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Master Thesis in Human Movement Science
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ABSTRACT

Introduction. When fitting a prosthetic socket to the residual limb in persons with a lower limb amputation, comfort and stability are key elements affected by pressure, displacement, and friction. There are several suspension systems available, but a systematic objective evaluation of the suspension systems with respect to resistance against rotation is lacking.

The aim of the study was to find the rotation resistance between the socket and the residual limb for five different suspension systems on four different axial loads.

Method. A prosthetic test rig was developed, and transversal rotational slip torque was measured at a liner-socket slip of 1 mm. The test rig consisted of a transparent socket, an artificial residual limb of silicone (mock) with a locking textile liner. A camera was fixed on the transparent socket to measure socket-liner transversal rotation displacement. Axial load and pressure were also measured. Ten investigations were made with five suspension systems at four axial loads (20, 40, 60 and 80 kg). The pin-locking textile liner suspension systems tested were “non-vacuum”, “sleeve-passive suction”, “sleeve-active vacuum”, “elastomeric coated liner-passive suction” and “elastomeric coated liner-active vacuum”.

Results. The highest average slip torque (6.1 Nm) was found with “sleeve-active vacuum” at an axial load of 80kg, and the lowest (0.6 Nm) with “none-vacuum” at 20kg. A univariate general linear ANOVA model on slip torque with suspension system and axial load as fixed factors, showed significant suspension system effects, an increase with axial load and difference between the factors. Post-hoc tests showed that “sleeve-active vacuum” and “elastomeric coated liner-passive suction” had the highest slip-torque, followed by “elastomeric coated liner-active vacuum”, “sleeve-passive suction”, and “non-vacuum”. All differences were statistically significant ($p<0.01$), except for “sleeve-active vacuum” compared to “elastomeric coated liner-passive suction”.

Discussion. The “sleeve-active vacuum” and “elastomeric coated liner-passive suction” had the overall highest rotation resistance with no significant difference between them. Active vacuum had higher resistance against rotation compared to passive suction with “sleeve” suspension, but lower rotation resistance than passive suction with the “elastomeric coated liner” suspension. “Non-vacuum” had the lowest rotation resistance. As expected, measurements with the prosthetic test rig showed significantly increased rotation resistance with increased axial loads which may be analogue to increased prosthetic limb loading in gait. Whether the observed slip-torques (between 0.6-6.1 Nm) and the differences between suspension systems observed in this mock limb are the same in real persons with a lower limb amputation, and how it affects comfort and control, should be evaluated.

SAMMENDRAG

Introduksjon. Komfort og stabilitet er viktige faktorer ved tilvirkning av protesehylse til amputasjonsstumpen hos personer med amputasjon av underekstremiteten og påvirkes av trykk, forskyvning og friksjon. Flere suspensjonssystemer finnes, men en systematisk objektiv vurdering av suspensjonssystemene med hensyn til rotasjonsmotstand mangler.

Målet med studien var å finne forskjellen i rotasjonsmotstand mellom protesehylse og amputasjonsstump for fem ulike suspensjonssystemer og fire ulike aksiallaster.

Metode. Testriggen besto av en gjennomsiktig hylse, en kunstig kopi av amputasjonsstumpen i silikon (mock) med en tekstilliner utenpå. Et kamera festet på hylsen målte rotasjonsmomentet (slippmomentet) ved 1 mm forskyvning av liner relativt til protesehylsen i en rotasjonsbevegelse. Aksiallast og trykk ble også målt. Ti undersøkelser med fem suspensjonssystemer ved fire aksiallaster (20, 40, 60 og 80 kg) ble utført. Alle tester var gjennomført med låsepinne festet til lineren. De fem suspensjonssystemene som ble testet var «ikke-vakuum», «sleeve-passivt vakuum», «sleeve-aktivt vakuum», «elastomerdekket liner-passivt vakuum» og «elastomerdekket liner-aktivt vakuum».

Resultater. Den høyeste gjennomsnittlige verdien på slippmoment var 6,1 Nm og ble funnet med «sleeve-aktivt vakuum» ved en aksialbelastning på 80 kg. Det laveste slippmomentet var på 0,6 Nm med «ikke-vakuum» ved 20 kg. En ANOVA-modell med slippmoment som avhengig variabel og suspensjonssystemer og aksiallast som faktorer viste signifikante forskjeller på suspensjonssystemer med økning av aksiallast, og en forskjell mellom faktorene. Post-hoc-tester viste at «sleeve-aktivt vakuum» og «elastomerdekket liner-passivt vakuum» hadde høyest rotasjonsmotstand, etterfulgt av «elastomerdekket liner-aktivt vakuum», «sleeve-passivt vakuum» og «ikke-vakuum». Alle forskjellene var statistisk signifikante ($p<0{,}01$), bortsett fra de to suspensjonssystemene med høyest slippmoment.

Diskusjon. «Sleeve-aktivt vakuum» og «elastomerdekket liner-passivt vakuum» hadde høyest rotasjonsmotstand og det var ingen signifikant forskjell mellom disse. Aktivt vakuum hadde høyere motstand mot rotasjon sammenlignet med passivt vakuum ved bruk av «sleeve», men lavere rotasjonsmotstand enn passivt vakuum med «elastomerdekket liner». Ikke-vakuum hadde den laveste rotasjonsmotstanden. Som forventet viste målinger med testriggen betydelig økt motstand mot rotasjon ved økt aksiallast, sammenliknbart med rotasjonsmotstand ved økt belastning av protesen i gange. Hvorvidt de observerte slippmomentene, og forskjellene mellom suspensjonssystemer observert i denne mockstudien er de samme hos mennesker med protese, og hvordan det påvirker komfort og kontroll, bør vurderes i fremtidige studier.

ACKNOWLEDGEMENTS

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The project was initiated because of a prosthetic user with a clinical socket rotation problem. I would like to thank the prosthetic user and the father for contributing with valuable input.

My sincere thanks to Toril and my three children Ingrid, Jakob and Liv and to my friends for being patient with me during this work. I am grateful to all my colleagues at TOV, especially orthopedic technician Emil Sørensen who had an essential role in developing the test rig and the methodical setup, and to Marie Langnes Bakke and Alex Tan for developing the test rig and contributing to the data collection. Thanks also to Sindre Wold Eikevåg and my supervisor Karin Roeleveld for meaningful discussions and contribution to the project.

There are no conflicts of interests.

TABLE OF CONTENTS

ABBREVIATIONS

ADL: Activities of daily living

ANOVA: Analysis of variance

AP: Anteroposterior

CT: Computer tomography

Hz: Hertz

kPa: Kilopascal

LTL: Locking textile liner

ML: Mediolateral

Nm: Newton meter

RL: Residual limb

TOV: Trøndelag orthopedic workshop

TSB: Total surface bearing

1. INTRODUCTION

Lower limb amputation has an incidence in the European population of 0.013 % per year and is defined as a limb loss from transpelvic to transmetatarsal area in the body (1). The main reasons are vascular diseases (94%), cancer (3%) and trauma (3%) (1). 79 % are over 65 years old and for most amputees a prosthesis is provided to improve function (1).

