CLINICAL EVALUATION OF A SENSORY FEEDBACK DEVICE: THE LIMB LOAD MONITOR[a]

Gunilla Wannstedt, L.P.T.
Research Physical Therapist

Medical Research and Training Center No. 8
Temple University
Philadelphia, Pennsylvania 19122

Rebecca L. Craik, M.S., L.P.T.
Research Physical Therapist

Rehabilitation Engineering Center
Krusen Center for Research and Engineering
Moss Rehabilitation Hospital
12th Street and Tabor Road
Philadelphia, Pennsylvania 19141

I. INTRODUCTION

Ambulation training is an important phase of the rehabilitation process for patients with any of a variety of pathological conditions. The ability to shift laterally in order to achieve single-limb balance is essential for functional gait, but may be impaired in patients with brain damage, lower-limb amputation, or hip joint replacements (1). In addition, a specific amount of weight-bearing on one limb is often prescribed for patients with various orthopedic conditions such as malunion fracture or pinned hip fracture. Therefore, the final ambulatory goal is often divided into such subgroups as standing balance, weight-shifting ability, and achievement of adequate limb loading. Various patients, however, are unable to achieve all of these sub-goals. For example, the patient who has just received a lower-limb prosthesis may be afraid to load the artificial limb fully. Patients with sensorimotor disabilities may lack the sensory information or sensory processing ability necessary to develop these standing skills and are, therefore, unable to achieve an optimal walking performance.

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In the usual clinical environment, the clinician has very few methods by which to help the patient appreciate appropriate limb loading. Two commonly used tools are bathroom scales and full-length mirrors (2). The use of the bathroom scale requires that the patient load the affected limb to the desired amount and then remember this load during walking. However, neither clinician nor patient is sure that the loading which occurs during walking matches the loading that occurred during standing on the bathroom scale (3). The use of the mirror serves to remind the patient to stand or walk "straight" and not to lean toward the sound limb and away from the affected limb. However, an erect posture does not necessarily correlate with symmetrical loading (4). Therefore, both of these methods are less than optimal in helping the patient to achieve proper loading.

In instances where enhanced sensory input may lead to development of controlled motor activity, augmented sensory feedback has been used. By use of adequate instrumentation, feedback equipment can give information through alternate sensory channels (e.g., auditory, visual) about the rate and amplitude of movement; augmented feedback is immediate and contingent upon the success, or lack of success, in achieving performance (5).

The Limb Load Monitor is a clinical tool used to enhance relearning of posture and locomotor skills of patients. Based on the rationale of augmented sensory feedback, this device is designed to provide a proportional auditory signal which correlates with the amount of weight placed on a limb. The auditory tone provides an error signal if actual loading does not match the intended loading. Therefore, the alert and oriented patient has accurate additional feedback information which may allow correction of aberrant performance. In addition, the clinician is provided with an objective measurement of the patient's progress in achieving the loading goal.

BACKGROUND INFORMATION

The Limb Load Monitor (LLM) was developed at the Krusen Center for Research and Engineering, Moss Rehabilitation Hospital, to enhance the ambulation treatment program. It was specifically designed to aid in the achievement of proper limb loading critical for optimal walking performance. In order to replace or augment such methods as bathroom scales and mirrors, the LLM had to be dependable, clinically useful, and practical enough to justify cost.

The Krusen Center staff focused on two major objectives during the development of the LLM: (i) to design a reliable electronics package and (ii) to document the clinical utility of the device.

Description of the Device

The LLM consists of a pressure transducer connected by wire to a small control box (Fig. 1). The transducer is built into a shoe insole and is meant to be worn inside the shoe. The control box, which weighs 9 oz, is meant to be worn attached to the patient's belt. The control box contains the source for an auditory signal which varies in frequency in proportion to the pressure being exerted on the transducer.

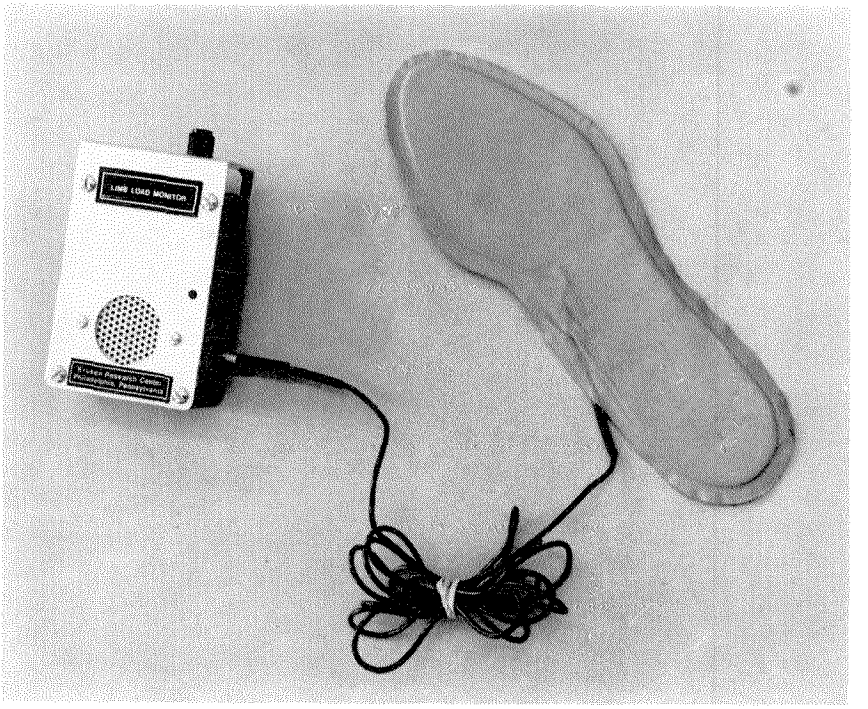

FIGURE 1.—The Limb Load Monitor (LLM) consists of a pressure sensitive shoe insole, connected by wire to a box containing controls and a sound-generating device. The box is intended to be worn on the patient's belt.

The LLM provides two treatment mode possibilities: in "Mode 2" the sound decreases in frequency with increased loading and becomes silent when the loading goal is reached; in "Mode 3" the sound begins at the calibrated loading level and increases in frequency with increased weight-bearing.

The controls include a switch for selecting one of the two treatment mode possibilities, and a control knob for adjusting the sound

"null" point which indicates to the patient that the desired loading has been reached. To calibrate the LLM, the patient loads the limb on a bathroom scale while the null point setting is adjusted. There is also a control for sound volume. The side of the control box provides a jack to accept the input from the transducer and another labeled "earphone." Insertion of an earphone plug automatically diverts the signal to the earphone and silences the small "loudspeaker" type sound generator in the control box.

Previous Clinical Testing "In-House" and Outside

With the clinician in mind, the Krusen Center felt it a responsibility to demonstrate not only the validity but the clinical efficacy of the LLM. Bench and laboratory testing at the Krusen Center during the past 5 years has shown that the final prototype accurately and reliably measures the vertical limb loading (6). In addition, Wannstedt and Herman conducted a clinical study on patients with hemiplegia (classified as stable) in their recovery of function (7). Findings of this study indicated that patients were able to use the LLM to learn to stand symmetrically and then were able to retain this skill in the absence of the feedback device. In this "in-house" study, the equipment was operated by trained personnel and engineering expertise was immediately available, so equipment failure was not a factor in the results which suggested that it was clinically feasible to incorporate the LLM into the treatment program of patients with locomotor dysfunction.

The next stage of testing naturally involved clinical use by staff physical therapists outside of the Krusen Center. Several clinical trials were conducted at various hospitals: three in Philadelphia, and one each in Massachusetts, New Jersey, and Kentucky.

Those tests were conducted to determine clinical acceptability, equipment reliability, and usefulness of the LLM to the patient and to the clinician. Results indicated that the clinician could learn to operate the device and that, when appropriately selected, patients with either neurologic or orthopedic disability (or both) were able to understand the purpose of the auditory signal. In addition, the prototype of an improved LLM was fabricated in response to the therapists' suggestions. Finally, as a result of those trials, an operating and treatment manual was developed with the purpose of transferring operating and equipment maintenance information to the clinician who would purchase the LLM (8,9).

The studies completed at the Krusen Center and within the various hospitals suggested that the LLM was a reliable device and that careful instruction on its use would enhance its clinical success. The results also indicated that the LLM could enhance postural con-

trol and loading awareness in patients. Therefore, the necessary next step was to conduct an extensive, more highly organized, trial to document the effect of the device on patient performance, the actual utilization of the device, and a practical method for introducing the device to the clinician.

FIELD TRIAL DETAILS

Purposes

The purpose of this field trial was to document: (i) transfer of information from the laboratory to the clinical setting; (ii) utilization of the LLM among patients with similar functional diagnoses; (iii) effectiveness of the LLM in attaining treatment goals; and (iv) reliability of the LLM in the clinical setting.

Outline of Procedure

The plan developed to fulfill the stated purpose can be outlined as follows:

1. identification of facilities interested in a cooperative investigation;
2. selection of a liaison with each facility;
3. training selected staff members in device operation;
4. having patients selected to use the device in treatment;
5. record keeping of initial and final status, outlined treatment goal, and patient's daily progress with the device;
6. evaluation of the clinical utility of the device.

