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Enhancing prosthesis fitting: A protocol for acquiring thermal and biomechanical data from lower limb amputees

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Abstract

Background: Despite advancements in prosthetic design, many lower limb amputees continue to experience discomfort and report abandonment rates between 25% and 57%. Issues at the residual limb-socket interface, such as pressure, friction, and poor fit, remain critical challenges affecting long-term prosthesis use. **Objective:** This study introduces a comprehensive protocol to collect and analyze quantitative data from transtibial amputees, incorporating thermal imaging and biomechanical measures to enhance prosthesis fitting in clinical settings.

Study Design: Cross-sectional quantitative clinical study evaluating thermal and biomechanical parameters of prosthetic socket fitting in unilateral transtibial amputees.

Methods: This is a cross-sectional study that employs quantitative analysis of thermal and biomechanical parameters in transtibial amputees. The study, conducted in a clinical setting, included independent unilateral transtibial amputees. Participants underwent a series of evaluations that included thermograms of the residual limb captured with a thermal camera, weight distribution using a plantar pressure platform, gait symmetry via an inertial sensor, and the 2-minute walk test (2MWT). The protocol aimed to compare the effectiveness of different suspension systems on prosthetic fit.

Results: The analysis targets temperature variations at the stump-socket interface and between-system differences in thermal and biomechanical metrics. We hypothesize that suction-based systems demonstrate better thermal consistency and symmetry, pin-lock systems exhibit higher proximal temperature, and valve systems achieve the longest 2-minute walk test distances. Variability in weight distribution and symmetry will inform individualized socket adjustments.

Conclusions: The integration of thermal imaging and biomechanical analysis provides a more comprehensive evaluation of prosthesis fitting. Infrared thermography (IRT), although underused, is a promising tool for identifying critical adjustments in prosthetic design. Further research and standardization of such protocols can enhance clinical outcomes and user satisfaction.

Keywords

amputee, prosthesis, lower limb, biomedical thermography, weight distribution, 2MWT, accelerometry, noninvasive monitorization

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Hypothesis

Integrating thermal and biomechanical data through a standardized protocol enables the identification of significant differences in prosthetic fit based on suspension type, offering a more accurate assessment than conventional clinical methods.

Relevance of the study

This study proposes a comprehensive protocol that combines infrared thermography (IRT), weight distribution, gait symmetry, and functional testing to provide an objective and reproducible tool for improving prosthetic fitting in transtibial amputees. Its implementation can support better clinical decision making, reduce prosthesis abandonment, and promote the standardization of prosthetic fit evaluations.

Background

Approximately 49%–95% of lower-limb amputees use a prosthesis.[1] Ensuring functional performance, therefore, requires careful optimization of socket design, materials, contouring, and the liner-suspension combination. Recent evidence reinforces this need: large-scale data show substantial dissatisfaction with prosthetic devices and related services,[2] and cohort analyses document disparities in prosthesis abandonment and mobility outcomes.[3]

The socket is a critical interface between the residual limb and the prosthetic device, subject to constant changes in pressure,

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temperature, volume, displacement, and shear stresses, which can affect functionality (Figure 1). It must ensure a proper fit, load transmission, stability, and control,[4] making it a key factor in prosthesis success or failure.

Despite recent advancements and the inclusion of biomechanical parameters in prosthetic design, amputees still report low satisfaction, with abandonment rates around 25%–57%.[4–6] This leads to significant economic consequences, such as higher costs for health insurers because of reprocessing prostheses or addressing secondary conditions caused by nonuse companies.[7,8] Therefore, ensuring long-term comfort and functionality is essential for the prosthesis success.[4]

Although prosthetic clinical practice relies on empirical evidence and prosthetists' clinical judgment, evaluations are often subjective, based on user feedback rather than medical training.[6] Various tools, methodologies, and tests have been employed to assess prosthetic adaptation, ranging from subjective instruments such as questionnaires and functional mobility tests to objective analyses involving kinetic, kinematic, and thermal parameters. Recent systematic reviews and experimental studies have highlighted the increasing use of pressure mapping, motion analysis, and thermography to characterize the residual limb-socket interface and optimize prosthetic fitting.[4,5,9,10]

