

NUTRITIONAL SUPPLEMENTS

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This paper was presented as part of the NSCA Hot Topic Series.

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DIETARY SUPPLEMENTS: A BACKGROUND

Nutritional supplements are those items that we commonly refer to as a “dietary supplement”. Congress defined the term “dietary supplement” in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product taken by mouth that contains a “dietary ingredient” intended to supplement the diet. The “dietary ingredients” in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet (in other words, the “food” must be labeled as a dietary supplement). Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of “foods,” not drugs, and requires that every supplement be labeled a dietary supplement 7, 10-11.

The intended use of a product guides what regulatory category the product falls under, food, drug, or cosmetic, and thus how it will be regulated. Intended use may be established in a number of ways. Among them are: 1) Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials. Certain claims may cause a product to be considered a drug, even if the product is marketed as if it were a dietary supplement. 2) Consumer perception, which may be established through the product's reputation. This means asking why the consumer is buying it and what the consumer expects it to do. 3) Ingredients that may cause a product to be considered a drug because they have a well-known (to the public and industry) therapeutic use^{1, 3, 6, 9}.

The Nutrition Business Journal has estimated that the dietary supplement business generated \$18.8 billion dollars in 2003 (the nutrition industry as a whole is considered to be a \$62 billion dollar industry) (11, 12). The “sports nutrition and weight loss” segment is currently thought to generate \$14 billion dollars, however there is a cross over of specific types of foods or drinks into this dollar amount as noted by the respected Nutrition Business Journal 14, 15.

REGULATION OF DIETARY SUPPLEMENTS

Dietary supplements are regulated by the Food and Drug Administration (FDA) within the confines of the 1994 Dietary Supplement Health Education Act (see <http://www.cfsan.fda.gov/list.html> for more detailed information). The FDA does mandate that all dietary supplement labels contain the following phrase “ This product is not intended to diagnose, treat, cure, or prevent any disease”. According to the DHSEA 1994 law, dietary supplement labels



must identify the strength of the product and the manufacturing must meet certain quality controls for purity and composition. Currently, many companies are ascribing to follow Good Manufacturing Practicing (GMPs) guidelines prior to GMPs being written into law^{13, 17}.

FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products. Under DSHEA, a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. This means that dietary supplements do not need approval from FDA before they are marketed. Except in the case of a new dietary ingredient, where pre-market review for safety data and other information is required by law, a firm does not have to provide FDA with the evidence it relies on to substantiate safety or effectiveness before or after it markets its products.

The marketing and advertising of dietary supplements is regulated by the Federal Trade Commission (see: www.ftc.gov). The Federal Trade Commission has taken action against dietary supplement companies for making unsubstantiated claims and these FTC actions appear to be occurring at a greater frequency, which is good for the public^{13, 19}.

The American Dietetic Association has developed guidelines concerning the recommendation and sale of dietary supplements as well as the ethics concerning these ^{12, 13, 16}. It is recommended that all dietetic and nutrition/health professionals read these papers and codes as to become aware of what is the current thought in evaluating dietary supplements, and the current science as related to dietary supplements and how recommendations fit into the professional scope of practice. These guidelines certainly apply to other health professions as well, certainly for those whose practice includes clients who ask about or want dietary supplements.

SPORTS NUTRITION LICENSURE AND/OR CERTIFICATION

Sports nutrition is not a licensed profession. The practice of dietetics/nutrition is licensed in many states. Many organizations (e.g., The International Fitness Professional Association, International Sports Sciences Association, etc.) supply certification examinations for sports nutrition. However, none of these organizations carries the clout of the International Society of Sports Nutrition (www.sportsnutritionssociety.org the only academic, non-profit organization that is dedicated to sports nutrition). Many Registered Dietitians automatically meet the scope of licensure guidelines, while others who want to practice sports nutrition will need to consider the alternative licensure or certification routes.



Sports nutrition is a complex field, and as it is believed, a good sports nutritionist has core competencies in nutrient metabolism (biochemistry and metabolism), exercise physiology, and psychology. Athletes today are demanding that his or her nutrition coach understand their sports. The traditional learning model has included basics of anaerobic and aerobic metabolism, but not much emphasis on sport-specific energy expenditure, nor the influence of post-exercise oxygen consumption (EPOC – thermic effect of exercise) or the specialty needs of post-exercise nutrition^{2, 5, 18}. Thus, advanced learning beyond that of a baccalaureate degree should be pursued. If you have or are pursuing a degree in the exercise sciences, consider a Masters degree or a minor in nutrition with an emphasis on the applied courses. The need for advanced education is evident, whether it is in the form of continuing education or a legitimate advanced degree certification (perhaps analogous to a Certified Strength & Conditioning Specialist).

Sports nutrition is often considered within the field to have divergent thought leaders. We know that since the science is evolving and not all keep up to date with the latest publications (journals or texts), not all of us are on the same advising page. Perhaps controversy is good. If we all were of the same opinion, then what would be the motivation for progress and the pursuit of new knowledge? Take for example the heated arguments that occur just over the protein needs of athletes as compared to sedentary folk, as well as anaerobic versus aerobic athletes. This alone drives the sales of many books and magazines. However, one needs to be cognizant that athletes often view food as one means of obtaining their goals, while ergogenic aids at times are believed to be the missing link. In this situation, knowledge about the safety and efficacy of ergogenic aids is paramount in truly helping your clients. As an aside, the NSCA, ACSM and certainly the ISSN all have educational tracks, seminars and other opportunities to learn about the research and the findings as surrounding sport-specific dietary supplements¹².

