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A preliminary report on the use of a practical biofeedback device for gait training of above-knee amputees*

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Abstract — A new type of biofeedback device for use in gait training of above-knee amputees is described. This device provides immediate and postsession performance feedback to both patient and therapist, based on programmable thresholds of prosthetic weightbearing and hip extension angle. The device is battery powered, lightweight, and completely portable. The design of the microprocessor-based control unit and the weightbearing and hip angle sensors is presented. Initial field trials at Massachusetts General Hospital show that this device meets the clinical requirements of simplicity and good human interface. Based on this experience, design recommendations are made for a general purpose physical therapy biofeedback and data acquisition system.

INTRODUCTION

The research reported here is part of an ongoing effort to provide means for performance measurement and evaluation for medical applications through the development of general purpose instrumentation. Since members of this research group have much previous experience with above-knee (A/K) amputees, the rehabilitation process for A/K amputees was chosen as a first target for study.

Most gait training begins soon after amputation. Some patients, mostly younger persons with amputation due to trauma or osteosarcoma, learn very quickly how to walk properly with a new prosthesis. Other amputees, particularly the elderly and victims of peripheral vascular disease, have great difficulty developing this new skill. Circulation is poor in both the residual limb and the sound leg. Reduced strength and stamina limit the ability to practice walking. In addition, there is often diminished proprioceptive feedback from both limbs.

Two characteristics are common in improper amputee gait: insufficient weightbearing and poor hip extension. Patients are often reluctant to trust the artificial leg, especially if they have experienced a fall. This may lead to timid or brief weightbearing and an unbalanced gait. An unbalanced gait is difficult to correct, partly because the therapist cannot easily determine the amount of weight being applied to the prosthesis. Bathroom scales, a commonly used training aid, provide only a static measurement, which can be misleading to the therapist. Some dynamic weight-measuring devices have been developed (and are mentioned below), but they are not in common use.

Hip extension problems are generally regarded to be the most common gait anomaly for A/K patients. Proper hip extension is essential for cosmetic gait. In most cases, the amputee must apply a hyperextensive moment to stabilize the prosthesis knee joint, which prevents buckling. **(Figure 1)** This is achieved by keeping the amputee's center of gravity in front of the knee axis. At first, many patients lean forward to accomplish this, as shown in **Figures 2 and 3.** That is a hard habit to break, especially

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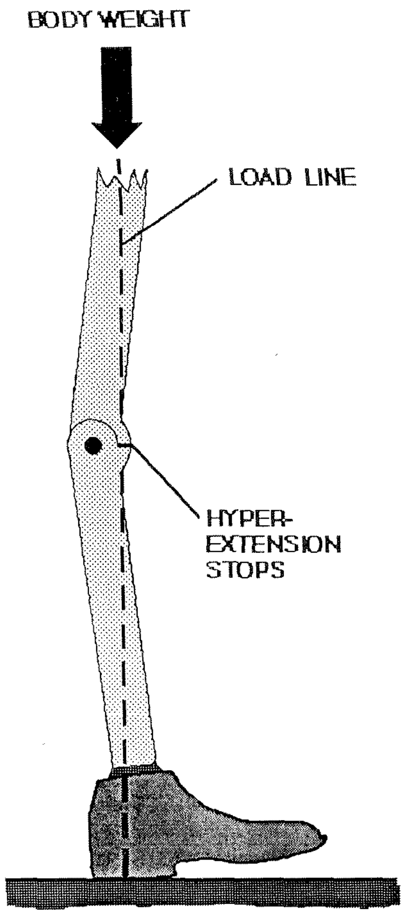

Figure 1
Stance stability resulting from alignment and hyperextension stops.

after the patient has developed confidence in the method. The therapist then tries to force the patient into an upright position by pushing the chest back and pulling the buttocks forward. However, with this form of teaching, which limits the ability to pick up speed, the patient may not learn to walk upright on his own.

Some patients learn quickly from the therapist by listening to verbal instructions and by accepting manual cues, such as those mentioned above, but weakness and poor stamina of many older or ill patients may make the necessary practice impossible. Still others have difficulty understanding the therapist's requests and may feel frustrated or criticized by the therapist. In such cases, there often is a place for auxiliary teaching techniques such as biofeedback.

Biofeedback is useful in informing the patient when he or she has achieved an adequate level of weightbearing, and it may help the therapist in evaluating the patient's skill level. By providing a non-judgmental, consistent way to let patients know when their weightbearing or hip extension is adequate, the biofeedback system provides a quantitative goal. It also allows the feedback to be given at any walking speed. A record of performance information could be useful in giving patients evidence of progress when they might otherwise feel frustrated.

Other research in biofeedback has focused on therapy training. Several systems have been built for providing weightbearing feedback (1,3,8,9,11,13,14). They are used for non-amputees as well. However, the transducers generally are not very accurate.

Hip-extension measurement instrumentation has been designed (7), but for laboratory studies only, and it is too bulky and delicate for clinical application.

