

SUMMARY OF CLINICAL RESEARCH INVOLVING THE ALTERG ANTI-GRAVITY TREADMILL®

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At AlterG, we are committed to proper scientific investigation of the potential clinical and athletic performance benefits of using our device. We are pleased to have multiple studies in clinically relevant areas currently underway by independent researchers, at highly reputable institutions in the U.S. and Internationally. Out of respect for the integrity of the scientific process, we will not cite specific authors or institutions until the studies have been published in peer-reviewed journals, presented at professional meetings, or until the author gives us permission. In the following sections, I will outline for you our new presentations or publications for the past quarter, previously published or presented research, present in aggregate format findings from studies already completed but not yet published, and provide a brief overview of planned studies and questions to be answered for the remainder of 2011. Additionally, I will outline the other available forms of clinical material, such as Case Reports, Case Series, Clinical Protocols, White Papers, and Clinical Guidelines.

WHAT'S NEW FROM THE PAST QUARTER

- Preliminary data from the e-Knee study at Scripps Clinic was presented, showing the world's only linear correlation between body weight unloading, speed and incline on actual knee joint reaction forces
- An obesity study from Texas A+M demonstrated significant AlterG effects on weight loss irrespective of diet
- A study of experienced runners performed at the University of Copenhagen showed significant improvements in running economy at the same time that runners could achieve VO2 max
- A previously presented study was published, showing significant improvements in gait for children with cerebral palsy
- A review article was published outlining principles for use of the AlterG in Achilles tendon surgery rehabilitation
- Subjective analysis of urinary urgency on the AlterG provides practical tips for clinicians to avoid problems with their patients
- Clinical protocols for Ankle Sprain, ACL Reconstruction, Achilles Tendon Repair, and Knee Microfracture were added to the website

Greenwood, M., Mardock, M., et al: Experiencing the Impact of Weight Loss on Work Capacity Prior to Initiation of a Weight Loss Program Enhances Success

Presented at International Society for Sports Nutrition, Las Vegas, Nevada, June 2011

- AlterG pretraining showed significant improvements over traditional exercise in weight loss, fat loss, free fat mass, and body fat
- There is an overall significant effect for weight loss and fat loss irrespective of diet

Kurz, Max; Corr, Brad; Stuber, Wayne; Volkman, Kathleen; and Smith, Nina: Evaluation of Lower Body Positive Pressure Supported Treadmill Training for Children with Cerebral Palsy
Pediatr Phys Ther. 2011 Fall;23(3):232-9. PubMed PMID: 21829114.

Patil, S., Steklov, N., Goldberg, T., Colwell, C.W., Jr., D'Lima, D.: Effect of Anti-Gravity Treadmill on Knee Forces. Presented at International Society for Technology in Arthroplasty, Brussels, Belgium, September 2011.

The authors presented preliminary data from four subjects with implanted load bearing sensors in total knee arthroplasty. Key points from the preliminary analysis include:

- There is a direct linear correlation between body weight unloading, speed, and incline on knee joint reaction forces.

- The authors will be publishing their results, which will show an equation to relate all variables unique to the AlterG.
- Jogging 4.5mph with 50% body weight was approximately the same knee joint reaction force as walking 3.5mph with full body weight.
- In the full paper, the authors intend to place various combinations of AlterG body weight support in the spectrum of activities for which they have obtained prior data.

Raffalt, P.C., Hovgaard-Hansen, L., Jensen, B.R.: Vertical ground reaction force and respiratory response during lower body positive pressure treadmill running. Presented at International Society for Biomechanics, Brussels, Belgium, July 2011.

This study showed the following key points:

- Experienced runners at high speeds can achieve VO₂ max with reduced body weight by increasing incline
- Body weight support was accompanied by reduced ground reaction force
- The economy of running was significantly improved as shown by a large increase in time to exhaustion (642 seconds) compared to full body weight running (477 seconds)
- Authors conclude that AlterG training is a relevant tool for healthy runners to reduce joint loading while maintaining or even improving the aerobic stimulus

Saxena, Amol: Review Article titled "Strategies for Rehab After Achilles Tendon Surgery" was published in Lower Extremity Review Online, September, 2011: <http://www.lowerextremityreview.com/article/strategies-for-rehab-after-achilles-tendon-surgery>

Tanza, S., Byl, N., Garcia, M.: Does Lower Body Positive Pressure Support (LBPPWS) Gait Training On The AlterG Affect Urinary Urgency?

