Traditional Rehabilitation versus AlterG Anti-Gravity Treadmill® Following Anterior Cruciate Ligament Reconstruction:
Clinical Outcomes from a Randomized Controlled Study

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OBJECTIVE:

This study compared the short-term functional recovery outcomes after surgical anterior cruciate ligament (ACL) reconstruction of patients who participated in physical therapy utilizing either the AlterG Anti-Gravity Treadmill system or a standard treadmill. The results were also compared to a similar cohort of age-matched controls with unaffected knees.

BACKGROUND:

The AlterG Anti-Gravity Treadmill is designed to allow normal treadmill walking with reduced lower extremity weight bearing. The device uses an inflatable "tent" surrounding the lower extremities to place an upward force on the lower body and thereby reduce ground reaction forces in the lower limbs. ACL injuries can be particularly difficult to rehabilitate because the physician and therapist must balance the desire for early mobility with significant weight bearing restrictions. The AlterG Anti-Gravity Treadmill may allow patients with ACL reconstruction to simulate walking mechanics earlier in the rehabilitation due to the partial weight bearing environment. This may lead to earlier functional recovery and decreased lasting deleterious effects from the injury.

SUBJECT SELECTION:

Subjects (n=15 [9M, 6F] height=1.73 ± 0.09m, weight=80.67 ± 16.42kg, age=32.04 ± 10.18 years) scheduled for primary ACL reconstruction by a single fellowship trained orthopedic surgeon and who were scheduled for post-operative rehabilitation sessions at The CORE Institute were recruited for the study. Ancillary procedures (e.g., meniscus repair, collateral ligament repair, etc) at the time of ACL reconstruction were not considered exclusionary as long as post-operative rehabilitation standards of care were not affected. Subjects who were pregnant or had diagnoses of any of the following conditions were excluded from participation: diagnosed arthritis (i.e., osteoarthritis, rheumatoid arthritis, psoriatic arthritis, etc.), significant diseases of other joints of the lower extremity; patients with a diagnosed movement disorder or other gait disturbance (e.g. lower extremity weakness, prior lower extremity arthrodesis, diagnosed movement disorders [Parkinson's, Multiple Sclerosis], etc.). Subjects' participation in the study was terminated if the affected knee required revision surgery or if females became pregnant during the post-operative study period.

Data was also collected from age-matched subjects with unaffected knees (n=7 [3M, 4F] height=1.74±0.10, weight=70.71±11.78, age=28.19±8.07) using the same exclusionary criteria relating to pregnancy and other lower extremity diagnosis as noted above.

METHODS:

Subjects who provided signed informed consent (approved by Western IRB), and who continued to meet inclusion/exclusion criteria following surgery, were randomized into one of two post-operative rehabilitation groups: AlterG or Traditional. Rehabilitation sessions for both groups followed the therapy clinic's standard of care for ACL reconstruction; with subjects in the AlterG rehabilitation group using the AlterG for all scheduled treadmill gait training sessions. The following data were collected prior to surgery and again at 2 weeks, 6 weeks, 12 weeks, and 20 weeks after surgery.

Biometric Measures
- Quadricpes Strength (dynamometer) (kg)
- Knee Range of Motion (º)
- Difference in Thigh Circumference (between legs)

Gait Parameters (over-ground)
- Walking Velocity (m/sec)
- Distance Traveled in 5 min (m)
- Clinical Scores
- Tegner Lysholm Knee Score
- KOOS (English version LK 1.0)
- LEAS

Length of Time
- Time to Non-antalgic Gait (days)
- Return to Driving (days)
- Time to Independence (days)
- Time to Straight Leg Raise Without Lag (days)

STATISTICAL ANALYSIS:

Descriptive statistics for each task were compiled for each group. Homogeneity of variances was determined by F-tests and the appropriate student t-test (with 2- tail distribution) was used to compare the groups within each time point.

RESULTS:

Two of the subjects who were consented were not randomized; one chose to have physical therapy at a location closer to home; the other had additional surgical procedures performed that delayed the start date for physical therapy. Of the 13 remaining subjects: 12 completed the 6 week visit; and 2 were lost to follow-up at 3 months. None of the 13 returned for the 20 week visit. In summary: prior to surgery n=15, 2 week n=13, 6 week n=12, 12 week n=11. Demographics of enrolled patients by group were as follows: AlterG group (n=7 [4M, 3F] height=1.73 ± 0.10m, weight=79.16 ± 16.35kg, age=34.3 ± 11.49 years); Traditional Group (n=6 [4M, 2F] height=1.75 ± 0.09m, weight=82.05 ± 18.08kg, age=29.49 ± 10.30 years); The 'Sports' sub-scores of the KOOS was not included in the analysis because it became apparent that each individual interpreted the questions differently with regard to rationale for functional limitations, e.g., functional limitations prescribed by the physician versus true functional limitations caused by pain and on-going recovery. A complete list of the surgical procedures and adverse events experienced within each group are noted in Tables 1 and 2.

