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CLINICAL REPORT

Report on the Evaluation of the Vannini-Rizzoli Stabilizing Limb Orthosis

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Abstract—The three models (Winter, Summer, and Elastic) of the Vannini-Rizzoli Stabilizing Limb Orthosis (V-RSLO) were evaluated over a two-year period (1989-1991). A total of 181 veterans with paralysis participated. Eighty-two percent of the participants were paraplegic, while 18 percent were quadriplegic. The primary objectives of this evaluation were to determine functional utility and patient acceptance through a subjective questionnaire; establish a selection criteria, develop a therapeutic treatment regimen, and establish methods to transfer the clinical experiences to other VA Medical Center physicians and clinicians. Through the course of the evaluation, a definitive selection criteria and treatment regimen was established to ensure the successful use of the V-RSLO. The findings showed that the V-RSLO was beneficial and was accepted by the participants as an alternative orthotic device for ambulation.

Key words: *ambulation, paraplegia, quadriplegia, stabilizing limb orthosis.*

INTRODUCTION

Paralysis of the limbs, particularly when both upper and lower limbs are involved, requires extensive and challenging activities to accomplish reciprocal ambulation. Individuals with paralysis often require the addition of an orthotic device and many long hours of rehabilitation and training to regain the ability to ambulate. Some mechanical orthoses currently in use (e.g., metal, long- and short-leg orthoses, and the reciprocating gait orthosis) are viewed as heavy, bulky, and cosmetically unappealing, and produce an awkward gait. As frustrating and challenging as it may be, many of these individuals continue to pursue the above activity hoping to derive useful benefits. The ability to walk again, even on a limited basis, may aid the physiological condition of the user, create a positive emotional impact, and elevate his or her overall psychological outlook at home, at work, and in the community.

The Vannini-Rizzoli Stabilizing Limb Orthosis (V-RSLO) is a polypropylene orthosis configured to the shape of the lower portion of the leg. The evaluation of the V-RSLO covered a period of two years with nine VA Spinal Cord Injury Services (SCIs) involved. A total of 181 spinal cord injured (SCI) veterans participated in the evaluation. The overall conclusion of the evaluation indicated that the V-RSLO could provide the SCI veteran with a useful and practical alternative to a standard mechanical orthosis. The potential candidate must meet the established selection criteria and be prepared to participate in the intensive pre- and post-exercise programs.

The orthosis is inserted into a specially designed leather boot and used to aid individuals with lower limb dysfunction in ambulation. The V-RSLO is an innovative approach for providing assistance in standing and reciprocal walking (one leg sequentially placed in front of the other) for SCI persons, especially paraplegics.

The level of the lesion (cervical, thoracic, or lumbar) and the type of injury (complete or incomplete) are major factors in the assessment and selection of an orthotic sys-

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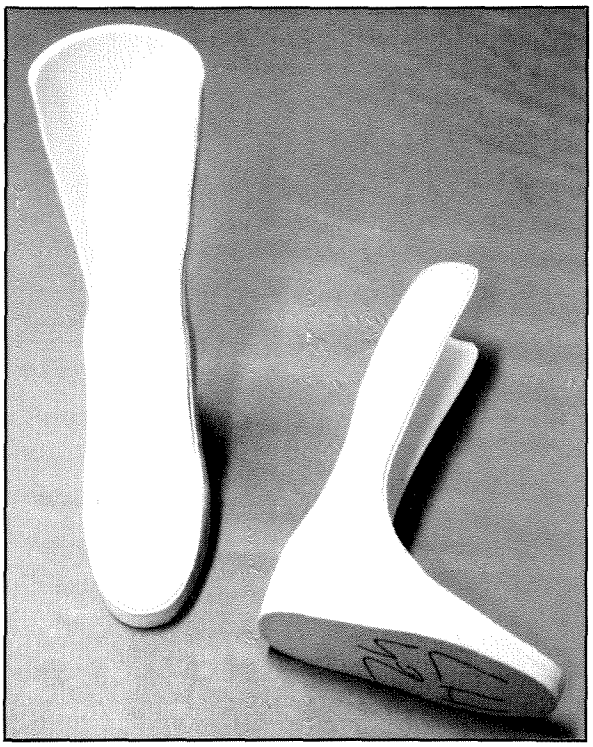


Figure 1.
Inner shell of the V-RSLO.

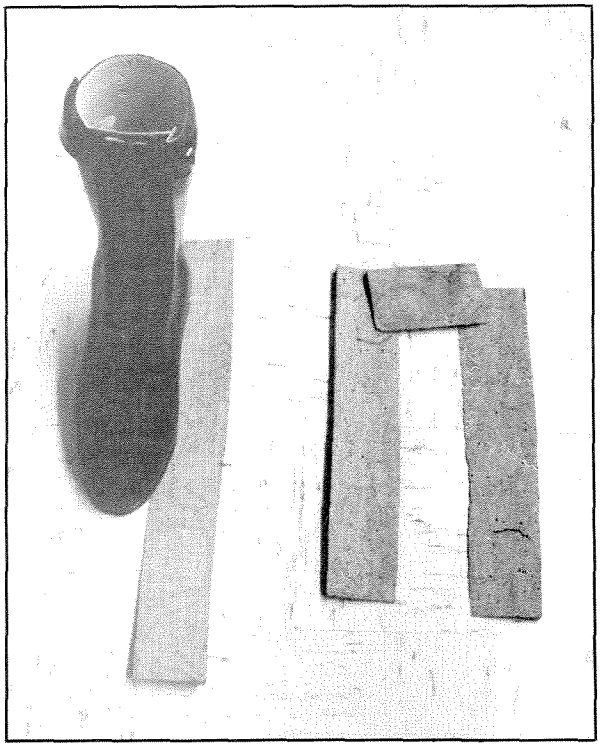


Figure 2.
Wedging to establish static equilibrium.

tem for the intended user. There are three fundamental approaches to the provision of reciprocal walking for high-level paraplegics: 1) a purely mechanical orthosis (i.e., the Louisiana State University Reciprocating Gait Orthosis); 2) hybrid devices comprising a mechanical orthosis with supplementary functional electrical stimulation (FES); and, 3) a purely FES system with no mechanical orthosis. None of these systems envisages walking without the use of additional walking aids (1). Mechanical orthotic systems are presently available for the clinician to use with SCI patients, but due to factors such as increased weight, cumbersome design, and the amount of energy consumption required on the part of the user to manipulate such a system, many paraplegics discontinue using the device and rely on a wheelchair for mobility needs. The hybrid and pure FES systems continue to be vigorously researched, but are not readily available for routine patient use.

The V-RSLO attempts to solve the problems encountered with mechanical orthotic systems by providing the paraplegic patient with a stabilizing orthosis that appears to be lightweight, simply designed, and easy to don and doff; one requiring reduced energy expenditure to accomplish a functional, reciprocal gait with the assistance of ambulation aids (i.e., canes, or a walker).

PURPOSE

The purpose of this evaluation was to determine the functional utility of the V-RSLO, establish the selection criteria, develop the required therapeutic treatment, determine patient acceptance, and transfer the clinical experience to other VA Medical Center (VAMC) clinicians and physicians.

DESCRIPTION

Function

The skeletal structure of the V-RSLO comprises a flat, rigid sole with a posterior, polypropylene half-shell designed to partially enclose the lower limb from approximately 2 centimeters below the distal portion of the patella to the distal end of the toes (**Figure 1**). The insole of the orthosis is angled to achieve 10 to 15 degrees of plantarflexion, thus shifting the center of gravity of the user forward and anterior to the ankle joint.

The angle of plantarflexion in which the foot is maintained stabilizes the knee upon standing. The patient controls static equilibrium by maintaining an upper body

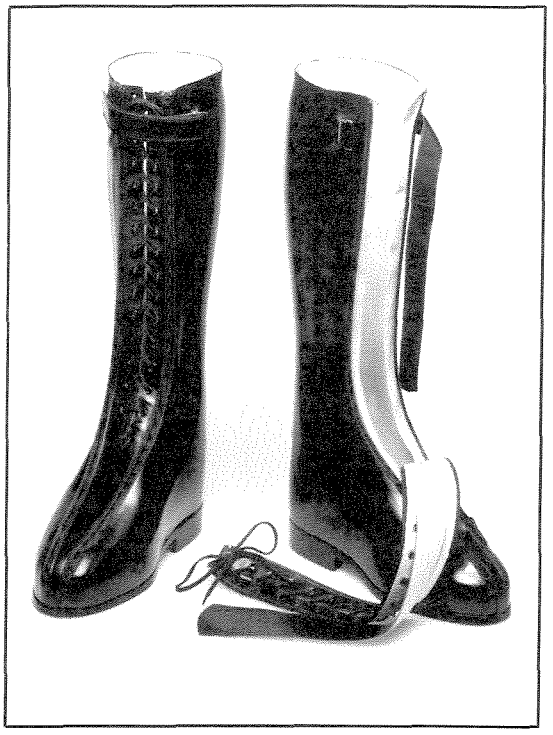


Figure 3.
Winter Model of V-RSLO.

Figure 4.
Elastic or Short Boot Model.

position in which the head is held high, with hips and knees in an extended position. During the measuring phase, adjustments to permit the patient to maintain static equilibrium are accomplished by appropriately placing wedges under the skeletal structure (measuring splints) to obtain the different angles of plantar/dorsiflexion or pronation/supination of the foot (**Figure 2**). The patient, by shifting his/her upper body slightly to the left or right and forward, causes the center of gravity to shift forward. The patient, supported by parallel bars, a walker, or quad canes, is then able to ambulate by moving the unweighted foot forward in a pendulum fashion.

The skeletal structure of the boot is internally padded or lined along the inner portion of the half-shell for skin protection. The approximate weight of the Winter Model is 4 pounds.

Physical appearance

The physical appearance of the V-RSLO varies only by the type of outer encasement. Three basic models are available: 1) the *Winter Model* is a high leather boot extending to a level just below the tibial tuberosity (**Figure 3**). It is fastened by a central lace and two zippers (one on each side of the lace). Once the lace is adjusted, this

Figure 5.
Summer Model.

procedure does not need to be repeated. The user then accesses the zipper(s) for donning and doffing. The boot is internally padded or lined along the inner wall of the half-shell for skin protection; 2) The *Elastic* or *Short Boot Model,* a shortened version of the Winter Boot, extends to approximately mid-calf height (**Figure 4**). Both models can be utilized for indoor/outdoor ambulation due to the leather exterior (the boots are available in 14 colors); and, 3) the *Summer Model,* an open version equipped with Velcro straps along the leg and foot, which is primarily intended for indoor use (**Figure 5**).

