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Static strength of lower-limb prosthetic sockets: An exploratory study on the influence of stratigraphy, distal adapter and lamination resin

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ABSTRACT

Knowledge about the mechanical properties of lower-limb prosthetic sockets fabricated with resin infusion lamination and composite materials is limited. Therefore, sockets can be subject to mechanical failure and over-dimensioning, both of which can have severe consequences for patients. For this reason, an exploratory study was conducted to analyze the effect of stratigraphy (layup and fibers), matrix (resin) and mechanical connection (socket distal adapter) on socket static strength, with the objectives of: 1) implementing a mechanical testing system for lower-limb prosthetic sockets based on ISO 10328:2016 and provide the mechanical design of the loading plates, 2) apply the testing system to a series of laminated sockets, and 3) for each type of distal adapter, identify the combinations of stratigraphy and matrix with acceptable strength and minimum weight.

Twenty-three laminated sockets were produced and tested. Sixteen met the required strength, with ten exhibiting an excessive weight. Among the remaining six, four combinations of stratigraphy and resin were identified as best option, as they all overcame ISO 10328 P6 loading level and weighted less than 600 g. The selected stratigraphies had limited or absent amount of Perlon stockinettes, which seems to increase weight without enhancing the mechanical strength. Sockets based on Ossur MSS braids and connector show the best compromise between strength and weight when the amount of carbon braids is halved.

1. Introduction

A lower-limb prosthetic socket is the custom-made structural element interfacing the residual limb of a person with an amputation to their prosthetic leg comprising off-the-shelf components [1]. The socket has to guarantee good fit and function while being lightweight and structurally sound during the activities of daily living relevant to the patient. Despite the importance of this medical device, there is no standard or widely accepted guideline dedicated to socket construction or to mechanical testing [1]. Therefore, the (publicly available) knowledge of its mechanical properties is limited. This might result either in over- or under-dimensioning of the socket. While the first may have negative consequences in terms of weight, and cause suspension issues, limb health problems and patient's fatigue, the latter could lead to socket failure and ultimately to patient's injury. Moreover, the lack of an established method to determine socket mechanical properties may hinder the application of innovative materials, distal attachment interface and fabrication processes to socket construction. Finally, a limited knowledge in the socket mechanical properties limits the possibility to comply with the current European Medical Device Regulation (MDR 2017/745), which requires even custom-made medical devices to carry a documentation regarding their expected performance.

The lack of knowledge is not limited to the most recent 3D printing construction method, but also to the most widely adopted technique of resin infusion lamination with composite materials. To the best of the authors' knowledge, the literature evaluating the mechanical strength of laminated sockets is limited to seven studies [2–8], with only two articles [3,4] providing a detailed description of the stratigraphy, i.e. the type of fiber and layup. Moreover, none of these studies analyzed the effects on socket strength of the combination of three critical factors that

Abbreviations: MDR, Medical Device Regulation; ISPO, International Society for Prosthetics and Orthotics; ISO, International Organization for Standardization; ASTM, American Society for Testing and Materials; MSS, Modular Socket System; TT, Transtibial; TF, Transfemoral; DIC, Digital Image Correlation.

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Table 1
Testing method adopted in this article according to the key elements defined in the systematic review [1].

Main category	Key element	Method applied in this article
Test sample	Socket shape model	98th percent male model of transtibial amputees described by Gerschutz et al. [6] scaled down by a radial 6 mm offset.
Test equipment	Mock residual limb	Single durometer of hard aluminum-reinforced polyurethane resin, full shape limb, interface with socket through 6 mm styrene liner with cotton socks; embedded stainless steel and aluminum rod for proximal connection and load transfer from test machine.
	Test sample components	Socket in isolation (without pylon and foot)
	Alignment among sample components	Socket positioned as low as possible within the test frame, with its distal adapter attached to the lower lever arm at the height of the hypothetical ankle-joint center, in accordance with the adaptation by Gerschutz et al. [6].
	Test configuration (load-line alignment)	Forefoot loading (test condition II of ISO 10328) with lever arm sizes defined by ISO 10328 P5-P6-P7-P8 loading levels.
Test procedure	Loading condition and procedure	Static loading, ISO 10328:2016 principal static ultimate strength procedure (loading rate of 100–250 N/s).
	Passing condition	ISO 10328 P5 – borderline ISO 10328 P6 – acceptable

are typical of sockets made in composite materials: stratigraphy, matrix (resin) and type of mechanical connection (socket distal adapter) between socket and the other modular parts of the prosthesis, such as pylon, knee or foot.

For this reason, we conducted an exploratory study to analyze the effect of these three factors on socket static strength. Specifically, our objectives were to:

- Implement a mechanical testing system for lower-limb prosthetic sockets based on the adaptation of ISO 10328:2016 [9] proposed by Gerschutz et al. in 2012 [6], providing the mechanical design of the loading plates which are not available in the literature;
- Apply this testing method to a series of prosthetic laminated sockets produced at the INAIL Prosthetic Center (Vigorso di Budrio – BO, Italy) that differ in stratigraphy, matrix and adapter;
- For each class of socket adapters:
  - identify the combination of stratigraphy and matrix that overcame the minimum static structural requirements of ISO 10328:2016 with minimum weight of the socket;
  - propose a set of practical guidelines for socket construction.

2. Methods

2.1. Testing method

The method for testing sockets used in this study applies some of the adaptations reported in the literature of ISO 10328:2016 [9], the current standard for structural testing of lower-limb prosthetic components distal to the socket. In general, the literature regarding structural testing of lower-limb prosthetic sockets is very limited, as highlighted by the recent systematic review by Gariboldi et al. [1] and by the recent scoping review by Baer and Fatone [10] (Table A.1). Only eighteen studies described performing structural testing of lower-limb prosthetic sockets [2-8,11-21], fourteen of which referred to ISO 10328. This standard was probably cited by the majority of articles because of the standardization level that it offers, especially in terms of test configurations, loading and passing conditions. However, because socket testing is not included in the scope of ISO 10328, none of the tests were conducted with full adherence to the standard and authors had to make modifications when adopting the standard for socket testing [10] (so-called “adaptations” [1]). Based on the systematic review [1], these adaptations can be summarized as follows:

- selecting the socket shape model;
- using a mock residual limb to transfer loads from the test machine to the socket and defining its design in terms of shape, material and interface with the test machine (rod) and with the socket (prosthetic liner);

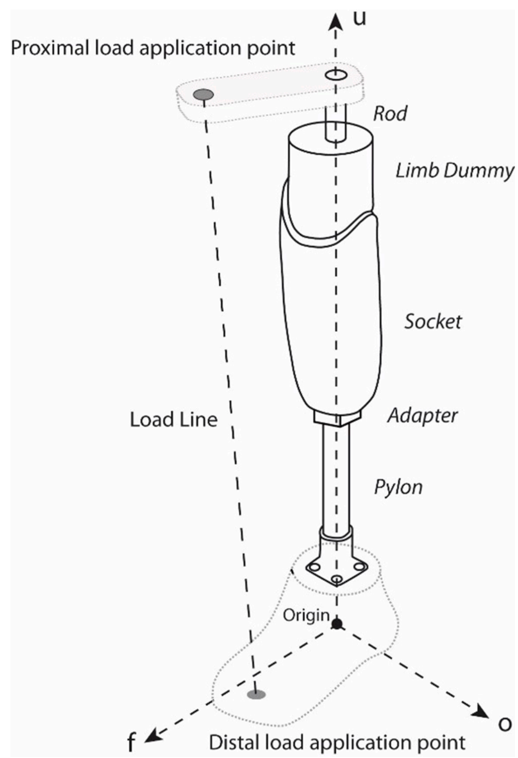


Fig. 1. Example of socket testing system applied to a transtibial socket.

