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A Method for the Verification of Structural Integrity of Lower Limbs Prostheses

C. Colombo[1], E.G. Marchesin[1], L. Vergani[1,2], E. Boccafogli[3] and G. Verni[3]

Abstract: In this study an experimental device for testing the structural integrity of lower limb (transtibial and transfemoral) prostheses is proposed and studied, in accordance with the ISO 10328 Standard. Aim of the development of this device is to mechanically test these kinds of prostheses, for claiming the compliance with the standard. In the first part of the paper, experimental setup of the laboratory is described for the different kinds of prescribed tests. In the second part, the test case of a transtibial prosthesis for children is proposed. After verifying the compliance with the standard of the studied prosthesis, values recorded during the test (i.e. strains or displacements) are used to validate a FE model of the component. The FE model represents a powerful tool to customize the prosthesis to fit the patient's requirements from the design phase and/or to check the possibility of optimizing it in terms of costs.

Keywords: lower limb prostheses, structural integrity, children prostheses.

1 Introduction

To ensure the safety and reliability of a product is always a key aspect of the design phase. This need is felt even more if the devices come, during their use, in direct contact with humans. This is the case of lower limb prostheses, which are worn by amputees in order to return them at least part of the lifestyle they had before the amputation. The damage that could be caused by the failure of a device is not only temporary, due to the physical pain, but also it can cause to the patient a permanent psychological disorder, which makes difficult the following use of similar devices.

For this reason the ISO 10328 was written; it is a standard which prescribes a series of tests to verify the suitability of a lower limb prosthesis for all categories of

[1] Politecnico di Milano, Department of Mechanical Engineering, via La Masa 1, 20156 Milano, Italy.
[2] Corresponding author: laura.vergani@polimi.it. Tel: +39-02-23998249.
[3] Centro Protesi INAIL, via Rabuina 14, 40054 Vigorso di Budrio, Bologna, Italy.

people. Before marketing these products, in fact, certifications for the final users are required: in this standard, requirements and test methods are described, providing indications for static and fatigue tests. These kinds of mechanical tests are necessary for the full prostheses or for their sub-components in order to claim compliance and to homologate the product.

There are many studies behind the drafting of the standard, based on the will to help people to walk normally. Some of these studies were developed long time ago: a state of the art was proposed by Eldestein already in 1988. According to this review, written mainly for physical therapists, the most important characteristics of lower limb prostheses to be taken into consideration in design and applications for patient's utility and comfort, should be:

1. reproduction of the dorsiflexion and of the plantar flexion;
2. motion in the sagittal, frontal and transversal plane;
3. damping and stiffness;
4. reproduction of the real walk, considering the release of the absorbed energy and the gait efficiency;
5. weight;
6. cost;
7. aesthetic appearance.

People with transtibial amputations must deal with the lack of active dorsi and plantar flexions: the dorsiflexion is important in the first stances of the step, right after the heel contact, while the plantar flexion provides active push-off and forward acceleration of the limb [Pitkin (2006); Winter (2009)]. It has been suggested that the ankle plantar flexors are responsible of the majority of the energy generated during walking [Winter (1983)].

The type of prosthesis (mainly the designed geometry and the used materials) is indeed an important factor deeply influencing the ambulation of individuals with transtibial or transfemoral amputations. Generally, amputees have indeed slower ambulation speeds and limitations especially in distance and high speed walking, jogging or running, due to the different gait efficiency with respect to normal ambulation people [Perry (1992); Czerniecki (1996)]. For a proper patient's rehabilitation and for the recovery of the muscle activity, mechanical or more complex robotic devices have been thought and designed.

Aim of the present paper is to describe the design and use of a mechanical bench to test prostheses and to claim the compliance in accordance with the standard. The studied bench is designed for different kinds of prostheses, so it is important to underline its versatility and adaptability to two and three dimensional tests, to full prostheses or components, and to different kinds of prostheses.

In the first part of the work, the available standard for tests on transtibial and transfemoral prostheses is presented and the preparation of a test bench for experimental tests on these devices is described.

In the second part of the paper, a test case is presented, to show the potentialities of the bench application in non conventional testing. The experimental phase is then followed by a numerical analysis of the component: during the tests, strains and displacements are recorded and then used to validate the numerical model. This model represents an useful and powerful tool from the perspective of customization of the prostheses on the individual patient.

2 Introduction to ISO 10328

The aim of the International Standard ISO 10328 (2006) is to provide a univocal method to assert a lower limb prosthesis safe in use. In general, a prosthesis is defined as an external device whose function is to replace the normal use of the lost limb. The Standard is referred to lower limb prostheses and, in particular, to transtibial and transfemoral ones. This kind of prostheses are made of (Figure 1):

- prosthetic foot: it plays an important role in supporting the weight of the entire body and in locomotion;
- ankle device: the human ankle is made up of four distinct bones: tibia, fibula, talus and calcaneus. The interaction between these bones allows movements of the joint characterized by three axes and three related degrees of freedom. In an ankle prosthesis in general only the flexion and the extension are reproduced;
- pylon: it represents the fibula and can be made of titanium, aluminum or steel;
- prosthetic knee: it has to mimic the function of the normal knee while providing stability and safety. It can be used a simple mechanical device (monocentric or polycentric mechanism) or a hydraulic or pneumatic mechanism;
- socket: it is the rigid component of the interface of the prosthesis with the human leg and it has the same shape of the amputee's leg allowing a more comfortable fitting of the prosthesis;

- liner: it is positioned into the socket and it is a soft component which works like a dumper to absorb the hit of the leg with the ground.

