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Publication date
2014

Document Version
Final published version

Published in
Proceedings of the Myoelectric Controls/Powered Prosthetics Symposium, MEC '14

Citation (APA)
Hichert, M., Plettenburg, D., & Vardy, A. (2014). A need for a more user-centered design in body powered prostheses. In W. Will, & E. Scheme (Eds.), *Proceedings of the Myoelectric Controls/Powered Prosthetics Symposium, MEC '14: Redefining the Norm* (pp. 88-92). University of New Brunswick.

A NEED FOR A MORE USER-CENTERED DESIGN IN BODY POWERED PROSTHESES

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INTRODUCTION

Users of body powered prostheses (BPP) complain about too high operating forces, leading to pain and/or fatigue during or after prosthetic operation. In the worst case nerve and vessel damage can occur [1, 2], leading to non-use of prostheses. Smit et al. investigated cable forces and displacements required to operate commercially available voluntary closing and voluntary opening hands and hooks [3, 4]. The capacities of prosthetic users to operate these terminal devices remain unknown. Taylor reported in 1954 forces and displacements measured with 50 ‘normal’ subjects for arm flexion (280±24 N; 5.3±1.0 cm), shrug (270±106 N; 5.7±1.5 cm) and arm extension (251±29 N; 5.8±1.7 cm) (mean±SD) [5]. Unfortunately, the measurement procedure is unclear. Moreover, the study reported forces and displacements from isolated movements instead of combinations of movements typically used for BPP operation. Our recent pilot experiments on 10 male subjects (28±2 years old) also without arm defects using a BPP harness revealed average values of 475 N and a peak value of 970 N for one subject. Although these values are higher, it remains unclear if these force levels are sufficient to comfortably operate a BPP, or too low leading to non-use. Importantly, knowing the capacities and limitations of prosthetic users will aid in choosing and redesigning future BPPs to prevent non-use.

The goal of this study is to investigate the maximum cable operating forces prosthetic users can develop on the control cable. These maximum forces will be compared to the cable forces required to operate commercially available BPP based on the measurements of Smit et al. [3, 4]. Furthermore, this study addresses the question, whether it is possible to predict maximum cable operation forces by the anthropometric data of users in terms of shoulder width, upper arm length and upper arm circumference (serving as a measure of muscle volume), facilitating the prosthesis fitting procedure and preventing the need for costly measurement equipment.

METHOD

This study was approved by the medical ethical committee of University Medical Centre Groningen (UMCG). The subjects were recruited from University Medical Centre Groningen, Erasmus Medical Centre, Rotterdam, and the rehabilitation institute De Hoogstraat, Utrecht.

Subjects

In this study 25 adults (13 females and 12 males, age: 49±13 years, height: 175±8 cm, weight: 75±14 kg, mean±SD) with a trans-radial deficiency participated. All participants were free of neurological, muscle, joint or motor control problems concerning the upper extremity or the torso (exclusion criteria). A total of 16 participants had a left deficiency, and 9 had a right deficiency, 15 had a congenital defect, and 13 had experience with BPP.

Equipment

Anthropometric data

The subjects shoulder width, upper arm length and remaining lower arm length was measured with an anthropometer (GPM - Model 101). For measuring the upper arm circumference a sewing tape measure was used. The subjects’ length was measured by a tape measure connected to the wall. Body weight was taken by Soenle Scale.

Maximum force measurements

For measuring maximum cable operation forces, a prosthetic simulator was used (Figure 1), consisting of a thermoplastic shell with a 3.5 mm neoprene cover at the inside. With Velcro straps the simulator can be fitted on the hard socket of the subject’s prosthesis. A 1.5 mm steel cable was used as operating cable running from the prosthetic simulator to the shoulder harness interrupted by a force sensor (S-Beam load cell ZFA 100kg). Cable excursion was disabled in this setup. The shoulder harness was adjustable to the subject’s dimensions. The force sensor was amplified (Scaime, CPJ) and sampled (NI USB-6008), and finally stored using a custom LabVIEW programme (LabVIEW 2012 version). Cable forces were recorded with a sampling rate of 333 Hz.

Procedure

Prior to the measurements subjects were requested to read the information letter and sign an informed consent form. Personal data (gender, age, dominant and amputated side, experience in prosthetic use, currently and previously used prostheses, cause of deficiency) were recorded and body measures (height, weight, shoulder width, upper arm length, remaining lower arm length, upper arm circumference affected and sound side) were taken. Anthropometric data were taken following the instructions of the NASA Reference Publication 1024 [6]. Shoulder width was taken according to "103. Biacromial Breadth", upper arm length of amputated side according to "751. Shoulder-Elbow Length", upper arm circumference according to "113. Biceps Circumference, Relaxed", remaining lower arm length according to "381. Forearm-Hand Length", where the fingertips are represented by the far end of the subjects' stump.