Presented at: Annual meeting of the California Chapter of the American Physical Therapy Association, September 21-24, 2011, Long beach, CA

- Authors recommend that all individuals void prior to using the AlterG
- Individuals with a history of bladder incontinence should exercise with a pad or diaper
- Authors speculate that AlterG training might be beneficial in training for better bladder control for individuals with a history of stress incontinence or urgency

PREMARKETING STUDIES AND TECHNOLOGY VALIDATION PROVE SAFETY AND EFFECTIVENESS OF ALTERG ANTI-GRAVITY TREADMILL®

The concept of using advanced differential air pressure technology for weight support was originally conceived by Dr. Robert Whalen and Dr. Alan Hargens while they were studying the biomechanics of exercise in space as part of an effort to design effective exercise regimens for NASA's astronauts. These early studies specifically using patented AlterG technology show that the machine is:

- Capable of accurate and precise unweighting across a variety of body types
- Comfortable and safe for most individuals, including those with stable cardiac, vascular, and respiratory disorders
- Able to reduce ground reaction force for walking and running in proportion to the amount of unweighting
- Effective in reducing pain in individuals whose lower extremity symptoms are related to full weight bearing ambulation or exercise

Burgar, C.G., Schwandt, D., Anderson, J., Whalen, R., Breit, G.: Differential Walking Assist: an inflatable walking support. *Rehabilitation R&D Center Progress Report, 1994.*

Buckley, E.L., Burgar, C.G., Cao, Y., Schwandt, D.F.: Partial Body Weight Support Using Air Pressure: Safety and Unloading. *Second National Department of Veterans Affairs Rehabilitation Research and Development Conference Proceedings, 2000.*

Eastlack, R.K., Hargens, A.R., Groppo, E.R., Steinbach, G.C., White, K.K., Pedowitz, R.A.: Lower Body Positive-Pressure Exercise after Knee Surgery. *Clinical Orthopaedics & Related Research. 431:213-219, February 2005.*

Cutuk, A.A., Groppo, E.R., Quigley, E.J., White, K.W., Pedowitz, R.A., Hargens, A.R.: Ambulation in Simulated Fractional Gravity Using Lower Body Positive Pressure: Cardiovascular Safety and Gait Analyses. *J Appl Physiol 101: 771-777, 2006.*

THESE PUBLISHED STUDIES ON THE ALTERG ANTI-GRAVITY TREADMILL® BUILD THE FOUNDATION FOR CLINICAL USE BY SHOWING PRESERVED KINEMATICS, EFFECTIVE REDUCTION IN GROUND REACTION FORCES, AND EQUATIONS FOR A METABOLIC PRESCRIPTION FOR EXERCISE

Early studies provide the foundation for the biomechanics of running and walking on the AlterG. They also show that for each individual a “metabolic prescription” can be achieved, thus maintaining metabolic load while reducing the ground reaction forces. The principles shown here can be applied to a wide variety of medical and athletic rehabilitation settings. Here are summary findings:

- For any given walking or running speed, weight support reduced metabolic demand by the individual
- For any given amount of weight support, metabolic demand can be increased by increasing walking or running speed
- Ground reaction forces are reduced at all levels of weight support
- Surface EMG electrode activity shows that muscle firing patterns and gait mechanics are maintained for all levels of weight support and speeds.
- Anti-gravity muscles show reduced activation with weight support
- Weight support causes a slight increase in Heart Rate and Systolic Blood Pressure, but Diastolic Blood Pressure and Mean Blood Pressure are not changed
- Individuals who use Heart Rate to create exercise regimens can continue to do so on the AlterG and they should expect a similar metabolic demand from body weight support as with unsupported exercise
- Dramatic improvements in gait mechanics are seen in children with cerebral palsy who use the AlterG for exercise

Evans, J., Shapiro, R., Moore, F.: Segmental Volume and Cardiovascular Responses to Changes in Body Position at Rest and During Walking Under Normal and Reduced Weight Conditions *J Gravitational Physiology*, 2011.

