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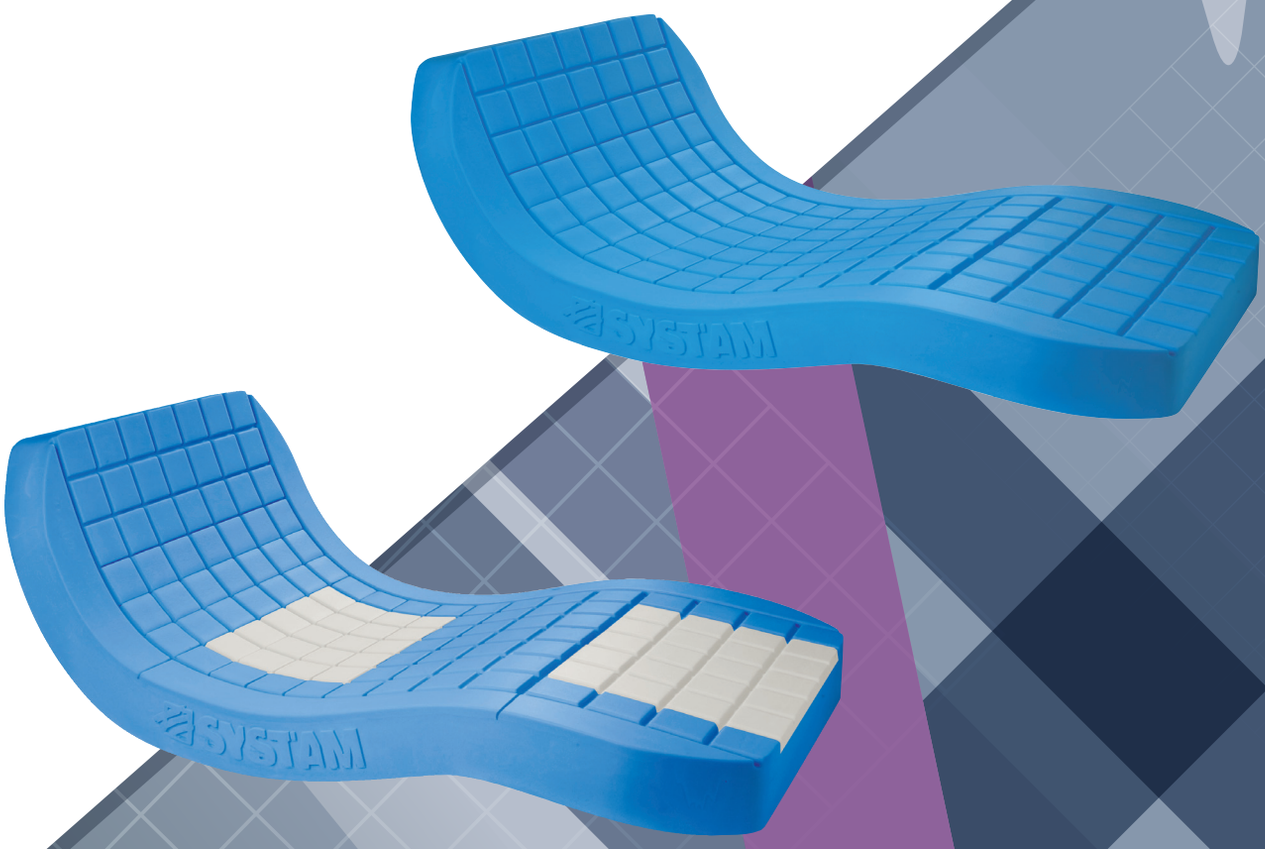
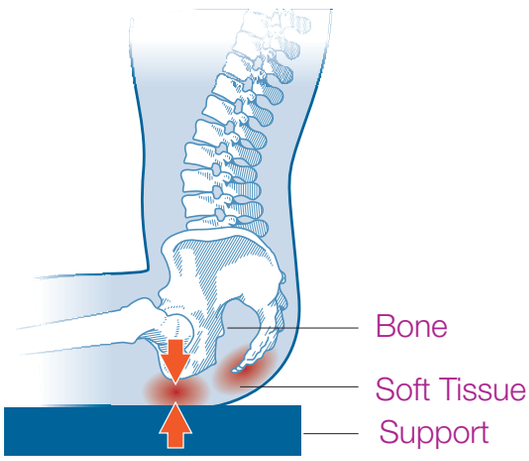
Harvest Healthcare Clinical Evidence

