

# GRADED COMPRESSION STOCKINGS FOR PREVENTION OF DEEP-VEIN THROMBOSIS AFTER HIP AND KNEE REPLACEMENT

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**We performed a prospective, randomised controlled trial in 177 patients who were having either total hip or knee replacement, to evaluate the use of both above- and below-knee graded compression stockings in the prevention of deep-vein thrombosis (DVT).**

**With above-knee stockings, we found no significant reduction of the overall, proximal or major calf (> 5 cm) DVT rates. With below-knee stockings, the overall thrombosis rate was similar to that of the control group but the stockings appeared to have altered the pattern of thrombosis. Patients who had total hip replacement and wore below-knee stockings had a significantly higher rate of proximal or major calf DVT ( $p = 0.03$ ). This pattern was reversed in patients with total knee replacement who developed a significantly lower rate of proximal or major calf DVT with below-knee stockings ( $p < 0.05$ ).**

**Our results showed that, with the exception of below-knee stockings in knee replacement patients, graded compression stockings were ineffective in preventing DVT after hip or knee replacement surgery.**

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Deep-vein thrombosis (DVT) is a potentially serious complication after total hip or knee replacement. The routine use of prophylaxis, either pharmacological or mechanical, has been strongly recommended (NIHCC 1986; Parker-

Williams and Vickers 1991; ECS 1992; THRIFT 1992). Unlike pharmacological agents, mechanical methods do not interfere with haemostasis and are unlikely to cause bleeding complications; consequently, they are popular with orthopaedic surgeons. A postal survey of orthopaedic surgeons in the UK showed that 68% used graded compression stockings as prophylaxis for DVT (Laverick, Croal and Mollan 1991). Their efficacy has been well documented in abdominal surgery (Holford 1976; Scurr et al 1977; Allan et al 1983; Turner, Cole and Brooks 1984; Wille-Jorgensen et al 1985; Jeffery and Nicolaidis 1990), but there is little information on their use in orthopaedic surgery (Barnes et al 1978; Ishak and Morley 1981; Ohlund, Fransson and Starck 1983).

In a recent meta-analysis of papers published in the last 30 years, Wells, Lensing and Hirsh (1994) identified only 12 articles which fulfilled their criteria for prospective, randomised trials, and of these only one was on patients undergoing joint replacement (Fredin et al 1989). The conclusions strongly favoured the use of compression stockings, the only exception being the orthopaedic study in which no statistically significant benefit had been demonstrated.

The aetiology and natural history of thromboembolism in orthopaedic surgery differ from those in general surgery (Sikorski, Hampson and Staddon 1981) and it is therefore illogical to extrapolate results from one specialty to another. Our aim was to perform a randomised, controlled prospective study to evaluate the efficacy of graded compression stockings in joint replacements.

## PATIENTS AND METHODS

We enrolled 177 patients admitted to Glenfield General Hospital for either primary total hip or knee replacement into a trial which investigated above- and below-knee stockings. Those who had a proven past history of thromboembolism, significant peripheral vascular disease, or were having revision surgery or bilateral replacements were excluded. Approval was granted by the local ethical committee and signed informed consent was obtained in all cases.

Of the 177 patients, 37 were excluded for reasons shown in Table I. Two more died, one from a myocardial infarction and the other from pulmonary embolism, before veno-

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**Table I.** Reasons for exclusion of patients from the study

	Number
Surgery deferred	4
Patient withdrawal preoperatively	5
Bilateral failure of venogram	5
Venogram refused postoperatively	3
Stockings removed by patient	13*
Failure to complete trial protocol	7
Total	37

\* non-compliant patients in the below-knee study were not excluded

lateral aspect of the thigh held proximally by a waist band. Both types of stocking were designed to generate similar graduated pressure profiles along the length of the leg.

The stockings were applied to both legs on the day before surgery. That on the operated leg was removed for the duration of surgery and reapplied immediately at the end of the operation. Thereafter, they were kept on until venography was performed. In patients having total knee replacements, the stockings were placed over the wound dressing, with a Robert-Jones bandage applied over the stocking for the first two days, at which time the patient was mobilised and knee flexion begun.

