

GODDARD MEMORIAL HOSPITAL

Boston, Mass.

STUDIES OF OVERALL RESULTS IN THE CARE OF SECONDARY COMPLICATIONS FROM IMMOBILITY AND THEIR EFFECTIVENESS IN THE CORRECTION AND PREVENTION OF DECUBITUS ULCERS — HIP AND FOOT CONTRACTURES IN THE QUAD. PARA. AND HEMI PATIENT.

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CLINICAL STUDY EVALUATION OF MULTI-PODUS SPLINT SYSTEM
FROM APRIL 1st TO AUGUST 19th, 1978

MULTI-PODUS SPLINT SYSTEM WAS USED ON TWENTY-EIGHT PATIENTS
FOR A PERIOD OF FOUR AND ONE-HALF MONTHS. RESULTS AS FOLLOWS.

(6) CASES NECROTIC DECUBITUS ULCERS:

These necrosis decubitus were located on the posterior calcaneal bones. All patients were being treated with heel cushionings, medications and heavy dressing, and bathing at three hour intervals. Healing process was slow and static. Upon application of the Multi-Podus Splint System, all dressing and padding was removed with the exception of a small 2" x 4" sterile pad with a strip of tape to hold it in place. Because the splint allowed good ventilation and clearance between heel and plastic shield and allowed no other contact with mattress, the healing process began immediately. All but one patient were removed from bed restriction and became ambulatory after one week of continuous use of the splint (twenty four hours daily). The same principle that was applied for bed use was also applied during ambulation, with the addition of a shoe or slipper to enable the patient to walk without pressure on the afflicted region. Total healing was accomplished in four to six weeks of continuous use and supervision. Four of the six patients had been suffering from this condition for eight months, and three were gangrenous at the time the Multi-Podus Splint System was administered. Total results were excellent.

(4) CASES C.V.A. HEMIPLEGIA

Four cases were post C.V.A. A four to six week period had elapsed before the application of the Multi-Podus Splint System was applied. At this time they had all had contractures of the heels and inverted deformities. The weight bags, foot boards, and all wrapping were removed. The splint was used to correct the deformities gradually, allowing a dynamic force upward to act as a stimulus to the tight muscle group. Patients found the splint extremely comfortable, and were not cognizant of the splint's gradual extension of the foot to a functional position. The patient was able to move freely about with the splint applied, cutting extensive nursing care in half while correction was taking place. However, daily periodic checks were made on the patients by the orthotist and physical therapist. These patients used the splint on a twenty-

four hour continual basis for five to eight weeks, and were able to use the splint as part of ambulatory and gait training. Application of a shoe or slipper to the foot caused the splint to act as a dorsi-flexor assist and helped the patient assume a normal physiological gait. This was an excellent assistance to the therapists who were treating these patients. Overall results were very good.

(4) CASES EARLY POST C.V.A. HEMIPLEGIA

These hemiplegia patients were given the Multi-Podus Splint System one to three weeks from affliction. It was used in the prevention of contractures and foot deformities. Excellent results were attained due to the early treatment of the Multi-Podus Splint System. These patients wore the splint for the total time of bed confinement and during their gait training phase for a period of three to six weeks on a twenty-four hour basis.

(3) CASES HEMIPLEGIAS

These immobile patients, with a combination of both foot contractures and heel decubitus, used the Multi-Podus Splint System for six to eight weeks on a twenty-four hour basis. Previous to the fitting of the splint, these patients were treated in the conventional method as indicated (necrotic decubitus ulcer, first paragraph, page one [1]) and were getting the usual unsatisfactory results. Bed sores healed well and contractures were reduced using the same treatment as those with the decubitus ulcers and foot contractures. There were no discomfort or pressure marks, even though many had poor circulation and edema.

