Chapter 69

Evolution of prosthetic feet and design based on gait analysis data

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Introduction: Prosthetic lower limb history and structure

Modern prosthesis, either standard or custom, have an elevated impact on daily life quality and are complex medical devices requiring superior technical knowledge level in design and development phases: in order to understand the evolution of the materials and technologies in prosthetic field, it is necessary to proceed step by step.

The first prosthesis was discovered in 2600 BC by the Egyptians (Fig. 1) made of wood and leather; the second in 300 BC in Capua (Fig. 2) made of bronze, iron, and with a wooden core; during Renaissance the prostheses were made of iron, steel, copper, and wood and acquired a functionality and an esthetic role. Amputation techniques improved in parallel with the evolution of technology: no longer suffering and the well-closed stumps created the need for an amputee to return to autonomous life. Mr. Parè (Fig. 3) in 1536 introduced the surgical procedures of modern amputation and construction of lower limb prostheses; he invented a wooden leg with articulated knee and foot in a fixed position. In 1843, Mr. Syme (Fig. 4) defined a new method of ankle amputation that allowed walking using a prosthetic foot. In 1912, Marcel Desoutter, the famous English amputee aviator, produced the first aluminum prosthesis. The American Civil War caused a large number of amputees and a patient named James Hanger, one of the first war amputees, invented the Hanger limb. After the World War II the solid ankle cushion heel (SACH) (Fig. 5) foot was developed at the University of California. After the Vietnam War, the first prosthetic foot dynamic elastic response (DER), made of Delrin (polyamide PA6) built in 1981. By the end of the 1970s the aeronautic and military field started the development of carbon-fiber feet and the continuum reduction of component's weight with aluminum alloys and titanium: the prosthetic limb acquires a new concept: lighter, more durable, and with release of energy (Fig. 6).

The lower limb prosthesis is made of four main components: the liner, the socket, the modular adapters, the foot, and the knee joint for the above-knee (AK) amputee. The liner, which is the interface between the socket and the stump, protects the stump from injuries and loads that the stump suffers during walking. It is made of soft and elastic material and the stump's comfort depends on this. The socket is the custom-made prosthetic component, obtained through the plaster cast on the stump. Socket is the most important prosthesis component: it has the function to contain the residual limb of the amputee, to permit the unloading of weight during gait, and to assure both stump comfort and prosthesis functionality. In fact, an incorrect socket design may generate heavy pressures on stump and may cause skin abrasion, which leads to the patient's suffering conditions until the impossibility of wearing socket. The modular adapters connect socket and foot.

The foot represents the active prosthetic component: it stores and releases the energy and reduces the stump traumas.

The evolution of materials and technologies generated a continuum change of prosthesis structure:

- The first liner was made of rubber, after that silicone, polyurethane, styrene, and thermoplastic gel with mineral oil were used in order to guarantee maximum comfort.
- The socket was made of wood, with metal parts, after that polyethylene was used and for the past 40 years composite materials are used in order to guarantee reduction in weight and maximum structural resistance to loads.
- The foot was made from wood and external polyurethane cover (SACH); by the end of the 1970s arrived the composite materials technology that allowed to realize DER feet.

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FIG. 1 Egyptian finger.

FIG. 2 Capua prosthesis.

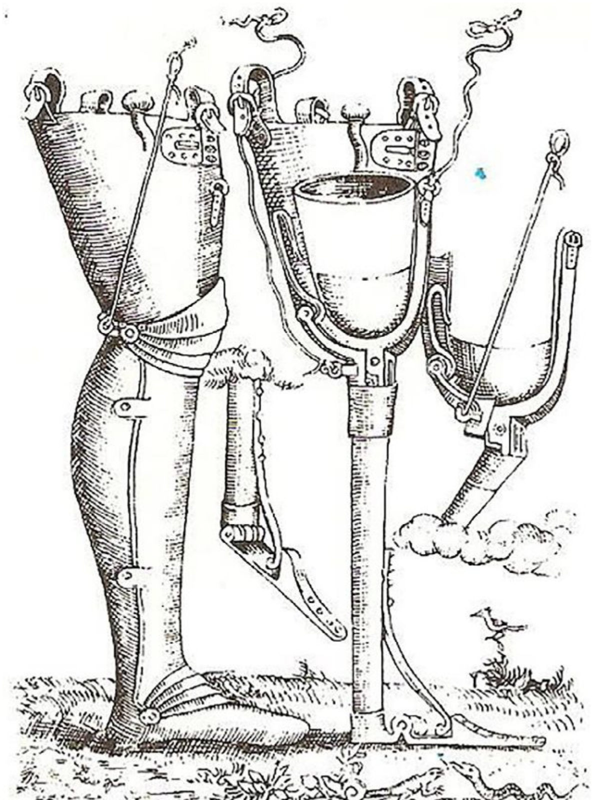

FIG. 3 Parè prosthesis.

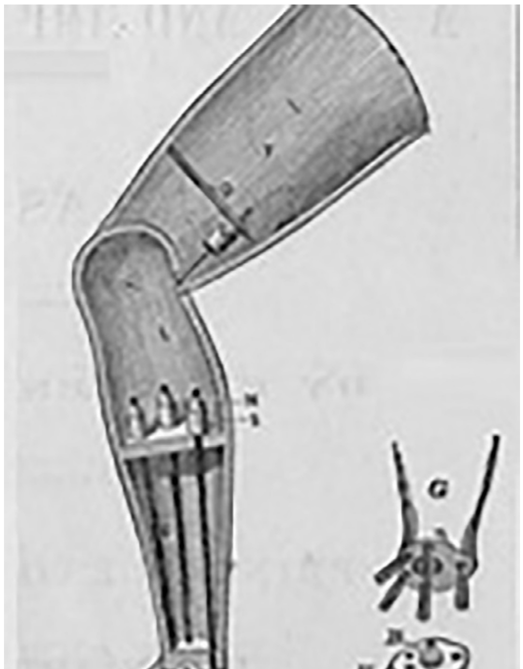

FIG. 4 Syme amputation.

