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Technical note

Evaluating shear and normal force with the use of an instrumented transtibial socket: A case study

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ABSTRACT

Patients with transtibial amputation experience ulcers on their residual limb. The loading between the device and underlying material plays a role in loads transmitted to the skin. The objective was to evaluate normal and shear forces at the socket/liner interface during walking.

A 53 year old male (85.45 kg and 177.8 cm) with a transtibial amputation participated in this case study. A transtibial prosthesis was instrumented with a load cell to measure normal and shear forces at the socket interface. Three conditions were evaluated during walking: gel liner, additional three ply sock and a hole in the gel liner.

Shear and normal forces were highest with the addition of a three ply. Longitudinal shear stresses ranged from 0.4–7.66 kPa, transverse shear stresses ranged from 0.01–7.79 kPa and normal stresses ranged from 2.7–61.9 kPa.

Increased shear and normal forces can cause a significant decrease in blood perfusion, linked to an increased risk of ulcer formation. Experimental force results are also important for future work involving finite element modeling of the skin/liner/device interface.

1. Introduction

Pressure ulcers are areas of tissue damage caused by loading on the skin from various body-interface conditions [1]. The loading between the device and the gel liner or liner/sock system plays a direct role in loads transmitted to the skin. Within an amputee's transtibial socket, understanding the normal (loads perpendicular to the skin) and shear loading (forces parallel to the skin) is imperative. The addition of shear load has been shown to decrease perfusion which increases the likelihood of pressure ulcer formation [2,3]. Furthermore, bony prominences beneath the surface of the skin along the fibula can create a stress concentration and increase tissue damage and ulcer formation [4,5].

This work evaluated forces within the socket for a patient using a gel liner and pin suspension. A gel liner functions to provide cushioning with respect to the rigid socket and is typically manufactured of urethane, silicone or a thermoplastic elastomer [6]. Gel liners are most commonly prescribed for individuals with transtibial amputations [7]. When a patient's limb fluctuates in volume throughout the day, additional sock layers are used to fill the extra space within the socket for a more comfortable fit. However, additional layers are not always necessary and could increase interface loads if worn when not indicated. Experimental investigation of loading within the prosthetic socket is needed to understand the differences in loading mechanics between the rigid socket wall and the gel liner, with and without the addition of a three ply sock. These conditions identify a common practice of patients wearing extra socks in the morning, even though not indicated, which is not easily monitored by prosthetists [8].

Studies have documented pressure distributions using pressure sensor technology within the socket [9–15]. Pressure distribution at the socket to limb interface has been used to compare differences in prosthetic componentry, suspension types, and liners [7,16–22]. However, these studies only addressed pressure related to the normal loading. Shear forces have been shown to be more detrimental to skin health [2,3], yet pressure sensors are unable to address both shear and normal forces at the socket to limb interface.

Load cells have been used to understand various moments and forces within the prosthetic device. Neumann et al. instrumented

Abbreviations: PTB, patellar tendon bearing; GDI, Gait Deviation Index; kPa, kilopascals; N, Newtons.

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a load cell at the base of the socket to obtain moment data for below knee amputees [23]. In another study, custom transducers were used to measure shear stresses within the socket, lined with a custom molded foam insert, designed to fit without the use of an additional sock or nylon sheath by using a sleeve suspension [24]. Sanders et al. [25] expanded shear stress measurement to thirteen locations on two patients with transtibial amputation. For this method, a gel liner interface was not required and the effect of adding a sock was not addressed. Thus, shear stresses are unknown for individuals using a gel liner interface. Zhang et al. [26] developed a custom socket to investigate prosthesis alignment changes on internal shear stresses in either cuff or supracondylar suspensions; however this also did not evaluate a gel liner interface. Schiff et al. [27] instrumented a transtibial socket likewise utilizing sleeve suspension to explore shear forces for amputees. However, sleeve suspension systems grip the prosthetic device from the outside of the socket while gel interfaced pin suspensions insert at a single distal pin location. The new work presented within this case study evaluated loading in the pin suspension system between the socket and gel liner interface. The pin suspension system is the most common attachment for below knees amputees [28]. Furthermore, finite element models can be created using these forces to estimate the effects of gel liner properties on the surface of the skin and deeper tissues.

