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Development of a modular Decubitus Prophylaxis System: DekuProSys

Abstract: Pressure ulcers (decubiti) are one of the most frequent side effects in the palliative care setting. Terminally ill and dying people have multiple comorbidities resulting in a high risk to develop pressure ulcers. These skin lesions are caused by pressure, friction and shearing forces in combination with several risk factors (e.g. moisture, tissue condition). People of all ages with reduced activity can suffer from decubitus ulcers. In palliative care, the treatment of symptoms to ensure the highest possible quality of life is of primary importance. Ethical controversies and difficult decision-making often lead to uncertainties and burdens for caregivers, patients and relatives. In the DekuProSys project, a decubitus prophylaxis system for inpatient and outpatient palliative care of people of all ages is being developed. The system will assist caregivers in patient care in multiple ways. It will capture and report risk factors for decubitus, assist at decision making and documentation. Furthermore, it will provide care information and instruction if needed. Aiming for an innovative and useful solution, the project follows a user-centered and interdisciplinary approach.

Keywords: Pressure ulcers, palliative care, decubits, monitoring.

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1 Introduction

Biomedically, a pressure ulcer is a locally limited damage of the skin and the underlying tissue. It is typically caused by

pressure, often in connection with shear forces, on bony protrusions. There are other factors associated with decubitus, but their significance remains to be clarified [1]. The skin of those affected is less resistant when irritated by pressure, friction and moisture. The body tissue can be susceptible to ulcer formation if dehydration, malnutrition or metabolic disorders impair blood circulation. Underweight or overweight, sensitivity disorders, incontinence or existing skin irritations can also promote the development of decubiti. External risk factors include the microclimatic conditions on the body surface (temperature and humidity), friction, pressure and shear forces, mobility and positioning techniques, medication as well as body hygiene [2]. Elderly people, children and adolescents in the field of palliative care are often affected by decubiti due to the significantly limited general condition and specific underlying diseases [3]. The aim of the project is to provide those affected with a high quality of life and to prevent complications due to skin lesions and pressure sores. Ethical controversies and difficult decision-making processes, such as mobilization versus bed rest for the patient, often lead to uncertainties and burdens for carers, patients and relatives alike [4].

1.1 State of the art and research

Monitoring systems for decubitus prophylaxis are a frequent research topic in the field of sensor technology. A metastudy published in 2015 [5] shows that most research projects focus on pressure distribution as the primary risk factor for the development of pressure sores (30 out of 36 systems). Sensors for monitoring other risk factors are used comparatively rarely. Furthermore, the authors show that important aspects for the successful use of a monitoring system for decubitus prophylaxis, such as patient comfort, integration into existing care systems and data management, are often neglected.

The frequency of a patient's movement is closely correlated to the pressure load over time [6]. Based on this, various approaches exist to monitor patient mobility for decubitus

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prophylaxis. Accelerometers are mainly used for this purpose, which are attached to bed [7], mattress [8] or the patient himself [9]. Other systems monitor the moisture of the skin or the moisture between the skin and mattress [10].

The decubitus prophylaxis systems currently available on the market range from passive soft bedding to complex active repositioning systems. In preventive monitoring there are a few commercial products available. One such system, which focuses on patient mobility as a risk factor for decubitus, is the Mobility Monitor by the company Compliant Concept [11]. It detects the patient's own movements via a pressure sensor placed under the mattress and warns if inactivity lasts too long. The company Leaf Healthcare offers a wearable sensor embedded in an adhesive plaster to monitor patient movement [12].

In the "DekuProSys" project, a prophylaxis system is being developed whose holistic approach goes beyond previously developed technical solutions. Multiple risk factors for decubitus are monitored. Recommendations for intervention based on the collected data are made available in a user-friendly information system. The adaptability of this information system and the modular structure of the sensor network make it possible for informal and formal caregivers to use it in inpatient and outpatient palliative care settings.

1.2 System overview

Figure 1 shows a schematic representation of the system. It is equipped with a wireless sensor network for monitoring various bedding parameters. Due to the modular design, sensors can be added or removed to adapt the system to the context of use. The sensor data are transmitted to a central device (labelled DekuProSys), which provides a database to manage bedding parameters and other data such as care

instructions. Access is possible via a platform-independent graphical user interface (GUI). Further interfaces are provided for the output of messages.

1.3 User-centered development & ELSI

The different user perspectives of caregivers as well as those of patients and relatives are included in the technical development through the integration of "ethical, legal and social issues (ELSI)" and user-centered methods. Both approaches deal with questions concerning the balance between caring and autonomy, which must be given special consideration in the sensitive area of palliative care. The significance of the use of technology for nursing practice is discussed from the outset. The aim of this method is to design the system in such a way that it does not impair those affected and makes it possible for users to directly experience added value. Based on different experiences, the challenges in the use of nursing support offers can be different. The consideration of social factors of the respective care situation is necessary to be able to consider possible problems in dealing with the planned system in everyday life when designing the system [13].

With the aim of developing usable medical devices, user-centered design processes focus on early involvement of users in the development and evaluation of design solutions. Against this background, prototypes are developed iteratively based on intermediate results of formative evaluation studies [14]. According to Backhaus [15], the selection of suitable methods depends on the level of operating risks, the available processing capacity and the development status of the product.

