

MEDITEC PNEU-AIR

Evaluation of dynamic
mattresses: Evidence 1

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1 Introduction

Alternating Pressure Air Mattresses (APAMs) are designed to prevent or treat pressure ulcers by a different principle from conventional support surfaces. Conventional “pressure reducing” support surfaces seek to achieve lower values of maximal interface pressures on the skin, by means of even distribution of pressure over the supported area. The aim is thus to bring interface pressures down to a continuously tolerable level. In contrast to this approach, APAMs are designed to provide cyclic loading to the skin, so that each area of skin experiences pressure only intermittently. Correct functioning of the APAM therefore relies on pressures **not** being evenly distributed. Pressure differentials between adjacent regions must be created to provide cyclic loading. For this reason, evaluation of APAMs cannot adopt the approach (commonly used for conventional support surfaces) of simply measuring maximum values of interface pressure at a given moment, but must characterise the time-varying behaviour.

Performance measures have been proposed^{1, 2}, in the scientific literature for quantifying the “pressure relief” behaviour of APAM systems. These measures are based on the proportion of the cycle time during which the skin interface pressure at a given location is maintained below a threshold value. The threshold value is arbitrary, and has variously been set at 10mmHg, 20mmHg, and 30mmHg.

It has also been shown² that the pressure profile can be improved by adjusting the air pressure according to the body mass of the bed occupant.

More recently, concerns have arisen over the use of APAM systems when the backrest of the bed is elevated, or in the “gatch” position, where the backrest is elevated and the thigh section is also raised to resist sliding towards the foot of the bed. As mentioned previously, APAMS rely for their effective operation on the maintenance of pressure differentials between adjacent areas of skin. If pressure differentials are not maintained, alternating behaviour is lost, and the skin does not experience an off-loaded part of the cycle where reperfusion may take place. In the backrest-elevated or gatched positions, air cells are often squeezed together, potentially causing equalisation of pressure between cells. Questions have been raised as to which geometries and arrangements of cells will be most susceptible to this problem.

It is thought that deep-cell systems will be more susceptible to this problem than shallower cell systems such as alternating overlays.



2 Aims

The aim of this study is to examine the performance of the Meditec Pneu-air Alternating Pressure Replacement System, set up according to the prescribed settings. 10 subjects of different body weights are used. Evaluation is based on a pressure- and time-based performance index to be defined in the “methods” section. The Pneu-air product is compared with the Huntleigh Alpha XCell, and the Talley Quattro each of which is an alternating overlay system, used in conjunction with a pressure reducing mattress.



3 Methods

APAM Performance Index (API)

Understanding of the aetiology of pressure ulcers is as yet at a very simplistic stage. Gross assumptions have therefore been made in deriving a performance index, and it must be noted that performance measured in this way can not necessarily be extrapolated to clinical outcome. However, randomised controlled trials to examine clinical outcome are almost prohibitively large undertakings for this category of product, and therefore simple efficacy measures are appropriate as long as the limitations of the study are understood.

The assumptions made in using this performance index are as follows:

- 1) It is unimportant how high the interface pressure is on an area of tissue during the loaded part of the cycle. We assume for these purposes that occlusion to blood is total while loaded, and that higher loading will not produce greater occlusion.
- 2) During the “unloaded” part of the cycle, longer duration at lower pressure is better.
- 3) No attempt is made to accommodate second-order effects such as reperfusion injury in the index.
- 4) The performance of the system as a whole is determined by that region on the pressure map showing the worst performance throughout the cycle

Considering a hypothetical loading cycle on a single body location as shown in figure 1: Interface pressure hypothetically measured in mmHg is plotted against time in minutes, giving an idealised sinusoidal waveform. We can see from this graph the cycle time of the pressure profile, as illustrated. 3 threshold levels, 10mmHg, 20mmHg, and 30mmHg are shown on the graph, and we can see the regions of the loading cycle where the pressure falls below these thresholds.

One option for creating an index of performance is to cite the time duration during which the pressure is measured to be lower than a particular threshold, eg 30mmHg. However, this approach fails to identify benefits of dropping far below the threshold value, as opposed to dropping just below the threshold value. For example, the profile shown in figure 2, having a similar duration below the threshold, would be seen to perform as well as that in figure 1, which falls well below the threshold for much of that duration.

One means of addressing this shortcoming is to cite durations at several different thresholds, and summing them or weighting them to give a compound value. Thus, values would be cited for time below 30mmHg, time below 20mmHg, and time below 10mmHg.



Alternatively, a compound value may be calculated by taking the area of the loading cycle beneath the threshold value, shown as the shaded area A30 in the figures. This area takes into account both the duration (width of the shape) and the degree of pressure reduction below the threshold (height of the shape). These are (expressed in mmHg x minutes) may then be divided by the cycle time, to give a value of pressure relief below threshold expressed in mmHg.