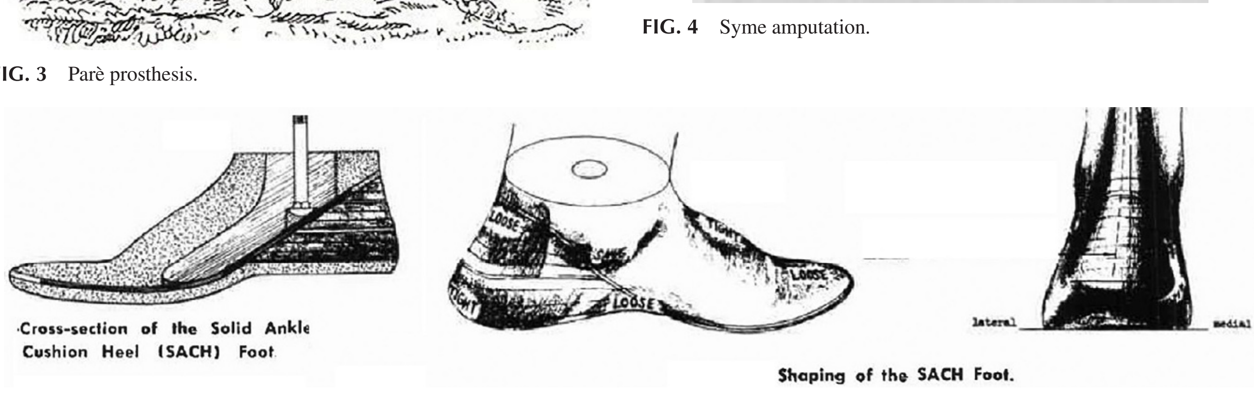

FIG. 5 Solid ankle cushion heel (SACH).

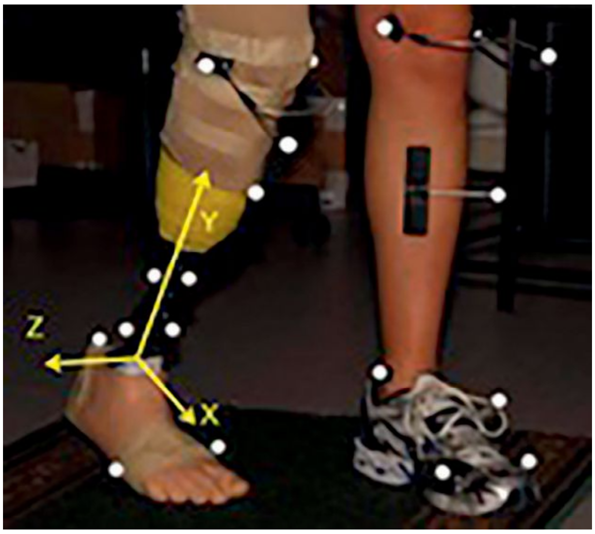

FIG. 6 Gait analysis of walking foot.

- The knee joint was mechanical, after hydraulic, pneumatic and with electronic control; was made in iron, stainless steel, aluminum alloys, titanium, and with composite materials parts.

During the prosthesis assembly, after socket production, the next important phase is the alignment of the components: the prosthesis must replicate as much as possible the patient's healthy leg, both considering the natural varus or leg valgus, and the possible foot intra- or extrarotation. It happens when the laser static alignment prosthesis does not fit at the best, so the orthopedic technician controls the component regulation during the dynamic alignment, observing patient gait and following his/her indications.

The best check of dynamic prosthesis alignment is the gait analysis that allows the measurement of range of motion of joints, but this is not used by most of orthopedic center. Another important step is the choice to assemble the prosthetic foot and knee joint: nowadays it is possible to choose between many products on the market. The choice depends on patient's key level, user's target, weight, and anatomical parameters (length of sound foot and distance of stump's apex on the ground).

K-levels systems to define a choice of prosthetics components and efficiency of feet

In 1995, Medicare adopted the US Health Care Financing Administration's Common Procedure Coding System, using code modifiers (K0, K1, K2, K3, and K4) as a five-level functional classification system to describe the functional abilities of persons who had undergone lower limb amputation (Gailey et al., 2002). The system also describes the medical necessity of certain prosthetic components and additions. By using this system, the physician and prosthetist determine the patient's ability to reach a defined functional state within a reasonable period. That decision is based on a subjective evaluation of

- the patient's past history (including prior prosthetic use, if applicable);
- the patient's current condition, including the status of the residual limb;
- concomitant medical problems; and
- the patient's desire to ambulate.

The standardization of this process would require an instrument that could classify the amputee subject by functional level and quantify function:

- The K0 patient does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility (not eligible for prosthesis).
- The K1 patient has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, a typical limited or unlimited household ambulator (external keel, SACH, or single-axis foot/single-axis or constant friction or blocked knee joint).
- The K2 patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces, a typical community ambulator (flexible keel feet or multiaxial ankle-foot/single-axis or constant friction or polycentric knee joint).
- The K3 patient has the ability or potential for ambulation with variable cadence, a typical community ambulator with the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion (flex foot and flex walk systems, energy-storing foot, multiaxial ankle-foot, or dynamic response foot/fluid and pneumatic knee joint).
- The K4 patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress or energy levels, typical of the prosthetic demands of the child, active adult, or athlete (ankle-foot and knee joint appropriate).

