Risks and risk-analysis for the development of pressure ulcers in surgical patients

B.P.J.A. Keller

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Keller, Bastiaan Paul Johan Aart

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(with a summary in Dutch)

Risico's en risico analyse
voor het ontwikkelen van decubitus
bij chirurgische patiënten
(met een samenvatting in het Nederlands)

Proefschrift

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Bastiaan Paul Johan Aart Keller,
geboren op 19 augustus 1969
te Dordrecht

Promotor: Prof. Dr. Chr. van der Werken
Afdeling Heelkunde
Faculteit Geneeskunde, Universiteit Utrecht

Copromotor: Dr. B. van Ramshorst
Afdeling Heelkunde
St. Antonius Ziekenhuis, Nieuwegein

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Ter nagedachtenis aan mijn vader

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Chapter 1

Introduction and Outline of the thesis

Introduction

A pressure ulcer is defined as "an area of localised damage to the skin and underlying tissues caused by pressure, shear, friction and or a combination of these" [1]. Pressure ulcers remain a serious problem for patients, nursing personnel and doctors, despite the increasing interest in nursing and medical literature over the past decades. This increasing interest is also illustrated by several academic theses that have appeared on the subject in The Netherlands and Belgium, only in the last couple of years [2-6].

The magnitude of the pressure ulcer problem has been emphasized by several publications on prevalence, incidence and costs. Prevalence is defined as the proportion of a population that has pressure ulcers at a specific point in time, whereas incidence is defined as the number of persons who develop a new pressure ulcer, within a particular time period. Prevalence figures for the Dutch situation have recently been published by Bours et al. [7]. They found an overall prevalence of pressure ulcers of no less than 13.2% for university hospitals and 23.3% for general hospitals. There are several limitations to the use of prevalence figures, which can vary widely over time while reliable comparison of different institutions is not possible because of differences between patient populations [8].

Consideration of incidence figures is indicated, when assessing causes of pressure ulcers or when conclusions on the effectiveness of preventive measures are to be drawn. Reported incidences in surgical patients vary from 2.7 to 66% and literature suggests that the origin of pressure ulcers mainly lays on the operating room [9-15].

The costs associated with pressure ulcers can only be estimated. A conservative calculation of these total costs for both intramural and extramural healthcare in The Netherlands, revealed an amount of 450 million € per year [16]. This was more than 1% of the total national health care expenditure in 1998.

All these figures clearly underline that pressure ulcers remain a highly relevant problem. By taking preventive measures in patients who are at risk, the chance of developing pressure ulcers will be reduced. Rational prevention is therefore only possible if these patients at risk are identified, risk factors are known and (validated) risk assessment scales are available. Obviously, prevention can only be effective with

the right materials and methods. This thesis is meant to contribute to the process of distinguishing risk factors and identifying patients at risk, hoping therewith to increase the awareness of medical personnel of the pressure ulcer problem.

Outline of the thesis

The aim of this thesis is to answer the following questions:

1. is it possible to identify risk factors for developing pressure ulcers in patients on a surgical Intensive Care Unit (ICU) and can a risk assessment scale be developed from these risk factors, especially for ICU patients?
2. is there a difference in pressure reducing and pressure distributing characteristics of different operating room table surfaces when tested with tissue-interface pressure measurements?
3. what interface pressures are obtained on support surfaces currently used for transporting and immobilizing severely injured trauma patients?
4. can the influence of external pressure on soft tissue oxygenation, in an area at particular risk of pressure ulcer development, be studied with a non-invasive method like Near Infrared Spectroscopy?
5. does the standard use of a high-specification pressure-relieving mattress for all surgical patients result in a lower incidence of pressure ulcers?

Several studies to answer the questions formulated above were performed and are presented in the following chapters.
All studies have been carried out in the University Medical Centre Utrecht and/or the St. Antonius Hospital Nieuwegein, The Netherlands. Studies involving actual patients had a prospective character.

A special group of surgical patients, particularly at risk of developing pressure ulcers, are those requiring treatment on an ICU. **Chapter 2** gives a review of (20 years) literature on several aspects of pressure ulcers in Intensive Care patients. The review focuses on prevalence and incidence figures, aetiology and consequences of the occurrence

of pressure ulcers. Finally, risk factors, risk assessment scales and potential preventive measures are considered.
In **Chapter 3**, we describe the results of a study performed in patients undergoing elective cardio-thoracic surgery and a postoperative admission to the ICU of 48 hours or more. The pressure ulcer incidence obtained in this population is presented. Also, the process of identifying potential risk factors and the development of a new risk assessment scale are illustrated.
Based on some of the outcomes presented in Chapter 3, there was a need to study the pressures that patients are exposed to at skin level (tissue-interface) intraoperatively. The results of interface pressure measurements (IPM), on three different operating table support surfaces, are reported in **Chapter 4**.
Severely injured patients are often immobilized for longer times, and are therefore at increased risk of developing pressure ulcers. In **Chapter 5**, we compare interface pressures obtained on three support surfaces frequently used for trauma patients.
Chapter 6 focuses on the influence of external pressure on tissue oxygenation as measured in a non-invasive way with Near Infrared Spectroscopy (NIRS).
Chapter 7 describes the introduction of new pressure-relieving mattresses on the Surgical Division of the UMC Utrecht and presents the results of a comparative study on the pressure ulcer incidence obtained on three different mattresses.
In **Chapter 8**, the content of this thesis is summarized and discussed in general by answering the questions formulated above. Finally, a summary in Dutch is provided in **Chapter 9**.

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Chapter 2

Pressure ulcers in intensive care patients: a review of risks and prevention

B.P.J.A. Keller, J. Wille, B. van Ramshorst, Chr. van der Werken

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Abstract

Objective: Review of the literature concerning pressure ulcers in the intensive care setting.

Data source and study selections: Computerized databases (MEDLINE from 1980 until 1999 and CINAHL from 1982 until 1999). The indexing terms for article retrieval were: "pressure ulcers", "pressure sores", "decubitus" and "intensive care". Nineteen articles met the selection criteria and seven more were found from the references of these articles. One thesis was also analyzed.

Results: Figures for prevention, incidence and costs of pressure ulcers in ICU patients are scarce. Overall, there are no conclusive studies on the identification of pressure ulcer risk factors. None of the existing risk-assessment scales was developed especially for use in ICU patients. It is highly questionable to what extent these scales can be used in this setting as they are not even reliable in "standard care". The following risk factors might play a role in pressure ulcer development: duration of surgery and number of operations, faecal incontinence and/or diarrhoea, low pre-operative protein and albumin concentrations, disturbed sensory perception, moisture of the skin, impaired circulation, use of inotropic drugs, diabetes mellitus, too unstable to turn, decreased mobility, high APACHE II score and mortality. The number of patients per study ranged from 5-638. The definition of "pressure ulcer" varied widely between authors or was not mentioned.

Conclusion: Meaningful comparison cannot be made between the various studies because of the use of different grading systems for pressure ulcers, different methods of data collection, different (or lack of) population characteristics, unreported preventive measures, and the use of different inclusion and exclusion criteria. There is a need for well-conducted studies covering all these aspects.

Introduction

Over the last few decades little has been written about pressure ulcers in the intensive care setting. It is obvious that critically ill patients who are sedated, ventilated and almost invariably confined to bed for long periods, are particularly at risk of developing skin breakdown. In this respect it is surprising that not every ICU patient develops pressure ulcers. This phenomenon could be considered the result of well-applied preventive measures but, at the same time, it is evident that not all patients run at equal risk. In many instances, extra - and costly - preventive measures are taken in patients who do not need them. Therefore the identification of patients at truly increased risk is important. Until now, risk factors and risk score analysis in the ICU setting have not been extensively dealt with. Serious questions can be asked about the predictive value, sensitivity and specificity of the various existing assessment scales (also known as risk assessment scales or risk scales) in an average hospital population. None have been validated for critically ill patients.

Pressure ulcers developing in hospital patients are definitely not, as was often thought in the past, due to poor nursing care. Though nursing expertise has increased enormously over the past few decades, pressure ulcers remain a major clinical problem. This proves that this is a multifactorial disease that is ignored by most medical staff.

This review of the literature is directed at pressure ulcers specifically in ICU patients, with an emphasis on the prevalence and incidence of the problem, specific risk factors and assessment scales for identifying specific patient groups at risk.

Methodology

A MEDLINE search of publications from 1980 - 1999, using the keywords “pressure ulcers”, “pressure sores” or “decubitus” in combination with “intensive care” revealed only 13 articles. Eight of these were published in nursing journals. An additional search in the Cumulative Index to Nursing & Allied Health (CINAHL) database from 1982 - 1999 revealed seven articles. Another six were found by searching through the reference lists of these

articles. No limit was set to the language of publication. All identified publications were studied, irrespective of whether they covered pressure ulcers in ICU patients. This selection criterion was met for all 26 publications. A thesis on this subject, written by one of the authors (J.W.), was also included for analysis.
As so little has been written about pressure ulcers in an ICU setting, we decided to use all available publications for our review. The literature thus consisted of eight review articles [1-8], one thesis [9], two retrospective and 16 prospective studies, of which three were randomized controlled trials. Study characteristics are summarized in **Table 1**.

Definition and classification of pressure ulcers

One of the problems with interpretation and comparison of the articles used for this review is the widely varying definition and classification of pressure ulcers. The European Pressure Ulcer Advisory Panel (EPUAP) [10] defined a pressure ulcer as "an area of localised damage to the skin and underlying tissue caused by pressure, shear, friction or a combination of these". Their classification system is summarized in the **Appendix** [10].

Prevalence and incidence

Pressure ulcer prevalence is based on the total number of existing cases among the whole population at a given time. Incidence is defined as the number of new cases during a specific period of time related to the number of patients. Community prevalence rates vary from 0.43 to 0.86% [11], from 2% to >20% in nursing homes [11-14], and from 3 to 22% in hospitalised patients [11-21]. In spinal units, prevalence figures range between 5 and 50% [20]. Incidence rates in hospitalised patients vary from 1 to 11%, with 70% of pressure ulcers developing within the first two weeks after admission [11,13,21-25].
ICU studies providing prevalence and incidence figures are scarce. Only one prospective, descriptive study was found, describing daily prevalence in a surgical ICU [26]. Over a 5 month period 583 observations were performed in 130 patients, resulting in a prevalence of 13.6% on the short-stay unit and 42.1% on the long

Reference	Year	Study characteristics	Population characteristics	n
Robnett [29]	1986	prospective, obtaining incidence	surgical	63
Bergstrom et al. [36]	1987	prospective, testing Braden scale	all specialties	60
Marchette et al. [31]	1991	retrospective, identifying risk factors	surgical, age > 59 years	161
Cubbin and Jackson [55]	1991	prospective, risk scale development	all specialties	5
Aronovitch [51]	1992	retrospective, establishing criteria for placement on special beds	medical & surgical	55
Batson et al. [56]	1993	prospective, identifying risk factors	medical & surgical age > 17 years	51
Hunt [33]	1993	prospective, testing Cubbin scale	all specialties	100
Inman et al. [50]	1993	RCT, comparison of 2 support surfaces	all specialties	100
Birtwistle [57]	1994	prospective, risk scale development	not mentioned	not mentioned
Clough [31]	1994	prospective, determining costs of prevention and therapy	all specialties	638
Jiricka et al. [32]	1995	prospective, testing Braden scale and DUPA	medical and surgical	85
Lowery [35]	1995	prospective, testing Cubbin scale	medical and surgical	8 and 15
Ooka et al. [60]	1995	prospective, comparison of 3 support surfaces	surgical	110
Gebhardt et al. [59]	1996	prospective, comparison of 2 support surfaces	all specialties	43
Takala et al. [61]	1996	RCT, comparison of 2 support surfaces	all specialties	40
Weststrate and Bruining [26]	1996	prospective, obtaining prevalence	surgical	130
Weststrate et al. [34]	1998	prospective, testing Waterlow scale	surgical	594
Inman et al. [62]	1999	RCT, testing 2 strategies for support surface assignment	all specialties	144

Table 1 **Summary of studies investigating pressure ulcers in intensive care patients**
DUPA Decubitus Ulcer Potential Analyzer, RCT randomized controlled trial

stay unit. Only grade 2 or higher pressure ulcers were defined as clinically relevant, according to the scale used by the National Pressure Ulcers Advisory Panel in the Netherlands [27]. This is practically the same as the EPUAP classification. In a prevalence study performed in two general hospitals, Shannon and Skorga found a prevalence rate of 82% in a very small subset of 11 ICU patients [28].

Only two prospective studies have focussed on measuring the incidence of skin breakdown in a surgical ICU. In the study by Robnett, only one of 63 patients developed skin breakdown that was classified as a pressure ulcer, according to the authors' definition of pressure ulcers as non-blanchable redness or worse [29]. This results in an incidence of 1%. Unfortunately, only 53% of all patients admitted to their ICU were included and the study was performed during a short period of only one month. Wille found an incidence of 40% of newly developed pressure ulcers in 65 patients [9]. In conjunction with data provided in

the other articles, the incidences vary between 1 and 56% [30-36]. In his detailed review of incidence in ICU patients, Defloor mentions percentages varying between 5-56% [5]. However, two publications cited in this article did not actually consider intensive care patients [37,38]. Unfortunately, meaningful comparisons between prevalence and incidence rates in different studies cannot always be made because of the use of different grading systems for pressure ulcers, different methods of data collection, different or lack of population characteristics, and the use of different inclusion and exclusion criteria [18]. Furthermore, preventive measures are not always reported.

Aetiology

According to the definition, pressure, shear and friction play the key role in the aetiology of pressure ulcers. These factors, by themselves, do not fully account for the formation of pressure damage. In 1999 Defloor formulated a conceptual scheme that attempts to explain this (**Fig. 1**) [39].

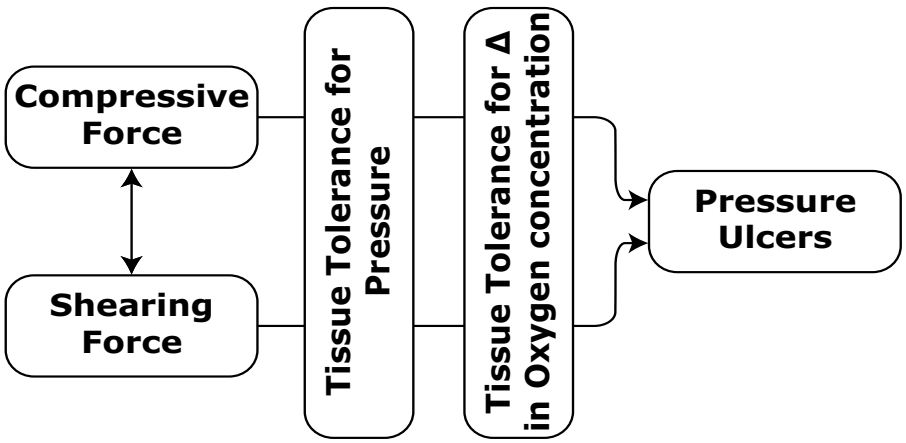

Fig. 1 **Conceptual scheme for pressure ulcer aetiology**

The essence of this scheme is that compressive and shearing forces above a certain threshold and lasting for a certain time will eventually cause damage to the tissues. The intermediate variable that determines how great these forces must be, and how long they must be maintained to cause damage, is called tissue tolerance. Tissue tolerance can be divided into two components: tolerance to pressure and tolerance to changes in tissue oxygen concentration.

Compressive forces refer to sustained pressure on a local point, for example, compression of the soft tissues between the bony prominences and the underlying surface. Shearing forces occur when two opposing surfaces slide over each other in opposite directions while friction occurs when two surfaces rub against each other [2]. A pressure higher than the capillary pressure will cause occlusion and, subsequently, thrombosis of the capillary. This results in tissue anoxia with release of toxic metabolites and, ultimately, cell death and the formation of pressure ulcers. In experimental research it was found that a constant pressure of 70 mmHg applied for two hours produced irreversible cellular damage [40,41]. Many factors exert influence on the pressure-time relationship and play a role in the aetiology of pressure ulcers [1,3,12,40-43]. In the conceptual scheme, these factors are divided into those that affect the intensity and duration of both compressive and shearing forces [39]. The intensity of compressive force is mainly determined by the type of support surface used, the posture in which a patient is nursed, and the patient's body build (significant overweight as well as underweight) (**Fig. 2**).

The duration of compressive force depends on the patient's capacity to perceive painful stimuli and on the degree to which a patient is able to relieve this. Intensity and duration are both influenced by a number of medical and nursing interventions. The intensity of shearing force is also determined by support surface and posture. Two other factors are maceration of the skin and friction.

The factors that determine the duration of shearing force are the same as those for the duration of compressive force (**Fig. 3**).

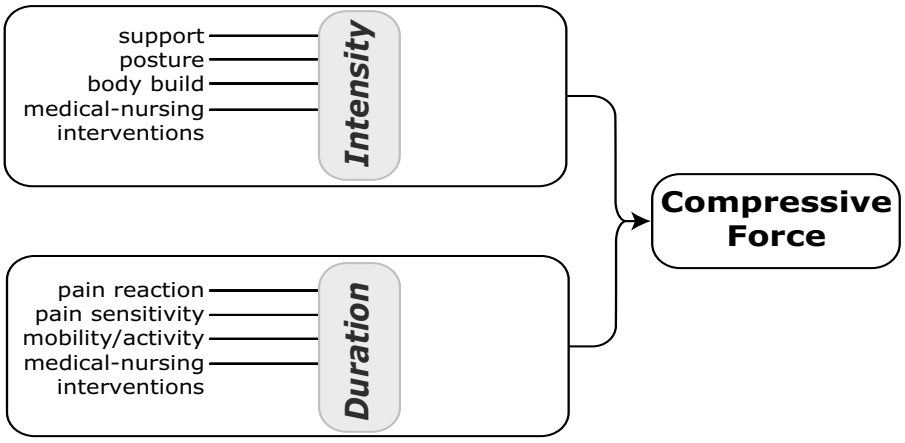

Fig. 2 **Factors influencing compressive force**

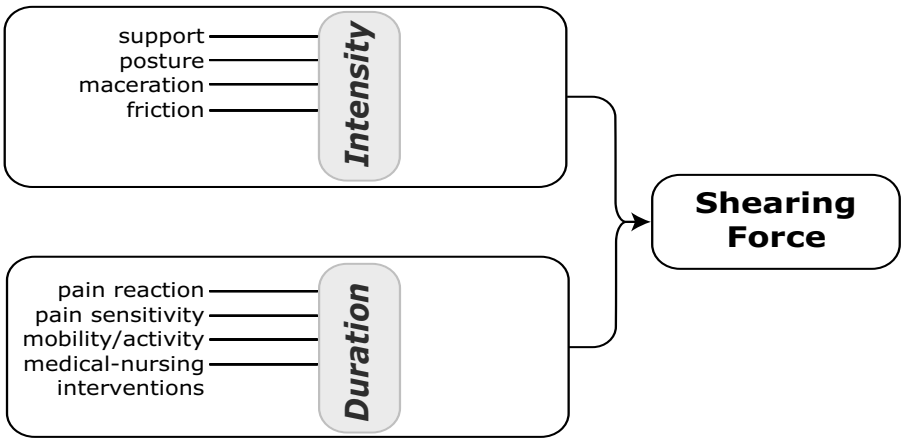

Fig. 3 **Factors influencing shearing force**

Factors that have a negative influence on duration and intensity of forces are commonly present in ICU patients. Examples are reduced activity and mobility, loss of sensory perception (mostly caused by ICU-specific medication such as anaesthetics, sedatives and analgesics), and maceration of the skin (due to incontinence, sweating or leaking wounds).

Tissue tolerance is also influenced by a number of factors (**Fig. 4**). Factors affecting tolerance to change in tissue oxygen concentration can further be divided into factors that influence tissue oxygen needs and tissue oxygen supply. In ICU patients, tissue tolerance is often adversely influenced. Possible causes are

patient conditions in which tissue oxygen needs are increased (due to elevation of body temperature) or where tissue oxygen supply is compromised (due to circulatory or ventilatory problems and use of inotropic drugs) [3].