**Table II.** Details of the patients in the groups

	THR			TKR		
	Control (n = 22)	Above-knee stockings (n = 24)	Below-knee stockings (n = 18)	Control (n = 32)	Above-knee stockings (n = 20)	Below-knee stockings (n = 22)
Age in years (mean; range)	64.8 (58 to 79)	69.9 (56 to 83)	67.2 (49 to 88)	69.9 (52 to 83)	70.0 (57 to 83)	71.1 (52 to 84)
Male:female	1:2.6	1:0.85*	1:2.6	1:1.3	1:1.5	1:1.4
Smokers (percentage)	22.7	8.3	16.7	18.8	10.0	4.5
Cemented prostheses (percentage)	95.5	95.8	100.0	78.1	70.0	81.8
Body mass index (mean ± SD)	24.6 ± 3.38	22.5 ± 2.5	24.7 ± 3.34	28.6 ± 3.38	26.7 ± 4.04	28.0 ± 4.84
Days to mobilisation (mean)	2.0	52.2	12.00	2.15	2.05	2.05
Pathology						
Osteoarthritis	19	22	17	29	19	22
Rheumatoid arthritis	2	2	1	3	1	
Avascular necrosis	1					

\* compared with control group p < 0.01

graphy was performed. This left 138 patients for analysis. Table II gives the number of patients in each group and their details which were tested statistically for any difference between the groups. For total hip replacements, the groups were found to be similar in every aspect except for the gender ratio between the control group and the above-knee stocking group; the latter had a significantly higher proportion of male patients. For total knee replacements, there were no significant differences in any of the groups.

In the hip replacement group, all but two patients had a cemented Charnley prosthesis inserted through the lateral approach. In the knee replacement group, all but one had a Press-Fit Condylar prosthesis (PFC; Johnson & Johnson, Rayham, Massachusetts); in 23% it was uncemented. We have a standard postoperative rehabilitation policy for hip and knee replacement patients and most patients were mobilised on the second day after operation. A few were mobilised slightly later because of minor postoperative complications but none waited beyond the fourth day.

**Above-knee stockings.** We randomised patients on a one-to-one ratio, into either the control or stocking group. The control group did not receive any form of DVT prophylaxis. The stocking group wore full- or thigh-length graded compression stockings. The thigh-length stockings were self-supporting with a non-occlusive elasticated band at the top. The full-length stockings had a flange extending over the

**Below-knee stockings.** We randomised patients on a one-to-four ratio into the control and stocking groups, so that for each patient randomised into the control group, four others were randomised into the stocking group. The randomisation was deliberately skewed to allow us to utilise the data from the control groups in the above-knee study. Six hip and eight knee replacement patients were randomised to the control group in this part of the study and they received no DVT prophylaxis. Those assigned to the stocking group wore knee-length stockings in a manner similar to that already described. The operations were performed by the same group of surgeons using the same prostheses and the same surgical technique. The post-operative mobilisation regime was also similar.

The end-point of the study was DVT as identified by bilateral ascending venography performed between the fifth and seventh postoperative days. Thrombi were classified as proximal when they involved the popliteal vein or above, as major calf thrombosis when they were more than 5 cm long but confined to the calf, and as minor calf thrombosis when they were less than 5 cm in length (Fordyce and Ling 1992).

**Statistical analysis.** We performed statistical analysis using the chi-squared, Fisher's exact probability and Student's *t*-tests. The statistical power of the study was calculated using the Epi-info statistical package (Centers for Disease

**Table III.** Rates of thrombosis (percentage of the number of legs with a successful venogram) in the groups

	Control	Above-knee stockings	Below-knee stockings
<b>Hip</b>			
Ipsilateral leg			
All thrombosis	27	22	50
Proximal	0	13	28*
Major calf	9	4.5	11*
Minor calf	18	4.5	11
No thrombosis	73	78	50
Contralateral leg (all thrombosis)	10	9	7
<b>Knee</b>			
Ipsilateral leg			
All thrombosis	78	65	68
Proximal	12.5	30	9*
Major calf	53	30	23*
Minor calf	12.5	5	36
No thrombosis	22	35	32
Contralateral leg (all thrombosis)	20	12	10

\* statistically significant when proximal and major calf thromboses were analysed in combination

Control and Prevention, Atlanta, Georgia). By assuming a three-fold difference in the DVT rates of the two groups, e.g. 60% in the control and 20% in the stocking, a sample size of 27 would give a power of 80% to the study.

In the above-knee study we did not perform venography on patients who failed to follow the protocol by removing their stockings prematurely. They were excluded from the final analysis (Table I). In view of the high rate of patients removing their stockings early, we performed the below-knee study on an 'intention-to-treat' basis (Altman 1990), and those patients who removed their stockings prematurely were submitted to venography. Patients who had failed venography on both legs were excluded (Table I).