Although these tools provide indirect feedback, high-accuracy instruments and new techniques are offering a more detailed understanding of the residual limb-socket interface. Recent studies have demonstrated the feasibility of combining biomechanical and thermal analyses to assess socket performance and tissue response. For instance, Živčák et al[11] used simultaneous pressure mapping and thermography to characterize load and temperature distribution at the stump-socket interface in transtibial amputees, identifying local stress zones associated with soft tissue irritation. Likewise, Cárdenas et al evaluated stump-skin temperature patterns and ground-reaction forces in transfemoral amputees under different alignment conditions, showing that prosthetic misalignment alters heat diffusion and loading symmetry during gait. These findings support the inclusion of thermal imaging and kinetic analysis as complementary, objective tools to optimize prosthesis fitting and comfort.[12]

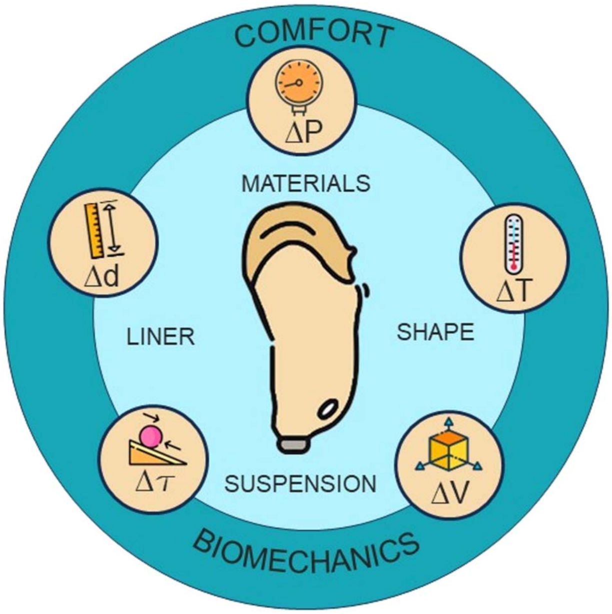

Figure 1. Schematic representation of the main factors affecting the stump-socket interface and their interplay.

This paper presents a protocol designed to acquire quantitative data from lower limb prosthesis users, with the aim of improving prosthesis fitting in clinical settings. The protocol collects 4 types of objective quantitative information: thermograms of the residual limb, weight distribution, gait symmetry, and the commonly used 2-minute walk test (2MWT). It not only provides data on variables frequently studied for prosthetic fitting evaluation but also includes thermographic images to analyze critical areas at the stump-socket interface. These images provide spatial temperature data of the stump-socket interface, which can be compared with biomechanical and functional measures. The integration of thermal and conventional metrics enables an objective, multiparameter assessment of prosthesis fitting.

Methods and procedures

Population

The protocol was implemented with independent unilateral transtibial amputees. The number of participants was defined by clinical availability. Rather than performing an a priori sample size calculation, the sampling error corresponding to the achieved sample (n = 32) was estimated. The calculated margin of error ranged from 4.7% to 6.8%, indicating acceptable precision for the exploratory scope of this protocol.

The participants had an average age of 40.3 ± 9.1 years, a body mass index between 18 and 30, and a residual limb length of 20.5 ± 4.6 cm. Males made up 84% of the group, and the distribution of amputations was balanced between the right and left sides. Regarding the causes of amputation, 84% were because of traumatic causes, 9% were congenital, and 6% resulted from infections. For suspension methods, 44% used pin-lock suspension, 34% employed subatmospheric suspension with a valve, 16% wore a knee brace, and 6% opted for subatmospheric skin suction suspension.

Participants ambulated autonomously using their prosthetic device without external aids. Bilateral amputees were excluded as the protocol required single-leg stance without a prosthesis for thermogram acquisition. Participants needed surgeries performed over 12 months before the study.

Prosthesis users reported any conditions affecting blood perfusion or thermogram capture, such as tattoos or wounds, including those from prosthesis use. Informed consent was approved by the Bioethics Committee of the XXX.

Equipment and software

Applying this protocol requires several resources: a thermographic camera, a plantar pressure platform, an inertial sensor, and a stopwatch. A rotating positioning device and a uniform background are ideal for thermogram acquisition. Alternatively, dark panels or rooms can minimize external radiation errors.

Thermograms were captured using an Optris PI 450i camera with an 8–14 μm spectral range, 382 × 288 pixel resolution, NETD (Noise Equivalent Temperature Difference) of 40 mK, ±2°C/±2% accuracy, and a working range of −20°C to +100°C. Optris PIX Connect version 3.18.3103.0 (OPTRIS GmbH, Berlin, Germany) software was used to process images, setting emissivity at 0.98. Ambient temperature was 22.46°C, with 60.43% relative humidity. The 2MWT used a stopwatch and distance markers (Figure 2(a)).

