Technical note

Conceptual design of a combined device for normothermia and venous compression

Z.C. Zheng [a,*], W.F. Yost [b]

[a] *Department of Mechanical Engineering, University of South Alabama, Mobile, AL 36688, USA*
[b] *Department of Anesthesiology, University of Mississippi Medical Center, 2500 North State Street, Jackson, MS 39216, USA*

Abstract

Hypothermia and venous thrombosis can cause complications during perioperative and postoperative periods which can even be fatal to patients' conditions. Separative devices have currently been used to prevent those two problems. The device proposed here is to combine in a simple unobtrusive fashion the desirable effects of both temperature control and deep venous thrombosis prophylaxis in perioperative patients. A design chart of the new device is provided and design issues are addressed. © 2000 IPEM. Published by Elsevier Science Ltd. All rights reserved.

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1. Introduction

Patients in the perioperative period face a number of physiologic and metabolic challenges, which include hypothermia and deep venous thrombosis. Perioperative hypothermia is known to cause increased incidences of infection, myocardial ischemia and infarction, coagulopathy, etc. [1]. Venous stasis associated with anesthesia and surgery can lead to deep venous thrombosis, which can often cause permanent damage to veins and occasionally can be fatal, due to pulmonary emboli. Experience has shown that this complex problem is much easier to prevent than to treat.

Currently, separate devices have been used to prevent hypothermia and deep venous thrombosis. There are extensive use of active warming of intravenous and irrigation fluids, warming pads, warming lights and warming operative environment. Mechanical methods have been used to milk the lower extremity to augment venous blood flow using devices such as Sequential Compression Device™.

Because of the large number of devices and tubes attached to those devices in the operating and recovering rooms, a need exists in the art to simplify and combine these two vital treatment goals. Until the description of the device proposed here, it has not been possible to combine in a simple unobtrusive fashion the desirable effects of both temperature control and deep venous thrombosis prophylaxis in perioperative patients.

There is no doubt that the market for this product is secure because of the requirement for normothermia and venous compression devices in ORs of all hospitals. Economic viability exists for such a product. Since the new design can possibly make use of or slightly modify some parts of the currently existing compression and normothermia devices, no major production line change is necessary for manufacturers to adopt the new design. The design can also follow the current specifications and safety features required by government regulations so that the product can get through government certification procedures easily.

2. Device description

Fig. 1 shows a sketch of the design. The device consists of a temperature controlled fluid reservoir (here water is chosen as such fluid), pumping and valving systems, timing, pressure and temperature controlling sys-

* Corresponding author. Tel.: +1-334-460-6168; fax: +1-334-460-6549.

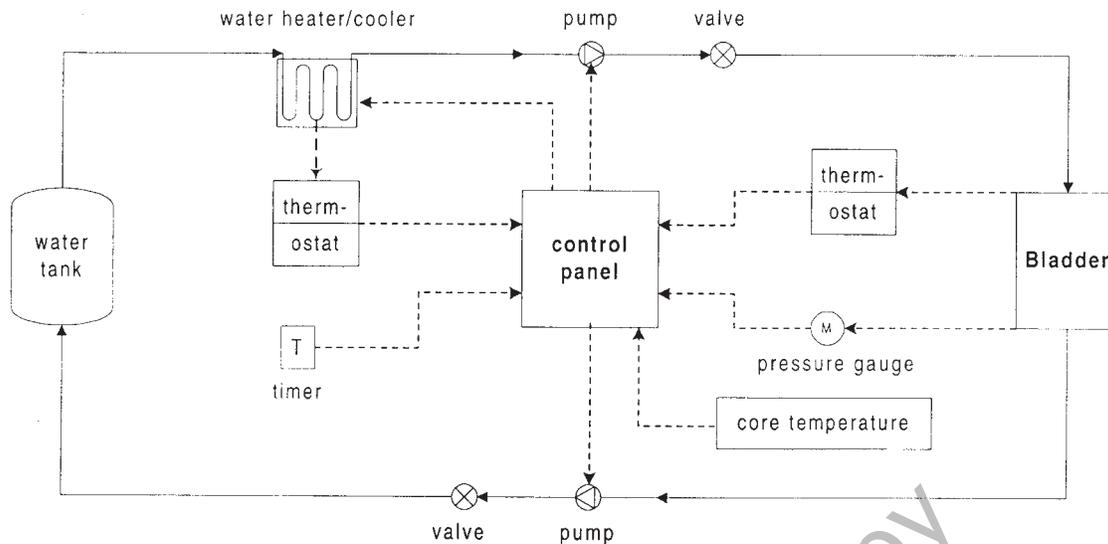*E-mail address:* zzheng@jaguar1.usouthal.edu (Z.C. Zheng).