P161M - Viscoflex Mattress
P161MOE - Viscoflex Evolutive Mattress



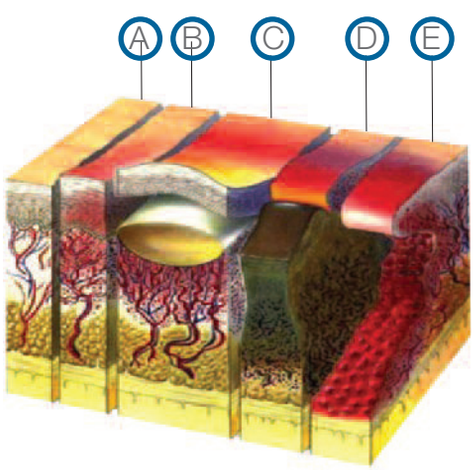
PRESSURE ULCERS AN INTRODUCTION

Definition



Pressure Ulcer:
Pressure ulcers (also known as pressure sores or bedsores) are injuries to the skin and underlying tissue, primarily caused by prolonged pressure on the skin.

Pressure Ulcer Classification System According to EPUAP



A = Stage 0 Skin in good state

B = Stage 1 Non-blanchable erythema
Intact skin with non-blanchable redness of a localised area usually over a bony prominence

C = Stage 2 Partial loss of thickness
Partial thickness loss of he skin presenting as a shallow open ulcer with a red pink wound bed

D = Stage 3 Full loss of skin thickness
Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle are not exposed

E = Stage 4 Full thickness tissue loss
Full thickness tissue loss with exposed bone, tendon or muscle

FIGURES ABOUT PRESSURE ULCERS

CLINICAL EVIDENCE

Frequency

- 700,000 people are affected by pressure ulcers each year
- On average, 2,000 pressure ulcers were newly acquired each month within the NHS in England
- The average age of these patients (in hospital): 76 Years.

Cost

- Pressure ulcers cost the NHS £3.8 million every day.
- 5 patients with pressure ulcer require the same budget as a 28 beds hospital service.

Life Expectancy

- Pressure ulcers in older patients are associated with a fivefold increase in mortality
- In hospital mortality of those with pressure ulcers is 25-33%