A lower limb prosthesis consists of a socket, suspension system, tube and prosthetic foot (a prosthetic knee is additionally provided for above knee amputees) (2). Good health and mobility of the residual limb (RL) are important for the prosthetic user (3-5).

A fabricated liner is critical for connecting the body and the prosthesis and commonly applied to the RL by the prosthetic user to increase soft tissue compliance, have cushioning effect, and reduce shear stresses in the socket-RL interface (2). A variety of liners available makes it possible to use different socket-RL suspension systems in the prosthesis (2-4).

A distal pin integrated in the liner for attaching the RL to the prosthesis (also called pin-lock) is a common and favorable suspension system among transtibial prosthetic users (2-6). Alternatively, a knee sleeve can be applied to make a seal around the proximal edge of the prosthetic socket and enable sub atmospheric passive suction (air is passively removed) and active vacuum (air is pumped out to pressure levels at 67-78 kilopascal) suspension in the socket-RL interface (4, 7-11). Suction and vacuum suspension systems are also provided by liners coated with elastomeric hypobaric sealing membranes which have advantages (more proprioception, less socket-RL pistoning) and disadvantages (resource demanding to handle) for the prosthetic user (2, 4, 5, 12, 13).

The suspension system is integrated in a prosthetic socket which encloses the RL and contributes to adequate pressure distribution in the prosthetic socket-RL interface and a good socket fit (14). Too tight pressure between socket and RL can result in pressure ulcers, sensitive skin, and soft tissue occlusions (2). Contrarily, too loose pressure can lead to socket-RL displacement which causes tissue deformation and blisters because of the occurred friction (3, 6). Displacement may also lead to reduced stability and comfort (15, 16).

1.1 Prosthetic torque and transversal rotation

Vertical socket-RL displacement (pistoning) is reported as a main challenge for prosthetic users and investigated frequently in the last decades (2, 3, 5, 15, 17). However, socket-RL interface rotation is also a challenge for prosthetic users and play a role in prosthetic locomotion and perceived comfort (4, 5, 12, 13, 18, 19). Former studies suggest that transversal torques in healthy subjects can reach up to 11.8 Nm or 13.6 Nm in the stance phase of gait (20, 21). Torques up to 8.5 Nm have been suggested in a prosthetic socket during gait (22). Furthermore, it has been stated that the suspension systems should prevent uncontrolled transversal rotation in the RL-socket interface (4, 5, 11, 18), but knowledge of how to manage the rotation challenge is limited. There is consensus among clinicians that suction and vacuum suspension decrease socket rotation compared to pin-lock suspension, and that active vacuum has an adhesive effect in the socket-RL interface (4, 9), but there is no strong evidence for this. By comparing pin-lock, knee sleeve and a combined pin-lock knee sleeve suspension without vacuum, a former study suggested that a knee sleeve attached to the socket decreases socket-RL displacement in AP direction (23). Another study reported the possibility of addressing socket-RL rotation challenges by adding fabric gripping strips inside the prosthetic socket (11). By measuring torque with fixed rotation angles in a test rig, the latter study suggested that texturing of the inner socket surface, combined with passive suction and active vacuum, improved socket transversal rotation resistance (11).

1.2 Prosthetic socket-RL interface displacement assessment

While methods measuring socket-RL displacement in the transversal plane are sparse, vertical displacement (pistoning) has been investigated with potentiometric, radiographic, fluoroscopic, ultrasonographic, electromagnetic, photographic, kinematic, magnet-kinematic, microprocessor-controlled, and computer tomographic (CT) methods (2-5, 24). Nevertheless, transversal displacement has been detected by analyzing prosthetic users in the sagittal and frontal plane (19, 23, 25-27). Different transversal rotation was detected on different sites of the RL in eight subjects with pin-lock (non-vacuum) suspension in a kinematic study (26). A single subject study used CT and analyzed socket-RL interface displacement between bone, soft tissue, liner, and socket in three planes, and detected transversal axial rotation with different static loads in a static (supine) position (27).

Furthermore, some studies have observed more socket-RL transversal displacement in the swing phase (19, 23, 25), which may indicate that axial loading of the prosthesis affect transversal socket-RL rotation. A single subject study used optical sensors in the frontal and sagittal plane showing almost no transversal displacement in the stand phase of gait cycle, but up to 3.1 mm ML and AP displacement towards and during swing phase (25). Using kinematics in the sagittal plane, another single subject study also observed that most of the socket-RL interface AP displacement happens towards and during swing phase in gait cycle (23). By using inversed dynamics and kinematics a study with three subjects showed socket-RL transversal rotation during the whole gait cycle increasing towards the swing phase (19).

Summarized, current knowledge of socket suspension methods on transversal rotation have methodic heterogeneity and objective data are lacking because of a limited number of subjects investigated. There are also several methodological limitations hampering generalization of the results. CT analysis systems are resource-intensive, expensive, constrained to machines and have radiation exposure (6, 24). Sensor displacement is reported (3). Kinematic analysis is resource demanding and limited to a laboratory setting (6). Studies evaluating transversal torque with rotation angles with mechanical (11) or kinematic (19) methods may give an incomplete assessment because of omitting the exact displacement in the socket-RL interface. Furthermore, studies mounting optical sensors inside the socket (25), or making holes in the prosthetic socket for placing kinematic markers (23) may disturb the socket-RL interface characteristics and limit the investigation of suction and vacuum suspension.
Therefore, to allow objective and standardized testing of prosthetic suspension systems, a new prosthetic test rig measuring both transversal displacement and torque with a silicone mock was developed and tested in collaboration with two machine technique engineer master students (28). Objective and quantitative data on video tracked socket-liner interface transversal displacement, rotation torque, axial load, passive suction and active vacuum were provided, and the experimental setup makes the basis for future testing in this field (28).

1.3 Aim of the study and hypotheses

The aim of the current experimental study was to investigate differences in rotation resistance using different suspension systems and axial loads in a realistic, standardized artificial RL model (mock) based on the RL of an adolescent prosthetic user. Specifically, the difference between active vacuum, passive suction and non-vacuum suspension systems was investigated as well as the difference between the use of pin-lock textile liner, knee sleeve with textile liner and elastomeric ring coated textile liner on different axial loads. Additionally, the intension was to contribute to more objective knowledge of transversal socket-RL rotation and validate the measurement system prior to application in a real situation with a prosthetic user.
It is hypothesized that a sleeve-sealed textile liner and an elastomeric coated textile liner assisted with passive suction and active vacuum give higher rotation resistance compared to non-vacuum textile liner, and furthermore, that active vacuum contributes to higher rotation resistance than passive suction. Additionally, it is hypothesized that transversal rotation resistance increases with higher axial load and thus influences rotation resistance in a prosthetic socket during different loading conditions.

