

Forté
Trauma[™]

Science-based, Targeted
Nutritional Support for Trauma Recovery

RECOVER

trauma product

Addressing the Nutritional Needs of Trauma Patients

Trauma incites a stress response—a variety of physiologic and metabolic responses, including decreased immunity, increased inflammation, increased levels of stress hormones, increased catabolism, and decreased anabolism. All of these stresses contribute to increased protein and energy requirements after acute traumatic injury—whether accidental or secondary to surgery—and may increase the risk of poor nutrition status, which is also linked to poorer outcomes and an increase in complications such as infection and slow wound healing.^{1,2} Supporting trauma patients with key nutrients post-injury or post-surgery may help them recover more quickly.

Figure 1. Systemic responses to surgery or trauma³

Sympathetic nervous system activation	Endocrine 'stress response'	Immunological and haematological changes
	<ul style="list-style-type: none"> • pituitary hormone secretion • insulin resistance 	<ul style="list-style-type: none"> • cytokine production • acute phase reaction • neutrophil leucocytosis • lymphocyte proliferation

Importance of Post-Traumatic Nutritional Support

The stress response to trauma or surgery is characterized by increased secretion of pituitary hormones and activation of the sympathetic nervous system.⁴ These pituitary hormones exert downstream effects on target organs, increasing cortisol secretion from the adrenal cortex and stimulating glucagon release from the pancreas, among other responses. Cortisol promotes gluconeogenesis, lipolysis, and protein breakdown and inhibits the accumulation of macrophages and neutrophils in areas of inflammation. The net metabolic effect of stress response-related hormonal changes is increased catabolism, which mobilizes substrates for energy and triggers mechanisms to maintain cardiovascular homeostasis.³

The increased nutritional needs associated with trauma may be exacerbated among elderly patients who have an increased baseline risk for malnutrition due to decreased lean body mass and a variety of other factors that may compromise nutrient and fluid intake. For these patients, oral nutritional supplements may enable an immediate and significant increase in energy and nutrient intake. While the elderly may be at higher risk for malnutrition, nutritional deficiencies are common among the general population as well, underscoring the need for appropriate nutrient support following surgery or other trauma.

1– Souba WW, Wilmore D. Diet and nutrition in the care of the patient with surgery, trauma, and sepsis. In: Shils M, Olson J, Shike M, Ross AC, editors. Modern nutrition in health and disease. 9th ed. Baltimore, MD: Williams & Wilkins; 1999. p. 1589-618.

2– Burden S, Todd C, Hill J, Lal S. Preoperative nutrition support in patients undergoing gastrointestinal surgery. Cochrane Database Syst Rev 2012 Nov 14;11:CD008879. doi: 10.1002/14651858.CD008879.pub2.

3– Desborough JP. The stress responses to trauma and surgery. British Journal of Anaesthesia 2000;85:109-117.

4– Desborough JP, Hall GM. Endocrine response to surgery. In: Kaufman L. Anaesthesia Review, Vol 10. Edinburgh: Churchill Livingstone, 1993:131-148.

And yet, physicians often forget to consider nutritional status or dietary supplementation to facilitate the recovery of patients from trauma. In fact, surgeons routinely advise their patients to stop taking nutritional supplements at least two weeks prior to scheduled surgery. This is due, in part, to the popularity of complementary and alternative medical treatments such as herbal supplements that may have serious and potentially harmful side effects when combined with medications commonly prescribed for surgical and trauma patients.¹ However, studies in gastrointestinal surgery and other surgical situations have shown the importance and benefits of nutritional support.^{2,3}

Figure 2. Hormonal responses to surgery or trauma⁴

Endocrine gland	Hormones	Change in secretion
Anterior pituitary	ACTH	Increases
	Growth	Increases
	TSH	May increase or decrease
	FSH and LH	May increase or decrease
Posterior pituitary	AVP	Increases
Adrenal cortex	Cortisol	Increases
	Aldosterone	Increases
Pancreas	Insulin	Often decreases
	Glucagon	Usually small increases
Thyroid	Thyroxine, tri-iodothyronine	Decrease

Key Nutritional Needs for Trauma Patients

Post-surgical wound healing and other acute trauma represent an anticipated drain on a patient's nutritional stores, which may already be suboptimal. In a prospective study of 500 patients admitted to a teaching hospital, including 200 surgical patients, 40 percent of patients were found to be undernourished at the time of admission.⁴ Supplementation with a targeted combination of critical vitamins, minerals, amino acids and trace elements can help patients recover from the physiological and metabolic stress of surgery or other trauma.