TABLE 1:

Summary of the number of subjects receiving types of procedures related to surgery.

		AlterG (n=7)	Traditional (n=6)
Graft			
	allograft	6	4
	bone-patellar/tendon-bone autograft	1	1
	compsite autograft and allograft	0	1
Tendon			
	peroneus longus	4	2
	achilles tendon	2	1
	semitendinosis	0	1
	quadriceps tendon	0	1
Ancillary Procedures			
	medial meniscus repair	0	1
	partial medial meniscectomy	5	1
	partial lateral meniscectomy	5	1
	lateral meniscus repair	1	0
	autologus platelet grafting	5	2
	chrondroplasty	3	2
	synovectomy	5	2
	limited synovectomy	2	0

TABLE 2:

Summary of the number of subjects reporting Adverse Events.

	Number of Subjects	Adverse Event	Relative time of occurrence
AlterG (n=7)	4	none	
	1	trip over baby gait	2 weeks
	1	"achiness" following work	12 weeks
	1	swelling	1 week
Traditional (n=6)	2	none	
	1	fever	3 weeks
		irrigation & debridement, synovectomy (findings: intact ACL nogross evidence of infection)	4 weeks
		extra week of no weight-bearing in PT	3 weeks
		intermittent popping of right knee	4 weeks
	1	subject chose home PT	6 weeks
	1	wound dehiscence, suture popping, & wound drainage	2 weeks
	1	rash on right leg thigh to ankle	2 days

PRIOR TO SURGERY:

There were no statistical differences between the surgical groups; the Tegner Lysholm and KOOS sub-scores for both surgical groups were statistically different from controls. At 2 weeks: biometrics, gait parameters, and clinical scores for both surgical groups were statistically different from controls with the exception of difference in thigh circumference. At 6 weeks: although the surgical groups were not statistically different from one another; the Traditional group was, and the AlterG group was not, statistically different from controls in gait parameters and dynamometer measures. At 12 weeks: the AlterG group had significantly higher 'pain,' 'symptom,' and 'quality' sub-scores compared to the Traditional group (note: a higher score indicates fewer symptoms); The AlterG group was similar to controls in all parameters except the 'quality' sub-score of the KOOS. The Traditional group differed from controls in 'pain,' 'symptom,' and 'quality' sub-scores and had a lower active range of motion. There were no significant differences in parameters related to 'length of time' between the surgical groups.

(See Table 3.)

DISCUSSION:

Although there were no differences in the surgical group pre-operatively, the subjects in the AlterG group had a greater number of ancillary surgical procedures (Table 1) beyond the index ACL reconstruction compared to the subjects in the Traditional group. Therefore it would seem that the AlterG group started the rehabilitation process needing to recover from a higher perioperative 'deficit' than the Traditional group. In contrast, the Traditional group reported more adverse events (Table 2) throughout follow-up and their return toward control-like parameters was slower compared to the AlterG group. While it is difficult to quantitatively assess these categorical variables at these samples sizes, this trend lends positively to the efficacy of the AlterG approach for rehabilitation following ACL reconstruction. Given the lack of significant differences in 'Length of Time' parameters (Table 3) between groups, it is possible that secondary gain effects from the novelty of the AlterG and the perceived reduction in risk related to falling and over-loading the knee may have contributed to more confidence and thus more aggressive approach on the subjects' part to their own therapy. Although both treatment groups were still 'recovering' at 12 weeks, the lack of control-like range of motion and the delay in restoration of walking velocity and distance in the Traditional group may be influencing the subject's perception of their healing as reflected in the difference in 'pain,' 'symptom,' sub-scores between the groups. **These data suggest that the AlterG is an effective means of achieving earlier functional recovery in level over-ground walking when compared to physical therapy that utilizes a standard treadmill.**

ALTER G®

REFERENCE:

Tegner:
Score: Tegner Y, Lysholm J. Rating systems in the evaluation of knee ligament injuries.
Clin Orthop Relat Res. 1985 Grading: Mitsou A, Vallianatos P, Piskopakis N, Maheras S. Anterior cruciate ligament reconstruction by over-the-top repair combined with popliteus tendon plasty. J Bone Joint Surg Br. 1990 May;72(3):398-404

KOOS:
Roos EM, Roos HP, Lohmander LS, Ekdahl C and Beynnon BD: Knee Injury and Osteoarthritis Outcome Score (KOOS)—development of a self-administered outcome measure. *J Orthop Sports Phys Ther* 1998, 28:88-96.