Fig. 1.   Design chart for a combined device for normothermia and venous compression.

tems, and stockings with bladders. The bladders of the modified compression devices are used to transfer heat and, at the same time, to apply pressure to the extremity of patients. This device minimizes or eliminates the probability of hypothermia by filling the bladders of the extremity stocking of the compression device with a temperature controlled fluid. It also takes advantage of and utilizes the peripheral vasodilation of anesthesia to improve the efficiency of heat transfer in the perioperative period. The improved extremity stocking is held in place on the patient's extremities with adhesive, snaps, ties or belts in close proximity to the skin, thus enhancing heat transfer by close contact. It is therefore possible to apply a controlled temperature to a patient in a circumstance of efficient heat transfer, as well as simultaneously obtaining the beneficial effects of the compression devices. The bladder cuffs are normally applied to the lower extremity, but it can be re-designed to be applied to the upper extremity if the operative considerations indicate the desirability of so doing. The extremity stocking can be applied to the patient preoperatively, intraoperatively, postoperatively or in a critical care or floor care area.

In the design chart, the solid-arrow lines indicate the fluid flow directions, and the dashed-arrow lines represent the system-control information flow directions. A control panel is designed to control temperatures, pressure levels, timing and sequencing of the extremity stocking bladders. It is not necessary to change them from their usual settings, although they can easily be changed. The device, at the option of the operator, can be either manually controlled at preset known safe limits, or alternatively, can use electronic or other temperature signals to maintain the patient's temperature at a desired physiologic or therapeutic level.

Temperature control includes water heater tempera-

ture, bladder fluid temperature and patient's core body temperature. Low levels of heat (less than 40°C) are necessary for the maintenance of normothermia in the presence of peripheral vasodilation. Higher levels of heat of up to 43–45°C are available for use, if necessary, to treat existing hypothermia. The patient's core temperature can give indications of the effectiveness of heat transfer and, as a safety feature to avoid overheating. Since occasionally patients require their temperature lowering rather than raising it (which is also indicated from the core temperature signal), the device also provides the ability to lower the temperature of the water used to fill the bladder by cooling the water supply.

If the compression period is set to be 1 minute, the pressure up and down time can be divided at 1:4 ratio, i.e., 12 seconds and 48 seconds, respectively. The upper pressure in the bladders is around 60 mmHg to 76 mmHg. The pressure in the bladder is measured by a pressure gauge and the signal is transmitted to the control panel to control the inflow pump. The timer is then started to count the pressure up time and sends a signal to the control panel to open the outflow pump once the up-time limit is reached. The sequencing, which applies pressure in a sequential fashion from distal to proximal from the patient's extremity as used in the Sequence Compression Device™, is not used in this design. From our limited experience, there have not been significant advantages of the sequencing in the effectiveness of enhancing blood flows when the patient is anesthetized or otherwise immobile.

3. Some design issues

Since the extremity stocking in the new design is used not only for compression, but also for heat transfer, it

needs to be modified. Compression sleeves currently in use are non-sterile and not reusable (one single patient's use only). The modified stocking has two layers: an inside layer of bladders which are sterile and reusable with an outside non-reusable cover. The bladder material and geometry need to satisfy the compression pressure condition as well as heat transfer requirement. The pressure condition can simply be stated as: for a maximum fluid volumetric change, ΔV, the pressure p has to reach the compression pressure of 60 mmHg to 76 mmHg. A rubber type bladder is chosen to satisfy the pressure condition.