POPULAR DIETARY SUPPLEMENTS IN SPORT

Creatine - Creatine has probably made the biggest impact on the sports nutrition landscape. To date, there are over 500 studies on this ergogenic aid. To date, the most promising strategies to augment gains in muscle size and strength appear to be consumption of protein-carbohydrate calories before and after resistance exercise, and creatine supplementation. Short-term creatine supplementation (e.g. 20 g/day for 5-7 days) has typically been reported to increase total creatine content by 10-30% and phosphocreatine stores by 10-40%. Short-term creatine supplementation has been reported to improve maximal power/strength (5-15%), work performed during sets of maximal effort muscle contractions (5-15%), single-effort sprint performance (1-5%), and work



performed during repetitive sprint performance (5-15%). No study to date has found an ergolytic effect of creatine. Creatine supplementation during training has been reported to promote significantly greater gains in strength, fat free mass, and performance primarily of high intensity exercise tasks. Not all of the studies examining athletic uses demonstrate an ergogenic effect; approximately 30% do not support the agent, although some report non-significant positive effects or influence of creatine monohydrate²¹⁻²⁸. Future research will determine what dose may be best for athletic uses. Also, as food science evolves, stabilized liquid forms of creatine for ease of use are expected to be developed¹⁹.

The popular media as related to creatine often discusses adverse or potential side effects. The only universal (or common) side effect reported from clinical studies in preoperative and post-operative patients, untrained subjects, and elite athletes have been weight gain. However, a number of concerns about possible side effects of creatine monohydrate supplementation have been mentioned in lay publications, supplement advertisements, and on the Internet. It should be noted that these claims of “unsafe” have not been substantiated in any prospective creatine monohydrate study. Unfortunately, many of these concerns have recently received significant media coverage thus they are worthy of discussion.

Since creatine is an amino acid, it has been suggested that creatine monohydrate supplementation may affect kidney and/or liver function. However, no studies have reported clinically significant elevations in kidney function markers or liver enzymes in response to creatine monohydrate supplementation. No study has found that creatine monohydrate supplementation has any negative effects on athletes (medical markers of safety) who participate in outdoor summer-type sports.

There have been some reports that creatine monohydrate supplementation may promote a greater incidence of muscle strains or pulls. No study however has found this to be true²⁶.

Beta-hydroxy-beta methylbutyrate (HMB) is a purported anti-catabolic agent. HMB is a downstream metabolite of the branched chain amino acid leucine. A recent meta-analysis concluded that HMB along with creatine are two dietary supplements that have substantial evidence indicating a positive effect on lean mass accretion when used with resistance exercise. However, the meta-analysis and most of the studies published on HMB have been conducted by the patent holder(s) and/or staff of the company who distributes HMB (MTI Biotech). Independent studies have found either no effect for enhancing lean body mass or only minor protective effects against stress induced muscle damage (as measured by changes in creatine phosphokinase and/or lactate dehydrogenase: CPK, LDH as markers of muscle damage). More research is needed in order to determine if there is



a true benefit for aerobic (no current research exists for examining the effect of HMB on time to exhaustion or respiratory quotient during exercise) athletes or for anaerobic athletes as an anti-catabolic agent¹⁹.

Multivitamins/minerals – Multivitamins and minerals are very popular with athletes. In fact, it has been found that approximately 45 to 47% of secondary school, collegiate and commercial gym attendees (athletically involved) take multivitamins with minerals daily. Although, none appear to positively influence performance, the major reason people take these are in an attempt to maximize their diet^{4, 8, 20}.

Protein Shakes/bars/meal Replacements - A brief review of protein needs of athletes reveals that the current recommended intakes of protein for strength and endurance athletes are 1.6 to 1.7 g/kg and 1.2 to 1.4 g/kg per day, respectively. Presently, most athletes consume an adequate amount of protein in their diet. However, depending upon overall caloric needs and the reality of obtaining all nutrition from foods alone will dictate the needs for protein supplementation. The timing and nutritional content of the post-exercise meal, although often overlooked, are known to have synergistic effects on protein accretion and glycogen repletion after exercise. New evidence suggests that individuals engaging in strenuous activity should be consuming a meal rich in amino acids and carbohydrate soon after the exercise bout or training session.

Meal timing has also been shown to have an effect on muscle protein synthesis (MPS). Affecting MPS may allow the downstream creation of new muscle mass (lean body mass). Recent data indicate that consuming a small meal of mixed macronutrient composition (or perhaps even a very small quantity of a few indispensable/essential amino acids) immediately before or following strength exercise bouts can alter significantly net protein balance, resulting in greater gains in both muscle mass and strength than observed with training alone. With aerobic exercise, some evidence suggests immediate post-exercise (but perhaps not pre-exercise) supplementation is also beneficial. Second, protein type may also be important owing to variable speeds of absorption and availability, differences in amino acid and peptide profiles, unique hormonal response, or positive effects on antioxidant defense. In addition to athletes, many others who desire to regain, maintain, or enhance muscle mass or function, including those with muscle-wasting diseases, astronauts, and all of us as we age, need to ensure that nutrient availability is sufficient during the apparently critical anabolic window of time associated with exercise training sessions. The additional data compiled from the cumulative studies examining the effects of low dose essential amino acids with or without carbohydrate (sucrose) indicate that the prudent use of supplemental protein may be the easiest way to augment the MPS response post-exercise. Since post-exercise carbohydrate intake alone does not



affect MPS, but essential amino acids do, there is much more to learn about post-exercise nutrition. Future studies are needed to fine-tune these recommendations^{19, 20}.

In conclusion, nutritional supplements are considered to be foods, but should be viewed by any coach, trainer or dietitian as something to use after maximizing the diet. In other words, eat real foods first, use fortified foods second and compliment the aforementioned with supplements when necessary, but never in place of eating a good, smart diet.



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