- Authors measured pressure in mmHg at various body weight reductions for each subject. Pressure required will of course vary by subject's weight and body mass, but roughly 30-40mm Hg pressure is needed for a 20% reduction in body weight.
- Fluid shifts from the legs to the abdomen and thorax with lower body positive pressure support. There was a slight increase in systolic blood pressure, no change in diastolic blood pressure,

slight decrease in heart rate, all of which can be expected with the fluid shift.

Grabowski, Alena and Kram, Rodger: Effects of Velocity and Weight Support on Ground Reaction Forces and Metabolic Power During Running. *J Appl Biomech* 24:288-297, 2008.

- This study was performed at the University of Colorado, and validated several core biomechanical principles associated with usage of the AlterG during running.

Grabowski, Alena: Metabolic and Biomechanical Effects of Velocity and Weight Support Using a Lower Body Positive Pressure Device During Walking. *Archives of Physical Medicine and Rehabilitation*, 91:951-957, 2010.

- This study uses similar methods to the running study by Dr. Grabowski referenced above but now focusing on individuals during walking. Proof of basic principles during walking is very important for the post-injury, post-operative, and other groups who would not be expected to run on the AlterG.
- Many combinations of velocity and BW resulted in similar aerobic demands, yet walking faster with weight support lowered peak GRF's compared to normal weight walking.
- Manipulating velocity and weight support during walking with the AlterG may be a highly effective strategy for rehabilitation, recovery following surgery, and gait re-training.

Hoffman, M.D., Donaghe, H.E.: Exercise responses during partial body-weight supported treadmill walking and running in healthy individuals. *Arch Phys Med & Rehab*, 2011.

- For walking up to 3.5mph: a 25% reduction in body weight requires approximately a half mile per hour increase in walking speed for the same VO₂.
- For running up to 9.0mph: a 25% reduction in body weight requires a 3mph increase in running speed for the same VO₂.
- Relationship between HR and VO₂ is not changed with support, thus runners who use HR as an indicator of training intensity can continue to do so on AlterG with weight support.

Kurz, M., Corr, B., Stuberg, W., Volkman, K., Smith, N.: Evaluation of Lower Body Positive Pressure Supported Treadmill Training for Children with Cerebral Palsy *Pediatr Phys Ther*. 2011 Fall; 23(3):232-9. PubMed PMID: 21829114.

- LBPPS treadmill training resulted in significant changes in the walking spatiotemporal kinematics and balance. After training the children had a

faster preferred walking speed, spent less time in double support, more time in single support, had improved overall balance, and improved walking balance. Furthermore, there was a trend for increased strength of the lower extremity anti-gravity musculature.

- LBPPS treadmill training utilizing the AlterG is an effective treatment for improving the walking biomechanics and balance of children with CP. The AlterG offered other advantages over conventionally used harness systems and was very well accepted by the children.

Liebenberg, J., Scharf, J., Forrest, D., Dufek, J., Masumoto, K., Mercer, J.A.: Determination of Muscle Activity During Running at Reduced Body Weight *J Sports Sciences* 29(2): 207-214, 2011.

- The purpose of this study is to investigate how lower extremity muscles are influenced by body weight (BW) support during running at different speeds. Reducing BW leads to a reduction in muscle activity with no changes in muscle activity patterns.

THE FOLLOWING STUDIES HAVE BEEN SUBMITTED OR ACCEPTED FOR PUBLICATION AND ARE UNDER EDITORIAL REVIEW. ONE STUDY PROVIDES THE FOUNDATION FOR FUTURE WORK IN CARDIOVASCULAR PHYSIOLOGY. OTHER STUDIES SHOW SIGNIFICANT EFFECTS IN POSITIVE ALTERATIONS IN GAIT PATTERNS FOR CHILDREN WITH CEREBRAL PALSY, AND ALSO INVESTIGATE BIOMECHANICAL PRINCIPLES IN THE PEDIATRIC POPULATION. A CLINICAL STUDY ESTABLISHES 85% BODY WEIGHT AS A SAFE LEVEL TO RETURN TO OVERLAND TRAINING AFTER ACHILLES TENDON REPAIR

Evans, J., Shapiro, R., Moore, F.: Segmental Volume and Cardiovascular Responses to Changes in Body Position at Rest and During Walking Under Normal and Reduced Weight Conditions Presented at Experimental Biology 2010, Anaheim, CA; and at International Society for Gravitational Physiology, Italy, June 2010; accepted for publication to *J Gravitational Physiology*, In Press

- Authors also measured pressure in mmHg at various body weight reductions for each subject. Pressure required will of course vary by subject's weight and body mass, but roughly 30-40mm Hg pressure is needed for a 20% reduction in body weight.
- Fluid shifts from the legs to the abdomen and thorax with lower body positive pressure support.