By bibliography the prosthetic feet on the market are divided into key level 1 with a range of efficiency 15%–30% (SACH has 25%), key level 2 with a range of efficiency 30%–45%, key level 3 with a range of efficiency 46%–60%, key level 4 with a range of efficiency 61%–70%, running or sport feet with a range of efficiency > 70% (Prince et al., 1998). The value of efficiency of the sound ankle is 241% (Lemaire et al., 1993; Mokha and Conrey, 2007).

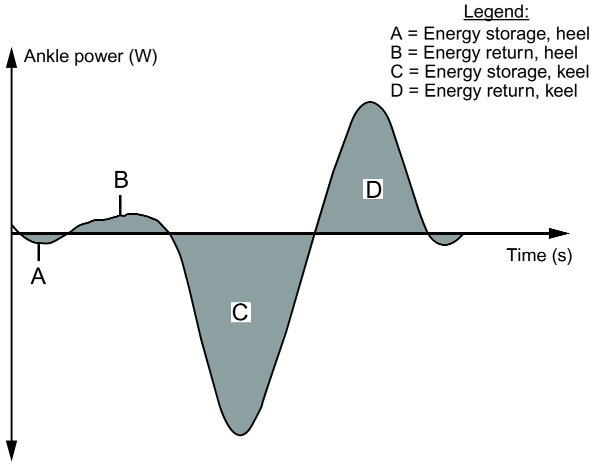

FIG. 7 Efficiency of prosthetic feet.

The mechanical/elastic efficiency (Fig. 7) of carbon-fiber feet with DER is calculated as a ratio between stored energy and released energy during gait analysis. The ankle's power is calculated as $P = M_A \times \theta'$ where M is the moment of force of the ankle and θ' is ankle angular velocity. The time integral of the ankle power at the ankle give the work absorbed and generated by the ankle muscles as $W_{ankle} = S * P_{ankle}$ DT (Hafner et al., 2002; Ehara et al., 1993).

The spring efficiency can be calculated as the percentage of ratio between energy released and energy stored (Ehara et al., 1993).

The efficiency of feet that orthopedic technician chooses for the patient is very important because the biomechanics of amputee is different with respect to sound people in order to restore walking autonomy:

- The walking requires an increase of 10%–40% energy consumption for below-knee (BK) amputee and 60%–100% for AK amputee.
- Compensatory mechanism of sound limb is necessary due to the functional loss of the ankle and limb amputated muscles.
- Prosthetic feet's plantar flexion and dorsiflexion are reduced with respect to sound limb.

Designing prosthetic foot to reduce the gap with sound limb and to allow the accessibility to high technology

Designing a prosthetic foot able to reproduce the anatomical-functional structure of the ankle-foot joint is very complicated: we can try as close as possible to the sound ankle functionality but it is impossible to obtain the same efficiency. The functionality of prosthetic foot depends on efficiency, morphology, thickness, different areas of stiffness, flexibility on heel and forefoot.

By making the toe and arch plantar more rigid and the heel more flexible, the performance of the prosthetic foot could be improved, which allow the reduction of the contribution of the sound knee during the early and the mid-stance and reduction of muscles consumption energy (Fey et al., 2012). The morphology and efficiency promote forward propulsion and reduce the consumption of energy during walking. The choice of size and stiffness of the same type of foot (thickness) depend on the length of sound foot and weight of the patient. The prosthetic foot with a stiffer toe allows a longer and more stable step and a reduction in load for the contralateral sound limb. Drop off (the toe compliance) generates excessive flexion of the knee in the last phase of the stance and during the transition of the load from the prosthetic limb to sound limb; drop off generates an increase in the initial load on the sound limb and energy consumption (Klodd et al., 2010) (Fig. 8).

The prosthetic components are usually designed based on a mix of quantitative and qualitative data, tested internally by the companies and launched on the market at expensive price.

Our methodology, Bonacini Daniele research and development approach, consists of:

- the use of gait analysis data of sound limb and limb with prosthetic feet available on the market; gait analysis data

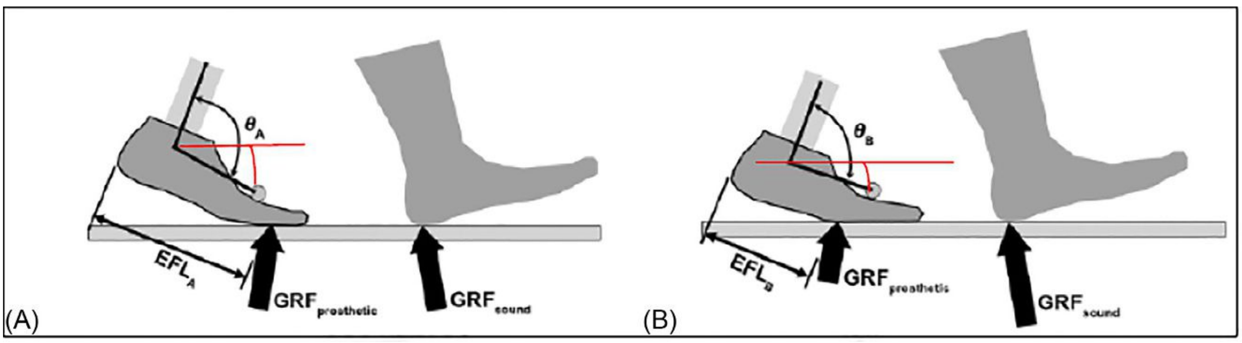

FIG. 8 Stiffener toe.

allows us to understand the performance of prosthetic feet and to compare it with the sound limb behavior; the main movement of the ankle joint during the walk is on the sagittal plane, therefore we analyze overall the movement on this plane during gait analysis; starting from sport devices, we analyze the prosthetic foot that has the higher stress, loads, and deformations; this is similar to the Formula 1 field, where the best innovations, after test of some years, are transferred on the automotive field of serial cars;
- defining targets (functionalities of sound limb and goals that we would obtain);
- designing and manufacturing a prototype;
- Fem analysis, structural check through static and fatigue internal test second ISO 10328 and optimization of lay up;
- official test outside of the company (by Politecnico, University of Milan or Berlin Cert);
- production between molds that allows to realize high quantity of pieces each cycle with the goal to reduce manufacturing cost (technology must be accessible to all);
- patenting of innovations (6 patents in 10 years).

