Evaluation of Nightingale ProAxis Plus Bed with regard to dynamic pressure attributes

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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 [i], [ii], 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 been suggested that the principles of the APAM may also be fulfilled by means of a dynamically moving mechanical bed.

[i] 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.

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

AIMS

To compare the dynamic pressure behaviour of the Nightingale bed with that of a conventional APAM (Huntleigh Nimbus III), which has been shown by randomised controlled trial to be clinically effective in reducing pressure ulcer incidence.

Criteria

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 address possible second-order effects such as reperfusion injury with 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.**

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. One means of addressing this shortcoming is to cite durations at several different thresholds, and summating 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 figure 1. 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 (expressed in mmHg x minutes) may then be divided by the cycle time, to give a value of pressure relief below a 30mmHg threshold.

So we define API :

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

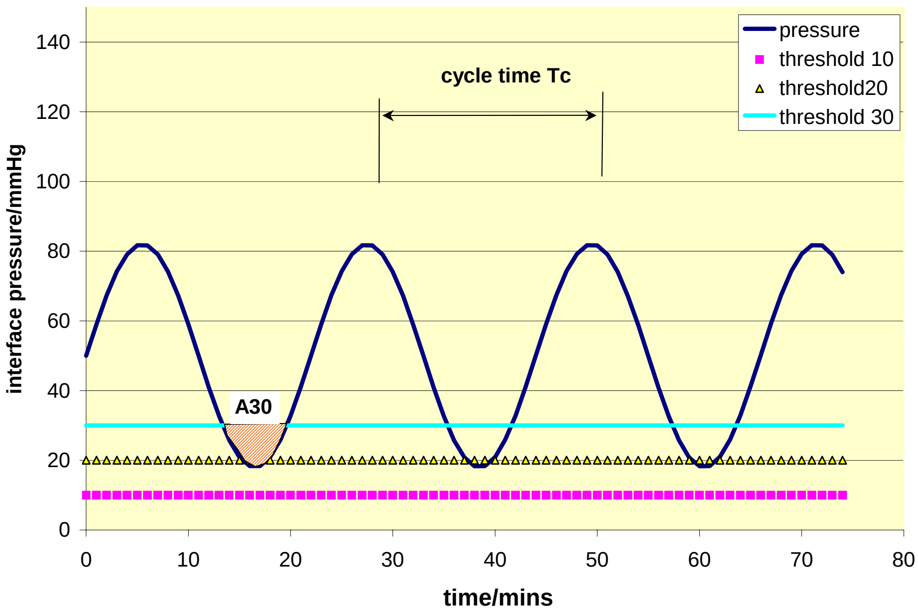


Figure 1: Hypothetical loading cycle at a single body location

Instrumentation

A Conformat flexible pressure mapping array (Tekscan Inc.) 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 stretchiness and flexibility of the mat.

Subjects

10 healthy subjects of a variety of different ages and body mass indices were used for the study.

Table 1: Subject group anthropometrics:

ID code	Age	Height	Weight
ID01	39	1.80m	74 kg
ID02	63	1.58m	95kg
ID03	60	1.66m	52kg
ID04	61	1.65 m	63 kg
ID05	23	1.62m	101 kg
ID06	33	1.65	55 kg
ID07	27	1.67m	64 kg
ID08	29	1.64m	45 kg
ID09	21	1.75m	72 kg
ID10	41	1.82m	79 kg

Test procedure

1) The bed was made up with a flat cotton sheet. The pressure mapping device (calibrated daily) was placed on the bed.

2) Each subject was placed on the bed with the pelvis aligned with the pressure mapping device.

3) The Nimbus mattress was set up with pressure settings according to the following rules:

Subject <50 kg:	soft
Subject 50kg-70kg:	soft-medium
Subject 70kg-80kg:	medium
Subject 80kg-100kg:	medium-hard
Subject >100kg:	hard

4) After 5 equilibration cycles, pressure was mapped over 3 pressure cycles.

5) Average API calculated over 3 cycles for every sensor region on the pressure map, and the region with the lowest value of API was recorded. This was repeated 6 times for each subject to give a mean and standard deviation lowest API value for each subject, to indicate the level of reproducibility.

6) This was repeated for all 10 subjects.

7) Each subject then placed on nightingale system, with pelvis aligned with pressure mapping device.

8) The Nightingale bed was set up to cycle between 0° and 60° in increments of 10°.