So we define API :

$$\text{API (mmHg)} = \frac{\int_{P=30}^{P=30} (\text{pressure} - 30) dt}{T_c}$$

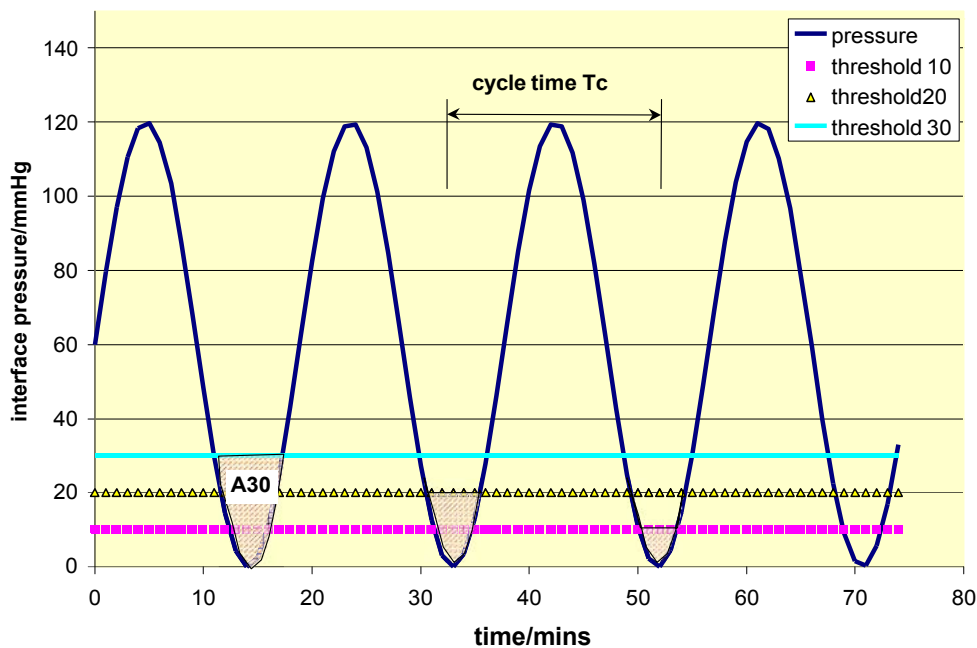


Figure 1: Hypothetical loading cycle at a single body location



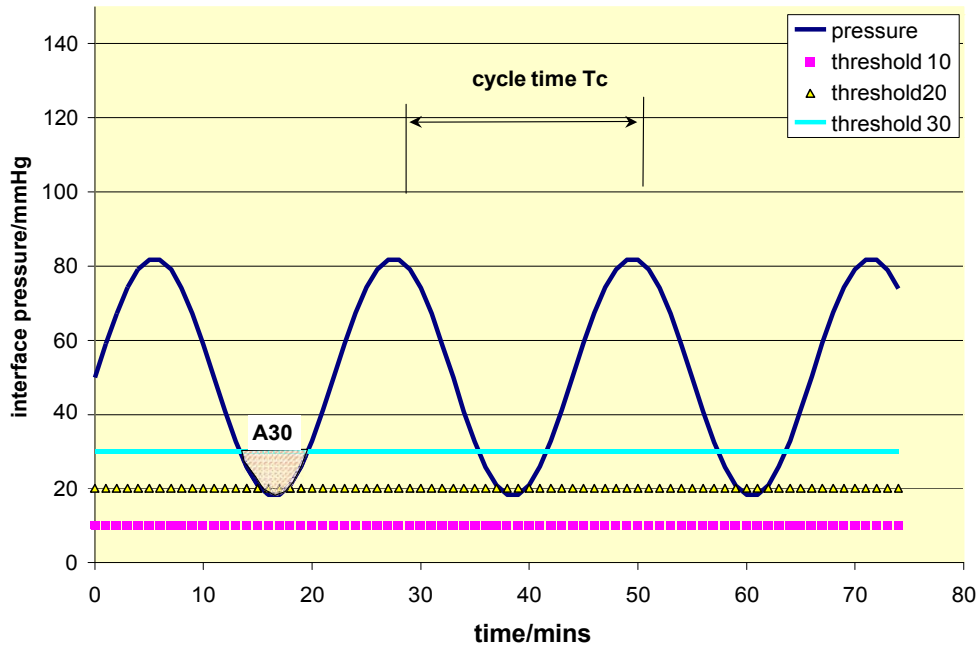


Figure 2: Alternative hypothetical loading cycle at same body location



Instrumentation

An Xsensor pressure mapping array was used for this study, on the basis that it is relatively flexible compared to most pressure mapping systems. One concern with pressure mappers is that the presence of the mat in the system will introduce mechanical artefacts to the system being measured, and these concerns are mitigated somewhat by the flexibility of the mat.

