

Report of Adeli Suit Pilot Testing in the United States

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Background

A research study was conducted by investigators at the University of Minnesota in collaboration with the staff of the Courage Centre, Golden Valley, Minnesota, to evaluate the efficacy of the Adeli Suit on individuals with cerebral palsy or who had suffered a stroke. The suit is an adaptation of the one worn by cosmonauts inside the space station to prevent the effects of weightlessness on bone density and muscle mass. Professor Arnold S. Barer of the Zvezda Corporation in Moscow who was one of the developers of the Adeli Suit, along with two Russian physical therapist physicians Drs. Galina Illitchevya and Leonid Razgon, carried out the treatment with the help of Courage Centre physical therapists or trainees and Russian interpreters. The study was approved by the University of Minnesota Committee on the use of human subjects. The pilot test was conducted on six patients over the period of June 30 to July 18, 1997. A follow-up took place four weeks later on August 14, 1997.

A pool of potential treatment subjects was selected by Ms. Paulette Olsen, Program Director Adult Rehabilitation Service at the Courage Centre, with the approval of the patients' physicians. Before selection into the study, each patient in the subject pool who had an interest in participating and the time available was personally interviewed by Dr. Barer together with Drs. Illitchevya and Razgon. These Russian physicians also reviewed the medical records and observed the individual's mobility and co-ordination. Following this step in the screening process, patients were administered the Vocabulary and Comprehension subtests of the Wechsler Intelligence Scale for Children – Third Edition (WISC – III) or the Wechsler Adult Intelligence Scale – Revised (WAIS – R), as appropriate for their age. The purpose was to assess whether the patient understood and agreed to the treatment procedures, and was able to communicate in the eventuality he or she felt pain or at a later time wished to terminate treatment. Subjects, and their parents (in the case of minors), also signed consent forms indicating their agreement to participate in this investigation.

Method

Subjects

Table 1 presents demographic and clinical data on each of the six subjects in this investigation.

Table 1: Demographics and clinical data

No	Subject	Sex	Age	Physique	Diagnosis	Gait Problems
1	A.S.	F	15	5'3"-5'4" 100 lbs	CP Quad	Independent ambulator with "CP" gait. Tight hip adductors, internal rotators, ham strings, heel cords. Has trouble with speed. Uses pool.
2	B.H.	M	22	5'10" 150 lbs	CP Paraplegia	Walks with reverse rotting walker (independent). Recent surgery – Baclofen pump.
3	D.A.	M	37	6'0" 150 lbs	CP Spastic	Lateral trunk movement. Low back initiates hip flexion with no knee movement. Posture equals crouch stance. Tight fingers on involved side, poor grip.
4	A.P.	F	19	5'5" 160 lbs	Stroke	Walks with ankle-foot orthotic and cane. Weakness from knee down. Right foot drop. No control of right arm from elbow down.
5	M.W.*	M	48	6'1" 180 lbs	Stroke, two previous aneurysms	
6	K.T.	F	54		Stroke	Hikes right hip during swing phase of gait. Decrease right hip and knee flexion in gait due to extensor tone pattern. Decrease ankle dorsi-flexion (weakness of muscle groups). Fatigue.

* This patient died of a sudden massive stroke 4 weeks after the treatment phase of the study was completed

Measures

Prior to the start of treatment, each subject was videotaped performing a standardised protocol for walking and sitting. The videotape procedure was repeated at the following intervals: Session 8, Session 13 (end of treatment), and at the four week post-treatment follow-up. Two University of Minnesota Division of Kinesiology graduate students carried out the timing, analysis, and evaluation of the video recordings. The bio-mechanical instrumentation used was a well known motion analysis system which compares various mobility and co-ordination parameters. This technique allows the comparison of individual videotape frames within a specific event, such as a step length during walking to evaluate the variables in question. A questionnaire was administered to participants and others at the end of treatment and at the follow-up. The purpose was to obtain additional information about mobility, co-ordination, mood and behavioural changes during treatment, and the stability of these changes over the follow-up interval. The end-of-treatment questionnaire was completed independently by the patient, a designated caregiver, and both the Courage Centre and Russian therapists who worked with the particular subject. At follow-up, the questionnaire was completed by the subject, caregiver, and Courage Centre therapist, if available. The follow-up questionnaire assessed changes from pre-treatment baseline to the four week follow-up. Respondents also answered the same questions reporting on the interval from the end of treatment to the follow-up, with the aim of assessing stability of change or possible improvement or decline in functioning over this time period. A speech evaluation was

conducted before the start of treatment and again on the last day of treatment on two participants with speech problems.

