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ORIGINAL ARTICLE

Design and development of a manual pump for bolus enteral nutrition☆

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Abstract
Introduction: Enteral nutrition (EN) is based on administration of liquid solutions into the gastrointestinal tract using a tube. After identifying unsolved practical difficulties in administration of EN using volume syringes, a new device to overcome such technical difficulties was proposed.
Material and methods: Specific technologies (CAD, 3D printing) were used in collaboration with the PRODINTEC Foundation (Gijón, Asturias). Clarke Modet, a law firm specialized in intellectual property, provided legal advice on formulas for legal protection of the invention.
Results and discussion: The resulting device is a manual pump for infusion of EN to patients that solves previously identified problems and is highly functional and compact. It would allow for comfortable and safe administration of solutions. Integration of a bottle into the device itself and pump dimensions facilitate transport and patient mobility. According to the described configuration, this invention has many advantages over the previously known procedures, such as a simpler administration within the field of intermittent EN, improving the standard nutritional support technique, which in this case is use of volume syringes. This would facilitate the work of caregivers while promoting patient self-care and autonomy. The pump was accredited novelty of design, inventive activity and industrial exploitation potential by the European Patent Office (EPO), to which a patent has been requested.

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PALABRAS CLAVE
Nutrición enteral;
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Diseño enteral

Diseño y desarrollo de una bomba manual para la nutrición enteral en bolos

Resumen
Introducción: La nutrición enteral (NE) se basa en la administración de soluciones líquidas en el aparato digestivo mediante el uso de una sonda. Tras identificar dificultades prácticas no resueltas en la administración de NE por bolos mediante jeringa de volumen, se planteó un nuevo dispositivo que superara estas dificultades técnicas.
Material y métodos: Para su diseño se utilizaron tecnologías específicas (CAD, impresión 3D) en colaboración con la Fundación PRODINTEC (Gijón, Asturias). Mediante el asesoramiento legal de Clarke Modet, especialistas en derecho intelectual, se buscaron fórmulas para la protección de la invención.
Resultados y discusión: El dispositivo obtenido se corresponde a una bomba manual para la infusión de NE a los pacientes. Solventa problemas previamente identificados, siendo altamente funcional y compacto. Permitiría una administración, de forma cómoda y segura, de soluciones líquidas. La integración de una botella en el propio dispositivo y su dimensionamiento facilitan su transporte y favorecen la movilidad del paciente. De acuerdo con la configuración descrita, la presente invención presenta múltiples ventajas respecto a las técnicas previamente conocidas, como simplificar las técnicas de administración dentro del campo de la NE intermitente, mejorando la técnica de aporte nutricional de referencia, que en este caso es el uso de jeringas de volumen, facilitando la labor de los cuidadores y al mismo tiempo promoviendo los autocuidados y la autonomía de los pacientes. Fue acreditada novedad de diseño, actividad inventiva y capacidad de explotación industrial, pendiente de concesión de una patente mundial por la Oficina Europea de Patentes.

Introduction

Enteral nutrition (EN) is a form of artificial nutrition based on the administration of liquid formulations in the gastrointestinal tract with the help of a tube. The proximal extremity of the tube is located outside the patient and is accessible for manipulation, while the distal extremity is positioned in the stomach, duodenum or jejunum, where it delivers the required nutrients.[1] Enteral nutrition is indicated in patients that have problems in ensuring adequate nutrition through active oral intake, but who have a functioning digestive apparatus.

The method of administration of the nutritional formula is a fundamental clinical decision. One route or other will be chosen depending on the type of needs and the characteristics of the patient. A nasogastric tube is usually chosen if EN is expected to be of short duration, while a gastrostomy may be considered if prolonged administration is expected. While EN is usually started in the hospital setting, it is commonly maintained in the home of the patient (home enteral nutrition [HEN]).