Perfusion Impulse Index

Blood content in the skin is measured non-invasively using Tissue reflectance spectroscopy (TRS). This has distinct advantages over laser Doppler in a dynamic situation, as it is far less prone to inaccuracies caused by movement artefact. TRS consists of white light shone into the skin, and then the backscattered light collected and analysed. This is done using a thin probe (1mm), illuminated and light collected by fine fibre-optics. The spectrum of backscattered light quantitatively reveals blood content in the skin. By this means, fluctuations in blood content associated with blanching, reflow, and hyperaemia during cyclic loading are monitored in real time.

For this study, we consider an index of performance, the Perfusion Impulse Index %, which is derived as follows:

For each subject, a baseline level of blood content in the skin is established. This we define as 100% baseline level for that subject. For this subject, the plot of skin blood content against time is relative to this level.

For each subject, a “zero” or total blanch level of signal can also be established.

It is now possible to integrate over the duration of the test the skin blood content as a percentage of baseline-zero, giving an average % skin blood content.

A level in excess of 100% at any one time indicates a reactive hyperaemic response following loading. This response is interpreted in different ways by different researchers. The hyperaemic response is possibly desirable following periods of ischaemia to redress metabolic deficits in the skin. However, as such it is an indicator that an ischaemic interval has taken place, and so is per se not a good sign. Therefore, the convention we adopt for this study in calculating the **Perfusion Impulse Index** is to truncate the values at 100% (treating any value in excess of 100% as =100%)

So:

PI = Sum (all values % (baseline-zero) maximum 100)/ number of values.



Subjects

10 healthy experimental subjects were chosen, each giving informed consent.

Table 1: Subject group anthropometrics:

ID code	Age	Height	Weight
ID01	60	1.43m	62 kg
ID02	63	1.66m	60kg
ID03	27	1.62m	90kg
ID04	45	1.81 m	71 kg
ID05	39	1.76m	63 kg
ID06	36	1.65	54 kg
ID07	29	1.67m	62 kg
ID08	27	1.61m	46 kg
ID09	43	1.84m	88 kg
ID10	10	1.84m	31 kg



Procedure: Comparison with Alpha Xcell and Quattro when flat

- 1) Each APAM was set up on the bed as with a flat sheet, and nominally inflated. In the case of the overlay surfaces, a pressure-reducing mattress (MSS Softform) was placed between the bed and the APAM.
- 2) The Xsensor (calibrated daily) was placed on the mattress
- 3) A TRS sensor was taped to the subjects skin on the sacrum.
- 4) A baseline reading of skin blood content (IHB) was taken.
- 5) A total skin blanch was effected to obtain a “biological” zero for the IHB measurement.
- 6) The subject lay supine on the mattress with the Xsensor array aligned with the pelvic area, showing the lower back to the upper thigh.
- 7) Pressure was set as instructed by the manufacturer according to body weight.
- 8) After 5 equilibration cycles, pressure was mapped over 3 pressure cycles.
- 9) Simultaneously, skin blood content was monitored, and scaled to the baseline level.
- 10) Average API was calculated over the 3 cycles, for every point on the map.
- 11) The point with the lowest value of API (averaged over 3 cycles) was recorded.
- 12) This was repeated 3 times to give a median and range value for each subject.
- 13) This was repeated for all 10 subjects