The objective of this research was to instrument a single transtibial socket with a three axis load cell to measure shear forces (longitudinal and transverse directions) and normal force during walking. Experimental data comparisons were evaluated for three conditions (1) gel liner, (2) addition of a three ply sock over the liner and (3) a hole cut in the gel liner to allow contact of the load cell with the skin. It was hypothesized that normal and shear forces would increase with increasing sock ply due to the added thickness. This simulates a common situation where a patient uses an added sock even when not indicated. Secondary objectives of this experiment were to obtain socket wall to gel liner interface forces for use in finite element models.

2. Methods

2.1. Participant

One male right unilateral transtibial amputee (53 years old, 85.45 kg and 177.8 cm) of K3 mobility grade was evaluated [29]. The study gained human research approval from Michigan State University and the participant provided written consent prior to participation (IRB# 14-089M). He underwent amputation twenty-nine years prior due to a traumatic accident. His current prosthetic device componentry included a 9 mm Alpha Willowwood gel interface liner with Willowwood Alpha Lock pin locking suspension, modified patellar tendon bearing (PTB) socket design and College Park Soleus prosthetic foot. At the time of testing, no pain or discomfort with his device was reported. He was seen within a month by a certified prosthetist who deemed his socket interface to be acceptable and alignment of his prosthesis to be appropriate. The modified PTB socket design was a combination of typical PTB socket development with characteristics of a total surface bearing socket, approximately 2.5 years old. No additional pads were within the socket and minimal reliefs existed at the distal tibia and fibular head. On the date of data capture, the participant's socket was fitting well without patient reported volume change.

2.2. Instrumented prosthesis

First, to allow for force measurement and preservation of the patient's original socket, a duplicate socket was manufactured to match the prosthesis fit and alignment. A certified prosthetist completed the duplication with standardized laboratory protocols of using a plaster positive within the original socket and alignment jig to maintain socket to pylon rotation and height. Measurements taken throughout the process double checked congruency of the two sockets. The duplicate socket was fabricated out of a clear thermoplastic material commonly used in fabrication of "test sockets" for clinical use leading up to a definitive socket.

Prior to load cell instrumentation a kinematic comparison was completed with the original and duplicated sockets to ensure the duplicate yielded identical walking patterns. A twelve camera motion capture system (Vicon Motion Systems Ltd.; Oxford, UK) was used to track the locations of all markers in three-dimensional space. Kinematics were calculated for the lower extremity and trunk joint angles during walking and processed in Nexus v. 1.8.5 using a custom biomechanical model. From this, a Gait Deviation Index was calculated for the walking trials by inputting parameters including three planes of hip and pelvis angles, knee flexion/extension, ankle dorsi/plantarflexion and foot progression [30]. Secondly, the participant's duplicated prosthetic was assembled with his existing pylon, foot and suspension components and data of lower extremity and trunk kinematics were captured with the same Gait Deviation Index. The two data sets were compared to determine if changes in gait were introduced between devices.

Once kinematic comparisons were completed, a 4 cm diameter hole was cut in the wall of the socket to mount the load cell. The hole's center was located 8.5 cm below the patient's fibular head on the lateral aspect of the residual limb. This location was selected because of the presence of muscle, complete contact with the load cell and avoidance of a bony prominence. Full contact was desired to obtain forces throughout the gait cycle. Clinically, this location is a region of interest based on patient reported complaints and literature noting it as a problematic location [4,5]. Thought was given to instrumenting more locations within the socket but care was given to not compromise the strength and integrity of the socket. Although, this single location of force measurement cannot be generalized to all forces within the socket.

An OptoForce HEX-70-CE load cell (OptoForce; Budapest, Hungry) was mounted securely (Fig. 1). A combination of brackets and anti-slip leveling feet were secured to the non-recording surface of the load cell. A non-deflecting abrasive strap wrapped around the circumference to ensure no slip of the load cell. The material removed from the socket wall was attached to the recording surface of the load cell. The space between the cutout piece and socket wall was small, equivalent to the thickness of a small saw blade. The mounting apparatus ensured that even space was maintained surrounding the recording surface. The purpose of inserting the removed piece was to preserve inner wall socket integrity, maintain the same material and friction across the entire socket with a flush inner surface, keeping the original internal socket curvature. Shear loads were measured along the long axis of the socket and perpendicular in the transverse shear direction. Normal force was perpendicular to the socket internal wall. Forces were measured at the socket to gel liner interface for the first two conditions. This is a valuable force measurement location which can be useful for future finite element models.

