14 July 2020

Meal Replacement Plus Testing Data

Background of Invention and Target Population

Special Operations Forces Operators (SOs) are an elite military group who are physically and mentally trained to perform under the worst possible conditions and battlefield scenarios. The physical prowess of SOs has been compared to that of elite athletes [1]. However, while elite athletes generally excel in one category of athletic ability, SO personnel must have an all-encompassing level of fitness that includes high aerobic capacity, muscular strength, endurance, and power [1]. A weak link in any level of an SO's chain of fitness or strength could mean the difference between life and death and/or mission failure. The intention of high-stress training is to effectively prepare SOs for any combat situation. [1,2,3]. SOs must endure conditions and demands that may have serious impacts on health and performance. For example, SOs are routinely exposed to prolonged and physically demanding training cycles that may result in significant changes in body composition, physical work capacity, and endocrine (hormone) function [1,4,6]. Researchers have suggested that the factors influencing these physiological changes can likely be attributed to (1) high physical demands that necessitate high energy expenditure (EE); (2) lower energy intake (EI); (3) a negative energy balance (EI-EE), and (4) sleep deprivation. Additionally, due to the nature and location of some missions and deployments, SOs may endure several days to weeks of extreme environmental conditions ranging from tropical climates to the subarctic/arctic regions and varying terrain (e.g., snow, mud, sand) and altitudes, further predisposing them to injury [1,3,4].

As noted, SOs are routinely exposed to high levels of physical and mental stress. For example, the U.S. Army Ranger School is a leadership course for elite soldiers who upon graduating can become part of Special Operations (i.e., 75th Ranger Regiment) or return to their units to lead Soldiers in combat. Soldiers must endure a grueling, physically and mentally demanding 61-day course, in heavily wooded areas, urban settings, mountainous terrain, and swamp-like conditions. Nindl et al. studied the physiological consequences of Ranger School (a 1992 class) on strength, power, body composition, and somatotrophic hormones [6]. Along with the challenges of adapting to environmental extremes, this study found that Ranger School students sleep only an average of 3.6 h/day, experience acute caloric deficits ranging from 1,000 to 4,000 kilocalories (kcals)/day during a 7-10 days of underfeeding per phase, and chronically expend more energy than consumed (e.g., net caloric loss) for the majority of the 8-week course. As a result of this 61 days of exposure to stressors, circulating concentrations of total testosterone decreased by an average of 83%, a level within the range for hypo-gonadism in males. Circulating concentrations of insulin-like growth factor 1 (IGF-1) decreased 55%, whereas cortisol increased 32% [1]. Similarly, for SOs in the deployment environment, high energy expenditure, sleep deprivation, heavy equipment loads, and environmental factors during Sustained Operations (SUSOPS) can also lead to changes in body composition and physical performance decrements, which may result in musculoskeletal (MSK) injuries and mission mishaps. O'Hara et al. (2014) reported that

loss of lean tissue, significant decrements in lower body power output and decreased testosterone can result from SUSOPS lasting as few as 72 hours [1]. As a countermeasure, Nindl et al., suggest the research and development of a novel therapeutic agent which would allow circulating concentrations of endogenous growth and anabolic hormones to be maintained, thus possibly attenuating losses of Fat-Free Mass (FFM) [6]. Therefore, the inventor formulated a meal replacement drink to stave off hunger, maintain endocrine integrity, and preserve lean tissue muscle mass. The invention was specifically designed for SOs to use during sustained operations missions and long duration training ranging from 3-day missions to 8 weeks of training. These types of missions and trainings result in high-energy expenditure and underfeeding [1,5,7]. Therefore, the invention was formulated and packaged specifically to meet the above demands of sustained operations missions and rigorous training demands.

