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Study of an ankle prosthesis for children: adaptation of ISO 10328 and experimental tests

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Abstract

Object of the present study is an ankle prosthesis for transtibial amputees, designed for children. Standards for protheses compliance available in literature are all related to adults, while very few studies are present for children. In the first part of the paper a discussion on the modification of the standard in terms of loads and distances is presented, to adapt the available data to the test case, a boy of 12 years and 45 kg. In the second part, experimental results are shown, considering four different types of tests: static proof and ultimate tests, fatigue tests and static torsion tests. Results were positive for the designed and tested ankle prosthesis.

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1. Introduction

Transtibial amputations are statistically one of the most frequent. In fact, they represent about the half of lower limb amputations [1]. Also children can be subjected to this type of operation and they have as many problems as an adult, or even more. Since children learn quickly posture and motion defects, the possibility of moving in a natural and correct way from the earliest moment is considered fundamental for their rehabilitation. The manufacture of special mechanisms which can provide these characteristics requires a cost increase. In addition, the prosthesis must follow the child growth: it is possible to adapt a previous model or to change the whole device in correspondence of morphological changes of the patient.

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For both these solutions the cost increase is clear. A possible solution for this problem is to design the most expensive components of a prosthesis in order to make them suitable for a longer period.

The final purpose of the manufacturer (INAIL) is the design and the production of two types of ankle prosthesis: the first one is thought for children up to 8 years and with a weight less than 35 kg; the second one can be used with children from 8 to 12 years-old and sustain a maximum weight of 45 kg.

The aim of this study is to tweak the second model by means of mechanical tests and numerical analyses. This ankle prosthesis is made up of (Fig. 1):

- two supports in Ergal, one for the support of the pylon (which represents the tibia of the human body) and one for the support of the foot;
- two journal box in G-CuAl11Fe4Ni4 UNI5275;
- an attachment in INOX steel to lock off the pylon;
- a transversal pin in INOX steel which the ankle is crossed by. It permits the rotation of the ankle around its axis;
- two pins in INOX steel for the penetration of the wooden part of the foot;
- two bumpers in elastomeric material: three pairs are available and interchangeable to offer different stiffness;
- an allen screw for locking transversal pin movements, as it is shown in Fig. 1c).

![Fig. 1. The ankle prosthesis object of study: a) the components, b) the assembly and c) the allen screw seating](image)

The human ankle is made up of 4 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. The allowed movements are:

- flexion-extension: the initial condition is the perpendicularity between foot plantar plane and leg longitudinal axis. During the gait, angles included in the range of 25\(^\circ\)- 35\(^\circ\) are allowed in this plane;
- adduction- abduction: it is the foot axial rotation. It has a range of movement from +5\(^\circ\) to -3\(^\circ\);
- pronation-supination: it is the rotation around the transversal axis. This movement admits angles between +10\(^\circ\) and -2\(^\circ\). [2]

As it is possible to notice from the geometrical properties of the device (Fig. 1), it admits only the flexion-extension movement of the human ankle joint, but it is considered sufficient to preserve a correct posture and gait for children.
2. Adaptation of ISO 10328 to children

Since it does not exist a standard strictly addressed to experimental tests on prosthesis for children, it is necessary to adapt the ISO 10328 [3], which is related to adults. The standard identifies two loading configurations at the maximum stress levels undergone by the limb during normal walk (shown in Fig. 2): condition I is related to the instant of maximum loading occurring early in the stance phase of walking, while condition II is related to the instant of maximum loading occurring late in the stance phase of walking [4].

ISO 10328 indicates, for each load configuration, three possible load levels depending on physical parameters, locomotion characteristics and other factors of the patient. These three categories concern adults and are:

- 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.

To rescale the loads addressing the tests to a prosthesis for children, the only objective information available in literature is referred to dummies. In fact, the standard is mainly based on geometrical dimensions of lower limbs and with these measures it is possible to make a comparison between adults and children. Dummies are used in the automotive sector, especially for crash tests, and their goal is to simulate physical properties of humans in order to evaluate the safety of vehicles. It is evident that their adherence to a real condition must be high and this is the reason why their measures are based on percentile curves [5].

