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Quantitative analysis of interface pressures in transfemoral prosthetic sockets

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Abstract

Background: Among the different factors affecting socket comfort, the pressure applied on residual limb tissues is a crucial parameter for the success or failure of any prosthetic device. However, only a few incomplete data are available on people with transfemoral amputation, in this regard. This work aims at filling this gap in the literature.

Methods: Ten people with transfemoral amputation wearing 3 different socket designs were recruited in this study: 2 ischial containment sockets featured by proximal trim lines that contain the ischial tuberosity and ramus and greater trochanter, 2 subischial sockets with proximal trim lines under the ischium level, and 6 quadrilateral sockets with proximal trim lines that contain the greater trochanter and create a horizontal seat for the ischial tuberosity. The pressure values at the anterior, lateral, posterior, and medial areas of the socket interface were recorded during 5 locomotion tasks (ie, horizontal, ascent, and descent walking, upstairs and downstairs) by using an F-Socket System (Tekscan Inc., Boston, MA). Gait segmentation was performed by exploiting plantar pressure, which was acquired by an additional sensor under the foot. Mean and standard deviation of minimum and maximum values were calculated for each interface area, locomotion task, and socket design. The mean pressure patterns during different locomotion tasks were reported, as well.

Results: Considering all subjects irrespective of socket design, the mean pressure range resulted 45.3 (posterior)–106.7 (posterior) kPa in horizontal walking; 48.3 (posterior)–113.8 (posterior) kPa in ascent walking; 50.8 (posterior)–105.7 (posterior) kPa in descent walking; 47.9 (posterior)–102.9 (lateral) kPa during upstairs; and 41.8 (posterior)–84.5 (anterior) kPa during downstairs. Qualitative differences in socket designs have been found.

Conclusions: These data allow for a comprehensive analysis of pressures acting at the tissue-socket interface in people with transfemoral amputation, thus offering essential information for the design of novel solutions or to improve existing ones, in this field.

Keywords

F-socket, pressure, prosthesis, residual limb, socket, transfemoral

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Introduction

Modern developments in rehabilitation research allowed for the design of high-tech lower-limb prostheses, thus resulting in useful and life-improving devices, able to combine advanced engineering principles with medical considerations.[1] However, even the most advanced systems are useless if simplicity and comfort are not guaranteed. In this scenario, the physical interaction between the artificial prosthetic device and the human body is Considered to be a major open issue.[2,3] Indeed, most people with lower-limb amputation report socket-related discomforts as a core cause of limited prosthesis use.[2,4,5]

Among the several parameters that can affect socket comfort and usability (eg, residual limb volume fluctuations, overheating and excessive sweating, and incorrect prosthetic alignment),[6-9] the interface pressure distribution is considered one of the most influencing factors for assessing the quality of the final device.[5] Indeed, the main challenge is to provide a socket able to guarantee a stable biomechanical coupling with the residual limb without generating excessive pressures on tissues, which are not able to tolerate high loads.[10] Thus, matching the prosthetists' experience with quantitative data can be the key for designing prosthetic interfaces able to meet the user's requirements.

Several works have been performed on interface pressure distributions in lower-limb sockets.[3,11-13] A large amount of previous clinical studies focused on people with transtibial amputation, which are subjected to relatively high loads because of the limited area of pressure action.[3,5,11] On the contrary, only a few and incomplete data have been acquired on people with transfemoral amputation. The first studies reported in the literature were performed by using ad-hoc sensorized sockets, about 50 years ago.[12-16] Among them, Lee et al[16] offered an insight into static and dynamic analyses for both quadrilateral (QUAD) and ischial containment (IC) direct skin-fit sockets. However, only 2 people with transfemoral amputation were recruited, and a new dedicated socket for each subject was required to integrate strain gauge-based sensors at the selected points of the prosthetic

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interface. This resulted in significantly heavier devices with a modified interface, which probably affected the final results.

Afterward, among the different available sensing technologies,[3,17] the F-Socket System (Tekscan Inc., Boston, MA) became the most widespread commercial solution for intrasocket pressure characterization.[5,18-20] This system allows for mapping the pressure distribution of almost the total prosthetic interface, without severely affecting the comfort and suspension of the prosthesis during dynamic tasks.[5] Neumann et al[18] exploited it to map the pressure distributions inside a direct skin-fit IC socket, whereas Kahle et al[20] compared vacuum-assisted IC and vacuum-assisted subischial (SUB-IC) sockets, both with liners, in 10 people with transfemoral amputation.