This plan was instituted using the procedure to be described.

Participants

The formal trial period was planned to extend from September 1976 to June 1977. Five centers agreed to participate in the trial. Participating centers and personnel were as follows:

1. **Ontario Crippled Childrens' Centre, Toronto, Canada**
   Physical Therapy Department
   Elaine Sharp, M.H.Sc., Coordinator
   [b] Linda Ross, P.T. (Attended Moss Workshop)
   [b] Marissa Marshal, P.T.
2. **Rehabilitation Engineering Center, Harvard-M.I.T., Boston Childrens' Hospital Medical Center, Boston, Massachusetts**
   Physical Therapy Department
   [b] Janet Cox, L.P.T., Coordinator (Attended Moss Workshop)
   Claire F. McCarthy, L.P.T. Director of P.T.

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[b] Staff members primarily responsible for clinical use of the LLM.

[b] Dana McLaughlin, L.P.T.
[b] Lynne Wiesel, L.P.T.

3. **Rehabilitation Engineering Center, Northwestern University, Chicago, Illinois**
   Mayola Cotterman, L.P.T., Coordinator (attended Moss Workshop)
   A. **Cook County Hospital**
      Physical Therapy Department
      Louise Nelson, Director of P.T.
      [b] Arlin Duboer, L.P.T.
   B. **Mercy Hospital**
      Rehabilitation Department
      [b] Maureen Birk, L.P.T., Director of P.T.
   C. **Rehabilitation Institute of Chicago**
      Physical Therapy Department
      Patricia Kammerer, L.P.T., Director of P.T.
      [b] David Duff, L.P.T.
   D. **University of Illinois Hospital**
      Department of PM&R/Physical Therapy
      June Schroeder, Director of P.T.
      [b] Kathy Manella, L.P.T.
      [b] Janice Hubatch, L.P.T.
4. **Rehabilitation Engineering Center, Rancho Los Amigos Hospital, Downey, California**
   Michael Quigley, C.P.O., Coordinator
   A. **Amputee-Fracture Service, Physical Therapy Department**
      [b] Norma Mills, L.P.T., Director of P.T.
      [b] Antje Hunt, L.P.T.
   B. **Long Beach Memorial Hospital**
      Department of Physical Therapy
      Norma Shanbour, L.P.T., Director of P.T.
      [b] Gail Teaford, L.P.T.
   C. **Physical Therapy Graduate Student Project (12)**
      [b] Melinda Allen
      [b] Joyce Landes
      [b] Stephanie Talley
5. **Woodrow Wilson Rehabilitation Center, Fishersville, Virginia**
   Physical Therapy Department
   Patty Altland, M.S., Director of P.T.
   [b] David Dery, L.P.T. (Attended Moss Workshop)

A coordinator was selected at each of the five sites to supervise the clinical trial within the original site or to identify other hos-

[b] Staff members primarily responsible for clinical use of the LLM.

pitals in the area where physical therapy departments would be suitable for clinical testing. In this latter instance, the coordinator would serve as a liaison between Krusen and the additionally selected hospitals, as well as with the original site.

Transfer of Information to Participants

On September 20-21, 1976, a two-day workshop was held at the Krusen Center for the coordinators and other representatives from the participating centers. The course was designed to transfer information about the purpose of the field trial and method of operation of the LLM.

Local Site Selection

Upon return to their facilities, each coordinator selected appropriate local testing sites—10 facilities were involved in this process. The coordinators at OCCC, WWRC, and Harvard-M.I.T. supervised the trial within their own institutions, while those at NU and RLAH selected additional sites.

The originally selected sites at Northwestern University included the physical therapy departments at the University of Illinois Hospital, Cook County Hospital and Mercy Hospital. Five months later, the Rehabilitation Institute of Chicago was added at its own request and the rehabilitation department at Mercy Hospital was selected to replace the general department.

Originally, the amputee and fracture service was the trial site for RLAH. At the 6-month site visit, San Pedro Peninsula Hospital joined the test facilities. Long Beach Memorial Hospital began to participate in the 8th month of the trial.

Table 1 lists the type of facility and patient population served at each site. (Of the 10 sites selected, information from 9 was found appropriate.)

LLM Distribution and Maintenance: Each of the five coordinators was given three LLM and 20 insoles of various sizes. They were instructed to request additional units if needed, and to return any equipment that did not work.

Materials Provided: Treatment manuals were provided for each LLM, and a sufficient number of forms for progress documentation was given to each facility (Table 1; Appendix A:1-2).

Communications with Participants: In addition to an initial evaluation and daily treatment evaluation, opinions of the clinical staff about the LLM were to be collected in two ways: formally, through

TABLE 1—*Sizes and Types of Participating Trial Sites*

Hospital	Facility	Patient population	Target patients/month	
			Amputees	Hemiplegias
OCCC	1. Teen Unit, P.T. Dept. 2. Prosthetics Unit, P.T. Dept.	1. Children; outPatient 2. All kinds of amputa.	– 2	4 –
Harvard-MIT	1. OutPatient Developmental Disability Clinic 2. InPatient Ortho-Neuro Clinic	1. Children; CP, very few hemiplegias 2. Children orthop.; amp. and neurology	– <1	n/a –
Cook County Hospital	Acute-care P.T. Department	Varied general-hospital clientele; long-term patients referred to rehabilitation facilities	2	–
Mercy Hospital	Rehabilitation specialty: long-term	All types of handicaps	(5)	6
RIC	Rehabilitation specialty: long-term	All types of handicaps	(41)	79
University of Illinois Hospital	Acute-care P.T. Department	Varied general-hospital clientele; long-term patients referred to rehabilitation facilities	4	(4)
Rancho Los Amigos Hospital	Amputee–Fracture service	All kinds of amputations for L.E., mostly "Syme's"	(60-90) 12-18	–
L.B.M.H.	Neurology and Rehabilitation	Neurological handicaps	–	10
W.W.R.C.	Vocational Rehabilitation	All kinds of long-term handicaps	5	3

Note: Figures in parentheses are approximate.

a questionnaire to be completed by the therapists at the end of the trial and, informally, at each site visit, through interviews at staff meetings. Visits to each of the clinical sites were made in October 1976, and in February-March and July, 1977. (Northwestern University was visited on one other occasion, in May 1977.) Regular contacts were made with the participants between visits via telephone calls and letters, and contact was established whenever any questions or problems arose at any of the centers.

Patient Selection Criteria and Therapy Goals

Two target groups had been identified for LLM training; patients with lower-limb amputation, and patients with hemiplegia. Each site was assigned a specific target group or groups.

In order to be a LLM candidate, the patient was to be either a patient with hemiplegia or a patient with a lower-limb amputation. In addition, the patient was to have a limb-loading problem and to fulfill the selection criteria outlined in the pre-evaluation form (Appendix A:1). If the patient was an appropriate candidate, the purpose of training with the LLM was to be able to achieve controlled weight-bearing on a limb. Specific goals for therapy were either (i) to prevent excessive loading, (ii) to maintain a load level, or (iii) to increase actual weight-bearing on the limb. The specific goal selected, and the daily progress made in achieving the goal, were to be recorded on the evaluation and progress note forms (Appendix A:2).

The training of controlled loading could be achieved either during quiet standing, or in shifting weight from side-to-side, or during walking. Therapists were asked to record the manner which they selected to approach this goal. They were also asked to record the mode of auditory signal used; i.e., either "2" where the sound decreases in frequency with increased loading, or "3" where the sound increases in frequency with increased loading beyond a calibrated threshold.

FIELD TRIAL RESULTS

Of a total of 75 participant months (determined by adding the number of months that each facility participated in the trial) 56 months were spent in actual testing of the LLM (Fig. 2).

Six additional LLM's were requested and distributed during the clinical trial. Only four LLM's used during this trial were reported to malfunction; these devices were either repaired by the Krusen staff or repaired locally. The insoles performed without problem

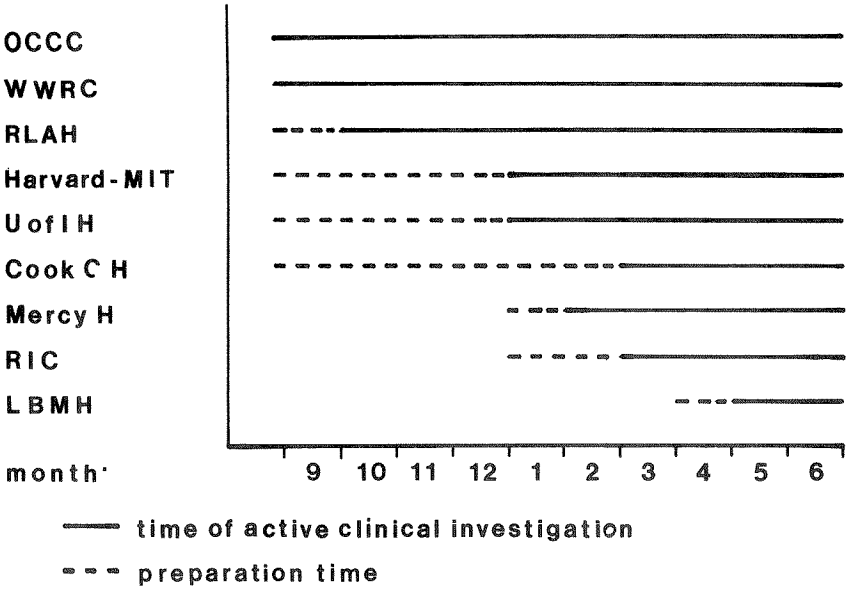

FIGURE 2.—Actual time period of involvement in study by the various centers.

and the insole breakdowns that occurred were the result of intensive use. (In one clinic, three insoles were worn so thin that they no longer worked accurately and had to be replaced. Where this occurred, the insoles had been taped to the outside of the shoe of the prosthetic foot because the shoe was too tight to allow room for the insole. Repetitive use in this fashion tended to wear out the transducers prematurely.)