Procedure

Treatment was conducted on a daily basis, five days a week over a three week period. Treatment began with approximately 20 minutes of massage, followed by dressing the patient in the Adeli Suit and conducting the walking and various physical therapy exercises as appropriate for the particular patient's ability level. Each therapy session was approximately two hours in duration. Subjects were allowed to rest as needed and drink water upon request.

Results

Questionnaire. Cerebral Palsy Patients

The reports of change over treatment and at the follow-up interval for the participants with cerebral palsy are presented in Table 2A, Table 2B and Table 2C.

Table 2A: Summary of Post-Treatment and Follow-up Function Questionnaire Information for Cerebral Palsy Patients

A.S.	Final-Treatment				Follow-Up		
	1	2	3	4	1	2	3
Improvement in arm function		x	x	x	x [^]	x [^]	x
Decline in arm function							
Improvement leg function	x	x	x	x	x [^]	x [^]	x
Decline in leg function							
Better able to stand w/o help	x	x	x	x	x [^]	x [^]	x
Less able to stand w/o help							
Walking with less swaying	x	x	x	x	x [^]	x [^]	x
More swaying while walking							
Improvement in balance	x	x	x	x	x [^]	x [^]	x
Decline in balance							
Improvement in purposeful movement	x	x	x	x	x [^]	x [^]	x
Decline in purposeful movement							
Improvement in ability to hold objects	x	x	slight	x	x [^]	x [^]	x
Decline in ability to hold objects							
Improvement in speech clearness	x	x	pos	x		x [^]	x
Decline in speech clearness							
Decrease in salivation	x	x	same	x		x [^]	x
Increase in salivation							
Overall positive change in emotions	x	x	x	x		x [^]	x
Overall negative change in emotions							

Improvement in confidence	x	x	x	x	x [^]	x
Decline in confidence						
Improvement in stamina	x	x	x	x	x [^]	x [^]
Decline in stamina						
Improvement in sleep quality	x	x	x	x	x	x [^]
Decline in sleep quality						
Better communication with other people	x	x	x	x	x	x [^]
More problems in communication with other people						

Rating of overall condition **B** **CB** **CB** **CB** **CB** **B**

[1]=Subject, [2]=Caregiver, [3]=Courage Centre therapist, [4]=Russian therapist

[*]=improved over follow-up interval, [^]=maintained function after follow-up

Rating of overall condition: [B]=better, [CB]=considerable better, [AS]=about the same

Table 2B: Summary of Post-Treatment and Follow-up Function Questionnaire Information for Cerebral Palsy Patients

B.H.	Final-Treatment				Follow-Up		
	1	2	3	4	1	2	3
Improvement in arm function	x	x	x	x	x [^]		
Decline in arm function							
Improvement leg function	x		x	x	x [^]	x*	
Decline in leg function							
Better able to stand w/o help	x		x	x			
Less able to stand w/o help							
Walking with less swaying	x		x	x	x [^]	x	
More swaying while walking							
Improvement in balance	x		x	x	x [^]	x*	
Decline in balance							
Improvement in purposeful movement	x		x	x	x [^]		
Decline in purposeful movement							
Improvement in ability to hold objects	x	x	x	x		x*	
Decline in ability to hold objects							
Improvement in speech clearness	x		x	x		x [^]	
Decline in speech clearness							
Decrease in salivation	x		x	x	x [^]		
Increase in salivation							
Overall positive change in emotions	x	x	x	x		x*	
Overall negative change in emotions						x	
Improvement in confidence	x	x		x		x [^]	
Decline in confidence							
Improvement in stamina		x	x	x		x [^]	
Decline in stamina	x						