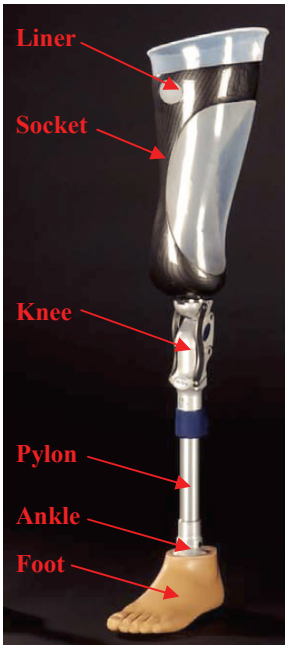

Figure 1: Components of a transfemoral prosthesis [www.ottobock.com]

Two main types of tests are prescribed: tests on the whole prosthesis, identified as "Principal structural tests", and tests on the components, "Separate structural tests". Depending on the device object of study, different tests are selected and performed. These two main types of tests are divided in subgroups:

- Proof strength: static load representing an occasional severe event, which can be sustained by the prosthesis without loss of functionality;
- Ultimate strength: static load representing a huge single event, which can be sustained by the prosthesis and can also damage it permanently;
- Fatigue strength: cyclic load which can be sustained by the prosthesis for a given number of cycles;
- Static strength in torsion: as the proof strength, but with a load applied in torsion.

Figure 2 is an overview of all possible tests. For each of them, the number of sample needed in order to claim compliance with the Standard is two.

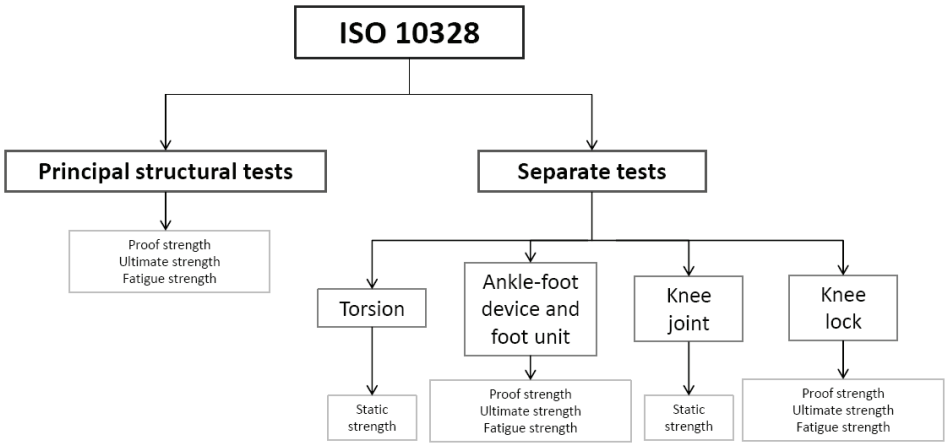

Figure 2: Flowchart of tests prescribed by the ISO 10328

To totally define a test, information about involved loads and geometric parameters of the test bench are required. The loading conditions and the positioning of the prosthesis in the space are defined dividing the amputees into three categories based on their weight. Data about each category are obtained from the gait analysis of amputees whose body mass falls within the limits:

- P3: for an amputee till 60 kg of weight;
- P4: for an amputee till 80 kg of weight;
- P5: for an amputee till 90 kg of weight.

In particular, each test configuration has to be defined in a coordinate system which contains a geometric system of planes, lines and points (Figure 3). The procedure allows defining reference parameters both for the position of the load line, corresponding to the direction of the test force, and for the alignment of the test samples within the coordinate system. Four planes are considered during the positioning of the prosthesis:

- Top reference plane
- Knee reference plane

- Ankle reference plane
- Bottom reference plane

Each plane is identified by its distance from the ground, measured along the axis of the prosthesis, shown in Figure 3 as the *u* axis.

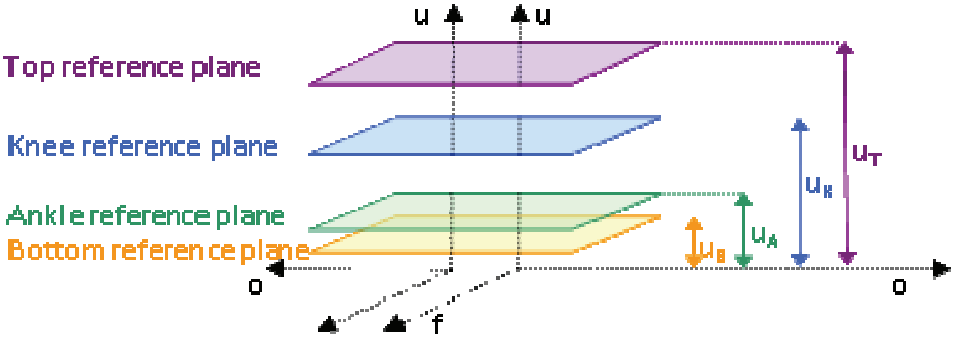

Figure 3: Schematization of the reference planes

Figure 4: Schematization of the stance for the normal walk and related interpretation of the ISO 10328 standard: a) heel contact and b) toe-off

Load reference points are fixed on these planes with an offset that depends on the weight category which the prosthesis is designed for (P3, P4 or P5) and on the required type of test. In fact, for principal tests the load line must be three-dimensional with respect to the axis of the prosthesis, whereas for separate test on ankle-foot device or foot unit it must be two-dimensional.

