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Title
Design & Evaluation of a Passive, Self-aligning Ankle Prosthesis

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Summary
We developed a passive, self-aligning ankle that mimics the non-linear stiffness of a natural ankle in all three planes of motion. Clinical evaluations indicate that the novel ankle can reduce the effect of misalignment by lowering socket moment.

Introduction/ basics
Transtibial prosthesis fitting process involves both static and dynamic alignment between the foot and pylon. This is time consuming and mostly subjective process with significant patient to patient variability. The “optimal” alignment may vary between prosthetists, between visits with the same prosthetist, and with changes in the amputee’s perception during alignment. Any misalignment increases forces and moments on the residual limb, resulting in discomfort and pain in short term. Lack of symmetry and balance as well as lower push-off energy increase the metabolic work and compel the patients to adjust gait over time. Longer term problems of misalignment are chronic pain in the upper and lower limbs, muscle atrophy and osteoarthritis. The objective of this study was to implement ‘self-alignment’ in an ankle prosthesis so that the residual limb pressure does not increase even under extreme misalignment. Self-alignment is also critical for walking on slopes and turns.

Material method; implementation/ process
The approach for this study was to achieve six degrees of freedom with non-linear compliance mimicking the natural ankle. Finite element method was used to develop detailed mechanics of the ankle prosthesis. IRB approved clinical evaluation was performed on 7 subjects, with both aligned and misaligned (22 mm misalignment in anterior, posterior, lateral and/or medial directions). The subjects walked at self-selected speeds - wearing their own sockets. A size- and weight-matched rigid ankle was used as the ‘control’ setup. Level ground tests

recorded spatio-temporal variables using the instrumented walk-way with spatio-temporal sensors walkway. Socket forces and moments in all 3 planes of motion were recorded with a commercially available 6 degrees of freedom load cell load. Five of the subjects also returned for a second visit and completed advanced ambulation tests, including a 6-minute walk test, figure of 8 walk test, four-square step test, stair ascent/descent, and slope ascent/descent.

Results

Ankle Design: Figure 1 shows the outcome of computational modeling. This design was able to modulate the ankle rotational stiffness that mimicked the angle-moment curve of a natural ankle. Prototypes made of Titanium and Aluminum alloys successfully underwent the ISO 10328 fatigue loading tests of 3 million cycles.

Figure 1. Finite Element Analysis of the self-aligning ankle for P6 loading in condition 1 (ISO 10328).

For level ground and straight path walking, the spatio-temporal parameters (such as normalized velocity, step length differential, base of support and stance as gait cycle percentage) deteriorated as 22 mm misalignment was introduced. However, under the same misalignment, the self-aligning ankle improved these parameters back to closely match the values obtained with a dynamically aligned control prosthesis. This reflects the desired characteristics of a self-aligning ankle. Similar trends were observed in the socket moments in the sagittal plane. The non-linear stiffness increase after weight acceptance allows the ankle to lower the socket moment for both the positive (Figure 2) and negative peak sagittal moment values ($p = 0.001$). On slopes and turns, the self-aligning ankle enabled better foot flat and continued to lower the socket moments.

Figure 2. Average positive peak sagittal plane socket moment.

Discussion/ conclusion; conclusion for the practice

The key aspect of the novel ankle prosthesis design is an optimally compliant, six degrees of freedom, planar spring that allows rotation of the ankle before weight acceptance. This enables self-alignment without imposing large socket moments even for 22 mm intentional misalignment between the foot and the pylon, or the misalignment arising from the slopes, stairs or turns. Non-linear stiffness increase after the weight acceptance allows the ankle to generate sufficient moments in the sagittal plane for normal walking. The findings will justify further clinical research and commercialization of a self-aligning ankle prosthesis for lower-limb amputees.

References

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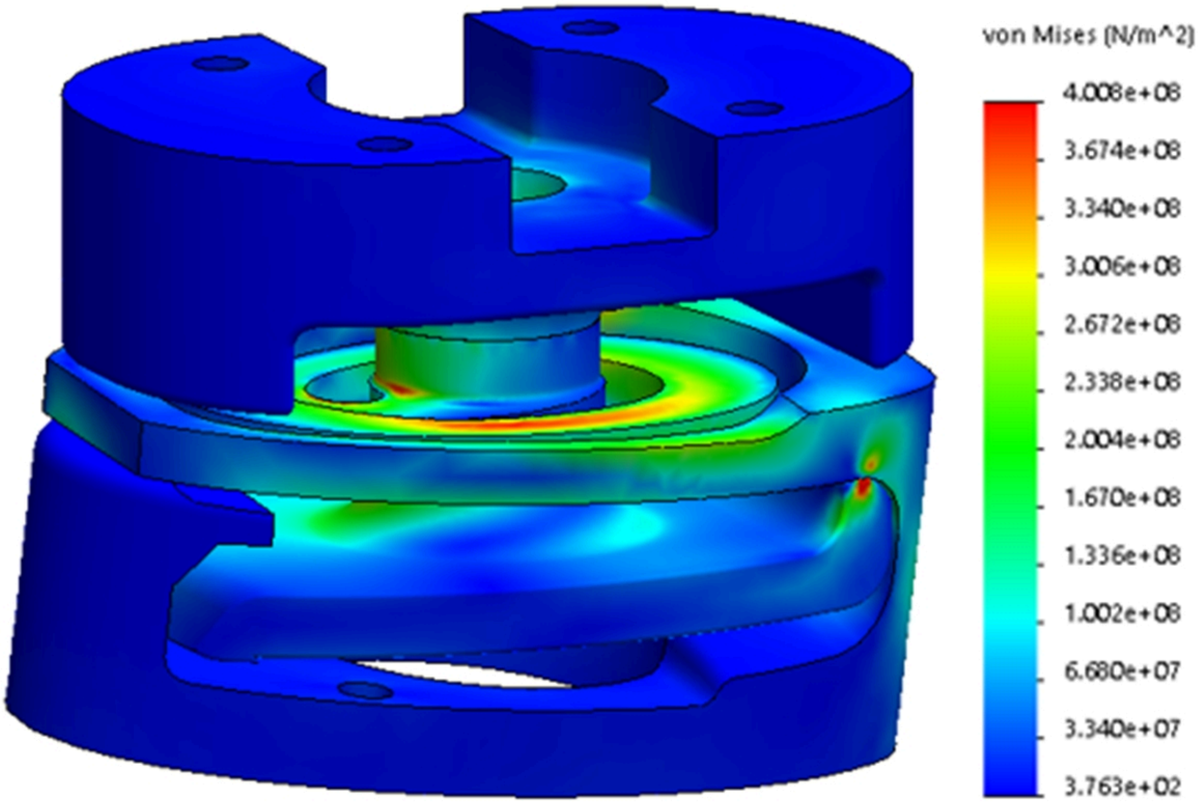
Image: Figure1_201.jpg



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