9) Average API calculated over 3 cycles for every sensor region on the pressure map, and the region with the lowest value of API was recorded . This was repeated 6 times for each subject to give a mean and standard deviation lowest API value for each subject, to indicate the level of reproducibility.

Results

Figure 2 (a-h) shows 6 snapshots of the pressure distribution at various times throughout the cycle on the Nightingale bed, using a sample subject. It can be seen that, although the pressures are generally higher in the pelvic area than in the surrounding areas, the loci of highest pressures move throughout the cycle. These pressure maps are included to illustrative the movement of pressure pattern, and so no legend is provided to show actual pressure values.

Note that the upper part of the sacral area, loaded highest in figures 2a, 2g, and 2h, (possibly showing a high point associated with the posterior superior iliac spine) are effectively unloaded in figures 2c and 2d.

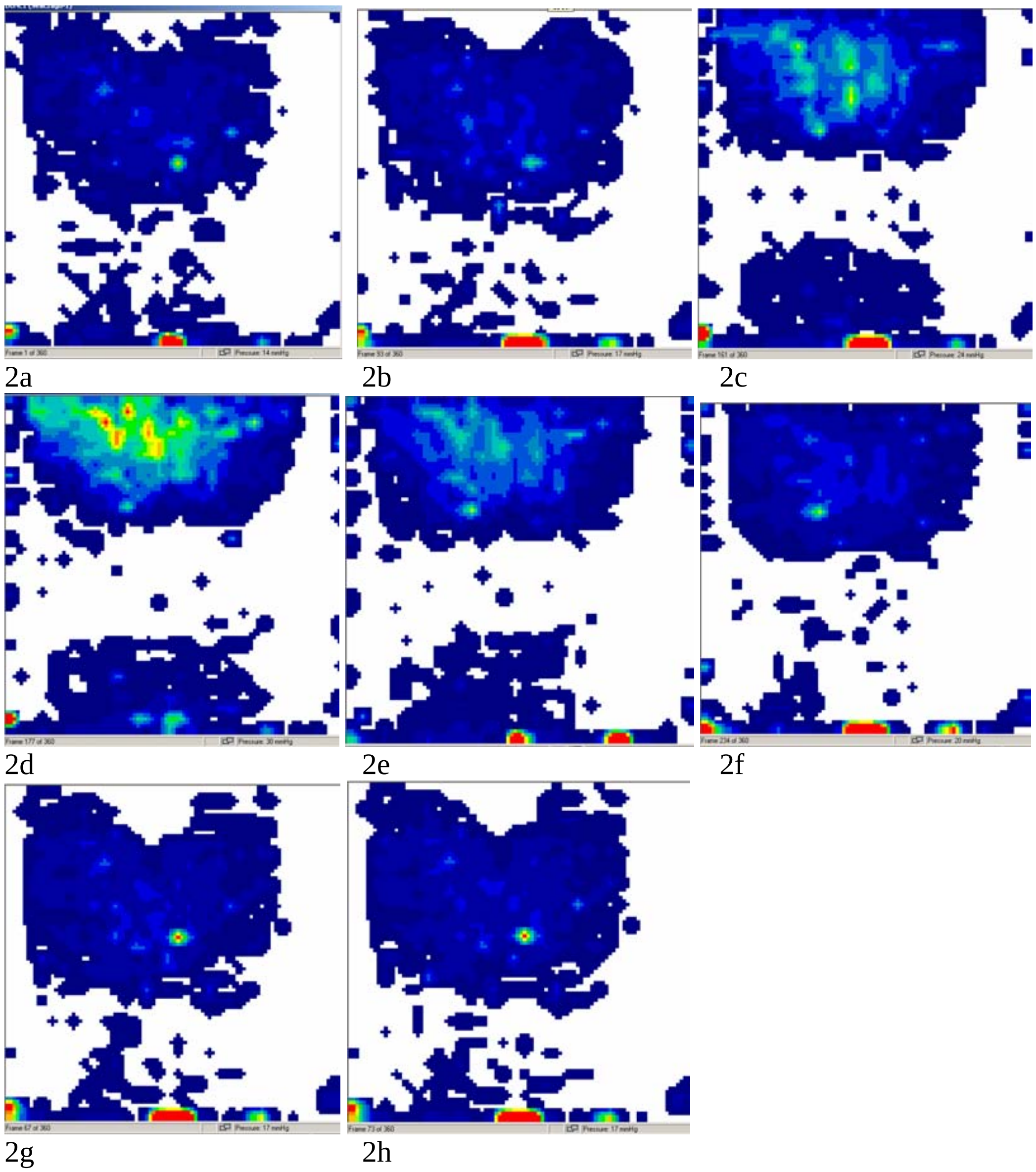


Figure 2 (a-h) Pressure distribution on Nightingale bed at various stages in the movement cycle, Subject ID01.