4 Results: dynamic pressure distribution

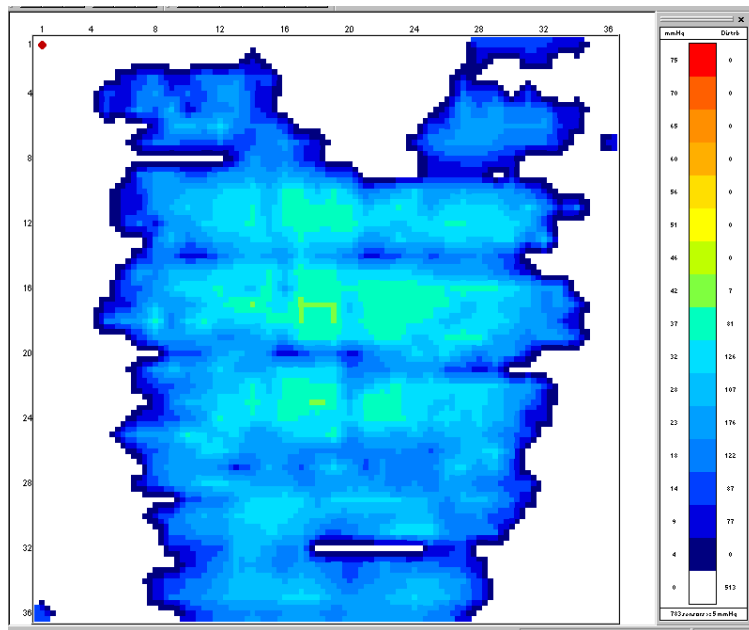


Figure 3A Pneu-air, beginning cycle, subject 1

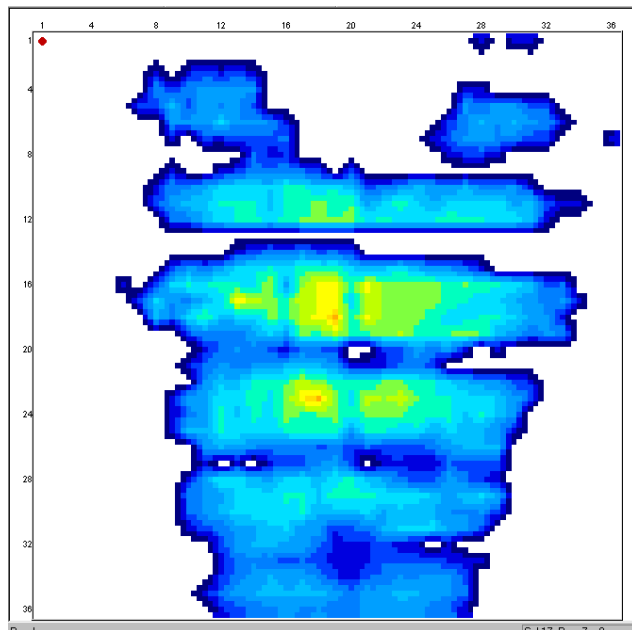


Figure 3B Pneu-air, mid cycle, subject 1

Figure 3 shows example snapshots of the pressure distribution at different times throughout the cycle, with the bed in the flat position, for a single subject on the Pneu-air. Pressures are not excessively high anywhere on the distribution, and movement of the loci of highest pressure is seen throughout the cycle.



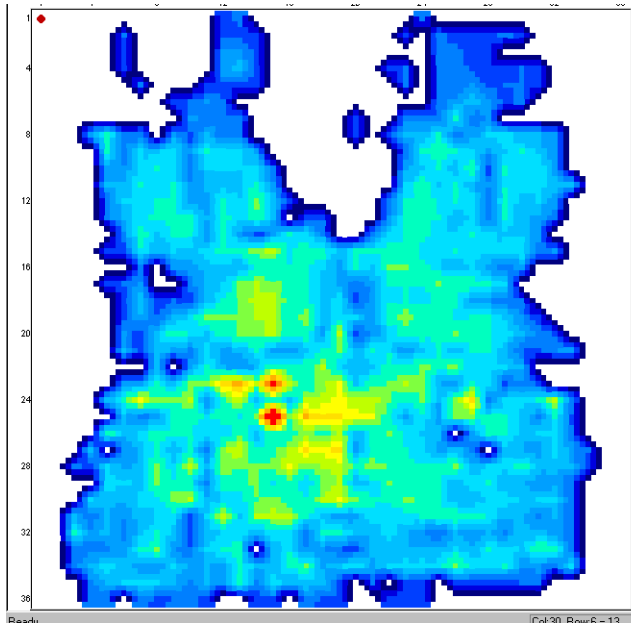


Figure 4A: Alpha XCell, Subject 1 , beginning cycle

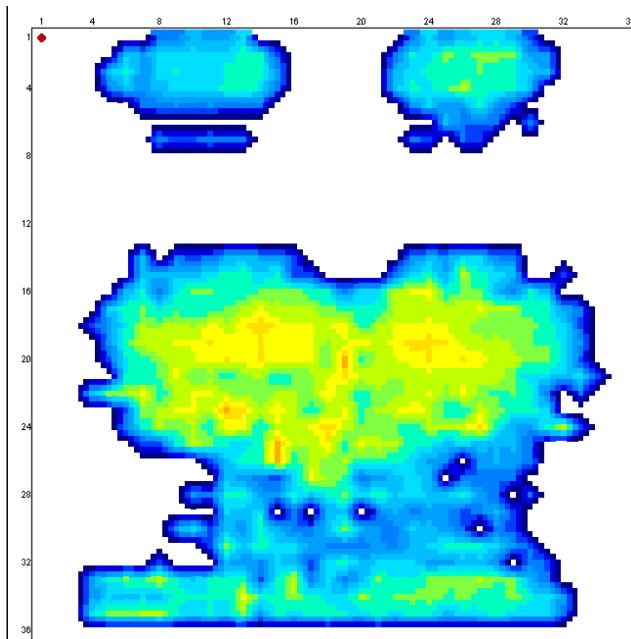


Figure 4B: Alpha Xcell, Subject 1 , mid cycle

Similarly, figure 4 shows movement of the high pressure loci on the Alpha Xcell surface.