Relative Utilization of the LLM in the Clinical Setting

Patient Sample

A total of 81 patients were selected; 44 were patients with lower-limb amputation and 37 were patients with hemiplegia. Table 2 shows the number of patients seen at each center.

The age range of the patients was 7-83 years, with a mean of 46.3 years. The clinics could be divided into three subgroups with regard to age: the two children's hospitals saw patients with a mean age of 14.6 years, the six rehabilitation or general departments for adults had a mean age of 59.2, and the vocational rehabilitation center served clients with an average age of 38.9 years. The mean ages for the hemiplegic and the amputee subgroups were the same as the corresponding age group in the overall sample.

TABLE 2—*Number of patients of each target group type who used the Limb Load Monitor.*

Target group	Name of center	Amputation			Hemiplegia			Total
		AK	BK	Other[a]	L	R	?	
Patients with Amputation	University of Ill. H.	5	0	4	3	—	—	12
	Cook County H.	2	5	0	—	—	—	7
	Rancho Los Amigos H.	5	3	1	—	—	—	9
Mixed	W.W.R.C.	2	4	2	4	4	—	16
	OCCC	2	2	0	4	2	—	10
	Harvard-M.I.T.	1	0	2	1	0	—	4
Patients with Hemiplegia	Mercy Hospital	—	—	1	1	1	3	6
	RIC	—	3	—	6	5	1	15
	Long Beach Memorial H.	—	—	—	1	1	—	2
Total	9	17	17	10	20	13	4	81

[a] "Other" include bilateral amputees and hip disarticulations
? = No information about side of lesion

Sample Size Compared with Target Group Population

The overall average percentage of the amputee population selected to use the LLM was 27 percent (7-41 percent), while the average percentage of the hemiplegic population selected was 21 percent (17-27 percent). These figures were computed by comparing the number of target group patients selected to the total number of target group patients seen by each facility per month. Figure

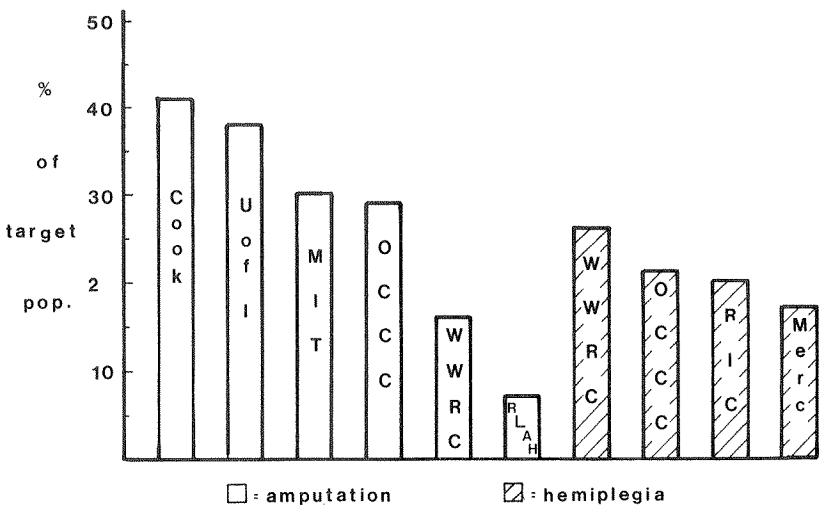

FIGURE 3.—Number of patients using LLM seen during the trial, expressed as percentages of the total target groups. (LBMH not included because of its short participation time.)

3 reveals the wide range of relative utilization in the various facilities.

LLM Usage Per Therapist

An estimate of the average number of patients using the LLM seen per therapist can be made, when the number of actively participating therapists is considered together with the number of patient forms submitted during the trial period. The number of patients selected per therapist per month was between 0.2 and 0.4 in both patient groups. This estimate is shown in Table 3 where it may be seen that, if only the target population is considered, the trial activity level remains fairly consistent among the various clinics.

TABLE 3—*LLM usage in terms of number of patients/therapists/month. The figures refer only to target groups, not total patient sample.*

	No. of therapists	No. of months	Patients with amputation	Patients with hemiplegia
Univ. of Illinois H.	5	6	0.3	–
Cook County H.	6	4	0.3	–
Rancho Los Amigos H.	3	9	0.3	–
W.W.R.C.	5	10	0.2	0.2
OCCC	2	10	0.3	0.3
Harvard-M.I.T.	2	6	–	0.3
Mercy Hospital	4	5	–	0.3
RIC	8	4	–	0.4
Long Beach Memorial H.	1	2	–	1.0
Mean ($\bar{X}$)	4	6.2	0.3	0.4

Number and Duration of Treatment Sessions with the LLM

The number of treatment sessions in which each patient used the LLM varied greatly among centers as well as among patient groups. The total number of sessions was 467, with an average of 6 treatments per patient. The hemiplegic patients used the LLM from 1 to 22 times each, with an average of 4 times, while the amputees used the device during 1 to 54 sessions with an average of 7 treatments per patient. Figure 4 shows the distribution of treatment activity among participating departments.

The actual duration per session in which the LLM was in use did not vary greatly (20-60 minutes) and only occasionally was a patient reported to use the device during a whole day.

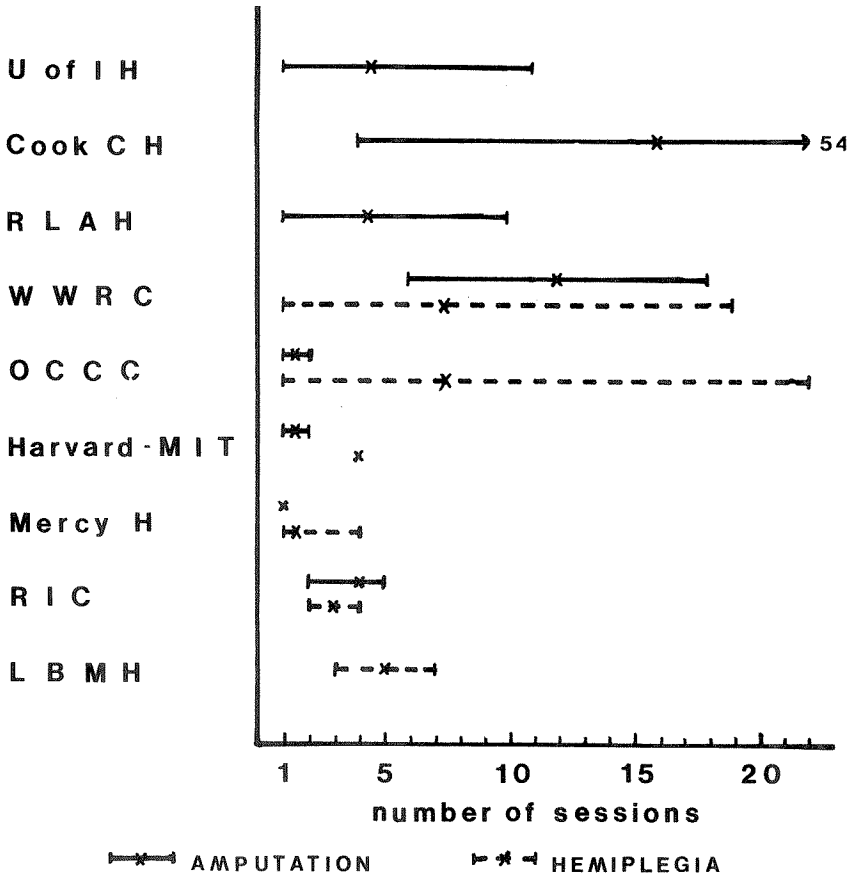

FIGURE 4.—Average and range of number of treatment sessions/patient at the various centers.

Estimated Utilization

The frequency of LLM use during this field trial was related to the number of therapists active at a center and to the type of patient population at the center. In Table 4, the reported trial activity can be seen as a function of "active" therapists and "active" time span. In a department geared towards total care of the patient with lower-limb amputation(U. of I., Cook County, WWRC, RLAH, see Table 1), the therapist applied the device an average of 2.7 times

per month. If, on the other hand, the therapist treated acute hemiplegic patients, or amputees with additional medical problems (Mercy, RIC, see Table 1), the actual number of sessions was less (average 0.9 sessions/therapist/month) but the same number of patients used the LLM (refer to Table 3).