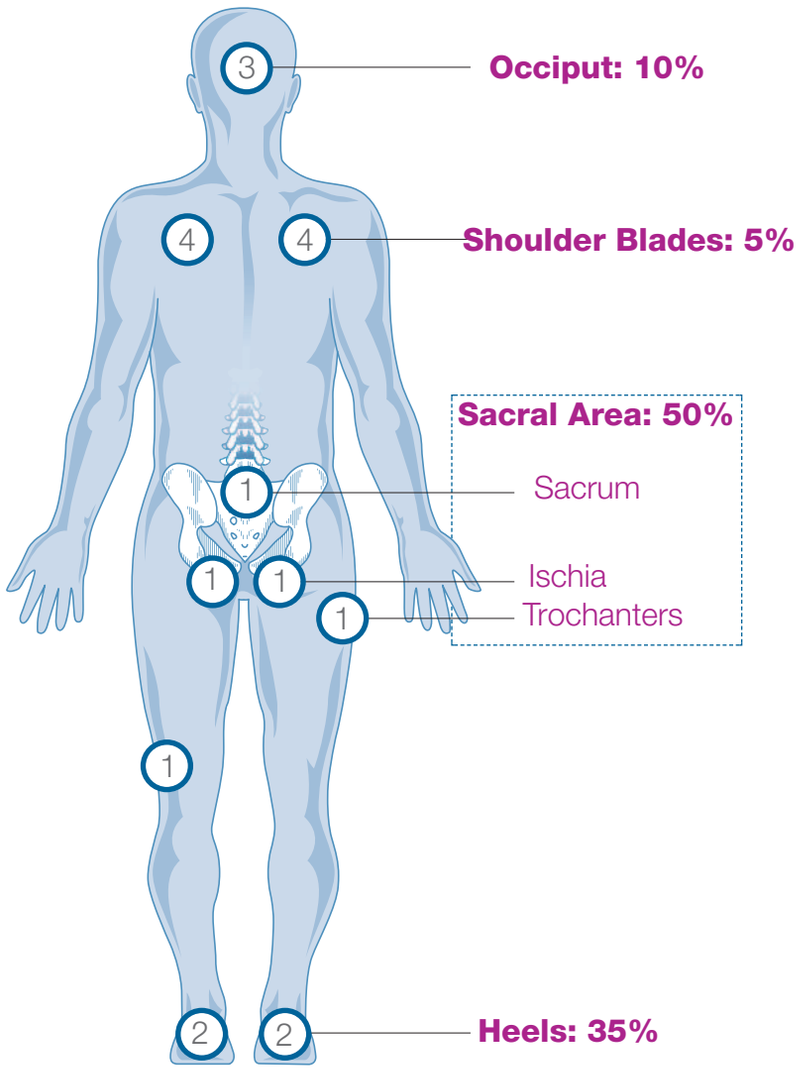
Pressure Sore Locations

1 **Primary zone:** the Sacro-Gluteal zone (50% of ulcers)

2 **Second zone:** The heels (35%)

3 **Third zone:** the occiput/back of the head (10%)

4 **Fourth zone:** the shoulder blades (5%)

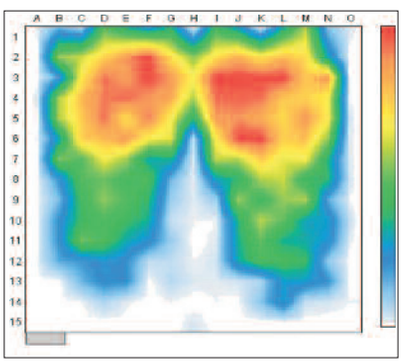


CLINICAL EVIDENCE 4

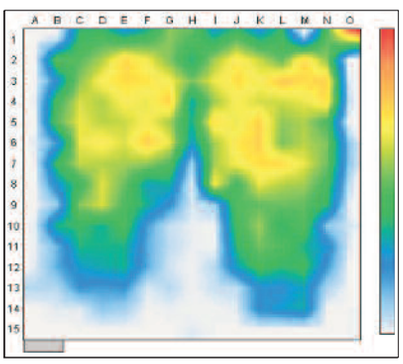
PRESSURE RELIEVING SUPPORTS

Role of Pressure Ulcer Prevention Supports

Areas at high risk of developing pressure ulcers are areas where pressure on the tissue is maximised between support and bones.
Pressure sore prevention supports reduce pressures through enlarging the support surface at contact points. The pressures transfer toward areas at lower risk enabling the reduction of pressures and therefore reducing the risk of pressure ulcers.



Without Support



With Support

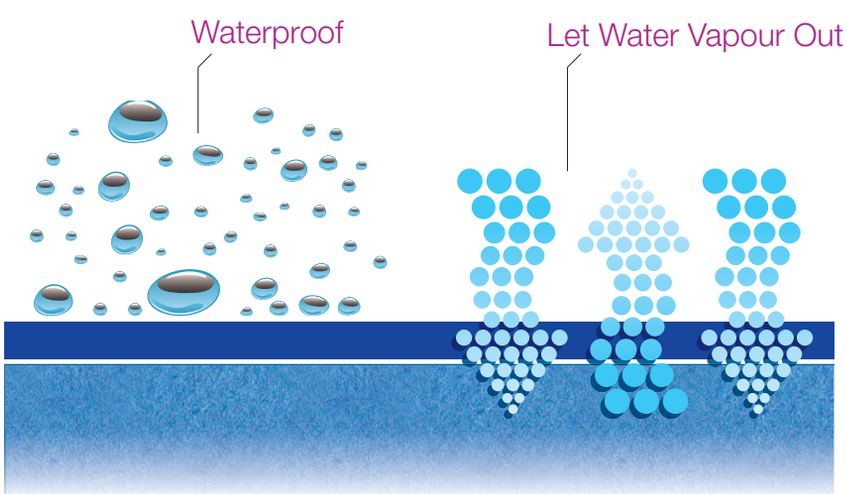
The pressures transfer from areas at high risk toward areas at lower risk through:

- The softness and elasticity of materials;
- The increase of the contact surface with the support;
- The reduction of frictions and shear forces.

Reduction of Moisture

Humidity and he softening and breaking down of skin represent major factors in developing pressure ulcers. The role of pressure ulcer prevention supports is to allow optimal ventilation and aeration.
This can be done:

- Through the breathability of the protecting cover;
- by the ventilation of the support.



P161M - VISCOFLEX

CLINICAL EVIDENCE 5

CLINICAL EVIDENCE

Materials

Visco Foam

High Resilience Foam

Hypoallergenic, waterproof, two-way stretch cover with non-slip base.

Moulded Viscoelastic Foam with Memory Effect

- Precise moulding of the body and increase of the body surface in contact with the mattress
- Better pressure distribution: reduction of pressures on areas at high risk and facilitates blood circulation
- Improved comfort and stability of the patient
- Skin effect obtained through the moulding process: protection of the foam against tears or crumbling
- Very high density to prevent deformation and sagging effects and prolong the life of the mattress.

LOW | MED | HIGH | V HIGH

PRESSURE RELIEF RISK

Maximum Patient Weight

P161MFPMHF	20 Stone / 130kg
P616MFPMHF120	42 Stone / 270kg

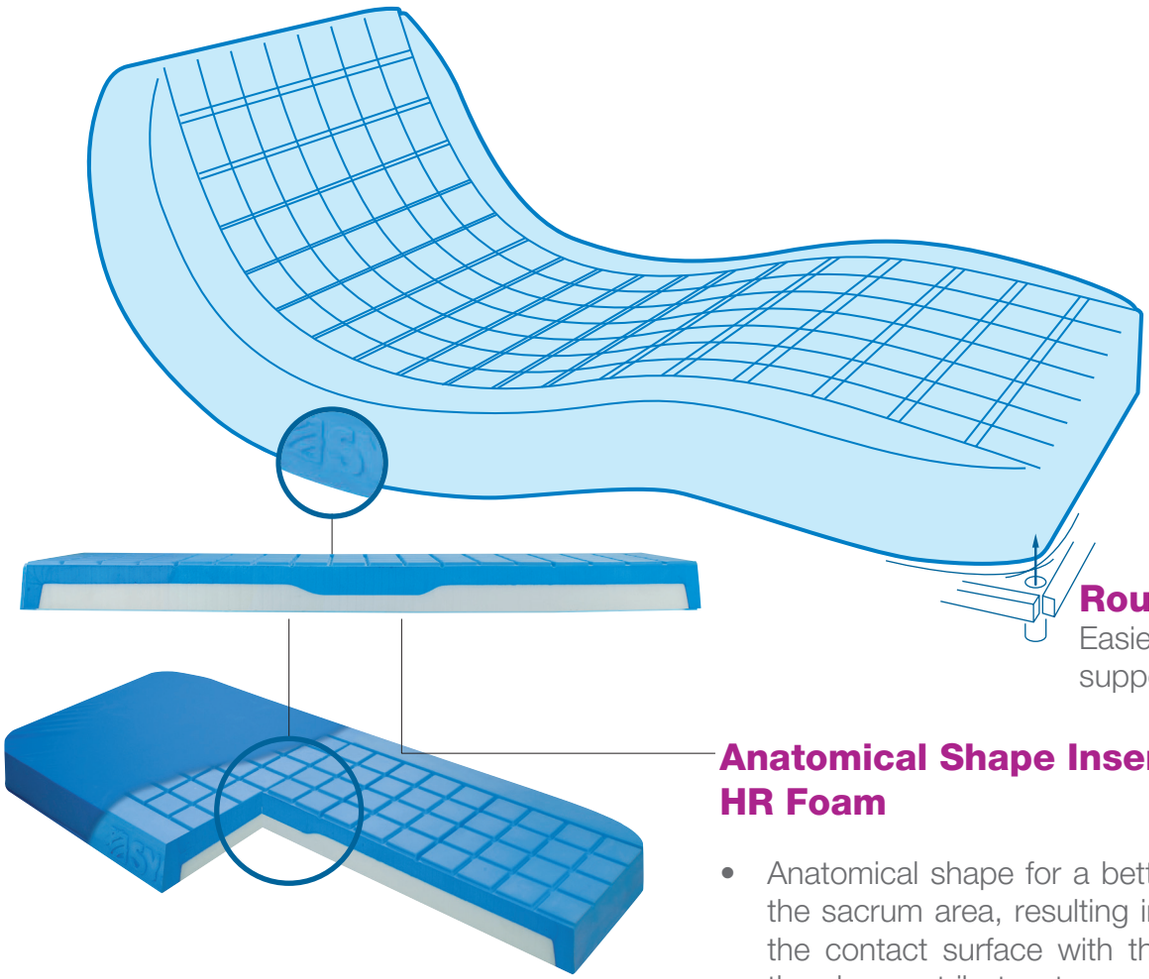
Delivered Compressed and Rolled