- deciding what components to include in the test sample, in other words whether to test the socket in isolation or in combination with distal components, such as pylon, knee and foot;
- defining an alignment among test sample components, i.e. how to position the test sample components with respect to one another inside the test machine;
- selecting the test configuration, i.e. load lever arms, in terms of ISO 10328 test loading condition (condition I, i.e. heel loading vs. condition II, forefoot loading) and loading levels (P3, P4 and P5-P6-P7-P8);
- selecting the loading condition (static vs. cyclic), loading procedure (principal static ultimate, principal static proof or principal cyclic) and passing conditions (defined again by loading levels P3, P4, P5, P6, P7 and P8) to apply.

For a definition of ISO 10328 loading levels, see Appendix B. The adaptations applied in this article are reported Table 1 and are displayed in Fig. 1.

Table 2
Test sockets manufactured, depending on the type of stratigraphy (rows), distal adapter (columns) and resin (in parenthesis, within each cell). A description of each variable is reported in other figures and tables of this article: Tables 3 and 4 and Fig. 5 (stratigraphies, fiber materials and weave visual examples), Fig. 3 (distal adapters) Table 5 (resins).

			DISTAL ADAPTER				
	Braids above adapter		3arm adapter Ottobock 4R41	Connecting plate Ossur A-122,100	Boxed attachment Ottobock 4R415	MSS direct socket Ossur M-100–501	Wood attachment block Ottobock 5R1=6
STRATIGRAPHY	No braid	0	S2 (R1+)				
			S17 (R2+)				
		1					S12 (R2+)
		1					S13 (R2+)
	6 K	1	S20 (R2+)				
		1		S7 (R2+)			
		1			S4 (R1++)		
					S5 (R3)		
					S16 (R2+)		
		3			S23 (R2+)		
		3			S15 (R2+)		
	12 K	1	S14 (R1+)				
		1	S1 (R1+)				
			S3 (R3)				
			S21 (R2)				
			S22 (R1)				
			S6 (R1+)				
	MSS	1				S11 (R2+)	
		2				S10 (R2+)	
						S18 (R1)	
						S19 (R1+)	
		3				S9 (R2+)	
		4				S8 (R2+)	

2.2. *Test sample*

Twenty-three sockets were manufactured at the INAIL Prosthetic Center (Vigorso di Budrio – BO, Italy) from the same identical plaster model (limb shape), using the traditional resin infusion lamination technique, with each socket having a different combination of stratigraphy (first variable), distal adapter (second variable) and resin (third variable). A list of these sockets, grouped by the three variables, are reported in Table 2. A general description of the sockets follows hereunder, whereas a more detailed description is reported in the Supplementary material S1.

2.3. *Limb shape*

In details, for the shape of the plaster model the limb shape described by Gerschutz et al. [6] was used. Gerschutz et al. [6] had extrapolated this shape to produce the 98th percent male model of transtibial amputees, with a circumference at the patellar tendon bar of 52.4 cm and a length from the patellar tendon bar to distal end of 19.2 cm (Fig. 2-a).

2.4. *Fabrication technique*

The traditional resin infusion lamination technique consisted in manually infusing liquid acrylic resin (matrix) in layups of one or more layers of fibers (stratigraphy) deposited on the plaster model together with the socket adapter, resulting in a fiber-reinforced plastics socket (Fig. 2-b and c). The infusion was performed under vacuum bagging at room temperature.

2.4.1. *Adapter*

The fabrication of each socket started with the selection of the adapter. These are listed in Fig. 3.

2.4.2. *Stratigraphy*

For each adapter, the stratigraphy had to satisfy the following requirements (Fig. 4):

1) Contain the limb and sustain weight of the person wearing the socket during the activities of daily living. Considering the size of the plaster model (US 98th percentile), the stratigraphy was dimensioned based on clinical experience for a person with minimum weight of 90 kg (average US male weight in 2016 [22,23]), which corresponds to level P5 in ISO 10328 (4025 N). This function is ensured by the layer(s) of carbon fibers covering the whole limb (braids).
2) Prevent a pull-out of the adapter (outward failure); this is ensured by the layer(s) of carbon fibers above and around the adapter.
3) Prevent the adapter from collapsing inside the socket (inward failure); this is ensured by the layer(s) of carbon fibers below the adapter (e.g. between the plaster model and the adapter), unless the adapter is intended for direct contact with a liner (e.g. Ossur A-122100 connecting plate and boxed sockets with Ottobock spacer 4R415).
4) Ensure medio-lateral stability; this is ensured by medial and lateral stripes; these layers are optional if the layers in point 1) are considered to satisfy this function (such as for MSS direct sockets).
5) Ensure containment of the limb; this is ensured by proximal and/or distal rings; these layers are optional if the layers in point 1) are considered to satisfy this function. The distal ring is not expected to serve for function 2) and 3) unless specified.

Finally, the use of Perlon stockinettes was used in some stratigraphies, where it was deemed necessary by the expert prosthetists of the facility to increase the degree of resin aspiration (for example to increase impregnation of fibers with viscous resins or in presence of limited air suction during vacuum bagging).

The various stratigraphies used in this study are reported in Table 3. They were grouped in four categories according to the type of carbon

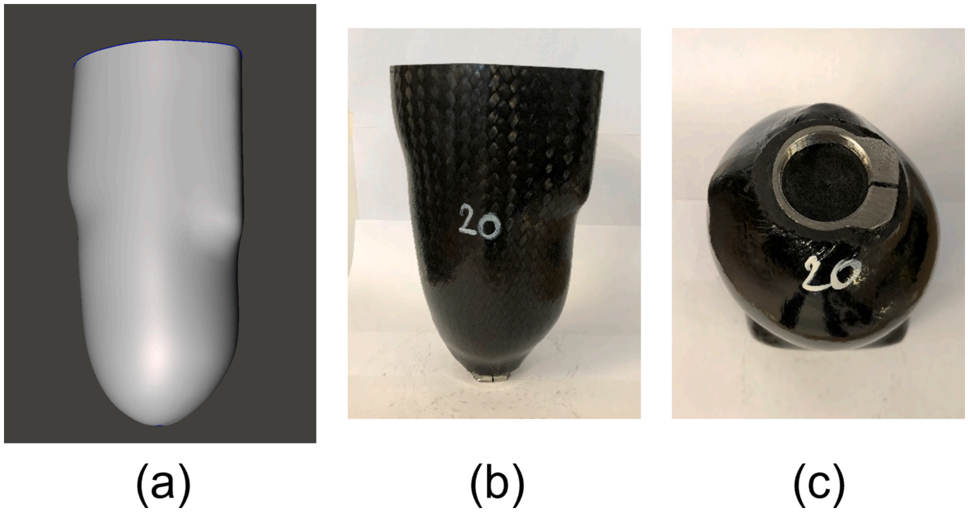


Fig. 2. Limb model used for the socket shape (a), example of test socket (b), example of distal adapter embedded in the test socket (c).

braid above the adapter: none (no carbon braids were used), 6 K (carbon braids with 6000 filaments per tow), 12 K (carbon braids with 12,000 filaments per tow), MSS (carbon braids integrated in the Ossur MSS direct socket M-100501). Within each category, different variations were used, depending on the type, amount and position of additional carbon fiber materials, for a total of fourteen variations based on current practice. The fiber materials that were used are listed in Table 4 and the corresponding type of weave is shown in Fig. 5.