Accordingly, a trace of a similar nature to those shown in figures 1 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.

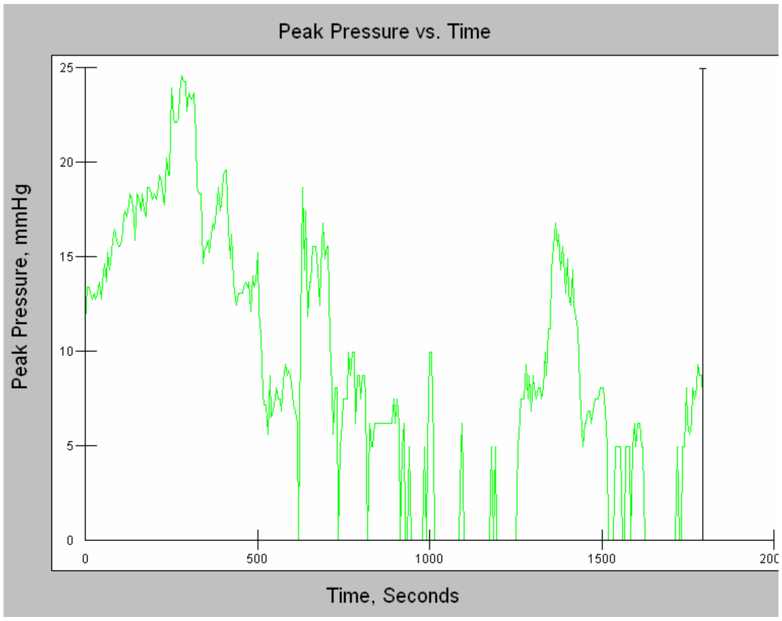


Figure 3a Pressure trace at a point on the sacrum, Nigtingale bed, Subject ID01

Figure 3a shows the variation of pressure with time, and reflects the total off-loading achieved at a specific point high on the sacrum chosen.

However, other parts of the pressure map do not show as much variation, and indeed do not experience total off-loading. Most notably, referring to figure 2, the region lower on the sacrum, nearer to the coccyx.

The corresponding pressure trace for this region is shown in figure 3b

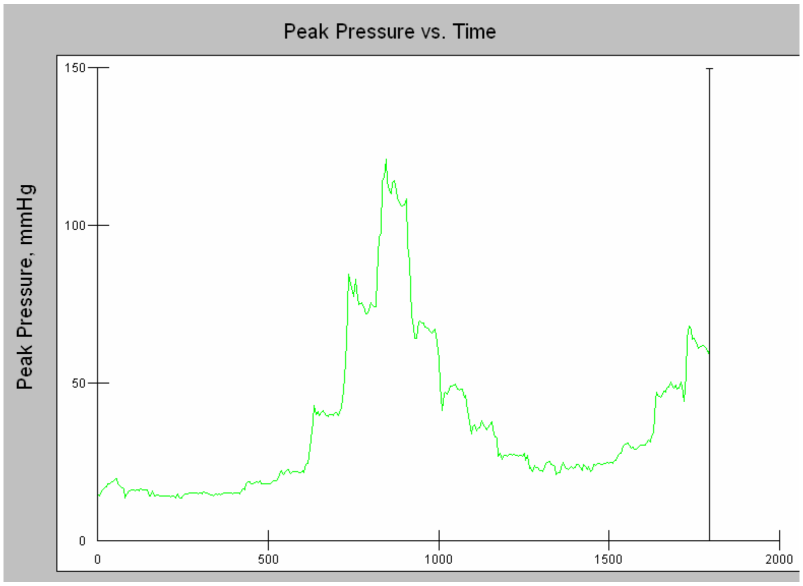


Figure 3b Pressure trace at a point on the sacrum, Nigtingale bed, Subject ID01

Here, we can see that, although total off-loading does not occur, great variation occurs in pressure value, and values range between approximately 120mmHg and 20mmHg at different parts of the cycle.

Other sample traces taken at different points on the map are shown in figures 3c-3e.

