1), Pyramid Foot Adapter (2) and Insert tube Foot Adapter (3), see examples in Figure 2.28.

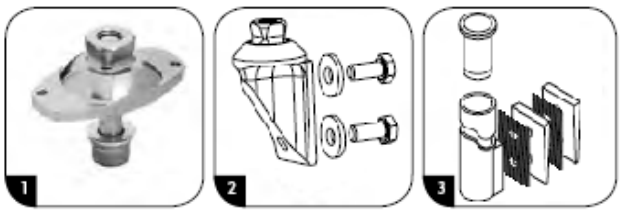

Figure 2.28: Examples of foot adapters [19].

After this general overview about TF and TT modular prosthesis components, in the following we are going to see in detail the traditional manufacturing process for both types of prosthesis.

2.2 – Process knowledge

As previously said, it has been considered the traditional manufacturing process of modular lower limb prostheses, both transfemoral and transtibial, for amputees who wear an hypobaric liner between the stump and the socket; in particular we have considered the realization of the Ischial-Containment socket typology for transfemoral amputees and the TSB socket for transtibial ones. All the process knowledge has been formalized by IDEF0 diagrams [48-50], this since IDEF0 are a simple and easily understandable format, also for the staff of the orthopaedic laboratory where we have studied the process. The technical staff has verified and validated the diagrams and the acquired knowledge. In the following we introduce the main diagrams of the traditional manufacturing process and the glossary.

2.2.1 – IDEF0 diagrams

In Figure 2.29 it is shown the main diagram of the traditional manufacturing process of lower limb prosthesis. The process consists of six principal activities:

- *A1 Evaluate patient;*
- *A2 Realize negative plaster cast;*
- *A3 Realize positive plaster cast;*
- *A4 Realize check socket;*
- *A5 Realize definitive socket;*
- *A6 Assemble prosthesis.*

We are going to see in detail each of this activity and the related IDEF0 diagram.

A0. Traditional manufacturing of lower limb prosthesis

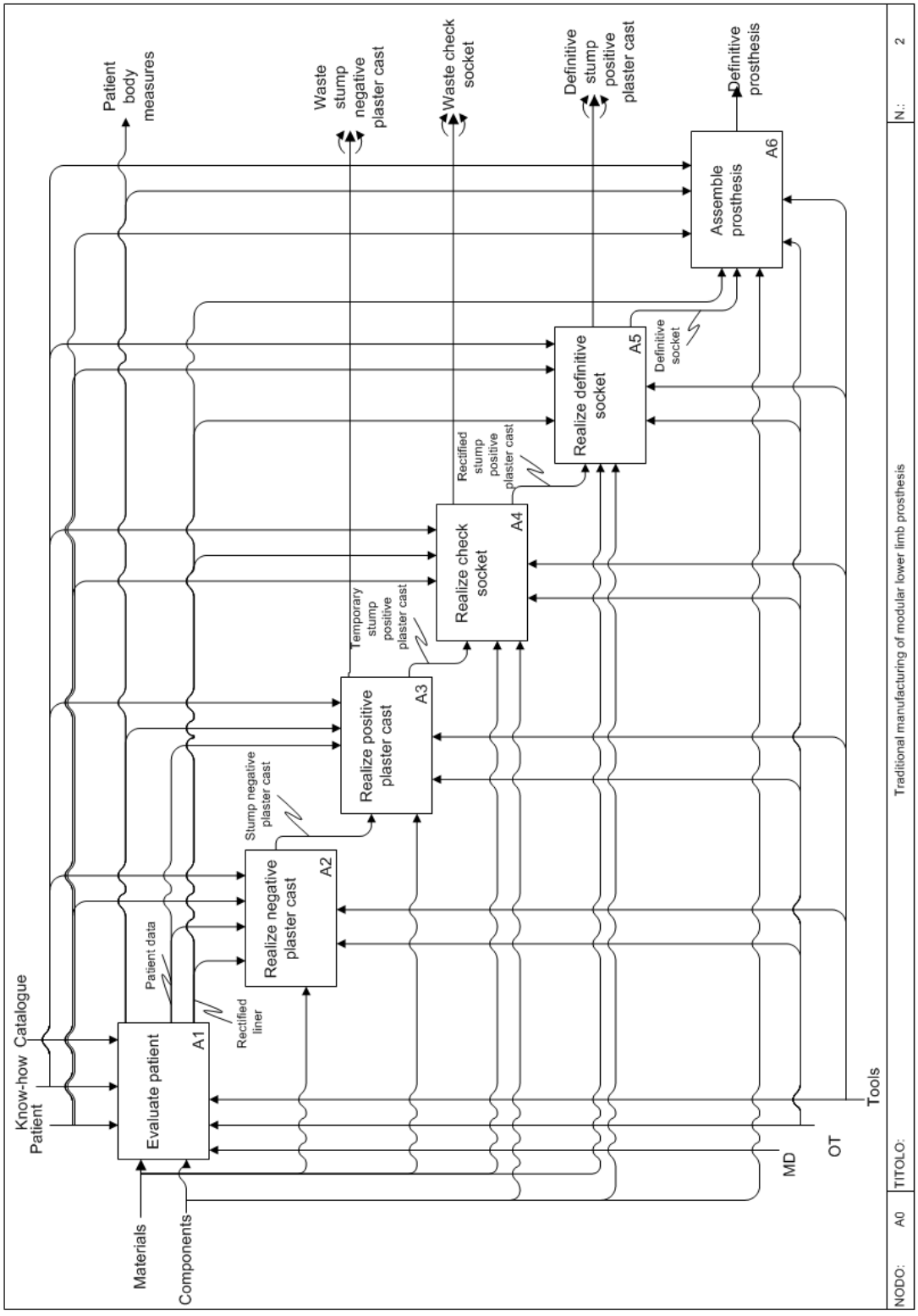

Figure 2.29: IDEF0 diagram of traditional manufacturing of modular lower limb prosthesis.

A1. Evaluate patient

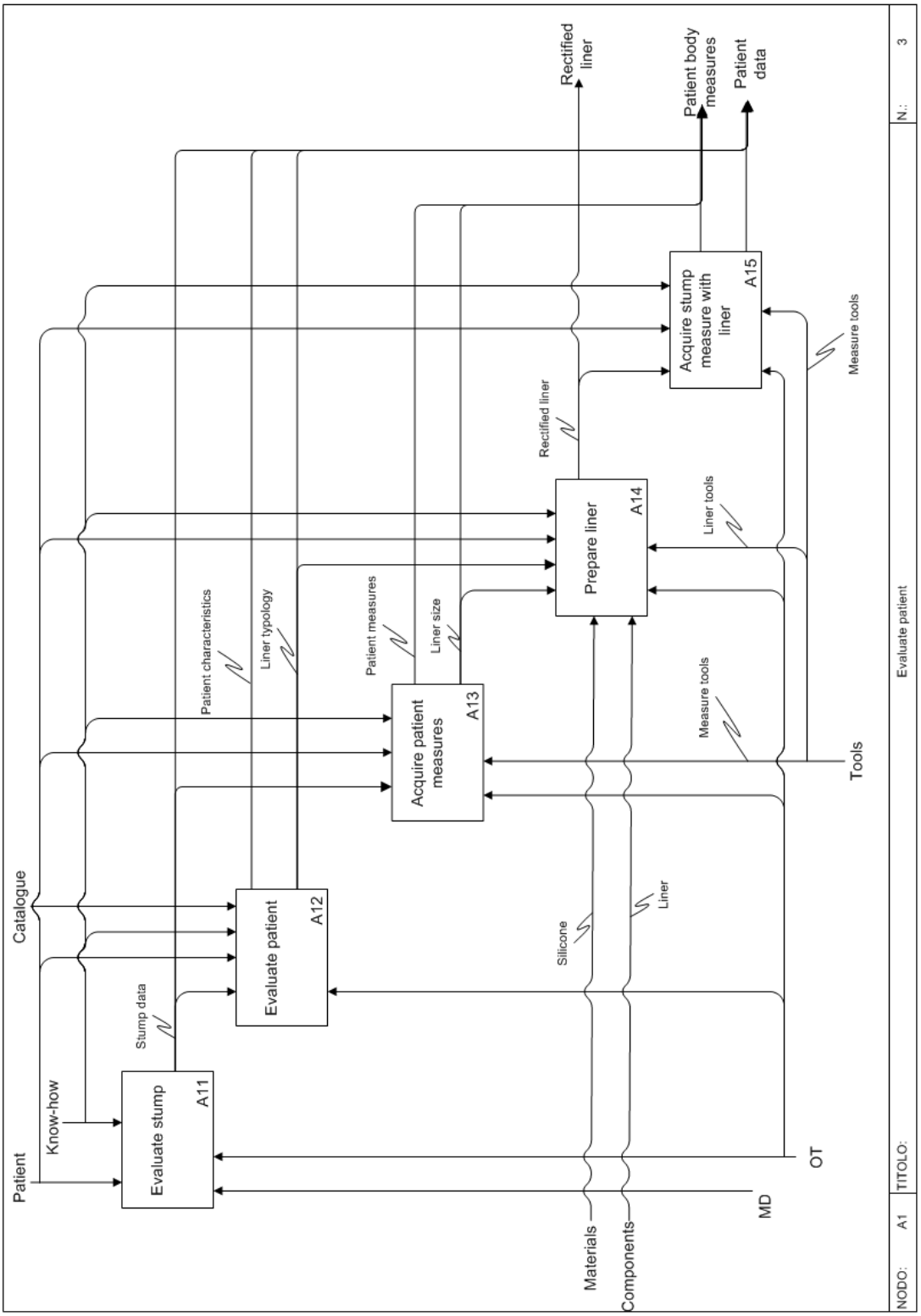

Figure 2.30: IDEF0 diagram of patient evaluation.

In this activity (see related diagram in Figure 2.30) it is done a clinical and technical evaluation of the patient to acquire all his/her characteristics necessary to design the whole prosthesis, including the patient anthropometric measures. It is also prepared the liner, which will be used by patient to wear the prosthesis. This activity consists of five principal operations:

A11: During the first step the patient, a TT (Trans-Tibial) or a TF (Trans-Femoral) amputee, is evaluated by a medical doctor and an orthopaedic technician, in order to design the most functional prosthesis for the patient characteristics. In detail first it is evaluated the patient residual limb and in particular they check:

- *Stump stability*: in relation to the time passed from the limb amputation, the stump undergoes a quick or slow change of volume; for example for a relative recent amputation (less than 1-2 years) the stump undergoes a significant volume reduction, while for less recent amputation (more than 4 years) the stump volume modification are quite slow;
- *Stump tonicity*: the level of tonicity of the residual limb muscles, strictly correlated to the patient daily activity before the amputation. In fact, after the operation, the muscles of the residual limb are only partially used by patient, and slowly they undergoes a process of atrophization;
- *Stump shape*: the morphological shape of the residual limb;
- *Bony protuberances*: where bony protuberances are located on the stump;
- *Skin*: the sensibility of the skin and if there are scars or scratches.

A12: Then they consider the patient characteristics and in particular:

- *Physical conditions*: the patient age, the presence of pathologies which can influence the patient mobility or quality of life, the patient physical force;
- *Level of mobility*: the level of deambulation , which corresponds to the patient case, e.g. if he/she can only walk or also run, if he can deal with stairs or climbs, etc.

A13: After this, the OT has to acquire manually some measurements on the patient, in particular:

- *Patient weight*: the patient weight in kg;
- *Stump length*: it is measured the distance between the stump top and the knee joint of the contralateral lower limb;
- *Stump measure for liner*: to choose the appropriate liner size, it is measured the stump circumference 4cm over the stump top, the correct liner size will be:

$$Liner\ size = Circumference\ measure - 2 \qquad (2.1)$$

The liner is correct if it fits perfectly on the limb, without air between the skin and the liner.

- *Knee height*: the patient sits on a chair and the OT measures the height of the centre of rotation of the knee from the floor; for TF it is also measured the same height for the prosthesis knee (see examples in Figure 2.31);

Figure 2.31: Position of the limb to measure the knee height (left) and measurement of the prosthesis knee height for a TF prosthesis (right).

- *Stump length*: the OT measures:
    - *For TF amputee*: the distance from the trochanter to the stump top;
    - *For TT amputee*: the distance from the rotula center to the stump top;
- *Measurements of the previous socket (when applicable)*: when available, the old socket is measured using a specific mechanical device , which measures some reference internal circumferences (see example in Figure 2.32). This is done to have subsequently a comparison with the new socket.

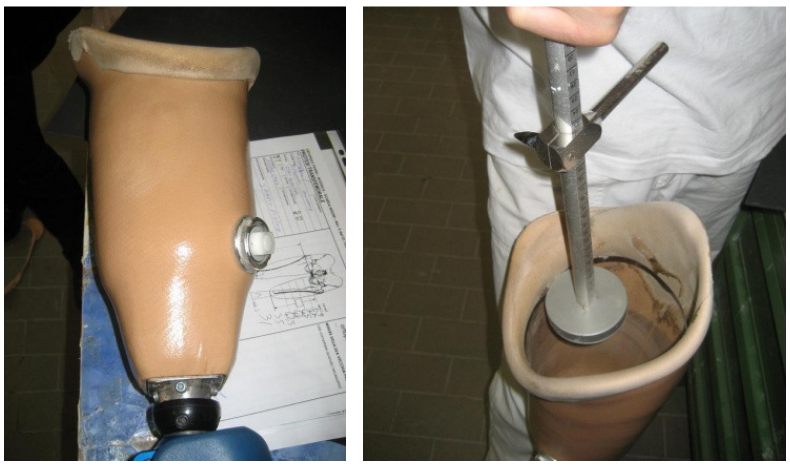

Figure 2.32: Old TF socket (left) and measurement of the internal circumferences (right).

On the base of these informations and his/her personal experience the OT (Orthopaedic Technician) can select from a commercial catalogue all the most appropriate standard components for the patient case.

A14: At this moment the OT has selected the appropriate liner typology and size, as said at the beginning in this case we are considering an hypobaric liner. Before to proceed with the next step, it is necessary to adapt the liner to the patient's anatomy. For this reason the liner is worn by the patient and the OT marks on the liner upper edge the patient anatomical shape using a pencil, in order to cut it and in this way reduce it to patient measure. The liner upper edge is finally sealed using silicone (see example in Figure 2.33).

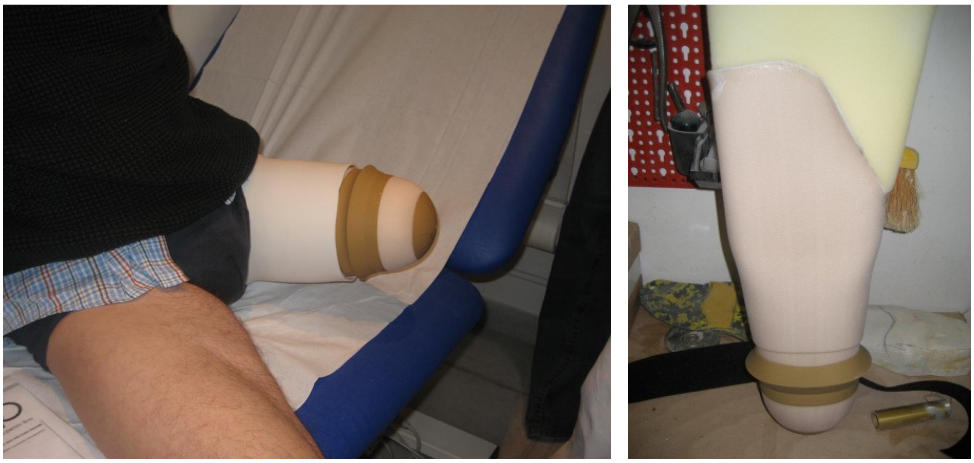

Figure 2.33: A TF amputee wears an hypobaric liner (left) and the same liner with the upper edge cut and sealed by silicone (right).

A15: The OT needs now to acquire other manual measurements on the patient. For this operation TF amputees have to stay standing upright with the stump in abduction, while TT amputees have to sit on a chair and keep the stump in horizontal position. The OT will acquire:

- *Stump circumferences with the liner*:
    - *For hypobaric liner with 1 membrane*: 4 circumferences are measured over the membrane at a distance of 4cm on each other, one is measured just over the membrane and one just below the membrane (see example in Figure 2.34);
    - *For hypobaric liner with 5 membranes*: circumferences of the membranes rings are measured, and the circumferences just over and below respectively the last and the first membrane (see example in Figure 2.35);

Figure 2.34: TF amputee standing upright (left) and positions of the circumferences for an hypobaric liner with 1 membrane (right).

- *Stump width with the liner*: at the same position of the circumferences of the previous step, the OT measures the stump width using a gauge (see example in Figure 2.35).

Figure 2.35: Measurement of circumferences with a 5 membranes liner (left) and measurement of a TT stump width(right).

A2. Realize negative plaster cast

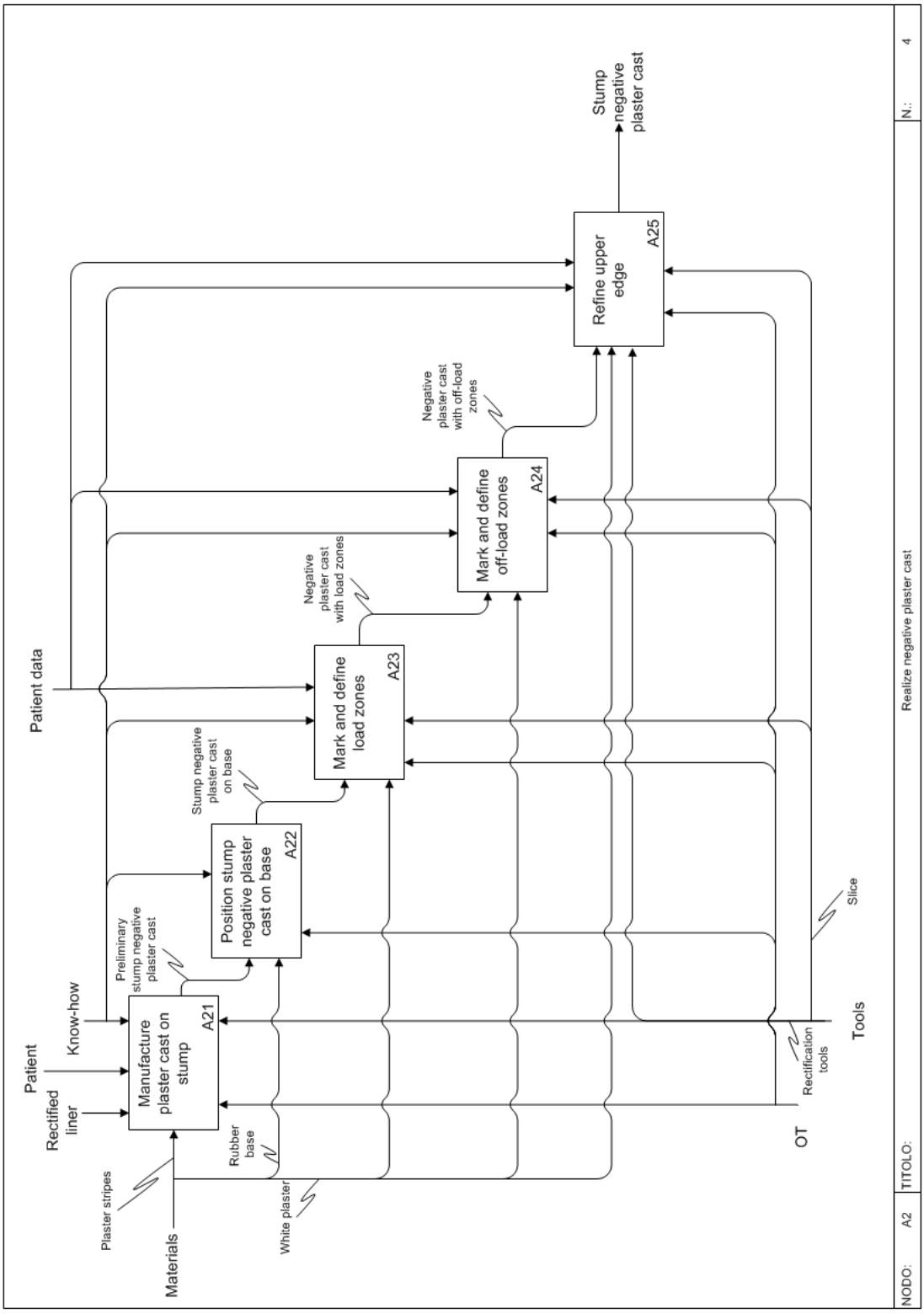

Figure 2.36: IDEF0 diagram of realization of stump negative plaster cast.

In this activity (see related diagram in Figure 2.35) it is realized the negative plaster cast of the patient stump, manipulating plaster stripes directly on the residual limb. This activity consists of five principal operations:

A21: For the realization of the negative plaster cast it is necessary to prepare the patient in this way:

- *For TF amputee*: the patient wears the liner and, with the help of crutches, is positioned in correctly aligned standing upright. The liner is covered with a transparent plastic film and the patient wears over it a cotton cover, open below the membrane level. The OT positions an elastic bandage , which passes over the groin and the ischium, crosses the trochanter and is finally fixed over the shoulders (see example in Figure 2.37). These bandages are necessary to highlight on the following cast the patient anatomical positions of groin, ischium and trochanter;

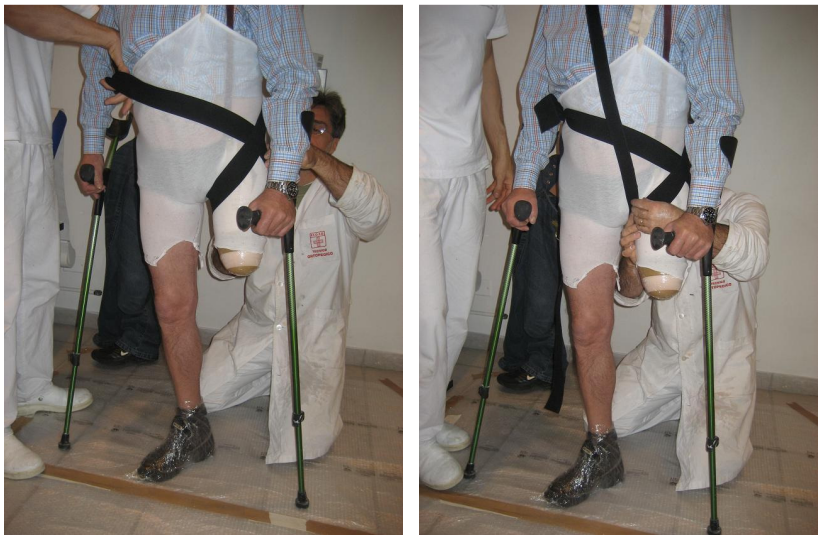

Figure 2.37: Elastic bandages positioned on a TF patient.

- *For TT amputee*: the patient wears the liner, sits on a chair and keeps the stump in horizontal position. The liner is covered with a transparent plastic film and the OT marks over it, using a permanent pen, some important anatomical points (see example in Figure 2.38): rotula, fibula head, tibia crest and other bony protuberances. These marks are necessary to highlight on the following cast the patient anatomical points just mentioned.

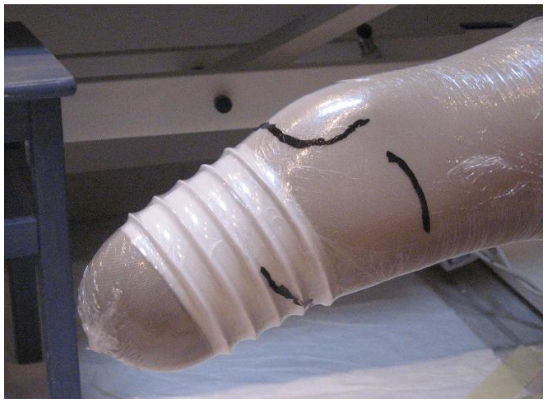

Figure 2.38: TT stump wearing the liner, covered with a plastic film and marked in the anatomical important parts.

The OT can now realize the cast over the patient stump. First he/she positions plaster stripes in vertical direction all around the residual limb, in order to avoid possible rotations of the cast. Then other plaster bandages are fixed circularly around the stump until the ischium location. Finally bandages are applied over the stump top to close the cast. Before that the plaster cast becomes too hard, the OT has to mark with manual manipulations some critical areas, in particular:

- *For TF amputee*: the OT presses the area of the ischium and the trochanter (see example in Figure 2.39);

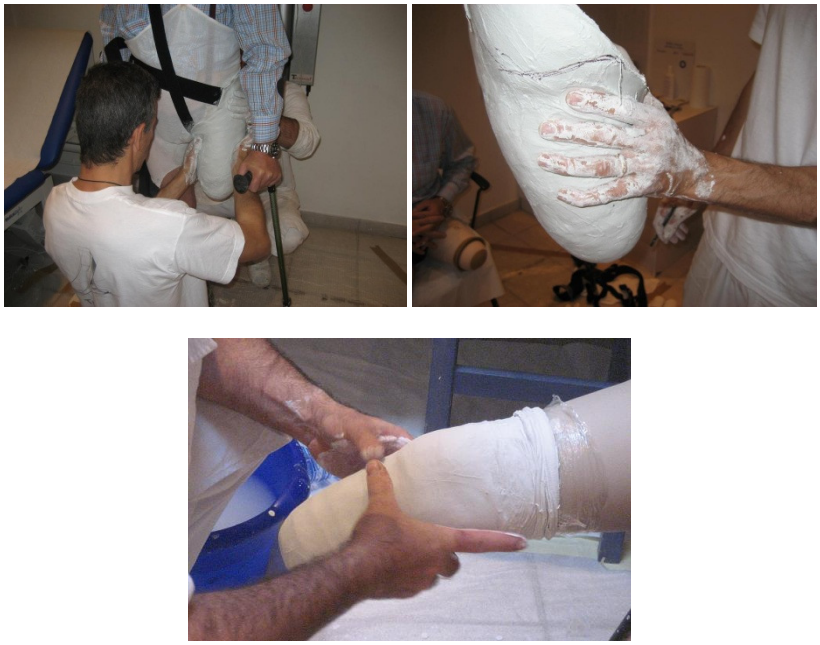

Figure 2.39: Manipulations of a TF cast (upper left), ischium area compression (upper right) and manipulations of a TT cast (below).

- *For TT amputee*: the OT presses the area of rotula, fibula head, tibia crest and other bony protuberances.

Once the cast has reached the appropriate hardness, it is slipped off and the upper edge is drawn with a pencil and appropriately cut (see example in Figure 2.40). The cast can be eventually tested on the patient to check its correct realization.

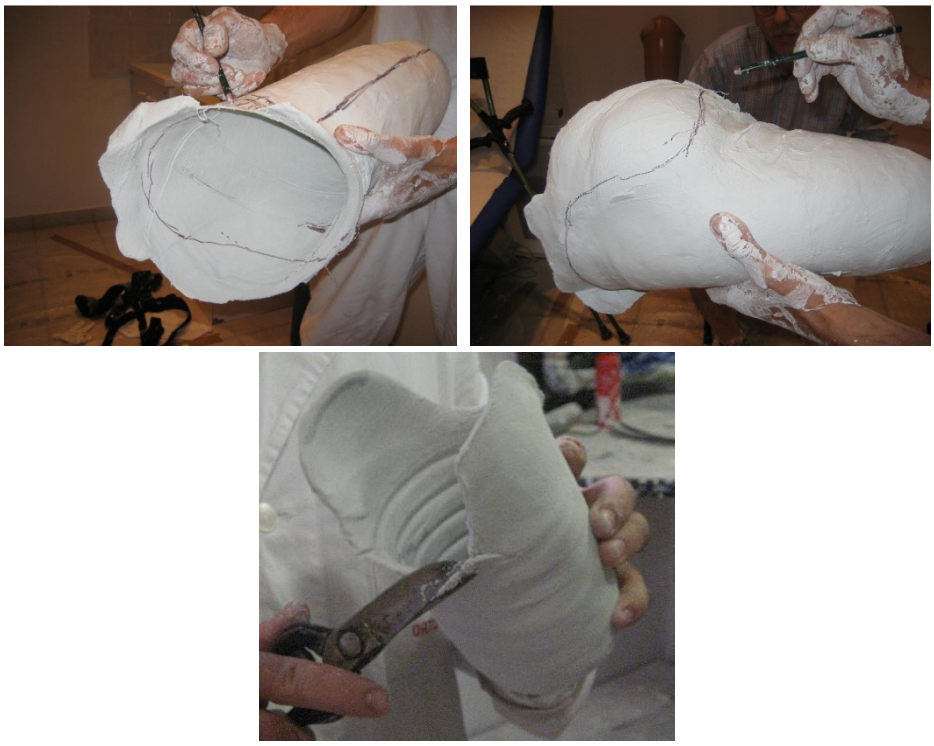

Figure 2.40: The upper edge of a TF cast is drawn (upper left and upper right) and a TT edge is cut (below).

A22: At this point the cast has to be positioned on a rubber base, respecting the natural inclination of human lower limbs and their symmetry with the contralateral limbs, see example in Figure 2.41.

Figure 2.41: Alignment of a TF negative cast (left) and position on the rubber base (right).

A23 and A24: The OT has now to mark on the negative cast the critical areas of the stump, necessary to properly shape the socket and guarantee prosthesis functionality and comfort. In particular, two types of zones have been identified:

a) Load zones, where there are not bony protuberances or tendons and it is necessary to constrict the socket closer to the limb and therefore to create a pressure to sustain the body weight;
b) Off-load zones, where there are bony protuberances or tendons and the socket does not have to press the limb and in the meantime not to be much wide since it could cause other physical problems.

We have identified these areas for both transtibial and transfemoral socket. For a CAT-CAM (transfemoral) one, main critical areas are shown in Figure 2.42; in particular, we can see in the left image the inguinal canal off-load zone (blue), the Scapa triangle support zone (red) and the frontal alignment reference line (green). In the central image it is shown the trochanter off-load zone (blue), the lateral load zone (red) and the load zone behind femur (yellow). In the right image, instead, there are underlined the ischium (blue) and the ischium load zone (red), the load zone behind femur (yellow) and the upper edge containment zone (green).

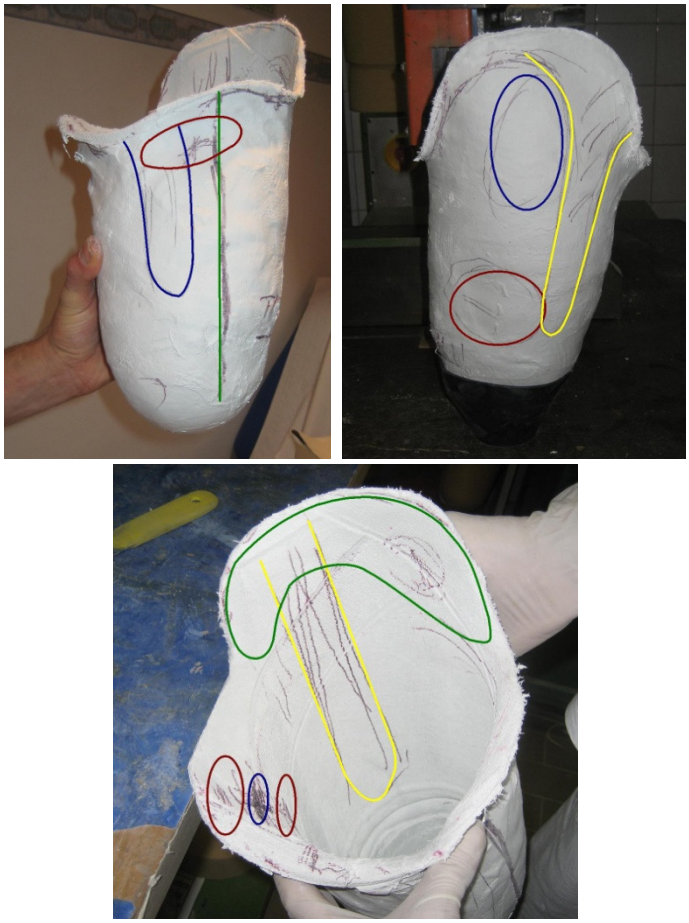

Figure 2.42: Critical manipulation areas for a TF socket, marked on a negative plaster cast.