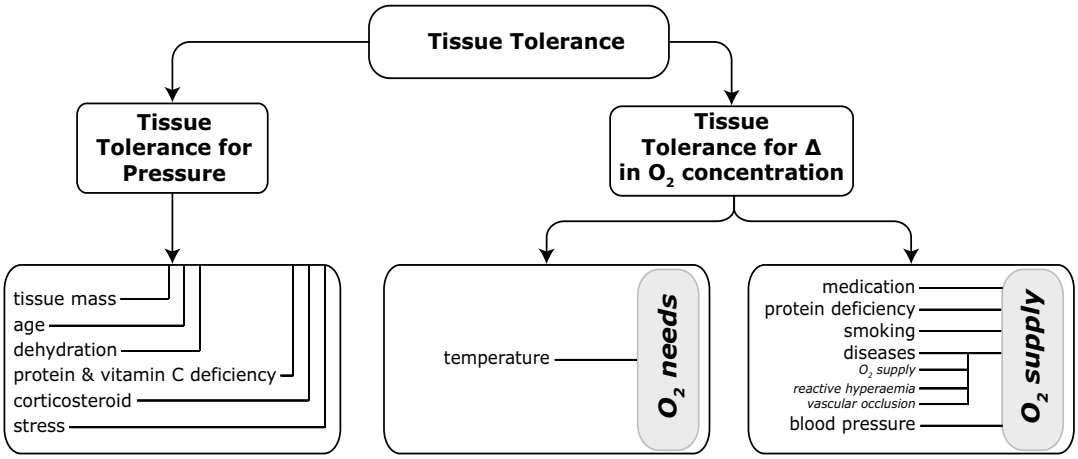

Fig. 4 **Factors influencing tissue tolerance**

Consequences

Development of pressure ulcers has major implications for both patient and nursing staff. Pressure ulcers are associated with negative patient outcome in terms of pain, loss of function and independence, increased risk of infection and sepsis, and additional surgical procedures [32]. These will result in prolonged hospital stay and, sometimes, even mortality [16]. In a non-ICU setting development of pressure ulcers was associated with a 4.5-fold increased risk of death [16]. This was confirmed for ICU patients in the prospective study by Clough [31]; mortality in the 525 patients without pressure ulcers was 15%, compared with 63% for the 113 patients with ulcers.

The increased mortality rate in patients with pressure ulcers is not inevitably caused by the presence of pressure ulcers. Patients who are more critically ill are more vulnerable and thus more likely to develop pressure ulcers, but also more likely to die. As no large randomized controlled trials have been performed to establish what is cause and effect, it remains an assumption that there is an association between the presence of pressure ulcers and increased

mortality.
The workload for ICU nursing staff increases by 50% once a pressure ulcer has developed [44]. Prolonged hospital stay and increased workload are mainly responsible for the major costs that are associated with pressure ulcer treatment. Lapsley found that average hospital stay increased by 11 days if patients had clinically relevant pressure ulcers [45]. Haalboom estimated that 65% of extra costs associated with pressure ulcers for a university hospital population is generated by a prolonged hospital stay, 25% by extra nursing care, 7% by the use of special devices such as mattresses and beds, and the remaining 3% by extra medication, dressings, physiotherapy and dietary measures [46]. Whether ICU stay is prolonged solely through pressure ulcer development is still not described in the literature. Extensive figures for the costs associated with prevention and treatment of pressure ulcers in an ICU setting are scarce. Only the prospective study of 638 ICU patients by Clough considered these costs [31]. He found that costs per patient were twice as low in the group of 525 patients who did not have pressure ulcers on admission and did not develop ulcers during their stay, compared with the 113 patients who were either admitted with, or developed, an ulcer. In the non-ulcer group, 60% of costs was generated by nursing time versus 44% in the ulcer group. Clough calculated that almost 5% of the total ICU budget was spent on prevention and treatment of pressure ulcers. This study confirms the conclusions of Haalboom and Lapsley, that treatment of pressure ulcers is more expensive than prevention [45,46].

Risk factors in ICU patients

The risk factors that contribute to pressure ulcer development in ICU patients are generally the same as those in a general hospital population. However, in critically ill patients they are exaggerated in terms of both a stronger influence and the presence of more factors at the same time. ICU patients are almost invariably limited in their overall physical activity and mobility, resulting in decreased ability to actively change their position in bed and thus an increased risk of experiencing prolonged and intense

pressures. Another problem frequently encountered in ICU patients is loss of sensory perception, frequently due to anaesthetic and sedative drugs. Sensory perception relates to both the level of consciousness and cutaneous sensation. Patients may be unable to perceive painful stimuli from intense pressure, change their position independently, or request a position change [32]. In many ICU patients there are changes in metabolism, resulting in a poor nutritional state. This particularly occurs in patients with major trauma, burns and sepsis and after major surgery [3]. The altered metabolism leads to a negative nitrogen balance with loss of subcutaneous tissue, resulting in over-exposed bony prominences and poor wound healing [1]. Low serum albumin, from whatever cause, results in interstitial oedema which compromises wound healing by decreasing nutrient passage to damaged tissue [47]. Holmes et al. showed that 75% of patients with a serum albumin below 35 g/L developed pressure ulcers compared to only 16% of patients with a higher serum albumin level [48]. Correction of nutritional deficiencies is very important for maintaining skin integrity and healing of pre-existing pressure ulcers [4,48]. A moist environment increases the risk of pressure ulcer development fivefold [49]. Skin moisture can be caused by faecal incontinence, leaking wounds and sweating due to fever and the higher ambient temperatures in the ICU. Urinary incontinence is not usually a problem since most ICU patients have a bladder catheter in situ.

Many ICU patients have impaired circulation and ventilation, resulting in reduced tissue oxygenation. This can be worsened further by the use of specific medication. Shannon and Lehman gave a good survey of ICU medication, with adverse effects potentially affecting the maintenance of skin integrity [4]. Vasoactive drugs such as norepinephrine cause vasoconstriction and further reduce peripheral tissue perfusion and capillary blood flow. The latter can also be impaired by the development of interstitial oedema.

Many of the above mentioned risk factors are considered in current severity of illness scores e.g. APACHE II and SAPS II. Clough found that the APACHE II score was highly correlated ($r=0.91$, $p=0.029$)

with the occurrence of pressure ulcers [31]; this was confirmed by Wille for the SAPS II score [9]. A significant relationship between the APACHE II score 72 hours after ICU admission and pressure ulcer development was also found by Inman [50]. The importance of severity of illness as a specific risk factor for ICU patients is also emphasized in the review by De Laat [6].
As intensive care patients are almost invariably confined to bed for long periods, they are thus commonly exposed to (excessive) compression forces. When a sedated patient requires repositioning, shearing forces easily occur. Elevation of the head and trunk of a supine patient to more than 30° and the Trendelenburg position produce a tendency to slide downwards. Both tissues of the sacrococcygeal area and the heels especially undergo shearing forces in this position [1].
In a retrospective analysis of a random sample of 161 elderly surgical ICU patients, Marchette et al. tried to identify risk factors for pressure ulcer development [30]. The incidence of pressure ulcers in this study was 40%. Significant relationships between the following risk factors and pressure ulcers were identified: redness of the skin (not specified), surgery and duration of surgery, faecal incontinence and diarrhoea, use of steroids and decreased total protein and albumin concentrations one day postoperatively. Using a combination of five factors (redness of the skin, number of days on a static air mattress for prevention, faecal incontinence, diarrhoea and low preoperative albumin level) it was possible to predict the development of pressure ulcers in 93% of the patients. Strangely, this list differs from the factors identified earlier in the same article. Although preoperative serum albumin level was not significantly related with the development of pressure ulcers, this factor was nevertheless considered a risk factor by the authors. In a retrospective chart audit of 55 patients placed on special beds in medical and surgical ICUs, Aronovitch [51] identified seven risk factors that could be used as a guideline for selection of patients for special beds, namely: general health status, activity, mobility, incontinence, nutritional intake and fluid intake.

Risk assessment scales

Several risk-assessment scales have been designed with the purpose of identifying patients at risk of developing pressure ulcers. Ideally, only patients selected by such a scale should benefit from and receive preventive measures. Theoretically, the perfect scale should be easy to use, reliable and validated in prospective studies, while the consequences in terms of preventive measures should be cost effective. Reliability relates to the frequency with which the nurses agree on the score for a specific patient, while validity relates to the predictive ability of a scoring system to correctly identify those who will develop pressure ulcers. As shown in **Table 2**, risk assessment scales describe the condition of the patient by using different combinations of items considered to be risk factors in the aetiology of pressure ulcer formation with a diversion into degrees of severity. Unfortunately, the validity and reliability of many scales are questionable [52,53]. Thus, no consensus exists regarding the utility of the various scales. Most criticism is directed at the fact that almost no scales are being validated in prospective studies, and that scales specifically developed for geriatric of orthopaedic settings are liberally used in other patient groups [52].

Factors	Norton	Gosnell	Andersen	Waterlow	CBO	Douglas	Braden	Pressure Sore Prediction Score
Neurology					+			
Sensory perception							+	
Activity	+	+				+	+	+
Mobility	+	+	+	+	+		+	+
Moisture								+
Friction							+	
Nutrition		+					+[a]	+
Physical condition	+					+		+
Mental state	+	+	+		+	+		+
Incontinence	+	+	+	+	+	+		+
Weight			+	+				
Skin state			+	+				
Gender				+				
Age			+	+	+			
Appetite				+				
Special risks				+[b]	+[c]	+[d]		
Pain						+		
Dehydration			+					
Temperature					+			

Table 2 **Summary of items considered by general risk assessment scales**
[a] also haemoglobin
[b] cachexia, sensory deprivation, anti-inflammatory/steroid therapy, smoking, orthopaedic surgery, fracture below waist
[c] diabetes, steroids, anticoagulants, sedatives, painkillers, tranquillizers, chemotherapy, antibiotics
[d] steroid therapy, diabetes, cytotoxic therapy, dyspnoea

Furthermore, there is concern about the invariably high sensitivity but rather low specificity in predicting pressure ulcers. This results in over-prediction of the real number of patients at risk and thus in considerable over-prevention.
The relative weight of each risk factor and possible correlation of separate factors in these scales are unknown.
Until recently the different variables were not tested separately as independent risk factors in the aetiology of pressure ulcers.
In a mainly geriatric population, Allman investigated 26 items in a prospective study and identified five independent risk factors by multiple regression analysis: non-blanchable erythema, lymphopenia, immobility, dry skin and decreased body weight (below 58 kg) [54]. Unfortunately, these factors were not used to design a new risk assessment scale. It is surprising that non-blanchable erythema is considered to be a risk factor as it is generally regarded to be the first stage of a pressure ulcer. It is clear that the possible correlation between risk factors and their role in the aetiology of pressure ulcers should be considered when new statistically justified assessment scales are being developed in the future.
Both the Dutch and American consensus reports recommend the use of risk assessment scales for better identification of high risk patients, for assigning preventive measures, and to increase both nurse and doctor awareness of the problem [15,27].

Testing of existing scales on ICU

None of the risk assessment scales presented in **Table 2** was developed especially for ICU patients. As described earlier, these patients form a special population and it is highly questionable to what extent assessment scales, that are not even reliable in "normal" care, can be used.
Thus far in the literature no consensus exists about which risk assessment scale should be used in an ICU setting. Bergstrom et al. tested the Braden scale prospectively in a general ICU on 60 consecutive patients who were followed over a two week observation period [36]. This scale ranges from 6 to 23, with lower scores indicating higher risk. The critical cut-off point, below which

patients are deemed to be at risk, was set at 16. This is the same value as used in earlier studies performed in a general hospital population. At this point the sensitivity of the scale was 83% and the specificity 64%. As an ICU patient's condition can change rapidly, it is inappropriate that the Braden score was only obtained once, on admission. The authors also calculated the sensitivity and specificity of the Norton scale and found it to be 89% sensitive, thus comparing favourably with the Braden scale. However, the Norton scale had a specificity of only 36% and thus tended to over-predict the risk of pressure ulcers developing far more than the Braden scale.

Jiricka et al. performed a prospective study in 85 adult ICU patients to determine the relative contribution of the six subscales of the Braden scale as risk factors in the development of pressure ulcers [32]. Sensory perception and moisture were found to be significant predicting factors. When patients had an initial Braden score of 11, the scale was 75% sensitive and 65% specific. A sensitivity of 100% was reached at a score of 15, but at this point the specificity dramatically decreased to 11%.

In a group of 594 patients Weststrate et al. prospectively studied whether the Waterlow scale had prognostic significance in the ICU [34]. When patients had a score of 25 on admission, their risk of developing a pressure ulcer was significantly increased when compared with patients with a lower score. Patients with scores <15 never developed pressure ulcers. The actual Waterlow score was the best indicator for the development of a pressure ulcer in the following 24 hours, indicating the importance of daily risk assessments. Unfortunately, the authors did not determine the sensitivity and specificity of the scale for use on the ICU. In her review, Barratt concluded that the Waterlow scale was more comprehensive than other scales and probably applicable to all categories, including ICU patients. Her considerations were not, however, based on scientific research [2].

Testing of newly developed scales for the ICU

Cubbin and Jackson felt that existing risk assessment scales had shortcomings for use in an ICU setting [55]. Their main criticism

was directed at the sections in the various risk scales scoring activity and mobility; these are usually superfluous as most ICU patients are both immobile and bedbound. They tried to develop a new scale by adapting the Norton scale but, strangely, this version still assessed patients on their ability to mobilise. This scale was tested in only five patients, so no conclusions can be drawn on its validity.

The Cubbin & Jackson scale was prospectively tested by Hunt in 100 consecutive ICU patients [33]. The incidence of pressure ulcers in this study was 13%, with pressure ulcers being defined as blanchable redness or worse. At a cut-off value of 24 the scale was 100% sensitive, but only 54% specific, implying over-estimation of risk. Since there were also large daily variations for an individual patient, the scale did not provide useful information about individual patient risk.

Lowery also tested the Cubbin & Jackson scale in a study of only eight patients so, again, no conclusions can be drawn about validity [35]. She modified the scale by leaving out mobility and hygiene aspects, but added three new items: transfusion of blood products, body temperature and special conditions such as diabetes mellitus, renal failure and vascular disease. With this scale a prospective study was performed in 15 ICU patients. Four patients developed a pressure ulcer, of whom three were at risk. At the same time, seven patients who were clearly at risk did not develop a pressure ulcer, once more indicating high sensitivity but poor specificity. Yet again, this study was far too small to permit statistical analysis. In her review, Sollars tried to compare the Waterlow scale and the modified Cubbin & Jackson on paper [8]. The author concluded that the scale categories differed too much to make a useful comparison. As a result, she only compared them at the bedside in just one patient, thereby preventing any useful conclusions from being drawn.

Jiricka et al. tested a newly developed risk assessment scale, the Decubitus Ulcer Potential Analyzer (DUPA) [32]. This is a modification of the Gosnell, Norton and Braden scales and consists of seven mutually exclusive subscales: mental status/sensory perception, nutrition, mobility, activity, moisture, friction and

shear and circulation. Each subscale is rated from 1 (least risk) to 5 (most risk) so scores range from 7 to 35. Unfortunately, no detailed descriptions of the subscale categories are given. When patients had an initial DUPA score of 24, the sensitivity was 69% and specificity was 65%. The Braden scale, tested in the same population, reached a higher sensitivity of 75% with the same specificity. Remarkable in this study is the fact that patients who were not allowed to be turned were excluded, though these patients would be particularly at risk.
Batson et al. tried to develop a pressure area scoring system in a prospective, descriptive study [56]. Twenty possible risk factors were evaluated in 51 adult ICU patients using multiple regression analysis. Five factors were found to be significantly related to the development of pressure ulcers: epinephrine- or norepinephrine infusion, diabetes mellitus, restricted mobility and being haemodynamically too unstable to turn. The authors do not mention whether these factors act independently. Unfortunately, no information is given about the incidence of pressure ulcers in this population, and the identified factors were not prospectively tested for validity.
Another risk assessment scale for the critically ill, the Birty Pressure Area Risk Assessment Scale, was developed by Birtwistle [57]. The validity of this scale is highly doubtful, since it was only evaluated by questionnaires returned by nursing staff.

Preventive measures

The essence in prevention is the relief of high degrees and extended durations of pressure. The most important measure, which also applies to ICU patients, is frequent patient repositioning. Since the patient's condition can change rapidly, risk assessment for pressure ulcers should be performed preferably on each repositioning manoeuvre [2,5,7]. If the medical condition allows, patients should be turned every 2-3 hours. An excellent method of positioning patients, without lifting and risk of friction damage, is the 30° tilt [58]. Another advantage of 30° tilt is that it generates lower pressures than the classical 90° lateral position. When patients are nursed on their backs, the position

that generates the lowest pressures is the semi-fowler position, with 30° elevation of the head and trunk and 30° elevation of the feet [5]. Special attention should be paid to the reduction of local pressure on the heels, for example by placing a pillow under the lower legs. The skin should be free from excessive moisture and the nutritional needs of severely ill patients should be met, including correction of any deficits [1].
Support surfaces play an important role in pressure ulcer prevention, but should not be regarded as the primary intervention. Special beds, typically seen in ICUs, are pressure reduction mattresses (usually made of foam), low air loss beds or mattresses (constant low pressure and alternating low pressure), lateral rotational beds and air-fluidized beds. There are no unequivocal criteria in the literature for determining which type of special bed should be chosen for any given patient.
Only a few studies have been performed that compare different support surfaces on the ICU. Until now, no conclusive evidence is available to state which type of surface is best [9,50,59-61].
In a randomized controlled trial in 103 patients, Wille compared an air-fluidized bed with a special mattress. Even using the high-tech air-fluidized bed, 12% of patients developed clinically relevant pressure ulcers, compared with 21% of the patients who were nursed on the special mattress (p=0.29) [9]. Inman et al. compared an air suspension bed with a standard ICU bed in a randomized controlled trial of 100 consecutive patients at risk of developing pressure ulcers. Ninety-eight completed the study protocol [50]. The overall incidence of pressure ulcers was 48%, however the air suspension bed was associated with fewer patients developing single, multiple or severe pressure ulcers (8% versus 40%). This study also included a cost-effectiveness analysis. The air suspension bed proved to be a more clinically effective and less expensive treatment than the traditional approach of frequent patient rotation. Nevertheless, special mattresses and beds are expensive, whether rented, leased or owned. One study compared the costs of two risk-directed strategies for surface assignment, and found that purchased products were cheaper than when rented [62]. Therefore, these beds should be employed thoughtfully and

protocols developed to help maintain cost-effectiveness.

Discussion

The development of pressure ulcers among hospitalized patients is a major problem in health care. Apart from individual discomfort, it is an increasingly costly problem as the result of an ageing population with associated morbidity, intensive nursing care, prolonged hospital stay, use of expensive devices and, sometimes, surgical treatment. In the past, pressure ulcers were mostly considered the result of inadequate nursing, and prevention and treatment were deemed typical nursing tasks. This is reflected by the fact that most literature on pressure ulcers is published in nursing journals. Nowadays it is clear that prevention and treatment of pressure ulcers are the responsibility of both nurses and doctors. Only recently, initiatives were taken to combine both disciplines. Examples are consensus meetings in several countries and the installation of Pressure Ulcer Advisory Panels in both the United States (1989) and Europe (1996).

