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Advanced Sensor-Based Cap Cooling System for Mitigating Chemotherapy-Induced Hair Loss

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ABSTRACT

Chemotherapy, a pivotal cancer treatment, frequently instigates alopecia, a psychologically distressing side effect that may deter patients from undergoing treatment. This paper presents a novel, sensor-equipped cooling cap designed to mitigate this hair loss by lowering scalp temperature, thereby reducing blood flow to the scalp before, during, and after chemotherapy. The innovation lies in substituting the conventional mechanical compressor-condenser system with electronic Peltier elements and a radiator, marking a significant evolution in cooling cap technology. The system, composed of a cap and a cooling section, was trialed on six breast cancer patients undergoing treatment with different chemotherapy drugs such as Taxol, Taxotere, and Anthracyclines. Initial observations reported hair retention in up to 89% and 59% of cases treated with Taxotere/Taxol and Anthracyclines respectively, suggesting variable efficacy based on the chemotherapy drug used. The lightweight, flexible system features a smart touchscreen control and an economical design using readily available components, offering user-friendly efficiency and comfort.

1. INTRODUCTION

Chemotherapy is a cancer treatment that involves the use of chemical substances. It is utilized for both curing cancer and extending survival time [1-3]. The toxicities and side effects of chemotherapy stem from the damage it inflicts on normal cells. Research indicates that the tissues most susceptible to these effects are those undergoing active division, such as bone marrow, hair follicles, and gastrointestinal mucosa [4-6]. Hair loss is frequently one of the most distressing side effects experienced by cancer patients undergoing chemotherapy treatments [7-9]. This side effect can pose a significant emotional challenge for women; in fact, nearly 47% of female cancer patients consider hair loss to be the most distressing aspect of chemotherapy. Surprisingly, 8% of these women would even refuse treatment due to the fear of experiencing this side effect [10-12].

Cooling the scalp skin reduces blood flow, which results in decreased drug absorption by the hair follicles. Additionally, it causes the hair follicles on the scalp to contract, which helps in preserving the hair. The most efficient approach to mitigating chemotherapy-induced alopecia (CIA) is through scalp cooling [13-15]. This technique has been in use since the 1970s and has proven highly effective. Scalp cooling, employed to prevent hair loss, functions by removing the heat produced during chemotherapy administration [16, 17]. Several factors influence the efficacy of scalp cooling in preventing alopecia, including variations in chemotherapy dosage and combinations, cooling duration, cooling temperature, hair condition, and the specific cooling device used [18-20]. The setup involves three main components: a cooling system, an electronic control system, and a cap system. To achieve the desired effect, the subcutaneous temperature needs to be lowered to below 22℃ [21-23].

This paper proposes a novel approach to scalp cooling using different components. Instead of using a compressor and condenser, this method employs a Peltier device and a radiator. The cap design features three layers: a silicone layer in direct contact with the scalp, an aluminum foil layer in the middle, and an external layer for insulation from room temperature.

Figure 1. Paxman scalp cooling device [11]

Over the years, several designs aimed at scalp cooling have been developed, utilizing various suitable temperature ranges [24-26]. These designs, including the Paxman device, have achieved significant success in preventing partial or complete hair loss (alopecia) during chemotherapy, yielding satisfactory results as illustrated in Figure 1 [27, 28]. For instance, in 2013, Unver [29] designed and developed a scalp cooling cap known as the Paxman system to minimize hair loss in cancer patients undergoing chemotherapy treatments. The system is available in two models: the Orbis I, suitable for single patient use in smaller chemotherapy suites or private beds, and the Orbis II, capable of simultaneously cooling one or two patients, with each cap functioning independently. This system houses a compact refrigeration unit featuring a unique coolant circulated at a temperature of -4°C through specialized coolant lines connected to custom-designed cooling caps. These caps are designed to be soft, flexible, and closely fitted to the patient's head, with easy-to-read touchscreen displays that allow for instant visual monitoring and clear indications when the desired temperature is achieved. This vital step ensures that the scalp reaches the necessary temperature before the administration of chemotherapy treatment.