Case study: Running foot

Sessions and time-space parameters

The phases of sprinting biomechanical analysis about amputee athletes with prostheses are two:

- The first session has been devoted to the comparison between normal and amputee athletes in order to analyze the positioning of the amputee inside the sample of normal ones at different competitive level (pro, junior, and amateur): it has been compared with the kinematics parameters (Cugini et al., 2006).
- The second session concerns the behavioral elastic-mechanic analysis of different feet which are on the market (Fig. 9); the final part of this research regards a deepened analysis related to the kinetic one of a wider sample: it is made of five amputee athletes, that is, four BK amputees and one AK, all paralympic athletes (Cugini et al., 2006).

The performance area is 12 m long and 5 m wide; we used VICON SYSTEM and KADABA protocol. The test session consists of six sprinting of 30 m. The time-space parameters, that have the greatest differences with respect to normal athlete, are as follows:

- Wide stride of the amputee is greater than the normal one in order to find balance (it depends on stump length).
- Length stride is lower than the normal ones since knee and hip have a limited flexion and there is absence of plantar flexion in the ankle joint.
- The stance phase and contact time are lower than normal athletes (search for adjustments due to the prosthesis compared to the sound foot).
- Cadence and sprinting velocity of the amputees are lower than the normal athletes of pro- and junior-level but greater than amateur ones.

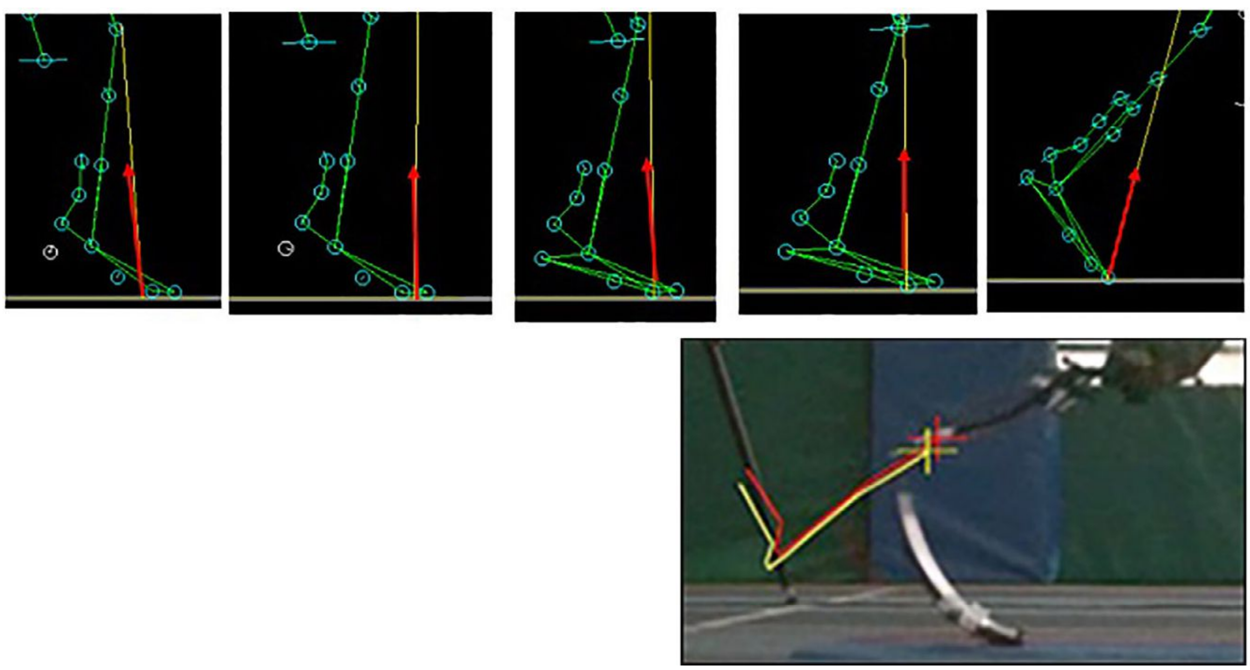

FIG. 9 Rotation of foot behind and negative component of the force on the hip joint.

The gait analysis data by the research will be used to optimize the performance of the athlete: the prosthesis has to be analyzed along the process of socket design and along with the alignment components phase. It has to be considered as a functional evaluation tool in order to understand the athlete condition along the training session and in order to optimize the training type for competitions.

Kinematic parameters of BK amputee

The range of motion of the pelvic tilt (Fig. 10) is proportional to the athlete energetic cost; as a matter of fact, the sprinter maintains the body forward and in the case of normal athletes it assumes lower values. Obliquity goes down on the prosthesis side in loading phase (spring phase). Extrarotation persists during stance phase and low intrarotation persists during swing phase.

Hip prosthesis side: extension close to zero, lower than the normal athletes (60 degrees) in relation to toe-off and a smaller value of the peak flexion during swing phase (about 10–20 degrees less than normal ones). On the frontal plane, during the contact phase, the hip of the amputee limb, in opposition to the sound limb, gets in abduction in order to compensate knee intrarotation. On the horizontal plane, it goes on extrarotation during swing phase).