2.3. Experimental protocol

The instrumented prosthetic was assembled with the patient's every day original componentry from below the socket to the pylon interface, maintaining the alignment of the device as a whole (Fig. 2). The patient walked with the instrumented socket for an adjustment period of at least 15 min between conditions. Between conditions, 10 min were allowed for the prosthesis to be doffed before donning commenced and the next 15 min

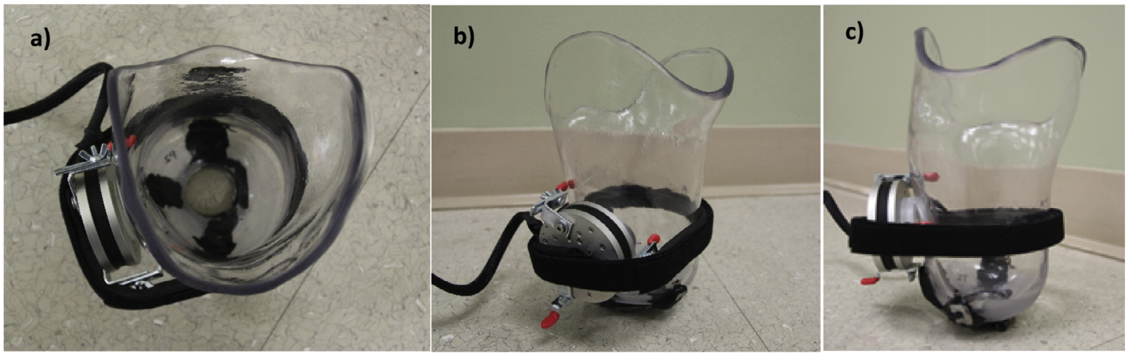

Fig. 1. (a) Top view of instrumented socket demonstrating flush internal curvature. (b) Oblique view of load cell attachment to prosthetic socket. (c) Side view showing attachment of inner removed socket wall to the recording surface of the load cell.

Fig. 2. Instrumented prosthesis as worn by the participant.

adjustment period began. Before the socket was donned at the beginning of a new condition, the load cell was zeroed with no contact being introduced to the recording surface. This allowed the force measurement to capture residual forces during swing that were merely the force of the residual limb on the socket wall without weight bearing.

The following walking conditions were conducted while the forces were collected:

- First, the participant wore his original gel liner within the socket.
- Secondly, a new three ply sock (Knit Rite Cool Max Sock) was added over the gel liner.
- Thirdly, the three ply sock was removed to evaluate the gel liner alone for an additional time.

Fig. 3. Hole in gel liner to allow for contact and force measurement at the skin surface.

- Lastly, the sock was removed and a hole was cut in the 9 mm gel liner, directly contacting the patient's skin for force measurement during walking (Fig. 3).

The hole was slightly larger than the recording surface on the load cell to ensure only skin contact was recorded. The skin protruded through the hole to the outer region of the liner and the mounting of the load cell was not changed. For all three testing conditions, multiple self-selected walking trials were collected and eight gait cycles were analyzed in each condition.

2.4. Data analysis

Forces were analyzed in gait cycles with respect to heel contact and toe off to define gait events for the residual limb [31]. Motion capture and load cell systems were synchronized with an external trigger to analyze forces based on motion capture gait events. Forces during the gait cycle were selected for each condition corresponding to the peak forces in the following phases of gait: initial contact, early stance, single support and swing using MATLAB. Within each condition, shear and normal forces from eight gait cycles were normalized with respect to the gait cycle and averaged. Based on the load cell surface diameter, normal and shear stresses were also calculated and reported in kPa.