2.4.3. Resin

Once the adapter and the stratigraphy were selected, the resin was chosen from a group of three base resins (R1, R2, R3) that were mixed with a varying percentage of sealer, for a total of six options all available in current practice (R1, R1+, R1++, R2, R2+, R3). Definitions of each resin is reported in Table 5. According to the manufacturer and expertise from current practice, the three base resins have comparable strength, but different stiffness and viscosity. The addition of the sealer is

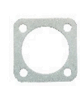
Adapter type	3-arm adapter	Connecting plate	Boxed socket with spacer	MSS direct socket	Wood attachment block
Adapter ID	Ottobock 4R41	Ossur A-122100	Spacer Plate 4R415	Ossur M-100501	Ottobock 5R1=6
Image					
Material **Weight** **P-level** [9]	Stainless steel 170 g P5	Aluminum 70 g P5	Aluminum 10 g N/A	Aluminum 110 g P7	Wood 155 g P5

Fig. 3. Different groups of distal adapters.

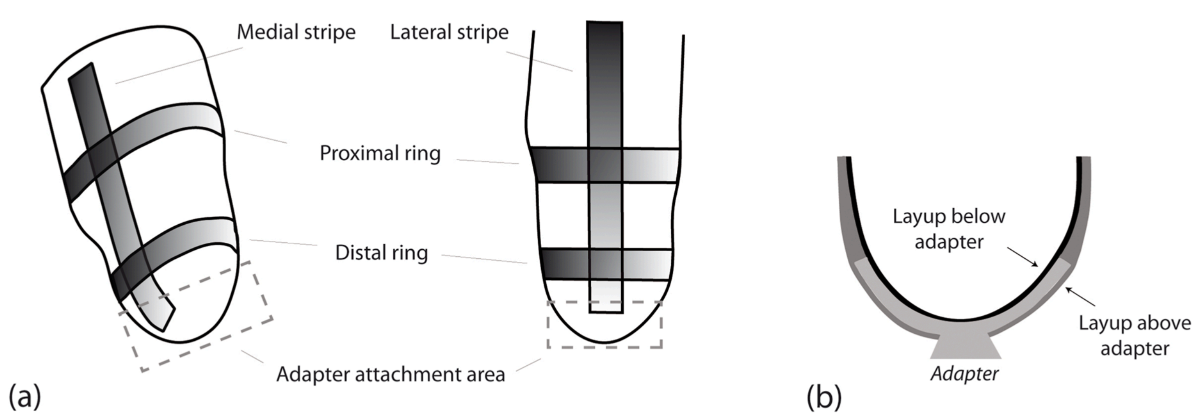


Fig. 4. Lamination areas on the socket.

Table 3
Different types of stratigraphy grouped according to the type (filament count) of carbon braid above the adapter (none, 6 K braid, 12 K braid, MSS braid). Each group is further divided depending on the amount of carbon fiber above and below the adapter, on the presence of distal and proximal rings and lateral stripes of carbon fibers, and finally on the presence and amount of Perlon stockinettes.

Stratigraphy	Type of braid above adapter	Above adapter		Below adapter		Medial and lateral stripes	Distal ring	Proximal ring	Perlon stockinettes
		Braids	Patches	Braids	Patches				
1A	None	0	2	0	4	Y	N	Y	6
1B	None	0	1	1	0	N	N	N	6
1C	None	0	2	1	0	N	N	N	6
2A	6K	1	0	0	3	Y	Y	Y	3
2B	6K	1	2	0	0	Y	Y	Y	1
2C	6K	1	10	0	0	Y	N	Y	2
2D	6K	3	6	0	0	N	N	N	0
2E	6K	3	13	0	0	N	N	N	0
3A	12K	1	1	0	2	Y	N	N	0
3B	12K	1	2	0	2	Y	Y	Y	5
4A	MSS	1	1	0	2	N	N	N	0
4B	MSS	1	1	1	1	N	N	N	0
4C	MSS	2	0	1	1	N	N	N	0
4D	MSS	2	0	2	0	N	N	N	0

supposed to increase strength and stiffness of the product. Resin R2+ was used as common ground for all adapter-stratigraphy combinations, except for 12K-stratigraphies, for which the base resin R1+ was used. In fact, R1+ resin is less viscous and less stiff than R2+ resin, and allows a better impregnation of 12 K braids, which are stiffer and thicker than other braids, while avoiding over-stiffening the final socket.

2.5. Test equipment

A socket testing machine was built in the Laboratory of Machine Design of the University of Padua (Padova – PD, Italy) (Fig. 6). The test machine consists of a main frame of aluminum square profiles that sustains the moving parts (actuated cylinders), the test sample (socket), the mock residual limb and the rigid mounting elements (loading plates) that allow load transfer from the actuated cylinders to the test sample. The loading plates allowed to apply the lever arms prescribed by ISO 10328 in test condition II and P5-P6-P7-P8 loading level and according to the adaptations described by Gerschutz et al. [6] (Fig. 6-c).

The load was applied vertically by the upper uniaxial loading cylinder (MTS Systems Corporations, Eden Prairie, USA; full-scale of 14,700 N) actuated by a hydraulic system (MTS Systems Corporation, Eden Prairie, USA) controlled by servo valves (MOOG, Elma, New York, USA). On the cylinder head, a load cell and potentiometer allowed recording of load and displacement. The lower loading cylinder was kept fixed and was used purely for alignment purposes. The ends of the upper and lower loading cylinders were connected to the upper and lower loading plates through spherical joints (Heim joint Uniball), to avoid applying unanticipated moments at the contact points. The load was transferred from the upper loading plate to the socket through a single durometer hard-resin (cured polyurethane resin reinforced with aluminum) custom-made mock residual limb, having the same shape of the test sockets but smaller dimensions: the limb was in fact scaled down by a radial 6 mm offset to allow interposition a 6 mm styrene liner (Shore A 30) to simulate a soft interface between mock residual limb and socket (Fig. 6-d). To ensure proper press fit between socket and limb, a set of cotton socks were also added on top of the liner. The socket was tested in isolation (without pylon and foot) and was positioned as low as possible within the testing frame, having therefore its distal adapter directly attached at the bottom loading plate, at the height of the hypothetical ankle joint center, according to Gerschutz et al. [6]. The

Table 4
Possible types of carbon fiber materials used in each stratigraphy. Fig. 5 shows an example of the weave for each material.