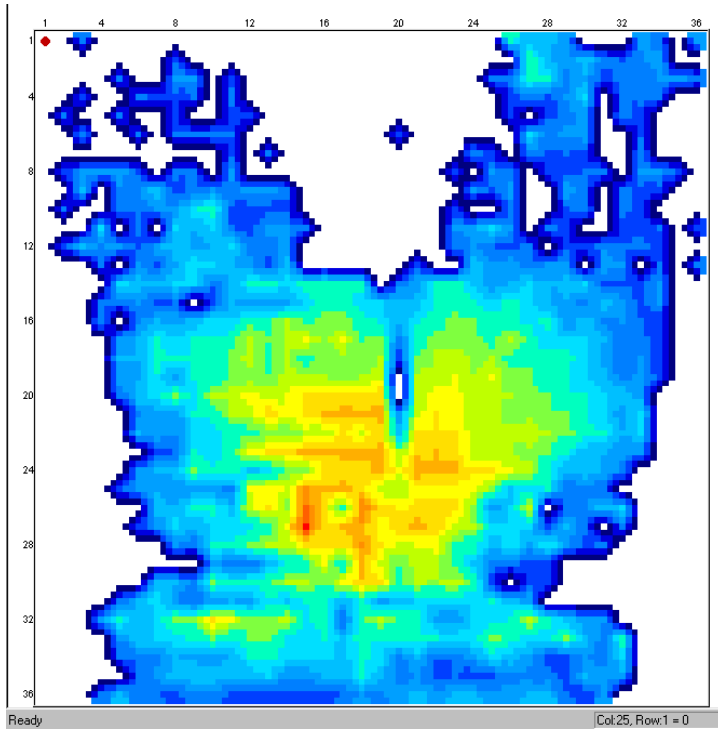


Figure 5A: Talley Quattro, Subject 1 , beginning cycle

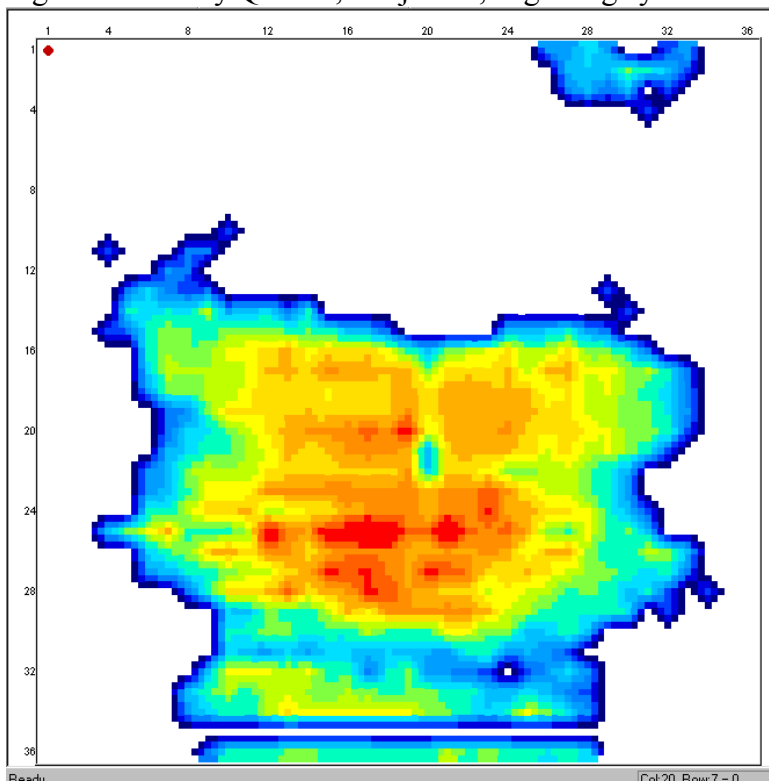


Figure 5B: Talley Quattro, Subject 1 , mid cycle

Figure 5 shows movement of the high pressure loci on the Alpha Xcell surface.



A trace of a similar nature to those shown in figures 1 & 2 can be drawn for a single sensor cell, and the API for that cell calculated. Similarly, API can be calculated for any cell on the map.

