

An Evaluation of the C.A.R.S.-U.B.C.¹ Knee Orthosis²

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More than 20 million Americans suffer from some form of arthritis. About 5 million have rheumatoid arthritis, and another 12 million have some type of osteoarthritis (1).

The knee, which is the largest joint in the body, is a common site of involvement for patients with osteo or rheumatoid arthritis (2). In either case, the patient characteristically has pain and ligamentous instability when bearing weight, and therefore decreased mobility. Thus, an unstable arthritic knee is a common clinical problem.

If the disease process goes unchecked, a permanent deformity of flexion with genu varum or valgum may result (3, 4). Such a deformity makes ambulation much more difficult, if not impossible (5). The treatment goals for an unstable knee are the relief of pain, maintenance of stability and mobility, and the prevention of further deformity.

The use of orthoses is an important non-surgical method of helping to attain these goals. However, a review of the literature shows an absence of any on-going clinical evaluation that documents the efficacy of the various knee orthoses currently in use. Consequently, the clinician is forced to choose an orthosis on the basis of trial-and-error experience.

The purpose of this study was to describe the over-all usefulness of the C.A.R.S.-U.B.C. orthosis (6, 7) in a sam-

ple of 10 arthritic patients with medial-lateral knee instability as a major complaint.

While recognizing that 10 is a small number for an evaluation program of this type, it was still felt that certain laboratory measurements should be made in an effort to determine if they could lead to better prescription guidelines.

The C.A.R.S.-U.B.C. orthosis (Fig. 1) is designed to stabilize a varus or valgus moment at the knee. It is a dynamic orthosis, providing maximum support when the knee is extended, as in the stance phase of gait. The orthosis consists of two plastic cuffs—one about the thigh and one about the shank, which are connected by a telescoping rod to provide complete freedom in the flexed condition but provides a force that tends to straighten the knee joint in the parasagittal plane upon full extension. When the knee is extended, the system becomes taut. When relief on the medial side is desired, the cuffs and rod are fitted to the lateral side of the leg, and the leather pad supports the medial side of the knee. The opposite scheme is used to obtain relief on the lateral side.

The units of the CARS-UBC knee orthosis were made available for evaluation by the University of British Columbia and the United States Manufacturing Company at the request of the Rehabilitation Engineering Center since the device fell

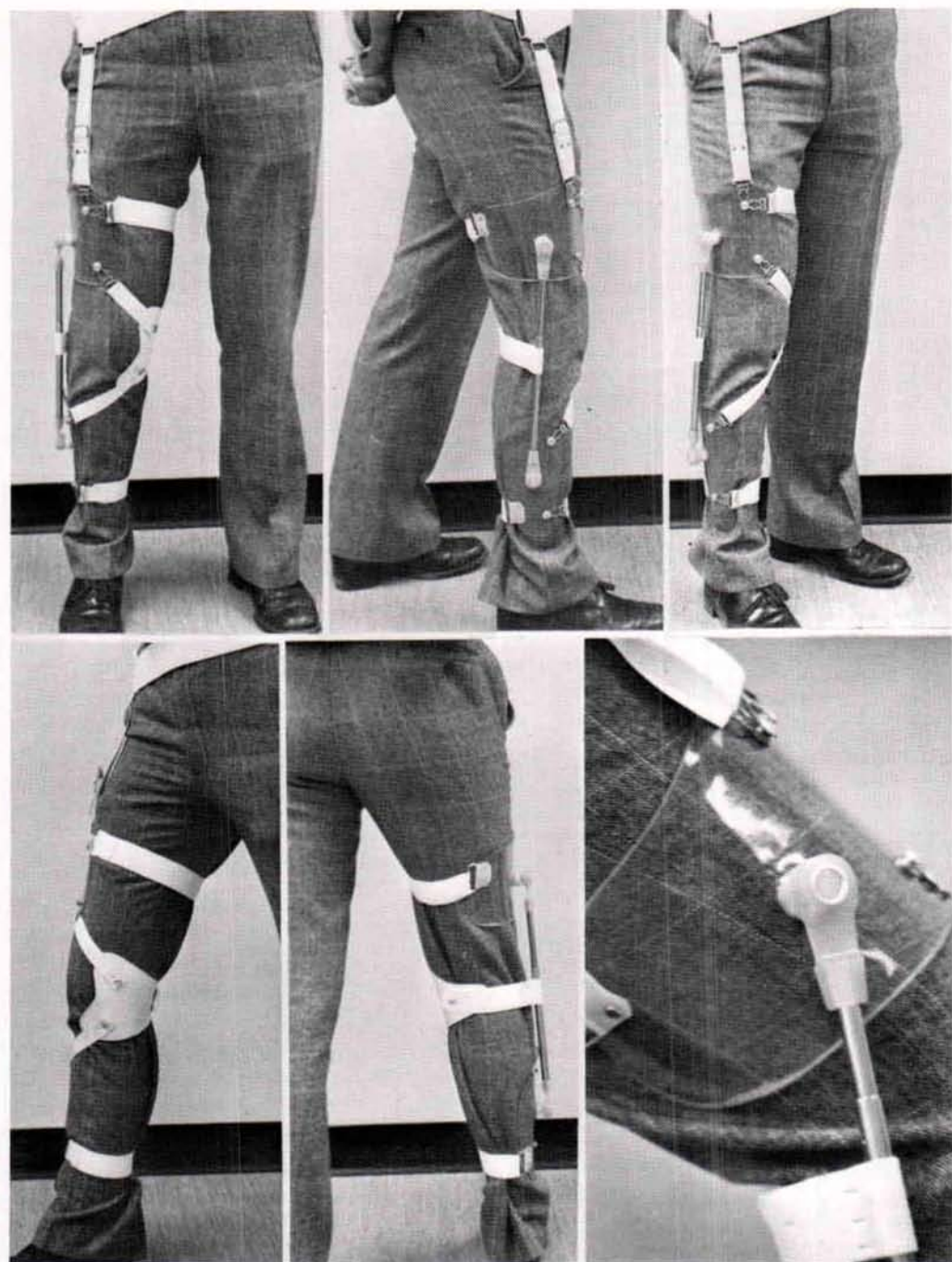


Fig. 1 Various views of the CARS-UBC knee orthosis for arthritis. These views show the orthosis fitted to provide for lateral instability. It can be fitted just as easily with the telescoping bar on the medial side of the knee to provide for medial instability. Although shown here being worn on the outside of trousers the orthosis may be worn next to the skin or simply with a stockinet over the knee.