Biofeedback has been used with above-knee amputees

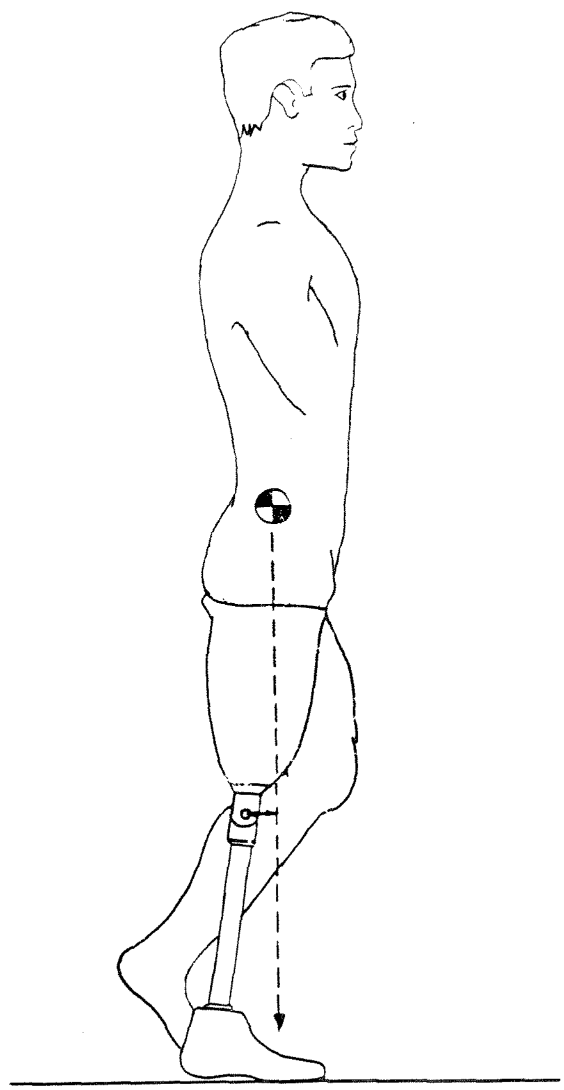

Figure 2
Body weight being used to create hyperextensive knee torque.

(6) to indicate prosthetic knee position. The two-state system generates a tone if the knee is flexed (not depressing a microswitch in the knee at the extension stops) to prevent the amputee from stepping onto the prosthesis with the knee still flexed. The system also alerts the therapist, via an error light, when the patient applies weight to the leg (as measured by a footswitch) when the knee is not hyperextended.

The work of Shepley (9) from this earlier group laid the groundwork for our current research. He provided audio biofeedback for prosthetic weightbearing and hyperextensive knee torque. Positive hyperextensive knee torque worked to increase the stability of the knee, and thus higher levels of knee torque were interpreted as indicative of better gait. This feedback was effective in increasing the level of these parameters so that they were above a pre-set threshold. However, Shepley's prototype device was too heavy and bulky for routine clinical use.

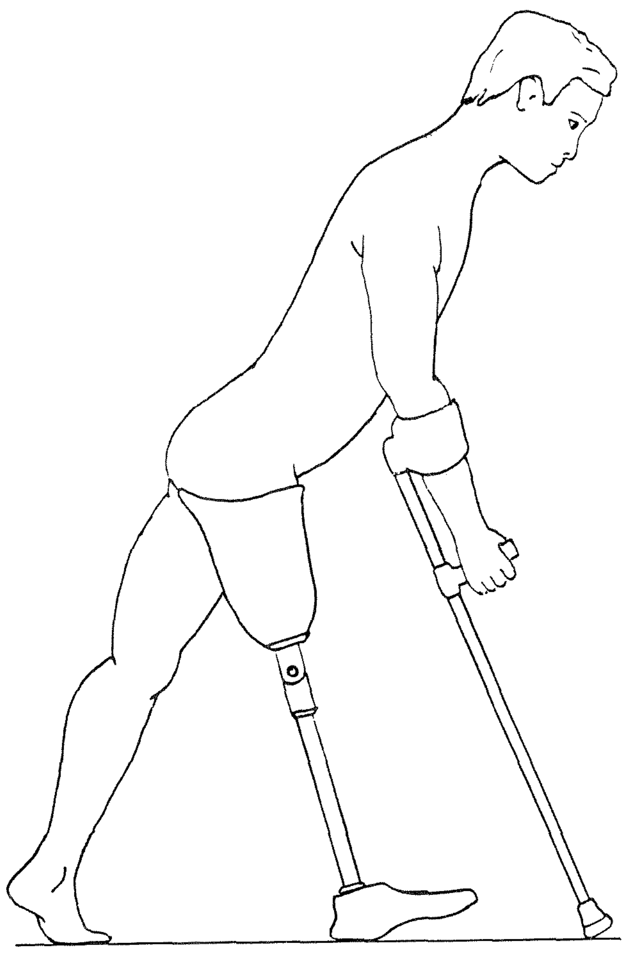

Figure 3
Incorrect way to create hyperextensive knee torque.

METHODS

The evaluation of our research was performed on postoperative patients undergoing gait training for the first time. They began as inpatients, but some continued to participate on an outpatient basis. The biofeedback system was named the "Strider."

Most studies of biofeedback have tried to answer the question, "Is the biofeedback valuable?" Such research is concerned with the actual efficacy of the biofeedback itself, isolated from concern about how that biofeedback will actually be achieved in practice. Sophisticated methods are used in statistical analysis of quantitative data, but the means of obtaining the data are often crude and unsuitable for general clinical use. The devices to provide the data are almost without exception dedicated devices, whose function cannot be changed should requirements change. In contrast, the present study assumes that biofeedback is useful for a broad range of tasks, and asks the more practical question: "What should the vehicle be for this biofeedback?"

Our research has focused on two issues. One of them is "use," or the factors involved in the interface between human and machine. The other is "performance evaluation," or the relationship between achievement of such narrowly defined biofeedback objectives as reaching a threshold weightbearing level and the actual goals of the therapy. To study these issues in a device trial, there were three items available as data: personal observation, questionnaires, and quantitative data collected from the Strider.