Finally, Laszczak et al[21] developed an innovative sensor technology for monitoring pressures and shear stresses in lower-limb sockets. A validation study was performed, but only on 1 subject with transfemoral amputation and with sensors placed just on 3 anatomical landmarks on the outside surface of the liner. Several other studies have been focused on the theoretical characterization of the contact pressure by using the finite element method analysis,[22,23] but no other clinical trials on people with transfemoral amputation are available in the state-of-the-art, to the best of our knowledge. Consequently, very few data are available, and the pressure distribution during dynamic tasks other than walking is currently unknown.[3]

This work aims to quantitatively assess the interface pressures in people with transfemoral amputation wearing different kinds of sockets and during different locomotion tasks to provide a comprehensive overview of the pressure range exerted by the residual limb on the prosthetic interface. These results can push forward the scientific advancements in the prosthetic field, providing insights for designing new transfemoral socket solutions.

Materials and methods

Experimental protocol and equipment

The experimental protocol simulated 5 everyday locomotion tasks measured in a laboratorial settings for each subject (Figure 1): (1) horizontal, (2) ascent walking, (3) descent walking (5 gait cycles, 3 times, for each task), (4) upstairs, and (5) downstairs (6 stairs cycles, 3 times, for each task). This set of tests provided a complete analysis of the mobility of people with transfemoral amputation.[11,24] A predetermined walkway was established in the hallway of the rehabilitation center to perform the horizontal walking. The ascent and descent walking were performed on a commercial treadmill, setting a +10% and −6% inclination, respectively.

For each subject, 2 9833E pressure sensors of the F-Socket System[25] (Tekscan Inc.; pressure range: 0–345 kPa) were cut into 2 symmetrical parts and calibrated before the data collection, in accordance with the manufacturer's recommendations. These pressure sensors were thin (thickness <0.2 mm) resistive sensor arrays, composed of a matrix of 240 sensels (16 rows and 15 columns), each one featured by a sensitive area of 8.9 × 6.7 mm^2. Similar to the procedure followed by Dumbleton et al[5] for people with transtibial amputation, anterior-posterior and medial-lateral axes were defined by referring to the alignment of the prosthetic components (ie, foot, pylon, and socket) (Figure 1). Then, the sensors were placed on the defined anterior, posterior, medial, and lateral areas of the socket, covering around 90% of the internal surface. These positions were reported on the residual limb, and the sensors were fixed between the liner and the skin (Figure 1). Indeed, the sensors compromised the vacuum suspension of the socket if positioned between the socket and liner. This positioning protocol was applied for each subject, thus allowing for the direct comparison of the pressure values among subjects. In addition, an F-Scan System[26] with a 3001E pressure sensor (Tekscan Inc.) was positioned on the shoe sole of the prosthesis to capture plantar pressures for gait segmentation.

Data analysis

The data acquisition of the pressure sensors inside the socket and shoe were synchronized in MATLAB R2018a (Figure 2(a)). Then, the plantar pressure was used to isolate the single steps of the aforementioned locomotion tasks. In particular, a threshold value was set to discriminate between the swing (featured by constant minimum plantar pressure, red area in Figure 2(b)) and the stance (featured by increasing plantar pressure green area in Figure 2(b)) phases of the gait. Then, the maximum value was automatically detected, and the first 2 points below the threshold (1 on the right and 1 on the left of the maximum) were used as stance phase delimiters. The swing phases were defined accordingly, as the pressure between the stance ones.

Once each step was discriminated, the corresponding pressure values in the 4 sites inside the prosthesis socket were extracted (ie, medial, lateral, posterior, and anterior) (Figure 2(c), for the lateral pressure). Then, the mean pressure pattern was obtained by averaging the single-step data of each subject and then among subjects, for each locomotion task (ie, horizontal, ascent, and descent walking, upstairs and downstairs). In addition, the minimum and maximum values were estimated for each step, and for each subject, the mean of maximum and minimum values among steps were calculated. Finally, the mean and standard deviation (std) among subjects were found for each locomotion task. Furthermore, this was repeated by splitting up the subjects based on the socket design (ie, IC, SUB-IC, and QUAD sockets).