well within the scope of its charge from its primary sponsor, the Rehabilitation Services Administration.

METHOD

The sample used in the evaluation consisted of ten patients referred from the Arthritis Center of Albert Einstein Medical Center. The subjects were diagnosed as having rheumatoid or osteo arthritis with knee instability. All of the subjects were female, ranging in age from 47 to 81. The mean age was 64.4. Patients were selected on the basis of the following general requirements:

1. Medial or lateral knee instability
2. The ability or potential ability to ambulate independently on stairs, ramp and level surface
3. Absence of complicating medical conditions which might contraindicate participation in the study
4. The mental and physical ability to don and doff the orthosis, or a family member who could do it
5. Informed consent of the patient and physician

The severity of involvement of each patient was assessed by using two knee-scoring scales, Slocum (8) and Kettlekamp (9). Each of these forms allows a score to be tabulated based on the knee range of motion, joint stability, functional capabilities of the patients, etc. The two scores were averaged. Patients were classified as minimally, moderately, or severely involved according to this score.

The subjects were tested in the laboratory initially and again two to four weeks later when the patient had become accustomed to the orthosis. The subject was fitted with instrumentation and then was asked to ascend and descend a set of stairs, a ramp, and to walk on a level surface. The three different surfaces were chosen to provide an overview of functional performance. Patients ascended

and descended the stairs (6 steps) and ramp (8 percent grade) twice, and they made four steady-state passes across force plates (1.5 m long) on the level surface. The instrumentation used on the stairs and ramp included adjustable force sensing transducers strapped to each shoe, and two knee electrogoniometers. The electrogoniometer used for the involved limb was a parallelogram type so that the orthosis would not interfere with range of motion measurements during the second test session. Analog data from these instruments were collected on a six-channel Gould pen recorder. For the level surface walking, the outsole force transducers were not used. Instead, the subject walked across strain-gage force plates in the locomotion laboratory. In addition, during level walking, a tachometer string was attached to a belt over the patient's lumbar area to record velocity. Level surface data were collected by means of a general sampling program on a PDP-11 computer at a rate of 40 samples per second. The parameters that were either measured directly, or derived from the data, are:

1. peak-to-peak range of motion (involved knee)
2. vertical load
3. rate of loading
4. swing/stance ratio
5. task time (stairs and ramp only)
6. velocity (level surface only)
7. Symmetry:
 - a. range of motion symmetry
 - b. loading rate symmetry
 - c. step length symmetry (level surface only)

In addition to the above parameters, static alignment photographs were taken of each patient before and after bracing (Fig. 2). This was done using the technique developed by Cook et al (10, 11). In this procedure, the floor-reaction force vector through the patient's limb is super-

imposed on the patient's image by means of an optical beam splitter while the patient stands on one of the force plates. In this manner, the force vector indicates changes in torque or alignment at the knee.

The parameters that were used were selected on the basis that if the orthosis stabilizes the involved knee, the patient should experience less pain on weight-bearing, and should feel more secure. Consequently, one would expect the patient to be able to walk faster and more vigorously. The parameters, except for task time and the measures of symmetry, would be expected to increase from pre-bracing to post-bracing. The assumption is made that if greater symmetry is an improvement (that it is more "normal") one would expect the symmetry values to decrease because the values used were the differences between right and left limb performance (ROM, loading rates, etc.).

At the time of the second testing, the subjects were asked to complete a questionnaire about the orthosis (Fig. 3). The questionnaire was based on the criteria established by Cousins and Foort (12). Each question was weighted numerically so that a score could be tabulated for the entire questionnaire. A perfect score was 10 points.

RESULTS

Severity of Involvement

Nine out of the ten patients were classified as moderately involved. The other patient (No. 8) was classified as severely involved.

Laboratory Results

In an effort to stay as "close" to the data as possible in describing the results, the patient's performances are presented

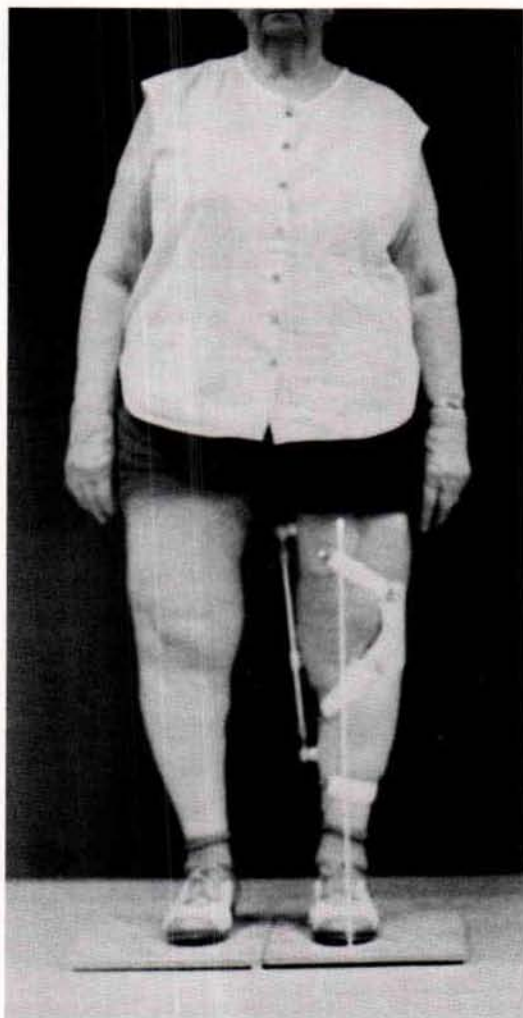


Fig. 2. Patient standing on forceplate so that position of weight line can be recorded. The length of the weight line is proportional to the force exerted.