Improvement in sleep quality	x			x^	x*
Decline in sleep quality					
Better communication with other people				x	x^
More problems in communication with other people					
Rating of overall condition	B	AS	B	B	B-CB

[1]=Subject, [2]=Caregiver, [3]=Courage Centre therapist, [4]=Russian therapist
[*]=improved over follow-up interval, [^]=maintained function after follow-up
Rating of overall condition: [B]=better, [CB]=considerable better, [AS]=about the same

Table 2C: Summary of Post-Treatment and Follow-up Function Questionnaire Information for Cerebral Palsy Patients

D.A.	Final-Treatment				Follow-Up		
	1	2	3	4	1	2	3
Improvement in arm function	x	x	x	x	x*	x	x
Decline in arm function							
Improvement leg function	x	x	x	x	x*	x	x
Decline in leg function							
Better able to stand w/o help	x	x	x	x			
Less able to stand w/o help							
Walking with less swaying	x	x	x	x	x*	x	x
More swaying while walking							
Improvement in balance	x	x	x	x	x^	x	x
Decline in balance							
Improvement in purposeful movement	x		x	x	x*	x	x
Decline in purposeful movement							
Improvement in ability to hold objects	x	x	x	x	x*		
Decline in ability to hold objects							
Improvement in speech clearness							
Decline in speech clearness							
Decrease in salivation							
Increase in salivation							
Overall positive change in emotions	x	x		x			
Overall negative change in emotions							
Improvement in confidence	x			x			
Decline in confidence							
Improvement in stamina	x			x			
Decline in stamina							
Improvement in sleep quality	?						
Decline in sleep quality							
Better communication with other people	?						
More problems in communication with other people							

Rating of overall condition

CB CB CB CB CB B B

[1]=Subject, [2]=Caregiver, [3]=Courage Centre therapist, [4]=Russian therapist

[*]=improved over follow-up interval, [^]=maintained function after follow-up

Rating of overall condition: [B]=better, [CB]=considerable better, [AS]=about the same

Examination of these data indicate substantial consistency in judgements of pre- to post-treatment progress among the subject, caregiver, and Courage Centre and Russian therapists. Each of the informants reported improvement in the following for all patients: arm function, leg function, ability to stand without help, walking with less swaying, purposeful movement, ability to hold objects. Overall positive change in emotions, improvement in confidence, stamina, and better sleep were noted by some. Improvement in clarity of speech in the two patients with speech problems, and better communication with other persons in the CP patient group as a whole were reported. Table 2 also documents that at the four week follow-up, the various respondents indicated that these improvements were maintained, and in some cases progressed further.

Questionnaire. Stroke Patients

The questionnaire findings for the three stroke patients are presented in Table 3A, Table 3B and Table 3C. The findings are similar to that observed with the cerebral palsy patients.

Table 3A: Summary of Post-Treatment and Follow-up Function Questionnaire Information for Stroke Patients

A.P.	Final-Treatment				Follow-Up		
	1	2	3	4	1	2	3
Improvement in arm function	x	x	x	x	x [^]	x [^]	
Decline in arm function							
Improvement leg function	x	x	x	x	x [^]	x [^]	
Decline in leg function							
Better able to stand w/o help	x	x	x	x	x [^]	x [^]	
Less able to stand w/o help							
Walking with less swaying	x	x	x	x	x [^]	x [^]	
More swaying while walking							
Improvement in balance	x	x	x	x	x [^]	x [^]	
Decline in balance							
Improvement in purposeful movement	x	x	x	x	x [^]	x [^]	
Decline in purposeful movement							
Improvement in ability to hold objects	x	x	x	x	x [^]	x [^]	
Decline in ability to hold objects							
Improvement in speech clearness	x				x [^]	x [^]	
Decline in speech clearness							
Decrease in salivation							