METHOD

A pilot study was initiated by the former Director, Margaret J. Giannini, MD, Rehabilitation Research and Development Service with the support of the Prosthetic and Sensory Aids Service, Department of Veterans Affairs, Central Office, Washington, D.C., at the Tampa VAMC in July 1989. Initially, nine SCI veterans were selected to participate in the study. Favorable results led to the emergence of a full-scale evaluation involving eight additional sites.

An evaluation protocol and a training package consisting of slides, video tapes, and manufacturers' literature were forwarded to the co-principal investigators at each participating site.

Evaluation sites

A total of nine Spinal Cord Injury Services (SCIS) within VAMCs were selected to participate in this evaluation: Brockton/West Roxbury, MA; Bronx, NY; Hines, IL; Long Beach, CA; Memphis, TN; Palo Alto, CA; Richmond, VA; San Diego, CA; and Tampa, FL. Principal and co-principal investigators consisted of Chiefs of Spinal Cord Injury and Rehabilitation Medicine (RMS) Services. Investigators included RMS physical therapists and kinesiotherapists, and the station orthotist. The Chief, Prosthetic and Sensory Aids Service (PSAS) in each of the nine VAMCs was the project coordinator for each station.

Subject selection

A total of 181 subjects participated in the evaluation of the V-RSLO. Eighty-two percent of the participants were paraplegic, while 18 percent were quadriplegic. All provided their informed consent. Potential candidates were required to meet specified selection criteria outlined in the evaluation protocol. Due to information gained through the course of the evaluation, the original selection criteria were revised and a new list of precautions and contra-indications

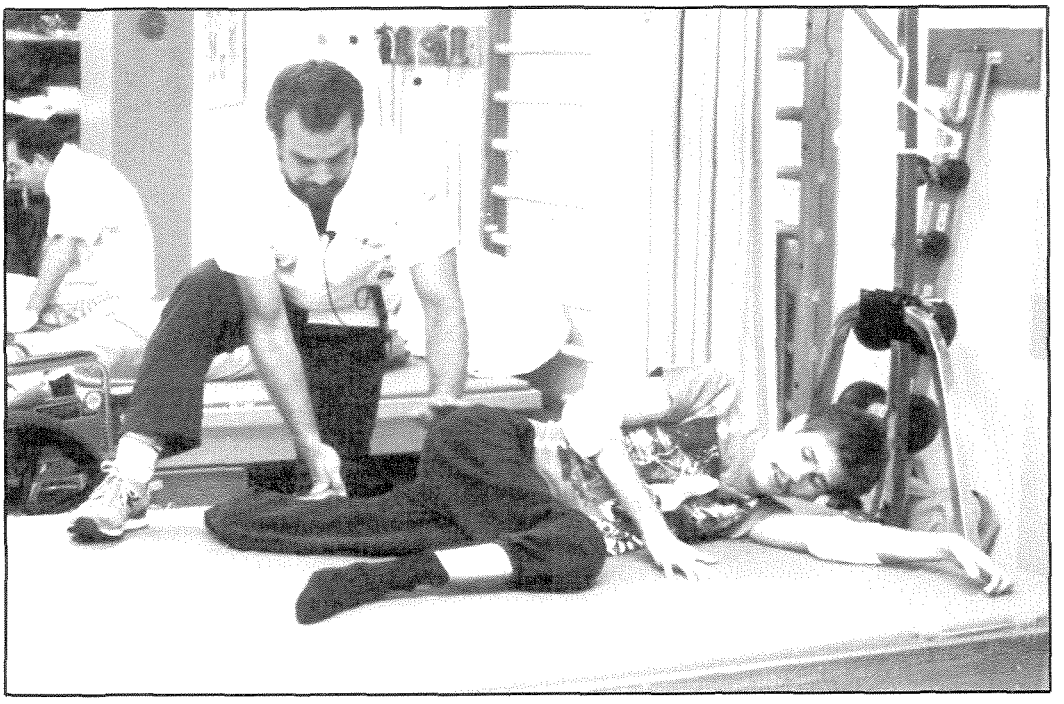


Figure 6.
Performing reciprocal movement exercise on mat.

was included (see **Appendix A**). These new criteria insured the highest potential for successful results using the V-RSLO.

Data retrieval

Background information was recorded on each selected subject (**Appendix B**). Once selected, measurements for the orthoses were taken by the orthotist and forwarded to the manufacturer, located in Italy, for fabrication (**Appendix C**). Selected subjects engaged in a therapeutic exercise program, 3–5 hours a day, 3–5 days a week as outlined in the protocol in **Appendix D**. The exercise program was recommended by Professor Antonietta M. Vannini, Director of the Rehabilitation Center of the Montecatone Hospital, Imola (Bologna), Italy, and consisted of mat and standing exercises geared toward reciprocal movement of the shoulders, hips, and knees (**Figure 6**). When standing, the subject was instructed to shift his total body weight from one leg to another (**Figure 7**). Upon receipt of the orthosis, the subjects participated in a post-orthosis exercise program, tailored to the progress of the subject (**Figure 8**). Generally, the emphasis shifts from mat to functional standing and ambulation exercises during this phase.

Follow-up documentation was required on each subject at the 3, 6, 9, and 12-month time frames, following receipt of the orthosis, by means of a questionnaire (**Appendix E**). Subjects began the evaluation and received their orthosis at varying times. Upon completion of this evaluation, 116 responses had been collected at the 3-month time frame, 72 after 6 months, 46 after 9 months, and 26 at the 12-month time frame.

Subject withdrawal

A total of 31 subjects withdrew during the course of the evaluation. Fifteen withdrew due to their inability to use the orthosis successfully. Those subjects were not able to sustain their static equilibrium or progress further than standing. Twelve subjects withdrew due to their inability to dedicate the large amount of time necessary for the pre- and post-exercises, or they lost interest. Three withdrew due to personal reasons, and an additional subject withdrew due to his inability to achieve full extension in the low back/hips due to the implantation of Harrington rods.

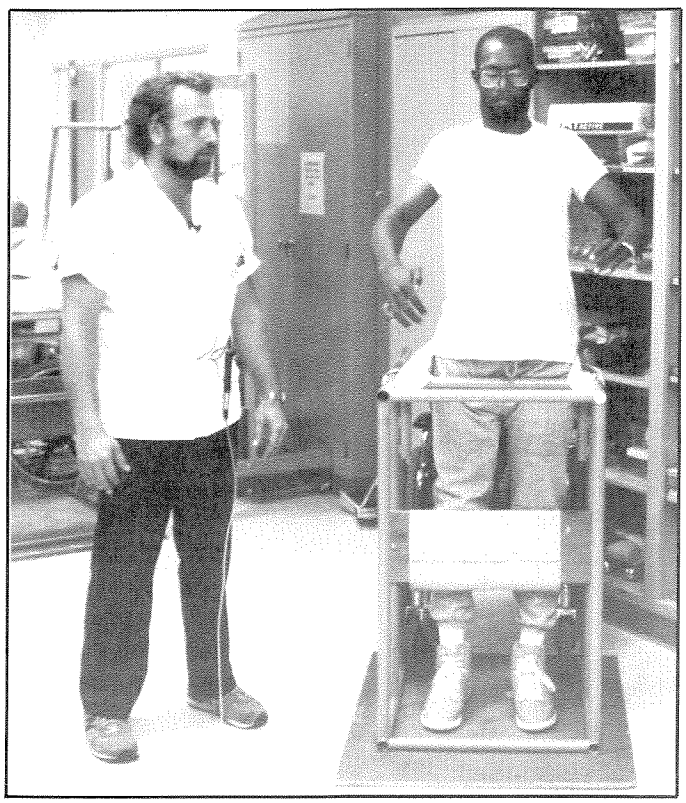


Figure 7.
Performing standing balance exercise.

Figure 8.
Performing gait training with V-RSLO.

Nine additional subjects were placed in a holding pattern until they could free themselves from other commitments and obligate the time needed for the evaluation.

RESULTS

Subject demographics

The subjects ranged in age from 20 to over 65 years: average age of 37 years. Levels of injuries ranged from C-4 to S-2, with the majority at the T-6 to T-12 levels. The subjects had been injured from one to over 30 years, with the majority injured from 1 to 5 years, followed very closely by subjects injured 6 to 20 years. Data revealed that those injured the least amount of years (1 to 5) were the most represented in the four follow-up response time frames.

Clinical findings

The general appearance of the V-RSLO was acceptable by all evaluation participants. The V-RSLO is unobtrusive and can be worn with a variety of clothing. There are no metal hinges to become snagged on the user's clothing, thereby reducing wear and tear on wearing apparel. The V-RSLO was found to be lightweight and not bulky, making it easily transportable. Because of its pleasing cosmetic appearance, the absence of heavy metal, and the decreased wear and tear on clothing, the V-RSLO was readily and easily worn by the participants.

Table 1 summarizes the responses obtained regarding the weight of the V-RSLO. The weight was consistently acceptable by the majority of subjects at all time frames. The remainder reported that the weight was heavy, which might be due to the weight of the orthosis being concentrated at the distal portion of the leg, instead of distributed throughout the length of the leg. Some individuals were accustomed to wearing street shoes only, while others may have interpreted the weight as being part of the effort required to raise their legs and feet.

Table 1 also represents the responses of the subjects regarding their independence in donning and doffing the orthoses. Doffing the orthosis was somewhat easier than donning. Modifications, such as grasping loops, can be incorporated into the orthosis to facilitate the process (**Figure 9**).

An individual must have sufficient strength and function in his upper limbs and trunk to achieve an upright position. **Table 2** summarizes the percentages of subjects able to independently attain a standing position at the 3, 6, 9, and 12-month time frames.

Table 1.
Levels of assistance and weight of V-RSLO.