The first step is to verify the proposed method comparing the distances of reference planes (bottom, ankle, knee and top) for an adult. Taking into consideration a Hybrid III 50th percentile male and P3 category of the standard, it is possible to compare the knee heights from the ground, $u_K$ (see Fig. 5), and the weights. P3 category is chosen because it is the nearest to children characteristic due to the lower weight considered. The values are shown in Tab.1.

Table 1. Comparison between P3 category of the standard and a Hybrid III dummy 50th percentile male [3][5]

|                | P3 ISO 10328 | Hybrid III | Ratio |
|----------------|--------------|------------|-------|
| $u_K$ [mm]     | 500          | 498        | 1     |
| Weight [N]     | 736          | 738        | 1     |
It is possible to make a comparison between ISO standard and the Hybrid dummy. Thus, it is now possible to take Hybrid III dummies as reference also for children geometric characteristics, having the aim of an adaptation of the standard. Dummies have different dimensions depending on children age (3, 6 or 10-years old) and the choice of the right model is based on the prosthetic ankle specifications:

- Maximum patient weight: 45 kg;
- Prosthetic foot length from 18 to 21 cm;
- Possibility of adaptation of the prosthesis to a wide range of ages and morphological characteristics, thanks to different models of bumpers with increased stiffness.

A possible empirical relationship between age and weight, in fact, can be achieved from foot length assuming a foot growth per year of about 9 mm [6]. The correspondence is shown in Tab. 4.

| Foot length [mm] | European size | Age          |
|------------------|---------------|--------------|
| min 180          | 30            | 7-years old  |
| max 210          | 34            | 11-years old |

Table 2. Correspondence between foot length and age [6]

Further studies showed a way to estimate reference subject’s weight starting from statistical data [7]. As it is possible to notice from Fig. 3, a 45 kg child would be about 13-years old if it is considered the 50th percentile, whereas data in Tab. 2 suggest 11-years old as the maximum age for this prosthetic ankle. The mismatch is probably leaded to the origin of statistical data represented in Fig. 3: they are referred to previous generations, which are smaller. If it is considered an average age between the results of the two methods (12-years old) and the fixed weight of 45 kg, Fig. 3 shows a result on the 75th percentile. Taking into account higher percentiles, it is possible to verify the device in complete safety.

Fig. 3. Weight-age percentile curves CDC (Centre for Disease Control); ages 2 – 20 [7]
Hence, the prosthetic ankle is suitable for children from 7 to 12-years old according to the 75th percentile.

For planning tests, the geometrical placement of the prosthesis is considered by the standard and in particular the distances between the reference planes are fundamental. The ratio of the knee heights from the ground for an adult and a child is assumed as coefficient for a linear proportional calculation of all other dimensions. The adult’s knee height is indicated in Tab. 1 whereas child’s one is calculated as follows. Children dummies are based on brief ranges of age (3, 6, 10-years old) and so an interpolation of their data is allowed without making mistakes. A parabolic interpolation between knee heights from the ground \( u_K \) of the three dummies is shown in Fig. 4: the \( u_{K,12} \) value referred to a 12-years old child can be extrapolated. The equation of interpolating curve is also shown.

![Fig. 4. Position of plane \( u_K \) during the growth](image)

The extrapolated value \( u_{K,12} \) allows the quantification of the factor of proportionality:

\[
k = \frac{u_{K,12}}{u_{K,\text{adult}}} = \frac{400}{500} = 0.8
\]

The distances of the other reference planes specified in the ISO 10328 for adults can be multiplied for \( k \), obtaining the values of the same distances for a 12-years old child. The results are shown in Fig. 5.

![Fig. 5. Schematization of the reference planes and related values for a 12-years old child](image)

| Plane   | 12-years old |
|---------|--------------|
| \( u_T \) [mm] | 520          |
| \( u_K \) [mm]  | 400          |
| \( u_A \) [mm]  | 64           |
| \( u_B \) [mm]  | 0            |
Once this proportionality value $k$ is obtained, the method used for the determination of the geometrical dimensions is applied also for setting the test loads. ISO 10328 prescribes different loads depending on the weight category: considering P3 category, it is possible to rescale its loads by the factor $k$. Final results are shown in Tab. 3.