The "use" issues focus on the environment in which normal (that is, non-interrupted, non-research) gait training takes place. Such issues can have a dramatic impact on the implementation of enhancements shown to be useful by research. For example, therapists typically have only 1/2 hour to 1 hour to conduct the daily training exercises. There are many skills the patient must learn, such as how to get out of a wheelchair or how to put on the prosthesis properly. If the system is hard to "install" on a patient, a therapist may not be inclined to use it no matter how powerful the instrument or how wonderful the results might be. Its use must be simple and easy to learn, yet it should do everything required of it. If the device must be semi-permanently installed, its use will be limited to a small population. Also, patients are less likely to be concerned about the basic accuracy of the measuring device than about their appearance while wearing it. There will be resistance to unattractive, heavy devices.

The "performance evaluation" issue involves taking a

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broad view of overall therapy goals. Much of the cited previous work has shown the efficacy of biofeedback in improving certain physical parameters. These may or may not be correlated with better overall performance. Amputee gait is a good example for study because of the complexity of the movement. For instance, exceeding a given weightbearing threshold may be counterproductive if the threshold is achieved after the torso becomes erect, or for only a small percentage of stance phase. This is because a quick weight transfer is essential to cosmetic stable gait. Achieving the feedback goal too late in the gait cycle may lead the patient to a false sense of accomplishment.

The Strider was designed to address both use and performance evaluation issues by being adaptable to changing requirements. The control unit is based on a CMOS microprocessor, the Intel 80C35. It monitors two transducer inputs, calculates various parameters, and stores them under programmable control. It provides feedback through a set of earphones or a speaker. Care was taken to give the system a professional appearance in keeping with desired cosmetic requirements. **Figures 4,5, and 6** show a functional block diagram of the Strider, a photograph of the complete Strider system, and the system in use.

Thresholds may be set by the therapist for each transducer. The Strider will provide a biofeedback signal when each threshold is exceeded. For example, a signal will change as soon as the weight on the prosthesis exceeds the predetermined weight threshold. Feedback is produced from only one transducer at a time. The desired transducer is switch-selectable.

Two types of feedback signal are selectable. The first is simply a beep which sounds when a threshold is exceeded. This type of feedback provides information without being irritating, as there is at most one beep per gait cycle. A continuously varying tone may also be selected. Its pitch is proportional to the magnitude of the parameter being measured (e.g., the tone rises as the hip is extended). This tone jumps suddenly in pitch when the threshold is exceeded and jumps any number of times per cycle. It is intended to give patients an idea of when they are getting close to the threshold, and also to allow them to "explore the feedback space;" that is, by moving and listening, to learn exactly what effort of theirs causes the pitch change. This feedback helps patients understand hip extension in the context of the therapist's instructions.

The data acquisition portion of the Strider can be read from two liquid crystal displays. It calculates and displays the number of steps taken, threshold values, the per-

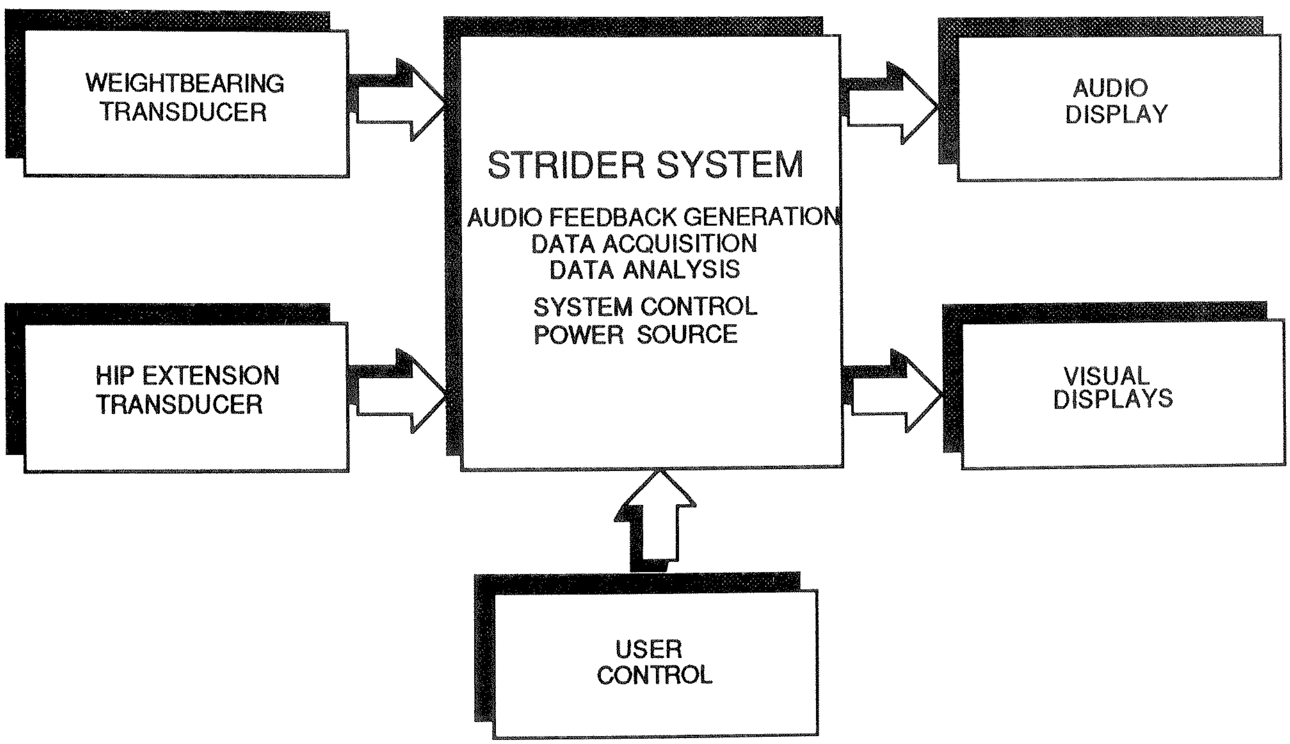

Figure 4
Functional diagram of the M.I.T. Strider.

centage of steps when hip extension or weightbearing was above threshold, the average weightbearing or hip extension per step, and the number of weightbearing steps above threshold. **(Figure 7)**

The weightbearing transducer (or load cell) is designed to be installed in the patient's prosthesis immediately below the knee unit. It is compatible with a U.S. manufacturing company temporary training prosthesis knee unit, although its concept could be applied to any knee unit, and could even be adapted to below-knee prostheses. It also was designed to require no modification to the prosthesis, such as cutting and shortening the leg tube. Therefore, the same load cell may be used by several different patients concurrently, and only a few minutes is required to install it.

