A randomised crossover study of low-ankle-pressure graduated-compression tights in reducing flight-induced ankle oedema

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ABSTRACT

Objective: To determine if low-ankle-pressure graduated-compression tights (GCTs) reduce flight-induced ankle oedema and subjectively rated travel symptoms of leg pain, discomfort and swelling, and improve energy levels, ability to concentrate, alertness, and post-flight sleep.

Design, setting and participants: Open, randomised crossover trial comparing the effects of GCTs (5 mmHg at ankle, 17–20 mmHg at calf and falling to 10 mmHg above knee and 4 mmHg at buttocks) among 50 adults on flights of 5 hours' or more duration between 1 May and 8 October 2006; 47 volunteers (pilots and passengers) completed the trial.

Main outcome measures: Differences in right ankle circumference before and after flight with GCTs and without GCTs; travel symptoms rated on visual analogue scales.

Results: Low-ankle-pressure GCTs decreased ankle swelling (mean difference, –0.19 cm; 95% CI, –0.33 to –0.65 cm; $P = 0.012$). Participants reported their legs felt better (mean, 1.6; $P < 0.001$; 95% CI, 1.0 to 2.1), warmer (mean, –1.1; $P < 0.001$; 95% CI, –1.6 to –0.6), and they had a better night's sleep (mean, 1.2; $P < 0.001$; 95% CI, 0.8 to 1.7) after the flight when they wore GCTs. Shifts in rating-scale probability distributions showed improvements in the ratings of pain (60%; $P < 0.001$), leg discomfort (50%; $P = 0.001$), leg swelling (45%; $P = 0.006$), energy levels (18%; $P = 0.016$), alertness levels (13%; $P = 0.031$), and concentration (12%; $P = 0.023$) when wearing GCTs.

Conclusions: Low-ankle-pressure GCTs reduce flight-induced ankle oedema and subjectively rated travel symptoms of leg pain, discomfort and swelling, and improve energy levels, ability to concentrate, alertness, and post-flight sleep.

Trial registration: Australian New Zealand Clinical Trials Registry ACTRN12606000150549.

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More than 90% of air passengers flying for more than 5 hours will develop some degree of ankle oedema.[1] Use of low-compression hosiery (8–20 mmHg at the ankle) reduces subjectively rated flight-related symptoms of discomfort, swelling, fatigue, aching and tightness.[2] However, the bulk of published research on flight-induced oedema results from studies that measure oedema with the incidence of symptomless deep vein thrombosis (DVT). Passengers can expect a reduction of both oedema and DVT when wearing below-knee compression stockings with ankle compression levels of 14–17 mmHg.[3,4] The most recent Cochrane review on this subject suggests the need for further research on the relative effects of different pressures exerted by stockings.[3] We initiated this trial because of the scarcity of reports on the effect of low-ankle-pressure graduated-compression tights (GCTs) on flight-induced ankle oedema and other flight-related symptoms.

The GCTs we used in our study comprised 76% nylon and Meryl microfibre, and 24% Roica spandex, and were developed by Australian sports physicians and sports scientists specifically to help athletes to recover more quickly from strenuous competition and training. They were full-leg-length gradient-compression stockings, similar (but with a lower compression) to antithrombosis stockings. The GCTs we used had the following pressures: about 5 mmHg at the ankle, 17–20 mmHg at the calf, and falling to 10 mmHg above the knee and 4 mmHg at the buttocks, compared with the frequently cited Scholl Flight Socks (SSL Australia Pty Ltd, Melbourne, Vic), which provide 14–17 mmHg of pressure at the ankle.[4] GCTs promote blood flow from superficial veins into deep veins and compress deep veins.[4-7]

The purpose of our trial was to test the hypothesis that low-ankle-pressure, full-leg-length GCTs significantly improve flight-induced ankle oedema and other flight-related symptoms. We subjectively assessed not only leg pain, discomfort and swelling, but also energy levels, ability to concentrate, alertness, and post-flight sleep.

