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Research article

Development of cryotherapy device using refrigerant compressor for decreased skin temperature

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ABSTRACT

Cryotherapy is a commonly used technique in sports medicine and physical therapy for the treatment of acute injuries and pain management. The application of cold temperatures leads to a decrease in skin surface temperature, which can have several physiological effects on the body. This can help to reduce inflammation, swelling, and pain in the affected area. Cryotherapy can be administered using various modalities, but controlled continuous cold devices are widely used in cryotherapy treatment due to their accurate temperature control, especially when treating large joints. These devices work by pumping cold water alternately into a cooling pad that is wrapped around a patient's limbs. The aim of this study is to develop a cryotherapy device that regulates low skin temperature for effective physical therapy treatment. This will be achieved by utilizing a refrigerant compressor in combination with a remote source of chilled water that is circulated through a cooling pad placed on the treatment site. The results show that this device can control temperature from 20^{o}C to 5^{o}C with a fluctuation of $\pm$ 0.4^{o}C at the cooling pad. A test study on 32 volunteers showed that the skin temperature in the knee area can drop to 15.1^{o}C$\pm$1.7^{o}C (95% CI, 18.6-11.1^{o}C) after 30 minutes of applying a cooling pad at 10^{o}C. The experimental cryotherapy results on the skin surface are consistent with the simulation test results, indicating that this device can be developed into a medical device that provides precise and continuous temperature control, thereby ensuring ease of use and maximum therapeutic benefit in the field of physical therapy.

Key words: Cryotherapy, Bio-heat transfers, refrigerant compressor

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INTRODUCTION

Cryotherapy, also known as cold therapy, is a commonly used technique in sports medicine and physical therapy for the treatment of acute injuries and pain management[1–4]. The application of cold temperatures leads to a decrease in skin surface temperature, which can have several physiological effects on the body, including a reduction in nerve conduction velocity, local blood flow, and cellular metabolic rate. These effects, in turn, reduce the inflammation process, swelling, and provide temporary pain relief in the affected injured area.

Cryotherapy is administered using various modalities, including vapocoolant sprays, cold or ice packs, and controlled continuous cold devices. Among these, controlled continuous cold devices are widely used in cryotherapy treatment due to their accurate temperature control, particularly when treating large joints[5]. These devices work by pumping cold water alternately into a cooling pad that is wrapped around a patient's limbs. The cooling pad should be set to a temperature between 10°C and 15°C[5], and the skin temperature can be lowered to about 20°C to achieve demonstrable intra-articular temperature changes[6].

Controlled continuous cold devices are also very effective in reducing swelling and pain, managing musculoskeletal injuries, especially knee joint injuries, and helping patients regain their range of motion after surgery[7–9]. Barber et al. evaluated the effectiveness of controlled continuous cold therapy for postoperative pain management in outpatient arthroscopic anterior cruciate ligament (ACL) reconstructions. The results of their study indicated that continuous-flow cold therapy is both safe and effective in reducing pain medication requirements for outpatient ACL reconstruction patients[7]. In another study, Webb et al. compared cold compressive dressings with wool and crepe in the postoperative management of 40 patients who underwent total knee replacement (TKR). The findings of their study suggested that the cold compression device was effective in reducing blood loss and pain following TKR[8]. Furthermore, Kullenberg et al. demonstrated that cryotherapy improves the control of pain, which might lead to an improvement in the range of motion (ROM) and a shorter hospital stay for 86 patients undergoing total knee arthroplasty[9].

Controlled continuous cold therapy devices can be manufactured using various technologies and tech-

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niques. However, they typically consist of a cold therapy unit combined with an adjustable wrap, also known as a cooling pad. The cold therapy unit can use thermoelectric cooling (TEC) modules [10] to bring the refrigeration source directly to the tissue being treated [11,12], or it can use a refrigerant compressor to cool water, which is then circulated through a pad to provide continuous cold therapy to the affected area [5]. The latter type of device includes a cold-water cabinet, a pump to deliver cold water through the duct, and a cold pad for application to the affected area. The cold water is stored in the cabinet and pumped through the duct to the cold pad, which delivers the cold therapy to the injured region. Various types of these devices have been specially designed and commercialized, such as the Aircast Cryo Cuff™ [5] and Game Ready [13], but they are usually quite expensive and require ice storage.

The aim of this study is to develop a cryotherapy device that can regulate low skin temperature for effective physical therapy treatment. This will be achieved by utilizing a refrigerant compressor in combination with a remote source of chilled water that will circulate through a cooling pad placed on the treatment site. Unlike similar devices that require an ice reserve as a source of cold [5,13–15] and are difficult to use for continuous operation and precise temperature control, this device will use electrical power to operate continuously at low temperatures for prolonged periods and with many patients. The development of this device will provide precise and continuous temperature control, ensuring ease of use and maximum therapeutic benefits.