Enteral nutrition can be administered on a continuous basis, intermittently (bolus dosing) or both. Different strategies are used depending on the method of administration, e.g., gravity drip, volume syringes or electronic infusion pumps.[2] Electronic pumps for nutrition are commonly used in the in-hospital EN setting and allow automatization with great safety,[3] though there are also serious inconveniences. In effect, these are complex devices equipped with pressure and flow sensors, and require electrical energy in order to be operated, programming for use, and adequate and exhaustive maintenance. They are, moreover, bulky and heavy – a fact that considerably complicates transport and handling. These features result in a serious loss of autonomy for both the patients and their caregivers. Lastly, their access and use is further limited by the high cost of these systems.

On the other hand, volume syringes are the most commonly used option in the ambulatory setting, with bolus dosing designed to simulate human mealtimes. Their use in intermittent EN also poses technical difficulties and some risks, fundamentally related to incorrect administration of the nutritional formula. The correct application of the technique requires an adequate flow in order to avoid complications associated with volume overload in the digestive tract, which results in abdominal pain, vomiting, nausea and reflux (gastroesophageal or through the ostomy) as the most common problems associated with this type of administration.[4,5]

Nutrient supply in the form of boluses delivered with a syringe requires enormous dedication on the part of the caregivers and results in a considerable loss of patient autonomy. This is further worsened by the fact that many of these patients present associated diseases that complicate motor function, such as Parkinson's disease, Alzheimer, myasthenia gravis, Guillain-Barré, amyotrophic lateral sclerosis or the sequelae of previous cerebrovascular events.

Innovation in the development of medical devices arises from the experience and inventive capacity of healthcare professionals, combining clinical practice, intimate knowledge of disease, and the inherent need to provide answers to problems that arise on a daily basis. It was the identification

of unresolved technical difficulties in EN using electronic pump and volume syringe bolus administration that led to our designing a device capable both of filling the technical gap between these EN methods and of satisfying existing needs.

Material and methods

After identifying weaknesses in the current EN techniques, different experts in nutrition were consulted in the search for possible technical solutions to the observed problems. A device was designed through collaboration with the PRODINTEC Foundation (Gijón, Asturias), and developed from specific technologies and methods.

The project was structured based on the following steps:

a) Step 1. Conceptual design: the definition of the technical requirements, conceptual design proposals and the manufacture of esthetic validation prototypes.
b) Step 2. Detail design: the specification of details, the validation of the design and an economic viability and scaling study.
c) Step 3. Prototype manufacture: the production of customized mechanical components and the assembly of the functional prototype.

The following starting specifications were defined for the device:

a) Standard EN parameters used as a reference: routine infusion regimens of up to 5–6 applications a day, infusion rate 15 ml/min (approximately), implying a total volume of 1800–2400 ml/24 h (1500–1800 ml nutritional formula and 300–600 ml water), with nutrition care requirements of up to 180 min a day and the need for manipulation of the nutritional formula.
b) Device optimization requirements: intuitiveness, easy use, mechanical technology, compactness, low weight, manual operation (with possible electrical motor assist), ergonomics, patient autonomy, convenience for the caregiver.

Results

Certain fundamental details were taken into consideration, such as the need to adjust to the task for which the device was designed, its adaptation to the user, the prevention of fatigue, and the avoidance of postures or practices requiring unnecessary effort. Furthermore, the maintenance costs were to be reasonable, and the device was required to afford sensory feedback to the user. Pre-dimensioning of the device was made to this effect (Fig. 1).

An ergonomic analysis was made of the design, with the following factors being taken into account: the total volume of the device (size, shape, orientation, section, surface and material), the operating force (weight and fixation status), the safety aspects (guards and stops), the prevention of vibrations, and the mode of activation (triggers and switches, crank handle). After progress had been made in these aspects, conceptual approaches were adopted based on industrial design techniques, followed by a technical assessment of the possible device (Fig. 2).

The initially defined device technically consisted of a housing for the manually activated peristaltic pump mechanism (Fig. 3A and B). The design was conceived to allow the circulation of a liquid solution contained in a bottle through a flexible feeding tube between an inlet extremity receiving the nutrient solution and an outlet extremity. The outlet extremity in turn was designed to be connected to the proximal extremity of a feeding tube positioned within the patient.

