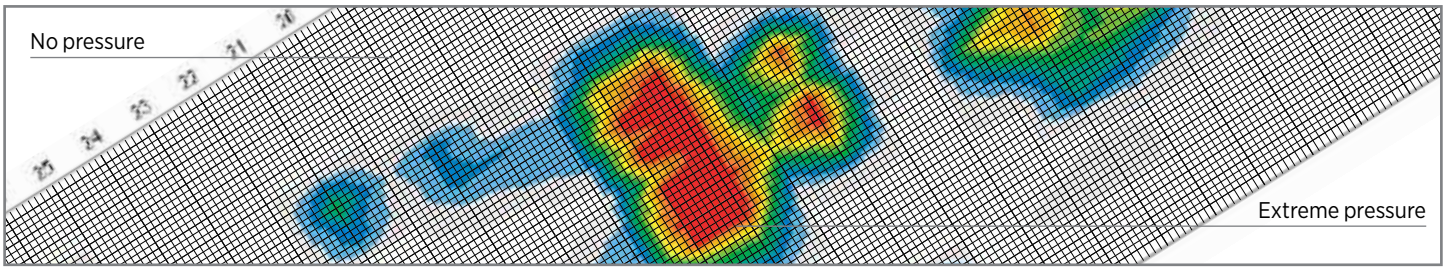
Interface Pressure Testing

Introduction

Pressure injuries are common and costly, posing a serious health concern impacting cost of care, reimbursement and quality of life, while affecting patients, healthcare workers and healthcare authorities alike.[1,7]

In the United States, annual estimates show 1.7 million patients develop pressure injuries with associated healthcare costs of $8.5 billion. In some European countries it has been reported that the cost of pressure injury prevention and treatment accounts for more than 1% of the total healthcare budget. This is the third largest cost incurred by healthcare providers after cancer and cardiovascular diseases.[2-4]

The reporting of pressure injury prevalence and incidence throughout the UK, Europe and USA is far from comprehensive, however, one point that continually stands out when looking at the figures reported over the last ten years is that there has been little change in the percentage of patients developing or presented with these wounds.



With the size of the problem posed by pressure injuries remaining apparently unchanged and the associated treatment costs continuing to rise, it is important to ensure that products aimed at the marketplace for prevention and treatment provide appropriate levels of pressure redistribution and relieve to patients.

While it is widely accepted that clinical outcomes represent the best method of proving clinical efficacy for a medical device, laboratory measurements still play an important role when assessing pressure care equipment.

Such measurements typically take the form of Interface Pressure tests. While such testing is ideally undertaken by an independent body, these tests are extremely costly and very time consuming – and as a result, the majority of manufacturers undertake these measurements in-house using highly specialised pressure mapping equipment.

The results of such tests can be used by Tissue Viability Nurses (TVNs) and their colleagues to help identify which products are likely to provide their patients with the appropriate levels of pressure redistribution and relief for pressure injury prevention and treatment.

What is pressure mapping?

A pressure map is a computerised clinical tool for assessing pressure distribution. To use it, you place a thin sensor mat on a mattress surface or seating area. When your patient lies on the mat, a computer screen displays a map of pressures, using colours, numbers and a graphic image of the patient. Typically, the hotter colours (the reds and oranges) indicate areas of higher pressures and the cooler colours (the blues and greens) indicate areas of lower pressures. The display usually has several options including a three-dimensional display of peak pressures and a statistical analysis.

Pressure mapping does have some drawbacks, including inconsistencies in the way manufacturers report and display the pressures, differences in measurable peak pressures among manufacturers and sensor accuracy and drift. Still, these visual displays provide key data that can augment nursing assessment of the areas of potential tissue damage.

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Pressure mapping accuracy – the facts

The historical definition for a 'pressure reducing' or 'pressure relieving' support surface was one that yielded pressure readings of 32mmHg or lower on most bony prominences most of the time. This 'gold standard' for optimal pressure (32mmHg), however, is not realistically possible. The number 32mmHg is capillary pressure at heart level. The capillary pressure is much greater than this down by the feet and research shows that 60mmHg is probably a much better number to use as capillary pressure.