(3) CASES POST HIP FRACTURES

All three of these cases had fixed hip contractures. Prior to the application of the Multi-Podus Splint System, weight bags and pillows were used with very little effect. Patients had to be watched continually by the nursing staff due to the moving about of the patient and the method used in maintaining a straight leg position. The splint was applied and by simply swinging out the de-rotator bar, the legs were then permanently placed in a correct functional position. Muscles were stretched sufficiently to prevent deformity and less nursing care again was required. As in all other cases where the Multi-Podus Splint System was used, these patients used the splint while in bed for periods up to four weeks, with no discomfort and beneficial results.

(3) CASES OPEN HEART SURGERY

These patients had poor circulation/edema and other complications. Continuous application of the Multi-Podus Splint System was very effective in both preventing and correcting deformities and pressure sores due to the necessary bed restriction confinement. However, prognosis was poor for this type of patient. Some have terminated; however of those who have made progress, the use of the splint was of definite aid

and was used in early gait training and ambulation at a later stage. No ill effects, such as phlebitis, pressure due to poor circulation and edema, and other pressure occurrences surfaced in the above cases studied, and none of the patients complained of any discomfort from the Multi-Podus Splint System. However, due to very poor circulation, extreme edema, colitis, epilepsy, and advanced diabetes, five patients showed only fair results and one patient had to be abandoned.

INDICATIONS FOR FURTHER USAGE OF THE MULTI-PODUS SPLINT SYSTEM:

1. POST FRACTURES OF LOWER LEG AND FOOT:
IMMOBILIZE AND MAINTAIN FUNCTION
2. POST SURGICAL PROCEDURES OF FOOT AND LOWER LEG (SUCH AS ACHILLES TENOTOME):
MAINTAIN CORRECTION
3. POST RELEASES IN C.P. CHILDREN:
MAINTAIN SURGICAL CORRECTION
4. FRACTURES OF THE METATARSUS AND/OR MALLEOLUS:
IMMOBILIZE, SUPPORT, CORRECT

NOTE: THE MULTI-PODUS SPLINT SYSTEM IS MADE TO FIT THE ADULT LEG (LEFT OR RIGHT), MALE OR FEMALE, REGARDLESS OF SIZE, GIRTH OR THICKNESS WITH THE EXACT SAME RESULTS.

SUNCOAST MANOR

St. Petersburg, FL

A STUDY IN PRESSURE ULCER CARE WITH THE MULTI-PODUS SPLINT SYSTEM AND ROUTINE CLEANSING

MAVIS BLEDSOE, D.O.N.
ROBERT LONARDO, C.O.

PURPOSE

THE PURPOSE OF THIS STUDY IS TO DETERMINE WHETHER THE MULTI-PODUS SPLINT SYSTEM HAS POSITIVE EFFECTS ON THE HEALING OF PRESSURE ULCERS WHEN USED IN CONJUNCTION WITH ROUTINE CLEANSING. IN ADVANCE STAGES OF IV AND V, PACKING WAS USED TO COVER THE WOUND WITH JUST TWO WRAPS OF BANDAGING TO HOLD THE DRESSING IN PLACE.

TIME SEQUENCE

August 14th thru September 16th, 1986

GOAL

To determine advanced healing process of necrotic ulcers with the treatments of the Multi-Podus Splint System.

FOLLOWING

Estimated time for healing a necrotic decubitus with this severity takes approximately six months or more if amputation is not precluded.

This study shows combination of minimum dressing applied with the Multi-Podus Splint System, showing that healing time is reduced drastically by 2/3rds, or 75%, of the normal allotted time required.

UPDATE

This ninety-three (93) year old female patient has had a stage IV necrotic pressure heel ulcer for four (4) months now. Prior to the Multi-Podus being administered, the ulcer was weepy, with necrotic tissue being clearly evident. A green oozy discharge was present with a foul smell. The wound was 7 cm by 5½ cm by 1½ cm deep, or 4½" by 4". The subcutaneous was quite infected and gangrene was present. Prior to the use of the Multi-Podus, this patient had been scheduled for amputation, with no hope of recovery anticipated. After a period of 1½ weeks using the Multi-Podus treatment procedure, new granulating tissue was

detected, and some of the dead tissue was removed manually. After a 2½ week period, the patient began to make a remarkable, unexpected recovery and the amputation was cancelled. The patient began taking steps with the Multi-Podus, and there was no pressure present on the patient's heel during the stages of ambulation. At this point localized grafting was considered, promoting a faster healing process due to the patient's poor circulation.

