A Reconfigurable and Adjustable Compliance System for the Measurement of Interface Orthotic Properties

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***Abstract*—Custom foot orthoses (CFOs) have shown treatment effectiveness by providing improved pressure/load redistribution, skeletal support and comfort level. However, the current design methodologies of CFOs have some problems: (1) the plantar surface is captured without considering the soft tissue impedance, (2) the stiffness of the CFOs is limited to rigid, semi-rigid and soft, which ignores the potential effect of local variation of stiffness on the interface pressure/load distribution and subjective evaluations, and (3) the lack of a human-in-the-loop may lead to multiple design-to-deliver iterations. A new prescription methodology of CFOs is required to satisfy the pressure/load distribution, improve comfort level and decrease iterations. Method: A measurement system which provides INterface with Tunable Ergonomic properties using a Reconfigurable Framework with Adjustable Compliant Elements (INTERFACE system) is developed to implement the *Rapid Evaluate and Adjust Device* (*READ*) methodology. The geometry and stiffness of the Medial Longitudinal Arch (MLA) support provided by the INTERFACE system can be adjusted via linear actuators and tunable stiffness mechanisms, based on objective interface pressure/load distribution and subjective feedback evaluations. Validation tests were conducted on 13 subjects to measure the plantar pressure/load distribution and record the subjective feedback in different combinations of geometry and stiffness. Results: The interface pressure/load distribution and subjective feedback of the support level indicate the efficacy of the adjustable geometry and stiffness. As the stiffness and geometrical height increased, the plantar loadings increased in the MLA region and decreased in the rear foot. Geometrical fitting can be achieved with the reconfigurable MLA support. The integration of locally adjustable stiffness makes it possible to fine tune the plantar pressure/load and provides the subjects with options of orthotic stiffness. Conclusion: The proposed INTERFACE system can be applied to conduct the measurement of the desired orthotic properties which satisfy the interface pressure/load requirement and the subject's comfort.**

***Index Terms*—Custom foot orthoses, geometry, interface pressure/load, measurement device, stiffness, subjective feedback.**

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I. Introduction

LOWER extremity injuries (LEIs) and deformities including plantar fasciitis [1]–[3], diabetic ulceration [4], [5], cavus foot deformity [6], [7], and flexible flatfoot [8], [9] are common physical problems. For the prevention and treatment of the LEIs and deformities, foot orthoses (FOs) have shown significant effectiveness [8]. The key benefits of FOs include: (1) pressure/load redistribution [6], [10]–[14], (2) providing skeletal support for the Medial Longitudinal Arch (MLA) [3], [15], and (3) providing pain relief and comfort [6], [8], [13], [16]. The pressure/load redistribution provided by the FOs is effective for the treatment of the diabetic ulceration [5] and the cavus foot deformity [6]. Furthermore, the vertical support of the MLA region provided by the FOs may lead to an off-loading of the plantar fascia, which is critical for the treatment of plantar fasciitis [3]. An improved design of FOs should consider the MLA support, pressure/load redistribution and patients' subjective feedback.

A significant variation of the plantar geometry [17] and soft tissue (ST) impedance [4], [18] is observed among the human population. Therefore, custom foot orthoses (CFOs) are commonly prescribed because fit and function are directly related, and fit considers the variation of the geometry and impedance. Typically, the geometrical fitting and material stiffness are considered important factors for orthotic function as evaluated objectively in control of plantar pressure distribution [5], [15], [19] or reduction of unwanted displacements/rotations [9]. In addition to objective methods, subject's comfort ratings [20], [21] are equally important for CFOs efficacy.

A. Typical CFOs Design Methodologies

Traditional measurement methods for capturing the plantar geometry include: foam/plaster [22], [23], footprint parameters [17], [24], radiographic [25], anthropometric measurements [26], and 3D scanning [19], [21], [27]. The disadvantages of these methods include: (1) inconsistent measurement due to both inter-physician and intra-physician variability (except 3D scanning) [28], [29], (2) inconsistency in support due to the lack of impedance analysis and related geometrical and stiffness design considerations, and (3) multiple design-to-deliver iterations [20] may be required to achieve desired orthotic performance and comfort level of the patient because these systems do not consider the human-in-the-loop [11], [22], [27].

B. Rapid Evaluate and Adjust Device (READ) Prescription Methodology With the 3D Ergonomic Measurement System (3DEMS)

The 3D ergonomic measurement system (3DEMS) developed by Qaiser *et al.* (2020) provides a novel measurement of the orthotic geometry, using the "*rapid evaluate and adjust device*" (*READ*) prescription methodology [20]. A discrete geometric framework of the 3DEMS is reconfigured to adjust the interface ergonomic shape properties resulting in changes in output plantar pressure and subjective ratings during the design-to-deliver process.

The 3DEMS, however, does not consider the effect of orthotic stiffness on interface support properties or the current standard typical practice of soft or rigid FOs prescription, and instead the system only provides a rigid adjustable geometry. It limits the possibility of adjusting CFOs stiffness to further investigate the problems and opportunities in current practices. However, geometrical adjustment and interface impedance may be just as important in consideration of the resulting contact pressure and subject's comfort ratings. Furthermore, it is hypothesized that an optimal combination of interface geometry and stiffness exists that is neither soft nor rigid which may be dependent on subject's plantar loadings [5], [30], [31], plantar ST properties, and comfort sensitivity that are subject- and region-specific [32], [33]. However, locally adjustable stiffness cannot be achieved with existing measurement systems including the 3DEMS for CFOs.