The Standard identifies two different test loading conditions, I and II, related to the maximum loads occurring at different instants during the stance phase of normal walking (Figure 4):

- Test loading condition I: related to the maximum load occurring early in the stance phase of walking (heel contact);

- Test loading condition II: related to the maximum load occurring late in the stance phase of walking (toe-off).

Both the configurations follow the data collected during the gait analysis.

An additional configuration concerns separate tests in torsion: the Standard prescribes to fix one end of the test sample and to apply to the other end a twisting moment, paying attention to put the ankle-joint centre and the knee-joint centre on the axis of torque application.

3 Test bench in accordance with the ISO 10328

A test bench was designed and built at the Department of Mechanical Engineering of Politecnico di Milano and can be used to perform tests according to the ISO 10328. The equipment is made up of two hydraulic actuators, a constraint to the ground, two plates and two disks for the application of the load on the foot and a control unit. These components can be arranged in various positions in order to satisfy the different configurations prescribed by the Standard. In Figure 5 and 6 two configurations are shown: the first one is referred to a principal static test and the load line is positioned in a three-dimensional way with respect to the axis of the prosthesis, the second one shows a separate static test on ankle-foot device and has a two-dimensional configuration.

In Figure 5, it is shown that the load application is performed by a single hydraulic actuator with a steel disk mounted at its extremity. In fact, the two load configurations (I and II) can be implemented separately. In correspondence of its free extremity, the pylon is constrained to a structure fixed to the ground, whereas the foot is loaded. To ensure a correct placing of the sample during tests, the prosthesis axis is tilted with respect to the hydraulic piston one. Experimental tests are in general performed in load control and piston displacements are recorded in the two different test configurations.

Figure 6 shows that for the separate tests two hydraulic actuators are involved and the prosthesis is fixed to the ground in order to maintain it horizontal. This time, the extremities of the actuators are linked to two plates, which push the foot and also allow transversal movements in order to load the structure in a more natural way. Each plate is covered by a rubber layer to facilitate the adhesion to the foot. In this case, the Standard prescribes fixed angles between the axis of the actuator and the axis of the prosthesis, as well as in the third plane (Figure 6).

Also separate static tests in torsion can be performed and in this case the prosthesis is fixed in correspondence of the end of the pylon whereas its other extremity, which is connected to the foot, is fixed to a bar that is loaded at its two extremities in order to transmit the torque (Figure 7). The rotation is calculated starting from