METHODOLOGY

Simulation of heat transfer in human skin

The human skin in Figure 1 was modeled using COMSOL Multiphysics as a cube with dimensions of 6x6x6 mm^3. It consists of three layers, arranged from top to bottom with the following thicknesses: epidermis (0.1 mm), dermis (1.5 mm), and subcutaneous layer (4.4 mm) [16]. The heat transfer in the skin tissue is governed by Pennes bioheat equation [13]:

$$\rho c \frac{\partial T}{\partial t} = k\nabla^2 T + \bar{\omega}_b \rho_b c_b (T_a - T) + q_{met} + q_{ext} \quad (1)$$

Where ρ is skin density [kg/m^3]; c *is* skin heat capacity [J/(kg.K)]; T is skin temperature [K]; k is skin thermal conductivity [W/m.K]; $\bar{\omega}$ is blood perfusion rate [1/s]; ρ_b is blood density [kg/m^3]; c_b is blood heat capacity [J/(kg.K)]; T_a is blood temperature [K]; q_{met} is metabolic heat souce [W/m^3]; q_{ext} is external environmental heat source [W/m^3].

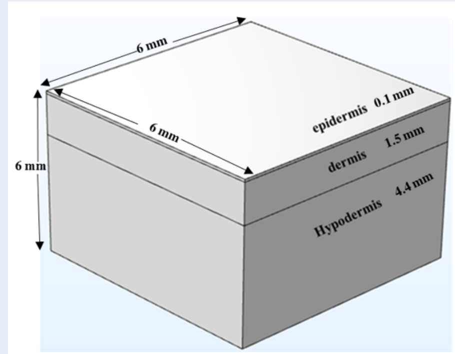

Figure 1: 3D human skin model

The biological heat transfer equation was solved using Comsol Multiphysics software, with the thermophysical properties of skin tissue for a three-layer model as presented in Table 1. For this study, the entire surface of the knee joint's skin was covered by a cooling pack (as shown in Figure 2), which prevented heat exchange with the surrounding environment (q_{ext} = 0). As for the boundary conditions, the skin was cooled at the surface using a cooling heat source (cooling pad) with a constant temperature of 10°C (or 283 K), while the skin's bottom was maintained at body temperature of 37°C (or 310 K).

Development of cryotherapy device

The cryotherapy device is designed to decrease the skin surface temperature in a controlled manner. The device's operating principle is illustrated in the block diagrams shown in Figure 2 and Figure 3. The device utilizes an FSCH019Z12 refrigerant unit [17] and a mini pump to circulate water from the water tank through the cooling block and transfer it to the cooling pad (elastic wrap). The cooling pad comes into contact with the human body, allowing for heat exchange through the skin. Once the heat exchange process is complete, the water is circulated back into the water tank to begin the next cooling cycle.

The cryotherapy device must meet technical requirements for maintaining and controlling temperatures within the range of 10-15°C. To ensure stable operation, a control board is used to manage the system's functions. Specifically, the ATmega2560 is programmed as the control board for this module. The circuit board, along with the temperature display system, working modes, and operation push buttons, allows users to customize the temperature level and

Table 1: Thermophysical properties of skin tissue for three-layer model [16]

Parameter	Epidermis	Dermis	Hypodermis
ρ (kg/m^3)	1190	1116	971
c (J/(kg.K)	3600	3300	2700
T (K)	310	310	310
k (W/m.K)	0.235	0.445	0.185
$\bar{\omega}_b$ (1/s)	0	0.001	0.001
ρ_b (kg/m^3)	0	1060	1060
c_b (J/(kg.K)	0	3770	3770
T_a (K)	0	310	310
q_{met} (W/m^3)	368	368	368

