A VENOUS FOOT PUMP REDUCES THROMBOSIS AFTER TOTAL HIP REPLACEMENT

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In a prospective, randomised controlled trial, the efficacy of the A-V Impulse System in the prevention of deep-vein thrombosis was investigated in 84 patients who had undergone total hip replacement. The incidence of venographically proven, and clinically significant postoperative deep-vein thrombosis was 40% in the control group and 5% in the treatment group ($p < 0.001$). No adverse reactions were recorded.

Deep-vein thrombosis occurs in up to 70% of unprotected patients after total hip replacement (Bergqvist 1983). Subclinical pulmonary emboli are seen in up to 23% of patients (Harris et al 1984) and 1% to 2% die from pulmonary emboli (Johnson, Green and Charnley 1977). The post-phlebotic limb syndrome, which may develop following thrombosis, causes considerable morbidity. Its true incidence after total hip replacement is unknown but it may be as high as the 51% reported following fractures of the long bones (Aitken, Mills and Immelman 1987).

Many prophylactic regimes have been described but none has proved ideal and there is no consensus of opinion as to the most suitable prophylaxis (Brenkel and Clancy 1989).

The use of low-dose heparin, although effective in some other operations, does not protect against the more serious proximal thrombosis in hip replacement (Hampson et al 1974; Morris, Henry and Preston 1974). Recently, it has been claimed that low-molecular-weight heparin is more effective in reducing the incidence of these dangerous proximal thrombi, but the evidence is conflicting. Planes et al (1988) found a reduction in the incidence of proximal vein thrombosis from 18.5% to 7.5% when low-molecular-weight heparin was compared with unfractionated heparin. However, Lassen et al

(1991) found an incidence of 25.8% in a group of patients treated with low-molecular-weight heparin compared with 36.1% in a group which had received a placebo.

Warfarin in various forms has been used but the need for regular monitoring, and the risk of drug interactions and bleeding complications have discouraged its wider employment. In fact, less than 20% of British surgeons routinely use anticoagulation although physical methods of preventing thrombosis have been widely accepted (Brenkel and Clancy 1989). In particular, graduated compression stockings (Ishak and Morley 1981) and 'early' mobilisation (Lassen et al 1990) have been shown to reduce the incidence of deep-vein thrombosis.

In 1983, Gardner and Fox described a previously unrecognised physiological pumping mechanism in the sole of the foot which is activated by weight-bearing. The A-V Impulse System (Fig. 1; Novamedix, Andover, England; distributed by Howmedica International) is designed to stimulate this venous foot pump artificially. The device has been shown to maintain venous circulation as effectively as does normal walking (McMullin et al 1989) and its use reduces post-traumatic pain, swelling and compartment pressures (Gardner et al 1990). In a prospective study the incidence of major deep-vein thrombosis following knee arthroplasty was reduced from 59.4% in the control group to 17.8% in the pumped group, with a decrease in proximal thrombosis from 18.7% to 0% (Wilson et al 1990).

The aim of the present study was to evaluate the prophylactic efficacy of the A-V Impulse System following total hip replacement.

PATIENTS AND METHODS

We studied 84 patients with osteoarthritis undergoing primary total hip replacements; none had a past history of thrombo-embolism. All had had cemented Exeter total

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Fig. 1

The A-V Impulse System. The impulse generator intermittently and rapidly fills the pad which is held in place by the retaining slipper. As the pad fills it flattens the plantar arch and empties the venous sinuses of the foot.

hip replacements performed in the lateral decubitus position.

All the patients gave fully informed consent and were measured pre-operatively for graduated compression stockings. On arrival in the recovery room the stockings were applied to both legs and the patient was randomly assigned to one of the two groups by the use of cards in sealed envelopes.

Those allocated to the treatment group had the A-V Impulse System fitted to the foot of the operated limb. An inflatable pad is placed under the foot, held in place by a slipper, and connected to an air-impulse generator (Fig. 1); this rapidly inflates the pad and deflates it fully after a period of three seconds. The cycle is repeated every 20 seconds – the time interval necessary to allow the venous plexus of the foot to refill before the next impulse.

The device was used whenever the patient was in bed or sitting at rest. For walking, the pad was either disconnected, leaving the slipper in situ, or the slipper was removed. The patients in both groups practised active leg exercises and were mobilised on the second postoperative day.