Pressure ulcer prevalences vary in ICU patients from 14 to 41%, whereas incidences vary between 1 and 56%. These figures are 2-3 times higher than for "general hospital patients", indicating that ICU patients should be considered as a separate risk category. The value of prevalence figures is limited since they only give an indication of the magnitude of the problem at one certain moment. Incidence figures do give information about how many new pressure ulcers developed during an episode. This variation in incidence is difficult to interpret as there are too many differences between various studies. The studied populations also differ strongly (**Table 1**) and the definition of pressure ulcers varies widely, from blanchable erythema to skin breakdown. In several studies the definition of a pressure ulcer was unclear and considerable numbers of patients were also excluded for unclear reasons. For future pressure ulcer-related studies, we recommend the use of an universally accepted pressure ulcer grading system to aid comparison. The two grading systems that are now generally accepted and which practically use the same definitions are those from the American National Pressure Ulcer Advisory Panel and the

European Pressure Ulcer Advisory Panel [10,15].
Overall, there seem to be no adequate studies for identifying risk factors or scales for ICU patients. It seems logical to identify independent risk factors and to put these together to create such a scale. Risk factors that might play a role and should be investigated in future studies include: duration of surgery and number of operations, faecal incontinence and/or diarrhoea, pre-operative protein and albumin concentrations, sensory perception, moisture of the skin, circulation, use of inotropic drugs, diabetes mellitus, too "unstable" to turn and decreased mobility.
The Braden and Waterlow scales are the only ones that have been tested scientifically for use on the ICU. For a general hospital population the Braden scale has been claimed to be the most reliable in terms of sensitivity and specificity, compared with the Norton and Waterlow scales. There still is no conclusive evidence that this applies to its use on the ICU and probably the cut-off point would have to be readjusted to increase its sensitivity. The Waterlow scale considers more risk factors that are relevant for ICU patients, but also lacks proper validation.
Problems with the existing scales are the relative weight of the individual items used and the potential correlation between these items and the aetiology of pressure ulcers. The validity of existing and newly developed scales is low. Sensitivities may be acceptable but specificities are invariably low, resulting in over-prediction of the risk of developing pressure ulcers. Thus too many patients will receive costly and inconvenient preventive measures they do not need.
Several authors have found a significant relationship between the severity of illness score and the development of pressure ulcers [9,31,50]. Therefore, it is surprising that none of the scales take severity of illness in account for risk assessment. When a new scale is developed, severity of illness should be taken into account.
Whichever scale is used, risk assessments should be performed regularly, at least whenever there is a change in the patient's condition. Risk assessment is only useful when decisions such as assignment of preventive measures and special support surfaces are based upon the assessment.

Conclusions

At present there are no studies available that cover all aspects mentioned in this review. This emphasizes the fact that the pressure ulcer problem is ignored and underestimated. There is no useful risk assessment scale available specifically for ICU patients. All existing and newly developed scales are sensitive but not specific. Since pressure ulcers form an increasing burden in health care and generate major costs, there is an absolute need for well-designed prospective studies that determine specific risk factors and test the influence of preventive measures.

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Chapter 3

An appraisal of pressure ulcer risk and incidence on a cardio-thoracic surgical intensive care unit

B.P.J.A. Keller, L. Schoonhoven, E. Buskens, Chr. van der Werken, B. van Ramshorst

Submitted

Abstract

Purposes: To identify independent risk factors associated with the development of pressure ulcers in cardio-thoracic surgical ICU patients and to develop a risk assessment tool, based on these risk factors.

Methods: A total of 204 patients admitted for elective cardio-thoracic surgery and with an ICU stay of ≥ 48 hours were included in a prospective cohort study. Patients were checked daily for pressure ulcers during their ICU stay. The association between 31 preoperative, intraoperative and postoperative possible risk factors for pressure ulcers and the actual development of ulcers was assessed, using univariate and multivariate logistic regression modelling.

Results: The cumulative incidence of pressure ulcers was 53%. Female sex, high age, duration of anaesthesia and intraoperative complications were found to be independent predictors for the development of pressure ulcers. The area under the curve of this prediction rule was 0.70. At a cut-off score of 8, 54% of the patients were correctly identified as at risk for pressure ulcers, also correctly identifying 66% of the patients in which a pressure ulcer occurred.

Conclusion: A clinical prediction rule based on 4 easily obtainable patient characteristics may help to identify patients with increased risk for pressure ulcer development in a cardio-thoracic surgical population.

Introduction

Pressure ulcers are a burden for patients and the health care system. Their occurrence is associated with adverse patient outcome in sense of pain, loss of both function and independence, and increased risk of complications, such as infection and sepsis. Pressure ulcers may result in a prolonged hospital stay, thus generating most of the costs associated with pressure ulcers and an increased workload for the nursing staff [1,2]. The annual costs of pressure ulcer prevention and treatment for the Dutch healthcare system were estimated as high as 450 million Euros, which was 1.3% of the total health care expenditure in 1998 [3].
Pressure ulcers are caused by pressure and shear. Whether or not pressure ulcers will finally develop is presumed to depend on a factor called tissue tolerance [4]. Many factors with an adverse effect on tissue tolerance are present in Intensive Care Unit (ICU) patients, putting them particularly at risk for developing pressure ulcers. One important factor recognised is undergoing major surgery. In a review article, Stotts mentioned incidence figures of pressure ulcers in general and orthopaedic surgical patients between 19 and 66% [5].
Incidence figures for ICU patients are scarce and vary between 1 and 56%, with most reports being published in nursing literature [6]. In a study by Wille et al., an incidence of 40 % clinically relevant pressure ulcers were found on a surgical ICU [7].
Pressure ulcers may be prevented if effective measures are taken in time. However, preventive measures can be quite expensive and sometimes are labour intensive. Applying preventive measures should thus be limited to those patients actually at risk. Many assessment scales have been proposed to identify patients at high risk for pressure ulcer development [8]. Most of these scales were not specifically developed for use in a (surgical) ICU setting nor were these properly validated for use in ICU patients [6,9].
The aims of this study were to obtain incidence figures for pressure ulcers in cardio-thoracic surgical patients and to identify independent risk factors associated with the development of pressure ulcers in this patient category. Subsequently, based on these risk factors, an assessment tool was developed for the identification of patients at risk for developing pressure ulcers.

Methods

Study design and patients

The study was designed as a prospective cohort study, including patients admitted to the St. Antonius Hospital Nieuwegein, The Netherlands, between February 2000 and December 2000. The study protocol was approved by the medical ethical committee of the hospital. Patients aged 18 years and older, who were admitted for elective cardio-thoracic surgery and had an expected postoperative ICU stay of at least 48 hours, were eligible.

Patients whose postoperative ICU stay was less than 48 hours and patients with grade 2 or worse pressure ulcers at admission to the hospital were excluded.

Patients who met the inclusion criteria were asked for informed consent on the day prior to their surgical procedure. A total of 493 patients were eligible for participation in this study, and gave their signed informed consent. Of this group, 289 patients were discharged from the ICU within 48 hours and were not included in the final analysis. Thus, 204 patients met all the inclusion criteria. The population consisted of 129 males (63%) and 75 females (37%). The mean age of the group was 68.6 years (21-89 years). Men were significantly younger than women (66.7 vs. 71.8 years; $p<0.0001$).

Data collection

Immediately after obtaining informed consent, the skin was checked for the presence of pressure ulcers. Pressure ulcers were graded using an internationally accepted classification (**Appendix**) [10].

Based on an extensive literature search, a list of 31 potential risk factors for developing pressure ulcers in ICU patients was composed (**Table 1**) [6].

Starting on the first postoperative day until discharge from the ICU, the skin was checked daily for the presence of pressure ulcers during the morning rounds. All those physical examinations were done by the same researcher (B.P.J.A.K.), together with the responsible nurse. If no agreement could be reached about the pressure ulcer grade, a third opinion was asked to resolve this discrepancy. Pressure ulcers were recorded for both grade and location.

Riskfactor	Category	Moment of assessment		
		Preop.	Intraop.	Postop.
Activities of daily living	dependent independent	+		
Age	in years	+		
Body Mass Index	weight/length^2	+		
Cardiac history	yes/no	+		
Diabetes Mellitus	yes/no	+		
Haemoglobin level	in mmol/l	+		
History of pressure ulcers	yes/no	+		
Incontinence (urinary and/or faecal)	yes/no	+		
Mental state	altered not altered	+		
Mobility	limited unlimited	+		
Neurologic history	yes/no	+		
Peripheral vascular disease	yes/no	+		
Serum albumin	in g/l	+		
Sex	female/male	+		
Smoking	yes/no	+		
Total serum protein	in g/l	+		
Circulatory arrest	yes/no		+	
Crossclamping of the aorta	yes/no		+	
Duration of anaesthesia	in minutes		+	
Duration of aortic crossclamping	in minutes		+	
Duration of extracorporeal circulation	in minutes		+	
Duration of surgery	in minutes		+	
Duration of systolic bloodpressure <90 mmHg	in minutes		+	
Extracorporeal circulation	yes/no		+	
Intraoperative complications	yes/no		+	
Intraoperative inotropics	yes/no		+	
Lowest body temperature	in °C		+	
Position on OR-table	supine lateral		+	
Systolic bloodpressure <90 mmHg	yes/no		+	
Type of surgery	cardiovascular pulmonary combination		+	
SAPS II				+

Table 1 **Potential risk factors for the development of pressure ulcers, derived from the literature**

Severity of illness, as expressed by the SAPS II, was only obtained once in the first 24 hours after admission to the ICU [11].
The choice of preventive measures for each patient was based on subjective criteria of the individual nurses on duty and was deliberately not influenced by the investigators. Although prescribed by the Dutch consensus protocol for the prevention of pressure ulcers, patients were not routinely turned every 2-3 hours [12]. Of the 204 patients, 183 (90%) were placed on the ICU standard mattress directly post-operative. The remaining 21 patients were placed on the Hill-Rom Clinirest system (n=19) or on the Hill-Rom Duo system (n=2).

Statistical analysis

Statistical analysis was performed using SPSS®, version 9.0.1. The association between all possible risk factors and the development of pressure ulcers was first assessed using univariate logistic regression. If a factor appeared significant on univariate analysis (p-value <0.05) or showed a tendency towards significance (p-value <0.15), it was entered into a backward stepwise multivariate logistic regression model. The prognostic ability to discriminate between patients with and without pressure ulcers was estimated using the area under the Receiver Operating Characteristic curve (AUC). AUC values between 0.7 and 0.8 represent reasonable discrimination [13]. For practical reasons, significant continuous variables were recoded into categorical ones. The resulting model was again analysed with AUC estimation. To correct for overfitting of the model, we used heuristic shrinkage [14]. The shrinkage factor was calculated using the following rule: (Model Chi^2-Degrees of Freedom)/Model Chi^2. For our model the shrinkage factor was 0.68. All regression coefficients were multiplied with this shrinkage factor. The reference category automatically received the value of zero. Weights for each variable were created by dividing the shrunk regression coefficients through the smallest coefficient and subsequent rounding to the nearest integer. By assigning points in accordance to these weights, and summing the results, a score was calculated for each patient. Patients were classified according to their risk score, and the proportion of patients with pressure ulcers was calculated for several risk scores. Finally, the sensitivity and specificity of the risk scale at different cut-off points were calculated.

Results

Table 2 shows a summary of the surgical procedures that were performed.

Procedure	Number of patients (%)
CABG	57 (28)
Cardiac valve plasty/replacement	42 (20)
Exclusion of thoraco(abdominal) aortic aneurysm (TAA(A))	34 (17)
CABG + cardiac valve plasty/replacement	32 (16)
CABG or valve surgery + TAA(A)	16 (8)
CABG or valve surgery + miscellaneous	18 (9)
other	5 (2)

Table 2 Cardio-thoracic surgical procedures performed in 204 patients

In 13 patients (6%) intraoperative complications occurred. Four patients had a major bleeding at the end of the procedure, requiring immediate rethoracotomy and another 4 had a major bleeding during the procedure, necessitating return to extracorporeal circulation in 1 patient. One patient developed acute tamponade, requiring immediate rethoracotomy and 1 patient the aortotomy disrupted, requiring patch plasty. Three patients had a prolonged intraoperative episode of shock, requiring high doses of vasopressors.

In the group of 204 patients that met the inclusion criteria, 109 developed pressure ulcers during their stay in the ICU, resulting in a cumulative incidence of 53.4%. In 66 patients (32.4%) a grade 1 ulcer developed while 43 patients (21%) developed a grade 2 or 3 ulcer. There were no grade 4 ulcers among our patients. In the group of 289 patients discharged from the ICU within 48 hours, information about pressure ulcers was available in 221 patients (76%). Twenty-three patients (10%) developed pressure ulcers, with only 2 patients having a grade 2 ulcer.

In the 109 patients, a total of 172 ulcers were found, with the sacral area and heels as most common locations (**Table 3**).

Pressure ulcer location	Number of patients (%)	
ear	4	(3.7)
nose	1	(0.9)
corner of mouth	2	(1.8)
scapula	2	(1.8)
elbow	9	(8.3)
finger	3	(2.8)
sacrum	53	(48.6)
ischial tuber	35	(32.1)
trochanter major	1	(0.9)
heel	54	(49.5)
ankle	4	(3.7)
other	4	(3.7)

Table 3 **Pressure ulcer distribution (in 109 patients with ulcers)**

Pressure ulcers were present after a median of 2 days postoperatively. For the majority of patients (87/109; 80%) who developed pressure ulcers, the first manifestations were present by the third postoperative day (**Fig. 1**).

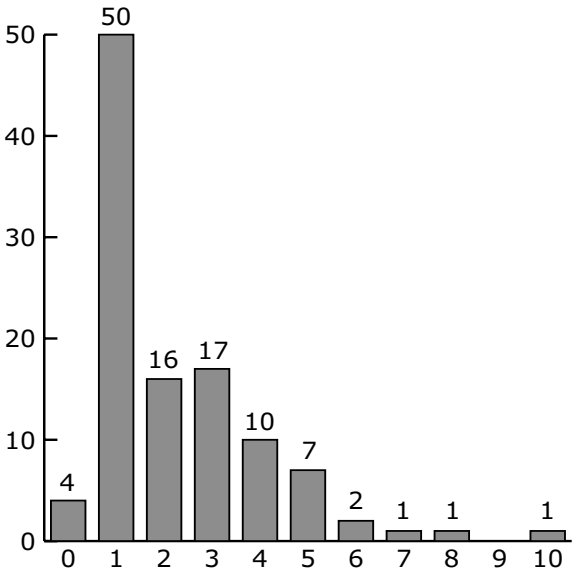

Fig. 1 **Number of patients with new pressure ulcer manifestations by postoperative day**

Risk factors

After performing univariate analysis, 5 risk factors were significantly associated with the development of pressure ulcers: sex, age, incontinence, preoperative haemoglobin level and the occurrence of intraoperative complications. Seven other risk factors showed a tendency towards significance: Body Mass Index, smoking, diabetes mellitus, duration of anaesthesia, surgery, aortic crossclamping and systolic pressure below 90 mmHg during surgery.

After backward stepwise multiple logistic regression analysis 5 independent predictors for pressure ulcers grade 1 or worse remained: sex, age, incontinence, intraoperative complications and duration of anaesthesia. The AUC of this model was 0.71 (95% CI: 0.64-0.78). Since incontinence was only present in 10 patients, limited clinical relevance was anticipated and this predictor was excluded. The AUC of the model without incontinence was 0.69 (95% CI: 0.62-0.76). The final model was obtained after recoding age and duration of anaesthesia in categories (**Table 4**). The AUC of this model was 0.70 (95% CI: 0.63-0.78). The prediction rule is also presented in **Table 4**.

Variable	Odds ratio (95% CI)	Regression coefficient*	p-value	Contribution to the score
Sex				
Male	RC			0
Female	2.2 (1.2-4.1)	0.54	0.014	3
Age at time of surgery (yrs)				
≤55	RC			0
56-70	2.9 (0.9-9.6)	0.72	0.8	5
≥71	4.3 (1.2-14.5)	0.98	0.022	6
Duration of anaesthesia (hrs)				
<3	RC			0
≥3-<5	1.3 (0.5-3.2)	0.16	0.61	1
≥5-<7.5	1.9 (0.7-5.3)	0.44	0.22	3
≥7.5	4.3 (0.8-24.0)	1.0	0.09	6
Intraoperative complications				
No	RC			0
Yes	3.8 (0.8-19.4)	0.91	0.10	6

Table 4 **Independent predictors of pressure ulcers grade 1 or worse**
***Regression coefficient after shrinkage; RC = Reference Category**
Prediction rule:
Score = 0 (if male) + 3 (if female) + 0 (if age ≤55) + 5 (if age 56-70) + 6 (if age ≥71) + 0 (if anaesthesia <3) + 1 (if anaesthesia ≥3-<5) + 3 (if anaesthesia ≥5-<7.5) + 6 (if anaesthesia ≥7.5) + 0 (if no intraoperative complications) + 6 (if intraoperative complications)

In our population the total score of the prediction rule varied between 1 and 21, with higher scores indicating higher risk. The AUC of this score was 0.70 (95% CI: 0.63-0.77).
In **Table 5** the number of patients with and without pressure ulcers across the outcome of the score are presented.

Risk score	Total number of patients (n=204)		PU(+) n=109		PU(-) n=95	
	n	(%)	n	(%)	n	(%)
1	5	(2.4)	2	(1.8)	3	(3.1)
3	8	(3.9)	1	(0.9)	7	(7.4)
4	1	(0.5)	0	(0)	1	(1.1)
5	8	(3.9)	3	(2.8)	5	(5.2)
6	40	(19.6)	15	(13.8)	25	(26.3)
7	32	(15.7)	16	(14.7)	16	(16.8)
8*	23	(11.3)	10	(9.2)	13	(13.7)
9*	28	(13.7)	16	(14.7)	12	(12.6)
10*	20	(9.8)	13	(11.9)	7	(7.4)
11*	16	(7.8)	13	(11.9)	3	(3.1)
12*	10	(4.9)	10	(9.2)	0	(0)
13*	3	(1.5)	2	(1.8)	1	(1.1)
15*	2	(1.0)	1	(0.9)	1	(1.1)
16*	3	(1.5)	3	(2.8)	0	(0)
17*	2	(1.0)	2	(1.8)	0	(0)
18*	2	(1.0)	2	(1.8)	0	(0)
21*	1	(0.5)	0	(0)	1	(1.1)

Table 5 **Number of patients with pressure ulcers, across outcome of the score**
*** patients at risk of proposed cut-off point of 8**

At a cut-off score of ≥8, the prediction rule correctly identified 66% (72/109) of the patients in which a pressure ulcer grade 1 or worse occurred. Also, 54% (110/204) of the total number of patients was identified as at risk for pressure ulcer development. Of the patients that did not develop pressure ulcers 40% (38/95) were falsely identified as at risk (false positives). Of the patients that developed pressure ulcers, 34% (37/109) were falsely identified as not at risk (false negatives). When choosing a cut-off score of ≥ 7, the number of patients correctly identified as having pressure ulcers increased to 81% (88/109), at the expense of an increase of false positives to 57%. The false negative rate was 19% (21/109). The number of patients identified as at risk went up to 70%.

Discussion

The most striking result in the present study was the high cumulative incidence of 53% pressure ulcers grade 1 or worse, found in a selected

population of cardio-thoracic surgical ICU patients. Although 32% of the patients developed a grade 1 ulcer, over 20% of our patients showed sequelae of grade 2 and 3 ulcers. The high cumulative incidence in patients undergoing elective cardio-thoracic surgery, emphasizes the relevance of the pressure ulcer problem in an ICU environment and underlines the importance of adequate prevention in this category of critically ill patients.

A possible explanation for the high incidence is the category of patients that was operated upon. Various authors have shown that pressure ulcers are a considerable problem in cardio-thoracic surgical patients. Stordeur et al. found grade 2 and 3 ulcers in 29.5% of patients in comparison to 21.1% in our study [15]. Unfortunately, the incidence of grade 1 ulcers was not documented. The study by Papantonio et al. reported about sacral ulcers only, following cardiac surgery (27.2%) [16]. Both studies thus underestimate the real cumulative incidence. Due to our decision to exclude patients with an ICU stay of less than 48 hours, the pressure ulcer incidence in our study is also underestimated. This choice was based on the results of a previous study by Wille et al., where the median pressure ulcer free period after ICU admission was three days for clinically relevant ulcers [7].