C. The Forward Design Approach Based on the ST Properties

Another design methodology for the interface properties is the forward design approach, which obtains preferable interface design specifications including geometry and impedance with simulations. The required processes include, (1) capturing geometrical information from 3D scanning and/or magnetic resonance imaging, etc., (2) ST impedance properties measurement from indentation tests [30], [34]–[36], (3) inverse finite element analysis (FEA) based optimization to calibrate the ST properties [34], [37], [38], and (4) applying optimization with FEA for interface design, e.g., CFOs [19], [39] and prostheses [40], [41].

The problems of the forward design approach include: (1) system complexity of ST measurement, i.e., a close loop feedback control [34], [42], (2) computationally expensive design, (3) requirement for skilled personnel in the field of FEA and optimization, and (4) long design-to-deliver iterations due to the lack of the human-in-the-loop [11], [22], [27].

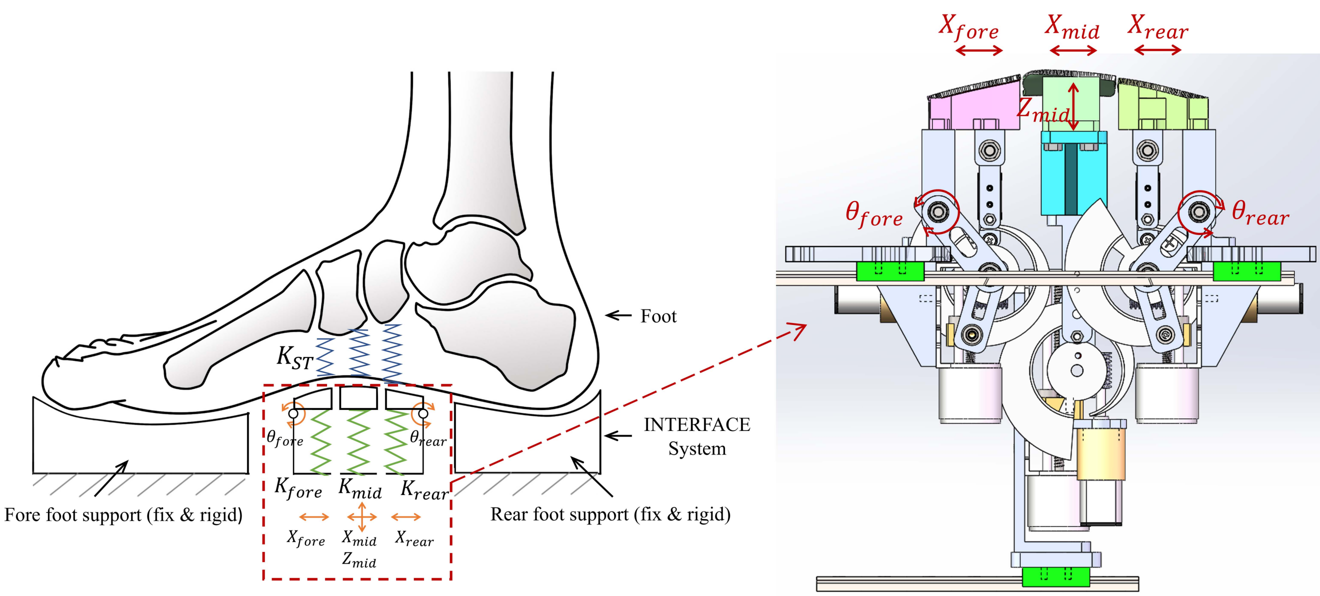
D. The INTERFACE System With the READ Prescription Methodology

Alternative to the forward design approach for interface design is the *READ* methodology which includes the human-in-the-loop, i.e., the design-to-deliver loop. The *READ* methodology directly evaluates the adjustable interface properties needed for fabrication instead of the indirect properties of the human ST impedance and geometry. In brief, a measurement system for the interface properties design should include the following capabilities: (1) geometric measurement with physiological loadings, i.e., half body weight on the foot in case of CFOs, (2) locally adjustable stiffness to deal with the regional variation of ST properties and comfort sensitivity, and (3) consideration of subjective feedback during the design-to-deliver loop to reduce unnecessary design iterations and material costs.