DIAGNOSIS OF DEEP-VEIN THROMBOSIS

Ascending venography was performed on the operated leg between the sixth and ninth postoperative days, using non-ionic contrast media (Thomas 1982). The venograms were independently assessed, blind, by two radiologists and a vascular surgeon as described by Stringer et al (1989). A thrombosis less than 5 cm long in a single calf vein was called a minor calf-vein thrombosis, more than

5 cm a major calf-vein thrombosis. Thrombosis in the popliteal, femoral or iliac veins was described as proximal thrombosis.

EXCLUSIONS

We excluded five patients from the study. Two, one from each treatment group, refused to have a venogram and in two, one from each group, it was not possible to perform venography. One, in the treatment group, died from a myocardial infarction on the first postoperative day.

RESULTS

Patients in the two groups were well matched for age, sex, weight and prevalence of varicose veins (Table I). The majority had a combination of general and spinal anaesthesia and operation through a posterior approach.

The haemoglobin deficit, blood loss and volume transfused were similar in both groups as was the duration of the operation. There were no serious haemorrhagic complications.

No adverse effects were recorded from the continuous use of the device and there was minimal disturbance of sleep.

Deep-vein thromboses. Deep-vein thromboses were divided into four types: proximal plus major calf thrombosis, proximal thrombosis, major calf thrombosis and minor calf thrombosis (Table II). The incidences in the control and treatment groups were compared by the chi-square test. For the purposes of statistical analysis we defined 'clinically significant thrombosis' as proximal thrombosis, with or without calf involvement, and major calf-vein thrombosis. In this category there were 16

Table I. Details of patients in the two treatment groups

	Control	A-V Impulse System
Number	40	39
Sex		
Male:Female	15:25	15:24
Mean age (yr)	71.2	68.1
Weight (kg)	69.9	69.75
Patients with varicose veins	22	16
Type of anaesthesia		
General and spinal	34	36
General alone	6	3
Surgical approach		
Posterior	33	34
Direct lateral	7	5
Mean haemoglobin deficit (g/dl)	1.1	1.7
Mean total blood loss (ml)	1318	1388
Mean volume transfused (ml)	1560	1355
Mean duration of operation (min)	112.6	104.5

thromboses in the control group and two in the pumped group ($p < 0.001$).

The site and extent of all the thromboses are shown in Figure 2. Those which occurred in the pumped group were small and localised, contrasting with the control group in which they were often extensive and, in eight cases, involved both the femoral and the calf veins.

DISCUSSION

Thrombosis after operations and injuries continues to be a major concern to surgeons. The drawbacks of anti-coagulation have focused attention on physical methods of prophylaxis. Compression stockings reduce the risk of thrombosis (Ishak and Morley 1981) by increasing the velocity of venous return and reducing the cross-sectional area of the venous conduits (Emter and Alexander 1989).

Electrical stimulation of calf muscles also accelerates venous flow in a physiological manner. It is too painful to use in conscious patients but during major general surgical operations it has been found to reduce the incidence of subsequent calf-vein thrombosis (Browse and Negus 1970).

A large variety of pneumatic boots and leggings has been used to improve venous return and reduce stasis and thrombosis. All these devices inflate relatively slowly and do not, therefore, imitate the action of the natural venous pump (Carn, Miranda and Greene 1986). Even the multicuff, sequential-compression types fail to imitate the natural sequence of the physiological venous flow. They are clumsy to use and may, when inflated, trap blood in the distal part of the limb (Rithalia, Gonsalkorale and Edwards 1989). Even so, Gallus, Raman and Darby (1983) reported a reduction of calf-vein thrombosis after

CONTROL GROUP

A-V IMPULSE SYSTEM GROUP

Fig. 2

Diagrammatic representation of the site and extent of 16 thromboses in the control group and four in the A-V Impulse System group.

PF = Profunda femoris vein
SF = Superficial femoral vein
POP = Popliteal vein
AT = Anterior tibial vein
P = Peroneal vein
PT = Posterior tibial vein.

Table II. Number and type of thromboses in the two treatment groups

Group	Type of thrombosis				All
	Proximal plus major calf	Proximal	Major calf	Minor calf	
Control	8	5	3	0†	16*
A-V Impulse System	0	2	0	2†	4*

* $p < 0.01$; for clinically significant DVT, $p < 0.001$ † $p > 0.9$

hip replacement from 45% to 16%. There was, however, little or no effect on the dangerous proximal thromboses (Paient et al 1987; Hull, Raskob and Smith 1990) which are caused, in part, by the kinking of the femoral vein during the operation (Stamatakis et al 1977; Planes, Vochelle and Fagola 1990).