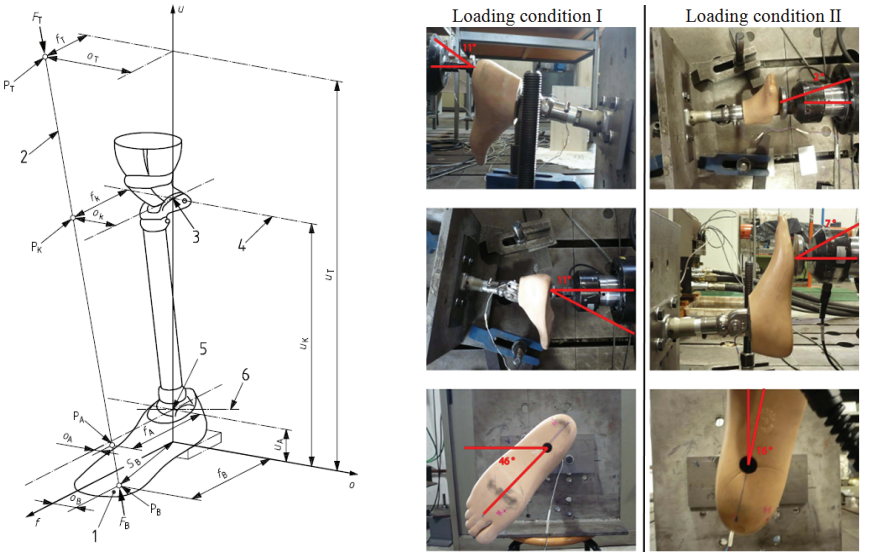

Figure 5: Principal tests: three-dimensional loading configuration

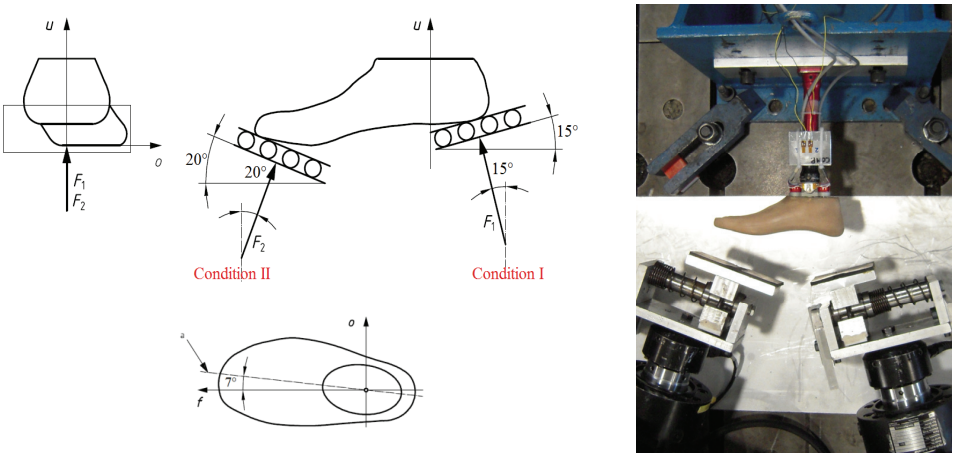

Figure 6: Separate tests on ankle-foot device: two-dimensional configuration

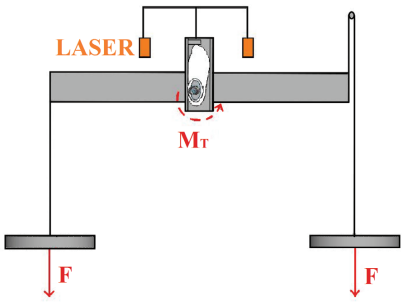

Figure 7: Separate test in torsion

the measurements of the vertical displacements by means of two lasers positioned at the middle of the free extremities of the rod.

The test bench can be adapted to all the configurations required and allows the homologation according to the ISO 10328.

4 Test case

The present paragraph describes a test case with a practical application of the designed test bench. This is an application related to the structural testing and monitoring of prosthetic devices, designed for transtibial amputee children and for their rehabilitation.

4.1 Ankle prosthesis designed for children

The device object of study is an ankle prosthesis, designed by INAIL (Italian institute providing sickness benefit to people injured at work) and addressed to children from 8 up to 12 years-old, with a maximum weight of 45 kg. Dealing with children, it is very important to ensure them the use of devices allowing dynamic movements and leading them towards a correct posture. Indeed, children learn quickly posture defects and movements, and it is more difficult or even almost impossible to correct them in their adulthood. Most of problems occurring during the design of a prosthesis addressed to children are linked to their growth: body morphology and mobility require frequent changes of the prosthesis characteristics. The resulting change of prostheses seems therefore inevitable, with a corresponding increase in costs for the patient. Aim of the design and study of this prosthesis is the minimization of the number of prostheses required by a child during his growing up.

The ankle prosthesis is made up of different sub-components, see Figure 8.

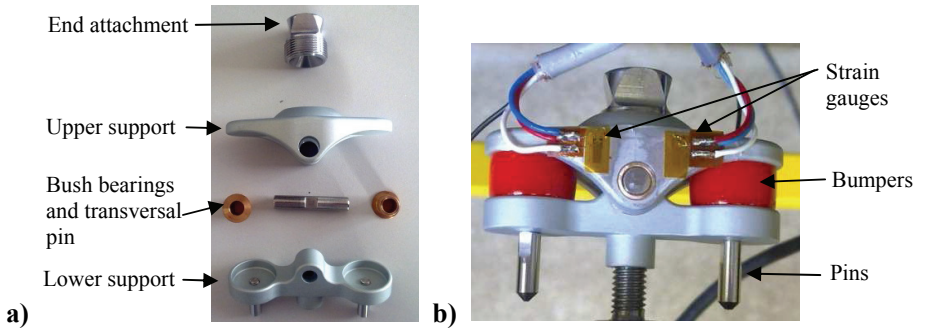

Figure 8: The ankle prosthesis for children: a) components and b) assembly

- two shaped supports in Aluminum alloy (Ergal): an upper one to be joined to the pylon (which represents the tibia of the human body) and a lower one to the prosthetic foot;
- two bush bearings in G-CuAl11Fe4Ni4 (UNI5275);
- an end attachment in Inox steel for the clamping of the ankle to the pylon;
- a transversal pin in Inox steel, crossing the ankle upper support. It permits the rotation of the ankle around its axis and foot movements of flexion/extension. This movement is considered sufficient to preserve a correct posture and gait for children;
- two pins in Inox steel, to completely fix the prosthesis in the wooden part of the foot;
- two bumpers in elastomeric material: three pairs of bumpers are available, to vary the ankle rotational stiffness and therefore to adapt it to the patient's needs. Lower stiffness is used for younger patients, while stiffness is increased with the weight and the loading forces acting on the ankle prosthesis: this ensures the adaptability of the device to a wider range of age;
- an allen screw for locking transversal movements of the transversal pin.

4.2 Loads and geometrical distances rescaling

Since a standard strictly addressed to experimental tests on prostheses for children does not exist in the literature, it is necessary to adapt ISO 10328, proposed for adults.