2. METHODS

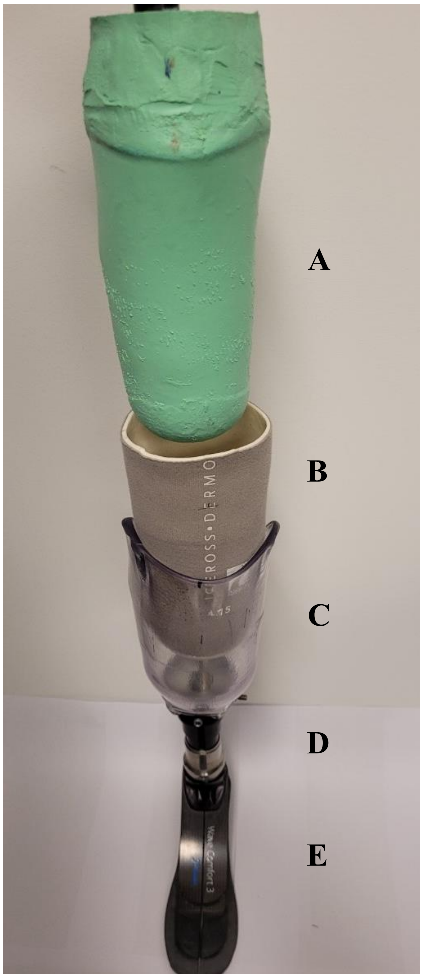

Figure 1:
A: Mock
B: Liner
C: Transparent socket
D: Tube
E: Prosthetic foot (not tested in the current study)

The prosthesis investigated (see figure 1) is based on an adolescent transtibial prosthesis user (42 kg) with socket residual limb (RL) rotation challenges during different loading conditions in activities of daily living (ADL). In line with previous studies (10, 11), the prosthetic user's RL was replicated, a mock of silicone was covered with a liner and tested for torque at 1 mm slip (slip torque) using different suspension systems in a test rig with different measure equipment (28). Two liners were chosen among a large selection due to their equality in shape and characteristics and compatibility with the combined pin-lock-valve locking system (see figure 2). Differences in transversal rotation slip torque were compared on locking textile liner (non-vacuum LTL), sleeve-sealed locking textile liner (sleeve LTL) and elastomeric coated locking textile liner (coated LTL). All systems were tested with a pin (see figure 2) and the two latter suspension systems were also tested with passive suction and active vacuum (see table 1).

2.1 Test specimen and transparent socket

The test specimen consisted of a mock (figure 1A) with a liner (figure 1B) wrapped around it. The mock was a copy of the original RL and liner, and thus slightly larger than the original RL of the prosthetic user. The mock was made of AlphaSIL® silicone with 27-31 shore A hardness. A metal frame with the shape of a triangular prism was welded to the metal pipe to prevent rotation inside the mock. The liner was measured in cm and sized to 23,5 (29). The test specimen was copied with a plaster cast and a total surface bearing (TSB) transparent socket was manufactured. The non-vacuum LTL and sleeve LTL suspension systems were tested with a Dermo locking ® liner and the coated LTL with a Seal in X locking ® liner from Össur (see figure 3). These liners have identical cross section characteristics (29) and thus gave the test specimen the exact same volume in all test cases. To omit volume change and risk of bias, the coated LTL was used without a recommended additional seal-ring (29).

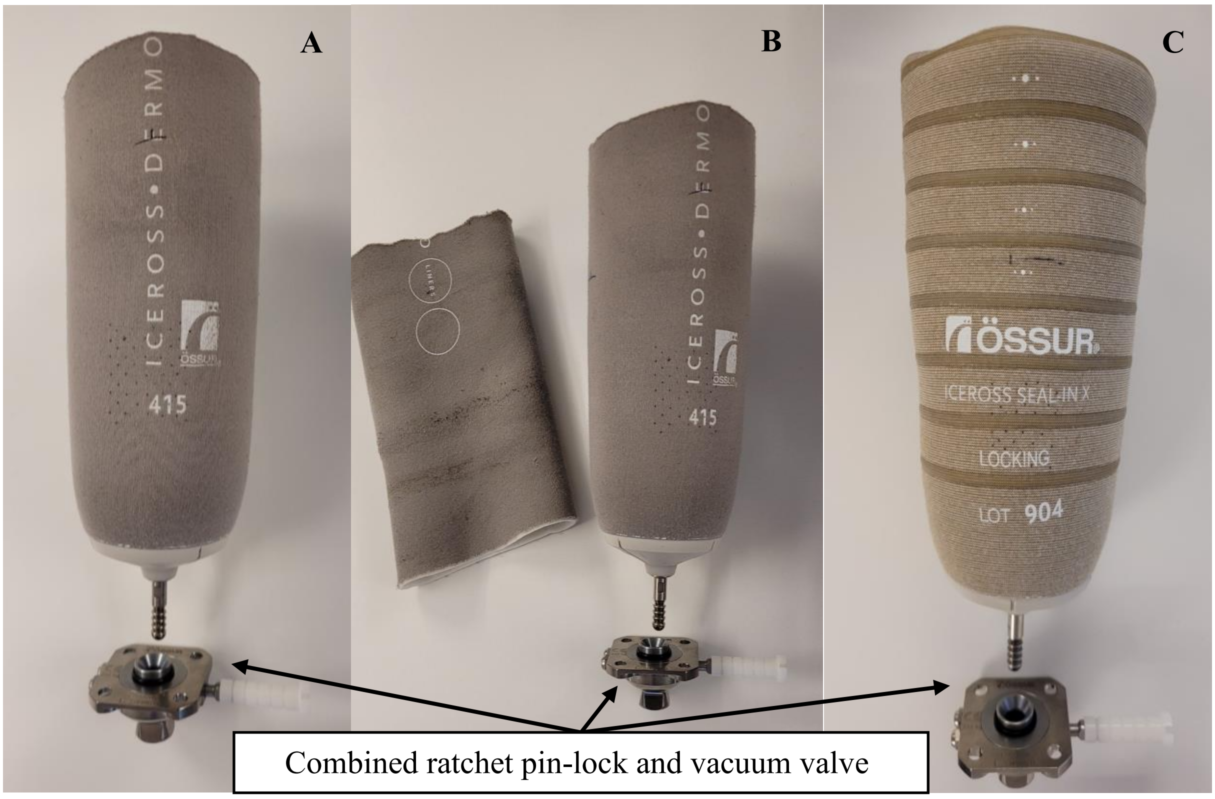

Figure 2: Components for the five suspension systems investigated
A: Non-vacuum LTL
B: Sleeve LTL for the use with passive suction and active vacuum
C: Coated LTL for the use with passive suction and active vacuum

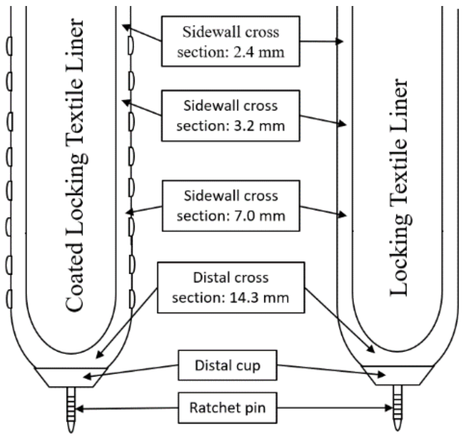

Figure 3: The cross section of the two liners

Figure 4: Ditches on the distal cup of the liners for proper air flow between the textile and valve

Table 1. Overview of suspension systems tested in the study. The components mentioned are all from Trøndelag Orthopedic Workshop (TOV) and manufacturers of prosthetic equipment. This also applies for the liners and suspension systems used for the tests.

