



Medical Devices and their Role in Supporting the Digestive System in Cases of Intestinal Failure

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Annotation: An artificial organ could replace many functions of gut, but only can assist or replace a few functions. In the human body, the exocrine functions of the liver, pancreas, and intestine contribute to its assist digestion, and further the cellular functions of the liver and bone marrow have effects on this digestion and absorption condition in the body. An artificial organ can replace the insulin secretion function of pancreas, gall secretion function of liver, substitution in parenteral nutrition (PN) or the absorption function of intestine, but it only assist the digestion function of the intestine to some extent. Consequently, development of an artificial device that can substitute as many of these functions as possible could be anticipated to facilitate complete digestion of food taken by the mouth, and will advance the quality of life, as well the activity of other artificial organs. In the living human body, the efficiencies of exocrine functions of the intestine, liver, and pancreas are of course good. Additionally, the ingested food substance is significantly small. Consequently, it is quite difficult

to completely substitute these functions by an artificial device. Alternatively, the device may replace only one or a few, and effort has been made to do so.

In the ancient human body, of the entire volume of the stomach and the small intestines is given to assist or complete the digestion and absorption of food. In the case of human or other animal under serious intestines weakens by reason of the disease, the amount of intake is limited, since normal digestion and absorption are difficult [1]. In such case, as a treatment method, a transplantation of the artificial intestine into the body is considered whereby it may be possible to save the life of patient. In the present, small intestine transplantation as a clinical case is performed. It is also considered for artificial intestine to be transplanted into the body. Hooking up of such a transplantation was discussed. On the other hand, there are means as may assist the digestion and the absorption even if not transplantation.

Keywords: Medical devices, intestinal failure, artificial organs, parenteral nutrition, digestive engineering, bioengineering.

1. Introduction

The digestive system has a number of vital roles for the maintenance of human life, of central relevance are the processes of digestion and absorption of nutrients required to live. The digestive system also plays a significant role in the host defence against pathogen invasion, and in maintaining state of normal health, including influencing the normal bowel flora, detoxification of substances, and protection against cancer. Any significant failure of any of these functions results in clinical disease necessitating medical attention. However, in a minority of cases digestive failure may be so severe that it presents within the definition of intestinal failure – this being a reduction in the functioning gut mass below the minimal amount necessary for the performance of these functions. Such cases usually require supportive parenteral nutrition which is complicated by its associated co-morbidities. There are a number of medical devices which are used in the and or gut adaptive and rehabilitative strategies used in the treatment of these patients that utilise the principles of adaptive physiology to allow the gut to, following a period of recovery. It is important to be cognisant about devices and the physiology behind these devices, particularly as they are most often sited by surgical collaborators whose understanding may be lacking. In the center, devices are used in 63% of adults and in 59% of children presenting with intestinal failure (IF) where all medical treatment options have otherwise been exhausted and the patient would require further intravenous feed without the surgical insertion of a medical discretionary device [1].

1.1. Background and Significance

Background and significance Recent advances in digital health have accentuated the importance of medical device development. Different types of programmable medical devices have been developed for monitoring and supporting the digestive system. For example, orally ingestible medical devices have been designed to measure the temperature, pH, pressure, and

movement of the digestive system. A recent example is given of a miniature robot capable of remotely repairing a wound. Inside the digestive space, they are designed to navigate through it effortlessly and passively through either natural gut wall deformations or biologically adhere to the GI mucosa covering the digestive space surfaces. Still, most medical devices residing inside the digestive tract are non-adhering, where typical limitations consist in the design of the device for either real-time interrogation or long-term monitoring. A wide range of non-invasive wireless data and power transfer technology has been developed for medical devices. They can be based on electromagnetic, ultrasonic, or optical systems. Another approach is to hook up the device with the exit site externally but leaving it still inside. This can be enabled by electromagnetic coupling [2]. These externally powered devices are closely attached to the skin and remain inside the body for hours or even days. Since they are adhesive, they are not allowed to roam around in any part of the digestive tract. Moreover, they demand a fixed body pose, being close to the adhesive device, which significantly hampers patient comfort and regular activities.

However, there is a notable lack of such devices suitable for EOST monitoring. In light of this, such a device for the proposed purpose is presented. One of the most challenging tasks is to navigate a device inside the digestive space that can cover the entire EOST snugly and steadily. In this study, an electrically controlled endoscope device is proposed.

1.2. Scope of the Work

This work is conducted in the scope of the Marie Curie project “Digestive Engineering”, where new orally ingestible medical devices will be designed to support the digestive system in cases of intestinal failure. The Digestive Engineering project has three objectives: (1) to survey and analyze existing technologies related to either diagnostic or therapeutic aspects of the digestive system, but which have low invasiveness, thus have the potential to be miniaturized and integrated into an orally ingestible medical device; (2) to design a new wide-angle camera based endoscope capable of being orally ingested and confirm the manufacturing readiness by a built prototype; (3) to combine the small endoscope with other medical techniques of low invasiveness into one multi-functional device that can be orally ingested and confirm the manufacturing readiness by a built prototype. This work focuses on the first objective.

Intestinal failure (IF) is a clinical condition where the small bowel can no longer absorb enough nutrients and water to support normal growth and health needs, requiring parenteral support or surgery [1]. Several diseases can cause IF in both children and adults. They can be either chronic or acute and can lead to complications, which can be life-threatening. A cure for most conditions leading to IF is often missing. The aim of this work is to devise a technical solution to support the digestive system in cases of IF by building, among other things, an orally ingestible medical device. While the classic limitations of existing and emerging technologies are the focus of the first part, proposed specifications for novel, not-yet existing medical devices that could be built are tackled in the second part. Ultimately, the work is anticipated to support further technological and industrial developments in the area of digestive engineering [2].

Literature Review

2. Anatomy and Function of the Digestive System

The intestine and liver are vital organs comprising the digestive system, which absorbs and processes essential nutrients that support human health. The digestive system involves the small bowel and liver and their products, bile and enzymes associated with absorption and metabolism, and diets that are consistent with the absence of the colon but not the small bowel and liver. The small bowel, or intestine, is a tube averaging about 6 m in length and 2.5 cm in diameter. It consists of the duodenum, along which bile and pancreatic juice waste products are returned from the liver, pancreas, and jejunum. The terminal ileum connects the jejunum with the large bowel (cecum or colon). The folded surface of the small bowel is lined with fingerlike projections on the wall of the tube, called villi, which increase its surface area to about 30 m².

The surface of the small bowel villi, in turn, is peppered with much smaller finger-like projections fixed with microvilli, to increase the surface area further to about 200 m² [3].