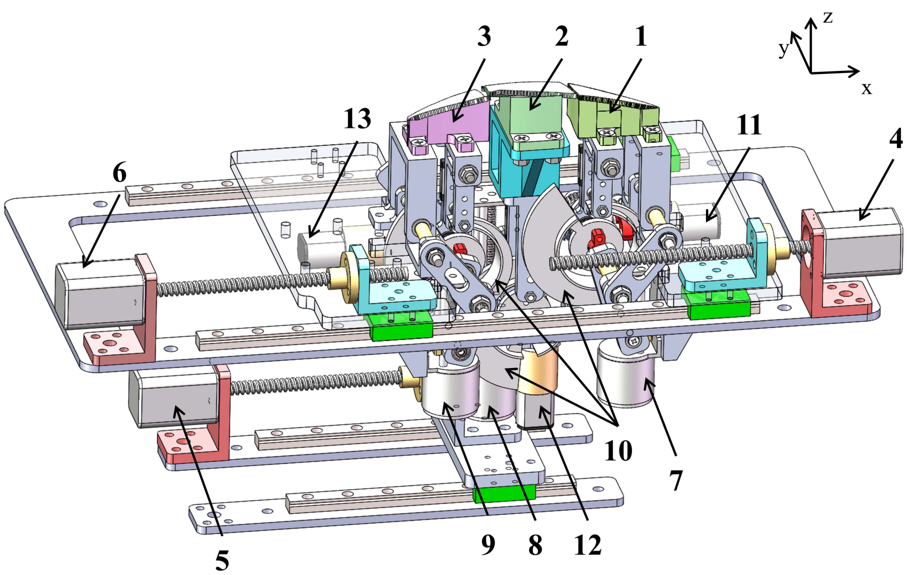
To satisfy the above requirements, a measurement device which provides INterface with Tunable Ergonomic properties using a Reconfigurable Framework with Adjustable Compliant Elements (INTERFACE system) was designed and developed in this research. Geometrical measurement with the proposed INTERFACE system is conducted with half body weight during balanced standing. The surface of the MLA support provided by the system is geometrically reconfigured to fit the plantar surface by adjusting the translations and rotations of the three segments whose shapes have been optimized to match the population's plantar surface [20]. In addition, tunable stiffness mechanisms (TSMs) [43], [44] were integrated into the device to provide locally adjustable interface stiffness for the MLA support. The INTERFACE system is designed to obtain the desired orthotic properties including geometry and stiffness based on the plantar pressure/load distribution and subjective ratings through the *READ* methodology. The objective of this research is to: (1) design and develop the INTERFACE system, (2) demonstrate the objective and subjective efficacy of adjusting geometry and stiffness during measurement, and (3) demonstrate the ability to provide the desired geometry and stiffness which satisfy the pressure/load requirement and subject's comfort.

II. Mechanical Design

CFOs are designed to provide skeletal support, pressure/load redistribution and comfort. For the locally adjustable geometry and stiffness in CFOs design, priority is given to the MLA region because vertical support leads to an off-loading of the plantar fascia, which results in the improved treatment for plantar fasciitis [3]. The geometry of the MLA varies in the population, so a reconfigurable support for the MLA is required for the INTERFACE system to measure CFOs fitting parameters. In addition to geometrical fitting, orthotic stiffness will also influence the interface pressure/load distribution and subjective ratings. One effective treatment strategy for foot conditions such as plantar fasciitis or plantar ulcers is to redistribute loadings from the fore foot (FF) or rear foot (RF)



(a) Schematic of the adjustable geometry (six DOFs) and stiffness (three TSMs) of the MLA support provided by the INTERFACE system



ITEM	DISCRIPTION
1	Rear segment
2	Mid segment
3	Fore segment
4	Actuator to control X_{rear}
5	Actuator to control X_{mid}
6	Actuator to control X_{fore}
7	Actuator to control θ_{rear}
8	Actuator to control Z_{mid}
9	Actuator to control θ_{fore}
10	Tunable stiffness mechanism
11	Actuator to adjust stiffness K_{rear}
12	Actuator to adjust stiffness K_{mid}
13	Actuator to adjust stiffness K_{fore}

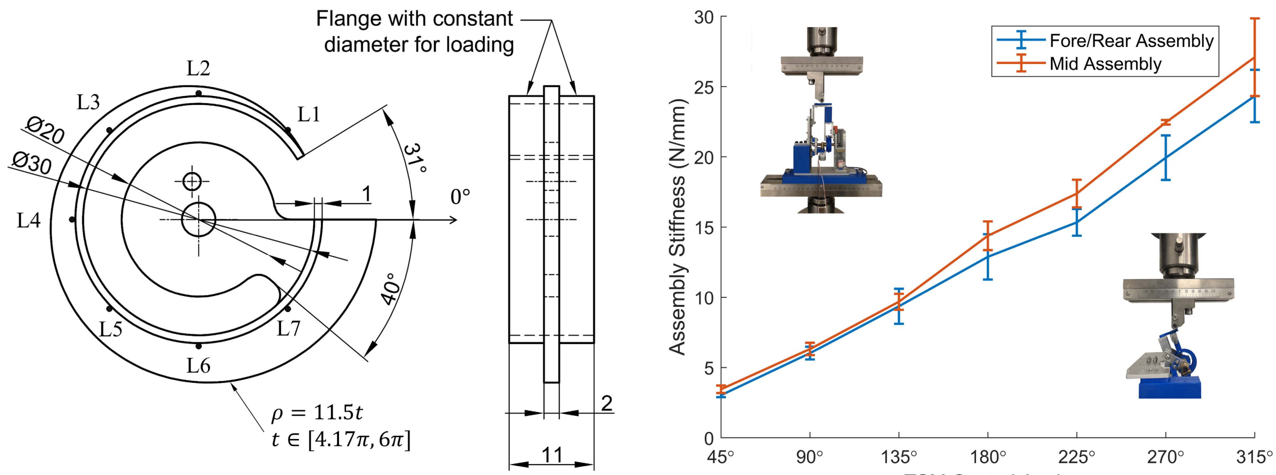
(b) Mechanical design of the INTERFACE system and the main components

Fig. 1. Design of the proposed INTERFACE system.

to the MLA region. However, since the pain pressure thresholds for different regions are different, e.g., pain threshold in RF > FF > MLA [33], only a portion of pressure can be redistributed to the MLA without exceeding the discomfort limit. Therefore, the geometry and stiffness of the MLA support which will influence the interface pressure/load in the MLA region should be carefully chosen to avoid discomfort. On the other hand, stiffness and geometrical adjustment in the FF and RF was rejected for this manuscript to reduce excessive system complexity. Future work, however, may include all plantar regions.