Type of fiber material	Layout	Weave	Dimensions*	Specific weight	Filament count tow***	Fiber	Fig. 5
Carbon fiber 6 K braid	Tubular	Braid	191 mm	163 g/m	6K	Eurocarbon B-144/10	A
Carbon fiber 12 K braid	Tubular	Braid	191 mm	489 g/m	12K	Eurocarbon D-144/06	A
Ossur Carbon fiber MSS** braid	Tubular	Braid	177 mm	N/A	N/A	N/A	B
Carbon fiber 3 K twill patch	Tape	Twill 2 × 2	50/100 mm	200 g/m^2	3K	Toray T300	C
Carbon fiber 12 K UD patch	Tape	UD	50/100 mm	375 g/m^2	12K	Mitsubishi 34,700	D

*diameter for tubulars, width for tapes.
**Ossur MSS direct socket M-100,501 – 4 braids with integrated distal adapter.
***it refers to the number of filaments per tow: 12 K means there are 12,000 filaments per tow, 6 K means there are 6000 and 3 K means there are 3000.


A B C D

Fig. 5. Possible types of carbon fiber weaves listed in Table 4: (A) braid, (B) MSS braid, (C) twill 2x2, (D) UD.

Table 5
Types of resins. The resins with a “+” sign were added with a percentage of the sealer Ottobock Orthocryl Siegelharz (617H21). The percentage refers to the solution.

Base resin	Resin option	% Sealer
Ottobock Orthocryl Laminierharz 80:20 (617H19)	R1	0
	R1+	20
	R1++	50
Ottobock Orthocryl Laminierharz 80:20 PRO (617H119)	R2	0
	R2+	20
Ottobock C Orthocryl (617H55)	R3	0

vertical distance between the upper and lower loading points (centers of the upper and lower spherical joints) was 650 mm, in accordance with ISO 10328:2016 [9].

2.6. Test procedure

The test machine was used to perform principal static ultimate strength tests, in accordance with ISO 10328:2016 [9]. The approximate time required for the setting up and performing a single static test was 15 min. The machine worked in force control and load was applied at a constant rate between 100 and 250 N/s until failure of the socket or of the distal attachment hardware was reached. Load and displacement were recorded at the cylinder head at a frequency of 100 Hz. The ultimate load at failure was compared with the upper level of the ultimate force for P5 and P6 loading level in test condition II, which correspond to 4025 and 4425 N, respectively. Sockets that did not reach P5 passing condition (4025 N) were considered to have failed the test; sockets that reached P5 but not P6 loading condition (failure between 4025 and 4425 N) were considered borderline; sockets that reached P6 loading level (4425 N) or higher were considered to have successfully passed the test. The total weight of each socket was also registered. The weight registered includes all modular parts that in normal conditions allow connecting the socket with the distal prosthetic pylon, i.e. the parts of the modular distal adapter that are integrated in the socket as well as the ones that are removable from the socket. For example, in case of the boxed attachments, Ossur MSS direct socket and wood attachment the weight includes a pyramid adapter with a pyramid receiver (such as Ottobock 4R22) for connection with the prosthetic pylon. The combination of stratigraphy and resin that, for each type of adapter, produced the highest acceptable load with lowest total weight was chosen to define a guideline for socket construction. A weight above 600 g was considered excessive by the certified prosthetists of the INAIL Prosthetic Center, and sockets displaying acceptable mechanical strength (above P6) that weighted more than 600 g were deemed over-dimensioned. If different combinations produced similar results in terms of load and weight, the one with the simplest stratigraphy (fewer materials, simpler

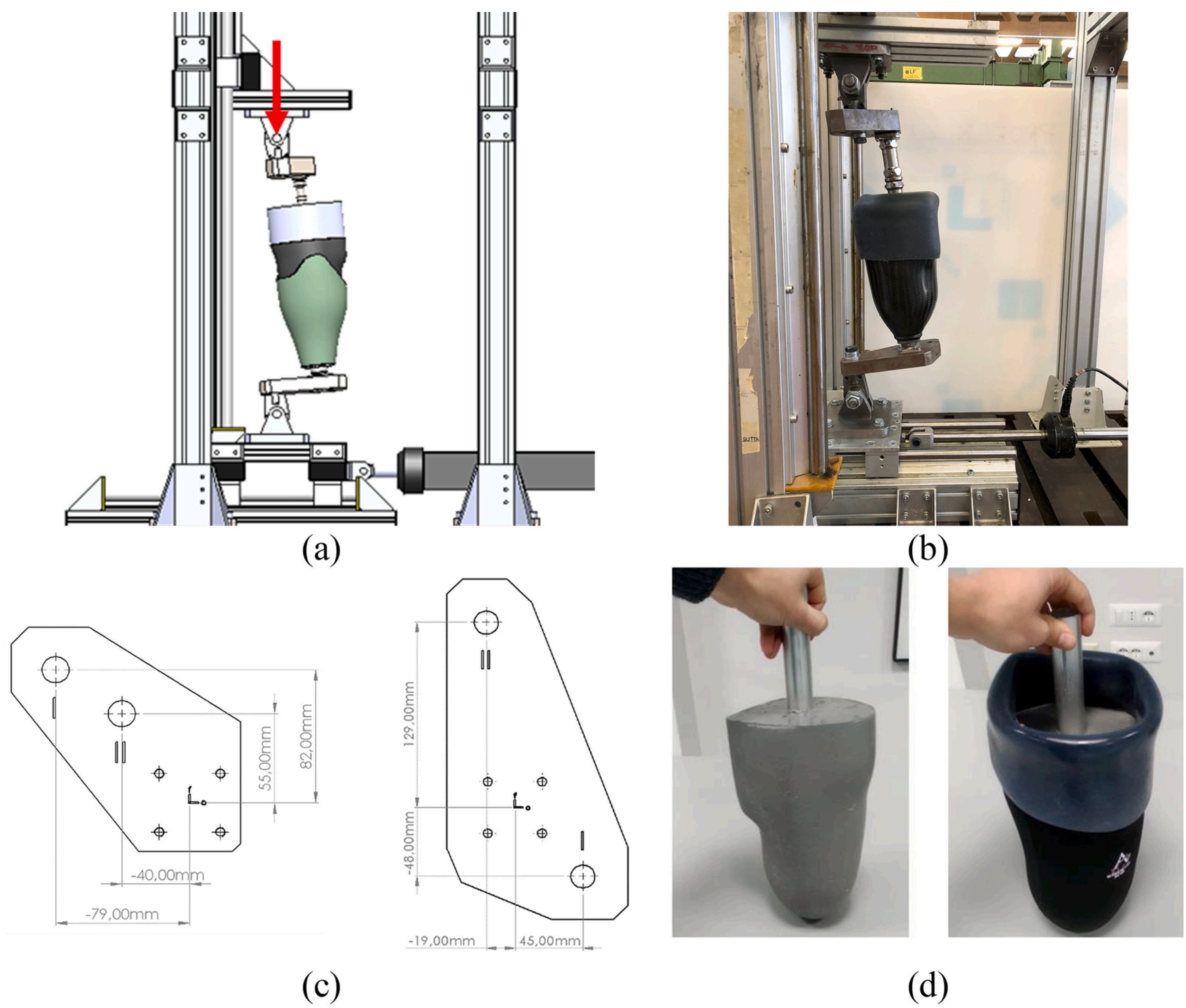


Fig. 6. Test machine for structural testing of lower-limb prosthetic sockets: (a) CAD model, (b) physical test machine, (c) loading plates (upper plate on the left and bottom plate on the right), (d) mock residual limb with and without liner.

Table 6
Schema for test procedure.