The heat transfer between the stocking and the patient's extremity can be estimated as conductive heat transfer [2]

$$q_s'' = k_b \frac{T_w - T_e}{\tau}, \tag{1}$$

where q_s'' is the heat transfer rate per unit surface area of the patient's extremity covered by the bladders, k_b is the heat conductivity of bladder material, T_e and T_w are the patient's extremity surface temperature and bladder water temperature, respectively, and τ is the thickness of the bladder wall. The heat resistance of the stocking cover and all the contact resistances are neglected.

Another heat transfer that needs to be considered is the heat loss during water transportation between the water tank and the bladders. Since kink-resistant tubes (with about 0.00635 m (1/4 in) diameter) as long as 7.62 m (25 in) will be used to connect the water tank and the stocking to allow enough mobile space, heat loss can be significant in the tubes. The power of the water heater should be high enough to maintain the set-up temperature. The heat loss from the tube consists of both conduction and convection processes. The conduction part is from the inner wall of the tube to the outer wall, while the convection is between the water flow and the inner tube wall. Using the cylindrical model shown in Fig. 2, we can integrate the steady-state heat conduction equation which gives the temperature distribution in the radial direction as [2]:

$$T = C_1 \ln r + C_2 \tag{2}$$

where C_1 and C_2 are the integration constants depending on the boundary conditions, and r is the radius at a certain tube layer. If the uniform heat flux, q_w'', is specified at the inner wall and the outer wall temperature is T_o, we can have

$$T = T_o - \frac{q_w'' r_i}{k_t} \ln \frac{r}{r_o}, \tag{3}$$

where k_t is the heat conductivity of the tube wall material, r_i and r_o are the inner and outer tube wall radii, respectively. For heat convection between the water flow and the inner tube wall, it can be found that for laminar, steady, uniform heat flux pipe flows
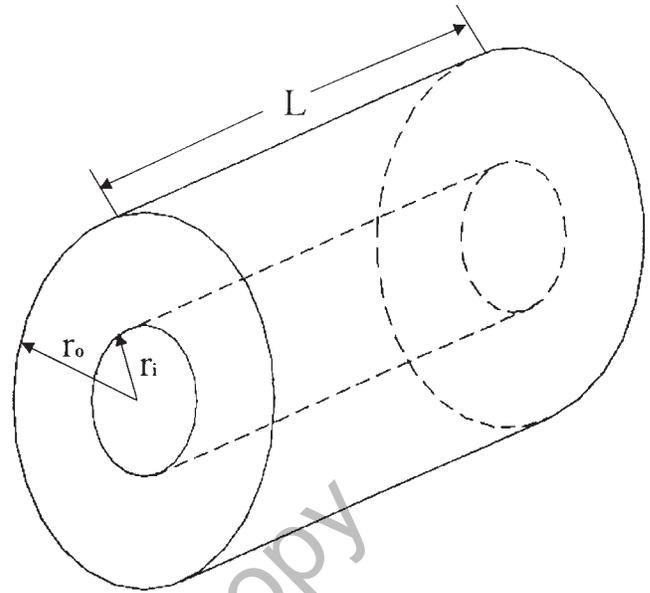

Fig. 2.   Geometry for heat transfer calculation in the tube.

