Study of composite elastic elements for transfemoral prostheses: the MyLeg Project

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CHAPTER 3

STATE OF THE ART

Abstract

In order to develop a new prosthesis that can introduce new features or that combines features that other prostheses have but separately, it is necessary to know what already exists on the market and what has already been studied and proposed in the literature. For this reason, a state-of-the-art study has been carried out by the author, with the intention of understanding how foot prostheses are currently. The results of the study are then presented in this chapter. The four categories of foot prostheses found by the author will be described and the most important prosthetic devices in the literature will be presented. From the analysis of the state of the art it may be useful to understand what to propose as a new prosthesis, with new or existing technologies but put together to ensure that the prosthesis can replicate as much as possible the behavior of the healthy human foot.

3.1 Introduction

3.2 Lower Limb Amputation Types

The object of this thesis is an ankle-foot prosthesis that replaces the part of the leg removed in a transtibial amputation. Transtibial amputation is one of several types of amputation of the lower limb. In general, amputation means surgical removal or accidental loss of a limb. The amputation involves the removal of all the tissue components of the limb involved, specifically: skin, subcutaneous tissue, nerves, blood vessels, muscles, tendons and bones. The amputation of a limb and specifically of a leg can be of two macro-types: minor amputations and major am-
Figure 3.1 shows the different types of lower limb amputations. The minor amputations, briefly listed and described in Section 3.2.1, are the represented in Figure 3.1a and Figure 3.1b. The major amputations, briefly listed and described in Section 3.2.2, are represented from Figure 3.1c to Figure 3.1g.

3.2.1 Minor Amputations

Lower limb amputations are categorized as minor amputations when amputation occurs at or below the ankle joint, and include partial foot amputations (Figure 3.1a – when the amputation occurs below the ankle joint) and ankle disarticulation (Figure 3.1b – when the amputation occurs at the ankle joint). More specifically, the various types of partial foot amputations and ankle disarticulation are:

- **Toe amputation**: this type of amputation occurs when part of the phalanges are cut off from the foot.

- **Metatarsophalangeal amputation**: this amputation occurs at the joints that join the metatarsal and phalangeal bones.

- **Transmetatarsal amputation**: the amputation takes place by cutting the metatarsal bones.

- **Tarsometatarsal amputation (Lisfranc)**: it is called tarsometatarsal amputation or Lisfranc amputation, the amputation that occurs by cutting away
the bones of the foot from the joints that join cuboid, lateral cuneiform, medial cuneiform and intermediate cuneiform with metatarsal bones onwards. Basically, the metatarsal bones and phalanges are removed from the foot.

- **Midtarsal disarticulation (Chopart)**: in this type of amputation, the navicular, cuboid, lateral cuneiform, intermediate cuneiform, medial cuneiform, metatarsal, and phalange bones are removed from the foot.

- **Syme amputation**: a Syme amputation is a disarticulation at the tibiotalar joint with resection of the malleoli. The foot is removed, saving however the heel pad, which is used to cover the end of the tibia, so the patient can put weight on the leg without a prosthesis [24–26].

- **Pirogoff amputation**: the same bones removed in the Chopart amputation are also removed in this type of amputation with the addition of the talus bone. The calcaneus is not removed, but is screwed to the tibia after having removed the talus. Compared to Syme amputation, the total length of the limb after the removal of the above-mentioned bones is greater in this case thanks to the preservation of the calcaneus [27, 28].

- **Boyd amputation**: Boyd amputation refers to the amputation at the level of the ankle with preservation of the calcaneus and heel pad. As for the Pirogoff amputation, the calcaneus is fixed to the tibia. It allows for complete weight bearing and provides both stabilization of the heel pad and suspension for a prosthesis [29].

Some of the mentioned partial foot amputation types are shown in **Figure 3.2**.
3.2.2 Major Amputations

All other amputations of the lower limbs which are above the tibiotalar joint are categorized as major amputations. Below, the various types of major amputations are listed in order from the amputation closest to the foot to the pelvis.

- **Transtibial amputation**: called also below-knee amputation, is a surgical procedure performed by removing the entire foot and part of the tibia, fibula and corresponding soft tissue structures [30] (Figure 3.1c). The part of the limb removed is replaced by an ankle-foot prosthesis. The connection between the remaining part of the shin and the prosthesis is explained in Section 3.5.

- **Knee disarticulation**: tibia, fibula and the entire foot are removed. In this type of amputation, the femur and patella remained untouched. It is considered non-traumatic surgical procedure since no bone and muscle tissue is to be dissected(Figure 3.1d). Furthermore, the thigh muscles are preserved [31].

- **Transfemoral amputation**: called also above-knee amputation, is a surgical procedure performed to remove the lower limb above the knee joint, by cutting through both the thigh tissue and femoral bone [32] (Figure 3.1e).

- **Hip disarticulation**: it is the surgical removal of the entire lower limb from the hip joint in which the ball is separated from the socket of the same hip joint [33] (Figure 3.1f).

- **Transpelvic amputation**: this type of amputation is a surgical procedure performed by removing the entire lower limb and a portion of the pelvic bones (Figure 3.1g). In the amputation, the acetabulum, ischium, rami, ilium and sacrum can be included [33].

In all these amputations, the removed lower limb part will be replaced by a prosthesis that will include an ankle-foot prosthesis.

3.3 Causes of Lower Limb Amputations

An amputation of one or more limbs can be mainly caused by a traumatic event (accident), diabetes, peripheral arterial disease (PAD), cancer or severe infection [34–36]. In the following sections, brief descriptions of these causes are given.

3.3.1 Diabetes

The high blood glucose level in diabetics is the main reason why wounds heal slowly: the higher the blood glucose levels, the more inflammatory processes can
increase. In addition, hyperglycemia compromises the normal activity of the immune system, as well as the normal metabolism and oxidative state of human cells [37]. According to Gordois et al., about 15% of diabetics then develop foot ulcers and some of them are then forced to be amputated to prevent the spread of infection due to the ulcer [38]. Many people with diabetes have an immune system that fails to activate promptly. Moreover, the cells responsible for healing wounds are reduced in number and are unable to perform their activity efficiently: this results in delays in the healing process [39]. Impaired immune system makes infection more likely. In addition, the higher the level of blood sugar, the greater the risk of infection: fungi and bacteria complicate even more the state of the wounds of those who have diabetes and the treatment of the same.

3.3.2 Peripheral Arterial Disease (PAD)

PAD can occur in any blood vessel of the limbs, although it is much more common in the legs or lower limbs. PAD is a common circulatory problem in which narrowed arteries reduce blood flow from the heart to the limbs. The accumulation of fat deposits in the arteries (atherosclerosis) can narrow the arteries and reduce blood flow to the legs and, occasionally, the arms. Fatty deposits (atheromas) consist of cholesterol and other waste substances [40–42]. People who smoke, diabetics, individuals with obesity problems, those with high blood pressure or those with high cholesterol levels are the subjects who have the greatest risk of developing PAD [42]. To reduce risks, it is recommended to exercise, eat a healthy diet, quit smoking and reduce alcohol consumption [41,42].