A Kolmogorov–Smirnovtest of normality resulted in the data being normally distributed and statistical methods proceeded using parametric methods. Four statistical comparisons were conducted using an ANOVA followed by a Tukey's post-hoc (MATLAB, 2016a). Comparisons analyzed the experimental normal and shear differences in force values across the three conditions. Separate peak force statistical analyses were conducted for these three

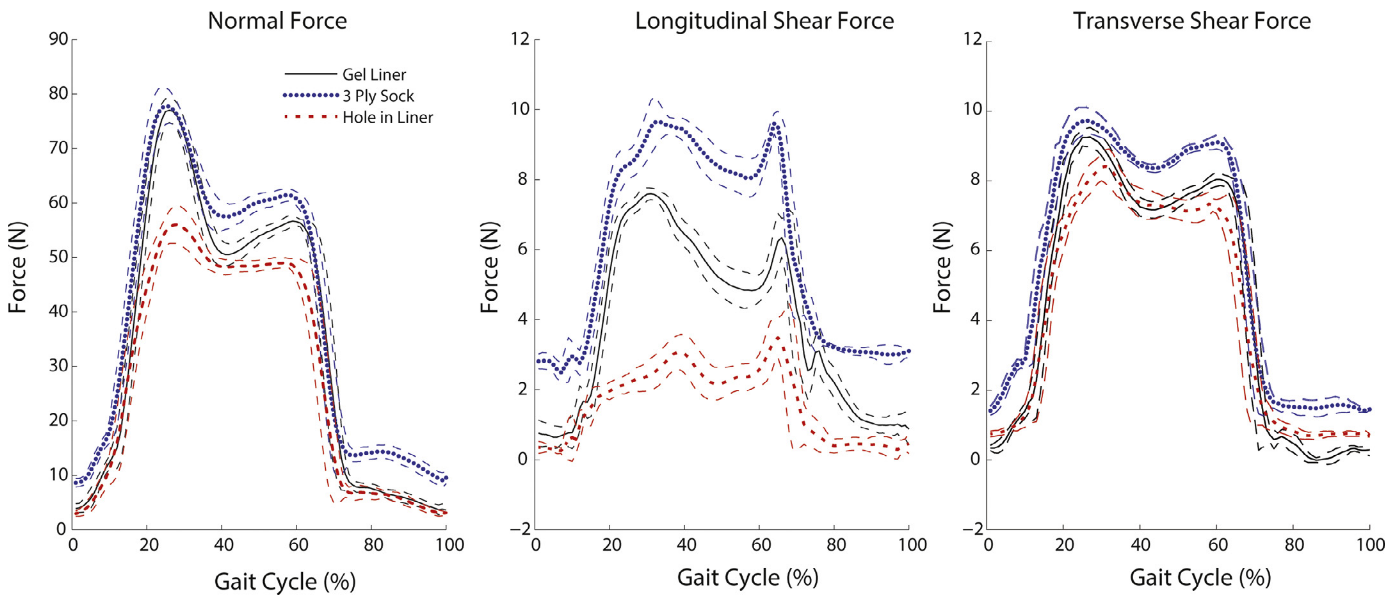

Fig. 4. Three conditions of normal and shear force during walking from heel contact to heel contact on the right residual limb. Sashed lines in the same condition color represent the ± standard deviation of force data as it was analyzed across eight gait cycles.

Table 1
Force comparison across three conditions for the four particular periods during the gait cycle reported in Newtons (N).

	Longitudinal shear force (N) (Avg ± SD)			
	Initial contact	Early stance peak	Single support peak	Swing
Gel liner	0.79 ± 0.33	7.68 ± 0.16	7.01 ± 0.25	0.97 ± 0.22
3 ply sock	2.86 ± 0.25	10.01 ± 0.21	9.85 ± 0.24	2.96 ± 0.21
Hole in liner	0.39 ± 0.13	3.17 ± 0.49	4.29 ± 0.38	0.40 ± 0.23
	Transverse shear force (N) (Avg ± SD)			
	Initial contact	Early stance peak	Single support peak	Swing
Gel liner	0.46 ± 0.20	9.32 ± 0.23	8.11 ± 0.22	0.01 ± 0.14
3 ply sock	2.10 ± 0.30	9.79 ± 0.36	9.15 ± 0.19	1.49 ± 0.19
Hole in liner	0.86 ± 0.09	8.59 ± 0.36	7.55 ± 0.21	0.73 ± 0.07
	Normal force (N) (Avg ± SD)			
	Initial contact	Early stance peak	Single support peak	Swing
Gel liner	4.99 ± 1.52	77.53 ± 2.15	57.06 ± 0.79	5.24 ± 0.88
3 ply sock	10.84 ± 1.39	78.21 ± 3.06	61.64 ± 1.17	11.52 ± 1.39
Hole in liner	4.71 ± 1.45	56.39 ± 3.36	49.49 ± 0.90	4.32 ± 0.68

comparisons within the four regions of the gait cycle (initial contact, early stance, single support and swing). Gel liner conditions before and after the three ply sock condition were statistically analyzed using paired *T*-Tests to compare influence of the sock condition on normal force (significance level $p < 0.05$).

