A DEVICE TO CONTROL AMBULATION PRESSURE WITH IMMEDIATE POSTOPERATIVE PROSTHETIC FITTING

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INTRODUCTION

Recently there has been a rapid increase in the immediate postoperative prosthetic application; however, success with the method has not been universal. One common cause of failure appears to be excessive weight-bearing on the stump during early phases of healing (1,3,5,10). Some weight-bearing during this period is highly desirable to minimize edema and deconditioning, but excessive pressure can be disastrous leading to disturbance or even disruption of the surgical wound or to necrosis in areas where revascularization is inadequate. This has caused some workers to eliminate early weight-bearing following amputation for peripheral vascular disease in spite of theoretical advantages (2,4), while others have completely discontinued immediate postsurgical fitting (5). Figure 1 shows the effect of excessive end-bearing for one patient.

The method commonly used to regulate such weight-bearing involves two bathroom scales (1). The amputee stands with one foot on each scale and gradually increases pressure on the prosthesis until the desired
scale reading is attained, as shown in Figure 2. He then must attempt to retain the mental image of the sensation produced by that pressure as he leaves the scales and ambulates with crutches or a walker.

Observing these patients led us to suspect strongly that this method was grossly inaccurate for older patients, for those with impairment of sensation or mental function, and for children. To check this belief, studies were made to test the individual’s ability to retain the mental image obtained on the scales during subsequent ambulation. These studies showed that the average person was unable to reproduce accurately the desired weight-bearing for more than a few steps. This was true not only for amputees judging stump pressure, but also for our therapists and ourselves judging pressures on our unimpaired feet. The increment of error produced by this method ranged from 5 to 32 lb., with an average of 16.4 lb. for a group of young adult and middle-aged subjects tested, and it would obviously be considerably higher in those categories mentioned earlier. The duration of time spent on the scales while becoming accustomed to the desired weight made no significant difference in the final results over a range of 30 seconds to 5 minutes.

Because of the deficiencies of this system, the Physical Medicine and Rehabilitation Service of the Portland VA Hospital desired a device that could be incorporated into the immediate postsurgical prosthesis to give an audible warning when a preset maximum pressure was reached.
Gerhardt et al.: Ambulation Pressure Control Device

The device was required to have the following qualities: to be adjustable (within the pressure range required); to summate pressures applied through heel and forefoot; to be sufficiently small and light to avoid interference with walking; to be relatively inexpensive; and to be capable of use anywhere, in the hospital or the home. This concept was submitted to the Western Research Support Center at the Sepulveda VA Hospital, where the desired unit was developed (9).

ENGINEERING CONSIDERATIONS

Measurement of forces in the prosthesis by electronic methods has been known for some time. Peizer (7) in 1968 showed two different types of instrumented pylons which allowed the measurement of as many as six components of force by means of strain gages attached to thin tubular sections of the pylon. This method was well-suited to laboratory measurements where the pylon could be connected to a set of strain-gage amplifiers by a cable, but it was unsuitable for use with the ambulatory patient outside of the laboratory. Even though the necessary strain-gage amplifiers, voltage comparator, and acoustical alarm could be incorporated into a fairly small package by using modern semi-conductor components, the high cost would limit the use of such a device. Mechanical methods, however, seemed to show greater promise for providing an economic solution. In such a device, the axial load must be converted into a mechanical displacement by means of an elastic member, while the torque and shear forces are taken up by the structure. A telescoping mechanism, similar to the VAPC flexion compensator (6), was considered first. The manufacture of the keyways which are required to take up the torque in such a mechanism, however, was beyond available workshop capabilities and it was feared that problems with friction would arise at the lower end of the force range required.

The electromechanical alarm device that was subsequently developed (3,9) is very simple and is essentially a cross between the standard front-end suspension of an automobile and a parallel spring suspension used in accelerometers. As shown in Figure 3, two leaf springs are mounted between the stationary support blocks at the right, and a movable support block at the left. Two slots have been cut into each spring close to the edges of the support blocks, which reduces the stiffness of the spring at these points. When a force is applied to the movable support block, the springs flex along the axes of the slots and the support block is displaced in a parallel motion by a distance proportional to the force applied. Torque and shear forces, nevertheless, are supported by this structure without deformation.

A complete device, as shown in Figures 4 and 5, has a microswitch attached to the movable support block. The plunger of the microswitch is opposite an adjustable stop in the base plate which can be set so that
the microswitch is activated for a preset axial load. The settings are continuously variable between 5 and 60 lb. Calibration is achieved quite...
simply by pressing the unit down on scales (Fig. 6) until the desired pressure is achieved and then setting the microswitch to just make contact at that point. It is important to use a microswitch that allows for over-travel of the plunger and that has a small differential of travel (microswitch Type BZ-2RS or equivalent). A second fixed stop supports

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**Figure 5.** Components of SCAP-I: 1. Pylon and clamp, 2. pylon insert, 3. upper spring plate, 4. rear spacer, 5. battery (9 v.), 6. lower spring plate, 7. front spacer, 8. threaded hole in base plate for SACH foot bolt, 9. SACH foot, 10. bolts, 11. Sonalert mount, 12. Sonalert, 13. plastic guard, 14. microswitch, 15. microswitch contact, 16. adjustment knob, 17. adjustment lock screw, 18. base plate.
the movable support block to prevent damage to the switch by exceeding its over-travel range.