3.3.3 Cancer

Amputation due to cancer is necessary when the removal of the same cancer is no longer possible. When bone cancer starts from the same bone it is called primary bone cancer, while when it starts from other tissues and then has spread into the bones, it is called secondary bone cancer [43].

3.3.4 Severe Infection: Meningococcal Bacteria

An example of severe infection is the entry of meningococcal bacteria into the bloodstream. It can cause a severe blood flow infection called septicaemia. Bacteria multiply and release toxins into the blood, which can damage blood vessels, resulting in reduced oxygen flow to organs and skin tissue. In the human body itself gives priority to vital organs in providing blood, often giving less importance to the extremities (limbs). Damage to the blood vessels caused by the release of toxins by bacteria, the extremities may not get blood, and therefore oxygen with the consequent death of tissues. Because of this, fingers and toes or limbs in general are amputated [44].
3.4 Rehabilitation Process after Amputation

Post-amputation rehabilitation includes general training exercises, hip and knee traction and strengthening of all muscles. The subject is encouraged to start exercises in an upright and balanced position with parallel bars as soon as possible. Endurance exercises are needed. The specific program prescribed depends on the amputation of one or both limbs and the level of amputation. Muscles adjacent to the amputated limb or surrounding the hip or knee joint tend to contract. These contractions usually result from prolonged time spent sitting in a chair or wheelchair or from lodging with the body out of alignment. Contractures limit the range of motion. In case of severe contraction, the prosthesis may not be adaptable, or the patient may lose the ability to use it. Ways to prevent contractures are taught to the subject. Therapists help patients learn how to treat the stump, to facilitate the natural process of reduction. The stump must shrink before the prosthesis can be applied. An elastic bandage to reduce the size of the stump, worn 24/7, can help shape it and prevent the accumulation of fluid in the tissues. Immediately after amputation, a temporary prosthesis can be applied in such a way as to allow early walking and thus facilitate the reduction of the size of the stump. A subject with temporary prosthetics can start with parallel walking exercises and continue walking with crutches or a stick until the permanent prosthesis is available. Physiotherapy continues even after the patient has received the permanent prosthesis, preferably by a team of specialists, with the aim of improving strength, balance, flexibility and cardiovascular shape. Walking begins with direct assistance and progresses with walking with a walker and then with a stick. Within a few weeks many subjects are able to walk without a stick. The subject is also taught how to use stairs, to climb and descend slopes and to cross other uneven surfaces. Progress is faster for athletic subjects, while it is slower and more limited in subjects with amputation above the knee, in the elderly and in weak or poorly motivated patients [45].

3.5 Osseointegration vs Socket

After a brief description of the various types of amputations of the lower limb and how the rehabilitation process takes place to get the patient used to the use of a prosthesis, in this section the author intends to briefly present how the connection between the prosthetic device and the remaining part of the limb involved in amputation occurs. The presentation is limited to transfemoral and transtibial prostheses.

Considering mainly the transtibial and transfemoral prostheses, the two main modes of connection between the prosthetic device and the healthy part of the amputated limb is through osseointegration and socket (Figure 3.3).

The socket connection is definitely so far the most used compared to osseointegration. The socket transfers the weight of the amputate to the ground via
the prosthetic components. Fit, comfort and suspension are the features that a socket must ensure. A socket must be light, with high mechanical properties, and typically the same bone properties to provide the same stress distribution in the area where the amputation took place. Carbon fiber composites with thermosetting polymer matrix are typically used. Having to practically go in direct contact with the remaining healthy part of the limb, the socket is built by the prosthetist directly on the leg of the user [46].

However, despite improved socket materials and designs, at least one third of the transfemoral amputees that have a socket as a connection between the remaining healthy part of the limb and the prosthesis have chronic skin problems associated with this type of connection [47–49] and these problems reduce mobility and quality of life [49–52]. Osseointegration, already widespread in the dental field [53, 54], has become more widespread also in the prosthetic field of limbs [55–60] As reported in the literature of the effects of the osseointegration [61], the osseointegration would bring improvements in stability, attachment with the remaining limb, maximum sitting comfort, a wider hip range of motion, quick donning and doffing [59, 62], better body perception [63], better observance [64–66], increased walking ability [67], better functional ability [68, 69] and a general improvement in the quality of life [59, 63, 70]. Osseointegration was discovered in the 1950s by Swedish Professor Per-Ingvar Brånemark and is based on the ability of human bone cells to attach to a metal surface. Currently osseointegration is used to allow the permanent anchoring of artificial limbs to the human skeleton. During surgery, a metal implant (titanium) is inserted into the bone of the amputated limb and released from the skin by wrapping an opening called a stoma. The prosthesis is easily connected to this implant with a connector [71].

Figure 3.3: Socket vs Osseointegration.

Figure 3.3a shows the main components of a transtibial prosthesis with the osseointegration system, while Figure 3.3b shows the main components of the same type of prosthesis with socket. Concerning the transfemoral prosthesis, Figure 3.3c and Figure 3.3d show the main components the main components for a
transfemoral prosthesis using the osseointegration system and socket respectively.

3.6 Levels of Ambulation

Perhaps it is thought that nowadays most amputees wear or prefer to wear robotic feet. Actually, the choice or preference is not so automatic. There are several factors that push the amputee to choose one type of foot prosthesis over another. Leaving aside the economic nature, the most influential factor on the choice of prosthetics to wear is certainly the level of activity, also called level of ambulation. The four of the five levels of ambulation are shown in Figure 3.4. According to the American Academy of Orthotists and Prosthetists, there is still no method that can be called a gold standard to determine the level of activity of the amputee, or determine the K-level. However, 5 activity levels can be generically identified, from K0 to K4. With K0, the amputee has no ability or potential to move safely without the aid of an external device and a possible prosthesis is not able to improve the quality of life or mobility of the patient K0. K1 patients, on the other hand, are able to move using a prosthesis, even if their ambulation is limited to constant speed walking and flat grounds. K2 patients are able to walk on steps of a staircase or on uneven surfaces, while maintaining a fairly steady gait. An amputee with a K3 activity level is able to move with a prosthesis with variable cadences, while amputees K4 are able to perform even relatively difficult movements: in fact, K4 is usually the level of activity of athletes.

![Levels of Ambulation](image)

Figure 3.4: Levels of Ambulation.

3.7 General Classification of Transtibial Prostheses

In order to understand the state of the art of foot prostheses, the author has analyzed what is proposed in literature and on the market, adopting the strategy schematized in Figure 3.5. As for what the literature proposes, what the author has done first is to analyze the review papers and consequently look for other publications using Google Scholar. Once he had carried out the analysis of the
publications, taking also cue from the review papers, he categorized the various prostheses of feet. In addition, to also understand what was invented, even a patent analysis was carried out. The patent analysis was made using Google Patent using the 'transtibial prostheses', 'lower limb prostheses' and 'foot prostheses' entries. As for commercial devices, the online catalogues of leading companies in the field of design and marketing of foot prostheses have been analyzed. For the work of analysing the review papers in the literature, the works of Versluys et al. [1,72] and Cherelle et al. [73], have been given greater consideration, thanks also to the clarity with which they analysed and subsequently classified the existing technologies with regard to foot prostheses.

