



EFFECTIVE SUBJECT BLINDING IN P&O RESEARCH

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INTRODUCTION

Subject blinding, concealing the group assignment from research participants, is an important element of sound research design (Schulz, et al, 2002), yet it is not commonly used in Prosthetic and Orthotic (P&O) research. This is partly due to the nature of typical research interventions, which – unlike, i.e., the administering of a (placebo) pill in a drug study – are substantially more obvious to the study participant. Previously described methods used to blind subjects (Orendurff, 2013) have many limitations, including the unintentional alteration of essential device properties that are brought about by adding cover materials.

Biases can also be problematic in the clinic, when a P&O device is being optimized by trying out different settings or parts. Ideally, the patient, whose perception plays an important role in informing the eventual decision by the practitioner, would base his or her feedback solely on the relevant functional effects and be unaffected by the optical appearance or any other bias that may be present without blinding.

The purpose of this study was to investigate the effect that vision blinding has on how lower-limb prosthesis users assess alignment changes to their prosthetic ankle. It was hypothesized that obscuring their vision will reduce the accuracy and confidence with which patients recognize such alignment changes.

METHOD

Subjects: Persons with an endoskeletal lower limb prosthesis, who were able to walk without aid and whose vision was not severely impaired, were recruited for this IRB approved study. A sample size of 12 was determined by power analysis, assuming an effect size of 0.8 as vision accounts for 80% of all sensory input.

Apparatus: Subjects were blinded by opaque glasses, a cardboard shield, a combination of both, or not at all. After each trial, they were asked to report the perceived alignment change as well as how sure they were of their assessment.

Procedures: Five ankle alignment perturbations (changes by 1.5 degrees in plantar, dorsiflexion, supination, or pronation, as well as a pretend change) were combined with the four blinding conditions for a total of $5 \times 4 = 20$ trials. The sequence of trials was randomized for each subject, and a credentialed prosthetist performed all the changes. Subjects were asked to determine the occurred alignment change by any means possible, including standing or walking with the prosthesis or observing the process. Between perturbations, the initial alignment was reconstituted.

Data Analysis: A one-tailed paired t-test was conducted to determine the main effect of blinding on accuracy and surety of assessments. Secondary analyses included ANOVA with alignment direction and blinding method as independent variables. A critical alpha of 0.05 was determined prior to analysis.

RESULTS

The 12 participants were all male, on average 54 years old, prosthesis users for 10 years, and slightly above average in mobility with a 63% rating in the mobility score (PLUS-M).

The t-test indicated no significant effect of blinding on the accuracy of alignment assessment ($p=0.233$). However, subjects' confidence in their assessment (Figure 1) decreased significantly with blinding ($p=0.009$).

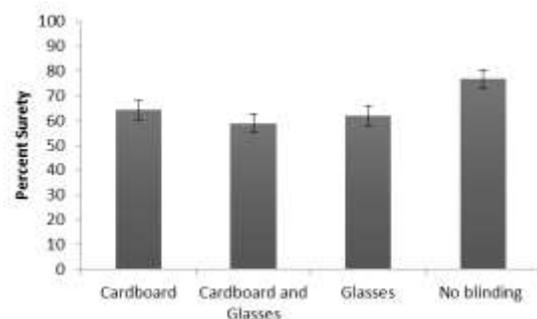


Figure 1: Average assessment confidence in the four different blinding conditions (n=12).

The direction of alignment change had a significant effect on a surety-weighted accuracy score ($p=0.039$).

DISCUSSION

Somewhat surprisingly, vision blinding seems to have no effect on patients' accuracy of detecting an intervention. Many of our subjects did not take advantage of the opportunity to observe alignment changes when not blinded or they misinterpreted their observations. Some tried to elicit the information by asking the investigators.

CONCLUSION

Vision blinding may be unnecessary in P&O research.

CLINICAL APPLICATIONS

P&O practitioners are conditioned to communicate any device alterations to their patients. This may introduce bias when patient feedback is solicited.

REFERENCES

Schulz, et al. The Lancet 359.9307 (2002): 696-700.
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