TABLE 4—*Average LLM utilization per month during the trial. Target group for each facility is underlined.*

Clinical Site	Amp.	Hemi.	Monthly Utilization
U. of I. H.	1.4	0.2	1.6
Cook County H.	4.7	—	4.7
RLAH	1.4	—	1.4
WWRC	1.9	1.2	3.1
OCCC	0.3	2.3	2.6
Harvard – MIT	0.3	0.3	0.7
Mercy Hospital	0.1	0.4	0.5
RIC	0.4	0.8	1.2
LBMH	—	5.0	5.0
$\bar{X}$ of all sites	1.2	1.1	2.3
$\bar{X}$ of target	1.7	1.7	—

Two of the participating clinics were in children's hospitals (OCCC, Harvard). At these particular physical therapy departments, the patients with amputation were seen as out-patients for fittings and checks only, and the LLM was used only once or twice; the occasional hemiplegic patients with loading problems sometimes stayed in the hospital and were treated for varying lengths of time in the children's centers (Fig. 4 and Table 4).

Effectiveness of the LLM in Attaining Treatment Goals

Treatment Approaches

Among the amputees, the LLM was utilized during walking in 73 percent of the cases (instead of in quiet standing or weight-shifting). The LLM was not utilized at a specific point in gait training by all therapists; instead, its use varied among therapists. For example, some therapists elected to use the device to control loading with an immediate-post-surgical fitting while other therapists used the device for attainment of normal weight-shifting or loading

during walking with the definitive prosthesis.

Thirty-five percent of the hemiplegic patients started use of the LLM in walking.

Fifteen percent of all the patients used the LLM throughout the ambulation training, i.e., for standing and weight-shifting, followed by walking.

The preferred treatment mode was "3" where the frequency of the signal increases with increasing load—78 percent of the amputees and 71 percent of the hemiplegics used this mode in treatment. The other patients used mode "2", in which frequency decreases with increased loading (Fig. 5).

Results of Treatment:

Of the 81 patient records collected, 4 percent (3 patients) of the patient records were not complete. Of the remaining sample, 79 percent (62 patients) were judged to improve with the LLM while 21 percent (16 patients) did not improve. Criteria used to determine improvement were based primarily on the therapist's comments about the ability of the patient to achieve controlled or improved loading or to learn the task of weight-shifting. The therapist's comments were also checked against a comparison of the treatment goal with the recorded progress notes. (Appendix A)

Reasons for lack of success include: (i) equipment malfunction; (ii) lack of patient cooperation; (iii) inability of the patient to understand the meaning of the auditory signal. (This last reason suggests that patients were not selected according to the outlined criteria—review of the progress notes suggests that 8 percent (6 patients) of the sample were improperly selected.)

Among the 79 percent of patients whose treatment with LLM were judged successful, the records from 19 percent (15 patients) indicated that the goal was achieved, but caused genu recurvatum or pain, or there was a lack of "carryover" of the loading in the absence of the LLM.

A separation of the results by target groups yields some interesting findings. The patients with lower-limb amputation achieved the goals in 84 percent of the cases, with 11 percent of these reported to demonstrate inconsistent carryover. Of the patients with hemiplegia, 68 percent responded well to the weight-bearing training, but 27 percent (10 patients) of the group exhibited faulty posture or no carryover from training (Fig. 6).

Closer examination of sub-categories within each of the two target populations showed that the statistics found for the entire group could also be applied at this level: of the 17 above-knee

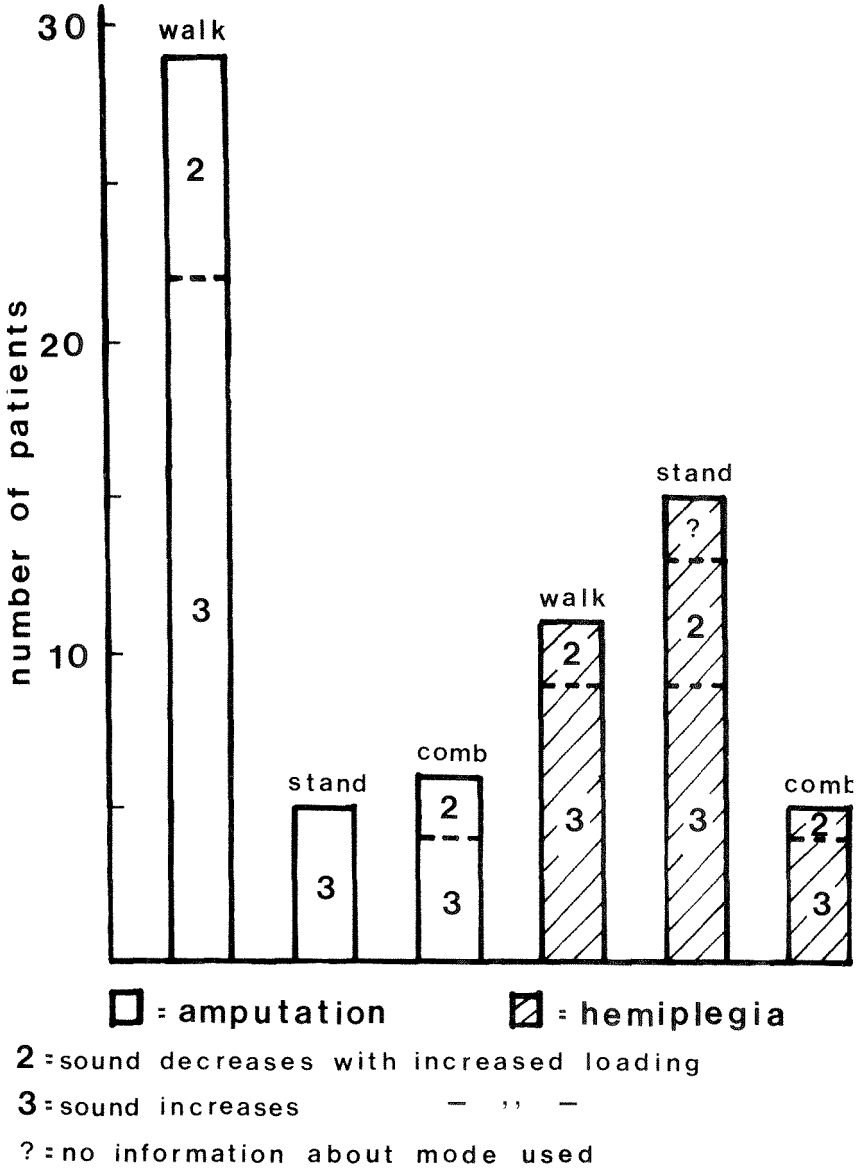

FIGURE 5.—Types of treatment approaches and modes used. (The abbreviated labels have the following meanings: stand = standing balance training; comb = combination of postural and locomotion goals; walk = gait training. 2 = Mode 2 in which frequency of the sound decreases with increased load; 3 = Mode 3 in which the frequency of the sound increases with increased load.)

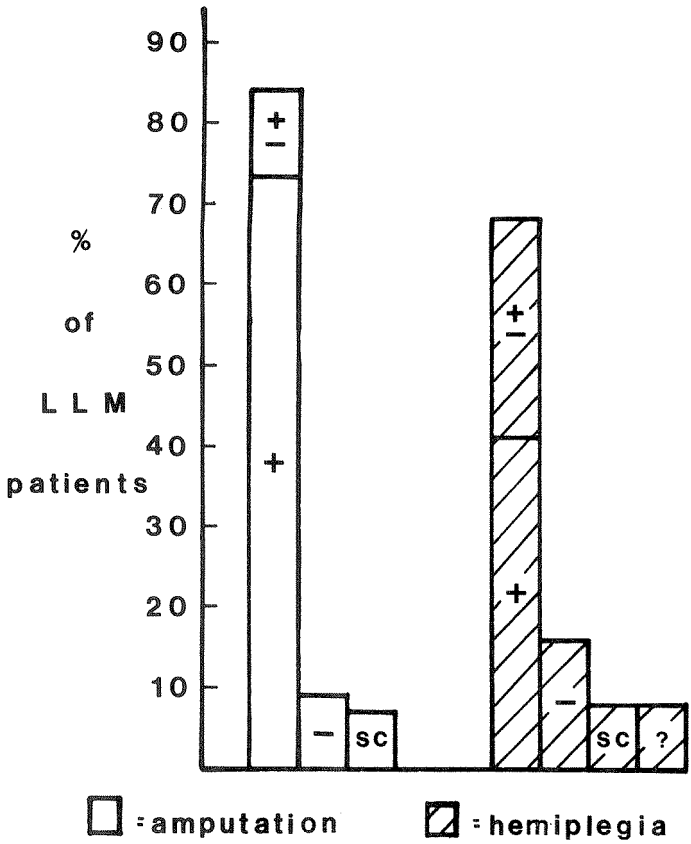

FIGURE 6.—Relative achievement of treatment goals according to the criteria outlined in the text. (Meanings of symbols are as follows: + = treatment goal; ± = not entirely successful; − = did not reach treatment goal; s.c. = not selected according to criteria; and ? = lost, no information about results.)

amputees who used the LLM, 82 percent (14 patients) did so with positive results, and of the 17 below-knee amputees chosen, 88 percent (15 patients) reached the treatment goals; 10 patients had bilateral amputations or hip disarticulations, and 70 percent (7 patients) of these responded well to the treatment.