The epithelial surface of villi and crypts is covered with a mucus layer with tightly packed glycoproteins (mucins). Rare secretory enteroendocrine cells produce hormones and peptides that are released into the underlying lamina propria to act on the vascular beds and immune cells. Gut hormones are an essential mediator of nutrient sensing by the intestine and expanding our understanding of gut-brain communication and metabolic regulation. Sensory and motor functions of the small intestine are regulated by a thoroughly integrated system of neuronal and transmitter networks. The enteric nervous system is composed of millions of neurons and three transmission systems: Sigma, nitric oxide, and ATP released by intrinsic primary afferent neurons. These, among many other transmitter molecules, interact in a combinatorial manner and regulate various cell types in the gut. Hormones are produced by endocrine cells located in the gut mucosa and act in an endocrine, paracrine, and neurocrinic manner. The gut mucosa releases at least 30 different hormones that participate in metabolic control, motor function, absorption, secretion, and manage the communication between the gut and the brain [4].

2.1. Overview of the Digestive Tract

Nutrition is critical to life as it provides the needed energy and building blocks for growth, maintenance, and repair. During the treatment of patients with IF, mixed feeding strategies need to be approached, as it is important to try to support the digestive system as much as possible. Intestinal Failure (IF) occurs when the small bowel cannot digest and absorb a sufficient quantity or quality of necessary nutrients and fluids to meet requirements for water, electrolytes, macronutrients, and micronutrients. In cases of IF, patients' gastrointestinal (GI) functions need to be at least partially replaced, while a multidisciplinary team (MDT) aims to restore or rehabilitate a more physiological state of GI function. Then there is a grey area between digestive insufficiency, determinable by absence of enteral autonomy, and IF, determinable by need for PN. Indeed, cases of confirmed digestive insufficiency do not always require PN nor do they always revert to digestion within two years. For these reasons, the general concept of IF appears pragmatic and is widely used in clinical practice to define a deranged condition that extends beyond pure digestion impairment, requiring adjunctive treatments or care programs.

Lifetime TPN treatment may be necessary because of reasons including: irreversible lesions in the bowel, specific vascular diseases that might forewarn bowel transplant failure, persisting accessibility problems, or patient choice. Interestingly, bowel adaptation can be allowed going on with enteral treatment, while TPN is only recognized as increasingly detrimental to the gut. Since the bowel recovers, it could be considered interesting to keep the gut as more untouched as possible. If an IF patient is affected by a GI disorder, TPN should be overlapped by continuation at least of some enteral feeding [5].

2.2. Key Organs and their Functions

The intestine performs diverse, crucial functions central to human health. Food broken down by stomach acid and digestive enzymes enters at the duodenum and slowly peruses along its 4-7-m length, being further digested and its nutrients absorbed. Ulcers, ischemia, or resection can render the intestine incapable of absorbing nutrients and fluids, leading to short bowel syndrome. This has a high associated mortality, but can be managed via a combination of diet and the direct intravenous administration of nutrients, termed total parenteral nutrition (TPN). However, TPN is itself injurious, causing liver failure in a majority of patients within two years primarily via a disruption in intestinal barrier function. [6] Fundamental to the digestive and absorptive functions of the intestine is its vast convoluted interior surface area. The large intestine recovers water and ions from the waste constituents of food before excretion. Both types have diffuse immune populations, with counts peaking in the jejunum and falling gradually to colonic levels. Each section has a different role and associated fauna and flora, with distinct molecular and morphological characteristics. Thus, various GI conditions are often section-specific.

The organs which lie along the rest of the ingestive GI tract modulate ingesta in increasingly refined ways. The pancreas releases bicarbonate and digestive enzymes into the duodenum. The gallbladder stores and doses bile acids produced in the liver, which emulsify fats. Heartburn arises from the backflow of acid up into the esophagus (gastroesophageal reflux disease, GERD). Inactivity of it can lead to distal esophageal stricture formation or Barrett's metaplasia. The latter increases the risk of developing esophageal adenocarcinoma. Varices or tears in the stomach or duodenum can cause severe and sometimes fatal bleeds. Anastomotic strictures created to bypass such lesions can also become blocked. The regular emptying of the stomach into the duodenum serves to grind and mix food into the correct consistency but the stomach can become paralyzed, losing its ability to generate peristaltic waves. Due to its interplay with pancreatic enzymes in the duodenum, this can result in fat maldigestion, chronic malabsorption of fat-soluble vitamins, and steatorrhea difficult to absorb vitamins.

Materials and Methods

3. Intestinal Failure: Causes and Consequences

Intestinal failure (IF) is a clinical enlargement with reduction in functioning gut mass below the minimal amount essential for adequate digestion and absorption of food . IF should be divided into these forms: type 1 is an intense state for a few weeks, or for a few days at risk of dire metabolic dysfunction and the insult for the patient; type 2 approval of lasting disfunction of the intestine that treats the deficit of macro and micro elements normally gained from the lumen of the digestive tract and fluid to reach an operational homeostasis; type 3 equivalent to type 2, but running over years and years to real nutritional deficiency as a remediless condition. (i) In a relevant design to suggest gut reparative medical product with intermittent use of nutritional therapy, as a prevention of type 3, hopefully bringing back to control type 1 and unburden the reacted permanent damage from every single episode, the worst hope condition could be avoided even in patients with such a complicated history. There are for the intestinal cells the extension concept resembling to what have for the past years been the productivity of respective organs, and the magnitude is in one order of class inferior in the intestine c-valve, which should be manageable with technologies available since more than a decade on current clinical research infrastructures around the world. (ii) Together with multiple units, a home-care accessible closed-loop supervising system can always be developed to determine the actual state of the ongoing proliferation in the intestine would allow a fast reaction in case pre-cancerous polyps are found, potentially along with a neurological controller to modulate the inflammatory congestion of the non-processive intestinal district. With an arbitrary set of parameters determining this model, this paper gives back as result a measure of the occurrence of relevant polyps as well as a statistic of the frequency of stopped peristaltic waves causing relevant diarrheas, along with the design of the devices suitable for the proposed technology.

