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THE DEVELOPMENT OF A CAD SYSTEM FOR THE DESIGN OF THERMOPLASTIC ANKLE-FOOT ORTHOSES¹

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Abstract

A computer aided design system has been developed to define the proper geometry of thermoplastic ankle-foot orthoses (AFO). The system is composed of two components: 1) a structural analysis computer program with pre and post processors customized for the distinctive geometry associated with orthoses; 2) and a patient test fixture to quantify patient load-response characteristics. A simple structural model of the biomechanical leg-AFO system was devised which incorporates the linear spring rate of the AFO, obtained from the structural analysis, and the spring rate of the patient's lower leg, ankle and foot, obtained from a patient test fixture. Design criteria were established by applying the system to the "best" designs produced by the current trial and error procedure in which several AFO's are manufactured and trial tested on the patient before an acceptable configuration is obtained. Future designs will reflect the "best" design criteria, with the first configuration manufactured the most acceptable configuration.

1. Introduction

A thermoplastic ankle-foot orthosis is an orthotic appliance which is attached to the calf and foot, crosses the ankle and extends to just below the knee (Fig.1). The device is used to provide support for the lower leg, to control movement of the ankle joint, and to apply forces and moments to the lower leg or foot for correction of gait or morphological abnormalities. The combination of the foot, ankle and associated musculature provides four major functions during gait. They are [3]:

- 1) Provide a base of support to maintain an upright position without undue muscular effort;

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2) Provide a mechanism for the absorption of rotation of the limb segments above it during the stance phase of gait;

3) Provide for the absorption of body weight shock at heel strike and provide for accommodation of uneven terrain; and

4) Act as a lever during push-off.

There are a number of diseases and impairments which can interfere with the above-mentioned functions, including cerebral palsy, polio, muscular dystrophy, stroke, orthopedic dysfunction, and other neuromuscular disorders. These diseases and impairments, if left uncorrected, can lead to foot deformities as well as further degradation of gait. The use of AFO's can correct or minimize gait abnormalities when certain physiological conditions exist. For instance, moderate-to-severe weakness of the ankle dorsiflexor muscles which result in the loss of toe clearance during the swing phase of gait (drop-foot-gait), is a common condition for which a posterior leaf spring AFO's (PLS AFO) are prescribed [5]. Not only does the PLS AFO correct the mechanical deficiency in this case, but it has been demonstrated that measurable decreases in energy expenditure occur with AFO use [1]. In another situation, the AFO may be prescribed to help correct a more severe condition. For example, weak quadracep muscles combined with shortened hamstring muscles can cause a condition known as crouch gait in which the individual cannot stand upright, but stands in a crouched position. This crouched position in which the lower leg makes an angle of substantially less than 90 degrees with the foot, may be unstable. In this case, it is the function of the solid ankle AFO (SAAFO) to provide forces and moments to correctly position the lower leg and foot so that a more normal stance is achieved. The SAAFO in effect locks the ankle and essentially allows no movement of the ankle joint. These corrective forces and moments are generated by the deformation of the SAAFO, and provide stability for the patient.

Both the PLS AFO and SAAFO are thin shell structures, usually made of polypropylene sheet stock of 3/32 to 3/16 inch thick, and thermally vacuum formed to a cast representing the patient's lower leg ankle and foot geometry. In appearance, the PLS AFO and the

Figure 1.

Sketch of AFO showing restraining strap and the general geometry of the sole and calf regions.

SAAFO are noticeably different, in keeping with their totally different functions. The PLS AFO is more slender and more flexible than the very stiff, more substantial SAAFO.

As previously stated, one of the purposes of a PLS AFO is to control the condition known as drop-foot gait. A patient with drop-foot gait will exhibit a tendency to drag their foot during the swing phase of gait. The AFO supplies a force to the bottom of the foot to move it to a more natural position, providing toe clearance during the swing phase. The magnitude of this positioning force is directly related to the spring rate of the AFO which is in turn a function of the geometry of the AFO. Since the size and surface of the AFO is dictated primarily by the patient's physiology, the orthotist controls the spring rate by establishing the extent of wrap-around in the section of the AFO from the ankle to just below the knee. The extent of wrap-around is a direct function of calf section trim lines (figure 2). Current practice requires the orthotist guess at trim lines, observe the AFO's performance on the patient, and make adjustments based on the characteristics of the corrected gait. This process may require that several braces be manufactured or modified until the "best" AFO is delivered.