These areas will be where appropriately highlighted and manipulated on the positive cast in the next step, but when necessary it is possible starting to mark them on the negative cast using plaster.

A25: Whatever the OT has to prepare the negative cast for the next step following two procedures:

- *Constriction of the upper edge*: the internal part of the upper lateral edge has to be filled with 1-2cm of plaster (see example in Figure 2.43);

Figure 2.43: Constriction of the upper edge (left) and final result of a TF cast (right).

- *Rise of the upper edge*: finally some plaster bandages have to be added at the upper edge in order to arise it of 6-7cm, this is necessary to facilitate the creation of the positive cast in the next step (see example in Figure 2.44).

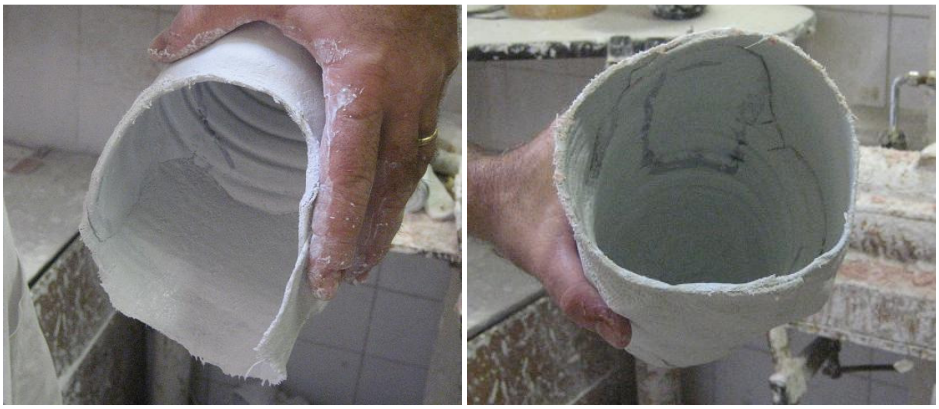

Figure 2.44: Plaster bandages added to the upper edge of a TT cast (left) and final result (right).

The next step is to realize a positive plaster cast of the patient's residual limb. In the following we are going to see all the details of this operation.

A3. Realize positive plaster cast

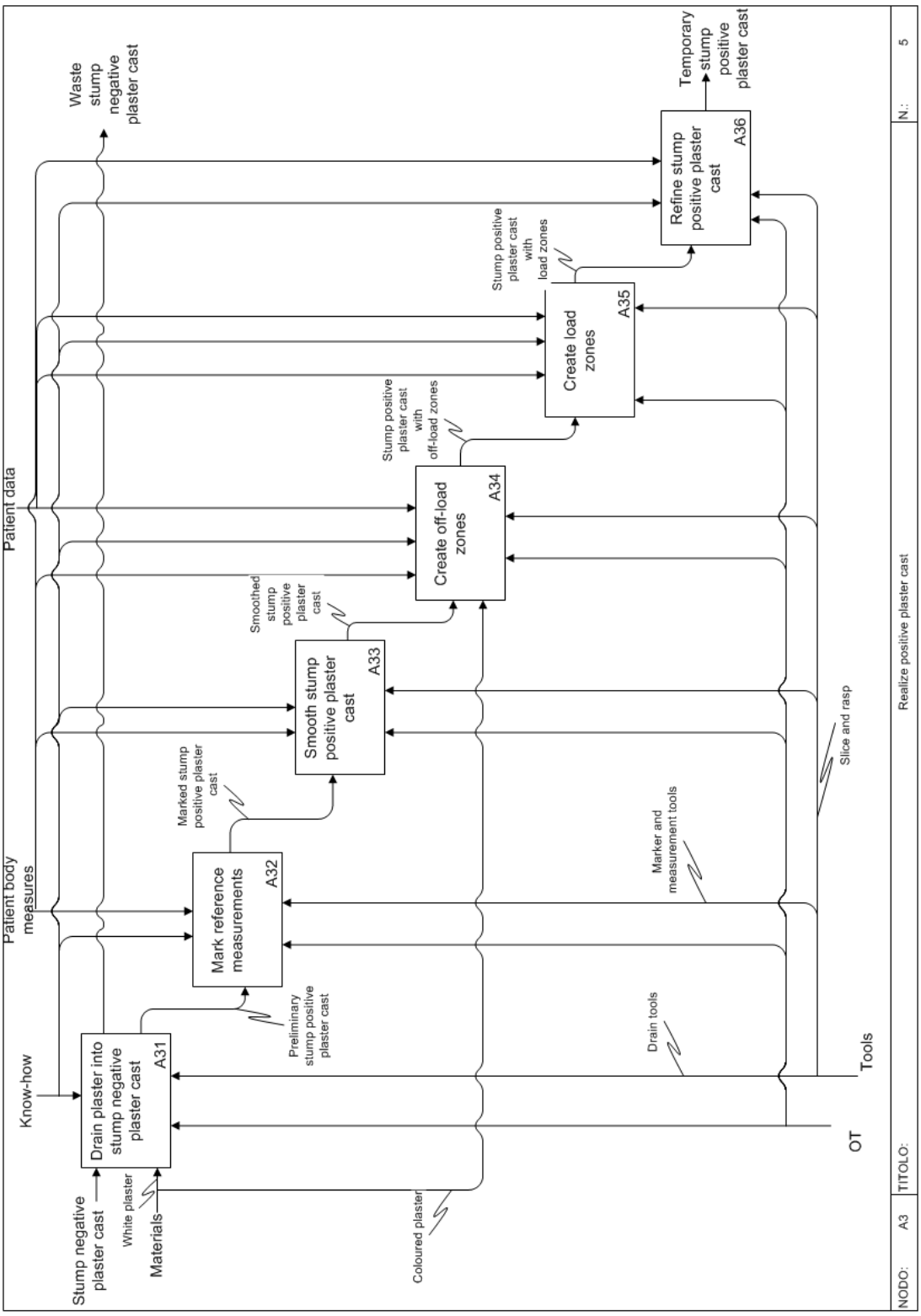

Figure 2.45: IDEF0 diagram of realization of stump positive plaster cast.

In this activity (see related diagram in Figure 2.45) it is realized the positive plaster cast of the patient stump, draining plaster into the negative cast obtained in the previous activity. This activity consists of six principal operations:

A31: The negative cast is now ready to be used to realize the positive stump cast. First the negative cast is fixed in vertical position into a bin full of sand. At the mean time the OT prepares liquid plaster perfectly homogeneous, keeping attention to avoid air bubbles and plaster lumps. This plaster is then slowly drained into the negative cast until the upper edge. After few minutes, before that the plaster becomes too hard, in the centre it is inserted vertically a metal tube , which will be subsequently used to prepare the socket (see example in Figure 2.46). It is finally let it dry for many hours.

Figure 2.46: Negative cast positioned into the sand bin (left), liquid plaster drained into the cast (centre) and metal tube inserted (right).

A32: Once the positive cast is completely dried, it is extracted and positioned on a workspace in horizontal position to be modeled by OT. First the technician remarks on the positive cast the locations of the stump circumferences measured in the first step, during the patient evaluation, and checks their correspondence. Then he/she calculates how much the cast has to be downsized, in order to be perfectly fitting on the patient's residual limb (see examples in Figure 2.47). In general, the socket must be more fitting for young or recently amputated patients, since the muscles and the body in general are still strong and tonic. Instead, for elderly or long standing amputated patients, where the muscles and the body are not anymore fully efficient, the socket needs to be more comfortable and not too much close fitting to allow an easier deambulation or physical therapy. In particular the first 4cm of the stump top will not be downsized, while the rest of the cast will be gradually scaled going up until the stump upper part. The percentage range of the circumferences scaling varies from 1% to 6%, in relation to the patient characteristics.
At this point the OT marks on the positive cast all the critical zones (previously divided in load and off-load zones) on which he/she will have to work adding or removing plaster in order to obtain a functional socket. Essentially two types of socket manipulations are performed:

initial plaster circumference reduction and critical zones manipulation, both performed on the basis of patient characteristics. See example of critical zones reported with a pencil on a TT positive cast in Figure 2.48.

Figure 2.47: Reference circumferences reported on a TF positive cast (upper left) and on a TT cast (upper right), and an example of calculation of percentage range of downsizing (below).

Figure 2.48: Critical zones reported with a pencil on a TT positive cast.

A33: At this point the OT starts removing plaster, using a rasp, to smooth the cast surface and delete all the imperfections and the crests left by the liner membranes during the negative cast manufacturing, see example in Figure 2.49.

A34: Then he/she can start to manipulate the cast to create the off-load zones, in particular the OT inserts into the position of off-load zones some nails, which protrudes from the cast of a quantity related to the desired plaster addition, and then he/she cover them adding plaster (see example in Figure 2.50). Finally he fills with the same plaster the possible holes or imperfections left on the cast by air bubbles during the positive cast manufacturing.

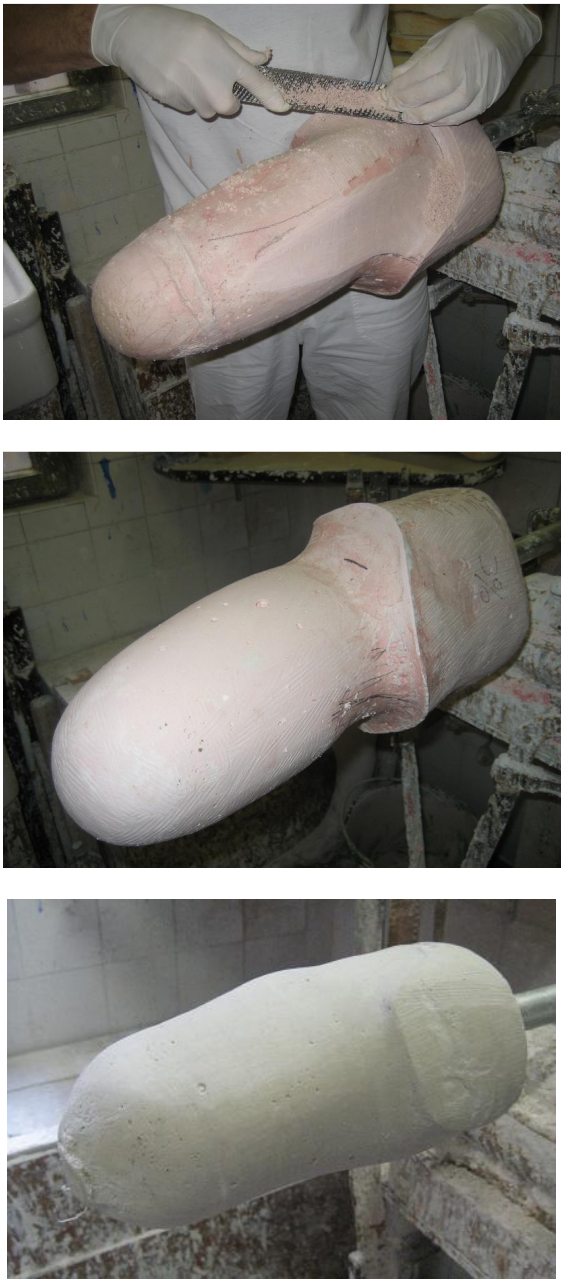

Figure 2.49: General smoothing of a TF positive cast (upper) and final result for a TF (centre) and a TT cast (below).

Figure 2.50: Nails inserted into the off-load zones of a TF cast (up-left) and on the same cast the inguinal canal filled with plaster addition (up-right); nails inserted into the off-load zones of a TT cast (below-left) and on the same cast these areas filled with plaster addition (below-right).

A35: A similar procedure is followed to create the load-zones, but in these areas the plaster is removed by a rasp. An example of the final result for a TT cast is shown in Figure 2.51. In the left image are highlighted the off-load zones of anterior fibula, patella, and tibial epiphysis; in the right image, there are the off-load zones of stump top and posterior tendons.

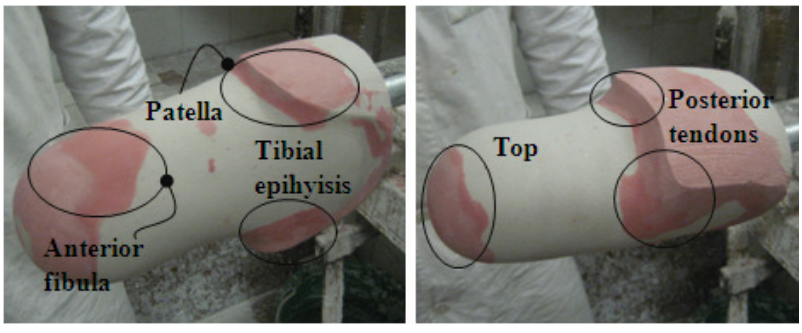

Figure 2.51: Critical zones on a TT cast.

A36: For the final refinement of the positive cast, the OT follows these last operations :

- *Creation of the valve zone*: using a rasp, it is flattened the area where it will be positioned the air valve of the socket (see position in Figure 2.52), normally it is located in the lower external lateral part of the socket.

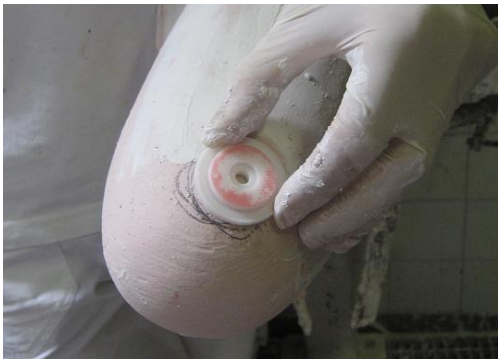

Figure 2.52: Location of the valve zone.

- *Smoothing:* the cast undergoes a final smoothing and the OT check for the last time the cast reference circumferences to see if it has been applied the correct scaling;
- *Drying*: the cast is left dry for almost half a day closer to a heating source (e.g. a heater).

The positive cast is now ready for the realization of the correspondent check socket. In the following we are going to see all the details of this operation.

A4. Realize check socket

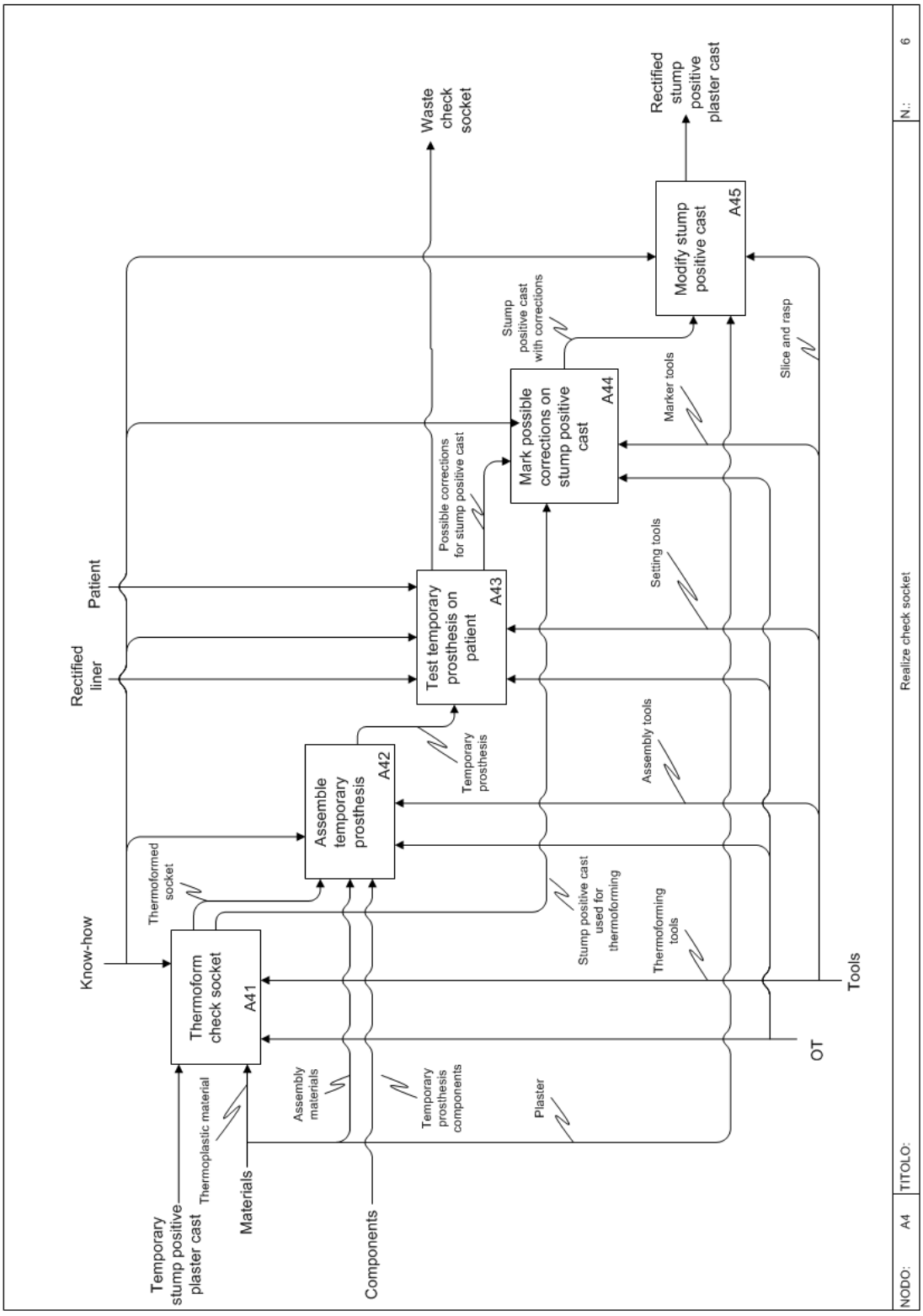

Figure 2.53: IDEF0 diagram of realize check socket.

In this activity (see related diagram in Figure 2.53) it is realized a check socket, made of thermoformable transparent material, directly on the positive plaster cast, and then it is tested on the patient. After the test, if necessary, the positive plaster cast is rectified to be more well fitting and comfortable. This activity consists of five principal operations:

A41: During this step it will be realized and tested on the patient the check socket. This socket is manufactured directly on the positive cast obtained from the previous procedures. In detail it is taken a sheet of thermoformable transparent material and it is wrapped and fixed around the positive cast. Then this is put inside a special oven and let it dry and harden. The resulting socket is cut at the upper part to reproduce the patient's anatomy and then it is ready to be assembled with the other prosthesis components. This kind of socket has a final homogeneous thickness of 3-4 mm. In Figure 2.54 it is possible to see an example of this socket.

Figure 2.54: Example of TF check socket.

A42: The check socket is now ready to be assembled with the other prosthesis components, generally temporary service standard components used just for testing. In detail to the socket are generally assembled in order starting from the socket base:

- *Wood base and lock*: it is normally fixed at the socket base a wood base, in particular:
    - *For short stump*: a wood base, an extension adapter and a lock;
    - *For normal stump*: only a wood base and a lock;
    - *For long stump*: only a thin lock;

- *All the other necessary standard components*: in general we have:
    - *For TF amputee*: a knee, a tube, a foot joint and a foot*;*
    - *For TT amputee*: a tube, a foot joint and a foot.

The total height of the prosthesis is finally regulated on the base of the patient anthropometric measurement acquired at the first step. Normally this regulation is done

acting principally on the tube length. For this operation, the formula used for a TT prosthesis is the following:

$$Tube\ length = TPH - FM - SM - TM \quad [mm] \qquad (2.2)$$

where:

- TPH = Total Prosthesis height;
- FM = Foot Module height;
- SM = Socket Module height;
- TM = Tube Clamps heights and Tube Extremities heights.

If (TPH-FM-SM-LM) < 20-25 mm, tube and tube clamps modules have to be substituted by a double adapter, and, if necessary, the single lock adapters can be changed.

Similar rules and formula are used to choose the transfemoral components, even if the procedure is more complex since we have to determine first the knee, and then consider the components above and below knee.
The assembled prosthesis has to be now statically aligned. The prosthesis is positioned on a flat floor in vertical and under the heel bone is inserted a thickness of 1-2 cm, in order to simulate the patient shoes heels. Using a laser device, it is projected a vertical line on the prosthesis, first laterally and then frontally, and we check that:

- *For TF amputee*: laterally the light must pass 5mm externally from the knee and cross the big toe, frontally the light must pass 5mm on the left of the knee (see Figure 2.55);

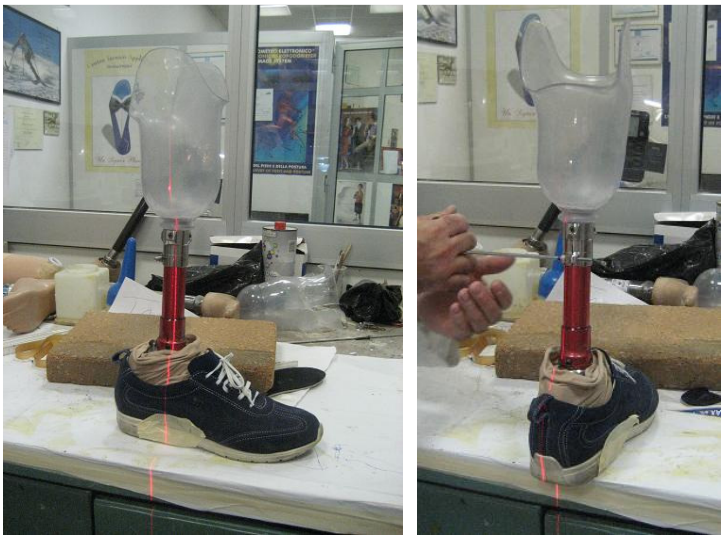

Figure 2.55: Static alignment of TT prosthesis, lateral (left) and frontal (right).

- *For TT amputee*: frontally the light must pass 1,3cm from the centre of the heel bone, laterally the light must cross the foot arc, and behind the light must cut the socket in 2 symmetric parts (see Figure 2.56).

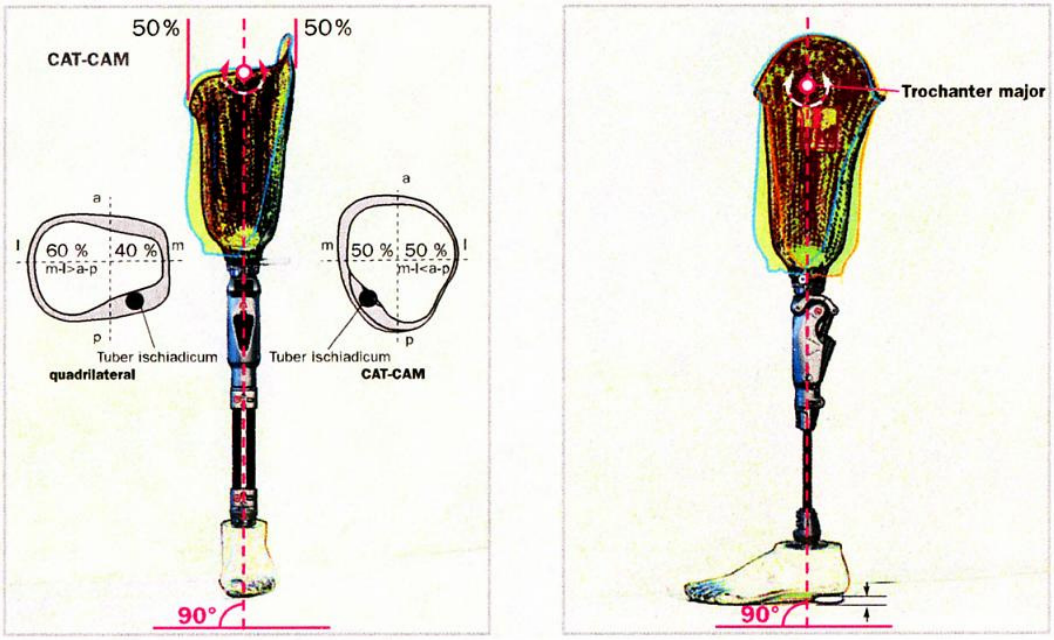

Figure 2.56: Static alignment of TF prosthesis, lateral (left) and frontal (right).

A43: At this point the prosthesis is ready to be tested on the patient, who wears first the liner and then the assembled prosthesis. The following four factors are evaluated during the test socket fitting [13]:

1. Socket comfort;
2. Distribution of weight-bearing pressure and biomechanical forces;
3. Suspension comfort;
4. Freedom of motion at the next proximal joint.

In particular it is done a visual examination of:

- *Socket fitting*: since the socket is transparent is easy to notice (see example in Figure 2.57):
    - *Where there is a perfect fitting between socket and liner*: here no modifications are necessary;
    - *Where there is "not" a perfect fitting between socket and liner*: here it is necessary to modify and optimize the stump positive cast before manufacturing the definitive socket.

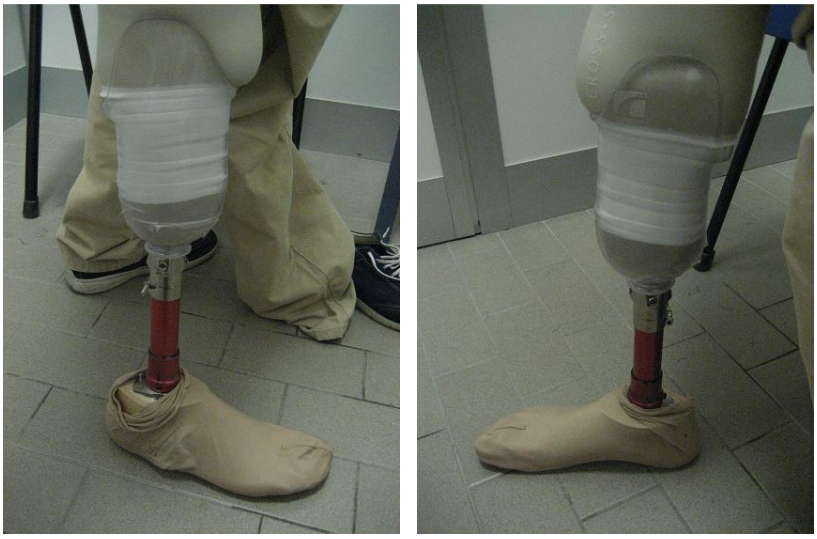

Figure 2.57: Patient testing the check socket, lateral external (left) and internal (right) view.

- *Skin conditions*: once slipped off the prosthesis and the liner, it is possible to notice:
    - *Where there is a uniform skin redding*: here the socket pressure is homogeneous and no modifications are necessary;
    - *Where there is an intense redding zone*: here the socket pressure is too high and the socket needs to be modified to become more comfortable (see example in Figure 2.58);

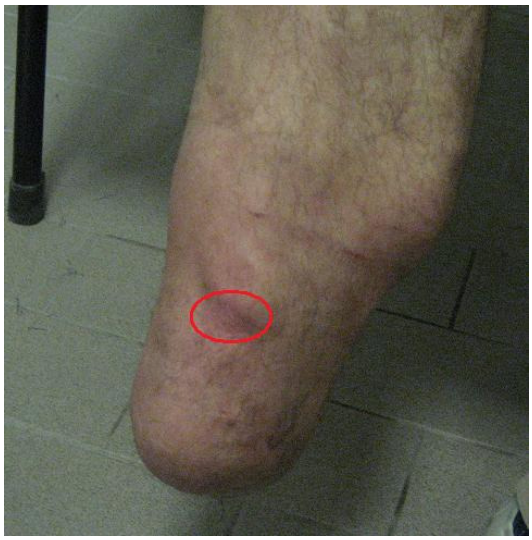

Figure 2.58: Example of intense redding zone on a TT stump, underlined with a red circle.

    - *Where there is a uniform and less intense redding zone*: here the socket pressure is too low and the socket needs to be modified to be more well fitting on the stump.

A44: After the check socket testing, it is necessary to mark on the positive cast the necessary modifications (A44), highlighted during the test. For this reason the OT marks with a pencil the positive cast in this way (see Figure 2.59):

- *Drawing vertical lines*: where the socket must be reduced to become more fitting and so where it is necessary to remove plaster;
- *Drawing horizontal lines*: where the socket must be enlarged to become more comfortable and so where it is necessary to add other plaster.

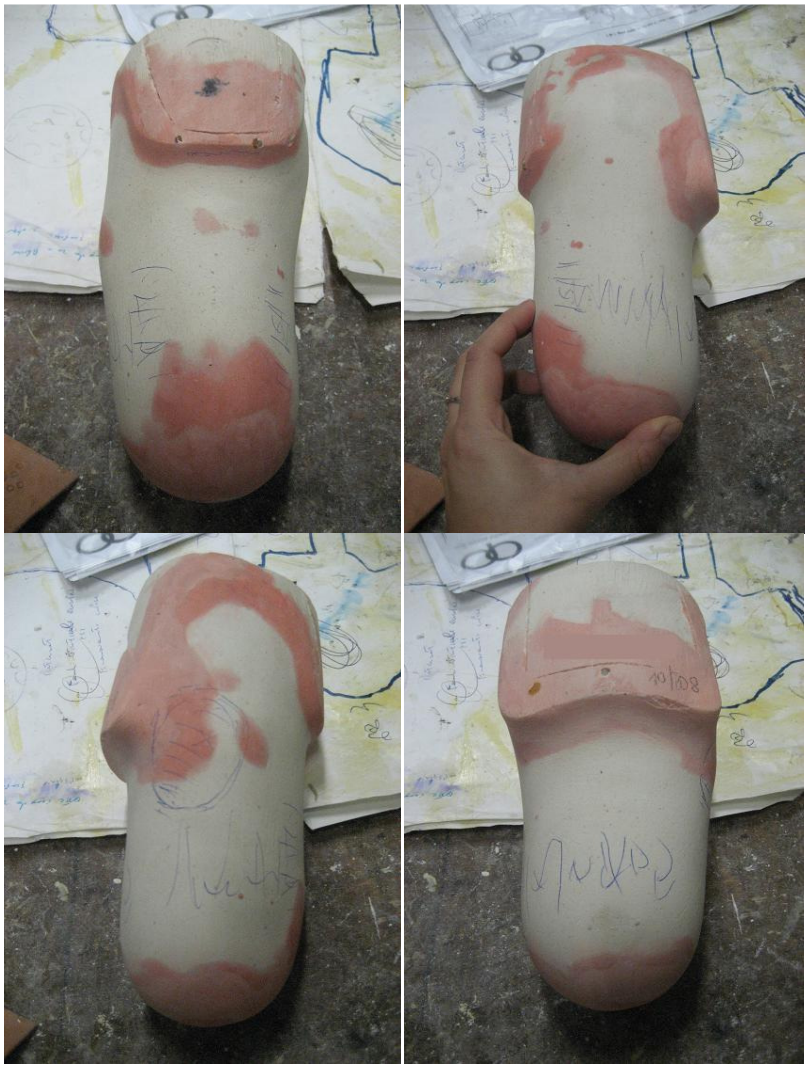

Figure 2.59: Positive TT stump with drawn the areas , which have to be modified, from the left to the right, from up to down, we have respectively: frontal, internal lateral, internal external and back view.

A45: The positive cast has to be now modified on the base of the area marked after the test. Positive model modification is a difficult and time-consuming procedure requiring much skill on the part of the OT. With proper modification, the OT can create a comfortable and stable

socket with good suspension characteristics and can relieve any particular problem areas that the patient has experienced in the test and also in previous prosthesis. The modification operations are executed using a slice and rasp, in the same way the OT has operated during the positive cast manufacturing. After this, the positive cast is ready for the realization of the definitive socket.

The next step is to realize a definitive socket. In the following we are going to see all the details of this operation.