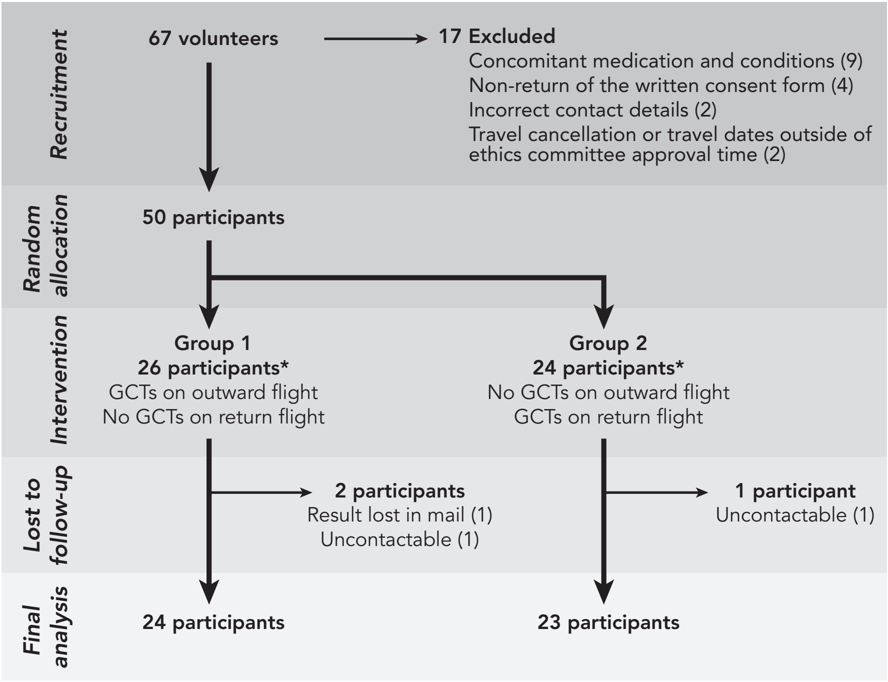
METHODS

We conducted our unblinded, randomised crossover trial according to International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use/Guidelines for Good Clinical Practice (ICH GCP) standards,[8] and the protocol was approved in advance by the Bellberry Human Research Ethics Committee.[9] Each participant provided written informed consent before participating.

Participants were volunteers aged 18 years or older who had a confirmed flight booking on a flight of 5 or more hours' continuous duration (with at least a 48-hour period between the forward and return flights) between 1 May and 8 October 2006. They included Qantas pilots referred by the Australian and International Pilots Association and general passengers who responded to advertisements in major metropolitan newspapers in Brisbane, or after being referred by other trial participants; volunteers were sought between 20 April 2006 and 16 September 2006. Volunteers were not eligible if they had received medical advice to wear GCTs in flight; had a previous history of DVT; had been prescribed medication for cardiovascular disease, coagulation disorders, varicose veins, bone or joint problems, diabetes or hypertension; had a body mass index (BMI) ≥ 35; or if they had had neoplastic disease within the previous 2 years (other than basal cell carcinomas). Thus, participants had a low to medium risk of DVT, and our study had the same inclusion and exclusion criteria as the LONFLIT 4 study.[4]

The GCT used was a Skins travel and recovery garment (Skins Compression Garments Pty Ltd, Sydney, NSW), listed on the Australian Register of Therapeutic Goods as a Class 1 medical device (ID: 80116). Participants were randomly assigned to wear low-ankle-pressure GCTs on either their forward

1 Recruitment and analysis for the study



GCTs = graduated-compression tights.

* 25 participants were randomly allocated to each group, but one participant allocated to Group 2 mistakenly followed the protocol for Group 1.

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or return flight. Random allocation was achieved by giving participants a sealed envelope with instructions according to a computer-generated randomisation sequence.[10] During the control flight (when GCTs were not worn) participants wore their usual clothes.

Suggestions for in-flight exercises were given to both groups. The exercises were described on an instruction sheet,[11] and included mild (mainly isometric) exercises and walking about the cabin and moving the legs for 3–4 minutes every hour.

Outcomes were self-reported. Participants were given oral and written instructions on how to measure around their ankle and how to complete the study questionnaire. They measured around the smallest part of their right ankle, marking three points on the ankle using a 150 cm plastic tape measure. They were instructed to take measurements in the airport waiting lounge (before take-off), 2.5 hours into the flight, and on landing (while on the tarmac), and were asked to take three measurements at each time.

The primary endpoint was the difference in change of ankle circumference (measurements taken before flight and after landing) between the control group (no GCTs) and treatment group (GCTs).

Secondary endpoints included leg pain, leg discomfort, perceived leg swelling, energy levels, alertness, and ability to concentrate, each rated on a unidimensional, 11-point numerical rating scale (NRS). A bidirectional Likert scale (–5 to + 5) was used to assess post-flight comparisons of sleep, comfort, coolness, and choice of future flight garment.

