Subjective Evaluation of the UCBL Polycentric Knee Linkage by Active Above Knee Amputees

A Prospective Trial

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ABSTRACT: In this study 20 active male above knee amputees were fitted with prostheses incorporating prototype UCBL four-bar polycentric knee units. The subjective responses of the amputees were evaluated in a prospective fashion. Additional information concerning the short-term durability and mechanical behavior of the device is presented. The average followup was 12.3 months. Sixteen of the 20 subjects felt that they benefited from the device, and seven of these stated that the research prosthesis was superior to all previous devices that they had used. Four subjects stated that they had received little or no benefit from the research limb. Previous levels of function and the ease of performance of specific activities were maintained or enhanced in almost all subjects. Most subjects felt that the ease of walking on inclines was improved, and found the increase in knee flexion afforded by the mechanism to be an advantage. Early in the study, problems were encountered due to air leaks in the pneumatic swing-phase control units and to excessive wear of the aluminum linkage pins. These problems were corrected easily, and the devices were found to function well during the remainder of the study. Given the encouraging results from this preliminary clinical trial, we conclude that further study and clinical application of the UCBL four-bar polycentric knee are indicated.

Introduction

A new prototype of the University of California Biomechanics Laboratory (UCBL) polycentric knee mechanism was studied prospectively in 20 active veteran above knee amputees. The knee unit consists of four machined aluminum linkage components connected by transverse pins, two proximal and two distal (Fig. 1). A pneumatic swing-phase control unit is located between the linkage components and is connected to the thigh and shank portions by separate pins. Unlike single-axis linkages in which the center of rotation remains constant throughout the range of knee flexion and extension, the UCBL four-bar poly-

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Fig. 1B: Posterior oblique view shows the four-bar unit in full flexion. The anterior and posterior longitudinal "bars" are connected to the thigh and shank components of the linkage by transverse pins.

centric device is designed in such a manner that the instant center of rotation changes location as the knee moves throughout a range of motion. The instant center of rotation migrates proximally as the knee is progressively extended (Fig. 2).
The movable instant center of rotation in the UCBL polycentric design permits enhanced voluntary control of knee stability at heel strike, requires less effort to initiate knee flexion at toe-off, and allows a greater amount of knee flexion. Secondary benefits potentially derived from these biomechanical advantages might be expected, such as less energy required for gait, less effort required to correct for disturbances in knee stability, and a more "natural" gait.

Fig. 2: The position of the instant center of rotation in the UCBL knee linkage as a function of the knee flexion angle. The instant center reaches its most proximal location with the knee in full extension.
In this brief report, subjective responses of above-knee amputees to prostheses incorporating the UCBL polycentric knee linkage are assessed. In addition, the safety and durability of the device during the trial period are evaluated.

Methods

Twenty active experienced above knee veteran amputees were selected to participate in the study. In none of these individuals were "safety" knee mechanisms deemed necessary because of previous problems with prosthetic knee instability. Each subject underwent initial and followup evaluations performed by an orthopedic surgeon, prosthetist, and physical therapist. The initial evaluation included an interview and written questionnaire designed to provide demographic data, medical history, specific information about the condition of the residual limb, previous prosthetic usage, and daily activity levels. The current prosthesis was examined and notations made as to its component parts, alignment, general condition, and weight.

Research prostheses that incorporated the UCBL polycentric knee were fabricated by local prosthetists who had been selected by the amputees and were under contract to the Veterans Administration. Supervision in fitting and alignment procedures was provided by a research prosthetist. The research limbs consisted of a total contact socket with quadrilateral brim, four-bar polycentric knee unit with pneumatic swing-phase control, endoskeletal shank with a rigid foam cosmetic cover, and SACH (solid-ankle cushion-heel) foot. The mean weight of the research limbs was 4 kg, representing a mean reduction in weight of 944 gm compared to the pretrial limb.

Followup evaluations of the subjects were carried out at three-month intervals beginning six weeks after full time use of the research limb had started. On each followup visit, interviews and questionnaires were completed and any changes in the subject’s general health or the condition of the residual limb were noted. On each return visit, the polycentric knee unit was dismantled and inspected to determine the degree of wear or deterioration in its component parts. Appropriate repairs or replacements were made as indicated and a record of maintenance kept for each device.

Responses from the interviews and questionnaires that were obtained at followup were coded and analyzed blindly. Each subject evaluated the ease of performance of specific daily activities that were affected by prosthetic function, and in addition gave an overall assessment of the device. Improvement or deterioration in each type of activity during the course of the study was noted. At the time of the final followup evaluation, the subjects were invited to respond to an open-ended question designed to elicit their particular likes and dislikes concerning the prosthesis.

Variables such as the age of the amputee, time since amputation, level of amputation, history of medical or orthopedic disabilities, a history of residual limb irritation, and past problems with socket fit were assessed in relation to the subjective acceptance of the research limb. In addition, the relationship of study-related factors to subjective outcome were assessed. Such factors included the length of followup, difficulty with initial prosthetic fit or fabrication, problems with the residual limb during the trial, and intercurrent unrelated medical or musculoskeletal disability.

