Intermittent Pneumatic Compression & Compliance Monitoring

Flowtron® ACS900 System

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Introduction & clinical context

Venous Thromboembolism (VTE) is a complex vascular disease that encompasses deep vein thrombosis (DVT) and pulmonary embolism (PE). A DVT develops most commonly in the deep veins of the calf, thigh and pelvis and becomes symptomatic when the clot limits blood flow (Figure 1).

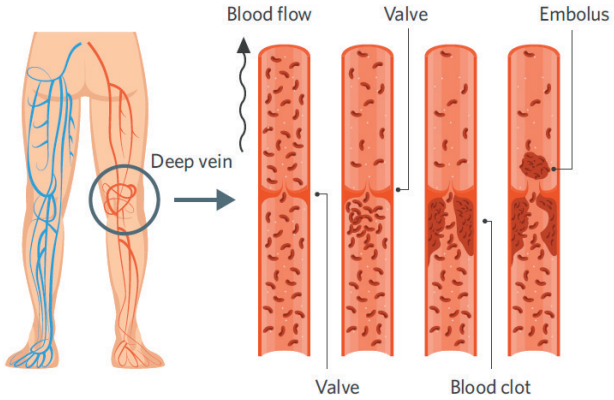

Figure 1: Formation of a Deep Vein Thrombosis (DVT)

A more serious condition is pulmonary embolism (PE) where part of, or all of the thrombus in the limb breaks off and enters the pulmonary arterial circulation, occluding blood flow to the lungs (Figure 2). If the embolism is large, it can be fatal.

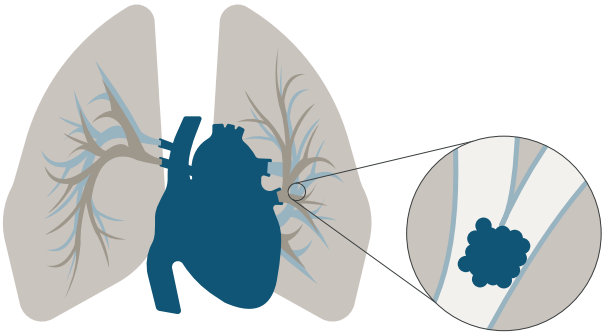

Figure 2: Pulmonary Embolism

VTE formation, although complex, depends on three key principles known collectively as Virchow's triad namely: Venous Stasis, Hypercoagulation and Vessel Injury (Figure 3). These factors come into play most commonly during periods of immobility (any cause), trauma and surgery or from a genetic predisposition to thrombophilia.

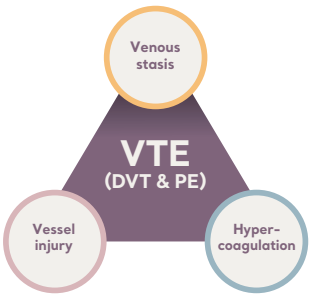

Figure 3: Virchow's Triad

Population incidence and consequence of VTE

Approximately 10 million cases of VTE are reported worldwide each year[1], with VTE posing a significant risk for hospitalised patients[2,3]. Sadly, around 30% of patients will die within 30 days of a VTE event, whilst 25% of unexpected inpatient deaths are only diagnosed with a PE at autopsy[4]. Aside from acute VTE, almost one third of patients go on to develop post thrombotic syndrome, suffering swelling and pain; in 25% of cases this leads to chronic recalcitrant leg ulceration[4].

Economic impact of VTE

VTE, the second most common complication of hospitalisation worldwide after adverse drug events[1], adds a significant financial burden to stretched health care systems [2,5,6,7,8]. For example, the USA spends up to $10 billion each year on VTE[7], while Europe has been estimated to spend up to €8.5 billion, of which up to €6.2 billion may be considered avoidable[9]. Alongside high financial cost is the human cost, with VTE a leading cause of morbidity and mortality accounting for around 7% of deaths in Australian hospitals[10] and 12,000 deaths each year in England[11]. The need to reduce the incidence of VTE is compelling particularly as VTE can be largely avoided[1].