Reference	ISO 10328:2016 – Principal static ultimate strength test – Test condition II [9]
Bench control mode	Force control. Loading rate between 100 and 250 N/s.
Sensing	Force and displacement at cylinder head. Sampling frequency of 100 Hz.
Test end condition	Failure of socket or of the distal attachment hardware.
Passing condition	If the load at failure (F_{end}) is: • F_{end} < P5-II (4025 N) [9]: test not passed • P5-II (4025 N) ≤ F_{end} < P6-II (4425 N) [9]: borderline • F_{end} ≥ P6-II (4425 N) [9]: passed
Classification of sockets that passed the test	Over-dimensioned sockets if: • F_{end} ≥ P6 & weight ≥ 600 g Best socket (for each type of adapter) if: • F_{end} ≥ P6 & lowest weight ≥ 600 g & simplest stratigraphy

layup) was chosen. A schema of the test procedure is reported in Table 6.

3. Results

3.1. Loading plates

The loading plates were produced in stainless steel according to the requirements of ISO 10382 to reproduce P5 loading condition. The complete mechanical drawings of the two loading plates are provided in the Supplementary material S2.

3.2. Socket weight and ultimate failure load

The test results in terms of ultimate load at failure and total weight of the test sockets were organized according to the combination of stratigraphy, distal adapter and resin in Table 7. Fig. 7 reports the distribution of the sockets in terms of ultimate load at failure and total weight. Different colors denote different stratigraphy categories, whereas different symbols refer to different adapters. The resin is not shown in this graph. Finally, Fig. 8 reports the load-displacement curves for each socket, grouped by distal adapter (by plot) and stratigraphy (by color).

3.3. Socket failure mode

In general, two main modes of failure were observed: failure of the socket in the distal region, at the interface with the distal adapter, and failure of a modular part of the distal adapter (Fig. 9). In particular, failure at the socket distal region was either a cave-in failure towards the mock limb (inward failure) or a pull-out opening failure (outward failure). Table 8 summarizes the number of failures for each mode, depending on the type of distal adapter.

3.4. Guidelines for socket construction

Based on the test results, the sockets that reached the highest ultimate load at failure with lowest weight, with the simpler stratigraphy, for each type of distal adapter, are reported in Table 9.

A detailed description of the stratigraphy and resin for each of these sockets is reported in the Supplementary material S3.

Table 10 reports the minimum, maximum and average value of ultimate load, with its associated standard deviation and coefficient of variation, for the sockets having the same type of distal adapter.

4. Discussion

The aim of this study was to implement a mechanical testing system for lower-limb prosthetic sockets based on an adapted version of ISO

Table 7
Results of tested sockets in terms of ultimate load at failure and weight. The single wildcard symbol (*) denotes failure of a modular part of the distal adapter instead of the socket itself. The background color is associated to the output of the test: not passed (red), borderline (yellow), passed (green). The results in bold characters represent the best combinations in terms of strength and weight (also reported in Table 9).

STRATIGRAPHY		DISTAL ADAPTER				
	Braids above adapter	3-arm adapter Ottobock 4R41	Connecting plate Ossur A-122100	Boxed attachment Ottobock 4R415	MSS direct socket Ossur M-100-501	Wood attachment block Ottobock 5R1=6
No braid	0	S2 R1+ 4165 N 680 g S17 R2+ 4891* N 692 g				
No braid	0					S12 R2+ 5555 N 747 g
No braid	0					**S13 R2+ 6057 N 730 g**
6 K	1	S20 R2+ 4110 N 540 g				
6 K	1		**S7 R2+ 5353 N 540 g**			
6 K	1			S5 R3 3400 N 590 g S16 R2+ 4390 N 664 g S4 R1++ 4432 N 557 g		
6 K	3			S23 R2+ 3027 N 593 g		
6 K	3			**S15 R2+ 4713 N 506 g**		
12 K	1	**S14 R1+ 5980 N 471 g**				
12 K	1	S1 R1+ 4859* N 707 g S3 R3 5097* N 662 g S21 R2 4538* N 730 g S22 R1 4574 N 716 g S6 R1+ 5664* N 675 g				
MSS	1				S11 R2+ 3350 N 410 g	
MSS	2				S10 R2+ 4350 N 552 g **S18 R1 6250* N 575 g** S19 R1+ 5721* N 576 g	
MSS	3				S9 R2+ 5830 N 720 g	
MSS	4				S8 R2+ 7330 N 822 g	