Body weight distribution was measured using the EcoWalk portable plantar pressure platform (Ecosanit, Arezzo, Italy) with its software EcoFoot v.4.0. This device comprises a 480 × 480-mm active matrix with 2,304 sensors and an acquisition rate of 40 fps[13] (Figure 2(B)).

Symmetry index (SI) was calculated using the G-Walk inertial sensor (BTS Bioengineering, Milan, Italy) and G-Studio v.3.2.25.0 software. The device includes triaxial sensors (accelerometer: 4–1,000 Hz, magnetometer: up to 100 Hz, gyroscope: 4–8,000 Hz) and Bluetooth 3.0 connectivity (range: 60 m[14]; Figure 2(c)).

Description of the protocol

The protocol data capture lower limb amputees' performance with a prosthesis during static standing and dynamic walking. This involves specialized equipment: a plantar pressure platform for baropodometry, an inertial sensor for gait symmetry, a thermographic camera for thermograms, and the 2MWT.

Thermograms reveal areas where the residual limb's surface temperature changes because of factors like pressure, shear stress, friction, or health conditions.[15] To standardize the analysis, thermograms taken before and after prosthetic gait were then processed using a defined procedure. Based on the residual limb length and inclination angle, a midline was drawn from the distal end toward the knee in each of the 4 thermograms captured per participant. These coordinates were entered into the camera's software to extract temperature values from the pixels intersecting the traced line. This approach allows consistent comparison of temperature variations along the residual limb and facilitates correlation with the socket design and residual muscle regions.

Lateral weight distribution is defined as the difference in the percentage of weight supported by the healthy ($\%W_s$) and the limb with prosthesis ($\%W_p$) based on baropodometry (using the plantar pressure platform; Equation 1). Percentages between 0 and 5% mean that the distribution of the load is homogeneous, indicating good bipedal support and, therefore, better prosthesis fitting.[16]

$$BWD\% = \%W_s - \%W_p \tag{1}$$

The SI quantifies the difference between the fully functional and amputated limb during stance or swing phases, with values between 75% and 100% indicating high symmetry.[14] Using raw acceleration signals, initial contact and take-off for each limb are identified, enabling the calculation of differences in stance and swing phase durations compared with normal gait benchmarks of 60% and 40%, respectively.

The 2MWT is a common standard test for prosthesis fitting, offering insights into the mobility and functionality of lower limb amputees. Distances exceeding 100 m are generally interpreted as indicative of good prosthesis performance.[17]

The protocol begins by ensuring participants follow specific premeasurement instructions: no creams, ointments, or foot powder on the residual limb, no food or drink 2 h before the test, and no intense physical activity for 14 h prior. The area should also be shaved 24 h prior if necessary. Failure to follow these instructions could alter thermal data.

After signing the consent form, participants wear disposable shorts for observation of the residual limb and a pelvic belt to hold the inertial sensor at the sacral base (S1). Anthropometric data such as height and weight are also collected.

Next, the prosthetic device is removed, and the participant undergoes a 15-min acclimatization period, sitting still to avoid affecting blood flow or temperature. Afterward, the participant moves to a dark area where thermal images are captured using a thermographic camera placed 1.15 m from the residual limb. The user must move carefully to avoid falling.

After thermal image capture, the lights are turned back on, the prosthesis is reattached, and the participant stands still on a plantar pressure platform for 60 sec to measure weight distribution. The pressure sensors calculate the weight supported by each limb.

The inertial sensor is then activated to calculate the SI. The participant walks at a self-selected pace while data are collected for the walking distance, typically during a 2MWT or its variants. The inertial sensor stops after the test is complete.