A5. Realize definitive socket

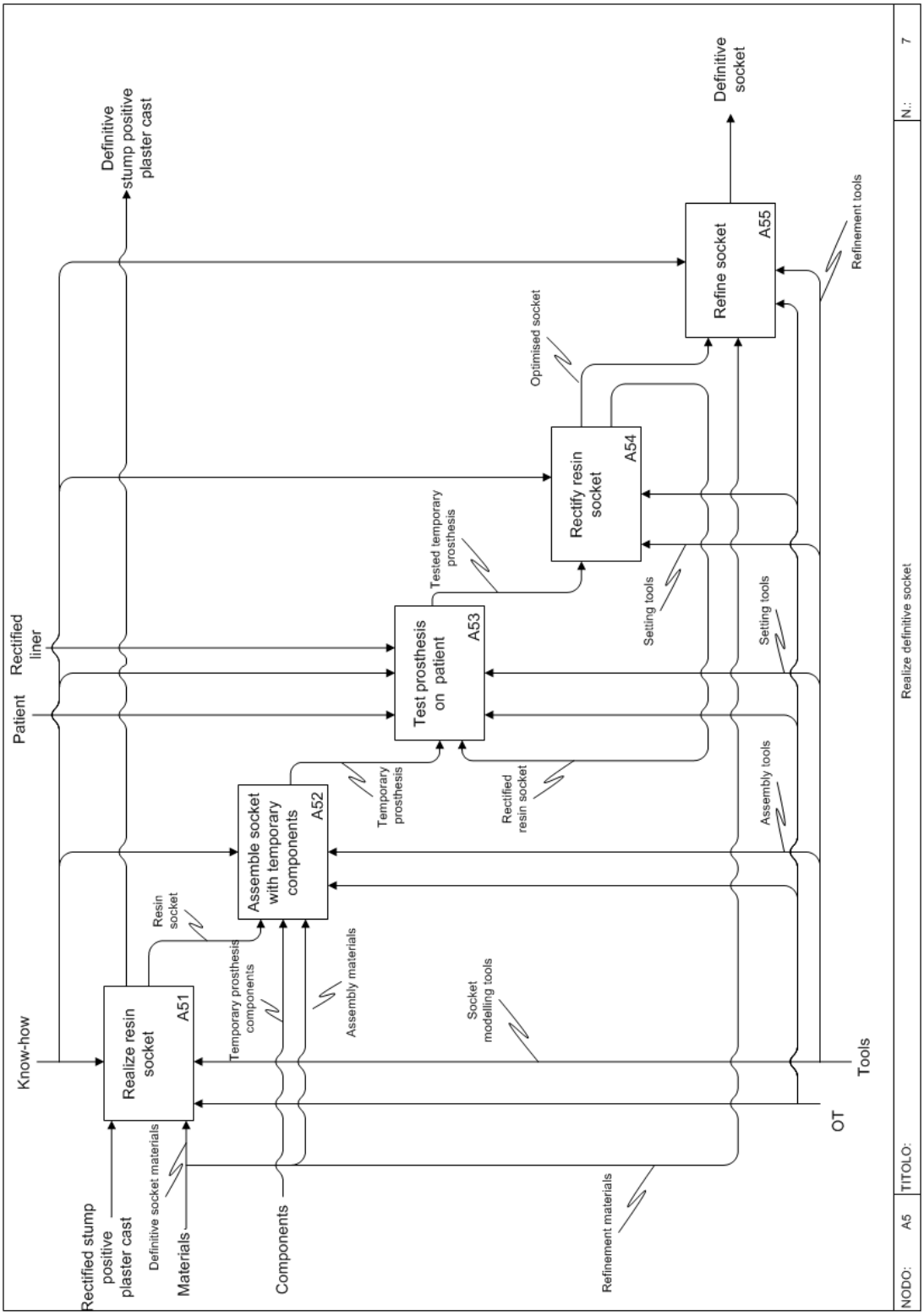

Figure 2.60: IDEF0 diagram of realization of definitive socket.

In this activity (see related diagram in Figure 2.60) it is realized the definitive socket directly on the rectified positive plaster cast and it is tested on the patient. This activity consists of five principal operations:

A51: The definitive socket is manufactured directly on the positive cast obtained from the previous procedures and optimized after the test on the patient (see related diagram in Figure 64). In particular the OT has to follow these operations:

- *Cover with a PVA bag*: the positive cast is positioned on a workspace in vertical position and it is covered with a PVA bag (PVA stands for Polyvinyl Acetate and it is a rubbery synthetic polymer), previously water soaked to become more tender;
- *Air suction*: all the air between the cast and the PVA bag is sucked out;
- *Felt layer*: all the PVA bag is covered with a felt layer of 5mm thickness;
- *Perlon layer*: all the felt layer is covered with many layers of perlon, a synthetic fabric of 0,5 mm thickness, previously resin soaked; in particular the number of necessary perlon layer is calculated in this way:

  $$N°perlon\ layers = Patient\ weight\ (Kg)/10 \qquad (2.3)$$

- *Another cover with a PVA bag*: the perlon layers are covered with another PVA bag, still previously water soaked;
- *Air suction*: all the air between the perlon layers and the PVA bag is sucked out;
- *Refinement resin*: some liquid synthetic resin is drained over the PVA bag and amalgamated using a fabric streak.

Once the resin socket is dried, the upper edge is cut to follow the patient anatomical shapes and it is reinforced with a soft rubber support. The final result of a TF socket is shown in Figure 2.61.

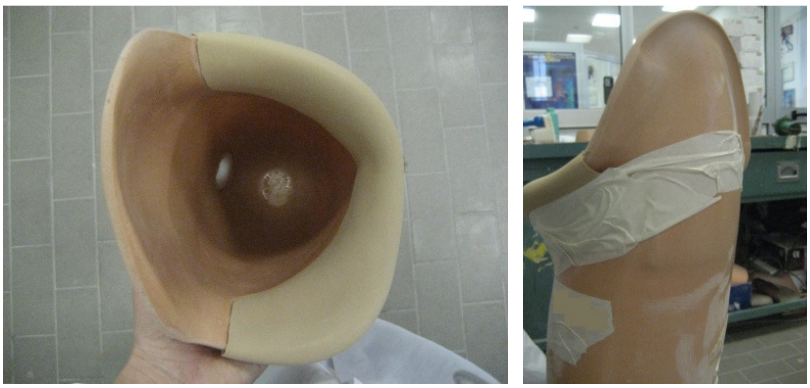

Figure 2.61: Internal view of a resin TF socket (left) and external view (right).

A52: The resin socket is now ready to be assembled with the other prosthesis components, generally they are the same temporary service standard components already used for the check socket testing (A42). The procedures of assembly and static alignment are the same already seen for the check socket, for further details see the correlated part of this Chapter.

In Figure 2.62 it is shown an example of assembled TF prosthesis with a resin socket. While in Figure 2.63 and 2.64 there are respectively and example of TF and TT prosthesis alignment.

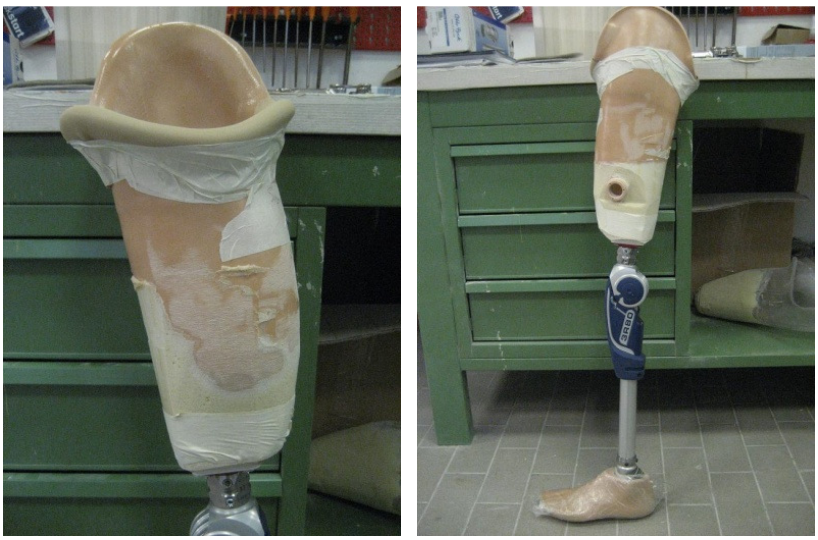

Figure 2.62: Example of assembled TF prosthesis with a resin socket; particular of the socket (left) and general lateral view (right).

Figure 2.63: Example of static alignment of TF prosthesis with a resin socket, frontal (left) and lateral (right) view.

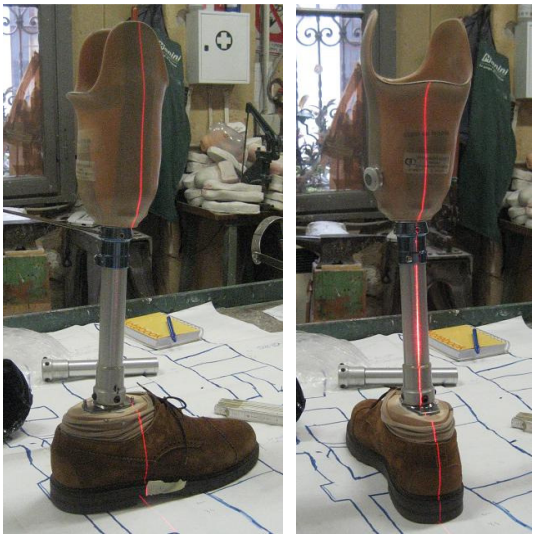

Figure 2.64: Example of static alignment of TT prosthesis with a resin socket, lateral (left) and back (right) view.

A53: At this point the prosthesis with the resin socket is ready to be tested on the patient, who wears first the liner and then the assembled prosthesis. Unfortunately in this case the socket is not anymore transparent, as the check socket, and all the OT skills are necessary to understand how to optimize the static and now also the dynamic fitting and alignment. Fitting and alignment of the prosthesis are not completed until both the prosthetist and amputee are convinced that the prosthesis is functioning as well as possible. More experienced individuals are usually able to provide accurate feedback concerning how the prosthesis fits and feels during walking. The prosthetist can then make adjustments in a rapid and accurate fashion, and the fitting proceeds smoothly. New amputees, however, cannot always provide accurate feedback; therefore, they are sometimes referred to a physical therapist for initial gait training prior to completion of dynamic alignment [13]. In particular the OT checks:

- *Patient standing upright*: if the socket causes particular pain in determined points;
- *Patient walking*: if patient is correctly balanced and if the socket causes particular pain in determined points;
- *Patient sitting on a chair*: divided in:
    - *For TF amputee*: if the socket upper edge prevents patient from maintaining a correct position;
    - *For TT amputee*: if the socket back edge prevents patient from a correct tendons movement.

A54: After all these considerations, the only possible rectifications on the socket are:

- *Enlarge where possible the socket*: in this case the interested zones are:

- *Internal bottom* : it can be done reducing the internal cushioning of the socket bottom;
- *Upper edge*: it can be done heating the resin by a drier and then enlarge it by a grab, or cutting the edge by scissors (see Figure 2.65);
- *Other zones*: it can be done by a milling cutter in the desired areas;

- *Shrinking where possible the socket*: in this case the interested zones are:
  - *Internal bottom*: it can be done adding the internal cushioning of the socket bottom;
  - *Upper edge*: it can be done inserting a thicker soft rubber support;
  - *Other zones*: it is "not possible", in this case if the socket is too wide, it could be necessary to re-manufacture the socket itself.

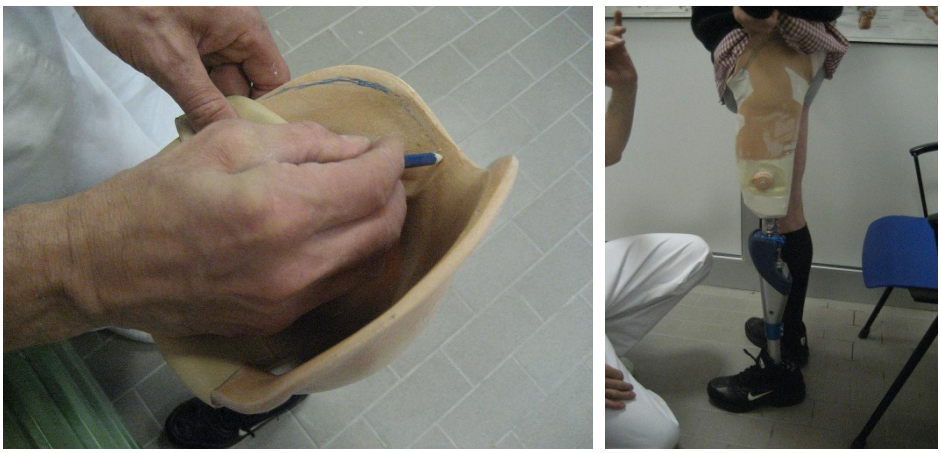

Figure 2.65: Example of rectification of the TF socket upper edge (left) and test on the patient (right).

A55: Once rectified and optimized as much as possible the socket, the OT can proceed to the final refinement of the socket itself. The socket is fixed on a workspace in a vertical position, and the OT applies these last materials:

- *Carbon fiber reinforcements*: the OT applies vertically for all the socket height a sequence of carbon fiber stripes. In fact carbon fibers are generally set in epoxy and can provide a material with a stiffness twice that of steel at a fifth the weight. In addition to this high strength-to-weight ratio, carbon fiber composites have a fatigue resistance twice that of steel, aluminium, or fibreglass;
- *Perlon layer*: all the socket is covered with 3 final layers of perlon, previously resin soaked.

The definitive socket is finally ready. It is possible to see an example of definitive resin TF socket in Figure 2.66. Now the OT can assemble all the definitive components of the prosthesis.

Figure 2.66: Example of definitive TF socket.

The next step is to assemble the definitive prosthesis. In the following we are going to see all the details of this operation.

A6. Assemble prosthesis

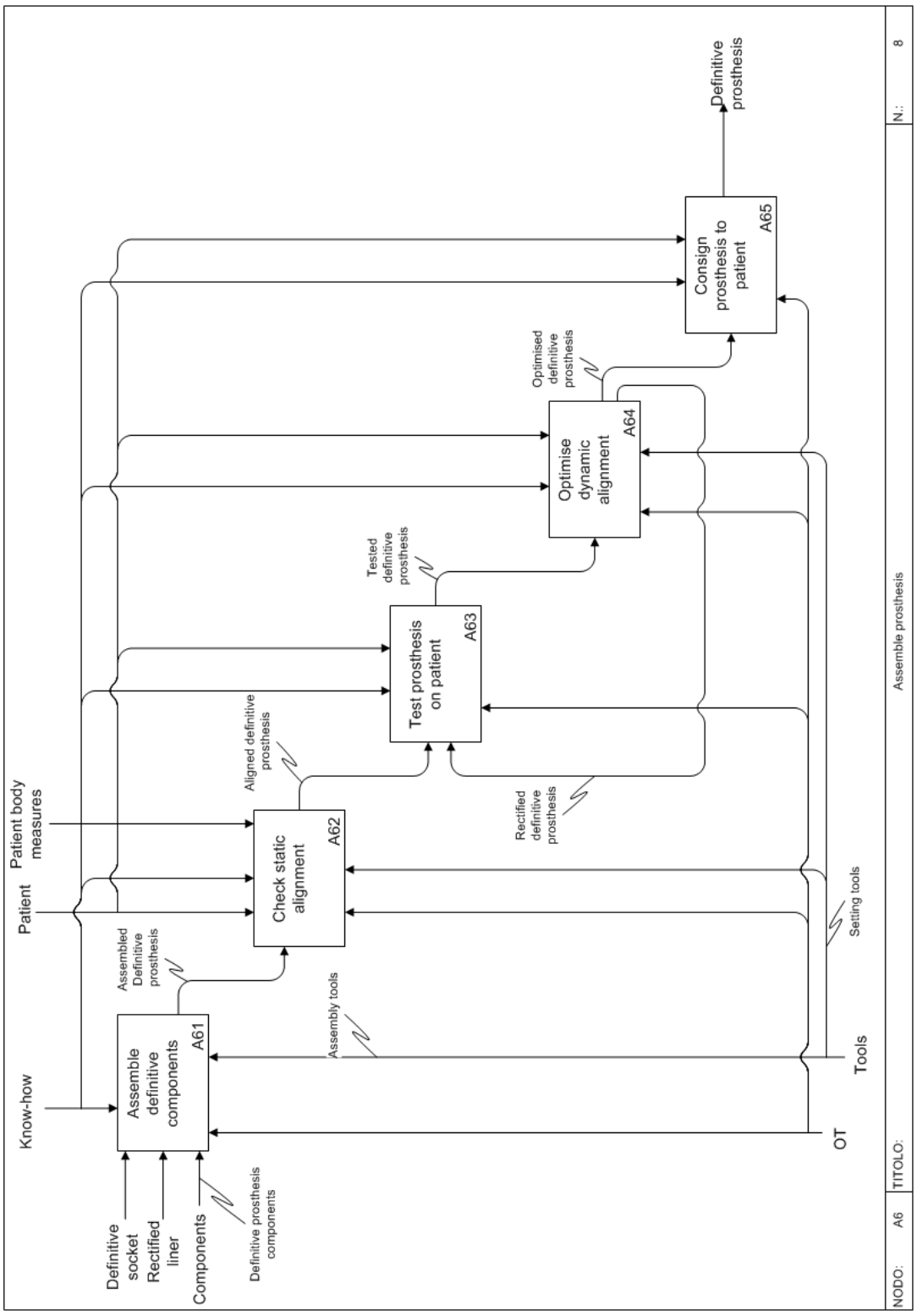

Figure 2.67: IDEF0 diagram of definitive prosthesis assembly.

In this activity (see related diagram in Figure 2.67) all the prosthesis components are assembled and the final prosthesis is tested and optimized on the patient. This activity consists of five principal operations:

A61 and A62: In this operation the OT assembles to the definitive socket all the definitive standard components, selected for the patient at the first step, during patient evaluation. The procedures of assembly and static alignment (A62) are the same already seen for the check socket (A42).

A63: At this point the patient dons the liner and then the definitive prosthesis for the last testing.

A64: In this procedure it is focused more attention on the dynamic alignment, since patient is wearing all his/her definitive components. Since each patient has a unique gait pattern and activity level, dynamic alignment of the prosthesis must be done on an individual basis. The purpose of dynamic alignment is to provide maximum comfort, efficient function, and cosmesis by adjusting the relative position of the components while the patient is using the limb in a number of controlled situations. During the alignment stage, the prosthesis must be durable and functional but must also be adjustable in all planes. Some patients may require more than one visit to optimize the alignment of the prosthesis since the more complex alignments may require several hours of adjustments and new patients are frequently not able to stand and ambulate for more than a few minutes at a time. Complicated cases, of course, also require additional time. Lower-limb alignment generally takes place within parallel bars in a private walking room in the prosthetist office. The following procedures summarize the basics of the alignment process [13]:

1. The function of the prosthesis is explained, and the amputee is instructed in how to don the prosthesis properly;
2. Contours are checked to ensure that the socket fits properly and comfortably;
3. The length and angulations of the prosthesis is checked;
4. The suspension is tested;
5. The patient is instructed to stand in a relaxed attitude while wearing the prosthesis;
6. Static alignment of the components is refined;
7. The patient begins to use the prosthesis in a controlled manner by walking inside parallel bars or operating the terminal device. Dynamic function of components is checked during use and adjusted to provide maximum efficiency, comfort, and cosmesis;
8. The prosthesis is checked with the patient sitting, and adjustments are made to increase comfort or function in this position as well.

Socket design and alignment complement each other and are the fundamental determinants of prosthetic function. No matter how sophisticated the components are, how well the prosthesis is finished, or how carefully it is fabricated, if it is not perfectly aligned or

uncomfortable, the overall function will be drastically reduced. The new amputee can practice with the prosthesis, and further adjustments can be made as endurance and ability to use the prosthesis improve. Generally, 1 week in physical therapy with the prosthesis will afford adequate time for the prosthetist to make decisions concerning the final alignment. The therapist also helps the amputee master more advanced activities such as negotiating inclines, stairs, and irregular terrain. It is often useful for the amputee to return to the therapist following fitting with the definitive device to further refine his prosthetic skills [13].

A65: After the final testing, the prosthesis can be consigned to the patient. The OT will take care to give to the amputee also:

- *Instructions about the liner use;*
- *Instructions about the socket use;*
- *Instructions about all the other components;*
- *An appointment in the upcoming future for another general check*.

In Figure 2.68 and 2.69 there are respectively an example of definitive TF prosthesis and TT prosthesis, worn by patients.

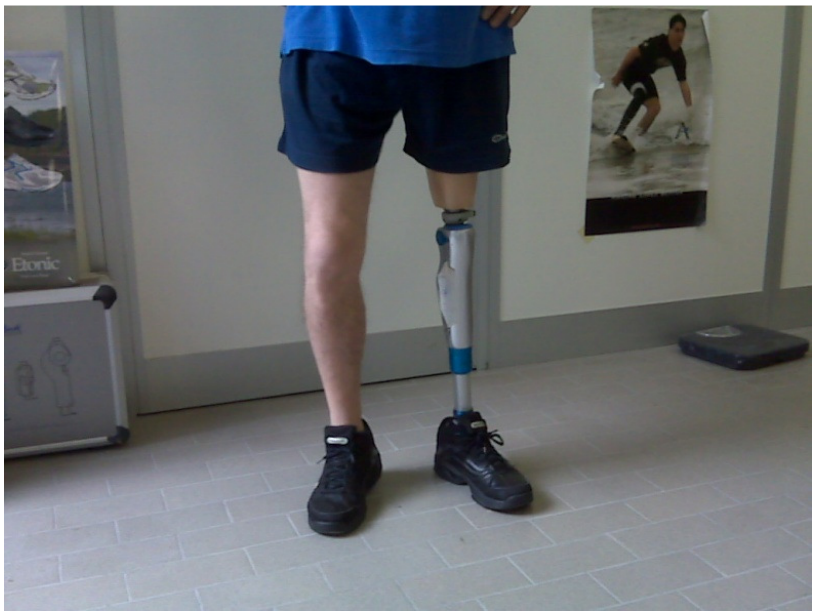

Figure 2.68: Example of definitive TF prosthesis worn by patient.

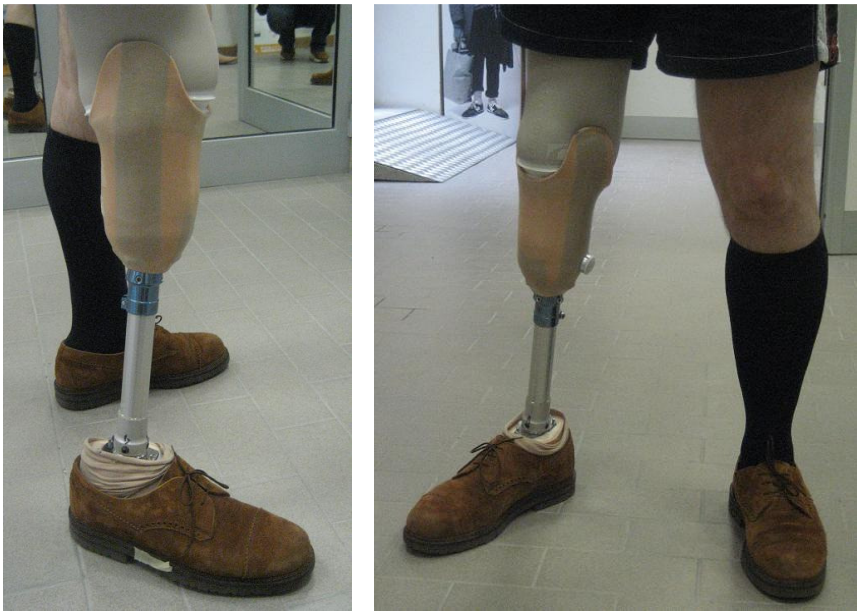

Figure 2.69: Example of definitive TT prosthesis worn by patient.

Proper patient follow-up is of critical importance in prosthetics [13]. New amputees in particular require follow-up at frequent intervals; they should be developing not only tolerance to pressures of the prosthesis against the skin but also general physical endurance. Patients will have many questions after wearing the prosthesis for a week or two, such as how to use the prosthesis while driving a car and during sports activities and dancing, choosing the proper shoes, and wearing the prosthesis to the beach. In addition, a number of minor problems can occur during the first few weeks of prosthetic wear from pressure areas in the socket, discomfort while sitting, or problems when wearing different shoes. These concerns can be easily corrected during a follow-up visit. Patients should be seen, at the very minimum, every 4 to 6 months. The prosthesis contains many moving mechanical components that require cleaning, maintenance, or replacement at intervals. Some components, particularly joint mechanisms, must be cleaned and adjusted on a regular basis because they directly affect the function of the prosthesis. Changes in the volume or shape of the patient's residual limb will frequently require socket adjustments, particularly during the first month of wearing a new prosthesis. In some cases, varying the thickness or ply of the prosthetic socks will improve the fit of the prosthesis, but in many cases more extensive modifications are required. Socket adjustments are made only after a careful analysis of the cause of discomfort is completed by the prosthetist. The prosthetist then has two choices: relieving the pressure area by removing material from the socket over the area of pressure or adding material elsewhere, thereby redistributing the forces. In some cases, minor alignment changes can be made to further reduce discomfort or pressures. It is important for the prosthetist to keep a good record of all follow-up adjustments. Such information will help guide future decisions regarding socket or component modification and prosthetic design [13].

2.2.2 – Glossary

In the following in alphabetical order the list of terms used in the IDEF0 diagrams.

Aligned definitive prosthesis: the definitive prosthesis is statically aligned.

Assembled definitive prosthesis: all the definitive components assembled.

Catalogue: commercial catalogues used by OT to select the standard components of the prosthesis on the base of his/her personal knowledge and the catalogue suggestions.

Components: all the standard components necessary to assemble and test the whole prosthesis:

- *Definitive prosthesis components*: all the standard definitive components selected for the patient on the base of his/her characteristics in A12;
- *Liner*: liner with membrane, selected on the base of patient anthropometric measures and characteristics, whose upper edge will be cut and sealed following patient's anatomy in A14;
- *Temporary prosthesis components*: all the temporary standard components assembled to the check socket to test it with the patient.

Definitive positive plaster cast: the positive cast used to manufacture the definitive socket.

Definitive prosthesis: the definitive lower limb prosthesis, assembled with all the components.

Definitive socket: the definitive socket assembled in the final prosthesis.

Know-how: personal skills, empirical knowledge and implicit rules applied by OT during all the manufacturing process:

  - in A11 it is necessary to evaluate the stump tonicity, shape, presence of bony protuberances and skin characteristics;
  - in A12 it is necessary to evaluate the patient general health conditions, physical force and his/her life style;
  - in A13 it is necessary to acquire all patient anthropometric measures necessary for the process, such as height, weight, stump reference circumferences and length, trochanter height, knee height, foot length;
  - in A14 it is necessary to leave abundant the upper edge of the liner until the definitive test of the prosthesis;
  - in A15 it is necessary to acquire the same stump measures as in A13 but wearing the liner;

- in A21 it is necessary to position the patient in an appropriate position, respectively: standing on foot with residual limb in abduction for TF (transfemoral) amputees, and sitting on a chair with the residual limb horizontally positioned for TT (transtibial) amputees;
- in A21 the plaster stripes have to be positioned vertically on the limb in order to avoid rotations of the cast, and it is necessary to press the cast in the load zones during the cast manufacturing;
- in A22 the cast has to be positioned on the rubber base in order to respect the natural inclination of a limb, 5° laterally and 7° frontally for a TF, and 5-10° laterally for a TT;
- in A23 and A24 it is necessary to add 1cm of plaster inside the cast on the load zones and on the edge of the off-load zones;
- in A25 it is necessary to arise the cast upper edge of 6-7cm, and overwhelm it inside of 1-2cm.;

- in A31 the liquid plaster has to be perfectly homogeneous in order to avoid air bubbles;
- in A32 all the critical zones and the levels of the reference circumferences have to be marked on the positive cast;
- in A33 the positive cast top until 4cm over the top doesn't have to be modified; from the 4cm level gradually going up until the stump upper part, the cast has to be scaled following these percentage values: 1% to 3% for very tonic residual limb; 3% to 5% for normal residual limb; 3% to 6% for not tonic residual limb;
- in A34 the amount of chalk added by the technician in these areas depends on the patient characteristics, from 1 to 8 mm of thickness, in correlation to the stump tonicity. For example, for a stump with normal tonicity, the thickness will be 3-4 mm, while if it is not too much tonic it will be 1-2 mm;
- in A35 the technician has to remove chalk symmetrically to the rule applied in A34;
- in A36 it has to be positioned the valve area on the positive cast, in a functional position, in order to be easily accessible to the patient;
- in A41 the check socket has to have a thickness of 3-4mm;
- in A42 the assembly has be statically aligned using laser device , which projects a vertical line on the prosthesis: for TF amputees laterally the light must pass 5mm externally from the knee and cross the big toe, frontally the light must pass 5mm on the left of the knee; for TT ones frontally the light must pass 1,3cm from the centre of the heel bone, laterally the light must cross the foot arc, and behind the light must cut the socket in 2 symmetric parts;
- in A43, once worn the check socket, mark the areas where there are visible air sacs (where the socket must be modified to be more fitting), and, after to

have slipped off the socket, mark the area where the skin is turn red (where the socket must be modified to be more comfortable);

- in A44 the OT marks the positive cast with vertical lines where to add plaster, and horizontal lines where to remove it;
- in A45 the positive stump is modified on the base of the results obtained in A43;
- in A51 the number of perlon fabric layer = patient weight (Kg)/10;
- in A52 see the same rules as in A42;
- in A53 the contours are checked to ensure that the socket fits properly and comfortably, the length and angulations of the prosthesis is checked, it is checked also with the patient sitting and adjustments are made to increase comfort or function in this position as well;
- in A54 the socket can be enlarged reducing the cushioning, but it can never be tightened;
- in A55 on the socket are added 3 more perlon fabric layer and carbon fiber stripes are vertically applied to reinforce the socket;

- in A61 see A52;
- in A62 see A52;
- in A63 see A53;
- in A64 see A54;
- in A65 the OT has to give clear informations about the use of the prosthesis and schedule with the patient an appointment to check the prosthesis. After this, patients should be seen, at the very minimum, every 4 to 6 months. The prosthesis contains many moving mechanical components that require cleaning, maintenance, or replacement at intervals. Some components, particularly joint mechanisms, must be cleaned and adjusted on a regular basis because they directly affect the function of the prosthesis.

Liner typology: type of liner selected on the base of patient characteristics, part of the patient data.

Liner size: liner size calculated on the base of the patient measures, part of the patient's body measures.

Marked stump positive plaster cast: positive plaster cast marked with all the critical zones the reference circumferences.

Materials: all the materials used during the whole prosthesis manufacturing process:

- *Assembly materials*: polyurethane foam to attach the socket to a base, glue, nails and screws to fix socket and the temporary components;
- *Coloured plaster*: coloured plaster used to define the critical zones on the positive cast;

- *Definitive socket materials*: a plastic bag to cover the positive cast, perlon fabric and resin to realize the socket, polyurethane foam to attach the socket to a base;
- *Plaster*: plaster to modify the positive cast;
- *Plaster stripes*: plaster stripes of 15 cm used to create the plaster cast directly on patient stump;
- *Silicone*: silicone necessary to seal the liner upper edge in A14;
- *Refinement materials*: a plastic bag to cover the positive cast, perlon fabric and resin to realize the socket, and carbon fibre stripes to reinforce the socket;
- *Rubber base*: a rubber base on which to position the negative cast;
- *White plaster*: white plaster to define where necessary the load and off-load zones;
- *Thermoplastic material*: a foil of transparent material thermoformed on the positive cast.

MD (Medical Doctor): medical doctor who evaluates the patient general conditions.

*Negative plaster cast with load zones***:** the negative cast with defined load zones.

Negative plaster cast with off-load zones: the negative cast with defined off-load zones.

Optimized definitive prosthesis: the definitive prosthesis optimized after the test with the patient.

Optimised socket: resin socket optimized after the test with the patient.

OT (Orthopaedic technician): orthopaedic technician who design and realize the lower limb prosthesis on the base of his/her personal knowledge and skills.

Patient: amputee for whom the prosthesis is realized on the base of his/her personal characteristics and on whom the prosthesis components are tested in different moments of the manufacturing process.

Patient's body measure: all the patient anthropometric measures necessary to design the whole prosthesis.

Patient characteristics: all the patient characteristics necessary to guide the whole prosthesis manufacturing process, part of the patient data.

Patient data: all the patient characteristics necessary to guide the whole prosthesis manufacturing process.