Vitamin C

In addition to acting as an antioxidant to protect cells from free radical damage, vitamin C is essential for normal immune system function, iron absorption, and production of collagen, a critical protein for wound healing. Due to its many biochemical functions, vitamin C is considered not only an essential micronutrient for maintaining health, but also an important therapeutic supplement in a variety of clinical conditions.⁵

According to the U.S. Centers for Disease Control and Prevention's most recent National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population, approximately six percent of Americans are deficient in vitamin C.⁶ Acute trauma compounds this problem by lowering blood vitamin C concentration, likely due to increased demand caused by redistribution and increased oxidative stress. In a small study of patients who underwent uncomplicated

1– Rispler DT, Sara J. The impact of complementary and alternative treatment modalities on the care of orthopaedic patients. *Journal of the American Academy of Orthopaedic Surgeons* 2011;19(10):634-643.

2– Akbarshahi H, et al. Perioperative nutrition in elective, gastrointestinal surgery – potential for improvement? *Dig Surg* 2008;25:165-174.

3– Lugli AK, Wykes L, Carli F. Strategies for perioperative nutrition support in obese, diabetic and geriatric patients. *Clinical Nutrition* 2008;27:16-24.

4– McWhirter JP, Pennington CR. Incidence and recognition of malnutrition in hospital. *BMJ* 1994;308(6934):945.

5– National Institutes of Health. Vitamin C – Fact Sheet for Consumers. Available at <https://ods.od.nih.gov/factsheets/VitaminC-Consumer/>.

6– U.S. Centers for Disease Control and Prevention. Second National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population 2012, Executive Summary. Available at http://www.cdc.gov/nutritionreport/pdf/exesummary_web_032612.pdf.

gastrectomy for gastric cancer, blood concentration of vitamin C decreased post-operatively and the reduction persisted for at least seven days following surgery.¹ As a result, doses much higher than the recommended daily allowance may be needed to normalize plasma and tissue vitamin C concentration in trauma patients.

Consumption of fruits, vegetables and plant foods is typically the main source of vitamin C.² Relatively high doses of supplemental vitamin C, combined with other trace elements, have been shown to dramatically accelerate wound healing. Most multivitamin preparations available in the U.S. contain approximately 200 mg of vitamin C. However, in uncomplicated surgery patients, more than 500 milligrams per day of vitamin C supplementation may be required to support wound healing. In cardiac surgery patients, vitamin C supplementation may prevent post-operative atrial fibrillation.^{2,3} Recently, it was shown that oral vitamin C supplementation, in association with beta-blockers, was more effective in preventing post-operative atrial fibrillation than beta-blockers alone.⁴

Vitamin D and Calcium

Vitamin D and calcium are the key nutrients for musculoskeletal development, maintenance and function, which are vital for the success of bone-related surgeries. Low vitamin D and poor bone mineral density may be significant factors in instrumentation failure, loss of deformity correction, adjacent fractures and the need for revision surgery.⁵ Research has shown that the active form of vitamin D—cholecalciferol, or 1,25-dihydroxyvitamin D₃— may help to enhance wound healing.⁶ In addition, calcium plays an important role in skin homeostasis and studies have shown an increased need for calcium to promote key events in the wound healing cascade.⁷

The body can produce vitamin D when exposed to sunlight, but calcium must be absorbed from food and requires vitamin D for absorption. While the Food and Nutrition Board (FNB) recommends a daily Vitamin D requirement of 600 IU, recent research indicates that the body needs at least 1000 IU per day to support optimal bone health and the Institute of Medicine has determined a safe daily upper limit of 4000 IU.⁸

Nearly one-third of the general population, and more than 50 percent of general medicine patients, have been found to have vitamin D inadequacy.⁹ Studies demonstrate that the majority of patients undergoing elective orthopedic surgery are deficient in vitamin D.^{10,11} Restoring vitamin D to appropriate levels may significantly improve outcomes following surgery.

