

Importance of fibres and Multi Fibre in enteral nutrition

Clinical Evidence Overview



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Advanced Medical Nutrition

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Introduction

Fibre is a component of the normal diet and is widely recognized as being an important part of healthy nutrition. There are many different types of fibres which are often classified as soluble or insoluble, and can be further classified as fermentable, non- or poorly-fermentable. Fibre has been shown to have many beneficial effects on gut health including improving stool consistency, normalizing gut transit time, generating production of short chain fatty acids, and restoring a balanced gut microflora.

Not all types of fibre have the same qualitative or quantitative effects. The full range of health benefits of fibre can best be obtained by consumption of a variety of fibre sources. Fermentable fibres are important for generation of short chain fatty acids and restoration of a balanced microflora. Less well fermented fibres enhance stool bulk, consistency and viscosity, and possibly contribute to reduced bacterial translocation.

Patients in need of nutritional support, either because of pre-existing malnutrition or because nutritional status should be maintained, require a feed meeting their special nutritional needs. The perceived abnormalities of bowel function in enterally fed patients, the growing body of literature in the field of fibre, and the improved technological possibilities to incorporate fibre into a liquid formula have paved the way for the addition of fibre to enteral formulas. These formulas are expected to improve bowel function, preventing or alleviating enteral feeding-related diarrhoea as well as constipation, and maintaining or improving gut structure and barrier function.

All these insights led Nutricia to develop a unique fibre mixture for their enteral nutrition range. Multi Fibre (MF6™) is a patented mixture of six fibres that reflect the proportions of different fibre types in a normal diet. The main benefits of enteral formulas containing Multi Fibre have been demonstrated in a number of clinical trials with various patient groups, and will be discussed in this booklet.

This booklet has been prepared in order to offer the information required to make the best choice for your patient. It includes useful background information on fibres, their physiological effects and the clinical benefits shown with Multi Fibre. The choice of fibre is an important one, as it can ultimately affect the gastrointestinal health of your patient.

What are fibres?

Dietary fibre, or short fibre, includes all indigestible portions of plant foods that move through the digestive system where they are wholly or partly fermented by the colonic microflora and/or partly excreted in the faeces.

According to the American Association of Cereal Chemist Expert Committee (2001), fibre is “the edible part of plants or analogous carbohydrates that are resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. This includes polysaccharides, oligosaccharides, lignin and associated plant substances.”

There is still much debate regarding the most appropriate definition and method of analyzing fibre. The fibre content of a food item can therefore deviate depending on the method used. Two of the most commonly used definitions are mainly based on analytical criteria and are generally used for the purpose of nutrition labelling, but do not measure all types of fibre.

- The Association of Official Analytical Chemists (AOAC) method of analysis has been used widely (with added improvements along the way) as the ‘gold standard’ (Horwitz, 2000). Using this enzymatic gravimetric procedure, fibre includes non-starch polysaccharides, lignin and a portion of resistant starch (DeVries, 2003). Further methods have been developed to analyze additional fibre components such as oligofructose and inulin.
- The other widely used method was established by Englyst and Cummings and measures fibre from its chemical components and only includes non-starch polysaccharides (Sanchez-Castillo *et al*, 1994; Englyst *et al*, 1995).

There are many different types of fibres which are often classified as soluble or insoluble, and can be further classified as fermentable, non- or poorly-fermentable. Important soluble fibres include pectin, acacia fibre, oat, inulin and oligofructose, whereas predominantly insoluble fibres are cellulose, soy polysaccharide and some types of resistant starch.



Recommended fibre intake

Fibre recommendations for healthy populations suggest that current dietary fibre intakes are inadequate and should be improved by increasing consumption of cereals, grains, fruits and vegetables.

Specific amount of fibre recommended in various countries

Country	Recommendation	Source of recommendation
France	25–30 g*	Agence Française de Sécurité Sanitaire des Aliments, 2001
Germany	30 g*	German Nutrition Society, 2000
Netherlands	30–40 g; 3.4 g/MJ*	Health Council of The Netherlands, 2006
Nordic countries	25–35 g*	Nordic Nutrition Recommendations, 2004
UK	18 g**	Department of Health, 1991
USA	38 g, men 19–50 years 31 g, men 50+ years 25 g, women 19–50 years 21 g, women 50+ years***	Institute of Medicine, 2002

*Dietary fibre, non-specific method **Non-starch polysaccharides (Englyst *et al*, 1982) ***Total dietary fibre (AOAC, 1995)
Adapted from ILSI 2006

For children probably the most common recommendation is the 'age in years + (5–10 g)' rule. For example, a child aged 7 years would have a fibre recommendation of 12–17 grams of dietary fibre per day (Williams *et al*, 1995).