There was a slight increase in systolic blood pressure, no change in diastolic blood pressure, slight decrease in heart rate, all of which can be expected with the fluid shift.

Kurz, M., Deffeyes, J.E., Karst, G.M., Stuber, W.A.: Influence of Lower Body Pressure Support on the Walking Patterns of Healthy Children and Adults. Accepted for publication to *Journal of Applied Biomechanics*, In Press

- The lower extremity joint angles and activity of the lower extremity anti-gravity muscles of children did not differ from those of adults
- Lower body positive pressure support resulted in reduced activation of the anti-gravity musculature, and reduced range of motion of the knee and ankle joints
- The magnitude of the changes in the lower extremity joint motion and anti-gravity muscle activity was dependent upon an interaction between body weight support and walking speed. Generally speaking, for any given amount of body weight support, knee and ankle joint ranges of motion are smaller with slower walking speeds.

Deffeyes, J., Stuber, W., Karst, G., Kurz, M.: Coactivation of Lower Leg Muscles During Body Weight Supported Treadmill Walking Decreases With Age In Adolescents Accepted for publication to *Human Movement Science*, In Press

- It is unknown how use of a body weight supported treadmill device affects muscle coactivation, which is important as these devices are commonly used for therapy and rehabilitation of individuals with musculoskeletal or neurological disorders.
- Coactivation was found to be higher in adolescents than in adults, but only for the lower leg muscles. These results show the importance of using age-matched controls in adolescent studies of pathologic agonist/antagonist coactivation of lower leg muscles during walking.

Saxena, A., Granot, A.: Use of an Anti-Gravity Treadmill in the Rehabilitation of the Operated Achilles Tendon: A Pilot Study. Accepted for publication to *J Foot and Ankle Surgery*, In Press

- Individuals are able to perform closed chain walking and jogging early on in the postoperative period after Achilles tendon repair, maintaining a training effect in spite of partial weight bearing
- Authors proposed 85% BW as a benchmark to return patients to unsupported training

PUBLISHED REVIEW ON KNEE MICROFRACTURE POSTOPERATIVE REHABILITATION USING THE ALTERG ANTI-GRAVITY TREADMILL® SHOWS CLINICAL EFFECTIVENESS

Wilk, Kevin E., Macrina, Leonard C., and Reinold, Michael M.; Rehabilitation Following Microfracture of the Knee. *Cartilage 1(2): 96-107, 2010.*

- Microfracture surgery requires a period of non-weightbearing or toe-touch weightbearing for several weeks, followed by progressive weightbearing. Phases are outlined in this rehabilitation protocol. Beginning in approximately week number 4 postoperative (termed the Transition Phase by the authors), and continuing on until full functional recovery, the AlterG may be used to provide safe, protected increases in weightbearing which promotes improvements in muscle control and function. This is an outstanding review of the science behind microfracture rehabilitation.

SEVERAL STUDIES WERE PRESENTED AT NATIONAL OR INTERNATIONAL MEETINGS, ADDING TO OUR UNDERSTANDING OF PHYSIOLOGICAL AND BIOMECHANICAL RESPONSES TO ALTERG ANTI-GRAVITY TREADMILL® UNWEIGHTING EXERCISE. A RECENTLY PRESENTED PAPER SHOWS THAT VO2 MAX CAN BE ACHIEVED FOR EXPERIENCED RUNNERS AT HIGH RUNNING SPEEDS

Athletic Performance

Raffalt, P.C., Hovgaard-Hansen, L., Jensen, B.R.: Vertical ground reaction force and respiratory response during lower body positive pressure treadmill running. Presented at *International Society for Biomechanics, Brussels, Belgium, July 2011.*