Our study identified 4 easily obtainable patient characteristics as independent risk factors for pressure ulcer development: sex, age, intraoperative complications and duration of anaesthesia. Of these factors, high age and duration of anaesthesia, in fact reflecting duration of surgery, have been previously reported [6]. Intraoperative complications were not previously described as a possible risk factor. It was surprising although unexplained that, contrary to the existing literature, women in our study had a higher pressure ulcer risk than men. This finding cannot be attributed to the significant difference in mean age between men and women in our series, as this would have shown in the multivariate analysis. Several authors [17,18] suggested to consider severity of illness scores as important indicators of pressure ulcer risk in ICU patients. The results of our study showed that the SAPS II was no useful indicator. This is in contrast with the study by Theaker et al. [19], who found the APACHE II score as a significant pressure ulcer risk factor. A possible explanation may be found in the difference in study populations. In our study, only patients undergoing elective

surgery were included, while studies showing the importance of severity of illness scores consisted mainly of emergency medical or surgical patients.

Based on the identified risk factors a prediction rule was composed, which identified 54% of the patients as at risk and correctly predicted 66% of the patients who developed pressure ulcers. Most of the existing risk-assessment tools are not applicable to ICU patients. These tools were mainly developed for a geriatric population and do not consider risk factors that are specific for ICU patients. The risk factors used in those tools are mostly based on expert opinion with weights of individual factors attributed subjectively, whereas our prediction rule is based on regression modelling, thus accounting for the mutual associations between predictors, with the weight of the factors assigned on the basis of regression coefficients. Cubbin & Jackson developed a tool for ICU patients by modifying the Norton scale [20]. The Norton scale assesses patients for general physical condition, mental state, activity, mobility and incontinence. In the modified scale age, weight, general skin condition, haemodynamic status, respiration, nutrition and hygiene were added as relevant aspects for ICU patients. The Cubbin & Jackson tool was tested prospectively by Hunt in 100 patients, yielding a sensitivity of 100% and specificity of 53% [21]. As their study was undertaken in "general" ICU patients, the sensitivity and specificity can not be compared with our figures, which were obtained in a strictly elective cardio-thoracic surgical population.

One of the pitfalls of developing prediction models is creating a prediction rule that is overoptimistic, resulting in inaccurate prediction of actual pressure ulcer risk. This may happen when only variables turning out to be significant on univariate analysis are selected for the multivariate logistic regression model. We therefore also entered variables that showed a tendency towards significance ($p<0.15$). Another method used to adjust for overly optimistic estimates of the regression coefficients of the predictors in the final model was heuristic shrinkage [14]. The shrink factor thus calculated was 0.68, and was used to shrink the regression coefficients of our prediction model. Due to the large shrink factor the stability of the final prediction model is limited. As a consequence, we suggest external validation of the prediction rule, before clinical implementation. The stability of the model

also depends on the size of the population and will probably increase when tested again in a larger population.
It is generally assumed that prevention is cheaper than treatment of an actual pressure ulcer. But if preventive measures are assigned based on wrong grounds rather than proper risk assessment criteria, many patients will receive costly measures, including patients in whom the risk is not actually increased, whereas others may be withheld clearly needed care. One of the aims of our prediction rule was to identify high risk patients, in order to assign preventive measures specifically to patients who really need these. For practical application of the prediction rule, we suggest that patients with risk scores of ≥8 should receive preventive measures. This cut-off point was chosen, because at this value only 40% of the patients without pressure ulcers will receive unnecessary prevention whereas at a cut-off of ≥7 this increases to 57%. Of course, the question rises whether a risk assessment scale is useful anyway, when more than half of a patient population develops pressure ulcers. Probably, it is a better policy to give prevention to all patients. Cost-effectiveness studies may identify whether applying preventive measures in all patients is a better strategy than a selective approach based on the prediction rule. This may also answer whether the suggested cut-off point is justified.
With an AUC of 0.70, our prediction rule unfortunately still has limited discriminative capacity, although the risk assessment scales currently available all have lower AUC's, varying from 0.55 to 0.61 [9]. Again, external validation studies are needed to assess the reproducibility of our prediction rule in similar populations and to evaluate the applicability of the rule in different populations of ICU patients.
In 80% of our patients, the first manifestations of pressure ulcers were present by the third postoperative day. As it is generally assumed that pressure ulcers may only become apparent 3 to 5 days after the underlying causative moment, the basis for the occurrence of pressure ulcers in our patients must already have been present prior to ICU admission.
The manifestation of pressure ulcers so early after operation, implicates a major role for undergoing surgery as causative factor. This is supported by the fact that 2 of the 4 items of our prediction model are indeed surgery related. Therefore, more efforts should be made to

adequately protect patients against the development of pressure ulcers during surgery.
In conclusion, the development of pressure ulcers in cardio-thoracic surgical ICU patients can be predicted with a prediction rule based on 4 easily obtainable characteristics: sex, age, duration of anaesthesia and the occurrence of intraoperative complications. Since our risk factor analysis was performed in a specific group of selected patients, it is not certain whether the newly developed prediction rule will also be applicable to "general" surgical ICU patients. This issue will have to be addressed in future validation studies. Also external validation will have to be performed before clinical implementation is possible.

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Chapter 4

Interface pressure measurement during surgery: a comparison of four operating table surfaces

B.P.J.A. Keller, J. van Overbeeke, Chr. van der Werken

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Abstract

Objective: To compare the pressure-reducing and pressure-distributing characteristics of four operating room (OR) table mattresses using interface pressure measurements, with patients in two positions adopted for surgical procedures.

Method: The mattresses tested were an overlay pad filled with fibres (the standard mattress), a custom made viscoelastic polyurethane foam mattress, a ROHO® Dry Floatation® OR Pad and a RIK® Fluid mattress. Support surfaces were randomly assigned to 80 patients. Using an XSENSOR full body pressure-mapping pad during surgery, interface pressures were recorded in 40 patients in supine position and in 40 patients in lithotomy position. Measurements were analysed for peak pressure, peak pressure index, total contact surface area and the occurrence of a significant increase in interface pressure during the surgical procedure, using XSENSOR software.

Results: The highest interface pressures were measured on the standard mattress, in both supine and lithotomy position. Overall, the RIK® Fluid mattress showed the best pressure reducing and pressure distributing capacities.

Conclusion: Clinical testing of operating table surfaces remains necessary, as long as no reference values are available for interface pressures, under which no pressure related damage will occur.

Introduction

Several studies have shown that the incidence of pressure ulcers in surgical patients is higher than in a "general" patient population [1,2]. More and more evidence arises that these pressure ulcers are actually acquired in the operating room (OR), on the OR table [3,4]. Especially after lengthy procedures, the probability of developing pressure ulcers seems higher, even in patients not previously identified as at special risk [5-7].

Perioperative prevention of pressure ulcers is clinically relevant. Both positioning of the patient on the OR table and the choice of OR table surface should be considered when dealing with prevention. A support surface may reduce the chance of developing pressure ulcers by minimising the interface pressure (IP) by enlarging the contact area. Many different surfaces for OR tables are commercially available, but the pressure reducing and distributing capabilities of most of these have not been tested in clinical practice. A method to test these capabilities is Interface Pressure Measurement (IPM). IP is the pressure that is applied to the skin by the supporting surface. A study by Williams et al. has shown that the capillary pressure varies between 20 and 40 mmHg in human beings [8]. Pressures above these values are likely to cause tissue ischaemia when sustained more than two hours, after which damage will be irreversible. Presently, no absolute IP threshold has been identified above which pressure ulcers will develop. Thus, IPM can only be used to evaluate and compare the relative performance of support surfaces.

In this study, we compared the performance of four different OR table surfaces. The main study questions were:

- Which surface had the best pressure distributing characteristics?
- How did these performances change with the two patient positions?

IPM was used to create a ranking in performance for the four surfaces.

Material and Methods

In a prospective study, performed in the University Medical Centre Utrecht and the St. Antonius Hospital Nieuwegein, 80 consecutive patients were studied using IPM's during surgery. The study protocol was approved by the medical ethical committee of both hospitals. Patients were asked for consent prior to surgery. Two different postures, in which patients are frequently positioned during surgery, were evaluated. Forty patients were operated in supine position and the other 40 in lithotomy position, where the legs are placed in knee crutches. Each of the 40 patients in every group randomly got one of the 4 OR table surfaces assigned, by pulling sealed envelopes. The studied population consisted of 38 men and 42 women, ranging in age from 20 to 84 years (mean age 58 years). The mean Body Mass Index (BMI) was 27.3 and ranged from 15.1 to 56.7. As a result of randomisation, patient groups on each of the 4 tested surfaces were comparable for age, sex and BMI.
The following OR table surfaces were tested:

1) a 3 cm thick pad, filled with polyurethane fibres (the standard mattress)
2) a custom-made 7 cm thick viscoelastic polyurethane foam mattress
3) a ROHO® Dry Floatation® OR Pad (ROHO; Belleville, Illinois, USA)
4) a RIK® Fluid Operating Table Pad (Kinetic Concepts, Inc.; San Antonio, Texas, USA).

All mattresses were used as an extra overlay on the Maquet OR table surface. ROHO advised individual adjustment for every patient on the Dry Floatation® OR Pad. Busy OR schedules in our hospitals didn't allow for this individual adjustment for every patient and therefore the operating table pad was adjusted to an 80 kg "standard" patient. Interface pressures were measured with the XSENSOR X2-6912 pressure-mapping device (XSENSOR Technology Corporation; Calgary, Canada). This system consisted of a thin, easily foldable full body pressure-mapping pad with 6912 capacitive sensors. The sensors in the pad had a 1.27 cm resolution, and consisted of a sensing strip with a width of 1.11±0.04 cm. Spacing between sensors was 0.16±0.04 cm. The pad was placed between the patient and the support surface, without folds. Connection of the pad to a laptop computer with XSENSOR software (version 4.2), allowed for real-time pressure recording. The

sampling rate was one frame per minute. Recording started when the patient had been positioned for surgery and was stopped at the end of the surgical procedure.

Data analysis

Each recorded frame corresponded with a separate colour-coded pressure map frame in the XSENSOR software window (**Fig. 1**).

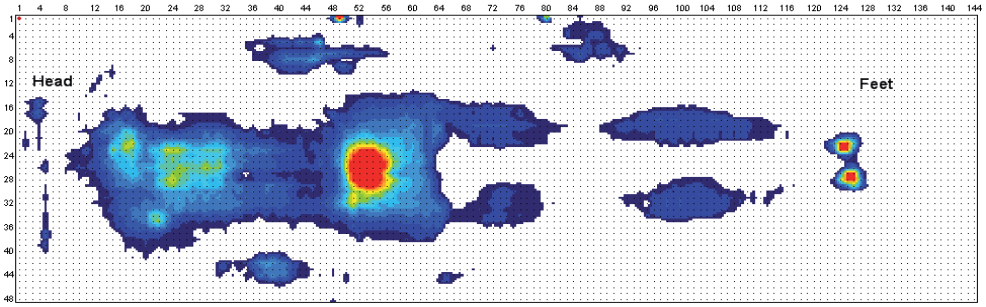

Fig. 1 **Example of colour-coded map as generated by XSENSOR software**
Red areas represent pressures >150 mmHg

Measurements were analysed at three contact areas considered to be at special risk for pressure ulcer development:

- Scapulae
- Sacrum
- Heels.

For each contact area, the peak pressure and peak pressure index (PPI) were determined. The peak pressure was defined as the highest pressure that was registered in the contact area. The PPI for the scapular and sacral area was defined as the mean of the values registered by the peak sensor and its 8 surrounding sensors. At the heels, the PPI was the mean of the peak sensor and 3 surrounding sensors.

The PPI is considered more reliable for assessing the pressure distributing capabilities of a support surface, since it examines a surface area of 25.8 cm^2 and not only the peak pressure registered by one single sensor, with a surface of only 1.61 cm^2. When the PPI approached the peak pressure, this indicated that the support surface was not able to distribute pressure sufficiently.

Also, the total contact IP and mean total contact IP were calculated by the XSENSOR software. The total contact IP was defined as the average

of the pressures registered by all sensors that were loaded in one frame; the mean total contact IP was defined as the average of the total contact pressures of all frames that were obtained during one surgical procedure. Lower total contact IP's meant better pressure distributing capacities of a mattress. From the number of sensors that were loaded during a sample, the total contact surface (in cm^2) was calculated. The mean of all samples was used for comparing the surfaces. The larger the total contact surface area for a mattress was, the better the surface was capable of distributing pressure.
Finally, the occurrence of a significant increase in IP was determined. This was defined as a ≥5% increase of the total contact IP during the surgical procedure. The total contact IP obtained at the start of the surgical procedure was the baseline value. The increase in IP was used to judge the surfaces for bottoming out, which meant that the surface reached its maximum compression, resulting in a decrease of pressure distribution.
During all surgical procedures in this study, electrosurgery was frequently used. Due to electromagnetic interference between the wire of the electrosurgical pencil and the sensors, measurements taken simultaneously with the use of electrosurgery showed distortion, resulting in false-positive high pressures. All frames that showed distortion due to the use of electrosurgery, were excluded from analysis. Statistical analysis was performed using SPSS 11.0.1. (SPSS®, Chicago, Illinois). IP, PPI, total contact IP and total contact surface area were calculated as median values. Differences in these values between the 4 surfaces were assessed using One-way ANOVA. Differences were regarded significant if $p<0.05$.

Results

The results are summarised in **Tables 1** to **3**. On the standard mattress, the highest IP's were measured at the sacral area, with a median peak IP of 185 mmHg, both in supine and lithotomy position. Patients in the lithotomy position showed a considerable lower peak IP at the scapular area than in the supine position. The standard mattress showed almost no pressure distribution at the sacral area, as was demonstrated by the PPI that approached the peak IP at the sacrum. Pressures were better distributed at the scapular area than at the sacral area. This was

		Scapular area		Sacral area		Heels	
Standard mattress	S	159.0	(55–184)	185.0	(177–189)	159.5	(143–163)
	L	100.0	(42–176)	185.5	(178–188)		
ROHO® Dry Floatation® OR Pad	S	125.5	(99–184)	173.5	(133–190)	157.0	(128–169)
	L	106.5	(44–175)	169.5	(138–184)		
Viscoelastic polyurethane mattress	S	70.0	(40–96)	152.0	(98–182)	148.5	(94–166)
	L	54.5	(35–112)	181.0	(117–201)		
KCI RIK® Fluid Operating Table Pad	S	62.5	(42–90)	86.5	(47–130)	106.0	(64–162)
	L	53.5	(40–102)	93.0	(63–194)		

Table 1 **Median peak interface pressure (mmHg) by contact site (range)**
S = supine, L = lithotomy

		Scapular area		Sacral area		Heels	
Standard mattress	S	97.0	(37–180)	181.0	(147–189)	153.0	(92–161)
	L	69.0	(39–137)	181.0	(98–188)		
ROHO® Dry Floatation® OR Pad	S	58.0	(44–90)	75.0	(56–98)	112.5	(61–151)
	L	45.5	(31–81)	75.0	(55–143)		
Viscoelastic polyurethane mattress	S	49.5	(39–86)	112.5	(79–174)	104.5	(56–166)
	L	44.0	(28–74)	152.5	(88–194)		
KCI RIK® Fluid Operating Table Pad	S	47.5	(36–61)	68.5	(45–110)	74.0	(53–143)
	L	43.0	(26–65)	78.5	(44-160)		

Table 2 **Median peak pressure index (mmHg) by contact site (range)**
S = supine, L = lithotomy

		Total contact IP	Total contact surface
Standard mattress	S	28.4	4249
	L	31.2	3673
ROHO® Dry Floatation® OR Pad	S	27.9	4391
	L	29.0	3134
Viscoelastic polyurethane mattress	S	24.1	5067
	L	29.2	4386
KCI RIK® Fluid Operating Table Pad	S	22.7	5226
	L	25.3	4374

Table 3 **Mean total contact interface pressure (mmHg) and mean total contact surface area (cm^2)**
S = supine, L = lithotomy

illustrated by the PPI, which at the sacral area was only 4 mmHg lower than the peak IP, whereas at the scapular area the PPI was 62 mmHg lower than the peak IP in the supine position. On the ROHO® Dry Floatation® OR Pad, the highest IP was also measured at the sacral area in both supine and lithotomy position. In both positions, peak IP's were lower than those on the standard mattress. The peak IP at the heels was comparable with that on the standard mattress. The ROHO® Dry Floatation® OR Pad showed very good pressure distribution, as demonstrated by a PPI at the sacral area that was almost 100 mmHg

lower (43% reduction) than the peak IP.
On the polyurethane mattress, the highest peak IP was also measured at the sacrum. In this area, peak IP's were 21.5 and 33 mmHg lower than on the ROHO® Dry Floatation® OR Pad and the standard mattress respectively. In lithotomy position, the peak IP was almost 30 mmHg higher than in the supine position. Such a dramatic increase was only found on this specific mattress and occurred at the sacral area only.
At the sacrum and the heels, the PPI was 28.5-44 mmHg lower than the peak IP, compensating for the high peak IP by good pressure distribution, in both the supine and lithotomy position.
On the RIK® Fluid mattress, the highest peak IP was measured at the heels and not at the sacrum, in contrast to the other 3 tested surfaces. This mattress showed the lowest IP's at all contact sites, in both the supine and lithotomy position, and outperformed the other three surfaces. In the lithotomy position, the peak IP was slightly higher than in the supine position, but not as much as on the polyurethane mattress.
The mean total contact IP was highest on the standard OR mattress and again the RIK® Fluid mattress performed best (**Table 3**). Pressures are higher in lithotomy position for all surfaces, since approximately the same weight has to be supported by a smaller surface, as is illustrated in **Table 3**. In both the supine and lithotomy position, the polyurethane and RIK® Fluid mattress showed higher contact surface areas, indicating better pressure distribution than the standard mattress and ROHO® Dry Floatation® OR Pad.
A significant increase in IP during the surgical procedure was noted in 9 of 40 patients in the supine position and in 10 of 40 patients in lithotomy position. In the supine position, this effect was seen equally often on each of the 4 surfaces, whereas in the lithotomy position, the significant increase occurred in 5 of the 10 patients on the standard OR mattress.

Discussion

Our study showed that extremely high IP's (in excess of 120mmHg) are reached on three out of four tested OR table surfaces. The IP's reached on our standard OR table mattress are that high, that it seems unjustifiable to place patients on such a surface during surgery. The bad performance of the standard mattress can probably be explained by the fact that it is rather thin, which causes bottoming out. This means

that the actual surface of the OR table, which is harder than the overlay mattress, is easily reached. The standard mattress also has limited pressure-distributing capabilities, which is shown by the fact that the mean contact surface area is almost 1000cm^2 smaller than that of the best performing surface.
Only one surface, the RIK® Fluid, was able to reduce IP's to values that are regarded as acceptable, at all three contact sites prone for pressure ulcer development. This mattress behaves like fluid and envelopes the patient, resulting in maximum contact surface and subsequent distribution.

Limitations

Contrary to the manufacturer's protocol, we did not adjust the ROHO® Dry Floatation® OR Pad for every patient studied. In the daily practice of our hospitals, with tight operating schedules, there was no time to do this for every individual patient. Without these individual adjustments, this mattress showed large discrepancies between the peak IP and the PPI, with values approaching 100mmHg at the sacral area. This discrepancy was noticed at all three contact areas. Due to the architecture of the mattress, hammocking of the measuring pad can occur between the cells, resulting in false-positive high peak IP's. This effect is undone when a larger area of sensors is considered (when calculating the PPI) and probably also when the cells are less inflated in case of individual adjustment. The mattress might have performed better in case the recommended adjustments would have been applied.
Several points must be considered when analysing measured tissue IP's. The effects of interface pressure on the deeper tissues, where the actual pressure related damage will arise, remain uncertain. It is known that applied pressure is a major causative factor in the aetiology of pressure ulcers, but till now no reference values are available above which pressure related damage will occur and also under which damage doesn't occur [9-11]. This makes it difficult to put our results into perspective. The scarce literature that is available suggests that the interstitial stresses are between 29 and 40% of the interface pressure [12]. Many reports mention the threshold value of 32 mmHg that was determined by Landis as early as in 1930 [13]. However, this value was based on pressures measured in skin capillaries within the nail folds.