3.7.1 Versluys et al.’s Classification

Versluys classified the foot prostheses mainly in three categories: conventional feet, ESR feet and ‘Towards’ bionic feet (Figure 3.6). It can be briefly said that this category of foot prostheses is mainly prescribed to K1 and K2 level of ambulation users. They are constructively the simplest among all the prosthetic feet and they are the most adapt to non-active users. According to Versluys et al. [1,72], the first ESR foot was the Seattle Foot (1981) which incorporated a
flexible keel inside a shell of polyurethane. The flexible keel can be assumed as a compression spring (Figure 3.7a) that stores elastic energy during mid stance (Figure 3.7b) and release it during push off (Figure 3.7c and Figure 3.7d).

Seattle foot was then followed by other prosthetic feet using the similar configuration, such as Dynamic (Plus) Foot and C-Walk (Otto ock HealthCare GmbH), SAFE (Campbell-Childs, Inc., White City, OR), Carbon Copy (Ohio Willow Wood Co., Mount Sterling, OH), STEN (Kingsley Manufacturing Co., Costa Mesa, CA) and many others [1]. Thanks also to improved technology, the study of human walking has brought increasingly useful results for understanding biomechanics. These results were then exploited over the years by researchers to design prostheses with the intention of approaching the behavior of a healthy foot. In their reviews [1, 72] (published in 2008 and 2009), Versluys et al. identified two approaches: one approach consisted of using muscle-like pneumatic actuators, while the other consisted of electrically drive devices.

### 3.7.2 Cherelle et al.’s Classification

The review papers of Versluys et al. date back to 2008 [1] and 2009 [72], while that of Cherelle et al. [73] is a work published in 2014. Between 2009 and 2014, new foot prosthetic devices were studied, thanks also to the improvement of biomechanical knowledge. As Verluys et al., Cherelle et al. mainly classified prostheses in the three categories already seen above: conventional feet, ESR feet and bionic feet (Figure 3.8). Cherelle et al. classified ESR feet in early ESR (already mentioned earlier in the work of Versluys et al.), advanced ESR and articulated ESR. The latter typically make use of electronic components and small servo motors to engage or disengage locking mechanisms. According to Cherelle et al., articulated ESR feet cannot be included in the classification of bionic feet because the
Figure 3.8: Cherelle et al.’s Prosthetic feet classification [73].

actuation does not contribute to propulsion. The following works were included in articulated ESR: AMP-Foot 1.0 and 1.1 [74], Collins and Kuo’s CESR foot [75] and Mitchell’s delayed plantar flexion prosthesis [76]. Cherelle et al. then divided the bionic feet into stabilizing and propulsive. The firsts are equipped with actuators that help stabilization, while the latter have motors that inject energy during the push-off. Compared to the previous review paper considered, Cherelle et al. have proposed a new categorization with a focus on the propulsive bionic feet. As a first categorization, Cherelle et al. have proposed a subdivision of the propulsive bionic feet in devices with stiff actuation and in devices with compliant actuation. An actuator is considered stiff when it is not able to store energy by elastic deformation, therefore only the electric motor compose the actuation system. During the level walking, as seen also in Chapter 2, the foot first rotates in plantarflexion (early stance) and then in dorsiflexion (mid stance) and then finish with a rotation in plantarflexion during the push off. In devices with stiff actuation, the motor must work in both dorsiflexion and plantarflexion by injecting power to the prosthesis. Based on Winter’s studies, a stiff actuation composed only of the motor should generate a torque at the ankle joint that is approximately 1.63 Nm per kg of body weight, which means a torque between 97.8 Nm and 163 Nm if the body weight range of adult is considered from 60 kg to 100 kg. As for devices with compliant actuation, Cherelle et al. mainly identified two subcategories: pneumatically actuated propulsive devices and electrically actuated propulsive devices. In the first, muscle-like pneumatic actuators (Pneumatic Actuators Muscles - PAM) have been used as antagonist muscles to rotate the foot around the ankle in both dorsiflexion and plantarflexion [77–84]. Cherelle et al. have identified several sub-categories of prostheses with compliant actuator - electrically actuated propulsive devices. The first category is the one with Series Elastic Actuators (SEA): in this case, a linear DC motor and a compression spring work in series. According to a study [85], the combination of a DC motor and a series spring reduces the necessary engine power. The use of a SEA was seen in the three prototypes of the SPARKy project (Spring Ankle with Regenerative Kinetics) [86–88]. The three SPARKy prototypes then led to the development of the ODYSSEY and JackSpring prostheses, marketed by
SpringActive. A system with a four-bar mechanism takes advantage of the configuration of the electric motor in parallel with a compression spring, and Bergelin et al. [89] designed, optimized and manufactured the prosthesis. Cherelle et al. then identified a work carried out by Zhu et al. in which two seas are exploited for the PANTOE prosthesis: the peculiarity of this prosthesis is the presence of toe joint, and this justifies the taking of a second SEA [90]. A second category is that of prostheses with **Series Elastic Actuation with Parallel Spring (SEAPS)** where in addition to the spring in series, there is also a spring in parallel. This configuration was used by Au et al. to develop more prostheses which then led to the commercialization of a prosthetic device under the name of BiOM [91–96]. Sup et al. developed a foot prosthesis (and a knee prosthesis) capable of accommodating to slope walking [97] that exploits the configuration of SEA. A third sub-category is that of prostheses with **Variable Stiffness Actuation (VSA)**. A prosthesis identified by Cherelle et al. that belongs to the VSA devices is the first prototype of the CYBERLEGs project, where a variable stiffness actuator is used. The first prototype also includes a knee joint with a locking and unlocking mechanism that has been incorporated to allow the transfer of energy stored by the knee joint from the knee joint to the ankle joint during push off. At the time of writing the review, Cherelle et al. had not yet identified prosthetics with **Variable Stiffness Actuation with Parallel Spring (VSAPS)**. A last category is that of prostheses with **Explosive Elastic Actuation (EEA)**: a spring is placed in series to a SEA, and a locking-unlocking mechanism acts on the spring in order to release the elastic energy accumulated by this in the desired moment, for example in a jump [98], kick [99], or launch [100]. Cherelle et al. considered that it can be considered a prosthesis with EEA AMP-Foot 2 [101] where a “catapult actuator” is used. The next version, the AMP-Foot 3 uses an extra locking mechanism to mimic the ankle position change after the flat foot.