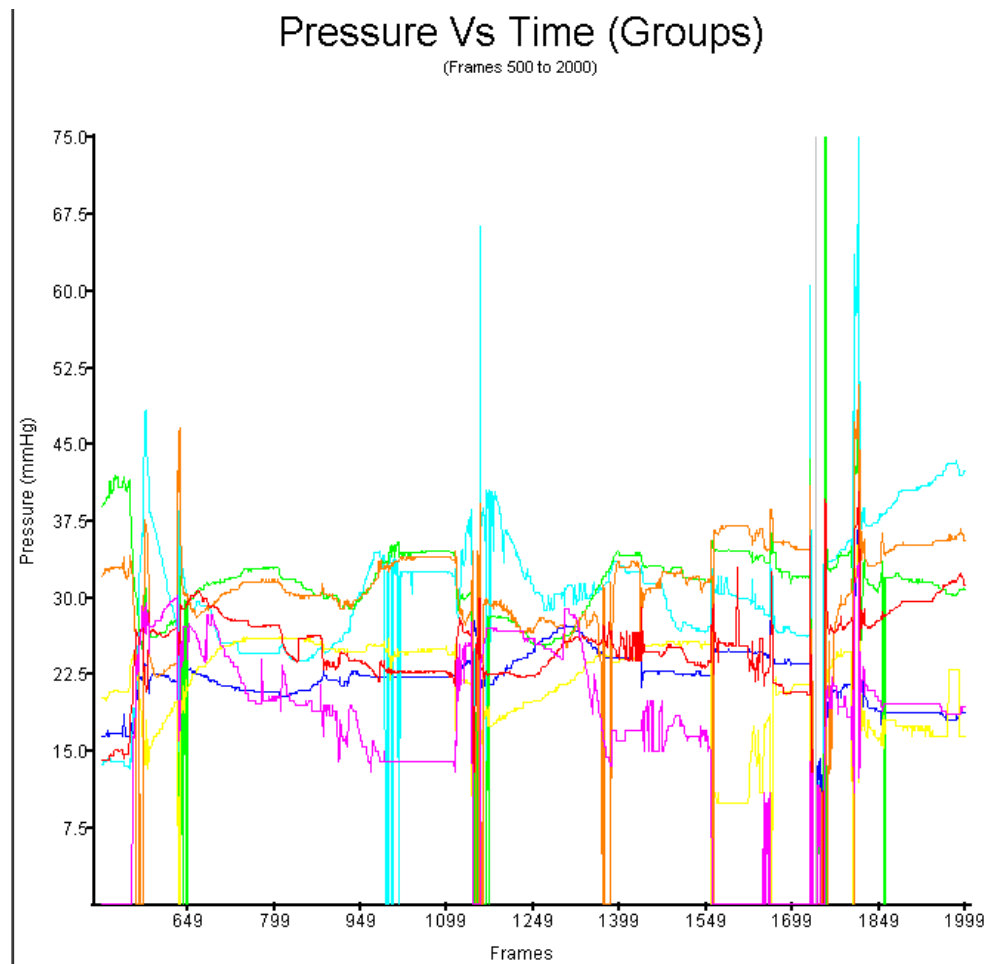


Figure 6 Pressure profile at sample points, Subject 1, Pneu-air

An example pressure vs time trace taken at various points on the map for the Pneu-air is shown in figure 6. Each different coloured line represents a different point on the surface of the mattress. For each different coloured line, API can be calculated as the integral of pressure.time below 30mmHg. It was noted that the alternating behaviour on the Pneu-air gave a somewhat random-looking pattern on this trace, with pressures changing at irregular times. It is not currently known whether this is advantageous or disadvantageous compared to the more 'sinusoidal' patterns of alternation seen for example in the Alpha Xcell: see figure 7.