Participants

Ten people with transfemoral amputation were recruited at the INAIL Prosthetic Center (Bologna, Italy). The inclusion criteria of the study determined the involvement of subjects between 18 and 65 years old and with a unilateral transfemoral amputation for at least 18 months. In addition, an activity level equal to or greater than K2* (*K level: rating system used to indicate the individual's potential functional ability. K1: no ability to ambulate; K2: able to perform activities typical of limited community ambulatory; K3: able to perform activities typical of community ambulatory; and K4: able to perform high-impact activities) was required. The study was approved by the ethical committee "Area Vasta Emilia Centro, Regione Emilia-Romagna CE-AVEC" (protocol ID: P-PPRAI1/2-01, CE protocol reference number: 105/2018/OSS/AUSLBO, date of registration: May 11, 2018; ClinicalTrials.gov ID: NCT04709367, date of registration: January 12, 2021). In accordance with the Helsinki protocol, all participants signed an informed consent form to take part in the test sessions.

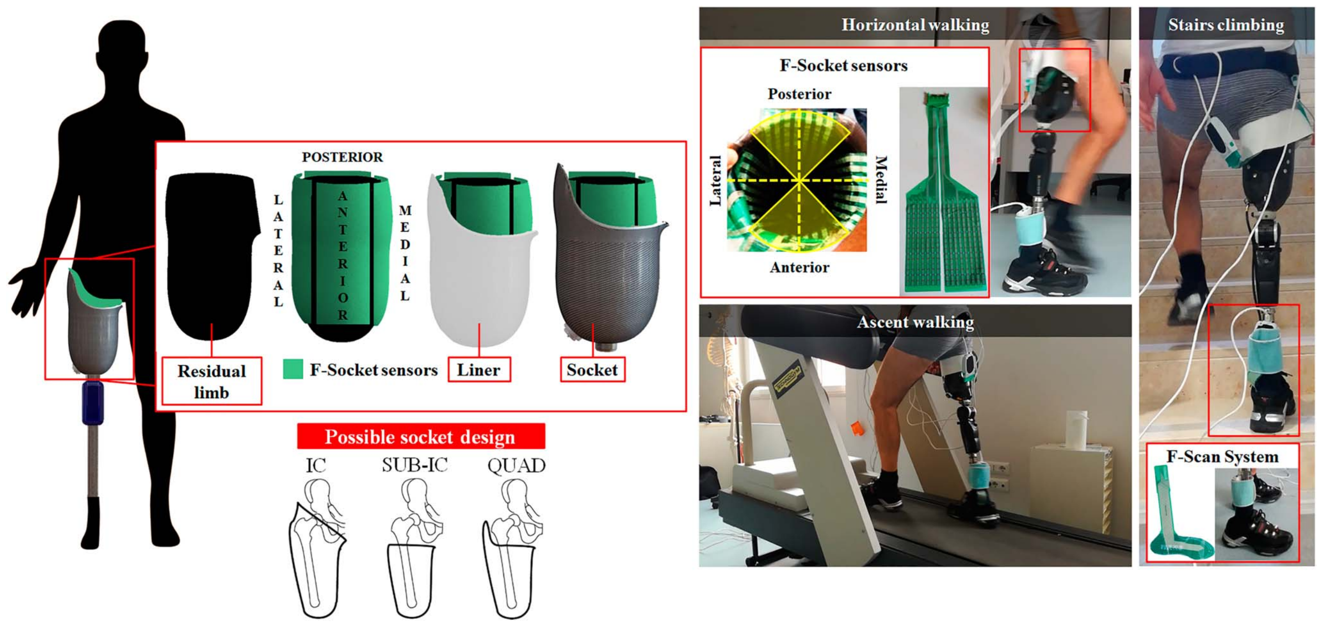


Figure 1. Two sensors of the F-Socket System were divided into 2 equal parts and positioned at the anterior, posterior, medial, and lateral areas of the prosthetic interface between the liner and the skin. An F-Scan System was used to measure plantar pressure and enable gait segmentation. Pressure values were recorded during horizontal walking, ascent, and descent walking on a treadmill, upstairs and downstairs. IC, ischial containment; QUAD, quadrilateral; SUB-IC, subischial.