This procedure was abandoned when it became evident that the eschar was flaking away on its own.

The following consists of documentations recording the weekly and bi-weekly intervals during the entire study.

Routine cleansing, and mild wrapping were applied for a period of approximately four (4) weeks. The area to be treated was submerged in the whirlpool, using one (1) capful of Betadine for a session of about thirty (30) minutes. The Multi-Podus Splint System was applied after the clean dressing. The Multi-Podus Splint System decreased any further pressure on the area.

Initially, the patient had a left decubitus on the posterior region of the heel. The decubitus on the calcaneus measured approximately 7 cm in diameter and 1½ cm deep.

Substantial progress was made during the course of this study. In approximately three (3) weeks of treatment the decubitus decreased in size by 3½ cm.

In conclusion: the decubitus is almost healed now as a result of daily Betadine and cleansing treatments, along with use of the Multi-Podus Splint System for a period of 7 weeks.

In this case the Multi-Podus Splint System clearly proved to be the most effective treatment in the healing of this patient's decubitus.

This case was studied for approximately 3½ weeks, with extremely good results.

In this case the Multi-Podus Splint System proved to be of great benefit for continuous protection and elimination of further pressure, allowing for no further deterioration.

Date: September 21, 1986

PATIENT NAME: AMY BRADLEY

Pressure ulcer on left heel was debrided manually in gradual steps. Necrotic tissue was removed slowly and treatments are more beneficial now that tissue is gone. Necrotic tissue appeared to be absorbing the water with solution.

Area surrounding pressure ulcer has improved. The skin is now a pinkish color except for a small eschar in the center.

There is a decrease in the size of the decubitus to 3 cm. Area surrounding decubitus is now 4 cm. Bright red blood is dripping from the area. After treatments and dressing, the Multi-Podus Splint System is applied on a continual basis to prevent any pressure to area.

Cleansing treatment continues. Decubitus ulcers have decreased in size. Further surrounding tissue looks good and skin color continues to improve. Size is now 1/2" by 1/4"; decubitus is now healing internally as well and medical staff has expressed astonishment. Multi-Podus Splint System continues for the unexpected healing progress of this patient.

Complete recovery is now anticipated, and this study and clinical progress are continuing.

Studies were continued and clinical progress was repeated on 12/2/86. Routine cleansing and constant use of the Multi-Podus Splint continued during the period from Sept-Dec. daily. Ambulation with the splint and a cast boot had been increased, which accelerated healing progress. Special emphasis was placed on this patient's capability to ambulate early, since the splint was first applied because of contractures being present, which were reduced by the splint during the time of bed rest and treatment of the heel ulcer, simultaneously.

All that remains now is *new, pinkish, healthy tissue!*

At this time all routine care has been discontinued, with the exception of continual use of the Multi-Podus Splint. . .

The pinkish color measured the size of a dime. . .

Complete healing took place *internally!*

By Jan. 30th, 1987, *total healing had taken place, and the splint was discontinued!*

Her attitude has improved considerably, enabling her to move about freely with the aid of a walker.

Total healing time for this advanced stage 4 decubitus took 125 days!

This study was completed by:

Dr. Franklin, M.D., Attending Physician

DON. Mavis Biedsoe

CO. Robert Lonardo

PHYSICAL THERAPY FORUM Wednesday, May 13, 1987

The Multi-Podus Splint

By Penny Hajj, LPT
(Special to the Forum)

There is a new product on the market, designed by an orthotist to solve many of the lower extremity problems of the long-term bed rest patient.