BRACE EVALUATION FORM
(ADOPTED FROM CARS-UBC)

Patient's Name: _____

Date: _____

1. Do you wear your brace: all the time only around the house
 only when going outside not at all

2. Has your brace been: a great help a moderate help
 no help a hinderance

3. Do you function better: all the time most of the time
 occasionally not at all

Please answer Yes or No:

1. Is your brace comfortable?	Yes	No
2. Is the fit of your brace good?	Yes	No
3. Is the weight of the brace noticeable?	Yes	No
4. Does the brace catch your clothes?	Yes	No
5. Does the brace soil your clothes?	Yes	No
6. Does the brace make you perspire?	Yes	No
7. Does the brace rub your skin?	Yes	No
8. Is cleaning the brace a problem?	Yes	No
9. Do you like the appearance of the brace?	Yes	No

REMARKS:

Fig. 3. Questionnaire administered to patients in study.

in the displays shown in Figures 4. Along the abscissa in each display, the patients are listed in decreasing order of their acceptance of the orthosis according to the questionnaire scores. The ordinate represents the mean value of each parameter for the patient during the pre-bracing and the post-bracing test. Heavy lines represent an improvement from pre-bracing to post-bracing. Conversely,

narrow lines represent a decrease in performance from pre-bracing to post-bracing. Symbols (circles, squares and triangles) indicate the pre-bracing value on each of the various walking surfaces: up or down the stairs or ramp, and level walking. Finally, the average performance of the group (\bar{X}) is represented at the extreme right-hand side of each display.

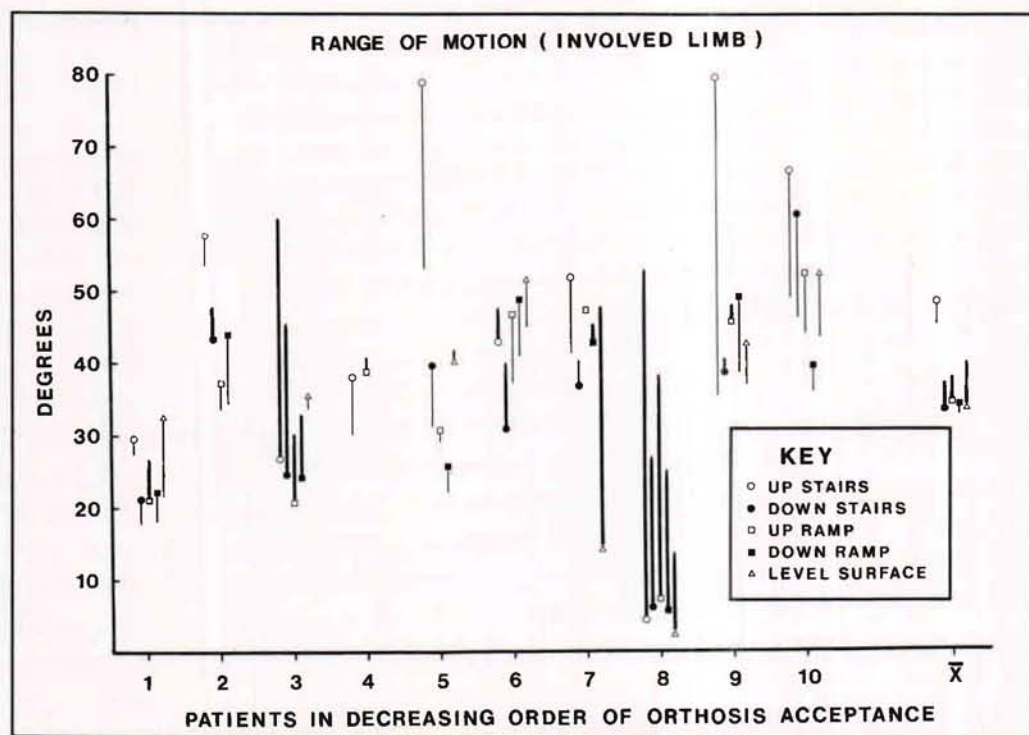


Fig. 4. Range of Motion (Involved Limb).