![Figure 3.9: Cherelle et al.’s Propulsive Prosthetic feet classification [73].](image-url)
3.7.3 Tabucol’s Classification

As was seen in the review paper published by Cherelle et al. in 2014, numerous foot prototypes were already developed and studied. Over the last few years, since 2014, many other works on prostheses have been published, both as new prostheses and as an evolution of existing devices that have also been presented in the same article. Having analysed the new published work on foot prostheses, the classification proposed by the author of this thesis is shown in Figure 3.10.

As already anticipated and as will be seen in the following chapters, the work of this thesis is mainly focused on the optimization of an ESR foot and then a semi-active foot prosthesis with variable stiffness. For this reason, the detailed descriptions are given only on the properties of the ESR feet and on existing semi-active prostheses. While in the review papers of Versluys et al. the various categories of foot prostheses were presented in a general manner, the review paper presented by Cherelle et al. was more concerned with bionic feet, also because the development of prostheses is heading towards them. The development of other prostheses, therefore, has been slightly neglected, or rather, in the review paper of Cherelle et al., has not been considered. Even in the very recent review paper of Asif et al. (2021) [102], some important passive foot prostheses have not been considered. However, according to the author, the development and optimization of passive prostheses can still have some importance, as not all amputees would want a bionic prosthesis or simply could not afford it, considering that already in 2018, passive foot prostheses costs were between 1,000 and 10,000 $ [103]. It is true that from the point of view of research itself and the development of technologies, it is probably needed to focus on bionic prostheses, but as just mentioned, the contribution that can also be made by passive or semi-active prostheses must not be underestimated.

Going back to Figure 3.10, according to the author of this thesis, foot prostheses can be divided into the following categories: passive prostheses, semi-active prostheses and bionic prostheses. A classification based on the level of actuation. In essence, passive prostheses do not have any type of actuator, while semi-active prostheses are equipped with electric motors with the sole function of making changes to the configuration or characteristics of the device. Finally, the active prostheses are equipped with electric motors with the function of injecting power for propulsion.
Passive Feet

In turn, passive prostheses can be mainly divided into three different categories: conventional feet, ESR feet and particular designs (Figure 3.11). Due to their similar characteristics, both conventional feet and ESR feet can be easily assigned in their respective categories, while for particular designs, they have different configurations.

**Conventional Feet**

The conventional feet (Figure 3.12) are the simplest foot prostheses both from the point of view of construction and from the point of view of the activities allowed. SACH (Solid Ankle Cushioned Heel) feet are the most common of those classified as conventional feet (Figure 3.13). The SACH feet are equipped with a sort of heel cushion that provides an absorption of the impact of the prosthesis with the ground and a pseudo-plantarflexion. The main body of the prosthesis, the keel, is made of wood or a rigid material that ensures stability during the mid stance. SACH feet are still commercialized and prescribed to K1 and K2 amputee users.

Other prostheses belonging to the category of conventional feet are those equipped with an ankle joint that allows a rotation of the foot in the sagittal plane. Paradisi et al. also studied the effect and possible improvements of a multiaxial SACH foot compared to a non-articulated SACH foot: they found out that multiaxial SACH feet could be used as alternative to standard SACH feet for hypomobile transtibial amputee users [104]. In another work, Zmitrewicz et
observed that hypomobile old transtibial amputees found more benefits in a multiaxial SACH foot prosthesis than an ESR foot [105]. Improvements brought by multi-axial foot prosthesis were also observed by Marinakis [106]. However, the SACH feet remain, as already mentioned, the most common conventional feet, thanks also to the fact that they are the cheapest and lightest of these provided with sagittal joint [1]. The SACH Feet, and the Conventional Feet in general allow to carry out the simplest activities: in fact, even if already on the market even before the 80s, they are still the most prescribed prostheses for amputated users with a K2 ambulation level.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{foot_diagram.png}
\caption{(a) The Otto Bock SACH+ Foot and (b) schematic representation of a SACH foot.}
\end{figure}

\textbf{ESR Feet}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{esr_diagram.png}
\caption{Classification of ESR Feet.}
\end{figure}

The design methodology mentioned in Chapter 1 and explained in detail in Chapter 5 has been developed in parallel to the design of an ESR foot with a hinged ankle joint (Chapter 6) and subsequently validated with the design of another ESR foot with a spherical ankle joint (Chapter 7). As can be seen later, the ESR foot with the spherical ankle joint is the natural evolution of the ESR foot with hinged ankle joint. And the variable stiffness prostheses presented in
Chapter 8 and Chapter 9 are the evolution of the ESR foot with the ankle joint spherical. As can be understood, since ESR feet is a category of particular importance in the development of the final prosthesis presented in this thesis, in the following lines the author provides a description of them.

Current commercially available prostheses which are the most prescribed for individuals with K3 and K4 levels of ambulation are the ESR feet, even if several companies also commercialize ESR feet for amputee with K2 ambulation level. As already mentioned earlier, ESR stands for Energy-Storing-and-Releasing. The name comes from the fact that the ESR Feet are passive devices made of elastic elements that store elastic energy during the mid stance and then release it during the late stance for the push-off [107, 108]. The elastic elements are generally leaf springs, also called blades, made of composite materials (carbon fiber-reinforced plastic—CFRP; or glass fiber-reinforced plastic—GFRP). The stiffness of the elastic elements is a crucial characteristic of foot prostheses, and in particular, of ESR Feet. The stiffness of prosthetic feet depends on the geometries and the material properties, especially for ESR feet [72, 109]. The stiffness that the elastic elements must have is related to the weight of the person who will use it and their level of ambulation and type of activities [110].

In their classification, Cherelle et al. [73] split the ESR Feet into early ESR, advanced ESR and articulated ESR. The first ESR feet were a middle ground between the SACH Feet and the advanced ESR, with elastic elements added to store elastic energy (Seattle foot - see Figure 3.7). The advanced ESR feet are more optimized version of the early ESR feet. And as specified earlier, the articulated ESR feet are equipped with actuator that engage and disengage a locking system.

Also the author of this thesis classify the ESR feet in the same way, making the same subdivision. Moreover, according the author, the advanced ESR feet can be subdivided in standard ESR feet and ESR feet with ankle joint. With standard ESR feet, he refers to the ESR feet without any ankle joint and the plantarflexion and dorsiflexion completely rely on the flexibility of the elastic elements. Examples of standard ESR feet are shown in Figure 3.15. ESR feet with ankle joint are the ones with at least a hinge joint that works as ankle joint. As can be seen in Figure 3.14, there are standard ESR feet with an ankle joint (a commercial example is
the Ossur Proflex Pivot - Figure 3.16a) and ESR feet with ankle joint and a damping system: the damping system can consist of an hydraulic system (Figure 3.16b) or a rubber bumper (Figure 3.16c).

**ESR Feet vs. SACH Feet**

According to several studies, ESR feet are better than SACH feet in terms of energy [111], gait symmetry in ascending stairs [112], ankle range of motion and impact absorption during weight bearing [113]. However, SACH feet are considered more stable and safer by hypomobile amputees [114–116]. In SACH feet the early stance (from heel-strike to toe-strike) lasts twice as long as in a normal gait, while the mid-stance (flat foot) is very short: this could be a disadvantage for uneven terrain [116], but also for descending stairs [117]. For hypomobile amputees, the energy return coming from the elastic elements of ESR feet is perceived as unstable [116].