In the hemiplegic group, 73 percent (16 of 22 patients) of patients with left hemiplegia and 67 percent (8 of 12 patients) of patients with right hemiplegia showed positive results. (The records from three hemiplegic patients did not indicate treatment results.)

Clinicians' Comments on Transfer of Information, Utilization, and Effectiveness

The questionnaires contained 25 questions. A summary of the responses (and the actual questions) is displayed in Appendix B. Some questions were not answered by all therapists; therefore, the results are expressed as the percentage of the response to each individual question.

Questionnaire Responses

A total number of 36 questionnaires were received from 9 centers. (For the number of involved therapists at each center refer to Table 3.) No forms were received from San Pedro Peninsula Hospital.

1. *Transfer of Information from Laboratory to Clinic* (questions 1, 2, 3). The instruction and treatment manual for the LLM was read by 61 percent of the clinicians; 43 percent of the respondents felt that the contents were clear, easily understood, and provided adequate material to allow for operation of the device; 61 percent of the therapists were taught how to operate the device by another clinician, and 25 percent taught themselves; 14 percent had participated in the workshop at Krusen Center.
2. *Ease of Operation and Device Reliability* (questions 9, 10, 11, and 13). Eighty-six percent of the therapists stated that it took less than 10 minutes to calibrate the LLM when they were first becoming familiar with the device (28 percent of these clinicians required less than 5 minutes to set the device). After some practice with the procedure, 81 percent of the sample reported being able to calibrate the device to the desired load in less than 5 minutes.

   Thirty-nine percent of the therapists found that, after the calibration was set to the desired weight, the setting remained stable throughout the treatment time; another 39 percent reported that the calibration changed during treatment, and 22 percent stated that the patient had changed the calibration or that they never checked the setting.

   When asked specifically about the ease of operation, 48 percent felt that the device was easy to operate, 46 percent thought it should be easier to manage, and 6 percent felt it was difficult to use adequately.

3. *Clinical Utility of the LLM* (questions 6, 15, 16, 17, 18, 21). Fifty-three percent of the clinicians stated that their patients always fulfilled the selection criteria, while 47 percent reported that some of the patients would not initially correlate the tone with performance. However, once the patients were selected, 59 percent of the therapists found that the patients were able to load the limb adequately most of the time (22 percent of the clinicians stated the patients were able, consistently, to load the limb to the calibrated level all of the time).

   Most therapists (91 percent) reported that the patients appropriately responded to the LLM during the first or second session. The remaining 9 percent stated that the patients were able to use the device properly by the third treatment session.

   A variety of treatment frequency schedules were employed. For example, 43 percent reported that the patients used the LLM about 3 times a week and 46 percent reported that the LLM was used in daily treatment. Eleven percent used the LLM once a week or one time only. Although 81 percent of the sample used the device only in the clinic, others had the patients utilize the device on the ward or at home. Besides the therapists, those who learned to operate the LLM also included physical therapy aides, students, and patients themselves or their family members.

   In evaluating for clinical utility, an important consideration is the patient's acceptance of the device. Sixty-one percent of the clinicians reported that most of the patients accepted the LLM as part of the treatment program, and 30 percent stated that all of the selected patients accepted the LLM.

4. *Applicability of the LLM* (questions 19, 20, 22). Although the therapists participating in this field study had been asked to record use of the LLM with certain specific patient categories, they had also been told to feel free to use the device on any other patient who seemed likely to benefit from this kind of patient approach. Of the patients selected to use the LLM, the patients with lower-limb amputation were most likely to be selected to use the device (50 percent) followed by patients with hemiplegia (39 percent) and the "other" category (11 percent) which included mostly

orthopedic patients.

When asked if they used the device with more than one category of patients, 21 therapists (58 percent) answered that the question was not applicable to them. Of those therapists who considered it applicable, the majority (66 percent) stated that it was most useful for the amputee category while 27 percent felt that the device was useful for a variety of patients.

When asked to estimate the percentage of the total patient population considered to be LLM candidates, the clinicians' responses were as follows: 38 percent felt that it was applicable to less than 10 percent of the population, 34 percent felt that it was applicable to 10-25 percent of the patient population, 12 percent felt that the LLM could be applied to 25-50 percent, and 16 percent of the sample felt the device would be applicable for more than half of the patient population.

5. *Device Maintenance and Suggested Changes* (questions 7, 8, 12, 23, 24). The majority of the clinicians reported that a working control box (69 percent) and an appropriate insole (56 percent) were available when needed for a patient.

When asked to comment specifically on any technical changes that would enhance the LLM, 11 percent of the sample were completely satisfied with the device. The remaining people suggested changes in the following factors:

Auditory signal (28 percent);
Insole cable (11 percent);
Weight of the unit (17 percent);
Size of the control box (13 percent);
Position and/or shape of the box (13 percent); and
Texture of the box (6 percent).

Fifty-one percent of the clinicians would suggest purchasing the LLM for use in a physical therapy department; 23 percent would purchase the device depending on the patient load or if certain changes were implemented (Fig. 7) and 23 percent would probably not recommend purchasing the LLM. (This last group did not comment any further regarding why they would not purchase the device.)

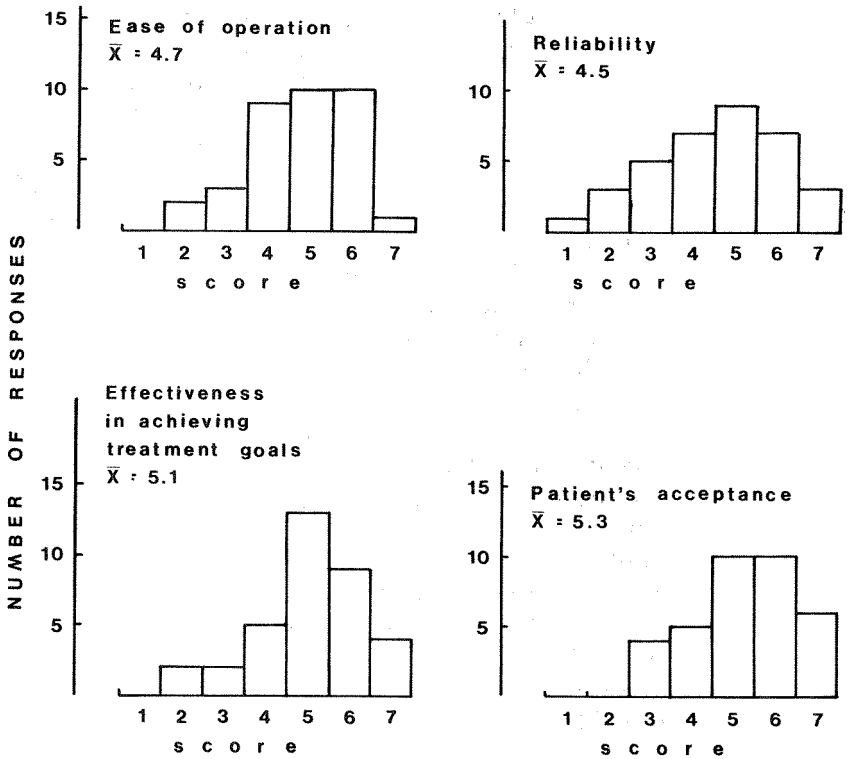

FIGURE 7.—Number of responses to the questions regarding ease of operation, reliability, use of device in achieving treatment goals, and patient acceptance. The therapists were asked to use a scale from 1 to 7, with 7 being the highest score.

In the last question, the clinicians were asked to rate ease of operation, reliability, use of device in achieving treatment goals and patient acceptance on a scale from 1-7, 7 being the highest score.

Ease of operation was rated with a mean score of 4.7 (Modes = 5, 6).

Reliability received a mean score of 4.5 (Mode = 5).

Utility of the LLM as an aid to treatment goals was ranked with a mean score of 5.1 (Mode = 5); and

Patient acceptance received a mean score of 5.3 (Modes = 5, 6)

See Figure 7.

Informal Comments on Questionnaires

Comments were offered on all questions. The most frequently appearing comments included the following:

1. *Comments about Ease of Operation and Reliability:* 23 comments in this area were made in relation to various questions. The largest group of comments (48 percent) dealt with instability and fluctuations of the calibration setting, mainly at low weight-settings such as those used for treatment of children or in limited weight-bearing with an immediate-post-surgical fitting. Eighteen percent explained that calibration time depended on practice or the kind of patient treated, and 17 percent felt that use of the device was either time-consuming or difficult.
2. *Comments about the Patient-Evaluation Forms:* 10 therapists made separate comments about the evaluation forms (Appendix A:1). Half of them remarked that it was rather long and time-consuming and that they, therefore, tended to estimate some measurements or leave some parts out; 30 percent thought that the forms gave too little information about the patient and wanted to include such things as attention span and a test for endurance; and 20 percent felt that the forms were useful for obtaining a baseline for treatment and for getting a picture of the gait problem.
3. *Comments about Patient Responses:* 20 clinicians commented specifically on patient responses to the device: of these 15 percent explained that patients responded adequately if selected properly.

   Twenty-five percent remarked that the patient category for which the LLM was most useful was the post-surgical fracture patients, and 35 percent stressed that the device was most useful for amputee patients.