- Experienced runners at high speeds can achieve VO2 max with reduced body weight by increasing incline
- Body weight support was accompanied by reduced ground reaction force
- The economy of running was significantly improved as shown by a large increase in time to exhaustion (642 seconds) compared to full body weight running (477 seconds)
- Authors conclude that AlterG training is a relevant tool for healthy runners to reduce joint loading while maintaining or even improving the aerobic stimulus

Pedlar, C., Burden, R.J., Hill, J.A., Whyte, G.: Physiological responses to simulated anti-gravity during treadmill running. Presented at *American College of Sports Medicine, Denver, CO, July 2011.*

Basic Science: Cardiovascular

Yates, J.W., Mohney, L.E., Abel, M.G., Shapiro, R.: Effect of unweighting using the AlterG Trainer on VO2, heart rate, and perceived exertion. Presented at *American College of Sports Medicine, Denver, Colorado, July 2011.*

Basic Science: Biomechanics

Donaghe, H.E., Hoffman, M.D.: Exercise Responses During Partial Body-Weight Supported Treadmill Walking and Running in Healthy Individuals. Presented at *ACSM annual meeting, June 2010, Baltimore, Maryland Med Sci Sport Ex 42(5) Supplement S445, 2010*

- This study has been accepted for publication, see "Hoffman, M.D. and Donaghe, H.E.: Exercise responses during partial body-weight supported treadmill walking and running in healthy individuals. *Arch Phys Med & Rehab, 2011*

Jensen, B.R., Hovgaard-Hansen, L., Cappelen, K.L.: Effects of Lower Body Positive Pressure on Muscle Activity and Joint Loads. (University of Copenhagen, Denmark) Presented at *The International Society of Biomechanics meeting, South Africa, July 2009.*

- This study showed that maintained horizontal ground reaction forces are most likely responsible for the normal gait patterns seen with all levels of weight support.
- Vertical ground reaction forces are decreased with weight support but horizontal ground reaction forces are maintained, thus leading to normal gait patterns at all levels of support
- Joint loads are reduced at the knee and ankle, with knee reduced slightly more than the ankle (data estimated)
- Surface EMG activity reveals reduced muscle contraction amplitudes with weight support, quadriceps and gastroc/soleus are reduced more than hamstrings and tibialis anterior

Forrest, Dana M., Dufek, J.S., Masumoto, K., Mercer, J.A.: Muscle Activity During Running at Reduced Body Weight (University of Nevada, Las Vegas) Presented at *American College of Sports Medicine Annual Meeting, Indianapolis, Indiana, May 2008.*

Applequist, B., Mercer, J.A.: The Effect of Simulated Anti-Gravity on Muscle Activity (University of Nevada, Las Vegas) Presented at *Southwest Meeting of ACSM, San Diego, October 2009.*

CLINICAL RESEARCH UPDATE



Liebenberg, J., Scharf, J., Forrest, D., Dufek, J., Mercer, J.A.: Muscle Activity During Running at Reduced Body Weight (University of Nevada, Las Vegas), *Presented at Southwest Meeting of ACSM, San Diego, October 2009*

- Ground reaction forces are reduced for running with weight support
- Running mechanics are maintained with weight support
- Surface EMG activity reveals normal muscle firing patterns during running
- Muscle EMG peak amplitude is decreased with reduced body weight but can be maintained with increased running speed
- Pressure inside the AlterG does not change muscle firing patterns by itself

Neurologic: Parkinson's Disease

Byl, N., Cox, L., Forte, A., Fedulow, I., Ide-Don, J.: Maintaining safe mobility in patients with Parkinson's disease: one year outcomes of dual task training under aerobic and moderate exercise. *Presented at International Movement Disorders, San Francisco, May 2010.*

- Significant gains were made in mobility, bilateral lower extremity strength, fall reduction and depression.