**Particular Designs of Passive Feet**

To mention among the particular designs there is definitely the ankle-foot prosthesis that adapts passively to inclined planes [118, 119]. The prototype proved to be able to adapt automatically and passively to the inclination of the plane. However, it was prone to wear and breakage as well as producing a lot of noise. Later the same authors worked on a second prototype having the same objective of obtaining a device that adapts to the inclination of the ground [120].

Another particular but interesting design is the one proposed by Unal et al. It’s a transfemoral prosthesis where the knee and foot prostheses work mechanically in symbiosis. Due to a particular mechanism and the biomechanics of walking in general, the knee prosthesis accumulates energy at the end of the stance phase and during the swing phase and this energy is transferred to the foot. The working principle of this device is appropriately explained in [121–127].
3.7.4 Semi-Active Feet

The prostheses presented in Chapter 8 and Chapter 9 are, as anticipated, two semi-active prostheses. The author therefore considered it important to make a slightly more thorough analysis of this category, to understand the state of the art. As seen in the analysis of the state of the art by Cherelle et al. and as will be seen in the next section, the semi-active prostheses proposed in the literature are not very numerous and also on the market are very limited in number. Cherelle et al. [73] placed these prostheses among the bionic feet in the stabilizing bionic feet sub-category. The author preferred to classify the semi-active feet separately from the bionic feet, which are instead real bionic feet designed and created to try to replicate as much as possible the behavior of the human foot. The bionic feet are equipped with actuators that work for propulsion, while the actuators of the semi-active prostheses are used with the aim of changing some properties of the entire prosthesis such as damping or stiffness. By changing some properties, these prostheses are stabilized or adapted to the walking condition. As schematized in Figure 3.17, semi-active (or quasi-passive) ankle prostheses can be distinguished in devices which can change their configuration or change the damping properties of a hydraulic system, or the stiffness of some elastic elements.

Commercial Semi-Active Feet

Currently, semi-active feet are available commercially. Among them, there is definitely Össur’s Proprio Foot to mention (Figure 3.18a-Figure 3.18d). By means of an actuator inserted in a mechanical connection to change its length, the angle of the foot with respect to the ankle is adjusted according to the activities, such as a walk up or down stairs [128] or ramps [129]. Proprio Foot can be classified as a semi-active variable configuration foot. A decrease in the length of the mechanical element to which the actuator is inserted leads to a pre-plantarflexion of the foot prosthesis, while in contrary conditions, the actuator leads to a pre-dorsiflexion. A commercial foot prosthesis that instead changes its damping properties is Endolite’s Elan Foot (Miamisburg, OH, USA) (Figure 3.18e). The damping properties can be modified with a hydraulic unit to adapt the foot to terrain conditions, especially for uneven terrain [130]. Elan is a microprocessor controlled foot that mimics natural muscle resistance and ankle motion by adapting hydraulic resistance lev-
els to optimise stability when standing and walking, on slopes and uneven terrain. This encourages more symmetrical limb loading, faster walking speed and reduced compensatory movements. The ankle pivot point is optimally positioned close to the natural weight line for a more natural response through the gait cycle [131]. With similar working principle of the Elan Foot, there are the two prostheses by College Park: the Odyssey K2 [132] (Figure 3.18f) and Odyssey K3 [133] (Figure 3.18g).

![Diagram of prostheses](image)

**Figure 3.18:** Össur Proprio Foot (a) picture and schematic representation in (b) normal condition, (c) pre-plantarflexed condition and (d) pre-dorsiflexed condition. (e) Endolite’s Elan Foot.

### The VSPA Foot - Sheperd and Rouse, 2017

The foot prosthesis designed and presented by Shepherd and Rouse in [134, 135], shown in **Figure 3.19a**, is a semi-active variable stiffness prosthesis. The stiffness is varied thanks to a glass fiber leaf spring, a slider that serves as a lower support and a cam system. The fiberglass leaf spring is a beam fixed in its front end (relative to the foot reference) that is loaded by the cam system at the other end. The stiffness changes by changing the position of the slider, i.e., by changing its distance from the fixed joint (or from the point of application of the force imposed by the cam system). Both during dorsiflexion and plantarflexion, the leaf spring is pushed down by the follower cam, which in turn is put into motion by the cam profile. The cam profile moves rigidly with the pylon of the transtibial prosthesis, i.e. the shank. By moving the slider back, the stiffness increases. The variation of the distance of the slider from the fixed constraint is thanks to the 10 W DC motor with a planetary gearhead (DCX 16 L, Maxon Motors, CHE) and the lead
screw (Nook Industries, OH USA). The shape of the cam can be designed in order to provide the desired ankle torque-angle curve.

![Diagram of the VSPA Foot](image1)

Figure 3.19: The VSPA Foot (2007) by Shepherd and Rouse [134].

The adjustment range of the VSPA is 85 mm. The authors moved the slider from the furthest position from the application of the force to the closest possible position obtaining a stiffness range from 0.17 kN/mm to 2.8 kN/mm, where the force is applied perpendicular to the leaf spring, as shown in Figure 3.19.

**Quasi-Passive Foot-Ankle Prosthesis - Lee et al., 2017**

![Diagram of the quasi-passive foot-ankle prosthesis](image2)

Figure 3.20: The quasi-passive foot-ankle prosthesis with pneumatic cylinder [136].

The prosthesis proposed by Lee et al. [136], shown in Figure 3.20, is composed by a pneumatic cylinder which is placed in series with leaf spring (fiber glass), and a solenoid valve that controls the flow of air between the two sides of the cylinder. The solenoid valve works as a mechanical clutch, enabling resetting of the ankle’s equilibrium position. By adjusting the pressure inside the cylinder, the prosthesis can be customized to provide a range of ankle mechanics and also to provide an adapted stiffness based on the activity. When the ankle dorsiflexes, energy is stored by the cylinder and by the fiberglass leaf spring.
The VSF - Glanzer and Adamczyk, 2018

Almost with the same working principle of the VSPA Foot by Sheperd and Rouse, the stiffness of the VS Foot designed by Glanzer and Adamczyk [137], shown in Figure 3.21, is varied thanks to the forefoot keel, which is an overhanging beam that changes its endpoint stiffness by moving a support fulcrum to vary the length of the overhang. Including the battery and the pyramid adapter, the VSF has a mass of 0.649 kg.