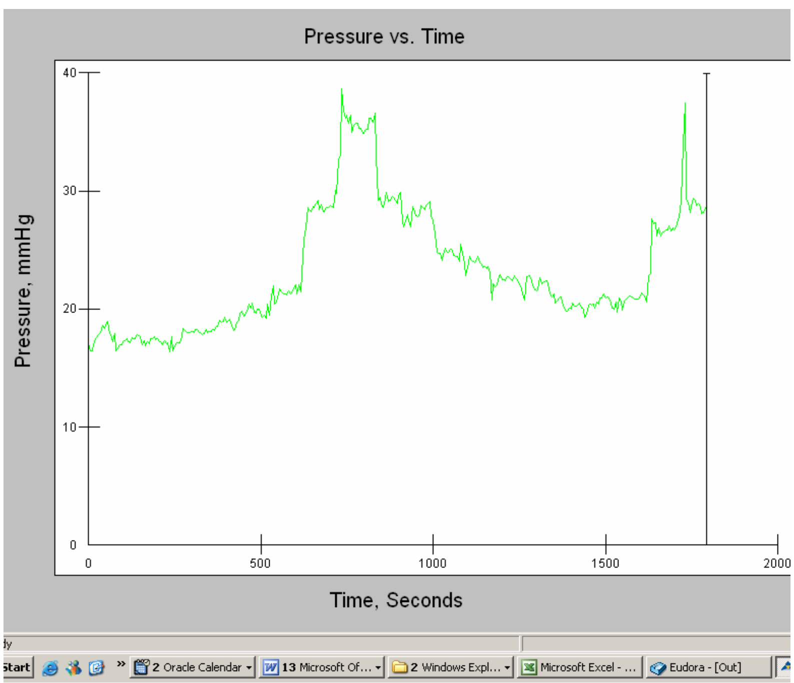


Figure 3c Pressure trace at a point on the buttock, Nigtingale bed, Subject ID01

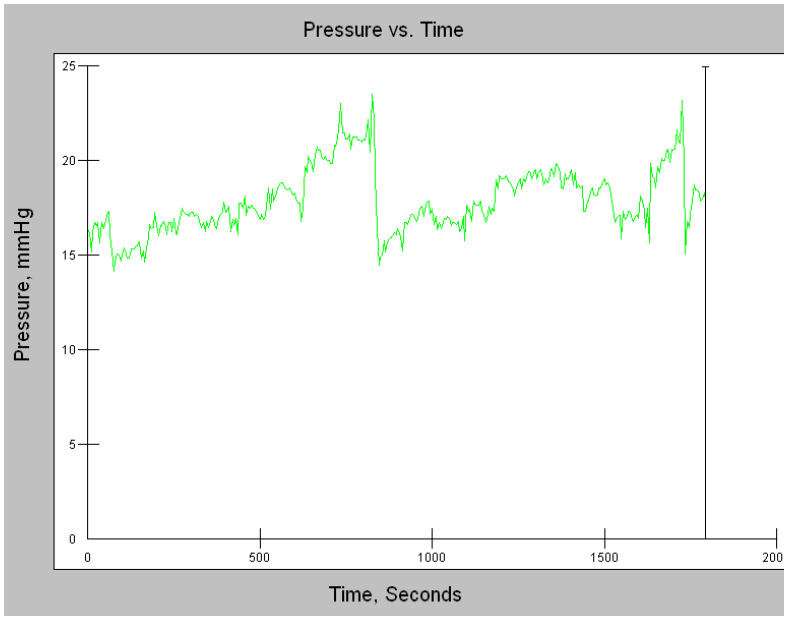


Figure 3d Pressure trace at a point on the thigh, Nigtingale bed, Subject ID01

In figure 3d, we see pressure values at the margins of the loaded area, exhibiting systematic and regular variation, and never exceeding our threshold value of 30mmHg. In isolation, this (or the trace in 3a) would give a very high value of PPI. However, as explained in the ***criteria*** section above, we are interested in those regions that perform worst, not those which perform best.