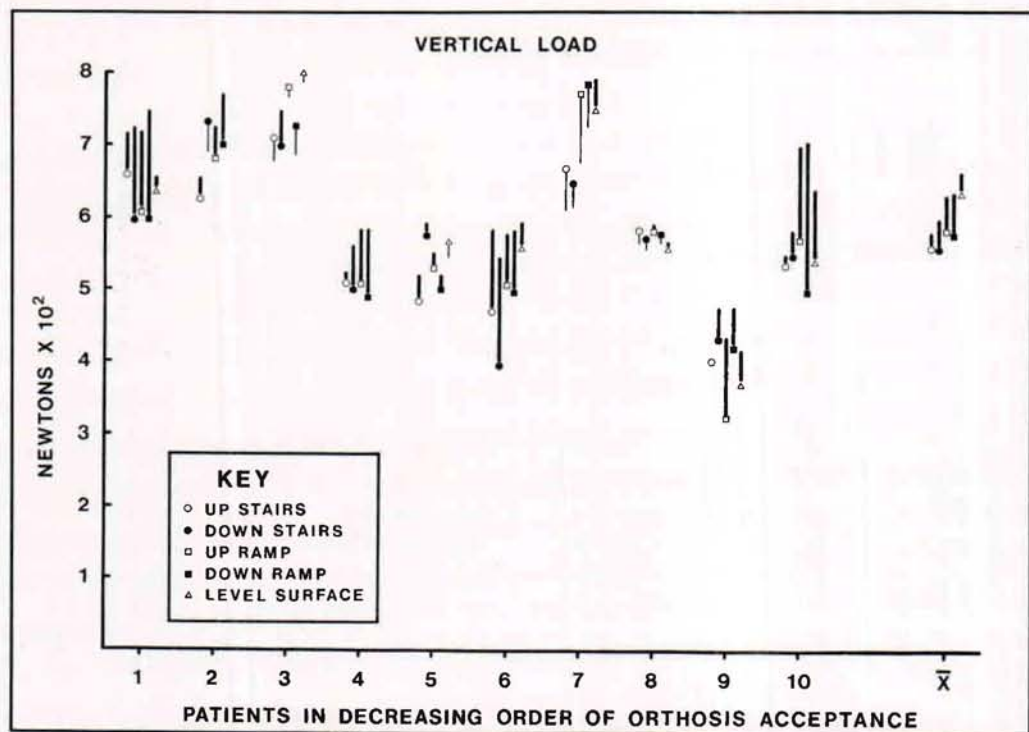


Fig. 5. Vertical Load

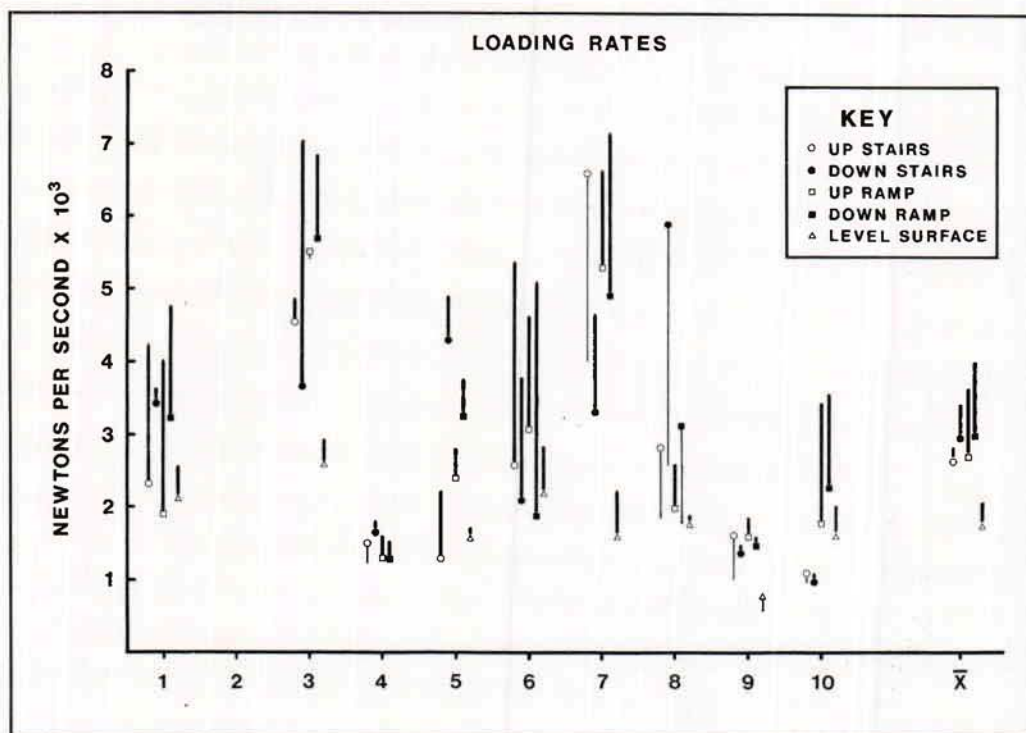


Fig. 6. Loading Rates

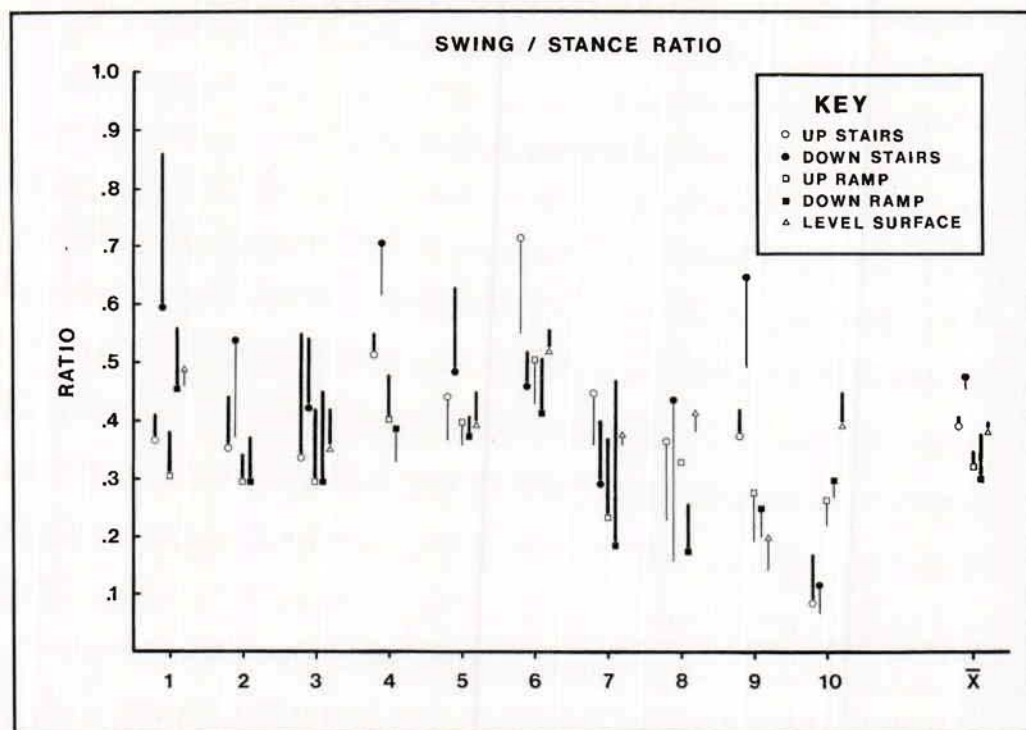


Fig. 7. Swing/STANCE Ratio

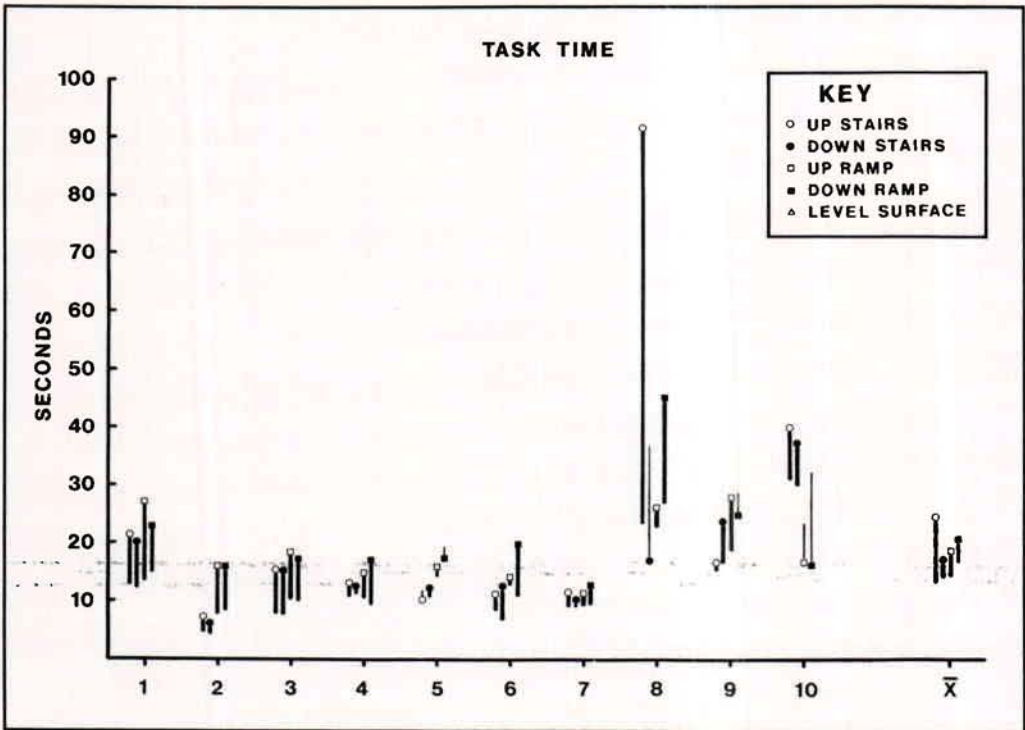


Fig. 8. Task Time

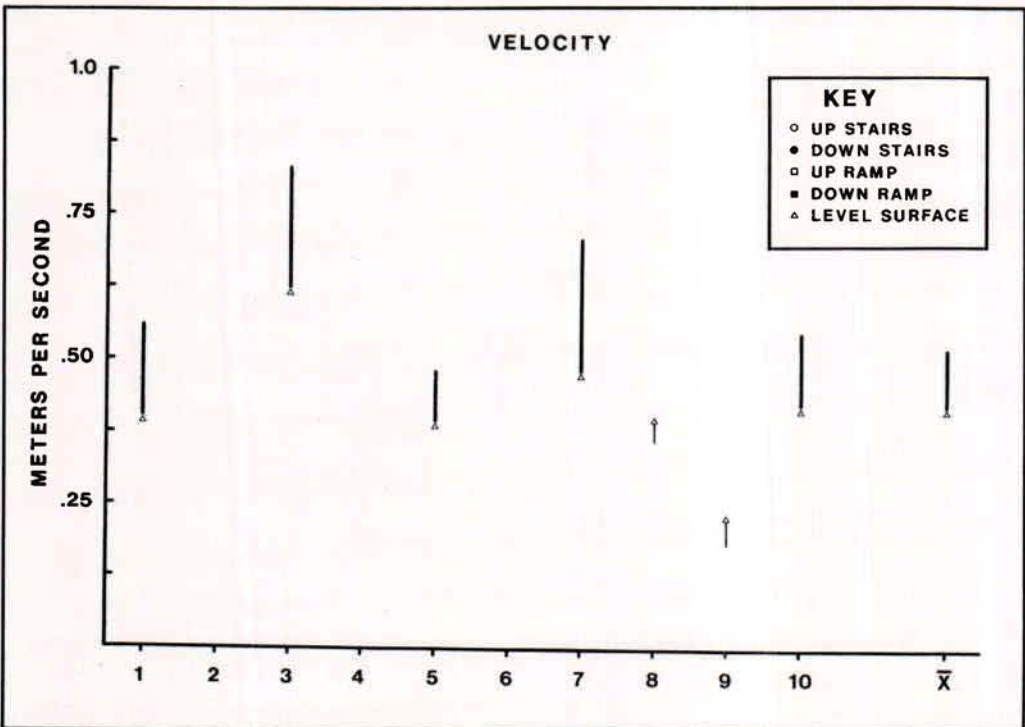


Fig. 9. Velocity of Walking

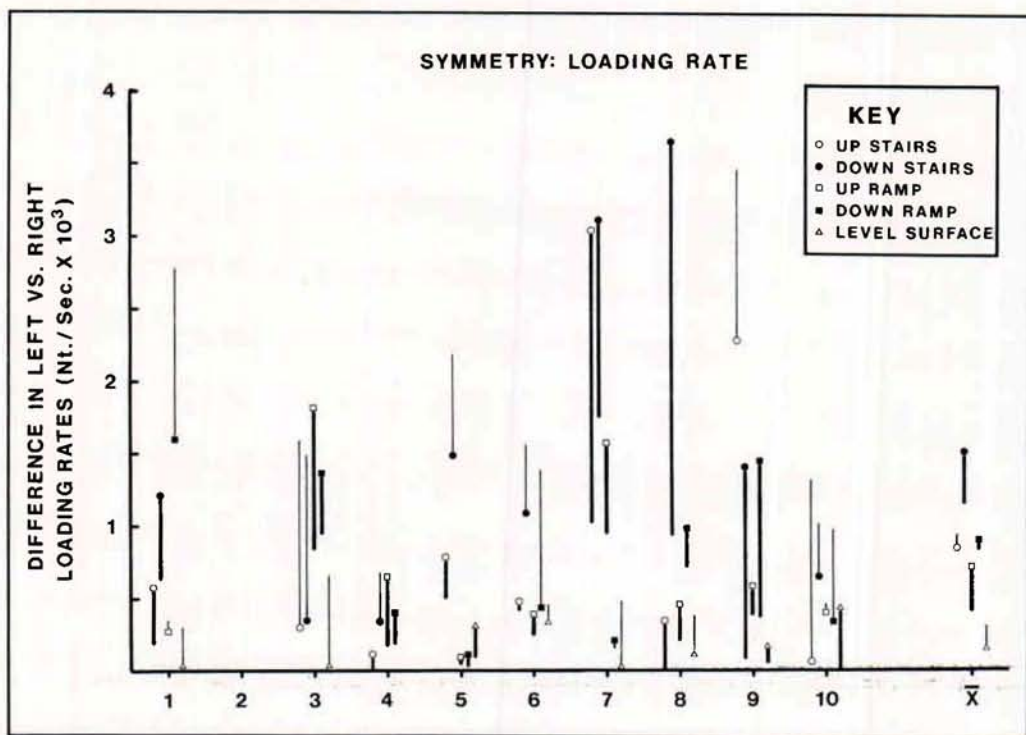


Fig. 10. Symmetry: Loading Rate

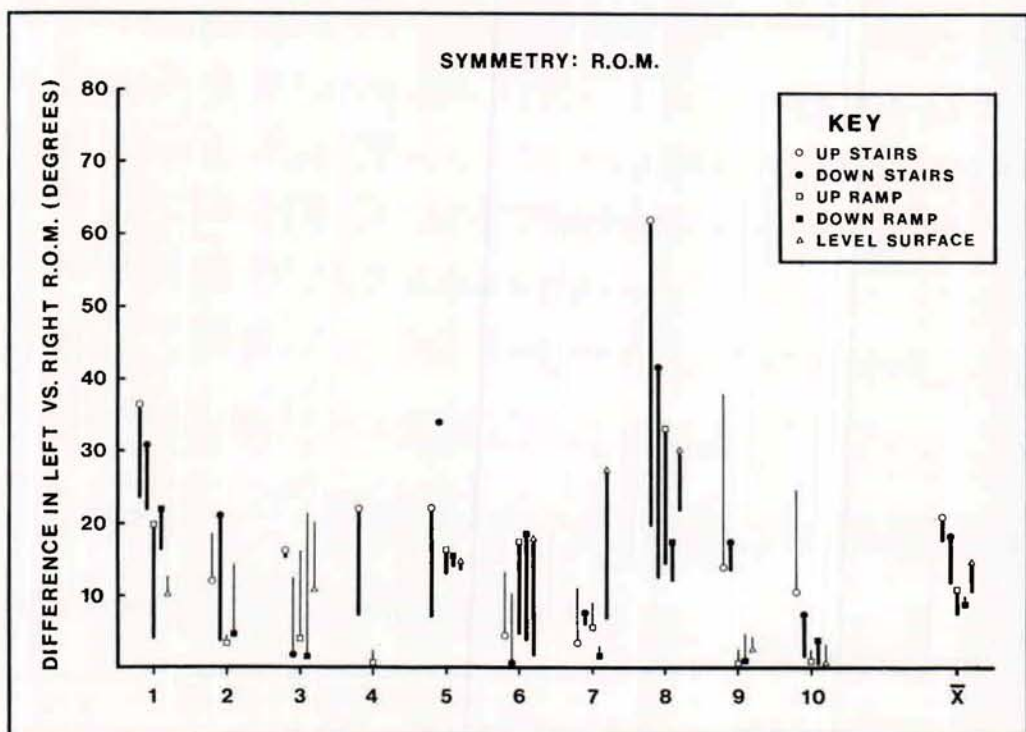


Fig. 11. Symmetry: Range of Motion

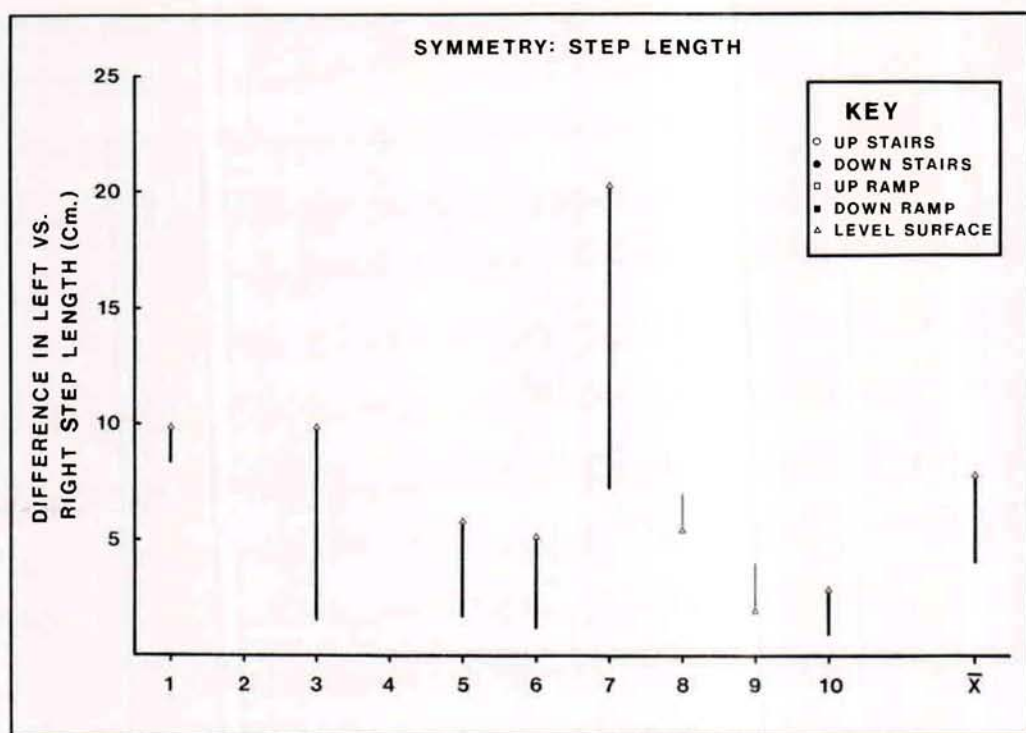


Fig. 12. Symmetry: Step Length

It appears that the group has no particular pattern of positive or negative change for the parameters of ROM, Swing/Stance Ratio, and Loading Rate Symmetry. This is true even though certain patients showed dramatic positive or negative changes on some or all of the surfaces. The group showed general improvement in the other parameters, although