In the early 1990's, many organisations important to wound care, such as the Wound Ostomy Continence Nurses Association (WOCN) and the National Pressure Ulcer Advisory Panel (NPUAP) defined pressure reduction as "reduction of interface pressure, not necessarily below the level required to close capillaries, ie capillary closing pressure."5 Pressure relief was defined as "reduction of interface pressure below capillary closing pressure".

It is important to note:

1. 32mmHg has been discredited as too general, and is a gross misrepresentation of work by Landis in 1930. WOCN, NPUAP and many other wound care organizations have worked for years to educate clinicians and consumers that this number is erroneous.
2. In clinical practice, the capillary closing pressure for many people is well below 32mmHg.
3. The capillary closing pressure for an individual can only be determined through invasive techniques.
4. The only non-invasive and objective tool a manufacturer has to approximate meeting this definition is interface pressure mapping. It is erroneous to believe that interface pressures are equivalent to capillary closing pressure. Interface pressures are read between the support surface and the patient's skin, while capillary closing pressure is read at the microscopic level.
5. When pressure mapping is used, one subject may yield interface pressures below 32mmHg, while another subject on that same mattress will record interface pressures above 32mmHg. This can be due to prominent bony prominences, body weight distribution, body weight in relation to height, and many other factors. The definitions are impossible to apply when subjects vary so widely in their pressure readings. This applies to nearly all support surface products on the market.
6. Pressure mapping systems only measure uniaxial pressure (vertical or straight down) and do not measure shear forces at all.
7. Pressure alone is not a reliable indicator of risk for skin breakdown. Pressure is not the only factor in pressure injury development. Heat, moisture from perspiration or urine, poor nutrition, sensory loss, age-related connective tissue changes, friction or shear and poor circulation all contribute to pressure injuries.

Novis Healthcare Limited recommends that laboratory test results form only a part of the decision making process in regard to pressure care equipment, which should also take into account clinical judgement and evaluation, or use of the product in a clinical setting with real patient outcomes. The approach of combining laboratory measurements with the experiences and views of respected clinical staff provides a more holistic view in assessing product acceptability and performance in a clinical setting.

This report details Interface Pressure measurements taken on a dynamic patient support surface – the ProCair Mattress Replacement – using a healthy volunteer. Data is reported as maximum and minimum pressures, and time spent below specific predetermined pressure thresholds.

Aim

The aim of this project was to examine the sacral interface pressures of a subject resting supine on the ProCair Mattress Replacement System.

Methodology

All Interface Pressure measurements were taken using the Xsensor X3 from Xsensor Technology Corporation. The Xsensor X3 is composed of a large bed sized pressure mapping mat with a grid of 160x64 individual pressure sensors. Pressure range was 0-100mmHg and interface pressure maps were saved at intervals of 0.5 seconds.

The ProCair Mattress was set up according to the manufacturer's instructions on a standard hospital bed frame with a bed base. The mattress replacement and X3 mat were placed directly onto the bed base and the system left to operate for a minimum of 60 minutes at maximum pressure before testing commenced.

The mattress pump has a cycle time of 12 minutes and was set to a cell pressure setting of up to 60mmHg.

A single healthy volunteer subject was used to test the support surface. The test subject was a 38 year old male, weight 84 kg, height 168 cm and Body Mass index (BMI) of 29.8.

All tests took place with the subject placed in a standardised supine position (lying flat on their back, legs shoulder width apart, arms resting by their side, head resting on static head cells. The subject was positioned with the sacrum over the apex of an inflated cell.

The subject was left to rest over two complete cycles, allowing the system to stabilise, before data was taken over the complete third cycle.

Data was analyzed to report maximum and minimum pressure measurements and also the time spent at or below interface pressure thresholds of 10, 20, 30 and 40 mmHg.

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Results

Maximum/Minimum Sacral Interface Pressures

Maximum Sacral Interface Pressure*	37 mmHg
Minimum Sacral Interface Pressure	0 mmHg

- The X3 mat had a lower limit of of 10mmHg maximum pressure; therefore pressures between 0 and 10mmHg could not be accurately read by the system.

Sacral Pressure Relief Indices (PRI)

The results below detail the time the test subjects' sacrum spent at or below specific Interface Pressure thresholds.

The test subject did experience a significant period of time (23% of 12-minute cycle, 2 minute, 47 seconds) at sacral interface pressure below 10mmHg when resting supine on the ProCair Mattress.