   Twenty-five percent felt that patients with hemiplegia in the acute stage would not benefit from the feedback treatment because there were so many other problems at hand at that stage.
4. *Comments about Technical Features:* The majority of comments were made about details concerning the device. Fifteen percent of the therapists wanted a greater variety of insole sizes—either smaller or larger than the full range of sizes they had been provided

with. Thirteen percent were concerned with the quality of the feedback sound which many found irritating or distracting for other patients in the clinic. Other comments dealt with the type and placement of the controls, weight of the box, sensitivity of the setting and price of the unit. The various suggestions about the LLM are listed in Figure 8.

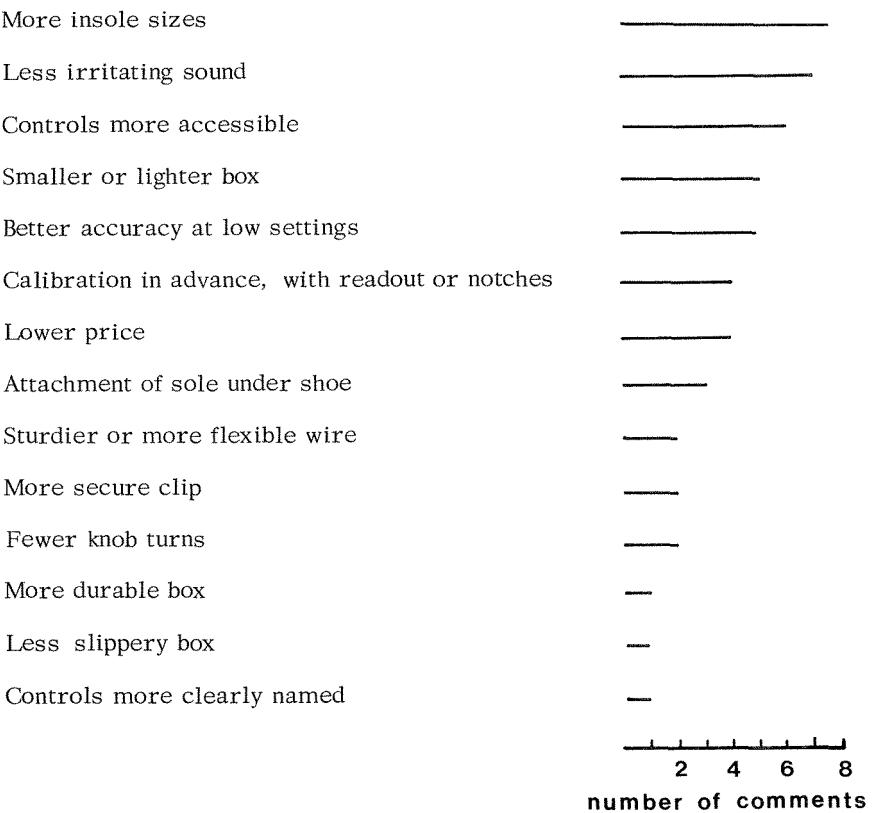

FIGURE 8.—Suggestions for improving the design of the LLM as listed by therapists at the end of the trial. (Length of dash is proportional to number of times each item on this list was suggested.)

Comparison with Questionnaire Responses from Another Group

The LLM has been available for sale at Krusen Research Center for two years, and has been purchased by nine hospitals. Those hospitals had used the LLM for various amounts of time, and without any special introduction or structure. Therapists at those

hospitals were surveyed by mail, using the same questionnaire that was used for therapists participating in the field study.

Results from that mail survey are remarkably similar to those obtained from the field study (10). There were some notable differences, however. For example, the mail-surveyed therapists offered fewer free comments and suggestions, and seemed to be more satisfied with the device as it was, than the field trial participants. For example, in Question 12, which dealt with technical features, 21 percent of the mail-surveyed therapists versus 11 percent of the field trial therapists were satisfied with the device, and in Question 13, which asked about the ease of operation, 69 percent of the surveyed clinicians felt it was easy, versus 49 percent of the trial therapists.

Another difference is seen in the questions that dealt with the type of patients who used the device. The field trial participants' instructions had emphasized selection of amputees or hemiplegics, and still they used the LLM for "other" diagnoses in 11 percent of the answers. The surveyed therapists had used the device in a wider variety of patients and their "other" category occupied 49 percent in the answers. When asked about the group of patients for whom the device might be most beneficial, the majority of each group mentioned the amputees (66 percent and 57 percent) but a considerably higher number of mail-surveyed therapists mentioned "hemiplegics" and "other" categories than did field-trial clinicians. A summary of the responses to the questionnaires is presented in Appendix B.

DISCUSSION

A review of all the results suggests that the transfer of material from the laboratory to the clinic was done successfully and, therefore, that the transfer procedure was adequate. In addition, the results suggest that the LLM is a clinically useful tool. The majority of therapists became comfortable with the device, used it with any patient they felt to be appropriate, and were familiar enough with the concepts to express a multitude of suggestions and feelings about this treatment approach. The comparison of this sample size (81 patients) to the sample size of other field trials which were similarly designed to assess efficacy of a clinical device, is an indication of this study's validity (8). Furthermore, the high percentage of success in achieving goals with this patient sample (79 percent) coupled with the clinicians' positive comments on the clinical utility, support the premise that the LLM is, indeed, a useful clinical tool.

As stated earlier (under *Methods*), this study was a demonstration designed to show that the limb-load monitor could be used clinically to assist in achieving treatment goals. A clinical evaluation of this open-ended type should not be construed as a scientific experimental investigation, for reasons that have been outlined by previous investigators (11). For example, a major source of error consists of the numerous uncontrolled variables which include lack of a control group, lack of a truly random sample, and lack of interrater reliability. Such sources of error may be to some extent unavoidable characteristics of a study such as this. But there were other types of problems which seem to have been built into the process as a result of the clinical study design that was used. These should be given consideration at this point, because it may be completely possible to mitigate or eliminate them in future clinical trials.

For example: it was difficult to establish guidelines regarding how much clinical time and effort should be specified for the device assessment project in place of, or in addition to, the usual staff responsibilities, and for this reason the actual time that each therapist did spend with the device became a point of investigation in this study. As indicated by the therapists, following the initial period of learning to operate the device and becoming familiar with the evaluation forms, they were able to carry on their routine treatment procedures very much in the usual fashion but with an added treatment tool at their disposal. Therefore, it would be useful to develop a mechanism to deal more efficiently with the "introductory period" of new devices in the future.

Another consideration in this type of demonstration project is whether the clinical staff has appropriate support throughout the trial period. From the reported results, it may be concluded that the Rehabilitation Engineering Center staff and the appointed coordinators adequately transferred appropriate materials and information. Their task involved ensuring that all materials and equipment were available, that the clinic selected had an adequate patient load, and that the therapists were properly trained in the use of the device. Despite this effort, there were therapists who "taught themselves" to use the LLM rather than being taught formally or having access to the manual.

Material or equipment breakdowns that occurred during this period were handled within a few weeks through repairs or replacements. Accordingly, malfunction was not reported to interfere with the number of patients selected in any instance.

Another very important consideration is whether the clinical staff consistently and accurately completed the data sheets required for each patient who used the device (Appendix A:1,2). Although

teaching skills or advice were available to the staff, it became obvious during the trial that some prospective LLM candidates were not being included or not recorded, especially during the first months of the trial. Inadequate record-keeping was confirmed at periodic informal meetings, where various staff members from different facilities reported similar clinical trial experiences.

In summary, it was felt that, with a very busy patient schedule, it is difficult for clinical staff members to take the initial extra time (from patient treatment time) to "practice" with any new device, particularly when (as in the case of the LLM) this also required additional "paper work." The result was that, during the initial practice period with the device, the forms were neglected or discarded because the evaluation procedure seemed cumbersome or because the forms were incorrectly completed.

Need for Workshop-Type Pre-Trial Training Confirmed

It seems evident that most, if not all, of these obstacles could be overcome by direct teaching in the form of a workshop with the physical therapy staff before a clinical trial begins. In addition, this information points to the need for thorough staff introduction to any new device added to the present treatment arsenal—this becomes increasingly important when the correct use of a device requires the understanding of recently acquired knowledge and concepts.

The time span, and number of therapists involved, varied considerably among the clinics. Since no specific number of patients was expected or suggested to the clinicians, the patients selected can be seen as a pseudo-randomly selected cross-section of patients with hemiplegia or lower-limb amputations, with remarkably even distribution between the two target groups and the various sub-group diagnostic categories. This is particularly true with the amputee sub-groups. Among the hemiplegic sub-groups, 60 percent had left-sided involvement and only 39 percent were right-hemiplegics: however, it would be expected that the patients with left-hemiplegia (who have a higher incidence of perceptual problems) might also have a higher incidence of weight-bearing problems (7,12).

There are large differences among the various clinics in the relative use of the LLM (percent of population) as well as the number of LLM sessions per patient. This may reflect the type of facility (Table 1) and thus may correspond to the goal of therapy as well as to the patient category utilized. This premise is supported by an examination of results in relation to the type of facility: for example, the two departments with the highest relative number of amputees selected (U. of I., Cook County) are similar in type, each

with a program of acute care as well as a total rehabilitation program for the amputees. Compared to the other facilities, the number of treatment sessions is moderate to large, which reflects the total care treatment approach.