certain subjects showed negative changes on some or all of the surfaces. How significant the various changes are is a debatable question especially when variability is considered. As described in the methodology, all of the pre- and postbracing values are mean values. This means that there is some variability about all of the plotted values. In some cases, when the prebracing to postbracing

change was very small, it was less than one standard deviation from the pre- or postbracing value. In other cases, where a pre- to postbracing change is very large, the change would certainly seem to be "clinically significant."

In an attempt to look at the data without attaching some critical level of significance to the size of the pre/postbracing changes, another type of plot was used (Fig. 13). Each parameter is plotted against the proportion of patients who exhibited any positive changes, no matter how small. The heavy bars indicate the proportion of positive changes for the group across all surfaces. The narrow bars indicate the proportion of positive change for an individual surface. The heavy bars are the most important since

they represent the proportion of positive changes in fifty pre/postbracing changes (10 patients x 5 surfaces). If the orthosis neither helped or hindered the patients as a group and no other factors affected their gait, a proportion of about 0.5 could be expected for all of the parameters, since according to the laws of probability, the pre/post changes would be positive as often as they were negative. It can be seen that all of the parameters, except for range of motion are above the 0.5 level. Two parameters, ROM symmetry and swing/stance ratio, are only slightly above the 0.5 level. Loading Rate Symmetry is somewhat higher. Three parameters, Vertical Load, Loading Rates and Task Time, are well above the 0.5 level. In fact, the number of positive changes in these parameters is significant

at the 1 percent level when subjected to the Sign Test for Significance. The parameters of Velocity and Step Length Symmetry are also well above the 0.5 level, but they must be considered with caution since they represent a smaller number of pre/post bracing changes (level surface only).

The results of the weight line photographs were that five of the eight pictures obtained showed a measurable change in weightline location. (A measurable change means a medial or lateral displacement of the line from prebracing to postbracing of 1 mm or more as measured at mid-patella on 3 in. x 5 in. glossy prints). All of the displacements were appropriate; i.e., for a valgus knee, the line was moved laterally and for a varus knee, the line was moved medially.