The discovery of the venous foot pump, activated mainly by flattening of the plantar arch, led to the design of a pneumatic device applied only to the foot. Unlike all other such devices, its rapid inflation (in under 0.35 seconds) imitates the haemodynamic effect of the stance phase of walking.

Natural weight-bearing, and the A-V Impulse System, both generate sudden and intermittent increases in venous flow. This pumping action is powerful enough to drive blood past a cuff around the calf inflated to more than 100 mmHg (Gardner and Fox 1989), and is therefore sufficient, in the erect posture, to force a column of blood up to the heart. Video phlebography shows that these venous pulses also produce turbulence in the valve pockets where thrombosis commonly begins.

Furthermore, both natural and simulated weight-bearing trigger a subsequent increase in blood flow throughout the limb (Gardner and Fox 1989). This hyperaemia is the result of a temporary reduction of peripheral vascular resistance (Morgan et al 1991). Recent studies on endothelial-derived relaxing factor (EDRF) provide the probable explanation for these observations. EDRF is nitric oxide, with a half life of approximately nine seconds (Ignarro et al 1987; Griffith and Henderson 1989; Griffith and Randall 1989; *Lancet* 1987, 1988). It is produced, particularly in venules, by shear stress caused by sudden pressure changes on the endothelium. It rapidly diffuses to the closely accompanying inflowing arterioles (Tangelder, Slaaf and Reneman 1984), temporarily relaxing their smooth muscle and so increasing tissue blood flow (Falcone and Bohlen 1990).

The antithrombotic effect of impulse pumping may be explained by the induction of turbulence in the venous valve pockets and the overall increase in blood flow, but the effect of EDRF is probably important also in preventing platelet aggregation and perhaps in producing disaggregation (Griffith and Henderson 1989).

An important question is the optimal duration of

impulse treatment. In this study the device was not used during the operation but such use may further reduce the incidence of thrombosis. In some high-risk cases it may be advisable to continue impulse treatment after discharge.

The overall rate of thrombosis detected by venography in the group treated with the A-V Impulse System was 10%, but more importantly, the rate of proximal thrombosis was only 5%, amongst the lowest figures ever recorded. Furthermore, the thromboses which did occur in the treated patients were much less extensive than in the control group (Fig. 2).

The A-V Impulse System significantly reduced both the incidence and the extent of deep-vein thrombosis following total hip replacement. The device proved simple to use, was well tolerated and had no adverse effects.

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REFERENCES

- Aitken RJ, Mills C, Immelman EJ. The postphlebotic syndrome following shaft fractures of the leg: a significant late complication. *J Bone Joint Surg [Br]* 1987; 69-B:775-8.
- Bergqvist D. *Postoperative thromboembolism: frequency, etiology, prophylaxis*. Springer-Verlag, Berlin, etc: 1983:20.
- Brenkel LJ, Clancy MJ. Total hip replacement and anti thrombotic prophylaxis. *Br J Hosp Med* 1989; 42:282-4.
- Browse JL, Negus D. Prevention of postoperative leg vein thrombosis by electrical muscle stimulation: an evaluation with 125 I-labelled fibrinogen. *Br Med J* 1970; 3:615-8.
- Carr RM, Miranda IP, Greene ER. Femoral vein flow velocity for devices used in the prevention of deep vein thrombosis. *Orthop Trans* 1986; 10:384.
- Enter M, Alexander K. Venous flow in the lower limb with compression therapy study with the duplex-scanner. In: Davy A, Stemmer R, eds. *Phlebologie*. London: John Libbey Eurotext Ltd, 1989:868-70.
- Falcone JC, Bohlen HG. EDRF from rat intestine and skeletal muscle venules causes dilation of arterioles. *Am J Physiol* 1990; 258: H1515-23.
- Gallus A, Raman K, Darby T. Venous thrombosis after elective hip replacement: the influence of preventive intermittent calf compression and of surgical techniques. *Br J Surg* 1983; 70:17-9.
- Gardner AMN, Fox RH. The venous pump of the human foot: preliminary report. *Bristol Med Chir J* 1983; 98:109-14.
- Gardner AMN, Fox RH. *The return of blood to the heart: venous pumps in health and disease*. London, etc: John Libbey and Co, 1989.
- Gardner AMN, Fox RH, Lawrence C, et al. Reduction of post-traumatic swelling and compartment pressure by impulse compression of the foot. *J Bone Joint Surg [Br]* 1990; 72-B:810-5.
- Griffith TM, Henderson AH. EDRF and the regulation of vascular tone. *Int J Microcirc: Clin Exp* 1989; 8:383-96.
- Griffith T, Randall M. Nitric oxide comes of age. *Lancet* 1989; ii:875-6.
- Hampson WGJ, Harris FC, Lucas HK, et al. Failure of low-dose heparin to prevent deep-vein thrombosis after hip-replacement arthroplasty. *Lancet* 1974; ii:795-7.
- Harris WH, McKusik K, Athanasoulis CA, Waltman AC, Strauss HW. Detection of pulmonary emboli after total hip replacement using serial C15 O2 pulmonary scans. *J Bone Joint Surg [Am]* 1984; 66-A:1388-93.