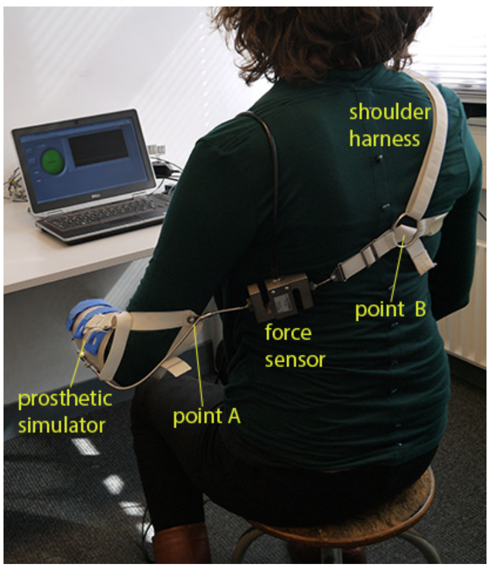

Figure 1: Measurement set-up.

Fit of equipment

A prosthetic simulator was connected to the subjects' prosthesis. For two subjects (one male and one female), which did not possess an own prosthesis, the simulator was placed on a temporary WILMER Open Fitting [7]. For two subjects (one male and one female) the simulator was placed on the remaining arm. The straps from the prosthetic simulator were fitted in a way that point A (Figure 1) was on approximately 1/3 of the upper arm length above the elbow. The harness ring was placed lateral to the spinal cord on the affected side at the level of the shoulder blade (point B in Figure 1). When the subject was standing upright, raising the sound arm to a 90 degree angle with the thorax, neither tension nor sag of the control cable occurred.

The end of the control cable was fixated to the prosthetic simulator and cable displacement was disabled. Once the equipment was fitted, the subject was instructed to use shoulder protraction of the sound side, humeral abduction and anteflexion on the affected side simultaneously to create cable forces. Next, after the measurement program was started by the experimenter, the subject delivered his/her maximal force level, i.e. cable force for 3 seconds. This procedure was repeated 3 times.

Data analysis

Data analysis was performed using Matlab (version 2013b), inspected visually and the maximum over the three trials was determined.

The upper-arm circumferences of 5 subjects with a BMI (weight [kg]/ (height [cm])^2) higher than 30 kg/cm^2 were removed from the analysis as their data would almost certainly be affected by fat depositions.

Statistics

For statistical analysis SPSS version 20 was used, and a significance level of α=0.05 was maintained. A three-way ANOVA was used to evaluate the effects of *gender* (male vs. female), *experience* (prior BBP experience vs. no BPP experience), *and defect type* (congenital vs. other causes). Correlations between maxima and anthropometric data were analysed using the Pearson correlation coefficient.

RESULTS

The maximum cable operation force averaged over all subjects was 267±123 N. The maxima deviated from 87 to 538 N over all subjects resulting in a range of 451 N. Forces created by female subjects (194±86 N) were significantly lower than those of males (346±108 N) ($F_{1,21}$=10,647, *p*=0.004). No significant effect of experience was found, experienced BPP-users (285±106 N), non-experienced BPP-users (247±141 N) ($F_{1,21}$=2,313, *p*=0,143). Finally, maxima of subjects with a congenital deficiency (222±76 N) showed no significant difference compared to the maxima of subjects with acquired arm defects (334±151 N) ($F_{1,21}$=3,459, *p*=0.077). However, a striking difference in the range of maximum delivered forces must be reported (260 N for subjects with congenital arm defects versus 451 N for subjects with an acquired arm defect).

These maximum operating forces of potential users were compared to the required operation forces for commercially available voluntary opening (VO) BPP, when realizing a hand opening of 50 mm and voluntary closing (VC) BPP, when creating a pinch force of 15 N [3,4].

Tables 1 and 2 show the number (percentage) of subjects which are able to operate a certain prosthesis with their full strength. Monod reported that the value for the critical force, the force that humans can conduct without fatigue effects during continuous isometric contractions, lies between

15 and 20% of the maximum voluntary contraction [8]. Hence, Tables 1 and 2 also show the number (percentage) of subjects, which are able to operate the devices with 20% of the measured maxima. Summarized, Tables 1 and 2 show, that 3 out of the 7 VC and 2 out of the 14 VO devices cannot be operated by all subjects with the highest force they can create on the control cable. When considering the non-fatigue level at 20% of the maximum operation force, none of the VC and VO devices can be operated by all subjects.