Table 3. Test loads for a prosthesis for a 12-years old child

| Test                              | Load                        |
|-----------------------------------|-----------------------------|
|                                   | P3 ISO 10328 | 12-years old |
| Separate static proof            | I    | II    | I    | II    |
|                                   | 1610 N | 1610 N | 1290 N | 1290 N |
| Separate static ultimate strength| I    | II    | I    | II    |
|                                   | 2415 N | 2415 N | 1935 N | 1935 N |
|                                   | 3220 N | 3220 N | 2580 N | 2580 N |
| Separate cyclic                   | I    | II    | I    | II    |
| (min)                             | 50 N | 970 N | 970 N | 777 N |
| (max)                             | 970 N | 970 N | 777 N | 777 N |
| (number of cycles)                | 2000000 | 2000000 |
| Separate static in torsion        | 50 Nm|

Tab. 3 shows constant values both for the minimum of the separate cyclic test and for the separate static test in torsion, since the standard prescribes same values for all the considered categories.

Following the ISO standard, all tests are duplicated. Therefore, two ankles are experimentally loaded for each type of test.

3. **Experimental static and cyclic tests**

The configurations represented in Fig. 2 are realized in a laboratory, as it possible to see in Fig. 6. The object under consideration is the ankle, but for the tests also other parts of a transfibial prosthesis are used: a pylon and a foot manufactured by OttoBock. The pylon can support a weight of 45 kg, as the ankle; the foot is a Dynamic model and has a length of 21 cm. In correspondence of its free extremity, the pylon is constrained to a structure fixed to the ground, whereas the foot is loaded by two hydraulic actuators. The plates at the end of the actuators, which push the foot, allow transversal movements in order to load the structure in a more natural way, as it is possible to notice in Fig. 6.b. Each plate is covered by a rubber layer to facilitate the adhesion to the foot.

![Fig. 6. Layout of the test equipment for separate static proof tests, separate static ultimate strength test and separate cyclic test: a) the general configuration and b) a particular of the transversal movement of the plates](image-url)
In Fig. 7 the ankle is assembled with red bumpers, but three types of bumpers can be used, depending on the stiffness required to offer to the patient a correct comfort. They are distinguished by three colors: yellow for a lower stiffness, red for a higher one and orange for an intermediate value. The difference between the two behaviours is definite: the percentage displacement variation between red and yellow bumpers is about 19%, as it can be qualitatively noticed from Fig. 7. The ankle is tested for a 12-years old child, so red bumpers were used in the tests, since they correspond to this age because of the increased child’s weight.

![Loading configuration II with 500 N: a) ankle with yellow bumpers and b) ankle with red bumpers](image)

Separate static proof tests, ultimate strength tests and cyclic tests are performed. In Fig. 8 it is represented the trend of loads and relative displacements for the ultimate strength test, whose maximum load is 2580 N. It is chosen because it represents a huge single event, bigger than the static proof test and thus more significant. Displacements in configuration II are more definite than in configuration I because of the toe is mostly made of rubber, which has a lower stiffness than other materials present in the heel.

![Experimental result: applied load (a) and resulting displacement (b) trends, separate static ultimate strength tests](image)

Also two cyclic tests are performed: the load profile is shown in Fig. 9.a and 2000000 cycles are carried out for both ankles. Fig. 9.b shows how the displacements of the whole prosthesis vary during the cyclic test: it can be noticed that there is a definite deterioration of the prosthesis, probably due to rubber characteristics. The result of the fatigue test was positive for both the tested ankles.
Fig. 9. Cyclic test: a) load profile and b) trend of displacements during the test [8]

Two separate static tests in torsion are done and 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 torque. The maximum applied load is 50 Nm: also for this kind of test the result was positive.

4. Conclusion

A valid method to adapt the ISO standard for testing adult prostheses to children ones is presented. To find a parameter that can be used as a factor of proportionality a wide literature research was carried out: using data related to dummies, a factor is found and both geometrical characteristics and loads prescribed by the standard are rescaled. Thus, different experimental tests were performed and duplicated on the same ankle model: static proof and ultimate, fatigue and static torsion tests. For all the performed experimental tests the results were positive, with expected trends of displacements.

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