THE DEVELOPMENT OF ARTIFICIAL LIMBS FOR LOWER LIMBS

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INTRODUCTION

This project represents a continuous effort of Mauch Laboratories toward the improvement of artificial limbs, particularly for the lower limbs. Work on five items has been underway: A semivoluntary Swing and Stance Control knee mechanism (S-N-S System), an automatically controlled Tri-axial Ankle mechanism, a fully Voluntarily Actuated Swing and Stance Control knee mechanism, a mechanical low-cost version of the S-N-S System for short-term use and for geriatrics, and a novel cosmetic cover for above-knee prostheses and for a tri-axial ankle mechanism.

FEATURES OF THE S-N-S SYSTEM

This system is basically a hydraulic cylinder-piston device. Its swing control part uses our patented design in which exit holes for the hydraulic fluid in the cylinder wall are progressively covered by the advancing piston, in both the flexion and extension direction, leaving fewer and fewer holes open, thus increasing the swing resistances in a pattern determined by the location of the exit holes. The patent covering this design was assigned by us to the Veterans Administration many years ago, and the design was adopted by the other two manufacturers of hydraulic swing control systems (Hosmer and U.S. Manufacturing Company) through a royalty-free license agreement. It is estimated that today more than 10,000 knee-control systems are based on this patent.

The stance control of the S-N-S System uses our so-called hyperextension control principle, which prevents buckling by providing a high weight-bearing flexion resistance about the knee joint at all times, except during the flexion portion of the swing phase for which it is eliminated by a preceding hyperextension moment about the knee joint of at least 1/10th of a second duration. This moment is automatically provided in walking by the ball pressure shortly before toe-off.

The moment can also be produced voluntarily by pressing the stump backward for a short instant immediately before flexion, allowing jack-knifing stair or ramp descent, sitting down quickly, etc.
The stance-control function can be eliminated by a switch to permit bicycling, rowing, etc. The same switch can also be used for locking the leg fully against flexion for activities such as operating the gas pedal of a car, etc.

DEVELOPMENT OF THE S-N-S SYSTEM

The S-N-S System has been in production since 1969. More than 3,000 are in use today. During these years, a great number of improvements (more than 50) have been incorporated in it on the basis of field experiences. This resulted in the elimination of noises, reduction of energy consumption caused by undesirable friction, change of its geometry and its resistance profiles to conform to the VA setup standardization, and extension of its initial maintenance-free lifespan from an average of 1 year to the present 2-year average. All this enabled us to go to a 12-month guarantee a little over a year ago.

During the last contract year, a very significant improvement was added, the so-called dynamic self-bleeding feature which eliminates automatically by walking motions any air which might have found its way into the hydraulic working spaces. (Such air causing erratic resistance patterns and noises.) This important feature and some of the other improvements mentioned are adaptable to the hydraulic systems of other manufacturers. Our progress reports contain basic information on these design ideas, and we are prepared to assist any interested manufacturers in adopting them. There are no patents involved here.

As to the future of the S-N-S System, we stated in our next year's contract proposal that, "We are not aware at the present time of any specific shortcomings which would call for further improvements." We are convinced that any as yet undiscovered shortcomings will be minor. At the request of VA staff personnel in New York, we will now update the so-called "Bible," which was started approximately 10 years ago, for our swing control ("B") system, by including all necessary stance-control information to enable any qualified manufacturer to produce the S-N-S System if the need should arise.

DEVELOPMENT OF A MECHANICAL VERSION OF THE S-N-S SYSTEM

A prototype model of a simple swing-control device based on mechanical friction was designed and built early this year. The device can be exchanged for any of the standardized hydraulic or pneumatic swing-control systems, including the S-N-S System, in pylon-type or in wooden legs while the systems are being repaired, and it may be an economic alternative for these systems in temporary prostheses and in the case of geriatric amputees who might not use the full potential of the more
expensive systems. Its design is based on the well-known principle of a step-wise progressive engagement of mechanical friction elements, such as used in the Northwestern above-knee setup and in an early Navy design. It differs from these precedents by having a total of nine steps for producing an almost continuous friction profile and by a longitudinal rather than rotational working principle which permits its use as a replacement for a cylinder-piston device.

The device was test worn by our amputee and worked as expected. The cost of this device is very low because punched plastic parts are used almost exclusively. The design permits further development to include a mechanical locking device for automatic buckling prevention based on the hyperextension control principle of the S-N-S System.

The swing-control device was shown to our local prosthetist and to Dr. Murphy. The consensus reached in these demonstrations was that the inclusion of the stance-control feature is essential for making the mechanical approach worthwhile. This development will be continued on a low priority basis.