Adverse-event data were collected as a specific written question about the occurrence of events, and a review of any comments recorded on the questionnaire. When participants mailed back their data, we performed an additional follow-up, either by telephone or email, during which we again prompted them to report any adverse event.

Statistical analysis

The expected difference between the means of the ankle circumference for the GCT and control groups was about 0.2 cm.

The standard deviation of the difference was assumed to be 0.3 cm. The sample size required to detect a 0.2 cm difference in ankle size with 80% power and 5% significance was 38 participants.[12] We estimated that 12 would drop out or be lost to follow-up, as the study was a self-assessment with no investigator visit. Thus, 50 participants were entered into the study.

All calculations were based on an intention-to-treat analysis. Ankle circumference differences were analysed using a crossover analysis of variance. The difference in means is given with appropriate *P* values and, where relevant, 95% confidence intervals.

The secondary endpoints involved ratings which were analysed using the non-parametric Wilcoxon matched-pairs signed rank test. We used InStat statistical software, version 3 (GraphPad Software, San Diego, Calif, USA). Count variables were analysed using a generalised linear model with a Poisson distribution and log link by means of GenStat for Windows (10th edition; VSN International, Hemel Hempstead, UK). A *P* value of less than 0.05 was used to indicate statistical significance.

RESULTS

Sixty-seven people (23 Qantas pilots and 44 passengers) volunteered to participate in the study, and 17 (16 passengers and one pilot) were excluded (Box 1). Of the 50 participants (22 pilots and 28 passengers) recruited to the study, 26 wore GCTs on their outward flight (Group 1; 18 men and six women) and the remaining 24 wore GCTs on their return flight (Group 2; 17 men and six women). Ultimately, 47 participants (24 in Group 1 and 23 in Group 2) returned data and so completed the study (Box 1). Their ages ranged from 24 to 71 years.

Box 2 presents baseline characteristics for the participants in terms of physical characteristics, leg symptoms and activity level, and proportion of time at work spent sitting and standing. There is nothing in these data to suggest that our participants would not be representative of the general healthy flying population.

When wearing GCTs, there was a decrease in ankle swelling compared with not wearing GCTs (mean difference, –0.19 cm; 95% CI, –0.33 to –0.065 cm; $P = 0.012$).

Measurements involving ratings were not analysed in a way that produced CIs of rating differences. Significant differences in Box 3 indicate a shift in the probability distributions of the ratings. So, for the rest of this section we make general observations on the ratings based on Box 3.

When subjects wore GCTs, they had a 60% improvement in their leg-pain rating at the end of the flight, a 50% improvement in their leg discomfort rating and a 45% improvement in their leg-swelling rating.

2 Baseline characteristics of the 47 study participants

Physical characteristics	Mean (95% CI)
Age	43 years (40–46 years)
Weight	81 kg (76–87 kg)
Height	173 cm (168–179 cm)

	Response				
Leg symptoms and activity	Never	Rarely	Occasionally	Often	Every day
Leg pain during day	23.4%	51.1%	23.4%	2.1%	0
Leg pain during night	19.1%	57.4%	19.1%	4.3%	0
Ankle swelling	37.0%	37.0%	23.9%	2.2%	0
Play sport	19.1%	12.8%	34.0%	29.8%	4.3%
Exercise	0	4.3%	31.9%	53.2%	10.6%

	Proportion of time				
Time at work	0	25%	50%	75%	100%
Spent sitting	0	8.5%	19.1%	57.4%	14.9%
Spent standing	25.5%	46.8%	17.0%	8.5%	0

There was also an 18% improvement in their energy-level rating, a 13% improvement in their alertness level and a 12% improvement in their ability to concentrate.

At the end of both flights, participants responded to a number of additional questions using a bidirectional Likert scale (–5 to + 5, with 0 representing no change). A *t* test was used to analyse the responses.

Participants reported their legs felt better after the flight (mean, 1.6; $P < 0.001$; 95% CI, 1.0 to 2.1), that they had a better night's sleep after the flight (mean, 1.2; $P < 0.001$; 95% CI, 0.8 to 1.7), and that their legs felt warmer after the flight (mean, –1.1; $P < 0.001$; 95% CI, –1.6 to –0.6) when they wore GCTs.

Participants reported improved comfort when wearing GCTs, but this did not reach statistical significance (mean, 0.6; $P = 0.057$). On the other hand, they would more than occasionally choose to wear GCTs on future flights (mean, 2.0; $P < 0.001$; 95% CI, 1.4 to 2.7).

