



➤ Product Review ◀

January 2023 #366

NEW PRODUCT IN DEVELOPMENT ELEMENTAL SELECT – PART I INTRODUCTION

As most of you know, over the last several years, **Moss Nutrition** has evolved into a company that specializes in the improvement of quality of life in chronically ailing patients. What does this entail? Certainly, there is a focus on product development specifically geared to this population, which has yielded well-received products such as the **SarcoSelect**[®] products, which focus on the epidemic of muscle mass loss seen in the chronic illness population. Another example of this focus is the often ignored and/or underappreciated alkaline electrolyte imbalances that are very common with these patients. Product examples of this focus include **K Alkaline**, **K Alkaline + Mg**, **Magnesium Select**[™], and **Magtein**[®]. However, this focus is not limited to product development. As we all know, the efficacy of products designed to address the sometimes difficult and complex case presentations seen with chronically ill patients is uncertain at best without knowledge of how to correctly use the products with each individual, often complex patient scenario. Therefore, as I hope you are all aware by now, we have made education about assessment and treatment of chronically ill patients a major priority. This prioritization is exemplified not only by the seminars I have taught and the newsletters I have been writing for over 30 years, but the excellent webinars and protocols created by the **Moss Nutrition**

chief medical officer Dr. Hedberg, and the outstanding **Moss Nutrition Digest** publications authored by Diana Allen, MS, CNS, the product development manager for **Moss Nutrition**.

Over the years I have sometimes been asked how we prioritize which products to develop and areas of education to emphasize. The answer is actually quite simple. Emphasis in these areas is in direct response to what you, the customers, feel the greatest need is in terms of chronic illness. Over the years, where does the greatest need reside? Without question, your input has been clear – the largest single category of chronic illness concern among patients who seek care from practitioners like you is gastrointestinal dysfunction, with chief complaints ranging from gas, bloating, constipation, and/or diarrhea to more severe diagnoses such as ulcerative colitis to Crohn's disease.

With this feedback in mind, we have created a somewhat vast menu of products from which you can choose the best for the specific and unique needs of any particular patient with GI dysfunction. Furthermore, we have created a vast array of educational products on GI dysfunction from the resources mentioned above.

Concerning the products designed to support the GI dysfunction of the chronically ailing patient, we are very proud of the fact that our menu of GI-related products can address many if not most of your product-related concerns. However, the key word in the previous sentence is "most."

Over the last 4-5 years we are noticing an increased prevalence of chronic GI patients whose symptoms are so severe that almost any food or supplement they ingest can exacerbate symptoms, including the powder-based products such as **SarcoSelect® DF/EAA** and the **AminoMeal Select™** products. Therefore, it has long been a desire here at Moss Nutrition to design a meal replacement product that can be used for a short time with these difficult, long-suffering patients to not only help reduce inflammation but stimulate repair and, so to speak, “give the gut a rest.”

ENTERAL NUTRITION – A MOSS NUTRITION HISTORICAL PERSPECTIVE

Interestingly, the need for short-term total meal replacement has been recognized for several years for severe, acute illness, hospital-based patient populations. Therefore, such products that fit under the collective term “enteral nutrition” are quite prevalent for in-patient, hospital use, all of which are ingested either orally by the patient or via tube feeding. In contrast, enteral nutrition products designed for out-patient home use and are, therefore, not only nutritionally replete but pleasant tasting and reasonably priced are quite rare in the professional supplement community.

With the above in mind, we at Moss Nutrition have been experimenting with different formula concepts for the last 3-4 years that would fit all the above criteria:

- Nutritionally replete from both a nutrient and caloric standpoint so as to meet the daily nutritional needs of the chronic GI patient with no requirement for additional solid or liquid food.
- Pleasant tasting
- Reasonably priced

We are now in the final stages of development of this product, which will be named **Elemental Select™**. Our hope is that we can make it available to you before the summer of 2023.

Given that I usually do not write about new products until they are in our warehouse and available for purchase, why am I discussing **Elemental Select™** now? Two reasons. First, because this, unlike what has long existed in hospitals, is a fairly new concept in the out-patient, functional medicine community, I wanted to take ample time before the product is released to make you aware of the significant body of published medical literature on the use enteral nutrition with severely ailing chronically ill patients experiencing conditions such as ulcerative colitis, Crohn’s disease and conditions that mimic these ailments. Second, I wanted to take ample time before the product is released to hopefully convince you, if you are not already convinced, that the chronically ailing GI dysfunction patient population that is clinically malnourished due to an inability to tolerate “healthy” solid foods and the usual meal replacement supplement is not only fairly substantial but growing in numbers, as I will point in out in the literature review that follows.