- Hull R, Raskob G, Smith F. Efficacy of intermittent pneumatic leg compression for preventing deep-vein thrombosis after total hip replacement. *J Bone Joint Surg [Br]* 1990; 72-B:537.
- Ignarro LJ, Byrns RE, Buga GM, Wood KS. Endothelium-derived relaxing factor from pulmonary artery and vein possesses pharmacologic and chemical properties identical to those of nitric oxide radical. *Circulation Res* 1987; 61:866-79.
- Ishak MA, Morley KD. Deep venous thrombosis after total hip arthroplasty: a prospective controlled study to determine the prophylactic effect of graded pressure stockings. *Br J Surg* 1981; 68:429-32.
- Johnson R, Green JR, Charnley J. Pulmonary embolism and its prophylaxis following the Charnley total hip replacement. *Clin Orthop* 1977; 127:123-32.
- Lancet*. EDRF: Editorial. *Lancet* 1987; ii:137-8.
- Lancet*. Yin and Yang in vasomotor control: Editorial. *Lancet* 1988; ii:19-20.
- Lassen MR, Borris LC, Christiansen HM, Schtj P, Olsen AD. Mobilization - a disregarded factor: influence on postoperative thromboembolism. *Acta Orthop Scand* 1990; 61 (Suppl 239):52-3.
- Lassen MR, Borris LC, Christiansen HM, et al. Prevention of thromboembolism in 190 hip arthroplasties: comparison of LMW heparin and placebo. *Acta Orthop Scand* 1991; 62:33-8.
- McMullin G, Scott HJ, Coleridge-Smith PD, Scurr JH. An assessment of the effect of the foot pump on venous emptying in chronic venous insufficiency. In: Davy A, Stemmer R, eds. *Phlebologie*. London: John Libbey Eurotext Ltd, 1989:69-71.
- Morgan RH, Carolan G, Psaila JV, et al. Arterial flow enhancement by impulse compression. *Vasc Surg* 1991; 25:8-15.
- Morris GK, Henry APJ, Preston BJ. Prevention of deep-vein thrombosis by low-dose heparin in patients undergoing total hip replacement. *Lancet* 1974; ii:797-9.
- Palment G, Wessinger SJ, Waltman AC, Harris WH. Low-dose warfarin versus external pneumatic compression for prophylaxis against venous thromboembolism following total hip replacement. *J Arthroplasty* 1987; 2:23-6.
- Planes A, Vochelle N, Fagola M. Total hip replacement and deep vein thrombosis. *J Bone Joint Surg [Br]* 1990; 72-B:9-13.
- Planes A, Vochelle N, Mazas F, et al. Prevention of postoperative venous thrombosis: a randomized trial comparing unfractionated heparin with low molecular weight heparin in patients undergoing total hip replacement. *Thromb Haemost* 1988; 60:407-10.
- Rithalia SVS, Gonsalkorale M, Edwards J. Effect of intermittent pneumatic compression on lower limb skin perfusion. *Angiology* 1989; 40:249-54.
- Stamatakis JD, Kakkar VV, Sagar S, et al. Femoral vein thrombosis and total hip replacement. *Br Med J* 1977; 2:223-5.
- Stringer MD, Steadman CA, Hedges AR, et al. Deep vein thrombosis after elective knee surgery: an incidence study in 312 patients. *J Bone Joint Surg [Br]* 1989; 71-B:492-7.
- Tangelder GJ, Slaaf DW, Reneman RS. Skeletal muscle microcirculation and changes in transmural and perfusion pressure. *Prog Applied Microcirc*. Frankfurt: Springer Verlag, 1984; 5:93-108.
- Thomas ML. *Phlebography of the lower limb*. Edinburgh: Churchill Livingstone, 1982.
- Wilson NV, Das SK, Maurice H, et al. Thrombosis prophylaxis in total knee replacement. *Br J Surg* 1990; 77:1417.