

A Clinical Evaluation of the Alpha Active 4 Mattress Replacement System

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Introduction & Clinical Context

Pressure injuries (also known as pressure ulcers), are a major global healthcare problem occurring in both acute, long stay and community healthcare settings, most frequently affecting frail patients with reduced mobility and complex co-morbid conditions. However, injuries also develop in young, previously fit and well individuals, such as those with major trauma or disability. These injuries have a significant humanitarian and economic impact^{1,2}, but are generally considered avoidable³. For prevention to be successful, it is essential that patients at risk of pressure injury are identified, and appropriate interventions are initiated early.

The recently updated international pressure injury guidelines⁴ view support surfaces as an important component in pressure injury prevention and treatment, since they can help prevent the effects of damaging tissue deformation and provide an environment that enhances perfusion of at risk or injured tissues⁵. The recommendations include, choosing a support surface that takes into account the individuals specific needs, including level of immobility and inactivity, the need to influence microclimate control and shear reduction, the number, severity and location of existing pressure injuries and the size and weight of the individual⁵. They further recommend that the key characteristics to consider when selecting a support surface are those features and characteristics that affect pressure redistribution, friction and shear force management and microclimate⁵.

With an ever-increasing number of support surface technologies available, clinicians often require evidence or clinical data to help support and justify their clinical decision-making, as part of a wider pressure injury prevention or management protocol. This paper reports simple outcome data based on a small observational case series, conducted with the Alpha Active 4 mattress replacement system, in 4 long-term care facilities in Europe.

The Alpha Active 4 Mattress Replacement System

Designed for the prevention and management of pressure injuries, the Alpha Active 4 (Fig 1) pressure redistributing mattress replacement system is suitable for a range of care environments including home and community care settings. It has been designed as a cost effective solution for vulnerable patients and residents, whilst remaining easy to use for the carer and simple to clean and maintain.



Figure 1: Alpha Active 4 Mattress Replacement System

Specific features of the Alpha Active 4 include:

- Electronic pressure setting – allows accurate and appropriate pressure settings to be set for various weight ranges
- Variable cycle times – In addition to a 10 minute cycle time, the Alpha Active 4 system offers the choice of an extended cycle period of 20 minutes, which may be desirable as patients begin to rehabilitate and the risk reduces
- Auto Firm – provides a stable support surface for patient transfer and nursing procedures
- 2 Modes of operation
 - Active / Alternating mode: periodically redistributes pressure away from vulnerable areas by alternately inflating and deflating cells beneath the patient
 - Reactive / Static mode: cell pressure is equalised to redistribute the body weight over a greater surface area –ideal for patients unable to tolerate a moving surface

Methods

An observational non-interventional case series was performed in 4 long-term care facilities within Europe; 2 facilities in France, 1 in Ireland and 1 in Belgium. Data was collected during routine use of the Alpha Active 4 from residents that were nursed on the system for a period of at least 2 weeks. Nurses working within the long-term care facilities were asked to provide their opinion of the Alpha Active 4 mattress in terms of ease of use, and general acceptability of the device.

An Arjo Clinical Trials manager coordinated the case series. Local representatives from each of the countries involved in the evaluation made contact with the facilities, provided training to the caregivers and agreed with them to collect data using a pre-defined questionnaire. The pre-defined questionnaire was designed to collect simple data including:

- Subject demographic data (age, gender, weight)
- Pressure Injury data (number, severity & location, progress of existing ulcers and/or new tissue damage)
- Indications for using the Alpha Active 4
- User acceptability data (ease of use, ease of cleaning etc.)

The presence and status of any pressure injuries was recorded at baseline, week 1, week 2 and week 4 of the follow up period.

The caregivers in each long-term care facility completed the questionnaires and overall evaluation of the device with no further input from Arjo.

Results

The observation period took place between July 2019 and February 2020. Each resident was followed for the period they were nursed on the Alpha Active 4 mattress or for a maximum of 4 weeks. The indication for using the Alpha Active 4 mattress were due to pressure injuries or as a result of reduced mobility. Below is a summary of the key results from this observational case series:

Demographic Data

- **14** residents in total were included in the observation from across the 4 European long-term care facilities. A breakdown is provided in Table 1
- The majority of residents included in the sample were female (n=10, 71%), 3 (21%) were male. Data on gender was missing for 1 resident.
- The number of days that residents were observed on the Alpha Active 4 ranged from **11-189 days** (mean 44 days, median 25 days)
- 3 residents were aged between 51 – 80 years with **11** of the residents were aged over 80 years
- **12** residents ranged in weight between 41-70 kg's whilst **2** residents weighed 71-100 kg's

Country	N° recruited
Belgium	3
Ireland	4
France site 1	5
France site 2	2
Total	14

Table 1: Number of Residents recruited by country

Pressure Injury Outcomes at Baseline & Post Observation Period

- Of the 14 residents observed **8 (57%)** of the residents had existing pressure injuries at the start of the observation (1 resident had 2 pressure injuries recorded at baseline). These were located in common anatomical locations including the sacrum, heel and ankle. Figure 2 provides a breakdown of the pressure injuries at baseline.

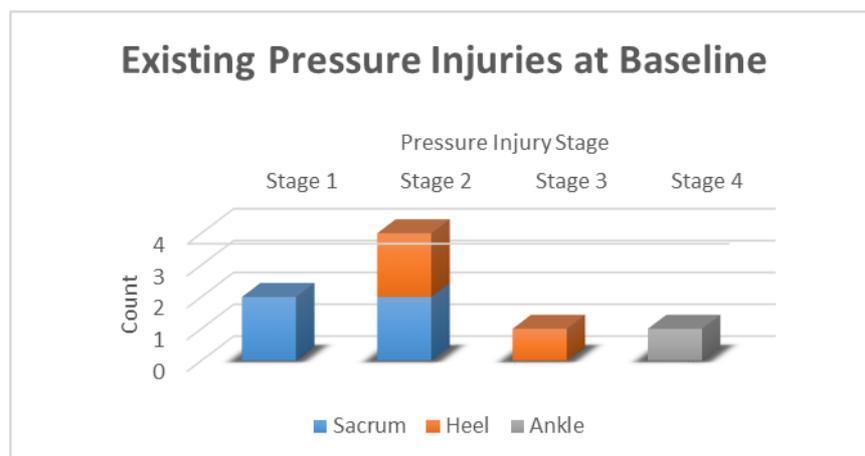


Figure 2: Pressure Injuries at Baseline

- 6 residents pressure injuries improved or healed on the Alpha Active 4 during the 4 week observation
- No new pressure injuries were reported during this observational period

User Acceptability of Alpha Active 4

- The majority of the caregivers (n=10, 71% at week 4) agreed that the AA4 is comfortable for residents and that it helped to increase patient stability whilst being nursed on the surface
- Of those caregivers who responded to the usability questions in the questionnaire (n=7, 50%), all considered that the Alpha Active 4 system was easy to clean and generally easy to use
- The majority also agreed that the auto firm function of the Alpha Active 4 helped to support caregivers during patient transfer and nursing procedures, although some did not use this function (n=6)

Conclusion

Due to the design of this case report series, the conclusion are not statistically significant, however the development of pressure injuries as well as the opinions of those caregivers that completed the usability sections of the questionnaire were consistent between the cases reported. Only the opinion about the Auto firm function varied between caregivers.

Overall caregivers considered the Alpha Active 4 to be easy to clean and provided comfort and stability for the resident. Not all caregivers used the Auto Firm function during the observation period.

In terms of prevention, no resident developed a pressure injury during the observation period, whilst the majority of those residents with pre-existing tissue damage improved or healed.

References

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