To rescale the loads prescribed in the standard and to adapt them to the experimental tests on a prosthesis for children, dummies are taken into consideration [Foster, Kortge and Wolanin (1977)] [Kaleps et al. (1988)]. Indeed, dummies are used in the automotive field, especially for crash tests, and their goal is the simulation of humans' physical properties in order to evaluate the safety of vehicles. It is evident that they have to completely reproduce the human answer in extreme situations: for this reason, their anthropomorphic dimensions are based on percentile curves. The comparison with crash tests dummies is directly related to ISO 10328 standard, since it is mainly based on geometrical dimensions of lower limbs. Considering the geometrical measures, it is therefore possible to make a comparison between adults and children.

Considering P3 category of the standard, which is the nearest to children characteristics due to the lower considered weight, it is possible to confirm that it corresponds to the Hybrid III dummy, 75^{th} percentile, male. This check is done by comparing the weight and the knee height from the ground, u_K (as defined in Figure 3). Given that it is therefore possible to use Hybrid III dummies as a reference in terms of geometrical dimensions, available data in the literature for these kinds of dummies are referred to 3, 6 and 10 years old children. These data have to be adapted to the studied test case, the 12 years old boy.

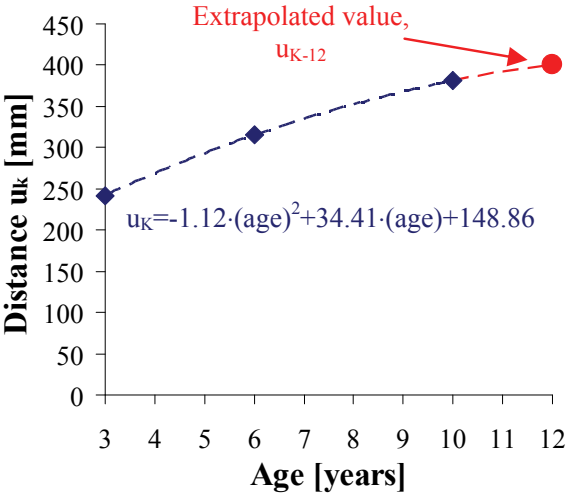

Figure 9: Trend of the u_k distance during children growth

To plan and perform experimental tests, the geometrical positioning of the prosthesis and the distances between reference planes (Figure 3) are fundamental. Considering u_K data for Hybrid III dummies at the different available ages, it is possible

to make a parabolic interpolation, as shown in Figure 9: u_{K-12} value, referred to a 12 years old child, can be extrapolated from this trend.

The ratio between the knee height from the ground (u_K) for an adult and a child can be assumed as a coefficient k of linear proportionality to calculate all the other dimensions. The u_{K-P3} for P3 category of the ISO 10328 standard is 500 mm; the extrapolated value for u_{K-12} allows defining k as:

$$k = \frac{u_{K-12}}{u_{K-P3}} = \frac{400}{500} = 0.8 \tag{1}$$

From this proportionality coefficient, a resizing of the distances related to the other reference planes specified in the ISO 10328 for adults is proposed. In this way, the values of the same distances for a 12-years old child, corresponding to the maximum loads which the prosthesis was designed for, can be obtained. Results are shown in Table 1.a. This method, used for geometrical dimensions determination, is applied to the test loads as well: Table 1.b shows the loads to be considered during experimental tests. In this table, constant values both for the minimum of the separate cyclic test and for the separate static test in torsion are reported, since the ISO 10328 standard prescribes the same values for all the considered categories.

According to the indications of ISO standard, all tests are duplicated. Therefore, two ankles are taken into account and loaded for each type of test.

4.3 Experimental tests

By means of the designed equipment and of the setup configuration described in Par. 3, experimental tests are carried out on the ankle prosthesis for children. To perform the tests, coupled to the ankle shown in Figure 8, other components for transtibial prostheses are required:

- a pylon, which can support a weight of 45 kg, as the ankle;
- a prosthetic foot, *Dynamic* model, with a length of 21 cm.

Both these components are commercially available and manufactured by OttoBock [www.ottobock.com], so the test is mainly addressed to the designed ankle. For this reason, test setup used for loads application, is related to “separate” type.

Moreover, since experimental tests are related to the maximum load that can be applied to the prosthesis, referred to 45 kg of the patient’s weight, the ankle is assembled with the most rigid bumpers.

Separate static proof tests, ultimate strength tests and cyclic tests are performed by using the setup configuration shown in Figure 10. According to the standard, if the

Table 1: (a) Geometrical dimensions and b.) loads for foot prostheses of a 12-years old child

(a)

Plane	**Distance [mm]**
u_T	520
u_K	400
u_A	64
u_B	0

(b)

Test	**Load**	
	I	**II**
Separate static proof [N]	1290	1290
Separate static ultimate strength [N]	1935	1935
	2580	2580
Separate cyclic (min) [N]	50	50
(max) [N]	777	777
(number of cycles)	2000000	
Separate static in torsion [Nm]	50	

prosthesis sample positively pass one of these tests, it can be used for the following one. The test sequence is as in Table 1.

Results of the static and ultimate static test are shown in Figure 11: it shows the trend of loads and related displacements. Ultimate static test involves a bigger load than the static proof test and thus more significant. Displacements in configuration II are more evident than in configuration I because of the foot toe is mostly made of rubber, which has a lower stiffness than materials present in the heel.