Finally, the prosthesis is removed again, and thermal images are captured immediately after. The lights are turned on, and the

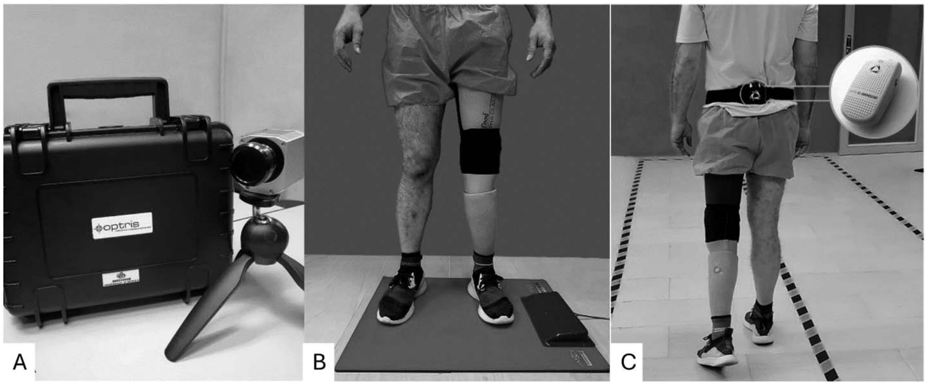

Figure 2. Equipment used: (a) thermographic camera, (b) plantar pressure platform, and (c) inertial sensor.

participant puts the prosthesis back on. The entire protocol lasts approximately 30 min, as shown in Figure 3.

Results and conclusions

The data obtained through the protocol correspond to the thermal profiles derived from tracing a midline on the thermograms based on the residual limb length and the values of biomechanical variables: body weight distribution, SI, and 2MWT.

The thermal profiles showed variations across different suspension systems and within each type. A temperature increase was observed in most users after walking, consistent in both planes. The suspension systems exhibited differences in the thermal profiles of the residual limb. The skin-fit suction system was particularly consistent, showing less variability between prewalking and postwalking temperatures, whereas the valve and knee brace systems displayed greater variability and more pronounced thermal increases, especially in the distal region. In contrast, the pin-lock system showed a notable temperature increase in the proximal region (Figure 4).

Valve and skin-fit systems generate negative pressure, producing thermal profiles with gradual temperature changes along the residual limb. Valve systems often show steeper temperature slopes than skin-fit suction. In contrast, pin-lock and knee brace systems, which lack suction, display flatter thermal profiles with minimal temperature variation. These distinctions emphasize tailoring each system to the patient's unique needs, as abrupt temperature peaks may disrupt the expected trends.

Temperature peaks need visual inspection of thermograms to assess prosthesis fit in the affected areas. For instance, user P20's atypical profile stems from their residual limb's unusual shape because of the amputation's etiology. User P14 exhibits a notable peak in the posterior plane during both measurements, linked to socket component-induced discomfort. Similarly, user P01's thermogram highlights a scar that must be factored into data interpretation (Figure 5).

Body weight distribution data show variability, especially with knee brace suspension, whereas skin-fit suction systems exhibit minimal variation despite limited observations. Weight-bearing lateralization reveals asymmetry, with 53.1% of participants favoring the fully functional limb. Extreme data require scrutiny, considering the amputation side. It is advised to evaluate prosthesis length, alignment, and pressure points causing discomfort (Figure 6).

For the SI, the skin-fit suction suspension system shows the highest mean and the lowest standard deviation, indicating greater consistency in the results. Conversely, the valve and knee brace suspensions exhibit higher variability in symmetry, possibly influenced by the presence of outliers with low symmetry indices. In these cases, it is recommended to review the prosthesis length, alignment in various planes, ensure there are no compensations through hip circumduction, and evaluate adaptation to the suspension type used.

In the 2MWT results, the valve suspension system demonstrates the highest mean, whereas the pin-lock system records the lowest. The skin-fit suction system shows a high standard deviation, reflecting greater variability, yet it remains the gold standard for assessing prosthetic adaptation. For users with atypical results, such as distances below 100 m, evaluating the prosthetic device's age and the user's adaptation to the suspension type is crucial, as these factors can affect stability during gait transitions and the cadence influencing test performance.

The protocol proposed in this paper offers a more in-depth analysis of an amputee's performance with their prosthesis. In clinical settings, a prosthesis might be deemed suitable based solely on the 2MWT results. However, analysis of the data collected with this protocol may reveal the need for further adjustments to the device, providing more detailed insights into factors that could be hindering proper adaptation to the prosthesis. This protocol can be implemented with minimal adjustments by integrating portable thermal cameras and simplified balance and gait assessment tools. Future clinical versions will include automated data processing and shorter acquisition times to facilitate routine use in rehabilitation settings.