Increase in salivation					x^	x^
Overall positive change in emotions	x	x	x	x	x^	
Overall negative change in emotions						
Improvement in confidence	x	x	x	x	x^	x^
Decline in confidence						
Improvement in stamina	x	x	x	x	x^	x^
Decline in stamina						
Improvement in sleep quality	x	x			x^	x^
Decline in sleep quality						
Better communication with other people	x	x			x^	x^
More problems in communication with other people						

Rating of overall condition

CB CB CB CB CB

[1]=Subject, [2]=Caregiver, [3]=Courage Centre therapist, [4]=Russian therapist

[*]=improved over follow-up interval, [^]=maintained function after follow-up

Rating of overall condition: [B]=better, [CB]=considerable better, [AS]=about the same

Table 3B: Summary of Post-Treatment and Follow-up Function Questionnaire Information for Stroke Patients

M.W.	Final-Treatment				Follow-Up		
	1	2	3	4	1	2	3
Improvement in arm function		x	x	x			
Decline in arm function							
Improvement leg function	x	x	x	x			
Decline in leg function							
Better able to stand w/o help	x	x	x	x			
Less able to stand w/o help							
Walking with less swaying							
More swaying while walking							
Improvement in balance	x	x	x	x			
Decline in balance							
Improvement in purposeful movement			x	x			
Decline in purposeful movement							
Improvement in ability to hold objects							
Decline in ability to hold objects							
Improvement in speech clearness		x	x	x			
Decline in speech clearness	x						
Decrease in salivation							
Increase in salivation							
Overall positive change in emotions	x	x	x	x			
Overall negative change in emotions							
Improvement in confidence		x		x			

Decline in confidence			
Improvement in stamina	x	x	x
Decline in stamina			
Improvement in sleep quality	x	x	
Decline in sleep quality			
Better communication with other people	x	x	
More problems in communication with other people			

Rating of overall condition CB CB CB

[1]=Subject, [2]=Caregiver, [3]=Courage Centre therapist, [4]=Russian therapist

[*]=improved over follow-up interval, [^]=maintained function after follow-up

Rating of overall condition: [B]=better, [CB]=considerable better, [AS]=about the same

Table 3C: Summary of Post-Treatment and Follow-up Function Questionnaire Information for Stroke Patients

K.T.	Final-Treatment				Follow-Up		
	1	2	3	4	1	2	3
Improvement in arm function	x			x	x*		
Decline in arm function							
Improvement leg function	x	x	x	x	x^	^	x
Decline in leg function							
Better able to stand w/o help		x	x	x	x	^	x^
Less able to stand w/o help							
Walking with less swaying	x	x	x	x	x*	^	x^
More swaying while walking							
Improvement in balance	x	x	x	x	x*	^	x
Decline in balance							
Improvement in purposeful movement	x		x	x	x*	^	x
Decline in purposeful movement							
Improvement in ability to hold objects					x*		
Decline in ability to hold objects							
Improvement in speech clearness							
Decline in speech clearness							
Decrease in salivation							
Increase in salivation							
Overall positive change in emotions	x	x		x	x*	^	
Overall negative change in emotions						x	
Improvement in confidence	x	x	x	x	x^	^	x^
Decline in confidence							
Improvement in stamina		x			x*	^	
Decline in stamina							
Improvement in sleep quality					^		

Decline in sleep quality

Better communication with other people

x

x^ ^

More problems in communication with other people

Rating of overall condition

B B CB B B CB

[1]=Subject, [2]=Caregiver, [3]=Courage Centre therapist, [4]=Russian therapist

[*]=improved over follow-up interval, [^]=maintained function after follow-up

Rating of overall condition: **[B]**=better, **[CB]**=considerable better, **[AS]**=about the same

Examination of Table 3 demonstrates substantial agreement among various informants regarding improvement on the various indices of motor performance. In addition to these changes in motor function and co-ordination, informants noted beneficial psychological changes such as a more positive mood, and greater confidence and ability to communicate with others. The follow-up evaluation indicated that the change on the various indices evaluated was maintained over the four week interval.