Design of an open-source transfemoral, bypass socket

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Abstract— The development of control algorithms and prosthetic hardware for lower limb prostheses involves an iterative testing process. Here, we present the design and validation of a bypass socket to enable able-bodied researchers to wear a leg prosthesis for evaluation purposes. The bypass socket can be made using a 3D-printer and standard household tools. It has an open-socket design that allows for electromyography recordings. It was designed for people with a height of 160 – 190 cm and extra caution should be observed with users above 80 kg. The use of a safety harness when wearing a prosthesis with the bypass socket is also recommended for additional safety.

Clinical Relevance— This makes the development process of transfemoral prosthetic components more time- and cost-efficient.

I. INTRODUCTION

Lower limb prostheses are becoming increasingly advanced and sophisticated. Automatically adjusted joint stiffness, updated in real time based on sensor input, is a standard feature in many commercially available prosthetic knees today. Some prostheses may even provide users with additional power to compensate for lost musculature. Research is also being conducted on the integration of biological signals for prosthetic control and sensory feedback.

These technologies have the potential to greatly enhance prosthetic function, but only if implemented reliably so that the user can trust the prosthesis. Ambulatory tests are essential in the development process to ensure reliability in the control algorithms and prosthetic hardware. However, testing is an iterative process that can be tedious and time-consuming, and therefore it is difficult, inefficient, and even economically unfeasible to recruit subjects with amputations who are able and willing to participate in this process.

To overcome these problems, preliminary testing can be performed with able-bodied test participants, using a bypass socket. Bypass sockets of various design have been used by several research groups [1]–[4], but their construction or design has not been described or made available for others to use. Bypass sockets normally immobilize the knee joint in one of the legs and allow for attachment of the prosthesis to the distal end of the socket. Consequently, the user can ambulate with the prosthesis in a manner comparable to that of an individual with amputation. In this way, research personnel may do initial user tests on themselves, or on other able-bodied

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participants. Using able-bodied participants with a bypass socket in early development is thus both time- and cost-efficient since the need to recruit external test participants with amputation is reduced.

The purpose of this article is to present the design and construction of an adjustable, lower limb bypass socket that can be easily built from inexpensive, widely accessible materials using 3D-printing and standard household tools for construction and assembly. The design, including drawings, CAD files and assembly instructions are made publicly available at the Open Science Framework (OSF) at https://doi.org/10.17605/OSF.IO/7J48W.

II. METHOD

A. Requirements

A requirement specification was created for the categories: compatibility, size, manufacturing, and durability. Within each category, features were designated as either requirements, with mandatory fulfilment, or as desired features. A summarized version of the requirement specification is shown in Table 1, and available in full length at OSF.

1) Dimensions

The bypass socket should be usable by people between 160 cm - 190 cm based on the height of Swedish citizens aged >16 years. The lower limit corresponds to the mean height of women minus one standard deviation. The mean height for

TABLE 1: REQUIREMENT SPECIFICATION OF THE BYPASS SOCKET.

	Criteria	Target value	Requirement/ Desired features
1.	Prosthetic compatibility		
1.1	Fit standard components	4-hole pattern OR pyramid adapter/receiver	Requirement
2.	Bypass compatibility		
2.1	Fit able-bodied leg	Fit able-bodied between 160-190 cm	Requirement
2.1. <i>I</i>	Highest minimum socket height	22.4 cm	Requirement
2.1.2	Lowest maximum socket height	32.6 cm	Requirement
3.	Durability		
3.1	Repetitive load	1 000 N	Requirement
3.2	Static load	4 300 N	Requirement
3.3	Cycles	162 500	Requirement
4.	EMG compatible		
4.1	Four sites	Quadriceps + biceps femoris	Requirement
4.2	More than four sites	Quadriceps + biceps femoris + others	Desired feature

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males plus one standard deviation is 187 cm [5]. However, for increased usability within our research group the upper limit was increased to 190 cm. The length of the thigh is 20 % – 24.5 % of the total body height [6], and we considered that 70 % of the thigh's length is needed for stability, which means that the socket wall should be adjustable between 22 cm and 32 cm.