Since this value represents a dimension of localised interstitial pressure, it is inappropriate to consider it a threshold value for IP at weight-bearing areas [12]. Effects of external pressure on the circulation are influenced by compensation mechanisms. These mechanisms fail when the external pressure approaches the diastolic blood pressure.
Also, no standard device for obtaining IPM's has been defined. Almost all reports concerning IPM's in patients on support surfaces described different measuring techniques, varying from systems using air-filled, electropneumatic sensors and systems with capacitive sensors, as used in our study. This makes comparison of different studies practically impossible [12].
Several authors studied OR table support surfaces using IPM's. In a test of two support surfaces, Blaylock reported IP's that were much lower than in our study. For both surfaces, mean values of 38 mmHg were found at the sacral area and values of 26 and 28 mmHg at the heels [14]. In a study by Defloor, five OR table mattresses were evaluated with healthy volunteers in four different positions [15]. Peak IP's varied between 32 and 49 mmHg in supine position and between 39 and 61 mmHg in lithotomy position. The lowest pressures were obtained on a 7 cm thick polyurethane mattress. The results in the latter study considered peak pressures only, irrespective of the site where the pressures were measured, not allowing rational comparison with the outcome of our study.
It is unclear whether lower IP's are synonymous with a reduction in pressure ulcer risk in clinical practice. It is therefore important that surfaces are also assessed when used in practice. This should preferably be done in a large prospective study that compares the incidence of pressure ulcers after surgery on different support surfaces. IPM's can be of help in selecting surfaces for such a clinical test.

Conclusion

High IP's on a standard OR table surface are common, but are also measured in patients on overlay surfaces that are especially developed for pressure reduction. Only one of the tested surfaces gave a satisfactory pressure reduction and distribution
Since no reference values for IP's are available, under which no pressure related damage will occur, there is still the necessity for clinical testing

of OR table surfaces. IPM's can be used to create a ranking in surface performance and thus to select surfaces for clinical tests.

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Chapter 5

Tissue-interface pressures on three different support surfaces for trauma patients

B.P.J.A. Keller, P.H.W. Lubbert, E. Keller, L.P.H. Leenen

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Abstract

The purpose of this study was to evaluate and compare tissue-interface pressures on three different support surfaces for trauma patients. The support surfaces were a semi soft overlay mattress, a vacuum mattress and a spineboard. Tissue-interface pressures were measured in a standardized way between the scapulae, the sacrum, the heels and the different support surfaces in twenty healthy volunteers. Appreciation of comfort of the support surface was assessed using a 10-point visual analog scale. High and potentially ischaemic interface pressures were found on all three support surfaces, with the highest pressures (exceeding 170 mmHg) measured on the spineboard. The spineboard got the worst comfort score. It was also noted that no support was given to the normal lumbar lordosis by the spineboard. There is a need for new support surfaces for trauma patients, that reduce interface pressures and are comfortable.

Introduction

In The Netherlands, polytrauma patients are often transferred on a spine board, as required by protocol, for spinal immobilization during transportation. Originally, the spine board was developed as an extrication device, for which reason it has to be rigid and light. Its use as a transportation device is good for the paramedics but not for the patient. In many emergency departments, patients may not be lifted from the spine board before the presence of spinal injury has been ruled out on clinical and radiological grounds. This means that these patients generally spend a significant period on the spine board, as is illustrated in a study by Lerner and Moscati [1]. They found that the total time a trauma patient spent on a spine board (including the period of transportation) averaged 63 minutes. When patients required radiological evaluation before removal from the backboard, the total spine board time averaged three hours.

Patients with supposed critical injury often enter a cascade of prolonged immobilization in a supine position during transport and in the emergency room, often followed by immobilization on the OR table and eventually during ICU stay. A known risk of this immobilization is the development of pressure ulcers, with reported incidences in trauma patients up to 31% [2,3]. Few studies have addressed the discomfort and potential harmful consequences of the use of spine boards. Although it is supposed and generally advocated that a spinal fracture is best treated by rigid immobilization on a flat surface, this can be questioned, and it may be argued that this way of immobilization may have harmful consequences. Moreover, the use of the rigid spine board is supposed to lead to the development of pressure ulcers in critically injured patients, because the hard surface produces high interface pressures between the skin and spine board.

In many European countries, alternative methods are used for the transportation of trauma patients, for example the vacuum mattress. The purpose of our study was to evaluate tissue-interface pressures on the spine board as well as on alternative transportation devices, e.g. a semi soft emergency department mattress and a vacuum mattress.

Material and Methods

We prospectively collected data from 20 healthy volunteers, who were not experiencing any pain at the time of the study, and did not have a history of chronic back pain. The study group consisted of 7 men and 13 women, with an average age of 40 years (range 20-56). The subjects average Body Mass Index (BMI) was 24 (range 20-27). The three different surfaces were tested by all volunteers, lying in a supine position for a period of five minutes on each surface. Devices were tested in a fixed order for all subjects: 1) the standard semi soft overlay mattress, which has a 5 cm thick foam core (Etesmi / JW Koch; Tilburg, The Netherlands) that is in use in our Emergency Department; 2) a vacuum mattress (Ambu®, Germa AB; Kristianstad, Sweden); 3) a spine board (Ferno-Washington, Inc.; Wilmington, Ohio, USA).

During the measurements, subjects were allowed to wear their normal clothing, but no shoes. The vacuum mattress was folded comfortably around the body before applying negative pressure, as if it were used for transportation. At the end of each five-minute period, subjects were asked to assess the tested surface for comfort on a 10-point visual analog scale.

Tissue-interface pressures were measured with the XSENSOR X2-6912 pressure-mapping device (XSENSOR Technology Corporation; Calgary, Canada). This system consists of a thin, easily foldable full body pressure-mapping pad, equipped with 6912 capacitive sensors. This pad was placed between the subject and the support surface, without folds. Placing pressure on the sensors results in the generation of a voltage difference, which increases linearly with the amount of pressure. Connection of the pad to a laptop computer with special XSENSOR software (version 4.0), allowed real-time pressure registration. Peak-pressures (in mmHg) measured at the scapulae, the sacrum and the heels were noted and compared for the three different surfaces.

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS®), version 11.0.1. Peak-pressures were compared using a Paired-Samples T test. Differences were regarded significant if $p<0.05$.

Results

The mean peak interface pressures on the three different surfaces are presented in **Table 1**.

Contact site	ER-overlay mattress mean (±SD)	Vacuum mattress mean (±SD)	Spineboard mean (±SD)
Scapulae	89.9 (±35.8)	131.6 (±50.9)	176.6 (±3.6)
Sacrum	118.0 (±28.4)	165.6 (±29.0)	174.9 (±15.8)
Heels	147.3 (±22.0)	123.3 (±45.2)	153.0 (±16.1)

Table 1 **Mean peak interface pressure by contact site and support surface**

For all three contact sites, the interface pressures measured on the spineboard were highest. Our standard overlay mattress compared favourably to both the vacuum mattress and the spineboard for interface pressures measured at the scapulae and the sacrum. These differences were highly significant. At the heels, the pressures on the overlay mattress were comparable to those on the spineboard and significantly higher than those on the vacuum mattress. At the sacrum, the pressures on the vacuum mattress and spineboard did not differ significantly.
A striking, but expected finding was that the spineboard did not give any support to the normally lordotic lumbar spine, as is illustrated in **Fig. 1**.

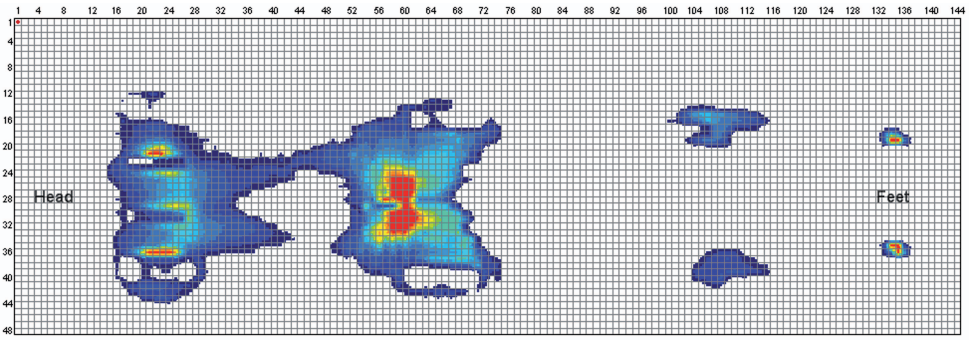

Fig. 1 **Contact sites on spineboard, without support of lumbar lordosis**

The volunteers appreciated the overlay mattress with a mean comfort score of 7.0 (±0.8), the vacuum mattress with a mean score of 6.6 (±1.3) and the spineboard with a mean score of 4.6 (±1.2). When considering these comfort scores, the difference in appreciation for the overlay mattress and the vacuum mattress was not significant. Appreciations for the overlay mattress and the vacuum mattress were both significantly better when compared with the spineboard.

Discussion

The results of our study confirm that high and potentially "ischaemic" pressures between the surface and the skin were reached on all of the three tested support surfaces at all three exposed contact sites.
To put these interface pressures in perspective, we must consider that maximum pressures that are measured on a good quality hospital mattress vary between 30 and 60 mmHg [4].
High interface pressures on the spine board have previously been reported. Lovell and Evans found mean pressures in the sacrum area up to high as 147 mmHg and they were able to reduce this to 115 mmHg by padding the surface [5]. It is therefore remarkable that during the past decade, in which the pressure ulcer problem gained attention, the layout of the spineboard was not changed. In the same study, interface pressures dramatically reduced to 37 mmHg by using a vacuum stretcher. This finding could however not be reproduced in our study.
The extent of the pressure ulcer problem in critically injured patients, with an incidence figure up to 30.6%, is illustrated by several studies [2,3]. In the study by Watts et al., 20% of trauma patients who were hospitalized more than 2 days developed at least one area of skin breakdown. In almost 50% of the cases, positional pressure was the most common cause for pressure ulcers.
One of the weaknesses of interface pressure measurements as these were performed is the interpretation of the outcome. It is uncertain whether pressures measured at the skin actually reflect the pressures that are present in the underlying tissues, the place where the ischaemic damage originates [6].
The good subjective appreciation for the vacuum mattress is remarkable, considering the fact that interface pressures at the shoulders and the sacrum are significantly higher than those on the ER overlay mattress are.

Conclusions

Given the high, potentially harmful pressures found on three different and frequently used support surfaces for trauma patients and the related unsatisfactory subjective comfort scores for two of them, there is a task for industrial designers to develop new, safe and more comfortable surfaces for the transportation of trauma patients. If there is no useful alternative, the time spent on a spineboard should be kept as short as possible.

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Chapter 6

Can the influence of external pressure on soft tissue oxygenation in the sacral area be studied using Near Infrared Spectroscopy? A feasibility study.

B.P.J.A. Keller, J.-P. Schuurman, Chr. van der Werken

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Abstract

Objective: To test whether Near Infrared Spectroscopy (NIRS) is applicable to examine the influence of external pressure on oxygenation of the soft tissues in the sacral area.

Method: Tissue oxygenation was measured in 33 healthy volunteers, in prone position. A NIRS probe was positioned over the sacrum and external pressure was increased with 10 mmHg increments, from 20 mmHg up to 200 mmHg and after that decreased. At each level, tissue oxygen saturation (StO_2) was measured. To test reproducibility, the protocol was repeated in 6 volunteers, in whom the thickness of the soft tissue envelope at different levels of external pressure was assessed using ultrasound.

Results: There was wide variability in StO_2 courses between the 33 subjects, with a non-linear relationship between pressure and StO_2. The only consistent finding was that the StO_2 was significantly higher after decreasing pressure than at the initial pressure of 20 mmHg, indicative of reactive hyperaemia. Despite the application of high external pressures, reasonable tissue oxygenation could be maintained in 19 of 33 subjects. Reproducibility of the measurements was poor. Comparison of soft tissue thickness with corresponding StO_2 values, showed that, with increasing pressure, the decrease in tissue thickness was higher in terms of percentage than the decrease in tissue oxygenation.

Conclusion: This study confirms that Near Infrared Spectroscopy is not useful for assessing tissue oxygenation in pressure ulcer research, because of unacceptable inter-individual variability and poor reproducibility of measurements.

Introduction

One of the major factors in the aetiology of pressure ulcers is external tissue pressure, with subsequent decrease of tissue perfusion and oxygenation. Whether irreversible damage occurs, depends on the intensity and duration of the pressure. Kosiak showed in animal experiments that external application of 35 mmHg pressure for one to two hours didn't result in any microscopically visible tissue damage, but with 70 mmHg pressure, after two hours, clear microscopic changes were found [1].

Groth and also Kosiak demonstrated, that nearly all pressure is transmitted from the skin surface to deep tissue layers, a finding that supports the theory that pressure ulcers are the consequence of tissue damage originating in the deeper layers [1,2]. Previous studies have shown that extremely high tissue-interface pressures (up to 185 mmHg) are not uncommon in surgical patients. Thus far, several non-invasive methods, such as laser-Doppler flowmetry and transcutaneous pO_2 and pCO_2 measurements, have been used to investigate the influence of external pressure on skin perfusion [3-6]. The influence of external pressure on the perfusion of the underlying tissues remains uncertain. Near Infrared Spectroscopy (NIRS) has never been applied to study the effects of tissue compression on perfusion of tissues deeper than the skin. NIRS allows non-invasive measurement of haemoglobin saturation of tissues up to 25mm, depending on the type of probe that is used. This is based on the fact that tissue ischemia results in increased oxygen consumption, resulting in a decrease in venous oxyhaemoglobin. Since more than 80% of blood in tissues is in the venous compartment, tissue oxygen saturation (StO_2) mostly reflects venous saturation and consequently the level of local ischemia. This study was designed to test the feasibility of NIRS for soft tissue StO_2 measurement in the sacral area. The main questions were, whether a relationship could be found between the application of external pressure and the StO_2 and whether the outcomes were reproducible.

Material and methods

Thirty-three healthy Caucasian volunteers, without any pressure related skin lesions, participated. The study group consisted of 16 men and 17 women, with an average age of 30.8 years (range 20.0–52.0) and an

average Body Mass Index (BMI) of 23.7 (range 18.3–31.5). Subjects were placed in prone position in an environment at room temperature. NIRS StO_2 measurements were obtained using an InSpectra™ Tissue Spectrometer (Hutchinson Technology Inc., Hutchinson, MN USA). The InSpectra Tissue Spectrometer functions as a tissue oxygen saturation monitor by sending light through the skin into underlying tissues and taking measurements of the light after it travels through the tissues. The measurement of haemoglobin oxidation values in tissue is based on spectrophotometric principles that relate light absorption to chemical concentration. The absorption spectra of oxygenated and deoxygenated haemoglobin are well characterized and provide a means to calculate the ratio of oxygenated haemoglobin to total haemoglobin expressed as percent haemoglobin saturation (%StO_2).
A plastic stamp with a contact surface of 12.266 cm^2 was especially developed for this study (**Fig. 1**). In the centre of its contact surface, a slot was milled, allowing insertion of the optical part of a probe. The NIRS probe was connected to a cable consisting of transmitting and receiving optical fibres. This cable was connected to the photo-sensitive detector in the spectrometer unit. The processed signal was displayed as per cent haemoglobin oxygen saturation in tissue (StO_2). Measurements were collected continuously every 3.5 seconds throughout the entire protocol and stored on a laptop computer, that was connected to the spectrometer unit and analysed afterwards. The probe measured tissue oxygenation until a depth of 12 mm. From the upper side of the stamp, a metal rod protruded. The stamp was placed in a stable position over the sacrum (**Fig. 2**). Calibrated, circular weights were stepwisely placed around the rod on the stamp. Weights were chosen in such a way, that they (in combination with the surface of the stamp) resulted in increments of pressure of 10 mmHg. The first weight was placed on the stamp and once a constant StO_2 signal was read in the InSpectra display, measuring was started. Every minute, weight was added corresponding with an increase of 10 mmHg in pressure. This was continued until a maximum of 200 mmHg was reached; after that weight was removed with 10 mmHg increments per minute, till a pressure of 20 mmHg was reached again.

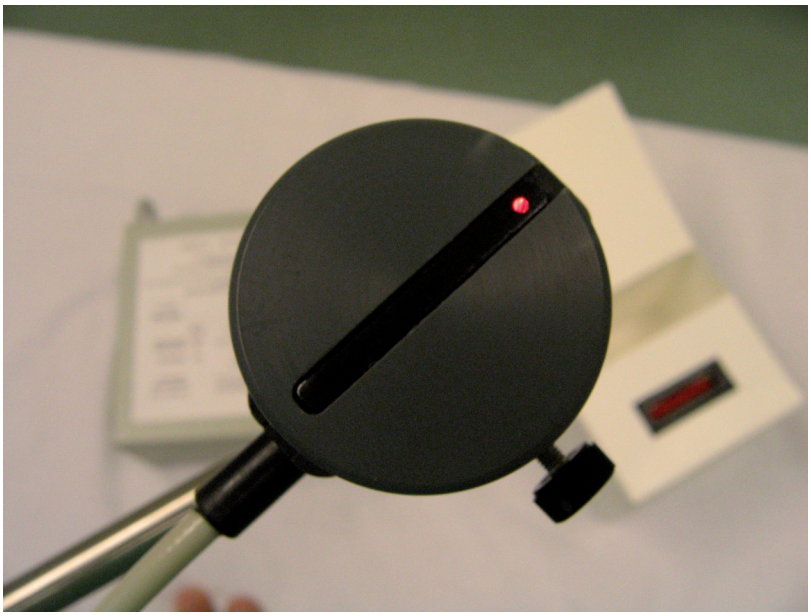

Fig. 1 **Stamp with NIRS probe incorporated**

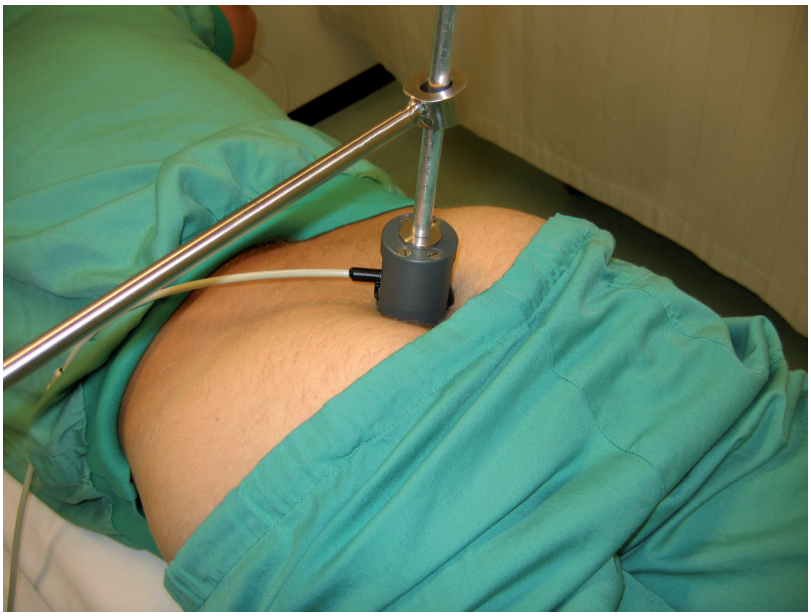

Fig. 2 **NIRS probe positioned over the sacrum, without weights**

Approximately one minute after each pressure increase and decrease, a stable StO_2 value was reached. These values were used for analysis. For every subject, StO_2 values were plotted against the corresponding pressures (**Fig. 3**).
To test the reproducibility of NIRS, 6 subjects underwent the same study protocol again after 2 weeks. Reproducibility of measurements was statistically assessed using the Pearson-correlation coefficient. The StO_2 at 9 levels of external pressure (20, 50, 100, 150, 200, 150, 100, 50 and 20 mmHg) during the first measurement were correlated with those obtained during the second measurement.
After repeating the study protocol, the thickness of the soft tissue layers over the sacrum was measured with ultrasound, using a linear probe (5-12 MHz). Tissue thickness was first measured without external load and than with 0.5 kg and 1 kg of weight resting on the ultrasound probe, using the same weights as for StO_2 measurements. Because the ultrasound probe had a lower surface size than the NIRS stamp, the pressures exerted on the sacral tissue by the ultrasound probe were higher than those exerted by the NIRS stamp when using the same amount of weight. For the repeat measurements, StO_2 values were also plotted against the corresponding pressures. From the resulting pressure-StO_2 curve, the StO_2 value that corresponded with 0.5 kg (83 mmHg) and 1 kg (166 mmHg) could be determined.