With the PRI threshold set at 30mmHg the test subject recorded sacral pressure equal to or less than 30mmHg for 53% (6 minutes 19 seconds) of the 12-minute cycle time (see *Table 1*).

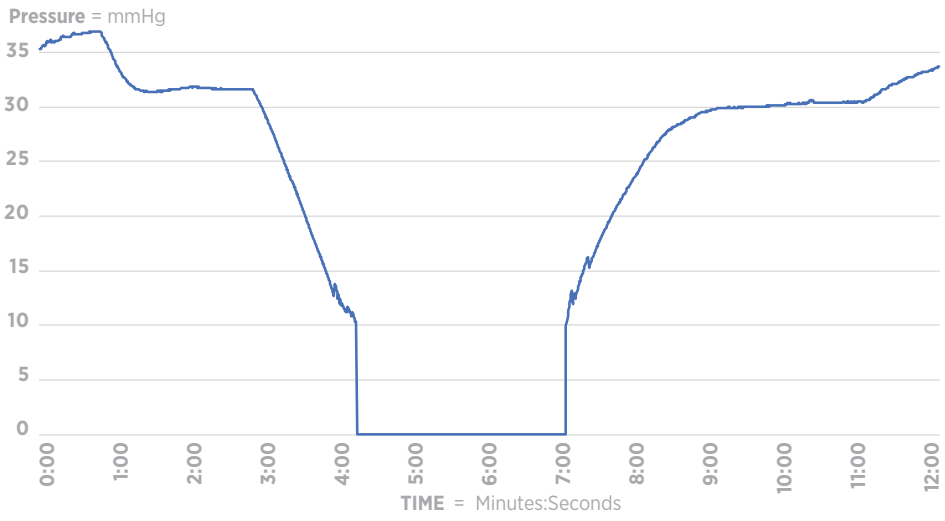
Table 1. Sacral PRI results for a subject resting supine on the ProCair.

PRI THRESHOLD (mmHg)	TIME (MINUTES:SECONDS)	PERCENTAGE OF 12-MINUTE CYCLE
Above 40	0:00	0%
Between 30 and 40	5:41	47%
Between 20 and 30	2:15	19%
Between 10 and 20	1:17	11%
Below 10	2:47	23%

Figure 1 demonstrates the rapid pressure drop off experienced at the sacrum as the air cell directly under the sacrum deflates. Interface pressure begins to build again as the cell is re-inflated with air.

Refer to *Appendix A* for whole body interface pressure maps of the test subject resting supine on the ProCair Mattress.

Figure 1. Actual Interface pressure at sacrum - Average Pressure vs Cycle Time



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Discussion

It is evident from the results reported above that the ProCair Mattress (dynamic mattress replacement system) is able to relieve and redistribute interface pressures effectively across the body/support surface interface every 12 minutes. With a subject in the supine position, the ProCair Mattress has the ability to reduce the sacral interface pressure to 0mmHg and the results of the Pressure Relief Indices (PRI) indicate that this dynamic support surface is regularly capable of providing the human body with several minutes of low pressure which may help with the prevention and management of pressure induced wounds.

While on the ProCair Mattress the subject in this test experienced sacral interface pressures in excess of 30 mmHg, however it should be noted that such pressures are rapidly relieved on a regular basis as the product runs through its cycle (refer *Appendix A*). It is this regular and rapid pressure relief that helps promote the normal physiological response of 'reactive hyperaemia' which can help maintain and promote tissue viability.

There is continued debate both nationally and internationally about how useful interface pressure measurements are and furthermore how they should be measured and analysed. In spite of working groups composed of representatives from the European Pressure Ulcer Advisory Panel (EPUAP) and the National Pressure Ulcer Advisory Panel (NPUAP)[6,7] it is worth noting that even with the academic backing of both Advisory Panels behind this topic, some of the statements made are somewhat conflicting.

With regard to the performance of support surfaces the following statements are made:

" Lower mean pressures over time are preferable "

" Greater percentage of time at low pressures and prolonged continuous intervals below selected thresholds (10, 20, 30mmHg) should be preferable to the opposite "

" Probable that a high amplitude cycle is preferable to a low amplitude cycle "

" Probable that a surface providing lower lows is preferable to one that off loads to a lesser extent "

Such conflicting statements indicate a degree of confusion and disagreement surrounding current interface pressure measurement practices. This level of discordance amongst healthcare academics makes it particularly difficult to ensure all appropriate aspects of test methodology and results presentation are covered when undertaking this work. With no clear resolution of these issues currently in sight, it is imperative that companies such as Novis Healthcare Limited continue to undertake in house testing and report the results of these tests to healthcare professionals to enable them to make a more informed decision when providing this type of support surface to their patients.