Protein

As part of the stress response to acute trauma, protein catabolism is stimulated by increased cortisol concentrations, resulting in the breakdown of skeletal and visceral muscle to release amino acids, which may be further catabolized for energy or used in the liver to either form acute phase proteins or be converted into glucose, fatty acids, ketone bodies, or other substrates.¹²

1- Fukushima R, Yamazaki E. Vitamin C requirement in surgical patients. *Current Opinion in Clinical Nutrition and Metabolic Care* 2010;13(6):669-676.

2- Lugli AK, Wykes L, Carli F. Strategies for perioperative nutrition support in obese, diabetic and geriatric patients. *Clinical Nutrition* 2008;27:16-24.

3- National Institutes of Health. Vitamin C – Fact Sheet for Consumers. Available at <https://ods.od.nih.gov/factsheets/VitaminC-Consumer/>.

4- Eslami M, et al. Oral ascorbic acid in combination with beta-blockers is more effective than beta-blockers alone in the prevention of atrial fibrillation after coronary artery bypass grafting. *Tex Heart Inst J* 2007;34:268-274.

5- Patton CM, Powell AP, Patel AA. Vitamin D in orthopedics. *Journal of the American Academy of Orthopedic Surgeons* 2012;20(3):123-129.

6- Tian XQ, Chen TC, Holick MF. 1,25-dihydroxyvitamin D₃: a novel agent for enhancing wound healing. *Journal of Cellular Biochemistry* 1995;59:53-56.

7- Lansdown, ABG. Calcium: a potential central regulatory in wound healing in the skin. *Wound Repair and Regeneration* 2002;10(5):271-282.

8- Ross CA, et al. Consensus Report: Dietary Reference Intakes for Calcium and Vitamin D. Washington, DC, Institute of Medicine of the National Academies, 2010: Available at <http://iom.nationalacademies.org/Reports/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D.aspx>.

9- Holick MF. High prevalence of vitamin D inadequacy and implications for health. *Mayo Clin Proc* 2006;81:353-373.

10- Stoker GE, et al. Preoperative vitamin D status of adults undergoing surgical spine fusion. *Spine* 2013;38(6):507-515.

11- Fisher A, et al. Hip fracture type: important role of parathyroid hormone (PTH) response to hypovitaminosis D. *Bone* 2010;47(2):400-407.

12- Desborough JP. The stress responses to trauma and surgery. *British Journal of Anaesthesia* 2000;85:109- 117.

Since the stress of surgery or other trauma creates a hypermetabolic state with increased protein and energy demands, supplemental protein is also beneficial for post-operative and acute trauma patients.¹ Essential amino acids play a crucial role in protein synthesis and muscle tissue repair. These amino acids are not produced or stored in the body, so they must be obtained through diet or supplementation. Specifically, L-arginine is an amino acid that has been shown to stimulate wound healing, while L-glutamine restores cellular energy stores and enhances the bactericidal function of neutrophils.² In clinical studies, patients given L-arginine supplementation after major surgery benefited from a faster recovery of immunological parameters and fewer infectious complications.³

Randomized clinical trials of patients undergoing surgery for hip fracture demonstrated that providing post-operative energy-protein supplements resulted in better recovery plasma proteins and fewer post-operative complications, even among patients with normal pre-operative nutrition status.^{4,5} In addition, a recent study showed that amino acid supplementation assisted with surgical recovery in patients who had undergone total knee arthroplasty, as demonstrated by attenuated muscle atrophy and accelerated return to functional mobility.⁶

Other Nutrients

Other vitamins, trace elements, and compounds are also important for trauma patients:

- Vitamin A supports immune system function and contributes to collagen strength, a necessary component of tissue repair.
- The complement of B vitamins are needed for cellular metabolism, tissue repair, and immune support.
- Zinc is an essential trace mineral used in enzymatic reactions and biochemical pathways involved in wound healing and tissue regeneration.⁷
- Copper and selenium are antioxidant minerals that support cell damage repair.
- Bromelain (a pineapple enzyme with anti-inflammatory properties) and quercetin (a phytoflavonoid with antioxidant and anti-inflammatory properties) may help reduce bruising, swelling and scarring.^{8,9}

1- Botella-Carretero JI, et al. Perioperative oral nutritional supplements in normal or mildly undernourished geriatric patients submitted to surgery for hip fracture: a randomized clinical trial. *Clinical Nutrition* 2010;29(5):574-579.