Shoulder width, upper arm length, upper arm circumference of the affected and the sound side were correlated with the maximum operation forces of subjects. Pearson correlation coefficients are shown in Table 3. The correlation coefficients were found to be significant for shoulder width, upper arm circumference of the affected and the sound side. Additionally, the correlation coefficients show a positive linear trend. However, the relatively low coefficients represent a large deviation of the correlated data points.

Table 1: Subjects able to operate voluntary closing BPP

VC Prosthesis	required cable force for a 15 N pinch [3]	subjects able to create required cable force	subjects able to create required cable force with 20% of max. force
	N (mean±std)	number of subjects (percentage of subjects)	number of subjects (percentage of subjects)
Hosmer APRL hand, 52541 (L) size 8	61±0.6	25 (100%)	9 (36%)
Hosmer APRL hook, 52601	62±0.0	25 (100%)	8 (32%)
Hosmer soft hand, 61794 (R) size 7 3/4	131±0.7	22 (88%)	0 (0%)
Otto Bock, 8K24 (L) size 7 3/4, frame	78±0.3	25 (100%)	3 (12%)
Otto Bock, 8K24 (L), size 7 3/4, frame and inner glove	90±0.9	24 (96%)	3 (12%)
Otto Bock, 8K24 (L) size 7 3/4, frame + inner glove, and cosmetic glove	98±0.5	24 (96%)	2 (8%)
TRS hook, Grip 2S	33±0.2	25 (100%)	19 (76%)

Table 2: Subjects able to operate voluntary opening BPP

VO Prosthesis		required cable force for 50 mm prehensor opening [4]	subjects able to create required cable force	subjects able to create required cable force with 20% of max. force
		N (mean±std)	number of subjects (percentage of subjects)	number of subjects (percentage of subjects)
Hosmer Model 5XA Hook	1 band	25 ± 0.3	25 (100%)	22 (88%)
	2 bands	50 ± 0.2	25 (100%)	14 (56%)
	3 bands	71 ± 0.2	25 (100%)	7 (28%)
Hosmer Sierra 2 Load VO Hook	Set. 1	40 ± 0.3	25 (100%)	15 (60%)
	Set. 2	82 ± 0.1	25 (100%)	3 (12%)
RSL Steeper Carbon Gripper	Set. 1	43 ± 0.3	25 (100%)	14 (56%)
	Set.2	48 ± 0.1	25 (100%)	14 (56%)
Otto Bock Model 10A60 Hook (2 × 2 Springs)	Set. 1	32 ± 0.5	25 (100%)	20 (80%)
	Set. 2	94 ± 0.3	24 (96%)	2 (8%)
Hosmer BeckerImperial Hand (ungloved)		63 ± 0.4	25 (100%)	8 (32%)
Hosmer Sierra VO Hand	Gloved	70 ± 0.6	25 (100%)	7 (28%)
Hosmer Soft VO Hand	Gloved	104 ± 0.9	23 (92%)	1 (4%)
RSL Steeper VO Hand	Gloved	81 ± 0.7	25 (100%)	3 (12%)
Otto Bock VO Hand	Gloved	79 ± 0.5	25 (100%)	3 (12%)

Table 3: Pearson correlation coefficient

		maximum force
shoulder width	Pearson correlation	0,594**
	Sig. (2-tailed)	0,002
	N	25
upper arm length	Pearson correlation	0,232
	Sig. (2-tailed)	0,264
	N	25
upper arm circumference sound arm	Pearson correlation	0,543*
	Sig. (2-tailed)	0,013
	N	20
upper arm circumference affected arm	Pearson correlation	0,449*
	Sig. (2-tailed)	0,047
	N	20

*.Correlation is significant at the 0.05 level (2-tailed)
**.Correlation is significant at the 0.01 level (2-tailed)

DISCUSSION

In this study 25 subjects with a trans-radial deficiency participated. On average they created a maximum cable force of 267±123 N. Males created significant higher forces than females ($F_{1,21}$=10,647, p=0.004). No significant differences were found for experienced BPP-users versus non-experienced BPP-users ($F_{1,21}$=2,313, p=0,143). In addition, forces created by subjects with a congenital arm defect versus by subjects with acquired arm defects showed no significant differences ($F_{1,21}$=3,459, p=0.077). Comparing these results to the study of Taylor (arm flexion (280±24 N; 5.3±1.0 cm), shrug (270±106 N; 5.7±1.5 cm) and arm extension (251±29 N; 5.8±1.7 cm)) the order of magnitude of the maxima is the same, although isolated movements of 'normal' subjects were measured [5]. It might be that the increase in length and strength over the past 60 years is compensated by the fact that isolated movements of 'normal' subjects were measured or there was never a difference between subjects with versus without arm deficiency. In that case the trial experiments as mentioned earlier are not representative for a large population.