High intensity, long-duration training leads to skeletal muscle atrophy that can most likely be attributed to nutritional deficiency, overexertion, and changes in hormone levels. Because little can be done to change the harsh conditions of Sustained Operations Missions (SUSPOS), an appropriate nutritional countermeasure may be beneficial in mitigating or preventing the losses of Body Mass (BM) and Fat-Free Mass (FFM) during such critical missions [1,7]. Therefore, the proposed invention was formulated for SOs who are expected to deploy into a variety of environments, under enemy threat, including all biomes, via any available method. Travel to the mission location may include parachute, all-terrain vehicle, helicopter, open/closed circuit underwater infiltration; and “dismounted” methods such as ski tour, snow-shoe, hike, etc. In all of these circumstances, minimizing gear weight to reduce strain on the human body is essential, because lighter loads expand operational radius and functionality, especially during dismounted operations. For example, Meals Ready to Eat (MREs) weigh between 1 and 1.5 lbs. each, and take up significant volume in the rucksack, making total food weight and size for an extended duration mission (3-5+ days) a significant detrimental factor. Water is procurable in most biomes (even in the desert, troops will negotiate with sympathetic indigenous populations to gain access to wells), negating water weight requirements, but nutritional sustainment is harder to procure and pack. Therefore, this supplement (invention) was formulated to not only preserve lean tissue mass and stave off hunger during missions but it was also pre-packaged to reduce carry weight, and to meet the high nutritional demands of the warfighter during combat.

During some tactical operations, SOs may conduct long duration movements on strict timelines that preclude time to stop and consume adequate food sustainment. Additionally, during longer kinetic engagements that may last several hours, SOs are sometimes unable to eat due to the tactical situation. However, they are typically wearing their hydration system and able to consume liquids while still maintaining tactical security and integrity with hands on a weapon, immediately able to engage targets of opportunity. This invention was specifically formulated to meet the unique needs of military special operations forces operators. To date this specific formulated invention serves a specific target population under specific conditions as listed below.

*****Using the invention as a meal replacement (not merely a supplement) for an extended period

*****Using the invention as sole sustenance during physically and/or mentally taxing activity in difficult conditions (e.g., high tempo, austere environments, high heat)
*****Using the invention on remote and/or long-term missions (e.g, stable/inhibits bacterial growth, encourages proper nutrition and fluid intake, easy to use under impaired cognition resulting from stress)
***** Using the invention when reducing overall equipment weight is vital for mission success. SOs determine a gear weight threshold based on mission type, duration, infiltration method etc. Ruck needs to be light enough to conduct the mission but also contain enough sustainment to complete the mission.
***** Using the invention in emergency situations. Escape and evade tactics may require SOs to "dump gear," meaning they will leave/destroy primary equipment, taking only a small survival bag. This facilitates faster movement and agility. Due to its long nutritional supplementation duration with low weight/volume penalty, this invention is ideally suited for use in the survival bag.

In the deployed environment, SOs have access to caffeine supplements and protein supplements, but packaging and nutritional deficiencies are not advantageous to the combat environment. For instance, high-sugar carbonated energy drinks typically contain in excess of 200 mg of caffeine per 8 oz serving but provide little to no nutritional value, and usually contain 35g or more of sugar. As expected, consuming these products causes an energy spike and subsequent crash that is not conducive to long duration missions that require steady state endurance and concentration. Additionally, these products come in aluminum cans making them all but un-packable for dismounted operations. Protein supplements typically come in powder packets that are then mixed with water, or also come in aluminum cans. Most of these supplements are also high in sugar, and because they are dairy based products, they quickly sour in the heat and become unconsumable. If mixed in a military issued bladder system, they will quickly mold and rot the apparatus, rendering the equipment unusable. This outcome can significantly endanger an SO's hydration and thus endanger mission success, as extra hydration bladder systems are rarely carried on combat operations.

Because the invention acts as a liquid meal replacement, SOs can reduce pack weight by increasing planned duration between MRE consumption. For instance, on a 5-day (120 hour) mission, an SO may typically plan to consume 2-26 oz. MREs per 24 hour period, weighing a total of approximately 16.25 lbs. for the 5 day mission. With use of this invention, this may be reduced to 1 MRE per 24-hour period, reducing total MRE weight to 8.125 lbs. Each supplement powder packet weighs 8 oz., and the estimated consumption during a mission is 2 packets per day (16 oz), so total supplement weight for 5 days is 5 lbs. Thus, use of the invention would reduce total meal weight by 3.125 lbs. To put this in perspective, a single, loaded rifle magazine weighs about 1.2 lbs. This would allow the SO to carry an additional 2.6 magazines, or approximately 78 rounds of ammunition without a weight penalty.