Failure of a PLS AFO usually results in insufficient toe clearance if the brace is too flexible, or a stiff legged gait which is inefficient and uncomfortable to the patient if the brace is too stiff. Therefore, the orthotist fine tunes the AFO's structural response until the "best" AFO is found. On the other hand, a failure of a SAAFO results in the loss of stability of the patient. Since the SAAFO is part of the biomechanical system, it's failure mode is also termed a stability failure. In structural theory, predicting the flexibility of a structure is much easier and more reliable than predicting stability. Therefore, this paper will focus on the development of a CAD system which can define the characteristics "best" PLS AFO's, thus defining the geometry of an AFO most likely to be successful before it is constructed. The goal of the implementation of such a system is the virtual elimination of the current trial and error procedure and the production of an optimized brace.

2. Biomechanical System Model

The biomechanical system model is comprised of two components and is founded on the theory of linear springs. The first component is a spring, symbolized by the spring rate K_B , which represents the load-deflection characteristics of the AFO. Results of previous work [5,6] have shown that a structural analysis based on beam theory will satisfactorily predict the AFO spring rate. The second component is a spring, symbolized by the spring rate K_L , which represents the load-deflection characteristics of the lower leg-ankle-foot (LLAF) system. The results of patient testing (reported below) indicate that the spring rate of the LLAF can be linearized to a first approximation. The AFO and the LLAF act together, with critical contact assumed to occur in the metatarsal area and fixity assumed at the position of the holding strap at the top of the AFO (figure 1.). Therefore, the combined system can be modeled as springs in parallel subjected to a common displacement (figure 3). It should be noted that the springs shown in figure 3 symbolically represent the rotation of the foot around the ankle of the LLAF.

In fitting the AFO to the patient, the orthotist externally flexes the AFO until it conforms to the ankle-foot uncorrected position, in effect pre-loading the AFO. This fitting position is defined as Δ_i in figure 4. Once the external fitting force is removed, the AFO spring contracts and loads the LLAF, moving the ankle-foot to a final position Δ_f as shown in figure 5. For a constant deflection problem, the fitting force varies with K_B and as such a stiff AFO will provide a greater positioning force and smaller Δ_f than a flexible AFO. The orthotist must balance the stiffness required to provide toe clearance

Figure 3.
Idealized spring model of biomechanical system.

Figure 4.
Pre-loading AFO prior to fit.

during the swing phase of gait with the flexibility required during the heel strike and toe off phase of gait. It has also been shown [8] that a quasi-static representation of the dynamic forces generated during gait is an acceptable first generation assumption.

For static equilibrium in the final position, $F_B = F_L$ or

$$K_L \Delta_f = K_B (\Delta_i - \Delta_f) \quad \text{or} \quad (1)$$

$$\Delta_f = (K_B / (K_B + K_L)) \Delta_i \quad (2)$$

3. Determination of AFO Spring Rate

A structural analysis computer program, based on beam theory and incorporating pre and post processors tailored to AFO geometry and loading, has been developed and tested [5]. The brace geometry is described to the program in sections: the calf section using sectors of circular rings (figure 6a) located at prescribed distances from the top of the brace; the sole section using channel and plate shapes (figures 6b, 6c) at locations measured from the toe. Also input into the program are the thickness and material properties of the polypropylene, and the position and magnitude of the loading. The brace spring rate, K_B , is calculated by placing a unit load at the metatarsal area and determining the rotation of the sole section relative to the calf section (figure 4). Typical program output is shown in figure 7. As described above, the spring rate is given in Newtons (pounds) per degree units. The degree of rotation is usually read from the slope of the sole section directly (figure 7d), as the sole section deflects primarily as a rigid body. For example, the K_B obtained for the AFO response shown in figure 7d is 1 lb/1.61 deg or 2.76 N/deg.

Figure 5.

Final position of AFO/patient system.

(a)

(b)

(c)

Figure 6.

AFO geometric sections.