Closure of the microswitch turns on a Sonalert acoustical alarm which is powered by a 9-volt transistor battery. This device emits a tone of 2.5 kHz with a sound level of about 70 dB.

Attached to the movable support block is a connection for the pylon tubing which is slightly offset to allow mounting on the SACH foot without overhang at the heel. The device adds only 3½ in. to the height of the foot (2½ in. in a newer modification) and can therefore be used even in cases of fairly low below-knee amputation. It is not suitable for amputations through the foot or ankle or for the unusually long below-knee amputation.

**CLINICAL TRIALS**

We have used the SCAP-I (System for Control of Ambulation Pressure) device for two purposes: 1. To prevent excessive weight-bearing. At the audible warning signal, weight should be shifted promptly to the crutch or remaining lower extremity to prevent damage to the stump. Diminishing the pressure to any level below the preset value stops the alarm signal. 2. To assure sufficient weight-bearing. Many patients are apprehensive, and without the assurance of the SCAP-I would bear virtually no weight. We ask them to walk so that they occasionally elicit a short warning signal, to make certain that they are approximating the desired pressure. For the average patient with peripheral vascular disease, our policy has been to commence with 5 lb. of weight-bearing
on the first postoperative day and gradually progress to 25 lb. maximum in about 2 weeks. In patients without vascular impairment (traumatic, neoplastic disease, etc.) the initial weight-bearing is also 5 lb., but we then increase by larger increments to 35 to 50 lb. Full weight-bearing is never permitted on the rigid dressing, which is not designed for such pressure.

Using the prototype model, SCAP-I was evaluated on 25 below-knee and two above-knee amputees over a 12-month period at the Portland VA Hospital. During this test period, it was found to be sturdy, reliable, accurate, and almost completely free of mechanical failure. The only mechanical difficulty encountered, since the beginning of the trial period, occurred recently when the bolt loosened which connected the lower spring to the anterior space block. This caused a signal to be elicited prematurely, at a pressure lower than that preset. This was readily corrected by tightening the bolt, and in the modified design a counterscrew and lock washer were used to prevent such problems. It should be noted that failure such as this will produce warnings prematurely, rather than permitting excessive pressure.

Of the 27 amputees using the device, 25 could closely control weight-bearing by its use. For these 25 patients this device appeared to perform in a highly satisfactory fashion. It was sufficiently simple in principle that even elderly patients could easily understand its use. The patients could walk while concentrating on good gait patterns, and were not preoccupied with the proper weight on the stump for each step. Therapists, too, were freed of uncertainty and fear in this regard, and could rely on their ears for prosthetic pressure while concentrating on gait pattern, posture, and evaluation of other features connected with gait training. Physicians following these patients were generally pleased with the progress of stump healing, and no complications occurred that appeared to result from excessive weight-or end-bearing in ambulation.

Two patients, however, were unable to control their weight-bearing and elicited an almost constant warning signal. One was unable to cooperate due to impaired cerebral circulation, and the other was unable to control his weight-bearing because of general weakness, including both upper extremities. Without SCAP-I we might not have recognized the degree of disability in these cases. In both cases, ambulation was discontinued, and controlled pressure to the sockets was applied on the tilt table using scales (see Fig. 1). Stump breakdown was thus prevented.

Two below-knee amputees were bilateral. One of these patients had amputations secondary to severe burns requiring extensive grafts, and had also a supracondylar femoral fracture on the right with fusion in 25 deg. of valgus and internal rotation. Prosthetic fitting was not possible initially, and rigid dressings with pylon and SCAP-I were used to determine how much pressure, if any, the tissues would be able to tolerate.
With closely controlled progression of weight-bearing in parallel bars, the stumps became increasingly tolerant to pressures, he performed well, and supracondylar femoral osteotomy was recommended to correct the valgus deformity. After this had been accomplished, rigid dressing with SCAP-I was used again to control postoperative weight-bearing for 30 days. This patient now wears bilateral patellar-tendon-bearing prostheses. He works full-time in an automobile wrecking company and is on his legs 12 hours each day without adverse stump changes.

The Prosthetics Research Study group in Seattle (10) has also made a clinical study of this device. In their experience, the unit has been reliable, accurate, and sturdy, and without evidence of mechanical failure. They also feel that it is an important adjunct in the management of these patients, particularly in the early postsurgical period when limitation of weight-bearing is of paramount importance.

SUMMARY

A device is described to control weight-bearing on amputation stumps after immediate postoperative prosthetic fitting. In clinical studies at two centers it has been found to be mechanically satisfactory, accurate, and reliable; and it is felt that use of this device will insure optimal pressure on the stump to promote healing and minimize complications.

Note: Since the writing of this article, new, improved devices (SCAP-la and SCAP-1b) have been developed, and they can be obtained from the Verrnillion Manufacturing Company, 4457 S.W. Stella Street, Roseburg, Oregon 97470.—Editor

REFERENCES