$$\bar{h}_c (T_b - T_i) = q_w'', \tag{4}$$

where $\bar{h}_c$ is the average heat transfer coefficient and is equal to 24 k_w/11 r_i under the current flow condition (k_w is the heat conductivity of water), T_b is the bulk temperature of the pipe flow and T_i is the inner tube wall temperature. Hence, it can be deduced from Eqs. (3) and (4) that

$$q_w'' = (T_b - T_o) / \left(\frac{r_i}{k_t} \ln \frac{r_o}{r_i} + \frac{1}{\bar{h}_c} \right) = (T_b - T_o) U_i \tag{5}$$

where U_i is defined as the overall heat transfer coefficient with respect to the inner tube wall surface. It has been noted that in order for q_w'' to be uniform, T_b and T_o have to be linear functions of the tube length distance. However, the difference between them is a constant. Thus, the heat loss rate in the tubes is

$$Q = 2\pi r_i L q_w'' = 2\pi r_i L (T_b - T_o) U_i, \tag{6}$$

where L is the total length of the tubes. If T_o is close to the room temperature, then $(T_b - T_o)$ can be at least 10°C. Therefore, the required power of the water heater, P, needs to be at least

$$P = Q + A q_s'' \tag{7}$$

where A is the contact surface area between the patient's extremity and the bladders.

4. A theoretical case study

The case study presented here is for the device under the operational conditions to treat hypothermia. Parameters that can be identified have been chosen. The heat conductivity of water is k_w=0.6 W/mK. Since higher

conductivity for bladder material enhances heat transfer at the patient's extremity, the heat conductivity for the bladder rubber material is chosen to be k_b=0.2 W/mK, which is at the higher end of heat conductivities for rubber material [2]. The bladder thickness, τ, is chosen as 0.00254 m (0.1 in). The tube geometric parameters are chosen as: r_i=0.00635 m (1/4 in), r_o=0.0127 m (1/2 in), and L=7.62 m (25 ft). The surface temperature of the patient's extremity is approximately 34°C in a cold condition corresponding to hypothermia. The contact area, A, is calculated based on the extremity stocking sizes. A typical compression stocking contact area size used on legs is 0.7112 m (28 in) by 0.3556 m (14 in). If used on arms, an area size of 0.4064 m (16 in) by 0.2032 m (8 in) is suggested. With these parameters, a functional relationship between the power requirement of the water heater, P, and the heat conductivity of the kink-resistant tube, k_t, can be obtained from Eq. (7). The function, $P=P(k_t)$, is plotted in Figs. 3 and 4 for the two different sizes of contact area of the lower extremity and the upper extremity. The calculations are performed under the condition that the temperature difference between the bulk temperature and outer surface temperature is allowed to be 10°C, as discussed in the previous section.

In Figs. 3 and 4, the solid curves are for the bladder water temperature of 40°C and the dashed curves for that of 45°C. They show that the power requirement for the heater increases with the heat conductivity of the tube material. Even for very high heat conductivity material for the tubes, the power requirement is no larger than 800 W, which can be easily achieved. The power values at k_t=0 are the heat transfer rate to the patient's body. It can be seen that in the lower extremity case, the heat

transfer rates are 238 W and 438 W for the two bladder bulk temperatures, respectively. If the the heat capacity of human body is approximately 0.86 kcal/kg °C and the average weight is about 68 kg [3], assuming the basal heat production is balanced by the loss of heat to the environment, then it takes about 17 and 9 minutes to raise one degree of total body temperature in each case. In the case of upper extremity application, the heat transfer rates are 78 W and 143 W for the 40°C and 45°C bladder temperatures, respectively. The time needed to raise one degree body temperature is correspondingly 52 and 28 minutes.

It should be pointed out that in observing the times needed to raise the patients' body temperatures to acceptable levels, the ideal assumption has been made that the heat loss to the environment is balanced by the basal heat production from the patients. Therefore, the energy provided by the device is used to raise body temperature only. For patients under weak physical conditions (e.g. during surgery), the basal heat production could be low and part of the heat from the device has to compensate for the heat loss to the environment, thus the time required to raise body temperature could be longer.

