

PRECIOSO CLINICAL DATA SUMMARIES

Pre launch report on clinical evaluations

Introduction

Equipment for the prevention and management of pressure ulcers has continued to develop over the past 20 years, and they now form an integral part of healthcare protocols for patients worldwide.

The impact of active mattresses and cushions has raised awareness of the need for appropriate intervention and cost effective solutions in pressure ulcer prevention and treatment.

The Precioso is a new product in the 3 cell cycle range of active mattresses. It is available as a mattress replacement or as a mattress overlay.

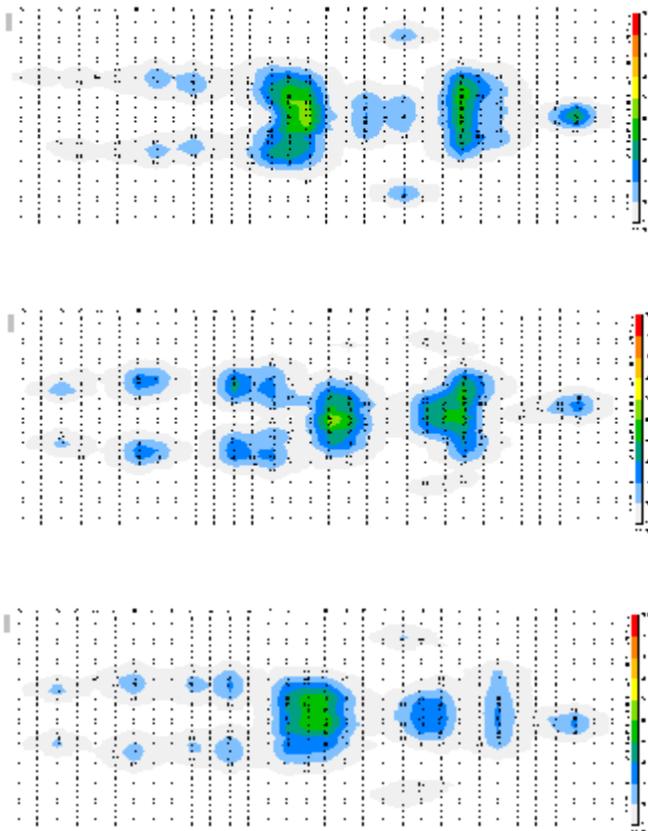
This report is a collection of the results gathered from evaluations in three care settings, general hospital, nursing home and community care. Patients included had a grade 3 or 4 pressure ulcer or were ulcer free but assessed, using local protocols, as being high/very high risk of pressure ulcer development. Inclusion followed discussion between the TVN and care provider, and appropriate consent gained.

The Precioso Alternating Pressure Mattress Replacement and Mattress Overlay Systems



Precioso mattress system has two separate layers. The top layer consists of a central set of 21 transverse air cells 18 of these alternate on a 7.5 minute 3 cell cycle, the three head cells remain static for patient comfort.. The lower layer, not used for the Overlay system, is made of three separate foam sections designed to follow the shape of the patient surface as the back rest or leg sections are raised or lowered these are contained within a waterproof cover. All sections are held together using plastic location toggles and polyurethane (PU) loops. The static side formers are approximately 40% larger than the alternating cells, the foot cells are 25% smaller than the alternating cells.