Preventing VTE

National and international evidence-based guidelines strongly support the use of routine thromboprophylaxis for vulnerable individuals[12–19]. The guidance considers such interventions to be cost-effective in bringing a reduction in mortality and adverse patient outcomes, many of which would otherwise be life-changing. Prevention strategies for VTE commonly incorporate the use of pharmacological prophylaxis (anticoagulant, antiplatelet) and mechanical methods including Intermittent Pneumatic Compression (IPC). These can be used as stand-alone therapies or, for the highest risk patients, used in combination for enhanced benefit[14].

Intermittent Pneumatic Compression

Intermittent Pneumatic Compression consists of a range of garments, typically applied to the foot, calf or calf and thigh, which are intermittently inflated and deflated by means of a powered pump (Figure 4). This technology represents a well-established strategy for VTE prevention[12–19].

Figure 4: Flowtron ACS900 & garment range

All IPC systems have the same principle objective and that is to squeeze blood from the underlying deeper veins of the leg causing it to be displaced in a proximal direction[19]. With simple, yet effective, external compression, IPC mimics the natural activity of the ambulatory calf muscle pump. The effect causes increased blood flow velocity in the deep veins, reduced stasis and a flushing effect on venous valve pockets where thrombi may originate.

In addition to a localised effect, the increased blood flow also creates a shear strain on the endothelial lining of the blood vessels causing biochemical mediators to be released globally: this further hinders clot formation, while enhancing fibrinolysis, platelet disaggregation and vasodilation[20,21]. IPC therefore directly addresses two of the three causative factors associated with VTE formation – venous stasis and hypercoagulation (Figure 3) without increasing the risk of haemorrhage.

Recommendations on IPC use

In order to achieve optimum VTE prevention, continuous use of IPC therapy is recommended for at least 72 hours or until the patient is fully mobile; it is also recommended that continuous wear time is a minimum of 18 hours/day[12].

Factors affecting adherence to IPC protocol

Despite multiple trials demonstrating the efficacy of IPC in preventing VTE events, non-compliance remains the principal barrier to IPC effectiveness[22]. Considerable variability in adherence has been reported[23,24,25,26] with compliance rates as low as 0–19%[19,24]. Reasons given include, pump not available, pump not working and, important for compliance-monitoring, garments not fitted correctly or at all. Similarly, a systematic review of seven studies in acute care reported a median adherence rate of 78% (range 40%–89%)[23] while a study of 123 mechanically ventilated patients found a misapplication rate of 50 percent[25]. Given that concordance with IPC therapy is linked to positive outcomes, it is important that clinicians can accurately identify interruption in therapy. Guidelines therefore recommend that IPC devices facilitate recording and reporting of proper wear time for both inpatients and outpatients[27].

Flowtron® ACS900 with Compliance Monitoring

The Flowtron ACS900 system delivers both uniform and sequential compression therapy across a range of lower limb garments that can be used alone or in combination. For security, SmartSense™ garment detection (Arjo®) automatically sets the correct pressure and compression cycle without the need for any additional user intervention, while compliance-monitoring software displays the actual wear time (Figure 5).

If the garment is removed, in addition to an audio-visual alarm, the elapsed 'non-compliant' time is displayed on the pump. This enables the clinician to check and accurately document concordance with prescribed therapy, including cumulative 'wear time' over the course of an individual patient care episode.

Figure 5: Flowtron ACS900 with compliance monitoring feature

In developing this Compliance Monitoring feature, stringent control and validation tests were carried out to ensure 'wear time' and 'lapsed time' data were accurate (quantitative), easily accessed (qualitative) by the end user and with a performance that matched or exceeded other 'smart' IPC systems in clinical use (control device). The results of these performance validation tests follow.

Compliance monitoring:

Measuring accuracy

Aim

To evaluate the performance of the compliance-monitoring feature in the Flowtron ACS900 when used with a range of uniform and sequential compression lower limb garments.

Primary objective

- Determine whether the device accurately records the presence (and absence) of a limb in a garment
- Compare the performance of the Flowtron ACS900 compliance-monitoring feature with a proprietary benchmark

Secondary objective

- Determine whether 'no garment fitted' alarms are activated appropriately (time, audio, visual) and the pump displays run/restart as expected

Methodology

Test subject

Four uniform compression garments (DVT60, DVT30, DVT 10, DVT5) and two TriPulse™ sequential garments (TRP60, TRP30) powered by the Flowtron ACS900 IPC device (Arjo®). Compliance alarms (no garment or limb fitted) are intended to automatically reset when the garment is reapplied.