Fig. 1 illustrates the schematic of the INTERFACE system design which provides MLA support with adjustable geometry and stiffness. The MLA support consists of three segments, i.e., fore, mid and rear, each of which has two degrees of freedom (DOFs). Actuated by linear actuators in the form of stepper motors with lead screw mechanisms, the fore and rear segments can translate along the x-axis and rotate about the y-axis ($X_{fore}, \theta_{fore}, X_{rear}, \theta_{rear}$) and the mid segment can translate along the x-axis and z-axis (X_{mid}, Z_{mid}). The surfaces of the three segments have been optimized to provide geometrical fitting for the population by adjusting the selected six DOFs [20].

In addition, a tunable stiffness mechanism is integrated in series in each segment to allow the local variation of stiffness for the MLA support. The e-spring is one type of



(a) Design parameters of the e-spring TSM

(b) Assembly stiffness in different TSM control angles

Fig. 2. Design parameters of the TSM integrated in the INTERFACE system and effective stiffness range of the assemblies.

controlled stiffness mechanism [45] which varies the stiffness by changing the moment of inertia and effective beam length [43]. The e-spring is selected for the INTERFACE system due to the following reasons: (1) compact design, (2) large stiffness range, and (3) easy adjustment of the stiffness. The stiffness of the e-spring can be adjusted by rotating the spring, which is actuated by a stepper motor. A pair of worm gears is used to connect the stepper motor and the e-spring to provide powerless locking. The e-springs were fabricated by 3D printing (Ultimaker 2+, China) with PLA material, whose designed parameters are illustrated in Fig. 2(a).

The stiffness range of the assemblies (fore and middle) were tested using the MTS with a 1000N load cell. The stiffness of seven locations (L1-L7) of the e-spring were observed, with the zero basis as the origin and 45° as increment, as shown in Fig. 2(a). Three e-springs were applied to each test to evaluate the repeatability. The result of the assembly stiffness with respect to the loading locations are illustrated in Fig. 2(b).

III. Method

The prototype of the proposed INTERFACE system was fabricated and experimentally validated, as shown in Fig. 3. Four force sensors were integrated in the bottom of the system to ensure half body weight was applied to the right foot, i.e., balanced standing. A common insole made of foam was added above the three blocks to provide peak pressure relief and shape interpolation. The hardness of the insole is 36.7 ± 0.8 Shore C. The thickness is 6.037 ± 0.048 mm in the heel region and 4.324 ± 0.097 mm in the other regions. A Novel Pedar insole (Novel GmbH, Munich, Germany) placed between the common insole and the plantar surface was used to measure the pressure/load distribution. Furthermore, a tibia alignment feature was employed to ensure the subject's standing position was consistent among the tests. Thirteen healthy subjects received an introduction of the study and gave their agreements to attend the tests, which were conducted based on the Declaration of Helsinki. The demographic characteristics of the subjects are shown in Table I.

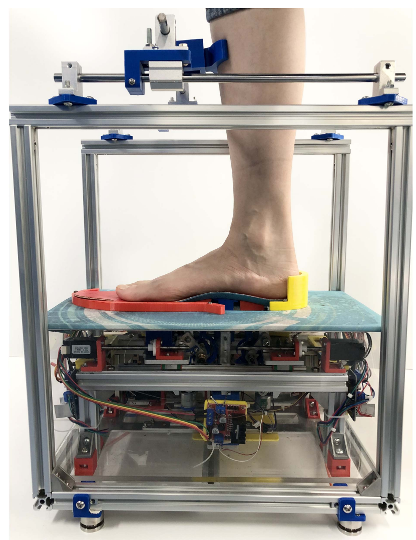


Fig. 3. Fabricated prototype of the INTERFACE system.

TABLE I
Characteristics of the 13 Subjects

Subjects' Information	Average (SD)
Age (years)	29.6 (13.4)
Height (cm)	166.8 (6.8)
Weight (kg)	60.8 (10.3)
Foot Size	40 (3)

The influence of geometrical configurations $X_{fore}, \theta_{fore}, X_{mid}, Z_{mid}, X_{rear}, \theta_{rear}$ and the stiffness $K_{fore}, K_{mid}, K_{rear}$ on pressure/load distribution and subjective feedback were explored in the tests. The stiffness of the three segments $K_{fore}, K_{mid}, K_{rear}$ were assigned with five levels including K1-K4 and Kinf. The levels K1-K4 were obtained by adjusting the three e-springs, whose assembly stiffness are shown in Table II. The three e-springs were

TABLE II
CORRESPONDING ASSEMBLY STIFFNESS OF THE FIVE LEVELS APPLIED IN THE VALIDATION TESTS

Stiffness Level	Corresponding TSM Location	Stiffness of Fore & Rear Assembly (N/mm)	Stiffness of Mid Assembly (N/mm)
K1	L1	3.04	3.46
K2	L3	9.36	9.68
K3	L5	15.33	17.38
K4	L7	24.32	27.09
Kinf	/	Inf	Inf