The general features of the enrolled subjects are summarized in Table 1. All the recruited subjects were males with a traumatic amputation. Their prostheses were all featured by a microprocessor controlled knee and a vacuum suspension of the socket based on a unidirectional valve and a silicone liner. Their socket designs were 2 IC, 2 SUB-IC, and 6 QUAD.

In some critical locomotion tasks, a smaller number of participants was obtained because of sensor failure. Indeed, the selected pressure sensors resulted in the most suitable solution for the proposed study, but they resulted fragile and could damage during the measurements. Specifically, in the horizontal walking, all subjects finished the exercise correctly, whereas in the ascent

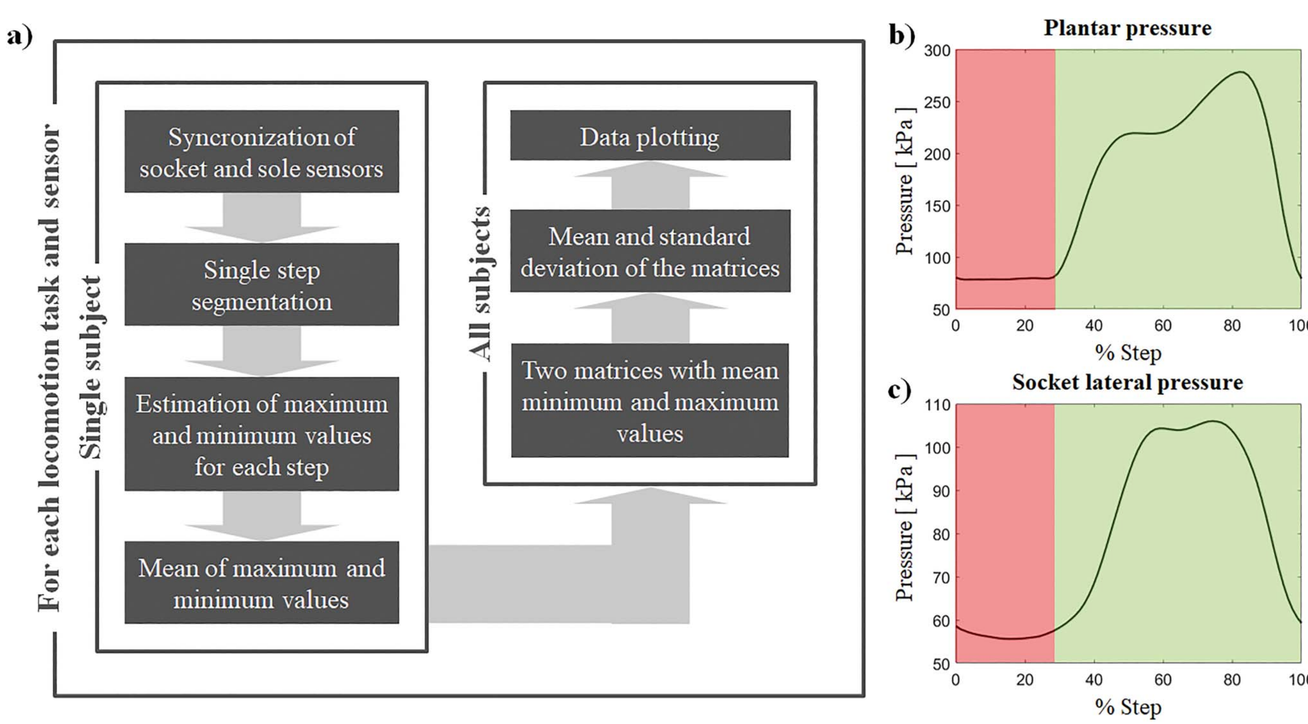


Figure 2. (a) Workflow of the data analysis. Segmentation of a step cycle into the swing (red) and stance (green) phases during walking: (b) example of segmented plantar pressure; (c) example of segmented intrasocket pressure registered by the lateral sensor.

Table 1. General features of the recruited subjects and their prostheses.