*Patient measur***es**: all patient anthropometric measures necessary for the manufacturing process, part of the patient's body measures.

Possible corrections for stump positive cast: indications to modify and optimize the positive cast obtained from the temporary prosthesis test.

Preliminary stump negative plaster cast: plaster cast slipped off the patient stump.

Preliminary stump positive plaster cast: positive plaster cast extracted from the negative cast.

Rectified definitive prosthesis: the definitive prosthesis rectified and ready for another test with the patient.

Rectified liner: after to have tested the liner selected for the patient, its upper edge is cut to be better adapted to the patient's anatomy and then sealed using silicone.

Rectified resin socket: resin socket , which has to be optimized after the test with the patient.

Rectified stump positive plaster cast: the positive plaster cast of the patient stump, which has been rectified after the check socket test.

*Resin socke***t**: resin socket realized on the optimized positive cast.

Smoothed stump positive plaster cast: positive plaster cast smoothed and scaled.

Stump data: all the stump characteristics necessary for a correct prosthesis design, part of the patient data.

Stump negative plaster cast: the negative plaster cast of the patient stump, used to realize the positive cast.

Stump negative plaster cast on base: the negative cast positioned on a rubber base.

Stump positive cast with corrections: positive cast modified after the temporary prosthesis test.

Stump positive plaster cast with off-load zones: positive plaster cast where the off-load zones have been realized.

Stump positive plaster cast with load zones: positive plaster cast where the load zones have been realized.

Temporary prosthesis: assembly of the temporary standard components and the check or resin socket.

Temporary stump positive plaster cast: the positive plaster cast of the patient stump used to realize the check socket.

Tested definitive prosthesis: the definitive prosthesis testes with the patient.

Tested temporary prosthesis: the temporary prosthesis tested with the patient.

Thermoformed check socket: transparent socket thermoformed on the positive cast.

Tools: tools used by OT during all the activities to realize the whole prosthesis:

- *Assembly tools*: a screwdriver and a hammer to assemble the prosthesis components;
- *Drain tools*: a bin full of sand in which it is positioned the negative cast and a metal tube inserted into the positive cast, subsequently used to suck out air during the socket realization;
- *Liner tools*: in A14 there is a pencil to mark the liner upper edge, which has to be cut on the base of patient's anatomy;
- *Marker and measurement tools*: a measuring tape to check reference circumferences on the positive cast and a pencil to mark on the positive cast the critical zones;
- *Marker tools*: a pen to mark possible modifications on the positive cast;
- *Measure tools*:
    - in A13 there are an instrument to measure internal circumferences of the old patient socket (where it is available), a measuring tape and a folding rule to measure patient anthropometric measures;
    - in A15 a measuring tape to measure stump reference circumferences with the liner;
- *Rectification tools*: a pencil and scissors to cut the upper edge of the negative cast;
- *Setting tools*: a laser device to check the prosthesis static alignment, a dryer to manually manipulate the check socket and a screwdriver to better set the prosthesis components;
- *Refinement tools*: an extractor fan to suck out air during the socket final refinement, an oven to dry the socket;
- *Slice*: a slice to apply plaster in order to define load and off-load zones on the negative cast;
- *Slice and rasp*: slice and rasp to modify the positive cast where and if necessary;
- *Socket modelling tools*: a jig for the valve, an air aspirator, an oven to dry the socket;
- *Thermoforming tools*: an oven to thermoform the check socket, scissors to cut the material in excess.

Waste check socket: after to have tested the check socket on the patient and rectified the positive cast, the check socket is thrown away.

Waste stump negative plaster cast: after to have drained plaster into the negative cast, this one it is cut in pieces in order to extract the positive plaster cast. These pieces are then thrown away.

2.3 – Conclusions

This analysis and formalization of the product and process knowledge has permitted us to identify rules applied by technicians during each task of the full process, which are strongly correlated with the personal technician skills. For example, how the technician selects and sizes standard components or how s/he manually manipulates the socket to reach the final optimal shape. On this basis we have identified main parameters that guide the prosthesis design and configuration process: the patient and the stump characteristics. In the following chapter we are going to see in detail the design rules and procedures extracted from patient characteristics and used to select the standard components and design the socket.

Chapter 3

Design rules and procedures

From the analysis of the product and development process we have extrapolated a set of design rules and procedures, as described in the following paragraphs. They have been evaluated and validated with the technical staff of the involved orthopaedic laboratory. In particular, we will describe patient characteristics, which guide the prosthetist during the prosthesis design, standard components selection and socket modelling procedures.

3.1 – Patient characteristics

Most of decisions taken by the technicians and the design procedures to realize the prosthesis are guided by patient characteristics. Identified characteristics have been divided in three main categories (see scheme in Figure 3.1):

- General patient parameters;
- Stump parameters;
- Anthropometric measures.

	Parameter	Value
Patient Evaluation	Gender	M,F
	Age [y]	<number>
	Patient force	very low, low, medium, high
	Life-Style	K1, K2, K3, K4
	Pathologies	YES,NO
Stump Evaluation	Amputation type	TT, TF
	Amputation Side	L,R,BOTH
	Stump stability	YES,NO
	Shape	cylindrical, conical, non-std
	Bone protuberances	widespread, on top
	Skin conditions	sensitive, normal, scars, scratches
	Tonicity	low, normal, good, very good
Anthropometric Measures	Weight [kg]	<number>
	Height [mm]	<number>
	Trochanter height [mm]	<number>
	Residual limb length [mm]	<number>
	Thigh length [mm]	<number>
	Dist. knee joint-stump top [mm]	<number>
	Knee joint height [mm]	<number>
	Foot lenght [mm]	<number>

Figure 3.1: Patient characteristics.

In the following a description will be provided:

- *Patient evaluation*: the general data about the patient are:
    - *Gender*: the sexual gender of the patient, male or female;
    - *Age*: the patient age in years;
    - *Patient force*: the general patient physical force, divided in 4 levels (very low, low, medium and high). For example, for an old patient who just walks only few steps at home, the level is very low; while for a patient who has a dynamic life and practices sport, the level is high;
    - *Life style*: from the indications of Medicare guidelines for functional classification of patients with prosthesis [53], it is classified in 4 deambulation levels from K1 to K4 (Figure 3.2, K0 indicates a patient who cannot deambulate and use a prosthesis). To select the right one we have elaborated a questionnaire, shown in Figure 3.3, to identify in automatic way the appropriate patient life style. Questions are divided in three categories:
        - *Physical general conditions*: 2 questions to evaluate the general patient health;
        - *Deambulation evaluation*: 8 questions to evaluate the patient level of mobility indoor and/or outdoor;

- *Ground adaptation*: 8 questions to understand types of grounds and obstacles the patient has to overcome.

K Code Level	Functional Level
K0	Not a potential user for ambulation or transfer
K1	A potential household ambulator including transfers
K2	A potential limited community ambulatory
K3	Community ambulator using variable cadence including therapeutic exercise or vocation
K4	High activity user which exceeds normal ambulation skills

Figure 3.2: K-code for Medicare classification for patients with prosthesis [53].

- *Pathologies*: it is considered the presence or not of pathologies which can influence the patient mobility or quality of life.

- *Stump evaluation*: the general data about the stump are:
  - *Amputation type*: if it is a transtibial (TT) or a transfemoral (TF) amputee;
  - *Amputation side*: the left, the right or both limbs;
  - *Stump stability*: in relation to the time passed from the limb amputation, the stump undergoes changes of volume; for example for a quite recent amputation (less than 1-2 years) the stump undergoes a significant volume reduction, while for less recent amputation (more than 4 years) the stump volume modification are quite slow;
  - *Shape:* the shape of the residual limb, normally can be cylindrical, conical. For the other rare cases, the shape is considered not standard;
  - *Bone protuberances:* where bony protuberances are located on the stump, if they are widespread or only at the top;
  - *Skin*: the sensibility of the skin, and presence of scars or scratches;

- *Tonicity:* the level of tonicity of the residual limb muscles, strictly correlated to the patient daily activity before the amputation. In fact, after the amputation, the muscles of the residual limb are partially used by patient, and slowly they undergo a process of atrophization. It is divided in 4 levels: low, normal, good or very good) For example a young patient, amputated from less than 3 years, tonicity is still good; while a middle-aged patient, amputated from more than 10 year, tonicity starts to be low.

Questionnaire
Physical general conditions
How are your general health conditions?
How is your general muscles tonicity?
Deambulation level
Do you walk only at home?
Can you walk only for few meters?
Do you walk at home and outside with some limitations?
Can you walk for maximum few hundred meters?
Do you walk at different speeds?
Do you walk for maximum 1-2 kilometers?
Do you walk at different speeds and do jogging?
Do you walk for more than 3 km?
Ground adaptation
Do you walk only on flat floors?
Can you walk only for few meters without height differences?
Can you go over only small obstacles such as edges or irregular floors?
Can you do only a few steps of a stair?
Can you do more than 1 floor of stairs?
Can you do slides?
Can you walk on uneven ground and overcome tough obstacles?
Can you go over any kind of slope?

Figure 3.3: Questionnaire to identify patient life style.

- *Anthropometric measures*: general measures of the patient's body (see general scheme for TF amputees in Figure 3.4 and for TT amputees in Figure 3.5):

  - *Weight*: patient weight in kg;

- *Height (H)*: patient height;
- *Trochanter height* (TRH): trochanter height measured on the contralateral lower limb;
- *Residual limb length (RL)*: total length of the residual limb;
- *Knee joint height (KH)*: contralateral knee joint height ;
- *Foot length (FL)*: length of the contralateral foot;
- *Thigh length (TL)*: length of the thigh, only for TT amputees;
- *Distance knee joint-stump top (KS)*: it is the vertical distance between the stump top and the contralateral knee joint, calculated as follows:

For TT*:* $KS = RL - TL\ [mm]$ *(3.1)*

For TF*:* $KS = TRH - RL - KH\ [mm]$ *(3.2)*

In the particular case of both limb amputation, the mentioned heights are identified on the base of the patient height before the amputation.
In some case, patients present unique factors that should be considered in the design of the prosthesis. For example, someone who lives near the ocean may need a prosthesis designed with maximum protection from salt corrosion and water damage. Cultural background is also significant. Asian amputees require a foot that allows the shoes to be removed easily when entering a home since that is custom, etc. Such personal factors should be added to the more generic factors discussed previously to ensure the proper match between prosthetic configuration and amputee goals [13].

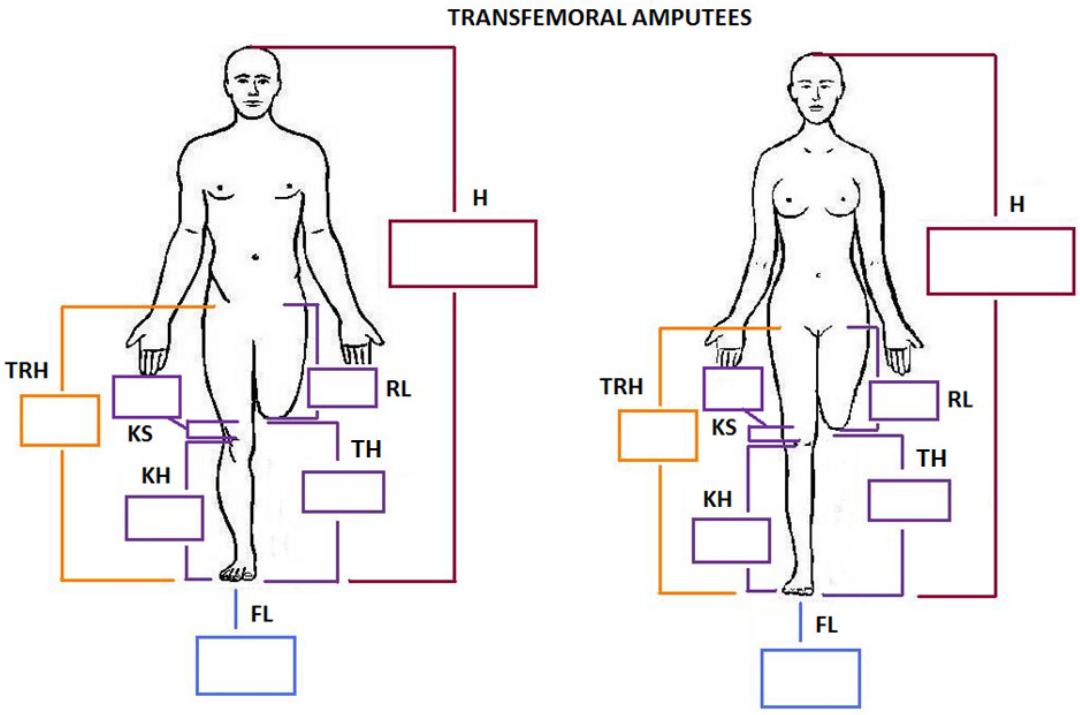

Figure 3.4: Scheme of anthropometric measure used to design a TF prosthesis.

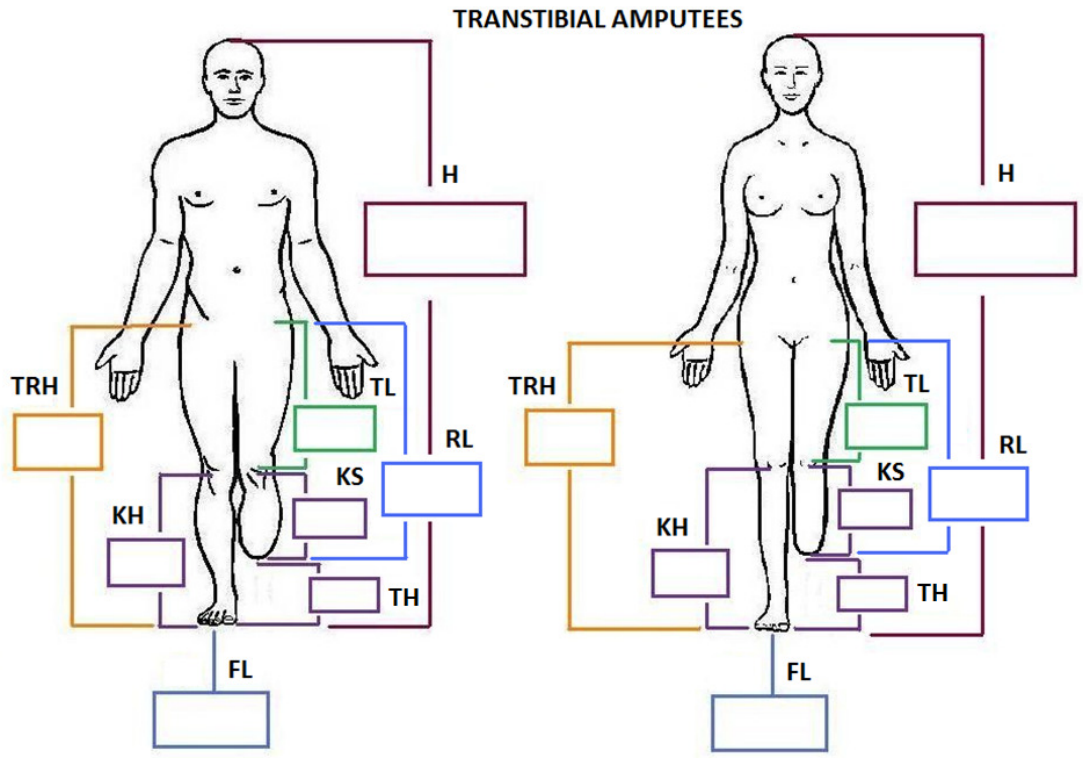

Figure 3.5: Scheme of anthropometric measure used to design a TT prosthesis.

3.2 – Selection procedures for standard components

As previously said all prosthesis components, apart the socket and rarely the liner, are standard components available on market and selectable from commercial catalogues. For the extrapolation of guidelines to select the standard components, we have studied the indications given in commercial catalogues by the most known prosthetic brands, and the rules adopted by technicians on the base of their personal expertise. Thus, we have elaborated a procedure and electronic sheets to choose automatically the appropriate components for each kind of amputee (transfemoral and transtibial) and accordingly size them. Before describing the procedure we introduce the underlying concepts.

3.2.1 – Prosthesis modules

First, we have divided the lower limb prosthesis in modules (as an example a TF prosthesis is shown in Figure 3.6) to better distinguish and calculate size of each component. In particular we have:

- *Socket module*: it includes the top liner thickness and the socket adapters;
- *Double adapter*: it includes double male or female pyramid adapters, available in different dimensions, which connects socket and knee in TF prosthesis, and can substitute a tube in both TT and TF prosthesis;
- *Knee module (only for TF amputees)*: it includes the prosthetic knee and the knee adapters;
- *Tube module*: it includes the tube and the tube adapters;
- *Foot module*: it includes the foot, the foot adapters and the patient shoes heel, called also “virtual heel”.

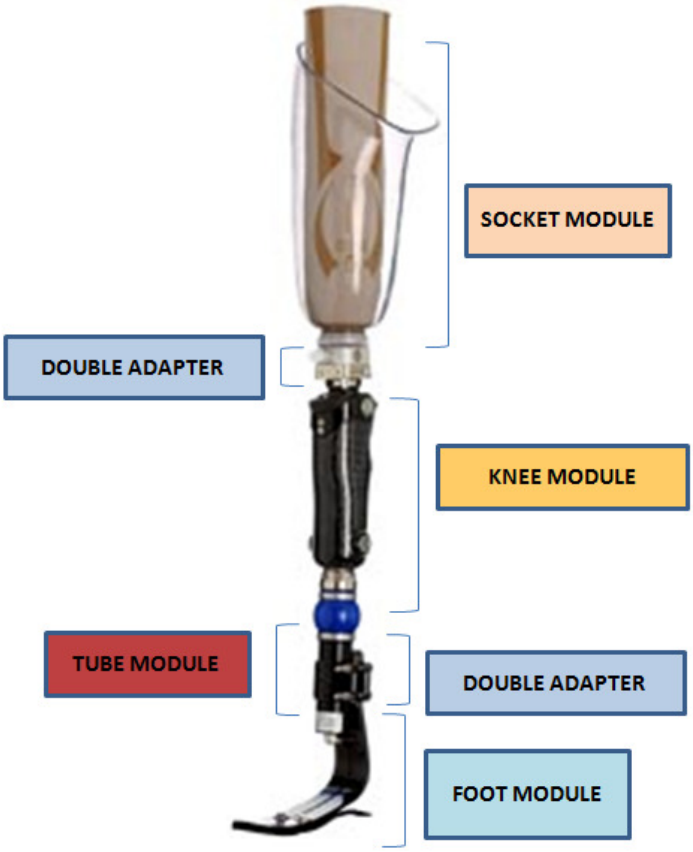

Figure 3.6: Scheme of a TF lower limb prosthesis modules.

3.2.2 – Patient parameters

Accordingly to what said before, main patient characteristics that guide the selection are:

- *Life style*: calculated on the base of the questionnaire described in § 3.1. It the most important parameter which influences the components selection, since where and how a patient lives is strictly correlated to the required prosthesis performance. For example, a patient who has very dynamic life and walks for more than 1 km everyday needs a more performing prosthesis than a patient who spends all day at home;

- *Age*: It has been divided in 2 categories: less than 65 years and equal or more than 65 years old. It can influence life style; for example a 30 years old patient can have a more active life, than a 70 years old patient;

- *Weight (w)*: patient weight in kg, divided in 4 groups: $w \leq 75$ kg, $75 \text{ kg} < w \leq 100$ kg, $100 \text{ kg} \leq w < 125$ kg, and $w \geq 125$ kg. The weight can influence the selection since some components cannot carry an elevate weight, while others are indicated for

heavy patients. For example a high energy foot is appropriate for young patients who weight more than 100 kg, because this typology can better support elevate stress;

- *Physical force*: it is divided as said in 4 levels (§ 3.1). For example an 80 years old patient normally has low force level, while a 25 years old sportive patient has a high force level. This means that in the first case the patient will be able to use a prosthesis with heavier components than the second case;

- *Residual limb length*: called also *stump length*, divided in 3 levels short, normal and long (for further details see § 2.2) which influences the calculation of Life style, since short stumps allow a weaker control of the prosthesis, while long stumps guarantee an elevate control and stronger interaction prosthesis-stump.

3.2.3 – Foot classification

For the foot component we have been identified the following categories (Fig. 3.7):

- *Rigid*: feet without ground adaptation, divided in:
    - *Sach*: rigid traditional foot made of wood;
    - *Foam*: rigid traditional foot partially made of wood, and partially by distributed synthetic foam, which allows flexibility of the foot anterior part;
- *Mono-axis*: feet with one single axis of ground adaptation, divided in:
    - *Single-axis*: SACH foot with ankle joint;
    - *Low*: foot, which during walking can store and release a low quantity of energy, normally made in carbon fiber;
    - *3-foils*: foot made of 3 foils of carbon fiber, which can store and release during walking a medium quantity of energy;
    - *Heel pad*: foot with a cushioning heel pad, which can store and release during walking a medium quantity of energy;
    - *3-points*: foot with 3 points of support on the ground during walking;
    - *High*: which can store and release during walking a high quantity of energy;
- *Multi-axis*: feet with more axes of ground adaptation, divided in:

- *C-spring*: foot with a “C” shaped spring under the ankle joint;
- *Sandwich*: foot built with 2 foils of carbon fiber and a soft part in the middle.

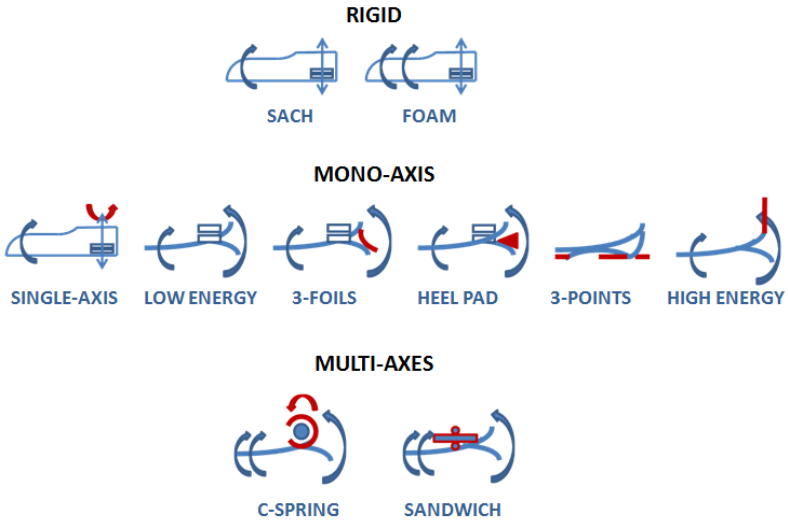

Figure 3.7: TT and TF feet categories and typologies.

3.2.4 – Knee classification

In similar way, we have identified the principal knee typologies for TF amputees (Figure 3.8) and grouped as follows (for details see also § 2.1):

- *Fixed*;
- *Monocentric*: monocentric knees divided in Selfbrake, Friction, Pneumatic and Hydraulic;
- *Polycentric*: polycentric knees divided in Selfbrake, Friction, Pneumatic and Hydraulic.

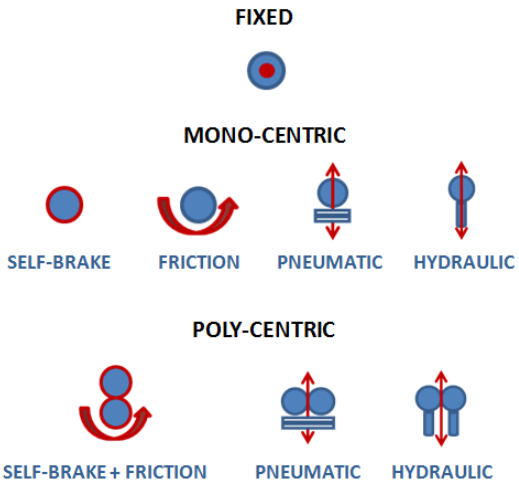

Figure 3.8: Knee categories and typologies.

3.2.5 – TT amputees selection

For transtibial amputees, the procedure for components selection is shown in Figure 3.9.

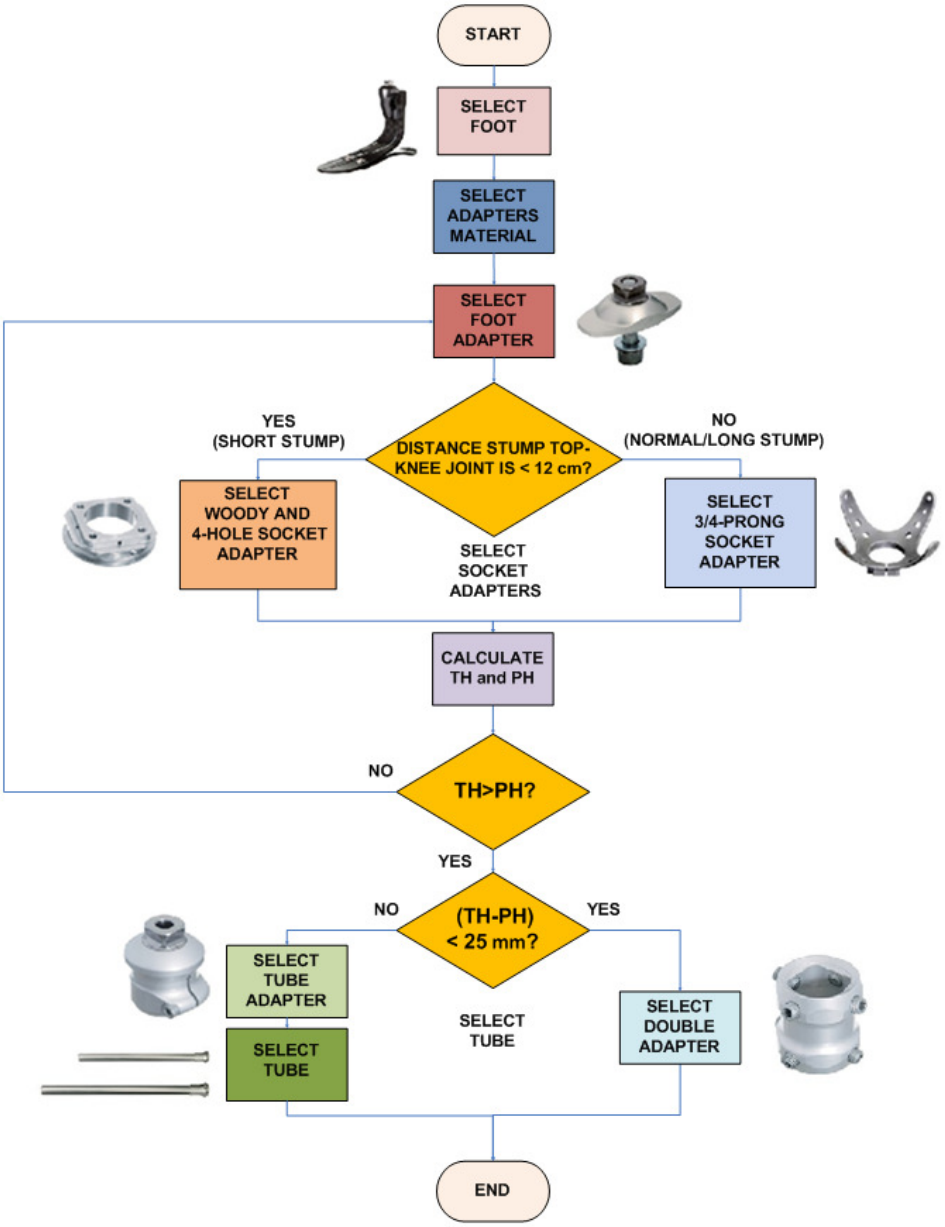

Figure 3. 9: Diagram used to selected appropriate TT components.

Selection is performed as follows:

1. *SELECT FOOT*

First, the most appropriate foot is selected, accordingly to some specific patient characteristics and foot properties. Figure 3.10 shows, as an example, the electronic sheet developed to select the foot. Since not all feet can bear the weight of heavy patients, a

preliminary check has done to exclude such types. Then, the main feature to choose the most suitable foot is the ground adaptation derived from the life style. Finally some specific characteristics of the feet (energy return and foot weight) are used to rank those considered suitable from previous criteria.

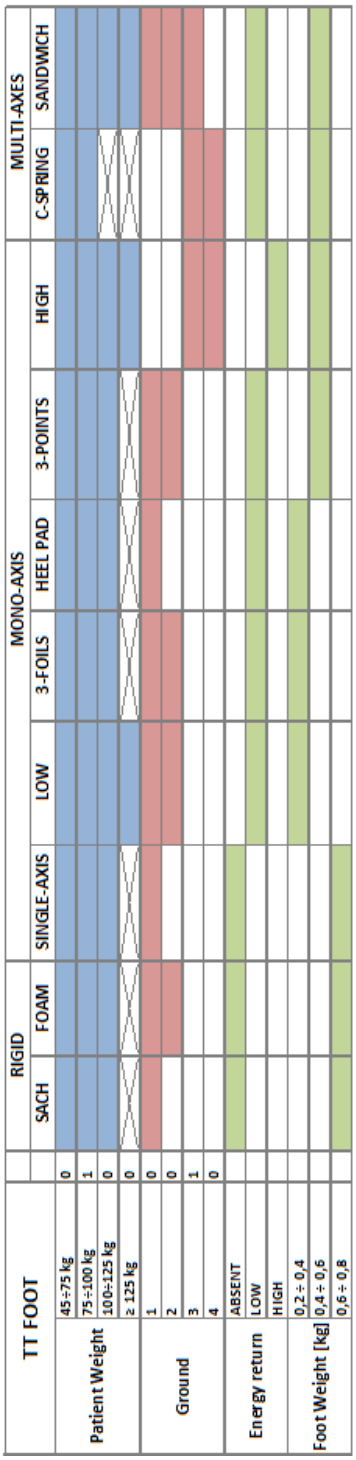

Figure 3.10: Electronic sheet used to selected appropriate TT foot.

2. *SELECT ADAPTERS MATERIAL*

First to select the next components, it is necessary to choose the appropriate adapters material, as follows:

- *Aluminium or stainless steel ada*pter: for patients weight equal or less than 100 kg;
- *Titanium or carbon adapter*: for patients weight more than 100 kg.

3. *SELECT FOOT ADAPTER*

On the base of the selected foot, the appropriate foot adapter is chosen. For example, Sach foot needs a specific Sach foot adapter, while multi-axes feet usually need a male pyramid adapter.

4. *SELECT SOCKET ADAPTER*

First stump length is acquired, calculating KS, i.e, the distance between the knee joint and the stump top, accordingly to (3.1). Stump length is classified as short if KS $\leq$ 12 cm or normal/long if KS > 12 cm. If the stump length is short, a woody and 4-hole socket adapter are chosen; otherwise a 3/4 prong socket adapter is selected.

5. *CHECK COMPONENTS HEIGHT*

Once selected foot, its adapter and the socket adapter, it is necessary to check the height id these assembled components and compare it with the prosthesis height. Figure 3.11 shows a table with typical standard dimensions in mm of the different prosthesis components when assembled; since it is necessary to know each effective component dimension when it is assembled with the other parts in order to calculate the correct whole prosthesis height. For a correct prosthesis sizing it is necessary to have two patient anthropometric measures (see § 3.1, Figure 3.5): the *distance knee joint-stump top (KS)* and the *knee joint height (KH)*. Total prosthesis height (TH), the vertical distance between the stump top and the floor, is calculated as follows:

$$TH = KH - KS \ [mm] \qquad (3.3)$$

The components selection is verified if TH>PH, where PH=sum of selected components heights. Otherwise it is necessary to come back to the previous selections and change components.

6. *SELECT TUBE*

To select the right tube, it is necessary to check if TH-PH<25 mm. If it is verified a double adapter is selected, on the base of the previously chosen foot and socket adapters; otherwise it is necessary to select the tube and tube adapters. The tube is sized as follows:

$$TM = TH - SM - FM \ [mm] \qquad (3.4)$$

where:

TM = tube module height;

SM = socket module height;
FM = foot module height.