Results

Fig. 3 shows that there was a wide inter-individual variability in StO_2 courses. **Fig. 4** shows the median StO_2 at every level of pressure, with the 95% confidence intervals (c.i.) and the range. **Table 1** gives a summary of StO2 values at 9 levels of pressure.

Pressure (mmHg)	StO2 (median)	Range	Minimum	Maximum
20	66	56	39	95
50	59	72	22	94
100	43	84	9	93
150	33	90	1	91
200	27	85	1	86
150	34	84	1	85
100	43	81	4	85
50	69	61	30	91
20	79	65	33	98

Table 1 **StO_2 values at different levels of external pressure**

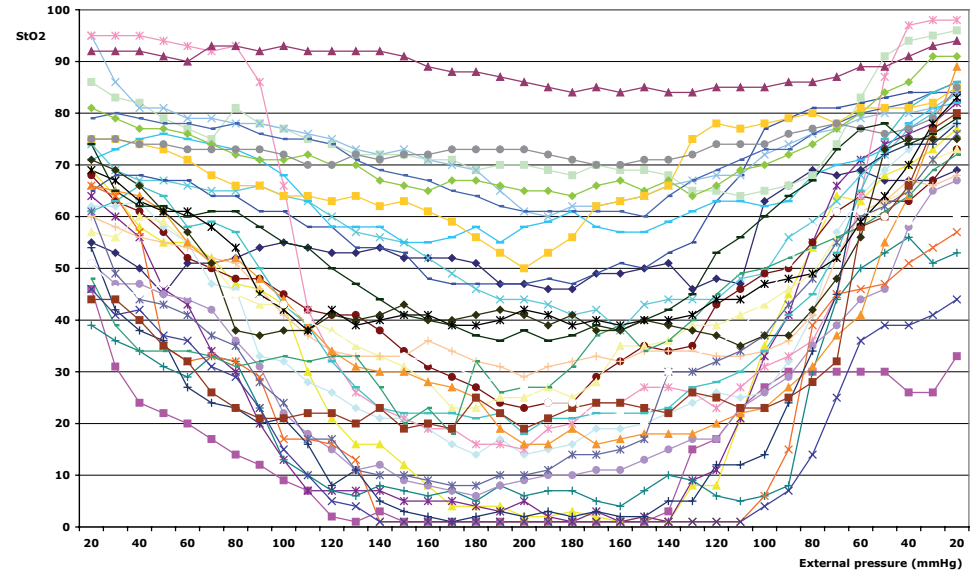

Fig. 3 **StO2 course, under influence of increasing and subsequently decreasing external pressure in the sacral area. Each line represents one subject. Note the large inter-individual variability**

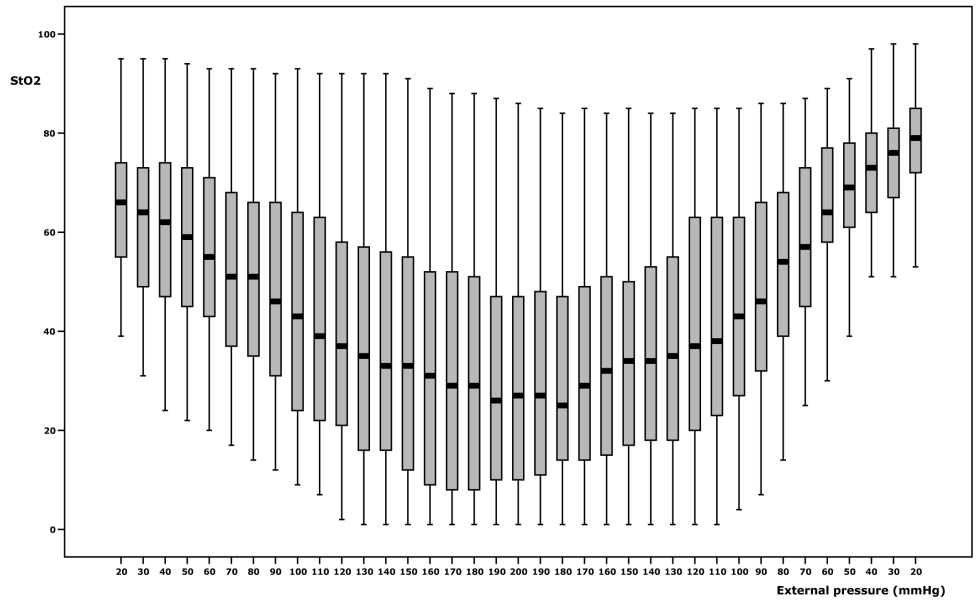

Fig. 4 **Boxplots showing the median StO2 (incl. 95% C.I. and range) at different levels of external pressure**

The median StO_2 value at the initial pressure of 20 mmHg was 66, with a minimum of 39 and maximum of 95. With rising pressure, 21 subjects showed a gradual decrease in StO_2, in eight the decrease was steep while in four StO_2 values were initially stable.
In 18 subjects, a plateau phase was more or less reached in the StO_2 course, meaning that the StO_2 didn't further decrease with rising pressure and also that the StO_2 didn't increase immediately when pressure was reduced. The pressure at which the plateau phase started varied between 40 mmHg (during pressure increase) and 180 mmHg (during pressure decrease). The height of the StO_2 during the plateau phase was also very variable, ranging from 1 till 66. The median StO_2 at the maximum pressure of 200 mmHg was 27, again, with a wide range from 1 to 86. At pressure reduction, immediate increase of the StO_2 was seen in ten subjects but in another five the StO_2 even decreased further. In 19 subjects, increase in StO_2 was not seen until the pressure had been reduced under 150 mmHg.
The median StO_2 at the point where the initial pressure of 20 mmHg was reached again was 79. Also here, there was a wide range from 33 till 98. In 23 of the 33 subjects, the StO_2 at the end of the study protocol was significantly higher ($p<0,0001$) than at the start, indicative of reactive hyperaemia. The duration of the study protocol ranged from 30 to 59 minutes, with a mean of 41 minutes.
Repetition of the protocol in 6 subjects revealed very poor reproducibility of the measurements (**Table 2**). Only the StO_2's at the initial pressure of 20 mmHg showed a reasonable Pearson correlation coefficient of 0.831 ($p=0.041$).
The median thickness of the tissue layers overlaying the sacrum without external load was 1.9 cm (range 0.88–3.75 cm), with a corresponding median StO_2 of 81 (range 56–94). With 0.5 kg of weight on the ultrasound probe, the median tissue thickness decreased to 1.29 (range 0.64–2.47) (32% decrease) and the corresponding median StO_2 decreased to 72 (range 43–90) (11% decrease). Further increase of the weight to 1 kg resulted in more tissue compression till a median of 1.18 cm (range 0.63–2.20), which is a 9% decrease compared with the value at 0.5 kg. Also a further decrease in StO2 was observed, to a median value of 67.5 (range 26–89), which is a 7% decrease compared with the value at 0.5 kg.

Pressure (mmHg)	Mean StO_2	Correlation coefficient (*r*)	p-value
20	72.3		
20 (R)	75.3	0.831	0.41
50	68.3		
50 (R)	73.6	0.7872	0.063
100	56.0		
100 (R)	63.8	0.584	0.223
150	43.7		
150 (R)	60.3	0.418	0.410
200	39.3		
200 (R)	56.3	0.407	0.423
150	43.0		
150 (R)	59.2	0.532	0.277
100	47.3		
100 (R)	62.7	0.391	0.443
50	75.7		
50 (R)	78.2	0.292	0.574
20	81.7		
20 (R)	85.8	0.445	0.376

Table 2 **Correlation between first and repeated measurement (R) in 6 subjects, at different levels of external pressure**

Discussion

The objective of this feasibility study in healthy volunteers was to determine whether NIRS could be of any diagnostic value in pressure ulcer research. As far as we could retrieve from literature, this was the first study using NIRS, to evaluate the influence of external pressure on tissue oxygenation. Since pressure ulcers are most often found in the sacral area [7,8] and interface pressure measurements showed the highest values in this area, we chose the sacral area for obtaining StO_2 measurements. The study was only performed in Caucasian subjects, because the reliability of NIRS is affected by skin colour [9].

The most important finding of our study was, that the measurements showed a high inter-individual variability in StO_2 values. Only rough similarities could be discerned when comparing the different StO_2 courses. As can be seen in the pressure-StO_2 curves, there was a non-linear relationship between pressure and StO_2. Repetition of the experiment showed also large intra-individual variability, meaning that measurements were hardly reproducible.

It is difficult to explain this great variety in StO_2 courses. In subjects with a thin subcutaneous layer in the sacral area, the measurements might be distorted by the sacrum itself. This is supported by the ultrasound results, showing compression of the tissue below the 12 mm measuring depth of the NIRS probe.

A skin perfusion study in rats, using laser-Doppler flowmetry, showed an initial increase in skin perfusion when low pressures were applied [10]. This could not be reproduced in our study.
A remarkable detail is that, despite the application of very high external pressures, reasonable tissue oxygenation could be maintained in deeper tissues. This is illustrated by the fact that in 19 volunteers the StO_2 never reached a level below 20.
The only consistent finding in our study was, that the StO_2 at the end of the study protocol was higher than the baseline value, indicating the occurrence of reactive hyperaemia after pressure relieve. This is a well known fact from other research, studying the influence of pressure on tissues [10]. It is mainly the reactive hyperaemia and subsequent occlusion-reperfusion damage that plays a major role in the aetiology of pressure ulcers. Not so much the occlusion of blood vessels, but the reopening and consequently the release of oxygen radicals is damaging to the endothelium. Endothelial damage attracts platelets and granulocytes, stimulating stasis of blood flow and thrombosis, further decreasing blood flow and thus stimulating the development of tissue necrosis [11]. Although the latter results were found in animal experiments, the same mechanism is probably valid in humans.
In conclusion, the results of our study do not support that Near Infrared Spectroscopy is a useful study method for the evaluation of tissue oxygenation in pressure ulcer research.

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Chapter 7

Standard pressure-relieving mattresses and pressure ulcer development

B.P.J.A. Keller, J. van `t Land, Chr. van der Werken

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Abstract

Objective: To test three different high-specification pressure-relieving foam mattresses in clinical practice, in order to select one to replace the mattress that was currently used in the Surgical Division of the University Medical Centre Utrecht and to find out whether this would result in a decrease of pressure ulcer incidence.

Background information: In the half year before the test, the incidence rate of grade 2 or worse pressure ulcers was 11.5%.

Method: Three different mattresses were selected by a panel of nurses from the participating wards: the Urtica Delta® (Ubica), the CliniPlot® III (Hill-Rom) and the Tempur® (Fagerdala). Between June 2000 and December 2000, all patients with an expected hospital stay of 5 days or more were asked to participate. Mattresses were assigned by randomization. During admission, patients were visited twice a week for a skin check. The main outcome measure was the occurrence of grade 2 or worse pressure ulcers. Participating patients were asked to rate their mattress in a satisfaction questionnaire.

Results: A total of 306 patients were included and met all inclusion criteria. The overall incidence rate of grade 2 or worse pressure ulcers was 5.9%. Mattress specific rates were 5.1% for the Urtica Delta®, 6.9% for the CliniPlot® III and 6.8% for the Tempur®. These differences were not statistically significant. The patient questionnaire revealed a significant difference in only one category (“Laying comfort”). The Urtica Delta® mattress was more frequently appreciated as ”too soft” than the other two mattresses.

Conclusion: No relevant differences in performance of the three tested mattresses were observed. The final mattress choice was therefore mainly made on financial grounds. This study suggested that standard high-specification mattresses may result in a lower incidence of pressure ulcers.

Introduction

Compressive and shearing forces play a major role in the aetiology of pressure ulcers [1]. The intensity of both forces can be influenced by the type of support surface a patient is placed on. The need for a good support surface has been emphasized by several pressure ulcer advisory panels [2,3]. The ideal pressure-relieving system, however, should be both comfortable and effective in reducing pressure and preventing tissue damage, because an effective but uncomfortable system will be rejected by patients.

Between January 1999 and June 2000, the prevention and Pressure Ulcer Risk Score Evaluation study (prePURSE) was performed in the University Medical Centre Utrecht [4]. In this study, patients with an expected admission of at least five days were included and visited on a weekly base for the development of pressure ulcers. A subgroup analysis of the results of this prePURSE study, showed a cumulative incidence of 11.5% grade 2 or worse pressure ulcers, in patients admitted to the Surgical Division (comprising General & Vascular Surgery, Urology, Orthopaedic Surgery and Plastic Surgery). These data endorsed that, in the Surgical Division, too many patients developed pressure ulcers on the standard hospital mattress, so that very expensive special pressure-relieving mattresses and beds had to be rented on a regular basis, for patients who developed pressure ulcers or had progression of an existing ulcer on the standard mattress.

At the moment the data of the prePURSE study were collected, the standard hospital mattress in use was at the end of its economic life and thus needed to be replaced. It seemed rational to perform a clinical test to compare different mattresses, instead of just buying the mattress that had the best specifications on paper. Therefore a low profile clinical study, in which 3 mattresses were tested, was performed.

Study goal

The primary goal of this study was to determine, which of the 3 selected mattresses performed best in meeting the needs of the daily practice. Therefore, the following aspects were taken into account:

1. a low incidence with regard to the occurrence of pressure ulcers
2. practical usefulness (**Table 1)**
3. patient satisfaction
4. price

made of foam, no bottoming out
comfortable
must not limit the patient's ability to cope for him/herself
may not stimulate perspiration
must fit every Division bed
applicable on a fowler and thus flexible
applicable in automated mattress washing machine
replacement for every onlay and Clinifloat® mattress
firm enough to perform Cardio Pulmonary Resuscitation on
cover non-permeable for fluid
cover may be no breeding ground for bacteria
fireproof
manageable by the nurses (Occupational Safety & Health-demands)
minimum life cycle of 10 years

Table 1 Demands, study mattresses had to meet

Selected mattresses

A panel of head nurses from the participating wards (General & Vascular Surgery, Urology, Orthopaedic Surgery and Plastic Surgery) selected potential mattresses to be tested. These were chosen on the base of the written information provided by the manufacturers. A mattress that fulfilled the demands mentioned in **Table 1**, was suitable for participation in this study. Thus, three different mattresses were chosen from the assortment that was available on the market. The mattresses we tested in practice were the Urtica Delta® (Ubica), the CliniPlot® III (Hill-Rom) and the Tempur® (Fagerdala). Mattress characteristics are summarized in **Table 2**.

Manufacturer	Type	Foam	Thickness (cm)	Weight (kg)
Fagerdala	Tempur®	Viscoelastic polyethylene-urethane	14	11
Hill-Rom	CliniPlot® III	Polyurethane (Bultex®)	15.5	8
Ubica	Urtica Delta®	Polyurethane (Safeguard®)	14	12.5

Table 2 Mattress characteristics

Patients and Methods

This prospective cohort study was approved by the local hospital Ethical Committee.

From the 1st of June till the 31st of December 2000, all patients who were electively admitted with an expected hospital stay of five days or more were considered eligible for participation in this study. Patients were asked for signed informed consent. Exclusion criteria were: age <18 years, the presence of grade 2 or worse pressure ulcers at admission and discharge after an actual hospital stay of less than 5 days.

Mattresses were assigned at random by aselectively opening of envelopes with coloured cards for every participating patient. The colour of the card corresponded with one of the mattress types. The CliniPlot® III mattress was not always available in the first part of the study, which resulted in an unequal distribution of mattresses, despite randomization.

During the nurses' intake, a risk assessment for developing pressure ulcers was done by filling out a form with the score that has been developed by the Dutch Institute for Health Care Improvement, also known as the CBO-score (**Table 3**). Patients with a score of ≥10 were considered at specific risk of developing pressure ulcers. This threshold was chosen on empirical grounds by the developers of the score.

Patients' length and weight were noted for calculation of the Body Mass Index (BMI).

During admission, skin checks for the presence of pressure ulcers were performed twice a week by the principal investigator (B.P.J.A.K.). Pressure ulcers were graded according to the European Pressure Ulcer Advisory Panel guidelines [5]. When the development or progression of pressure ulcers necessitated the use of a special preventive support surface, this was noted including the type of special surface.

At discharge, patients were asked to fill out a questionnaire considering their satisfaction with their assigned mattress.

All data were collected on data forms and entered into a database. Statistical analysis was performed using SPSS®. Categorical data were analysed using the chi-square test and continuous data with a One-Way Analysis of Variance (ANOVA). Differences were regarded significant when $p<0.05$. A power analysis revealed that over 2000 patients per mattress were needed, in case a reduction of pressure ulcer incidence from 10% to 7.5% was aimed for.

Medication:	0 = no analgesics, sedatives, tranquillizers, oral anti-coagulants, corticosteroids 1 = one of the above 2 = two of the above or oral antibiotics 3 = three of the above or parenteral antibiotics or chemotherapy
Mobility:	0 = fully mobile 1 = slightly limited, walks regularly with help or out of bed all day; wheelchair patient with good arm function, passive on chair all day 2 = mostly bedridden, only out of bed during washing and bed cleaning 3 = fully bedridden
Mental state:	0 = alert 1 = listless, depressed, disoriented, anxious 2 = severe depression, confused, psychotic, fully apathetic 3 = stuporose, comatose
Neurology:	0 = no disorders 1 = slight disorders, loss of strength, mild hemipareses 2 = sensibility disorders 3 = hemipareses (x2), paraplegia (below Th6: x3) (above Th6: x4)
Circulation:	0 = direct capillary refill 1 = delayed capillary refill 2 = mild oedema 3 = moderate till severe oedema
Nutritional state:	0 = good 1 = moderate (if patient has not eaten for several days) 2 = poor (not eaten >1 week; during vomiting and diarrhoea) 3 = cachectic (as in severely undernourished patients)
Incontinence:	0 = none 1 = sometimes for urine (without catheter) 2 = for urine (with catheter) or faeces 3 = for urine and faeces
Diabetes:	0 = none 1 = diet only 2 = diet and oral medication 3 = diet and insulin
Temperature:	0 = <37,5°C 1 = 37,5°C– 38,4°C; <35,5°C 2 = 38,5°C–38,9°C 3 = >39,0°C
Age:	0 = <50 years 1 = 50–59 years 2 = 60–69 years 3 = ≥70 years

score ≤9: normal risk
score 10–19: increased risk
score ≥20: strongly increased risk

Table 3 CBO pressure ulcer risk score

Results

Three hundred and fifty-nine patients were included in the study. Of these patients, 306 (85%) met all inclusion criteria: 140 men and 166 women, with a median age of 58.8 years at admission (range 20–93). The median CBO-score for all included patients was 3 (range 0–16), indicating a relative low pressure ulcer risk. Between the three groups, there were no significant differences in age, sex, CBO-score at admission, BMI and number of skin checks during admission (**Table 4**).