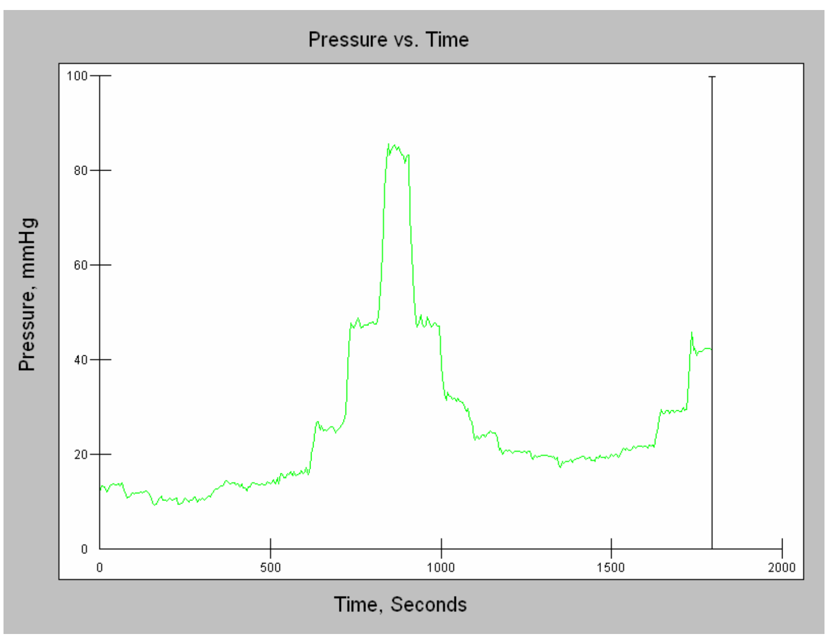
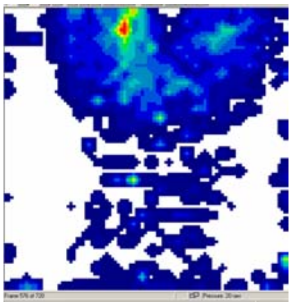
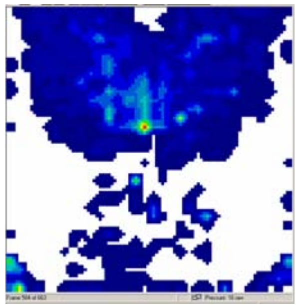
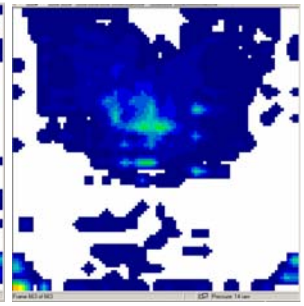


Figure 3e Pressure trace at a point on the scapula, Nigtingale bed, Subject ID01


4a


4b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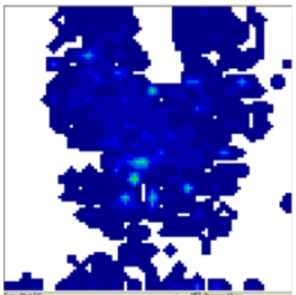
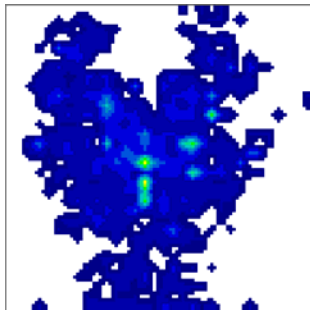

4d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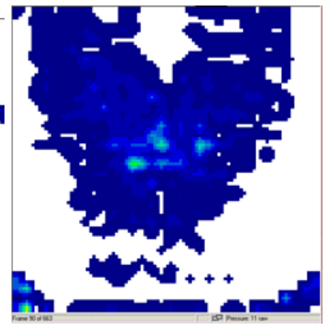
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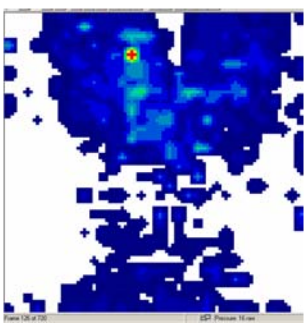
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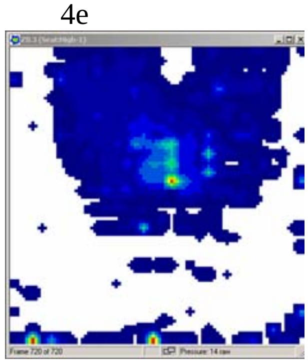
4h

Figure 4 (a-h) Pressure distribution on Nimbus III at various stages in the inflation cycle, Subject ID01

Referring to figure 4 (a-h), it can be seen that the loci of pressure on the Nimbus III also move substantially during the cycle.