DIS-ABILITY	DON				DOFF				WEIGHT		
	Ind.	Min.	Mod.	Max.	Ind.	Min.	Mod.	Max.	Light	Acc.	Heavy
3 MONTHS (116 responses)											
Q	13	2	1	5	15	2	0	4	1	13	7
P	92	2	0	1	91	4	0	0	27	61	7
Totals	105	4	1	6	106	6	0	4	28	74	14
Percent	91%	3%	1%	5%	92%	5%	0%	3%	24%	64%	12%
6 MONTHS (72 responses)											
Q	7	1	1	2	9	0	0	2	0	8	3
P	61	0	0	0	61	0	0	0	15	41	5
Totals	68	1	1	2	70	0	0	2	15	49	8
Percent	95%	1%	1%	3%	97%	0%	0%	3%	21%	68%	11%
9 MONTHS (46 responses)											
Q	7	0	1	0	8	0	0	0	0	6	2
P	37	0	1	0	37	1	0	0	8	26	4
Totals	44	0	2	0	45	1	0	0	8	32	6
Percent	96%	0%	4%	0%	98%	2%	0%	0%	17%	70%	13%
12 MONTHS (26 responses)											
Q	6	0	0	0	6	0	0	0	0	4	2
P	20	0	0	0	20	0	0	0	5	14	1
Totals	26	0	0	0	26	0	0	0	5	18	3
Percent	100%	0%	0%	0%	100%	0%	0%	0%	19%	69%	12%

Q = Quadriplegic
P = Paraplegic
I = Independent
Min. = requires minimal assistance
Mod. = requires moderate assistance
Max. = requires maximum assistance
Acc. = acceptable

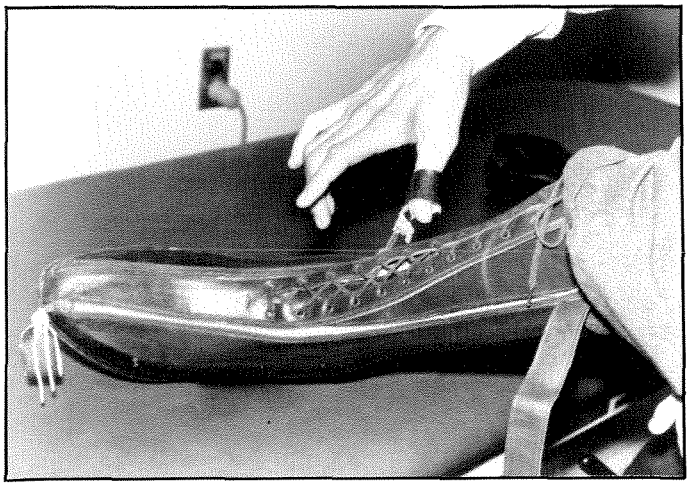


Figure 9.
Grasping loop modification performed to V-RSLO.

Table 2.
Levels of assistance and stability using V-RSLO.

LEVEL OF INJURY	ASSISTANCE STANDING				ASSISTANCE SITTING				STABILITY STANDING			STABILITY AMBULATING			
	Ind.	Min.	Mod.	Max.	Ind.	Min.	Mod.	Max.	Excell.	Accept.	Un-Accept.	Excell.	Accept.	Un-Accept.	Not Ambu.
3 MONTHS (116 responses)															
C_{4-7}	13	2	2	4	15	3	2	1	7	11	3	3	11	1	7
T_{1-5}	7	3	3	0	12	1	0	0	6	5	2	2	4	3	4
T_6-T_{12}	51	5	6	3	61	1	2	1	24	33	8	19	28	8	9
L_{1-3}	13	0	1	0	14	0	0	0	9	4	1	6	7	1	0
L_4-S_2	3	0	0	0	3	0	0	0	1	2	0	0	3	0	0
Totals	87	10	12	7	105	5	4	2	47	55	14	30	53	13	20
Percent	75%	9%	10%	6%	91%	4%	3%	2%	41%	47%	12%	26%	46%	11%	17%
6 MONTHS (72 responses)															
C_{4-7}	6	1	4	0	7	3	0	1	7	3	1	2	5	2	2
T_{1-5}	4	2	1	0	6	1	0	0	4	3	0	0	4	1	1
T_6-T_{12}	34	4	2	2	40	0	1	1	20	18	4	12	20	6	4
L_{1-3}	8	0	1	0	9	0	0	0	5	3	1	3	5	1	0
L_4-S_2	3	0	0	0	2	1	0	0	1	2	0	0	3	0	0
Totals	55	7	8	2	64	5	1	2	3	29	6	17	37	10	7
Percent	76%	10%	11%	3%	89%	7%	1%	3%	51%	41%	8%	24%	51%	14%	11%
9 MONTHS (46 responses)															
C_{4-7}	5	0	2	1	6	1	1	0	3	4	1	3	3	1	1
T_{1-5}	2	2	0	0	4	0	0	0	1	3	0	0	3	0	1
T_6-T_{12}	20	1	1	2	23	1	0	0	12	10	2	5	13	3	3
L_{1-3}	6	2	0	0	7	1	0	0	3	3	2	2	5	1	0
L_4-S_2	2	0	0	0	2	0	0	0	0	2	0	0	2	0	0
Totals	35	5	3	3	42	3	1	0	19	22	5	10	26	5	5
Percent	76%	10%	7%	7%	91%	7%	2%	0%	41%	48%	11%	22%	57%	11%	10%
12 MONTHS (26 responses)															
C_{4-7}	5	0	1	0	5	1	0	0	3	3	0	3	2	0	1
T_{1-5}	2	1	0	0	3	0	0	0	2	1	0	0	2	0	1
T_6-T_{12}	12	0	0	0	12	0	0	0	8	4	0	4	8	0	0
L_{1-3}	4	0	0	0	4	0	0	0	2	1	1	2	2	0	0
L_4-S_2	1	0	0	0	1	0	0	0	0	1	0	0	1	0	0
Totals	24	1	1	0	25	1	0	0	15	10	1	9	15	0	2
Percent	92%	4%	4%	0%	96%	4%	0%	0%	57%	39%	4%	35%	58%	0%	7%

Ind. = Independent
Min. = requires minimum assistance
Mod. = requires moderate assistance
Max. = requires maximum assistance

Excell. = excellent
Accept. = acceptable
Un-Accept. = unacceptable
Not Ambu. = not ambulatory

The acquired feeling of stability while standing and ambulating is of utmost importance in the usage and functionality of the V-RSLO (**Figure 10**). This feeling may increase patient acceptance and the amount of utilization of the V-RSLO. **Table 2** shows that the percentage of subjects reporting excellent-to-acceptable stability was high and steadily increased over time. The same pattern was true of stability while ambulating.

Additional data from the questionnaires revealed that the percentage of subjects who were independent in ambulation with the use of a mobility aid (walker, canes, crutches), increased during each 3-month time span (**Table 3**).

The participating subjects reported that usage of the V-RSLO for standing and ambulation, enhanced, or made possible, their ability to independently perform many of

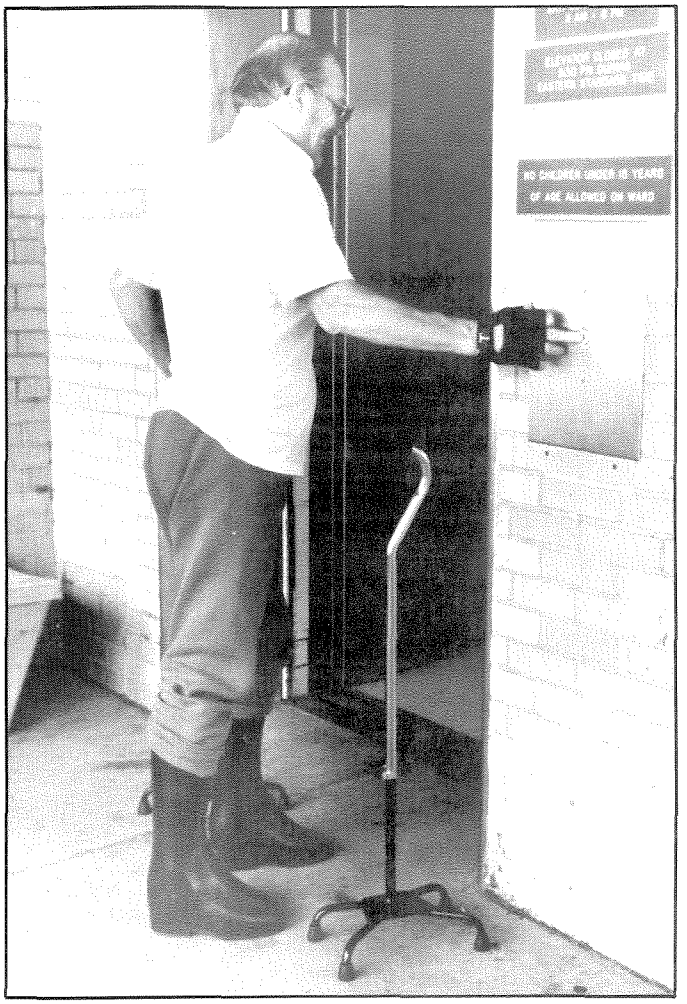


Figure 10.
Standing and ambulation stability.

the activities of daily living (ADLs)—such as, brushing teeth, shaving, preparing meals, etc. The majority of subjects using the V-RSLO for functional ambulation, used it in their ADLs in home settings, or to perform activities that they could not perform from a wheelchair (**Figure 11**). All subjects continued to use their wheelchairs for traveling long distances.

Observations

There were several reports of injuries incurred while wearing the V-RSLO. In one report, a subject reported a tibial plateau compression fracture of the right knee and a second fracture to the left knee while wearing the V-RSLO, although the cause of injury was unclear. It was never determined if the V-RSLO caused these fractures or if the subject was sufficiently osteoporotic to warrant exclusion from the evaluation. Modifications can be incorporated into the orthosis to provide additional support, if warranted (**Figure 12**). There were several reports of redness along the bony prominence of the lower leg (tibial crest) and toes after several hours of wear. The attending orthotist provided additional foam padding and/or stretching of the leather at these points.

Robert W. Hussey, M.D., Chief, Spinal Cord Injury Service, VAMC, Richmond, VA, a Principal Investigator in this study, observed the development of a syringomyelic cyst (sac containing fluid), which extended from the site of one subject's spinal cord injury into the cervical spinal cord and produced upper extremity symptoms. Dr. Hussey

Table 3.
Levels of assistance and ambulation aids.