	Urtica Delta® (n=116)		**CliniPlot® III** (n=87)		**Tempur®** (n=103)	
Sex						
Male	51		38		51	
Female	65		49		52	
Mean Age (±SD)	57.2	(±17)	60.3	(±17)	62.0	(±17)
Body Mass Index (range)	24.7	(16.5–36.8)	24.8	(16.4–35.5)	25.0	(16.3–39.0)
Median CBO-score at admission (range)	3.0	(0–15)	3.0	(0–16)	3.0	(0–15)
Median hospital stay in days (range)	9	(5–75)	10	(5–86)	9	(5–48)
Median number of skin checks during admission (range)	2	(1–20)	2	(1–16)	2	(1–13)
Number of patients finally not included	17		19		17	

Table 4 Patient characteristics for the three tested mattresses

The main reason why patients were not included, was an unforeseen hospital stay of less than 5 days, which occurred in 16 cases. Eleven patients were not actually placed on the mattress that was assigned by randomization. Another 15 were temporarily admitted to the ICU and were - after transfer back to the ward - not placed on the original mattress type. Three patients refused further participation in the study, because they disliked their assigned mattress. Seven patients could not be analyzed because of incomplete data. The patients who were not included were equally distributed among the three groups (**Table 4**).

Reasons for admission per type of mattress are summarized in **Table 5**.

	Urtica Delta® (n=116) (%)	**CliniPlot® III** (n=87) (%)	**Tempur®** (n=103) (%)
General surgery	39 (33.6)	25 (28.7)	29 (28.2)
Surgical Oncology	20 (17.2)	18 (15.5)	19 (18.4)
Vascular surgery	5 (4.3)	10 (11.5)	12 (11.7)
Traumatology	4 (3.4)	2 (1.7)	5 (4.9)
Orthopaedics	33 (28.4)	21 (18.1)	24 (23.3)
Urology	14 (12.1)	11 (9.5)	11 (10.7)
Plastic Surgery	1 (0.9)		3 (2.9)

Table 5 **Reasons for admission**

During participation in this study, 40 of the 306 patients (13.1%) developed pressure ulcers. Grade 1 ulcers were the most common and occurred in 22 patients, grade 2 ulcers in 16 and 2 patients had grade 3 ulcers, while no grade 4 ulcers were observed among. The overall incidence rate of clinically relevant ulcers (grade 2 or worse) was 5.9%. The mattress specific incidence was 5.1% for the Urtica Delta®, 6.9% for the CliniPlot® III and 6.8% for the Tempur®.
There were no significant differences in pressure ulcer incidence and pressure ulcer grade between the three mattresses (**Table 6**). The first manifestation of pressure ulcers was visible after a median period of 7 days (range 2–23 days).

	Urtica Delta® (n=116) (%)	**CliniPlot® III** (n=87) (%)	**Tempur®** (n=103) (%)
No pressure ulcers	101 (87.1)	80 (92.0)	85 (82.5)
Grade 1	10 (8.6)	1 (1.1)	11 (10.7)
Grade 2	4 (3.4)	5 (5.7)	7 (6.8)
Grade 3	1 (0.9)	1 (1.1)	-

Table 6 **Pressure ulcer distribution by maximum grade**
Note: difference between 3 mattresses for grade 2 and higher is not significant (p=0.48)

Six patients were transferred to various other support surfaces. Reasons for this were development of pressure ulcers in three patients and progression of an existing ulcer in one.
The questionnaire, on patient satisfaction, was filled out by 272 of the 306 patients, giving a 89% response rate (**Table 7**). There was no

significant difference in response rate for the three mattresses. Only in one of the categories a difference between the 3 groups was observed. Significantly more patients judged the laying comfort of the Urtica Delta® as "too soft" compared with the other 2 mattresses. The median report mark for all mattresses was 8, on a 1 to 10 scale.

		Urtica Delta® (n=99) (%)	**CliniPlot® III** (n=83) (%)	**Tempur®** (n=90) (%)
Did you experience painful skin areas on the hospital bed?	No	89 (90)	72 (87)	71 (79)
	Yes	10 (10)	11 (13)	19 (21)
How do you judge the comfort of the mattress with respect to laying on it?	Too hard	2 (2)	8 (10)	6 (7)
	Too soft	17 (17)*	5 (6)	8 (9)
	Good	79 (81)	69 (83)	73 (81)
	No opinion	0	1 (1)	3 (3)
How do you judge the comfort of the mattress with respect to sitting on it?	Too hard	0	5 (6)	8 (9)
	Too soft	13 (13)	13 (16)	8 (9)
	Good	77 (79)	60 (72)	68 (75)
	No opinion	8 (8)	5 (6)	6 (7)
Were you able to easily change your position in bed?	No	17 (17)	17 (21)	26 (29)
	Yes	71 (72)	57 (69)	61 (68)
	No opinion	11 (11)	8 (10)	3 (3)
Did you experience excessive perspiration due to the mattress?	No	78 (79)	65 (78)	62 (69)
	Yes	11 (11)	11 (13)	20 (22)
	No opinion	10 (10)	7 (8)	8 (9)
What is your general impression of the mattress?	Very good	22 (22)	11 (13)	11 (12)
	Good	57 (58)	48 (58)	53 (59)
	Neutral	14 (14)	16 (19)	19 (21)
	Poor	6 (6)	7 (8)	6 (7)
	Very Poor	0	1 (1)	1 (1)
Median report mark (range)		8 (4–10)	8 (1–10)	8 (4–10)

Table 7 **Summary of patient satisfaction questionnaire**
*** p=0.03**

Discussion

The cumulative incidence of 5.9% grade 2 or worse pressure ulcers, found in our study, is lower than the incidence of 11.5%, found in the prePURSE study [4]. These data can be well compared, since both studies were - though metachronously - performed within the same Division, both including patients with a hospital stay of 5 days or more. There were no significant differences in pressure ulcer incidence rate between the 3 mattresses ($p=0.16$). The rate of the Tempur® mattress (17.5%) was twice that of the CliniPlot® mattress (8%), but this was mainly due to a higher incidence of grade 1 ulcers, which are regarded clinically hardly relevant. When grade 1 ulcers were left out of consideration, mattress specific incidence rates hardly differed.

In a study by Hofman et al., a high-specification pressure-relieving mattress was compared with a standard hospital mattress, showing that both the occurrence and severity of pressure ulcers could significantly be reduced by the use of a preventive mattress [6]. This study can not be compared with ours, since it was performed in a different population of patients with femoral neck fractures who had a high CBO-score of ≥8. The median CBO-score for all patients included in our study was only 3.

In a recent Cochrane analysis by Cullum et al., assessing the effectiveness of pressure relieving mattresses, only five trials of mixed quality could be included for comparing foam alternatives with standard hospital mattresses [7]. The authors found a pooled relative risk of 0.40, which means a relative risk reduction of pressure ulcer incidence of 60% in favour of preventive mattresses. The authors concluded that high-specification foam mattresses were more effective than standard hospital mattresses in moderate-high risk patients.

Our study has several limitations. A study like this, with the nursing personnel closely involved, may easily result in extra attention for the pressure ulcer problem and increased use of preventive measures. This might have influenced the observed pressure ulcer incidence. Also, use of preventive measures, like frequent repositioning, use of pillows and foam wedges, was not recorded.

Nevertheless, the results of our pilot-handling study provided valuable information to guide the management of the Surgical Division in the selection of a new high-specification pressure-relieving mattress. Since there were no important differences in performance between the three

mattresses, the main argument that determined choice was a financial one. Ubica made the most favourable deal and therefore the Urtica Delta® was chosen.

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Chapter 8

Summary and General Discussion

With prevalence figures of 13% for university hospitals and 23% for general hospitals, pressure ulcers are a major health care issue in The Netherlands. Pressure ulcers in surgical patients are frequently encountered, as is illustrated by reported incidence rates up to 66%. Due to a tendency to perform more complex and longer surgical procedures, risk of developing pressure ulcers will increase likewise. The number of patients at risk will probably also grow, due to an ageing population. That certain categories of surgical patients, like Intensive Care Unit (ICU) patients, are specifically at risk, is illustrated in **Chapters 2** and **3**.

In **Chapter 2**, the results of an extensive review of literature on pressure ulcers in ICU patients are presented. Figures on the occurrence of pressure ulcers (prevalence and incidence) in ICU patients, are 2-3 times higher than those for "average hospital" patients. This makes clear that ICU patients must be regarded as a separate risk category.
Many risk factors for pressure ulcer development are mentioned in literature: duration of surgery and number of operations, presence of faecal incontinence and/or diarrhoea, poor nutritional state, poor sensory perception, moisture of the skin, impaired circulation, use of inotropic drugs, diabetes mellitus and limited mobility. All these factors have a negative influence on tissue tolerance for developing pressure ulcers, as was described in a conceptual scheme by Defloor [1].
Consequences of pressure ulcer development are considerable morbidity and even mortality for the patients and an increased workload for nursing staff, with related increase in costs. Preventive measures that should at least be applied in bedridden patients, are frequent repositioning and the use of preventive support surfaces, although no clear criteria are available as to which surface should be used in which case.
Several consensus reports and pressure ulcers advisory panels advocate the use of risk assessment scales, in order to identify individuals at risk, who thus are in need of prevention. Most of the existing scales were not specifically developed for an ICU population. New scales are generally modifications of existing versions and are not properly validated for this category. This explains that there exists currently no ideal risk assessment scale for (surgical) ICU patients.

Therefore, a prospective clinical study in 204 patients was designed, in which 31 possible risk factors were correlated with the actual development of pressure ulcers in postoperative ICU patients. The results are described in **Chapter 3**. Only patients with an ICU stay of at least 48 hours were finally included. A striking finding in our study was the high cumulative incidence of pressure ulcers of 53%, of which 21% were grade 2 or higher. Using univariate and multivariate logistic regression modelling, four independent predictors for the development of pressure ulcers grade 1 or worse were identified: sex, age, duration of anaesthesia and the occurrence of intraoperative complications, like major bleeding, return to extracorporeal circulation and prolonged episodes of shock, necessitating high doses of vasoactive medication. From these parameters, a new prediction rule was composed.
A good prediction rule should identify the majority of patients that will develop pressure ulcers and keep the number of patients falsely identified as at risk (false positives) as low as possible. At the cut-off score that we chose, 54% of the patients were identified as at risk of developing pressure ulcers. By allocating preventive measures to this "at risk" group, 66% of the patients, normally developing grade 1 or worse pressure ulcers, will receive the measures rightfully. However, still up to 40% of patients will falsely be identified as at risk, therewith receiving unnecessary and costly prevention.
Our prediction rule had a limited prognostic ability to discriminate between patients with and without pressure ulcers, but its performance was better than that of all currently available risk assessment scales [2]. The prognostic ability was only calculated when applying the prediction rule to our own study population. This is no guarantee that the rule is applicable in other ICU settings and therefore external validation is required before clinical implementation.
As was illustrated in **Chapter 2**, pressure ulcer risks are not static, but vary over time and depend on patient condition. Therefore, renewed risk assessment should be performed at any significant change in patients' condition.

A remarkable side finding from the risk factor analysis study was the observation that pressure ulcers are found so early after surgery. In 80% of our patients, the first manifestations of pressure ulcers were

present by the third postoperative day. This was another indication that undergoing surgery is a major causative factor in pressure ulcer development and that the operating table is often the basis for pressure ulcers. **Chapter 4** describes a randomized clinical study that was conducted to confirm this assumption. Tissue-interface pressure measurements were performed during a surgical procedure in 80 patients. Interface pressures were obtained with an XSENSOR full body pressure mapping pad, containing 6912 capacitive sensors. Four different operating table surfaces were compared, with 40 patients in supine position and 40 patients in lithotomy position. The results showed that high interface pressures were very common, even on special pressure-relieving support surfaces. The median peak interface pressure measured in the sacral area on the standard OR table mattress was 185 mmHg, which was 100 mmHg higher than on the best performing pressure-relieving surface, the RIK®Fluid. Our results indicate that one of the prerequisites for developing pressure ulcers, namely the presence of high compressive forces, is fulfilled in patients undergoing surgery. A recent study by Weststrate et al. has shown, that interface pressures are not reliable parameters to predict development of pressure ulcers [3]. Caution is advised as to the interpretation of interface pressures. Because there is a lack of threshold values, above which pressure related damage will occur and also under which no visible damage is observed, the measurement of interface pressures can only be used for the relative comparison of pressure-relieving and distributing capacities of support surfaces. Clinical testing of surfaces, including incidence studies, will remain necessary for determining which surface is most effective in daily practice.

Chapter 5 describes another study using interface pressure measurements, namely for comparing three support surfaces used for the temporary immobilization of severely injured trauma patients in an emergency department. Interface pressures were measured using the same full body pressure mapping pad as was used on the operating table. This study was conducted in healthy volunteers, who were each positioned on all three surfaces. The tested surfaces were a spineboard, a vacuum mattress and a semi soft overlay mattress. Extremely high interface pressures, exceeding 170 mmHg for the sacral area, were

found on the spineboard, the device that is currently the standard support surface for immobilization and transportation of severely injured patients in The Netherlands. Before the study was performed, we considered the vacuum mattress as a possible alternative for the spineboard. However, with interface pressures exceeding 160 mmHg in the sacral area, this surface appeared to be not appropriate for replacing the spineboard. Of course, the same comments - regarding the careful interpretation of interface pressures - apply to these measurements. Based on the outcome of this study, it seems rational to keep the time trauma patients spend on a spineboard as short as possible, in order to prevent the start of tissue damage in a category of patients that is already vulnerable. There is a clear need for new, safe and more comfortable surfaces for the transportation and immobilization of trauma patients.

The results described in Chapters 4 and 5 made obvious, that high interface pressures are indeed common in surgical patients. However, to what extent external pressure influences tissue perfusion and thus tissue oxygenation at deeper levels remains unclear. Several non-invasive methods, like transcutaneous pCO_2 and pO_2 measurements, have been performed to indicate decreased blood flow under pressure, but only at skin level. A possible alternative study method is Near Infrared Spectroscopy (NIRS). NIRS is a technique that uses light in wavelengths between 680 and 800 nm to quantify tissue saturation. The reflection of near infrared light by chromophores like haemoglobin is used to determine the percentage of saturated haemoglobin. **Chapter 6** describes a feasibility study, to assess whether NIRS can be used in pressure ulcer research. Oxygen saturation (StO_2) was measured in soft tissues overlying the sacral area of 33 volunteers under different external pressures. Simultaneous with the StO_2 measurements, external pressure was increased in the sacral area by putting calibrated weights on the NIRS probe. External pressure was increased step by step up to 200 mmHg and thereafter decreased till the baseline value of 20 mmHg. The results showed that there was a wide inter-individual variability in StO_2 course. Another point of concern was the very poor reproducibility of measurements, which became evident during rehearsal of the study protocol in six of the volunteers. This study confirms that Near Infrared

Spectroscopy is not useful for assessing tissue oxygenation in pressure ulcer research.

Pressure-relieving surfaces play an important role in the prevention of pressure ulcers. In **Chapter 7** we describe a randomized clinical study, in which three high-specification pressure-relieving mattresses were compared. Background information, was the outcome of a recent study, which showed that the incidence of grade 2 or worse pressure ulcers within the Surgical Division of the University Medical Centre Utrecht was 11.5%. The results of our study were used for the rational selection of a new standard mattress for all patients admitted to the wards of the Surgical Division. In our study, patients with an hospital stay of at least 5 days were included. A total of 306 patients could be included in a half year period. The overall incidence of grade 2 or worse pressure ulcers was 5.9%, without significant differences in incidence between the three mattresses. Patient satisfaction was assessed with a questionnaire and neither revealed important differences between the three mattresses. This study suggested that standard high-specification mattresses may result in a lower incidence of pressure ulcers in surgical patients. One of the three surfaces was selected to replace the current mattress, mainly on the basis of financial arguments.

In the Introduction of the thesis, a number of questions were formulated. These questions can be answered through the research presented in the previous chapters.

- **Is it possible to identify risk factors for developing pressure ulcers in patients on a surgical ICU and can a risk assessment scale be developed from these risk factors, especially for ICU patients?**
  Four risk factors for the development of grade 1 or worse pressure ulcers in surgical ICU patients could be identified: female sex, high age, duration of anaesthesia and the occurrence of intraoperative complications. A clinical prediction rule was composed, of these four easily obtainable patient characteristics. This prediction rule had a better prognostic ability than existing scales, but needs external

validation in another population.

- **Is there a difference in pressure reducing and pressure distributing characteristics of different operating room table surfaces when tested with tissue-interface pressure measurements?**
  Interface pressure measurements showed large differences in pressure reducing and distributing characteristics. Interface pressures obtained on a standard OR table mattress are that high, that we advise against its use during long surgical procedures. On two surfaces that are recommended as pressure-relieving, high interface pressures were nevertheless obtained as well.

- **What interface pressures are obtained on support surfaces currently used for transporting and immobilizing severely injured trauma patients?**
  High interface pressures were found on all the tested support surfaces, with the highest values (exceeding 170 mmHg) measured on the spineboard. Even on the vacuum mattress, a surface that was considered as a possible alternative for the spineboard, interface pressures exceeding 160 mmHg were measured.

- **Can the influence of external pressure on soft tissue oxygenation, in an area at particular risk of pressure ulcer development, be studied with a non-invasive method like Near Infrared Spectroscopy?**
  The inter-individual variability of StO_2 measurements is that high and the reproducibility that low, that there doesn't seem to be a role for NIRS in pressure ulcer research.

- **Does the standard use of a high-specification pressure-relieving mattress for all surgical patients result in a lower incidence of pressure ulcers?**
  Although a causative relationship was not proven, the results from a randomized comparative clinical study suggest that

the introduction of a high-specification pressure-relieving mattress may result in a decrease of pressure ulcer incidence in surgical patients.

In conclusion, this thesis has demonstrated that the pressure ulcer problem is still highly relevant in surgical and ICU patients. Patients undergoing surgery are subject to high compressive forces on the operating table and patients who are postoperatively admitted to an ICU, develop pressure ulcers very frequently. Therefore, it is important to identify those patients that are really at risk of developing pressure ulcers; this can be done with a relatively simple risk assessment scale. Prevention should start as early as on the operating table, keeping in mind that not all surfaces are effective in reducing and distributing pressure. Use of standard high-specification pressure-relieving mattresses on a surgical ward seems advisable.

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Chapter 9

Samenvatting voor niet-ingewijden en leken

Decubitus (in de volksmond ook wel doorligplek of drukplek genoemd) wordt gedefinieerd als weefselversterf (necrose), als gevolgd van de inwerking op het lichaam van uitwendige druk-, schuif- en wrijfkrachten of een combinatie van deze factoren.
Decubitus wordt onderverdeeld in vier gradaties:

Graad 1 Niet wegdrukbare roodheid van de intacte huid. Verkleuring van de huid, warmte, oedeem of verharding (induratie) zijn andere mogelijke kenmerken.

Graad 2 Oppervlakkig defect van de opperhuid (epidermis), al of niet met aantasting van de huidlaag daaronder (lederhuid of dermis). Het defect ziet er uit als een blaar of oppervlakkige ontvelling.

Graad 3 Huiddefect met schade of necrose van de huid en het onderhuidse weefsel (subcutis). De schade kan zich uitstrekken tot aan het onderliggende bindweefselvlies (fascie).

Graad 4 Uitgebreide weefselschade of necrose van spieren, botweefsel of ondersteunende weefsels, met of zonder schade aan opperhuid en lederhuid.

Decubitus vormt een belangrijk probleem voor de gezondheidszorg, ook in Nederland. In 1999 bedroeg de prevalentie van decubitus in academische ziekenhuizen 13% en in algemene ziekenhuizen 23%. De mate waarin een bepaalde afwijking in een groep personen voorkomt wordt weergegeven als prevalentie en incidentie. Onder prevalentie wordt het aantal gevallen van een afwijking verstaan, dat op één specifiek moment aanwezig is en onder incidentie het aantal nieuwe gevallen dat gedurende een bepaalde periode ontstaat.
Bij chirurgische patiënten komt decubitus vaak voor, hetgeen wordt geïllustreerd met in de literatuur genoemde incidenties tot wel 66%. Door de tendens om steeds complexere en langduriger chirurgische ingrepen te verrichten, neemt het risico op het ontwikkelen van decubitus nog eens toe. Daarnaast zal het aantal patiënten dat risico loopt op het ontwikkelen van decubitus stijgen, door een toenemende veroudering van de bevolking.