No clear recommendations exist for specific patient groups regarding the optimal amount of fibre for addition to enteral formulas (Slavin, 1990; Sobotka *et al*, 1997). In addition, it appears from the results of various studies that there is also some inter-individual variation in the level of fibre required in an enteral diet in order to influence bowel function (Kapadia *et al*, 1993; Liebl *et al*, 1990). In some patients who have not consumed fibres over a long period it might be useful to start slowly with fibre-containing feeds to allow the gastrointestinal tract to adjust to higher levels of fibre.

Benefits of fibres

Fibre intake influences carbohydrate, fat and sterol metabolism, stool bulking and weight, and colonic fermentation. It also influences gut structure and gut barrier function, and may even have some impact on immune function (Green, 2001).

Many dietary fibre components are partially or completely fermented by microflora in the colon. Fermentation occurs by a large and diverse population of bacteria that produce enzymes capable of digesting the food mass, producing gases and short-chain fatty acids, as well as an increased bacterial mass, which ultimately leads to increased faecal weight (Green, 2001). It is these short-chain fatty acids, principally acetate, propionate and butyrate, that have significant health properties (ILSI, 2006; Gibson, 2004; Compher *et al*, 1996).

Health benefits of short-chain fatty acids

- Provide nutrition for the mucosal cells of the colon (butyrate is the preferred fuel source)
- Lower colonic pH subsequently affecting the balance of microflora in the colon and inhibiting growth of pathogens
- Induce beneficial changes in glucose and lipid metabolism through stimulation of pancreatic secretions and other gastrointestinal hormones
- Enhanced sodium and water absorption to prevent osmotic diarrhoea
- Increase proliferation of colonic bacteria beneficial for intestinal health – bifidobacteria and lactobacilli
- Improve barrier properties of the colonic mucosal layer through regulation of the proliferation of epithelial cells and differentiation in the colonic mucosa

Not all types of fibre exert all physiological effects to the same degree. Soluble fibres tend to have the largest impact on gastric emptying, small intestinal transit time, short-chain fatty acids production in the proximal colon, microbial mass and stimulating the generation of colonic epithelium. In contrast, the more insoluble types have the greatest effect on maintenance of the colon's muscle layer, prevention of bacterial translocation, short-chain fatty acids production in the distal colon and stool bulking, which is influenced by the water-retaining properties of these fibres (Green, 2001).



Prebiotic effect of certain fibres

Some of the soluble fibres are described as being prebiotic (i.e. stimulating beneficial bacterial strains in the colon). Inulin and oligofructose/fructo-oligosaccharides (FOS) have been shown to possess the necessary metabolic selectivity to stimulate the growth and/or activity of bifidobacteria and alter the balance of the microflora in favour of a healthier composition, including displacement of potential pathogens by reducing their numbers selectively (Wang and Gibson, 1993; Gibson, 2004). Acacia fibre and resistant starch are also now under discussion for their possible prebiotic effects.

Bifidobacteria constitute up to 25% of the total bacterial population in the adult gut and up to 95% in the newborn (Kawase *et al*, 1981; Harmsen *et al*, 2000). An increased number and activity of this bacteria is desirable for its positive effects on human health. These include:

- The production of strong acids such as acetate and lactate that lower the pH of the gut thereby exerting an antibacterial effect. A reduction in the pH levels is also a factor in directly inhibiting a range of pathogenic bacteria, which are further inhibited by bifidobacteria interfering and enhancing colonization resistance in the intestine (Gibson and Wang, 1994; Orrhage and Nord, 2000; Whelan *et al*, 2006).
- In a recent study of 20 patients on a fibre free enteral feed, faecal samples over 14 days indicated that there were significantly lower numbers of bifidobacteria in patients experiencing *Clostridium difficile* associated diarrhoea, providing further weight to the beneficial actions of bifidobacteria (Whelan *et al*, 2006).
- The production of digestive enzymes and vitamins, the majority of which are B vitamins (Gibson and Roberfroid, 1995).
- Bifidobacteria act as immunomodulators, e.g. they can promote an attack against malignant cells. The reduced pH levels in the gut may also aid in the excretion of carcinogens (Rowland, 1995).
- Bifidobacteria are used to restore the normal intestinal microbiota during antibiotic therapy.