1. Non-vacuum LTL	Normally called a pin-lock suspension and is most often used without vacuum (5): The liner has a pin (smooth or ratchet) which the prosthetic user puts into a lock mechanism distally inside the socket.
2. Sleeve LTL with passive suction	The air in the socket is pushed out from the socket by a one-way valve while the RL enters the socket. A knee sleeve seals the suction that occurs in the socket-RL area.
3. Sleeve LTL with active vacuum	The air in the socket is pushed out from the socket by a one-way valve while the RL enters the socket, and a knee cuff (sleeve) seals the vacuum. Air is extracted from the RL-socket interface with a pump through a valve to create negative pressure at 60 kPa (active vacuum level in the current study).
4. Coated LTL with passive suction	The liner has several circular coating sealing rings around its surface from proximally to distally. The air in the socket is pushed out from the socket while the RL enters the socket through a one-way expulsion valve, and the socket is kept in place by the negative pressure (suction) that occurs in distal area of the socket because of the sealing-ring coating.
5. Coated LTL with active vacuum	The liner has several circular coating sealing rings around its surface. The air in the socket is pushed out from the socket while the RL enters the socket through a one-way expulsion valve. Air is extracted from the RL-socket interface with a pump through a valve to create negative pressure at 60 kPa (active vacuum level in the current study).

Ditches were made at the distal cup of the Dermo® liner to make similar socket-test specimen interface air flow in the respective liners (see figure 4). The transparent socket was fabricated with a combined pin-lock and vacuum valve suspension (Icelock 562 hybrid®) compatible to a ratchet pin. The sleeve (see figure 2B) used for sealing the passive suction and active vacuum in the sleeve LTL cases was cut off from the Dermo® liner.

2.2 Test rig with measurement equipment

A GOPRO® camera was mounted on a custom-made 3D-printed camera house (chamber) on the transparent socket. Load cells and the pressure sensor were mounted on the test rig (figure 5). The video from the GOPRO camera was stored on a secure digital card with a sampling frequency of 120 frames per second and used for tracking the socket-RL displacement. The pressure, torque and axial load were sampled through Arduino Mega2560 with an average sampling frequency at 15 Hz. A led light changed color inside the chamber when the torque measurement started. An on/off button registered the start of the cantilever arm movement.

2.3 Experiment setup and protocol

Due to the different suspension systems investigated, both general and specific preparations and protocols were completed for the respective suspension system cases. The five suspension systems were tested in ten trials with four different axial loads.

2.3.1 General preparation

The mock was inspected, and the liners were prepared and checked for damage and excessive wear and tear. The test specimen (mock and liner) was mounted to the test rig and aligned in frontal and sagittal plane with a laser, and the test rig was inspected for loose parts and screws.

2.3.2 Preparation of each suspension system case

The textile liner was donned to the mock. Control measurements were taken to make sure that the liner was donned and centered equally on each investigation case. The ratchet pin (see figure 2 and 3) was donned to the liner before entering the test specimen to the pin-lock mechanism in the socket. Furthermore, several points were marked with 0.2 mm pen on the dorsal part of the two liners in the middle of the camera frame for detection in the video tracking analysis. The test specimen was donned into the socket by hand, and by adding axial load with the upside-down car jack. It was properly entered to the transparent socket when four clicks on the ratchet pin were registered (figure 6). Reference marks were made to align the test specimen in the same position before and after the rotation procedure on each trial