These results could improve the standard evaluation of prosthetic fit, aiding in the design and manufacturing of better prosthetic sockets and suspension systems. It is recommended to review the suspension type and prosthesis length, as an overly long prosthesis may affect symmetry. Irregularities inside the socket that

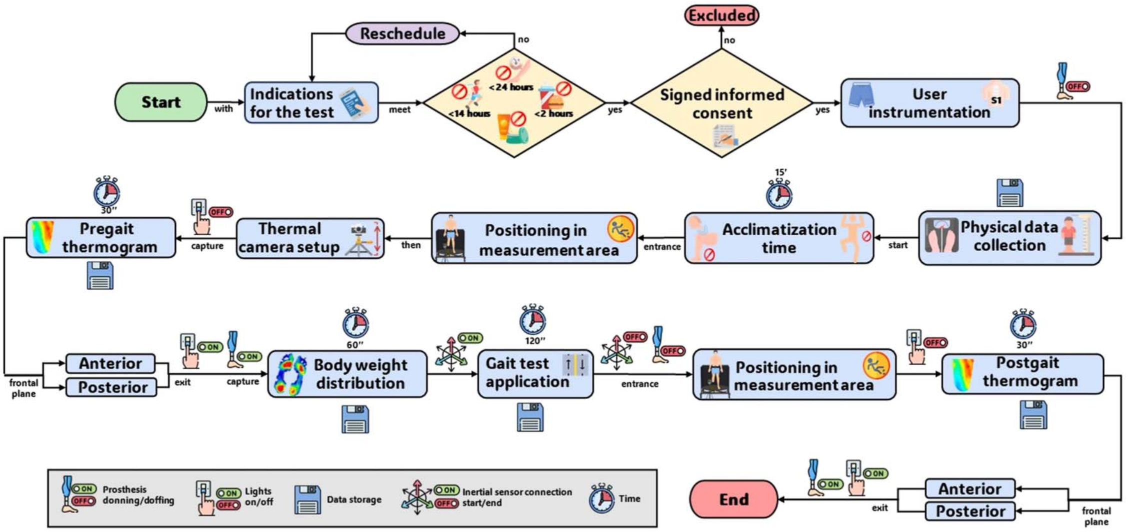

Figure 3. Flowchart illustrating the protocol for acquiring thermal and biomechanical data from lower limb amputees.