Role of fibre in disease

There is a growing body of literature showing protective and preventative effects of dietary fibre on disease, especially on diseases of the colon and cardiovascular system. Several epidemiological studies have shown that a low fibre intake has also been associated with many other diseases such as colon cancer, obesity, diabetes mellitus and gastrointestinal disorders including constipation and diverticulitis (ILSI, 2006; Sobotka , 1997). Increasing the intake of fibre may play a role in reducing the risk of such diseases (Compher , 1996; Wakai , 2007).

Fibre-free formulas had been used in the hospital and home setting for many years before the introduction of fibre-containing formulas. Some typical gastrointestinal problems found among patients receiving fibre-free formula include:

- Significant decrease in anaerobic bacteria (unbalanced microflora) (Schneider , 2000).
- Decreased production of short-chain fatty acids (Schneider, 2006).
- Significantly prolonged gut transit times (Silk, 2001).

These situations can then lead to commonly seen tolerance issues including diarrhoea, constipation and bloating. Based on these findings, it is expected that addition of fibre to enteral formulas may prevent or alleviate enteral-feeding related diarrhoea, maintain or stimulate intestinal mucosal cell morphology and gut health.

A recent systematic review was performed on the clinical and physiological effects of fibre-containing formulas (M. Elia, M. B. Engfer, C. J. Green, 2007). 51 studies were included, enrolling 1.762 subjects. Meta-analyses showed that the incidence of diarrhoea was significantly reduced in the hospital setting when using fibre-supplemented formulas. Furthermore, a unique modulating effect of fibre was revealed: bowel frequency was reduced when baseline frequency was high and it was increased when baseline frequency was low. The review concludes that fibre-supplemented formulas have important physiological effects and clinical benefits.



Perceived limitations

Along with the benefits associated with a high fibre intake, there are also some perceived limitations or potential adverse effects of fibre administration. These concerns include:

- **Compromising energy intake**

This is linked to the possibility of fibre affecting the intake of other nutrients, however because this concern relates to reduced dietary intake and possibly due to the slower chewing process, it does not apply to fibre in enteral formulas.

- **Reduced absorption of macronutrients, increased faecal energy losses**

Despite the fact that some studies have shown increased faecal nitrogen losses during consumption of a high fibre diet, this is offset by a compensatory decrease in urinary nitrogen loss (Birkett 1996; Tetens 1996). Therefore, overall nitrogen retention is not affected. Although faecal fat excretion is increased on a high fibre diet, various studies have demonstrated that at modest levels of fibre intake, the minimal energy loss is unlikely to be significant (Van Calcar , 1989).

- **Reduced bioavailability of micronutrients**

It is thought that impaired mineral absorption is only likely to be of consequence with very high intakes of fibre and phytate, or when mineral and trace element intake is limited. This is not the case with fibre enriched enteral formulas (Kapadia, 1993b).

In summary, most of these concerns are of minor relevance. Only a few real limitations or contraindications apply to fibre-containing enteral feeds (Green, 2001).

Limitations/contraindications for fibre-containing enteral feeds

- Patients with bowel disorders might require a fibre-free diet, unless under strict medical supervision
- Patients receiving drugs that suppress intestinal tract function
- Patients with intestinal ileus, unless under strict medical supervision
- As a preparation before bowel investigation or surgery

Why is a mixture of fibres better?

The majority of studies investigating the effects of formulas supplemented with single fibre sources on bowel function in enterally fed patients have been inconsistent, suggesting that they have only restricted potential (Silk *et al*, 2001). This may not be difficult to explain, as fibre in the normal diet is composed of a mixture of many types of plant based food components. Not all types of fibre have the same qualitative or quantitative effects, with the physiological effects being primarily dependent on the physical properties of a fibre.

Therefore, it is hardly surprising that a single fibre source is unable to emulate the wide variety of different types of indigestible carbohydrates normally consumed in the diet (Green, 2001).

Consumption of an increased amount of a single fibre source might lead to tolerance problems. Indeed, tolerance issues including diarrhoea and flatulence were seen when single soluble fibres such as hydrolysed guar gum (Wierdsma *et al*, 2001) and inulin (Sobotka *et al*, 1997) were used. Furthermore, constipation was evident when higher amounts of insoluble fibres such as cellulose were given (Kies *et al*, 1984).

Based on the possible negative effects of fibres derived from a single source, a recent systematic review concluded that fibre-containing formulas are best tolerated when given as fibre mixtures (reference).