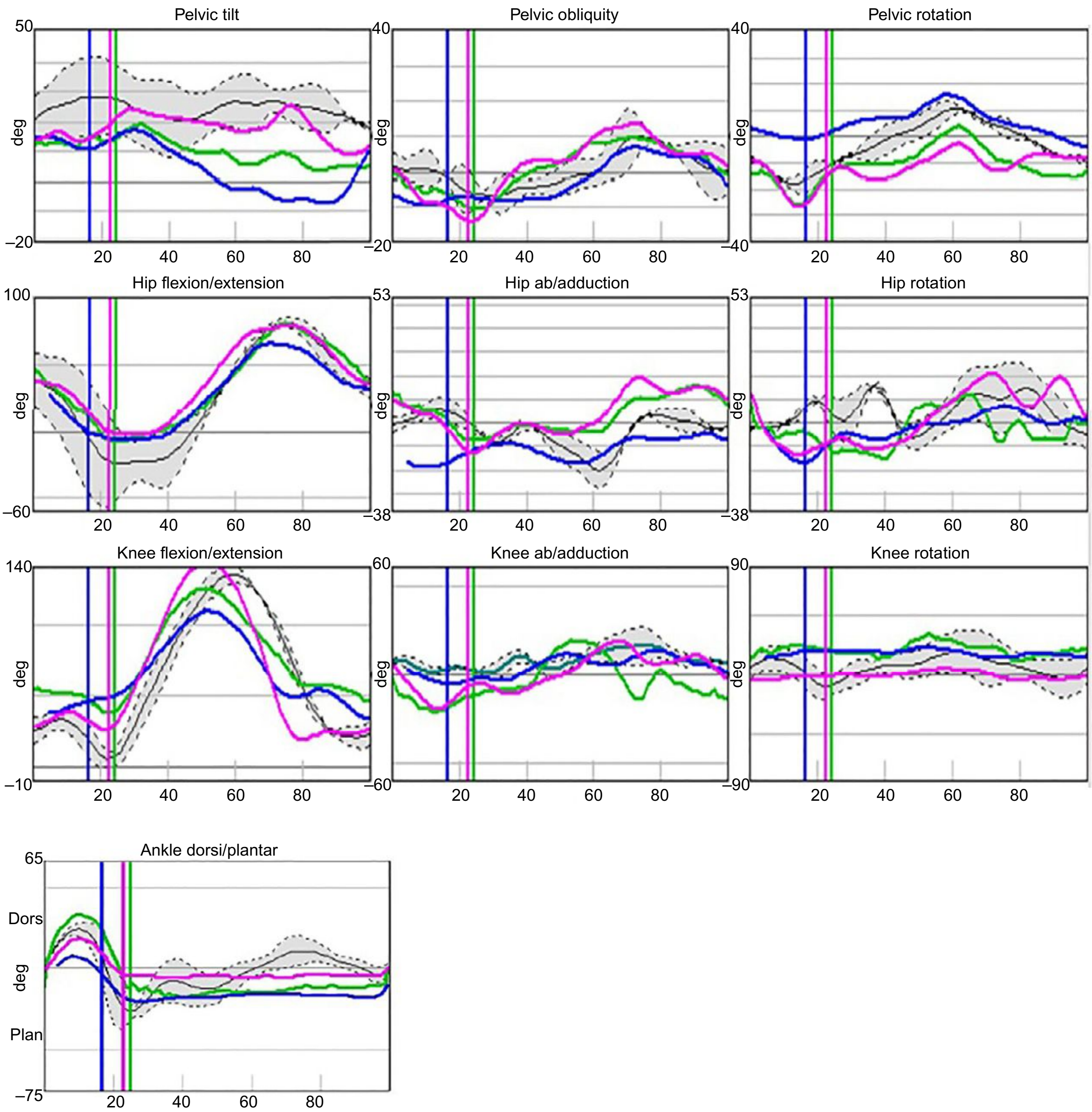

FIG. 10 Joints range of motion during running analysis.

Knee: the knee of the amputee limb gets a limited flexion due to socket ties and a limited extension for the alignment between socket and foot, which maintains a flexion of about 10–20 degrees. On the frontal plane, it shows abduction during stance phase. On the horizontal plane, it shows a constant intrarotation due to the length and morphology of the stump (blue line presents shorter stump).

Ankle: prosthesis ankle angle lower dorsiflexion due to the shape and elasticity of the mechanical foot, close to the horizontal during swing phase due to the maintenance of the angle shaped by the foot profile.

Kinetic parameters of BK amputee

The force unloaded to the ground depends on some parameters: athlete muscle strength, physical attitude, type of prosthetic foot, and class of prosthetic foot (stiffness). Analysis of the same athlete has these values: force on the ground with sound limb is 3234 N and with prosthetic feet is between 1900 and 2200 N.

Limits of running feet and design of new running foot

During foot's flexion, due to foot geometry and stiffness, the foot's posterior vertex (marker that corresponds to the "virtual heel") goes down and back and the connecting line heel-ground contact point rotate by 5 degrees clockwise (Figs. 9 and 10). This generates a negative component of the force (opposite to forwarding direction) (Fig. 11) that increases (by 2/3) muscular work for prosthetic limb. The negative component ceases when the knee rotation center of prosthetic limb go over the perpendicular line through contact point.

The new running foot design (Figs. 12 and 13) obtains these goals:

- Eliminate the negative component force opposite to forward direction (thanks to a new morphology and different stiffness of each foot longitudinal zones).
- The foot morphology has to guarantee a higher plantar flexion.
- Maximum elastic response: the lower ratio between vertical and longitudinal forces Fz/Fx in mid-stance phase, in order to have the best propulsion (thanks to morphology and different thickness areas).
- Functionality of foot similar to functionality of Achilles tendon (it is responsible for 90% of leg efficiency) thanks to morphology and 15 degrees of fixing foot's bracket.
- Optimization of foot-socket alignment in order to maximize ground force (thanks to fixing bracket).
- Larger transversal section foot, that is in contact with the ground, in order to guarantee the best balance between two limbs.