Clinical Data – Interface Pressure Mapping

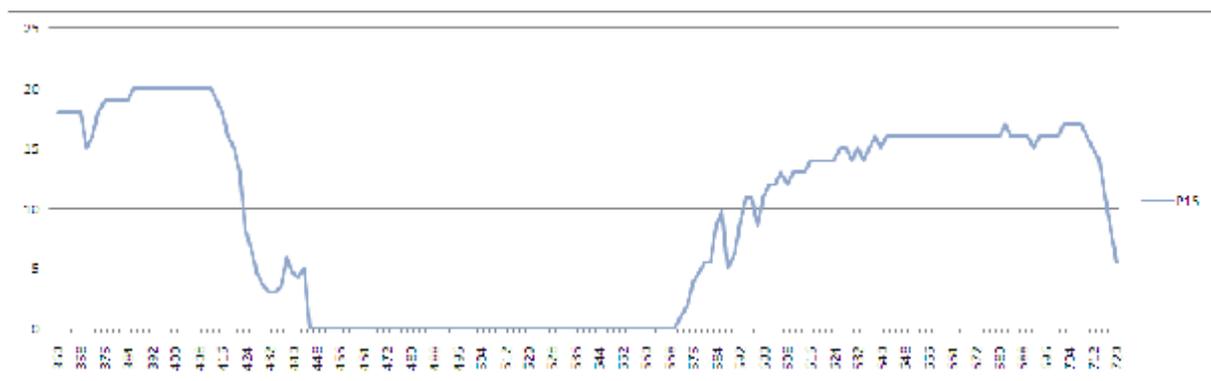


The Precioso alternating pressure mattress replacement was placed on a Profiling Bed Frame with a smooth solid base. The supine position was used for each subject; the FSA (Forced Sensor Array) bed mat was placed directly onto the mattress, both mattress and sensor mat were set up as per manufacturers instructions, calibration of the sensor mat was completed inline with manufacturer's instructions prior to testing.

Two complete cycles (7.5 minutes per cycle), were allowed to run prior to data collection. The subjects continued to lie supine for a further two cycles whilst measurements of the contact pressures were recorded every 2 seconds.

The focus of the evaluation was to observe the low pressures achieved at the highest pressure area (Sacrum). The scans were analysed by focussing on the identified sacral area of high pressure and observing the cycle through from inflated to deflated and return. The pressures being noted down at the various stages of the cycle, with the lowest values being reported on.

Initial findings show that the Precioso MR provides excellent pressure reducing properties



Example 1: A 53Kg female (illustrated above) pressure range on the sacrum 0 – 20mmHg with a mean of 9.5mmHg

Example 2: A 86Kg male pressure range on the sacrum 3.1 – 56mmHg with a mean of 32.3mmHg

Clinical Data – Case One

Introduction

A 66 year old lady suffering from Multiple Sclerosis and Parkinson's Disease had developed a grade 4 pressure ulcer to the right ischael tuberosity 12 weeks prior to the evaluation of the **Precioso Alternating Pressure Mattress Replacement**. The lady was being cared for in a long term nursing care facility and receiving wound care support from the local Community Tissue Viability Team.

Patient's Condition

This lady was bed and chair bound due to her medical condition and assessed as being at very high risk of pressure ulcer development, her BMI score was assessed as acceptable (20-25) despite her nutritional score putting her at risk.

Pressure Relief

She was admitted to the Community Tissue Viability Team caseload due to a grade 4 pressure ulcer, an active mattress replacement (3 cell cycle) was issued, and time sat out of bed limited to 1 – 2 hours with a pressure relieving cushion in place.

12 weeks following admission to the caseload the lady was stepped down to the Precioso Mattress (3 cell cycle) for a duration of 4 weeks with 4 hourly repositioning.

Pressure Ulcer Progress

Prior to product evaluation

Week 1 – Black eschar occluded ulcer measuring 3cm x 2.5cm

Week 2 - Ulcer debrided of eschar and measuring 6cm x 4cm to a depth of 1cm

Week 3 – Ulcer now 3.6cm x 2.8cm with undermining to 1.5cm on the right side with the ulcer showing 10% slough and the remainder granulating.

Week 11 – Ulcer now 2cm x 1.5cm to a depth of 1cm with no undermining.

Week 12 – Stepped down to Precioso

No change to ulcer condition

Week 13 – Ulcer measuring 1.5cm x 0.5cm

Week 15 – Ulcer recorded as measuring 0.5cm x 0.5cm

Week 16 - Ulcer 0.5cm x 0.2cm and 100% granulation.