2) Durability

We set 100 kg as the upper weight limit for potential users, and consequently require that the bypass socket withstands repetitive loads with an ambulatory force of 1000 N. This is more than previously observed empirically with the highest measured forces at 845 N [7]. For safety, the bypass socket should withstand the static loading scenario of falling without total failure. For a 75 kg person, this can be expected to be 3274 N [8], and therefore the ultimate load limit was set as the static, resultant falling force of 4300 N.

3) Compatibility

Electromyographic (EMG) recordings of muscle activations in the residual limb may be used to decode and predict user intent, and thereby be used for prosthetic control [9]–[12]. Surface electrodes can be utilized for EMG recording of superficial muscles, and common muscles for prosthetic control in research are the *vastus lateralis*, *vastus medialis*, *rectus femoris* and *biceps femoris* [9]–[12]. These muscles are used in the extension and flexion of the knees [6] and are thereby of interest when that motion is to be reproduced in an artificial knee joint. We therefore designate ability to record EMG from these muscles as a requirement.

The bypass socket must be compatible with standard prosthetic lower limb components which use pyramid adapters/receivers. A 4-hole pattern is standard for attaching a pyramid adapter/receiver to a socket or flat surface and was thus a primary consideration for our design.

B. Design

EMG recordings using electrodes inside the socket suffer from problems such as motion artifacts [11], [13], localized pressure zones [13], and perspiration affecting the electrodeskin interface [11]. To reduce these problems, we employed an open-socket design with space for the placement of surface electrodes. The majority of the load is transferred between the distal end of the bypass socket and the immobilized knee, and therefore the amount of force on the socket walls is substantially lower for an able-bodied bypass socket as compared with an ordinary transfemoral socket, leading to opportunities for material and weight reduction. Our open-

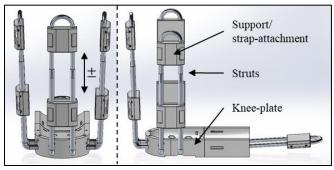


Figure 1: Anterior and lateral view of the CAD-model of the bypass socket.

socket design consists of three vertical pins/struts around the thigh instead of socket-walls, see Figure 1. Multiple primary design concepts were evaluated using a design evaluation matrix considering height adjustment, knee-placement, vertical thigh support, and support between the socket and the leg. Each of these functions were divided into sub-functions or features and then weighted based on the possibility of fulfilling the requirement specification. The main- and sub-functions are presented in Table 2. Two concepts were chosen for further development in computer aided design (CAD) using SOLIDWORKS 2018 SP5.0, Dassault Systems. The models were re-evaluated with focus on durability and building simplicity, after which a single design was selected.

We then built the bypass socket with tools available in a typical household and a 3D-printer. In early versions, most components were 3D-printed with polylactic acid (PLA) for an initial evaluation of strength and functionality of the design. The final version was made with PLA and aluminum components and used in the evaluations presented here. Tools and settings used for the prototype are available at OSF.

C. Evaluation

Three participants, P1, P2 and P3, tested the bypass socket to validate the functionality based on the requirements specified in Table 1. P1's height was 167 cm and P2's height was 194 cm, thus covering most of the required range. P3 weighed 100 kg, and thus evaluated the 100 kg durability requirement. Three additional users, A1, A2 and A3, all within the specified user height and weight limits, performed shorter tests, limited to providing feedback regarding comfort and usability. A pyramid receiver was attached on the distal side of the bypass socket via a standard 4-hole pattern. A passive, mechanical knee joint of type "Seattle Select Stance Flexion Knee" and two "Xtend Foot H10-526" prosthetic feet without ankle joint were used during the evaluations. P1, P2, A1 and A2 all used the left foot suitable for 61 kg – 80 kg, and P3 and A3 used the right foot suitable for 81 kg – 100 kg. As part of

Table 2: The functions and sub-functions included in the design evaluation matrices.