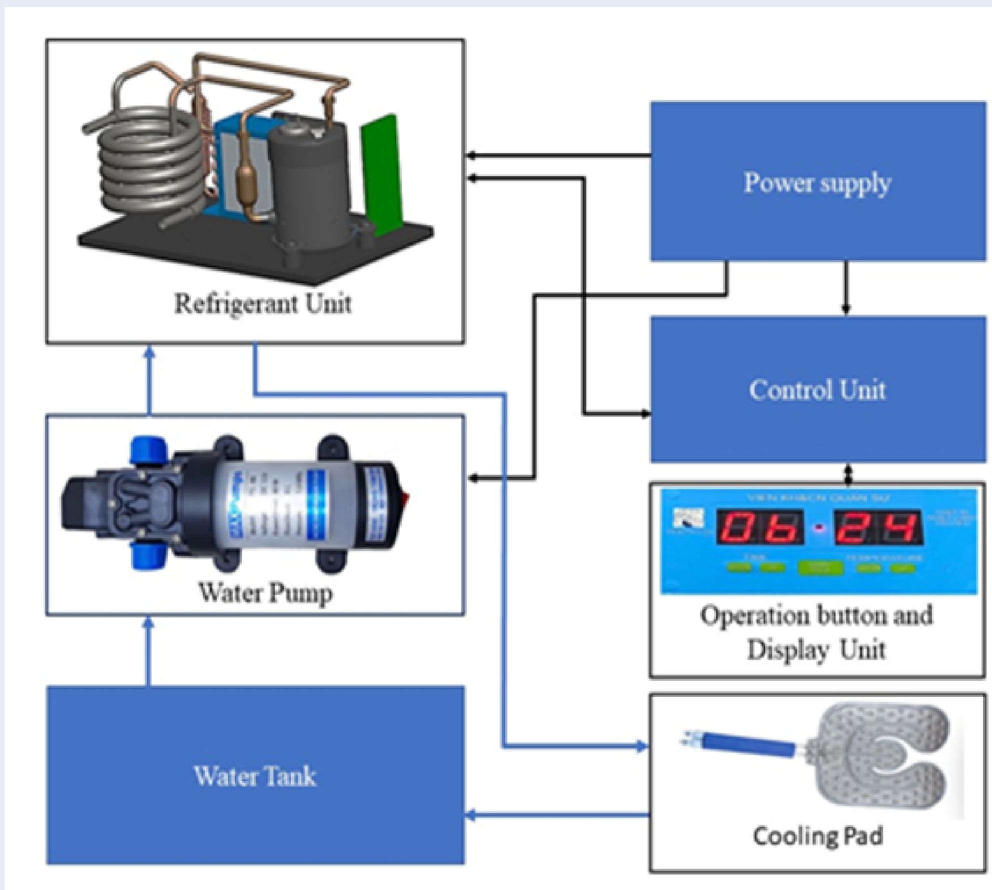

Figure 2: Block diagram of the cryotherapy device

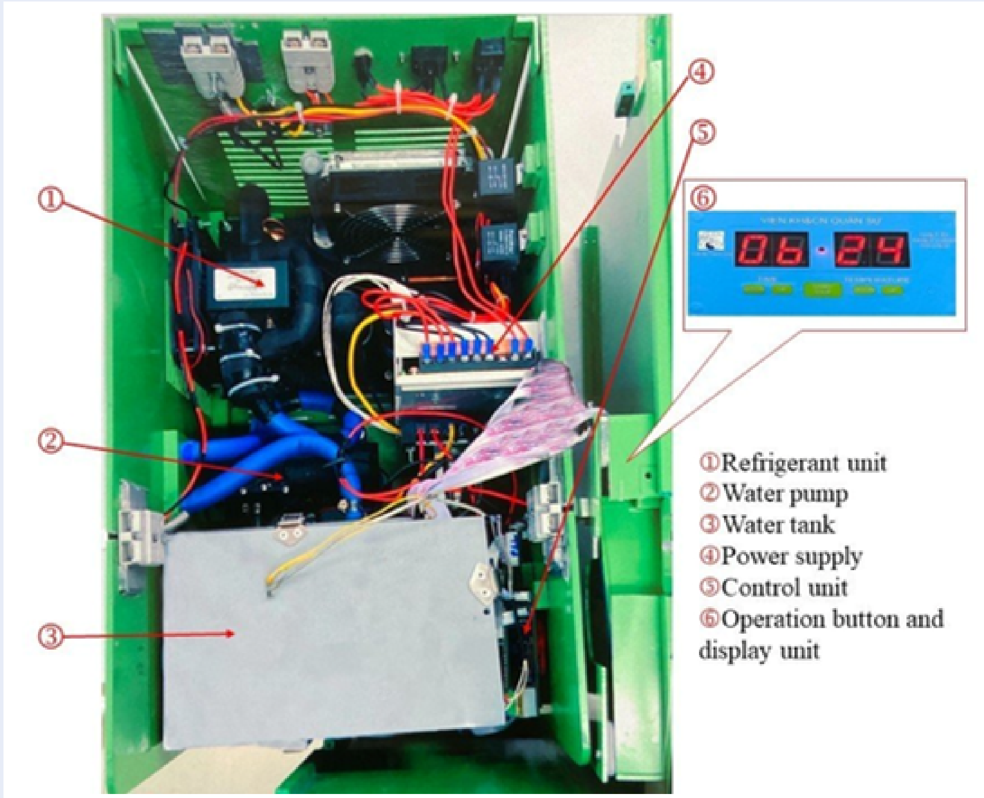

Figure 3: Block diagram of the cryotherapy device in practice

cooling mode. The control and display unit circuits were designed using Altium Designer software and are detailed in Figure 4 and Figure 5.

The control circuit consists of several components. The main part is the ATmega2560 microcontroller (1), responsible for collecting and processing input signals such as water temperature and signals from button systems to control the operation of the refrigeration unit. In order to maintain the operation of the microcontroller, the LM7805 IC (2) is used to convert the input power suitable for the operating parameters of the IC and the LED display screen. In addition, the control circuit also utilizes temperature sensors (5) and signal transmission headers (3) to communicate with other functional units and keep the circuit board compact in size.

The display circuit includes four 7-segment LED circuits (1) used to display the module's output temperature and operating time. The signal of each LED is controlled and processed by a separate 74HC53 IC, which is then combined with signals from the control button system (4) and directed to the main IC of the display circuit, the 7447 (2), for synthesis and communication with the control circuit via signal transmission headers (3).

To ensure the continuous operation of the device, an input power board is required to provide power to the refrigeration module's components, which include the FSCH019Z12 refrigeration unit, mini pump, and control circuit board. The control circuit board will regulate the operation of the cryotherapy device based on electrical signals. The board will monitor the system's condition by reading temperature and pressure sensor values. If necessary, the board will adjust system parameters such as liquid temperature and refrigerant power to ensure efficient operation. In case of any malfunction, the control board will send an alert signal to the user and can automatically shut down the system to prevent hazardous situations.