3.1. Definition and Types of Intestinal Failure

Intestinal failure is a condition where the gastrointestinal tract's absorptive function is compromised. It's a notable cause of nutritional insufficiency, increasing morbidity and mortality significantly [7]. The incidence of intestinal failure is rising with an annual increase of 10% to reach 24 per million population in 2015. This is thought to be due in part to the increasing prevalence of inflammatory bowel disease (IBD) worldwide and an increment in life expectancy of the population, and in part to a better definition of the disease and more accurate diagnosis. Pediatric patients comprise a large part of the total intestinal failure population and show a higher prevalence compared to adults [5]. The definitions and classifications of intestinal failure and gastrointestinal insufficiency are acknowledged by various specialist medical societies, with the general aim to standardize nomenclature and make possible more accurate and comparable epidemiological and clinical studies in this population. With these criteria, any patient with type 2 and 3 intestinal failure is by definition dependent on a long-term regimen either involving artificial nutritional supplements such as parenteral nutrition (PN) or with the

use of medicines, which may unexpectedly require them to use medical devices for the feeding or administration of those therapies. This is true in regard to patients with special gastrointestinal disorders as well. Under this newly agreed definition, it is to be expected that a relevant part of the pediatric gastroenterology, hepatology, and nutrition practice should have to assist this widening population of long-term dependent patients. This redefine may introduce legal issues concerning the reimbursement of the home-based enteral and parenteral therapies, which provides further importance to this issue. At the same time, it is assumed that a more accurate definition of the pathological mechanisms involved in the various diseases may help to further improve therapy. The process of formulating new guidelines on the deprived specialties has been overlooked, so that an overall practice coherent with the new definitions may be addressed across different units involved in the care of patients with intestinal failure. This is specifically true in the case of patients that may require the use of medical devices, for which an evidence-based research is limited, and the input of the professional medical community is particularly necessary if inappropriate use is to be prevented.

3.2. Complications and Effects on Health

The gastrointestinal tract plays a fundamental role in human physiology, thanks to a structure and functionality aimed at digesting and absorbing food. With its vast mucosal area, the intestine digests and absorbs nutrients, water, and electrolytes, being the principal region for calorie and protein absorption. The upper small bowel has a primary function in the digestion of macronutrients and water and electrolyte absorption, while the terminal ileum is selectively involved in water and vitamin B12 and bile salts' absorption. Studies have highlighted that decreased functionality in specific bowel segments can direct the amount and/or pattern of normal intestinal flows to other sites. The alterations in motility patterns lead to increased maldigestion or malabsorption of ingested food, and therefore to the need for integration of important nutrients, calories, liquids, electrolytes, and vitamins through specially designed solutions: Parenteral Nutrition (PN). PN is a process that involves the use of central and peripheral venous catheters and a complex system that includes several sterile devices as well as a pump and an infusion monitor. Once the energy requirements are provided, PN should guarantee a proper balance of fluids, carbohydrates, lipids, amino acids, vitamins and roughage, with the goal to provide a sufficient amount of all macro and micronutrients, avoiding the excess that could lead to the appearance of serious complications. To facilitate the infusion of PN and avoid local complications related to phlebotomy, the positioning of a venous access device, in particular a central venous catheter (CVC), is required. Randomized clinical trials and meta-analyses have shown that CVC are generally better than peripheral PN at diminishing the occurrence of complications [1]. This was confirmed by an observational study conducted in Italy on the CVC usage for PN in children, with a proportion of CVC patients aged more than 1 year approximately twice as much as that in a similar but more recent observational report from Germany. In general, most centers apply CVC when the need for PN continues for a long time, given the inherent complications of these devices, particularly infections.

Results and Discussion

4. Role of Medical Devices in Supporting Digestive Function

Digestive function requires a coordinated cascade of molecular and cellular events that combine secretion, mixing, and nutrient absorption to reduce food to molecular content ready for systemic absorption. The food content travels a distance of approximately 5 meters in the human gut, passing through a wide array of physiological fluids with different pH levels and enzyme composition. To meet the manifold needs for complex digestive functions one can enlist a range of different medical devices. Such devices can include a mechanical pump device which uses a peristaltic-driven actuation unit to create a series of fluid backflow pumps that may mimic the anisotropic flow pattern generated by the small intestine and a multi-layer capsule that can switch from an expandable polymeric membrane at body temperature to a compressed

configuration at room temperature inside the gastrointestinal tract. An ingestible magnetic device may be designed to clench onto tissue surrounding a disease spot within the stomach or GI tract, or hold and retrieve a local sensor therein by magnetically attracting the sensor within the cap. Tablet-shaped devices may incorporate C-arm X-ray fluoroscope imaging like a standard capsule endoscope, under sealed X-ray-transparent biodegradable foils to allow biodegradation and clearance after usage, an ultrasound gel injector for increasing imaging contrast, or a piezoelectric transducer actuated by an ingestible radio frequency control module. Data signals may be transmitted by electrodes that, when securitized in contact with biofluids, may amplify electric fields and wirelessly transmit data signals. Alternatively, a wireless power receiving device may be used to power the consumable liquids. As the current technology advances, so too do the needs for improved monitoring, diagnostics, and intervention of the digestive system. Medication can also be delivered directly to areas with increased acidity created by various diseases that damage the epithelia, such as gastric ulcer or neoplasms [2].

4.1. Enteral Feeding Devices

Patients with intestinal failure often have impaired anatomy or function of the digestive system so that they cannot tolerate oral nutrition. Therefore, they rely on some form of artificial nutritional support. The use of enteral feeding can reduce the risk of liver failure compared with the use of PN-based nutrition, because the provision of a balanced diet may reduce the risk of steatosis. Enteral feeding may also prevent insoluble calcium salts precipitation into the gallbladder, thus reducing the risk of biliary problems. However, patients with IF are often affected by anatomical or functional problems that prevent feeding via oral, gastroduodenal or gastro enteric access. Various problems can affect these patients. Their ability to chew and swallow food orally can be compromised or their gastrointestinal absorption may not be sufficient due to short bowel. In these cases, nutritional support must be provided through the parenteral route and delivered directly to the circulatory system. Nutritional support is indispensable for the small number of patients who are unable to eat normally. However, long-term and complex parenteral nutrition is associated with many significant adverse effects [8].

4.2. Parenteral Nutrition

Nutritional support can be used safely and effectively in patients with intestinal failure. This often includes enteral nutritional support but in cases of severe intestinal failure, total parenteral nutrition (TPN) is occasionally necessary. Key to providing TPN is a multidisciplinary approach and access to a well-coordinated service [9].

Most healthcare facilities use pre-prepared parenteral nutrition solutions known as 'all-in-one'. These normally contain glucose, essential amino acids, vitamins and electrolytes. Pre-prepared solutions rarely provide adequate lipid in adult patients so the prepared infusion is usually supplemented with a separate lipid emulsion. The usual aim is to prepare a parenteral infusion that provides approximately 20 kcal/kg/day, a balanced salt solution and one that is isotonic to the blood. A physiological concentration of amino acids is generally infused and these also provide the nitrogen requirements.