Study Group

The study group consisted of 19 above knee amputees and one individual with bilateral lower limb amputations (above knee on one side and a knee disarticulation on the other). The mean age of the subjects was 45.8 years (range: 30 to 62 years). Nineteen of the 20 subjects sustained their limb loss due to trauma, and one as a result of elective amputation for a malignant tumor. None of the amputations resulted from ischemic vascular disease. All subjects were experienced prosthesis wearers with a mean interval since amputation of 23.8 years (range: 9 to 42 years). The mean duration of use of prior prostheses was 3.2 years per prosthesis. All but one subject was wearing a prosthesis with a single axis knee linkage prior to the trial, and most (75%) used hydraulic swing-phase control units.

A history of occasional residual limb pain was given by 15 subjects. Intermittent ulceration or dermatitis of the residual limb had occurred in a similar number. Four of the 20 amputees had noted some occasional discomfort in the hip or knee of the sound leg, and five reported a history of intermittent backache. Sixteen of the 20 subjects were employed full time, and the initial questionnaire revealed that the group as a whole maintained high levels of daily activity. Fifteen of the 20 walked an average daily distance of over six blocks, and 16 of the 20 used no walking aids. Thirteen of the 20 amputees engaged in recreational activities such as swimming, golf, fishing, and ping pong. Prior to the study, seven subjects complained of some difficulty in arising from chairs, five had noted frequent falls, and two had occasional difficulty in climbing stairs.

Thirteen amputations were through the middle third of the femur and seven through the distal third. Mild mechanical skin irritation was noted in three residual limbs, and suboptimal shaping was present in nine cases. Muscle power and range of motion in the hip of the amputated side was graded as normal in all subjects. Two subjects had clinical findings suggestive of significant degenerative disease in the remaining knee.

Results

Subjective Evaluation

Subjects were followed for an average of 12.3 months after beginning full time use of the four-bar prosthesis (range: 5 to 19.5 months). Fourteen of the subjects were followed for periods longer than ten months. Two subjects felt that they had gained no benefit from the research prosthesis and withdrew from the study after five and 7.5 months, respectively. One amputee became terminally ill with carcinoma of the gall bladder and was unable to return for followup after using his prosthesis for 6.5 months. Delays and interruptions in the trial occurred in six cases due to difficulties in obtaining a comfortable socket fit. Four subjects developed transitory mechanical skin irritation in the residual limb, and significant changes in the shape or volume of the limb due to body weight fluctuations occurred in 12 of the 20 subjects during the course of the study. Such changes occasionally necessitated socket modification or replacement. Significant medical illnesses occurred in four subjects during the study and resulted in interruptions in the trial. Four other subjects developed transitory musculoskeletal complaints including a flare-up of low back pain in two, symptomatic degenerative arthritis of the knee in one, and metatarsalgia in one. One subject attributed an exacerbation of preexisting low back pain to use of the research prosthesis.

Seven subjects registered a highly enthusiastic overall assess-
TABLE 1

CHANGES IN VARIOUS ACTIVITY PARAMETERS REPORTED BY AMPUTEES AFTER USE OF THE RESEARCH LIMB (N = 20)

<table>
<thead>
<tr>
<th></th>
<th>No. Improved</th>
<th>No. Worse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prosthesis Wearing Time</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Daily Distance Walked</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Need for Walking Aids</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Walking on Inclines</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>Walking on Rough Ground</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Frequency of Falls</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Ability to Climb Stairs</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Getting into/out of Chairs</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Getting into/out of Cars</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Amount of Daily Fatigue</td>
<td>7</td>
<td>0</td>
</tr>
</tbody>
</table>

The research limb was judged to be better than any previous device that they had used. Nine subjects indicated a positive overall assessment, reporting that the four-bar knee unit functioned at least as well as the best previous device that they had used. Four individuals, including the two who voluntarily withdrew from the study, reported that they had received little or no benefit from the four-bar prosthesis.

Most amputees reported improvement in one or more categories of function or activity during the trial period, whereas worsening was noted only occasionally (Table 1). An increase in the daily distance walked was reported by five subjects, and a decrease by four. An improved ability to walk on inclines was noted by 11 subjects. A decrease in fatigue at the end of the day was reported by seven. Several subjects reported greater ease in getting into and out of chairs and automobiles, and others noted less difficulty in walking over rough or uneven ground. All subjects were able to kneel with the four-bar prosthesis. All but one subject reported that the increased amount of knee flexion allowed by the mechanism was an advantage, especially when sitting in public places with limited leg room.