PUBLISHED RESEARCH ON NUTRITIONAL INTERVENTIONS ON SEVERE GI DYSFUNCTION WITH A FOCUS ON INFLAMMATORY BOWEL DISEASE

The first paper I would like to review on inflammatory bowel disease and how it can be addressed with enteral nutrition is “Selected aspects of nutrition in the prevention and treatment of inflammatory bowel disease” by Panufnik et al (Panufnik P et al. *Nutrients*, Vol. 14, No. 4965, published online November 23, 2022). The first quote I would like to feature from this paper emphasizes what I

stated above concerning the ever-increasing incidence of often severe inflammatory bowel disease:

“As shown by numerous analyses, the prevalence of inflammatory bowel disease increases year by year. Crohn’s disease and ulcerative colitis are increasingly diagnosed in both the pediatric and adult populations in developed as well as developing countries. At the turn of the 21st century, inflammatory bowel disease has become a global health problem. Its prevalence is on the increase in developing countries while having already exceeded the level of 0.3% in developed countries.”

As you know, many in the traditional medicine community regard inflammatory bowel disease as an entity that is largely genetic with little influence from environmental concerns. Panufnik et al make it clear that published research indicates that this position is not consistent with reality:

“The exponential increase in the incidence of IBD worldwide indicates that environmental factors that have significantly changed over the past decades play a key role in the development of inflammatory bowel diseases.”

What are these environmental factors?

“In addition to non-modifiable genetic factors, a number of modifiable factors such as gut microbiota, diet, or lifestyle have been identified. Diet shapes the gut microbiome, and it uses food ingredients for growth.”

Using enteral nutrition in the management of inflammatory bowel diseases

While Panufnik et al discuss several interventional modalities that can be used to address inflammatory bowel diseases, with **Elemental Select™** in mind I wanted to focus on the section of the paper that highlights enteral nutrition. The first quote I would like to feature gives an overview of the concept of enteral nutrition and how it is administered:

“Exclusive enteral nutrition (EEN) is the best-tested approach to nutritional management aimed at inducing remission in mild to moderate Crohn’s disease. EEN is recommended by the European Crohn’s and Colitis Organization (ECCO) and European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) as the treatment of choice in pediatric patients. The premise of exclusive enteral nutrition consists of complete liquid formula being administered to the patient as the only source of nutrition for 6 to 8 weeks. Nutrition may be administered orally or via a nasogastric tube. A response to the dietary treatment should be observed within 2 weeks. As the intervention is completed, the patient should gradually expand their diet by including solid products for the next 2 to 3 weeks.”

How well does enteral nutrition perform in terms of resolution of symptoms? It may surprise you to see that it performs as well as glucocorticosteroids:

“The efficacy of exclusive enteral nutrition in achieving clinical remissions in the pediatric population was comparable to the efficacy of glucocorticosteroids and amounted to about 80%...”

Equally interesting is the fact that exclusive enteral nutrition performed better than glucocorticosteroids in relation to mucosal healing:

“...intestinal mucosal healing was observed more frequently in patients in the exclusive enteral nutrition group.”

What is the mechanism that is responsible for improvements seen with exclusive enteral nutrition? The authors’ comment:

“Mechanisms responsible for the effectiveness of EEN include anti-inflammatory effects, recovery of the intestinal epithelial barrier, bowel rest, and modification of the intestinal microbiome.”

Of course, the quotes above relate to pediatric Crohn’s disease. What does research on

exclusive enteral nutrition demonstrate in terms of adult populations?

“The high efficacy of exclusive enteral nutrition in terms of achieving remission of Crohn’s disease in the pediatric population encourages the use of this approach in the adult population. A literature review by Wall et al. points to the comparable efficacy of EEN and glucocorticosteroids in terms of adult remissions while drawing attention to the high percentage of patients who fail to complete the treatment. Depending on the study, this could be as much as one-half of the subjects.”

Why is the compliance rate so poor for adults? As you might expect, this issue is simple and straightforward – taste and a desire for solid food:

“The low rate of compliance with EEN recommendations was usually due to the flavor of the nutritional formula and patients unwillingness to feed exclusively on it.”