Function	Support	Height adjustment	Knee-placement	Vertical thigh support
	Manufacture complexity	Manufacture complexity	Manufacture complexity	Manufacture complexity
	Support	Stability	Material access	Material access
Su	Material access	Strength	Number of parts	Stability/ Control
b-fu		Visual intuitiveness	Stability, strut connection	Horizontal forces
nci		Functional intuitiveness	Strut compatibility	Shin support
Sub-function or feature			Moment resistance	EMG capability
or fe			Axial force resistance	Angular adjustment
atur			Shin support capability	Height adjustment
é			Angular adjustment	Visual intuitiveness
			Dimension adjustment	Functional intuitiveness
			Visual intuitiveness	

each evaluation, the width and height of the socket was adjusted to fit the participant. The prosthetic components were aligned visually and reported as comfortable by the users. Participants then ambulated on a treadmill using both hands for support on the handrails of the treadmill. To evaluate the usability during the evaluation, the participants gradually decreased the support from two hands to one hand, and eventually no hands on the handrail if feeling sufficiently confident. Furthermore, the speed of the treadmill was gradually increased to 2.0 km/h for P1 and P2, and P3 insisted on increasing to 2.5 km/h. For each participant the entire test session lasted 30 minutes of which 10 minutes was spent ambulating on the treadmill with the bypass socket. After all the evaluations were completed, the bypass socket was analyzed for damages.

For the evaluation of EMG compatibility, electrodes were placed on the targeted muscles on the quadriceps and the hamstrings on participant A1 for EMG measurement, while strapped into the bypass socket. Myoelectric pattern recognition (MPR) was used for offline discrimination of flexion and extension of the leg during non-load bearing. Participant A1 then performed ambulation with the prosthesis while EMG data was recorded.

III. RESULT

A. Design

The bypass socket consists of a knee-plate, three struts around the thigh, one proximal strut supporting the shin, eight support/strap-attachments, and five straps (Figure 2a). The knee-plate is a 3D-printed PLA plate on which the bent knee of the user is placed, simulating an above-knee amputation. The plate consists of two parts, an anterior and a posterior part for easier printing, joined with a dovetail joint and locked with screws. A 4-hole pattern is positioned on the distal side of the knee-plate for attachment of standard prosthetic components. Medio-lateral and anterior-posterior stability was achieved by

vertical struts extending from the medial, anterior, and lateral side of the knee-plate, creating an open-socket, which can potentially simplify EMG recordings compared with a conventional socket design.

Each strut had a proximal and two distal segments, all of which were hollow with circular cross sections. The proximal segment can slide within the distal segments for continuous height adjustment and the position can be rigidly fixed at the desired height using standard hose clamps. A 92° bend at the distal end of the distal segments allows them to slide into the knee-plate for a \pm 15 mm-width adjustment. This results in medial-lateral dimensions ranging from 136 mm – 166 mm at 230 mm from the knee-plate and from 143 mm – 173 mm at 320 mm from the knee-plate. A 15 mm adjustment in the anterior direction is possible for the anterior strut. The distal segments were fixed inside the knee-plate using screws. A horizontal, posterior strut extends posterior from the kneeplate to provide support to the distal portion of the shin. The proximal segments of the medial, anterior and lateral struts, as well as the posterior strut, had similar designs and were made by a bent 8 mm diameter aluminum tube (AlMgSi0.5), while each distal segment consisted of a 10 mm diameter tube of the same material. Each strut has two supports/strap-attachments which distribute the forces for increased comfort and attach to the straps that stabilize the bypass socket to the limb. Two straps were secured around the thigh with an additional strap on the distal side of the thigh, between the medial and lateral strut to prevent them from bending towards the anterior strut. Two straps were attached around the shin. Padding foam was glued to the surfaces in contact with the user for better comfort. Further instructions, drawings and 3D-models are available at OSF.

