Effectiveness of blinding research subjects in limb orthotic and prosthetic research

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Figure 1: Opaque glasses blinding condition

Figure 2: Cardboard and opaque glasses condition

Figure 3: Cardboard blinding condition

Figure 4: No blinding condition

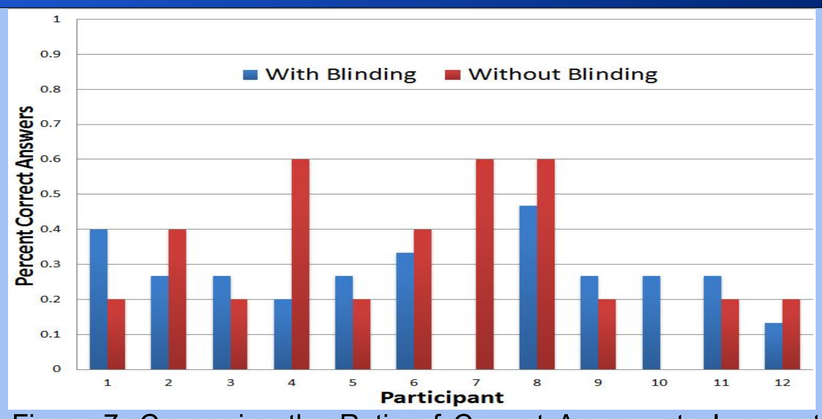

Figure 7: Comparing the Ratio of Correct Answers to Incorrect Answers with and without Blinding for Each Participant

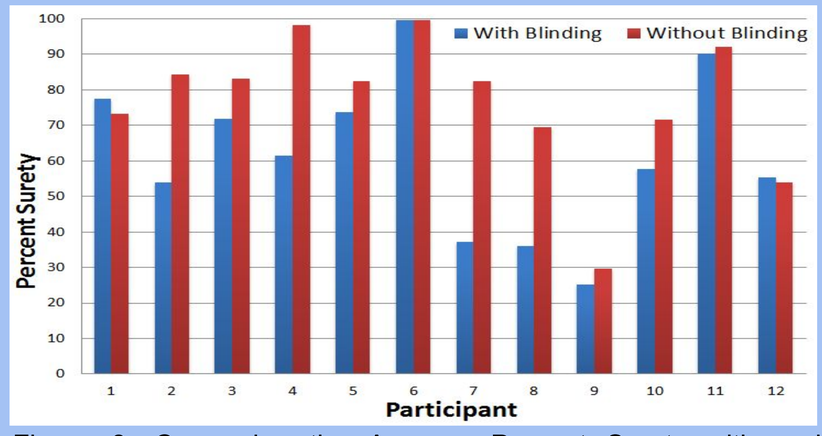

Figure 8: Comparing the Average Percent Surety with and without Blinding for Each Participant

Abstract

Blinding of research subjects (concealing the group assignment) is one important aspect of a good trial design and adds credibility to research because it eliminates biases [1]. Previous studies have used different methods to obscure the Prosthetic and Orthotic (P&O) devices, but limitations arose. For example, some studies used socks to cover the prostheses [2,3], which could have added a safety risk to the protocol and limited the function of the device.

There are gaps in the knowledge of how to best blind participants in limb P&O research studies. Hence, the purpose of this study is to address how people with limb prostheses can be most effectively blinded to a typical research intervention. It was hypothesized that the accuracy and surety of subjects' assessment of the intervention would decrease as the effectiveness of blinding was increased.

Methods

This study was approved by the University of Pittsburgh's IRB. A sample was recruited consisting of 12 subjects who were 18+ years old with lower limb loss who used a prosthesis for at least 6 months and could walk across a room 20 times with breaks in between. Exclusion criteria included having a visual impairment that would prevent observation of the alignment processes, having an acute health problem that prevents proper prosthesis use, or using a prosthesis that is not easily modified for alignment adjustments.

In the protocol, each subject completed 20 randomized trials (Table 1) to include 4 different blinding levels (Figures 1-4) and 5 different alignment perturbations.

Table 1: Randomized list of 20 trials

1	Cardboard Blinding, Supination
2	Cardboard and Glasses, Fake
3	No Blinding, Pronation
4	Cardboard and Glasses, Pronation
5	Cardboard Blinding, Plantar Flexion
6	Glasses Blinding, Plantar Flexion
7	No Blinding, Plantar Flexion
8	Cardboard Blinding, Fake
9	Cardboard and Glasses, Dorsiflexion
10	Cardboard and Glasses, Supination
11	Glasses Blinding, Fake
12	Cardboard Blinding, Dorsiflexion
13	Glasses Blinding, Supination
14	No Blinding, Dorsiflexion
15	No Blinding, Supination
16	No Blinding, Fake
17	Glasses Blinding, Pronation
18	Glasses Blinding, Dorsiflexion
19	Cardboard Blinding, Pronation
20	Cardboard and Glasses, Plantar Flexion

After a trial was completed, all blinding was removed and the participants performed the number of standing and walking trials required to come to an assessment of the alignment change. Participants were then given the survey in Figure 5.