The results of Table 1 and 2 showed that 3 out of the 7 VC devices and 2 out of the 14 VO devices cannot be operated by all 25 users with the exertion of their full capacities. None of the devices can be operated when correcting the subject's maximum forces with a fatigue level (20% of the maximum force). This represents the poor match between user capacities and user demands the prosthetic devices offer. Ideally, the prosthesis must be operated without pain nor fatigue [1, 2]. Is seems that the user demands have not been heard the past 25 years [4].

Note that estimations of fatigue presented in Table 1 and 2 are based on theoretical values of Monod [8], who reported a critical force between 15 and 20% of the MVC, thus with 20% the conservative value was taken. Furthermore, the required cable operation forces are only representing the prehensors and are not taking into account any friction losses due to the Bowden cable transmission. The reported efficiencies of Bowden cables in BPP-use can decrease to 60%, depending on the curvature of the cable and the material the cable is made of [9]. Even so, the pinch force level of 15 N set as a measurement requirement for voluntary closing prehensors in Smit and Plettenburg's study is only an estimation [3].

This study addressed the possibility of predicting maximum cable operation forces by the anthropometric data of users in terms of shoulder width, upper arm length, and upper arm circumference of both arms. Significant Pearson correlation coefficients were found for shoulder width, upper arm length, upper arm circumference of affected and sound arm. Shoulder width and upper arm circumference seem to have a predicting quality, even though it is a weak one. The exact maximum cable operation force cannot be predicted for a specific user by taking the anthropometric data, but due to the dimensions of shoulder width and upper arm circumference the user can at least be categorized (e.g. in S, M, L, XL). However, the upper arm circumference, as a measure of muscle volume, cannot be applied for users where large fat deposits interfere with the muscle estimate. As such, participants with a BMI > 30 kg/cm^2 were excluded from the analysis. The significant correlations are a useful insight for designing prostheses in the future. The CPO may base the choice of device based solely on an relatively easy anthropometric measurement.

Study limitations & recommendations

This study did not evaluate the maximum cable excursions BPP-users can achieve. Additionally, the isolated operation movements have not been measured. A future study should address these questions.

Before exerting the maximum forces on the cable the subjects did not have any training. They were only instructed in which movements they should perform. This might partly explain the deviations in maxima. As a result of training, the maximum forces might be even higher. However, no significant differences were found between experienced and non-experienced BPP-users.

CONCLUSIONS

The goal of this study was to investigate the maximum operating forces prosthetic users can create on the control cable. The created maximum forces were compared with the cable forces required to operate commercially available BPP based on the measurements of Smit et al [3,4]. Furthermore, the question whether it is possible to predict user capacities in terms of maximum cable operation forces by the anthropometric data of users was addressed in this study.

On average cable forces of 267±123 N were created. With the measured maxima 3 out of the 7 VC devices and 2 out of the 14 VO devices could not be operated by all 25 subjects. When correcting the measured cable forces for fatigue effects during continuous operation (20% of the maximum force) none of the VC and VO devices can be operated by all 25 potential users. Significant Pearson correlation coefficients for shoulder width, upper arm circumference of affected and sound side versus the maximum cable operation force show a positive linear trend. However, with the anthropometric data of users it is not possible to predict maximum forces, but for a categorization of users strength the anthropometric data seems to be an appropriate measure.

Summarized, this study proves quantitatively that the forces commercially available BPP require are too high, with the result of not being applicable for all prosthetic users. The provided data helps us to understand how a BPP must be designed and serves as design requirements for new *user-centred* prosthesis design.

ACKNOWLEGEMENTS

The work presented in this paper is part of on-going research on physiological prosthesis control systems at Delft University of Technology, partly funded by Fonds NutsOHRA (grant no. 1101-049). The author would like to thank colleagues from UMCG, Erasmus MC and De Hoogstraat for help with subject-recruitment.

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