LEVEL OF INJURY	ASSISTANCE DURING AMBULATION					AMBULATION AIDS			
	Ind.	Min. Assist.	Mod. Assist.	Max. Assist.	Total of Subjects	Walker	Crutches	Canes	Parallel Bars
3 MONTHS									
C_{4-7}	9	4	1	1	15	6	1	2	6
T_{1-5}	3	1	1	4	9	2	0	1	6
T_6-T_{12}	35	15	3	2	55	36	3	7	9
L_{1-3}	11	3	0	0	14	4	4	5	1
L_4-S_2	3	0	0	0	3	2	0	1	0
Totals	61	23	5	7	96	50	8	16	22
Percent	64%	24%	5%	7%		52%	8%	17%	23%
6 MONTHS									
C_{4-7}	3	3	2	1	9	4	1	0	4
T_{1-5}	1	2	1	1	5	2	0	1	3
T_6-T_{12}	30	3	2	3	38	21	1	8	8
L_{1-3}	7	2	0	0	9	2	3	4	0
L_4-S_2	3	0	0	0	3	2	0	1	0
Totals	44	10	5	5	64	31	5	14	15
Percent	69%	15%	8%	8%		118%	8%	21%	23%
9 MONTHS									
C_{4-7}	4	1	1	1	7	4	1	0	2
T_{1-5}	0	1	2	0	3	2	0	1	0
T_6-T_{12}	16	4	0	1	21	13	0	5	3
L_{1-3}	6	2	0	0	8	2	3	3	0
L_4-S_2	2	0	0	0	2	0	0	2	0
Totals	28	8	3	2	41	21	4	11	5
Percent	69%	19%	7%	5%		51%	10%	27%	12%
12 MONTHS									
C_{4-7}	3	2	0	0	5	3	0	0	2
T_{1-5}	0	0	2	0	2	1	0	0	1
T_6-T_{12}	12	0	0	0	12	8	0	4	0
L_{1-3}	3	1	0	0	4	1	3	0	0
L_4-S_2	1	0	0	0	1	0	0	1	0
Totals	19	3	2	0	24	13	3	5	3
Percent	79%	12%	9%	0%		55%	13%	19%	13%

Ind. = Independent
Min. = requires minimum assistance
Mod. = requires moderate assistance
Max. = requires maximum assistance

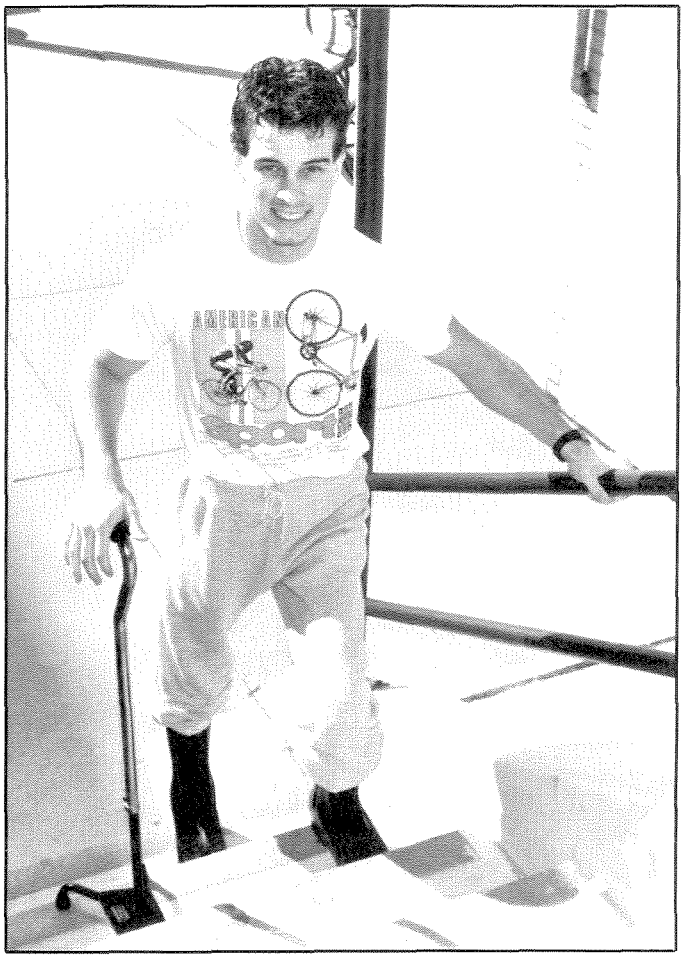


Figure 11.
Stair-climbing using the V-RSLO.

Figure 12.
Addition of thigh cuff to V-RSLO.

indicated that this might be considered a complication arising from use of the orthosis. The development of this type of cyst may stem from increased intracerebral fluid pressure associated with maneuvers such as Valsalva's maneuver. This type of maneuver would commonly occur as a result of a person lifting himself, using the arms, and quite possibly from the type of assisted walking employed by some individuals using the V-RSLO. The patient underwent successful surgical decompression of the cyst, with arrested development of further symptoms. The patient has not been allowed to resume post-orthotic gait training in order to diminish the possibility of recurrence, until the cyst has been stable for at least one year.

There were reports of both increased and decreased spasticity by participating subjects. However, no formal study on this effect was performed. The sudden change in blood pressure (hypotension) often created by standing up too quickly did not present itself as a problem. Subjects who could not adjust to the standing position during the screening process were not selected as participants.

Table 4 shows the responses obtained regarding energy expenditure. An energy consumption study was performed jointly by the Pathokinesiology Service at the Rancho Los Amigos Medical Center, under the direction of Jacquelin Perry, M.D., and by the Special Team for Ambulation, Prosthetics/Orthotics (STAMP) at VAMC, Long Beach, CA. Motion, stride, and energy cost analyses of two veterans using the V-RSLO were performed in order to evaluate their gait. In one case, the use of the V-RSLO with a reciprocal gait and quad canes was compared with the use of knee-ankle-foot orthoses (KAFOs) with forearm crutches using a swing-through gait and using a reciprocal gait. Results indicated that the swing-through gait with the KAFOs was the most efficient gait pattern for this individual. Further observations during this study revealed that the energy demand of ambulation with the V-RSLO is greater; however, the V-RSLO is advantageous over other orthotic devices in areas such as donning/doffing, cosmesis, portability, reduced wear and tear on clothing, and reduced weight of the orthosis. There were no other energy studies brought to the attention of these authors.

Table 4.
Ambulation distances and energy required.

LEVEL OF INJURY	AMBULATION DISTANCES (Before Fatigue)		ENERGY EXPENDITURE			
	No. of Subjects	Avg. (ft.)	EASY	ACCEPT	DIFFICULT	TOTALS
3 MONTHS						
C_{4-7}	15	70.0	1	11	3	15
T_{1-5}	9	27.0	0	7	2	9
T_{6-12}	55	332.7	3	40	12	55
L_{1-3}	14	385.7	2	9	3	14
L_4-S_2	3	273.3	0	2	1	3
		Totals	6	69	21	96
		Percent	6%	72%	22%	
6 MONTHS						
C_{4-7}	9	88.8	2	4	3	9
T_{1-5}	5	24.3	0	3	2	5
T_{6-12}	38	382.8	5	23	10	38
L_{1-3}	9	143.0	1	7	1	9
L_4-S_2	3	303.3	0	3	0	3
		Totals	8	40	16	64
		Percent	13%	62%	25%	
9 MONTHS						
C_{4-7}	7	186.4	2	3	2	7
T_{1-5}	3	34.0	0	3	0	3
T_{6-12}	21	151.0	5	10	6	21
L_{1-3}	8	200.2	1	6	1	8
L_4-S_2	2	305.0	0	2	0	2
		Totals	8	24	9	41
		Percent	19%	59%	22%	
12 MONTHS						
C_{4-7}	5	235.0	2	3	0	5
T_{1-5}	2	15.3	0	2	0	2
T_{6-12}	12	248.7	4	7	1	12
L_{1-3}	4	248.0	1	3	0	4
L_4-S_2	1	600.0	0	1	0	1
		Totals	7	16	1	24
		Percent	29%	67%	4%	

No. = number of subjects
Avg. = average distance ambulated
Accept. = acceptable

DISCUSSION

The intent of this project was to conduct a basic clinical evaluation to determine the usefulness of the V-RSLO as an alternative orthotic device and to establish the selection criteria for usage. During the course of the evaluation, scientific studies relating to the use of the orthosis surfaced. Whereas the results in this study were obtained through clinical and home use of the orthosis, the authors welcome and encourage follow-up research studies on the overall use of the V-RSLO to determine the long-range effects it may have on the user.

CONCLUSIONS

The results of this evaluation indicate that the V-RSLO can be a safe, reliable, and feasible orthotic option for the SCI patient. The intended patient must meet the selection criteria, have an intense motivation/desire to ambulate, and have the time and means to participate fully in both the pre- and post-orthotic exercise programs. The V-RSLO provided an opportunity for success to those SCI patients who were not considered to be ambulators, and for others, an alternate choice of an orthotic device. The quality of life for the SCI patient who meets all criteria for selection (physical, emotional, and mental), may be enhanced through the use of the V-RSLO.

AVAILABILITY

Veterans interested in usage of the V-RSLO are encouraged to contact the Chiefs, Prosthetic and Sensory Aids Service (PSAS), Spinal Cord Injury Service (SCIS), or, Rehabilitation Medicine Service (RMS) at their local VA Medical Center.

ACKNOWLEDGMENTS

We appreciate and thank Eleanor M. Travers, M.D., former Acting Director Rehabilitation Research and Development Service, VA Central Office, Washington, DC for her support and encouragement in the writing of this article. In addition, we thank all participating staff members from the evaluation sites and staff from the VA Prosthetics Assessment and Information Center, Baltimore, MD, for their support and involvement with this project.

We would especially like to thank Mary Cupo, Kinesiotherapist/Health Science Specialist, who played a major role as a Co-Project Monitor in this evaluation.

REFERENCES

1. Stallard J, Major RE, Patrick JH. A review of the fundamental design problems of providing ambulation for paraplegic patients. Paraplegia 1989;27:70-5.

APPENDIX A

SELECTION CRITERIA

Individuals must possess:

1. Full range of motion (ROM) and stability in joints of the lower limbs
2. Good-to-normal wrist, triceps, and shoulder ROM and strength
3. The ability to lift themselves into a standing position and support their body weight, using an assistive aid(s)
4. The ability to develop a tolerance for standing for at least one hour within the trial period, using an assistive aid(s)
5. Good physical condition, based on a medical/physical report from a physician
6. A firm commitment to participate.

PRECAUTIONS

1. Scoliosis
2. Stabilizing rods/devices (except Harrington rods)
3. Low back pain
4. Spasticity—if condition is unmanageable it would inhibit functional use of the V-RSLO
5. History of lower limb fractures with orthopedic clearance for weightbearing
6. Cardiovascular disease history, or at risk, unless specifically given cardiology clearance
7. Overweight by more than 20 percent of ideal body weight as determined by physician.

CONTRA-INDICATIONS

Method to determine who will *not* be a candidate:

1. Fixed contractures of lower and/or upper extremities that inhibit functional usage of the limb
2. Ligament laxity of the knees, whereby modifications to the orthosis will not compensate
3. Unstable spine as determined by medical records
4. Heterotopic bone formations in hip area as determined by medical records.