Case study: Walking foot

The sessions of biomechanical analysis about walking amputees with prostheses are two:

- The first session has been devoted to the comparison of walking between the amputee with different prosthetic feet that each use every day since almost 3 months (Cugini et al., 2006).

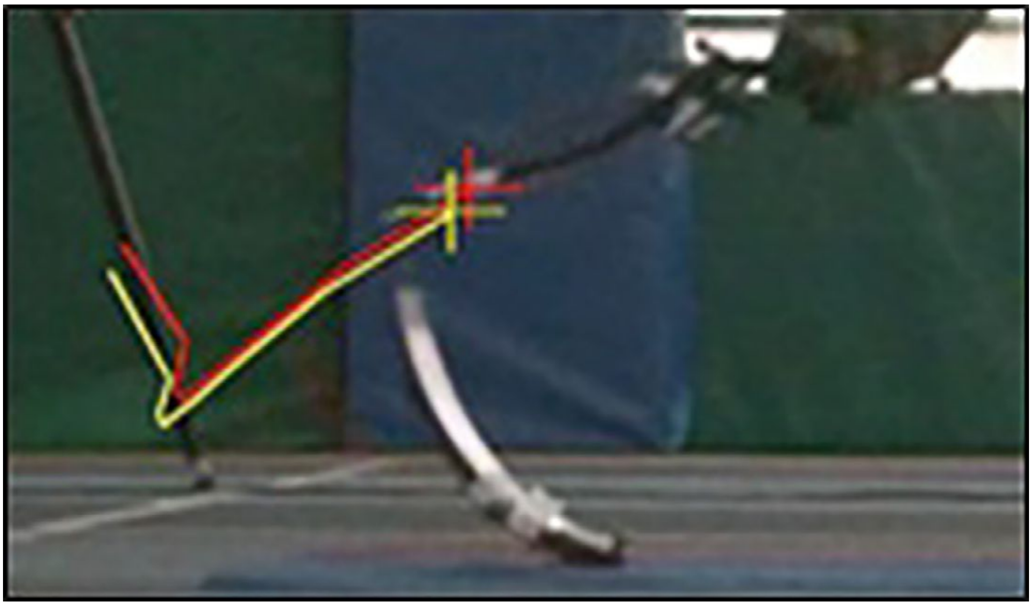

FIG. 11 Rotation foot behind and negative component of forces on the hip.

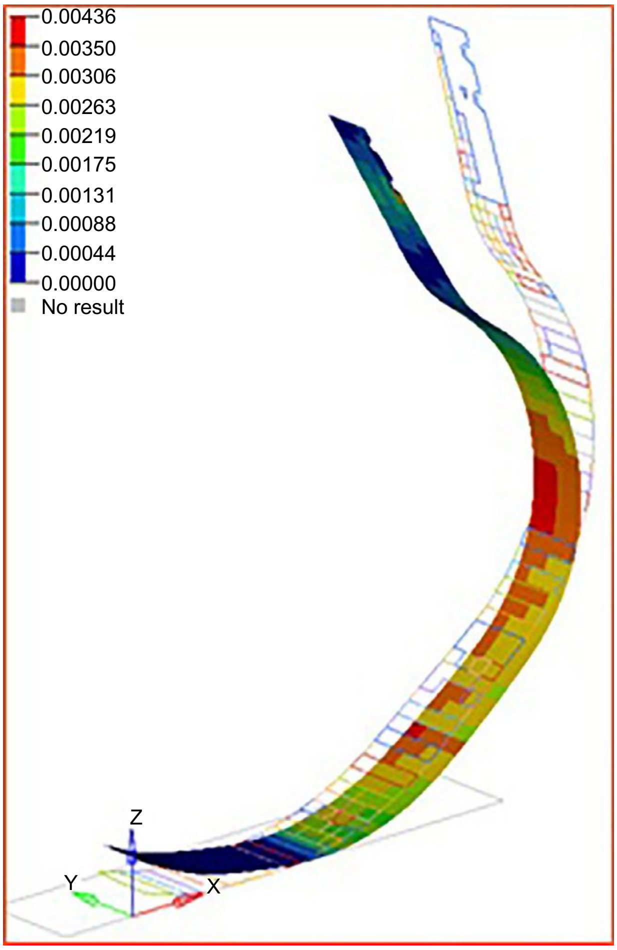

FIG. 12 FEM analysis new running foot.

- The second session is with regard to the walking of amputee with the same prosthetic foot that we give for 1 month of trial so that we can compare the walking amputee with the same prosthetic foot (Figs. 14 and 15) (Cugini et al., 2006).

The gait analysis data by the research will be used to optimize the performance of amputee walking: the prosthesis has to be analyzed along with the process of socket design and the alignment components phase. It has to be considered as a functional evaluation by observing the walking of each amputee with two different feet (foot that uses every day and foot that is in use since 1 month) and different deformation, energy released and efficiency of different prosthetic feet to define the goals of new foot's design.

The critical points of prosthetic feet on the market are as follows:

- low length step (SACH and single-axis 1.2–1.4 m, carbon-fiber feet 1.40–1.6 m);
- limited ankle dorsiflexion (SACH 4 degrees, single-axis 10 degrees, and carbon-fiber feet 10–15 degrees) and low knee flexion during load acceptance;
- Limited rollover between heel and forefoot that increase the muscles work;
- Too flexible the toe of prosthetic feet on the market: the prosthetic foot with a stiffer toe allows a longer and more stable step and a reduction in load for the contralateral sound limb (Fig. 8) (Klodd et al., 2010).