Similarly, traces of pressure against time can be plotted for any point on the map. Illustrative examples are shown in figures 5 (a-d)

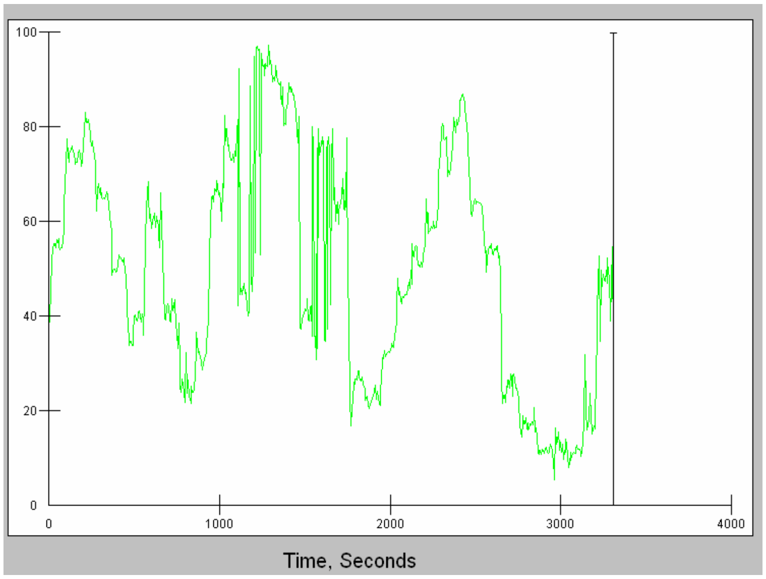

Figure 5a Pressure trace at a point on the thigh, Nimbus III, Subject ID01

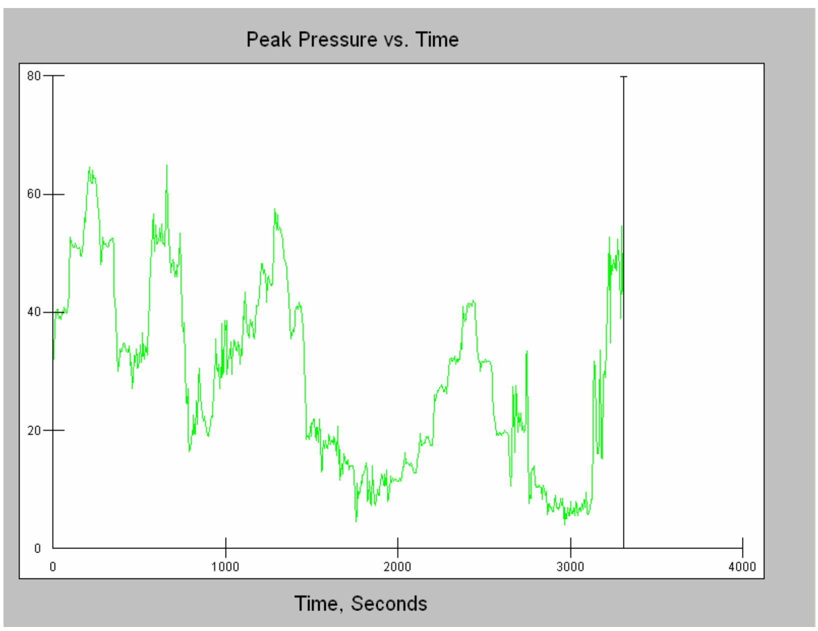

Figure 5b Pressure trace at a point on the sacrum, Nimbus III bed, Subject ID01

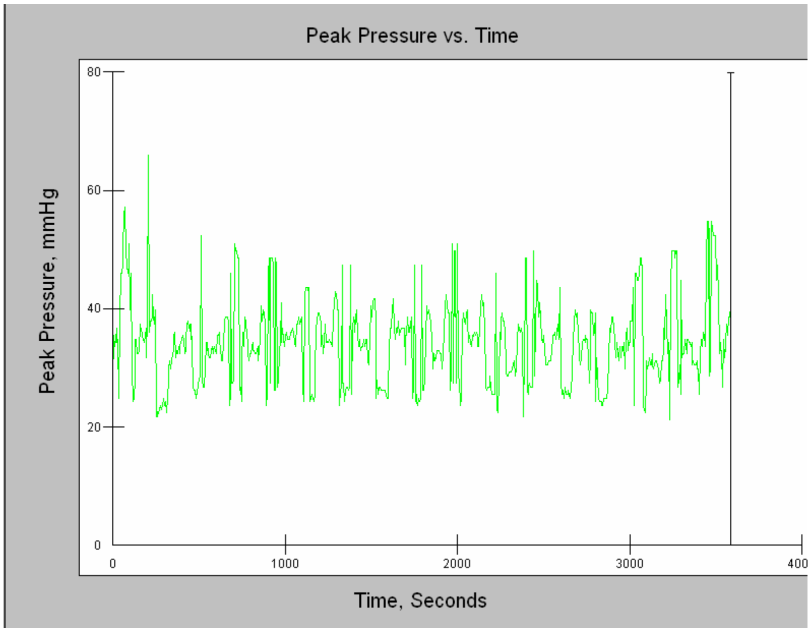

Figure 5c Pressure trace at a point on the buttock, Nimbus III bed, Subject ID01

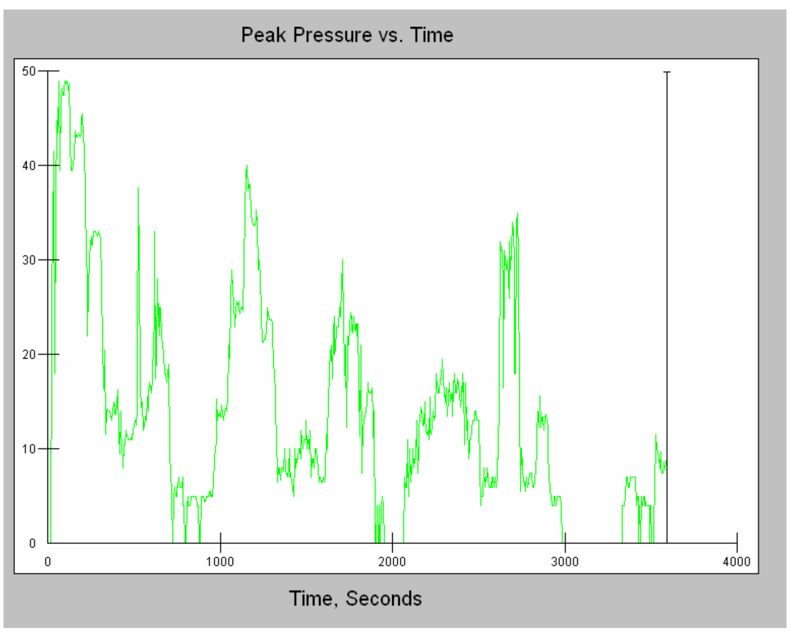

Figure 5d Pressure trace at a point on the scapula, Nimbus III bed, Subject ID01