In 2016, Komen et al. [30] monitored the scalp skin temperature of 62 breast cancer patients undergoing up to six rounds of Anthracycline-containing chemotherapy during the scalp cooling procedure. The cooling effect reached its maximum 45 minutes post chemotherapy infusion and lasted for 90 minutes. The scalp skin temperatures ranged from 10°C to 31°C, averaging at 19°C. Notably, 13 out of the 62 patients (21%) did not require a wig or head covering, having a significantly lower mean scalp skin temperature (18°C) compared to those who experienced hair loss (20°C). The coolant in the refrigeration tank was maintained at a temperature of -10°C.

In 2019, Mane et al. [31] devised a scalp cooling system that reduced the scalp area temperature, limiting the amount of chemotherapy drugs such as anthracyclines and taxanes reaching the hair cells. This system incorporates a cooling system, an electronic control system, and a cooling cap. Operating on a vapor compression cycle principle, it circulates cooled liquid through pipes in the cap. The connector lines are insulated with polystyrene. The system features a submersible pump situated in the evaporator, responsible for circulating the coolant, in this case, water. It was concluded that the goal of developing a cost-effective solution was successfully achieved.

In 2021, Mitric et al. [32] investigated the effectiveness of scalp cooling in preventing hair loss in patients undergoing treatment for gynecological cancers. This study included patients who underwent scalp cooling during their treatment. Participants were divided into two groups based on their treatment regimen: Group 1 received conventional Paclitaxel 175 mg/m^2 every three weeks, and Group 2 received Paclitaxel 80 mg/m^2 weekly. Of the 28 participants in the pilot study, 8 were in Group 1, and 20 were in Group 2. However, patients in Group 1 discontinued scalp cooling therapy after just two sessions due to significant hair loss. It was concluded that scalp cooling facilitated hair retention in patients receiving combination chemotherapy with Carboplatin 5–6 and weekly Paclitaxel 80 mg/m^2.

The objective of the current study is to introduce a novel method utilizing distinctive components, differentiating it from previous research in this field, as outlined in Table 1.

Table 1. Comparison between the main designs in the traditional studies and the present study design depends on hardware system design

The Design from Earlier Studies	Main Design in the Present Study
Cap system: 1- Inside silicone 2- Insulated cap cover (neoprene cover)	**Cap system:** 1- Inside silicone 2- Aluminum middle 3- Insulated cap cover
Refrigeration system: The system operates on the principle of a vapor compression cycle to flow the cooled fluid through the cap's tubes. This setup allows for efficient cooling and circulation of the liquid throughout the cap. The apparatuses of the system are: 1- Evaporators 2- Air compressor 3- Temperature sensors 4- Condensing device 5- Submerged pump	**Refrigeration system:** The system utilizes the Peltier cycle to circulate the refrigerated fluid through the cap's hoses. This setup ensures efficient cooling and proper circulation of the liquid within the cap. The apparatuses of the system are: 1- Peltier device 2- Temperature sensors 3- Radiators 4- Fans 5- Pump of water 6- Relays one of them for (Peltier 1 channel 30 Amp) and another Relay for (fans, radiators and pump of water) 1 channel.
Mechanical system design	**Electronical system design**

Over the previous years, several designs have been developed with the objective of cooling system cap, employing different temperature ranges, have realized distinguished success in preventing partial or complete hair loss (alopecia) during chemotherapy. The proposed design depends on the principle of an electronically system design that uses a Peltier and a radiator instead of a mechanical system design that uses a compressor and condenser in the cooling system, which is a new idea because no one had previously used Peltier to manufacture the device.

2. MATERIALS AND METHODS

In this paper, the system design process will be discussed in terms of hardware and software design. The present work includes designing a scalp cooling system that is used to prevent hair loss during chemotherapy. To assess the effectiveness of the device, patients were selected depending on the type of chemotherapy drug that causes hair loss. There were no inclusion or exclusion criteria; the extent of hair loss was measured through actual observation under physician supervision, taking pictures before and after, and then comparing them throughout the treatment. The patient's scalp needs to be monitored throughout the treatment to determine the extent of hair loss. When the level of hair loss is minimal, it indicates the success of the system. The system discussed in this paper comprises two components: the cap unit and the cooling unit.

(A) The cap system consists of three layers, each serving a specific function

The first layer is made of silicone and is in direct contact with the scalp, including skin temperature sensors. The middle layer is composed of aluminum foil, designed to distribute the cooling effect evenly across the head. Peltiers are installed on this layer. The third layer acts as external insulation to protect against room temperature.