At WWRC patients are admitted primarily for vocational rather than physical rehabilitative goals. Here, again, the large number of treatment sessions administered is consistent with the long-term-care type of facility.

The low relative use of the LLM at RLAH may be correlated to the fact that this facility specializes in treating the "problem" patients with amputation; i.e., those with secondary complications, a fitting problem, etc.

The relative use of the LLM was equivalent at the two children's hospitals (Harvard-M.I.T. and OCCC) i.e., 29 percent and 30 percent of the total amputee population, respectively. The number of LLM sessions at these two facilities was never more than two per patient. Perhaps these results reflect the fact that the children with amputations were seen as outpatients for fitting of the prosthesis and were not reported to be as hesitant about loading their limb as many elderly patients.

The relative use of the LLM for hemiplegia patients is also fairly even between centers. Except for the facilities with non-acute patients (WWRC and OCCC), the number of sessions tends to be lower than that of the amputee target group. This is explained by many therapists as due to the fact that, in the case of acute stroke patients (and in contrast to the patient with an amputation) there are many aspects other than weightbearing and posture that have a higher treatment priority (Fig. 3 and 4).

The number of patients selected to use the device as compared with the number of possible patients in each target group was calculated to be rather low; i.e., one new LLM candidate would be selected by each staff therapist every month. The clinical reality is naturally different, since the bulk of the selected patients in this study were treated by a few appointed therapists who carried the desired patient load and assumed responsibility for the study activities. The average number of sessions at which each therapist used the LLM varied according to type of clinic (Table 4), but for the number of patients per therapist selected, the average was very similar among departments and actually coincided with the result of an earlier clinical trial done with a prototype of the LLM (13). In Figure 9, the distribution of patient work over the trial period is displayed along with the number of clinics involved each month.

For accurate prediction of the expected use of the LLM in any type of clinic, consideration must be given both to the size of the

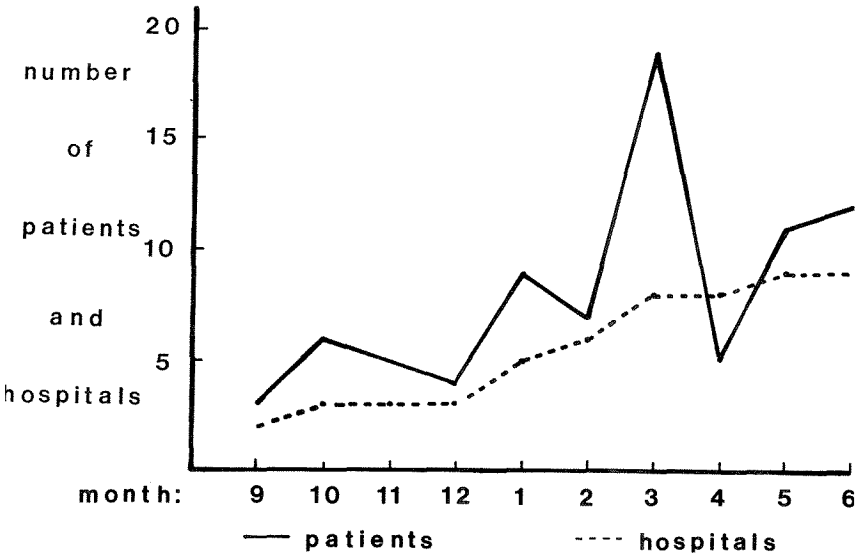

FIGURE 9.—Number of patients seen and hospitals involved per month over the trial period.

staff and to the target population. In counting population, in addition to patients with amputation or hemiplegia, orthopedic patients with prescribed control of loading were suggested by the therapists to be a population which would benefit from LLM treatment (see Results and Appendix B). This is supported by the results of our earlier clinical trials in which patients with limb fractures and total joint replacements were reported to benefit from use of the LLM (8, 13).

It is not uncommon to find physical therapy departments with standard pieces of equipment about which no one knows the frequency of use, or the device's subjective or objective value to treatment. Future studies should attempt to assess the relative use of any new device with various patient categories. This type of information would aid the clinician's decision of whether or not a device could be useful to the particular patient population seen in that facility. Until such studies are conducted, the clinician is forced to continue to select equipment based on tradition and intuition.

Not all patients selected for LLM training could benefit from this approach to weight-bearing training. The highest percentage of positive results was achieved among the amputee patients, which might be expected in view of the fact that proper weight-bearing on the prosthesis is a major goal in itself within the rehabilitation pro-

gram for this patient group. When the goal of weight-bearing was not achieved, that could be related to problems such as delayed wound healing or improper fitting of the prosthesis. In this situation, the LLM could serve as a tool for monitoring and evaluation of loading performance as such, another function that the device often served during the continued rehabilitation of a patient who had concluded the actual feedback training period.

For the hemiplegia population, the result achieved in terms of weight-bearing or weight-shifting was more often insignificant or temporary, because of the number and complexity of therapeutic problems encountered in patients with brain damage, especially during the early phase of rehabilitation. It seems likely, however, that problems such as faulty posture or lack of knee control, could be approached in conjunction with LLM use, or that specific weight-shifting training could be instituted at a later date when the patient had developed improved body image and motor control. A few trial sessions and monitoring with the LLM could also serve as an indication of whether increased weight-bearing is at all possible to achieve in some cases. Many of the clinicians' comments and suggestions in this area may serve as a basis for further studies, and for teaching and introduction of feedback therapy with the LLM.

When a comparison was made between the field trial questionnaire answers and the same questions used in a hospital mail survey, the answers dealing with treatment instructions and patient use were very similar between the groups, but the opinions about general usefulness varied somewhat (Appendix B). The response rate to the mail survey was high (64 percent) but it is very likely that the clinics which responded were the ones which had actively used the LLM the most, had investigated its possibilities and, therefore, approached the structured situation established for the formal trial sites. In comparison, the therapists who participated in the formal trial were forced to use the device with specific patient types, required to fill in forms, and constantly had to comment on the device utility. And, yet, if one considers that 36 percent of the mail-surveyed therapists did not even respond, the results of the formal trial are more positive than the results from the mail-surveyed therapists. Perhaps this is additional support for the need to have some type of workshop where clinicians can become familiar with the device operation.

CONCLUSION

Based on records of 81 patients who used the LLM, and on questionnaire answers and comments from clinicians, the following can

be concluded:

1. The LLM can be operated easily after a minimum of training. It does not break down with extended clinical use when handled properly.
2. The LLM manual provides sufficient information for proper operation and clinical use of the device.
3. The number of patients in a clinic who can benefit from LLM training can be predicted, if consideration is given to the type of facility and the size of the patient population and physical therapy staff.
4. The largest diagnostic group of patients who can benefit from LLM therapy are lower-limb amputees, followed by hemiplegic and orthopedic patients.
5. The general selection criteria outlined initially proved sufficient. A patient who is selected properly can be expected to respond to the feedback signal (i.e., make a weight-bearing adjustment) within the first or second session.

RECOMMENDATIONS

1. The LLM as a device: If possible, the type of sound should be less irritating, the controls should be more accessible or of different design, and the calibration should be more accurate at low settings.
2. Information: For immediate and optimal use of the device, direct teaching in the form of clinical workshops or a cassette slide show should be available to purchasers.
3. Further studies should be initiated regarding the quantity and quality of use (in general) of clinical equipment and procedures.
4. There are several other commercially available devices designed to indicate loading level to the patient. A study should be conducted to assess the validity of, and compare the utility of, these devices.
5. The clinicians selected to participate in a clinical evaluation study should be thoroughly aware of the purpose of the project. The procedures expected of the clinical staff involved should be outlined. Sites should be geographically close to the original center to ensure maximal support to the staff.

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APPENDIX A

Appendix A:1 KRUSEN CENTER FOR RESEARCH & ENGINEERING
LLM
PATIENT EVALUATION

I. Criteria for participation. All seven should be positive:

1a Hemiplegia ☐
1b Amputation ☐
2 Adequate Hearing ☐
3 Comprehension ☐
4 Has no preventive condition (Heart-Lung, Amp./Hemipl., Other Neur.)
5 Asymmetry in walking or standing ☐
6 Can sit without any support 1 min. ☐
7 Can stand with assistive device 1 min. ☐

II. Special patient information:

Code _____
Side of Involvement _____
Onset Date _____
P.T. Discharge Date _____
Complications during hospital stay _____
Age _____
Therapy Goal _____

Primary Diagnosis _____
Orthosis or Prosthesis Type: _____
P.T. Admission Date _____
Outpat. Therapy time: (From-To) _____
Body weight _____ Height _____

Date: _____ First/Second Evaluation

III. Symmetry Evaluation:

Walking

1. Assistive Device
   - parallel bars or walker ☐
   - q-cane or crutches ☐
   - straight cane ☐
   - nothing ☐
2. Average Loading (Norm:100%)
   - less than 70% of bw ☐
   - 70% - 85% ☐
   - more than 85% ☐
3. Velocity (Norm:1m/sec)
   - less than 0.3 m/sec ☐
   - 0.3 - 0.7 m/sec ☐
   - more than 0.7 m/sec ☐
4. Single support time (Norm:35% of stride)
   - extremely uneven gait, less than 10% of stride ☐
   - uneven gait, 10% - 25% of stride ☐
   - almost normal more than 25% ☐

