Clinical Highlights

ACTitouch® Adaptive Compression Therapy System

ACTitouch System Improves Quality of Life; High Adherence to Therapy and High Satisfaction in Patients with Venous Leg Ulcers

Original Article:	Adaptive compression therapy for venous leg ulcers: a clinically effective, patient-centred approach
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BACKGROUND

Current multi component compression treatment options for venous leg ulcers (VLUs) often negatively impact a patient's quality of life (QoL), creating a need for innovative therapies that provide effective compression while preserving QoL. Combining intermittent pneumatic compression (IPC) with sustained gradient compression has been shown to accelerate healing[1,2] but has thus far been impractical in real world settings. ACTitouch adaptive compression therapy applies both on-demand IPC as well as the sustained compression provided by multi-layer bandage systems, and does so without many of the common limitations[3].

The ACTitouch device provides dual-therapies that are applied by four pneumatic pressure chambers linked to a microprocessor that individually monitors and controls the pressure in each chamber to targeted pressures. The ACTitouch was designed to support mobility, quality of life, and ease-of-use, all of which are important to develop patient adherence to therapy.

OBJECTIVE

Efficacy, functionality, safety, patient perceptions and impact on QoL were evaluated for ACTitouch adaptive compression therapy compared to a standard four-layer bandage (4-LB) (Profore™ Multi Layer Bandaging System, Smith & Nephew Medical Wound Management, U.K.) for the treatment of patients with VLUs.

METHODS

- Prospective, randomized controlled trial
- N = 90
- Duration: 12 weeks
- Treatment Protocol:
  - ACTitouch subjects were to wear the ACTitouch during all waking hours, except bathing, using sustained compression mode for most of the day, supplemented with 2 hours of IPC mode.
  - 4-LB subjects were to wear bandages 24 hours/day without removal even when sleeping or (sponge) bathing. Application of the 4-LB was done weekly by a trained clinician following manufacturer instructions.
  - All subjects received local ulcer management with a standardized non-adherent dressing held in place with a tubular dressing.

METHODS CONTINUED

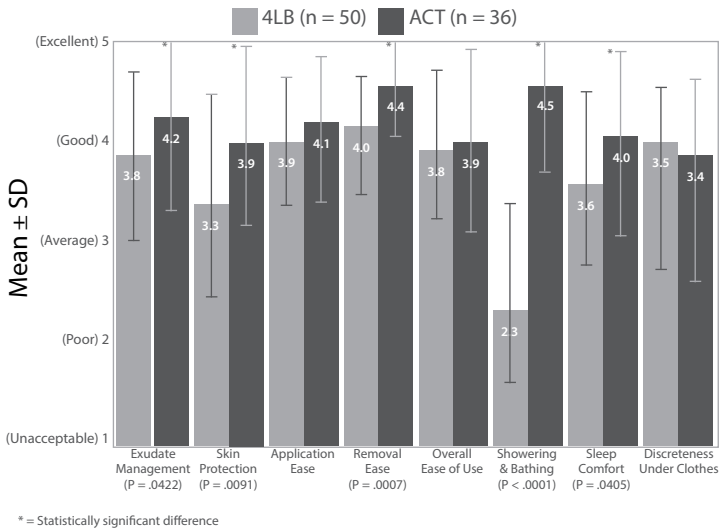
Primary outcomes:

- Wound closure (tracings)
- Safety (Frequency and type of adverse events)

Secondary outcomes:

- Ulcer pain (10 point VAS)
- Device comfort (4 point scale)
- Patient perceptions of treatment performance (5 point scale)
- QoL (EQ-5D)
- Adherence (ACTitouch built-in therapy tracker; subject diary)

Patient Rating of Performance



* = Statistically significant difference

Demographics and Baseline Ulcer Characteristics

Characteristic		4-LB	ACT
Gender	*Male*	29 (56%)	17 (45%)
	Female	23 (44%)	21 (55%)
Age	*Mean(SD)*	62.6 (15.41)	60.9 (16.72)
Duraction of Ulcer (years)	*Mean(SD)*	2.57 (4.84)	2.43 (4.05)
Ulcer Size (cm^2)	*Mean(SD)*	14.18 (15.15)	14.08 (20.40)
Ulcer Depth	*Superficial*	17 (33%)	5 (13%)
	Shallow	32 (62%)	32 (84%)
	Deep	3 (6%)	1 (3%)
Ulcer Stratification			
	<10 cm^2 / <6 Months Duration	16 (31%)	12 (32%)
	<10 cm^2 / ≥6 Months Duration	21 (40%)	14 (37%)
	≥10 cm^2 / <6 Months Duration	4 (8%)	2 (5%)
	≥10 cm^2 / ≥6 Months Duration	11 (21%)	10 (26%)

RESULTS

Healing time and rates were comparable between the two groups. ACTtouch QoL index score was significantly higher than the index score for 4-LB with a statistically significant P value of 0.0375. Patients rated ACTitouch significantly higher than 4-LBs for exudate management, skin protection, removal ease, bathing and sleep comfort; other performance ratings were comparable between the two groups. Adverse events were comparable in type and frequency with no serious adverse events in either group.

DISCUSSION

While critical to clinical outcomes, adherence to therapy is a challenge in the VLU patient population. Patients using ACTitouch exhibited high adherence to therapy, wearing the device an average of 10.5 hours with sustained compression and 1.8 hours of IPC each day. This infers the significantly higher QoL provided by the ACTitouch device augments patient compliance. Additionally, the ACTitouch achieves clinical efficacy comparable to standard of care without requiring the patient to wear the device 24/7 as is required with 4-LBs. Given comparable healing, other key factors such as ease of use, patient performance ratings, and QoL become primary factors in treatment selection.

CONCLUSION

ACTitouch is a safe and effective therapy that significantly improves patient QoL when compared with a traditional 4-LB. Given more control over their own therapy, patients are empowered to perform daily activities such as showering/bathing, and unencumbered sleep while engaging in an effective treatment regimen.

KEY POINTS

- Patients rated ACTitouch significantly higher than 4-LB for exudate management, skin protection, removal ease, bathing and sleep comfort.
- The practical benefits of ACTitouch translate into statistically greater improvement in QoL for patients as compared to 4-LB while yielding comparable ulcer healing rates.
- Compression bandage systems are associated with limitations[1] such as inconsistency in application techniques, pressure loss, bandage slippage and decreased QoL.
- ACTitouch produces consistent and controlled interface pressure independent of application technique.
- ACTitouch is self-applied and removed, enabling frequent dressing changes at home and normal bathing and sleep, all of which support increased adherence with therapy.

REFERENCES

The full article can be found in the:
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