2- Furukawa S, et al. Glutamine-enhanced bacterial killing by neutrophils from postoperative patients. *Nutrition* 1997;13(10):863-869.

3- Tepaske R. Immunonutrition. *Curr Opin Anaesthesio* 1997;10:86-91.

4- Botella- Carretero JI, et al. Perioperative oral nutritional supplements in normal or mildly undernourished geriatric patients submitted to surgery for hip fracture: a randomized clinical trial. *Clinical Nutrition* 2010;29(5):574- 579.

5- Botella-Carretero JI, et al. Effects of oral nutritional supplements in normally or mildly undernourished geriatric patients after surgery for hip fracture: a randomized clinical trial. *J Parenter Enteral Nutr* 2008;32:120-128.

6- Dreyer HC, et al. Essential amino acid supplementation in patients following total knee arthroplasty. *J Clin Invest* 2013;123(11):4654-4666.

7- Desneves KJ, et al. Treatment with supplementary arginine, vitamin C and zinc in patients with pressure ulcers: a randomized controlled trial. *Clinical Nutrition* 2005;24:979-987.

8- MedlinePlus. Bromelain. Available at <http://www.nlm.nih.gov/medlineplus/druginfo/natural/895.html>.

9- WebMD. Quercetin. Available at <http://www.webmd.com/vitamins-supplements/ingredientmono-294-quercetin.aspx?activeingredientid=294&activeingredientname=quercetin>.

Meeting the Need for Appropriate Nutritional Support in the Trauma Setting

Poor nutrition status has long been linked to increases in post-operative complications and adverse outcomes in trauma patients. Despite the evidence validating the role of nutritional elements in recovering from the stress of trauma, there is a significant unmet need for high-quality, pharmaceutical-grade nutritional supplements specifically designed to support the nutritional needs of trauma patients. Mediceutical supplements address this significant unmet need by tailoring nutritional products to address specific clinical and medical conditions, using nutrients and dosages that have been validated by evidence-based research.

Forté Elements Trauma Drink is a Mediceutical developed by physicians specifically to support patients recovering from surgery or other acute trauma. Unlike nutritional supplements or nutraceuticals that lack regulatory oversight or a rigorous testing, mediceuticals are produced using pharmaceutical-grade ingredients and manufacturing practices, and undergo a scientific, transparent testing process. Forté Elements Trauma contains vitamins A, B, C and D, as well as key trace elements and a proprietary blend of amino acids, at the supplemental doses that clinical research indicates will be beneficial in trauma patients. For example, Forté Elements Trauma Drink contains 1500 mg of vitamin C to address the deficiency related to oxidative stress and surgery, as well as appropriate doses of vitamin D and L-arginine to support wound healing.

Forté Elements Trauma Drink

A significant body of research supports the relationship between nutritional status and quality of patient care, and improved attention to nutritional status may positively affect clinical outcomes. The nutritional density of hospital food is often poor and not well-targeted for specific clinical situations. Even among patients who are given nutritional support and dietary supplementation, studies have shown that conventional approaches still provide most patients with an inadequate diet.¹ Forté Elements Trauma Drink helps to bridge this gap by providing the right blend of micronutrients to support repair, recovery and restoration of the body from the myriad physiological effects of trauma.

The multi-nutrient support provided by the Forté Elements Fracture Drink provides the essential protein, natural antioxidants and anti-inflammatories, minerals, and vitamins needed for healing from physical traumatic events.