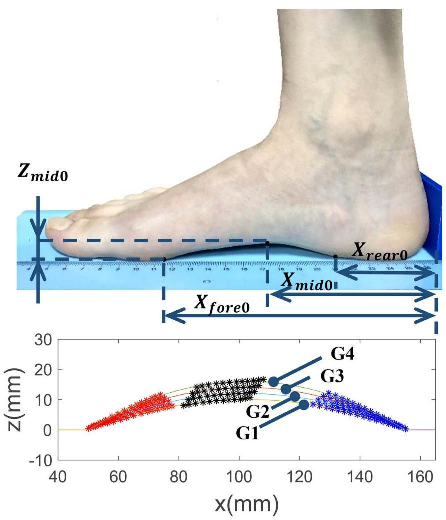


Fig. 4. Anthropometric measurement for the generation of geometrical variables.

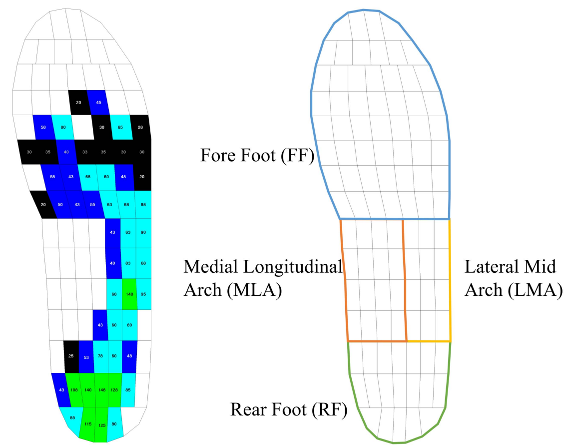


Fig. 5. Definition of the four plantar regions based on the barefoot pressure/load distribution of each subject.

then replaced by rigid connections with effectively infinite stiffness, which is denoted by Kinf.

The geometrical configurations were specified with four levels including G1-G4. To determine the subject's initial configuration G1 of the MLA, an anthropometric measurement was conducted. Three anatomical landmarks are primarily important for the characterization of the MLA shape including the start point, the peak point and the end point of the MLA, which can be easily identified with the anthropometric measurement. As shown in Fig. 4, the x-coordinates of these points i.e., X_{fore0}, X_{mid0}, X_{rear0} and the z-coordinate of the peak point Z_{mid0}, were measured, which are only sufficient for the generation of a second-order polynomial to roughly simulate the curve of the subject's MLA. The initial configuration $G_1(X_{fore1}, \theta_{fore1}, X_{mid1}, Z_{mid1}, X_{rear1}, \theta_{rear1})$ was determined by minimizing the error between the two-dimensional surface coordinates of the three segments and the generated second-order polynomial. The other three geometrical height levels G2, G3, and G4 were determined in the same way by adding 2mm, 4mm and 6mm to Z_{mid0}, respectively. For each set of geometrical configurations, the assemblies were assigned with five stiffness levels (K1-K4 and Kinf), which resulted in 20 tests in total for each subject.

Four plantar regions of each subject were determined, including fore foot (FF), medial longitudinal arch (MLA), lateral mid arch (LMA) and rear foot (RF), which are shown in Fig. 5. The definition of the regions was based on the subject's pressure/load distribution during barefoot standing on a flat plane and the anthropometric measurement result. To be specific, the area which showed almost zero pressure was defined as the MLA region. Before the measurement was conducted, the tibia alignment feature was adjusted according to the subject's self-selected standing position. For each set of geometrical configuration and stiffness, the subject was guided to align the heel and tibia and then stood on the INTERFACE system with half body weight, which was indicated by the four force sensors, as shown in Fig. 6. Considering it was difficult for the subjects to keep the exact half body weight during the measurement, a range of half body weight was set to be allowable, i.e., half body weight ± 2 kg. After the alignment process which took around 5 seconds, the subject's interface force (IF) and mean peak pressure (MPP) in the four regions were measured for 10 seconds at a sampling rate of 50 Hz. In addition, an integer value varying from 0 to 10 was used to represent the participants' subjective feedback of the support level, in which 0, 5 and 10 stands for inadequate support, perfect support and excessive support, respectively. After the measurement, the subject took a seat for around 2 minutes, during which the geometry and stiffness of system were updated.

The IF and MPP in the FF, MLA and RF region were observed in particular. In addition, the correlations between the geometrical height level, stiffness level, IF, MPP and subjective support level were analyzed with the Spearman Analysis using

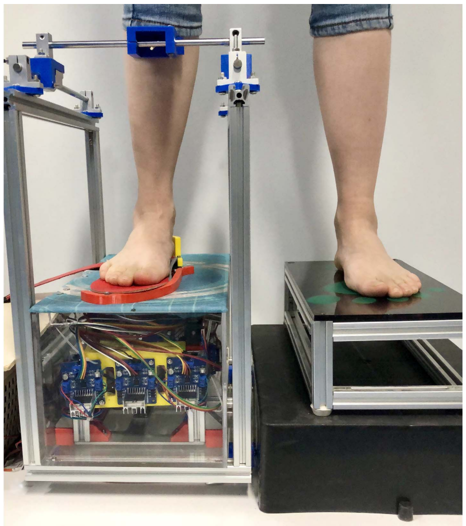


Fig. 6. Validation test in subject's balanced standing.