Variable Stiffness Prosthetic Foot Based on Rheology Properties of Shear Thickening Fluid

Perhaps it is not appropriate to classify it as one of the semi-active prostheses, but the prosthesis proposed by Tyggyvason et al. certainly falls within the variable-stiffness prostheses [138, 139]. The stiffness of the prosthesis varies in relation to the rotation speed of the ankle. The goal that the authors had was to design a foot prosthesis that provides flexible support for very low walking speeds without, however, sacrificing the advantages of an ESR, namely the accumulation and release of energy that are beneficial for normal walking. Without going into too much detail, a system that exploits the rheological properties of shear thickening fluid is used. The system replaces a fully rigid mechanical link (Figure 3.22a) and is placed in series and parallel with a spring system (Figure 3.22b).
Variable Stiffness Prosthesis

In the prosthesis proposed by Lecomte et al. [140], shown in Figure 3.23, the pylon of the prosthesis deforms a vertical composite plate when it rotates in the sagittal plane. Varying the point at which the pylon starts to impress the force on such composite blade, the stiffness of the system varies. The variation occurs by lowering or raising a system through an actuator. The authors stated, on the basis of the results of their own simulations and experiments, a variation of stiffness of 50% with a system displacement of 20mm, both for the dorsiflexion and for the plantarflexion, with an average of 2.5% variation in stiffness every mm of adjustment.

A Semi-Active Prosthesis for Rock Climbing - Rogers et al., 2020

The foot prosthesis designed by Rogers et al. [141], shown in Figure 3.24, is a semi-active prosthesis for rock climbing. This device is a prosthesis with two degrees of freedom at the ankle. The foot is customized for rock climbing and is screwed to the foot plate. A U-Joint is used to form the joint of the ankle and the subtalar joint. The actuators move the foot in such a way as to allow the rotation of dorsiflexion and plantarflexion and the rotation of inversion and eversion. As the actuators are configured, when they move together in the same
direction, they generate dorsiflexion and plantarflexion. When, instead, they move in opposite directions, they generate eversion and inversion. The prosthetic ankle-foot is designed with the size to be 60% of the 50th percentile feet of the male foot (thinking about the application of rock climbing). The foot is 3D printed. The two actuators are two brushed DC motors (Maxon, DCX 22S) with an output torque of 1 Nm each. A load cell (Futek Advanced Sensor Technology, LCM 200) in axis with each of the two actuators is mounted to provide accurate torque information. The encoder of the motor is a quadrature incremental optical encoder with 512 counts per turn (Maxon Group, ENX16 EASY 5121MP). The battery is a single 3-cell lithium polymer with 800 mAh capacity. The weight of the entire system is 1292 grams.

**Design of a Variable Stiffness Pneumatic Ankle Prosthesis With Self-Recharging for Weightlifting Exercise**

![Figure 3.25: CAD model of the foot prosthesis designed by Mrazsko et al. [142].](image)

The variable stiffness device proposed by Mrazsko et al. [142], shown in Figure 3.25, is a pneumatic transtibial ankle prosthesis concept with semi-active control of ankle stiffness to adjust the prosthesis’ properties for a wider range of gym exercises such as back squat. As opposed to the bionic feet or ESR feet, the pneumatic actuation (Pneumatic Cylinder, bore = 40 mm, Grainger, Part C76F40-50) of this semi-active prosthesis moves the foot around the ankle joint. The component is low-cost compared to bionic feet and it provides powerful force output for usage in a gymnasium environment. The entire prosthesis was designed to withstand a theoretical maximum load of 240.4 kg, representing an 81.6 kg person lifting a 158.8 kg exercise weight while standing on one foot. By means of a control system and a valve, the pressure of the pneumatic cylinder is changed, with the consequence of changing the stiffness of the foot prosthesis for the different activities.

### 3.7.5 Bionic Feet

Not being the focus of this dissertation, details on the state of the art of bionic feet are not given. However, information on the various sub-categories of bionic
feet is still provided, also taking advantage of the work already done by Cherelle et al. [73].

Once the study of literature regarding bionic feet had been carried out, Tabucol classified them and divided them into five sub-categories (Figure 3.26).

**Direct Drive Actuation**

What the author has defined bionic feet with direct drive are the devices in which the electric motor, through a transmission system, directly actuates the foot in such a way that it rotates around the ankle to perform a plantarflexion or dorsiflexion. Prostheses with this type of actuation system are for example the PKU-RoboTPro I [143] (Figure 3.27a) and PKU-RoboTPro II [144] (Figure 3.27b). The prostheses with direct drive actuation are the prostheses that Cherelle et al. have defined bionic feet with stiff actuation system.

**Pneumatical Actuation**

A second classification is that of pneumatically actuated prostheses. Some examples have already been mentioned above. However, new bionic feet with pneumatic actuation have been studied and implemented. One of these is the one proposed by Zheng and Shen (2015) [145,146,146] which utilizes a pneumatic cylinder-type actuator to power the prosthetic ankle joint to support the user’s locomotion. Also
Gabert et al. (2020) [147] designed a prosthetic foot, in this case a polycentric ankle foot prosthesis, using as actuator a pneumatic cylinder. Pneumatical actuation have been used also in semi-active prostheses, as was seen previously.

### Series Elastic Actuators (SEA)

The approach of actuation an ankle-foot prosthesis via a SEA is already a fairly consolidated approach, as Cherelle et al. [73] have also been pointed out in their review paper. As already mentioned above, the SEA was mainly used as an approach to power a bionic feet by the Massachusetts Institute of Technology (MIT) to optimize a prosthesis that was then made marketable first under the name of BiOM, then, with further improvements, with the name of Empower by Ottobock. The author of this thesis schematized in Figure 3.28 the configuration of three of the prototypes that MIT developed. As can be seen, in the first version (Figure 3.28a), there is also a parallel spring, not only the series one, therefore this device could be classified also as SEAPS. Both the springs are helical springs. In the second version (Figure 3.28b), both the springs became leaf springs made of composite material. Finally, the BiOM version was equipped only with the series leaf spring (Figure 3.28c). The series spring had the double function to protect the DC motor from strong and sudden loads and to accumulate elastic energy during the mid stance [76, 91–96, 148, 149]. The parallel spring that was used to accumulate additional elastic energy during the dorsiflexion [91–94, 148].

Also the prostheses developed under the name of SPARKy are actuated with a SEA, as already mentioned previously. The author schematized the configuration of SPARKy 1 [88] and SPARKy 3 [87] in Figure 3.29. The first version, SPARKy 1 relied on a SEA. It was composed by a robotic tendon, composed by a low-power motor, a transmission mechanism and a spring all in series, and it was mounted to the entire foot prosthesis as shown in Figure 3.29a [88]. SPARKy 2 was the optimized version of SPARKy 1, while in the third version (SPARKy 3 - Figure 3.29b), retaining the same working principle of the SEA, a new feature was integrated, such as the universal ankle joint to obtain also the rotation in the frontal plane, in addition to the dorsiflexion/plantarflexion degree of freedom [87].
Figure 3.29: SPARKy and SPARKy 3 reproduced from [88] and [87].