In addition, a receptacle was designed in the housing to hold the nutrition solution bottle. The caudad extremity of the receptacle was equipped with a needle to establish communication between the solution in the bottle and the feeding tube. This considerably lessened the risk of manipulation of the bottle contents, and the reduced contact with the exterior implied less oxidation and risk of contamination of the nutrient formula, thus optimizing its organoleptic properties (Fig. 3B and C).

In the context of the safety standards for EN, and as part of the processes referring to nutrition pump safety and care, both the needle and the feeding tube conducting the liquid were replaceable. In this regard the needle was designed with threading to fit in the lower base of the housing, making it accessible for simultaneous extraction along with the entire tube. In order to facilitate device maintenance (as in replacing the interior system of the pump), the housing was equipped with an opening allowing access to the interior (Fig. 3C).

Within the device, the driving axis comprised a dentate perimetry geared to the transmission, while the transmission axis consisted of a dentate wheel geared to the transmission and an extremity linked to the rotor (Fig. 3D).

The pumping mechanism was based on a crank handle that could be activated manually by the caregiver or by the patient, and was designed to be assembled on either side of the housing. The side contralateral to the crank handle was equipped with anchorings for a grasping handle that likewise could be fitted to either side. In this way the pump could easily be adapted for use by right- or left-handed persons, or be manipulated either by the patient or by the facing caregiver (Fig. 4A and B).

The pumping system involved a peristaltic mechanism with a rotor fitted with multiple rollers designed to compress the feeding tube, causing the bottle contents to flow through the latter. In turn, the cylindrical chamber comprised an inlet opening with an inlet deflector that redirected the feeding tube toward the receptacle, and an outlet opening with an outlet deflector redirecting the feeding tube toward a housing outlet orifice (Fig. 4B and C).

Details in the design geared to optimize the use of the system included the presence of a series of fixation points to affix the exterior segment of the feeding tube and retrieve the outlet extremity when the pump was not in use. In addition, elastic blocking elements could be used to secure the position of the bottle once it was placed in the receptacle (Fig. 4A and D).

As a result of the work done, we initially applied for a European patent from the European Patent Office (EPO), based on the European Patent Convention (https://euipo.europa.eu/ohimportal/es) through the

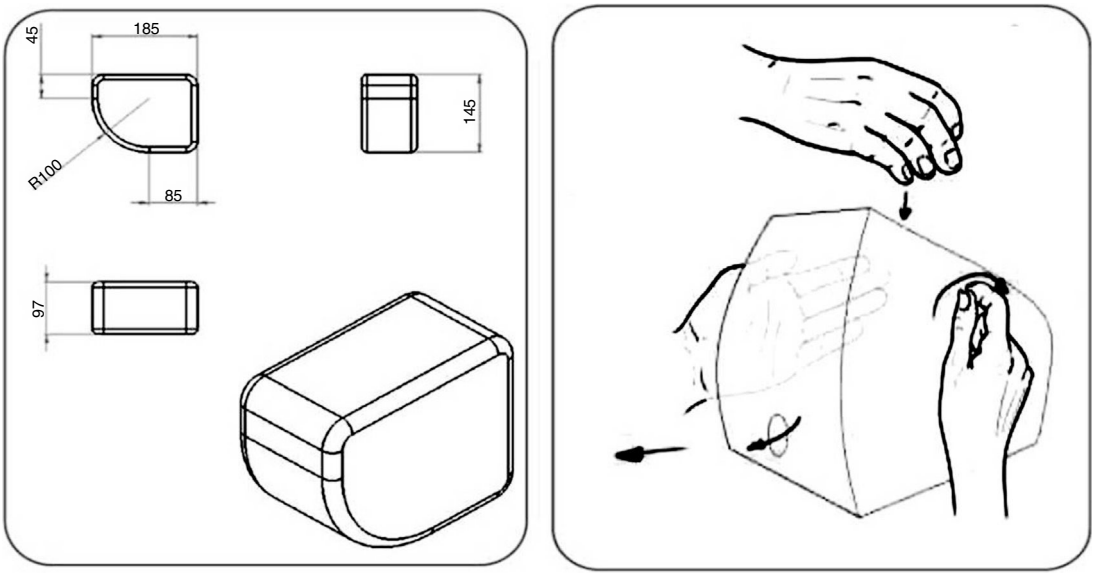

Figure 1 Pre-dimensioning of the device.