It is the Medicare-approved "Multi-Podus Splint," called a System because of the many problems it solves. It is a fleece-lined, plastic splint, constructed of a special material which has "memory" and will return to the correct 90 degree angle if plantar-fixed. For cases where susceptibility to a heel decubitus is increased by diabetes mellitus or peripheral vascular disease, there is relief built into the splint so that the heel cannot develop a decubitus, and healing will be promoted if one is already present. This heel relief allows for full aeration and observation when desired, or for a light dressing, and there is no possibility of contact or pressure on the heel while the splint is being worn.

There is another major feature of this system. On the posterior aspect of the splint, there is a bar which can be turned perpendicular to the axis of the leg and thus prevent any internal or external rotation of the hip. This splint with the rotation bar in place also helps to decrease a knee flexion contracture. This aspect has proven particularly useful in cases of CVA, spinal cord trauma, head injuries, burns and lower extremity fractures.

There are other software parts which may be added to the "system." There is an abduction bar, which, when used between two splints can maintain up to 40 degrees of hip abduction. With the addition of a cast boot, the patient can be tested for ambulation with a dorsi-flex assist, prior to making a decision about the need for a brace or MAFO. If lower extremity traction is needed, a special traction strap can be attached over the splint, allowing up to 25 lbs. traction.

The inventor of this splint, Robert Lonardo, born in 1932, developed polio at the age of three, and grew up wearing a brace and attending special schools for disabled children. In 1965, he became a certified orthotist, and utilizing his experience as a brace-wearer and maker, he worked with the medical staff at Brown University in Providence, Rhode Island, to develop this splint. They were especially looking at the crippling effects of long term bed rest. Following two years of extensive research, it was determined that many of the conditions an immobile patient is confronted with occur while he/she is bedridden. Also, many of these patients would remain bedridden because of these secondary afflictions even after they were treated for their primary problem. Heel decubitus, foot drop, knee and hip deformities are among the most common of these. Bob Lonardo's contribution was to take the principle of a brace and reverse it to accommodate the immobile patient. This would allow the patient to avoid the adverse effects of

immobility and be prepared to ambulate at an earlier stage, with better results. The next two years were spent working with the advice of a physical therapist, researching, testing and perfecting the various biomechanics and principles of this system on patients in several of the teaching hospitals in New England.

There are multiple advantages to this splint. It fits right or left, and sizes for extra large and pediatric cases are available. It is easy to care for, the padding is washable, and there is minimal frictional contact with the skin. Pressure areas may be relieved by cutting out additional areas on the ankle, the rotator bar can be used to right, left or bilaterally, and there is no need to remove the splint for side lying; simply flip the bar to the center. By using the toe post, toe flexion can be controlled, and this also eliminates pressure from the bedclothes. Thus, no foot board, sandbags or doughnuts are needed. Although the toe post is malleable and can have its angle adjusted, the main splint is manufactured from a different type of plastic, and its shape, though flexible, is unalterable once pressure is removed. The splint can be used for early ambulation, is very comfortable to wear in bed, keeping the foot warm — especially appreciated by the elderly — and it is reimbursable by Medicare.

For more information contact Mrs. Penny Hajj, LPT, 315 Ogden Ave., Swathmore, PA 19081, or call (215) 543-1310.

(Initially, Bob Lonardo and his wife did all the manufacturing, marketing, etc. themselves, working out of a two-car garage. Then their son, Bob, joined them and eventually five more members of the family. In 1979, the splint received Federal Medicare Coverage. In 1982, Bob Jr., moved to Florida to investigate the nursing home market there, and in 1985 the family moved to Largo, Florida. A nationwide survey study of the splint had been made, and 150 institutions had given overwhelming approval of the splint. Japanese and Australian dealers also became interested, and the splint was launched.

The splint is patented in the U.S. and nine foreign countries. Having moved twice to larger quarters in Florida, the L'Nard Company has started to create a nationwide network of nurses, physical therapists and other medical consultants to develop the nursing home and hospital market throughout the country.)