3. Results

The patient was 1.77 m in height, mass of 85.5 kg, and 53 years old. Gait Deviation Indices (GDI) were calculated for the original socket and duplicated socket [30]. On the GDI scale, detectable gait changes fall outside ± 10 points with a GDI of 100 being non-pathological when compared with non-symptomatic normal gait [30]. Comparisons were made for the participant between the original socket configuration and the duplicated socket walking trials. The participant's original socket GDI score was 99 with the duplicated socket calculated as 98; therefore, no detectable change in lower extremity gait patterns were observed between the socket configurations.

The force results obtained from the instrumented socket revealed differences throughout the gait cycle across condition types (Fig. 4). First, longitudinal and transverse shear forces averaged across eight gait cycles revealed statistically significant differences across all comparisons with respect to the peaks identified during the gait cycle (Table 1). During all four analyzed regions of the gait cycle, the longitudinal shear force magnitude was the largest for the condition with the addition of a three ply sock and smallest for the skin contact condition. Transverse shear forces varied throughout the gait cycle for gel liner and hole in liner conditions. Notably during swing phase, the transverse shear forces decreased. However, transverse shear forces were consistently greater throughout the gait cycle during the three ply sock condition when compared to gel alone or the hole condition.

Comparing normal forces, only two comparisons were not statistically significant (Table 2). First, during *initial contact*, the gel liner and hole in liner conditions were not statistically different from each other, but the three ply sock was significantly different from both. Secondly during *early stance*, the three ply sock did not demonstrate a statistical increase in normal force when compared with the gel liner alone condition, however later in single support, all conditions were statistically different from each other for normal force. It is also notable that a residual normal force during

Table 2
Initial contact, early stance, single support and swing statistical p values noting statistical differences reported for normal force comparisons.

	Initial contact normal force comparison		
	Gel liner vs 3 ply sock	Gel liner vs hole in liner	3 ply sock vs hole in liner
p value	$p = 0.0001$	$p = 0.726$	$p = 0.0001$
	Early stance normal force comparison		
	Gel liner vs 3 ply sock	Gel liner vs hole in liner	3 ply sock vs hole in liner
p value	$p = 0.615$	$p = 0.0001$	$p = 0.0001$
	Single support normal force comparison		
	Gel liner vs 3 ply sock	Gel liner vs hole in liner	3 ply sock vs hole in liner
p value	$p = 0.0001$	$p = 0.0001$	$p = 0.0001$
	Swing normal force comparison		
	Gel liner vs 3 ply sock	Gel liner vs hole in liner	3 ply sock vs hole in liner
p value	$p = 0.0001$	$p = 0.04$	$p = 0.0001$

swing phase of gait was highest with the three ply sock addition, which was statistically significant when compared with the gel liner and hole in liner conditions. Although, hole in liner results should be interpreted with the understanding that material was removed to expose the skin to the within prosthetic wall measurement surface and are not necessarily a realistic *in-vivo* scenario.

Statistical comparisons between normal forces in the gel liner alone condition were evaluated before and after the three ply sock condition. The purpose was to evaluate the possibility of forced limb volume changes due to the three ply sock. Statistical evaluation revealed no statistically significant differences in normal forces before and after the additional ply sock was worn.

Shear and normal stress during walking were calculated based on the embedded load cell contact area within the socket. Longitudinal shear stresses ranged from 0.4–7.66 kilopascals (kPa), transverse shear stresses ranged from 0.01–7.79 kPa, and normal stresses ranged from 2.7–61.9 kPa when evaluated across the three conditions and throughout the gait cycle. For the gel liner condition, peak normal stresses were calculated to be on average 61.7 ± 1.7 kPa. On average during the entire gait cycle, normal stresses for the gel liner condition were calculated to be 27.45 kPa.