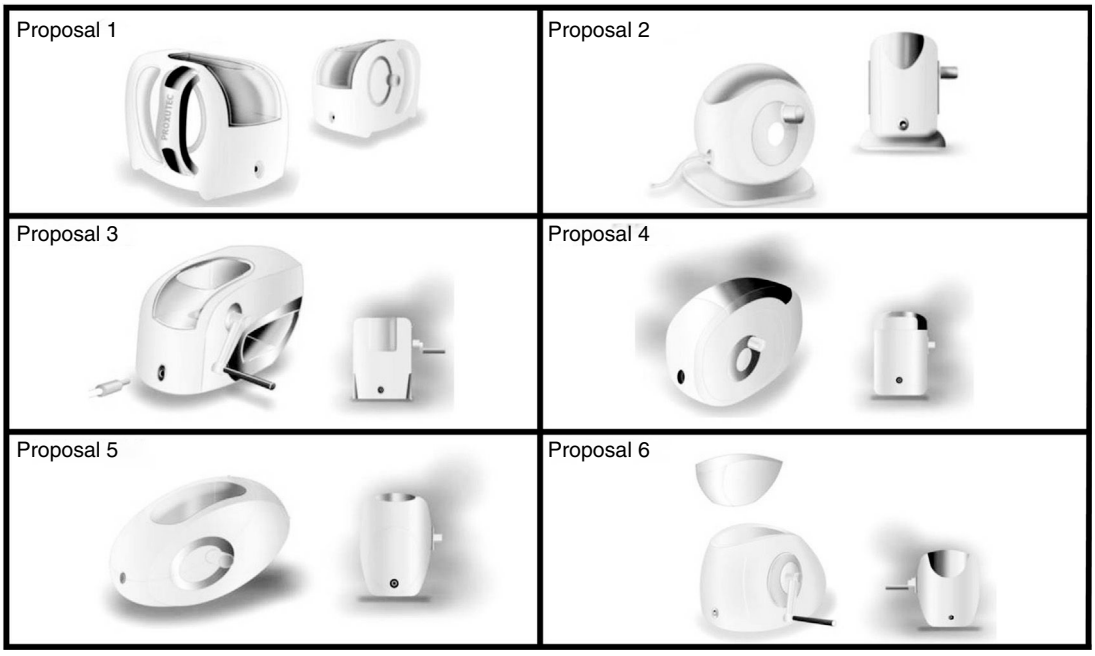

Figure 2 Conceptual approach to the possible prototypes designed.

Spanish Office of Patents and Brands (*Oficina Española de Patentes y Marcas*) (www.oepm.es). Following different evaluation phases, the application was accepted and subsequently expanded as a protection application according to the Patent Cooperation Treaty (PCT) (corresponding to a world patent). In this application the device was defined through the description of 15 claims, which were accepted, with the recognition of the novelty of its design, inventive activity and industrial exploitation capacity.[6]

Discussion

The design and development of medical devices constitutes a challenge for both medicine and engineering, and often requires their collaboration. In the period between 1990 and 1996, a full 20% of the over 26,000 patents presented in the United States were innovations developed by physicians. According to different indicators, these patents in turn exerted an increasing influence upon posterior

