# CHANGES IN PRESSURE DISTRIBUTED WITH ALIGNMENT CHANGES

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## INTRODUCTION

There is general consensus in the prosthetic community that prosthetic alignment is directly related to clinical outcomes. There is, however, not enough clinical outcomes data to adequately support and understand stresses experienced at the residual limb (Al-Fakih, 2016). Such studies can advance prosthetic socket design, and can further help meet the demand for evidence-based care and payment justification by health care payers.

Our hypothesis is that changes in the alignment of distal componentry relative to the socket will result in a significant difference in socket forces applied to the residual limb, functional outcomes measures, and Socket Comfort Score (SCS).

## METHOD

Motion sensors and thin force sensors were integrated into an adjustable trans-tibial socket design. Force sensors were attached to the socket's distal end, along the long axis of the socket, and at the proximal aspect of the socket. Force sensors mapped the pressure distribution within the socket and motion sensors coupled to the socket were used to analyze socket movement. Data was recorded while the subjects performed subsequent functional tests.

A convenience sample of 10 randomly selected subjects were fit with and aligned in a subject and practitioner perceived neutral fit and alignment. From this neutral alignment, distal componentry alignment was shifted/offset lateral, medial, anterior, and posterior a specified amount (20 mm / 0.79 Inches) for offset variables. L-test, two-minute walk test, and FSST functional outcomes measures were conducted at these variables. Subjects also recorded a SCS at the conclusion of functional outcomes measures at each variable.

## RESULTS

Data analysis across different users showed statistically significant trends. Compared to the neutral alignment position, greater peak pressures occurred in the proximal-medial and lateral-distal aspects of the socket when alignment was shifted medially. When shifted laterally, greater peak pressures occurred in the proximal-lateral and medial-distal aspects of the socket. When shifted anteriorly, greater peak pressures occurred in the proximal-anterior and distal-posterior aspects of the socket. When shifted posteriorly, greater peak pressures occurred in the proximal-posterior and distal-anterior aspects of the socket.

Functional outcomes measures and SCS were best at the user and prosthetist perceived neutral alignment. Similarly, excessive varus/valgus and flexion/-extension movements were minimized at the neutral position.

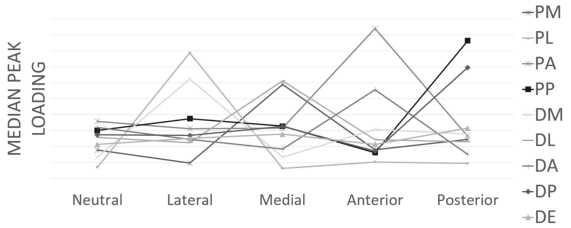


Figure 1: Mean peak pressures during functional outcomes measures for the given variables.

## DISCUSSION

Altering the alignment of distal componentry relative to the socket caused a significant difference in subject outcomes. The regional location of increased and decreased peak pressures was correlated directly with the direction of offset from a neutral alignment. Motion sensors within the socket also showed significant differences among variable conditions. Compared to neutral alignment, relative motion was significantly higher for all other variables and the direction of increased motion was different for each condition.

Results suggest that measurements of regionally specific socket pressures applied to the residual limb can aid in determination of an optimal alignment. More specifically, regional profiling of socket pressures applied to the residual limb can help guide proper prosthetic alignment by giving specific recommendations on the direction and magnitude of alignment shift needed to reduce peak pressures and improve outcomes.

Functional outcome tests show reductions in both biomechanical control and functional capacity under all variables that deviated from neutral alignment. SCS results consistently reported less socket comfort with all variables that deviated from neutral alignment.

## CONCLUSION

There are evident correlations among alignment, distribution of forces on the residual limb, functional outcomes, and patient perception. Future studies will be directed to increasing the number of subjects tested to further validate this correlation.

## CLINICAL APPLICATIONS

Data that is collected from socket forces applied to the residual limb can be used to inform optimal prosthetic alignment. Results of this study and related future studies can be used to validate the need and billing for alignable prostheses and the need for appropriately aligned prostheses.

## REFERENCES

Al-Fakih, Ebrahim A., Noor Azuan Abu Osman, and Faisal Rafiq Mahmad Adikan. "Techniques for Interface Stress Measurements within Prosthetic Sockets of Transtibial Amputees: A Review of the Past 50 Years of Research." Sensors 16.7 (2016): 1119.

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