B. Evaluation

The prosthetic components were aligned such that the feet were evenly placed in the anterior direction in a manner that felt comfortable and appropriate to the user. The alignment of

. Knee-plate

- placement for the knee

2. Struts

 supports the thigh, with a proximal segment and two distal segments allowing height adjustment

3. Posterior strut

supports the shin

4. Support/strap-attachment

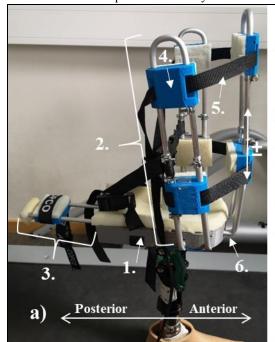
 distributes force for comfortability/ attachment for the straps

5. Strap

- fixates the socket to the thigh

6. Attachment of struts

 slides 15 mm into the knee-plate for width-adjustment, locked with screws



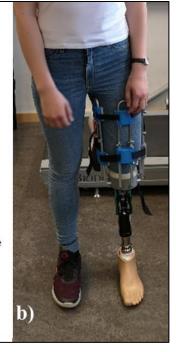


Figure 2: a) Final prototype of the bypass-socket, b) participant 1 for the final evaluation.

P1 is seen in Figure 2b. P1 could walk with two, and one hand as support, but was not able to walk without any support. P2 could walk without support and P3 needed one hand for support but could momentarily walk without it. P1 and P2 walked at 1 - 2 km/h and P3 walked at 2.5 km/h. Instability occurred for all participants with a relative medial movement between the proximal end of the bypass socket and the thigh, and a lateral bending moment of the bypass socket and prosthesis. P2 abducted the hip to compensate for the lateral bending moment and P3 stated problems with controlling the prosthesis as the participant rotated the shin externally during the swing phase. A limping motion was present for all the participants, but the higher speed of P3 resulted in a noticeably less limp compared with the gait at the slower pace. P3, A1, and A3 became sore in the fold of the knee caused by a strap, and P2 and P3 felt pain in the patella due to insufficient padding. For P3, a considerable deflection was present in the dovetail joint of the knee-plate and the struts had difficulty withstanding the lateral bending moment. A3 used the bypass socket after P3, with and without support. During the unsupported ambulation, the participant accidentally fell and landed on the bypass socket. A3 did not sustain any injury from the fall and no signs of failure were observed on the components. The trial was therefore continued using a safety harness. After the trial, the bypass socket was more closely evaluated for damage and during this examination, fractures were observed on both distal bends on the distal segments of the medial strut along with a relative twist between the kneeplate and the medial and lateral struts, and a slight curvature of the anterior strut.

We positioned six pairs of EMG recording electrodes on A1 and successfully recorded extension and flexion of the knee for offline training and during ambulation.

IV. DISCUSSION

A. Evaluation and requirement fulfilments

The required range of use for the bypass socket of 160 cm - 190 cm was fulfilled. P2 was 194 cm and could be fitted with the socket well, implying that the upper limit is greater than required. P1 was 167 cm and thus slightly taller than the lower limit. During the usage, the lengths of the struts were set to 4 cm above their minimum length. This indicates that shorter people should be able to use it as well, fulfilling the range of the user height requirement.

The cause of instability during the tests were due to multiple factors. The participants were naive prosthetic users and did not receive any training prior to the evaluation. Improved stability was observed during the session for each participant. The straps were tightened by hand which resulted in the thigh being firmly attached to the bypass socket during normal stance. During the gait cycle, however, the lateral bending increased the pressure on the thigh and compressed the soft tissue. This created a relative movement which was perceived as instability by the user. The alignment was not conducted by a prosthetist; hence a perfect alignment was not ensured. The prosthetic leg had a non-articulate ankle and a passive, mechanical knee joint which flexed when a moment threshold was surpassed, typically during terminal stance/preswing. As all ambulatory support in the prosthesis was removed when flexed, this moment threshold could cause