During long duration movements that preclude consuming food and especially during long duration kinetic engagements, SOs can use this invention to continuously consume appropriate sustainment while simultaneously shooting, moving, and communicating. This method of sustainment lends itself to extended combat endurance with zero detrimental effect on combat security and operability.

Contrary to high-sugar commercially available supplements meant for short duration burst activity typically found in sporting events, this invention provides long duration nutritional sustainment tailored to the dismounted environment in which SOs are carrying gear loads in excess of 70 lbs. for days, not hours. Avoiding insulin spike and crash is vital to mission success in this unique group of military warfighters.

Being able to utilize this invention in a government issued liquid bladder system in any variety of environments without it rendering the equipment unusable because of molding or souring ensures equipment sustainment and unfettered use of the hydration system. SOs incur significant operational risk by introducing currently available water-soluble supplements into bladders systems and typically will not carry sealed aluminum canned drinks because of pack weight and volume restrictions.

Preliminary Data from the Invention

Subjects: A convenience sample of senior level SOs ages 25–33 with more than ≥8 years of experience volunteered to participate in this field-testing event. Each participant served as their own control. Participants testing this supplement (invention) during a rucksack march outdoors under similar conditions.

Methods: The Dependent Variables measured were: satiety (hunger/fullness), perceived physical exertion, taste, urine color (measure of hydration status), and urine frequency (total urine volume) **(Table 1)**. Subjects completed the same ruck march two times; once using only plain water, and once using the supplement solution (invention) only. The supplement solution was prepared as follows: Subjects were instructed to mix one 8 oz. packet of the supplement (invention) with water for a total 100 oz. of solution in an MSR Dromedary bag, with an MSR tube and mouthpiece, similar to a standard camelback. Each participant consumed the same amount of water (Day 1) and the supplement (invention) on Day 2 at 30-minute intervals during the training event. Participants were instructed to eat the same meals for Day 1 and Day 2. For this field investigation, participants ruck marched 10 miles, reaching a 3,600-foot elevation gain, wearing a 70 lb. pack on their back. Subjects recorded starting and ending bodyweight and total urine output, both of which are indicators of hydration status. Participants reported that the temperature during Day 1 was 80 degrees Fahrenheit (F) while the patrol event (Day 2) temperature was 60 degrees F. Although temperature varied from Day 1 to Day 2 participants consumed the same quantities of fluid at the same time intervals. Although temperature varied significantly between Day 1 and Day 2, SOs are routinely required to wear personal protective equipment (PPE) which may contribute to heat injuries even when environmental conditions alone do not impose a significant threat and when wet-bulb globe temperatures are as low as 65 degrees F.

Table 1. Outcomes

Outcome	Source	Time collected
Bodyweight	Digital Scale	Pre and Post event
Satiety (hunger/fullness)	After Action Report (AAR)	During 10-mile event
Physical Exertion	Rating of Perceived Exertion Scale	During 10-mile event
Taste	AAR	During 10-mile event
Urine color (Hydration status)	Urine test strips	Pre, during, and post 10-mile event
Urine frequency	Urine measured container	During 10-mile event
Total Urine Volume	Urine measured container	Pre, during, and post 10-mile event

Results

At the completion of all testing participants completed an After-Action Report (AAR), which included both qualitative and quantitative outcome measures (**Table 2**). During the events participants reported that when they started to feel hungry they immediately consumed 8 ounces (oz) of the supplement (invention) which reduced their feeling of hunger significantly more than water. This was an unexpected and newly reported outcome. Additionally, participants did not experience stomach cramping, discomfort or any other negative side effects after consuming the supplement (invention). Participants in this test group reported that they do not like to drink sugary drinks during prolonged missions and that the taste of this supplement (invention) was pleasurable to their palate, which increased their desire to drink more of the supplement (invention) throughout the event. Three participants reported that they do not like consuming processed drinks during training or prolonged missions and that they typically will dilute the drink by 50% to get a lighter taste for better palatability.