APPENDIX B

CAS 101

PATIENT BACKGROUND INFORMATION
VANNINI-RIZZOLI STABILIZING LIMB ORTHOSIS

1. NAME: _____ 2. SS # _____ ____ _____ 3. DOB _____
4. ADDRESS: _____ 5. PHONE # (____) _____ _____ 6. M/F _____
7. HEIGHT _____ 8. WEIGHT_____ 9. HIGHEST EDUCATION LEVEL _____
10. OCCUPATION _____
11. LEISURE TIME PURSUITS _____

12a. CURRENT MOBILITY STATUS (SPECIFY ORTHOSIS IF USED) _____
W/C _____ STANDING _____ WALKING INDOORS _____ WALKING OUTDOORS _____

b. GOAL OF V-RSLO
STANDING _____ WALKING INDOORS _____ WALKING OUTDOORS _____

13. SCI DIAGNOSIS: _____
LEVEL OF INJURY _____ NEUROLOGICAL LEVEL OF INJURY _____

	RIGHT	LEFT
SENSORY LEVEL	_____	_____
MOTOR LEVEL	_____	_____
MOTOR INDEX SCORE	_____	_____
TOTAL MOTOR INDEX SCORE	_____	
FRANKEL CLASSIFICATION	_____	
IF COMPLETE, ZONE OF PARTIAL PRESERVATION	_____	
IF INCOMPLETE, ANATOMICAL CLASSICATION	_____	

14. DATE OF INJURY/ONSET _____
15. CAUSE OF INJURY _____
16. MECHANISM OF SPINE STABILIZATION _____

17. SPASTICITY: NO _____ YES _____ (IF YES, SPECIFY) MINIMUM _____
MODERATE _____
SEVERE _____

18. SECONDARY MEDICAL DIAGNOSES _____

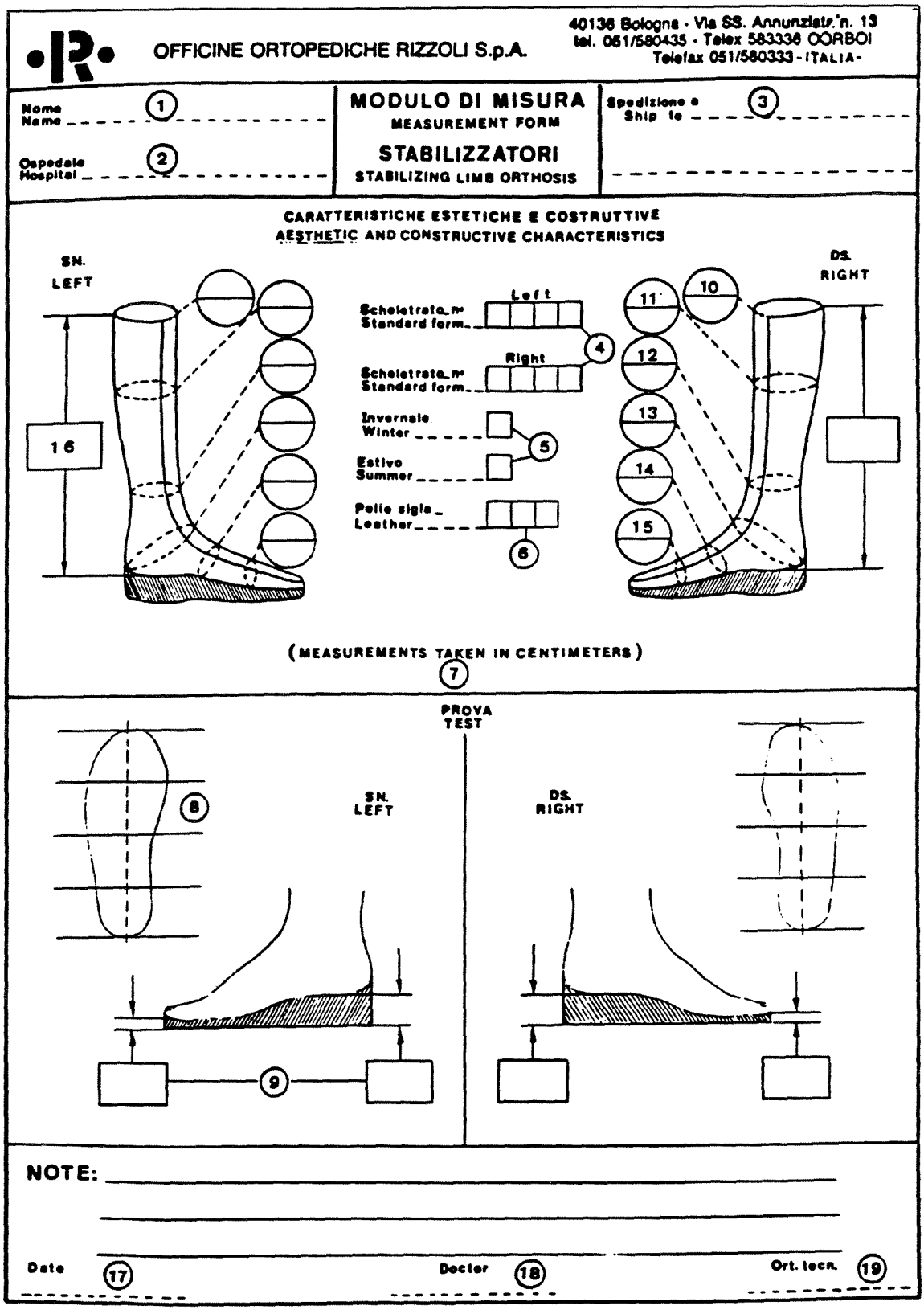
19. FRACTURE HISTORY _____

20. CURRENT MEDICATIONS _____

21. SMOKER: NO _____ YES _____ (IF YES) PPD _____ X _____ YEARS
PHYSICIAN(S) NAME/TITLE _____

APPENDIX C

ORIGINAL MANUFACTURER'S MEASUREMENT FORM



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APPENDIX D

PRE-ORTHOSIS EXERCISES

The exercises illustrated here are recommended by Professor A.M. Vannini, M.D., Director of the Rehabilitation Center of the Montecatone Hospital, Imola (Bologna), Italy. These exercises are basically elementary coordinated movements designed to replicate ambulatory movements required by individuals with paraplegia or quadriplegia. Your SCI exercise program may consist of many of these movements; therefore, you may only need these exercises to supplement your current program.

- The exercises are grouped according to position (prone, sidelying, supine, and standing)
- Within each group, the exercises are sequenced and illustrate progression of movement patterns
- Subjects must perform the exercises 3–5 hours per day, 5 times weekly
- The subject should be encouraged to utilize any residual muscle strength
- The therapist should add resistance to the exercises as success is achieved
- All exercises are performed bilaterally
- Subjects may require protective pads for elbows and knees during some of the mat exercises
- The therapist may require the assistance of an attendant when exercising the subject or for some of the more difficult movements, as indicated in the illustrations.

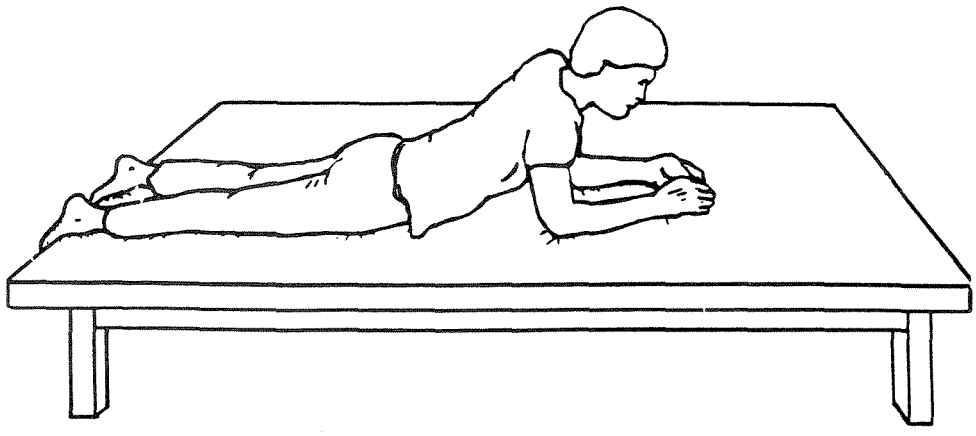

Figure 1.

PRONE POSITION

- Elbows positioned to support the shoulders at a 90 degree angle.
- Extension of the hips is also accomplished.

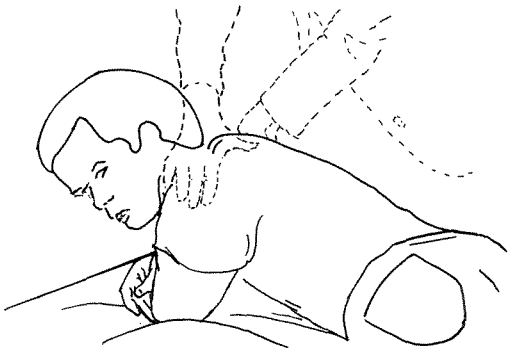

Figure 2 (a).

- Subject rotates upper body side-to-side while simultaneously looking over the elevated shoulder.

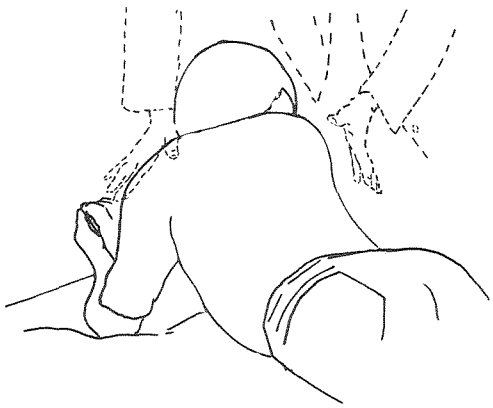

Figure 2 (b).

- Elbows remain in contact on mat (maintain 90 degree position).

Figure 3.

- Subject extends elbow, rotating hip off mat.
- Resistance should be provided at the hip joint.

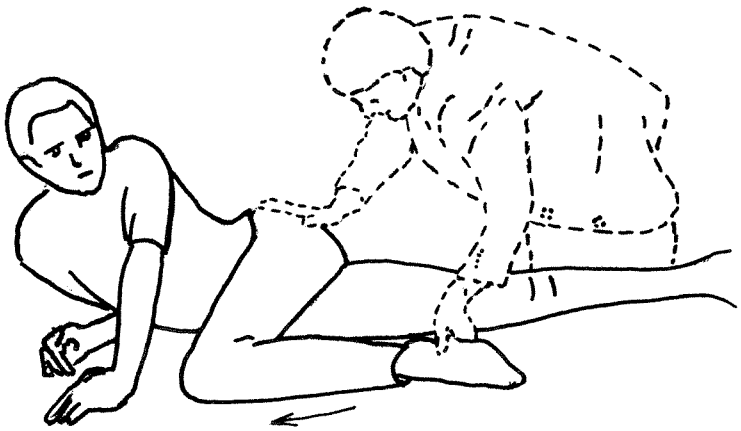

Figure 4.