IBM SPSS Statistics (IBM Corporation, Armonk, NY). The Spearman Correlation Coefficient denoted by r_s is in the range of -1 to +1.

IV. Results

The percentage of the interface force in the plantar regions are calculated to reduce the influence of the variation of the subjects' weight. Fig. 7 shows the average and standard deviation of the IF percentage in the MLA, RF and FF region of the 13 subjects with respect to different geometrical height levels and stiffness levels. In the MLA region, there is an obvious increasing trend of the IF percentage as the height of the MLA support increases, whose correlation is strong and significant ($r_s \in (0.604, 0.669), p < 0.001$). In addition, the stiffness has a positive influence on the IF percentage regardless of the geometrical height levels ($r_s \in (0.727, 0.771)$, $p < 0.001$). As for the RF region, a negative correlation between the geometrical height and the IF percentage is observed ($r_s \in (-0.441, -0.329), p < 0.05$). Furthermore, the IF percentage also shows an obvious decreasing trend with the increasing stiffness ($r_s \in (-0.684, -0.514), p < 0.001$). However, the changes of geometrical height and stiffness do not show significant influences on the IF percentage in the FF region ($p > 0.1$).

As shown in Fig. 8(a), the MPP in the MLA region shows a significant increasing trend with the increasing height levels ($r_s \in (0.446, 0.599)$, $p < 0.001$) and stiffness levels ($r_s \in (0.308, 0.462)$, $p < 0.05$). As for the RF region, a less obvious but significant decreasing trend of the MPP is observed as the stiffness increases ($r_s \in (-0.433, -0.306), p < 0.05$). However, the correlation between the MPP and the geometrical height is not significant ($p > 0.1$). Besides, the MPP in the FF region does not show any obvious trends ($p > 0.1$), as shown in Fig. 8(c).

Table III illustrates the correlation between the IF percentage, MPP in the MLA, RF and FF region and the subjective support level. The subjective feedback of support level has a stronger correlation with the IF percentage than the MPP. In particular, the subjective support level is strongly correlated with the IF percentage in the MLA region ($r_s = 0.667$).

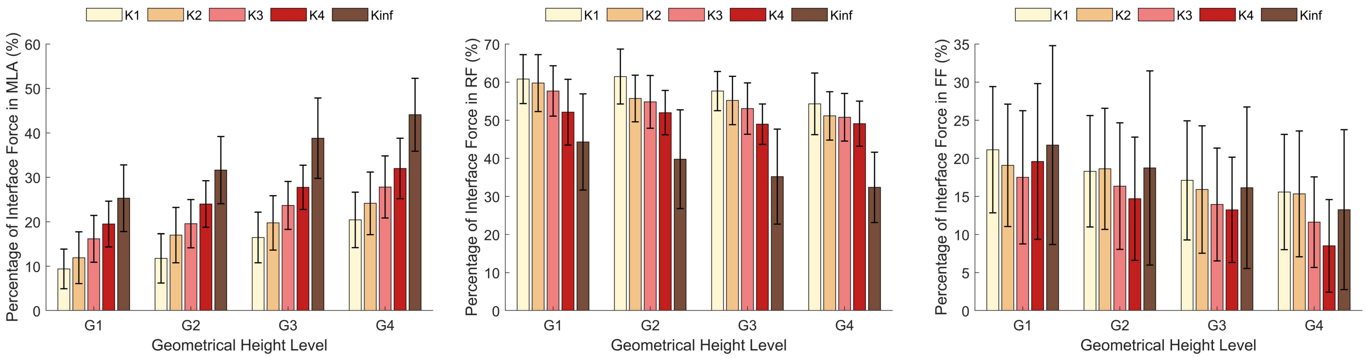
TABLE III
Correlation Between the Interface Force (IF) Percentage, Mean Peak Pressure (MPP) and Subjective Support Level (N = 13) **Significant at the 0.001 Level and *Significant at the 0.01 Level

	Subjective Support Level
IF Percentage in MLA	$r_s = 0.667^{**}$
IF Percentage in RF	$r_s = -0.406^{**}$
IF Percentage in FF	$r_s = -0.309^{**}$
MPP in MLA	$r_s = 0.464^{**}$
MPP in RF	$r_s = -0.160^{*}$
MPP in FF	$r_s = -0.215^{**}$

The subjective feedback of support level (SL) in the range of 0-10 was converted to subjective rating (SR) in the range of 0-1 by $SR = \frac{5-|SL-5|}{5}$. For example, the support level of 3 or 7 represents the normalized subjective rating of 0.6. Fig. 9(a) shows the average values of the normalized subjective ratings of the 13 subjects with respect to different combinations of geometrical height levels and stiffness levels. High subjective ratings (0.70-0.82) are located in the diagonal as highlighted in Fig. 9(a), which indicates that the designed stiffness range (K1-K4) can provide comfort for the population. The stiffness in the range of K2 to K3 together with geometrical height in the range of G2 to G3 might be a preferred stiffness and geometric design choice. In particular, G3&K3 received the highest score (0.82) in the subjective evaluations. Low stiffness combined with low support height and high stiffness combined with high support level were scored less due to the inadequate and excessive support they provided respectively. Fig. 9(b) shows the average IF percentage in the MLA region of the 13 subjects. The percentage of IF corresponds to high subjective rating is in the range of 16.5%-31.6%, which is highlighted with red border. In particular, the optimum percentage of body weight that is redistributed to the MLA region is 23.7%.