Inclusion of a mixture of fibres represents a more physiological approach than supplementing products with a single fibre source. A mixture of fermentable fibres can be used for the generation of short-chain fatty acids and restoration of a balanced gut microflora. Less well fermentable fibres can be used for purposes of enhancing stool consistency and mass, improving intestinal muscle bulk and possibly contributing to reduced bacterial translocation in order to achieve tolerance and increasing the potential for disease risk reduction (ILSI, 2006).



What is Multi Fibre – MF6™?

Due to the fact that the normal diet contains a range of fibres, Nutricia developed the patented Multi Fibre mixture (MF6) for its enteral nutrition products. MF6 is composed of six fibres carefully selected and differing in their solubility and fermentability, in proportions reflective of those found in a healthy diet.

- 1. Oligofructose** or fructo-oligosaccharide (FOS) is a fructan (i.e. a mixture of fructo-polysaccharides and fructo-oligosaccharides) with a shorter chain length than that of inulin. It occurs naturally in a wide variety of vegetables, fruits and cereals. Oligofructose is soluble, and it is accepted as being highly fermentable. Oligofructose has been demonstrated to have prebiotic effects.
- 2. Inulin** is a fructan. Inulin is a storage polysaccharide and occurs naturally in a wide range of vegetables such as artichokes, asparagus, leeks, onion, garlic and chicory. Inulin is soluble in water and it is accepted as being highly fermentable. Inulin is described as a prebiotic fibre.
- 3. Acacia fibre** is extracted from selected Acacia tree exudate. The chemical composition of acacia fibre is the same as standard arabic gum, but has almost no viscosity. It is completely soluble. Acacia fibre is accepted as being highly fermentable.
- 4. Soy polysaccharide** is comprised of cell wall material of soy bean cotyledons derived from processing dehulled, defatted soy bean flakes. Soy polysaccharide is largely insoluble and is classified as a fermentable fibre.
- 5. Resistant starch** is the sum of starch and starch products of starch degradation, not absorbed in the small intestine of healthy individuals. The resistant starch in Multi Fibre is obtained from high-amylose maize. It can be regarded as insoluble and largely non-fermentable.
- 6. Alpha-cellulose** is purified, mechanically disintegrated cellulose prepared by processing alpha-cellulose obtained as a pulp from fibrous plant materials. It is insoluble and not fermentable.

Clinical evidence for MF6

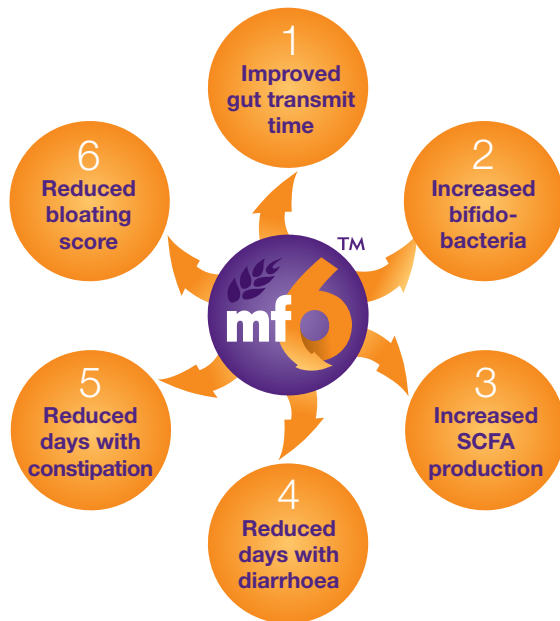
The wide variety of fibres carefully selected for Multi Fibre

Fibre	Soluble*	Insoluble*	Fermentable*	Non-fermentable*
Soy polysaccharides		✓	✓	
Alpha cellulose		✓		✓
Acacia fibre	✓		✓	
Inulin	✓		✓	
Oligofructose			✓	
Resistant starch		✓		✓

* The majority of fibres have both soluble and insoluble fractions, and can be partly fermentable or non-fermentable. This table indicates which classification is predominant.