A range of parenteral solutions are available for use that provide different proportions of amino acids, glucose and lipid. The most common solutions used supply amino acids as a 170 g lysine/16 g nitrogen base, but a number of other solutions are available. To meet the nitrogen requirement the prescribed volume of amino acid solution is calculated to provide the correct amount of nitrogen. Normally 1 g of amino acids will provide around 15%, 1.7 kcal, 1 mmol of phosphate and around 1.5% volume of fluid. It is also necessary to calculate the volume of parenteral nutrition solution required to supply the correct amount of glucose. Most parenteral nutrition solutions contain 50% glucose. Finally, some instructions need to minimize the risk of mineral and electrolyte deficiency.

Similarly to the blind placement of a nasogastric tube more than any other procedure, insertions

related to the long-term need for enteral nutrition (EN) have the potential to transform patients' lives. Hundreds of thousands of percutaneous endoscopic gastrostomies (PEG) are performed each year. PEG is usually the preferred technique because of the abundance of data. In early 1980, a series of patients in whom a G-tube was endoscopically inserted with the pull method, and without laparotomy, was described. This report introduced the era of minimally invasive nutrition.

5. Types of Medical Devices Used in Intestinal Failure

1. Total Parenteral Nutrition (TPN) The ultimate goal in patients with intestinal failure is to promote bowel adaptation and reach enteral autonomy while maintaining healthy growth and development. A multidisciplinary team has to manage the care of patients with this complex condition. In specialized units, a broad spectrum of medical devices is used to monitor and support the digestive system [7]. The alimentary and motility tracts can be assessed with scintigraphy, magnetic imaging, or endoscopy. Balloon-assisted enteroscopy can also provide diagnosis and treatment in the non-surgical management of small bowel diseases. Endoscopic techniques enable the treatment of postsurgical fistulas, compression of strictures, or carcinoid syndrome. Stents can be placed in the small or large bowel. 2. Enteral Nutrition Regarding the management of intestinal failure, enteral feeding formulas with a high content of medium chain triglycerides are commonly used due to their enhanced intestinal absorption. Catheter jejunostomy is preferred to gastrojejunostomy, particularly when gastric feeding is contraindicated, for instance after distal gastrectomy or in patients with gastroparesis. In percutaneous endoscopic jejunostomy, the endoscope is inserted into the bowel through the mouth instead of the common percutaneous endoscopic gastrostomy. This technique is advantageous when there is difficulty in gastric access, either through a stenosed gastric outlet or because of previous surgery [5]. Balloon endoscopic enteroscopy is a pivotal procedure for treatment of small bowel diseases.

5.1. Gastrostomy Tubes

Patients with prolonged intestinal failure might need a long-term transpyloric feeding system to prevent malnutrition and malabsorption. Most gastroenterologists have experience with gastrostomies, and gastrostomy tubes are already used in many patients with or without chronic intestinal failure [10]. However, the literature on success, safety and the best technique for long-term transpyloric feeding by gastrostomy tube is scarce. Gastrostomy tubes are often used in patients with or without chronic intestinal failure to bypass swallowing dysfunction or to decompress the stomach. Bilevel gastrointestinal feeding and drainage systems for venting in case of some types of obstruction can also be inserted. A small series showed mean time of medical use 2.6 years with 25 or 30% malposition and 25% tube dysfunction rate. Feasibility, safety and inexpensive materials to transpylorically insert a double-balloon gastrostomy tube with an ultra-thin transduodenal, endoscopic, rigid, 0-5-mm instrument in five patients [11]. During 146 to 290 days of transpyloric feeding, there was a mild gastric colonization, one minor aspiration pneumonia, one minor dysfunction 225 days after placement and gastroscopy confirmed duodenal patency of tube position.

5.2. Jejunostomy Tubes

Early resumption of feeding is essential in surgical patients to enhance postoperative recovery. Enteral feeding is preferred over parenteral nutrition in those with a functionally intact gastrointestinal tract. Feeding jejunostomy (FJ), or retrocolic jejunostomy (RCJ), sleeve gastrectomy, has been performed as a concomitant procedure in various major upper gastrointestinal tract surgeries. Feeding through a jejunostomy tube is advantageous in patients who are unable to feed adequately by the oral route because of various upper gastrointestinal pathologies. However, there are various reported complications related to feeding jejunostomy (FJ). These complications are classified as mechanical, metabolic, nutritional, and septic. Mechanical complications include tube obstruction, displacement, kinking, coiling, and bowel

perforations. Metabolic complications include electrolyte imbalance due to fluid and electrolyte loss from the jejunum. Gastric jejunostomy patients also need more managing prokinetic agents. Such complications are reportedly less after initial MD analysis. Nutritional complications occur due to malabsorption of various vital nutrients like thiamine, folic acid, and copper from the jejunum, resulting in sudden metabolic derangements. Septic complications are periwound infections of the jejunostomy wound that sometimes can extend to a deep-seated collection and eventually form an abdominal wall abscess, fistula, cellulitis, or even septicemia [12].

Long-term enteral nutrition in chronically ill, malnourished children poses a clinical challenge if adequate feeding via nasogastric or gastrostomy tubes fails. This study evaluated a new type of surgical jejunostomy that allows for easier positioning and replacement of the jejunal feeding tube in children. A novel method for the surgical insertion of a replaceable jejunostomy in nine children (median age: 12 years and 3 months) was used during a 10-year period. Replaceable jejunal feeding tubes (RJFT) were inserted by an open-end procedure connected to a plastic guide thread (PT) that exited through a separate tiny opening of the abdominal wall. Surgery-related data, as well as complications, handling, and outcomes during the long-term use of the RJFT with a median follow-up of 63 months were retrospectively evaluated. In five of nine patients, severe respiratory problems compromised transnasal tube positioning. In one child, replacement of a slipped permanent RJFT was required, which necessitated reconstructive surgery. Another child had to be operated on due to a knotting of the tube with subsequent intraabdominal abscess formation. The remaining patients benefitted from the temporary replacement of the tube by the family at home. The RJFT permitted continuous enteral feeding or bolus application of liquids marked as select if all followed using a syringe and facilitated easy replacement of the tube [13].