The weightbearing load cell consists of a pair of concentric aluminum cylinders with cast silicone elastomer between them. A strain-gaged beam is deflected by the load. The transducer is quite accurate, and has very low crosstalk from the large bending moments present during walking. (An additional article is being prepared to present the design in more detail.)

The hip-angle transducer is designed to provide the least possible impedance to normal walking. There are no hinged arms or other members strapped onto the limb. Instead, a small transmitter attaches to the socket with Velcro, and a receiver unit mounted on a waistbelt is connected to the transmitter by a flexible cable. Its design is discussed in more detail in a previous paper (5). The transducer is calibrated by having the patient stand as erect as possible while the transmitter on the socket is rotated to produce the observed angle (nominally zero degrees) on the control unit display. The threshold for hip extension is set by having the patient assume the desired hip angle and then recording that value by pressing the "Hip Set" button.

Figure 5
The M.I.T. Strider.

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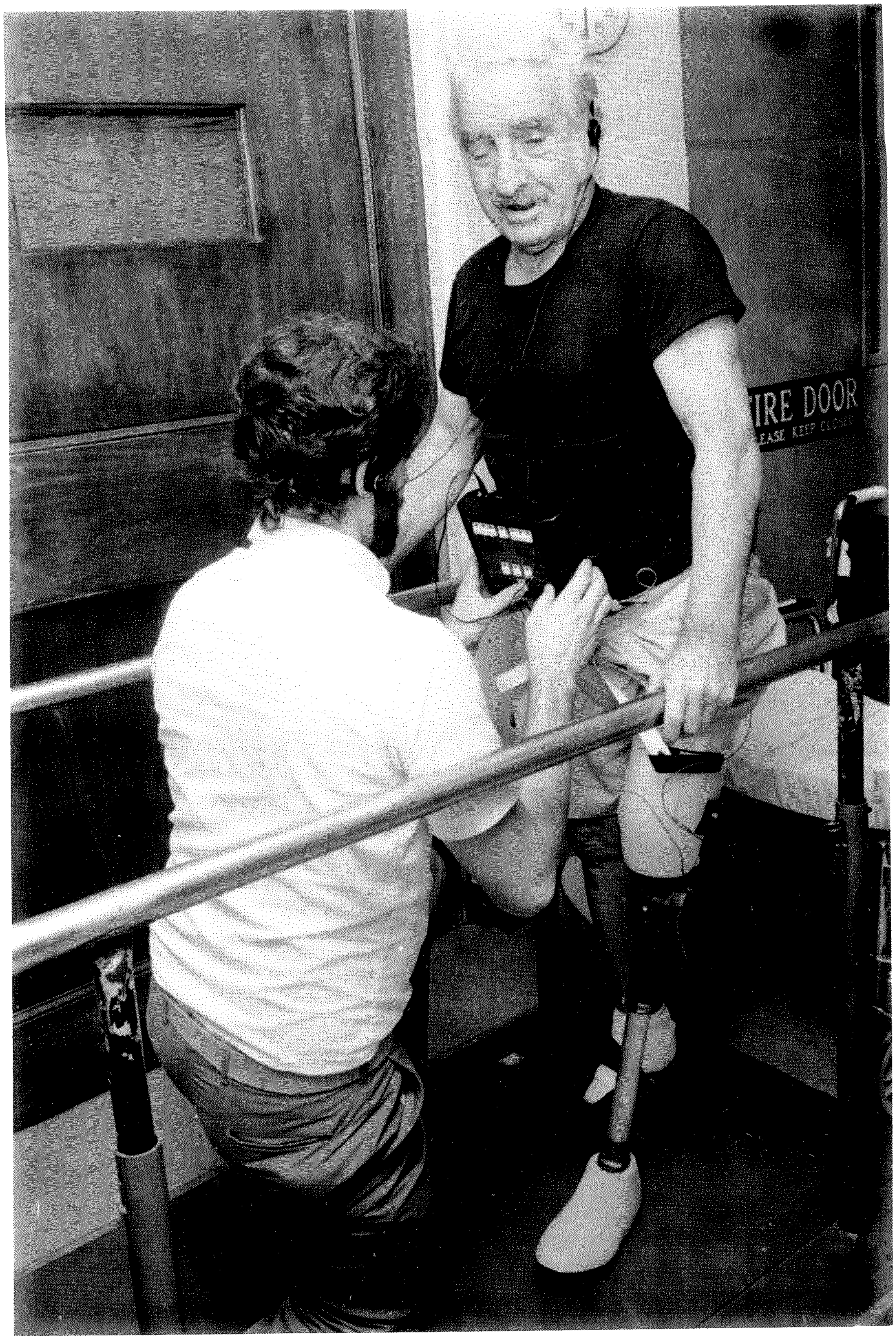

Figure 6
The Strider in use.