	Sex	Age (y)	Height (m)	Weight (kg)	K-level	Years since amputation	Prosthetic knee	Socket
S1	M	42	66.0	1.60	3	16	MPK—C-leg	IC
S2	M	48	68.0	1.60	4	20	MPK—Genium	SUB-IC
S3	M	44	79.0	1.77	3	17	MPK—Genium	IC
S4	M	48	87.4	1.70	3	14	MPK—Genium	QUAD
S5	M	62	60.7	1.72	3	46	MPK—Genium	QUAD
S6	M	58	65.7	1.70	3	12	MPK—C-leg	QUAD
S7	M	41	52.7	1.60	3	8	MPK—Genium	QUAD
S8	M	39	61.9	1.73	3	15	MPK—Genium	SUB-IC
S9	M	57	74.7	1.70	2	38	MPK—C-leg	QUAD
S10	M	65	77.3	1.66	3	58	MPK—C-leg	QUAD
Mean ± std		50 ± 9	1.68 ± 0.06	69.3 ± 10.3		24 ± 16		

Abbreviations: IC, ischial containment; M, male; MPK, microprocessor controlled knee; QUAD, quadrilateral; std, standard deviation; S, subject; SUB-IC, subischial.

walking, the sensors failed in 1 case. Concerning descent walking, upstairs and downstairs, a total number of 8 participants (2 IC, 2 SUB-IC, and 4 QUAD sockets) were analyzed, successfully.

Results

The mean and std of participants' pressure patterns during different locomotion tasks can be found in the Supplemental Digital Content (http://links.lww.com/POI/A169). As expected, a double-peaks pattern of the socket interface pressures was found for the different locomotion tasks, with minimum pressure values in the swing phase and maximum in the stance phase. The double-peak pattern was less evident in some tasks such as the downstairs, probably because of noisier signals.

The mean and std of the minimum and maximum pressure values are reported in Figure 3 for each locomotion task and intrasocket sensor position, in both graphical and numerical form. More specifically, the interface pressure ranged from a mean minimum value of 41.8 kPa (posterior sensor in stair descent) to a mean maximum value of 113.8 kPa (posterior sensor in ascent walking). The mean changes in the contact pressure (ie, the mean difference between the maximum and minimum pressure in a single step cycle) were found equal to 50.2 ± 29.7 kPa, 55.1 ± 29.6 kPa, 49.2 ± 26.5 kPa, 44.6 ± 22.3 kPa, 33.6 ± 17.1 kPa (mean ± std) for the horizontal, ascent, and descent walking, upstairs and downstairs, respectively.

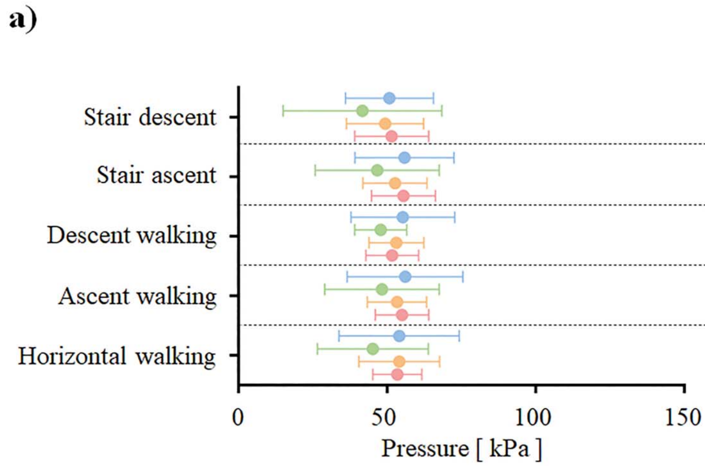
Figure 4 shows the comparison between the different types of sockets. In this framework, some qualitative differences can be observed, even if a larger pool of participants should have been recruited to allow for statistical analyses among the 3 designs. The IC socket showed higher pressures at the lateral and medial areas for all 5 tasks, as expected because of its specific narrower mediolateral dimensions that intimately fit the ischial tuberosity and greater trochanter. In particular, during horizontal walking, maximum values of 136.6 kPa (range: 91.8–181.4 kPa) and 128.6 kPa (range: 75.5–181.7 kPa) were found at the lateral and medial sites, respectively, vs. 102.1 kPa (range 72.4–131.7 kPa) and 122.5 kPa (range 73.3–169.8 kPa) at the anterior and posterior ones. Regarding the SUB-IC design, greater pressure values were found at the posterior and medial region during horizontal, ascent, and descent walking. The mean pressure at the medial site during horizontal walking (105.9 kPa, range: 99.1–112.6 kPa) confirmed the value founded by Kahle and Highsmith[20] of 109 ± 61 kPa. Regarding the high pressure in the posterior region, this is linked to the posterior area of this socket which has to be parallel to the limb axis, to push forward the limb and ensure better stability.[27] Therefore, during the rectification process of the positive cast, a greater amount of plaster has to be removed in the posterior region to flatten it.[27] This results in higher pressures on tissues. In addition, this design does not interact with the greater trochanter and ischial tuberosity, thanks to the lower proximal edges (the flexible inner socket is featured by proximal edges that are ~12 mm under the ischial tuberosity and ~25 mm under the greater trochanter, whereas the outer rigid socket is at least ~75 mm below the flexible socket).[27] As a consequence, the SUB-IC design is featured by smaller values at the lateral site with respect to the IC design. The higher value at the anterior region in upstairs and downstairs could be due to the pushing effect of muscles during these tasks. Finally, the data regarding the QUAD design have greater std, and they were generally more disturbed. This could be due to the more significant relative movements occurring in this socket design, which is not able to ensure a strong fitting. This is confirmed also by the lower interface pressures with respect to the other more stable designs.