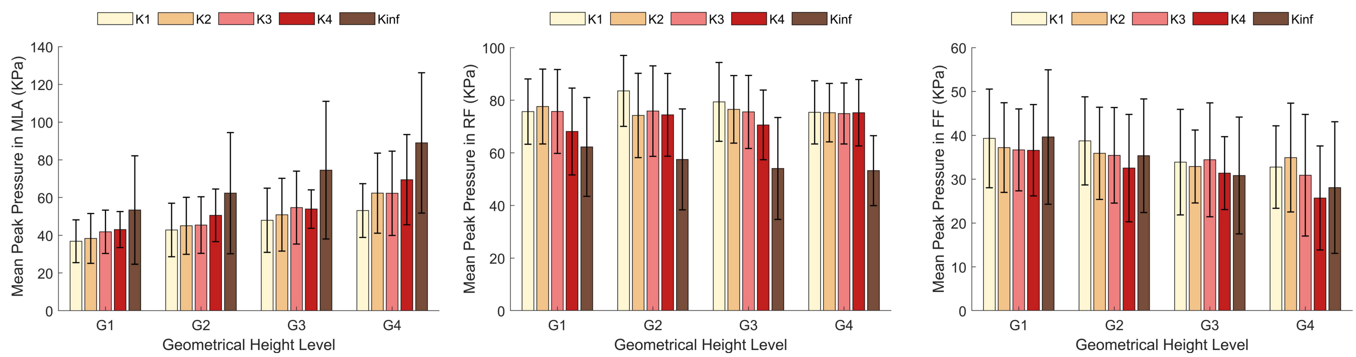
V. Discussion

Compared to the IF percentage, the geometrical height and stiffness have less obvious influences on the MPP in the plantar regions. The possible reason is that MPP is the maximum pressure in the region, which is less sensitive to the change of geometry and stiffness than the IF. In addition, there is a large variation of the MPP due to: (1) the variation of the 13 subjects' weight, and (2) the 'half body weight' applied to the right foot was in a range, i.e., half body weight ±2kg. To reduce the influence of these two problems, the percentage of interface force rather than the original value is considered. Therefore, an obvious increasing trend of the IF percentage in the MLA and a decreasing trend in the RF region are observed. It indicates that as the geometrical height or stiffness of the MLA support increases, plantar loadings is effectively redistributed from the rear foot to the MLA region.



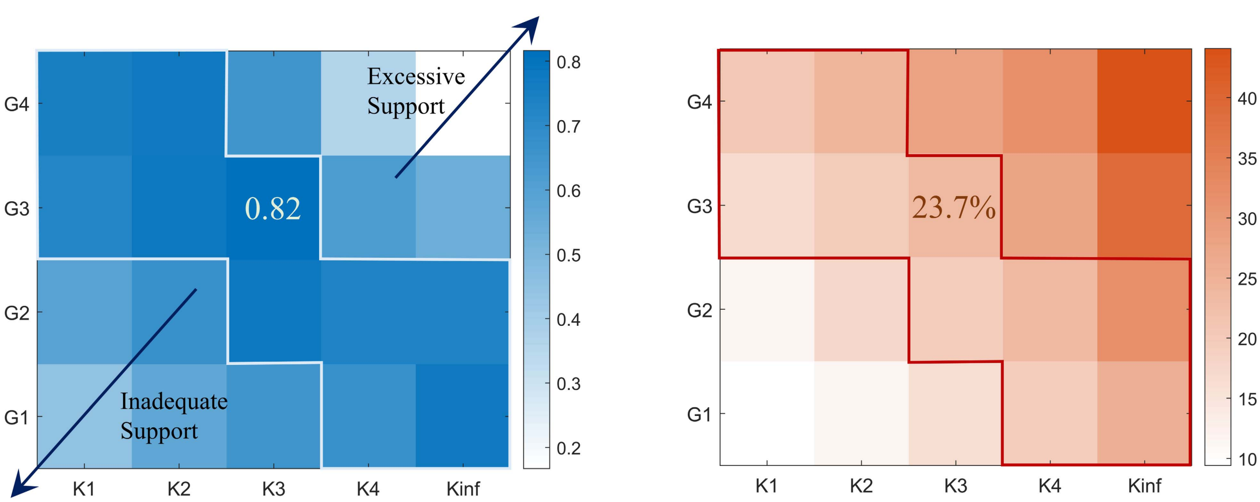
(a) IF Percentage in the MLA region (b) IF Percentage in the RF region (c) IF Percentage in the FF region

Fig. 7. Average and standard deviation of the interface force percentage in different geometrical height levels and stiffness levels (N = 13).



(a) MPP in the MLA region (b) MPP in the RF region (c) MPP in the FF region

Fig. 8. Average and standard deviation of the mean peak pressure in different geometrical height levels and stiffness levels (N = 13).



(a) Average subjective ratings (N=13) (b) Average IF percentage in the MLA region (N=13)

Fig. 9. Average subjective ratings and IF percentage in the MLA region (N = 13) in different combinations of geometry and stiffness.