In order to increase the efficiency and released energy, we realize the new feet concept with three-point on the ground that has four laminates that work always to obtain continuum rollover between heel and forefoot and to reduce muscles work.

This new prosthetic foot (Roadwalking foot, Figs. 16 and 17) is composed of four main laminates: one *inferior laminate*, which defines the calcaneus and the forefoot; one *posterior laminate*, which defines the heel and functions like soleus-Achilles' tendon apparatus; two *superior laminates*, which define the instep and functions like anterior tibialis muscle. A pyramid adapter closer to the ankle helps the pylon attachment. The *inferior laminate* starts its work during initial contact: the durability and elasticity must allow load acceptance and storage with a shock absorption function to guarantee comfort to the user but at the same time stability. Its functions stop during the final phase of toe-off when the forefoot gives the final propulsion. The *posterior laminate* functions like Achilles tendon and soleus, which work in eccentric contraction during second rolling, to steady the foot on the sagittal plane; when the foot contacts the ground, during mid-stance, the posterior laminate starts loading and releases propulsion, allows the transition from mid-stance to final stance phase. The two *superior laminates* function like the anterior tibialis muscle permitting a gradual foot rollover until forefoot contacts the ground managing the transit from initial contact to the mid-stance phase. Through their loading, they guarantee dorsiflexion during mid-stance phase and plantar flexion during final propulsive phase. These laminates are connected to the inferior laminate with two screws in the forefoot and other two in the ankle area (Fig. 16).

The pattern of the *ground reaction forces* guarantees a high comfort in the loading phase when we have the first foot contact with the ground (A) and allow to produce a high propulsion force in the final stance phase (B), while in competitors' feet it is lower (Fig. 17).

The evolution continues: bionics, electronics, and nanomaterials are the new fields that can generate the next innovations but it is very important that the innovations are accessible for all amputees as requested on the paper of United Nations for disabled's rights.

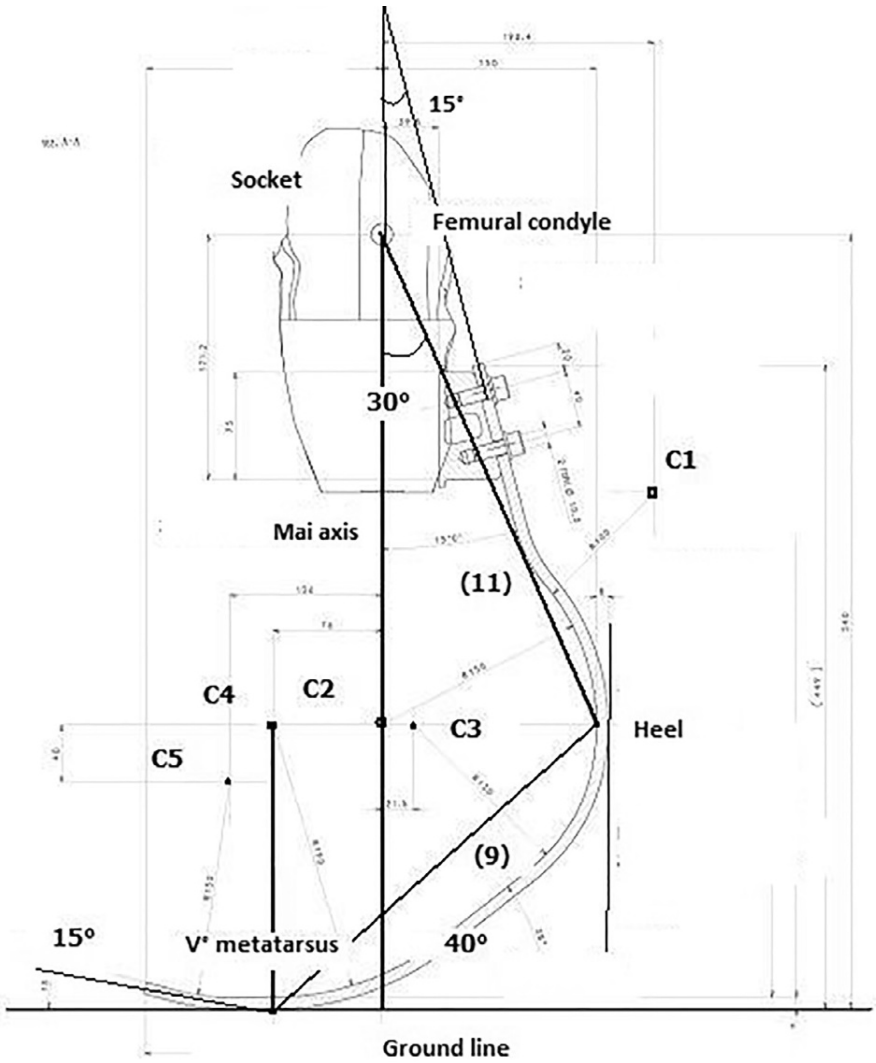

FIG. 13 New running foot, Sprinter's King.