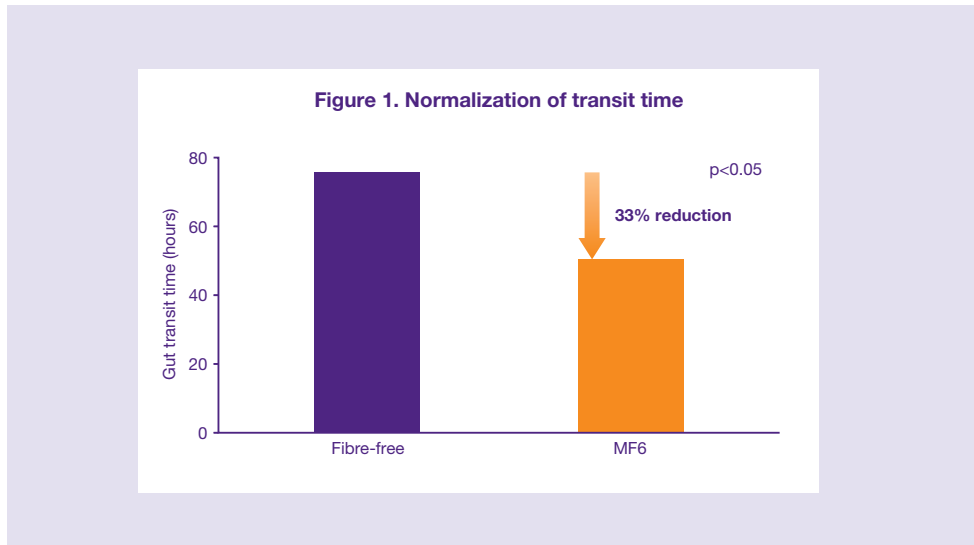
Clinical studies using Nutricia's Multi Fibre have demonstrated the following beneficial effects, which will be discussed in more detail over the following pages.

- Improved gut transit
- Increased bifidobacteria use
- Increased short-chain fatty acid production
- Reduced diarrhoea
- Reduced constipation/reduced laxative
- Improved tolerance, e.g. reduced bloating



MF6 improves gut transit

In a randomized study of 10 healthy volunteers' **whole gut transit time was significantly faster in subjects receiving Multi Fibre** than in those receiving a fibre free formula (see Figure 1; Silk *et al*, 2001).



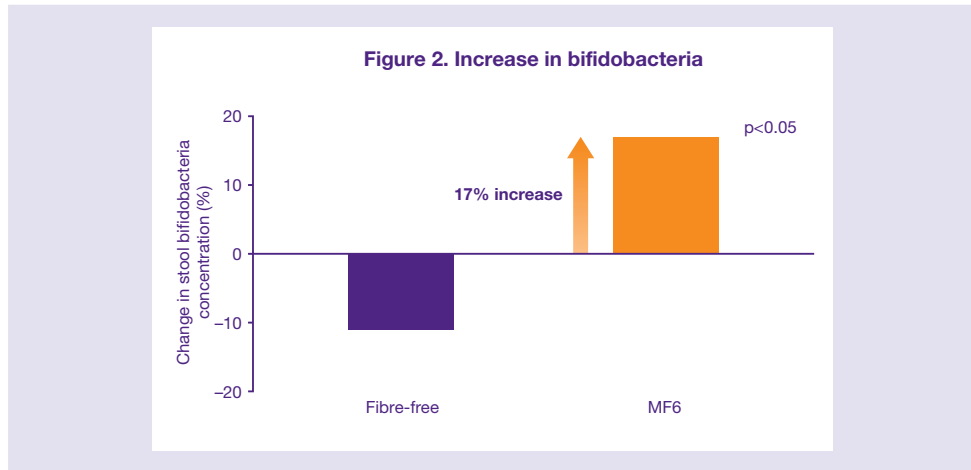
Whereas a fibre-free formula prolonged transit time significantly, the transit times of patients receiving Multi Fibre were very similar to those seen in subjects on a normal diet (see table below). This normalization of transit time indicates a significant beneficial effect of Multi Fibre on overall gastric motility.

Nutrition	Whole gut transit time (hours)
Self-selected diet	46.1 ± 7.0
Multi Fibre formula	50.4 ± 6.8
Fibre-free formula	75.7 ± 12.6

MF6 shows prebiotic effects

Recently, Guimber et al (2007) investigated in a double-blind, randomized, cross-over study the effects of feeding Multi Fibre to a group of 20 patients (age 11.9 ± 3.9 years), the majority of whom were neurologically impaired.

Patients fed the **Multi Fibre feed had a significant reduction in stool pH and a significantly higher proportion of gut bifidobacteria (+17%)** compared with children fed the fibre-free control feed who showed reduced levels (see Figure 2). Therefore the addition of Multi Fibre resulted in improving the balance of microflora and supporting a healthy colon.