Referring to cyclic tests, $2{\cdot}10^6$ cycles are carried out for both the two considered ankles. The displacements of the whole prosthesis vary during the cyclic test: a progressive deterioration of the prosthesis, probably due to rubber characteristics, was observed. This degradation of the mechanical properties was more evident at the beginning of the test, while remained almost constant from $5{\cdot}10^5$ cycles till the end of the test.

Two separate static tests in torsion are performed, considering the setup shown in Figure 7. All the described tests, performed on the ankle prosthesis designed for children, gave positive results.

4.4 FE modeling

Together with the experimental tests on the prosthetic device, a numerical FE model is developed by means of the software *Abaqus V6.9*. This model needs to be validated through the comparison with experimental tests in terms of piston displacement (in configuration I and II) and strains on the ankle prosthesis. During experimental tests, indeed, strain gauges were placed on the upper support of the ankle, in the position shown in Figure 8.b. This was the only free region of the ankle prosthesis where it is possible the application of this devices for experimental strain measure: the recorded values are used for the numerical model validation, as shown in the following. Once the numerical model is validated and reliable, indeed, it could be an useful tool to customize the ankle to the patient's needs and/or to optimize the prosthesis design with respect to many parameters important to the manufacturer (i.e. costs, materials, machining...). In this light, an example will be shown in the following paragraph.

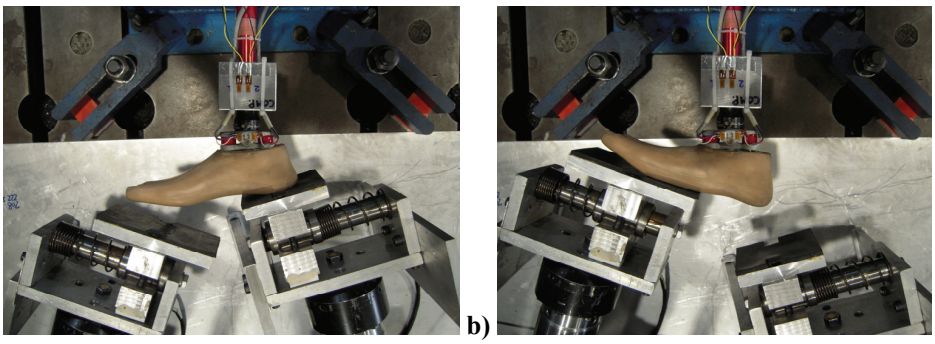

Figure 10: Layout of the test equipment; a,b) Loading configuration I and II

The numerical study is related to the separate static tests. Before considering the full prosthesis, a FE model of the single elastomeric bumper is created. Indeed, to better simulate its hyper-elastic behavior and get its stiffness, experimental compression tests are carried out on the bumper, at the load level applied during the static test. In the numerical simulation, the used law to describe the mechanical behavior of the bumper is the *neo-Hooke* [Hibbitt, Karlsson and Soerensen (2009)]. The material is considered as incompressible, and the constants to describe the model are evaluated iteratively, based on the experimentally measured displacement.

Once obtained the information about the mechanical behavior of the bumpers, the

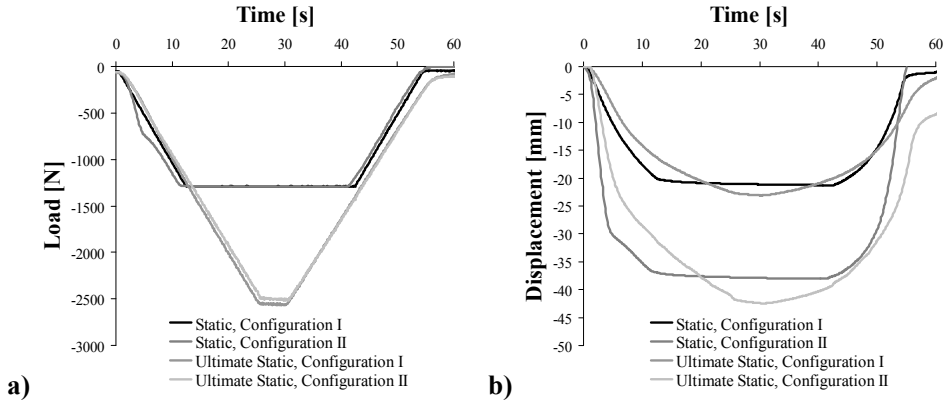

Figure 11: Experimental result: applied load (a) and resulting displacement (b) trends

attention was focused on the prosthetic foot, commercially available and structurally certified by the producer. The foot is therefore not object of study, but it is a part of the prosthesis which actively conveys the loads from the pistons to the ankle. For this reason, it is modeled as a "black box" with a linear elastic behavior, as in [Colombo, Marchesin, Vergani, Boccafogli and Verni (2011)].

The three-dimensional profile of the foot is collected by a 3D scanner (Konica Minolta Non-contact 3D Digitizer - Vi-9i Model). The foot is internally composed of an inner wooden core, and a series of foam layers in different densities, in order to provide the patient with cushioning and displacements similar to a healthy limb. To simplify the numerical analysis, the foot is divided into two parts (shown in Figure 12). The upper part (A) corresponds to the wooden core characterized by a bigger stiffness, which will be in contact with the lower support of the ankle device. The lower part (B) corresponds to the foam, easily deformable. The mechanical properties (the elastic modulus and the Poisson's ratio) of these two parts will be obtained by iterations, as discussed in the following.