FEATURES OF THE HYDRAULIC ANKLE

The functions of this artificial ankle (Fig. 1) must duplicate as closely as possible, within the weight, space, and price limitations, the functions of the natural human ankle around all three spatial axes:

a. **The Medio-Lateral Axis.** A hydraulic vane-type piston which moves in a housing through a range of about 30 degrees, provides toe-slap damping, and toe pickup. The most important feature of this new ankle is a variable dorsiflexion stop which adapts itself automatically in every step to the changing upward-downward inclinations of the walking surface (see Fig. 2). Toe-slap damping and toe pickup are not shown in this schematic drawing. Its purpose is to illustrate the control principle used for the automatic adapting of the dorsiflexion stop. The piston rod (1) is attached to the shank, and the housing (3) to the foot of the prosthesis. The vane-type piston (2), which is part of the piston rod and therefore of the shank, rotates about the bolt (4) which is attached to the housing and therefore to the foot. The housing is filled with hydraulic fluid which is contained by the rubber boot (5). The vane-type piston has a port (8) which connects the chamber behind the piston with the chamber in front of the piston. A ball (6), which is guided by the cage (7), but can roll freely forward and backward on the bottom of the housing, will always tend to seek the lower-most point. The port (8) in the piston is so arranged that the ball (6) will close it on contact and prevent fluid flow from the rear chamber to the front chamber, thus blocking dorsiflexion of the foot. Contact will occur whenever the piston rod and therefore the shank are vertical, no matter whether the housing and therefore the foot are inclined downward or upward or are horizontal. This means that in
walking uphill the dorsiflexion stop will occur later than in a standard ankle which eliminates the need for the so-called "pole-vaulting," and that in walking downhill the dorsiflexion stop will occur sooner than in a standard ankle which prevents knee buckling. A bypass (9) through the piston is closed by a valve (10) and valve stem (11) whenever the amputee steps on the leg. It opens upon weight removal which permits the return of the foot to its normal position relative to the shank under the influence of springs which are not shown.

b. The Anterior-Posterior Axis. Eversion-inversion control is achieved by the way the front pad and rear pad of the ankle housing are attached to the foot. Exchangeable rubber pieces which are interposed between these pads and two attachment yokes within the foot come in shapes which the prosthetist can arrange to produce either elastic yielding in the eversion and inversion direction, or in the inversion direction only, or in neither direction. We prefer the second alternative which yields medially but provides lateral stability.
c. The Vertical Axis. Transverse rotation control is achieved by the way the piston-rod tip is attached to the shank. Again as in the previous point exchangeable rubber pieces, which are interposed between the flat side surfaces of this piston rod tip and corresponding parts inside the shank, come in shapes which the prosthetist can arrange to permit either elastic forward and backward rotation of the pelvis during the stance phase, or forward rotation only, or rotation in neither direction. Again we prefer the second alternative which provides more freedom in striding out without backsliding of the pelvis at the initiation of a step.

THE DEVELOPMENT OF THE HYDRAULIC ANKLE

The development of this device was often interrupted by higher priority work and was delayed several times by test findings which called for major redesigns. The design was unusually difficult for the following reasons:

a. The design space available is very limited. We do not know at present what minimum foot size can be accommodated, but we do intend to include as many as possible in the women and adolescents' sizes.
b. The weight of the device must be as low as possible because of its location at the most distal end of the artificial leg, which gives its mass a maximum momentum. We compared the weight of two identical lower legs, one with a single bolt ankle joint and the other one with our hydraulic ankle, and found that the weight increase is only approximately 2 1/2 oz.
c. During walking and especially running, the device is subject to severe pounding particularly on hard ground. This must not damage it.
d. In walking through sand or puddles, the danger of contamination and corrosion exists and must be counteracted by the design.
e. Severe temperature variations are possible at a location so close to the ground, in walking through ice and snow or on hot pavement. These variations must not impair the proper function.
f. All functions must be practically noiseless, which sounds much simpler than it is.
g. In spite of all these requirements, the device should last at least 2 years without maintenance, except for the occasional exchange of external spare parts.
h. Last but not least, the price of the device should not be excessive, i.e., not over $150.

In order to achieve all these goals the Ankle underwent a drastic redesign during the past contract year. This was prompted by test findings during initial shakedown testing by three different amputees. The redesign was completed and two prototypes were built using patched-up existing parts. The prototypes are presently being test worn by our own amputee and an amputee in the New York area. A third
FIGURE 2.—Hydraulic Ankle Control Unit, schematic.

The prototype is being built as a spare. The acceptance of this redesigned ankle by the test amputees was excellent. All the functions are exactly as planned. The noise is below the tolerance threshold.

The work ahead includes the following: At least five more amputees must be equipped with ankles to learn about variations among the
amputee requirements. At least one below-knee amputee must be included. The additional ankles needed for these amputees must not be made from patched-up existing parts but from final parts. This calls for a certain redesign involving new casting patterns and a new rubber mold for the U-seal. In the meantime the tests must continue to reveal about possible noises, symptoms of wear, and maintenance problems. Any findings in this respect may lead to the need for design modifications.