NEW YORK UNIVERSITY MEDICAL CENTER

Department of Rehabilitation Medicine
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CABLE ADDRESS: NYU MEDIC

June 5, 1978

LNard Associates
PO. Box 9226
Providence, R.I.

Dear Sirs:

In response to your inquiry regarding "the Multi-Podus Foot and Leg Unit" (MPF & L Unit) it is the consensus of the Adult Rehabilitation Service that this splint is surely a valuable piece of equipment offering continuous protection to the heel.

Since receiving the Multi-Podus Splint System, we have used it on three patients (2 paraplegics and 1 multiple fractured patient). The following results were noted:

1. With the ulcers of the heels well protected, both paraplegic patients were able to be on intensive rehabilitation programs.
2. Continuous wearing of the splints both day and night helped to promote healing especially for one of the paraplegic patients (a 46-year-old male) in so much that he was discharged with a splint much earlier than had been anticipated.
3. The other user of the Multi-Podus Splint System was a 56-year-old male who suffered multi-fractures to his lower extremities resulting in muscle weakness, excessive external rotation and heel cord shortening. He was given a splint so as to counteract and minimize the above problems.

To recapitulate the effectiveness and usefulness of the Multi-Podus Splint System, we found that it met the standards of:

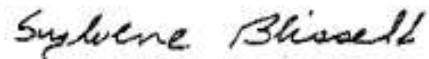
1. Protecting areas on heel prone to breakdown.
2. Correcting and minimizing rotation at the hip with the use of the rotation bar.

3. Offering correct position of ankle to 90° in patients who are not severely spastic.

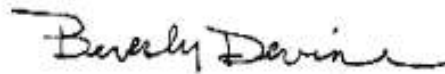
4. Allowing the performance of functional activities — being durable, lightweight and washable.

In general, we have seen in our Adult Rehabilitation Service the success which this Unit offers to our patients aiding at the same time in the hastening of their Rehabilitation Time.

Sincerely,



Sylvene Blissett, RPT



Beverly Devine, RPT.
Unit Supervisor



Jack M. McResh, Director
Physical Therapy



The Ohio State University

Department of Physical Medicine
Dodd Hall
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Robert Lonardo, C.O., President
L'Nard Associates, Inc.
12087 62nd Street N. — Suite 7
Largo, Florida 33541

Dear Mr. Lonardo:

As I mentioned in our phone conversation, this splint has proved helpful in a *preliminary, non-controlled trial* on a few of our patients.

The first was an approximately 80-year-old man with a diagnosis of polymyositis, which rendered him essentially paraplegic. When he was transferred to our rehabilitation unit, there appeared to be fixed contractures of the heel cord bilaterally because of prolonged inactivity. After a trial of the Multi-Podus Splint on his right foot, there was significant reduction of the contracture. We then transferred the splint to the left, and noted similar improvement. We were able to maintain our gains with range of motion. By the time he was ready to be ambulant, he made further gains on the tilt table. We feel that use of the Multi-Podus Splint decreased the amount of time spent on the tilt table. The patient now ambulates independently and has been discharged from the unit.

Case #2 concerned a woman in her early thirties rendered incompletely quadriparetic secondary to hemangioblastoma of the spinal cord. Although she did not have contractures of her Achilles tendons, she tended to lie in a position of plantar flexion bilaterally, right more than left, because of spasticity. She was able to tolerate only low doses of anti-spasticity medication. The Multi-Podus Splint System was tried on the right on an empiric basis. The result was a clinical reduction in spasticity after a week to 10 days. Range of motion of her right ankle became easier. The patient was able to learn transfer activities and was discharged as a therapeutic ambulator.

Case #3 was a quadriplegic man in his late thirties who had sustained his spinal cord trauma 17 years previously. He had significant lower extremity spasticity and a decubitus ulcer on his right heel. The ulcer was a recurrent problem and had been present for a period of months. Although the Multi-Podus Splint did help reduce contracture on the right leg by about 5°, this was not considered significant. However it allowed healing of his right heel ulcer over a period of 3 to 4 weeks.