Discussion

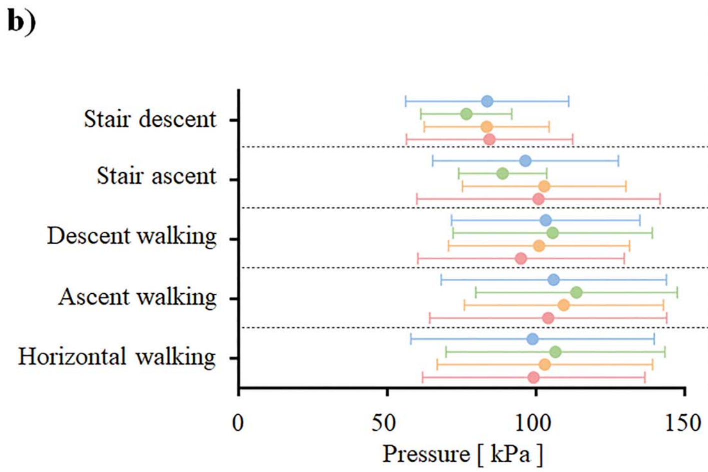
In lower-limb prostheses, the socket is a fundamental component for the success of the final device. Indeed, it has to guarantee both stable and comfortable biomechanical coupling with the residual limb, able to yield the prosthesis an integral part of the user's body. As a consequence, a broad spectrum of design requirements and user needs has to be accounted in the development of efficient and effective solutions.

Despite recent advancements, dermatological problems affect ~65% of patients with a transfemoral amputation[28] and temporarily compromise the prosthesis use in ~60% of people with lower-limb amputation.[3,4] These data clearly point out the need for novel and smart solutions for the socket.[29,30]

However, the integration of smart technologies into the socket requires the assessment of precise design specifications, starting from the results of clinical studies on the main parameters affecting



Minimum pressure – Mean (Std)			
Anterior	Lateral	Posterior	Medial
51.6 (12.5)	49.5 (13.0)	41.8 (26.7)	50.9 (14.8)
56.4 (11.0)	53.7 (9.21)	47.9 (8.75)	55.3 (17.5)
51.8 (8.89)	53.2 (9.36)	50.8 (6.72)	56.6 (17.6)
55.1 (9.02)	53.5 (9.95)	48.3 (19.2)	56.2 (19.5)
53.5 (8.20)	54.2 (13.6)	45.3 (18.6)	54.2 (20.2)



Maximum pressure – Mean (Std)			
Anterior	Lateral	Posterior	Medial
84.5 (27.9)	83.6 (20.9)	76.7 (15.3)	83.7 (27.4)
100.9 (40.1)	102.9 (27.5)	88.9 (14.8)	96.6 (31.2)
95.1 (34.7)	101.1 (30.4)	105.7 (33.5)	103.4 (31.7)
104.2 (39.8)	109.5 (33.5)	113.8 (33.9)	106.1 (37.9)
99.3 (37.4)	103.1 (36.2)	106.7 (36.8)	98.9 (40.9)

Figure 3. Means and stds of (a) minimum and (b) maximum interface pressures for each intrasocket sensor and for each locomotion task. Red = anterior sensor; orange = lateral sensor; green = posterior sensor; blue = medial sensor. std, standard deviation.