5.3. Total Parenteral Nutrition (TPN) Systems

Maintaining appropriate nutrition in patients is paramount to any clinical service, particularly in those patients recovering from surgery or other critical states associated with altered impedance to food ingestion. However, providing appropriate nutrition to patients is not always an easy task. Multiple factors may prevent or significantly delay the achievement of a goal-oriented enteral alimentation including, but not limited to: lack of consent, prior intolerance to enteral feeds, gastrointestinal dysfunction, critical illness, prior surgery that alters the gastrointestinal anatomy, lack of functional gastrointestinal tract as in cases of Necrotizing Enterocolitis or Gastroschisis, or lack of motivation to initiate or continue enteral intake. In this context, patients at risk of or with an altered alimentation via the GI suffer what is known as Intestinal Failure. Intestinal Failure is a devastating disorder related to the inability to maintain long term enteral nutrition due to its inherent complications, comorbidities and lack of absolute cure. Its management is highly complex and requires a multidisciplinary approach in specialized medical centres.

Although being part of a multidisciplinary approach, managing and supporting the digestive system in cases of Intestinal Failure is usually considered the responsibility of the medical services. Current options include directly providing nutrients into the blood stream, therefore bypassing the GI route, with the use of parenteral nutrition via Total Parenteral Nutrition systems. In adults, enteral nutrition is traditionally started within 72 h of admission, although older studies did not find harm in postponing enteral nutrition up to 5–7 days in critically ill patients. Nevertheless, up to 65% of patients receiving enteral nutrition fail to absorb a sufficient amount of provided calories. Nutrients would be prescribed based on measuring resting energy expenditure and the route and volume of formula fed, among other factors. Nutritional failure in critically ill patients not achieving their caloric needs via the GI is a principal concern and a main target of parenteral nutrition therapy.

6. Considerations for Device Selection and Management

In this section, examples for novel orally ingestible devices that have been engineered for

sampling GI material will be highlighted. In the conclusion, the regulatory pathways by which such and other devices might be approved, and future needs to develop this new family of medical devices, will be discussed.

Intestinal failure is rapidly becoming a major healthcare issue because it requires acute intervention and precise medicinal or nutritional therapy to prevent malnutrition, rapid dehydration, sepsis and death. Comparable to other major organs, the failure of the GI system is a dangerous, life-threatening state, where medical devices represent both the safest and most cost-effective solution in the majority of cases. Hence, it follows that a great need presently exists for GI-support devices to be used over protracted periods of weeks to months, either following initial emergency treatment or as a result of chronic pathology, including intestinal failure. Meanwhile, future devices allow for treating and monitoring of various other digestive disorders. This sensing and sampling migrant GI material can be indicated and subsequently delivered to an external lab. In this sense, these devices play a key role in the nascent field of biome-chatronics, i.e. the integration of electromechanical devices with living tissue. This promising technology has recently been highlighted in the context of on-demand treatment delivery of physostigmine, a 'neostatic', as indicated by neural sensors in patient-generated seizures. Intestinal Failure occurs whenever the gut can no longer absorb the necessary fluids and nutrients, usually as a result of a massive resection. This condition requires the administration of total parenteral nutrition either through a continuous intravenous drip or through implantable central venous access port. Orally ingestible devices are a cost-effective, minimally invasive approach for achieving controlled delivery and improved monitoring of gut-fed drugs and supplements. Machines for cutting, drilling, and threading are used to rapidly prototype through-hole polymer coating for programming drug release. The coating is tested for water tightness with a model drug and for controlled rate release through a fiber optic spectrophotometer. A membrane made of Cab-O-Sil and paraffin seal layer made of cholesterol can achieve a fluid tight seal. The rate of water ingress into the device and the resulting drug release can be controlled. Sub-millimeter wall thickness is sufficient for smooth coating and comparably controlled release. This system can be used by those who need dual-release systems. [14][15][16]

6.1. Patient-Specific Factors

Patient-specific factors known to affect the dose of parenteral nutrition (PN) are both pathology-related factors, which include type of disease/complications and metabolic state, and individual patient-related factors that may occur independently of the primary pathology or the disease state. Practices exist as medical procedures, pharmaceutical treatment and choice of medical devices. Choice of medical devices may either directly affect the patient's dose, in bypassing the metabolic processes that would otherwise have influence on the dose of PN, or impart clinical conditions that may necessitate changes in the PN dose otherwise needed.

The digestive system typically absorbs 45-75% of the protein, 70-80% of fat and 85-95% of carbohydrates in the diet. In cases of intestinal failure, the digestive system is unable to function efficiently due to disease, injury, treatment or congenital problems, and hence the balance of nutrients needs to be maintained solely intravenously, with possible supplementation with vitamins, amino acids, coenzymes, etc. Invasive medical devices generally bypass the metabolic processes that would otherwise have influence on the dose of the nutrients to absorb. Enteral feeding pumps and devices may put the patient in a situation where hypersomnolence, perfusion, or psychological reactions to a "full stomach" come into play, leading to changes in the patient appetite or bowel function.

6.2. Technical Specifications

The robotic pill endoscope for the intestinal transmission system should have robust bidirectional communication capabilities to and from a designated outside communicator. The robotic pill should incorporate full-duplex transmission ability for the external network. For the wireless

link, a license-free band should be selected and preferably one with minimum attenuation by human tissues. A robust and reliable link should be assured with no data packet loss even during the pill's rotation. The crawling pill design also utilizes an external transmitter and receiver to communicate with the capsule. The communication system consists of a transmitter and receiver part. The transmitter's main function is to communicate with the capsule, retrieve image data stored in the capsule, and process them to display the final image. Alternatively, instead of implementing a separate device for external communication, other more clinical robust communication methods have been proposed. The solution is to use an embedded transceiver to create a closed loop communication system, in which both the capsule and the PIS are active elements. A device has the capability to sample GI fluid, sense biomarkers with genetically engineered bacteria, store the detected biomarker information, and telemetrically transmit the data outside of the gastrointestinal tract. This is achieved by fitting the device with a mechanical suction and a timed release sampling system. A partial vacuum is created mechanically on demand, serving to open a flexible valve with a tensile backbone, resulting in fluid intake. In addition, an osmotic pressure-driven suction device is demonstrated. This device can take in GI fluids continuously for up to 48 hours and has a magnetized microneedle that significantly extends retention time in the small intestines for increased sampling duration. The medical invents sector is undergoing major transformation. Citing cases of faulty hip implants and breast implants, the Medical Device Regulation policy has been revamped, and as of the new deadlines, active medical devices will be governed by some of the strictest controls. This regime is followed by a 12-month adaptation period, by when invasive control systems will have to comply with the significant process that has been put forward. [17][18][19]