Experiments

To assess the device's temperature control performance, we conducted an evaluation of its ability to maintain stable temperatures on the surface of the elastic wrap (cooling pad). The device was set to four different temperatures: 5, 10, 15, and 20°C and maximum power (150W). The room temperature was

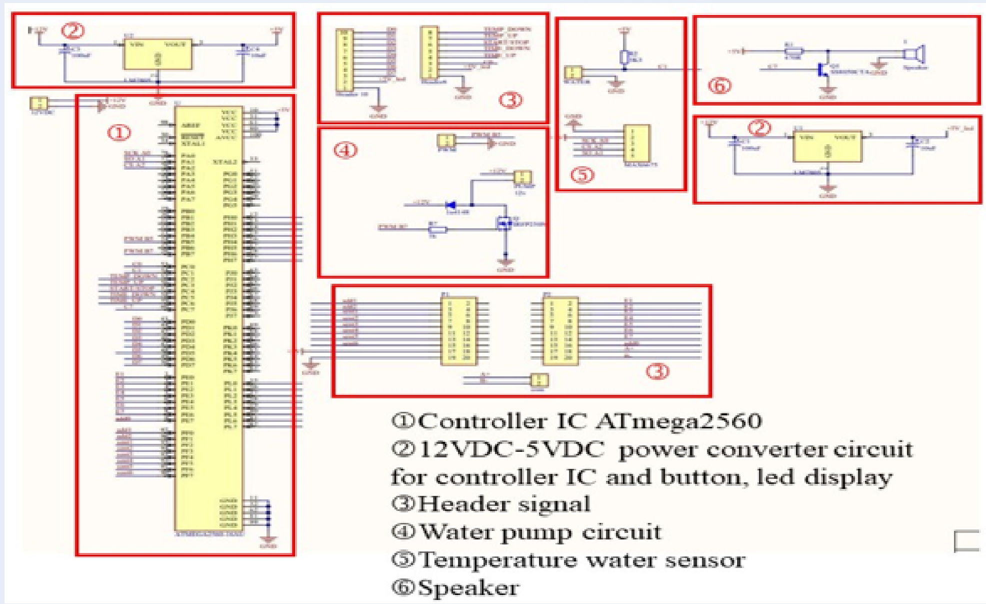

Figure 4: Circuit diagram control unit

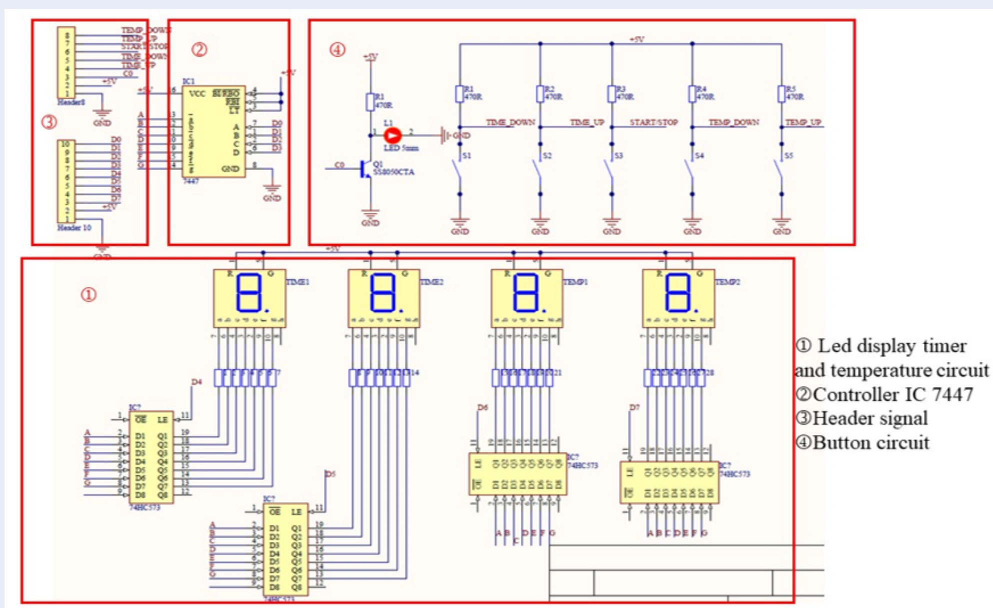

Figure 5: Circuit diagram display unit

maintained at a mean of 27°C. We used an Elitech device thermometer (RC-4HC) to measure the cooling pad surface temperature, with a display resolution of 0.1 °C and an accuracy of ±0.1°C. The thermometer probe was mounted and fixed on the elastic wrap surface to measure and record temperature data every minute. The collected data was then analyzed using Origin 7 software to evaluate the device's ability to reduce and stabilize the temperature over time.

