DISCUSSION: These preliminary data on specific commercial supplemental products indicate that the selected enzymes could sustain the simulated gastric fluid environment. The exact conditions of these experiments (i.e., direct contact of the enzymes with the harsh simulated gastric fluid) do not occur under normal conditions. For instance, it should be noted that upon taking supplemental digestive enzymes with meals, various food macromolecules act as a "protective shield," protecting the direct exposure of the enzymes to the low pH. Further, some foods actually contribute some buffering of the gastric content during the initial phases of eating. During that time, supplemental enzymes within the food bolus continue their hydrolytic action.

Therefore, the data collected here indicate that even without the protective shield and buffering capability of ingested foods, the supplemental enzymes used in this study could still sustain the stomach environment (as can be deduced from the simulated gastric fluid exposure) and thereby help in enhancing the digestion of food macromolecules. Under some conditions, the enzymes appeared to temporarily lose their activity. However, when they reached a more favorable environment in the small intestine, they regained that activity (see graph). This is exactly what normally happens when food moves from the stomach into the small intestine. Under this in-vitro condition, the argument could therefore be made as to the stability or preservation of enzyme activity in low pH condition similar to the human gastric environment.

RECOMMENDATIONS: The activity of any digestive enzyme supplement in the small intestine presupposes that the enzymes in the supplement survive the acidity of the stomach. From the above experiments, we have established that Transformation's fungal digestive enzymes do survive the acidity of the stomach and work in the small intestine. In fact, our research has demonstrated that Transformation's fungal enzymes not only survive the acidity of the stomach, but also are active in that harsh environment where most other types of enzymes are inactivated.

The results of a related independent study show that digestive enzyme supplements that are effective and GI stable can substantially increase the digestibility and bioaccessibility of proteins and carbohydrates in the lumen of the small intestine, not only under impaired digestive conditions but also in healthy human digestion. Considered together, these results validate the use of digestive enzymes in cases of impaired digestion and further show that most healthy adults can benefit by using a digestive enzyme supplement, provided the enzymes are stable and effective as shown in this study.

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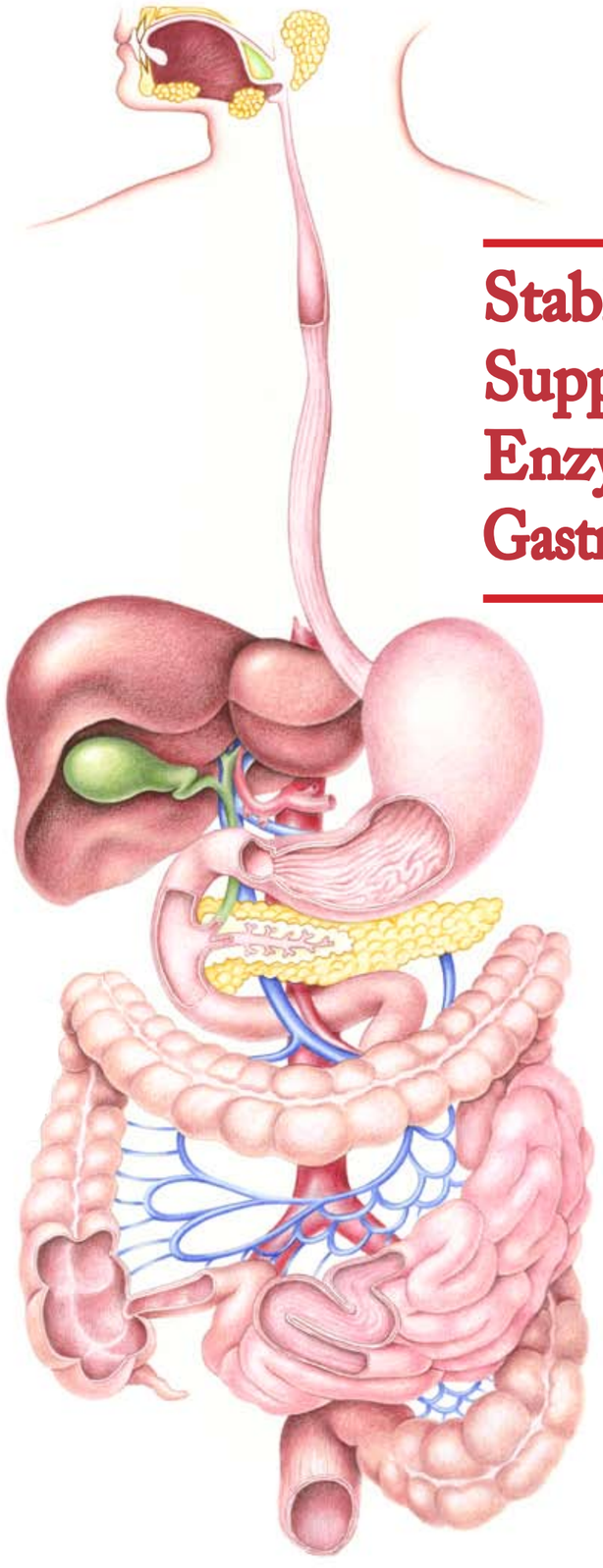