2.5 times less volume

Dimensions

P161MFPMHF	1990 x 860 x 140mm to suit 2000 x 900mm bed
P616MFPMHF120	1970 x 1150 x 140mm to suit 2000 x 1200mm bed

P161M - VISCOFLEX
P161MOE - VISCOFLEX EVOLUTIVE



Rounded Corners

Easier installation of supports in bed base

Anatomical Shape Insert Made of HR Foam

- Anatomical shape for a better immersion of the sacrum area, resulting in an increase of the contact surface with the mattress and thereby contributes to a reduction in high pressure values;
- Reinforced prevention against pressure ulcer on the sacrum region.

Anti-punching Insert Made of High Resilience Foam

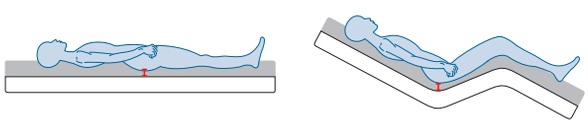
Formed by moulding, this multi-material foam provides perfect adhesion that lasts:

- It does not split
- It does not require glues or solvents
- Perfect adhesion of the 2 materials

Made of high resilience foam (HR) with high density (40kg/m3) to prevent sagging.

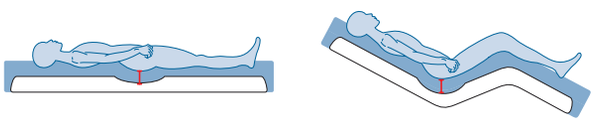
Regular Viscoelastic Foam Mattress

The viscoelastic foam is strongly compressed in the area at risk, especially when profiled.



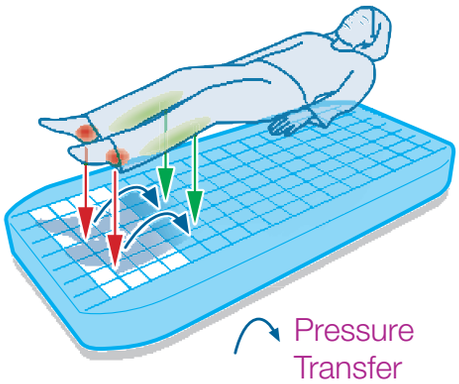
Viscoflex / Viscoflex Evolutive Mattress

As the insert follows the body shape in the sacrum area, the thickness of the viscoelastic foam is maximised to foster better prevention in areas at risk.