4. Determination of LLA_F Spring Rate

In order to measure K_L , the spring rate of the LLA_F system, a simple patient test fixture was devised (figure 8). The test fixture is comprised of a goniometer strapped to the patients leg at two points with the pivot point positioned at the ankle. A moveable sling/strap is attached to the lower arm of the goniometer so that it can be moved to the appropriate metatarsal area. A digital scale is attached to the sling and an upward force is applied. The angle change of the foot relative to the lower leg and measured from the rest (Δ_i) position is read from the goniometer for several load levels. The largest load applied occurs at the point where Δ_{TL} equals Δ_i . In practice, the test is performed with the patient seated on a table such that their lower leg is extended over the edge of the table and is unsupported externally. The force applied by the test fixture measures the resistance of the LLA_F musculature to a positioning force. Satisfactory results cannot be obtained if the patient exhibits excessive spasticity. The results of a test on a typical responsive patient are shown in figure 9.

As a first approximation, the relationship between F_{TL} and Δ_{TL} is assumed to be linear, which appears to be a reasonable assumption. A linear regression analysis yields the slope of the best fit straight line which is the linear spring rate K_L .

5. Biomechanical System Calibration

Because of the simplifications and assumptions inherent in the formulation of the parallel linear springs system model, calibration of the model against the actual

Figure 7.
Typical structural analysis program output for a 1 lb. load applied at the metatarsal location.

PY = 1.0 at 1.5 from toe

response of a patient wearing an AFO was necessary. In the model, the system spring rate was calculated to be $K_L + K_B$ (equation 2). The actual system spring rate was obtained by performing the same tests that were used to obtain K_L only this time the patient was tested wearing the AFO. A typical patient response is shown in Figure 10. Again, a straight line functional relationship is seen to be a reasonable assumption. A regression analysis will yield the actual system spring rate, K_S . In theory, $K_L + K_B$ should equal K_S . In Figure 11, K_S is plotted against $K_B + K_L$ where perfect correlation is represented by the 45° line. A linear regression of the data yields the following relation,

$$K_S = 1.167 + 1.276 (K_L + K_B). \quad (3)$$

Rewriting (2) as $K_B (\Delta_i / \Delta_f) = K_S$ and substituting (3) for K_S ,

$$K_B = \frac{1.167 + 1.276 (K_L)}{\Delta_i / \Delta_f - 1.482}. \quad (4)$$

For each patient, knowing K_B and K_L , the design parameter Δ_i / Δ_f was calculated using (4) and the results averaged to give Δ_i / Δ_f of 2.30 with a standard deviation of 0.28. Substituting this value into (4),

$$K_B = 1.175 + 1.246(K_L). \quad (5)$$

6. CAD Procedure

To supply an AFO using the system described, the Orthotist makes a plaster cast of the patient's leg. The contours of the AFO will match the contours of the cast and initial geometry requirements are input to the structural analysis program. The patients LLAF spring rate, K_L is obtained using the patient test fixture. Next, the target AFO spring rate, K_B is calculated using equation (5). AFO trim lines are adjusted analytically using the

Figure 8.

Patient test fixture

Figure 9.

Typical patient load vs. deflection data.

structural analysis program by increasing or decreasing the included angle of the circular arc sectors of the calf section (Figure 6a) until the target K_B is attained. This usually takes three or four tries spanning 10 to 15 minutes of seat time. For the limited amount of cases in which this procedure has been applied, an AFO acceptable to the Orthotist and the patient has been produced on the first try.

7. Summary

A CAD system for designing posterior leaf spring AFO's has been developed which incorporates analytical results obtained from a structural analysis computer program and test results from a patient test fixture. Empirical design constants were obtained by applying the system to several "Best" designed AFO produced by the trial and error method and an equation which predicts the appropriate AFO geometry, and hence spring rate, was derived. For a limited number of trials, the system has produced an acceptable AFO on the first geometry built.

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NOMENCLATURE

AFO = Ankle Foot Orthosis

LLAF = Lower Leg, ANkle, Foot

K_L = Linear rotational spring of LLAF, N/Degree

Figure 10

Typical patient/AFO load vs. deflection data.

Figure 11.

Comparison of calculated system spring rate and measured system spring rate.

K_B = Linear rotational spring rate of AFO, N/Degree	F_p = Initial positioning force - N
Δ_i = AFO alone - Deformation in fitting position, Degrees	F_B = Final force in AFO -N
Δ_f = AFO and LLAF combined - Deformation in final position, degrees	F_L = Final force in LLAF - N
Δ_{TL} = Rotation of LLAF measured from Δ_i - Degrees	

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