To assess the cooler's ability to reduce skin temperature, experiments were performed on healthy volunteers (23 males and 9 women) who were staff members at the Institute of Biomedical Physics in Ho Chi Minh City. Prior to participation, each subject completed a questionnaire to ensure they were healthy, had no injuries, and no contraindications for cryotherapy. The average age (±SD) was 35.8 ± 10.3 years and body mass index was 23.7 ± 2.8. Each subject participated in a single trial, with room temperature maintained at a mean of 27°C. An Elitech temperature measuring device (RC-4HC) was used to measure the temperature on the skin surface of the knee joint. The device temperature was set to 10°C, and 35 minutes after the setup began, a 30x30 cm^2 cooling pad, as shown in Figure 6, was wrapped around the knee joint of each volunteer. The cooling pad was applied to the skin surface of the knee joint for 30 minutes while skin surface temperature data was recorded on a minute-by-minute basis. Statistical analysis was performed using SPSS 22 software. A P value of less than 0.05 was used to determine statistical significance.

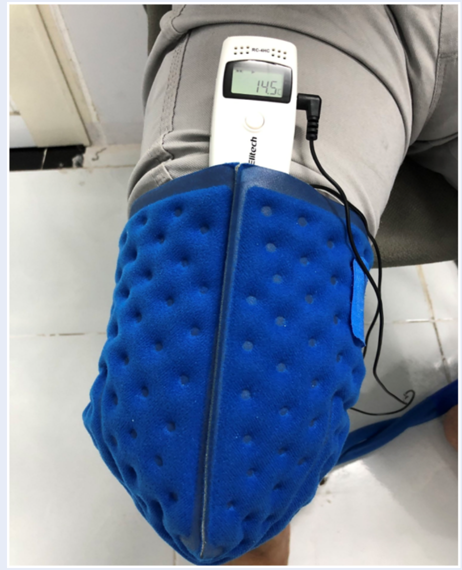

Figure 6: Knee joint of the volunteer wrapped with a cooling elastic pad during the experiment.

RESULT

Simulation of results of bio-heat transfer in the skin tissue

The simulation results of skin tissue temperature at different time intervals of 5, 10, 15, and 30 minutes are shown in Figure 7a, Figure 7b, Figure 7c, and Figure 7d, respectively, when a cooling pad with a temperature of 10°C is applied to the skin surface.

The temperature profile results revealed a rapid decrease in skin tissue temperature during the initial 15 minutes, and there was not much difference in the skin temperature simulation results at 15 and 30 minutes. These results indicate that the temperature of the skin is significantly reduced and stabilized in all three layers after 15 minutes, and remains almost stable for the subsequent 15 minutes.

Figure 8 illustrates the depth of cold penetration and temperature changes using a cooling pad set to 10°C for 30 minutes at three different points (epidermis 0.05 mm, dermis 1.5 mm, and dermis 3 mm) in the skin tissue, as shown in the contour map of Figure 9.

Based on the simulation results, the skin tissue temperature (from the epidermis to the hypodermis) ranged from 12-18 °C, 11-16 °C, 11-15.5 °C, and 11-15°C at 5, 10, 15, and 30 minutes, respectively. The simulation results indicate that the curve illustrating the decrease in skin temperature when using the cooling pad at 10°C is comparable to the curve presented by P. Zare et al. [18]. Both results exhibit a quick reduction in skin temperature within the first 15 minutes followed by a gradual decrease. However, the skin temperature changes observed in this study differ from those reported by P. Zare et al. [18] since the latter conducted simulations on the effects of applying ice packs at various temperatures to the skin surface.

Temperature stability results on cooling pad surface

To demonstrate the device's temperature control ability, we tested different temperature settings: 20°C, 15°C, 10°C, and 5°C. Figure 10 displays the temperature set points of the device (red line) and the cooling pad (blue line) over time. Lower temperature settings require more time to stabilize. For example, it took 65 minutes for the device to reach a stable temperature of 5°C, while it took 35, 25, and 15 minutes to reach a stable temperature at settings of 10°C, 15°C, and 20°C, respectively. Once the temperature setting on the device stabilizes, the temperature on the cooling pad also stabilizes, but there is a slight corresponding fluctuation of $21.88^{o}C \pm 0.26, 17.25^{o}C \pm 0.29$, $12.49^{o}C$

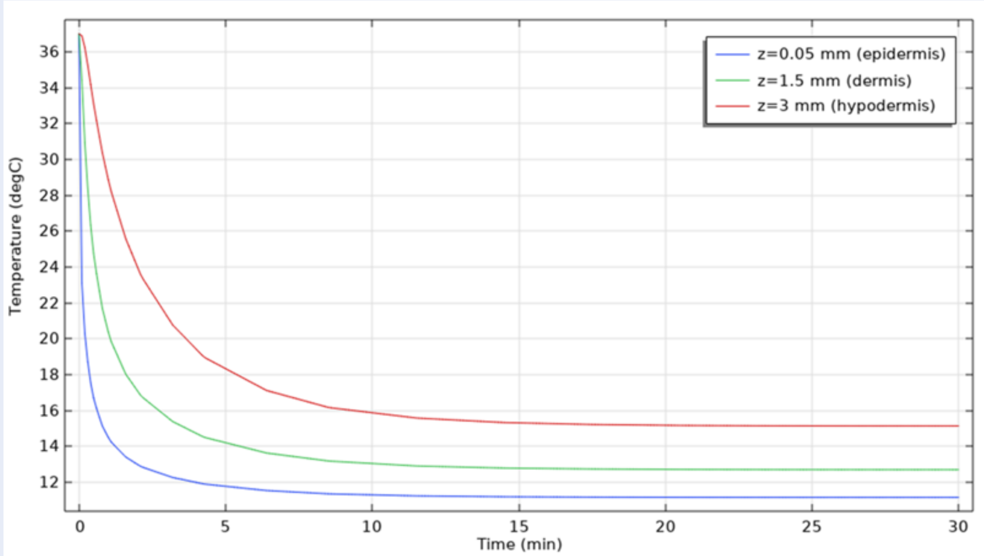

Figure 8: Three skin layers' temperature during the application of the cooling pad of 10°C for 30 minutes