7. Clinical Guidelines and Best Practices

This is a systematic process for the treatment of adult patients diagnosed with intestinal failure (IF). The purpose of this document is to provide current evidence and best practice recommendations for the use of medical devices in the support of the digestive system for adult patients. Mechanical constraints, patient tolerability and safety concerns can lead to a large and growing list of negative outcomes associated with longer-term MC use. Of particular interest are the benefits of novel technologies, the performance of a latent demand analysis of the market for MC-related settlements and future research priorities for devices to mitigate the negative outcomes of MC use. Although these mainly consist of nutrition supply systems, the review includes a wide variety of devices and technologies. This approach reflects the multifaceted, multidisciplinary problem of replacing intestine function with devices. Broadly, the review shows how the field of medical device research and development can help tackle unmet needs and ongoing challenges in the nutritional management of chronic intestinal failure (CIF). The combination of a structured review with an analysis of an unmet need in the context of the wider market for medical devices is a novel contribution to the field. Since the criteria for CIF and its treatment programmes have been passed, a close monitoring of patients was mandated. Thus, the emergence of volume accumulated around MC use, this issue is broadly used for the first time, including detailed consideration of the MC itself. In comparison to previous works on long-term MC use, there is more emphasis on monitoring and on treatment of complications, particularly in relation to devices. Serious IF is rare, highly disabling and carries a poor estimated survival rate of less than 50% at 5 years. Better integration of pre-existing knowledge of clinical care pathways for the treatment of long-lasting, costly and less than ideally effective interventions and the development of new device technologies is essential for further research on adult patients. The overarching objective is to track and summarize the broader development of the field, drawing on existing knowledge and identifying priorities for subsequent work on technology.

7.1. Enteral and Parenteral Nutrition Guidelines

Nutritional support is essential in patients with organ failure who have a limited capability to maintain their body weight with a normal diet. In these patients, oral feeding is the main

approach to ensure a sufficient intake of nutrients. When oral feeding cannot guarantee adequate nutrition, one of the following approaches can be adopted: • Jejunal or gastric feeding tubes, which can be easily positioned during common endoscopic procedures • Total or partial resection of the small bowel, although this is not common • PN through the implantation of a subcutaneous venous access, typically a Port-a-Cath All three of these solutions pose long-term complications. Endoscopic nasojejunal tubes can be a valid alternative to prolonged support with PN. However, this approach is not always well tolerated and can cause the patient discomfort which may require administration of high doses of analgesic drugs for proper tolerability. This approach is mostly suitable for patients who are hospitalized in an intensive care unit (ICU) or sub-intensive care unit (SICU). To allow feeding the NAJ tube must be connected to a nutrition pump and the patient usually has to remain in supine position often sedated. Patients who have one or more non-functional nostrils and patients who require a prolonged nasal cannula supplementation are unsuitable candidates for NAG/NAJ tube positioning. Alternatively, an endoscopic percutaneous gastrostomy (PEG) or jejunostomy (PEJ) could be positioned to allow feeding outside ICU and a better ambulation of the patients.

Nutritional support is essential in patients who have limited capability to maintain their body weight with a normal diet. Organ failure of the liver, renal or lung is estimated to affect about 1% of the European population and leads to functional limitation in the case of liver, acute life-threatening condition in the case of lung and renal, until end-stage renal disease [8]. On the other hand, the incidence of intestinal failure (IF), characterised by the reduction in length or function of the gut, as a cause of intestinal (nutritional) insufficiency, is underestimated and believed to affect around 1 in 10,000 subjects. In IF, the nutrient absorption capacity of the gut is impaired, thus requiring the administration of an elemental diet or an admixture of nutrients which bypasses the normal digestive process to craft an already-digested solution to be absorbed. The route of access can be oral, by the approach of a feeding tube, or parenteral, with the infusion of nutrients directly into the bloodstream.

7.2. Monitoring and Complications Management

Intestinal failure (IF) occurs when the gut's absorptive capacity or digestive function is inadequate for nutrient absorption. Medical devices are used for the support of the digestive system in IF cases, and many devices are implanted in the GI lumen, e.g. long-term access lines, while others are inserted per-anum, e.g. cannulas, stents, feeding tubes, or endoscopes. Because of the broad variety of possible complications, including perforations, narrowed areas, leakage, incompatibility to body tissue, addition of harmful substances, failure of the devices, or infections, currently two projects are being initiated focusing on monitoring of devices in the GI-tract as well as minimally-invasive systems for the management of GI-device related complications [2]. Complications of medical devices in the GI lumen that are caused by the device itself have only been relatively recently identified as an independent risk factor for IF, but are now suspected to significantly contribute to IF cases. Together with bacterial infections, these are very difficult to treat, as the biofilms which often form on the devices are very resilient against common medical treatment and also require the respective drug to be applied systemically. Interventional endoscopic treatment typically relies on high-power laser or on an electrical current being routed through the target tissue, thus inherently bears the high risk of high-temperature kills with necrotic scarring, potentially perforating the tissue at the intervention location. However, an overflow of usually low-conductivity saline solution bathes the intervention site, increasing the current pathway resistance. This can lead to an excessively high voltage being applied to the tissue, causing deep, unintended coagulation of healthy tissue referred to as steam pops.

8. Advancements in Medical Device Technology

Significant advancements have been made in medical device technology paving the way for the development of either ingestible, injectable or non-invasive devices with important applications

in supporting the digestive system. These wide ranging advancements include a needle-less injection system for subcutaneous delivery of high viscosity fluids, a robotic device with modular soft tentacle-based continuum arm for less-invasive surgery, a biocompatible air cathode liquid probe for tissue enhanced broad-spectrum photodynamic hypertherapy and a method for screening anti-biofilm agents based on the quantification of metabolic flux distributions of D-glucose in the TCA cycle of *Pseudomonas aeruginosa* biofilms. Angie Xie and co-workers disclosed a system for robotic UV disinfection of hospital rooms by combining UVC emitters on a mobile robot with a UV-C emitting lamp high above the patient's bed. For the treatment of intestinal diseases, the ability to deliver drugs locally and directly to the intestine is considered superior to invasive surgery, which comes with risks such as infection, adhesion formation, and prolonged recovery time [20]. For a versatile drug delivery system used in accordance to the complexity of the disease-state and location, fabricating irradiation patterned polymeric sheets with different swelling rates. In treatments for colorectal and duodenal cancers, wedging endoscopic delivery systems for improvements in macroscale aspects of the target and miniature drug delivery devices used for microparticles or nanoparticles have been proposed. Further developed for this purpose are expandable stents with embedded drug-coated therapeutic micro tanks and reservoirs. To track the location in the GI tract, magnetic composites are introduced that can be activated by a magnetic field. Flex sensors or shape sensors are attached to existing miniature devices to improve the control and localization of these drug delivery devices.