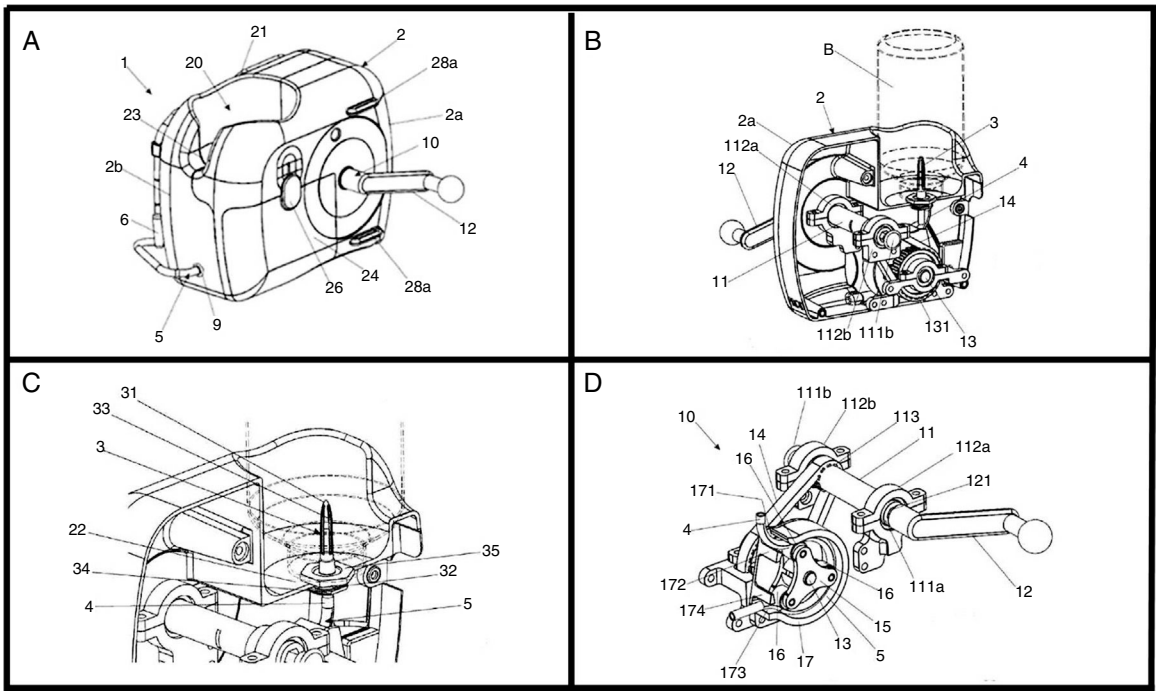

Figure 3 Detailed design of the final device.

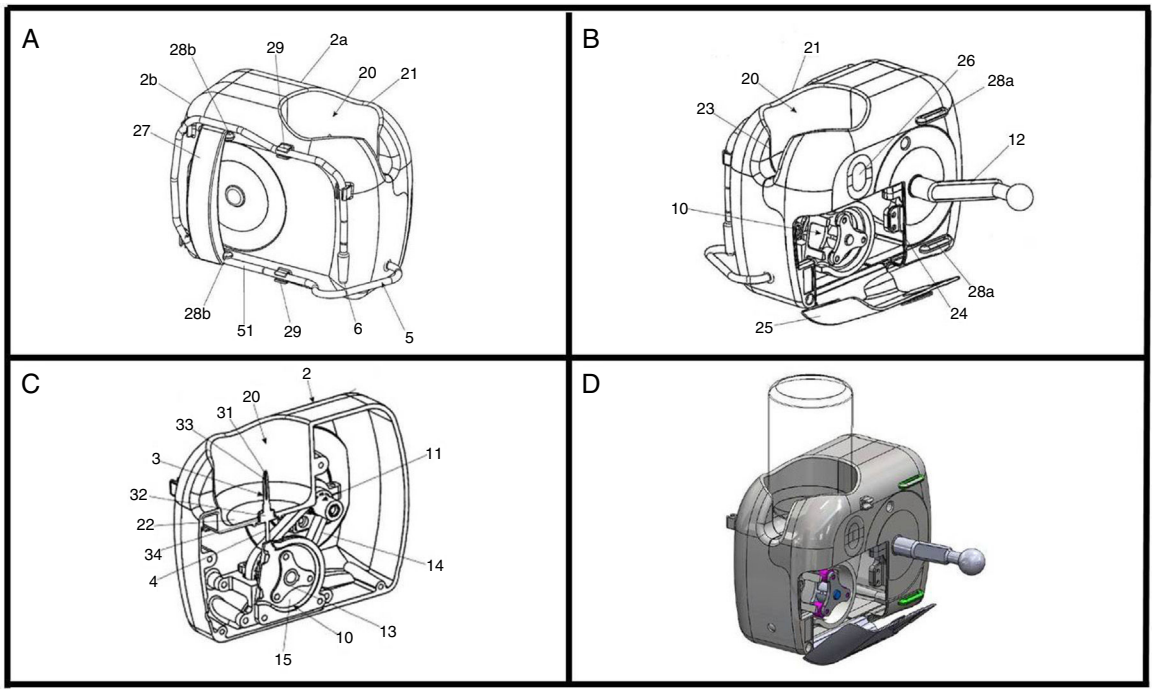

Figure 4 Detailed design of the final device.