In our proposal for the coming contract year we stated, "The continuation of this work will constitute our highest priority effort during the contract period... We will attempt to push this project sufficiently to come up with an ankle ready for field testing by the end of this contract year." We feel that eventually the hydraulic ankle will advance prosthetic ankle joints as much as hydraulic knees advanced prosthetic knee joints.

FEATURES OF THE VOLUNTARY SWING- AND STANCE-CONTROL SYSTEM

Voluntary control of the above-knee prosthesis has been the goal of designers for decades. In spite of the advances made in recent years, present above-knee prostheses still limit the activities of an amputee substantially, forcing him to conform to the built-in response patterns of the prosthesis rather than allowing him to vary the pattern to fit the situation. This applies even to the semivoluntary S-N-S System.

A simple method of giving the amputee control of the yielding rate in the stance phase would increase stumbling safety and would open up a much broader area of physical activity than is available to him now. Such everyday activities as descending ramps or stairs could be performed in a much more natural way and if, in addition, it were possible for the amputee to lock the stance control at will, an even wider range of activities including athletics would become available to him. Moreover, locking the stance control, but at the same time providing a degree of resiliency about the knee joint, would enable him to execute the so-called double knee bend after heel-contact, resulting in a more natural gait. This is not feasible in a nonvoluntary system because, to avoid energy dissipation during the double knee bend, full lock is required and full lock in a nonvoluntary prosthesis is potentially dangerous.

Any voluntary control of the yielding rate in the stance phase could also be adapted to control the flexion resistance during the swing phase in a voluntary way. This would provide the amputee with a cadence control far superior to the programed cadence control of present swing-control systems. Voluntary swing control would be very helpful in sports activities (you could kick a football) and would even permit dance steps. Control of the extension portion of the swing phase to provide a variable terminal deceleration could also be made an integral part of a voluntary control system.
To exploit these potentialities fully the amputee has to be kept informed about the position of the shank relative to the thigh by a feedback. This position feedback will supplement the stump pressure feedback from the socket.

These were the considerations and the resulting features which we set out to achieve almost 10 years ago.

DEVELOPMENT OF THE VOLUNTARY SWING- AND STANCE-CONTROL SYSTEM

As usual, the road has been an arduous one with many interruptions and delays due to the difficulties of the problem and because of other higher priority work.

It was clear from the beginning that a hydraulic-cylinder-piston device would be used for controlling the knee joint. It was also clear that this device would not pose serious problems and in fact would be much simpler and less expensive than the S-N-S System. So we worked on its design over the years whenever there was some time available. Then we built the parts which we will assemble as soon as our workload permits.

It was also clear from the beginning that there are a number of relatively straightforward ways to feed back to the amputee information regarding the knee angle. We plan to use a low-frequency vibratory or galvanic signal acting on the posterior stump surface. Increasing frequency will indicate more knee flexion. In order to save battery life and avoid numbness of the skin there will be no signal when the leg is fully extended, such as in standing and when it is flexed beyond 70 deg. as in sitting and kneeling. The hydraulic system mentioned before contains a potentiometer which will provide this kind of feedback.

Finally, it was clear from the beginning that the really crucial problem was how to obtain from the amputee a control signal which would enable him to produce a gradual scale of at least four distinct control states and to do this approximately one million times per year with sufficient reliability to avoid accidents.

Since myoelectric control was coming of age during these years and seemed a natural choice, we consulted many workers in that field, including Robert Scott, from whom we purchased one of his three-state devices; Childress, Wirta, Taylor, and Finley, who were kind enough to visit us in Dayton for this purpose; and Reswick, Ko, and Mooney. We also conducted for a time myoelectric in-house research and studied all the reports we could find. As a result of these efforts, we became convinced that myoelectric control of a lower-limb prosthesis, using skin contact electrodes, was not safe enough.

Because of these doubts we also investigated the use of ultrasonic echoes from a muscle as a signal source. The results were disappointing. We then conceived and designed a vibrating-muscle hardness sensor,
which might work but is somewhat complicated.

A basically simpler solution may be the so-called bio-carbon buttons developed by NASA and adopted by Reswick and Mooney of Rancho Los Amigos for transmitting signals into the neuromuscular system. As a result of their cooperation and encouragement, we are considering these carbon buttons for obtaining a more reliable myoelectric signal from the amputee's stump. Without any internally attached wires these buttons will reduce the percutaneous impedance by up to 90 percent as compared to skin contact electrodes. This would make the influence of electrical outside interference or of perspiration negligible. The buttons can be inserted by any qualified doctor in his office under local anesthesia in a few minutes. Healing takes place in a few days. The buttons have remained in the skin of subjects for over 3 years without infection or irritation. They are practically flush with the skin surface and do not interfere with skin care. The hydraulic system mentioned before contains an electromagnetically operated throttle valve, which will be controlled by the signal derived from the carbon buttons or from the muscle hardness sensor.

We believe that we now have all the ingredients for a voluntarily controlled knee joint, and that this development will eventually open up a new chapter in the rehabilitation of above-knee amputee.