8.1. Innovations in Enteral Feeding Devices

Miniaturization of endoscopes and the diffusion of tiny sensors have contributed to the growing interests of the medical community towards minimally invasive methods applied to the collection of physiological data not necessarily available to other diagnostic tools. This broader scenario is often referred to as capsule endoscopy. It can be actually grouped in a larger family of methods including both ingestible capsules (often with sensing capabilities) and endoscopes lacking exterior control and actuation units. Support systems enabling the steerable control and the propulsion of these devices within the gastrointestinal (G) tract are then required in order to guarantee their effectiveness in the diagnostics and their eventual control by medical personnel. The hardware component of such systems generally consists of a positioning unit provided with a support surface where the patient lies down during the procedure and one or more robotic arms designed to release, actuate and direct the device. There are also so-called endorobots targeting the large intestine which are used to passively address typical bends in such tract thanks to the use of a snake-like rigid elongated structure. Treatment through the minimally invasive long term placement of unattended part magnetic elements is being studied with a companion interest in the design of systems aimed at magnetically actuating the element. The main geometry of the gastrointestinal tract, which is an organ that penetrates the body cavity, but can be interfaced with the external world only through openings, such as the mouth and the anus. It consists of the hollow long tube wound up in loops formed by the stomach, the small intestine and the large intestine. The natural propulsive mechanisms of the gastrointestinal tract can be of different kind, depending on the affected segment of the tract. As an example, antiperistaltic contractions, i.e. overstudied voluntary control, are responsible for food intake. Moreover, many diseases may slow down the natural propulsive mechanisms leading to stasis and thus altering the peristalsis [8].

8.2. Smart Technology Integration

Novel medical devices have advanced unique capabilities for the support, restoration, or substitution of the digestive system. The digestive system consists of the gastrointestinal (GI) tract, including the esophagus, stomach, and intestines. Medical devices are essential for the support of the digestive system due to acute or chronic disease. The liver, pancreas, and intestines are crucial digestive organs that can fail and require support. Ingestible medical devices can help the support and surveillance of the digestive system by monitoring

physiological conditions, delivering drugs to a specific site, or even aiding surgeries, but are often limited by their size, materials, and power supply. Wireless electronic capsule and miniaturized ingestible bio-robot are introduced and biotechnologically extended to provide complex functions. The integrated system consists of an electronic capsule with sensors and actuators, a miniaturized bio-robot that can be precisely guided, and a magnetic-based recharging platform [2]. This device will be reviewed in regards to how it can support, replace, or restore the digestive system as an ingestible medical device. Available devices in the market will also be examined, including the investigational ones, outlining their focus in the domain of digestive system impairment.

Around the world, there is an increasing interest and production focused on developing wearable health monitoring devices, where a small part of them also target the GI system. However, the majority of the devices are still invasive, have an unpleasant drinking procedure, a strong dependency on data link, or do not specifically target the digestive system. Therefore, a device that is easy to consume and removes the need for data link is needed, which will measure the level of biomarkers and pH level in the GI tract. An ingestible medical sensor system consisting of a non-invasive personal reader, an acid-resistant capsule, and a 2-electrode sensor, for analysis of biomarkers and pH level in the GI tract will be examined. Available research studies that aim to reduce the common use of endoscopy for digestive system exploration monitoring will be reviewed, with a significant speedup in a prototype for a similar solution [21]. The purpose of this research initiative is to identify devices that could be improved and developed further in the laboratory environment to be mission-oriented towards the better support of the digestive system.

9. Case Studies and Clinical Outcomes

Intestinal failure is life-threatening condition, which is diagnosed based on the inability to absorb sufficient nutrients in patients with defined diminished functional gut length. Facts about chronic and acute intestinal failure are provided in line with an overview on the etiology and pathophysiology of short bowel syndrome (SBS) and no gut syndrome [22]. Additionally, the clinical symptoms, mechanism of adaptation, principle approach and medications are discussed about the various types of management of intestinal failure for providing a full view of the disease. The role of medical devices in supporting the digestive system with a focus on their application in cases of chronic intestinal failure or patients suffering from underlying diseases with the risk of intestinal perforations along with their use in the postoperative period for peritonitis, ileus or anastomosis leaks is evaluated. Moreover, other valuable findings from the surgical and hospital-connected observations are presented. Mercifully rare, the loss of central venous access is a catastrophe for patients with intestinal failure requiring parenteral nutrition. A 62-year-old woman with end-stage venous access lost permanent central access. Inadvertent button-gastric-j-tube placement ended in a hemicolectomy for a distal jejunostomy wound dehiscence, with intended subsequent completion colectomy and feeding jejunostomy. The patient had underlying diseases prompting a jejunal perforation requiring an extensive bowel resection, ICU admission, and multi-domain septic shock managed with CRRT and vasopressors. PPN was begun via a right CVC on post-op day 12 and a jejunal fistula emerged on day 42. Malnourished (BMI:10.5) and frail, end-stage vascular access with central venous stenosis was part of her extensive comorbid history. Currently existing central central venous access options were exhausted with long-standing right Vascuport leading to loss of permanent central access. Achieving enteral autonomy with jejunal fistulas untreated with intestinal transplantation was deemed as unrealistic and the case was brought up to the Multi-Disciplinary Team Meeting on the Intestinal Failure Service [23].

9.1. Real-world Applications of Medical Devices

Contrary to traditional open and closed human systems, our bioenvironment is a highly controlled environment whereby food and pollution can be regulated as necessary. This aspect makes it challenging to develop robust and safe designed medical devices and positioned drugs

for wear or transplantation. The paradigm designs including implantable, wearable, controlled release, transport, and amplification, all provide a variety of possible solutions interacting with the digestive system. If medical devices are frequently used or continuously needed for a specific treatment, organic routes are accessible. This sales service enables the absorption of food and guaranteed distribution of medicine. One of the outcomes of intestinal failure is the difficulty of preserving essential operations. Though parenteral nutrition has been a powerful last resort, it establishes liver failure and postabsorptive nutrient disorders and predisposes septicemia. Anywhere from 20,000 to 40,000 Europeans having parenteral nutrition in a limited intestine, the use of a high-cost additional drug is unavoidable. High-protein and Low weight solutions are applied by means of intravenous infusion. However, the feed tube should not be less than 2 mm, which is current punishable to 25% from a vein's last volume. Conversely, the parenteral nutrition amino acid derivative system is applied mainly by injection due to the weak bioavailability of the GI path. Butt-channeling stoma is a primary strategy for preventing a widely spread coating wet product interference. Nevertheless, this coating approach produces diarrhea and signifies small prosperity for a long period. Pre-biopsy samples were also shown to significantly alter microbiota composition. Purposive antibiotic treatment would reduce bacterial population variability and strengthen colonization resistance. Correspondingly, colonization was significantly greater in the absence of representative microbial bacteria. The outcome stresses the significance of the based community in shaping microbial gut ecology. Transferred become a part of the intestinal biofilm, shifts microbiota composition, and co-polyomizes with multifocal colorectal tumundenoma. [24][25][26]

9.2. Success Stories and Challenges

In the setting of multicentre studies and data sharing platforms, the availability of personalised medical devices allowing the performance of additional therapeutic procedures is increasingly possible. Two innovative applications of medical devices developed for unrelated disciplines are described.