Orthopaedics: Achilles Tendon

Saxena, A., Granot, A.: Use of an Anti-Gravity Treadmill in the Rehabilitation of the Operated Achilles Tendon: A Pilot Study. *Presented at American College of Foot and Ankle Surgeons Annual Conference, Las Vegas, Nevada, February 2010*

- Individuals are able to perform closed chain walking and jogging early on in the postoperative period after Achilles tendon repair, maintaining a training effect in spite of partial weight bearing
- Authors proposed 85% BW as a benchmark to return patients to unsupported training

Overweight/Obesity

Greenwood, M., Mardock, M., et al: Experiencing the Impact of Weight Loss on Work Capacity Prior to Initiation of a Weight Loss Program Enhances Success *Presenting at International Society for Sports Nutrition, Las Vegas, Nevada, June 2011*

Urology

Tanza, Sara; Byl, Nancy; Garcia, Maurice: Does Lower Body Positive Pressure Support (LBPPWS) Gait Training On The AlterG Affect Urinary Urgency? *Presented at: Annual meeting of the California Chapter of the American Physical Therapy Association, September 21-24, 2011, Long Beach, CA*

- 16 healthy individuals between ages 23-69 were studied using a VAS for urinary urgency during and exercise session on the AlterG.
- Body weight was incrementally decreased to

- 80%, and then increased back up to 100%
- 100% of subjects experienced urinary urgency with weight support
- 87.5% continued to have some urgency as weight support was removed

Conclusions:

- authors recommend that all individuals void prior to using the AlterG
- individuals with a history of bladder incontinence should exercise with a pad or diaper
- authors speculate that AlterG training might be beneficial in training for better bladder control for individuals with a history of stress incontinence or urgency

MORE THAN TWENTY STUDIES ARE UNDERWAY MOVING TOWARDS VALIDATION OF THE ALTERG AS A REHABILITATIVE TOOL LEADING TO IMPROVED FUNCTIONAL OUTCOMES COMPARED TO CONVENTIONAL REHABILITATIVE TECHNIQUES, AND EXPANDING ON PRIOR PHYSIOLOGICAL AND BIOMECHANICAL STUDIES

Orthopaedics: Real-Time Telemetry Data Utilizing the e-Knee

- Study underway at Scripps Clinic, La Jolla, California under direction of Daryl D'Lima, M.D., Ph.D., and Clifford Colwell, M.D. Four patients with custom designed total knee arthroplasties with load bearing sensors implanted in the hardware. The sensors allow these four patients to transmit real-time telemetry data on knee joint loading in a variety of activities.
- This study completed data collection in February 2011, and will provide objective data on actual knee joint unloading at various levels of body weight reduction on the AlterG.
- This one-of-a-kind data will be invaluable to clinicians and researchers designing rehabilitation protocols for use with the AlterG. It will be the only available data to correlate body weight unloading with joint reaction forces.
- Knee joint reaction forces with partial weight bearing will for the first time be compared to knee joint reaction forces with other activities such as full body weight walking, jogging, stair climbing, and stair descent.
- Data analysis and manuscript preparation are underway.

Basic Science: Biomechanics

- EMG comparison of AlterG to deep water running
- Force plate analysis during running, with 3-D telemetry

- Several studies comparing AlterG to harness suspension and pool running. What is the effect of the various systems on muscle firing patterns, gait patterns, muscle amplitude, joint reaction forces, etc.?
- Effects of weight support on stride length and stride rate during walking and running

Basic Science: Cardiovascular

Segmental Volume and Cardiovascular Responses to Changes in Body Position at Rest and During Walking Under Normal and Reduced Weight Conditions

- What is the effect of lower body positive pressure on fluid volume shifts in the lower extremity, abdomen, and thorax?
- What is the effect of lower body positive pressure on cardiac output?
- What is the correlation between applied pressure and weight reduction?
- How are the above findings influenced by volume depletion with a diuretic?

Orthopaedics: Arthritis

- Arthritis Gait Pain and Exercise Study
- The effect of treadmill walking exercise with a partial reduction of body weight on knee osteoarthritis disease progression
- Nonsurgical management of knee osteoarthritis using the AlterG
 - What is the effect of the AlterG on perceived pain levels during exercise for patients with knee osteoarthritis?
 - Will patients with knee osteoarthritis choose to exercise more on the AlterG compared to other forms of exercise?
 - What are the quality of life improvements for exercise on the AlterG?