Standing

5. Assistive Device
   - person ☐
   - parallel bars or walker ☐
   - q-cane or crutches ☐
   - cane ☐
   - nothing ☐
6. Comfortable straight loading on inv. leg
   loading in lbs: (Norm: 43-57%)
   - less than 30% of bw ☐
   - 30% - 43% ☐
   - 43% - 57% = even ☐
   - more than 57% ☐
7. Maximal loading on inv. leg (Norm:100%)
   loading in lbs.
   - less than 40% ☐
   - 40% - 60% ☐
   - 60% - 80% ☐
   - more than 80% ☐

8. Endurance Walking
   - only few steps ☐
   - about 100 ft. or functional indoors ☐
   - less than 1 block outside ☐
   - more than 1 block outside ☐

KRUSEN RESEARCH CENTER

LLM

DAILY TREATMENT RECORD

NAME_____ DIAGNOSIS_____ INSOLE SIZE_____

Target Function Check One	Treatment Approach Check One	Mode Selection Check One	Treatment Goal Check One
Insuff. loading during walking....☐	Walking.....☐	2 ☐	Increased loading in walking.....☐
Insuff. loading during standing...☐	Prolonged standing.....☐	3 ☐	Full loading walking.....☐
Other.....☐ .....☐	Weight shift for maximal load..☐	window ☐	Symmetrical standing.....☐
	Weight shift around optimal load..... ☐	Other.....	Other..... .....☐

PROGRESS RECORD:

Date	Time Used	Weight Calib.:	Assistive Device	Changes & Comments

APPENDIX B

A total of 36 clinicians responded to the questionnaire from the clinical trial study group and 40 clinicians responded to the questionnaire from the mail survey group. The percentage of each sample who responded to a specific question is listed to the right of that question in the presentation of the questions and responses which follows.

KRUSEN RESEARCH CENTER

Physical Therapist's Evaluation of the LLM

This form has been designed to learn your opinion of the LLM as a treatment tool. LLM utility is based on its ease of operation, reliability, and its usefulness in helping achieve treatment goals. Please be honest with your remarks regarding the LLM and don't spare our feelings. Your input will be instrumental in helping us specify the utility of this device.

Please circle one answer to each question unless otherwise specified:	PERCENTAGE	
	Study Group	Surveyed Group
1. What did you think of the quantity of material contained in the instruction and treatment manual?		
a. I never saw the manual.	17	23
b. I never read the manual.	22	3
c. The manual provided adequate material to allow me to operate the LLM.	58	61
d. The manual provided too little material to allow me to understand the operation of the LLM.	0	10
e. The manual provided much more material than was necessary to understand the operation of the LLM.	3	3
2. How was the clarity of the instruction in the treatment manual?		
a. I never saw the manual.	17	20
b. I never read the manual.	22	5
c. The material had to be read several times before it could be clearly understood.	33	35
d. The material had to be read once and was easily understood.	28	40
e. No matter how often I read the manual, I couldn't understand some of it.	0	0
3. How did you learn to operate the LLM?		
a. I taught myself.	25	32.5
b. Another therapist demonstrated its operation and application.	53	57.5
c. A doctor showed me how to operate it.	0	0
d. Other (specify):	8	5

	Study Group	Surveyed Group
e. I attended the workshop in Philadelphia.	11	.25
f. The Krusen people taught me during a visit here.	3	0
4. What did you think of the quantity of evaluation items that had to be completed for each patient?		
a. Too long.	31	N.A.
b. Too short.	8	N.A.
c. Adequate.	53	N.A.
d. I never used the evaluation forms.	8	N.A.
5. What did you think of the quality of the patient evaluation forms?		
a. Very subjective.	6	N.A.
b. Somewhat subjective.	24	N.A.
c. Somewhat objective.	46	N.A.
d. Very objective.	24	N.A.
6. Did the patients selected relate the auditory signal to performance?		
a. Never.	0	3
b. Always.	53	47
c. Sometimes.	47	50
7. Was an insole (transducer) available in the appropriate size when needed for a patient?		
a. Never.	0	5
b. Always.	56	63

	Study Group	Surveyed Group
c. Sometimes.	44	32
8. Was a working control box available when needed for a patient?		
a. Never.	0	8
b. Always.	69	57
c. Sometimes.	31	35
9. When you were first learning to use the LLM, how much time did it take to calibrate the device?		
a. Limited time (less than 5 minutes) with minimal loading and unloading of the patient's designated limb.	28	36
b. Required at least 5 to 10 minutes of continuous loading and unloading of the patient's limb.	58	51
c. Required more than 10 minutes and patient had to rest before calibration was complete.	14	13
10. After you practiced calibration procedures, how much time did it take to calibrate the device?		
a. Limited time (less than 5 minutes) with minimal loading and unloading of the patient's designated limb.	81	76
b. Required at least 5 to 10 minutes of continuous loading and unloading of the patient's limb.	19	19
c. Required more than 10 minutes or more and patient had to rest before calibration was complete.	0	5

	Study Group	Surveyed Group
11. How was the stability of calibration during one treatment session?		
a. Unstable - patient changed calibration.	8	3
b. Unstable - reason unknown	39	34
c. Stable - stayed at the same weight during session	39	45
d. Never checked	14	18

12. Would a change of any of the following factors enhance acceptance of the device? (Circle as many as are applicable):

		Study	Survey			Study	Survey
a.	Color	0	0	f.	Sound	28	34
b.	Texture	5.5	0	g.	Odor	2	-
c.	Size	13	6	h.	Position of unit	5.5	13
d.	Cable (wire)	11	24	i.	Shape	7	3
e.	Weight	17	18	j.	No changes	11	21

13. Regarding ease of operation, do you feel that the LLM		
a. Operates adequately with ease.	48.5	69
b. Should be easier to operate.	45.5	26
c. Is extremely difficult to use adequately.	6	2.5
d. Is impossible to use adequately.	0	2.5

	Study Group	Surveyed Group
14. Did the patients accept the LLM as part of the treatment program?		
a. All.	30.5	35
b. Nobody.	5.5	0
c. Most of them did.	61	60
d. Only a few did.	3	5
15. On the average, when selected to use the LLM, did the patient		
a. Use the device in daily treatment.	46	46
b. Use the LLM about three times per week in treatment.	43	43
c. Use the device about once per week in treatment.	11	11

16. In addition to yourself, who else applied the LLM to your patients (circle as many answers as appropriate)?

		Study	Survey		Study	Survey
a. Family member	f. P.T.	a. 5	5	f. 46	54
b. P.T. Aide	g. O.T.	b. 14	26	g. 0	5
c. Patient	h. Physician	c. 19	15	h. 0	5
d. Orderly	i. Other (specify)	d. 0	5	i. 16	21
e. Nurse		e. 0	8		

	Study Group	Surveyed Group
17. On the average, was the LLM used (circle as many as are appropriate):		
a. Only in the clinic.	81	72
b. In the clinic and on the wards.	5	26
c. Only on the wards.	0	0
d. "Day room" or lounge.	0	0
e. Going to meals.	0	10
f. Outdoors.	0	8
g. Indoors.	7	15
h. Other (specify):	7	3
18. Did patients selected consistently load their limb to the desired level?		
a. Most patients - most of the time.	59	58
b. Some patients - all of the time.	14	21
c. All patients - all of the time.	8	0
d. Most patients - none of the time.	11	5
e. Other (specify):	8	16
19. With what categories of patients did you use the LLM?		
a. Amputees (lower limb).	50	74
b. Patients with hemiplegia.	39	56
c. Other (specify):	11	49
20. If you used the device with more than one category of patient, was the LLM more useful for one group?		
a. Yes - amputees.	66	57

	Study Group		Surveyed Group
b. Yes - hemiplegia.	7	24	24
c. Yes - other (specify):	0		19
d. No.	27		N.A.
21. In general, how long did it take the usual patient to respond to the LLM?			
a. During the first or second session.	91		90
b. Not until the third session.	9		5
c. It took more than one week of continuous treatment for the patients to respond.	0		5
22. Thinking back over all the patients you saw in the test period, roughly what % were LLM candidates?			
a. Less than 10%	37.5		45
b. About 10 - 25%.	34		27
c. About 25 - 50%.	12.5		15
d. More than 50%.	16		N.A.
23. Would you suggest purchasing the LLM for use in your Physical Therapy Department?			
a. Definitely not.	3		0
b. Probably not.	23		11
c. Maybe - depends on: (comment please).	23		21
d. Yes.	51		68
24. What else should we know about application of the LLM in your facility?	Comments on 81% of answers of Study Group questionnaires		

25. On a scale of 1 - 7 (7 is highest), how would you rate the LLM on: (circle one for each column):

See Fig. 7.

		Ease of Operation	Relia-bility	Use for P.T. Goals	Patient Acceptance
Highest		7	7	7	7
		6	6	6	6
		5	5	5	5
		4	4	4	4
		3	3	3	3
		2	2	2	2
Lowest		1	1	1	1
Study Group	$\bar{X}$	4.7	4.5	5.1	5.3
Survey Group	$\bar{X}$	4.9	4.5	5.2	5.4