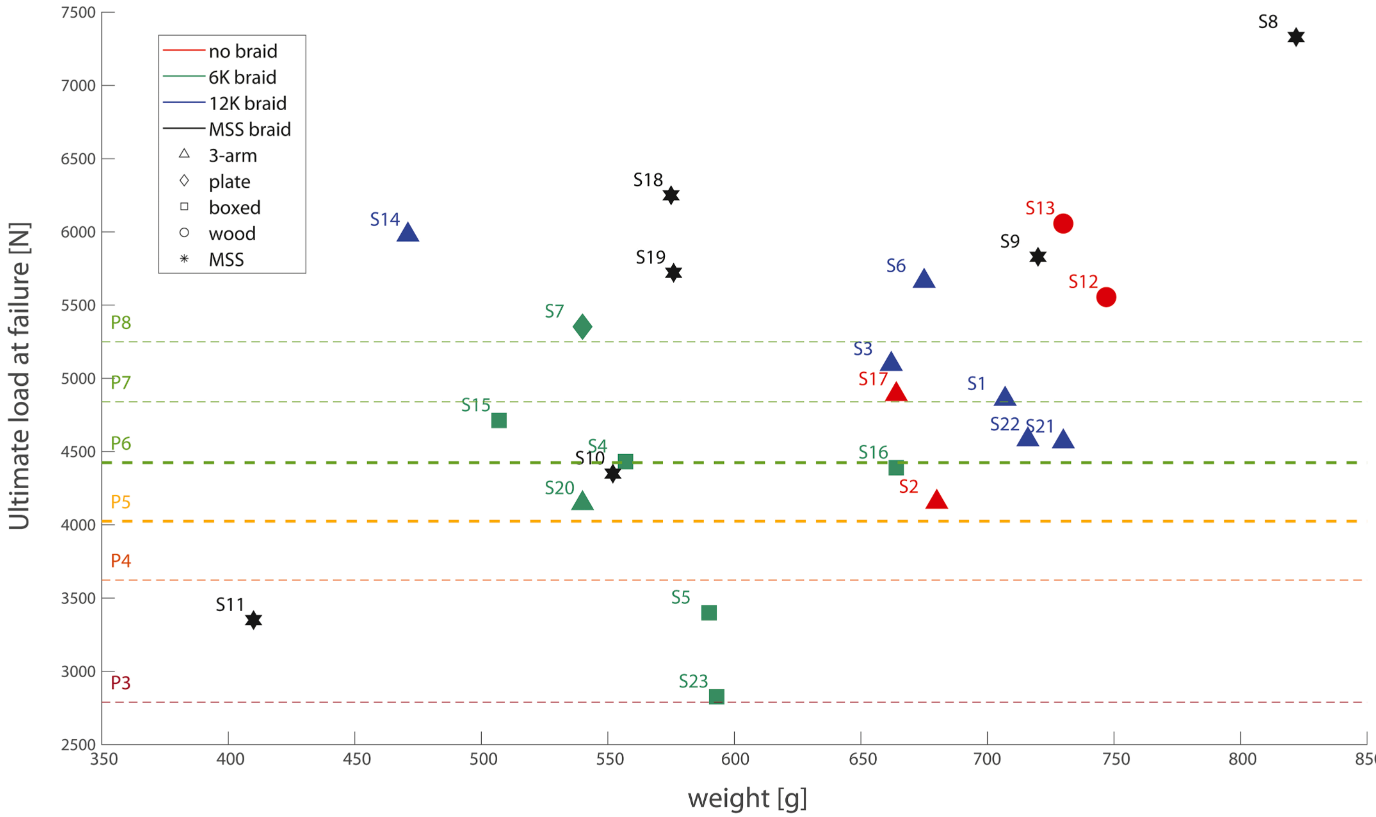


Fig. 7. Distribution of sockets based on the ultimate load at failure and weight. The different colors refer to the different groups of stratigraphy, whereas the different symbols indicate the different groups of distal adapters. The horizontal dotted lines correspond to the six test loading levels defined in ISO 10328. Levels P5 and P6 were used to determine the test outcome.

10328:2016, and to use it to conduct static testing on a batch of twenty-three laminated sockets, having the same residual limb shape but a different combination of stratigraphy (lamination material and layup), distal adapter and lamination resin. The ultimate goal was to identify, for each type of socket adapter, the combination of stratigraphy and resin that maximized the mechanical resistance while minimizing the total weight of the socket, and for each combination provide a set of practical lamination guidelines for socket construction.

In this study, the authors implemented the adaptation of ISO 10328:2016 proposed by Gerschutz et al. [6] in forefoot loading condition (test condition II of ISO 10328) and P6 loading level [9], because it represented a worst-case scenario for different reasons. First, testing the socket in isolation, by positioning it as low as possible within the testing frame, applying forefoot loading condition and using P6 level lever arms are all actions that generate the highest bending moments at the socket distal end [6]. Moreover, the limb increased dimensions provided a worst-case scenario for this type of test [6]. Finally, a P6 level passing condition (4425 N) was considered quite conservative, as it is associated to patients weighing up to 125 kg, 25 kg more than P5 level (100 kg) which is identified by ISO 10328:2016 as the minimum requirement for lower-limb prostheses [9].

The loading plates were very simple to produce and to mount. They allowed to recreate the compound loading condition described in the standard through a single load applied by a single moving actuated cylinder.

In general, out of the twenty-three tested sockets, twelve (i.e. around 50%) weighted more than 600 g and were therefore deemed too heavy for the size of the limb (S1, S2, S3, S6, S8, S9, S12, S13, 16, S17, S21, S22). Seven of all twenty-three sockets (30%) did not reach the required strength, namely P6 loading level (S2, S5, S10, S11, S16, S20, S23), even though four of them were at least above borderline condition, i.e. P5 level (S2, S10, S16, S20). Altogether, the sockets that displayed sufficient strength (above P6) and acceptable weight (below 600 g) were six (S4, S7, S14, S15, S18, S19) (i.e. less than 30%). Among these sockets, we were able to select, for each type of distal adapter, the combinations of stratigraphy and resin that displayed maximum strength with minimum weight (Table 9, Supplementary material S1 & S3). For each of these combinations, further investigation is required, as to test repeatability of each process, fatigue behavior and influence of the resin. However, these preliminary results will allow to simplify the fabrication process to the combinations of stratigraphy-adapter-resin that met the established strength requirement with minimum weight.

These preliminary results have shown that the absence of an established method to quantify socket strength leads to a tendency of over-dimensioning. In fact, among the sixteen sockets that reached the required strength (S1, S3, S4, S6, S7, S8, S9, S12, S13, S14, S15, S17, S18, S19, S21, S22, S23), nine overcame P8 level (two levels above the required P6) (S6, S7, S8, S9, S12, S13, S14, S18, S19) and ten weighted above 600 g (S1, S3, S6, S8, S9, S12, S13, S17, S21, S22). Over-dimensioning should be avoided as it is associated to an unnecessary waste of material that contributes to environmental pollution and increased costs. Moreover, the excessive weight can also cause suspension issues, compromise the health of the residual limb (e.g. ulcerations due to increased shear stresses on the residual limb during the swing phase) and greatly fatigue the person wearing the prosthesis.

From Fig. 7, it is possible to identify some clusters and trends. Sockets S11, S10, S9, S8 display a linear trend; they belong to the same category of stratigraphy (MSS) and have the same distal adapter (MSS direct sockets) and resin (R2+). We can hypothesize that as the amount of MSS carbon braids increases, the weight and the strength of sockets increase linearly. Sockets S18 and S19 have the same particular stratigraphy of socket S10 (2 MSS braids), but show different strength results because they were produced with different resins (R1 and R1+).