Also Pantoe 1 [90, 150, 151] and Pantoe 2 [152, 153] are active foot prostheses with SEAs. The peculiarity of these two prostheses is the presence of toe joint, which like the ankle joint is actuated by a SEA. Pantoe 2 is the evolution of Pantoe 1. Pantoe 1 is composed of two rigid parts: the rear part that works as the main body of the foot and the toe. Pantoe 2, on the other hand, consists of an elastic heel and a toe (two leaf springs) and a mid foot. This variation from Pantoe 1, according to the authors, improved the absorption of the impact of the foot with the ground. In addition, the spring in series at the metatarsal actuator has been replaced by a spring positioned parallel to the same motor to adjust the stiffness at the metatarsal joint. The schematic representation of the two Pantoee are shown in Figure 3.30.

Figure 3.30: Pantoe 1 and Pantoe 2 reproduced from [90,150,151] and [152,153].

It can be included among the prostheses with SEA also AMP-2.0 [154], a bionic feet that Cherelle et al. have included among the Explosive Elastic Actuators (EEA), with the peculiarity that it is equipped with two springs that can be considered in series with the motor. As a followup of the AMP-Foot 2, the AMP-Foot 3.0 was designed and realized, using an improved actuation method and using two locking mechanisms for improved energy storage during walking [155,156].
Parallel Elastic Actuator (PEA)

As the name suggests, parallel elastic actuator or PEA, the spring is parallel to the motor instead of being in series as in SEA. A remarkable work is that carried out by Sup et al. at Vanderbilt University (USA) [82, 97, 157] where they made two prostheses with the same concept, but as seen in Figure 3.31a and Figure Figure 3.31b, it changes the placement of the implementation. In the first version (Figure 3.31a), an extension of the entire implementation system involves a plantarflexion of the foot, while the plantarflexion in the second version (Figure 3.31b) occurs when the entire system is shortened.

The AMP-Foot 2.0 (2012)

Cherelle and their research team developed (Vrije Universiteit Brussel), prototyped and tested the AMP-Foot 2.0 prosthesis [154, 158]. This prosthesis is equipped with an plantarflexion spring that accumulates elastic energy during the dorsiflexion in mid stance and an electric motor that loads a push-off spring during the stance phase. A locking mechanism ensures that the elastic energy accumulated by the push-off spring thanks to the electric motor, can be injected when it is needed. In this way it is not the motor that must give the power during the push-off but the spring, thus reducing the size of the same motor.

The 3DOFs Transtibial Prosthesis by Madusanka et al. (2014)

Madusanka et al. [159] proposed a foot prosthesis which has 3 DOFs, with the DF/PF and the AB/AD actuated with DC motors, while the IN/EV is a passive degree of freedom. While the DF/PF is active thanks to the ball screw motor system, the degree of freedom in the transverse plane (AB/AD) is active thanks to the belt motor system. The stiffness of the passive inversion-eversion motion is created by means of springs.
The 3DOFs Transtibial Prosthesis by Masum et al. (2014)

Masum et al. [160] proposed a prosthesis equipped with a spherical ankle joint where the rotation in the transverse plane is blocked, while the rotation in the sagittal plane is active thanks to a motor-gear system. Rotation in the front plane is possible, and a spring-damper system creates a torsional stiffness in the inversion and eversion rotations.

A Bionic Foot with Parallel Elastic Actuator from The Chinese University of Hong Kong

Gao et al. have developed at The Chinese University of Hong Kong a foot prosthesis with a Parallel Elastic Actuator [161, 162]. The ankle actuation system consists of a DC motor, a timing-belt and a ball-screw for transmission. A spring is in parallel with the actuation system, and it is compressed by a cam during the dorsiflexion accumulating elastic energy, in such a way is returned during the plantarflexion contributing together with the engine to the generation of the power necessary for the push-off.

The 3DOFs Transtibial Prosthesis by Rad et al. (2016)

A conceptual design of a 3 DOFs foot prosthesis is proposed by Rad et al. [163], where the dorsiflexion/plantarflexion motion is actuated, while the ankle inversion/eversion is passive, likewise the sagittal plane rotation at the toe joint. For DF/PF movement, motors are used as muscles, while cables are used as tendons. Helical springs provide stiffness on rotations in the frontal plane, while a spring with one end attached to the toe and one to the main body of the foot provides stiffness to the toe joint.

A Two Degrees-of-Freedom Bionic Foot Prosthesis from The University of Manchester (UK) and the University of Salford (UK)

At The University of Manchester (UK) and The University of Salford (UK), Agboola-Dobson et al. [164] developed a foot prosthesis that has two degrees of ankle freedom. The rotation in the sagittal plane is actuated by a SEA to emulate the biomechanics of the calf and Achilles tendon. This SEA works in parallel with a spring system. The rotation in the front plane is instead passive to give inversion/eversion.

An Electro-Hydrostatic-Powered Ankle-Foot Prosthesis from Beihang University (Beijing, China)

The prosthesis proposed by Tian et al. [165] is a foot prosthesis operated with an electro-hydraulic system. The elongation of the cylinder-piston system generates a dorsiflexion of the foot, while a shortening generates a plantarflexion.
Jang et al., 2021

The prosthetic foot proposed by the Jang et al. [166] has two degrees of freedom active in the sagittal plane and in the frontal plane to allow dorsiflexion/plantarflexion and eversion/inversion.

CYBERLEGSL-alpha Prosthesis

CYBERLEGSL-alpha is included among the special designs, because, like WalkMECH, it is a transfemoral prosthesis that includes knee and ankle-foot and that has the concept of functioning to recover energy from the knee and then transfer it to the foot-ankle system. The basic difference it has with WalkMECH is the fact that in WalkMECH the ankle, as the knee is passive, while in CYBERLEGSL-alpha, the ankle has as actuator a MACCEPA. CYBERLEGSL-alpha then evolved into CYBERLEGSL-beta where the knee became active. In this analysis the details of the two prostheses in question are not reported and the reader is referred to the works published by the authors who worked on this project [167–169].

3.7.6 Multi-axial Ankle-Foot Prostheses

Although most studies of prosthetics and biomechanics of walking in general have focused on kinematics and kinetics in the sagittal plane, the possibility of having a foot prosthesis with a multiaxial ankle is nothing new. Indeed, in previous studies and/or devices, different approaches were followed to address the same necessity of creating flexibility in all directions of rotation at the ankle-foot prosthesis. The author analyzed the prosthetic foot devices that give the possibility of having rotations on the frontal and transverse planes.
Elastomers were used together with composite components to create the desired flexibility of the foot prosthesis in all directions [170–174]. Split geometries are used in current commercial ESR feet: the elastic parts of the foot prosthesis are cut partially in the longitudinal direction to allow slight eversion and inversion of the foot in case of uneven terrain or laterally sloped grounds. Special modules that create internal/external rotation of the foot prosthesis, besides the function of absorbing the impact of the foot with the ground, are also used; these modules are added externally to ESR feet, such as Elite VT (Figure 3.32a) and Echelon VT (Figure 3.32b) by Blatchford (blatchford.co.uk, accessed on 2 January 2022), the Pro-Flex LP Torsion (Figure 3.32c) and the Pro-Flex XC Torsion (Figure 3.32d) feet by Össur (www.ossur.com, accessed on 2 January 2022) and the Taleo Harmony (Figure 3.32e) and Triton VS (Figure 3.32f) feet by Ottobock (www.ottobock.com, accessed on 2 January 2022). The Triton Side Flex foot (Figure 3.32f) by Ottobock guarantees a rotation in the frontal plane by means of a torsion bar inside a system mounted externally to the elastic group of the ESR foot. Spherical joints have been used in conventional feet using elastomeric bumpers [175–179] or springs [180–182] to create rotational stiffness and damping in at least two rotations.