Control

Two adjustable sequential compression garments (calf/thigh, calf) and intermittent compression pump from an alternative supplier. Compliance alarms (no garment fitted) required a manual reset when the garment is reapplied.

Both pumps were in calibration and set up in line with the manufacturers' instructions and the compliance-monitoring features cleared of all previous data and reset. Garments were fitted as recommended by the manufacturer and the same test (human) volunteers used across both the test and control conditions to avoid inter-subject variability.

Across a series of test interventions, garments were removed and reapplied to the limbs to a predefined schedule (Figure 6): each test series ran for 105 minutes. This schedule is intended to demonstrate usage found in a typical clinical setting. It includes both longer and shorter periods of use and non-use that are associated with patient and clinical activities and so represent a real life challenge to the pump timing.

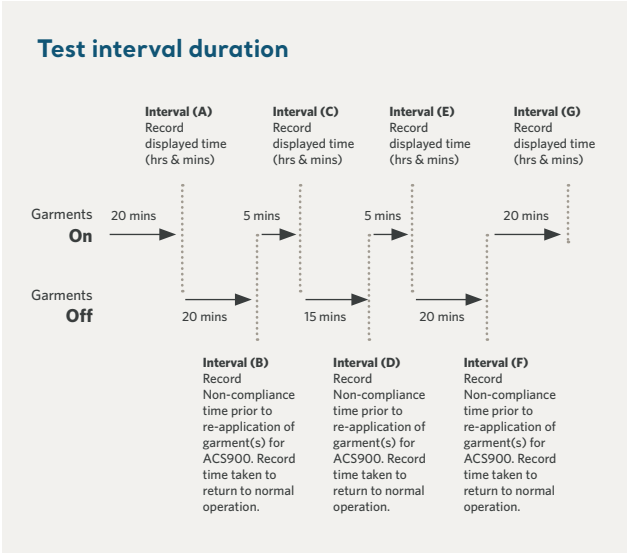

Figure 6: Test protocol

Garment applied (compliant) and lapsed (non-compliant / no garment) time from the individual pump displays were captured. In addition, an observer recorded garment compliance and whether the alarm conditions were triggered and reset as outlined in the user manuals.

At the end of each test run device-reported compliance (pump data) were compared to expected compliance (actual wear time). Once all results were collated statistical analysis (Mann Whitney U test) was used to determine comparative performance between the Flowtron ACS900 IPC system and the control device.

Results

Flowtron ACS900 IPC system

The pumps detected the presence or otherwise of a garment at the point of inflation. If the garment was still being removed or replaced during the inflation cycle it was picked up within 60 seconds at the next inflation cycle giving a maximum error time of ±1 minute. In all cases the alarms activated when they should, the pump continued to run during the alarm condition and the alarms stopped automatically upon reattaching the garments. For each combination of garments the total wear time was 50 minutes (Table 1).

- **Average recorded wear time was 48.7 (range 47–51) minutes, which is an accuracy of 97.3%.**

Control device

The 'garment-off' alarm was activated 5 minutes after garment removal in each test series and stopped only when reset by the operator at the point of garment reapplication. Average recorded wear time was, in all cases, longer than actual garment application (Table 1). At the upper range, garment wear time was recorded at 75 minutes, which is 50% greater than actual wear time (50 minutes).

- **Average recorded wear time was 66.7 (range 63–75) minutes, which is an accuracy of 66.5%.**

The two datasets were compared using a Mann Whitney U test and revealed a significant difference in the performance of both pumps. With regard to compliance monitoring, the Flowtron ACS900 IPC system has been shown to be the more accurate device (p=<0.0036) with pump-recorded wear time closely representing actual wear time.

Compliance Monitoring:

Usability

While technical bench testing is an important validation step for product development, the device must also have a high level of usability, because a product that is difficult to use will undoubtedly lead to lower compliance and increases the risk of misuse. Getting end user feedback is critical to the evolution of a class-leading device.