Moreover, from Fig. 7 it is also possible to identify clusters of sockets

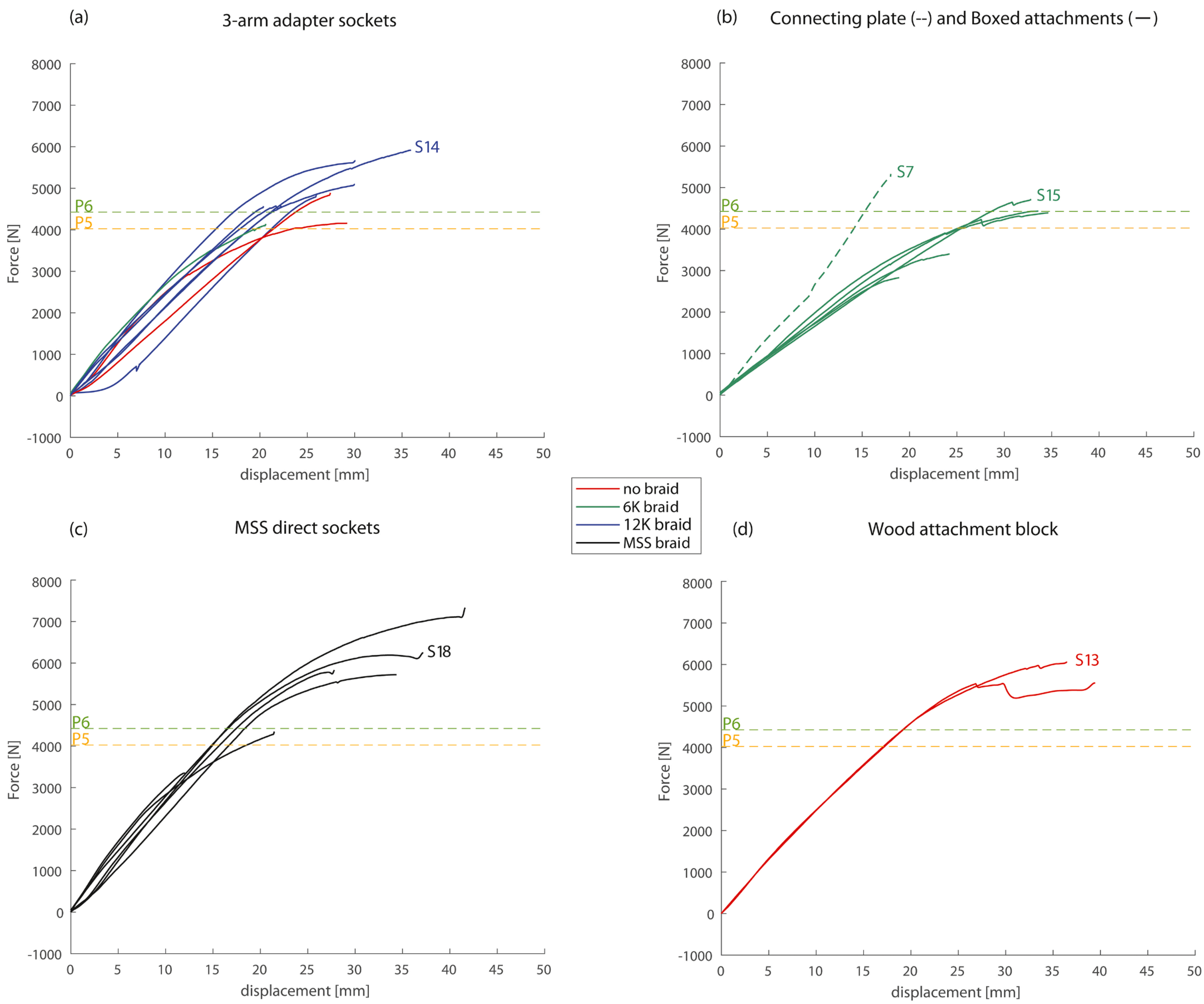


Fig. 8. Force-displacement curves for the sockets with 3-arm adapter (a), connecting plate (b, dotted line) and boxed attachment (b, solid line), MSS direct socket (c) and wood attachment block (d). The four different colors refer to the 4 groups of stratigraphy (no braid, 6 K, 12 K and MSS braid). In each graph, the two horizontal dotted lines represent ISO 10328 P5 (yellow) and P6 (green) loading levels.

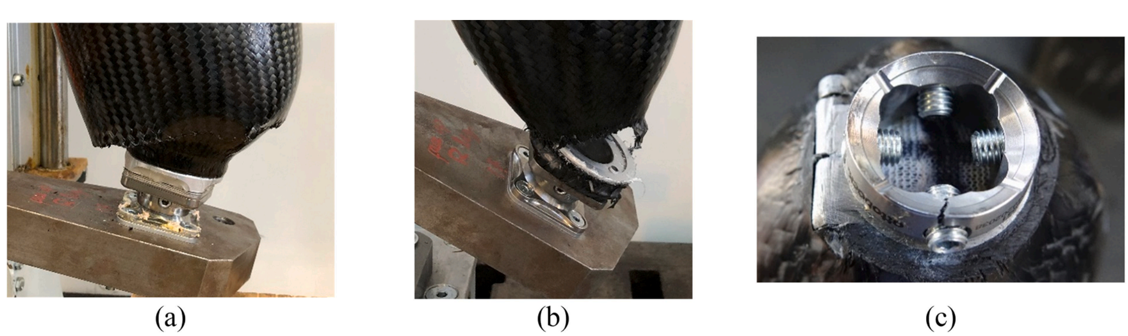


Fig. 9. Example of the three main modes of failure: (a) socket inward failure at the distal end, (b) socket outward failure at the distal end, and (c) failure of the modular adapter.

based on the type of stratigraphy and distal adapter. By grouping the sockets according to their stratigraphy, it is possible to identify three clusters: a cluster of sockets with 6 K stratigraphies ("green cluster": S4, S5, S7, S15, S16, S20, S23), a cluster of sockets with 12 K stratigraphies ("blue cluster": S1, S3, S6, S21, S22), and a cluster with no braid stratigraphies ("red cluster": S2, S12, S13, S17). By grouping the sockets according to their adapter, it is also possible to identify three cluster: a cluster of sockets with the boxed attachment or connecting plate

Table 8
Failure modes grouped by type of distal adapter.

Sockets grouped by distal adapter	Failure of socket distal end		Failure of modular part of adapter	Total
	Inward failure	Outward failure		
3-arm adapter	1	3	5	9
Connecting plate	0	1	0	1
Boxed attachment	5	0	0	5
MSS direct socket	1	2	3	6
Wood attachment block	1	1	0	2

("square cluster": S4, S5, S7, S15, S16, S23), a cluster of sockets with the 3-arm adapter ("triangle cluster": S1, S2, S3, S6, S17, S21, S22), and a cluster with the wood attachment block ("circle cluster": S12, S13). Because of production constraints, the adapter and stratigraphy clusters are almost superimposed, with all boxed attachment sockets and connecting plate sockets being fabricated with 6 K stratigraphies (green cluster and boxed cluster), most 3-arm adapters fabricated with 12 K stratigraphies (blue cluster and triangle cluster) and all wood attachment sockets fabricated with no braid stratigraphies (red cluster and circle cluster).

From both points of view, the three clusters show a linear trend of increasing weight and strength, with the green and square cluster showing the lowest weight and strength and the red and circle cluster showing the highest weight and strength.

Sockets with 3-arm adapter and 12 K stratigraphy (blue and triangle cluster) area in general characterized by high strength but also high weight. In this cluster, 5 out of 7 times failure affected the modular components and not the socket itself, therefore we could assume that the combinations of stratigraphies and adapter are equivalent in the sense that they are stronger than the modular connecting elements. The only two sockets with 3-arm adapter that are not included in the triangle cluster are sockets S14 and S20, which show a strength comparable to the mean strength of the cluster with a much lower weight. This difference in weight could be justified by the smaller amount (S20) or absence (S14) of Perlon stockinettes in the stratigraphy of these two sockets with respect to the amount of the Perlon within the cluster (5 or 6 stockinettes). From this result we can hypothesize that the addition of Perlon stockinettes in the stratigraphy causes a notable increase in weight, probably because they get very impregnated by resin, without however generating an increase in strength. Moreover, considering socket S14 it seems that reducing the amount of Perlon stockinettes is the only possibility of using 12 K stratigraphies and keep the weight limited.

Sockets with boxed attachment or connecting plate and 6 K stratigraphies (green and square cluster) are in general very light (weight below 600 g) but have limited strength. In this cluster, failure affected the socket distal base and not the modular connecting elements. The only two sockets that reached acceptable strength levels in this cluster are socket S15 that has a boxed attachment and reached a strength between P6 and P7 levels, and socket S7 that has the connecting plate and overcame P8 level. These two combinations of stratigraphy and adapter seem to represent an excellent compromise between weight and strength; further investigation should be carried out to test repeatability and resin influence. Also in this cluster it is possible to observe that the addition of Perlon stockinettes appears to increase weight without enhancing the mechanical properties: in fact, socket S16 with 2 Perlon stockinettes is heavier and weaker than socket S15 which has no Perlon.

Sockets with the wood attachment block and no braid stratigraphy (red and circle cluster) are characterized by very high strength but also excessive weight. Although the sockets in this cluster (S12, S13) do not display any carbon braid in their stratigraphy, they were treated with a significant amount of sealer to enhance proper attachment of the wood block to the inner socket, which may have contributed to enhance strength.