## RESULTS

The thrombosis rates of the study groups are shown in Table III. We used the chi-squared test with Yates' correction or Fisher's exact test to compare the two stocking groups with the control groups. Hip replacements were studied separately from knee replacements. Because the numbers in some of the categories were too low for analysis, we constructed two-by-two contingency tables by combining proximal and major calf thromboses into one category and minor calf and no thromboses into another category. These groupings were chosen because there is evidence to suggest that minor calf thrombi of less than 5 cm in length resorb spontaneously and can be considered as 'safe' (Kakkar et al 1969). By contrast, proximal thrombi have been shown to be associated with an increased risk of pulmonary embolism (Moser and Le Moine 1981). For the contralateral leg, the rates of thrombosis in the different sites were so low that valid statistical analysis could only be performed on the overall rates.

We failed to perform venography in both legs in five patients and they were excluded. In a further 12 patients,

venography was successful only in one leg. These patients were not excluded but since valid findings were available only for one leg, the results were presented as the percentages of the number of legs with successful venograms. We therefore performed statistical analysis separately on the ipsilateral side (that operated on) and the contralateral side, based on the proportion of legs with successful venograms.

**Hip replacement and above-knee stockings.** We found no statistical difference between patients who wore above-knee stockings and those who did not in terms of the overall, proximal or calf thrombosis rates. In the stocking group 13% of patients developed proximal thrombosis in the operated leg compared with none in the control group, but this difference was not statistically significant. In the contralateral leg, the thrombosis rates in the two groups were similar.

**Hip replacement and below-knee stockings.** In the stocking group 28% of the operated legs developed proximal thrombosis compared with none in the control group; the difference was statistically significant (Fisher's exact probability test,  $p = 0.03$ ). The overall thrombosis rate was 50% in the stocking group and 27% in the control group but the difference was not statistically significant. In the contralateral leg, the thrombosis rates in the two groups were similar.

**Knee replacement and above-knee stockings.** The overall thrombosis rates in the operated leg were generally high; 78% in the control group and 65% in the above-knee stocking group. A similar pattern to that in hip replacement patients was observed. Patients who wore above-knee stockings had a tendency to develop proximal thrombosis (30%) compared with the control group (12.5%), but the difference was not statistically significant. There was also no significant difference in the overall and calf thrombosis rates between the two groups. The contralateral leg had a similar rate of DVT in the two groups.

**Knee replacement and below-knee stockings.** The proximal and major calf thrombosis rates in the operated leg were significantly reduced in patients who wore below-knee stockings; 32.0% in the stocking group and 65.5% in the control group (chi-squared test with Yates' correction,  $p < 0.05$ ). The overall thrombosis rates of 68% in the stocking group and 78% in the control group, however, did not differ significantly. Below-knee stockings appeared to influence the distribution of the thrombi but did not alter the thrombogenicity. No significant difference was observed in the contralateral leg.

We performed a stratified Mantel-Haenszel chi-squared test to evaluate the overall result by combining the hip and knee replacement patients. We found no significant benefit from the use of graded compression stockings ( $p = 0.274$ ). The odds ratio was 2.02 (95% confidence limits 0.49 to 8.57).

In our series the non-compliance rate was high; 13 of the 57 patients (23%) in the above-knee study removed their stockings before completion of the protocol. Venography was not performed on these patients and they were excluded from the final analysis. In the below-knee study, 7 out of 40 patients (17.5%) removed their stockings prematurely. Using the 'intention-to-treat' principle, postoperative venography was performed and the results were included in the analysis. Of the patients who removed their stockings prematurely, one developed proximal thrombosis, one had major calf and one had minor calf thromboses. The overall thrombosis rate in this group was therefore 43%. By combining knee with hip replacement patients, the overall thrombosis rate in patients who wore the stockings properly was calculated to be 49%. Patients who did not wear the stockings properly had a marginally lower rate of DVT than those who wore them properly and faithfully, although the difference was not statistically significant.

To compare the efficacy of above-knee with below-knee stockings, we had to exclude the results in those patients who removed their stockings prematurely in the below-knee study because the 'intention-to-treat' principle was applied only to the below-knee and not to the above-knee group. No significant difference was noted in the overall thrombosis rate in the hip replacement (chi-squared test,  $p = 0.072$ ) or knee replacement patients (chi-squared test,  $p = 0.056$ ) which suggests that there is little to choose between the two types of stocking.