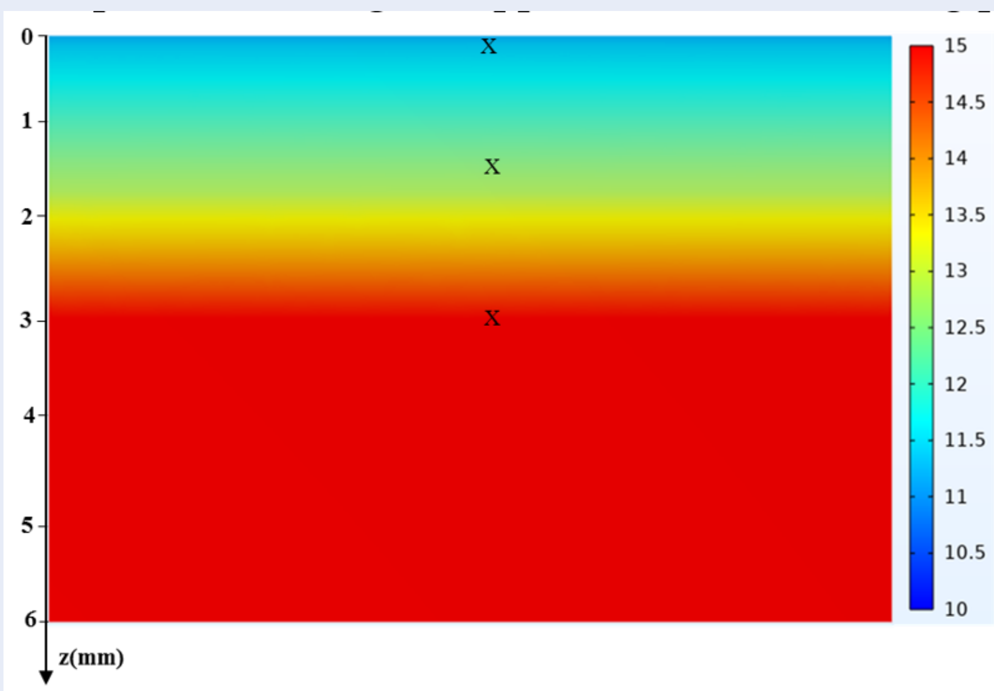

Figure 9: Map contour (XZ) of heat transfer from the skin surface (epidermis) to the hypodermis after 30 min cooling.

±0.43, and 5.74^{o}C ±0.38 for temperature settings of 20°C, 15°C, 10°C, and 5°C, respectively. This fluctuation is due to heat loss to the environment through the recirculation system in the water to the cooling pad.

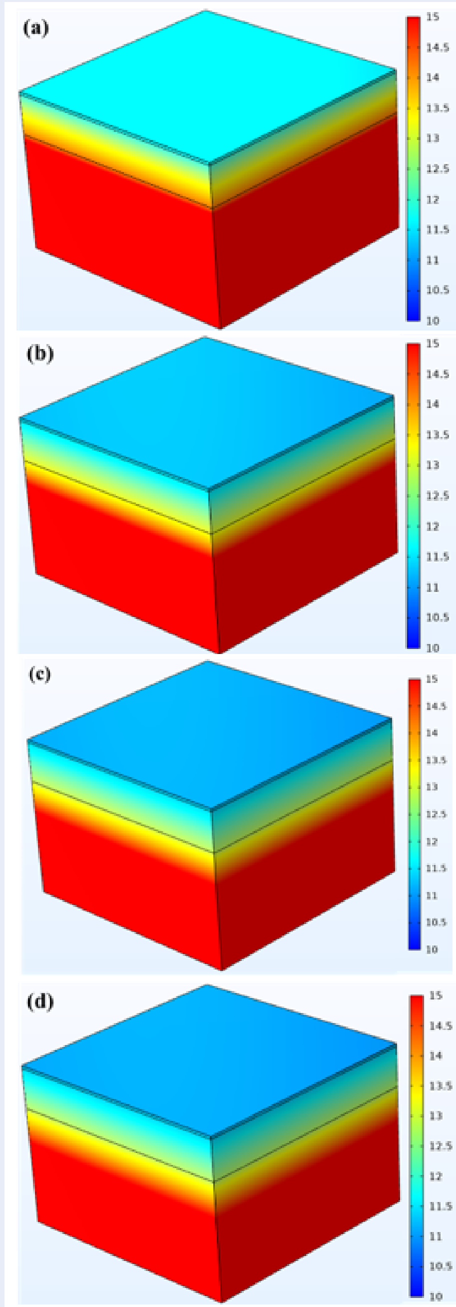

Figure 7: Simulation results of skin tissue temperature from epidermis to hypodermis at different time intervals (5, 10, 15, and 30 minutes) with a cooling pad at a surface temperature of 10°C.