Having sampled other exclusive enteral nutrition products in the professional market, I can understand why taste is one of two major factors affecting compliance. Therefore, a major focus for us in the development of **Elemental Select™** has been taste. While we will be providing single-serving taste samples for you to try before making a purchase so you can determine palatability for yourself, we are very confident that many if not most patients will report that **Elemental Select™** tastes as good or better than any other similar exclusive enteral nutrition product in the professional marketplace. Concerning the second compliance concern about the desire for solid food, we would like to propose that, given the pleasant taste of **Elemental Select™**, compliance will be so good that improvements in GI health will be rapid enough to allow patients to reintroduce solid food in a comparatively short period of time.

Of course, given the fact that patients would prefer a protocol that is composed of a combination of **Elemental Select™** and solid food, you may wonder whether use of both would give good enough results to use at the outset of the program instead of later after clinical improvements are seen with exclusive enteral nutrition. Unfortunately, outcome efficacy data does not support this approach:

“Partial enteral nutrition (PEN) combines liquid formula and solid foods. Its efficacy was examined in 2006 by Johnson et al. in a study involving 50 pediatric patients who were assigned to two study groups receiving either EEN or PEN (with 50% of the caloric demand originating from the liquid formula, and 50% from any type of oral diet as per the patient’s preference). A much higher efficacy was demonstrated for EEN as compared to PEN, with the efficacy of PEN being as low as 15%.”

Would the results have been better if the solid food portion of the diet was composed of the quality whole foods that you and I might recommend? Unfortunately, this approach was not considered in the Panufnik et al paper. However, it is my opinion that this approach would probably not improve efficacy rates given that **Elemental Select** was designed for patients who appear to experience symptoms from ingestion of virtually any solid food no matter what the quality.

Nevertheless, Panufnik et al do offer some hope in terms of a combination approach – using just a small amount of solid food along with a product such as **Elemental Select**:

“After the caloric demand met by the enteral formula in the partial enteral nutrition was increased to 80-90%, the efficacy of PEN was raised to 65% and the compliance rate was 87%. Due to the greater acceptability of PEN as compared to EEN, the former appears to be a promising option for treatment.”

With the above in mind, if your patient is adamant about resistance to exclusive use of **Elemental Select™** for any period of time, you may find that a small amount of quality solid food will not only increase compliance but be small enough as to not retard clinical improvement.

The next quote I would like to feature suggests another way to gain acceptable efficacy with a combination of solid food along with **Elemental Select™** – the use of what is known as the Crohn’s disease exclusion diet (CDED) along with **Elemental Select™**:

“Due to the unsatisfactory response to partial enteral nutrition combined with a diet of preference and the difficulties with compliance with exclusive enteral nutrition, a diet has been developed that is based on generally available foods and excludes potentially proinflammatory products. The diet is referred to as the Crohn’s disease exclusion diet (CDED). The dietary intervention aimed at achieving remission consists of two phases, each of them lasting 6 weeks. The first phase is more restrictive and assumes that 50% of the caloric demand is provided from the formula. The second half of the demand is provided from the diet which consists of obligatory products which have to be eaten every day and complementary products proven to have no negative impact on the intestinal mucosa. Compulsory products include 150 g of chicken breast, two eggs, two bananas, one apple, and two steamed and cooled potatoes. In the second phase of the CDED, the compulsory products remain unchanged while the list of complementary products is extended and the caloric demand to be provided from the formula is reduced to 25%. Avoidance of products with proven proinflammatory effects continues to be the basic premise of the diet.”

How does a diet that combines a product such as **Elemental Select™** with CDED compare to a diet consisting of a product such as **Elemental Select™** alone? As you will see in the quote below, the comparison is impressive:

“A study comparing the efficacy of exclusive enteral nutrition with a combination of the CDED and partial enteral nutrition in a pediatric population revealed a marked superiority of the CDED with PEN in terms of tolerance and compliance with no statistical differences being observed in the efficacy of the dietary interventions of interest regarding clinical remission after 6 weeks of treatment. After 12 weeks, when the dietary restrictions were loosened for EEN patients, remission maintenance was significantly higher in the CDED/PEN group.”

What about adult populations? Panufnik et al point out:

“The efficacy of the Crohn’s disease exclusion diet was also demonstrated in a population of adult subjects by Szczubelek et al. After 6 weeks of dietary intervention, clinical remission was achieved in 76.7% of patients, with the percentage increasing to 82.1% after 12 weeks of treatment. This effectiveness was also confirmed by Yanai et al. in a randomized trial on an adult population of CD patients. This study showed that both the CDED plus PEN and CDED alone were effective inducing and maintaining remission of CD.”