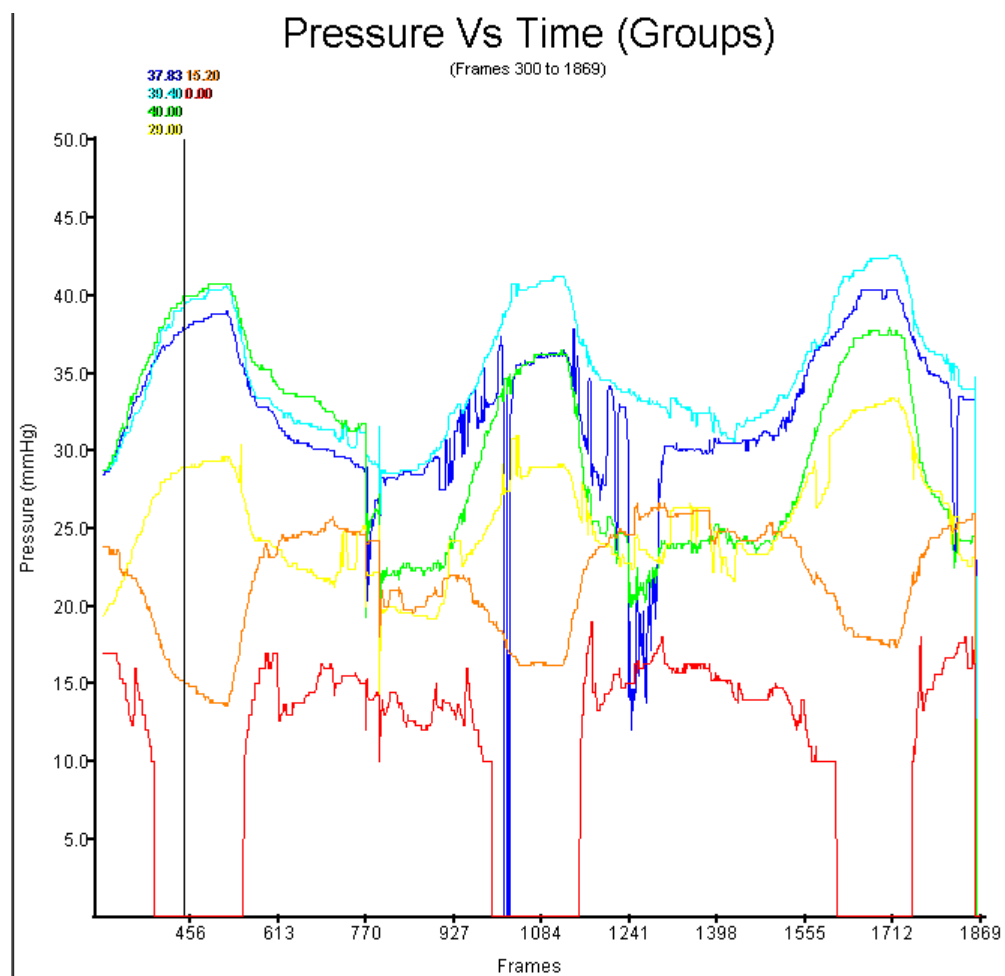
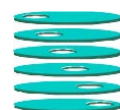


Figure 7: Pressure profile at sample points, Subject 1, Alpha Xcell

Referring to figure 7, it can be seen that the Alpha Xcell gives a relatively smooth, near-sinusoidal pressure profile, with sensor cells falling into 2 easily recognisable groups on opposite cycles. In the case of this subject, although total pressure relief was observed by some of the cells in one part of the cycle (red trace), those cells that were inflated in that part of the cycle do not fully deflate in the opposite part of the cycle (blue and green traces). This means that, for at least some body regions, “total pressure relief” does not occur.