The correctness and surety values for a given trial were combined into one value between -1 and 1. If the answer was correct, the combined value was positive, and if the answer was incorrect, the combined value was negative. The surety percentage was used as the decimal value. With the significant alpha of 0.05, repeated measures analysis of variance (RMANOVA) was used to analyze the main effects of blinding and alignment.

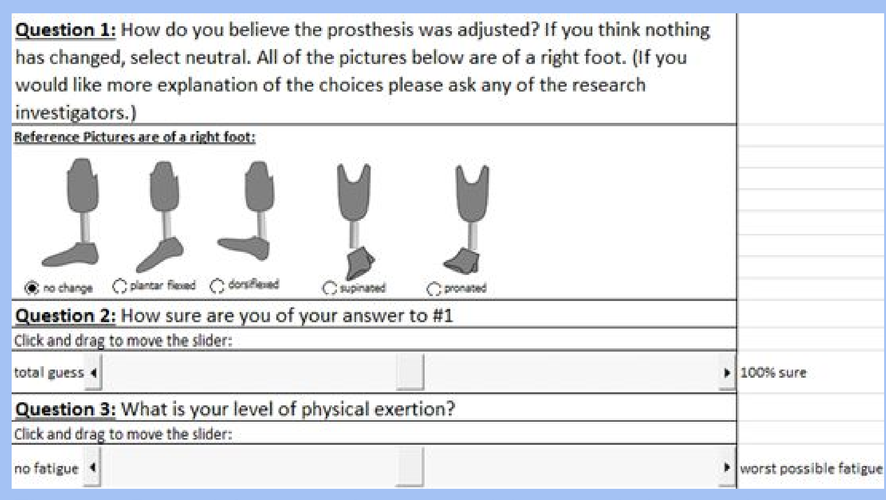

Figure 5: Post-trial survey given to participants administered using a touch screen laptop

Results

A one tailed, independent samples t-test compared the combined values of correctness and surety in the blinding conditions against the conditions with no blinding. The means (-0.259 for blinding conditions and -0.310 for the no blinding conditions) were not found to be significantly different (p=0.233). Similarly, RMANOVA was used to analyze the surety values from 1-100. It was found that blinding was significant (p=0.009) and alignment was not significant (p=0.151). However, there was a significant difference between no blinding and all other blinding conditions (Figure 6).

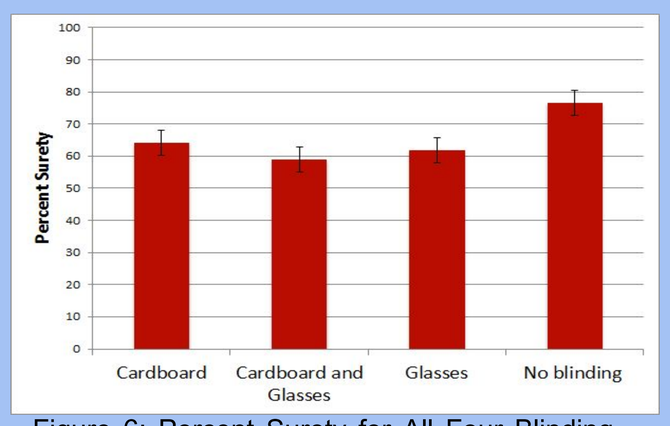

Figure 6: Percent Surety for All Four Blinding Conditions with Standard Error Bars

Discussion and Conclusion

The main effect of blinding had no significant effect on participant accuracy (Figure 7), so the hypothesis was not supported. However, participant surety was decreased by blinding (Figure 8). For this reason, any of these blinding methods could be used to limit the confidence that an individual has in guessing their group assignment.

It is possible that the act of not talking to the participants about which trial was occurring was enough to blind them from the alignment change.

This is a simple adjustment that could be made to standard P&O research protocols in order to largely blind the participants.

When practitioners tell their patients exactly how they change the prosthesis and the reasons they think it will help, the patients probably develop biases towards the adjustments being made. For this reason, it may be useful for clinicians to limit what they tell their patients about the changes they are making until the patient has had a chance to test it.

Acknowledgements

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