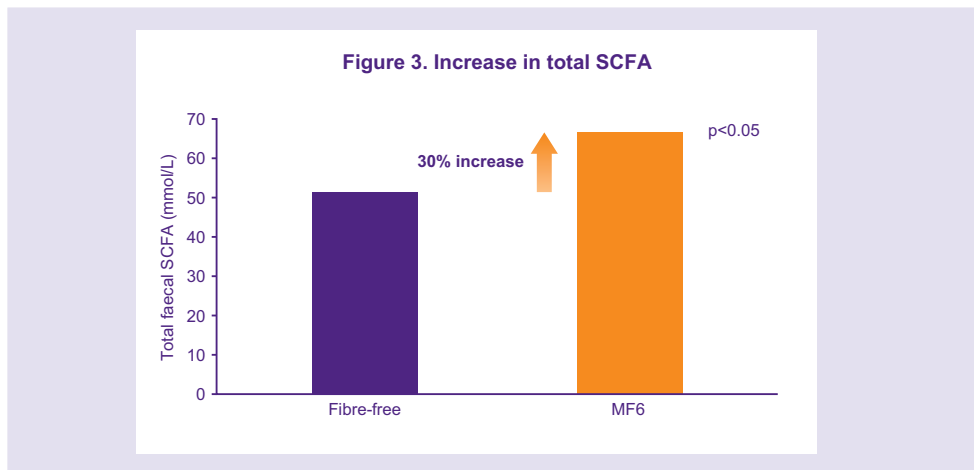


MF6 increases short-chain fatty acids (SCFA)

SCFA are one of the most important by-products of fibre fermentation occurring in the colon. As discussed previously, SCFA have many benefits for the gastrointestinal tract. The types of SCFA produced will be influenced by the fibres consumed (Green, 2001).

In a recent randomized, double-blind cross-over study, 15 patients requiring long-term enteral feeding and diagnosed with dysphagia, were randomized to receive a fibre-free formula for 2 weeks, followed by the same formula containing Multi Fibre for 2 weeks, or vice versa (Schneider *et al*, 2006).

At the end of the Multi Fibre period **a significant increase in acetate, butyrate and total SCFA** was recorded compared with baseline levels, and a significant increase in total SCFA and butyrate of 30% and 31%, respectively was seen compared with that in the fibre-free period (see Figure 3).

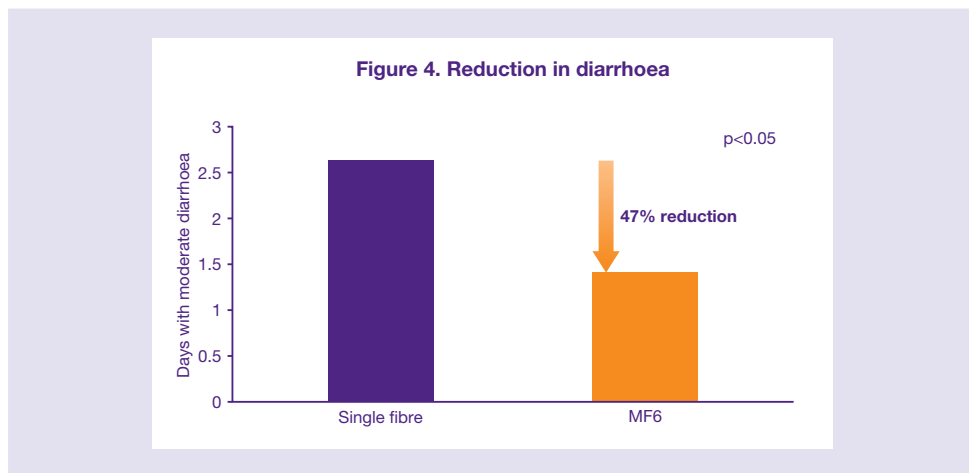


This study supports earlier *in vitro* work (Green, 2001), which demonstrated that after 48 hours, Multi Fibre continued to produce SCFA at a higher volume than any of its components, fermented and measured as single fibres, with the exception of inulin. At the same time, Multi Fibre induced the lowest gas production with the exception of cellulose (high gas production by inulin and oligofructose). These findings demonstrate that **Multi Fibre has the best SCFA : gas production ratio of all fibres examined (Green, 2001).**

MF6 reduces diarrhoea

Diarrhoea remains a common complication associated with enteral feeding particularly in the acute care setting, resulting in increased morbidity and hospital costs. Diarrhoea has been found in up to 67% of hospital patients on fibre-free feeds (Bliss *et al*, 1992). The development of diarrhoea in tube-fed patients has been associated with multiple factors including hypoalbuminaemia, severity of disease, antibiotics, multiple medicines and acquisition of a nosocomial pathogen, e.g. *C. difficile* (Guenter *et al*, 1991; Smith *et al*, 1990; McFarland, 1995).