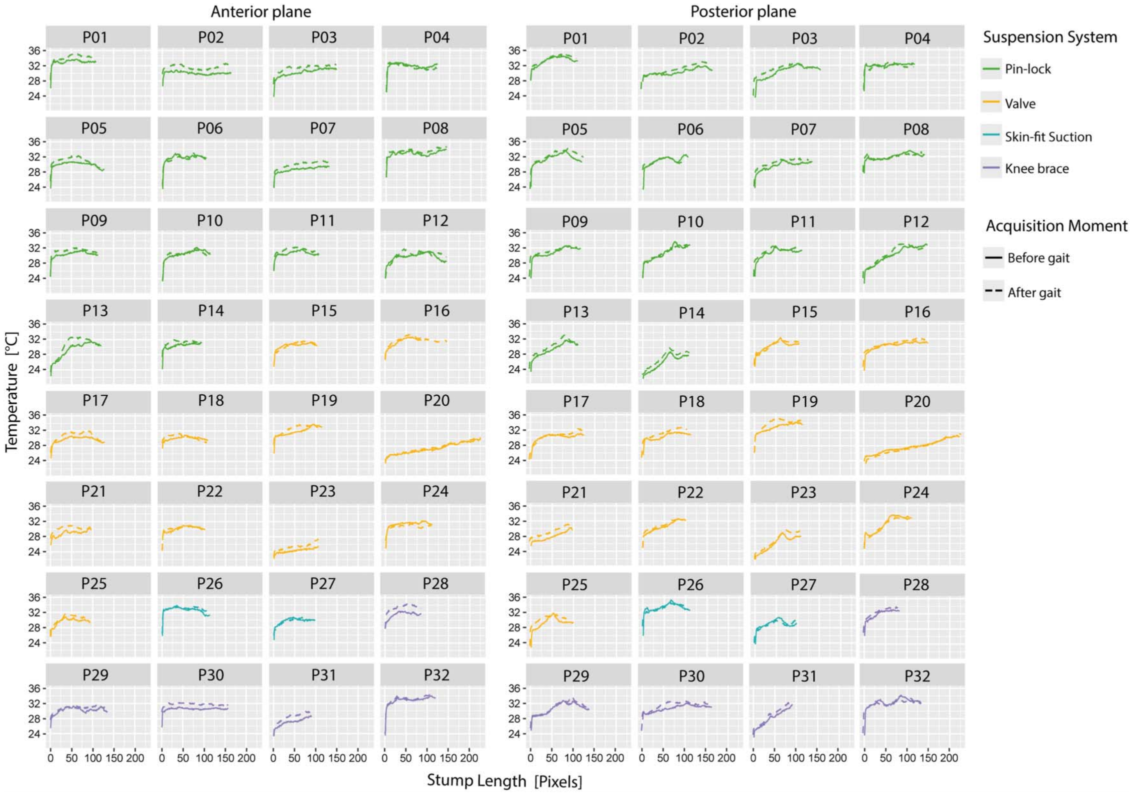

Figure 4. Thermal profiles of prosthesis users categorized by the suspension system used: pin-lock (green), valve (yellow), skin-fit suction (blue), and knee brace (purple). Solid lines represent temperature profiles before walking, whereas dotted lines correspond to profiles after walking. The profiles are plotted from the distal part of the residual limb to the knee.

affect bipodal support should also be assessed. In addition, the "milking effect" caused by the suspension type may affect the stump, and this phenomenon can be detected and evaluated using thermography, suggesting that thermography could be useful for predicting its impact on users.

The key feature of this protocol is the use of IRT in prosthetics, which has gained attention in recent years. However, its full potential in evaluating prosthetic fit remains constrained by significant methodological challenges. Previous studies have tried to incorporate thermography as a diagnostic tool at the stump-socket interface but have revealed various shortcomings in their design and execution.

For instance, Živčák et al employed a thermographic camera and pressure sensor to analyze temperature and pressure at the socket-stump interface. However, their study had a small sample size, limiting its generalizability.[18] In addition, the study only analyzed thermographic data from the anterior frontal plane, potentially overlooking important variations in the posterior frontal plane. This narrow focus limits the understanding of thermal interactions at the interface. Moreover, the pressure sensor used within the socket could have influenced the fit, potentially affecting the comfort and adaptation of the prosthesis, a potential bias that was not addressed in the study.

Similarly, Cutti et al[15] combined thermography with a portable system that monitored temperature and relative humidity in 5 lower limb prosthesis users. Their protocol involved acquiring thermograms after 15 min of walking and again after 15 min of rest. However, this approach has several issues. First, baseline temperature should have been recorded before physical activity, as postexercise measurements may reflect changes because of the effort, rather than the natural thermal state of the interface. The arbitrary choice of a 15-min walking duration also makes it difficult to compare results with standardized clinical tests, such as the 2MWT, commonly used to assess prosthetic adaptation. The study lacked clear guidelines on when and how the thermograms were acquired, potentially introducing variability into the data. In addition, the use of electronic devices within the socket could have caused discomfort or influenced the thermal measurements, although patients did not report significant discomfort.

Despite these methodological limitations, the potential of thermography to identify inflammatory or painful areas in the stump remains clear. Cutti et al[15] concluded that IRT could be an effective tool for pinpointing critical areas at the stump-socket interface that may require adjustments in prosthetic design. Identifying such areas could guide clinical decisions, helping improve the comfort and effectiveness of prostheses. In addition, Mendes et al[19] performed a qualitative analysis of thermography as an indicator of pressure distribution within the socket in a single subject. Although their study lacked a detailed methodology, they proposed that thermography could be a useful tool for identifying pressure patterns within the stump and socket, potentially aiding in the adjustment of prosthetic fit. This preliminary analysis highlights the complementary role that IRT could play alongside traditional diagnostic tools in the production and rehabilitation of prostheses.