(B) The cooling system is composed of many components

Touch screen (model Nextion 7 in), Microcontroller, Water hose, Power supply 12V 30A, Three air fans, Two radiators (large, small), Water pump, One relay for the Peltier and another relay for the fans, radiators, and water pump, Voltage regulator step down from 12V to 5V, Coolant tank.

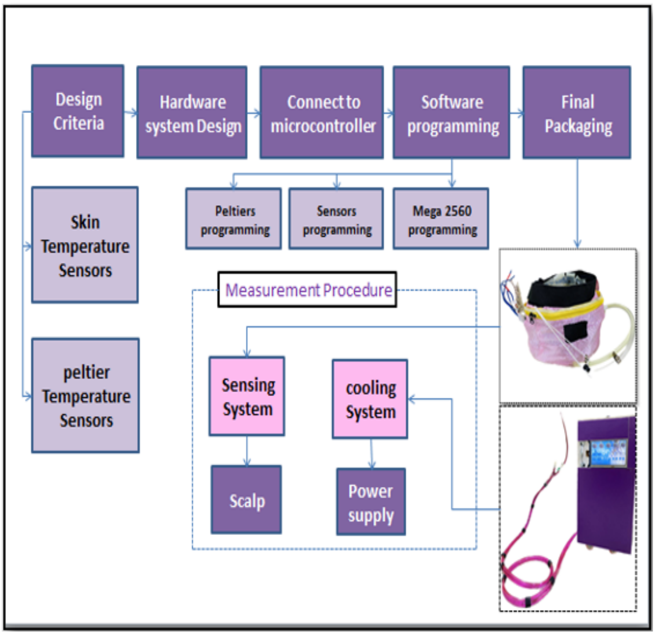

Figure 2. The block diagram of the system

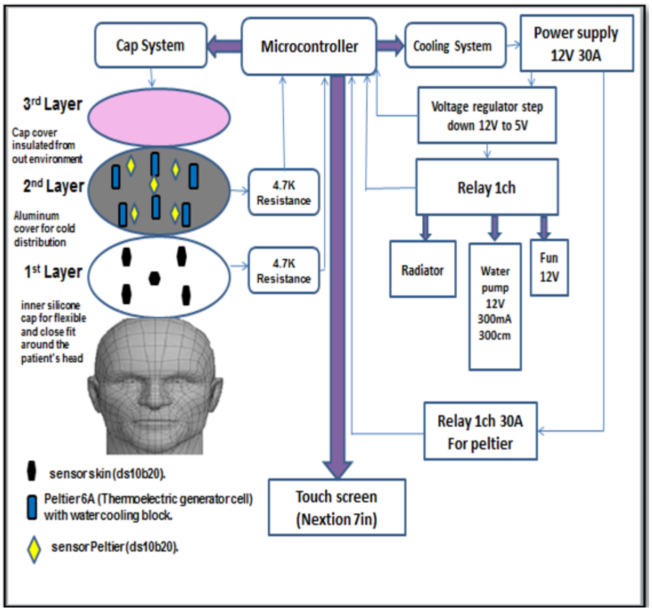

Figure 3. Proposed cap system and cooling system showing how the sensors are connected to the microcontroller and the layers of the cap system, as well as the components of the cooling system connected to the microcontroller

To monitor the scalp temperature, a set of five non-invasive sensors were utilized. These sensors were strategically placed around the silicone cover, covering the right, left, front, back, and top areas of the scalp. Additionally, there are six Peltiers positioned around the aluminum foil cover, each accompanied by a thermal sensor to measure the temperature of the Peltier. The microcontroller serves as the central connection point for all the Peltier units and skin sensors, allowing them to communicate with the smart touchscreen. Figure 2 illustrates the block diagram of the system, and Figure 3 illustrates the components of the system consisting of the cap system and cooling system.