Bodyweight (BW)

Participants pre and post bodyweights were self-reported and measured on a digital scale. Bodyweight is an important measure, as a 2% loss of BW impairs cardiovascular and temperature regulation, which may result in decrements in physical performance [7]. Weight loss during the training event/exercise represents lost body water, which is indicative of hydration status. Day 1, participants measured BW 2 hours prior to starting the 10-mile training event and consumed only water. Immediately after the event participants weighed themselves and reported a mean loss of 5.4 pounds (lbs.), which equated to a greater than 2% BW loss indicating that they were dehydrated. On day 2, participants measured BW 2 hours prior to starting the 10-mile training event and consumed the supplement (invention) and reported a mean loss in BW of 2.2 lbs. This is indicative of maintaining adequate hydration levels throughout the training event.

This is a positive trend that demonstrates the possible hydration and performance benefits of the supplement (invention), especially in this unique population where heat illness is highly prevalent. Although consistent water consumption plays a major role in preventing heat injury, it may not be sufficient by itself to prevent illness and may actually cause a condition known as hyponatremia, defined by a serum sodium concentration of less than 135 mmol/L. Sports drinks containing carbohydrates, as well as sodium and chloride ions are frequently recommended to increase water absorption and retention, and prevent dangerous drops in serum sodium levels [8].

Hydration

Participants reported an overall higher urine volume after consuming the supplement (invention) when compared to water alone. One participant indicated that he urinated twice before starting the training event after he consumed the supplement (invention), otherwise he reported that his urine frequency and volume would have been even more. Higher urine volume implies that enhanced absorption occurs in the small intestine. This is an unexpected outcome and suggests that the supplement (invention) may prevent dehydration during similar events that SOs encounter during long patrol missions, as urine frequency is a valid indicator of hydration status. The higher urine frequency may imply that the supplement (invention) may be absorbed at faster rates in the small intestine, which consist of three functionally defined sections: the duodenum (closest to the stomach), the jejunum (midsection), and the ileum (closest to the colon). Although, we did not check for absorption location during these field events, this deserves further exploration. Glucose contained in the supplement is primarily absorbed in the duodenum and jejunum by the sodium-dependent transporter (SGLT 1) in conjunction with two sodium ions. In contrast to other sports drinks containing sugars (mostly absorbed in the duodenum), research is needed to determine if the longer carbohydrate (CHO) chains in this supplement (invention) may decrease digestion in the duodenum/jejunum and allow for more of the CHO to reach the ileum, which may result in a slower and more sustained release of glucose, supporting energy status as well as cognitive function [8].

In this specialized population of SOs maintaining hydration, energy, and performance is critical during war and training, because military personnel are routinely exposed to a variety of environmental conditions that can alter judgement and physical performance and even result in death. For example, when a SO suffers from a heat-related illness of any kind, an estimated four members of the unit/platoon are needed to carry that member any distance to safety. Therefore, use of this supplement (invention) could ameliorate heat illness among SOs, thereby reducing exertional heat illness (EHI) and improve field performance [1,5,8]. Based on the results of this small cohort supplement (invention) could not only prevent heat injuries in this specialized population but could ultimately save lives.

Physical Performance Outcomes

Participants who consumed the supplement (invention) during the training events reported overall lowered ratings of perceived effort during the training event compared to water (**Table 2**). For example, participant's average rating of perceived effort was16 out of 20 (Hard to Very hard) when consuming water during the training event and 12 out of 20 (Fairly light to Somewhat hard) when consuming the supplement (invention). The lowered perceived effort

reported by participants who consumed the supplement (invention) may be related to adequate hydration levels (euhydration). This finding is may be important, as hypohydration (lower than normal volume of water in the body) is known to alter cardiovascular function. Specifically, it causes the heart rate (HR) to increase in an attempt to maintain cardiac output (CO) as stroke volume (SV; the amount of blood pumped from the heart per contraction) decreases (thus; CO=HR x SV). One of the primary determinants of blood pressure is CO; therefore, altered CO affects blood pressure and exercise heart rate regulation [8].