Finally, the whole model of the prosthesis is built up and it consists in a series of sub-components: the prosthetic foot, the ankle components of the prosthesis including the bumpers, and a rigid plate corresponding to the end of the piston. The imposed constraints in the numerical simulation are:

- a clamp at the top of the upper support: in this way, the tibia pylon is not schematized in the model;

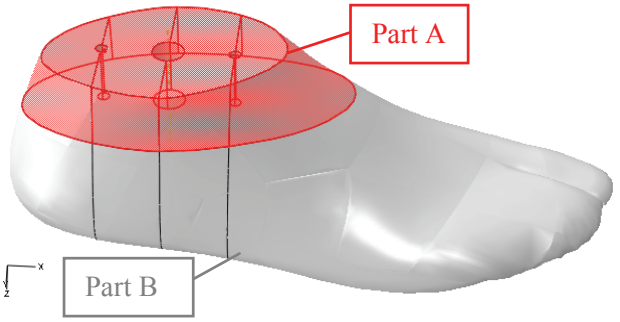

Figure 12: Schematic representation used for the numerical simulation of the foot prosthesis

- a tie between the foot and the ankle: this joint is ensured in the real component by the two pins in the wood and by the application of a bi-component glue. The pins are therefore not introduced in the numerical model;
- a tie between the lower support and the bumpers, which are indeed forced into the lower support. The joint between the bumpers and the upper support is a tie only if the bumper is loaded in compression, otherwise it is free;
- a tie between the bush bearings and the upper support, and a small sliding contact between the bearings and the transversal pin, so that this last element is free to rotate and to transmit loads;
- a unilateral contact between the rigid plate and the foot; no friction is considered.

The experimentally measured displacements at the pistons are applied to the model, separately for configurations I and II, and the reaction force at the clamp of the upper support is evaluated. The numerical model is calibrated by iterating the values of the elastic modulus of A and B foot parts, till this reaction force is equal to the experimentally evaluated one. In particular, for configuration I a displacement of 20 mm is imposed, whereas 40 mm in configuration II, both corresponding to a reaction force at the clamp of 1290 N.

In Table 2.a the imposed values of elastic modulus and Poisson's ratio are reported for the different considered materials; the obtained values from numerical simulations on the prosthetic foot are reported in Table 2.b. In Figure 13 a comparison

Table 2: Imposed (a.) and evaluated (b.) mechanical properties for the elements of the prosthesis.

(a)

Component	**Material**	**E [MPa]**	ν **[-]**
Upper and lower supports	Ergal	71700	0.33
Transversal pin	Inox steel	196000	0.29
Bush bearings	Bronze	110000	0.32

(b)

Foot part	**E [MPa] configuration I**	**E [MPa] configuration II**	ν **[-]**
(A)	54	250	0.3
(B)	1.1	7.4	0.495

between real and numerical displacements is also shown.

Once calibrated, the model must be validated by a comparison with the strains recorded during the test, as shown in Table 3. As it can be evinced from the data reported in this table, the numerical simulation is in good accordance with the experimental data. The percentage differences in strains values reflect the difficulty of modeling all the interactions between the different parts in accordance with their real behavior; the numerical model slightly underestimates the experimental strains.

Finally, Figure 14 shows the von Mises (vM) stresses in the most stressed components of the prosthesis: the transversal pin and the lower support of the ankle prosthesis. The component involved by the highest stress is the transversal pin; the stress peak corresponds to specific areas with sharp edges, not true in real components. In none of the considered load cases, in fact, components are yielded or permanently deformed.

The developed model can therefore be considered as validated through the comparison with experimental data; in the following paragraph, this model is used for comparisons and discussions on the used materials and considered geometry.

4.5 Considerations from numerical simulations

In this section, an example on the use of the prosthesis numerical model is presented. It deals with a comparison between two possible design solutions for the ankle: the one already commercially available in titanium alloy (Ti 6Al-4V), and the new version in aluminum alloy (Ergal), used for the previously described experimental tests. These two versions of the prosthetic ankle are different both in the material and in the geometry. The parts where these changes are more evident are

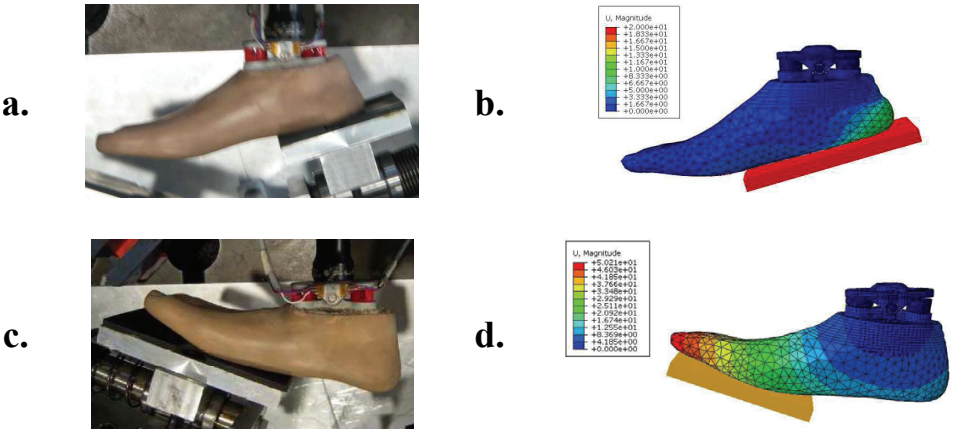

Figure 13: Comparison between experimental and numerical displacements in configuration I (a,b) and II (c,d).