RESULTS

The use of the Strider system was observed for 4 months at the White 9 and ACC (Ambulatory Care Center) physical therapy wards of the Massachusetts General Hospital. To date, five patients have trained with the Strider system. Use of the system was completely voluntary. Only one patient refused to try it; this elderly woman said it felt too heavy, and she did not want to sign consent forms. The five patients who tried the system are males ranging in age from 19 to 68.

The type of feedback chosen was based on preferences of the patient and therapist. Physical therapists had complete freedom to use the Strider for weightbearing or hip extension improvement, or not to use it at all, according to the goals of a particular therapy session. Its use primarily was to encourage better hip extension. Although the average weightbearing per step was recorded for each session for most patients, only one attempt was made to change the level of weightbearing through biofeedback. In that case, the weight level was actually too great, and the patient was instructed to "not make the tone jump" during his step.

Methodology Refinement

The Strider appeared to be a useful tool for encouraging hip extension and was used often by the therapists for this purpose. It was found, however, that simply exceeding the threshold was not necessarily desirable, and a more careful methodology was then developed by the therapists. A description of the procedure followed on one elderly patient illustrates this.

CE, a 68-year-old man, could exceed the threshold every time by stepping onto his prosthesis, stepping onto his sound leg, and *then* extending his hip. This was a more sedentary motion, and hence easier to perform, but it was improper in that it would not allow him to get his weight forward of the knee before weightbearing on the prosthesis (he was walking with the knee locked). The therapist began to coach him in making the tone "jump" *before* he lifted his sound foot off the ground. This forced him to take his sound foot back and start over again if he did not make the tone "jump" first. The arrangement worked quite well in eliciting the desired behavior from CE; however, he would stop trying as soon as the tone jumped. The therapist wanted him to keep "pushing through" at the hip as he stepped forward. She instructed him to keep the tone high throughout the step, as this feedback helped him to maintain his hip extension after it was achieved. With the beep feedback his posture would sag upon reaching the threshold.

The therapist also felt that attaining the correct hip angle at the correct position and time was not the only determinant of stability. She wanted good isometric hip flexion at the beginning of prosthetic stance and encouraged CE in this activity using manual feedback, such as pressing against his socket as he stepped, which resisted his motion. The methodology was used with most amputees, since the therapists felt it was the most effective way to train patients with this type of feedback.

The Strider system does seem to enchance the learning of some amputees at certain points in their training. The sample tested is quite small, but certain characteristics are suggested from observation. The people who appeared to benefit from the feedback were the ones who had diminished awareness of their bodies, as well as reduced strength. Therefore, elderly patients are preferred candidates for using the Strider. CE commented early in his training, when asked to stand up more straight, "What do you mean? I am standing up straight!" After several weeks of training, he was more likely to say, "That hurts! Nobody walks that way anyway." He learned exactly what it took to exceed the threshold and he did not always like it because the objectivity and unambiguity of the device made it impossible for him to pretend confusion.

Successes and Shortcomings

The clinical acceptability of the Strider system is quite good. However, there is room for improvement. The care taken in packaging paid great dividends: no user's comment reflected mistrust of the system, no patient expressed fear of walking on the load cell, and therapists quickly became comfortable with the device and came to accept the data of the Strider as "gospel." After 3 months of near-continuous evaluation, the therapists were just as willing to use the Strider system as they had been when the study began.

Some features of the Strider detracted from its comfort and ease of use, however. Every effort had been made to use as few wires as possible. The patients were quite good-natured about the three wires that did have to be attached, calling themselves "the six million dollar man" or "the astronaut." Given the kidding and humorous banter common in a physical therapy ward, perhaps this should not be taken too seriously. Even so, wires seem to add greatly to the perceived complexity of the system. For this type of situation, the inescapable conclusion is that one wire is too many.