5. Conclusion

A need exists to combine two treatment goals for hypothermia and venous thrombosis. It is the first time that such a design concept has been developed. The new design can possibly make use of the currently existing compression and normothermia devices and therefore
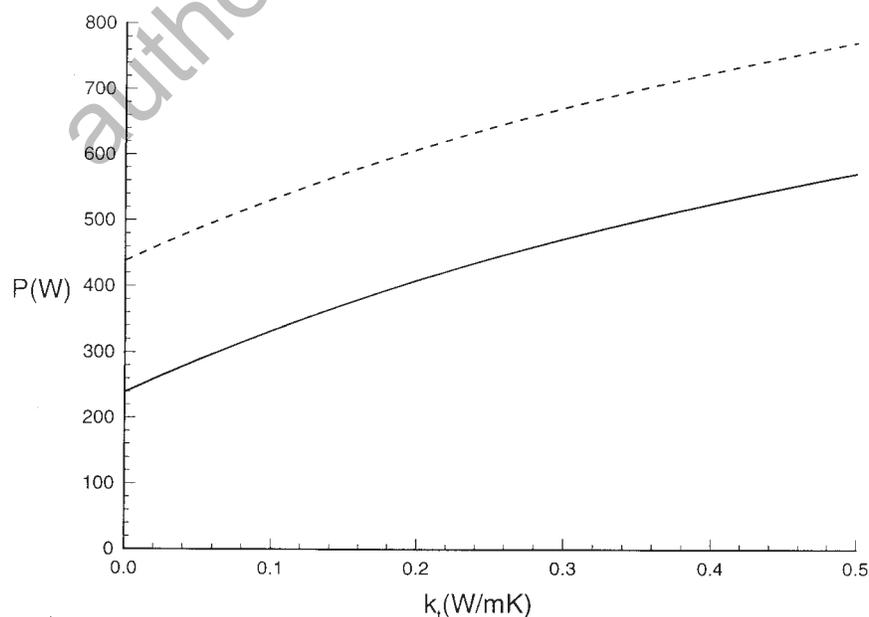
Fig. 3. Heater power requirement P (in Watts) versus the tube heat conductivity k_t (in W/mK) for the lower extremity application. The solid curve is for the bladder water temperature of 40°C and the dashed curve is for that of 45°C.
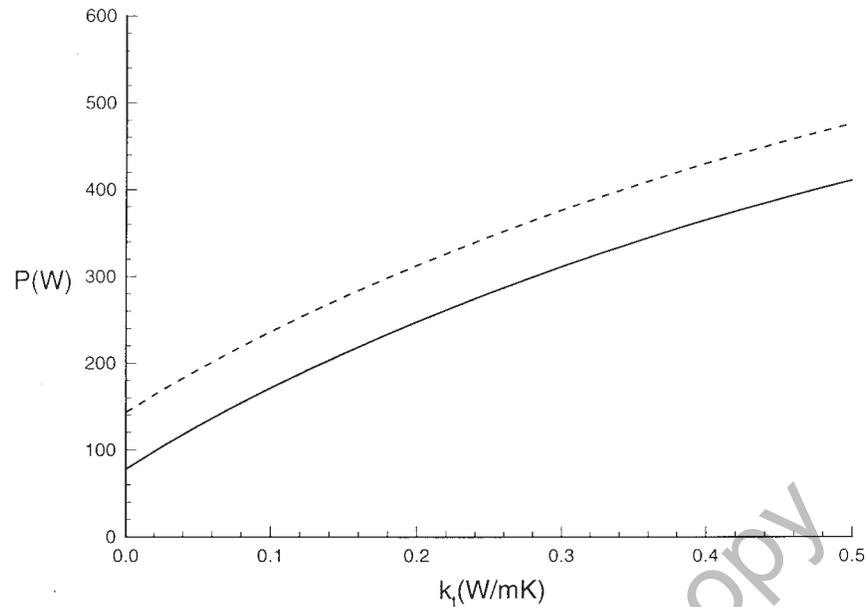
Fig. 4.   Same as Fig. 3, but for upper extremity application.

maintains economic viability for the manufacturer who adopts this technology. A detailed design chart and its description have been presented in the paper. Design issues such as heat transfer effects have been studied theoretically.

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