- From previous figure, therapist assists subject in flexion of the knee and hip.
- Perform reciprocating movements.

NOTE: For the spastic subject, flexion or curling of the toes by the therapist releases extension spasm following flexion of the lower extremity.

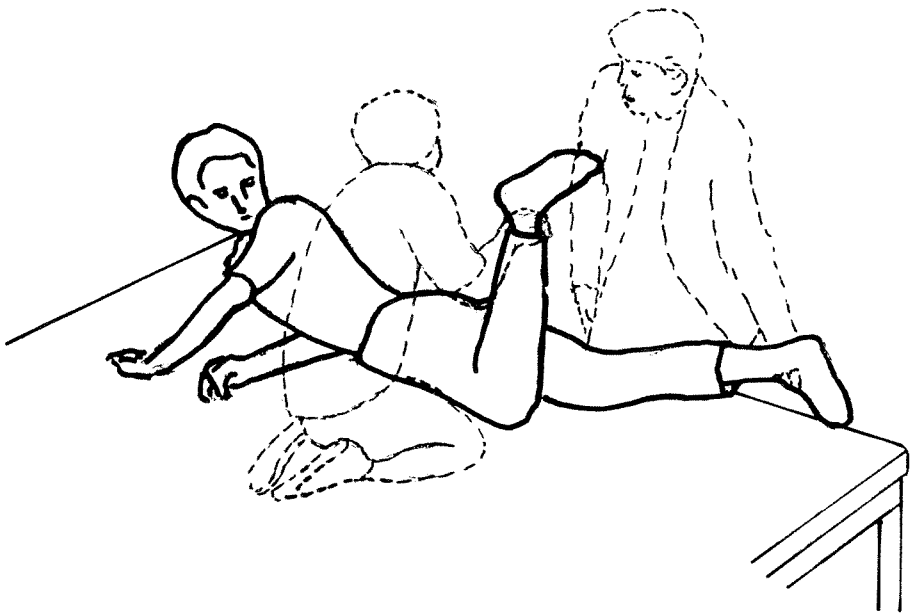

Figure 5.

- Same upper extremity movement as in **Figure 4**, but with reciprocating knee flexion added.

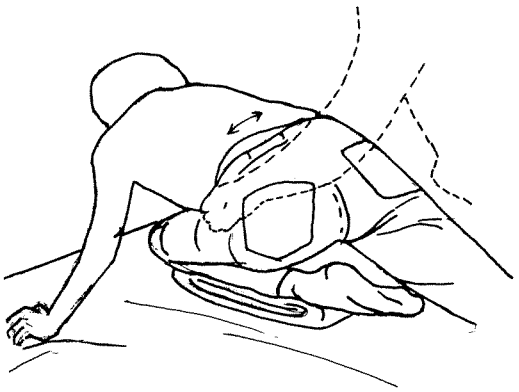

Figure 6.

- To achieve full hip extension, a pillow is placed under the flexed lower extremity while the opposite extremity is fully extended.
- Elbows remain in contact with mat (maintain 90 degree position).
- After a period of static stretching, the therapist assists the subject in shifting weight from side-to-side.

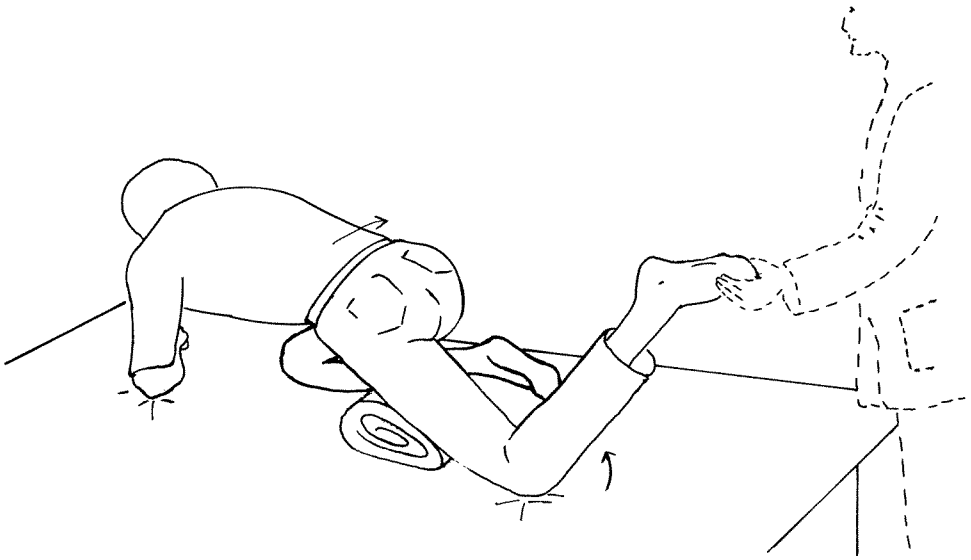

Figure 7.

- With elbows on mat, extended knee is flexed as weight is shifted toward the opposite side.

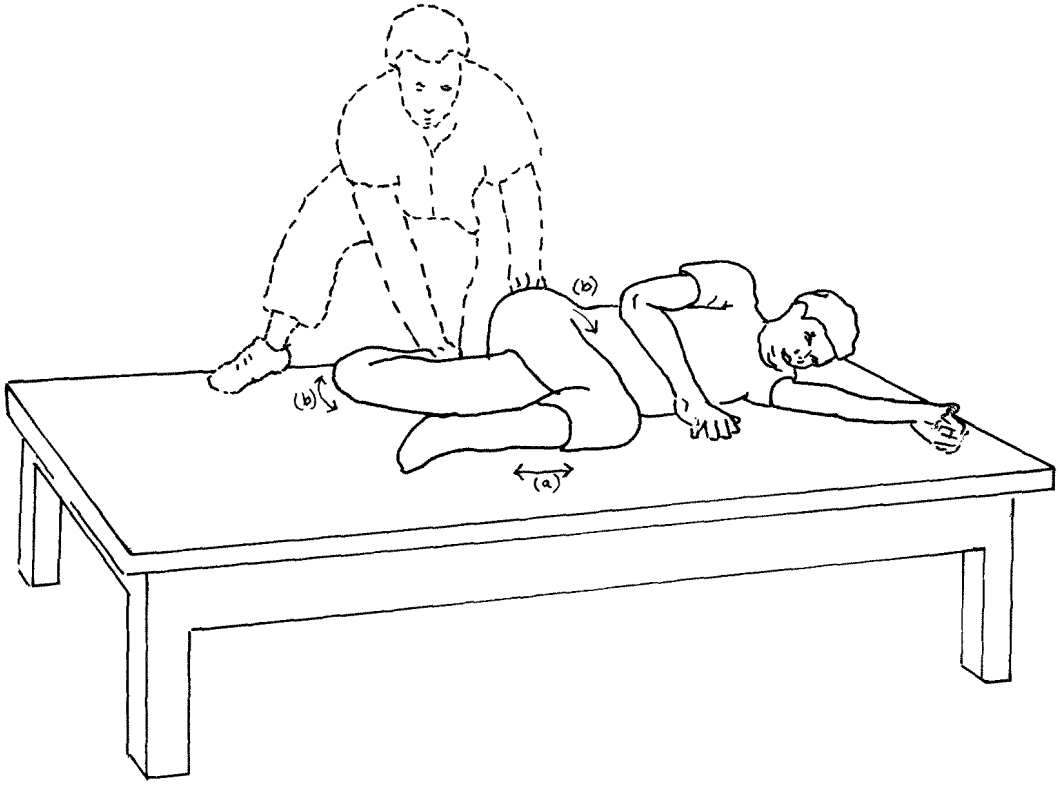

Figure 8.

SIDE-LYING POSITION

The following exercises are performed from the side-lying position with the bottom knee flexed and the hip extended.

(a) Assistance is provided to flex the top extremity followed by unassisted extension of the same extremity. The subject utilizes trunk rotation to accomplish this movement.
(b) The therapist stabilizes the top extremity in a flexed position and rotates the subject's hip toward the mat while the subject extends the flexed knee of the bottom extremity.