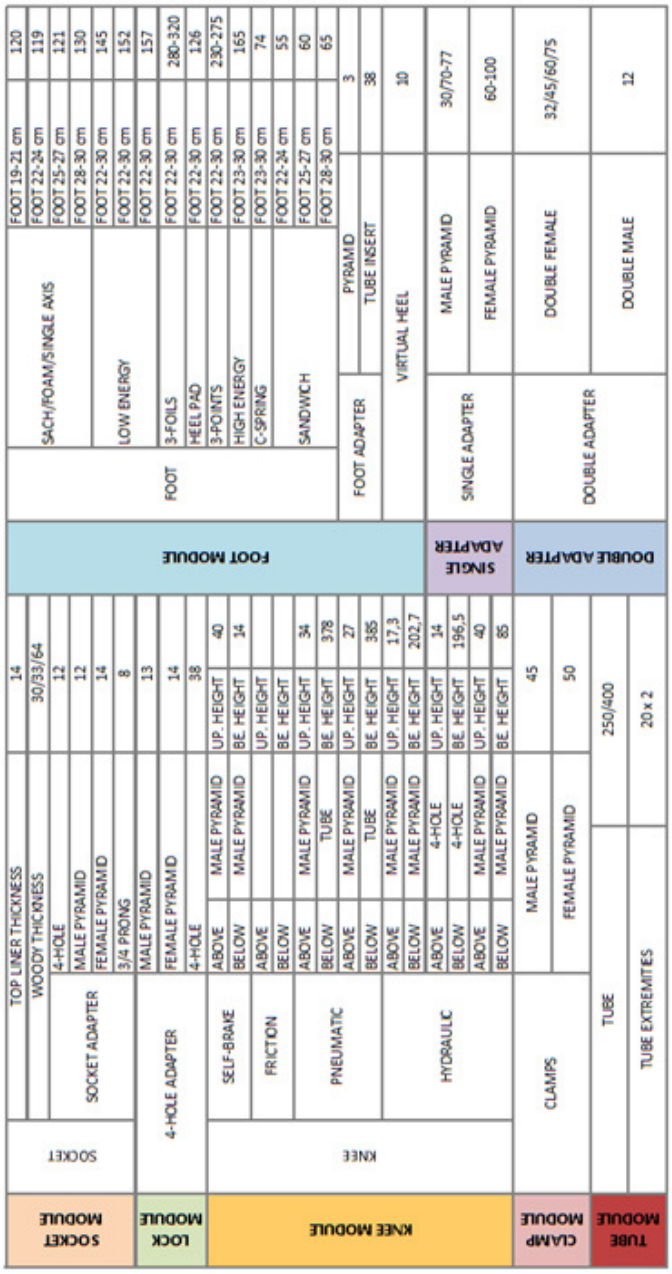

Figure 3.11: Table of standard dimensions in mm of assembled lower limb prosthesis components

3.2.6 – TF amputees selection

Similar procedure and rules have been defined to choose the transfemoral components. In this case first the knee is selected, and then the components above and below knee, as

shown in Figure 3.12. Similarly to the previous case, electronic sheets have been developed to select some components, such as knee and foot.

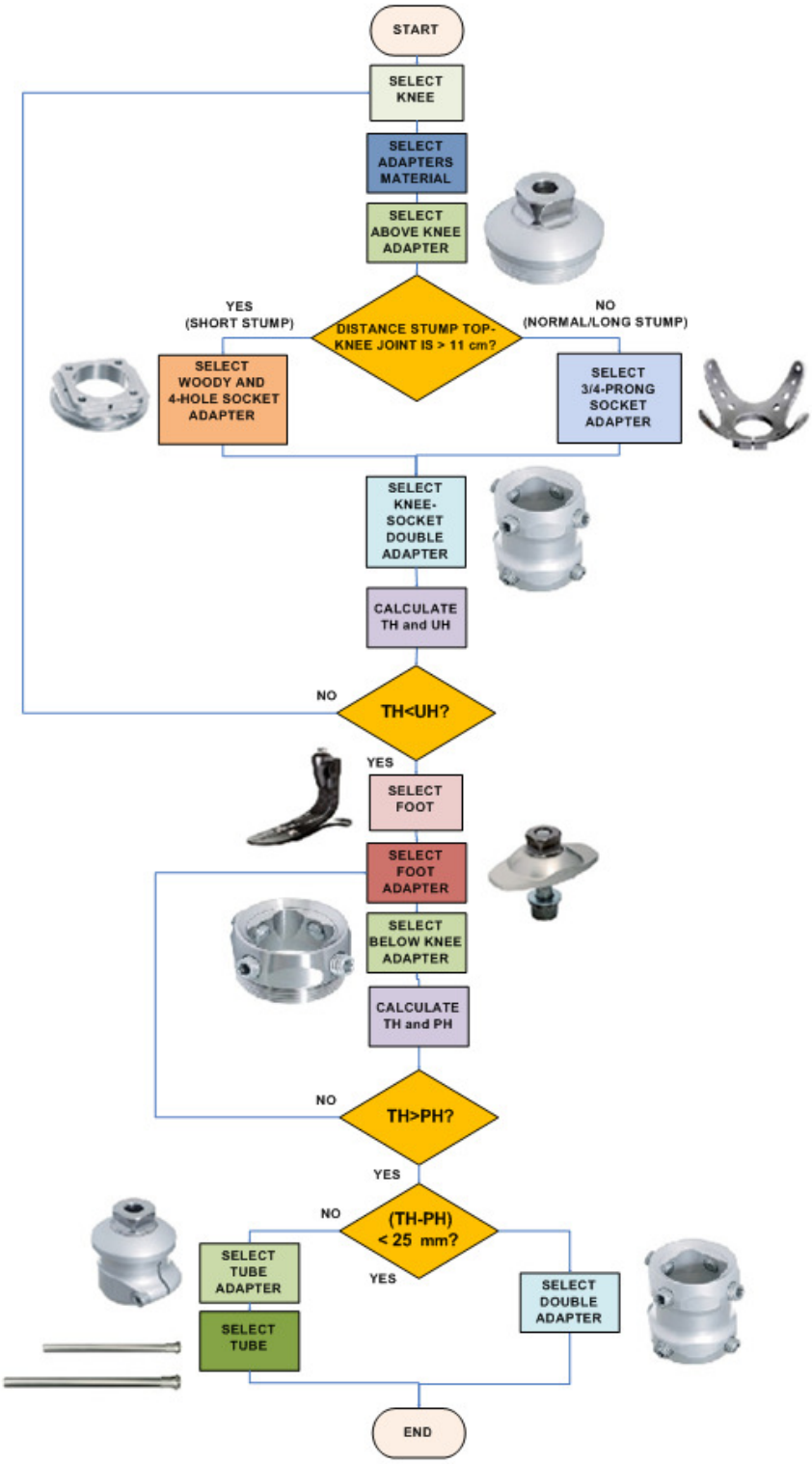

Figure 3. 12: Diagram used to selected appropriate TF components.

Steps to select above and below knee components are similar to those for TT prosthesis. It is important to notice that in this case the stump length is classified as short if KS ≥ 11 cm or normal/long if KS < 11 cm. While the Total prosthesis height (TH) is calculated as follows:

$$TH = KH + KS \ [mm] \qquad (3.5)$$

3.3 – Socket procedures and rules

The socket functionality is strictly linked to the technician ability. The design guidelines to model the socket have been extrapolated from the analysis of operations performed by the technicians to reach an optimal shape, described in § 2.2. This lead to the identification of which stump zones are manipulated and where add or remove materials in the positive model to ensure a correct prosthesis functionality and comfort. S/he first highlights on the positive model the areas to be modified and, then, starts to modify them adding or removing plaster. Essentially, three types of operations have been identified:

- *Initial plaster circumference reduction;*
- *Identification of critical zone;*
- *Critical zones manipulation*.

In the following we describe the design guidelines derived for these three operations.

3.3.1 – Circumference reduction

In general, the socket must be tighter for young or recently amputated patients, since the muscles and the body are still strong and tonic. Instead, for elderly or long standing amputated patients, since the muscles and the body are not anymore fully efficient, the socket needs to be looser and not too much tight to allow an easier deambulation or physical therapy. We have identified and collected in a table the appropriate reduction in relation the specific patient characteristics.
The range of percentage varies from 1% to 6%. It is not uniform on the stump, but it starts with 1% at 4 cm over the stump top, and increases gradually going up until the stump upper part. For example, for a tonic stump and a patient very active, the reduction is low since the muscles are strong (e.g. for a young amputee, dynamic and without particular disease, the reduction starts from 1% until to 2%).
Figure 3.13 shows a screenshot of the table, which summarises the reduction to be applied in relation to patient characteristics. These parameters influence the decision about the appropriate values:

- *Stump stability*: stable stumps need a looser socket and therefore a lower reduction (1÷3%), while unstable stumps a tighter socket and a higher reduction (3÷6%);

- *Stump tonicity*: less tonic are the stump muscles, more reduction is necessary to obtain an appropriate socket fitting. For this reason a reduction of 4÷6% is

appropriate for low stump tonicity, 3÷5% for normal, 2÷3% , for good, and 1÷2% for very good;

- *Stump skin*: more sensitive is the skin and looser must be the socket, so we have for sensitive skin a reduction of 1÷2%, for normal of 2÷6%, and for skin with scratches maximum 1÷3%;

- *Patient weight*: normally heavy patients need a well tight socket, since they normally have a flaccid stump. For this reason for patients who weight more than 100 kg the reduction is 3÷6%, for patients between 75 and 100 kg is 2÷6%, and for patients less than 75 kg it is sufficient 1÷5%;

- *Life style*: the patient life style influences the reduction since a patient with an intense or very intense life needs a stable and tight socket (respectively 3÷6% and 4÷6% of reduction), a normal life style needs a moderately looser socket (2÷5% of reduction), while patients with a low profile need only a looser socket (1÷5% of reduction);

- *Patient pathologies*: the presence of pathologies, which can influence the patient mobility, requires a socket not too much tight (1÷3% of reduction). While a patient in good health needs a well fitting socket (3÷6% of reduction).

SOCKET			SCALING			
			1 ÷ 2%	2 ÷ 3%	3 ÷ 5%	4 ÷ 6%
STUMP EVALUATION	STABILITY	Stable				
		Unstable				
	TONICITY	Low				
		Normal				
		Good				
		Very good				
	SKIN	Sensitive				
		Normal				
		Scratches				
PATIENT EVALUATION	WEIGHT	< 75 kg				
		75 ÷ 100 kg				
		100 ÷ 125 kg				
		> 125 kg				
	LIFE STYLE	Low				
		Normal				
		Intense				
		Very intense				
	PATHOLOGIES	Yes				
		No				
TOTAL						

Figure 3.13: Reference parameters to evaluate the downsizing of the positive plaster cast in relation to patient characteristics.

The most appropriate reduction, accordingly to the patient characteristics, is selected identifying the range with the highest number of occurrences.

3.3.2 – Identification of critical areas

In the traditional process the technician first identifies with markers the areas, which have to be modified on the positive model. In particular, we have divided these areas in two categories:

a) *Load zones*, where there are not bony protuberances or tendons and it is necessary to constrict the socket closer to the limb and therefore create a pressure to sustain the body weight;

b) *Off-load zones*, where there are bony protuberances or tendons and the socket does not have to press the limb and in the meantime not to be much wide since it could cause other physical problems.

Figure 3.14 shows a map of identified areas for a transfemoral amputation and Figure 3.15 for a transtibial amputation. For a transfemoral socket, the most important critical areas are in particular the inguinal canal off-load zone, the Scapa triangle support zone, the trochanter off-load zone, the lateral support zone and the femur support zone
While for a transtibial socket, the most important critical areas are the off-load zones of anterior fibula, patella, tibial epiphysis and posterior tendons.

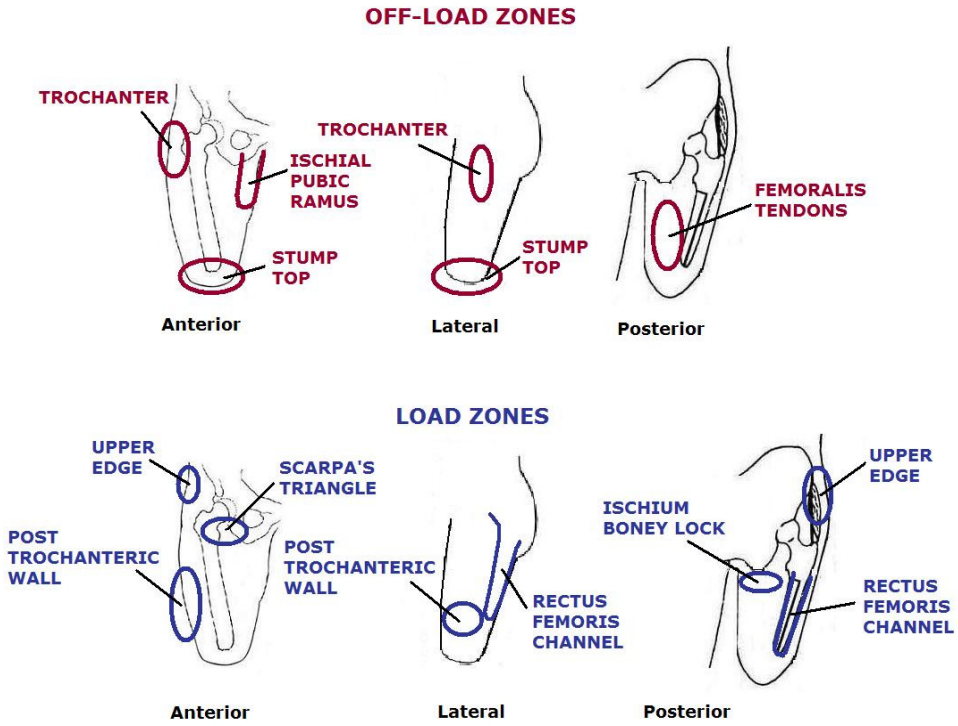

Figure 3.14: General scheme of the load and off-load zones for transfemoral stumps.

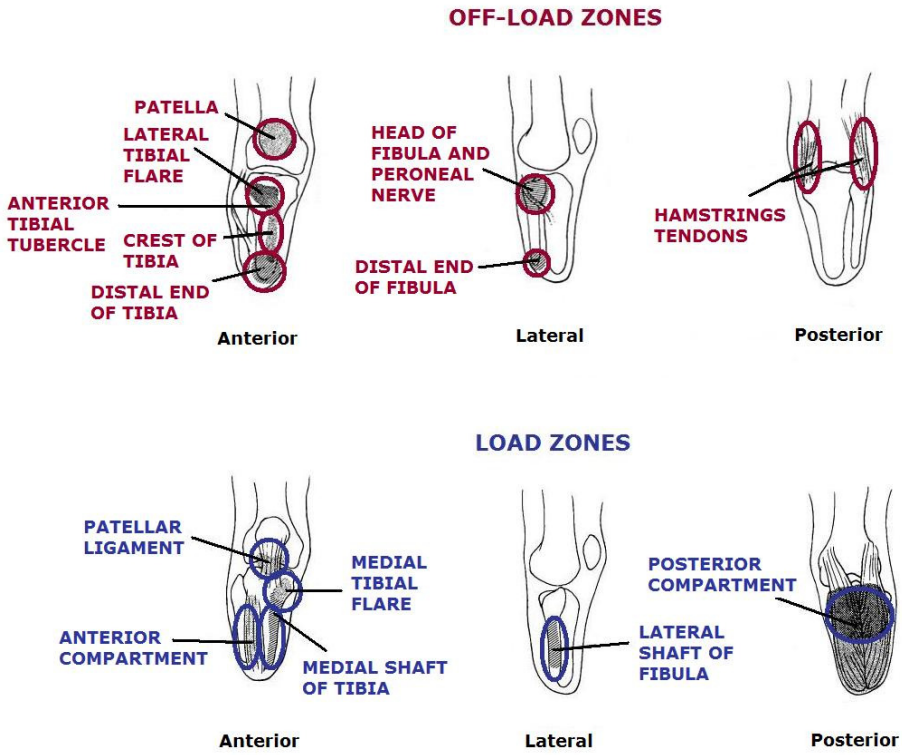

Figure 3.15: General scheme of the load and off-load zones for transtibial stumps.

3.3.3 – Critical areas manipulations

Once identified the critical areas, these have to be modified adding or removing plaster. In detail, in the off-load zones, the technician removes material from the positive plaster cast since in that zones the socket does not have to press the stump and be quite loose. While in the load-zones the plaster has to be added in order to have a socket more well tight and also self-supporting.

Regarding to the amount of chalk added or removed by the technician in the critical areas we have identified eight manipulation levels, from 1 to 8 mm of thickness, in correlation to the stump tonicity, as shown in Figure 3.16. For example, for a stump with normal tonicity, the plaster thickness to be removed or added will be 3-4 mm.

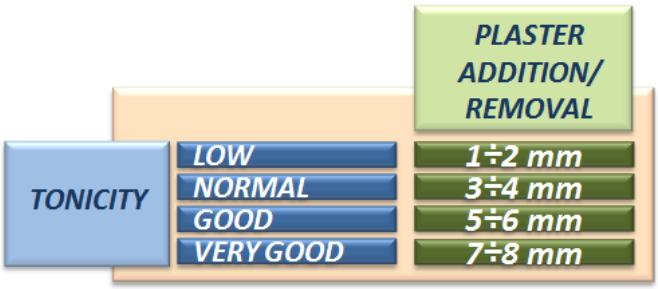

Figure 3.16: Reference values for the choice of the plaster additions/removing.

3.3.4 – Socket thickness

Finally we have also derived the formula to calculate the final socket thickness:

$$\textit{Socket thickness [mm]} = \textit{Patient weight [kg]}/20 \qquad (3.6)$$

Chapter 4

New design framework

On the basis of previous study and analysis of product and process knowledge required for lower limb prosthesis manufacturing, we have reengineered the prosthesis design process and developed a knowledge design framework, which guides the technicians step by step providing for each activity specific knowledge and rules (e.g. dimensioning or selection rules for standard parts). The system integrates virtual prototyping and knowledge management techniques. In the following we are going to describe in detail the new design process and the architecture and functionalities of the innovative knowledge-based framework used to design the prosthesis.

4.1 – New design process

In order to overcome limits of the traditional process and commercial CAD/CAM software available on market, we propose a new design process for modular lower limb prosthesis centered on domain knowledge and on the digital model of the amputee, represented at different level of details according to the specific design task. The underlying idea is to guide the orthopaedic technicians during each step of the product development process suggesting and applying, in automatic or semiautomatic way, rules and procedures derived from the analysis of traditional manufacturing process. The new process integrates the direct management of experts' knowledge in order to guarantee a product of high quality. In detail it integrates computer aided tools for:

- domain technical knowledge management both of product and process (KBE tool);
- virtual modelling of standard components (e.g. tube, foot and knee) and their assembly (commercial 3D CAD system);

- virtual modelling of the custom-fit product, the socket, directly on the patient digital model or parts of it (SMA, specifically developed);
- functional behaviour simulation to fully validate the final model of the prosthesis (FE system for socket-stump interaction and multi body system for walking analysis).

Each task is supported by the management of specific domain knowledge through virtual assistants, which provide procedures and/or suggestions to perform best choices and, when possible, execute them automatically (e.g. choosing components and materials or sizing parts).
We have formalized the new design process by IDEF0 diagram. Figure 4.1 portrays the IDEF0 diagram that represents the main activities of the new process:

- *A1 - Acquire patient characteristics*: the medical doctor and the orthopaedic technician acquire all the patient data described in § 3.1 by means of a preliminary clinical evaluation. All these data are fundamental to take all the decisions in the next phases on the base of experts' knowledge and design procedures. Then, it is acquired the 3D virtual model of the patient's residual limb;

- *A2 - Design socket*: the orthopaedic technician creates the 3D virtual model of the socket directly on the stump digital model (acquired with Reverse Engineering equipments [59]) applying in automatic or semiautomatic way the same rules adopted during the traditional process of socket manufacturing. This step foresees the use of an ad hoc socket modeller and FEA tools to study the stump-socket interaction and verify socket functionality;

- *A3 - Select standard components*: the framework drives the user to the selection of the standard components for the considered patient following the acquired and implemented procedures. A kind of virtual catalogue is available, from which 3D parametric models of the most common standard components are extracted and properly sized;

- *A4 - Assemble prosthesis:* the system finally assembles the socket 3D model and the selected standard components;

- *A5 - Virtual test:* the complete prosthesis 3D model is virtually tested simulating set-up operation and patient deambulation using a patient virtual avatar wearing the prosthesis. Once completely verified, the system automatically generates the prosthesis BOM (Bill Of Materials).

Once the prosthesis and particularly the socket model have been optimized and verified, the definitive socket can be realized by a rapid prototyping machine [57-59] and assembled with all other components for the final test with the patient.
As mentioned before, we put here the attention on the socket modelling phase, which is the core of the framework and design process. In fact, a good manufacturing of the socket means a correct functionality and usability of the whole prosthesis. Typically, a socket is mainly

hand-made and the technician really needs high professional skills to realize it. The socket is strongly dependent on the human body anatomy and it has to be perfectly close fitting to each patient's residual limb. Beyond, it has to permit a good response to forces and mechanical stress, avoiding pain and skin problems to the patient.

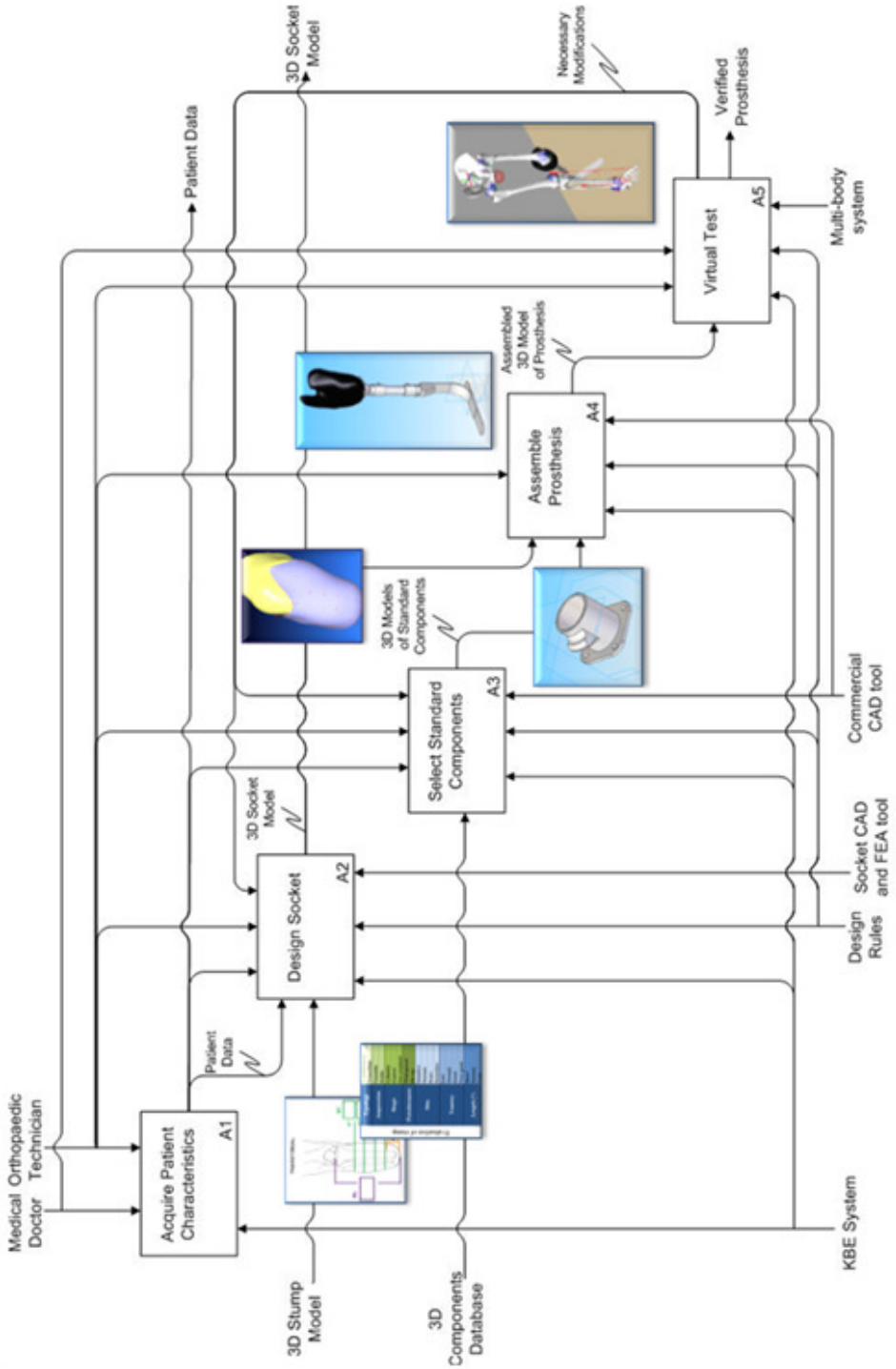

Figure 4.1: New design process.

In the following we introduce the main diagrams of the new design process.

A1. Acquire patient characteristics

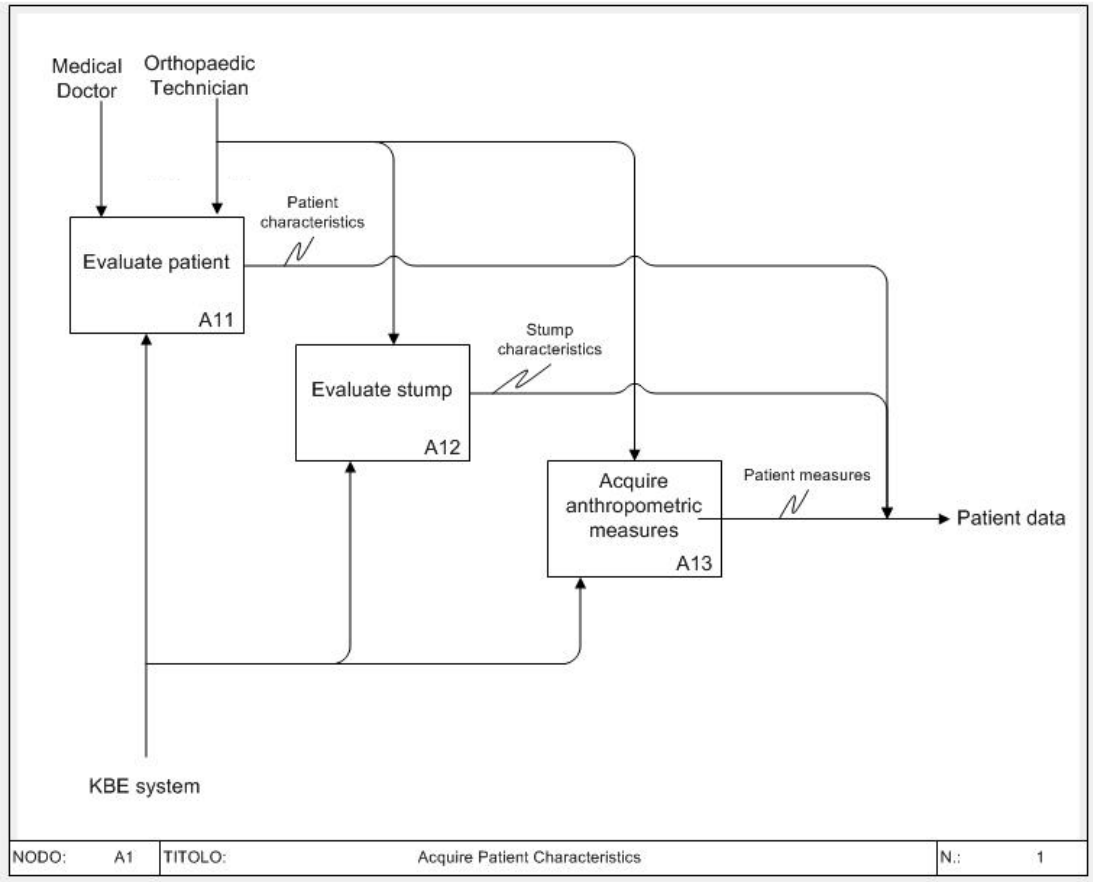

Figure 4.2: IDEF0 diagram of activity A1.

In this activity (see related diagram in Figure 4.2) the patient characteristics are acquired. This patient data will be used in the next steps to properly design the socket, select the appropriate standard components, assemble and size the prosthesis, and finally check with a virtual test the patient deambulation. This activity is consists of three principal operations:

A11. Evaluate patient: the medical doctor and the orthopaedic technician evaluate the patient and identify the necessary patient characteristics;

A12. Evaluate stump: the medical doctor and the orthopaedic technician evaluate the patient's stump and identify the necessary stump characteristics;

A13. Acquire anthropometric measures: finally the technician acquires the required patient anthropometric measures.

A2. Design socket

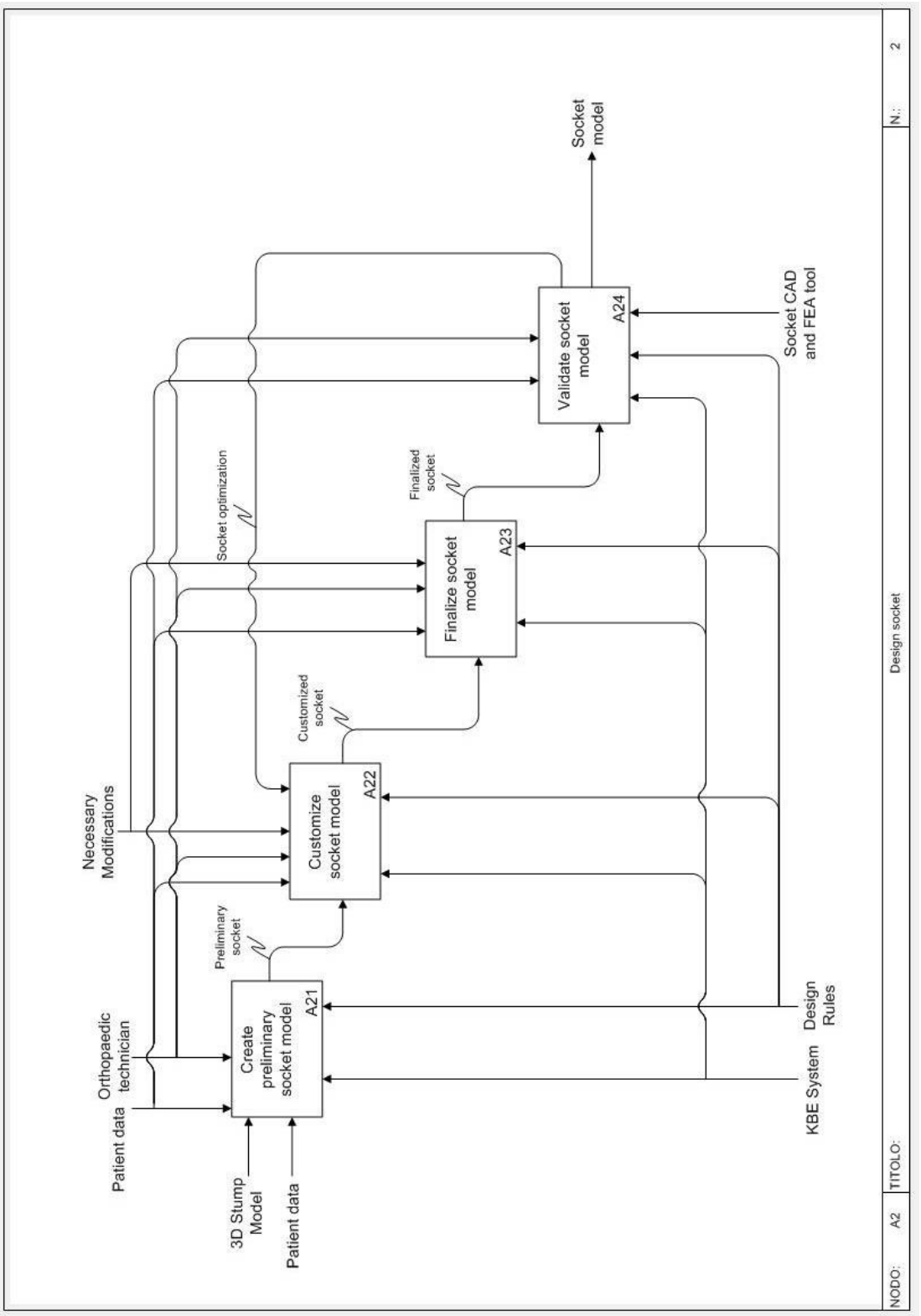

Figure 4.3: IDEF0 diagram of activity A2.