For the completely rigid support Kinf, the influence of adjusting the geometrical height with 2mm on the pressure/load was equal to that of rotating the e-springs with approximate 90 degrees. Therefore, the integration of adjustable stiffness provides possibility to fine tune the pressure/load to satisfy the objective pressure/load requirement. From the subjective perspective, the participants could perceive similar comfort level in different combinations of geometry and stiffness. Therefore, the proposed measurement system provides more than sufficient range of geometry and stiffness, and this enables physicians and subjects to choose interface parameters based on their needs and preference. Although the sensitivity may be different among the subjects, the subjective ratings were high with stiffness in the range of K2-K3 and geometry in G2-G3, which might be a preferable range for the majority of the population.

The INTERFACE system provides the MLA support with tunable geometrical surface and stiffness by adjusting the six geometrical DOFs and the three e-springs control angles. Therefore, there are nine adjustable variables in total, which may provide limitless combinations. Excess control results in some complexity, however, this may be reduced somewhat by methods given in the text including (1) initial estimation of geometrical shape by polynomial fitting of the anthropometric measurement aiding the constraint of six variables, and (2) setting e-spring stiffness levels to the same constant which constrains the three additional variables. In this case, the numerous combinations of geometry and stiffness can be constrained to limited sets, e.g., 20 combinations with 4 levels of geometrical height and 5 levels of stiffness. The limited combinations will receive an evaluation based on subjective ratings or pressure/load distribution, among which the set with the highest score will be fine adjusted to further improve the interface performance.

Typically, the geometry and stiffness of CFOs will influence the pressure/load distribution and the patients' subjective feelings. However, most design methodologies of CFOs only focus on capturing geometrical surface such as foam/plaster and 3D scanning. The options for the CFOs' stiffness are limited to rigid, semi-rigid and soft [22]. In addition, the patient is not able to evaluate the orthotic properties (i.e., geometry and stiffness) before fabrication, which may lead to excessive design-to-deliver iterations. Therefore, the INTERFACE measurement system was proposed to follow the *READ* prescription methodology capturing the interfacial properties of CFOs including geometry and stiffness based on the objective pressure/load distribution and subjective ratings.

There are some potential limitations of this study. One major limitation is that the INTERFACE system can only provide a static measurement. Whereas, it has been shown that the peak pressure and force in static measurement are different from that in dynamic measurement [46]. In addition, Chatzistergos *et al.* (2017) found that the optimum insole stiffness which maximizes the peak pressure reduction is lower in static standing than that in dynamic walking [31]. Although it is uncertain whether the subjective feedback will be influenced, a static measurement system may be insufficient. Another limitation of the proposed system is the fixed size of the three segments. It is not applicable to foot size less than 36, otherwise the segments will interfere with each other or the elastic movements of the segments will be constrained. For subjects with long MLA, e.g., $L_{MLA} > 115$mm, the limited size of the three segments will lead to large gaps, which could be recognized by the subjects even though a foam was used to provide interpolation. Besides, the fixed size of the segments in the lateral direction may also influence comfort perception for different foot sizes. To solve this problem, the shape of the three segments can be optimized based on the MLA size of the population. Another problem is that the validation tests were conducted only on healthy subjects with a limited range of body weight and foot shapes. Furthermore, the thickness and hardness of the Novel insole may bring deviation to the validated results.

In spite of these limitations, the proposed INTERFACE system can provide the desired orthotic properties with less design-to-deliver iterations by applying the *READ* prescription methodology. The measurement result will provide guidance for the orthotist/podiatrist to design the flexible base of the CFOs with specified geometry and stiffness, which is covered by a cushioning foam. Commonly, additive manufacturing techniques are applied in the fabrication process [21]. The geometry of the CFOs base can be determined based on the optimal geometrical configuration obtained by the INTERFACE system. The local variation of stiffness can be achieved with structural design. For example, for CFOs made of thermoplastic or fiber reinforced composite, transverse cutting in the MLA region of the CFOs can be applied to achieve the desired stiffness by varying the cutting depth, i.e., varying the length of the cantilever beam based on $k = \frac{3EI}{L^3}$, in which E, I, L is the material modulus, moment of inertia of the beam and beam length, respectively. Future study may also focus on the geometrical and structural design of CFOs to match the desired interface pressure/load distribution. In addition to plantar measurement, the INTERFACE system may also be used to further explore the potential relationship between the ST properties and optimum orthotic design.

VI. Conclusion

In this research, an adjustable stiffness and reconfigurable measurement system, the INTERFACE system, is proposed and developed to implement the *rapid adjust and evaluate device* (*READ*) methodology. The interface geometry and stiffness of the MLA support provided by the proposed system are tunable by adjusting the six DOFs and rotating the three e-springs. Therefore, a rapid adjustment can be implemented based on objective and subjective evaluations during the measurement. A prototype of the INTERFACE system was developed and used for the validation tests with 13 subjects. The distribution of interface force and pressure in 20 combinations of geometrical height and stiffness of the MLA support shows the efficacy of adjusting geometry and stiffness. In addition, the subjective feedback of the support level has a strong correlation with the IF percentage in the MLA region, which indicates that the subjects were sensitive to the change of the interface force. Geometrical and stiffness properties of the interface may be obtained by a coarse and fine adjustment of the parameters with the reconfigurable surface and e-Springs. The integration of rapid adjustable properties makes it possible to fine tune interface pressure/load. The proposed INTERFACE system can improve the communication between physicians, subjects and fabricators on CFOs specifications through the *READ* methodology.

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