By using a simulation platform, biomedical engineers design three-dimensional printers to produce customised prostheses. A 3D-printed obturator is designed to restore palatal function in a patient following surgical intervention for oral malignancy, gaining volume in the soft palate. Changes in respiratory pressure when air is expelled through the mouth are used in the dynamic test. The prosthetic obturator is designed using 3D software and printed in ABS filament, besides being biocompatible, water-resistant, and resilient to tear strength. With the obturator, there is no change in breathing pressure, favouring the speaker's speech and competence as a lawyer.

Telediagnostic scans are obtained from a patient candidate for the provision of a customised hollow obturator, a medical device for the treatment of palatal defects. Using a finite element analysis, the temporary obturator is redesigned to improve its structural behaviour. The customised obturator is positioned in a patient with a congenital isolated cleft palate, promoting the separation of the oral and nasal cavities, which are anatomically interconnected in the condition. The patient is included in an ethics-approved research project and a \$750 government grant is accessed to address the cost of the treating the patient. Playing LEGO® as a child, the patient receives 35 pieces from a CITY product line, accompanying its construction manual. With the customised obturator, the patient can speak fluently and is not expelled food and beverages through the nasal cavity during deglutition to promote social interaction [27].

10. Future Directions and Research Opportunities

This article has aimed at providing an overview of the development, structure, and functioning of the devices intended to support the digestive tract with respect to nutritional management in patients treated for chronic IR. The aforementioned structures are most commonly developed for interventions undertaken in the upper GIT but the larger bowel holds an equal role according to its anatomy and functions. For patients with chronic IR, the use of medical devices is fundamental to provide for sufficient and correct nutrition, in addition to medical therapies.

Because the consequences of chronic IR may impair the ability to meet the body's needs with oral nutrition alone, and all patients were convinced to have lost their autonomy in daily routines. It is of particular importance to continue developing the field of the so-called future medicine, which stands for innovative technologies and solutions for health care in multidisciplinary terms, like new materials, micro and nanoengineering, telemedicine, and data processing, among others. They are devoted not only to the medical routine basis, but social and psychological support, and to enhance dignity and comfort in patients, broadly without age limits. [28][29][30]

10.1. Emerging Technologies and Therapies

Since the origin of tissue engineering developments, pancreas, liver, kidney, and skin tissues have been considered for bioengineering concepts. Today, contemporary improvements in technology have seen the start of smart and high-end computers based on electronic devices, such as smartphones. In a developing world where technology exists beyond imaginative limits, implant devices are revolutionizing body organ monitoring, analyses, and processing. For early detection or to stabilize disease severity, ingestible or implantable devices are now widely used and marketisable for such purposes. The current article emphasizes the unexplored bioengineering of the gastrointestinal tract (GI) for the proposal of Plastic, E-texturized, Elastomer, 3D, Implant Device (PEE3ID) based gastrointestinal tract engineering. This versatile biocompatible device can monitor any GI tract including the small intestine, colon, or multioperational activity occurring in the gut [2]. Intestinal or multivisceral transplantation is a viable option for selected patients with irreversible intestinal failure (IF) who can no longer tolerate conventional therapies. IF is defined as a reduction of functional gut mass below the level necessary for adequate digestion and absorption of nutrients and fluids. A wide array of primary gastrointestinal (GI) disorders leads to IF, but regardless of the cause, the clinical consequences are similar.

10.2. Unmet Needs and Areas for Improvement

Digestive system-focused medical devices play a major role in supporting the digestive system in cases of intestinal failure. These devices either partially or completely replace the functions of the digestive tract. Artificial clinical nutrition is delivered using enteral or parenteral ways and can replace the physiological functions of each part of the gastrointestinal tract. Microbiome therapy is anticipated to substitute for some of the functions performed by the gut microbiota. The most promising strategies rely on probiotics, prebiotics, postbiotics, or fecal transplant.

Despite the recent progress in these technologies, many unmet needs and opportunities for improvement are still identified. Lack of appetite and dietary variety minimizes the need to incorporate an extensive range of sensors in smart medical devices for the digestive system. A novel technology for continuous, comprehensive measurement of food intake is reported. Smart caps are described, which monitor the ingestion of medicines and nutrients. Methods to monitor the digestion of meals and the functions of the intestines are discussed. [31][32][33]

11. Conclusion

Intestinal failure (IF) is a severe clinical condition characterized by the loss of absorptive capacity and/or the inability to thrive in individuals with short bowel syndrome (SBS). Neonatal conditions and necrotizing enterocolitis (NEC) are primary causes of SBS in early childhood, and SBS-associated mortality is considerable in premature infants. In later years, acquired conditions due to major gastrointestinal surgery or other chronic gastrointestinal diseases result in pediatric cases of SBS leading to IF. Nonsurgical treatment modalities should be intensified to prevent irreversible SBS in a timely fashion. Conversely, diseases originating in organs outside the gut and leading to intestinal dysfunction require a more patient, delayed and complex frame over time to end in IF. Recent data from long-term nationwide surveys invite the implementation of supportive strategies, such as intestinal rehabilitation and multidisciplinary patient assistance teams, to care for cases with anticipated less favorable outcomes. All-needs support to the

gastrointestinal system is compatible with life. We could assume that the digestive system allows the other organ systems to function, as it is responsible for processing food into a digestible form and then delivering nutrients to tissues to support nutrition. In cases of SBS complicated by intestinal failure, multiple aspects of gastrointestinal physiology can be disrupted, including gastrointestinal absorption, hormone synthesis and secretion, and gut-originating immunity and/or integrity. Besides the supportive role, the gut studies show the interplay with it and others in innate and adaptive gut homeostasis. When failure occurs, a concomitant system is necessary to replace the absorptive, neurological, endocrine, immune, and gut functional support losses. By reviewing enterally infused medical devices involved in each system, we aim to elucidate how the needs of the gastrointestinal system can be met in case of gut failure and restore the gut system.

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