Multi Fibre has been shown to help modulate bowel function by reducing diarrhoea. In one study of 78 patients with head-neck cancer, either a formula containing Multi Fibre or a single fibre source (guar gum) was given for at least 10 days postoperatively (Wierdsma *et al*, 2001). **The number of days with moderate diarrhoea was significantly reduced in the group receiving the Multi Fibre supplemented formula** (1.4 days versus 2.63 days, see Figure 4).



Further studies have also shown a reduction in the duration of diarrhoea when Multi Fibre is used rather than a fibre-free enteral feed. In a cross-over study of 16 children (median age 60 months) requiring tube feeds, **the mean number of days with diarrhoea was reduced from 2.44 days when on the standard feed to 1.44 days when receiving Multi Fibre** (Trier *et al*, 1999). Grogan *et al* (2006) studied the effects of Multi Fibre in a small group of long-term enterally fed children and showed a clinical improvement in loose bowel movements in over 40% of the children.

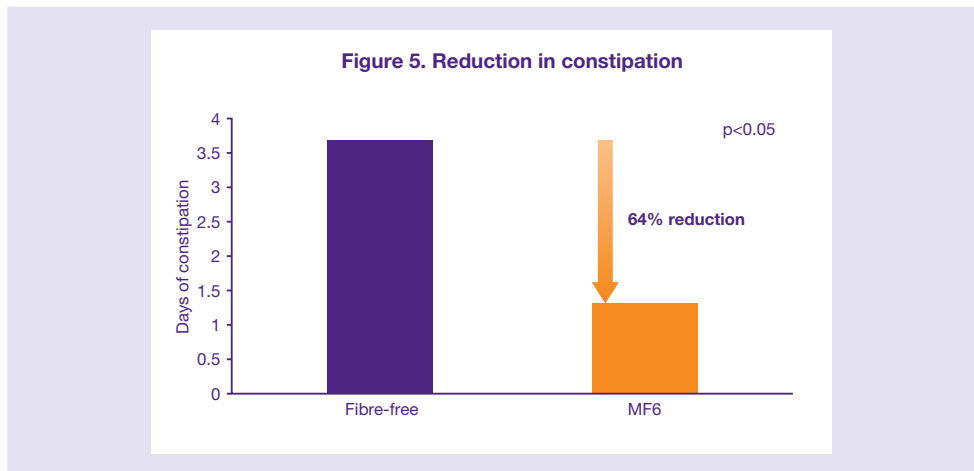


MF6 relieves constipation

Constipation, faecal impaction and the need for laxatives are the most commonly cited gastrointestinal problems in chronically ill patients. This is mainly due to the use of multiple medications, restricted movement, exercise and often inadequate fluid intake.

Fibre has an important role in bulking stool and providing a stimulus for gastric motility. It helps to stimulate the passage of the food mass through the colon, thereby contributing to the regular passage of stool (Green, 2001). An increase of fibre in the diet is a key recommendation in helping to alleviate constipation in the general population, and should therefore be of benefit to patients receiving long-term enteral feeding (Cheskin *et al*, 1995).

In a double-blind, cross-over study of young, enterally fed children, **Multi Fibre was able to significantly reduce the number of days that they were affected by constipation by 64%**, compared with when these children received a fibre-free feed (see Figure 5; Trier *et al*, 1999). In an additional study, a significant improvement in stool consistency has been demonstrated with the use of Multi Fibre (Grogan *et al*, 2006).



MF6 reduces laxative use

Several studies have demonstrated the benefits of Multi Fibre compared with fibre-free formulas in reducing laxative use in enterally fed patients:

- 50% of patients on fibre-free feeds required laxatives, compared with only 13% of patients receiving Multi Fibre (Hofman *et al*, 1999).
- 41% of patients who were commenced on Multi Fibre were able to stop or reduce their use of laxatives (Daly *et al*, 2004; Grogan *et al*, 2006).