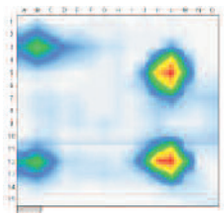


P161MFE - VISCOFLEX EVOLUTIVE

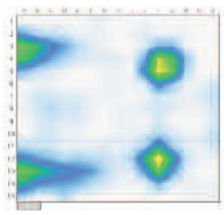
CLINICAL EVIDENCE



Pressure Transfer

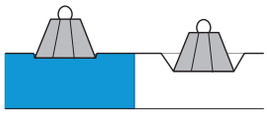


Viscoelastic Foam Mattress



Viscoflex Evolutive

Performance of the Multibearing concept



The multibearing surface enables a better pressure distribution through the transfer of support from areas with low bearing capacity toward areas with high bearing capacity.

White Area:

Areas with low bearing capacity (softer foam) giving an increased prevention on areas at risk (heels).

Blue Areas

Areas with high bearing capacity (firmer foam) for parts of the body showing a lower level of risk.

Maximum Patient Weight

P161MFEPMHF	20 Stone / 130kg

Dimensions

P161MFEPMHF	2000 x 900 x 140mm to suit 2000 x 900mm bed

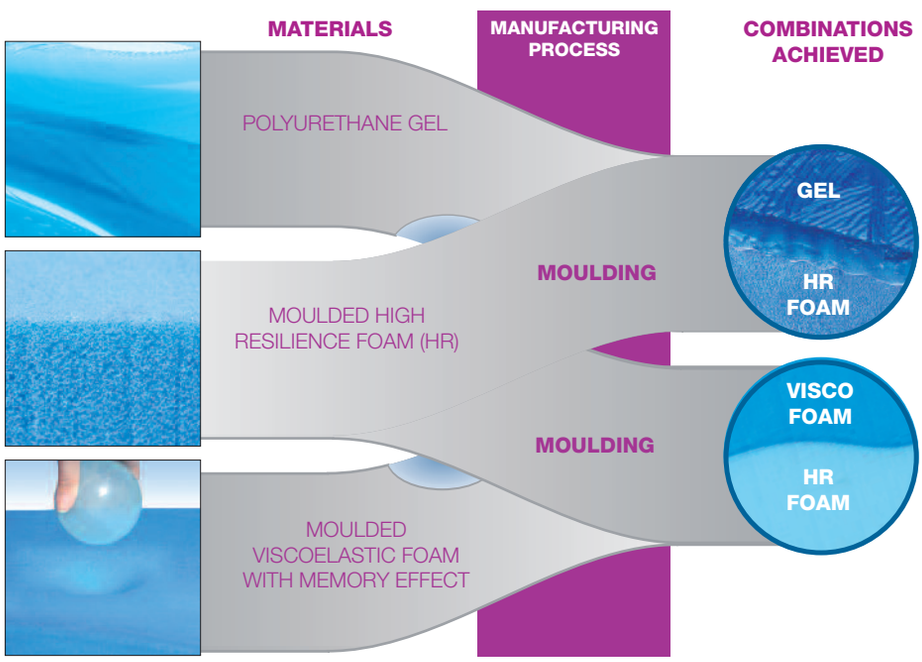
MATERIALS

Moulded High Resilience Foam (HR)

The high resiliency foam is moulded and of high density (40 kg/m3, medical grade) offering great comfort, flexibility and durability.
Its physical features (elasticity, weight bearing capacity) ensure great resistance against sagging and therefore avoid bottoming effects.

Moulding of Materials

The addition of a high-resiliency foam base improves the pressure reduction through an increased contact surface and a greater immersion of bony protuberances. The comfort and the stability of the patient are optimised as well. Moulded together, these 2 layers of materials are completely bonded.