Aim

To evaluate the usability and acceptability of the compliance-monitoring feature in the Flowtron ACS900, when used with a range of uniform and sequential compression lower limb garments, and monitored by minimally trained healthcare staff.

Primary objective

- Determine whether minimally trained users can correctly identify alarm conditions
- Determine whether minimally trained users can correctly record non-compliant time (garment removed)
- Determine whether minimally trained users can correctly record the total compliant (therapy) time

Methodology

A minimum of six nurses or other healthcare professionals, familiar with the Flowtron ACS900 IPC system or similar IPC devices, were invited to participate; the evaluation took place within a hospital stroke unit. Participants were invited to read the troubleshooting section of the Instructions for Use (IFU) and a period of at least 60 minutes minimum between reading the IFU and carrying out the task was enforced to allow for learning decay.

TEST CONDITION	FLOWTRON ACS900	CONTROL	MANN WHITNEY U TEST
50 minutes (wear time)	48.7 (range 47–51)	66.7 (range 63–75)	p=<0.0036
Accuracy	97.33%	66.5%	

Table 1: Compliance monitoring accuracy

USABILITY GOAL	GOAL	ACCEPTANCE CRITERIA	RESULTS	PASS/FAIL
1	Minimally trained users shall be able to identify the alarm correctly.	95%	100%	PASS
2	Minimally trained users shall be able to identify the time the leg hasn't been in the garment correctly.	80%	100%	PASS
3	Minimally trained users shall be able to identify the duration of therapy delivered correctly.	80%	100%	PASS

Table 2: Usability performance goals

The Flowtron ACS900 IPC system was set up according to the manufacturer's instructions and a DVT 10 garment fitted. Participants were asked to leave the room before and between tests and, on return, were presented with three different scenarios (below). Each was asked to correctly identify therapy status from the alarm indicators and record the duration of compliance / non-compliance with therapy.

- Garment has been unplugged from the pump
- Garment has been removed from the leg [non-compliance time]
- Garment fitted correctly and pump in normal therapeutic mode [compliance time]

An independent observer recorded participant responses and pass-fail usability benchmarks were set as shown in Table 2

Results

Six healthcare professionals participated across a range of disciplines including staff nurses, a nurse specialist, an educator, an occupational therapist and a medical engineer. All were familiar with Arjo IPC systems and had between three weeks and sixteen years experience.

In all test conditions the six participants correctly identified and addressed the simulated faults and were able to determine the duration of either therapy or non-compliance. Five of the six individuals disconnected the garment from the pump before reapplying to the limb and then reconnecting to the pump (quoted: 'easier to remove residual air'). The least experienced clinician reapplied the garment without pump disconnection and, in all cases, normal therapy resumed without further intervention or need to interact with the pump. Anecdotally, all reported that they refit and plug in the garment without stopping the pump, benefiting from automatic functionality.

Summary

Technical bench tests are an important step in the validation of product features, particularly when assessing clinical capability. Where a European or International performance standard has not been defined, it is appropriate to compare performance against an established device that has substantial market presence and acknowledged clinical efficacy. The findings of the modest test series presented here shows the Flowtron ACS900 IPC device triggers appropriate alarms to alert the caregiver to garment removal and records total wear time with a level of accuracy that is clinically appropriate and does not overestimate therapy compliance. In addition, the device automatically cancels the alarms when the garment is reapplied, a welcome usability feature for the busy healthcare environment.

A device also has to be easy to use and accessible in order to be of benefit in a busy healthcare environment. Features such as audio-visual alarms and longitudinal compliance monitoring can flag therapy interruptions, such as delayed initiation and garment removal, which have been identified as a major barrier to compliance[5,24,25,28,29]. The simple usability study reported above was able to confirm that the compliance-monitoring feature is an intuitive extension of the standard alarm system on the Flowtron ACS900 IPC and enables caregivers to accurately assess both therapy duration and periods of non-compliance.

Conclusion

The ability to monitor patient wear time during IPC therapy and provide patient specific data related to concordance with mechanical prophylaxis is an important component of the VTE care pathway. Validation and usability testing has shown the Flowtron ACS900 IPC device monitors compliance and does so with a level of accuracy and usability that significantly exceeds that of the benchmark competitive Sequential Compression Device.

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