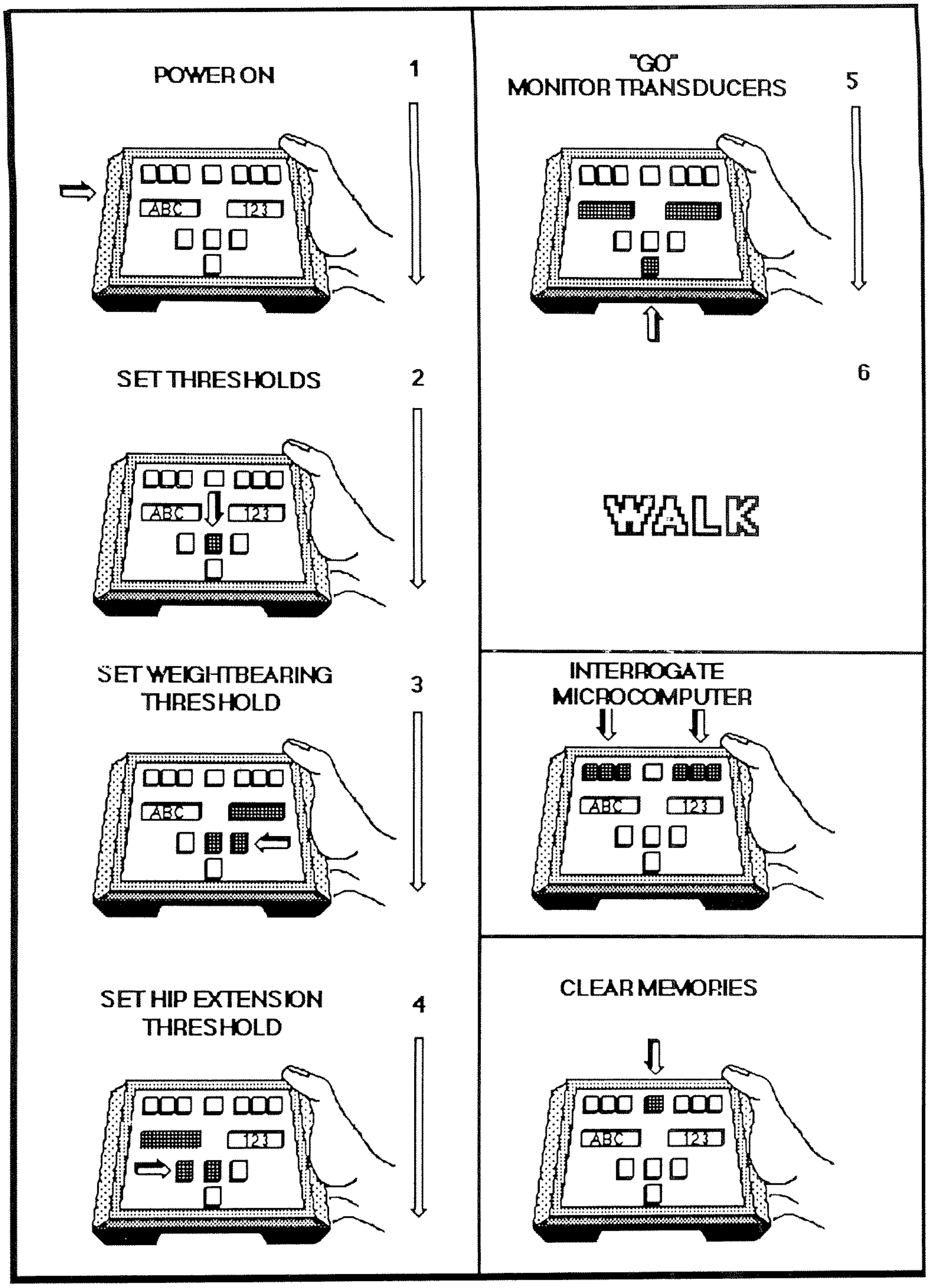

Figure 7
The Strider threshold selection panel.

The Strider control unit was made to be small and lightweight. Nevertheless, it weighs 2.4 pounds (1.1 kg), and is too large to wear unnoticed under a garment. The weight of the Strider tends to make it sag as it is worn. For all the functions it performs the Strider is amazingly compact, but for a device that is worn on the stomach it is quite large and heavy. One of the more active and agile patients felt that wearing the Strider changed the way he walked, but commented that it may have been because of its novel presence.

Calibrating the radio goniometer (hip-angle transducer) took a substantial part of the setup time. It also reduced data value, as error was introduced.

The use of earphones to give feedback was a mistake. It was originally felt that the need for privacy would justify the awkwardness. All of the therapists found that they had to make a choice: either to listen to the feedback and be tied to the Strider unit, or stand back and watch the patient from a more favorable position. Listening to feedback forced them to give up their usual methods of observation and critique, and rely too heavily on Strider feedback. They needed to know when and how patients reached a threshold, or if they did not, to properly interpret it through their actions. This was impossible for all but the slowest patients. Even for these, tying therapist and patient together by wire was extremely constraining, making actions such as turnaround at the end of the parallel bars awkward and difficult, and others like stairclimbing impossible. A portable speaker attached to the Strider control unit was added later, but the use of this has not been studied enough for comment.

The Strider showed that it can teach therapists about gait. The objectivity and consistency of the Strider measurements give a benchmark against which to compare their subjective evaluations and observations. One therapist commented that having unambiguous data about hip extension magnitude was not as important as data on the timing of the hip extension relative to weightbearing.

As mentioned above, some therapists almost never set achievement of the threshold as a goal in itself, but rather aim to achieve it early (for hip extension), and to maintain it throughout stance. The beep feedback mode did not allow them to do this, and the patient would often stop trying as soon as the threshold was reached. The primary difference between the two modes is that the beep supplies "event" feedback, i.e., it signals when the threshold has first been reached, but after that no further information is available. The feature of the tone signal which was useful here is its ability to deliver "state" feedback in which above/below information is continuously available. The proportional quality of the tone feedback was used by patients during the first few sessions to discover the relationship between the feedback and their movement.

One type of feedback not available that might have been useful is "negative" feedback which would produce a signal only when an error is made and shut off the tone feedback when the threshold is exceeded. It would also reduce the amount of constant noise heard by the patient, and may have some improved efficacy over other types of feedback. (A good overview of feedback studies for motion learning is contained in Armstrong (2).)

Figure 8 shows a steady increase in weightbearing for the patient, CE, over approximately 2 months, even though no feedback was used to encourage this. The data acquired and stored by the Strider was not used by the therapists, however. This may be because they were not familiar with it; it was never available to them. (It might be more useful once a large body of data is available for comparison purposes.) Therapists also generally have a large workload, with evaluation sheets and patient progress reports to fill out between training sessions. Thus, if data are to be useful, their collection must be virtually automatic. A computerized system larger than the Strider which could record data, maintain files on patients, and graph their progress might be quite attractive to therapists, especially if it would reduce their present clerical workload. Other dedicated devices, if they supply data, require recording of the data by the therapist. This will discourage its collection and widespread use.