4. Discussion

The objective of this case study was to evaluate the normal and shear forces during walking for a transtibial amputee using a *gel liner interface pin suspension* prosthetic design. Forces were obtained for three specific conditions: a gel liner alone, a three ply sock worn over the gel liner, and a hole cut in the gel liner exposing the skin. Our results hypothesis was confirmed when shear forces increased with the addition of a three ply sock. The inclusion of shear forces in experimental work is critical. Shear force causes a decrease in blood perfusion when compared with normal force loading alone [2,3] and leads to increased tissue necrosis [32]. In an amputee population, evaluating limb interface mechanisms is important with the high risk for pressure ulcer formation. Our results demonstrated that while normal forces throughout the gait cycle did not vary greatly with the addition of a three ply sock, the shear forces were all significantly increased. Shear force knowledge can be combined with previous data calculating gel liner displacements within the socket to further inform clinicians of mechanical loads [33,34]. Results measured at the socket interface can be utilized in finite element models to determine if increased loading conditions would transfer to the skin, including specific gel liner mechanical properties within the models.

There is a void in the literature regarding the interface between the device and gel liner particularly for pin-locking suspension systems [33–35]. Thus, it would be hypothesized that wearing an extra sock thickness, when not clinically indicated, could produce conditions related to ulcer formation. Therefore, patients should be educated on sock usage, and clinicians should be mindful of this potential issue when prescribing an additional sock ply.

For the condition with the hole in the gel liner, shear and normal forces were collected at the surface of the skin. A challenge of conducting experimental research in below knee amputees wearing a gel liner is the inability to directly access the surface of the skin. Historically, this is a reason why thin film pressure measurement devices were used extensively in published literature. They are able to be placed beneath the surface of the gel liner, while still utilizing the typical suspension method. However, shear forces are not able to be measured with pressure sensors. Our results indicated a significant decrease in shear and normal forces throughout the gait cycle when the skin condition was compared to the intact gel liner condition. A likely reason for the decreased forces is the absence of material thickness, even though skin tissue protruded into the hole and was in contact with the load cell. The tissue was less constrained and greater displacement within the socket was permitted. Interpretation of the skin shear and normal forces should be evaluated mindfully with the limitation that gel liner material was removed.

Stresses were calculated based on the contact area of the load cell within the socket. For the gel liner condition, peak normal stresses were on average 61.7 ± 1.7 kPa. This result compares well with that reported by Sanders et al. [25], who measured normal stresses for a sleeve suspension in the mid-fibular region to be on average 61.3 kPa [25]. Our results average normal stresses for the gel liner were 27.45 kPa throughout the entire gait cycle. Gholizadeh et al. conducted an experimental study with pressure sensors mounted on transtibial limbs and found an average pressure throughout the gait cycle to be 36.05 ± 11.4 kPa in the mid to distal fibular region [22]. Considering the findings of Sanders et al. [25], and the large standard deviations across the pressure measurements evident in the study by Gholizadeh et al. [22], the current single case study falls within reported values for both. Schiff et al. evaluated correlation coefficient comparisons of stresses through the use of load cells instrumented in the socket wall but magnitudes were never presented [27]. Limited shear force and stress data are available in the below knee amputee population particularly with regard patient using a *gel liner interface with pin suspension* design.

A limitation of this study includes the singular location where force was measured. The targeted region was selected based on tissue thickness in this anatomical region of the residual limb. Future studies could include additional measurement locations to compare regional anatomical variances in soft tissues versus bony prominences. However, more locations require the removal of the socket wall to accommodate the instrumentation which could affect the integrity of the prosthetic. Secondly, our results represent a single case study as a means to evaluate our experimental methodology. To relate findings to a larger effect size, additional participants could be studied with development of each patient-specific instrumented socket.

5. Conclusion

Overall, this work provided data on shear forces at the socket to limb interface for a pin suspension system. Sleeve suspensions without patients wearing an interface material had previously investigated and this case study provided a focused example of a patient wearing a gel liner. Also, the effects on normal and shear forces were evaluated for the addition of a three ply sock and removal of the sock and liner. Finally, these results will be helpful for creating future finite element models based on experimentally captured data and can be driven by load data to evaluate the gel liner to skin interface.

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Conflicts of interest

None.

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Ethical approval

The study was approved by the Michigan State University Institutional Review Board (# 14-089M) and written informed consent was obtained from the participant.

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