Neurologic

Parkinson's Disease Randomized Clinical Trial - University of California, San Francisco

- Does exercise on the AlterG improve functional indices, fall risk, and quality of life for patients with mild to moderate Parkinson's Disease?
- Does exercise on the AlterG improve functional indices, fall risk, and quality of life for patients with acute and chronic stroke?
- This study is expected to complete data collection by September 2011.

Parkinson's Disease Randomized Clinical Trial - University of Copenhagen, Denmark

Obesity

The overweight individual must deal with a number of issues that make exercise very difficult, such as poor cardiovascular conditioning at baseline, and presence of painful lower extremity joints due to osteoarthritis.

Modalities such as aquatic therapy, bicycle, and full body weight walking are commonly recommended, in addition to nutritional modification and lifestyle changes. It is believed that the AlterG enables overweight individuals to exercise in ways they could not otherwise.

- The ability to "feel what their body is like at a lower weight" is highly motivational
- Unweighting allows them to exercise in a pain free range
- Metabolic demand can be maintained even with unweighting by increasing walking speed

Athletic Performance

- Overspeed training
- Strength gains in healthy runners
- Effect of Reduced Body Weight Running on Footstrike Haemolysis
 - The author hypothesizes that reduced body weight running will decrease the amount of heelstrike haemolysis, and thus perhaps lead to lower rates of exercise induced anemia.

International Researchers

- Fukubayashi, T., Japan, biomechanics studies in professional soccer
- Jensen, B.R., Denmark, Parkinson's disease, multiple biomechanical studies
- Magalini, M., Italy, sport specific rehabilitation protocols using AlterG
- Mester, J., Germany, biomechanics, athletic performance
- Weiss, R., Germany, obesity

STUDIES BEGINNING IN THE THIRD QUARTER 2011 WILL FOCUS ON CORE CLINICAL AREAS IN ORTHOPAEDICS, NEUROLOGY, GERIATRIC CONDITIONING, AND FALL RISK REDUCTION. THESE RANDOMIZED PROSPECTIVE TRIALS WILL BE HIGH LEVEL OF EVIDENCE STUDIES LIKELY TO TAKE A YEAR OR MORE TO COMPLETE

Please note that many of these studies are in the early planning stages. Study protocols are being developed and IRB approval may not have been granted. We provide this information as reference, but cannot guarantee that the studies will be started or completed.

Orthopaedics: ACL Reconstruction

A procedure in which the patient can be "weight bearing as tolerated" immediately after surgery, but typically chooses to use crutches for several weeks due to pain, stiffness, disuse atrophy, and muscle weakness is an opportunity in which the AlterG can be used very early. It

is hypothesized that very early postoperative use will lead to improved near term functional outcomes, the ability for the patient to gain an early cardiovascular training effect, and faster return of running activity in a manner that is safe for the ACL graft. A randomized prospective clinical trial is set to begin in the third quarter 2011.

Orthopaedics: Total Knee Arthroplasty (two studies)

Evaluation of functional outcomes, pain scores, range of motion, gait, and satisfaction scores after total knee arthroplasty. Two randomized prospective studies have been proposed for the AlterG vs conventional rehabilitation.

- It is hypothesized that patients using the AlterG will have improved near term functional outcome, and decreased time off crutches/walker due to the patient's ability to achieve pain relief from unweighting during ambulation training.

Geriatric Conditioning: Effects of AlterG Treadmill Training on Balance, Mobility, and Lower Extremity Strength of Community-Dwelling Adults

Certain geriatric conditions result in a loss of independent ambulation, loss of strength, and increased fall risk. The AlterG provides a totally unique conditioning environment where an individual with functional deficits can exercise in a safe manner. It is hypothesized that training on the AlterG will improve functional performance and possibly reduce fall risk in the geriatric population.

PROSPECTIVE STUDIES PROPOSED, IN EARLY PLANNING

Orthopaedics: Acute Rehabilitation After Open Reduction and Internal Fixation for Intertrochanteric Hip Fracture

The investigators hypothesize that immediate post-operative rehabilitation on AlterG will result in improved near term functional outcomes compared to traditional rehabilitation, and will also reduce the length of inpatient hospitalization or transitional care

Obesity: Effects of AlterG Exercise on Body Measurements and Metabolic Markers

Obese individuals will more effectively exercise on AlterG, resulting in improved measurements of body fat, free fat mass, glucose tolerance, and exercise tolerance.