DISCUSSION

In summary, a set of requirements which should be met by clinical biofeedback devices for motion training are:

1. It should allow the patient to hear feedback from his or her performance, based on standards defined by the therapist.
2. It should allow the therapist to hear the same thing the patient does, without requiring proximity to the patient.
3. It should allow the therapist to change the threshold level as the patient is performing a task, without requiring proximity to the patient. Watching a task in progress from the most advantageous position allows for the best determination of when the performance is correct.
4. It should be possible to set any threshold without requiring the patient to assume the threshold condition. For example, the therapist should be able to punch in "-3 degrees" for hip extension, and not have to manipulate the patient to make the setting.
5. The therapist should have maximum flexibility in defining the feedback type and should be able to choose from among at least event, state, proportional, and negative feedback. For example, the therapist should be able to ask for "no tone" upon reaching threshold, or "tone."
6. Therapists should have flexibility in defining the threshold conditions. They should be able to combine timing, the state of all the sensors, and the durations of those states to create an appropriate threshold. The defining must be a simple process, and the defined condition should be able to be remembered by the unit for later use.

7. Whatever device is worn by the patient should be so small, so lightweight, and so quick and easy to put on, that its use does not detract from performing any other physical therapy task. In other words, there should be no reason to want to take it off, except to put it away for the night.

8. All the sensors should be repeatable from day to day. They should require little or no calibration.

9. There should be no wires on the patient, except perhaps for headphones.

10. There should be an easy way to disable the unit from recording bad, or "false" steps, from a distance, for use in calculating average values per step.

11. One should be able to install the system on a patient by using only two hands. One would be better.

12. Each sensor should be usable with the system independently of the others. For example, the angle sensor should not require step information from the load cell in order to function, or this requirement should be removable by the therapist.

13. All feedback functions should be completely programmable to allow for arbitrary feedback type. For instance, a digital-to-analog converter should be used to drive a voltage-controlled oscillator for tone generation (this was not done in the Strider). One should even be able to modulate another signal to convey feedback; i.e., to reduce or increase the volume of music as the error decreases.

14. It might be an advantage for the therapist to have a remote control unit, which could perform functions such as shutting off the feedback when he or she wants the patient to concentrate on something else. It could also be used to change the feedback level. Such a unit could be like a remote control unit for a television.

15. For research purposes, the system should have outputs available to drive strip chart recorders, real-time data acquisition devices, etc.

Concept of "Next Generation" System

The Strider as currently realized might be a viable

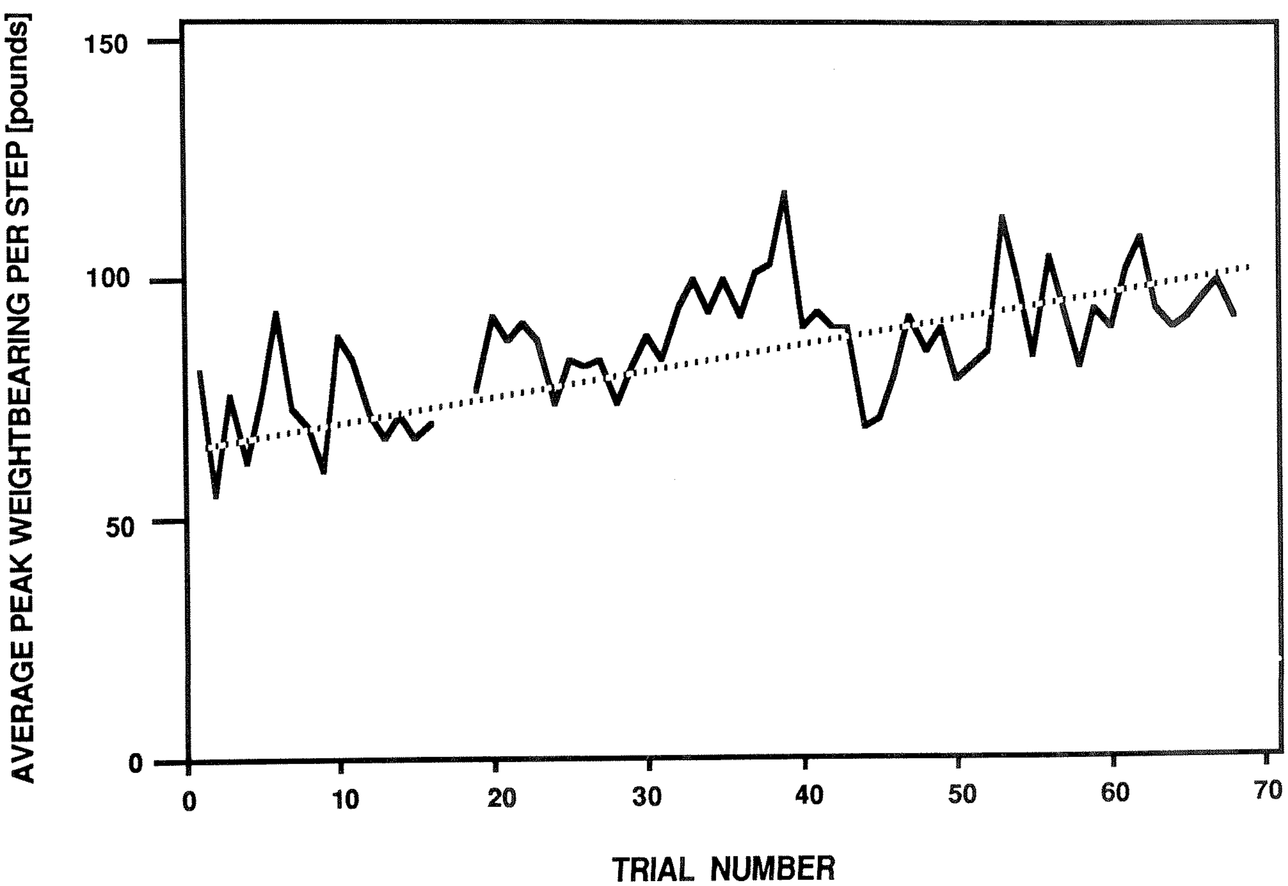

Figure 8
Average weightbearing for CE.

commercial product. Certainly it would be better for the therapy community to have the Strider than nothing at all. After observing its use for several months, however, it is impossible not to think of what the best system, or at least the next step towards the best system, should be. A brief conceptual description of this system is given below.