The open-ended question soliciting particular likes and dislikes regarding the prosthesis from the subjects prompted various responses. Nine volunteered that they walked "more naturally" with the research limb, and six stated that they noted greater ease in controlling knee stability. Only one subject commented that his gait was less natural, and two that the knee was occasionally unstable. Four amputees commented positively on the reduced weight of the prosthesis. Two subjects volunteered satisfaction with the cosmetic appearance of the research limb. Eight individuals complained that their pants intermittently became caught in the knee mechanism, and in six cases there were tears in the foam cosmetic cover as a result of kneeling. Four amputees stated that the pneumatic swing-phase control of the mechanism did not respond readily to changes in cadence, even after adjustment of the appropriate valve controls. Complaints of excessive noise due to wear of the anodized aluminum linkage pins used initially were registered by 14 subjects.

Mechanical Performance of the Four-Bar Mechanism

Initially, the linkage components of the UCBL polycentric knee device were connected by anodized aluminum pins proximally and distally. Unexpectedly rapid wear of the anodized surface resulted in noise in 14 of the 20 mechanisms. This problem was solved by replacing the aluminum pins with stainless steel pins of the same diameter. These stainless steel replacement pins were observed for an average of eight months. They demonstrated no measurable wear and were not found to cause noise in any case.

Early in the study, erratic behavior of the pneumatic swing-phase control unit occurred in nine cases because of air leaks arising from worn damper seals. This problem was corrected by adding a Teflon ring next to the O-ring seal in the damper piston. The modified damper pistons were followed an average of 9.3 months without further air leaks.

During this preliminary trial, there were no instances of fatigue failure or sudden breakage of metal components in the four-bar unit. One subject slipped and fell in such a manner that the prosthetic mechanism was forced into hyperflexion. The two posterior linkage bars were bent, resulting in malfunction of the device.

Proper shaping of the rigid foam cosmetic shank cover was found to be somewhat difficult. Tearing or permanent deformation of the medial and lateral fairings of the cover at the level of the knee occurred in six cases with kneeling. Meticulous care in the shaping and fitting of the cover proximally was required in order to prevent this problem.

Discussion

The results from this preliminary prospective study indicate that 16 of the 20 experienced active above knee amputees who tested prostheses incorporating the prototype UCBL polycentric knee unit felt that they had benefited from the new limb. Seven of the subjects reported that the four-bar prosthesis was superior to all previous prostheses that they had worn. Of the 19 who were able to continue using a prosthesis at the time of final followup, 17 elected to continue use of the research limb thereafter. In almost all cases, amputees reported that previous levels of daily activity had been maintained or augmented during the trial period. Diminished activity levels and increased difficulty with specific activities were reported only occasionally.

An attempt was made to identify any specific characteristics or findings peculiar to the four amputees who realized little or no benefit from the four-bar prosthesis. Various study-related factors and background data from these four subjects were compared statistically with similar information from the 16 amputees who benefited from the device. This comparison failed to reveal any significant differences. Of further interest is the fact that a more detailed analysis of activity levels and various gait parameter measurements failed to reveal a difference between the two groups. At this time, specific recommendations regarding prescription criteria will have to be derived from more widespread experience with the UCBL device.

There are multiple variables that may determine the subjective response of an above knee amputee to a new prosthesis. The ease with which a prosthesis may be used in various activities is a function not only of the knee unit, but also of other important factors such as socket fit and comfort, overall alignment of the limb, and foot function. In this study, a special effort was made to provide uniform care with respect to such variables. The research limbs were fabricated by community prosthetists who had been chosen by the amputees and who used standard fabrication.
techniques and materials. Critical assessment of the research limbs was not begun until all adjustments had been completed and all deficiencies corrected at the start of each trial. In some cases, the trial was delayed until problems not related to the knee mechanism were corrected. No statistically significant correlation was found between such difficulties and the final subjective assessments expressed by the amputees.

Early in the study, deficiencies in the damper seals of the pneumatic swing-phase control units and in the aluminum linkage pins were identified. Anodized aluminum linkage pins were selected for use at the outset in order to save weight; however, the anodized surface was not found to be sufficiently resistant to wear, and this resulted in excessive noise. The problem was corrected by substituting heavier but more wear-resistant stainless steel pins. Similarly, modification of the damper seal in the piston of the pneumatic swing-phase control unit corrected air leaks that resulted in erratic behavior in a few prostheses. Once these problems had been corrected, the UCBL polycentric device was found to be safe, reliable, and easy to maintain by community prosthetists who had received proper instruction. Because this preliminary trial was not carried out for a longer period, the long-term durability of the device has not been determined. During this initial evaluation, it was determined that further refinements in the design of the proximal portion of the cosmetic shank cover will be necessary since accurate shaping and fitting of the cover proved somewhat difficult.

While this preliminary study suggested that the UCBL polycentric knee mechanism is well accepted by active males who have sustained their limb loss from trauma, the device may have usefulness in those with amputations due to other causes such as dysvascular disease, ablative tumor surgery, or congenital limb deficiency. The encouraging results in the single bilateral lower limb amputee who wore the UCBL knee suggest a possible application in these amputees as well. We conclude from our early experience that more widespread clinical application and study of the UCBL four-bar polycentric knee mechanism are indicated.

References


241