In the DekuProSys project, a scenario catalog with concrete application examples of the system and ethnographic vignettes were developed based on interviews with the different user groups (informal and professional caregivers) and participant observation in palliative care settings. The catalog was used as a tool to make different problems in the field tangible for the developers and support interdisciplinary discussions. The acquired system requirements are implemented in prototypes and iteratively optimized with user participation. The MEESTAR model [16] was used to develop a map of ethically relevant problem complexes that have an influence on the design and functionality of the decubitus prophylaxis system. Ethical, legal and social aspects are continuously reflected in project meetings and included in the development.

Figure 1: Schematic overview of the systems components

2 System Design

When defining and specifying the system requirements, the results of the literature research and own laboratory tests with commercial and newly manufactured sensor technology were included in addition to the results of the user involvement and social scientific research. Central requirements with which the system distinguishes itself from existing systems and those described in the literature are

1. unconditional compatibility with conventional soft bedding systems,
2. modularity,
3. practical suitability of the devices and user interfaces.

Based on these requirements, technical solutions for the areas of sensor technology, system architecture and integration into existing infrastructures were developed.

Furthermore, the decubitus prophylaxis system was designed to have the following key features, which were identified as being critical for the practical suitability, i.e. the acceptance and success of a prophylaxis system based on patient monitoring. The system is adaptable to the care context and not the other way around, where carers, care processes and patients need to adapt to the system. The system gives the caregiver control over the settings of the patients' individual comfort zones regarding activity and microclimate. It notifies if the risk for pressure ulcer development might be rising and lets the caregiver assess the situation without creating an obligation to act. Data recording is transparent and under control of the caregiver. Beyond monitoring, the system assists with the process of nursing documentation, without it being fully automated and beyond the control of the individual caregiver.

The graphical user interface is platform independent and available on stationary and mobile devices.

The system helps implementing the expert standard of pressure ulcer prevention [17] by presenting general care instructions and information. It facilitates the communication between caregivers.

2.1 Sensor modules

Two approaches were pursued in the development of the sensors. The aim of the project is to provide both usable and innovative sensor technology (low development risk) as well as to contribute to the development of new measuring techniques for the acquisition of bedding-relevant data. On the one hand, commercially available (standard) sensors are used. Here the focus of research is on the way these sensors

are integrated into the patient's environment and on the development of adapted and optimized algorithms to describe the bedding situation. On the other hand, newly developed sensors manufactured at the Medical Technology Department of the TU Berlin are used. The focus here is on compatibility with conventional soft bedding systems and the robustness of the sensors used close to the patient. Iteratively optimized functional models of the sensor modules are used in laboratory and volunteer tests and as demonstrators in user tests. At the same time, the algorithms for representing the bedding situation are being developed using the obtained data. The following shows four of the functional models for monitoring the bedding parameters mobility and microclimate which are currently being developed.

The sensor modules shown in Figure 2 (left) have two operation modes, following the modular and adaptable approach. In the fixed position mode, four of them are placed on the mattress near the edge at head and hip height. The integrated inertial sensors (STMicroelectronics LIS3DH) are used to monitor the self repositioning of the patient in bed. In the free position mode, a single sensor module is placed on the mattress near the patient under the blanket. Besides the inertial sensor, which is again used to monitor patient activity (but without the ability to localize movement), the integrated temperature and humidity sensor (Sensirion SHT31) is used to monitor the body climate.

Different bedding positions can be distinguished by analysis of the sensor modules static angular positions. A comparative amplitude and frequency analysis of the inertial sensors' signals allows for the differentiation between inactivity, minute movement that doesn't relieve skin pressure, self repositioning that effectively relieves the skin and spasms. The soft TPU-encasing and appealing appearance of the sensor pucks make them suitable for the application in a children's environment.

Another approach for monitoring the body climate is shown in Figure 2 (right). The climate blanket is a quilt bed equipped with combined temperature and humidity sensors. Besides the SHT31-sensors, the buttons contain wireless transmitters and an energy source and allow for the imperceptible integration of the sensors in the patients' environment.

Figure 2: Sensor modules for monitoring movement and body climate (left) and a quilt bed with integrated climate sensors

Figure 3: Functional models of mattress toppers with integrated sensors for monitoring movement (left) and wetness (right)

Besides the commercial sensors, two manufactured, fabric-based sensors are being tested. Both aim at being low-tech, cost-effective solutions with unconstrained soft bedding compatibility. Fig 3 (right) shows a mattress topper with integrated wetness sensor, based on resistive measurement between stainless steel threads. Fig 3 (left) shows a topper with fabric based mechanical switches for basic pressure sensing and movement monitoring.

2.2 Testing and evaluation

Besides the functional models of the sensors and a clickthrough prototype of the GUI, a patient dummy (Figure 4) has been manufactured to be employed in laboratory and user tests alike. It has the dimensions and weight distribution of an average 3-year-old. Since the dummy is far lighter and smaller than grown-up volunteers, the lower limits for significant measurement results with different sensor positions and evaluation algorithms can be explored without the need of minor volunteers.

Author Statement

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Figure 4: Setup for a user test with dummy, functional models and clickthrough GUI

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