Supplement Facts

Serving Size 1 Pack (61 Grams)
Servings Per Container 42

Amount Per Serving

	% Daily Value*
Calories 125	6%
Total Fat 1g	2%
Cholesterol 30mg	10%
Total Carbohydrate 8g	3%
Dietary Fiber 1g	4%
Protein 15g	30%
Vitamin A (Beta-Carotene & Acetate) 8000 IU	160%
Vitamin C (Calcium Ascorbate) 1500mg	2500%
Vitamin D (Cholecalciferol) 2000 IU	500%
Vitamin K (Fat Soluble) 75mcg	94%
Thiamin (Vitamin B1) 100mg	6666%
Riboflavin (Vitamin B2) 20mg	1176%
Niacin (Vitamin B3) 35mg	175%
Vitamin B6 (Pyridoxine) 20mg	1000%
Folic Acid 600mcg	150%
Vitamin B12 (Cyanocobalamin) 200mcg	3333%
Biotin 200mcg	67%
Pantothenic Acid 20mg	200%
Calcium 1200mg (Carbonate, Lactate, Phosphate, Ascorbate)	120%
Iron (Gluconate) 30mg	167%
Phosphorus (Calcium Phosphate) 100mg	10%
Iodine 150mcg	100%
Magnesium (Hydroxide) 350mg	88%
Zinc (Gluconate) 30mg	200%
Selenium 220mcg	314%
Copper (Gluconate) 4mg	200%
Manganese (Gluconate) 5mg	250%
Chromium (Polynicotinate) 50mcg	42%
Sodium 200mg	8%
Potassium 80mg	2%

Proprietary Blend 15.9g

**
L-Arginine, L-Glutamine, L-Lysine, Strontium Citrate, Taurine, Glucosamine HCl, Quercetin, Bromelain, Oat Bran Fiber, Chondroitin Sulfate, Coenzyme Q10, Lacto-wise Probiotic Blend, Orthosilicic Acid and Boron

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs.
**Daily Value not established.

OTHER INGREDIENTS: WHEY PROTEIN CONCENTRATE, SWEET WHEY, COCOA POWDER, CITRIC ACID, NATURAL VANILLA FLAVOR, STEVIA (NON-NUTRITIVE SWEETENER), AND SUCRALOSE. **CONTAINS:** MILK AND CRUSTACEAN SHELLFISH. ARTIFICIAL FLAVORS.

THIS IS A GLUTEN FREE PRODUCT

WARNING: ACCIDENTAL OVERDOSE OF IRON-CONTAINING PRODUCTS IS A LEADING CAUSE OF FATAL POISONING IN CHILDREN UNDER 6. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, CALL A DOCTOR OR POISON CONTROL CENTER IMMEDIATELY.

THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FDA. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE

1- Duncan DG, et al. Using dietetic assistants to improve the outcome of hip fracture: a randomized controlled trial of nutritional support in an acute trauma ward. *Age and Aging* 2006;35:148-153.



Access to Quality, Pharmaceutical-Grade Nutritional Supplements

The abundance of clinical research validating the role of nutritional elements in recovering from physical trauma is counterbalanced by the lack of high-quality, pharmaceutical-grade nutritional supplements specifically designed to support the nutritional needs of trauma patients. Mediceutical supplements address this significant unmet need by tailoring nutritional products to address specific clinical and medical conditions, using elements and dosages that have been validated by evidence-based research.

Mediceutical supplements like Forté Elements Trauma were developed by physicians specifically to support patients recovering from traumatic physical events. Mediceuticals are an emerging category of nutritional products that have been specifically formulated to support specific health conditions or situations. Unlike nutritional supplements or nutraceuticals that lack regulatory oversight or a rigorous testing, Mediceuticals must meet the following requirements:

1. Be formulated to support a specific health condition or situation
2. Contain only non-synthetic, pharmaceutical-grade ingredients that are Generally Recognized as Safe (GRAS)
3. Contain elements that have been validated by clinical research for the specific health condition or situation, as published in peer-reviewed journals
4. Conform to pharmaceutical-grade dosage standards for the specific health condition or situation
5. Be produced in FDA-compliant manufacturing facilities using pharmaceutical-grade manufacturing practices
6. Product has a Certificate of Analysis available confirming that product ingredients meet the Mediceutical standard and are as listed on the product label.



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