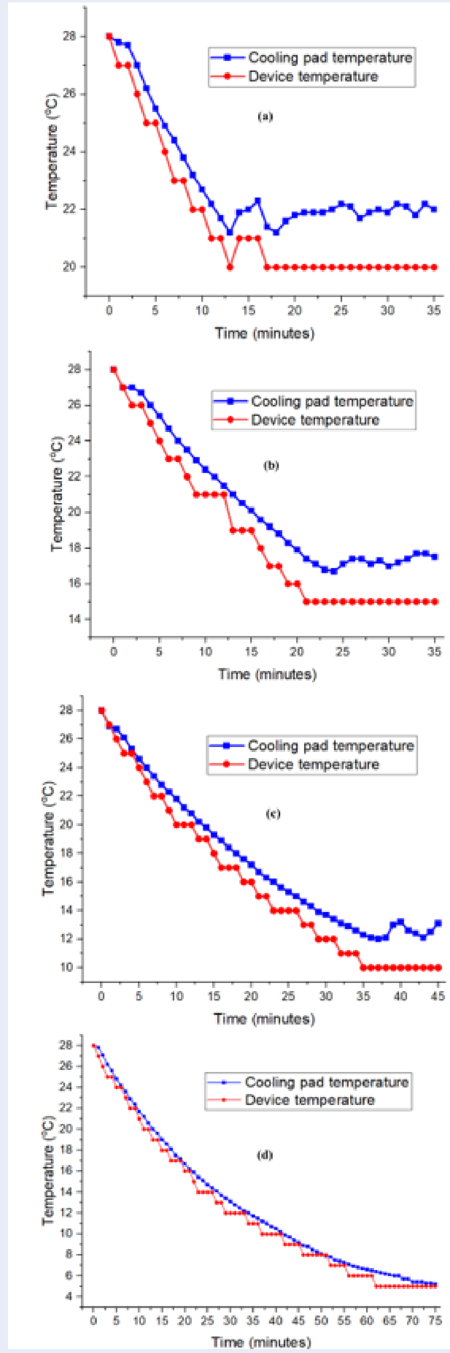

Figure 10: Stability of the cryotherapy device with a temperature setting of 20^{o}C (a), 15^{o}C (b), 10^{o}C (c) and 5^{o}C (d).

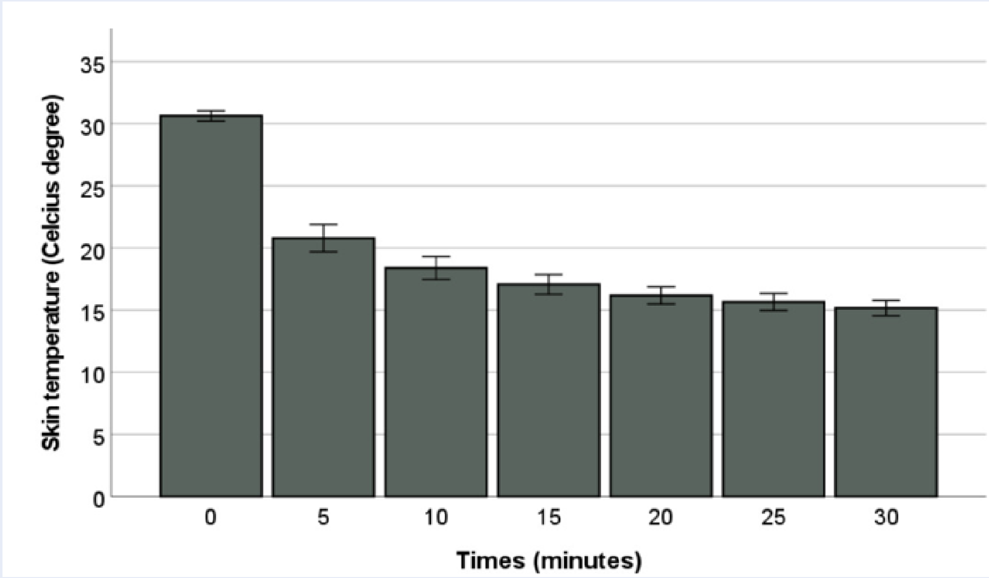

Figure 11: Mean surface skin temperature (with SD bars) at baseline and after 5, 10, 15, 20, 25 and 30 minutes of cold application at 10^{o}C.

Result of decreased skin surface temperature

Figure 11 summarizes the mean surface skin temperatures at each time point. Before application, the mean skin temperatures were similar and ranged between 28°C and 32.2°C at a room temperature of 27°C. After 15 minutes of application using a cooling pad at 10°C, the mean skin temperatures decreased substantially to 17.1°C ±2.2 (95% CI, 13.2-21.2°C). From the 15th minute onwards, the mean skin temperature continued to slightly decrease, with the mean skin surface temperature recorded at 15.1°C at the 30th minute. The mean skin temperature values at the time points after 5, 10, 15, 20, 25 and 30 minutes are statistically significant ($p<0.05$) in the Table 2. The temperature values displayed in Figure 11 and Table 2 represent skin temperature measurements taken at a specific point on the surface of the knee joint. These measurements reflect the mean temperature of the entire skin surface area surrounding the probe [14,15], because the cooling pad was tightly wrapped around the entire surface of the knee joint's skin. The experimental results on human skin are consistent with the results of a study by Holwerda et al. [13], which showed a clinically significant decrease in skin temperature between 12°C and 17°C when using the same cooling system for ice on ten healthy subjects (23±3 years) during a 30-minute cryotherapy treatment.