As with the Nighingale bed, the Nimbus shows substantial variation in performance, depending on the point of the map chosen. Once again, points can be chosen that show incomplete off-loading. The effectiveness of this product clinically has been demonstrated convincingly in randomised controlled trials. This suggests that "total relief" is not a prerequisite for effectiveness.

Interestingly, the apparent cycle time on the Nimbus varies depending on the point chosen on the map. This may reflect complex pressure behaviour at regions that border 2 air-sacs.

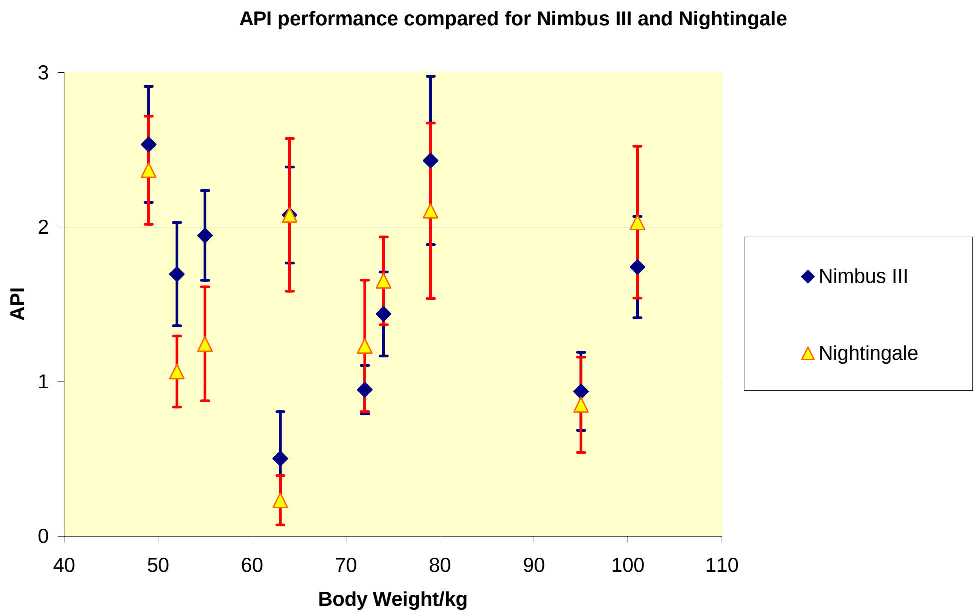

Figure 6 Results for all subjects, with error bars to show 95% confidence intervals for all repeat tests on each subject.