The lady was then discharged from the caseload back to the care facility.



Ulcer site at end of evaluation period

Patient and Staff Comments

The lady found the mattress very acceptable providing a soft and comfortable support and did not notice the action of the mattress cells filling and emptying.

The lady stated 'thought she was in heaven' and much preferred the Precioso to the previous mattress.

Staff reported that they found the mattress easy to use and clean. It met all their expectations in the management of the pressure ulcer and prevention of further damage.

There were no problems reported throughout the evaluation, with care staff very happy to use the Precioso again.

Clinical Data – Case Two

Introduction

This 57 year old gentleman has been bed bound for 12 months due to suffering from Psoriatic Arthritis. The **Precioso Alternating Pressure Mattress Overlay** was made available for this man as he was suffering from severe body pain and had found other mattress systems uncomfortable and was unable to tolerate them. He had also developed two grade 3 pressure ulcers on the previous support surface; a two cell cycle mattress overlay (AlphaXcell). The gentleman was being cared for in his own home by his wife with District Nurse input each morning.

Patient's Condition

This gentleman's condition and pain prevented him from regular turning side to side, he was therefore nursed supine on a profiling bed frame which allowed him to sit up and change position without physical exertion. Unfortunately this gentleman had gone on to develop a grade 3 pressure ulcer to his heel and his sacrum, superficial damage was also seen along his spinal vertebrae. Assessment scores showed this man to be at very high risk of further tissue damage, he was also nutritionally at risk and underweight. He suffered severe body pain from his condition on movement which he scored 9/10; he also had constant pain from his wounds which he scored 6/10 for severity.

Pressure Relief

He was admitted to the Community Tissue Viability Team caseload due to the pressure damage and to support the District Nurse Team in wound care and prevention of further tissue damage. A key objective in the management of this man was to provide a comfortable support surface that he could tolerate due to his pain, pressure ulcer management was also important but secondary to comfort. Prior to the Precioso three 2 cell cycle systems had been tried (Bi-Wave Carer, Viaclin, AlphaXcell) without success. The Precioso 3 cell cycle overlay was suggested as it provided increased support and effective pressure relief.

Pressure Ulcer Details

At the start of the Precioso evaluation:

The Left Heel pressure ulcer was assessed as;
Measuring 5cm x 5.5cm with 20% slough, 20% deep tissue damage.

The Sacral pressure ulcer was assessed as;
Grade 3 measuring 2.5cm x 2.4cm occluded by 25% slough, 25% Escar with the remaining 50% of the wound dull granulation tissue.

Appropriate wound dressings were in use along with Flamazine Cream.



Sacral Pressure Ulcer at 12 weeks into evaluation.

Pressure Ulcer Progress

Progress during the 12 weeks has been monitored by the District Nurse Team and the Tissue Viability Team. Throughout this time all wounds have showed improvement. The Heel and Vertebral ulcers have now healed, whilst the sacral ulcer continues to granulate and reduce in depth.

Patient and Staff Comments

The gentleman found the mattress very acceptable providing a firm and comfortable support and did not notice the action of the mattress cells filling and emptying. He stated that 'It is the best mattress he has had and scores it 12 out of 10!'

Staff reported that they found the mattress very easy to use and clean. It met all their expectations in the management of the pressure ulcer and prevention of further damage.

There were no problems reported throughout the evaluation, with staff very happy to use the Precioso again.

The Precioso remains in place on evaluation to monitor wound progress and maintain the gentleman's comfort

Clinical Data – Case Three

Introduction

This 79 year old lady suffering from Dementia and End Stage Parkinson's Disease had developed four Sacral pressure ulcers prior to the evaluation of the **Precioso Alternating Pressure Mattress Replacement**. The lady was being cared for in a long term nursing care facility and receiving wound care support from the local Community Tissue Viability Team.