Stability and Activity of Supplemental Digestive Enzymes in a Simulated Gastric Fluid Environment

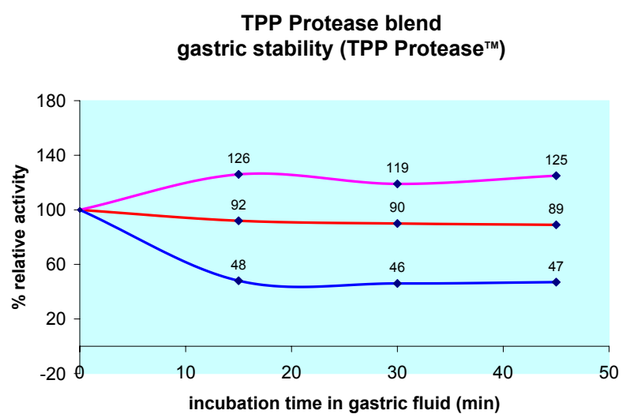
Quantitative Evidence Proving the Efficacy of Supplemental Enzymes

research spotlight on...
GASTRIC STABILITY

BACKGROUND: The use of supplemental digestive enzymes has often been the subject of controversy as to its effectiveness. One of the main reasons of that controversy relates to the susceptibility of proteinaceous molecules to the gastric environment. Although that may be true in some cases, there are proteins that are acid stable and can sustain the gastric environment. Therapeutically, pharmaceutical enzymes (pancreatic extracts) used to correct pancreatic insufficiencies are enterically coated to help prevent their denaturation and hydrolysis by the gastric fluid. Recently, through careful and selective fermentation and isolation processes, specific enzymes with wide pH stability and ability to hydrolyze human dietary macromolecules in an equally wide pH range have been used as digestive aids and for other benefits. With respect to the growing health concerns and other factors related to some animal derived products, the proven safe and effective plant and fungal dietary supplemental enzymes constitute a good alternative for pancreatic insufficiencies and other disorders. Several of these fungal and plant enzymes are ordinarily taken with meals to enhance hydrolysis of the macromolecules.

OBJECTIVE: The goal of this study is to determine the level of enzyme activity after subjecting specific orally administered supplemental enzymes to a simulated gastric fluid as used in many pharmaceutical gastric dissolution studies.

METHODS: Specific fungal enzymes used as human dietary supplements and commercially available were incubated in a USP simulated gastric fluid at pH 2.0 and containing 3.2 mg pepsin per ml (1,130 U/mg) for various times at 37oC. Following their respective incubation times, enzyme samples were taken, reacted with appropriate substrate, and their enzymatic activity assayed.



RESULTS: The supplemental enzymes assayed in this study proved to be stable and maintained variable levels of enzymatic activities ranging from 41% to 126% as a function of incubation time when compared to the enzymatic activity of the controls, i.e., enzymes not exposed to the simulated gastric fluid. However, when enzymes exposed to gastric fluid were pH-adjusted to conditions in the small intestine and assayed, the enzymes regain their full activity levels, indicating that the gastric fluid did not irreversibly denature the enzymes.

CONCLUSION: The enzymes used in this study sustained the simulated gastric fluid and further helped to hydrolyze their respective substrates. Such enzymes when taken with meals could enhance cellular nutrient acquisition and alleviate some digestive disorders.

*adapted from *Stability and Activity of Supplemental Digestive Enzymes in Simulated Gastric Fluid* by M. Mamadou, S. Marr, K. Paydon, and R. Medhektar presented at the Scripps Conference in San Diego, January 7-9, 2005