2.1 Hardware system design

The proposed system is designed using the following parameters: five non-invasive digital Peltier thermo sensors (DS18B20 Non-Waterproof Temperature Sensor) and six non-invasive digital skin thermo sensors (DS18B20 Waterproof Temperature Sensor), with five being used for measuring skin temperature and one for monitoring the cooling tank's temperature. All sensors share the same feature of being able to communicate with devices using a 1-wire interface. The microcontroller serves as the central hub for all the sensors, collecting data from each sensor through an analog-to-digital converter. To prevent noise interference in the signal transmission, all skin temperature sensors and Peltier sensors are connected to the microcontroller via a 4.7k resistor, to ensure optimal results; parameters are as follows:

- The first stage involves designing the sensing system by connecting the sensors and Peltier units to the microcontroller. These sensors are temperature sensors.
- The second stage is focused on software design, which involves programming these sensors and Peltier units into the microcontroller for monitoring the parameters.
- Finally, in the third stage, all the sensing and Peltier systems are packaged into a cap system to be wearable for the patient, and all components of the cooling system are packaged in a cooling system box with a smart touchscreen. Figure 4 illustrates the hardware system design components.

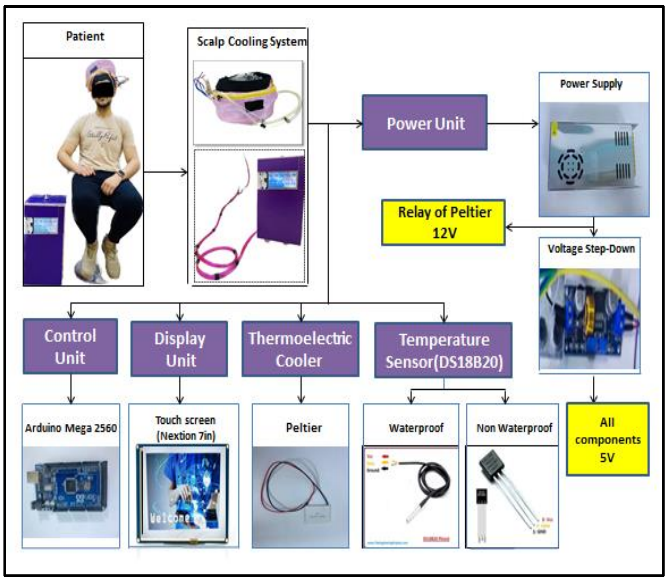

Figure 4. Hardware system design parts

2.2 Software system design

In the first step, we load the two libraries, SD and SPI, for saving and transporting data. We define the RTC timer to program it, then load the Nextion library for defining the relay and the button on the touchscreen. After that, we load the temperature and one-wire libraries for defining the sensors for skin temperature, Peltier units, and the tank. In the second step, the sensors and RTC are tested by connecting them to a PC (Personal Computer) via USB to check their functionality. The third step involves creating a loop of functions for the sensors to generate codes and operate the Nextion interface, followed by displaying the data on the Nextion screen. The last step involves establishing a data logging loop to save all the data. The code consists of 423 lines. The general programming of the Mega 2560 on the RTC software is illustrated in Figure 5. Temperature software coding and programming are depicted in Figure 6. The algorithm of this current design is explained in Figure 7 to illustrate the steps of the internal run of the scalp cooling system.

The implementation design of the present system and its connections is shown in Figure 8.