The one point that all academics are agreed upon is that different data sets should never be used to make direct product comparisons as they will have been generated using different test methodologies, equipment, test subjects and/or data analysis techniques thereby making it inappropriate to compare products reported in different tests.

Conclusion

In this test it is evident that the ProCair Mattress dynamic mattress replacement system has the ability to regularly redistribute pressure across the patient support surface interface (refer *Appendix A*).

This regular pressure redistribution is likely to help benefit the patients who may be at risk of pressure injury development, or to treat patients suffering from pressure injuries, provided that these products are provided in conjunction with a dedicated patient specific care plan for their pressure area care requirements.

References

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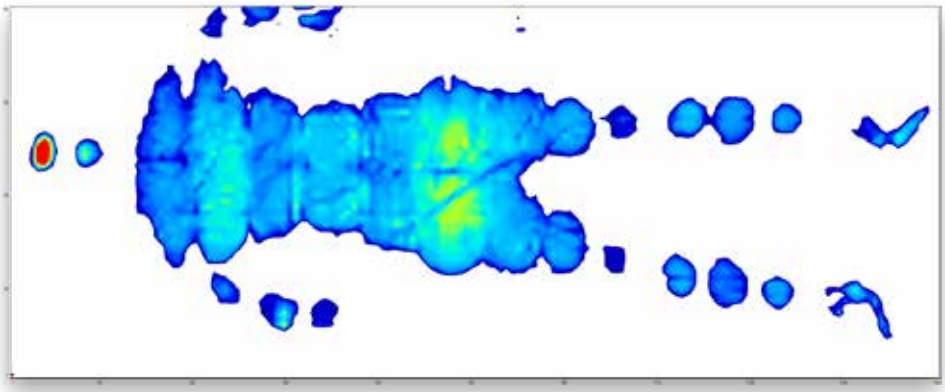
4. O'Dea K. Prevalence of pressure damage in hospital patients in the UK. **Journal of Wound Care**. 1993;2:221-5.
5. Wound Ostomy and Continence Nurses Society (WOCNS). **Guideline for Prevention and Management of Pressure Ulcers**. Mount Laurel, New Jersey. WCONS, 2010.
6. **European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel. Treatment of pressure ulcers: Quick reference guide**. Washington DC. National pressure Ulcer Advisory Panel, 2009.
7. Australian Wound Management Association. **Pan Pacific Clinical Practice Guideline for the Prevention and Management of Pressure Injury**. Osborne Park, WA. Cambridge Media, 2012.

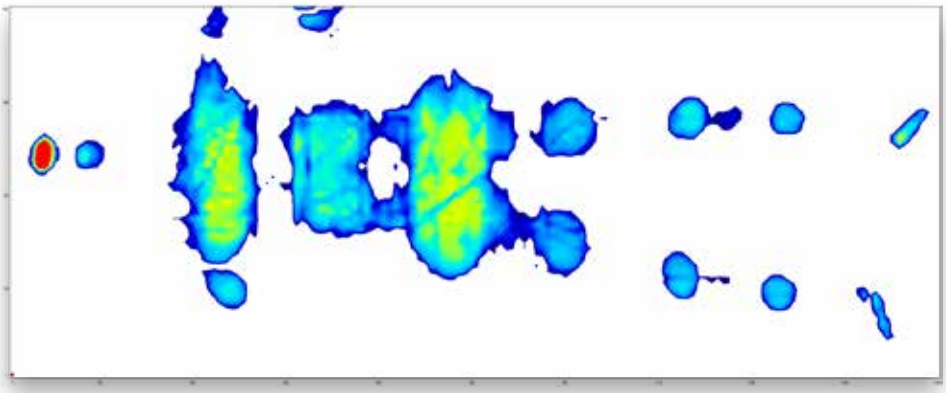
APPENDIX A – ProCair interface pressure maps

Pressure Legend

All cells inflated



'Zone A' cells deflated



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