Finally, the effect of resin could be evaluated by considering the pools of sockets having the exact same stratigraphy, distal adapter and that only varied based on the resin. These pools can be appreciated from Table 7 and are: pool 1 (S2, S17), pool 2 (S1, S3, S6, S21, S22), pool 3 (S4, S5, S16) and pool 4 (S10, S18, S19). Unfortunately, no reliable conclusion about the effect of resin can be drawn from pool 1, 2 and 4, as in most cases failure affects the modular connecting elements and not the socket itself. Results from pool 3 seem to indicate that resin R1++ produces stronger sockets than resin R2+ which in turn produces stronger sockets than resin R3. Nevertheless, it is important to clarify that the effect of a certain resin depends on the interaction with a specific stratigraphy, therefore these conclusions may not apply to a different category of stratigraphies.

This study has limitations. It is an exploratory study that implements an un-regulated testing method with the objective of exploring existing combinations of stratigraphy-adapter-resin and establishing a benchmark based on the current practice of the INAIL Prosthetic Center (Vigorso di Budrio – BO, Italy). Unfortunately, we were not able to test the repeatability of results because, with one exception (S1, S6), only one socket sample per combination of stratigraphy-adapter-resin was tested. Future work should focus on investigating the influence of resin by producing at least three sockets with identical stratigraphy-adapter combinations and different types of resin.

Moreover, a complete investigation of the effect of the resin on socket strength was not possible, because of the high strength of stratigraphy-adapter combinations which often caused the modular connecting elements to fail before reaching the actual failure of the socket. Nevertheless, this result is also comforting as it proves that most sockets from the current practice would not fail before failure of a

Table 9
Best combinations (in terms of ultimate load at failure and weight) of stratigraphy and resin, for each type of distal adapter. The wildcard symbol (*) is associated to failure of a distal modular component.

Distal adapter	Socket ID	Stratigraphy	Resin	Ultimate load at failure [N]	Weight [g]
3-arm adapter	S14	12K	R1+	5980	471
Connecting plate	S7	6K	R2+	5353	540
Boxed attachment	S15	6K	R2+	4713	506
MSS direct socket	S18	MSS	R1	6250*	575

Table 10
Statistics of ultimate load at failure for each type of distal adapter.

Distal adapter	Sample size	Min [N]	Max [N]	Mean [N]	Std Dev [N]	CV [%]
3-arm adapter	9	4147	5980	4883	625	13
Connecting plate	1	5353			N/A	N/A
Boxed attachment	5	2827	4713	3952	802	20
MSS direct socket	6	3350	7330	5472	1415	26
Wood attachment block	2	5555	6057	5806	355	6

modular component, which are engineered off-the-shelf elements subject to standard testing.

Furthermore, the tests were conducted based on a set of adaptations of ISO 10328 based on a worst-case scenario approach. However, as the literature in this field is still very limited, the actual effect of different adaptations is unknown, especially concerning socket size and interface with the limb. For example, different limb sizes and shapes might result in different findings and other extreme sizes and shape could require different design recommendations for acceptable or optimal socket strength.

Finally, this study only focuses on ultimate static strength, and does not investigate the behavior under cyclic loading.

5. Conclusion

The first aim of this article was to implement a testing method to quantify the mechanical strength of lower-limb prosthetic sockets according to ISO 10328:2016. This study proved that establishing such testing system was feasible and relatively simple. Designs of the loading plates were provided for replicability purposes. Moreover, this study was able to fill a knowledge gap regarding the mechanical strength of laminated composite sockets.

Among the twenty-three sockets tested, six met the required strength with acceptable weight. Among these sockets, for each type of distal adapter, we selected the combination of stratigraphy and resin that maximized the mechanical strength while minimizing the total weight of the socket. These sockets, reported in Table 9, reached 5980 N with 471 g (S14, 3-arm adapter), 5353 N with 540 g (S7, connecting plate), 4713 N with 506 g (S15, boxed attachment) and 6250 N with 575 g (S18, MSS direct socket). These four sockets are characterized by a stratigraphy with limited or absent amount of Perlon stockinettes, which seems to increase weight without enhancing the mechanical strength. Sockets with 3-arm adapters and 12 K stratigraphies show high strength but also high weight. Sockets with connecting plate or boxed attachment and 6 K stratigraphies are very light but in most cases show limited mechanical properties. MSS direct sockets show the best compromise between strength and weight when the amount of carbon braids is halved (2 tubular braids instead of 4). Sockets with wood attachment block were deemed too heavy even if very strong. Results from a pool of three sockets with same the stratigraphy and adapter seem to indicate that resin R1++ produces stronger sockets than resin R2+ which in turn produces stronger sockets than resin R3.

These conclusions should be considered as hypotheses to be further confirmed in additional experimental and simulation studies.

Ethical approval

Not required.

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Declaration of Competing Interest

None declared.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.medengphy.2023.103970.

Appendix A

Table A1.

Table A.1
Articles reviewed by Gariboldi et al. [1] and Baer et al. [10] in their systematic and scoping review, respectively.

Authors	Year	Socket testing	Material testing	Reviewed by Gariboldi et al. [1]	Reviewed by Baer and Fatone [10]	Reference to standard or guideline
Wevers et al. [11]	1987	x		x		ISPO 1978
Coombes et al. [12]	1988	x		x		ISPO 1978
Current et al. [3]	1999	x		x	x	ISO 10328
Neo et al. [2]	2000	x		x		ISO 10328
Goh et al. [13]	2002	x	x	x	x	ISO 10328 ASTM D638
Phillips et al. [24]	2005		x		x	ASTM D3039
Lee et al.	2005	x		x		ISO 10328
Faustini et al. [15]	2006	x		x	x	–
Graebner et al. [4]	2007	x		x		ISO 10328
Gerschutz et al. [25]	2011		x		x	ASTM D638
Campbell et al. [5]	2012	x		x	x	ISO 10328
Gerschutz et al. [6]	2012	x		x	x	ISO 10328
Lindberg et al. [17]	2018	x		x		ISO 10328
Campbell et al. [16]	2018	x		x		ISO 10328
Saey et al. [21]*	2019	x			x	–
Kadhim et al. [26]	2019		x		x	ASTM D638
Jweeg et al. [20]**	2019	x			x	ASTM D638
Pousett et al. [7]	2019	x		x	x	ISO 10328
Abbas et al. [27]	2020		x		x	ASTM D638
Nickel et al. [18]	2020	x		x	x	ISO 10328
Owen and DesJardins [8]	2020	x		x	x	ISO 10328
Stenvall et al. [19]	2020	x		x		ISO 10328

*Conference proceeding.
**Socket testing through DIC, experimental validation by means of material testing, no socket testing.

Appendix B

ISO 10328:2016 defines six loading levels (P3, P4, P5, P6, P7 and P8), each based on locomotion data acquired at the time of the development of ISO 10328:1996 from amputees of a certain range of body weight: less than 60 kg (P3), less than 80 kg (P4), less than 100 kg (P5), less than 125 kg (P6), less than 150 kg (P7) and less or above 175 kg (P8). For each loading condition (condition I, heel loading and condition II, forefoot loading), each loading level defines both the sizes of the load lever arms as well as the passing conditions in terms of admissible load for static tests and loading range for cyclic tests. While increasing loading levels describe increasing values of loads, it is not the same for the sizes of lever arms. In fact, from P6 to P8, the sizes of lever arms are the same of P5, and account in general for patients weighing more than 100 kg.

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