Figure 9 shows a concept of the next generation system in use. The heart of the system, the microcomputer, would no longer be worn by the patient; patients would wear no device but sensors. All devices used by both the patient and therapist would be peripherals of a central computer, communicating via telemetry, most likely on the FM band. The load cell and goniometer would broadcast their signals to receivers located at the computer. Each would contain its own battery, and with less processing electronics on board, the power requirements would be quite low. The goniometer should not require the connecting cable between transmitter and receiver. All feedback would be broadcast by the computer. A speaker could be mounted on the therapist to provide the signal for both, or patient and therapist could each have their own headset FM radio, which are inexpensive and widely available now.

The computer could be mounted anywhere out of the way. Hanging it on a wall would be convenient where it would not require scarce table or floor space. It would have a bus-based system, so that any number of expander cards for memory, broadcast/receive systems, and signal processing could be added as a budget permits and requirements demand. There would be a game-cartridge-type port, so that therapists could quickly and easily add new functions and programs. New transducers could be added for new applications, requiring only a receiver/signal processing card and a program on a game cartridge to interface with the system. This computer would plug into the wall, so low power consumption would not be a dominant consideration. Therapists would carry lightweight controllers, very much like television remote-control units, to allow them to set thresholds by typing in the desired number, or to raise and lower the threshold as

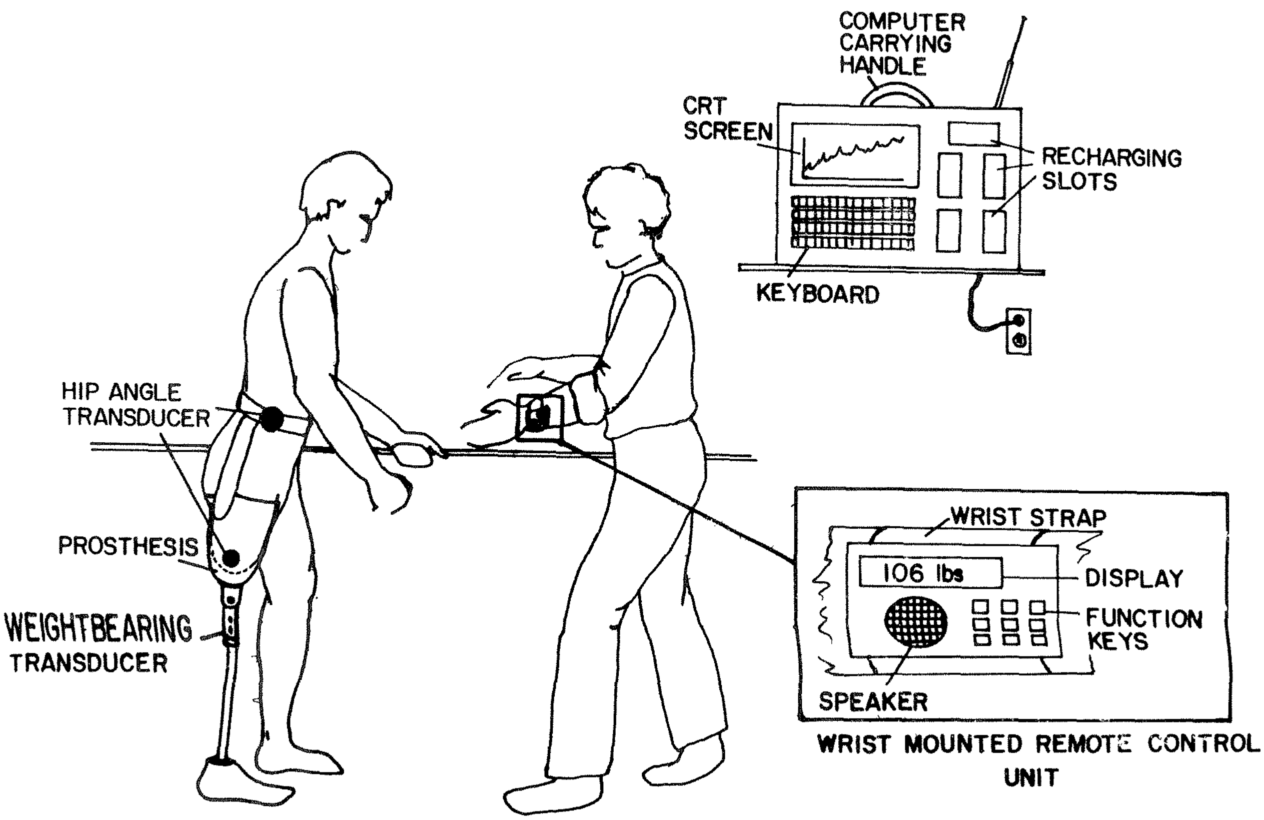

Figure 9
Concept of a Next Generation Gait Training Aid.

the patient walks. Spurious steps could be prevented by a hold function. There would be start and stop functions, as well as data functions such as average weightbearing. An alphanumeric display would give a line of information for this purpose.

Such a system would have far more flexibility than the present Strider unit, yet the hardware on patient and therapist would be drastically reduced, and there would be no wires. It would make possible the implementation of a simple "therapist command language" to define a complete set of threshold conditions and feedback types.

This is only one view of a future system. It is necessary, however, to keep in mind a very important goal: getting such a system into the market because the best system in the world does no good confined to a research lab. We hope that efforts will be directed towards making a Strider-like system available to therapists and patients everywhere.

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