With the above in mind, for many of your most severe inflammatory bowel disease patients you do have options in terms of predictability of success. If your patient is willing to comply with the CDED diet, use of the diet alone or the diet in combination with **Elemental Select™** will probably, according to published research, result in clinically acceptable results.

The last quote I would like to feature from the Panufnik et al paper discusses another important aspect of use of the CDED diet alone or with a product such as **Elemental Select™**. What was the impact of each of these interventions on gut microflora? The authors state:

“The use of the CDED plus EEN, as well as EEN, resulted in changes in the composition of

the gut microbiome in patients. These changes were greater among patients who achieved disease remission during the intervention. This suggests a significant impact of the modification of the intestinal microbiome, as a result of the applied nutritional intervention, on its effectiveness.”

Still another study on exclusive enteral nutrition with inflammatory bowel diseases

Another paper that discusses the use of enteral nutrition with inflammatory bowel diseases is “Nutritional management of inflammatory bowel disease” by Rehman et al (Rehman R et al. *Rhode Island Medical Journal Archives*, pp. 31-37, December 2022). While much of the paper presents the same information as the Panufnik et al paper discussed above, it does provide some more detail on the different enteral formulas available in the nutritional marketplace:

“Different forms may be tried depending upon protein source and are classified into amino acid based (elemental), oligo/dipeptide based (semi elemental) and whole protein based (polymeric)”.

Elemental Select™, as the name suggests, is an amino acid-based elemental formula. The specific amino acid formulation consists of the nine essential amino acids plus arginine, a non-essential amino acid (Once we have finalized the complete formula, we will be sharing the total composition of the product with you. This will occur close to the time the product will be available for purchase.).

WHY WE OPTED FOR AN AMINO ACID-BASED FORMULA

As I mentioned above, **Elemental Select™** was specifically designed for patients with such severe GI dysfunction that almost any foods had a history of creating some sort of significant GI distress. This would include our protein-based products, **Select Whey® Vanilla,**

Organic Select Pea®, and **SarcoSelect® DF**. Of course, **SarcoSelect® DF** and the **AminoMeal Select™** products do contain the same amino acid formulation as **Elemental Select™**. However, they also contain other constituents that may create GI distress in patients who have extremely reactive GI tracts. Furthermore, the low caloric content of these products and ratio of macronutrients disqualifies them for ideal total meal replacement for any length of time. Rather, our protein-based products were specifically designed to complement a healthy diet where they would, at the most, replace 1-2 meals per day.

Interestingly, published research has demonstrated that, when elemental and polymeric (whole protein) formulas are compared in terms of improvement with active Crohn’s disease symptoms, efficacy is about the same for each formula, as noted in the study “Controlled trial comparing two types of enteral nutrition in treatment of active Crohn’s disease: elemental v polymeric diet” by Rigaud et al (Rigaud D et al. *Gut*, Vol. 32, pp. 1492-1497, 1991):

“To determine whether an elemental diet or a polymeric defined formula diet would be more effective for treating active Crohn’s disease, we conducted a prospective randomized clinical trial in 30 patients with active Crohn’s disease unresponsive to steroids and/or complicated by malnutrition. They received a four to six week enteral nutrition course with either an elemental diet or a polymeric diet. Clinical remission occurred in 10 of the 15 patients on elemental diet compared with 11 of the 15 patients assigned to polymeric diet. Both groups showed similar improvements in nutritional status, biological inflammation, α_1 antitrypsin clearance, and colonoscopic lesions (diminished in 17 out of 24 patients).”

If the two forms perform equally, why did we choose an amino acid-based formula for

Elemental Select™? We are assuming that you have already tried our whole protein products indicated above or products similar to them as part of a partial enteral nutrition program with unsatisfactory results. Therefore, our intent with **Elemental Select™** was to give you another option for this group of patients.

Of course, with the above stated, as suggested by the Rigaud et al study, we realize that some of your more severe GI dysfunction patients may do well with our whole protein-based products as part of a partial enteral nutrition program. Therefore, if, based on your assessment of any particular severe GI dysfunction patient, it is your professional and clinical judgement that our whole protein-based products will give satisfactory results, by all means consider their use. However, if your clinical judgement is that whole protein-based products as part of a partial enteral nutrition program may be inappropriate for any particular patient, we strongly feel that **Elemental Select™** should be considered.

In upcoming newsletters, I will be reviewing many more studies that assess the use of enteral nutrition with severe GI dysfunction patients to provide further evidence that **Elemental Select™** may be an excellent option for many of these very challenging cases.