this interface. In this scenario, the high pressures applied on lower residual limbs are a key aspect in terms of perceived comfort and risk of dermatological problems. Hence, in this study, quantitative data were acquired on 10 participants with 3 different kinds of sockets and during 5 various everyday locomotion tasks, thus offering a comprehensive overview of this parameter. Two F-Socket sensors divided into 2 symmetrical parts were placed inside the sockets between the liner and the residual limb to capture pressure values at 4 different areas of the prosthetic interface. Another sensor was positioned on the shoe insoles, allowing for gait segmentation. In the future, these data can be exploited for finite element method model validations and enable further advancements in the design of new smart prosthetic socket solutions with integrated pressure sensor systems.[29,30]

The total pressure range (41.8-kPa posterior sensor in stair descent—113.8-kPa posterior sensor in ascent walking) seems slightly higher but comparable with the preliminary data found in literature.[16,21] In particular, Kahle and Highsmith[20] measured the pressure in 10 people with transfemoral amputation during walking by using a similar sensor system positioned between the liner and residual limb as in our study. They found a mean peak value equal to (1) 112 ± 80 kPa and 72 ± 44 kPa at the proximal-medial and distal-lateral areas of IC sockets and (2) 109 ± 61 kPa and 100 ± 75 kPa at the proximal-medial and distal-lateral areas of SUB-IC sockets. In other studies, a range from 11 to 103 kPa was measured in an IC skin-fit socket during walking,[18] and a maximum pressure of 34 kPa for standing and 95 kPa for walking was found in 2 people with transfemoral amputation with both QUAD and IC skin-fit sockets.[16] The pressure profiles reported in that study—measured on 1 subject with a QUAD skin-fit socket (ie, without liner) during walking—seem significantly lower than the ones we found in our study, even if we positioned the sensors under the liner. The difference could be partially related to a not-optimal adherence of the sensors to the residual limb in the previous study and to the different sensing technology. Indeed, in that case, 8 load cells were integrated at specific points of the prosthetic interface, thus obtaining pressure patterns with maximum values variable from ~20 kPa at the distal level to ~100 kPa at the ischial seat.[16] On the contrary, in our study, the pressure was averaged on 4 macroareas of the interface, and the values measured during the swing phase were very different. Indeed, they reported a pressure close to zero,[16] which means that the contact between the residual limb and the socket was minimal. In our study, this pressure maintained higher values (ie, mean minimum pressure >40 kPa for all sensors), demonstrating a more robust coupling between the residual limb and the socket. On the other hand, Mu et al[31] found a significantly higher maximum pressure of 258.9 kPa at the distal end of the residual limb. However, the measurement at that point