inventive activity. This observation supports the keeping of an open environment for collaboration between medicine and industry for the development of medical devices.[7]

According to Reich,[8] design is a process whereby description serves to define an invention that fulfills a desired function and satisfies a series of predetermined restrictions. An approach to the industrial design process implies planning of the product and clarification of the task, conceptual design, global design and detail design (Fig. 5).

In general, innovations seek to optimize clinical processes (diagnostic or therapeutic) and to offer patients better resources.[9] In view of the identification of unresolved technical difficulties in EN using volume syringe bolus administration, we compared ideas and defined conceptual

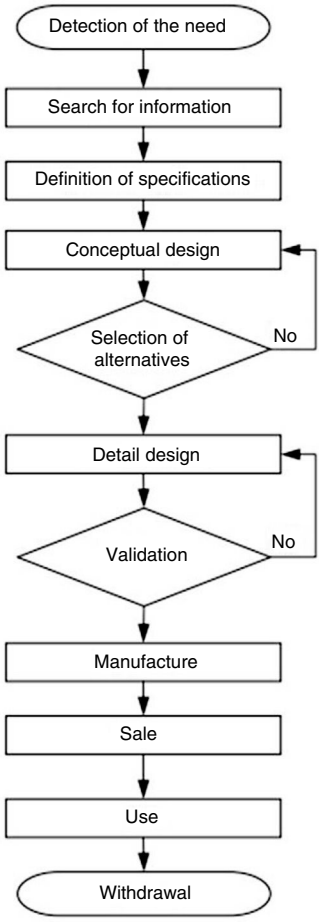

Figure 5 Phases of the product design and development process.

approaches with engineers who were experts in industrial design, with a view to developing the device.

Due to the inventive novelty which we believed the design concept to contain, legal counseling was taken regarding the protection of intellectual property rights, to obtain protection of the device in its development phase, prior to any industrial and/or economic exploitation of these improvements.

The device described herein is a novel and manually activated infusion pump for EN, designed to administer liquid formulations to patients (nutritional formulas, drugs or water) via the enteral route. The device is indicated for both hospital and home use. It resolves the above mentioned problems in EN thanks to its highly functional, compact and simple design, allowing the convenient and safe administration of EN to patients.

The design allows for the integration of the bottle or container holding the liquid solution in the device housing itself, thereby avoiding possible manipulation of the nutrient formula, which can cause contamination of the solution,[10] and facilitating transport and patient mobility. Taking into account the materials used and the contents of the nutrition bottle (assuming single-dose bottles of 250–300 ml), the weight of the device should not exceed 1000 g. On the other hand, handling is facilitated by the fact that the system can be held not only in the hand but also resting on the lap of the patient or on some nearby flat surface.

Based on the described configuration, the pump offers a range of advantages with respect to the existing techniques, such as simplifying procedures in the field of intermittent EN, improving the reference nutritional support technique, in this case volume syringes. Likewise, mention must be made of the simple configuration of the device, its adaptability to different conditions of use, and its easy handling characteristics. The controlled administration of a volume of nutritional formula per unit time, conditioned to a crank handle cycle of 2–3 turns per second, reduces the risk of associated complications such as abdominal pain, nausea, dumping, gastroesophageal reflux, bronchoaspiration or diarrhea.

The purpose of our device is to reduce the complications associated with enteral EN in the form of boluses and to facilitate patient self-care and functional autonomy, with improved perceived health and an adequate nutritional status. Moreover, it can contribute to improvements in the patient-caregiver relationship, optimizing complementary external care time and improving care quality and the work setting of the caregiver. The need for manipulation of the nutritional formula is also reduced, thereby increasing patient safety.

Conflicts of interest

The authors state that they have no conflicts of interest.

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