In a study by Vandewoude and colleagues (2005), the addition of Multi Fibre had a regulatory effect on bowel function in the elderly patients studied. Stool consistency improved with less watery diarrhoea and with bowel movements that followed a more regular scheme. This was confirmed by the observation that the use of laxatives was considerably lower in the fibre group. As laxative use is very common, especially by nursing home residents, a reduced requirement seems to be of high importance to regain physiological bowel function (Bosshard *et al*, 2004). Whereas physical activity can hardly be improved in these patients, increased fibre intake, in addition to adequate fluid intake, can be achieved potentially resulting in an improvement in quality of life.

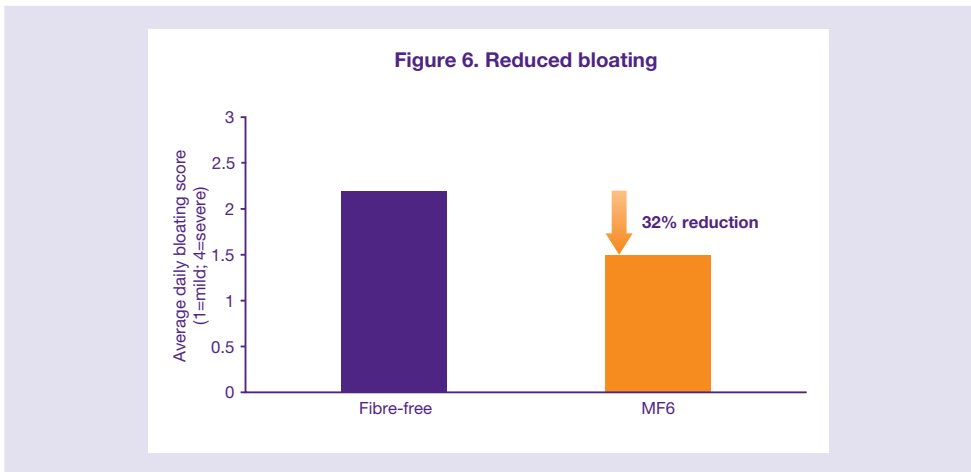


MF6 is well tolerated

Tolerance of an enteral feed is generally measured in terms of how well a patient's gastrointestinal tract responds to the delivery of the formula. Typical adverse effects associated with enteral feeding are usually minor and include nausea, vomiting, abdominal cramping and bloating, constipation and diarrhoea.

Next to non-feeding related factors, such as the use of antibiotics, many of these problems can be linked to patients not receiving the correct amount and mix of fibres. Other influential factors are inadequate fluid intake, the temperature of the feed at delivery and the method and speed of delivery. It is well known that a sudden introduction of a large amount of fibre (especially of one single source) can result in tolerance issues.

Several clinical studies have shown that enteral formulas containing Multi Fibre are well tolerated in both adults and children with minimal adverse effects (Liu *et al*, 2005; Grogan *et al*, 2006). In fact, **Multi Fibre has been shown to be at least, if not better tolerated than its fibre-free counterpart** (Silk *et al*, 2001). In addition to the reduction in the average daily subjective bloating score (based on incidence as well as severity with 1 = mild to 4 = severe, see Figure 6), the subjects also showed a reduced incidence of nausea (daily score of 1.0 versus 2.1).



Summary

The use of dietary fibre in enteral nutrition is a relatively new concept that is only recently gaining recognition for its importance in regulating bowel function and maintaining or improving gut health.

Up until the last few years, the majority of fibre containing enteral feeding products used only a single fibre source (most commonly soy polysaccharide). However, these products were unable to consistently demonstrate a clear benefit of fibre supplementation in clinical trials.

It seems obvious that the dietary fibres used in enteral feeding formulas should reflect the mixture of fibres found in a healthy diet if anticipated benefits of supplementation are to be realized. Multi Fibre (MF6) is a mixture of 6 soluble and insoluble fibres of varying degrees of fermentability which closely mimic the fibres found in a normal diet. Various clinical studies have demonstrated that Multi Fibre, in comparison with a fibre-free or single-fibre source, has the ability to:

- Improve gut transit
- Increase bifidobacteria
- Increase SCFA production
- Reduce diarrhoea
- Reduce constipation/reduce laxative use
- Improve tolerance, e.g. reduced bloating

In conclusion, fibre, particularly a mixture of fibres, has important gastrointestinal effects. Fibre should be regarded as an essential ingredient of a healthy diet but also as a standard ingredient for enteral formulas.

Supplementation of enteral nutrition with Multi Fibre has shown gastrointestinal health benefits in numerous studies.



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