Hoofdstuk 1 vormt de Inleiding van dit proefschrift. In dit hoofdstuk wordt de opzet van het proefschrift beschreven en er worden vijf onderzoeksvragen geformuleerd.

In **Hoofdstuk 2** en **3** wordt geïllustreerd dat (chirurgische) Intensive Care (IC) patiënten in het bijzonder risico lopen op het ontwikkelen van decubitus.
In **Hoofdstuk 2** worden de resultaten gepresenteerd van een uitgebreide beschouwing van de literatuur die in een periode van 20 jaar is verschenen over decubitus bij Intensive Care patiënten. Prevalentie en incidentie cijfers blijken bij IC patiënten 2-3 maal hoger dan bij "gemiddelde ziekenhuis" patiënten. Dit benadrukt dat IC patiënten als een aparte risico categorie moeten worden beschouwd.
In de literatuur worden veel risicofactoren voor het ontwikkelen van decubitus genoemd: de operatieduur en het aantal operaties, aanwezigheid van incontinentie en/of diarree, slechte voedingstoestand, slechte sensorische gewaarwording, vochtigheid van de huid, verminderde circulatie, gebruik van bloeddruk ondersteunende medicijnen, diabetes mellitus (suikerziekte) en verminderde mobiliteit. Al deze factoren hebben een negatieve invloed op de weerstand van weefsels tegen het ontwikkelen van decubitus.
Wanneer decubitus ontstaat, resulteert dit vaak in een aanzienlijke ziektebelasting en soms zelfs sterfte voor de patiënt en een sterke toename van de werklast voor het verplegend personeel, met een overeenkomstige stijging van de kosten.
Preventieve maatregelen, die tenminste moeten worden toegepast bij bedlegerige patiënten, zijn het toepassen van wisselligging en het gebruik van speciale matrassen. Helaas zijn er geen duidelijke criteria beschikbaar voor welk matras in welk geval moet worden gebruikt. Diverse consensus rapporten en decubitus adviesraden raden het gebruik van risicoscoreschalen aan, met als doel die patiënten te identificeren met een verhoogd risico, die dus preventieve maatregelen nodig hebben. De meeste van de bestaande schalen zijn niet ontwikkeld voor het gebruik bij IC patiënten. Nieuw ontwikkelde versies zijn over het algemeen aanpassingen van bestaande schalen en ze zijn onvoldoende getest voor het gebruik bij IC patiënten. Dit verklaart dat er momenteel geen ideale risicoscoreschaal is voor (chirurgische) IC

patiënten.

Daarom werd een klinische studie verricht bij 204 IC patiënten, waarin 31 mogelijke risicofactoren voor het ontwikkelen van decubitus werden gecorreleerd met het daadwerkelijk optreden van decubitus. De resultaten van dit onderzoek worden beschreven in **Hoofdstuk 3**. Alleen patiënten die ten minste 48 uur op de chirurgische IC verbleven werden in dit onderzoek opgenomen. Een opvallende bevinding van deze studie was de hoge cumulatieve (samengevoegde) decubitus incidentie van 53%, waarvan 21% graad 2 of hoger was. Gebruik makend van statistische rekenmethoden (univariate en multivariate logistische regressie technieken), konden vier onafhankelijke risicofactoren voor het ontwikkelen van graad 1 of hoger decubitus worden geïdentificeerd. Deze risicofactoren waren: vrouwelijk geslacht, hoge leeftijd, lange anesthesieduur en het optreden van peroperatieve complicaties (zoals ernstige bloeding, terug aan de hart-longmachine na een hartoperatie en langdurige episode van shock (lage bloeddruk) met de noodzaak tot het geven van hoge doseringen circulatie ondersteunende medicatie). Met deze vier risicofactoren werd een nieuwe risicoscore samengesteld. Een goede risicoscore dient de meeste patiënten die decubitus zullen ontwikkelen tevoren te herkennen, maar tegelijkertijd het aantal patiënten dat ten onrechte als risicopatiënt wordt geïdentificeerd (vals-positief) zo laag mogelijk te houden. De door ons ontwikkelde risicoscore verloopt van 0 tot 21 punten. Wanneer bij 54% van alle patiënten (hoogrisico patiënten met een score van 8 punten of meer) preventieve maatregelen worden toegepast, zal 66% van de patiënten die normaal gesproken graad 1 of hoger decubitus ontwikkelen, deze maatregelen terecht ontvangen. Helaas wordt 40% van de patiënten ten onrechte als risicopatiënt aangeduid en ontvangt derhalve onnodige en dure preventieve maatregelen.
Het vermogen van onze risicoscore, om onderscheid te maken tussen patiënten die wel en geen decubitus ontwikkelen, is dus beperkt, maar nog altijd beter dan dat van alle andere risicoscoreschalen die momenteel beschikbaar zijn. Het voorspellend vermogen is alleen nog maar berekend voor de door ons onderzochte groep patiënten. Dat is geen garantie dat de regel toepasbaar is in andere IC situaties en daarom moet de waarde van deze voorspelregel eerst extern getoetst

worden, voordat deze in de praktijk kan worden toegepast.

Een opmerkelijke nevenbevinding van de studie die werd gepresenteerd in **Hoofdstuk 3** was, dat decubitus al zo kort na een chirurgische ingreep werd gezien. De eerste manifestaties van decubitus waren bij 80% van de patiënten al op de derde postoperatieve dag aanwezig. Dit was een indicatie dat het ondergaan van een operatieve ingreep een belangrijke oorzakelijke factor is voor het ontwikkelen van decubitus en dat daarvoor op de operatietafel vaak letterlijk de basis wordt gelegd. In **Hoofdstuk 4** worden de resultaten van een gerandomiseerde, vergelijkende klinische studie beschreven, die werd uitgevoerd om deze indruk te onderbouwen. Bij 80 patiënten werden interfacedrukmetingen verricht gedurende de chirurgische ingreep die zij ondergingen. Interfacedruk is de druk die gemeten wordt tussen de huid en de onderlaag waarop de patiënt ligt. Interfacedrukken werden gemeten met een XSENSOR "full body" drukmeet mat, die 6912 capacitatieve meetpunten bevat. Er werden vier verschillende operatietafel matrassen met elkaar vergeleken:

1. een dun vezelmatras (standaard matras)
2. het ROHO® Dry Floatation® matras
3. een viscoelastisch polyurethaan matras
4. het KCI RIK® Fluid matras

Veertig patiënten werden in rugligging en 40 patiënten in steensnedeligging (met de benen in steunen) geopereerd. Welke van de vier matrassen werd gebruikt, werd "door het lot bepaald" (randomisatie). Uit dit onderzoek bleek dat hoge drukken zeer vaak optreden, zelfs op matrassen die als drukreducerend aanbevolen worden. De mediane piek interfacedruk die op het standaard OK-matras ter hoogte van het heiligbeen werd gemeten bedroeg 185 mmHg (mm kwik), hetgeen ruim 100 mmHg hoger was dan de druk die werd gemeten bij patiënten op het best presterende matras, het RIK®Fluid. Onze resultaten laten zien dat aan één van de voorwaarden voor het ontwikkelen van decubitus, namelijk de aanwezigheid van hoge compressiekrachten door uitwendige druk, wordt voldaan bij patiënten die een operatieve ingreep ondergaan. Interface drukken zijn echter geen betrouwbare factoren voor het voorspellen van het ontwikkelen van decubitus. Daarom moet ook de nodige voorzichtigheid

worden betracht bij het interpreteren van deze drukken. Omdat er geen grenswaarden bekend zijn, waarboven druk gerelateerde schade zal optreden of waaronder geen zichtbare schade voorkomt, kan het meten van interface drukken alleen worden gebruikt voor het testen en vergelijken van de drukreducerende en –verdelende eigenschappen van ondersteunende onderlagen. Derhalve blijft het klinisch testen van onderlagen, inclusief incidentiestudies, noodzakelijk voor het bepalen welke onderlaag in de dagelijkse praktijk het meest effectief is.

In **Hoofdstuk 5** worden de resultaten van een studie beschreven waarin eveneens interfacedrukmetingen worden gebruikt, maar nu voor het vergelijken van drie onderlagen die worden gebruikt voor de tijdelijke immobilisatie van ernstig gewonde traumapatiënten (ongevalslachtoffers) op de Afdeling Spoedeisende Hulp. Interfacedrukken werden gemeten met hetzelfde systeem zoals beschreven in het **Hoofdstuk 4**. Deze studie werd uitgevoerd bij gezonde vrijwilligers, die elk ruggelings op alle drie de onderlagen werden gepositioneerd. De onderlagen die getest werden, waren een zogenaamde wervelplank, een vacuüm matras en een half zachte oplegmatras. Op de wervelplank werden extreem hoge interfacedrukken (>170 mmHg) ter hoogte van het heiligbeen gemeten. Dit is de onderlaag die momenteel in Nederland als standaard wordt gebruikt voor het immobiliseren en transporteren van ernstig gewonde traumapatiënten. Op het vacuüm matras werden echter ook interfacedrukken boven de 160 mmHg gemeten ter hoogte van het heiligbeen en daarmee lijkt deze onderlaag niet geschikt ter vervanging van de wervelplank. De laagste drukken ter hoogte van het heiligbeen werden op de half zachte oplegmatras gemeten (gemiddeld 118 mmHg). Uiteraard gelden voor deze resultaten ook de kanttekeningen met betrekking tot de interpretatie van interfacedrukken.
Op basis van de uitkomsten van deze studie, lijkt het verstandig om de tijd die ongevalpatiënten op een wervelplank moeten doorbrengen zo beperkt mogelijk te houden, met het oog op preventie van weefselschade bij een categorie patiënten die toch al zo kwetsbaar is. Er is een duidelijke behoefte aan een nieuwe, veilige en comfortabelere onderlaag voor het vervoer en de immobilisatie van traumapatiënten.

In **Hoofdstuk 4** en **5** werd beschreven dat hoge interfacedrukken inderdaad zeer gebruikelijk zijn bij chirurgische patiënten. Wat het effect van externe druk op weefseldoorbloeding en de zuurstofvoorziening (oxygenatie) van weefsels is, blijft onduidelijk. Met diverse niet-invasieve meetmethoden, zoals kooldioxide- en zuurstofspanning metingen, is gebleken dat de bloedstroom afneemt onder invloed van druk, maar hierbij is alleen op huidniveau gemeten. Een mogelijke alternatieve niet-invasieve studiemethode is Near Infrared Spectroscopie (NIRS), waarbij infrarood licht met golflengtes tussen 680 en 800 nm wordt gebruikt voor het vaststellen van het zuurstofgehalte in weefsels. De weerkaatsing van licht door hemoglobine wordt gebruikt voor het bepalen van het percentage met zuurstof verzadigd hemoglobine. In **Hoofdstuk 6** wordt een toepasbaarheidstudie beschreven, waarin werd bekeken of NIRS zou kunnen worden gebruikt bij decubitus onderzoek. Bij 33 gezonde vrijwilligers werd de zuurstofverzadiging in de weke delen over het heiligbeen (StO_2) gemeten bij verschillende uitwendige drukken. Gedurende deze metingen werd de externe druk ter plaatse stapsgewijs verhoogd, door gekalibreerde gewichten op de NIRS meetsensor te plaatsen. De externe druk werd stap voor stap verhoogd tot een maximum van 200 mmHg en daarna weer afgebouwd tot de beginwaarde van 20 mmHg. De resultaten lieten een grote inter-individuele variabiliteit in het StO_2 beloop zien. Daarnaast waren de metingen zeer matig reproduceerbaar. Uit deze studie bleek dat NIRS niet zinvol is voor het bepalen van de weefseloxygenatie bij decubitus onderzoek.

Drukverlagende onderlagen spelen een belangrijke rol in de preventie van decubitus. In **Hoofdstuk 7** wordt een gerandomiseerde klinische studie beschreven, waarin drie kwalitatief hoogwaardige matrassen met elkaar werden vergeleken. Belangrijke achtergrondinformatie was de uitkomst van een recent onderzoek, waaruit bleek dat de incidentie van graad 2 of hoger decubitus binnen de toenmalige Divisie Chirurgie van het Universitair Medisch Centrum Utrecht 11,5% bedroeg. De resultaten van onze studie werden gebruikt voor de verantwoorde keuze van een nieuw standaard matras voor alle patiënten die worden opgenomen op de verpleegafdelingen binnen de Divisie Chirurgie. In deze studie werden patiënten met een opnameduur van ten minste 5 dagen toegelaten. In

een periode van een half jaar konden 306 patiënten in de studie worden opgenomen. De incidentie van graad 2 of hoger decubitus was 5,9%, zonder dat significante verschillen in incidentie tussen de drie matrassen werden gevonden. De tevredenheid van patiënten werd getoetst met een enquête, waarbij eveneens geen belangrijke verschillen tussen de drie matrassen werden gevonden. Deze studie suggereerde dat het gebruik van standaard, kwalitatief hoogwaardige matrassen kan resulteren in een verlaging van de decubitus incidentie bij chirurgische patiënten. Eén van de drie werd gekozen als nieuw matras, waarbij financiële argumenten de doorslag gaven.

In de Inleiding van dit proefschrift werden enkele vragen geformuleerd. Deze vragen kunnen worden beantwoord dank zij de onderzoeken die in de voorgaande hoofdstukken zijn gepresenteerd.

- *Is het mogelijk risicofactoren te identificeren voor het ontwikkelen van decubitus bij patiënten op een chirurgische IC en kan van deze risicofactoren een risicoscoreschaal speciaal voor IC patiënten worden ontwikkeld?*
  Er konden vier risicofactoren voor het ontwikkelen van graad 1 en erger decubitus worden geïdentificeerd: vrouwelijk geslacht, hoge leeftijd, anesthesieduur en het optreden van complicaties tijdens de operatie. Van deze eenvoudig te verkrijgen patiëntgegevens werd een klinische voorspelregel samengesteld. Deze voorspelregel met een matige, maar desondanks betere voorspellende waarde dan alle bestaande schalen, moet extern getoetst worden in een andere patiëntengroep voordat toepassing in de praktijk kan plaatsvinden.

- *Is er een verschil in drukreducerende en drukverdelende eigenschappen van verschillende operatietafel onderlagen als deze getest worden met interfacedrukmetingen?*
  Interfacedrukmetingen lieten grote verschillen zien in drukreducerende en drukverdelende eigenschappen. Gemeten interfacedrukken zijn zo hoog op een standaard OK-matras, dat het gebruik hiervan tijdens langdurige

ingrepen moet worden ontraden. Ook op twee onderlagen die als drukreducerend worden aanbevolen werden hoge interfacedrukken bereikt.

- *Welke interfacedrukken worden verkregen op onderlagen die momenteel worden gebruikt voor het transport en de immobilisatie van ernstig gewonde traumapatiënten?*
  Hoge interfacedrukken werden op alle drie de geteste onderlagen gevonden, waarbij de hoogste waarden (>170 mmHg) op de zogenaamde wervelplank werden gemeten. Zelfs op het vacuüm matras, een onderlaag die als een mogelijk alternatief voor de wervelplank wordt beschouwd, werden interfacedrukken boven de 160 mmHg gemeten. Met een gemiddelde van 118 mmHg werden de laagste drukkend gemeten op het "half zachte" matras.

- *Kan de invloed van externe druk op de oxygenatie van weke delen, in een lichaamsregio die in het bijzonder risico loopt op het optreden van decubitus, worden bestudeerd met Near Infrared Spectroscopie, een niet-invasieve methode?*
  De inter-individuele variatie van de uitkomsten van de metingen van de zuurstofverzadiging in weefsel was dusdanig hoog en de reproduceerbaarheid zo laag, dat er geen rol lijkt weggelegd voor NIRS bij decubitus onderzoek.

- *Kan door het gebruik van kwalitatief hoogwaardige matrassen als standaard voor alle chirurgische patiënten het risico op ontwikkelen van decubitus worden beperkt?*
  Alhoewel een oorzakelijk verband niet bewezen is, suggereren de resultaten van een door ons uitgevoerde gerandomiseerde vergelijkende studie, dat de invoering van een kwalitatief hoogwaardig, drukverlagend matras, kan resulteren in een afname van de incidentie van decubitus bij chirurgische patiënten.

Concluderend, hebben de studies die in dit proefschrift werden beschreven, laten zien dat het decubitusprobleem nog steeds zeer relevant is bij chirurgische en IC patiënten. Patiënten die een operatie ondergaan staan bloot aan hoge uitwendige drukken terwijl ze op de operatietafel liggen en patiënten die postoperatief worden opgenomen op een IC ontwikkelen zeer frequent decubitus. Derhalve is het belangrijk om patiënten die daadwerkelijk risico lopen op het ontwikkelen van decubitus tevoren te identificeren, hetgeen tot op zekere hoogte kon worden gedaan met een relatief eenvoudige risicoscoreschaal. Preventie moet in een zo vroeg mogelijk stadium worden gestart en bij voorkeur al op de operatietafel. Hierbij moet in het achterhoofd gehouden worden dat niet alle onderlagen even effectief zijn in het verlagen en verdelen van druk. Het standaard gebruik van een kwalitatief hoogwaardige drukverlagende matras op een chirurgische afdeling lijkt aan te bevelen.

Dankwoord & Curriculum Vitae

Dankwoord

Prof. dr. Chr. van der Werken, promotor, dank voor uw begeleiding tijdens dit project. Mede door uw tomeloze energie en regelmatige pep-talks is dit proefschrift tot een goed einde gekomen. Op momenten dat bij mij de klad erin zat, wist u me toch weer te motiveren. Ook ik heb mogen profiteren van uw inmiddels in vele dankwoorden geroemde snelheid en kwaliteit van corrigeren. Ik ben blij dat ú de handdoek nooit in de ring heeft geworpen!!

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Leden van de leescommissie, prof. dr. I.H.M. Borel Rinkes, prof. dr. Y. van der Graaf, prof. dr. J.R.E. Haalboom, prof. dr. C.J. Kalkman en prof. dr. M. Kon, hartelijk dank voor de genomen tijd en moeite voor het beoordelen van mijn manuscript.

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Curriculum Vitae

The author of this thesis, was born on August 19th of 1969 in Dordrecht, The Netherlands. He attended secondary school at Het Christelijk Lyceum in Dordrecht, from 1981 till graduation in 1987. His medical study started in 1987 at the Rijksuniversiteit Leiden. The doctoral exam was passed in 1991 and in February 1992 he started internships. His medical degree was obtained in July 1994. The same month, he started as a resident (AGNIO) at the Department of Surgery in the Academisch Ziekenhuis Leiden, where he worked till October 1995. In January 1996, his AGNIO career continued at the Department of Surgery in the Zuiderziekenhuis, Rotterdam. He worked here till October 1997 and in November 1997, he started working at the Department of Surgery of the St. Antonius Hospital, Nieuwegein (head: Dr. P.M.N.Y.H. Go). After five unfruitful attempts to obtain a surgical training place, he was given the opportunity to perform a scientific research project on pressure ulcers, which was the basis for this thesis. He did full-time research from January 1999 till December 2000. In 2000, he finally succeeded in obtaining a training place. Surgical training started in January 2001 in the Universitair Medisch Centrum Utrecht (head: Prof. Dr. I.H.M. Borel Rinkes). In January 2003 he returned to the St. Antonius Hospital for the peripheral residency, where he hopes to complete training in December 2006.

Appendix

Grade I:	Non-blanchable erythema of intact skin. Discolouration of the skin, warmth, oedema, induration or hardness may also be used as indicators, particularly on individuals with darker skin.
Grade II:	Partial thickness skin loss involving epidermis, dermis or both. The ulcer is superficial and presents clinically as an abrasion or blister.
Grade III:	Full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia.
Grade IV:	Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss.

Pressure ulcer classification as defined by the European Pressure Ulcer Advisory Panel