In this activity (see related diagram in Figure 4.3) the virtual socket model is realized on the base of the patient data using the KBE system. Finally the socket model functionality is verified using FE tools which check the stump-socket interaction. This activity is consists of four principal operations:

A21. Create preliminary socket model: on the base of the patient data the preliminary socket model is created into the KBE system;

A22. Customize socket model: the preliminary socket model is customized on the base of the patient characteristics;

A23. Finalize socket model: the customized socket model is finalized and exported to be tested;

A24. Validate socket model: the socket model is tested using an FE tool to verify the socket-stump interactions. If the socket needs to be optimized, the user has to come back to the customize step and modify the model.

A3. Select standard components

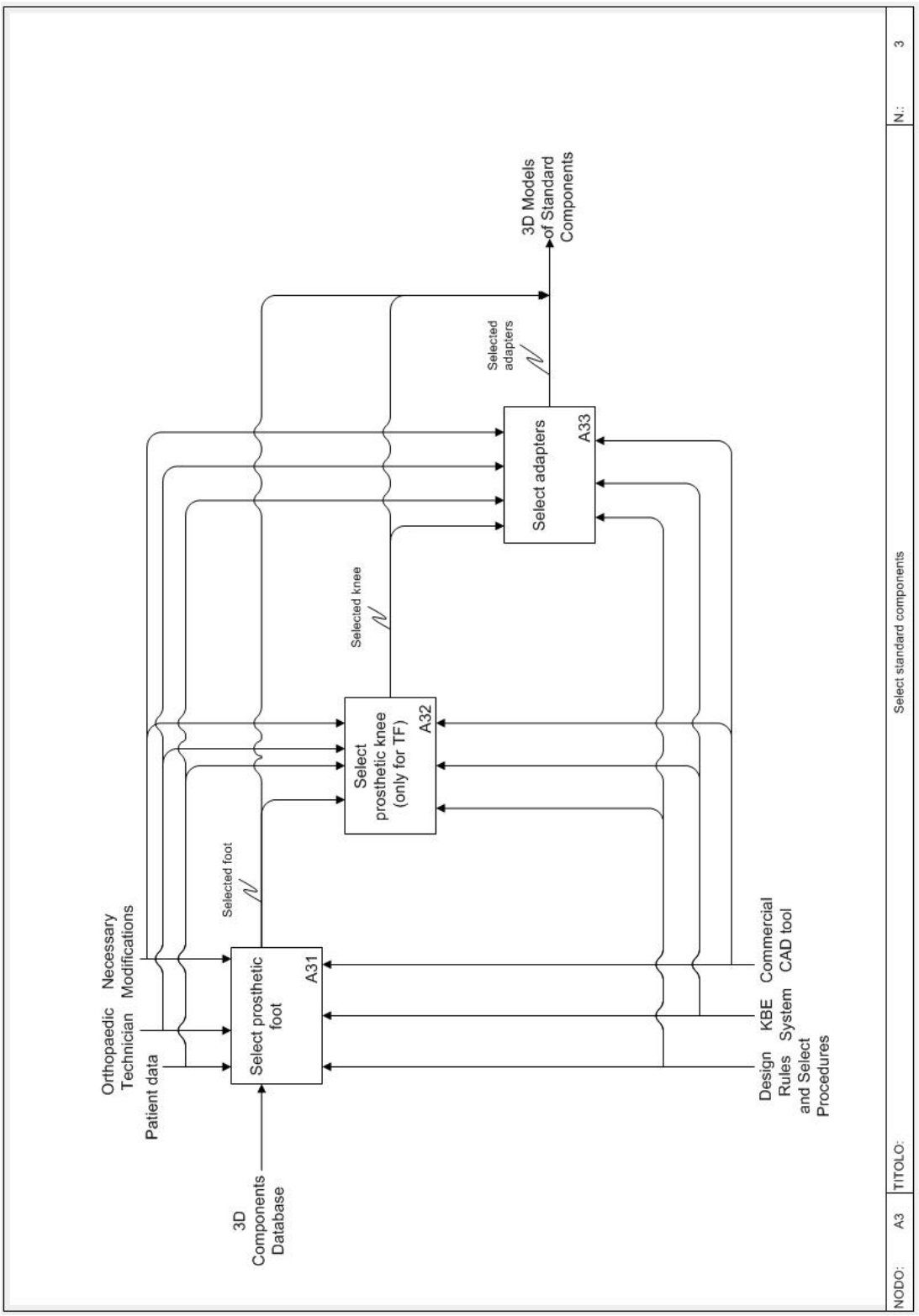

Figure 4.4: IDEF0 diagram of activity A3.

In this activity (see related diagram in Figure 4.4) the KBE system guides the user into the standard components selections. First it is selected the appropriate foot, then for the TF amputees it is chosen the knee, and finally all the correlated adapters. This activity is consists of three principal operations:

A31. Select prosthetic foot: the KBE system guides the user into the selection of the most appropriate prosthetic foot on the base of the patient data;

A32. Select prosthetic knee (only for TF): only for the case of TF amputees, the KBE system guides the user into the selection of the most appropriate prosthetic knee in relation to the previous selected foot;

A33. Select adapters: on the base of the patient data and the previous selection the system suggest the appropriate adapters to complete the prosthesis model.

A4.Assemble prosthesis

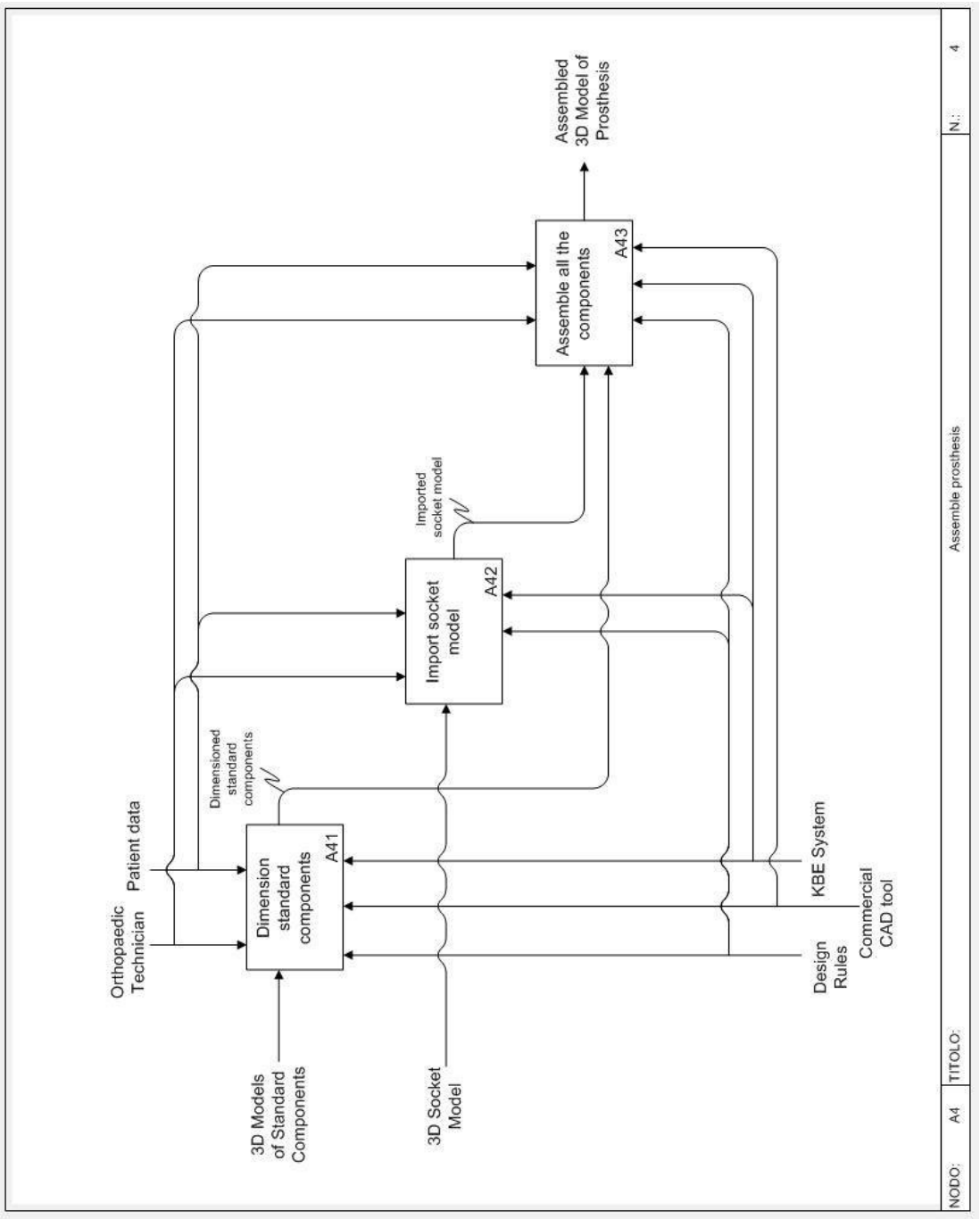

Figure 4.5: IDEF0 diagram of activity A4.

In this activity (see related diagram in Figure 4.5) it is assembled the virtual prosthesis model, in particular the standard components are appropriately sized on the base of the patient data, and it is imported the socket model previously created. This activity is consists of three principal operations:

A41. Dimension standard components: the standard components, selected in the previous activity, are automatically sized on the base of the patient data by the KBE system;

A42. Import socket model: the socket model, created and verified in A2, is imported to be assembled with the other components;

A43. Assemble all the components: the KBE system finally assembles all the standard components and the socket model and it is obtained the complete virtual prosthesis model.

The last activity A5. Virtual Test is still under study and development. In this activity the prosthesis model will be tested into a multi-body system to check the appropriate deambulation of the patient. If the results identify that it is necessary to modify it, the KBE system will come back to the previous activities and will perform different selections and decisions to obtain an optimized prosthesis.

Figure 4.6 shows the main difference between the traditional socket manufacturing process and the new one proposed. In the traditional process we have:

- Patient data are collected on a paper form;
- The stump model is acquired modelling a plaster cast;
- All the procedures are hand-made by the technician;
- It is necessary to create one or more check socket and then a definitive socket;
- The socket is tested directly on the patient;
- All the process knowledge is strictly correlated to the technician knowledge.

While in the new design process we have:

- Patient data are collected in an electronic sheet and are automatically managed from the system;
- The stump model is acquired as a 3D digital model;
- All the procedures is made in a virtual laboratory and guided step by step from the system;
- It is necessary to create only one digital model of the socket, which can be in any time modified;
- The socket is tested by FE system that check the virtual socket-stump interaction;
- All the process knowledge is integrated into the KBE system.

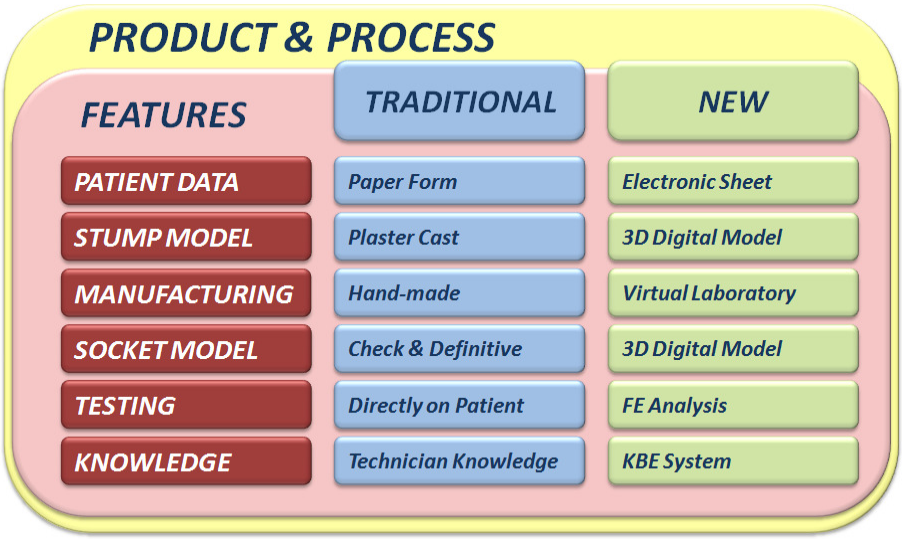

Figure 4.6: Scheme of difference between the traditional and the new design process.

4.2 – Framework architecture

On the base of the new design process it has been implemented a knowledge-based framework specifically conceived to support and guide the orthopaedic technician during the prosthesis development process providing rules and suggestions to execute design tasks. This framework integrates ad hoc tools for domain technical knowledge management both of product and process, virtual modelling of components both standard (e.g. pylons and tubes, prosthetic feet) and custom-fit defined directly on the body digital model or its parts, and tools for behaviour simulation (e.g. by means of FE and multibody techniques) to investigate component-human body interaction.
In particular the work developed in this thesis has regarded the part about the acquisition of necessary patient parameters, the rules applied for design socket, the modelling and selection of 3D standard components models, and the final prosthesis assembly.
Figure 4.7 shows the high-level architecture of the proposed framework. As shown the framework it is composed by three database:

- *Database of standard parts*: includes all the parametric 3D CAD models of most diffused standard components of TT and TF prosthesis, more details will be described in § 4.2.2;

- *Database of patients characteristics*: includes all the collected data of the patients characteristics, necessary for prosthesis design, saved in electronic sheets;

- *Database of stumps digital models*: includes all the 3D digital models of the acquired patients stumps (for further details on this procedure see § 4.2.3).

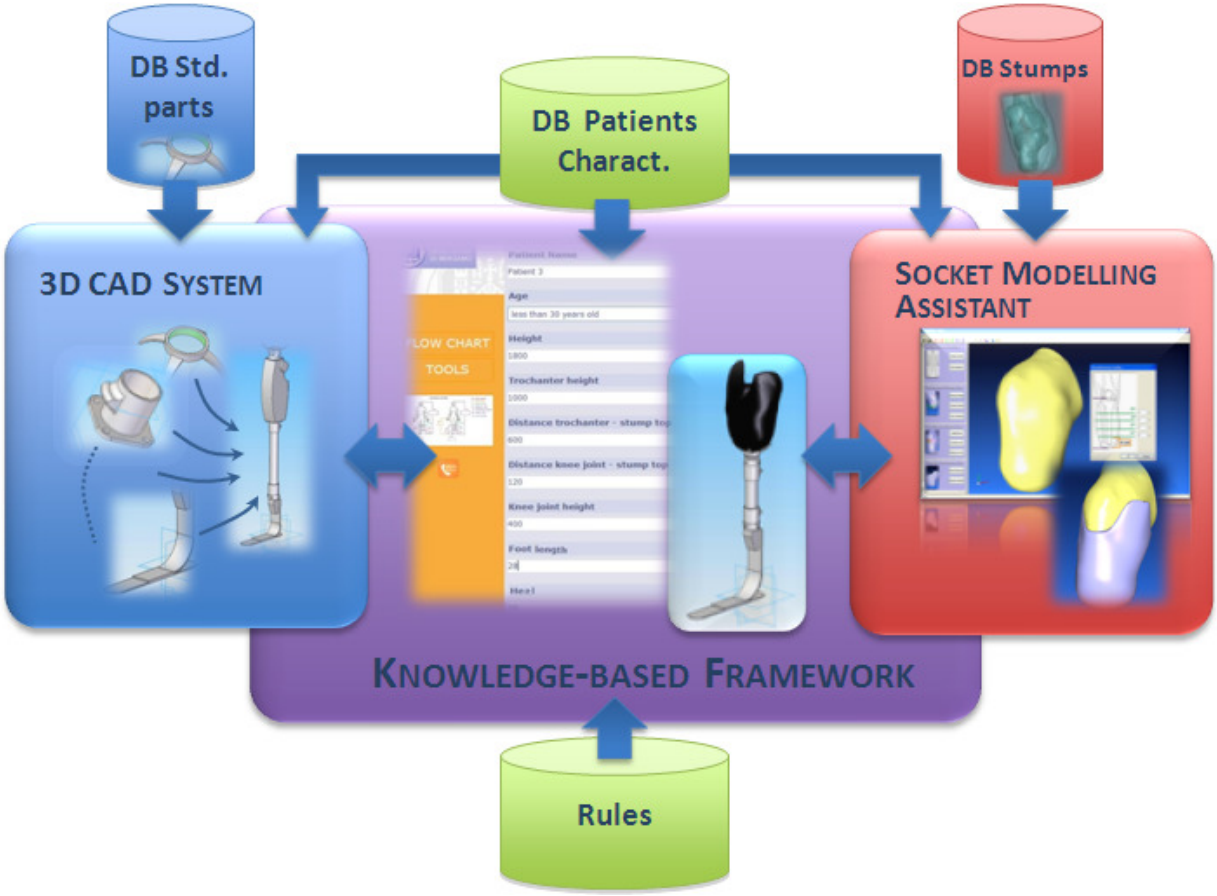

Figure 4.7: General architecture of the framework.

The framework has been realized using a commercial KBE system (Ruledesigner® Configurator [60]). A commercial 3D CAD system (Solid Edge Siemens PLM Software [61]) has been used to create the 3D parametric models of the standard parts and the final prosthesis assembly; while the Socket Modelling Assistant (SMA), has been implemented for the socket modelling. It provides a set of virtual tools that permit to virtually emulate the tasks traditionally performed by the technician.

In the following we are going to see more in detail the KBE system, the 3D CAD components, and the socket design phase, which is executed with Socket Modelling Assistant (SMA), kernel of the knowledge-based framework.

4.2.1 – KBE system

Knowledge management is a procedure well known in Design Automation and in all the phases of product lifecycle, such as manufacturing, maintenance, diagnostic, dismissing and so on [62-64]. KBE is an engineering method that represents a merging of object oriented programming (OOP), Artificial Intelligence (AI) techniques and computer-aided design technologies, giving benefit to customised or variant design automation solutions [65]. The

KBE systems aim to capture product and process information in such a way as to allow businesses to model engineering design processes, and then use the model to automate all or part of the process. The emphasis is on providing, informational complete product representations, captured in a product model. The product model represents the engineering intent behind the product design, storing the how, why and what of a design. The product model is an internal computer representation of the product design process and can contain information on both the product and processes that go to create the part. Attributes can describe geometry, functional constraints, material type and processes such as the methods required to analyse, manufacture and cost a part. The KBE product model can also use information outside its product model environment such as databases and external company programs. The ultimate goal of the KBE system should be to capture the best design practices and engineering expertise into a corporate knowledge base (see scheme in Figure 4.8). The KBE methodology should provide an open framework for formally capturing and defining the process of design creation [65].

To develop a KBE system we need to first acquire, represent, reason and then communicate the intent of the design process, Developing a KBE system is similar in nature to developing a solution in the design environment. The problem is first understood at a conceptual level, then decomposed into understandable working objects, developed further through an iterative process until a satisfactory outcome has been reached [65].

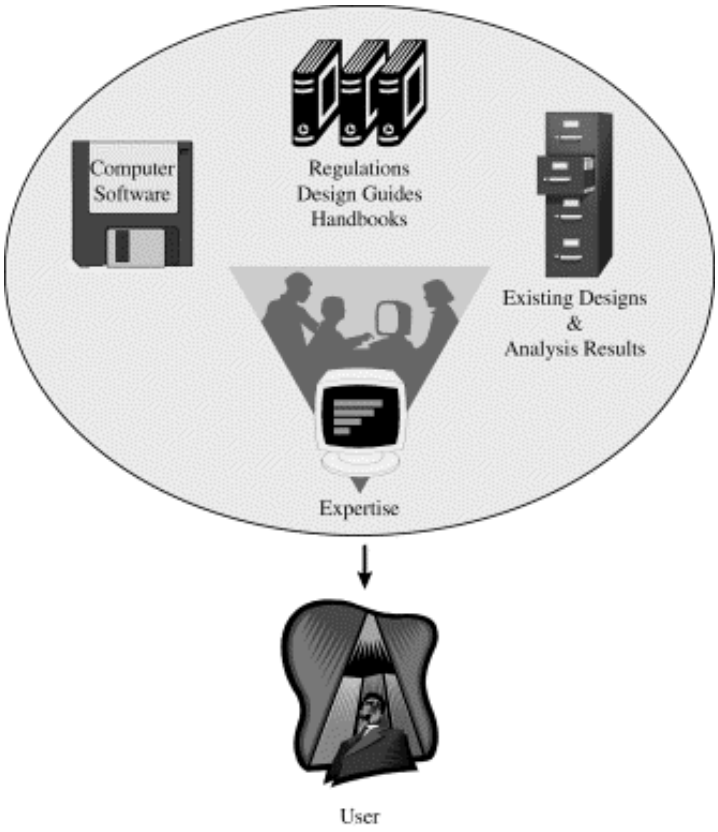

Figure 4.8: General scheme of a KBE system [65].

As previously said in the proposed frame work we have used a commercial KBE system, Ruledesigner® Configurator, which allows the rule-based development of systems that robotise complex processes in order to create products configuration, working cycles, bill of materials, CAD sets, drawing tables, handbooks and documents in a configurable structure [60]. Further detail on the use of this system into the new framework and its experimentation will be given in § 5.

4.2.2 – Database of standard components

For the creation of the database of standard parts we have used, as previously said, a commercial 3D CAD system (Solid Edge Siemens PLM Software [61]). We have first identified the most diffused standard components necessary to assemble a lower limb prosthesis (for further details see § 2.1 and 3.2) and then we have created the 3D parametric models of these parts. These models have not been realized performing a detailed modelling, since our purpose was to have principally functional models in relation to our aims: the correct virtual prosthesis assembly and sizing on the base of the patient data, and the future virtual test of the patient deambulation. For these motivations, the models created correspond perfectly to our needs.
In particular we have created 8 groups of standard components modules:

- *Socket module*: includes the socket adapters, in detail the 4-prong, the 4-hole, the woody, the male and female pyramid, the slim, and the 4-hole adapters, in detail the male and female pyramid, and the clamp (see examples in Figure 4.9);
- *Single adapter*: includes single male and female pyramid adapters (see examples in Figure 4.10);
- *Double adapter*: includes double male or female pyramid adapters heights (see examples in Figure 4.11);
- *Knee module (only for TF amputees)*: includes the monocentric and the polycentric knee (see examples in Figure 4.12);
- *Tube module*: includes male and female pyramid adapters for the tube, and the tube (see examples in Figure 4.13);
- *Foot module*: includes the foot adapters, tube insert and male pyramid (see examples in Figure 4.14), and the most diffused feet, in detail the C-spring, the sandwich and the low/high energy (see examples in Figure 4.15).

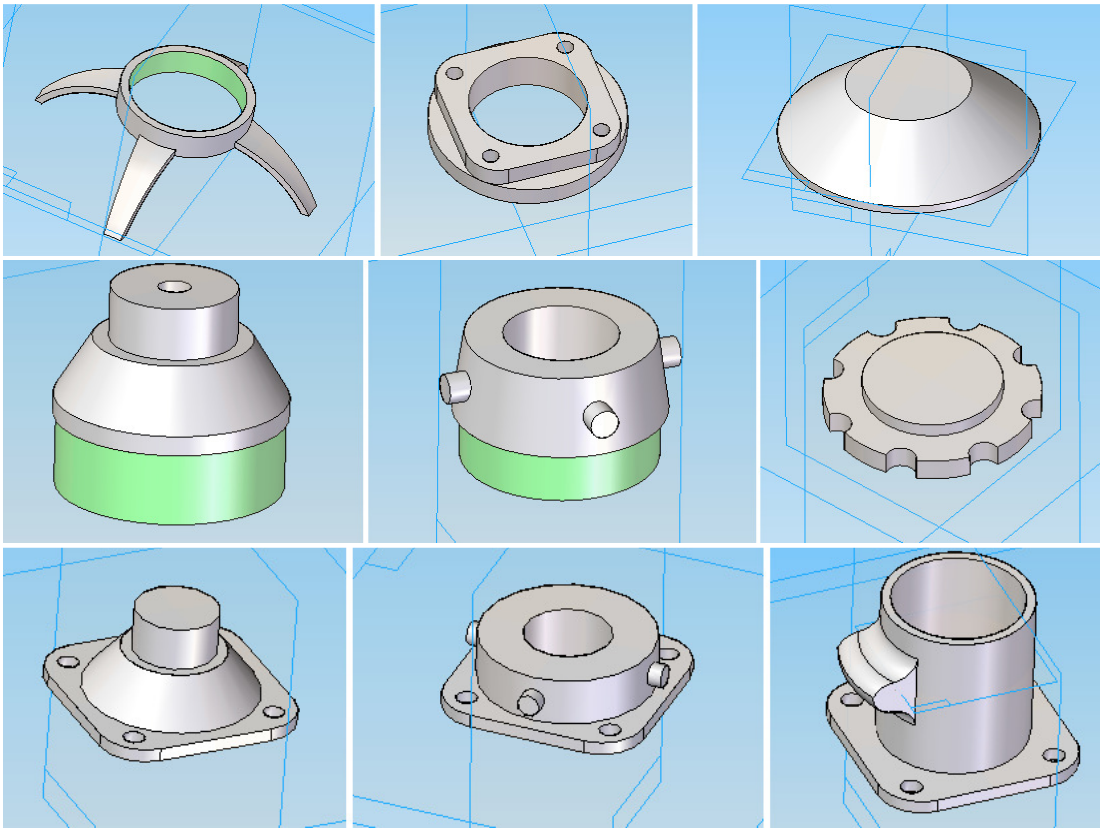

Figure 4.9: 3D CAD parametric models of socket adapters: in the first row the 4-prong (left), the 4-hole (centre) and the woody (right); in the second row the male pyramid (left), the female pyramid (centre) and the slim (right); in the third row 4-hole adapters: the male pyramid (left), the female pyramid (centre) and the clamp (right).

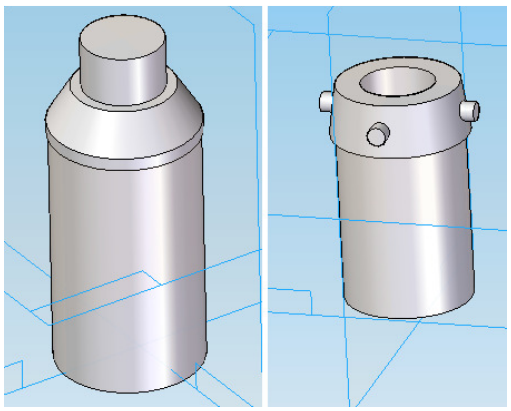

Figure 4.10: 3D CAD parametric models of single adapters: the male pyramid (left) and the female pyramid (right).

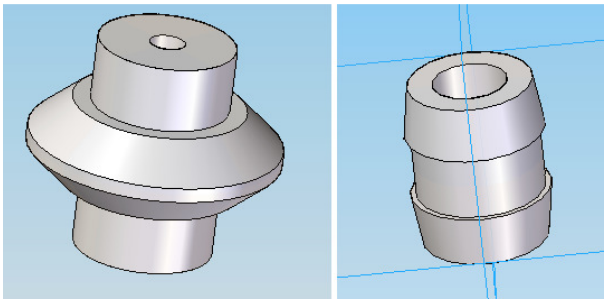

Figure 4.11: 3D CAD parametric models of double adapters: the male pyramid (left) and the female pyramid (right).

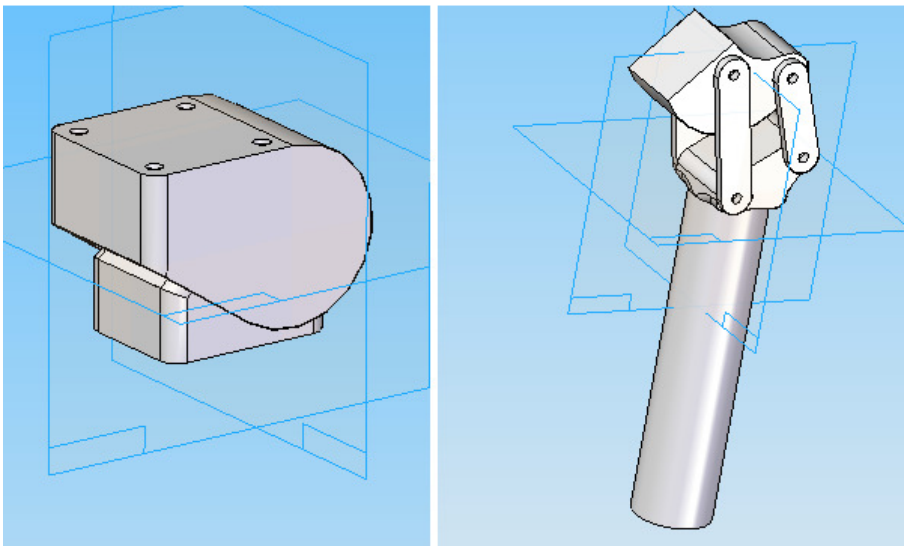

Figure 4.12: 3D CAD parametric models of knees: the monocentric (left) and the polycentric (right).

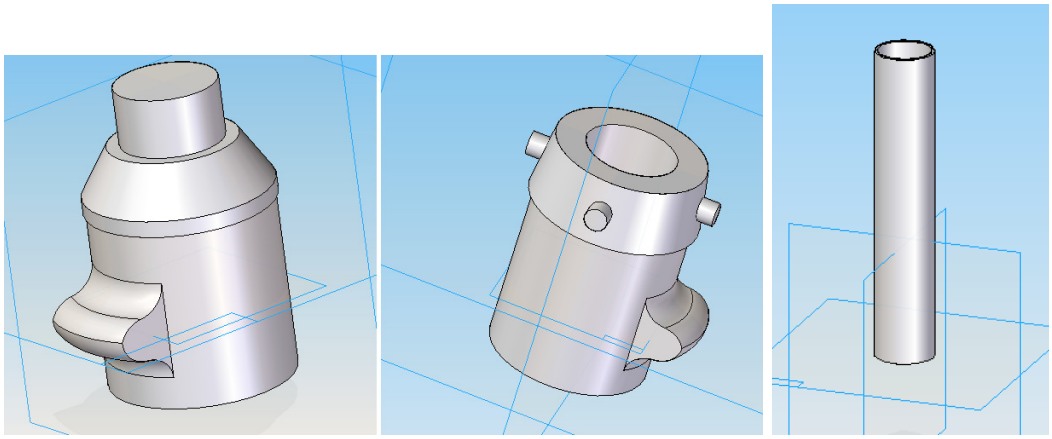

Figure 4.13: 3D CAD parametric models of clamps and tube: the male pyramid clamp (left), the female pyramid clamp (centre), and the tube (right).

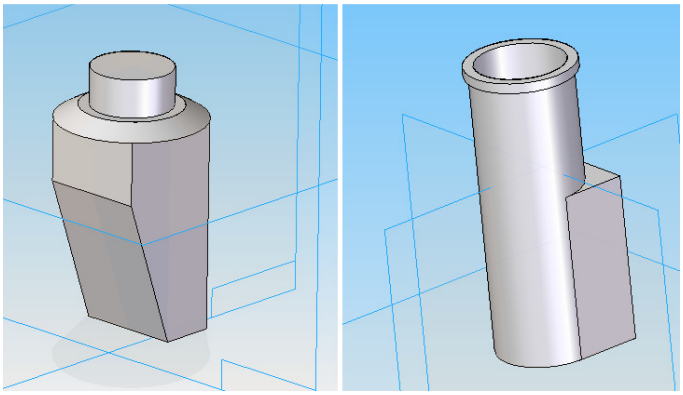

Figure 4.14: 3D CAD parametric models of foot adapters: the male pyramid(left) and the tube insert (right).