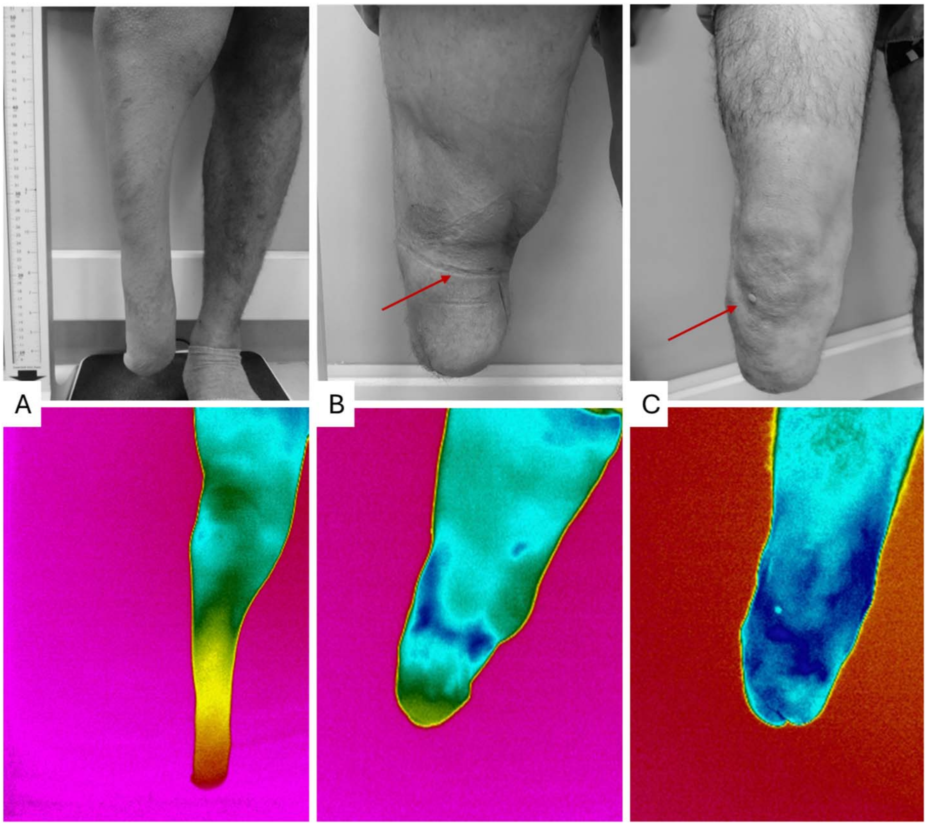

Figure 5. (a) User P20: congenital malformation; (b) user P14: evident marks of skin pressure; and (c) user P01: circular scar at the knee level.

The protocol proposed in this article seeks to address some limitations of previous studies by integrating IRT with additional objective measurements, such as weight distribution, gait symmetry, and the 2MWT. By including these variables, it offers a more comprehensive and accurate assessment of prosthetic fit, advancing the standardization of clinical evaluation methods. Unlike earlier studies, which lacked consistent protocols or detailed guidelines for data collection, the proposed protocol aims for greater consistency and strives to minimize experimental errors in measurement.

Beyond prosthetic applications, this framework could also be adapted for the evaluation of orthotic devices. Infrared thermography and biomechanical assessments can be applied to analyze load distribution, and user-device interface conditions in orthoses. For instance, temperature mapping could help identify areas of excessive friction or pressure in ankle-foot or knee-ankle-foot orthoses, whereas symmetry and balance analyses could quantify compensatory movements. These adaptations align with recent studies highlighting the need for more objective and user-centered approaches to optimize orthotic design and comfort.[20–22]

In conclusion, although IRT remains an emerging tool in the field of prosthetics, it holds significant promise for improving the evaluation of prosthetic fit. Many authors agree that IRT could be a valuable method for assessing prosthetic adaptation, as thermographic cameras, widely used in medical diagnostics, may also serve as a complementary tool for identifying poorly fitted prostheses or incorrect socket alignments. An ideal prosthesis should not cause significant temperature variations in the regions of interest under normal use, indicating proper fit and alignment.

However, despite the growing interest in IRT, its clinical application in prosthetics is still limited by the complexities involved in processing the data it generates. This highlights the need for standardized protocols to ensure consistent interpretation and accurate diagnosis by health care professionals. Although progress has been made, the use of IRT in the prosthetic adaptation process, particularly for lower limb amputees, remains an area for further exploration. More research is required to establish a clear, standardized measurement protocol for clinical diagnostic applications and for prosthetic device production settings.

Limitations

The need to use specialized equipment (ie, thermographic camera, plantar pressure platform, and inertial sensor) can limit the implementation of this protocol, although these devices are commonly found in places where movement analysis is performed. However, broader clinical adoption may be constrained by acquisition costs, limited access in small rehabilitation units, and the time required for data acquisition and analysis. We strongly suggest implementing this protocol, as the potential clinical benefits outweigh these costs.