Subjective Outcomes (GI issues, taste, and hunger)

Participants reported that the supplement staved off hunger significantly during the 10-mile march, compared to water alone. The supplement (invention) was compared to water during each event since water is the primary recommended hydration solution for military personnel assuming that SOs have access to MRE's during prolonged missions.

Participants reported no souring of the supplement (invention) in the MSR Dromedary bag and reported no signs of bacterial growth in the tube or mouthpiece during the event. During and post training, event participants reported no ill effects from the supplement (invention) such as GI tract issues. Participants reported that the taste was moderately sour but they would not change the taste at the expense of the supplement's (invention) efficacy in staving off hunger and improving their overall performance levels. Additionally, they endorsed the consumption of this supplement ad libitum during prolonged missions, and felt the most beneficial effect was the supplement's ability to stave off hunger during the training event. Further, they stated that because this supplement is not simply another water sweetener they would endorse its use during both hot weather training and sustained missions, for all SOs.

Limitations / Future Directions: There were several important limitations to this preliminary investigation: 1) There were only 5 subjects, too few to draw any statistically meaningful conclusions; 2) The temperature was 20 degrees F cooler on the second day of the exercise, and no attempt was made to randomly assign supplement vs. water on each day to control for this; 3) There was no recovery period between Day 1 and Day 2, so any effects on performance that may have resulted from having done a 10 mile, heavy ruck march the previous day were not controlled for; 4) No baseline physical physiological testing was done prior to day 1 to account for any significant differences in fitness among subjects. Nonetheless, these preliminary findings are important because they suggest that further research is feasible. Due to the nature of the SO population and their mission, it is extremely important that any potential countermeasure for meeting the nutritional challenges encountered during SUSOPS be investigated, hence the need to protect this invention while it is being studied.

Table 2. Outcome Measures

Dependent Variable (s)	Water	Supplement (Invention)
Bodyweight[1]	Pre= 177.6 Post= 172.2 (-5.4 lbs.)	Pre=177.2 Post= 175.0 (-2.2 lbs.)
Mean urine color[2]	3 (hydrated)	2.5 (hydrated)
Mean urine volume[3]	34 ounces	48 ounces

Mean Rating of Perceived Exertion (RPE)[4]	16 (Very hard)	12 (Fairly light)
Mean urine frequency[5]	6	11

[1]**Bodyweight**: taken before and after exercise and over the course of days at consistent times, can give a general indication of sweating rates and fluid requirements.
[2]**Urine color:** The lower number on a scale of 1 (very pale yellow to clear is normal and indicates that a subject is well hydrated) – the higher number on a scale of 8 (brownish-green indicates a subject is severely dehydrated).
[3]**Urine Volume:** Greater urine volume may indicate higher absorption rates in the small intestine to maintain and prevent dehydration.
[4]**Ratings of Perceived Exertion (RPE):** Is a valuable indicator in monitoring an individual's exercise tolerance. Often used while conducting graded exercise tests, perceived exertion ratings correlate highly with exercise heart rates and work rates. RPE was developed to allow the exerciser to subjectively rate his/her feelings during exercise, taking into account personal fitness level, environmental conditions, and general fatigue levels. The original scale of 6 (Very, very light effort) to 20 (Very, very hard effort) provides exercisers of all fitness levels with easily understood guidelines regarding exercise intensity. RPE is highly correlated to exercise heart rates and is a valid indicator of exertion.
[5]**Urine frequency:** a valid indicator of hydration status. For example, a subject that urinates five times in a 24-hr period is well hydrated compared to a subject that urinated three times in a 24-hr period.

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