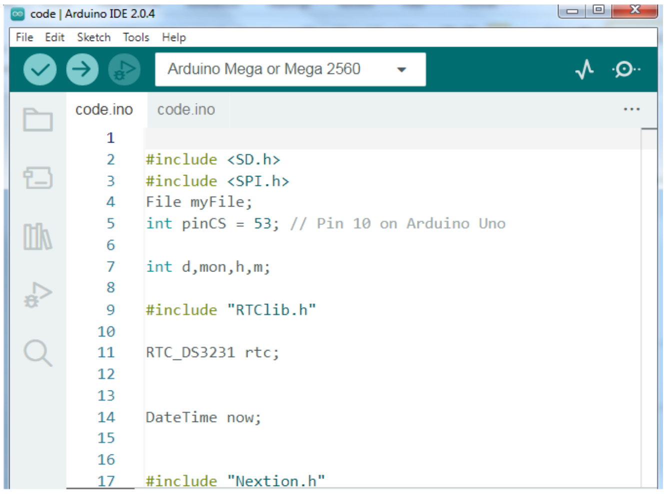

Figure 5. Programming of the Mega 2560 on the RTC software

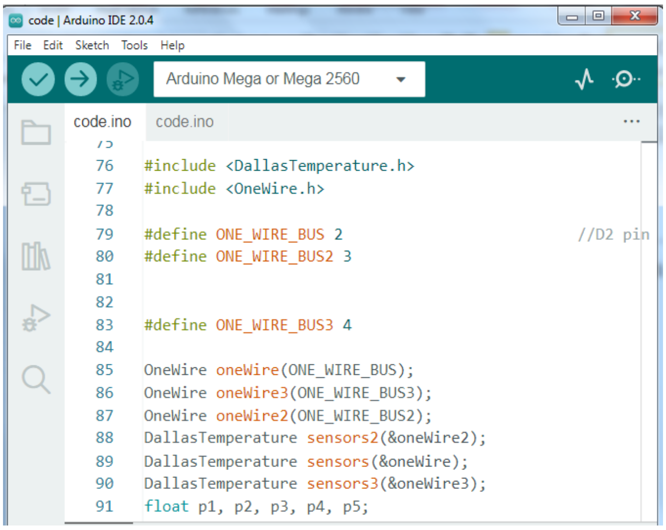

Figure 6. Temperature sensor software programming

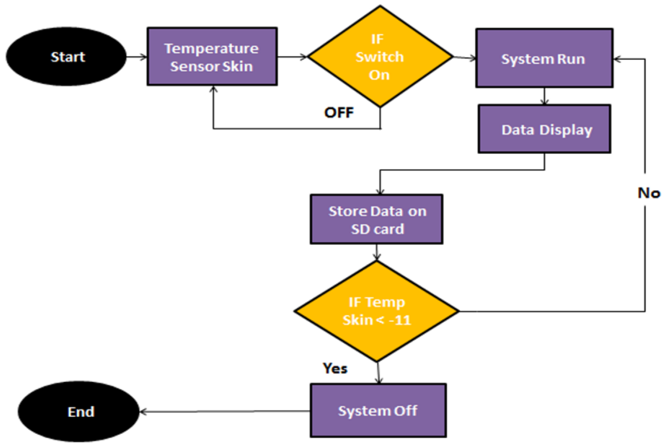

Figure 7. Algorithm of scalp cooling system

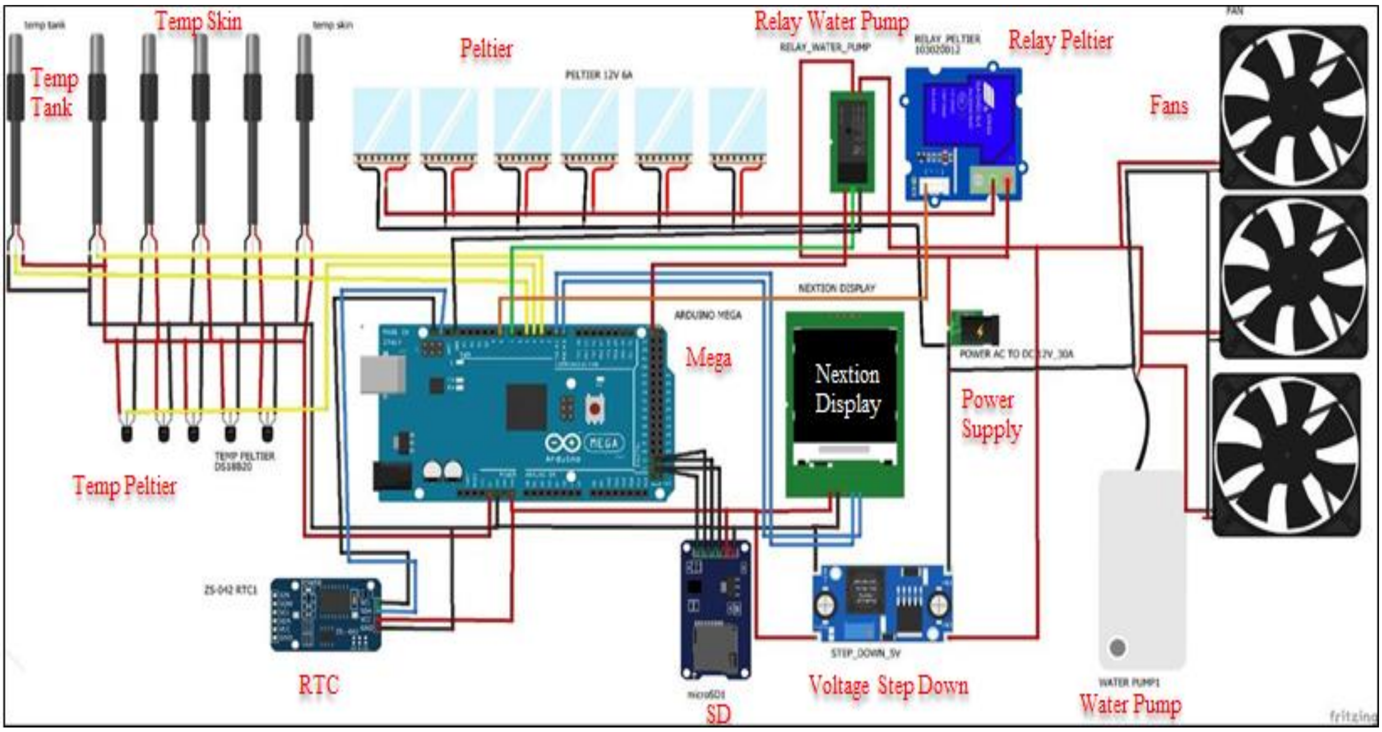

Figure 8. Implementation design of the present system and its connections

2.3 Testing the device

Test the device on six participating patients with breast cancer, aged between 40-60 years. All the participants gave written informed consent, as evidenced by the ethical approval from the Biomedical Engineering Department at Al-Nahrain University in Iraq, as shown in Appendix. They underwent various types of chemotherapy depending on the type of chemotherapy drug that causes more than 70% hair loss, such as taxotere, taxol, and anthracyclines. The effectiveness of the cooling cap protected hair to an extent of 59-89%, and the participants were then monitored for two sessions. The results after two sessions were assessed through actual observation under physician supervision to assess the extent of hair preservation, whether partial or complete. They were classified into three groups depending on the type of chemotherapy and its impact on hair loss.

(a) Type Taxol

Figure 9. Two patients have taken a chemotherapy type of taxol wearing a cap cooling system

The first two patients, aged 59 and 60 years, were administered a type of chemotherapy involving taxol with carboplatin. They wore the cooling cap system for 30 minutes both during and after the session, for a total of 30 minutes each time. The length of the treatment session for these two patients was five hours, during which they wore the cooling cap, as shown in Figure 9.

(b) Type Taxotere

Figure 10. Two patients have taken chemotherapy type of Taxotere wearing a cap cooling system