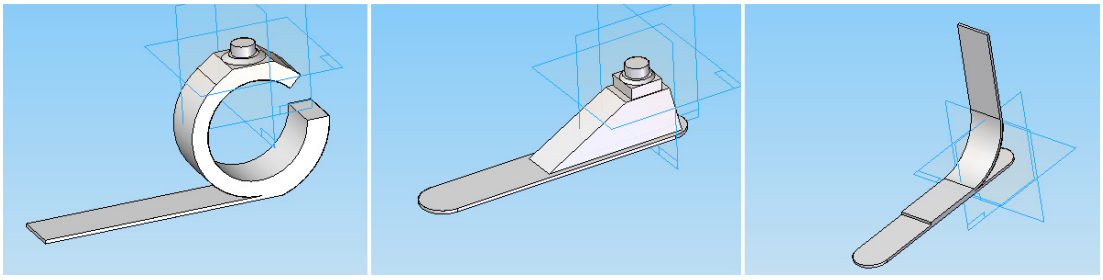

Figure 4.15: 3D CAD parametric models of most diffused feet: the C-spring (left), the sandwich (centre), and the low/high energy (right).

The dimensions of these components have been taken from real components and from data available on commercial catalogues. All these models are parametric, this means that on the base of the patient data the framework automatically select from the database the appropriate components and dimension them, following the rules described in § 3.2.

After this description of the standard models, in the following we will describe in detail the kernel of the KBE system, the SMA.

4.2.3 – Socket modelling assistant

The knowledge acquired has been implemented into the Socket Modelling Assistant (SMA), which is a virtual laboratory where the technician can work using virtual tools that permit to emulate the traditional procedures applied for socket manufacturing. The socket modelling tools have been specifically developed by VK Group at the Industrial Engineering Department of University of Bergamo. In SMA the socket design is centered on the data and on the digital model of the patient integrating the direct management of experts' knowledge in order to guarantee a high level of product quality and improve the amputee quality of life.
In this context SMA focuses on the process milestone, the socket design phase, where an excellent mastery of expert knowledge is necessary to realize a correct and functional product. In the Socket Modelling Assistant (SMA), the new design process (described in Figure 4.16) and the procedures to model the socket have been divided in 4 steps:

1) *Patient case history*: all the amputee data, related both to the general patient and to the detailed stump characteristics, are acquired;

2) *Preliminary modelling*: the patient stump digital model is imported into the system and a list of preliminary procedures is applied on it to prepare the model for the more distinctive operations made in the next step to reach the final socket shape;

3) *Customized modelling*: a sequence of manipulation procedures is applied to the model to be perfectly shaped on the patient taking into account the physical and morphological characteristics;

4) *Finalization modelling*: the last operations to finalize the socket model are applied and the model is finally ready to be exported into a FE system to check the interaction between the stump and the socket digital models.

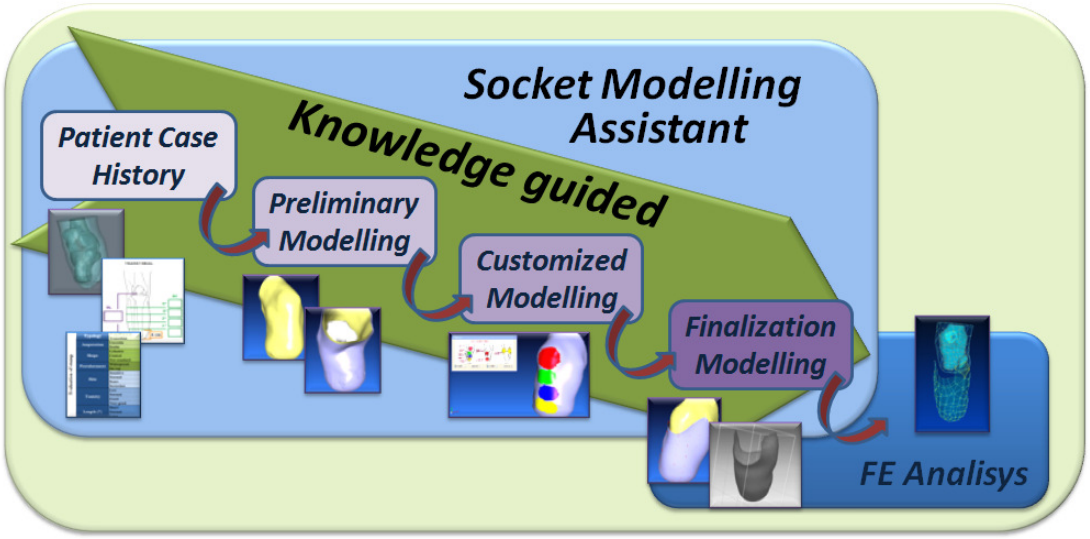

Figure 4.16: New socket design process implemented into the SMA.

This process requires, as said, a digital model of the stump. The digital model of the patient's residual limb is very important and its acquisition should be repeated anytime the patient needs a new socket. Normally this happens every 2 years, since the stump stands continuous morphological changes. The procedure consists of two steps: stump morphology acquisition and generation of the stump virtual model.

In previous national and international projects [62, 66-68], different equipments and RE techniques have been experimented to obtain a digital model, which includes both external shape and inner parts (muscles and bones). In particular, for the acquisition of the external shape, we have adopted a non-contact laser scanner (Minolta Vivid VI-9iTM). For the internal parts, we have considered Computer Tomography (CT) for bones and Magnetic Resonance Imaging (MRI) for soft tissues and muscles. For further details on human morphology acquisition techniques see § 1.2.2. Moreover, a specific protocol has been followed to ensure

the repeatability and accuracy of patient posture positioning and the post-acquisition data alignment (for further detail see [59]).
Regarding stump virtual model, a tasselled (STL) geometric model and a NURBS surface model have been reconstructed. The skin model has been generated from the laser point cloud, which guarantees a high quality of morphological details, absolutely necessary for the simulation of stump-socket interaction. While for bones, soft tissues, and muscles, models have been obtained from CT and MRI images. Finally, the three different models are aligned using reference markers adopted during the acquisition phase. An example of stump digital model is shown in Figure 4.17.

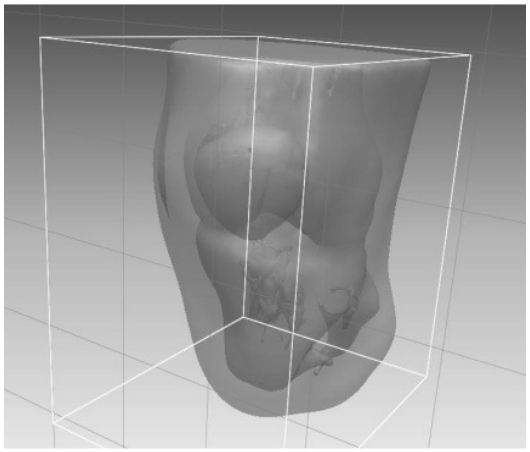

Figure 4.17: The digital model of a stump.

After the acquisition of the stump model, we can move to the SMA. This system has been developed in C++ language. The 3D geometry visualization has been created using graphics API OpenGL, while the user interface has been implemented with Microsoft Foundation Class (MFC) framework. The software is object-oriented, and in particular it has been created a family of tools to allow the addition of new functionalities in a more efficient way. Figure 4.18 portrays the mind map [51-52] of the software architecture. In detail, The `BaseDoc` class manages all the application work flow; within the frame work it is hosted a `SceneManager` class instance, which contains all the functionalities to create and to import 3D objects into the scene, modelled by `Object3D class` instances. Besides the `BaseDoc` class contains the `ToolManager` class, which manages all the tools set for `Object3D` objects deformation and connects the active tools with the `SceneManager` objects. The `BaseDoc` class gives also the rendering data to the 3D visualization class, `OpenGLView`, and manages the user input flow. The patient data and variables calculated and used during the virtual socket creation (e.g. scaling measurements, offset measurements, etc.) are managed by a module inside the `BaseDoc` class. The `Object3D` class represents the 3D objects of the application (e.g. residual limb and socket); geometry can be polygonal or NURBS (`PolyObject` and `NurbsObject sub-class`), depending on the used type of 3D model manipulation. There are two conversion class between NURBS and polygonal objects, called respectively `NurbsToPolyConverter` and `PolyToNurbsConverter`. An

`Object3D` object can use an auxiliary class, called `Markers`, which allows setting zones on the geometric model zones that should be deformed according to patient characteristics.

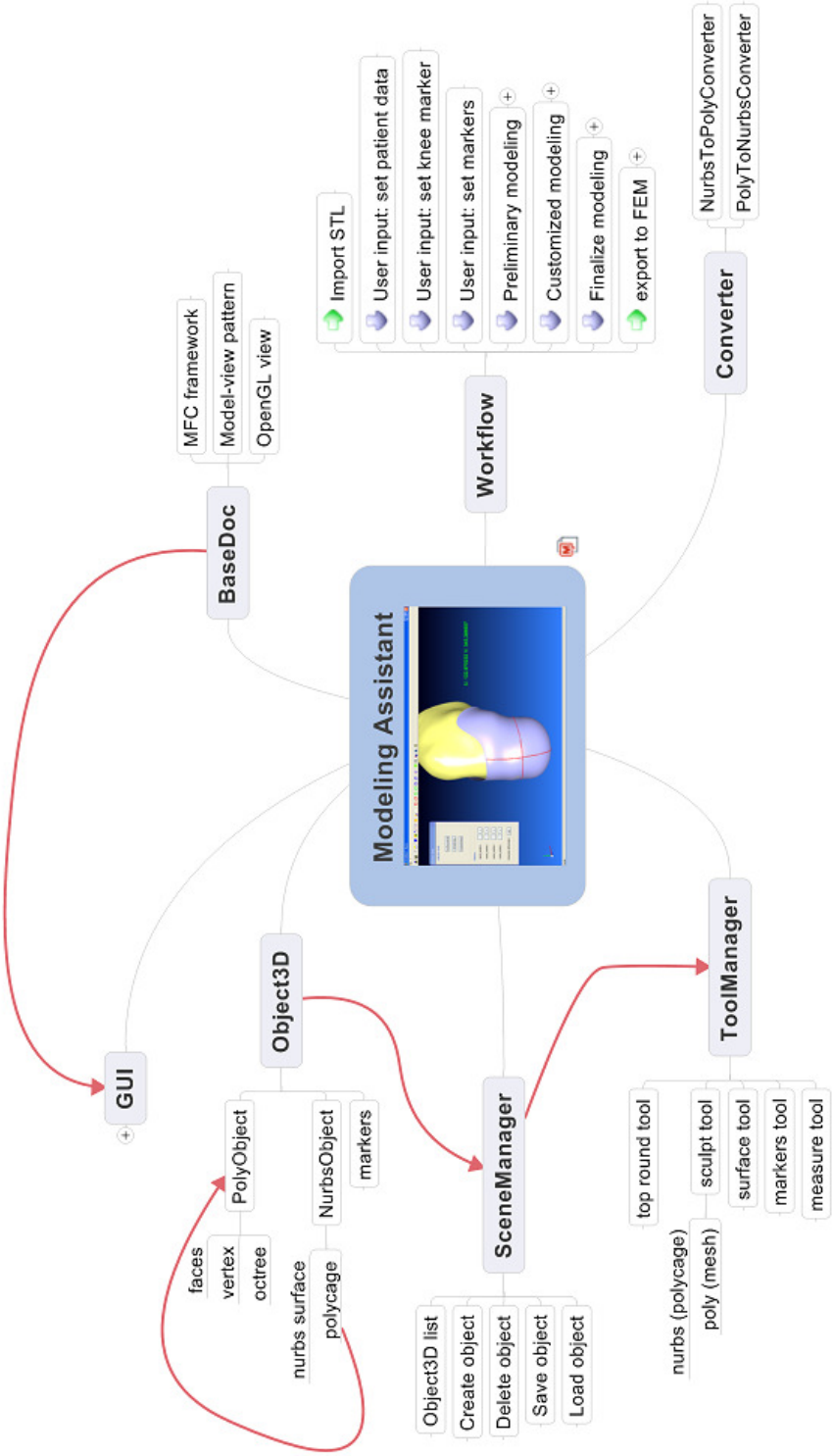

Figure 4.18: Mind map of the SMA architecture.

Figure 4.19 shows the user interface. In the upper part there is a toolbar, which allows selecting the available tools divided into: file management, preliminary modelling, customized modelling, finalization modelling, visualization tools and help. It is shown also an example of the workflow wizard, which guides the user step by step during the socket design process.

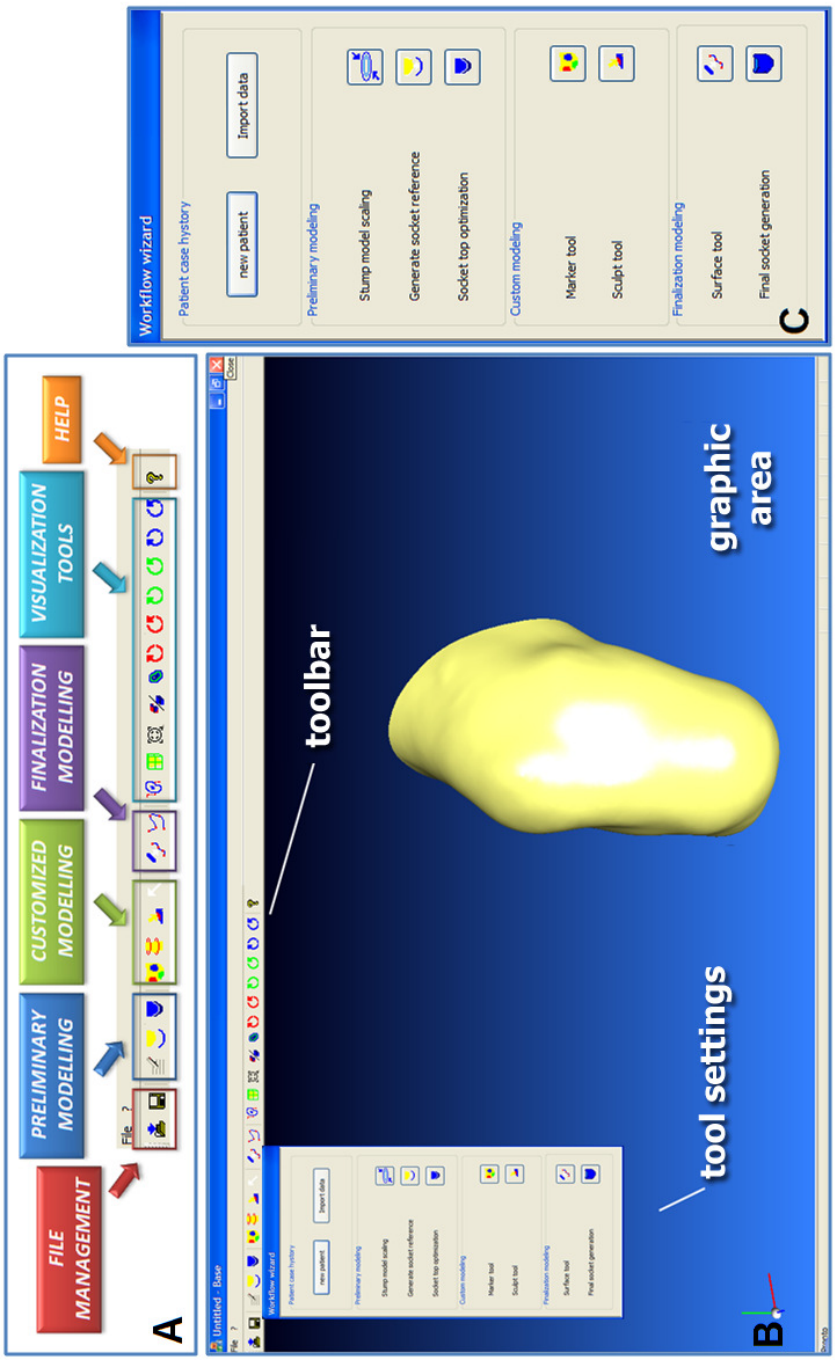

Figure 4.19: The SMA user interface: the toolbar (A), the graphic area (B), and the workflow wizard (C).

Chapter 5

Experimentation

The system has been experimented in two different phases: first the procedure to select the standard components have been verified with the technical staff of the orthopaedic laboratory involved into this work; then we have considered the configuration of two test-cases: a transtibial and a transfemoral amputee. For both cases we have acquired the stump digital model and we have configured the virtual prosthesis model. We briefly illustrate the steps for the configuration of the lower limb prosthesis:

1 *Enter patient characteristics*: first the user has to enter the patient data requested by the system, such as age, weight, etc. All this information is necessary for the following selection of components and assembly of the prosthesis;

2 *Import Socket Model*: the socket is created using the SMA module and stored into the stumps database. Then, it is imported into the present patient case to be subsequently assembled with the other components;

3 *Select standard components and assemble prosthesis*: on the base of the data entered into the system, it automatically suggests the most appropriate components for the patient case and finally assemble the prosthesis.

In the following we are going to see more in detail the experimentation of the selection procedures, and the two basic study cases, a transtibial and a transfemoral prosthesis.

5.1 – Rules and procedures validation

Once elaborated the rules for the standard components selection on the base of the patient data and automated the procedure using electronic sheets (for further detail see § 3.2), we have tested the procedure on 10 amputee cases (5 transtibial and 5 transfemoral) and verified the results with the orthopaedic laboratory. Figure 5.1 shows the parameters of the 5 transtibial test cases and the obtained results, while Figure 5.3 shows the 5 transfemoral ones. In particular in the first column there are the patient parameters, in the second one the results calculated by the system, and in the last column there are the technicians components selections.

TRANSTIBIAL		SYSTEM	TECHNICIAN
PATIENT WEIGHT	50	HIGH ENERGY	HIGH ENERGY
LIFE STYLE	4	C-SPRING	3-POINTS
STUMP LENGHT	3		C-SPRING
PATIENT FORCE	2		
PATIENT WEIGHT	73	HIGH ENERGY	SANDWICH
LIFE STYLE	3	SANDWICH	HIGH ENERGY
STUMP LENGHT	3	C-SPRING	
PATIENT FORCE	3		
PATIENT WEIGHT	80	SANDWICH	SANDWICH
LIFE STYLE	2	3-POINTS	3-FOILS
STUMP LENGHT	3	LOW	C-SPRING
PATIENT FORCE	2	3-FOILS	
PATIENT WEIGHT	65	SANDWICH	3-FOILS
LIFE STYLE	1	3-POINTS	C-SPRING
STUMP LENGHT	2	LOW	
PATIENT FORCE	1	3-FOILS	
PATIENT WEIGHT	110	SANWICH	C-SPRING
LIFE STYLE	2	3-POINTS	HIGH ENERGY
STUMP LENGHT	2	3-FOILS	
PATIENT FORCE	3	LOW	

Figure 5.1: Parameters of the 5 TT amputees cases used for the experimentation and related results.

For each patient we had the four parameters necessary for the selection of the standard components: the patient weight [kg], the level of life style (1, 2, 3 or 4), the stump length (1=short, 2=normal, 3=long)), and the level of the patient force (1, 2, 3 or 4). Once acquired these data, the system automatically provides the selection of the most appropriate prosthetic feet for all the cases, and the most appropriate knees for the 5 transfemoral cases. The system could provide as results from 1 to 4 feet, and knees from 1 to 3 for each patient.

TRANSFEMORAL		SYSTEM	TECHNICIAN		SYSTEM	TECHNICIAN
PATIENT WEIGHT	52	HIGH ENERGY	3-FOILS		MONO HYDRAULIC	POLY PNEUMATIC
LIFE STYLE	4	C-SPRING	LOW		MONO SELFBRAKE	
STUMP LENGHT	1	SANDWICH				
PATIENT FORCE	4					
PATIENT WEIGHT	105	SANDWICH	C-SPRING		POLY PNEUMATIC	MONO SELFBRAKE
LIFE STYLE	2	3-POINTS	SINGLE AXIS		POLY IDRAULIC	POLY IDRAULIC
STUMP LENGHT	2	LOW	FOAM			
PATIENT FORCE	2	FOAM				
PATIENT WEIGHT	85	SANDWICH	3-FOILS		MONO HYDRAULIC	MONO HYDRAULIC
LIFE STYLE	2	3-POINTS	3-POINTS			
STUMP LENGHT	1	LOW	C-SPRING			
PATIENT FORCE	3	3-FOILS				
PATIENT WEIGHT	78	HIGH ENERGY	HIGH ENERGY		MONO PNEUMATIC	MONO HYDRAULIC
LIFE STYLE	3	SANDWICH	3-POINTS		MONO HYDRAULIC	
STUMP LENGHT	3	C-SPRING	3-FOILS		MONO SELFBRAKE	
PATIENT FORCE	3					
PATIENT WEIGHT	1	3-POINTS	SINGLE AXIS		POLY SELFBRAKE	POLY PNEUMATIC
LIFE STYLE	2	LOW	FOAM		POLY PNEUMATIC	POLY SELFBRAKE
STUMP LENGHT	3	FOAM			POLY IDRAULIC	
PATIENT FORCE	1	3-FOILS				

Figure 5.2: Parameters of the 5 TF amputees cases used for the experimentation and related results.

After this we submitted to the orthopaedic technicians the same 10 test cases, asking them to select the most appropriate components for each patient on the base of their personal knowledge.

Finally we have compared the results obtained with the system and the selections proposed by the technicians. The results of the comparison were quite good, since we obtained an elevate correspondence of the results. Besides the technicians appreciated the automated procedure and validated the good results of the system. The test cases, for which we didn't find an appropriate correspondence of the results, were explained from the fact that some patient characteristics are not quantifiable. For example, for a middle-aged patient in good health but not motivated, a less performing prosthesis is preferred since it would be easier to use, shortening the training time.

For this and other reasons, it is not possible to integrate into the system all the possible factors of a patient case, but only the most common and quantifiable ones.

5.2 – Transtibial case

We are going to describe the study case of a transtibial amputee following the steps previously indicated.

1 ENTER PATIENT CHARACTERISTICS

First the user enters into the system the patient data necessary to configure appropriately all the components and model the socket. Figure 5.3 shows the user interface with the a part of the patient data values entered by the technician. In this case, they are related to the transtibial amputee case study. The complete list of data required by the system have been described in detail in § 3.1.
Once entered this data, the system automatically saves them into an electronic sheet, which is stored into the patients characteristics database. This information will be used from the system for the socket modelling, the standard components selection and the final assembly of the prosthesis. Next step consists in modelling the socket.

Figure 5.3: User interface with entered patient parameters.

2 IMPORT SOCKET MODEL

At this point the system automatically opens the SMA module and the user can design the socket model directly on the patient stump digital model (for further details see § 4.2.3). Once the 3D socket model is ready it is automatically saved into the stumps database and imported into the configurator. In the following we describe the mentioned steps of the new socket design and the system functionalities applied into the SMA. For each step we illustrate

how each procedure is done in the traditional process, and how instead they are executed with the new module and which new functionalities have been added to the process.

1) Patient case history

The first step consists in collecting patient case history. The patient characteristics are necessary in the next phases to apply rules and/or suggest the most appropriate procedures to the user during each step of the socket design process. For example, the socket must be tighter for young or recently amputated patients, since the muscles and the body in general are still strong and tonic. Instead, for old amputated patients, where the muscles and the body are not anymore fully efficient, the socket needs to be looser and not too much tight to allow an easier deambulation or physical therapy. Besides, on the base of the patient daily activities, s/he needs different behaviours from the prosthesis. For example, a young amputee, who is always on the go, needs a held socket but also quite loose; while an older patient, who just walks short itineraries every day, needs a looser socket, but also a more self confident prosthesis.
We have elaborated the data , which influence the whole prosthesis design process, detailed described in § 3.1. All this information entered in the system substitute the paper form used in the traditional process to collect the patient case history and are used to guide the technician in an appropriate socket realization following the same rules applied during the traditional process.

2) Preliminary modelling

The aim of this phase is to generate a preliminary geometric model of the socket on which the technician will apply afterward other specific modifications to reach the final socket shape. It is constituted by a sequence of operations executed in automatic or semi-automatic way on the base of the patient characteristics, collected in the previous phase. After having imported the stump digital model composed by skin, muscles and bones, three main operations are carried out: stump model scaling, generation of socket reference surface and socket top optimization. In the following we briefly describe mentioned procedures.

- *Stump model scaling*

In the traditional process the first operation applied on the stump positive plaster cast is the rasping procedure to reduce the stump volume. This is done since the socket, manufactured directly on the positive model, has to be perfectly close-fitting on the patient's residual limb. In particular the technician first identifies on the plaster cast the same reference circumferences previously measured on the patient's residual limb, and then starts to file harmoniously the plaster until these circumferences are reduced of the desired percentages. From the analysis of the technician work, we have identified the percentage values for this operation (for further details see § 3.3.2). The range of percentage varies from 1% to 6%. It is not uniform on the stump, but it starts with 1% at 4 cm over the stump top, and it increases gradually going up until the stump upper part. For example for a tonic stump and a patient

very active, the reduction is low since the muscles are strong (e.g. for a young amputee, dynamic and without particular disease, the reduction starts from 1% until to 2%).
For this procedure the system first identifies the socket top, calculating the lowest point of the geometric model. Then, starting from this point, the system selects 4 reference circumferences at a distance of 4 cm from each other. For each of the 4 sections it is calculated the middle point and then the distance of each circumference point is scaled by the appropriate percentage. All the other sections situated between these 4 reference ones are scaled by interpolated values, in relation to their position on model. Figure 5.4 portrays this procedure: the system shows a mask with the proposed percentage values for the 4 reference circumferences; the user can accept these values or modify them, and then the system automatically scales the model.

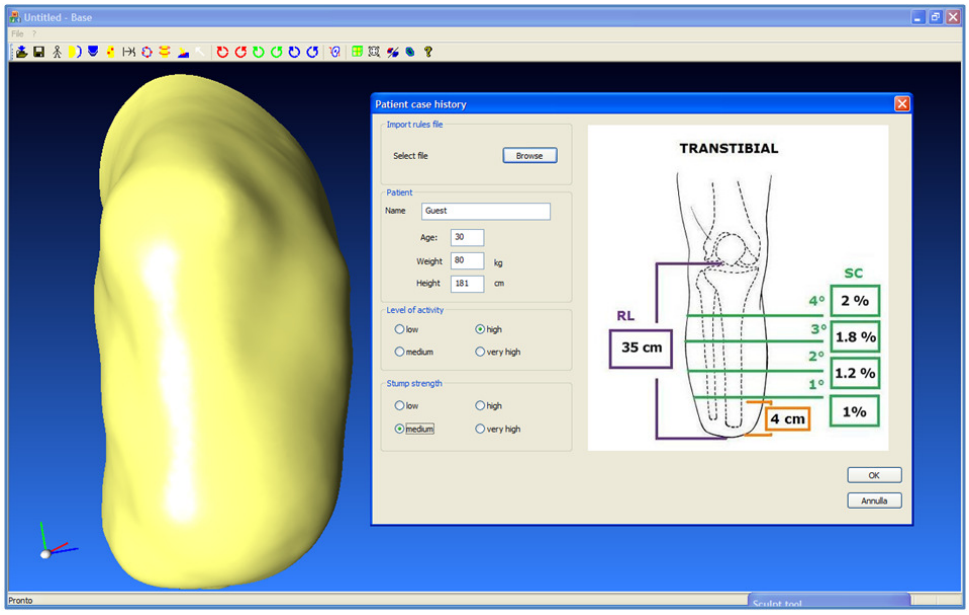

Figure 5.4: Example of suggested values for the stump model scaling.

- *Generation of socket reference surface*

Once scaled the model, the system automatically realizes a reference socket surface creating an offset with constant distance from the previously modified stump geometry. Figure 5.5 shows an example of the generated offset surface. This surface constitutes the socket internal surface and will represent the starting point for the customized modelling.

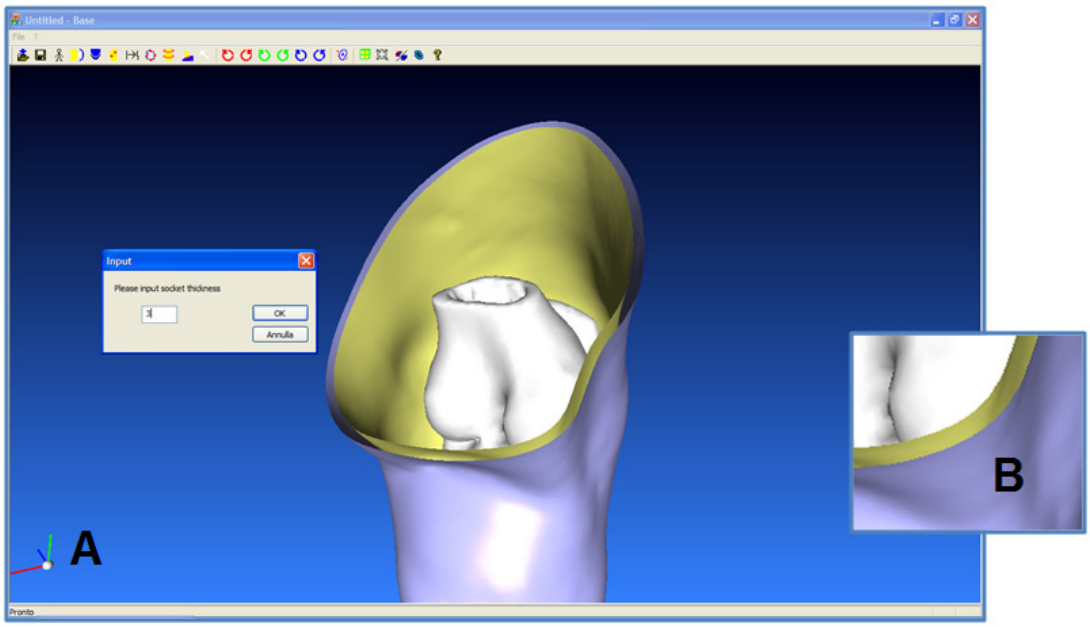

Figure 5.5: Example of the suggested offset distance (A) and a detail of the generated offset surface (B).

- *Socket top optimization*

An important procedure applied in the traditional process is to make round the low extremity of the positive plaster cast. Since normally the stump top has an irregular shape due to bone protuberances and scars, the orthopaedic technician creates a smooth and rounded area around the cast top, so that the model has a more functional shape with a view to wear the liner. This step is automatically executed from the system, which modifies the socket surface but not the stump model. Figure 5.6 portrays the socket top before the optimization (A), after the optimization (B) and an internal view of the stump inside the optimized socket (C). This operation can be also set up manually indicating the starting point for the rounding.

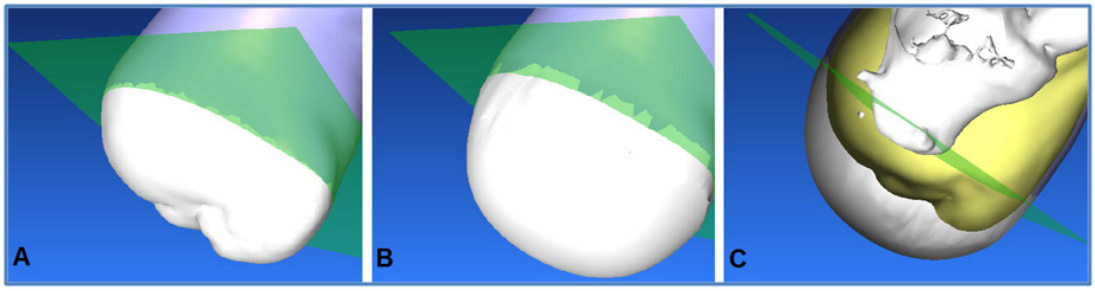

Figure 5.6: Example of automatic socket top before the optimization (A), after (B) and the optimized socket with the internal stump (C).

After these preliminary operations, the model is ready for a more detailed socket modelling phase.

3) Customized modelling

This is the most important and critical phase of the whole process. Here the socket model is shaped directly on the stump digital model to be perfectly customized on each specific patient's anatomy.
In the traditional process the technician first identifies with markers the areas on the positive model , which have to be modified and then starts to modify these zones adding or removing plaster . All information about these procedures has been given in § 3.3.
For these procedures we have implemented two different tools: *Marker tool* and *Sculpt tool*. These tools simulate respectively the traditional operations of:

a) *Marker tool*: highlighting the critical zones with pencils and adding/removing different coloured plaster in these zones;

b) *Sculpt tool*: adding plaster by a slice or removing plaster by a rasp.