Bellman et al. realized SPARKY 3, which is a prosthetic foot with actuated motions in the sagittal and frontal planes [87] (Figure 3.33a) by means of a SEA. Seeing in their studies that the rotation of the ankle in inversion/eversion significantly changed during turning maneuvers when compared to straight walking, Ficanha and Rastgaar developed a prosthetic foot with two DOFs, dorsiflexion/plantarflexion and eversion/inversion, both actuated [183] (Figure 3.33b).
Madusanka et al. designed and tested a foot prosthesis with three DOFs at ankle joint, where the dorsiflexion/plantarflexion and adduction/abduction are active, leaving the inversion/eversion passive [159] (Figure 3.33c). A spherical joint is used by Masum et al. in a conceptual design of an ankle system in which the rotation in the sagittal plane can be actuated and the rotation in the frontal plane is passively actuated by means of springs and dampers [160] (Figure 3.33d). Agboola-Dobson proposed a novel powered ankle-foot prosthesis which provides two DOFs motions at the ankle joint: thanks to a custom U-joint ankle joint, the extra-rotations in the frontal plane is permitted, while the motion in the sagittal plane is actuated through a series elastic actuator that emulates the biomechanics of the calf muscle and Achilles tendons [164] (Figure 3.33e).

3.8 Functionality Evaluation of Foot Prostheses

Prosthetic feet are developed according to an underlying hypothesis concerning its clinical value. However, before it can be put into actual use, this clinical value must be established by testing. There are different ways of assessing the biomechanics of human walking in general and with ankle-foot prostheses and they were reviewed in [184]. The functional performance of a foot prosthesis can be determined by two main methods: one method consists in testing the device without interaction with humans (mechanical properties testing), while the other consists in having the prosthesis worn by amputees (human subjects resting) and having them perform one or more activities [184].

3.8.1 Mechanical Properties Testing

In mechanical properties testing there is no interaction between the prosthesis and the human user, but the prosthetic device is tested using a press that compresses the same prosthesis simulating the ground reaction force under certain conditions. In some mechanical tests, the foot prostheses are loaded at different angles of inclination that correspond to the angle of the shank with respect to the ground during the walk [185–187]. In other works, the foot prosthesis is tested statically using the procedure given in ISO 10328 standard to determine the stiffness of the foot and to determine its strength to more critical loads [188], or dynamically, following the procedure given in ISO 22675 [139]. The American Orthotic and Prosthetic Association [189] offers a guideline to perform both static and dynamic tests on foot prostheses, and both in the sagittal plane and in the other two planes, transverse and frontal. Custom testing are also used to carry out the mechanical properties evaluation of foot prosthesis or to verify their functionality [89,190].

3.8.2 Human Subjects Testing

In human subjects testing, the performance of foot prostheses can be evaluated qualitatively, through questionnaires, or quantitatively, through direct or indirect
measurements of kinematics and kinetics. The user can give feedback regarding the benefits or negative sides of the prosthesis and/or answer questions regarding the perceived sensations or even the aesthetics of the device [191–198]. In some tests, the qualitative evaluation is carried out by comparing two or more prostheses during the same human subject testing [192, 199], asking the participants which device they prefer and the reason for the choice [192]. In other cases, a new prosthesis is tested by participants [193,195,196]. Subsequently, they are asked to give feedback about the new device never tested before, as well as compare whether gait and balance have improved, worsened or remained the same in switching from their prosthesis to the new one [193,195].

The most common forms of motion assessment in human subjects testing with ankle-foot prosthesis are the gait analysis on level ground [74,76,82,88,91,95,111,134,136,137,140,143,145,147,149,151–153,157,161,162,166,169,185,186,193–195,200–231], stair [125–127,134,138,143,144,147,211,224,227] and ramp ambulations [95,97,119,120,129,134,143,144,193,202,209,223,230,232,233]. Particular forms of motion assessment are the side-stepping [183,234] and step turning [183,234,235] to evaluate the behavior of the prosthesis in the frontal rotations. Also sit-to-stand situations has been evaluated in some works [227], while a prosthesis for a particular application, rock climbing, was also tested [141].

3.9 Conclusion

To answer the RQ2 (Section 1.3.2), the author of this dissertation made a study of the literature on the state of the art of transtibial prosthetics. They identified and classified the various existing categories of foot prosthetics. Currently, according to the author, the below-knee prostheses can be divided into four main categories: conventional feet, ESR feet, semi-active feet and bionic feet. The conventional feet are the simplest foot prostheses, both in terms of construction and functionality and activities allowed: in fact, they are the category of foot prostheses that have been on the market for longer and are currently prescribed to patients with a relatively low level of ambulation (K2). The ESR feet, like the conventional feet, are passive foot prostheses, with the difference that, with their carbon fiber and/or glass composite elastic elements, they accumulate elastic energy during mid stance and they release it during late stance to help the amputee for the push-off. ESR feet are typically prescribed for amputees with a high level of activity, i.e., K3 and K4.

As will be seen later in this thesis, comparing with the devices already present in the literature and on the market, it can be argued that the features presented in the proposed designs can already be encountered in existing devices. MyFlex-γ is a foot prosthesis that ranks among the ESR feet, the most common category of foot prosthesis and most used by users with an outpatient level K3 and K4. There are already tens of them on the market among the various world manufacturers of prostheses. MyFlex-δ is also an ESR foot prosthesis but with the addition of
a spherical ankle joint. As already said, the ESR feet are already widespread and foot prostheses, even active, are already equipped with an ankle joint with degrees of freedom not limited only to rotation in the sagittal plane. MyFlex-ε is an ESR passive prosthesis with variable stiffness, and therefore it can also be considered comparable to existing technologies. What is proposed in this thesis, however, is an alternative prosthesis that combines important features that are instead separated into other prostheses. MyFlex-ζ is instead an ESR prosthesis with variable stiffness but with the possibility to change the stiffness automatically with a motor. The goal with the final prosthetic device, MyFlex-ζ, is to have a device that is efficient from the point of view of metabolic energy (being ESR foot), which allows adaptations according to the conditions of the ground (thanks to the ball ankle joint) and that can change stiffness according to need (thanks to the active system that makes the stiffness variable). In addition, the MyFlex-ζ will be integrated with an innovative knee prosthesis and control system, in addition to the fact that the next version will be equipped with sensors made of smart materials directly integrated with the composite components. Details about these topics will not be included in this thesis as they are activities carried out by other Phd students of the University of Bologna and the University of Groningen.