DISCUSSION

The results demonstrate that the device is capable of stable operation in the range of 5^{o}C to 20^{o}C with a temperature stability at the cooling pad of ±0.4^{o}C. Application of cold heat at 10^{o}C on a cooling pad can reduce the temperature on the skin surface by 11.1^{o}C -18.6^{o}C after 30 minutes. The simulation and experimental results of this study demonstrate clear similarities in the reduction of skin temperature upon applying the cooling pad to the surface. Specifically, within the first 10 minutes, the simulation results indicate a rapid decrease in skin temperature to 12-16 ^{o}C for 3 layers, followed by a slower decrease over the remaining 20 minutes. Likewise, the experimental results showed that the mean skin temperature of 32 volunteers decreased rapidly within the first 10 minutes to 18.4 ± 2.5^{o}C and then decreased slowly over the next 20 minutes. These findings demonstrate that the skin model and heat transfer equation used are equivalent to actual conditions, and the device was able to maintain a stable temperature at the cooling pad.

CONCLUSION

This research involves the development of a cryotherapy device that is easy to move and carry and has the ability to control stable temperature within the appropriate treatment range. This controlled continuous cold device has the potential to be fully developed into a commercial device for widespread use in physical

Table 2: Peak temperature of skin surface over times

Times (minutes)	Temperature (oC)	
	Mean SD	95% CI
0	30.6 1.1	28, 32.2
5	3.0	16.0, 28.0
10	2.5	14.0, 24.2
15	17.1 2.2	13.2, 21.2
20	16.2 1.9	12.4, 20.2
25	15.7 1.9	11.7, 19.5
30	15.2 1.7	11.1, 18.6

therapy and rehabilitation, particularly for the treatment of acute injuries in various joints.

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LIST OF ABBREVIATIONS

ACL: Anterior cruciate ligament.
TKR: Total knee replacement
TEC: Thermoelectric cooling module
SD: Standard deviation

CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

AUTHOR CONTRIBUTIONS

All authors contributed equally to this work. All authors have read and agreed to the published version of the manuscript.

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Thiết kế thiết bị nhiệt lạnh trị liệu sử dụng máy nén để giảm nhiệt độ trên bề mặt da

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TÓM TẮT

Nhiệt lạnh trị liệu là một kỹ thuật thường được sử dụng trong y học thể thao và vật lý trị liệu để điều trị chấn thương cấp tính và kiểm soát cơn đau. Việc áp dụng nhiệt độ thấp dẫn đến giảm nhiệt độ trên bề mặt da, gây ra một số tác động sinh lý trên cơ thể, giúp giảm viêm, sưng và đau ở vùng bị tổn thương. Phương pháp nhiệt lạnh có thể được thực hiện bằng nhiều phương thức khác nhau, trong đó các thiết bị nhiệt lạnh liên tục có kiểm soát nhiệt độ được sử dụng rộng rãi trong điều trị do khả năng kiểm soát nhiệt độ chính xác, đặc biệt là khi điều trị các khớp lớn. Các thiết bị này hoạt động bằng cách bơm tuần hoàn nước lạnh vào tấm làm lạnh quấn quanh các chi của bệnh nhân. Mục đích của nghiên cứu này là phát triển một thiết bị nhiệt lạnh trị liệu có thể điều chỉnh nhiệt độ thấp ở da để điều trị hiệu quả bằng cách sử dụng một máy nén lạnh kết hợp với một nguồn nước lạnh từ xa lưu thông qua tấm áp làm mát đàn hồi đặt tại vị trí cần điều trị. Kết quả cho thấy thiết bị này có thể kiểm soát nhiệt độ từ 20^oC đến 5^oC với mức dao động $\pm$ 0,4^oC tại tấm làm lạnh. Nghiên cứu thử nghiệm trên 32 tình nguyện viên cho thấy nhiệt độ da vùng đầu gối có thể giảm xuống tới 15,1$^oC \pm$ 1,7^oC (95% CI, 18,6^oC-11,1^oC) sau 30 phút quấn tấm làm lạnh 10^oC. Kết quả liệu pháp áp lạnh thử nghiệm trên bề mặt da của các tình nguyện viên cũng phù hợp với kết quả thử nghiệm mô phỏng. Nghiên cứu này minh chứng rằng thiết bị hoàn toàn có thể được phát triển để trở thành thiết bị y tế có khả năng kiểm soát nhiệt độ chính xác và liên tục trên da người, dễ sử dụng và đem lại lợi ích điều trị trong lĩnh vực vật lý trị liệu.

Từ khoá: Nhiệt lạnh trị liệu, truyền nhiệt sinh học, máy nén nhiệt lạnh

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