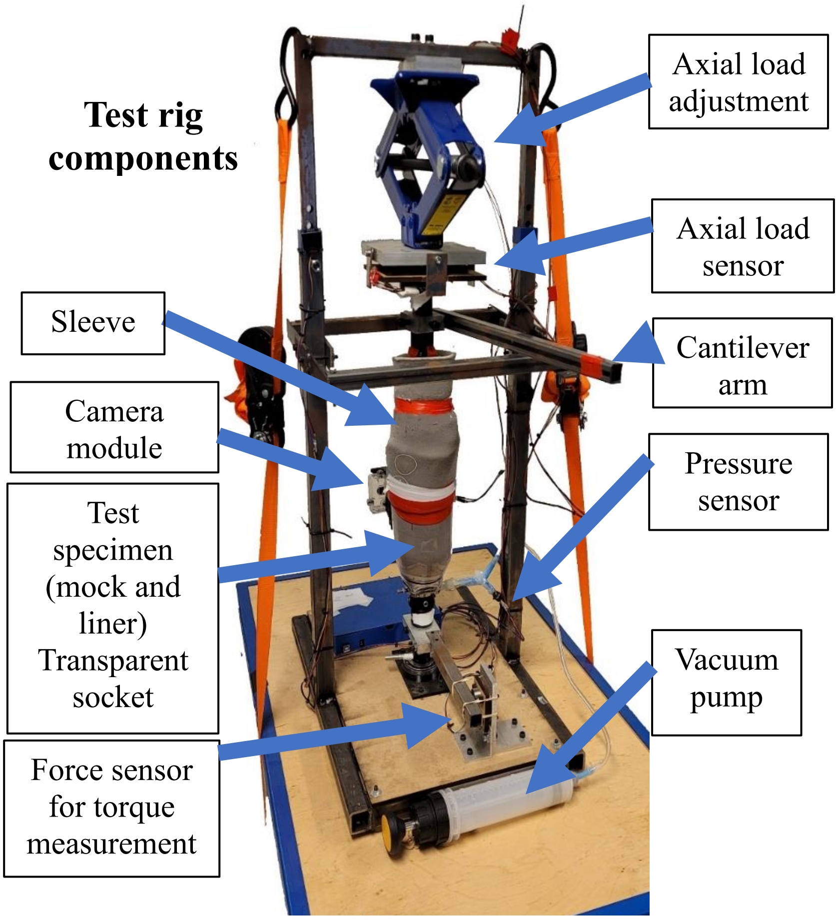

Figure 5: The test rig with equipment

Figure 6: Sleeve and coated LTL

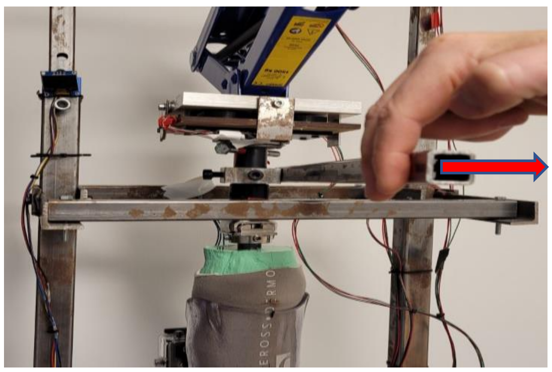

Figure 7: The cantilever arm

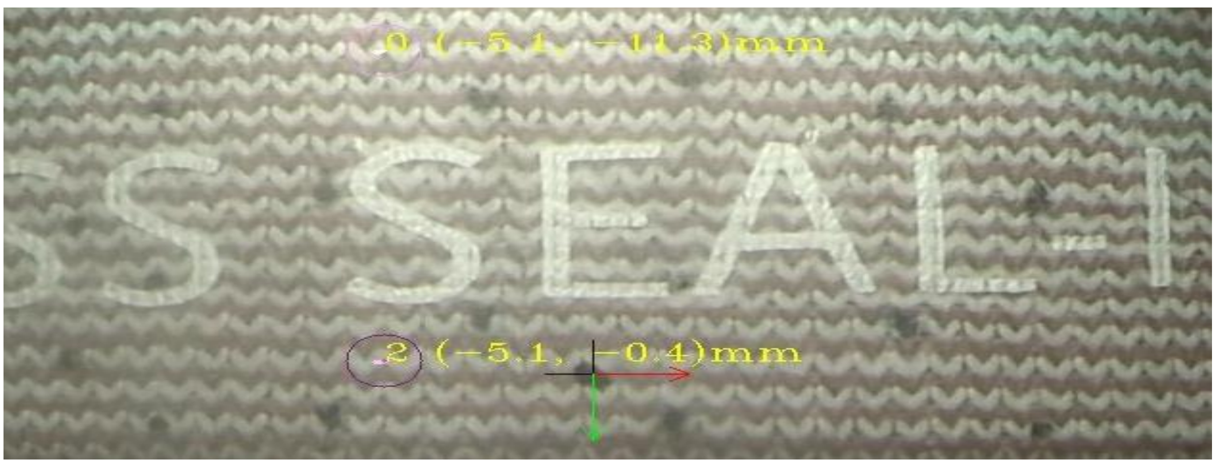

Figure 8: Two displacement coordinates in a specific frame relative to the origo point, the y-coordinates were not taken into consideration

with corresponding marks on the socket. When the sleeve was mounted with elastic tape to create suction and vacuum (table 2, point 2 and 3), the reference points were visually obstructed by the sleeve and three other reference marks more distally on the liner were made. Furthermore, 100 kg was applied and released to the system five times, and the cantilever arm was moved from side to side ten times to make sure the test specimen was in a steady state inside the socket before the test procedure, followed by a caliper control measurement between the test specimen and the test rig. The axial loading cell was unloaded completely to zero, and the system was reset and ready for data collection.

2.3.3 Specific protocol for the suspension systems

Specific test protocols for the suspension systems are shown in table 2 in the appendix.
The axial load was adjusted two times the actual axial load before each trial analogue to a donning procedure as the prosthetic user may put extra axial load in real life to make sure the prosthetic is properly donned.

2.3.4 General protocol for the suspension systems

After the specific protocol, the torque sensor was reset. The arm touching the torque sensor was attached with a rubber band on all trials. Torque, pressure, and the axial load measuring system were started by countdown and video recording was started manually by pressing the camera button. An oral message recorded by the camera specified case, load, and test number. A specific movement to generate rotation of the test specimen by pulling a cantilever arm to the side (right) by a person’s external muscle power was executed (see figure 7). The test specimen inside the socket then rotated relative to the socket. Torque per time in the actual movement was registered to get information on slip torque after exactly 1 mm transversal displacement of the test specimen. The measuring systems and camera system were switched off when the test specimen had rotated an excessive distance from the initial slip position, based on visual inspection of the reference marks on the liner and the socket. The cantilever arm was then positioned into its original position according to the reference marks on the liner and socket. Furthermore, the axial loading cell was unloaded completely, and the mock and the tube were inspected frequently for fatigue or damage.

2.4 Data analysis

A reference point marked on the transparent socket centered in the middle of the video picture made a consistent reference point (origo) for the coordinates in the displacement detection tracking program during socket-test specimen interface rotation (see figure 7 and 8). In advance, a grid sheet had been placed between the socket and liner to calibrate to metrical values before video tracking analysis in OpenCV®. There were three vertical points at the liner registering displacement and the most proximal point displaced first (28). The 15Hz sampled pressure, torque and axial load signals were interpolated to 120Hz to get a value of each video frame (28). The torque data were registered per millimeter displacement (28). The video tracking, slip torque, axial load and negative pressure were then merged to one dataset.

2.4.1 Statistical analysis

Statistical analyses were performed using SPSS version 27 with slip torque as the dependent variable. The different suspension systems and axial loads were included as the two factors (independent variables) to explain the variance in the slip torque. 10 trials were evaluated on five suspension system cases and four different axial load cases, 200 trials in total. Shapiro-Wilk test was used to assess the normal distribution over the entire dataset, the suspension system and axial load groups, and each suspension system and axial load case. All datasets were log transformed and retested for normality. Furthermore, a univariate analysis of variance (ANOVA) and post hoc tests were performed to evaluate the main differences in slip torque between suspension systems on respective axial loads. A correlation test with regression line was also completed to check for correlation between slip torque and axial loads on all five suspension cases.

A three-dimensional bar chart and a graph with clustered box plots were provided to present the results with statistical information. A statistical significance level was set at alpha level $p<0.05$.

3. RESULTS

The main average results from the study are illustrated in figure 9 and shown with variance in figure 10. The highest average slip torque value observed was 6.1 Nm testing sleeve LTL with active vacuum at 80 kg. Non-vacuum LTL had the lowest average slip torque value with 0.6 Nm at 20 kg (see table 3 in the appendix). Furthermore, sleeve LTL active vacuum had the largest slip torque difference between 20 and 80 kg and non-vacuum LTL had the least slip torque difference between these axial loads.

