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To improve patients' empowerment by self-connection in home parenteral nutrition

Abstract: One promising approach for patients who need parenteral nutrition to live an almost normal life, is to provide extra-hospital therapy. This therapy is supported by an ambulatory care service whose staff connects and disconnects the nutritional fluid day by day. The nutrition therapy takes a long time every day and studies show that this therapy significantly disturbs patients' daily life. Although home parenteral nutrition is part of the range of services provided by the statutory health insurance (German GKV), it is also expensive in the long run. Therefore, the cost-effectiveness of this form of therapy is constantly reviewed on an individual basis. Aim of this project is to enable a more autonomous life for patients by self-determined in between disconnection and connection of the therapy independently of the ambulatory care service.

It has to be taken into account that any interruption of the nutrition process poses health risks to the patient, e.g. if air bubbles or bio contaminants enter the tube system. Flushing with saline solution before and after connecting is therefore an elementary component of the nutrition process. The redesigning of the connecting/disconnecting system and the subsequent development of an automated port flushing system integrated into a mobile feeding pump to realize a safe interruption of the therapy is the overall goal of the project.

This paper deals with redesigning the connecting system. After having analysed group discussions, detected impact factors are used as basis of an experimental setup to get the final requirements for redesigning the connector system. The experimental study is done according to the rules of Design of Experimental (DoE). DoE is a statistical method to determine the optimal number of tests by using a complete factorial design. Two repetitions of the tests were carried out to analyse the significance of the impact factors by ANOVA (Analysis of Variance).

Keywords: home care, parenteral nutrition, patients' empowerment, product development
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1 Introduction

Home parenteral nutrition is one possible therapy in home care and it is often required for patients with tumours, short bowel syndrome, severe mobility disorders and radiation enteritis [1]. It is estimated that in Germany, about 6,000 patients per year receive home parenteral nutrition [2]. One of the challenges: Patients who require parenteral nutrition in ambulatory care are tied 12-16 hours to the nutrition therapy day by day. This affects patients' everyday life. Scientific studies with patients confirm that they feel intensely strained by the therapy [3]. Nowadays, patients must perform daily routines such as shopping for food or picking up children from kindergarten while being connected to a nutrition solution in a backpack, because the therapy is connected and disconnected only once a day by ambulatory nursing professionals in home care – it is too expensive to do this every time when it is needed.

However, due to medical reasons, it is possible to interrupt the daily therapy for 1-2 hours [4], but it must be taken into consideration that this can pose health risks to the patients, too. Examples are life-threatening infections caused by poor hygiene, lipids in the feeding solution which can clog veins, and invading air bubbles that may cause blood clots, etc. [5, 6, 7, 8].

The interdisciplinary research project "EasyGoing@Home" focuses on improving those patients' quality of life. In this project, engineering and nursing scientists of the Frankfurt University of Applied Sciences work together with the industrial partners Fresenius Kabi Germany GmbH and Spang&Brands GmbH to develop a technical support which helps patients and can decrease the workload of German health care staff to save money.

First, a system analysis of the manual nutrition therapy was reconstructed with nursing scientists and experts to get a better understanding of the process. Hereby, two major challenges were identified that needed to be technically improved:

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- The **closure system** sometimes gets jammed and leaks and is difficult to use by the patients in front of their own bodies. The connector system has to be redesigned, preferably in coordination with the users.

- The **flushing process** with saline solution is absolutely necessary before connection and after disconnection. Unfortunately, the flushing process is not standardized and is performed intermittently according to the experience of the health care experts. An automated flushing which guarantees a contamination-free flushing within the feeding pump in one system has not been technically implemented yet.

The overall objective is to develop such a system that safely and sterilely supports the whole process of connection and disconnection during the nutrition therapy. This paper deals with the development of the closure system.

2 Methods

To figure out the requirements for a new closure system, an extensive market and patent research were conducted. The closure system comprehensively used is the LuerLock system, which is standardized by the DIN EN ISO 80369-7. The standard provides a large tolerance field for manufacture. Therefore, the use of components from different manufacturing plants can result in the connection problems mentioned above. Ongoing research has shown that the search for solutions to meet the challenges is in progress. Thus, the new draft version of the DIN EN ISO 80369-7 standard includes marginal constructive changes. The challenges become visible in extended systems with additional wings, too, which have already been implemented by manufacturers. However, a one-hand operation of the LuerLock system (in front of the patient's own body) has not been developed as a technical solution yet, showed by an ongoing patent research. Additionally, the connection system was addressed in focus group discussions with nursing professionals to increase user involvement in the product development process, and furthermore an experimental study with test persons was conducted. Results led to a redesigned closure system.

2.1 Focus group discussions

In two focus group discussions with five health care professionals - nurses with expertise in outpatient palliative care, port-catheter and medical devices - further weaknesses of the closure system were analysed. Focus groups are a special form of group discussion used in qualitative social research and aims to identify new aspects on a given topic

caused by different impulses of the participants [9]. In guided interviews, the participants were given the freedom to express themselves about the pain points in home nutrition care. The conversations were recorded, transcribed, and evaluated with the content analysis of Mayring [10]. The categories identified were discussed and operationalized again in a second step. Afterwards the results were partly translated in technical requirements.

2.2 Experimental study

In an experimental study, users are confronted with a simulated connectivity situation in front of the body to test the handling of the connector system.

Four different closure systems are provided for connecting and disconnecting in this study:

- A self-designed wing adapter (larger wings than commercial LuerLock wing adapters),
- a bayonet adapter,
- a click adapter (Chemfort Syringe from the company Simplivia) and
- a needleless connection (plug-in system).