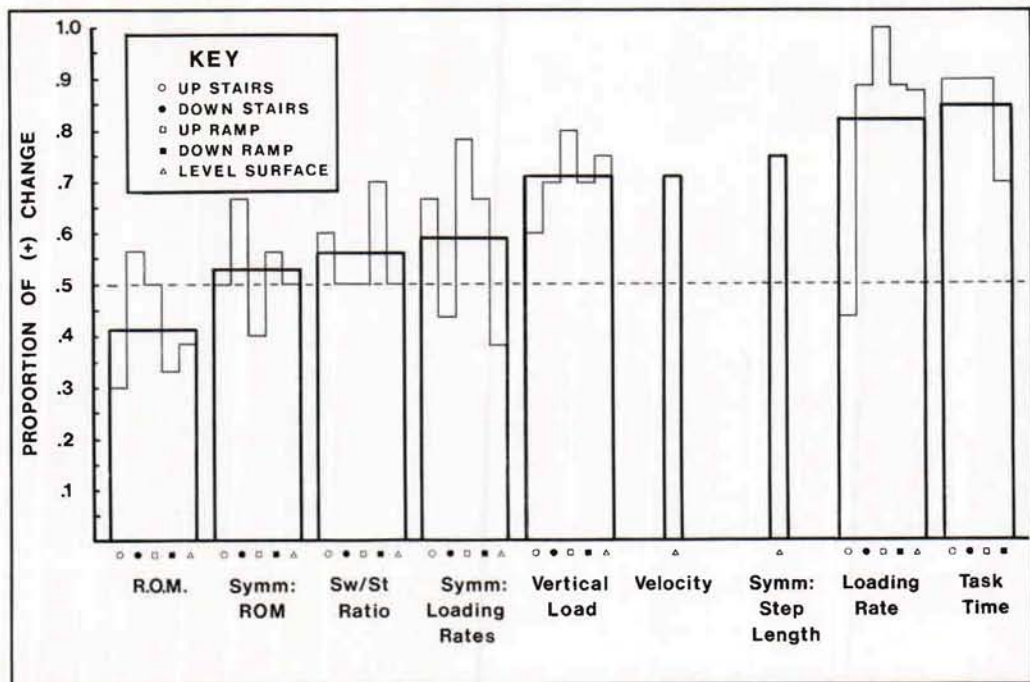


Fig. 13. Proportion of Positive Changes

	Wearing Time		Helpfulness		Better Function		Comfortable?		Good Fit?		Weight Noticeable?		Catch on Clothing?		Soil Clothing?		Cause of Perspiration?		Rub Skin?		Clothing a Problem?		Do you like its Appearance?		Score
	All the time	Only outside	A great help	No help	All the time	Most of the time	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
1. 78 yrs., DJD Left Valgus	X		X		X		X		X		X		X		X		X		X		X		X		9.5
2. 53 yrs., DJD Right Valgus	X		X		X		X		X		X	X		X		X		X		X		X		X	9.25
3. 47 yrs., RA Right Varus	X		X		X		X		X		X	X		X		X		X		X		X		X	8.25
4. 56 yrs., RA Left Valgus	X		X		X		X		X		X	X		X	X		X		X		X		X		8.0
5. 74 yrs., DJD Right Varus	X		X		X		X		X		X	X		X	X		X		X		X		X		7.75
6. 61 yrs., DJD Left Valgus	X		X		X		X		X		X	X		X		X		X		X		X		X	7.5
7. 74 yrs., DJD Left Varus	X		X		X		X		X		X	X		X		X		X		X		X		X	7.25
8. 53 yrs., RA Left Valgus	X		X		X		X		X		X		X		X		X		X		X		X		7.25
9. 81 yrs., DJD Left Valgus	X		X		X		X		X		X		X		X		X		X		X		X		7.0
10. 68 yrs., RA Left Varus	X		X		X		X		X		X	X		X	X		X		X		X		X		3.75

Fig. 14. Results of the Questionnaire

Questionnaire Results—The data from the questionnaire is presented in Figure 14.

It appears that the patients at the time of the follow-up wore their orthoses at least some of the time, a few wore it all the time. All but one thought it was a great or moderate help and that they functioned better with it. The other patient felt that it was no help. The greatest problems seem to be cosmesis, interference with clothing, and excessive perspiration. There are no obvious correlations between patient responses and age, type of arthritis, or type of instability.

DISCUSSION

The laboratory data indicate that except for range of motion, the overall

functional performance of the patients showed general improvement with bracing. How clinically significant the magnitude of these changes are an open question, but there were consistently more positive changes than negative. This was especially true for Vertical Load, Loading Rate and Task Time. These three parameters may be more critical indicators of change than the other parameters. Velocity, being the level surface counterpart to task time may also be a parameter worthy of further study. Although the average performance of the group in Range of Motion showed gains on three out of five surfaces, the pre/post bracing changes were negative more often than positive. This implies that overall, the orthosis does not promote an improved range of motion in the sagittal plan. It may in

fact hinder knee movement slightly in some patients. The group gains in range of motion can be attributed to dramatic improvements by patients 3 and 8.

The data from the questionnaire indicate that a majority of the patients tested thought that the C.A.R.S.-U.B.C. orthosis was a reasonably good solution to their knee problem. It must be pointed out, however, that the sample consisted mostly of moderately involved arthritics. An additional twenty candidates refused to participate in the study. Although the severity of involvement of those patients was not documented by the knee scoring scales, it seems probable that most of them would have fallen into the minimally involved or severely involved categories. The patients who were "minimally" involved seemed to reject the orthosis because of its size and cosmesis. They preferred the idea of a knee corset. The "severely" involved patients, particularly those with rheumatoid arthritis, seemed to reject the orthosis because of problems in donning and doffing. Many had hand deformities and difficulty bending forward, which prevented them from doing these tasks independently. Reconstructive surgery was a more palatable option for many of these patients. The moderately involved patient's pain seemed severe enough to outweigh the cosmesis considerations, yet they were capable of donning and doffing the orthosis independently.

Although it was difficult to observe clinically reduced varus or valgus moments when the patients walked, the weight line photographs showed definite alignment changes in some cases. This, along with the generally favorable acceptance of the brace by the patients, leads one to the hypothesis that the orthosis reduces the end-range of a medial-lateral movement. This could be enough to relieve pain. The result is a symptomatic relief but not a dramatic realignment of

the limb.

This study should be considered in light of the fact that the patient sample is small, and that there could have been extraneous variables affecting gait in the two to four weeks between tests. Examples of such variables are weather conditions, a temporary remission of symptoms, or a placebo effect from the orthosis.

CONCLUSION

In summary, the study found that the C.A.R.S.-U.B.C. orthosis can exert corrective forces to an unstable knee in the medial-lateral plane. Our sample of moderately involved arthritics generally liked the orthosis, and they showed general improvement in the gait parameters measured.

ACKNOWLEDGEMENT

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Footnotes

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