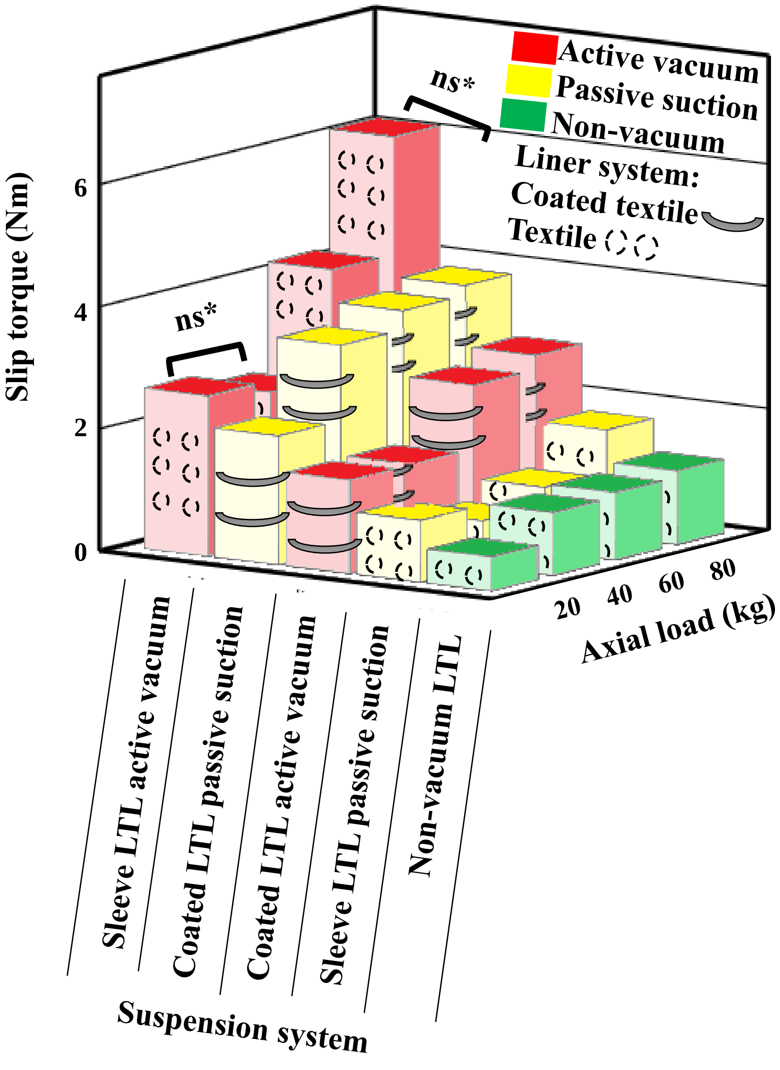

Figure 9: All suspension systems displayed with average slip torque, compared with the different axial loads. The trend is increased slip torque with passive suction, active vacuum and increased axial load. The vacuum and suction suspension systems have higher slip torque than non-vacuum suspension system. Non-significant differences are marked "ns" and apply to the corresponding rows.*

Normal distribution tests showed that the entire dataset of 200 trials and the residuals of the ANOVA model were positively skewed and became normally distributed with log transformation.
Furthermore, the respective suspension system groups and axial load groups also became normally distributed after log transformation, except from slip torque in the 60 kg group which was not normally distributed in the original or in the log transformed dataset. Coated LTL passive suction (0.049 significance level in Shapiro-Wilk test) was incorporated in the log transformed dataset after visual inspection of QQ-plot and histogram. The residuals of the ANOVA model also became normally distributed after log transformation. Thus, the premises for ANOVA was fulfilled and the log transformed dataset were used for further analysis.

The ANOVA model showed significant differences in slip torque between suspension system and axial load groups. The difference between sleeve LTL active vacuum and coated LTL passive suction suspension was not significant when all axial loads were taken into consideration. All other differences between suspension systems were statistically significant ($p<0.01$). Coated LTL with passive suction had significantly more slip torque than coated LTL with active vacuum. A general observation was that increased axial load also increased the average slip torque values. However, there was a non-significant difference in slip torque between 20 kg and 40 kg axial load when all suspension system cases were taken into consideration. All other axial load differences were statistically significant ($p<0.005$).

The different suspension systems also had different variance between the trials. The dataset indicates a lower standard deviation and variance of the non-vacuum LTL and sleeve LTL passive suction than the respective suspension systems (see figure 10). All the respective suspension system cases were normally distributed except from sleeve LTL active vacuum at 40 kg. This may be explained by the outlier (see record “78” on figure 10) and positively skewed dataset in this box. There was a statistically significant ($p<0.001$) positive correlation with slip torque and axial load on both original axial load data and log transformed data. Furthermore, a positive relation between slip torque and axial load was observed with a linear regression line for all five suspension systems.

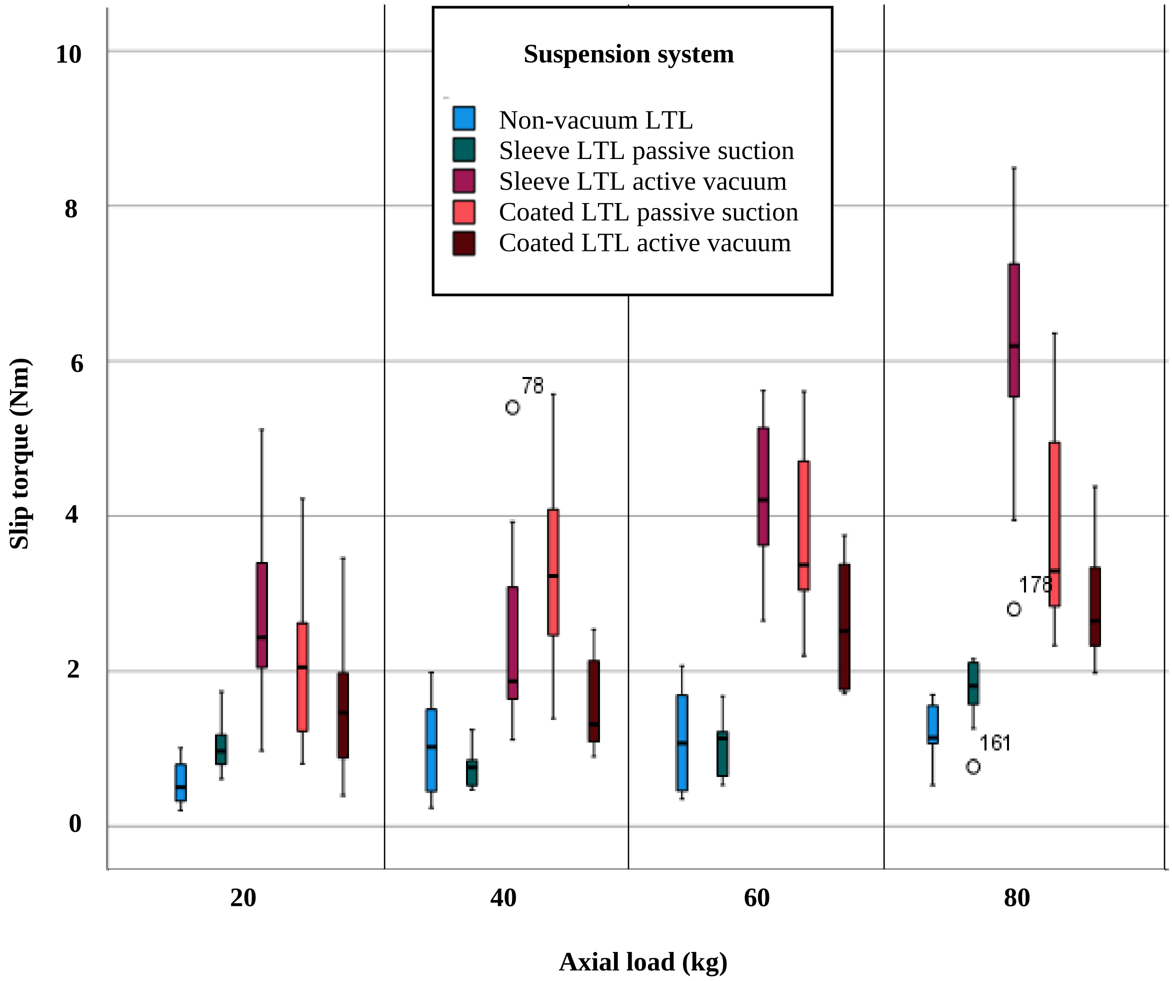

Figure 10. Boxplots of the slip torque in the different axial loads with outliers show the variance and distribution of the dataset.