insecurity with the naive prosthetic users as they may be unsure when the knee will flex, which may have affected their gait. The spring-assist extension function of the knee did prevent the knee from staying flexed during the swing phase, increasing the risk that the prosthetic foot would be dragged along the ground, particularly during slow ambulation as the knee joint sprang back to the extension phase before the swing phase was completed; reduced risk of this was observed at the higher walking pace for P3. Two methods to prevent this was observed, each causing an unnatural gait behavior: 1) to ensure foot clearance during the swing phase, the users leaned toward the sound leg and raised the contralateral hip in compensation, or 2) users took a shorter step with the prosthesis by finishing the gait cycle during midstance instead of terminal stance, causing a limp. If the prosthesis is not fully extended when the weight is transferred to the prosthesis, the knee joint starts flexing and may cause an accidental fall, which is what happened to participant A3.

The slight curvature that was observed after the test on the proximal segment of the anterior strut indicates plastic deformation of the aluminum tubes. This occurred due to the convex shape of the thigh when the leg is flexed, creating a distance between the vertical, anterior strut and the thigh. When the proximal strap was tightened, the distance was reduced, and the strut was permanently deformed.

It could not be determined with certainty if the fracture of the medial strut was a result from usage by P3, the heaviest of the participants, or if it was due to the fall of A3. The small radius of the 92° angle at the distal end of the distal segments of the struts caused the aluminum tube to buckle when forming the angle during the construction phase, leading to reduced strength of this component and likely a contributing factor to the observed fracture. During the test with P3, the aluminum struts appeared too weak to fully withstand the lateral bending moment, most likely caused by the reduced strength at the buckled segment at the distal bends of the tubes. Considerable deflection of the dovetail joint in the knee-plate, and minor sounds from the plastic under stress, also raised a concern about the durability. As a safety precaution it was therefore recommended that the bypass-socket should not be used without a safety harness and that it should be used with extra caution by users with body mass between 80 kg and 100 kg.

The EMG recordings performed on participant A1 showed that signals could be recorded during usage of the bypass-socket both during non-loadbearing for offline training and during ambulation. The open-socket design allowed accessibility of targeted muscles for electrode placement without disturbance.

B. Recommended design adjustments

To reduce the risk of convex deformation of the anterior strut, it is recommended to increase the diameter of the struts by 2 mm as this would lead to a 110 % increase of the area moment of inertia when increasing from an 8 mm to 10 mm diameter tube, and an increase of 80 % when increasing from a 10 mm to 12 mm diameter tube. The inner dimensions of the 3D-printed support/strap-attachments could also be increased to decrease the distance between the proximal end of the vertical strut and the thigh.

To eliminate the risk of buckling during fabrication of the 92° angle at the distal bends of the distal segments, it is recommended to instead use a pipe elbow (90°) for this feature for improved strength and easier construction. Since the biological knee is slimmer than the thigh, material should be added to the support/strap-attachments to compensate for the 2° reduction of the angle (90° instead of 92°). It is also recommended to print multiple distal and proximal supports with varying inner-dimension for better fit with varying thigh dimensions. CAD-models and other design changes are available at OSF.

V. CONCLUSION

Here, we presented the design and evaluation of an opensource bypass socket for leg prostheses that allows simulation of transfemoral amputation. The height of the bypass socket can be adjusted to fit users between 160 cm – 190 cm tall and the width can be adjusted between 136 mm – 166 mm and 143 mm – 173 mm, at 230 mm and 320 mm from the knee-plate. respectively. We strongly advise to always use a safety harness and extra caution should be observed for users above 80 kg. The bypass's open-socket design allows for wide accessibility of targeted EMG. A pyramid adapter/receiver can be attached on the distal side via a 4-hole pattern for compatibility with prosthetic components. Although improvements can be made, our results indicate that this bypass socket can be used by researchers for initial evaluations of lower limb prosthetic control and devices.

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