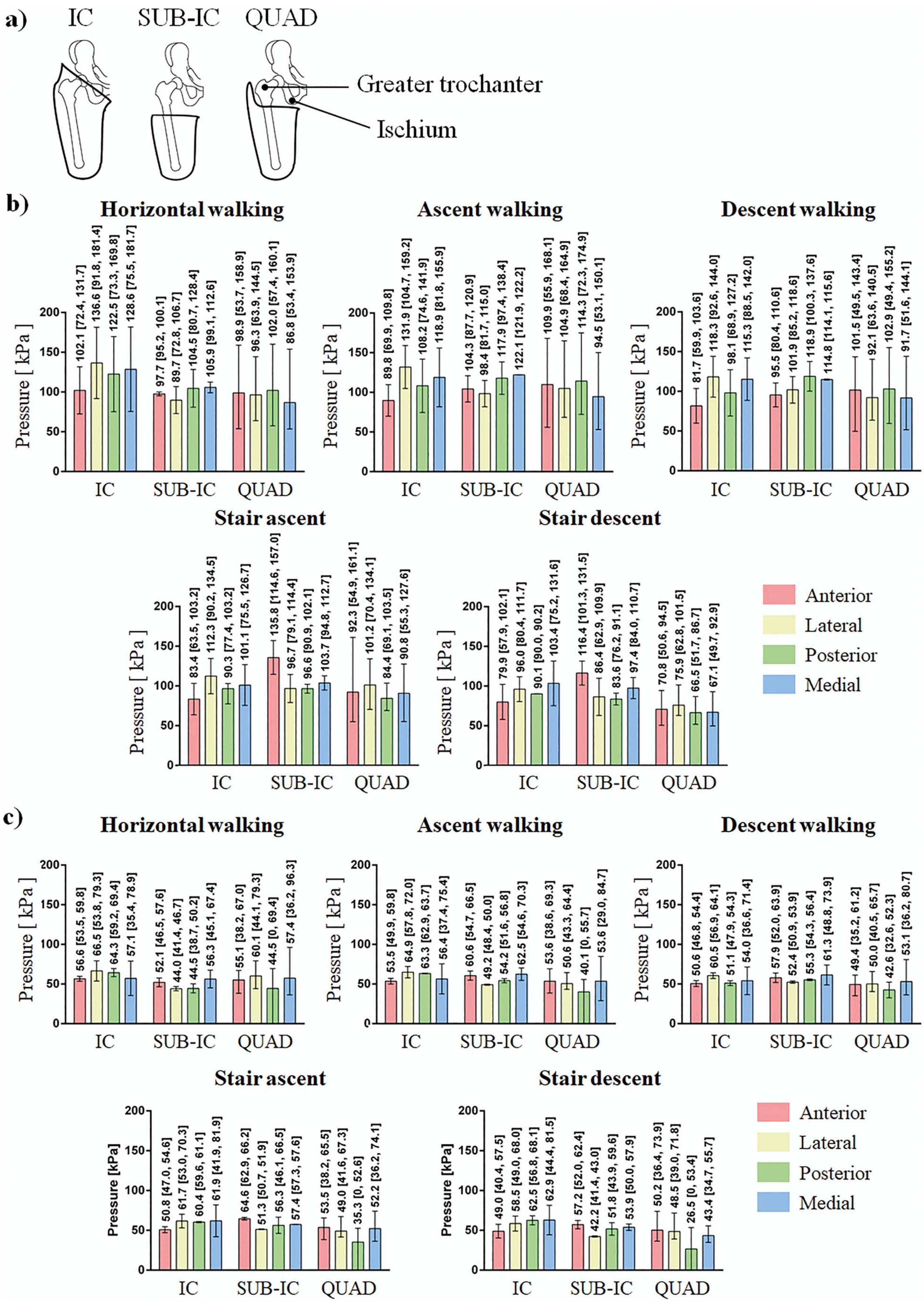


Figure 4. (a) Schematic representation of the 3 analyzed socket designs. Comparison of (b) maximum and (c) minimum interface pressures (mean [range]) for the 3 types of sockets: IC (2 subjects), subischial (SUB-IC) (2 subjects), and quadrilateral (QUAD) (6 subjects for horizontal walking, 5 for ascent walking, and 4 for the other tasks). Red = anterior sensor; yellow = lateral sensor; green = posterior sensor; blue = medial sensor. IC, ischial containment.

was not acquired in our study (Figure 1); thus, a comparison turns out more difficult.

The study proposed in our article shows some limitations. The disparity in the number of socket designs (ie, 2 IC, 2 SUB-IC, and 6 QUAD sockets) did not allow for statistical comparison, and some sensors failed during the tests reducing the amount of available data, especially in stair tasks. The recruiting prosthetic center introduced a bias in the features of the enrolled subjects, all males with a traumatic amputation (Table 1). Indeed, it is a national rehabilitation facility dealing mainly with traumatic disabilities because of work-related accidents (INAIL, Italian National Institute for Insurance against Accidents at Work). In this study, the mean pressure of 4 macroareas of the prosthetic interface has been characterized, whereas in the future, a higher spatial resolution should be targeted to allow a more accurate and detailed analysis. On the other hand, we gave priority to the robustness of the sensing system and to the comfortable integration into the socket. In addition, correlations with other parameters, such as muscle strength or hip joint function, should be investigated to further improve clinical knowledge.

Conclusions

The proposed work offers an insight into the characterization of the residual limb-socket interface pressures in people with transfemoral amputation. Data were measured in 10 subjects during horizontal walking, in 9 subjects in ascent walking, and in 8 subjects in descent walking, upstairs and downstairs. The minimum and maximum interface pressure values, as well as the mean pressure patterns, were analyzed, resulting in a total range of 41.8–113.8 kPa. A qualitative comparison of 3 different socket designs was also provided. However, in the future, a larger pool of participants will be required to allow for statistical analysis of different socket designs. These data represent the first step toward a better understanding of the interface pressures in people with transfemoral amputation.

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Declaration of conflicting interest

The authors disclosed no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Supplemental material

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