Figure 6 shows the API values summarised for all subjects on both beds. Each data point represents the mean value of worst API for a single subject, measured over 6 repeated tests. The error bars represent the 95% confidence intervals for these values, giving an indication of the reproducibility of the test.

It can be seen that variations between individuals are large, and there is also some variation between repeats for each individual.

In 2 instances, the Nimbus III performs significantly better than the Nightingale bed. However, these are both subjects of very low body weight. On the remaining 8 subjects, no significant differences in performance are observed, and both systems give very respectable values of API.

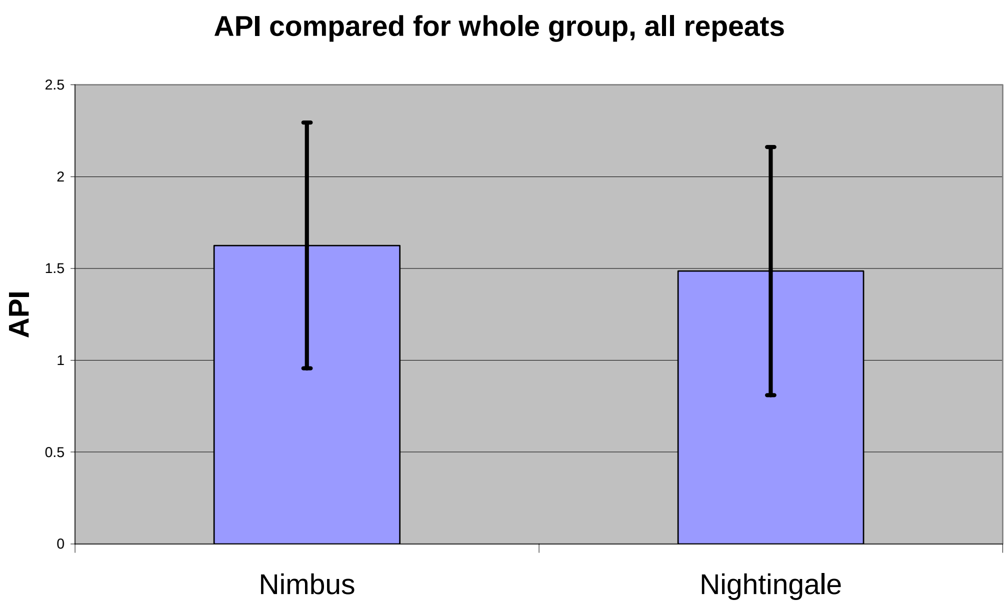

Figure 7 Mean and standard deviation results for all subjects

Figure 7 shows a summary chart of API performance for all subjects. Overall, results for the Nightingale bed did not differ significantly from those for the Nimbus III (paired t-test, $p=0.11$).

It should be noted that this in itself does not demonstrate equivalence between the 2 systems, but rather that this method has not distinguished between them. This may be due to large intra-subject variations.

However, very respectable values of API were achieved by the Nightingale bed in all cases, suggesting that its efficacy as a dynamic pressure system should be taken seriously.

Conclusions

Extensive and repeated measurement with 10 subjects show that the Nightingale Pro Axis Plus bed exhibits substantial efficacy in dynamic pressure redistribution.

The level of performance, as measured using the API index, was not found to be significantly different from the Nimbus III over all subjects. Experimental reproducibility limitations inherent in live subject experiments may have masked any differences that exist.

Additionally, concerns have recently arisen over the use of inflatable 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. Furthermore, more body weight is put on the pelvis in the elevated position, raising the interface pressures in this region. For these reasons, APAMs generally perform worse in the elevated position in terms of API than in the lying flat position. It should be noted that in this study, the Nimbus III was used in the flat (non-elevated) position, and may have performed worse when elevated.

There may be subjects where regular postural change is indicated, for example for lung drainage. Similarly, there may be bariatric patients whose weights preclude the use of inflatable alternating pressure devices. The satisfactory performance of the Nightingale product using subjects of a variety of different sizes and weights suggest that this type of system should be taken seriously in terms of dynamic pressure redistribution.