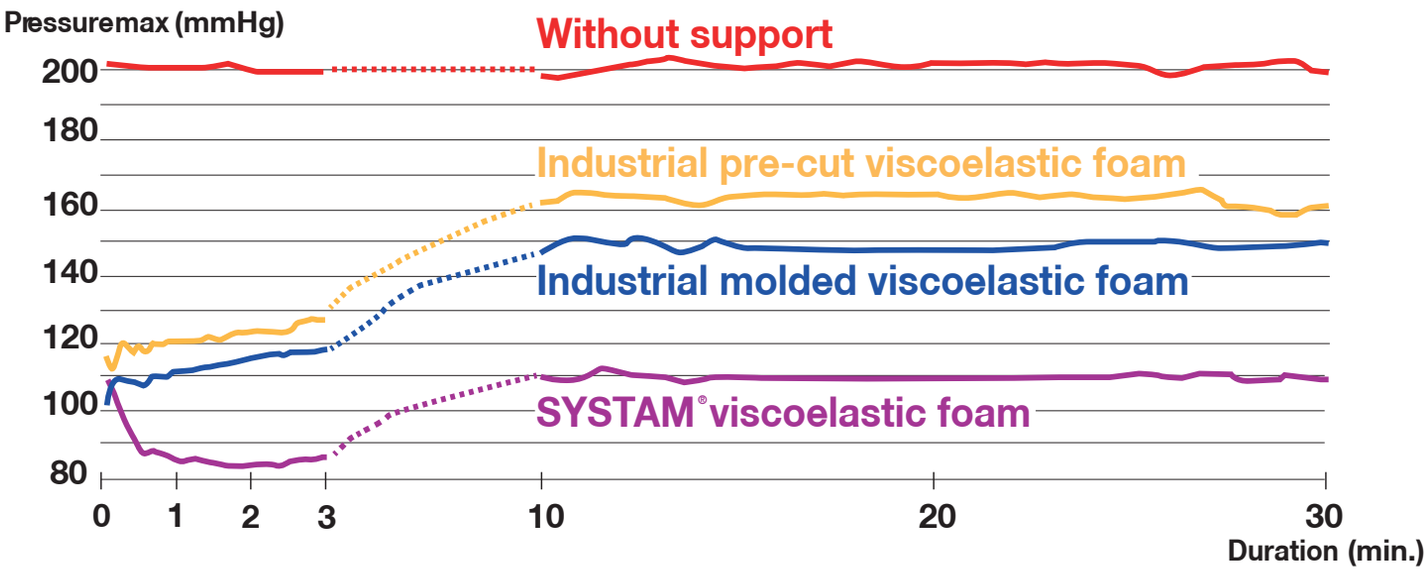


Moulding of Inserts and Multi-Materials

The insert made of high resilience foam (HR) avoids bottoming out (especially in the sacrum area), sources of hyper-pressures and high risk of skin outbreaks. It has mechanical resistance features and a spring effect.

MATERIALS

Measurement and Progression of Pressure Distribution Over Time



From 0 to 3 minutes : Relaxation time of the viscoelastic foams.

From 3 to 10 minutes : Stabilisation time of the viscoelastic foams

The max. pressures are not relevant because the foams are not yet stabilised.

After 10 minutes : Final compression stabilised.

Conclusion

The graph clearly shows that the viscoelastic foam used in the Viscoflex mattress offers a higher level of pressure relief than other viscoelastic foams . It is also able to maintain its compression ratio preventing bottoming out.

CLINICAL EVIDENCE

Clinical Trials

Two clinical trials have been carried out on the Viscoflex mattress. The full reports are available to read or a summary can be found below.