The only adverse event reported was transient discomfort from the footstrap of the GCTs, reported by nine participants (19%).

DISCUSSION

The use of GCTs to improve blood flow for patients with chronic venous insufficiency is routine. The rationale is based on the observation that oedema is the first symptom when venous blood flow is not adequately maintained and that compression stockings increase blood velocity by mechanically reducing the size of the larger veins. In addition to this, they also increase perivascular pressure and inhibit the outflow of blood and plasma factors from the endothelial venular gaps. This reduces contact with tissue factors and subsequent coagulation and thrombosis formation.[13]

Importantly, the 2006 Cochrane review established that compression garments worn during flight reduced oedema and the risk of symptomless DVT.[3] Our findings show that low-ankle-pressure GCTs are effective at reducing flight-induced ankle oedema.

Our trial showed that even small quantitative increases in actual ankle circumference are associated with perceptions of leg swelling and associated pain and discomfort. This is consistent with the literature assessing compression stockings in healthy volunteers.[14-16]

Crew, and some passengers, actively work during flights. The impact from sleep disturbance (circadian rhythm disruption) and a reduced arterial partial pressure of oxygen (PaO_2) have been implicated in reduced cognitive function in pilots[17] and cabin crew.[18] We explored self-assessed ratings of alertness, ability to concentrate and general energy levels in passengers. When wearing GCTs, participants had increased perceptions of alertness, ability to concentrate and higher energy levels compared with the flight where they did not wear GCTs. There are scarce data on passenger cognitive performance and recognition by research groups[19] and other bodies of the need to conduct further studies.[20]

Visual analogue scales have been used to assess leg discomfort and swelling in flight attendants;[2] however, only the pain intensity NRS adopted in this study has published reliability and validity in adults.[21] While we made no objective tests of cognitive function, and unvalidated NRSs were used, our findings support improved cognitive function during flights when GCTs are worn, and further investigation is warranted.

A final consideration is the length of the garment which, as a full lower-body gar-

3 Differences (means and 95% CIs) in selected parameters after flying with and without graduated-compression tights (GCTs)

Parameter	GCTs	No GCTs	*P*
Difference in ankle circumference (cm)	0.23 (0.13–0.32)	0.42 (0.32–0.52)	0.012
No. of alcoholic drinks — passengers	2.0 (1.1–2.8)	2.0 (1.2–2.8)	0.405
No. of non-alcoholic drinks — crew	7.4 (5.6–9.2)	8.7 (6.9–10.5)	0.082
No. of non-alcoholic drinks — passengers	4.0 (3.2–5.0)	4.6 (3.4–5.7)	0.405
Rating* for:			
Leg pain	0.6 (0.4–0.9)	1.5 (1.0–2.0)	< 0.001
Leg discomfort	1.1 (0.8–1.7)	2.2 (1.6–2.8)	0.001
Perceived leg swelling	1.2 (0.7–1.6)	2.2 (1.6–2.9)	0.006
Energy levels	5.3 (4.7–5.9)	4.5 (4.0–5.0)	0.016
Alertness	5.3 (4.7–5.9)	4.7 (4.2–5.1)	0.031
Ability to concentrate	5.7 (5.1–6.3)	5.1 (4.6–5.7)	0.023
Flight duration (hours)	9.6 (8.4–10.8)	9.7 (8.4–11.0)	0.160

* Rated on a unidimensional, 11-point numerical rating scale.

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ment, applies pressure to about 45% of the body. Classic graduated-compression stockings are generally below-knee and apply pressure to about 18% of the body. A study comparing below-knee graduated-compression stockings with full lower-body GCTs would test the hypothesis that greater protection from depressurisation offered by these GCTs might lead to improvement in the quantitative and qualitative measures we assessed in this study. Further research on the comparative effects of total body GCTs is planned.

COMPETING INTERESTS

Funding for this study was provided by Skins Compression Garments of Sydney, NSW. Melissa Hagan was contracted to conduct the study independently, and received no other funding from the company other than to conduct this research. Stephen Lambert is under contract as a scientific consultant for Skins Compression Garments. The study was initially designed by Stephen Lambert. Melissa Hagan independently collected, analysed and interpreted the data, and wrote the article. The agreement to publish the results was made prior to data collection with the Bellberry Human Research Ethics Committee, which approved this study. Skins Compression Garments had no influence over the decision to publish, and Melissa Hagan had final approval over the article's content. The trial was registered with the Australian Clinical Trials Registry (trial no. 12606000150549) and was initiated on 19 April 2006.

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