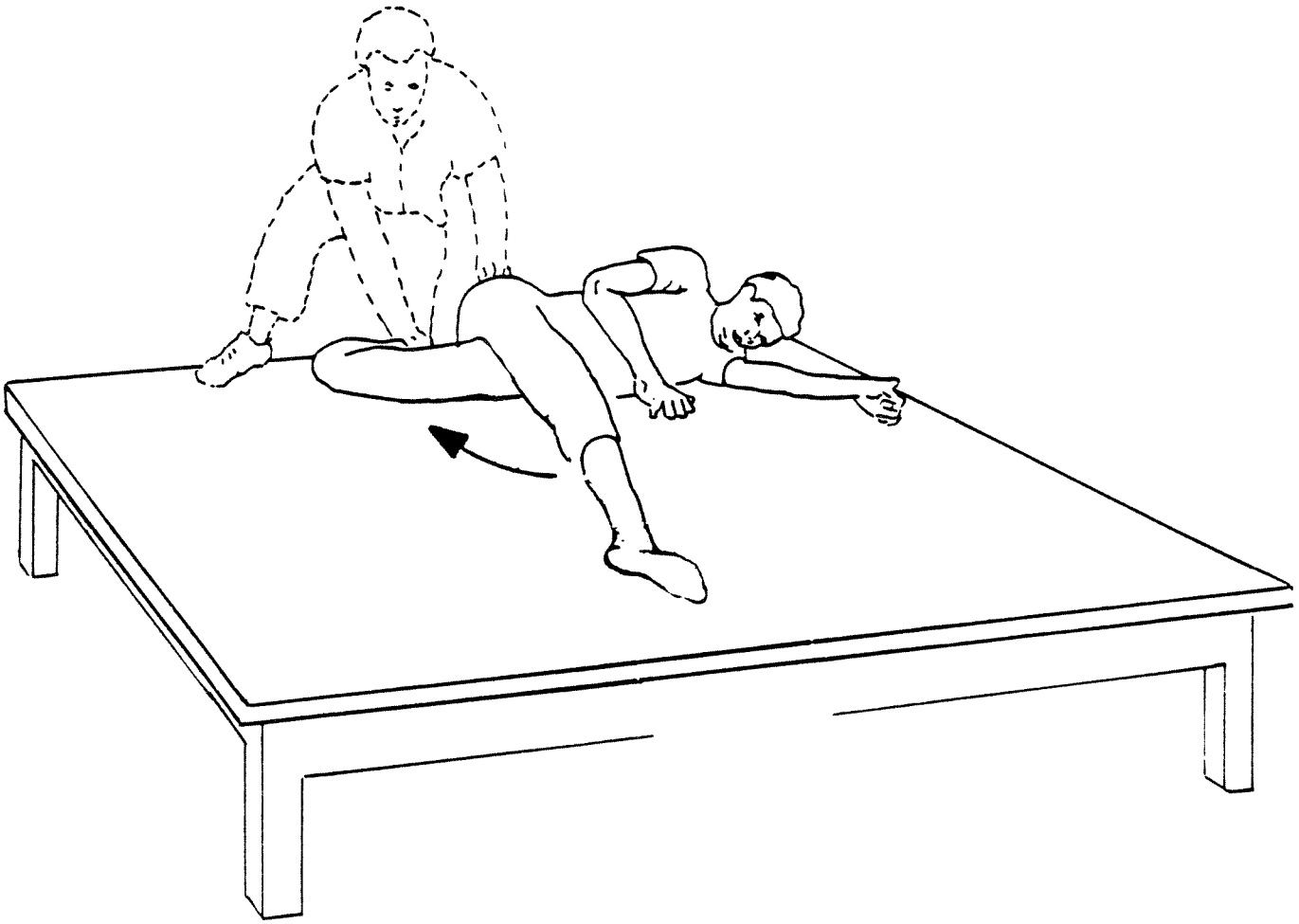

Figure 9.

- Positioned as in **Figure 8**, but top extremity is stabilized with hip flexed and knee extended.
- Hip extension of the top extremity is accomplished by the subject externally rotating his trunk and upper body.

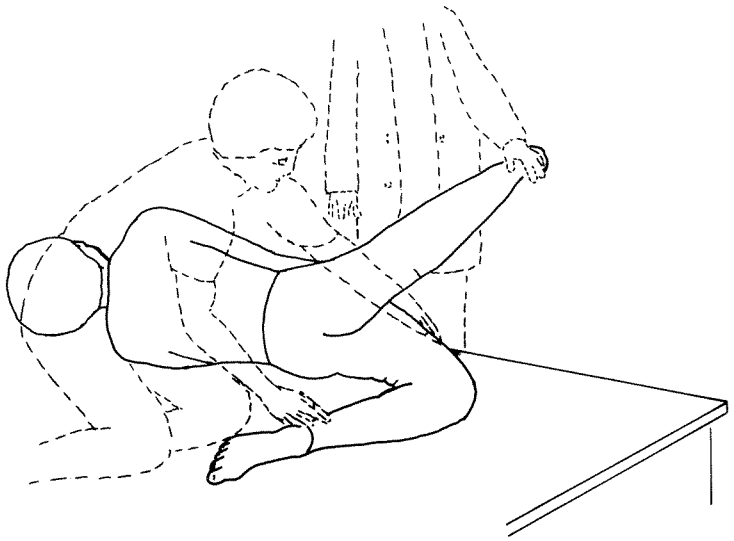

Figure 10 (a).

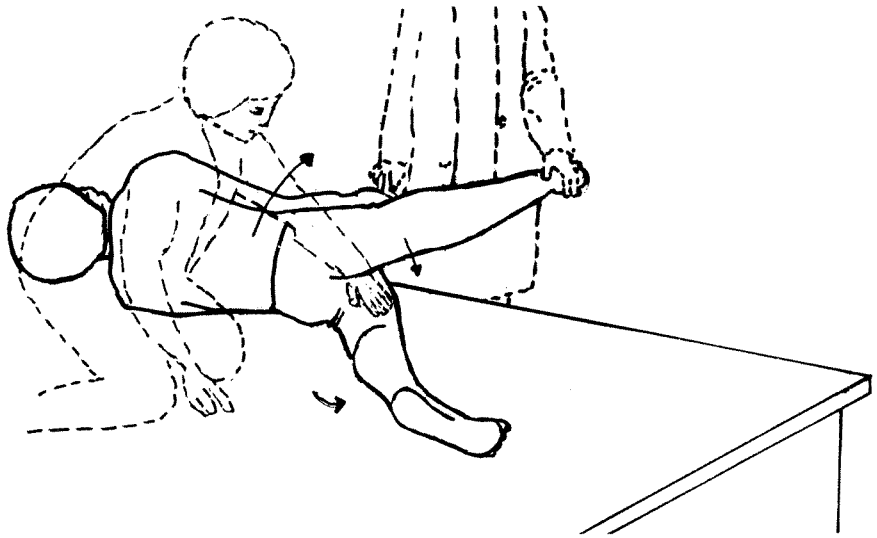

Figure 10 (b).

- Top extremity is held with hip flexed and knee extended while bottom extremity is held with hip hyperextended and knee flexed as shown in **Figure 10(a)**.
- Subject initiates hip extension while rotating trunk toward mat. This movement simultaneously produces knee extension of the bottom extremity as shown in **Figure 10(b).**

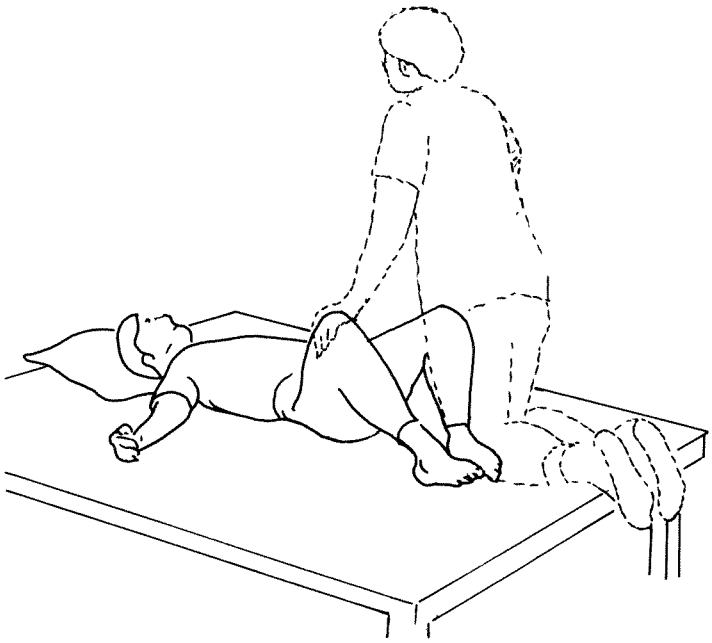

Figure 11.

SUPINE POSITION

- A basic stretching exercise of the hip adductors in the supine position.

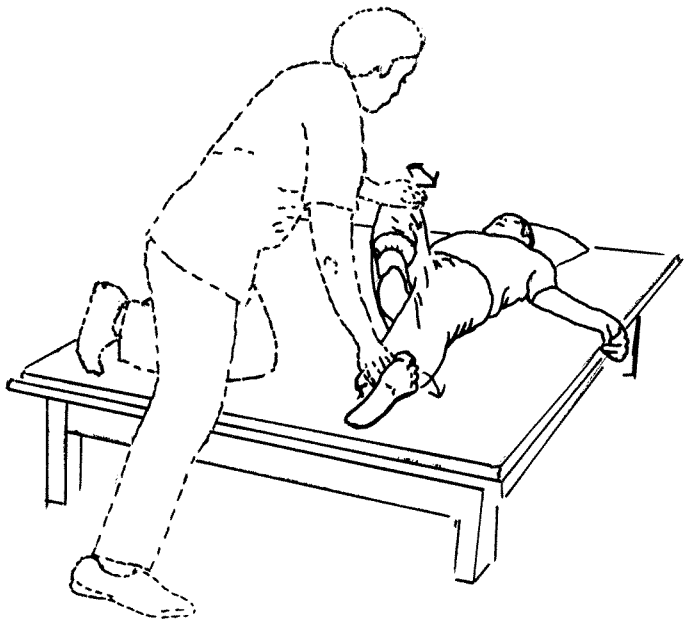

Figure 12.

- The therapist assists in external and internal rotation of the hip, with knee flexed, while the opposite lower extremity is extended and stabilized in external rotation.

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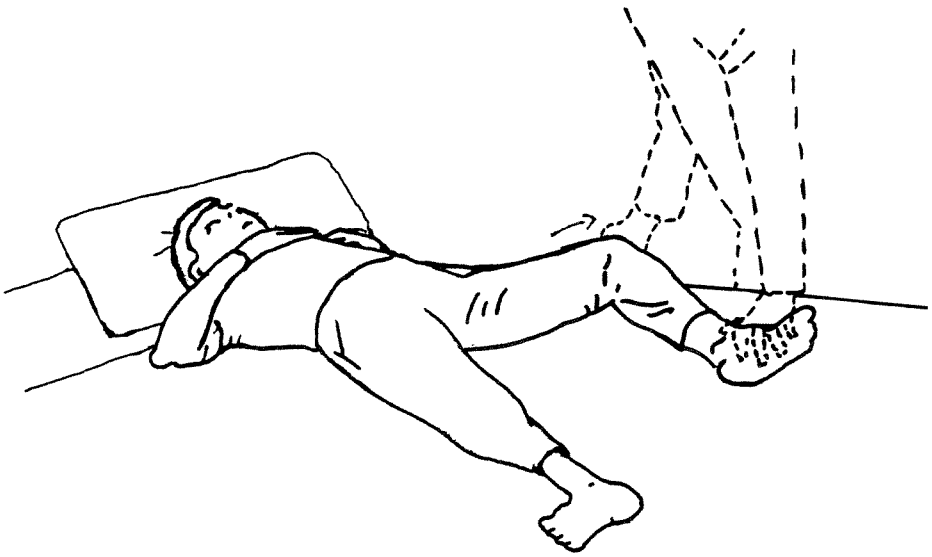

Figure 13 (a).