Villeneuve-sur-Lot Hospital

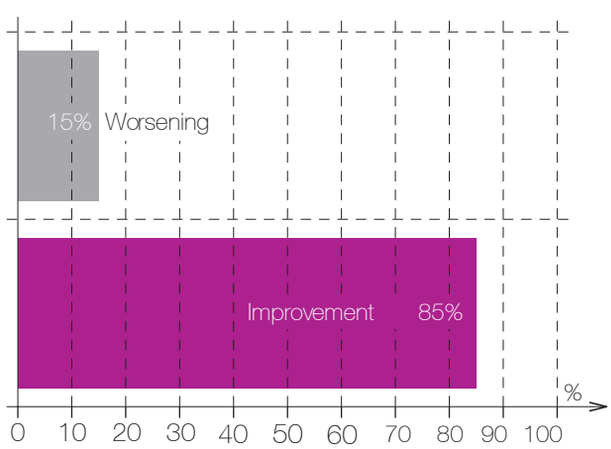
Introduction

A clinical trial with the Viscoflex Mattress was carried out at Villenueve-sur-Lot Hospital with 20 patients.
The average age of the patients was 88.7 years with a minimum of 79 years and a maximum of 94 years. The average weight was 54.9kg, the minimum weight was 39kg and the maximum was 83kg. 40% were underweight, 40% had a normal BMI, 10% were overweight and 10% were obese.
45% of the patients had a past history of pressure ulcers and 40% had an existing pressure ulcer. 20% of the patients were at high risk of getting a pressure ulcer and 80% were at very high risk.

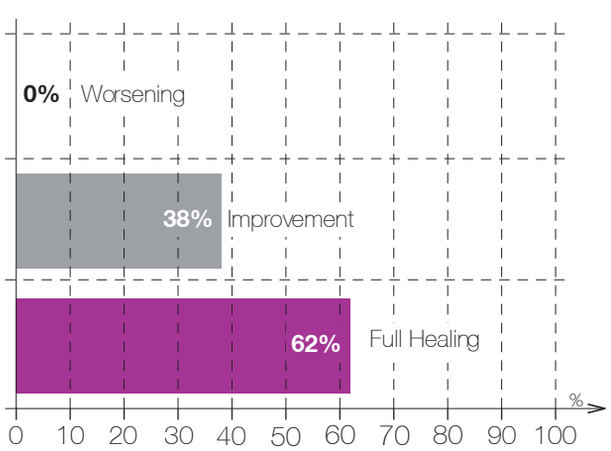
Results

Notable improvement of the skin was seen in 85% of all patients. Of those using the mattress for prevention of pressure ulcers, there was 75% stabilisation of the skin. In patients using the mattress for treatment of pressure ulcers 62% saw full healing and 38% saw improvement. 95% rated the comfort as good or very good and 85% wanted to retain the mattress.

Change in Skin Condition of All Patients



Change in Skin Condition of Those Needing Treatment



Cahors Hospital

Introduction

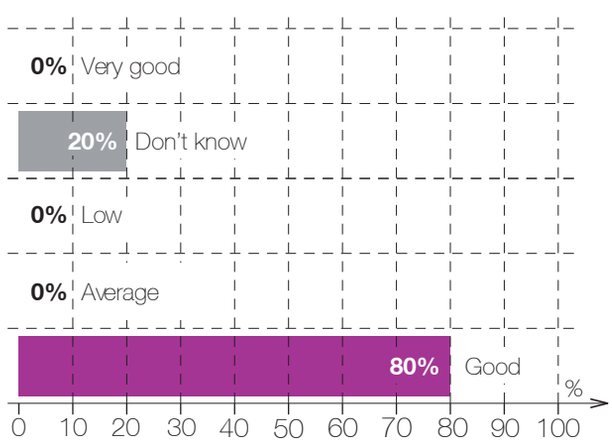
A clinical trial with the Viscoflex Mattress was carried out at Cahors Hospital with 20 patients. The average age of the patients was 82.3 years with a minimum of 56 years and a maximum of 96 years. The average weight was 59.9kg, the minimum weight was 43kg and the maximum was 92kg. 30% were underweight, 60% had a normal BMI and 10% were obese.
35% of the patients had a past history of pressure ulcers and 30% had an existing pressure ulcer. 45% of the patients were at high risk of getting a pressure ulcer and 55% were at very high risk.

Results

40% of patients had pressure ulcers on their sacrum/ischium areas, of these 75% saw improvement/full healing. 60% of patients had pressure ulcers on their heels/ankles, of these 50% saw improvement/full healing and 17% retained a stable condition. 80% rated the comfort as good.

	Pre-existing Pressure Ulcer	Worsening	Improvement/ Full Healing	Stable Condition
Sacrum/ischiums	40%	25%	75%	0%
Heels/ankles	60%	33%	50%	17%

Feeling of Comfort



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