4. DISCUSSION

The present study showed significant differences in rotation resistance when comparing non-vacuum, passive suction, and active vacuum suspension systems. Sleeve LTL with active vacuum had the highest rotation resistance and the largest difference compared to non-vacuum LTL, but a non-significant difference to coated LTL with passive suction. A higher rotation resistance was observed on coated LTL compared to non-vacuum LTL with both passive suction and active vacuum. However, coated LTL with passive suction had higher rotation resistance than coated LTL with active vacuum which was not consistent with the hypothesis. The observed increased rotation resistance with higher axial load may contribute to more knowledge of suspension systems in different loading situations during gait and other activities. In the following text, the difference in rotation resistance between the different suspension systems and its clinical implication will be discussed, followed by considerations on strengths and limitations of the used experimental setup.

4.1 Rotation resistance in the different suspension systems

Most of the results were as hypothesized, but some observations may contribute to future discussions of the difference between suspension systems.

4.1.1 Non-vacuum LTL

Non-vacuum LTL, equal to pin-lock suspension, had the lowest measured rotation resistance among the suspension systems investigated with 0.6 Nm observed at 20 kg and 2.6 Nm slip torque at 80 kg. The hypothesis that non-vacuum LTL has lower rotation resistance than both suction and vacuum suspension systems is supported . These observations are consistent with former studies suggesting that suction and vacuum have advantages regarding rotation compared to non-vacuum pin-lock suspension (4, 11). On the other hand, the reported disadvantages with suction and vacuum and the fact that pin-lock suspension is popular among prosthetic users (4, 5), suggest that future qualitative and quantitative studies should investigate why pin-lock is preferable in ADL despite of the relatively low acquired rotation resistance achieved in this suspension system.

4.1.2 Sleeve LTL

The hypothesis claiming that rotation resistance increases with both passive suction and active vacuum in the RL-socket interface was supported on the sleeve LTL suspension system. The current study indicates that sleeve LTL active vacuum had the highest rotation resistance compared to non-vacuum LTL of all suspension systems and supports the theory that the liner becomes more adhesive to the socket with active vacuum (4, 9). The different rotation resistance found between passive suction and active vacuum investigating sleeve LTL is consistent with a previous study that observed significantly increased torque with active vacuum compared to passive suction on a smooth socket surface using sleeve (11). Interestingly, the sleeve LTL results indicate more than three times higher rotation resistance with active vacuum suspension (60 kPa pressure) compared to passive suction suspension at 40, 60 and 80 kg. Furthermore, the observations in the present study are consistent with a previous one suggesting the use of a knee sleeve to hinder transversal AP displacement in gait (23). However, AP displacement is not necessarily equivalent with transversal rotation and the present study did not investigate sleeve without suction or vacuum like the latter. Different sleeve characteristics in respective studies may also impair comparison of results.

4.1.3 Coated LTL

The results on coated LTL suspension showing that passive suction and active vacuum had higher rotation resistance than non-vacuum suspension is consistent with the hypothesis. The observation that coated LTL passive suction had torque values not significant different from sleeve LTL active vacuum, is partly consistent with a previous study showing that passive suction on textured socket surface occasionally had torque values similar to active vacuum on smooth socket surfaces (11). These observations indicate that gripping surfaces on liners with passive suction suspension could be as adhesive to smooth socket surfaces as textile liners with active vacuum, and thus be an alternative suspension system for prosthetic users with socket-RL rotation challenges. Moreover, coated LTL with passive suction had significantly higher rotation resistance than coated LTL active vacuum which was not consistent with the hypothesis. The reason for this may be that coated LTL active vacuum contributed to much more sub atmospheric pressure distally in the socket compared to passive suction and thus, a slight volume gain in the distal area followed by a volume loss and reduced pressure in the proximal area of the socket may have occurred (9).

4.2 The effect of axial load on rotation resistance

The hypothesis claiming that rotation resistance increases with increased axial loads was supported in the current study, and analogue to gait phases, these observations are consistent with earlier studies showing less socket-RL rotation in stand phase (19, 23, 25). It was observed that increased axial load significantly increases rotation resistance from 40 to 80 kg but increase of rotation resistance between 20 and 40 kg was not significant. These observations indicate more risk of socket-RL rotation when the prosthesis is not fully loaded in ADL, but more studies are needed to substantiate this. Furthermore, previous investigation of the coated LTL suspension showed increased sub atmospheric pressure in the socket-RL interface with decreased axial load (28). Thus, double axial load was added and removed before each trial to create sub atmospheric pressure. The larger slip torque of coated LTL compared to sleeve LTL with passive suction suggests that less sub atmospheric pressure was achieved in sleeve LTL after this action. A reason may be that coated LTL had less air to be passively removed from the distal area of the socket than sleeve LTL, and the air in the sleeve LTL suspension may have accumulated in the more proximal area of the socket instead of getting ventilated out of the valve. This may underline the need of removing excessive air from the entire socket-RL interface with a pump to create more rotation resistance in sleeve LTL suspension systems, and may also explain the relatively large difference in rotation resistance between sleeve LTL active vacuum and passive suction (chapter 4.1.2).

4.3 Strengths and limitations of the experimental setup

This present study could be considered as a mechanical single “subject” study because the mock was a copy of a human RL. By investigating different factors in one standardized condition this study contributed to increased number of trials and data compared to single subject studies in the past. To increase the generalizability to prosthetic users in the future, more mocks with different characteristics may contribute to more “subjects”. Furthermore, previous studies used a mock with 60 shore A inner hardness and 20 shore A outer hardness (10, 11). The mock in the present study had 27-31 shore A hardness. The mock with metal frame in this present study managed loads up to 1600 N. In comparison, earlier studies have shown mock damage at 1000 N after cyclic testing (10, 11). Thus, more research on mock materials similar to human soft tissue, and fatigue testing of mocks are needed.

To the author’s knowledge, there exists no cross-section standard on liners across prosthetic equipment manufacturers. To provide equality in liner cross section two liners from the same manufacturer were chosen for investigation. Other studies on socket-RL interactions of different suspension systems have tested liners with similar, but different volume characteristics (4, 5, 30). However, by testing a variety of combinations, a former study showed that only one pin-lock liner contributed to research on three non-vacuum suspension systems (23). Thus, more future research with equal liner types is needed.