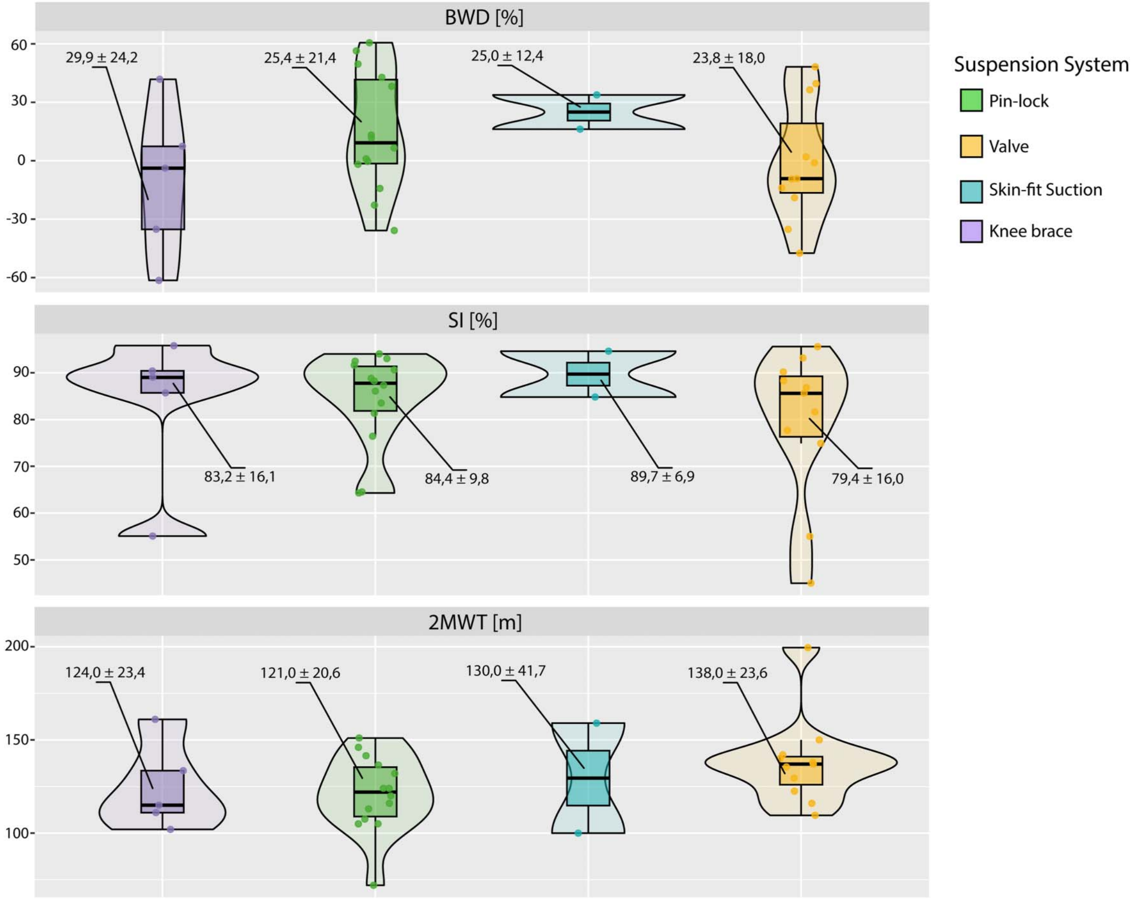

Figure 6. Violin and box plots for the biomechanical variables are categorized by the suspension system used: pin-lock (green), valve (yellow), skin-fit suction (blue), and knee brace (purple). For each violin plot, the mean and standard deviation are also displayed.

Likewise, the technical conditions of the thermography (which provides the thermograms) may limit the participation of certain individuals. According to the protocol, patients should avoid topical medications, intense physical activity, eating, or taking medication before thermogram capture—conditions that may be difficult to control in some clinical settings. These should, therefore, be communicated as preparation requirements before the exam.

Finally, the quantitative interpretation of the data obtained using this protocol may require specialized processing and analysis, which could limit their usefulness if orthotists or prosthetists are not trained. But we encourage health staff to look for specialized training and equipment to improve their diagnosis. Clinical expertise is needed to interpret the results in cases where these variables are inherently altered, such as in patients with bilateral amputations, disarticulations, or any condition that affects local circulation in the residual limb.

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

No supplemental digital content is available in this article.

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