## DISCUSSION

Our results show that in hip replacement, neither above- nor below-knee graded compression stockings offer any advantage in the prevention of DVT. We also found that a higher proportion of patients developed proximal thrombosis when wearing the stockings; this difference reached statistical significance with below-knee stockings ( $p = 0.03$ ). This is an unexpected but important finding since there is good evidence to suggest that proximal thrombi pose a greater risk of pulmonary embolism (Kak-

kar et al 1969; Moser and Le Moine 1981). Paradoxically, the only fatal pulmonary embolism in our series occurred in the knee replacement control group although the true incidence of pulmonary embolism may present a different picture as clinical detection is grossly inaccurate.

For knee replacement, above-knee stockings gave no significant improvement in the DVT rate but once again there was a higher proportion of patients with proximal thrombosis. The only significant advantage of using graded compression stockings was found in knee replacement patients wearing below-knee stockings. There appeared to be a significant reduction in the rate of proximal and major calf thromboses (chi-squared test with Yates' correction,  $p < 0.05$ ). There was, however, an increased rate of minor calf thrombosis in the below-knee stocking group and the overall thrombosis rates showed no difference.

Graded compression stockings are designed to reduce venous stasis and improve blood flow in the leg by generating a precise pressure profile. Sigel et al (1975) studied femoral venous blood flow in healthy human volunteers lying in a horizontal position or with a 15° downward tilt. They concluded that a pressure profile of 18, 14, 8, 10 and 8 mmHg from ankle to thigh gave the highest flow velocity. Their findings were further supported by Lawrence and Kakkar (1980).

Joint replacement patients differ considerably from normal volunteers. All our patients were mobilised early, and during the day they spent most of their time in either a sitting or standing position. Furthermore, such patients very often develop leg swelling which may interfere with the ideal, smooth pressure gradient. Localised swelling around the hip and the knee may generate an abnormally high compression pressure, causing stagnation in the more distal segment. This may partly explain our results which showed that graded compression stockings altered the pattern of thrombosis but had no influence on the overall thrombogenicity. This suggests that there are other factors such as local endothelial damage (Comerota et al 1989; Coleridge-Smith, Hasty and Scurr 1990) involved in thrombogenesis in joint replacement patients.

Below-knee stockings are cheaper and previous studies have shown them to be as effective as above-knee stockings (Williams and Palfrey 1988; Porteus et al 1989; McNally et al 1995). Our results confirm that there is no significant difference between the two types of stocking in terms of efficacy. Neither type, however, gives any significant reduction in the overall thrombosis rates when compared with the control group.

It has been shown that both above- and below-knee stockings are generally poorly applied but that the below-knee were better than the above-knee (Williams et al 1994). In our study, the stockings were regularly inspected with close adherence to the manufacturer's guidelines. With this strict regime, 23% of the patients in the above-knee stocking group and 16% in the below-knee stocking group found the garment too uncomfortable and requested their removal.

There are few clinical trials on graded compression stockings in orthopaedic patients. In a small study on 18 patients, Barnes et al (1978) used Doppler ultrasound for the detection of DVT and found that graded compression stockings were effective after total hip replacement. Ishak and Morley (1981) studied 76 hip replacement patients using bilateral venography and also concluded that graded compression stockings were effective. In their study, however, Dextran 70 was given in a non-randomised manner and patients did not follow a uniform mobilisation regime. Their results were presented as overall thrombosis rates and there was no differentiation between ipsilateral or contralateral legs, nor was there any clarification as to the site of thrombi. In a third study, Ohlund et al (1983) reported their findings in 62 patients who had a mixture of hip procedures. Using the fibrinogen uptake test, they favoured the use of graded compression stockings, but only in male patients.

We chose to use venography for our study because it is the gold standard of DVT research (Whitehouse 1987). In hip replacement patients our results differed from those previously reported in that we found no significant benefits from the use of either above- or below-knee stockings. In the knee replacement group our results showed that below-knee stockings significantly reduced the rate of proximal and major calf thromboses but did not influence the overall rate of thrombosis. Above-knee stockings were ineffective in knee replacement patients.

The use of graded compression stockings in hip or knee replacement is based on weak scientific and clinical evidence and it is surprising that most British orthopaedic surgeons and a number of published reports recommend their use (NIHCC 1986; ECS 1992; Murray, Carr and Bulstrode 1995). Our study shows that, with the possible exception of below-knee stockings in knee replacement patients, graded compression stockings are ineffective as prophylaxis for DVT.

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