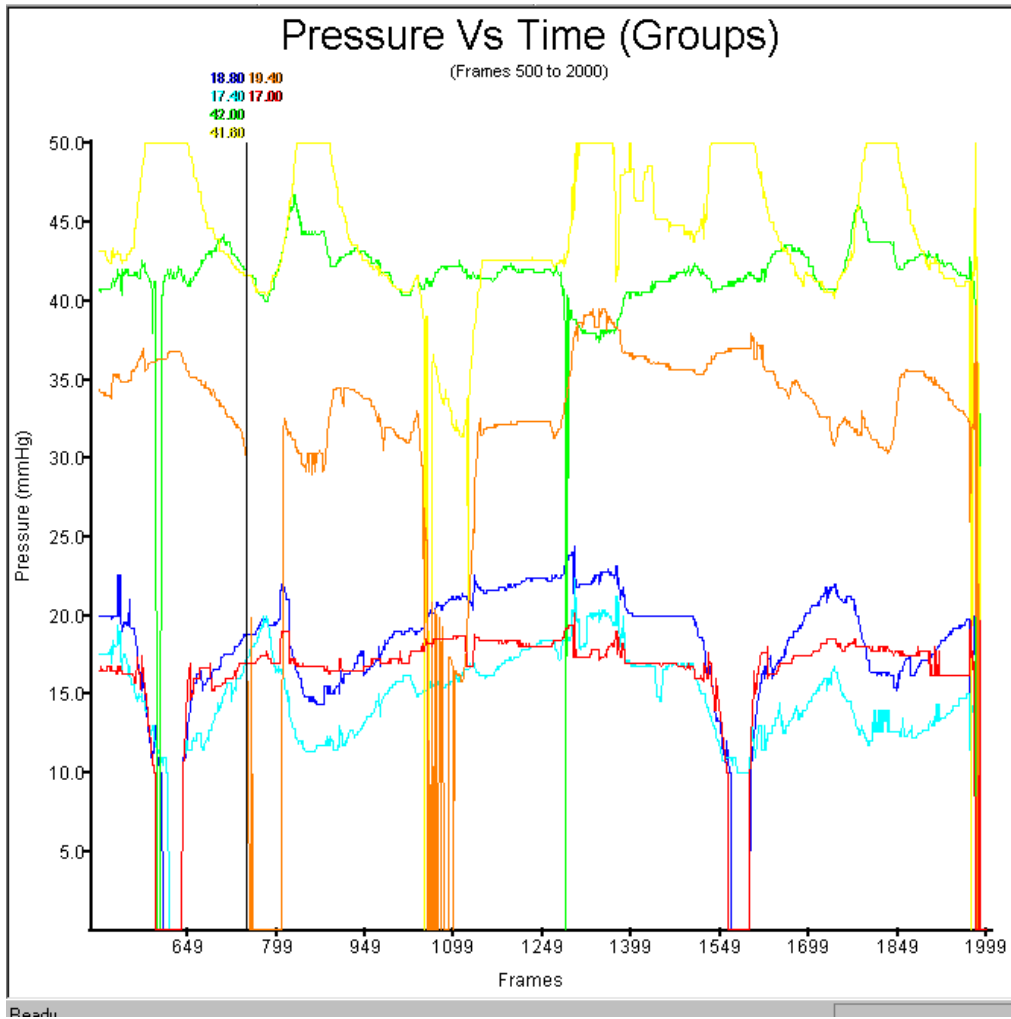


Figure 8: Pressure profile at sample points, Subject 1, Quattro

Figure 8 shows the corresponding trace for the Quattro, which also exhibits a more irregular pattern than the Alpha Xcell.



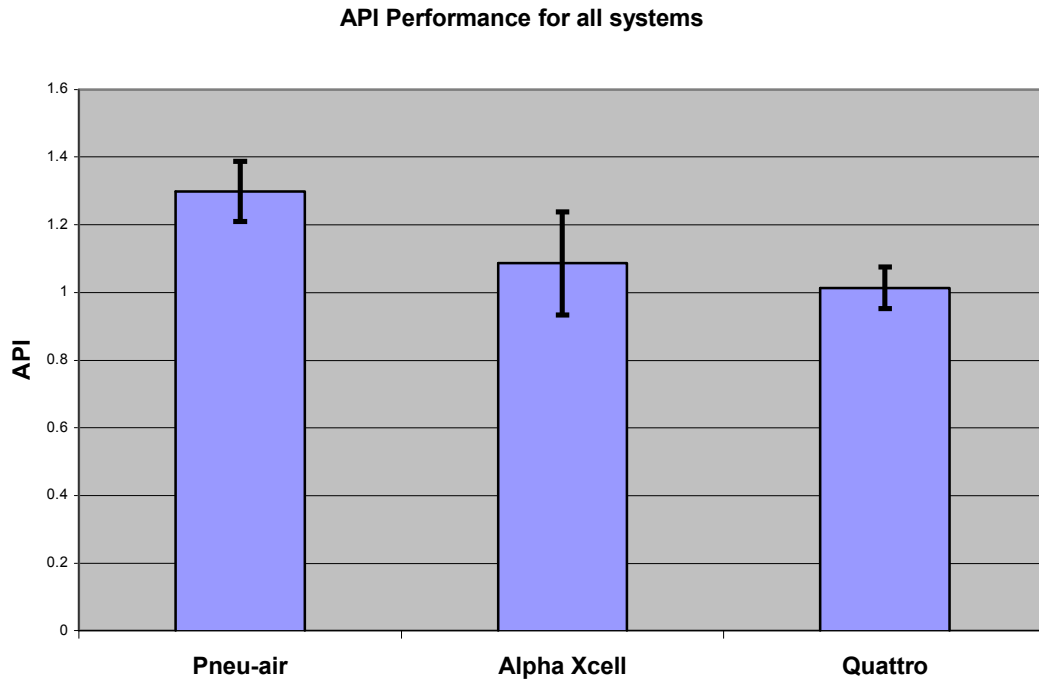


Figure 9: API performances compared for 10 subjects

Figure 9 shows the performance of the Pneu-air compared to that of the Talley Quattro and the Huntleigh Alpha X-cell, for all subjects.

Taken across all 10 subjects, the Pneu-air performed significantly better in terms of API than the other 2 surfaces ($p=0.05$), paired t-test. No significant difference is observed between Alpha Xcell and Quattro.



5 Conclusions

Performance of the Pneu-air was significantly better than the overlay systems in the study, in terms of API index. No statistically significant differences were observed between the overlay surfaces.

This study consisted purely of laboratory evaluations, and no clinical outcomes data is presented or implied.

REFERENCES

¹ Rithalia SV, Heath GH, Gonsalkorale M. Assessment of alternating-pressure air mattresses using a time-based pressure threshold technique and continuous measurements of transcutaneous gases J Tissue Viability. 2000 Jan;10(1):13-20.

² Rithalia SV, Evaluation of alternating pressure air mattresses: one laboratory-based strategy J Tissue Viability. 2004 Apr;14(2):51-8.