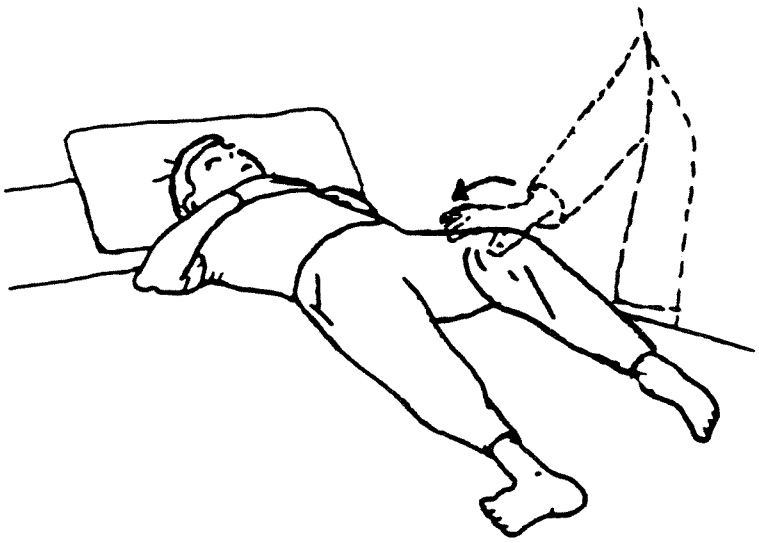

Figure 13 (b).

- With one lower extremity extended, the opposite extremity is externally rotated with the knee flexed as shown in **Figure 13 (a)**.
- The same extremity is then internally rotated as shown in **Figure 13 (b)**.
- This movement is then repeated on the opposite extremity.

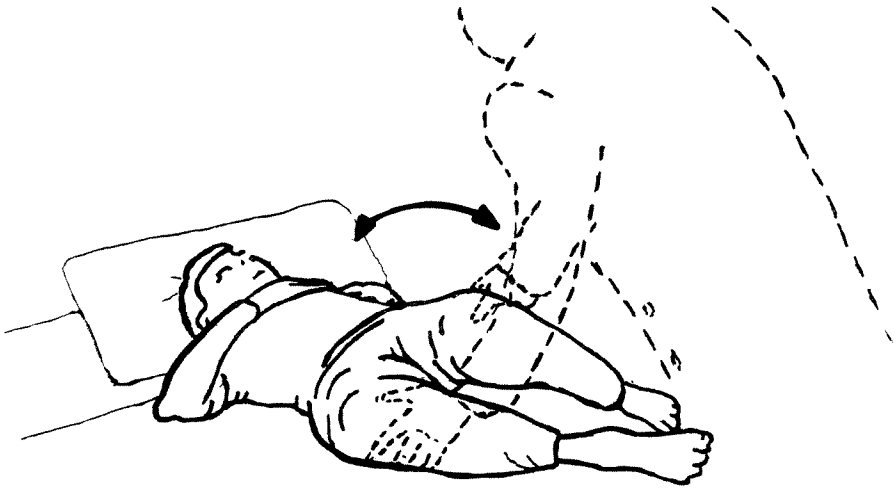

Figure 14.

- The therapist assists the subject in trunk rotation with both knees flexed.
- This is performed as a reciprocating movement pattern.
- The subject's upper body should be stabilized.

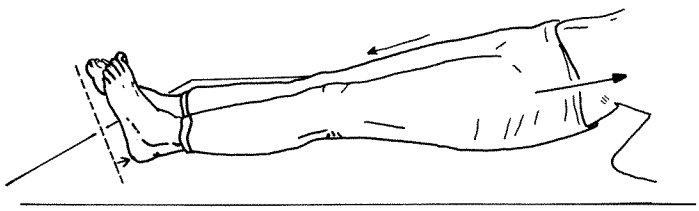

Figure 15.

- This is a reciprocating hip-hiking exercise.
- As the subject hikes his left hip, the therapist pulls in the opposite direction and observes the downward motion of the right lower extremity.
- This position is held for 5 seconds.

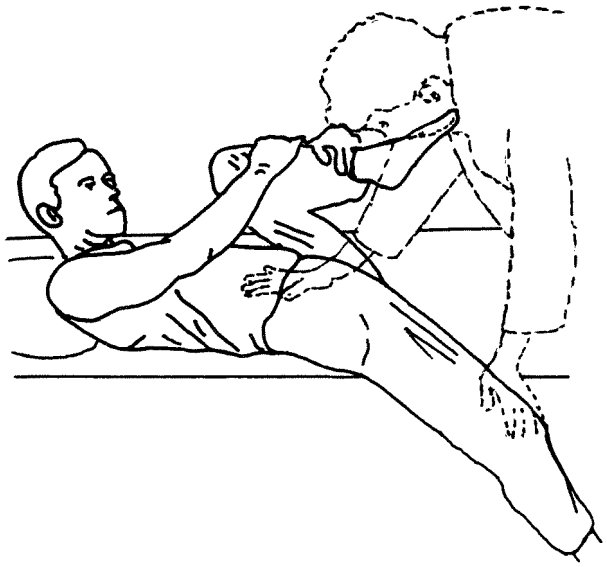

Figure 16 (a).

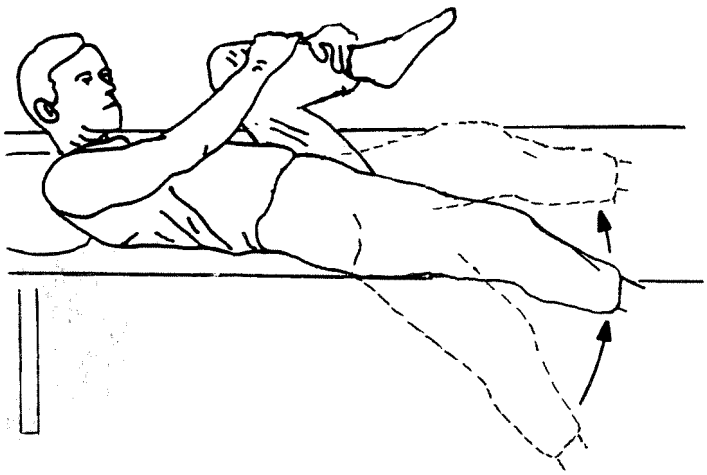

Figure 16 (b).

- Therapist assists subject in hyperextension of the hip and flexion of the knee, while the opposite extremity is held in full flexion.
- Upon release of the lower extremity, subject elevates the extended hip and extends knee as shown in **Figure 16 (b)**.

NOTE:
- This exercise is best achieved on an elevated treatment table.
- When able, subject should assist therapist as shown.

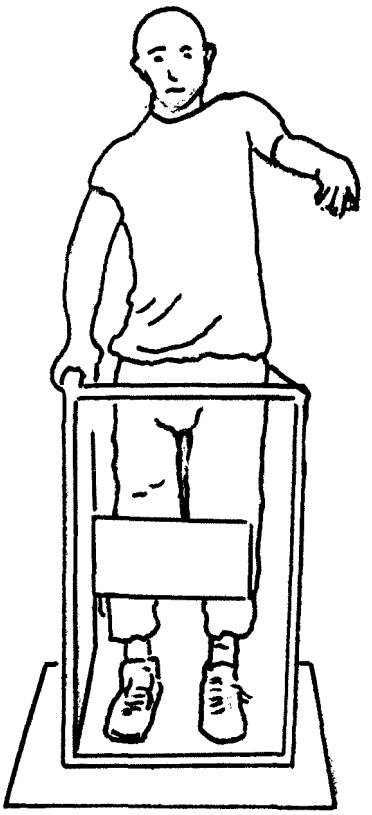

Figure 17.

STANDING POSITION

Several exercises can be performed in the standing frame:

- standing tolerance
- balance
- stretching
- weight shifting

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APPENDIX E

CAS 104

THERAPIST/PATIENT RESPONSE FORM

To be completed at 3, 6, 9, and 12-month intervals

Date: _____ Patient Name: _____ SS # _____

1) Model Boot Used: Winter _____
Summer _____
Short Boot _____

2) Donning: independent _____ min. _____ mod. _____ max. _____ assistance required
As compared to previous orthosis: easier _____ same _____ more difficult _____ not applicable _____

Doffing: independent _____ min. _____ mod. _____ max. _____ assistance required
As compared to previous orthosis: easier _____ same _____ more difficult _____ not applicable _____

Comments: _____

3) Weight: light _____ acceptable _____ heavy _____
As compared to previous orthosis: lighter _____ same _____ heavier _____ not applicable _____

Comments: _____

4) Cosmesis: excellent _____ acceptable _____ unacceptable _____
As compared to previous orthosis: more cosmetic _____ same _____ less cosmetic _____
not applicable _____

Comments: _____

5) How much assistance is required to assume the standing position:
independent _____ min. _____ mod. _____ max. _____ assistance required

Comments: _____

6) How much assistance is required to assume the sitting position:
independent _____ min. _____ mod. _____ max. _____ assistance required.
As compared to previous orthosis: easier _____ same _____ more difficult _____ not applicable _____

Comments: _____

7) Stability:
(a) during standing: excellent _____ acceptable _____ unacceptable _____
As compared to previous orthosis: more stable _____ same _____ less stable _____ not applicable _____

Comments: _____

(b) during ambulation: excellent _____ acceptable _____ unacceptable _____
As compared to previous orthosis: more stable _____ same _____ less stable _____ not applicable _____

Comments: _____

8) Distance ambulated until patient fatigues (level surfaces): _____ feet
(a) energy expenditure to ambulate this distance is: easy _____ acceptable _____ difficult _____
As compared to previous orthosis: easier _____ same _____ more difficult _____ not applicable _____

9) During ambulation, how much assistance is required:
none _____ min. _____ mod. _____ max. _____
As compared to previous orthosis: better _____ same _____ worse _____ not applicable _____

Comments: _____

10) Does the patient utilize assistive devices during ambulation:
yes _____ no _____ If yes, please list devices used:

Comments: _____

11) Average usage of Stabilizing Limb Orthosis:
a. Orthosis is worn _____ hr(s) per _____ day(s)
b. Patient ambulates _____ feet per _____ day(s)

Comments: _____

12) Has the patient experienced any prolonged redness or other skin irritation after use of the Stabilizing Limb Orthosis:
Yes _____ No _____ If yes, please describe (also include measures taken to solve the problem):

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13) Level(s) of Function:
- 0: No Functional Levels Achieved
- 1: Standing Only
- 2: Ambulation with Assistive Device and Supervision
- 3: Independent Ambulation with Assistive Device
- 4: Continues to Require Wheelchair (i.e., for long distances, etc.)
- 5: Wheelchair No Longer Required
- 6: Ambulates Level Surfaces (indoor only)
- 7: Ambulates Level and Uneven Terrain (indoor and outdoor)
- 8: Negotiates Stairs

From the above levels, please select the number(s) that best describe the patient's functional status:

_____

Comments: _____

_____

_____

_____

_____

Completed By: _____

VAMC: _____