Besides Marker tool allows the user to apply the modifications in automatic way, since it is the system itself suggesting the most appropriate levels of addition or removing plaster. While with Sculpt the user can freely manipulate the model and decides the level of modification. In the following we will briefly describe the mentioned tools.
In the Socket Modelling Assistant the areas on , which the technician has to work are suggested by the system and they can be highlighted using coloured pencils: these operations are allowed from the *Marker tool*. Figure 5.7 shows the automatic highlighting of the critical zones with different colours (left) and the window with the suggested areas (right). Once determined the zones, the system automatically modifies them on the base of the patient weight and muscles tonicity, as previously cited.

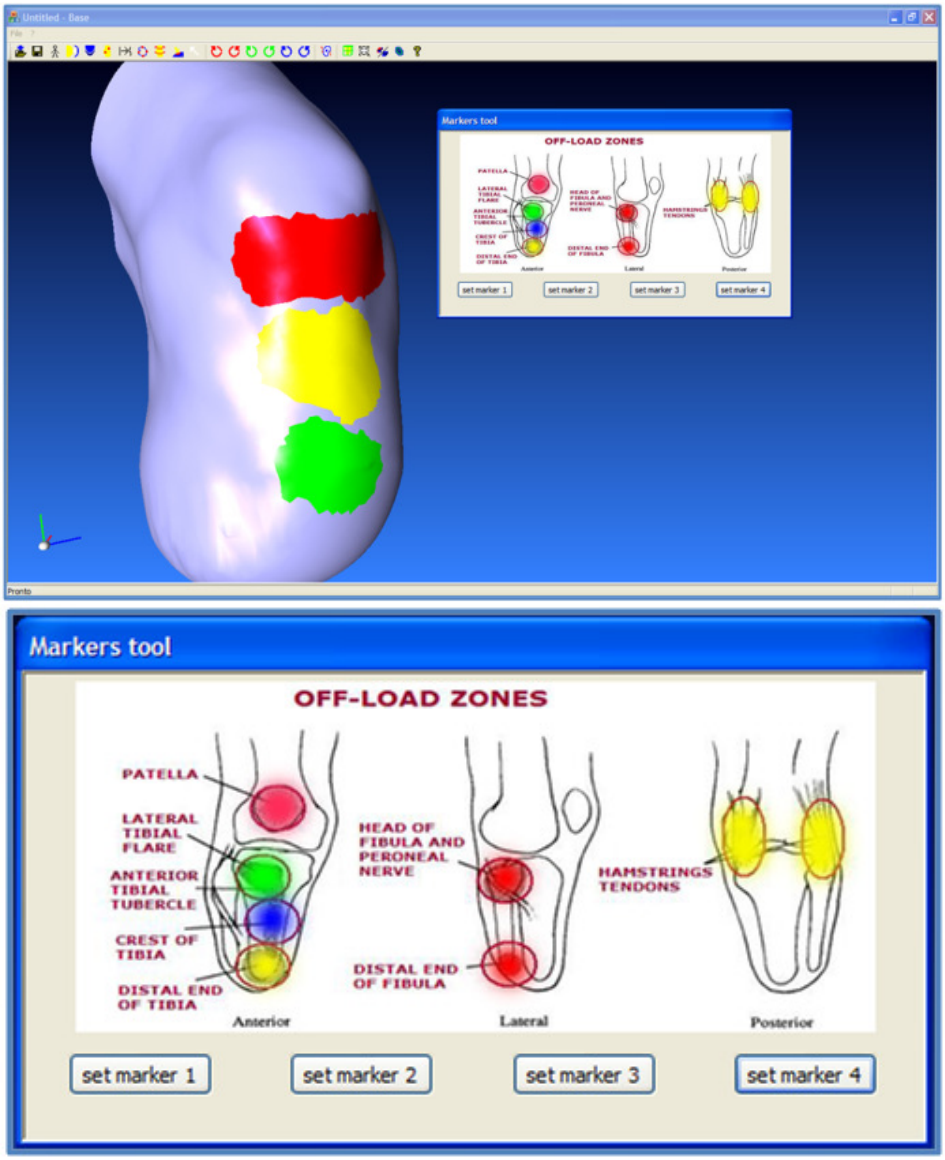

Figure 5.7: Example of Marker Tool functionalities: highlighting the critical zones (above) and a window with the suggested areas (below).

The other tool to apply or removing material in a semi-automatic and interactive way is *Sculpt tool*. Sculpt tool is a virtual utensil , which can slide on the socket surface, and can push and pull this surface, simulating the action of adding or removing plaster. The dimension of the cursor working area can be modified manually by the user. Figure 5.8 shows how this tool works: there is a mask , which allows the user to choose between push or pull operation, the force applied from the cursor, and the dimension of the cursor itself. It is very similar to the real tools used by technicians in the traditional process to manipulate the plaster cast.

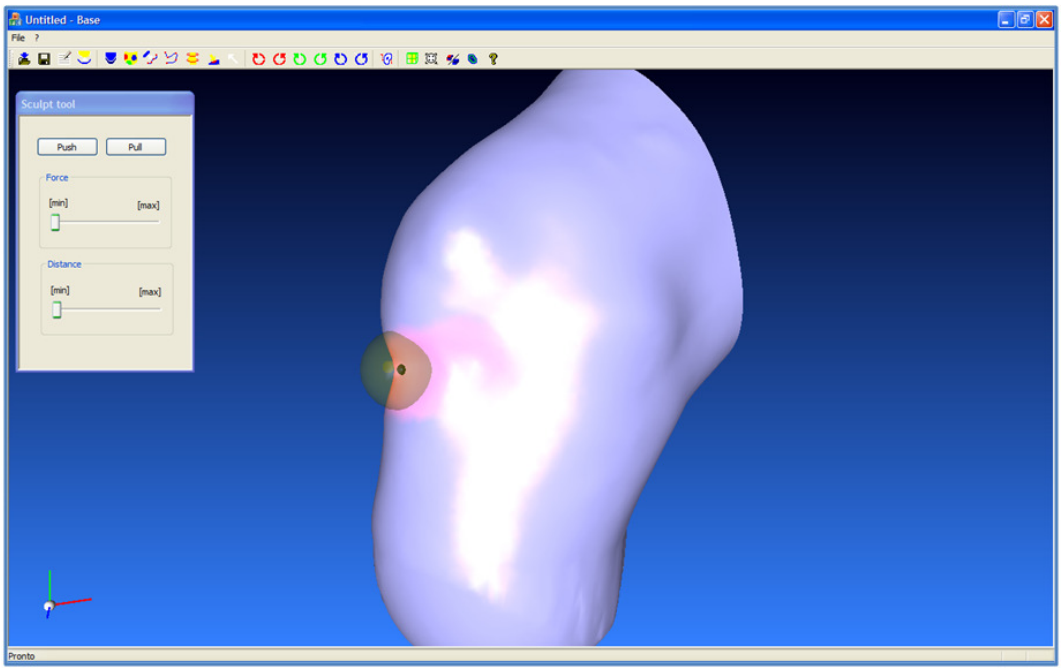

Figure 5.8: Example Sculpt tool functionalities.

The user can move the cursor everywhere on the virtual socket surface: the correct coordinate where to position the cursor is identified by the system through an intersection test between all the geometry polygonal faces and a line perpendicular to the surface, whose point of departure is the mouse arrow. The 3D point, on which the line crosses a polygonal face, coincides with the sphere centre of Sculpt tool. The virtual socket faces are organised in an Octree hierarchical space to optimize the intersection tests.
In the deformation phase first a test is performed to check which faces are inside the range of the sphere cursor; then the average of the internal faces normal vectors is calculated. Finally the internal faces vertexes are moved along the average normal vector, of a length inversely proportional to the distance from the sphere centre. This displacement can be positive or negative, in correlation to the different modalities “push” (vertexes moved inwards) or “pull” (vertexes moved outwards).
Once the technician has finished modifying the critical zones, the socket model is ready for the finalization procedures.

4) Finalization modelling

In the traditional process, after all the operations applied on the positive plaster cast, the technician creates directly on this model the socket. After the customized modelling, the socket model has to be finalized moulding the upper edge and giving a final thickness to the model. For the last operations there is available a tool named *Surface tool*.
This one allows the user to obtain really smooth and harmonious deformations, since it permits to act on the single surface control points of the model. It can work on different

sections of the model, both horizontal and vertical. Moving the control points, the surface is modified in a homogenous way and it is also possible to scale the surface in the different sections. It is also present a function, which avoids that the control points can penetrate inside the socket shape, while it is allowed to enlarge it outwards. With this tool the user can model the socket upper edge. Figure 5.9 illustrates how Surface tool works where the user can choose to act on the surface (left) or on horizontal and vertical sections (right). This tool permits also to measure the socket dimensions.

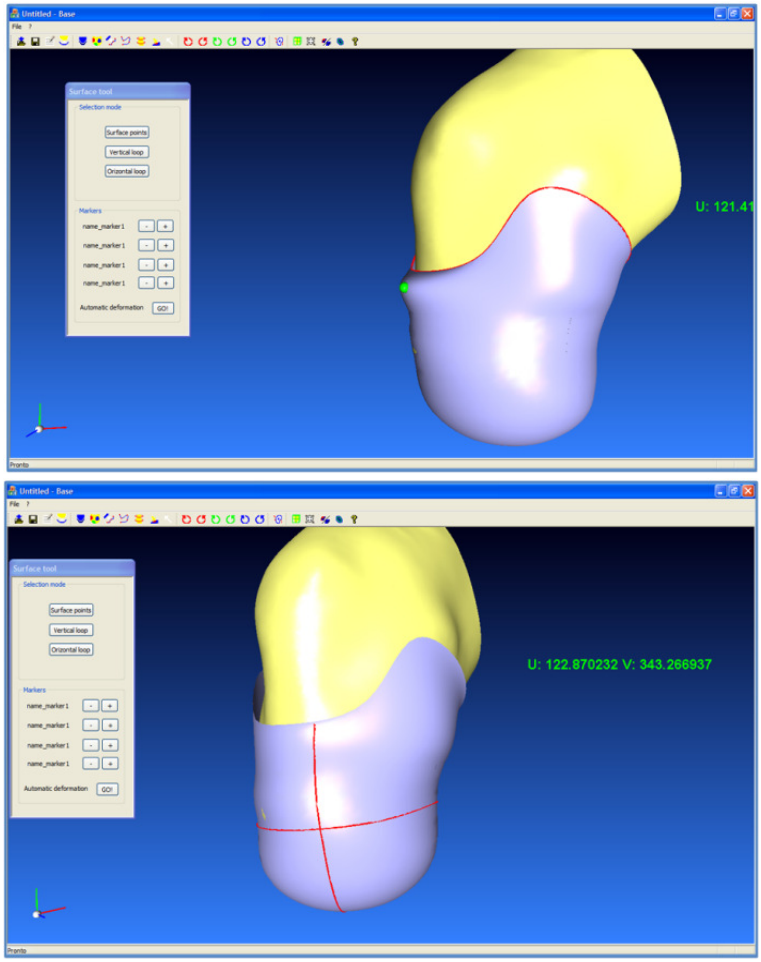

Figure 5.9: Example of Surface tool functionalities: moving the surface control points (above) and acting and measuring different sections (b.

The operation of socket thickening is automatically executed by the system creating a surface offset outwards. This generated offset surface represents the socket external surface and the offset distance is the final socket thickness. Such as in the traditional process, the distance value is decided in relation to the patient weight: more is the weight, more is the socket thickness. Usually it goes from 2 mm until 6 mm. Figure 5.10 shows the final socket model with the generated offset external surface.

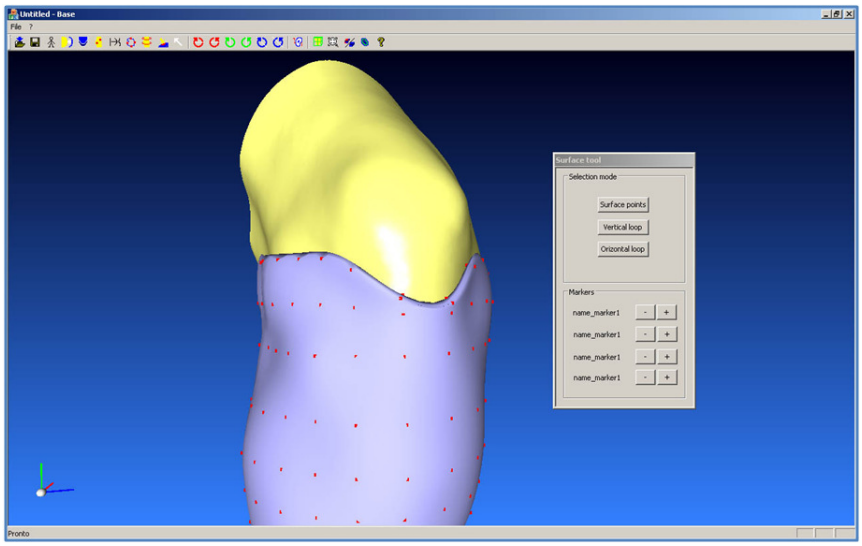

Figure 5.10: Example of a definitive socket model.

The geometric model of the socket together with the stump one could be exported into a FE system to analyse the interaction between the stump and the socket. An example of the exported model is shown in Figure 5.11.

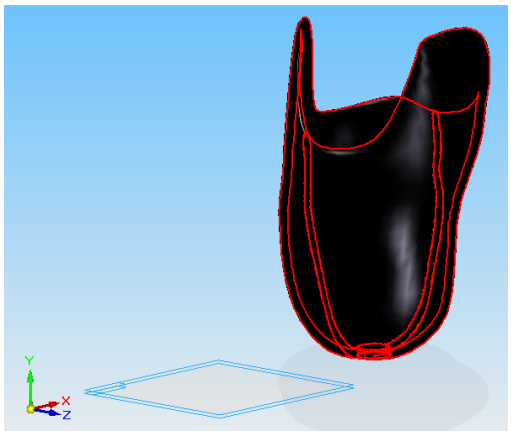

Figure 5.11: Example of TT virtual socket model.

3 SELECT STANDARD COMPONENTS AND ASSEMBLE PROSTHESIS

On the base of the patient data previously entered, the user, guided by the framework, can move to the selection of the commercial components and the system can automatically size them (for further details on this procedure see § 3.2).
For example, for the transtibial amputee, the foot is the first component to be selected. On the basis of the patient data, the system proposes a list of the prosthetic foot typologies , which are most suitable for the specific patient.

Figure 5.12 shows an example of the list of suitable foot typologies: three different carbon fibre feet with energy storage and release. Since each of them has different properties, the configurator shows a diagram with all the basic characteristics of the three models; in this way the user can select the most suitable one.

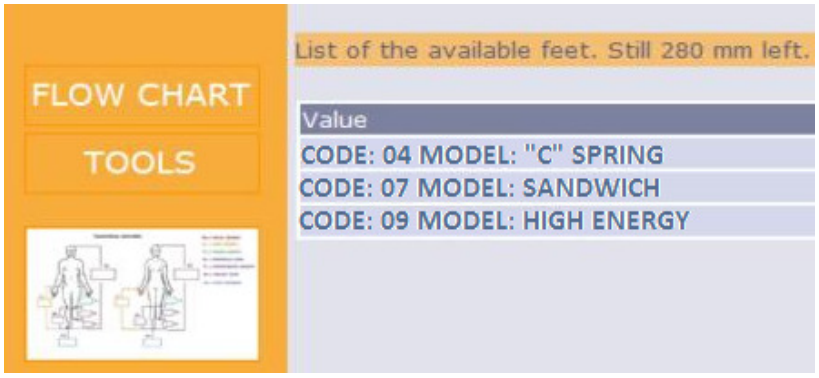

Figure 5.12: List of proposed prosthetic feet.

Once selected the proper foot, the system proceeds to the selection of other components, from the possible adapters that can be connected to the selected foot (e.g. male or female pyramid, or clamp) to other ones composing the prosthesis, as previously described in § 3.2. Figure 5.13 shows an example of the list of assemblable adapters for a High energy prosthetic foot with a Male pyramid adapter.

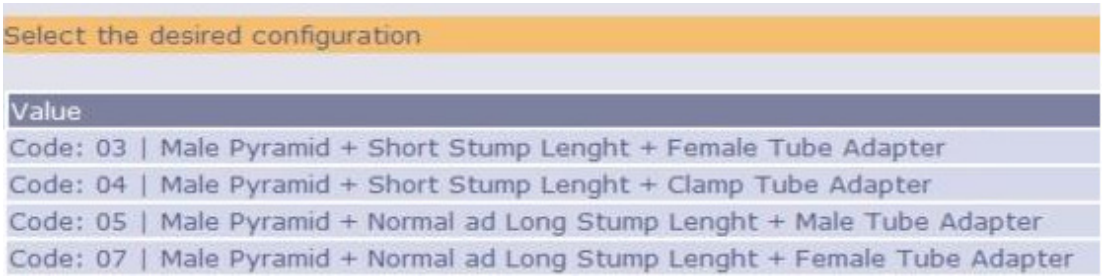

Figure 5.13: List of possible adapters for a High energy foot.

For example, the first row suggests for the specific foot a male pyramid adapter for amputees with short stump length and a female tube adapter.
At this point, the configurator, interacting with the 3D CAD system, extracts from the database the parametric models of selected components, sizes them, and assembles them together with the 3D socket model. In Figure 5.14 it is shown the assembly of the standard components and in Figure 5.15 the final prosthesis assembled with the socket model.

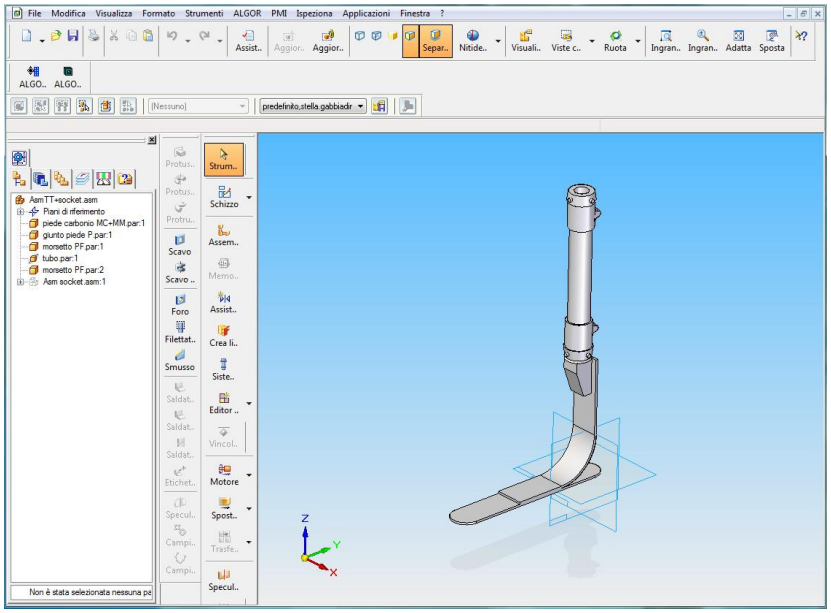

Figure 5.14: Assembly of selected standard components for a TT prosthesis.

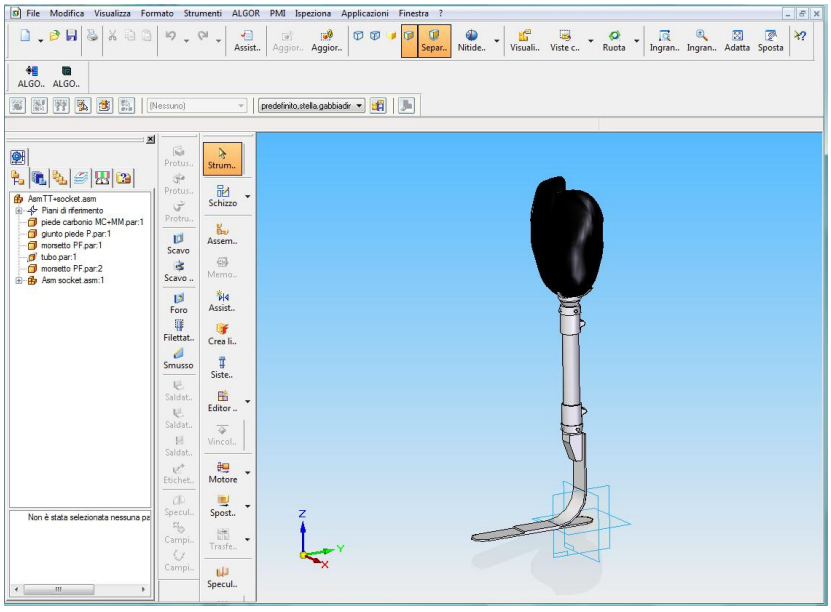

Figure 5.15: Assembly of the complete TT prosthesis with the socket model.

Finally the systems automatically creates the Bill of Materials (BOM) of the assembled prosthesis, with the indications for each component of typology and material. Figure 5.16 portrays the BOM for the specific configuration.

TRANSITIBIAL PATIENT 3 - HYPOBARIC LINER - TBS SOCKET		
PART	TYPOLOGY	MATERIAL
Foot	High energy	Carbon Fibre
Heel	10 mm	--
Tube Adapter	Male Pyramid	Stainless steel
Liner	16,2 mm	Polyethylene
Internal Thickness	Woody	Woody
Socket Adapter	4-Hole	Stainless steel
Upper Clamp	Female	Aluminium
Lower Clamp	Female	Aluminium
Tube Length	73 mm	Aluminium

Figure 5.16: The related BOM of the assembled TT prosthesis.

5.3 – Transfemoral case

We have proceeded analogously for the transfemoral case-study. All the design rules and procedures have been already portrayed: the patient data are shown in § 3.1, the socket modelling procedure is described in § 3.3 and § 4.2.3, and the final configuration, dimensioning and assembly is detailed in § 3.2 . Figure 5.17 portrays the TF socket model, Figure 5.18 shows the standard components assembly, and Figure 5.19 shows the configuration of the final transfemoral prosthesis.

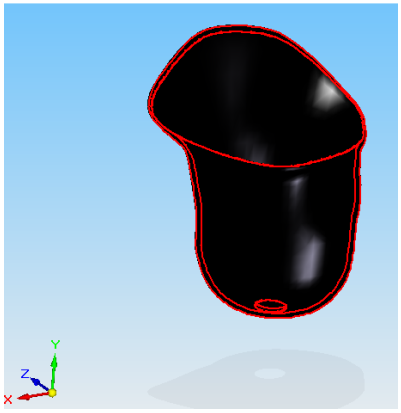

Figure 5.17: Example of TF virtual socket model.

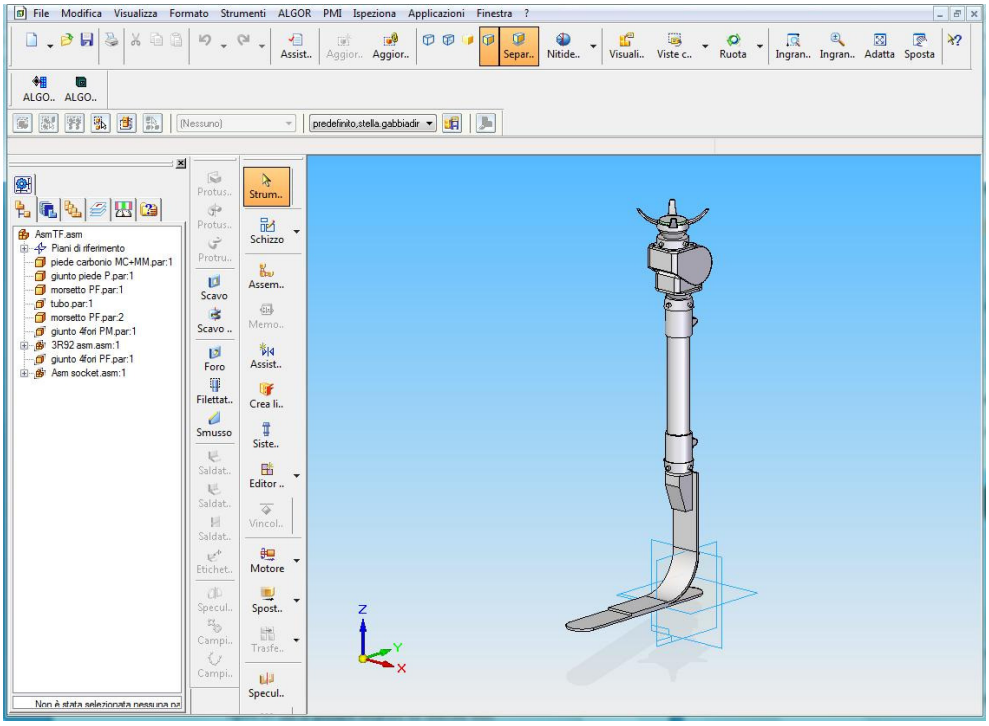

Figure 5.18: Assembly of selected standard components for a TF prosthesis.

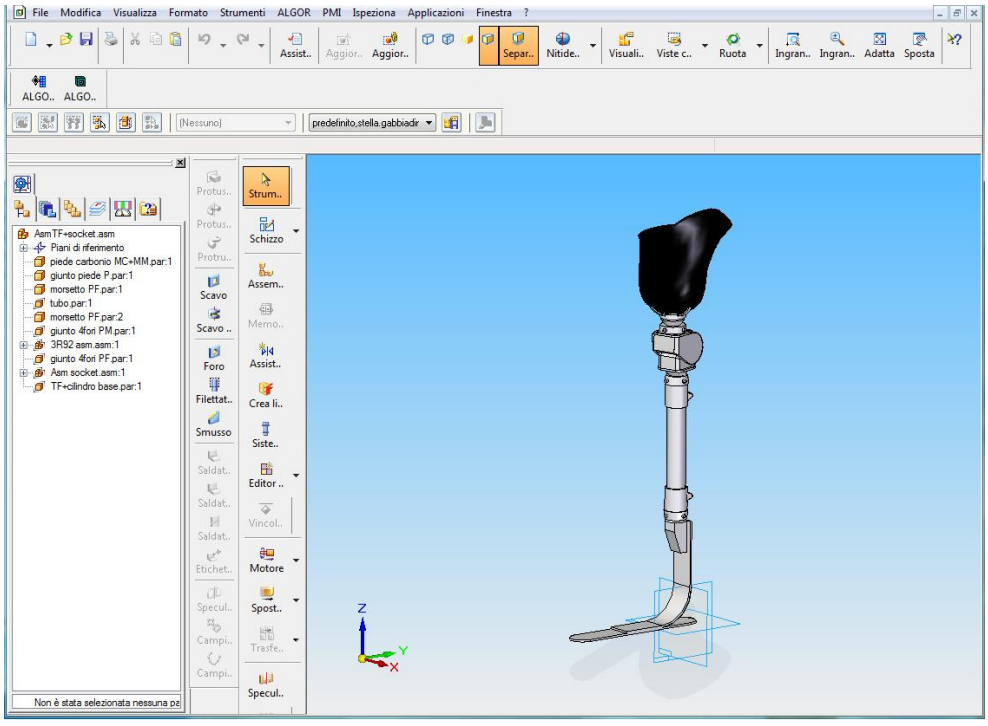

Figure 5.19: Assembly of the complete TF prosthesis with the socket model.

5.4 – Discussion

As said, we experimented the system in two different steps: first testing the automated standard components selection with 10 amputees cases, and then configuring the prostheses of two patients, one TT and one TF.
In the first part of the experimentation, we have tested the implemented automatic procedures to select the most appropriate foot and knee, based on the patient data, with 10 patients cases, 5 TT and 5 TF. Then we have proposed the same patient cases to the staff of the orthopaedic laboratory, without showing them the results previously obtained with the system, and we have asked them to select feet and knee for each case, based on their personal experience and knowledge. The correspondence of the two groups of results was good. The cases with different results can be explained since some factors about the personal patients profiles cannot be evaluated using an automatic system, but technicians can take them into consideration. For example the system doesn't evaluate the esthetical components aspects, while technicians consider them; in fact a woman could prefer a smaller and slim component to better hide the prosthesis, while the system could choose a bigger component but with better performance. Another important factor could be also the component price; the system could select a quite expensive component, while the technician could prefer for the patient a cheaper solution.
Anyway these cases are a small number compared to the majority of amputees, and in most of cases the automatic result is anyway close and appreciable. The automatic selection could be anyway refined implementing other factors, which can be easily evaluated and can be quite important. This is part of a future development. We can finally say that the automatic selection has been appreciated by technicians and sometimes has suggested them to consider of more models than concentrating only on few traditional ones.
In the second part of the experimentation we have configured the complete lower limb prostheses of two patient cases, one TF and one TT. First it has been acquired the stump digital model of both amputees, then the KBE system has been used to design their prostheses. Once entered the required patient data, the system has opened the SMA and the socket models have been created, following the system suggestions step by step. Then the system has proposed to the user the appropriate components and adapters for each patient case, finally providing the prosthesis BOM, assembling all the parts and properly size them. The results have been the virtual prototypes of the complete prostheses. The system has been also validated by technicians. The SMA and the final prostheses models were quite appreciated, and defined of simple use and with a friendly user interface. Even if the components models have not been modelled in detail, their functionality was appropriate for our general purpose. The configurations suggested by the system have been considered in line with those ones obtained following traditional procedures, with the advantage that the various configurations can be more easily generated and compared. As far as concerns the socket, technicians appreciated the level of knowledge provided and the interactive tools to manipulate socket shape.

Conclusions

Nowadays the good results of the traditional manufacturing process of lower limb prosthesis is strictly correlated with the orthopaedic technicians skills. The prosthesis is composed by standard components, selected by technicians from commercial catalogues, and the socket. This is the most critical component, totally hand-made and customized on the patient's residual limb. There are ICT tools available on market which can support some specific steps of the process, but they don't' offer any kind of assistance or suggestions to the user, and the technician knowledge and experience are still required.

This thesis work has presented an innovative design process for lower limb prosthesis, experimented with a high qualified orthopaedic laboratory.

First it has been investigated the State of the Art of lower limb prosthesis and the ICT prosthetic tools available on market. The conclusion has been that actual systems can overcome only few steps of the process and cannot provide any kind of assistance to the user. All the domain knowledge is still strictly correlated to the personal technician skills and experience.

Then it has been acquired and formalized the product and process knowledge. In particular all the most diffused prosthesis components have been studied and analyse to understand their functions and their properties, and how they can influence the prosthesis functionality. A deep study of the traditional manufacturing process has been executed, studying literature, scientific publications, but above all directly participating to the process in an orthopaedic laboratory. All the acquired knowledge has been formalized using IDEF0 diagrams, since they are a simple and clear language, easy understandable also from technicians.

At this point all the design rules and procedures have been identified and it has been highlighted that all the process is based on a specific set of parameters: the patient characteristics. These parameters have been deeply studied and analyzed, and on this base

all the procedure to select the standard components, correctly model the socket and size the prosthesis have been derived.
After all these considerations, a new design process has been implemented, totally based on the virtual model of the patient's body. This new method has been also described using IDEF0 diagrams. The system guides the designer in each process activity on the base of the product and process knowledge and rules, starting from the components selection, the socket modelling and the final prosthesis assembly.
Finally the system has been experimented with the staff of the orthopaedic laboratory. The results for the component selection and the tool for socket modelling have been considered positively and encouraging. The technicians appreciated the whole system functioning and the possibility to use the framework to simplify the work of by experienced technicians but also to train junior designers who can learn more quickly about lower limb prosthesis design. However, further refinements have been identified both for selection procedures and socket modelling procedures.

In summary, most important results have been:

- the acquisition of product and process knowledge and the identification of rules and procedures;
- the realization of an innovative design process based on virtual models of the patient's body;
- the implementation of a knowledge based framework for the design and configuration of lower limb prosthesis;
- the realization of an ad hoc tool to virtually model the socket, critical and central component of the whole process.

Anyway, future developments could improve the obtained results:

- the integration within the knowledge-based framework, of tools for FE analysis to study the interaction between the stump and the socket;
- the integration of multi-body systems to simulate prosthesis set-up and check the deambulation of the patient wearing the designed prosthesis;
- enlarge the set of parameters which influence the components selections, keeping into considerations more details, such as the prosthesis costs.

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