The developed test rig investigating interactions between video tracking, torque measurement, suction/vacuum pressure and axial loads may contribute to establish a more standardized testing system for suspension systems, which meets encouragements in earlier studies (10, 11, 23, 25). The accurate socket-RL displacement results suggest that the camera can be extracted from the test rig and used to investigate directly on a transparent socket of a prosthetic user in the future, in line with earlier studies on socket-RL interface displacement during gait (19, 23, 25, 26). Kinematic and mechanical methods (11, 19) for additional angular movement assessment of the cantilever arm could also be a future development of the test rig and ease the comparison with other studies. The use of CT (27) in combination with the test rig for additional investigation of metal frame-mock-liner displacement may also contribute to more knowledge of interface interactions between different layers in the future. The active vacuum pressure level was somewhat higher than previous studies (7-11), and comparison of different socket-RL pressure levels should be further evaluated. More studies investigating generalizability to prosthetic users, and validation of the experimental setup are also needed.

The highest average torque among suspension systems detected in was 6.1 Nm at 80 kg. This indicates that the slip torque values in the present study do not reach the torque levels in normal or prosthetic gait (20-22), and thus the rotation resistance in all the respective suspension systems in the current study may be too low to hinder socket-RL rotation in ADL. However, slip torque values in the test rig should be validated in future studies before generalizing to prosthetic users.

4.3.1 Test rig limitations

Regarding transferability from test rig to dynamic movements on human beings, a mock will never be the same as a human residual limb and does not take into account socket pressure distribution, bone-tissue displacement, liner-skin displacement, volume changes during ADL, temperature regulation and perspiration, pain, muscle tension and RL health (2, 8, 11-13, 17, 27, 31). A prosthetic user is also exposed to multiaxial loads in ADL, but the test rig only investigates uniaxial loads (8, 10, 11). Furthermore, the test rig cannot test central qualitative factors in the choice of suspension system such as the ease of donning/doffing the prosthesis, perceived RL-socket steady state (may take time in real life), perceived comfort and successful fitting (4, 5, 12, 13, 17, 32). The bulkiness and size of the camera may also limit the possibility to analyze several sites of the residual limb (25, 26).

4.4 Other limitations and considerations

The inconsistent variance in slip torque among the factors and the need of log transformation of the skewed dataset may limit the validity of the experimental setup in the present study. A reason for these trends in the data may be the interpolation of the torque data to get synchronized with the sampling frequency of the camera system. A faster sampling frequency would also have been beneficial. Other reasons could be inconsistent movement of the cantilever arm or undetected movements in the test rig. Furthermore, there was less variance in the suspension systems with the lowest slip torque. This suggest that a textile liner with little or no sub atmospheric pressure have a more stable and predictable socket-test specimen slip after 1mm than an elastomeric coated liner or a textile liner with active vacuum. Nevertheless, more data are needed to substantiate the results and trends. Future mock studies should also assess different mocks to achieve more independency in the statistical analyses.

4.5 Conclusion

The results indicate that active vacuum increases rotation resistance in the residual limb-socket interface compared to non-vacuum suspension and contributes more to rotation resistance with increasing sub atmospheric pressure on the entire surface of the socket-liner interface. Furthermore, it is indicated that elastomeric coating on the liner increases rotation resistance with passive suction compared to non-vacuum suspension systems. A general observation was increased rotation resistance with increased axial load. More studies on both human residual limbs and artificial mock limbs on differences between suspension systems are needed to substantiate the observations in the current study.

4.6 Clinical implications

The observations may contribute to more knowledge among clinicians and prosthetic users of the choice of suspension systems in cases with socket rotation challenges. However, the results must be used carefully because of the generalization uncertainty and the need of future substantiation of results on real subjects.

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6. APPENDIX

Table 2. Specific protocols for the respective suspension methods

1. Protocol for non-vacuum LTL	1. Axial load adjusted 2. See general protocol (2.3.4)
2. Protocol for sleeve LTL with passive suction	1. Air was pumped out from the specimen to get rid of excessive air inside the socket and sleeve. 2. Pressure was released to one atmospheric pressure by pushing the one-way valve button on the vacuum adapter. 3.Clamp was put on to the tubing (to keep constant vacuum). 4. Axial load adjusted 5. See general protocol (2.3.4).
3. Protocol for sleeve LTL with active vacuum	1. Air was pumped out from the specimen to get rid of excessive air inside the socket and sleeve. 2. Pressure was released to one atmospheric pressure by pushing the one-way valve button on the vacuum adapter. 3.Additionally, the air was pumped out from the specimen socket interface up to five times to get rid of excessive air inside the sleeve and socket. 4. Clamp was put on to the tubing (to keep constant vacuum). 5. Axial load adjusted 6. With clamp open, air was extracted from the test specimen-socket interface by a vacuum pump to 20-30 kPa at this point. The tube was then closed by the clamp. The release button on the one-way valve was opened very shortly several times to adjust the pressure to 60 kPa. 7. See general protocol (2.3.4).
4. Protocol for coated LTL with passive suction	1. Pressure was released to one atmospheric pressure by pushing the one-way valve button on the vacuum adapter. 2. Clamp was put on to the tubing (to keep constant vacuum). 3. Axial load adjusted 4. See general protocol (2.3.4).
5. Protocol for coated LTL with active vacuum	1. Pressure was released to one atmospheric pressure by pushing the one-way valve button on the vacuum adapter. 2.Clamp was put on to the tubing (to keep constant vacuum). 3. Axial load adjusted 4. With the clamp open, air was extracted from the test specimen-socket interface by a vacuum pump to 20-30 kPa at this point. The tube was then closed by the clamp. The release button on the one-way valve was opened very shortly several times to adjust the pressure to 60 kPa. 5. See general protocol (2.3.4).

Table 3: Mean slip torque values with standard deviation of the investigated suspension systems

Axial load	Suspension system	Mean	Std. Deviation	N
20	Non-vacuum LTL	0.55	0.27	10
	Sleeve LTL passive suction	1.00	0.32	10
	Sleeve LTL active vacuum	2.62	1.14	10
	Coated LTL passive suction	2.11	1.06	10
	Coated LTL active vacuum	1.53	0.87	10
40	Non-vacuum LTL	1.03	0.58	10
	Sleeve LTL passive suction	0.75	0.23	10
	Sleeve LTL active vacuum	2.43	1.32	10
	Coated LTL passive suction	3.34	1.29	10
	Coated LTL active vacuum	1.54	0.59	10
60	Non-vacuum LTL	1.10	0.64	10
	Sleeve LTL passive suction	1.05	0.36	10
	Sleeve LTL active vacuum	4.19	0.94	10
	Coated LTL passive suction	3.65	1.08	10
	Coated LTL active vacuum	2.58	0.75	10
80	Non-vacuum LTL	1.20	0.37	10
	Sleeve LTL passive suction	1.73	0.44	10
	Sleeve LTL active vacuum	6.11	1.75	10
	Coated LTL passive suction	3.81	1.38	10
	Coated LTL active vacuum	2.81	0.73	10