KOOS User's Guide 2003

TABLE 3:

Descriptive statistics for Biometric Measures, Gait Parameters, Clinical Scores, and Length of Time measures.

		Prior to Surgery		2 Weeks		6 Weeks		12 Weeks		
		AlterG	Traditional	AlterG	Traditional	AlterG	Traditional	AlterG	Traditional	Controls
Biometric Measures										
	Quadriceps Strength (dynamometer) (kg) +	18.75 ± 6.63	17.52 ± 4.54	+	+	15.11 ± 5.59	**11.46 ± 3.31**	27.73 ± 6.23	19.92 ± 6.52	22.66 ± 8.6
	Active Knee Range of Motion (°)	127 ± 9.57	133 ± 10.93	**72.28 ± 23.87**	**67.83 ± 22.71**	**125.71 ± 16.33**	**119.2 ± 13.88**	136 ± 4.18	**131 ± 4.18**	141.14 ± 7.01
	Difference in Thigh Circumference (between legs)^	-0.5 ± 0.76	0 ± 1.26	-26.04 ± 30.92	-1.15 ± 1.74	**-1.86 ± 1.43**	**-2.5 ± 1.58**	-0.2 ± 0.44	-0.6 ± 0.89	-0.21 ± 0.56
Gait Parameters										
	Walking Velocity (m/sec)	1.13 ± 0.18	0.86 ± 0.51	**0.75 ± 0.23**	**0.64 ± 0.16**	1.11 ± 0.28	**0.92 ± 0.15**	1.3 ± 0.2	1.14 ± 0.19	1.26 ± 0.17
	Distance Traveled in 5 min (m)	340.53 ± 54.79	298.46 ± 109.17	**226.05 ± 69.57**	**194.01 ± 49.13**	379.93 ± 138.51	**278.08 ± 48**	390.98 ± 61.68	343.3 ± 57.42	360.11 ± 16.4
Clinical Scores										
	Tegner Lysholm Knee Score	**61.14 ± 18.69**	**66.33 ± 24.26**	**32 ± 14.93**	**52.83 ± 18.64**	**67.85 ± 14.36**	**67.6 ± 16.5**	88.83 ± 4.53	83.8 ± 10.03	94.14 ± 13.42
	LEAS	13.28 ± 3.59	12.33 ± 4.22	**6.42 ± 1.61**	**7.66 ± 2.65**	**10.14 ± 3.28**	**9.8 ± 3.27**	13 ± 2	12.4 ± 2.96	14.14 ± 1.77
	KOOS									
	Pain sub score	**65.87 ± 16.33**	**76.38 ± 15.78**	**43.25 ± 14.41**	**55.09 ± 7.54**	**69.44 ± 13.98**	**71.66 ± 6.91**	*92.12 ± 5.93	***80.55 ± 7.08**	97.22 ± 6.21
	Symptom sub score	**63.77 ± 21.86**	**75.59 ± 15.71**	**44.89 ± 12.85**	**45.23 ± 5.37**	**68.87 ± 13.47**	**57.85 ± 15.02**	*92.85 ± 7.49	***72.85 ± 14.85**	93.87 ± 8.92
	ADL sub score	**75.21 ± 15.84**	**83.08 ± 15.63**	***37.98 ± 17.55**	***65.58 ± 13.01**	**78.99 ± 10.03**	**84.7 ± 6.46**	96.56 ± 3.79	**93.52 ± 2.86**	99.36 ± 1.66
	Quality sub score	**22.32 ± 16.47**	**26.04 ± 23.18**	**16.96 ± 18.99**	**17.7 ± 9.19**	**43.75 ± 19.09**	**33.75 ± 12.96**	***75.0 ± 12.5**	***37.5 ± 11.69**	96.42 ± 9.44
		Over Course of Study								
Length of Time										
	Time to Non-antalgic Gait (days)	45.57 ± 17.98	55.6 ± 15.58							
	Return to Driving (days)	17 ± 9.67	18.83 ± 14.1							
	Time to Independence (days)	27.28 ± 5.21	43.33 ± 25.06							
	Time to Straight Leg Raise Without Lag (days)	40.85 ± 24.56	23.4 ± 19.15							

^: Affected minus Contralateral +: not taken therapy restrictions on quad function * : Significant between surgical groups Bold: Significant from controls