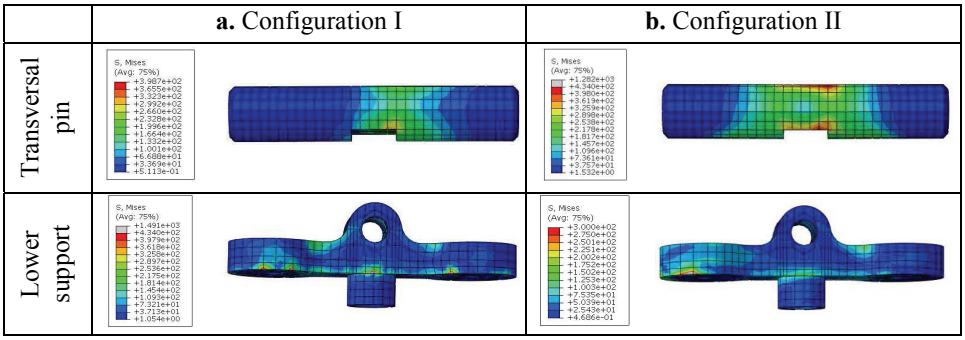

Figure 14: Von Mises stresses in the two most stressed components

Table 3: Comparison between experimental and numerical strains on the ankle

Position of the strain gauge	Configuration	ε_{exp} $[\mu\varepsilon]$	ε_{num} $[\mu\varepsilon]$	Difference [%]
Front	I	+ 28.2	+ 24.8	- 12 %
Rear	I	- 102.1	- 93.3	- 8 %
Front	II	- 85.6	- 82.4	- 4 %
Rear	II	+ 25.7	+ 19.8	- 24 %

the upper and the lower supports of the ankle. No experimental tests were carried out on the ankle in titanium, but, by exploiting of the validated numerical model, a comparison between the two design solutions can be proposed. The numerical model of the titanium ankle differs from to the previous one:

- in the geometry, in particular in the fillet radii of the supports;
- in the support material: for the titanium alloy, an elastic modulus of 113800 MPa and a Poisson's ratio of 0.34 are taken into account, in accordance with the literature [Welsh, Boyer and Collings (1994)].

The imposed pistons displacements in configuration I and II and the elastic modulus of the two sub-parts of the prosthetic foot are the same as in the previous paragraph.

Table 4: Comparison between the numerical models of the ankle, in Al and Ti alloys

		Model in Al alloy		**Model in Ti alloy**	
Configuration	**Component**	σ_{max} **[MPa]**	η	σ_{max} **[MPa]**	η
I	Lower support	289	1.5	235	3.7
	Transversal pin	272	1.9	289	1.9
II	Lower support	136	3.2	122	7.2
	Transversal pin	299	1.9	247	2.3

Results of the numerical simulations of the two models are shown in Table 4. The comparison is proposed in terms of stress obtained in the most stressed components, which are the same for both the models (i.e. the lower support and the transversal pin). In order to obtain a safety factor η, the ratio between the maximum Von Mises stress and the yield stress of Ergal (434 MPa) and of Ti 6Al-4V (880 MPa) is considered. Note that the η values are similar or higher in the case of titanium alloy, if compared to Ergal. In accordance with the manufacturer, however, the

safety factors are considered sufficient for the ankle model in Ergal, which will be merchandised in the future.

5 Conclusions

In this paper it is schematically shown the procedure to claim compliance with the Standard ISO 10328 for lower limb prostheses, in particular for transtibial and transfemoral ones. After some considerations on the procedure, a test bench was designed and built *ad hoc* for these kind of tests. Its strong point is the versatility: it is possible to test all types of prostheses and also single components. During each test, the component is equipped with the instruments necessary to obtain strain values. In this way, not only the compliance with the Standard is reached as an output of the test, but also information required to validate a FE model. The comparison between real and numerical strains and displacements allows the validation of the FE model, which becomes a valid tool in the following phase of customization of the prostheses. The numerical model can be modified both in the geometry and in the involved materials in order to analyze the prosthesis adaptability to the individual patient early in the design phase or to reduce the cost of the device.

To explain clearly the procedure and its powerfulness a particular test case is chosen. It is referred to a mechanical ankle prosthesis designed for children till 12 years and 45 kg of weight. Experimental tests on the device are carried out in accordance to the standard, adapted to the case of children in terms of distances and applied loads. The ankle passed all the four prescribed kind of tests: static proof and ultimate strength, cyclic and torsion tests. Numerical simulations of the ankle and foot prosthetic devices are run to get a validated model. This model is used to check the most stressed parts in the prosthesis sub-components and to improve the design phase of the device, varying material and geometry of the ankle.

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