Patient's Condition

This lady was bed and chair bound due to her medical condition and assessed as being at very high risk of pressure ulcer development, she was assessed as underweight with her nutritional score putting her at risk. She was also incontinent of urine and faeces, was confused and unable to provide any self-care.

Pressure Relief

She was admitted to the Community Tissue Viability Team caseload due to the pressure ulcer damage, an active mattress replacement (3 cell cycle) was issued, she had previously been nursed on a 2 cell cycle overlay (Harvest Healthcare). The lady was bed bound and did not sit out in a chair.

The Precioso MR was put in place due to the lack of progress in the healing of the sacral pressure ulcer.

Pressure Ulcer Details

Prior to product evaluation

Pressure Ulcer 1 – Grade 2 measuring 1cm x 0.8cm

Pressure Ulcer 2 – Grade 2 measuring 0.5cm x 0.3cm

Pressure Ulcer 3 – Grade 3 measuring 3.6cm x 1, with 30% necrosis on wound bed

Pressure Ulcer 4 – Grade 3 measuring 5.5cm x 1.5cm, with 30% necrosis on wound bed.

All of the pressure ulcers had 20% - 30% slough.

Photographic documentation not available as appropriate consent could not be obtained.

Pressure Ulcer Progress

Week 2

Pressure ulcers 1 & 2 no change

Pressure ulcer 3 – measuring 3.5cm x 0.8

Pressure ulcer 4 – measuring 4.3cm x 1.5cm

Week 5

Pressure ulcers 1 healed

Pressure ulcer 2 – measuring 1cm x 1cm

Pressure ulcer 3 – measuring 2cm x 1.2cm

Pressure ulcer 4 – measuring 3cm x 1cm

Week 10

Pressure ulcer 2 – healed

Pressure ulcer 3 – measuring 1cm x 0.8cm

Pressure ulcer 4 – measuring 1.3cm x 1cm

A hydrocolloid dressing was used on all wounds throughout

Staff Comments

Staff reported that they found the mattress very easy to use and clean. It met all their expectations in the management of the pressure ulcer and prevention of further damage.

There were no problems reported throughout the evaluation, with care staff very happy to use the Precioso again.

The Precioso remains in place on evaluation to monitor wound progress to healing of all pressure ulcers

Clinical Data – Case Four

Introduction

This 80 year old lady suffering from Dementia was admitted to the orthopaedic ward of a general hospital following a fracture to the left neck of femur and left wrist. The lady had no pressure ulcer damage prior to the **Precioso Alternating Pressure Mattress Overlay** being used.

Patient's Condition

This underweight lady was bed bound due to her medical condition and assessed as being at very high risk of pressure ulcer development. She was also incontinent of urine.

Pressure Relief

She was admitted to the ward, a 2 cell cycle mattress overlay was issued with repositioning every 4 hours. 10 days after admission she was allocated the Precioso mattress overlay and continued to be repositioned 4 hourly. The base mattress used was a standard foam mattress.

Patient and Staff Comments

The patient found the mattress acceptable and had not noticed the movement of the mattress cells.

Staff reported that they found the mattress easy to use and clean. It met all their expectations in the prevention of tissue damage.

Staff also reported that they found the 'Transport Mode' aided in the care of this patient.

There were no problems reported throughout the evaluation, with care staff very happy to use the Precioso again.

Summary

This report has reported & reviewed the results of four patient case studies recently carried out in various UK healthcare facilities and interface pressure measurements performed in the laboratory by PSP Technology Staff.

This data represents the initial output from an ongoing programme of Europe wide activity aimed at producing a significant library of data to support the performance of the Precioso.

The case studies indicate that the clinical outcomes achievable with this product & its acceptability to both patients & staff will be at a high level when compared to other products in this price range.

The laboratory interface pressure results also show excellent levels of pressure removal but need to be repeated with greater number of subjects with varying BMIs.