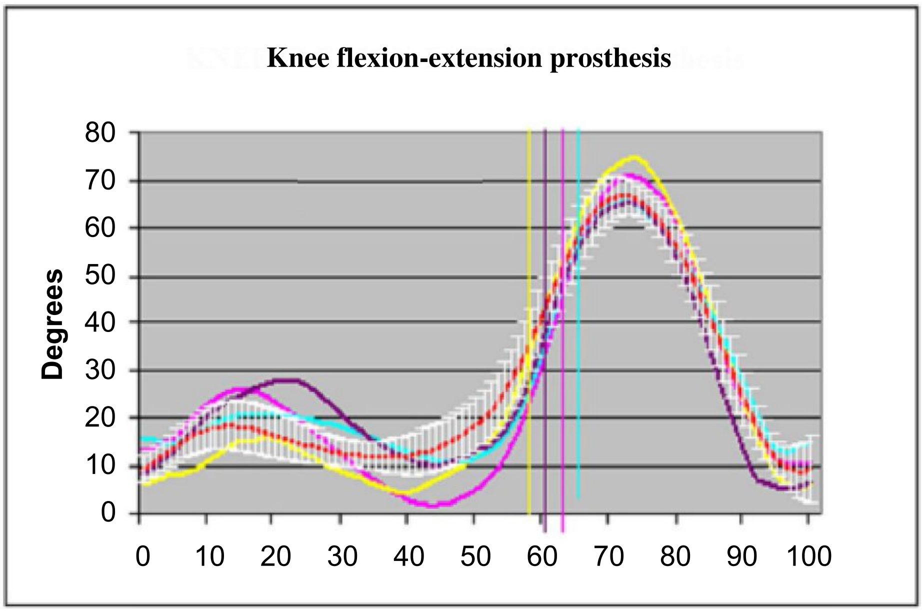

FIG. 14 Knee flexion-extension prosthesis during walking.

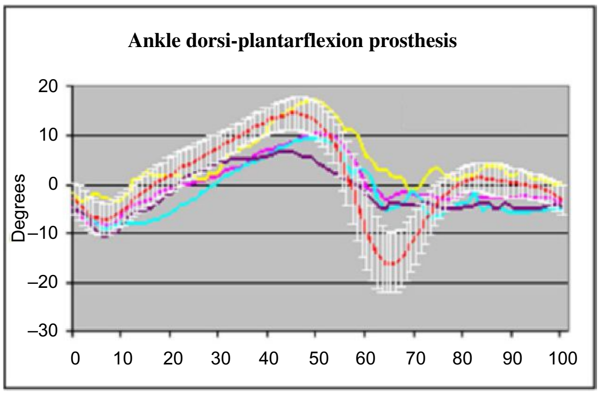

FIG. 15 Ankle dorsi-plantarflexion prosthesis during walking.

FIG. 16 New designed Roadwalking foot.

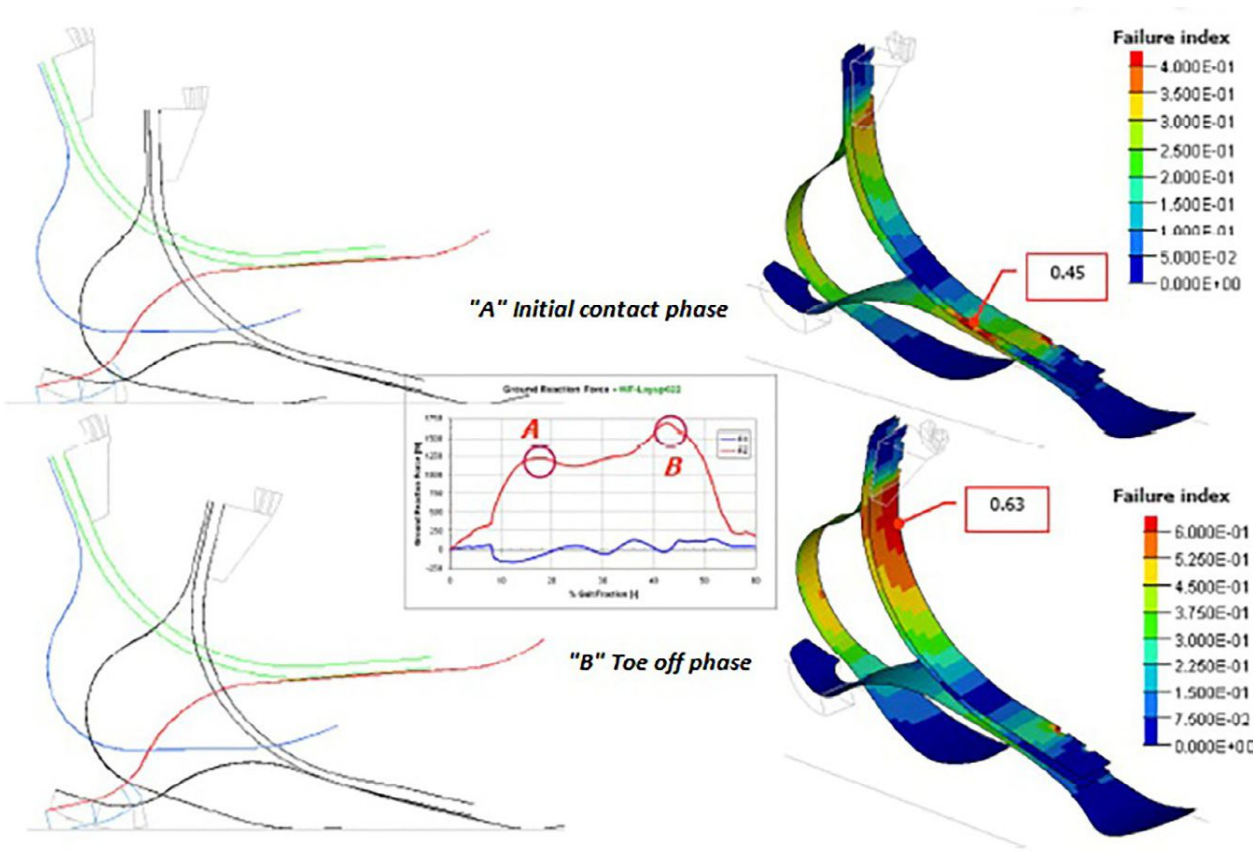

FIG. 17 Roadwalking foot FEM analysis.

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