In addition to usability (handling, time), the safety of the closure system (leakage, involuntary opening) is tested. However, we do not measure the quantity force to disconnect, because we consider this as a subjective experience, but we measure the possible finger strength of the test person in advance. The goal of this experimental study is to better assess whether patients are independently able to connect and disconnect themselves and, as a result, to make a general recommendation.

As shown in figure 1, the experimental setup consists of a vest with steplessly adjustable belts to adapt the vest to the size of the torso of the different test persons. The tube set of the device is simulated by a syringe with a piece of tube where the male part of the connecting system is attached. The syringe enables a permanent level of fluid in the tube. The female part is attached to a tube ending in a container to simulate the port side. These two parts are attached to the vest, thus the connecting parts can be manipulated in front of the chest of the test person. In order to simulate a stuck together connection system, a sugar solution is used. The implanted port catheter is integrated in a kind of corset made of tensile material. The actual position of the port on the body is taken into account to simulate the actual operational angle of the adapter.

To quantitatively determine the interaction between the influencing and target variables, an optimal Design of Experimental (DoE) is used. The idea of using DoE is to rationally reduce the number of test persons. [11]

Figure 1: Set up for experimental study

After the test, the test persons had the possibility to give their impression of the connection process in ordinal scaled questions. The quantitative results were evaluated by a multifactorial regression and Analysis of Variance (ANOVA). Therefore evaluation classes were formed by influencing variables. The question is: Which influencing variables are significant and which kind of interaction between the influencing variables does exist?

The effects on connecting are measured in connecting time, the occurrence of leaks during the flushing and the correct fastening of the connection systems.

The impact parameters are age, the maximum finger force which can be applied on the connector, the number of connecting attempts and the connecting experience. According to a complete factorial design, 16 test persons are needed. An additional three centre points were generated, thus the total number of test persons is 19. To conduct an analysis of variance, two supplemented test procedures have to be carried out. The total number is 57.

The impact parameters age, finger force and connecting attempts can be measured continuously, whereas the experience is a qualitative parameter which is ranged by a scale from 1 to 5. The complete test plan was randomized (calculated by the software MODDE).

The analysis of the system is carried out by a regression giving the linear effects of the impact factors and their interaction with each other by a bilinear approach. Testing is carried out for non-linear effects by quadratic term. The significance of each term is carried out by an ANOVA. The analysis is conducted by MODDE. In Addition to the quantitative

aspects, there was a questionnaire to evaluate the subjective perception of the manipulation of the different connecting systems by the test persons.

3 Results: Requirements for redesigning the connector system

Preliminary results of the focus group discussions are listed below in table 1.

Table 1: Anchor points of focus group discussions

item	important requirements of the FG*1/2
operating force	Safe and easy operation even in the 'worst case' (e.g. when patient is fatigued). FG1: "Fine motor skills and strength can fluctuate throughout the day". FG2: "rather pushing than screwing".
state 'not connected' - open line	Safe closure of the open line (against germs) FG1: "Safety adapter", "safe against jamming and non-interchangeably".
disinfect-ability	FG2: Desire: Automated disinfection, but according to research no possibility so far. FG2: Disinfection cap
indicator for 'connected'	Safe product, must also inspire confidence! FG1: "Patients do not dare to connect the device on their own (but they do dare to disconnect it)." FG1: "Fear of therapy (...) or of using the device on their own responsibility (connection)". FG2: Auditive signal to indicated that closing was successful (click tone, magnet connector or vibration as for example with the cell phone ...)
backflow preventer	FG2: Posiflow (check valve on port side) --> with positive bolus

*FG = Focus Group

Afterwards, the requirements for a new closure system were transferred to a technical list of requirements.

The experimental study confirms that a click adapter system is preferred by the test persons. An acoustic signal takes away patients' fear of not being connected correctly. Now the question arises if the needle of the click adapter can maintain the pressure for pulsatile flushing of the port catheter without flow losses.

The results of both, the focus group discussions and the experimental study supplemented the technical requirements defined by market analysis and literature research to redesign the connector system. The most important requirements are listed in table 2.

Table 2: Requirements list

class.	requirement	specification
F	connectivity number	approximately 10 times (at least two interruptions per day; three days in a row, after three days the port needle is usually changed by a nurse)
F	operating force	less, patients often fatigue
F	Flow rate	Feeding mode: 60-125 ml/h Flushing mode: up to 60 ml/min without pressure drop (maximum flow/peak flow during manual pulsatile flushing must be determined in follow study).
F	Transport medium	infusion solution (contains protein, fat, carbohydrates, vitamins, minerals and trace elements) Saline solution (NaCl)
F	Port site	LuerLock male
F	Infusion site	LuerLock female
F	Backflow prevention	Backflow in the event of disconnection or air entrainment must be prevented
F	Snap-in function	no independent loosening
F	Airtight	no bubble formation DIN EN 20594-1; DIN EN ISO/IEC 80369-7
W	Reusability	If possible no one-way system

*F = fixed demand / W = wish

4 Conclusion

Results of the project should take current research one step forward in enabling empowerment for patients by self-connecting in home parenteral nutrition due to redesigning the closure of the tube system to the port catheter. In a follow-up project, the automated flushing process with saline solution through a pump will be developed.

A main requirement for the self-empowerment of patients to connect and/or disconnect from nutrition therapy is the automated flushing. This new approach – allowing for different flow rates, for the feeding mode as well as for pulsatile flushing in one mobile pump for home parenteral nutrition – is the next challenging step within this project.

Author Statement

The experimental study is approved by an ethical approval by Deutsche Gesellschaft für Pflegewissenschaften e.V. /

Duisburg and therefore research related to human use complies with all the relevant national regulations and institutional policies.

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