Analysis of Bearing System in Controlled Passive Energy Management (CEPM) Prosthetic Foot

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Synopsis
Since its invention, the Niagara foot model 2 has undergone 21 versions in preparation for large scale release. With a looming mass production run, the final problems with the model 2 are being addressed, and lessons learned are being compiled for an upcoming third model. Because the Niagara Foot is an injection-molded plastic component, it is not viable to change design aspects without permanently modifying the molding tool. Therefore, proposed design changes for M2 and design features for M3 must be based on careful review of current performance. Several ideas have been generated and modeled, with the most promising being optimization of a Controlled Passive Energy Management (CEPM) feature.

Introduction
The Niagara Foot is a low cost performance foot intended to restore mobility and quality of life to a variety of demographics, notably low income regions. It was designed for manufacturability, customizability and durability. One feature, dubbed “Controlled Passive Energy Management (CEPM)” is being developed to not only tune the force displacement characteristics, but also the rollover sensation that patients experience. The CPEM is comprised of a bearing surface and twin protrusions known as “horns”. Where most energy management in prosthetics is performed by means of a spring component, opportunity for passive management of pre-existing elastic components permits a more customizable user experience without extra system complexity. A Nylon 6,6 bearing was added to prevent noise generation, however wear still occurs on the horns throughout the foot’s lifecycle.

Methods and Results
A literature review and questionnaires were used to generate a list of expected and quality features as defined by the Kano system for different user groups. The foot was conceptually divided into geometric regions and each of these was subdivided into a series of engineering variables. These were used to construct a quality function deployment, which was weighted based on data from past experimentation. The quality function deployment showed that the most important features to review were the toe material quality, heel sagittal geometry and CPEM sagittal geometry. The toe material quality has been addressed and is currently being tested, and after thorough review and patient input the heel geometry was left in its current configuration. The CPEM, though functioning, was deemed non-optimal, and thus the design review was focused on the sagittal geometry.

An area of concern was the fact that the bolt hole that connects the foot to its adaptor is located anteriorly to the point of contact in the CPEM. This causes a significant rise in both the moment in the top plate and a very large force in the CPEM itself.

<table>
<thead>
<tr>
<th></th>
<th>Current Configuration</th>
<th>Horns moved 10mm anteriorly</th>
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<tbody>
<tr>
<td>Vertical force in C spring</td>
<td>2601N</td>
<td>1849N</td>
</tr>
<tr>
<td>Vertical force against horns</td>
<td>3756N</td>
<td>3005N</td>
</tr>
<tr>
<td>Peak Moment</td>
<td>104N*m</td>
<td>92N*m</td>
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Video footage and contact film was then used to find both the contact area in the CPEM (250mm²) and the relative velocity between the horns and the bearing surface (6.35mm/s). This was then used in conjunction with the static forces to calculate the pressure velocity (PV) values of the bearing interface. It was found that the current configuration has a PV value of 2724 [psi ft/min] and the 10mm anterior horn variant has a PV value of 2179 [psi ft/min]. These can be compared to the recommended maximum PV values for Nylon 6,6 (~3000 [psi ft/min]) [1] and Hytrel (1800 [psi ft/min]) [2]. While both the current and proposed geometries are safely below the Nylon 6,6 PV values, they both remain above that of Hytrel. This indicates that further geometric changes must be made to either the geometry of the horns to increase the area or the contact vector to reduce relative velocity.

Conclusions
An appropriate PV value must be achieved without jeopardizing other features of the foot. Although there is potential to increase the contact area, this will likely require changing the top plate transverse geometry as well as the horn sagittal geometry. Every time a variable is changed, testing must be performed. Mathematical optimization of the parameters is difficult due to the many constraints and unknown variables that could negatively affect patient comfort. Once an optimization is decided upon, it will be prototyped and tested thoroughly. If this is successful, changes may be incorporated in the new molding tool.

Sources