PLANNED CASE SERIES TO PROVIDE CLINICAL DATA ON SPECIFIC CONDITIONS

These case series are set to begin or already underway in the third quarter 2011.

- Pelvic stress fracture in elite runners

- Knee cartilage repair
- Hip arthroscopy for femoro-acetabular impingement

FULLY REFERENCED CASE REPORTS FROM UNIVERSITIES DEMONSTRATE THE ALTERG'S EFFECTIVENESS AS AN ENABLER OF EXERCISE WITH TWO DIFFICULT CLINICAL CONDITIONS

Moore MN, Vandenakker-Albanese C, Hoffman MD. Use of partial body-weight support for aggressive return to running after lumbar disk herniation: a case report. *Arch Phys Med Rehabil* 2010;91:803-805.

- A highly motivated physician/runner successfully used AlterG training within one week of an acute lumbar disc herniation when he was experiencing considerable pain with unsupported walking and lower extremity weakness. He continued its use until he adequately improved to allow return to his regular over-ground running program. This case demonstrates how partial body-weight support can allow aggressive running training early after a lumbar disc injury when normal impact forces cannot be tolerated and when leg weakness is a limitation.

Simonson, S.R., Shimon, J.M., Long, E.M., Lester, B: Effects of a Walking Program Using the AlterG Anti-Gravity Treadmill System on an Extremely Obese Female: A Case Study. *Clinical Kinesiology* 65(2); Summer, 2011: 29-38.

- This case study examined the effects of a 14 wk walking program on one extremely obese (BMI 69.2) Caucasian 44 year-old female utilizing the AlterG Anti-Gravity Treadmill. At the conclusion of the study, exercise tolerance time increased 3-fold while caloric expenditure increased 10-fold without an increase in heart rate or perceived pain in her lower extremities. The participant demonstrated a 2.75% weight reduction, a decrease in upper body circumference measurements and lower extremity edema of her knees and ankles, and a 9.7% decrease in fasting blood glucose (102mg/dL). Overall, the AlterG Treadmill enabled the participant to exercise and walk pain-free at a distance, intensity level, and speed that she could not accomplish while walking on her own.

CASE STUDIES FROM PHYSICAL THERAPISTS AND OTHER CLINICIAN USERS DEMONSTRATE THE EFFECTIVENESS OF ALTERG REHABILITATION FOR A BROAD RANGE OF SPECIFIC CLINICAL CONDITIONS. TWENTY-NINE CASE STUDIES ARE CURRENTLY AVAILABLE, WITH ADDITIONAL STUDIES PLANNED FOR THE REMAINDER

OF 2011. WHEN COMPLETED, THE CASE STUDY COLLECTION WILL REPRESENT A COMPREHENSIVE END-USER EXPERIENCE WITH THE ALTERG

- Hip: labrum repair, microfracture, total hip arthroplasty, arthroscopy for femoro-acetabular impingement, bilateral hip resurfacing, slipped capital femoral epiphysis, bilateral hip arthroplasty, femoral neck stress fracture
- Knee: acl reconstruction, microfracture, nonsurgical rehabilitation after acl tear, partial meniscectomy, unicompartmental knee replacement, total knee replacement, patellofemoral pain syndrome
- Ankle: lateral ligament reconstruction, open reduction and internal fixation of ankle fracture
- Foot: plantar fascia tear, metatarsal stress fracture in elite runners
- Leg: bilateral compartment syndrome release, fibula stress fracture, tibia stress fracture, tibia fracture intramedullary rod
- Femur/Thigh: femur fracture intramedullary rod
- Neurologic: chronic stroke rehabilitation
- Cardiovascular: postural orthostatic tachycardia syndrome

CLINICAL PROTOCOLS FROM CLINICIAN AND THERAPIST EXPERTS IN REHABILITATION OF COMMON CONDITIONS WILL BE AVAILABLE IN THE THIRD QUARTER 2011

- Grade III ankle sprain
- Achilles tendon repair
- ACL reconstruction
- Knee cartilage repair
- Total knee replacement (in development)
- Lower extremity fracture (in development)