The next two patients, aged 55 and 58 years, were administered chemotherapy with a combination of Taxotere and endoxan. They wore a cooling cap system for 30 minutes, both during and after the session, lasting 30 minutes each time. The length of the treatment session for these two patients was three hours, during which they wore the cooling cap, as shown in Figure 10.

The last two patients, aged 42 and 45 years, underwent chemotherapy with a regimen of Anthracyclines (specifically Adriamycin, ADM) combined with endoxan. They wore a cooling cap system for 30 minutes during and an additional 30 minutes after the session. The duration of the treatment session for these two patients was three hours, during which they wore the cooling cap, as depicted in Figure 11.

(c) Type Anthracyclines

Figure 11. Two patients have taken chemotherapy type of anthracyclines wearing a cap cooling system

3. RESULTS

This paper tested the device on six participating patients with breast cancer aged between 40-60 years. They underwent various types of chemotherapy, such as Taxotere, Taxol, and Anthracyclines, and were monitored over two sessions. The results, documented through pictures, were classified into three groups depending on the type of chemotherapy and its impact on hair loss. Through close observation under physician supervision, it was noted that the patients undergoing Taxol treatment were monitored for three sessions. Utilizing the cooling cap system and analyzing the pictures taken before and after each session showed an 89% success rate in preventing hair loss. Similarly, those receiving Taxotere were monitored for two sessions, with a comparable success rate of 89%.

On the other hand, patients administered Anthracyclines, specifically Adriamycin, showed a 59% partial success rate over two sessions. Hair loss in cancer patients typically manifests twenty-one days after the first session, setting the timeframe for this experiment over three and then two sessions, as depicted in Figures 12, 13, and 14. Patients start treatment at grade 0, progressing to grade 1 after the first session, grade 2 after the second session, and grade 3 after the third session. The sample size was small, encompassing only six patients, due to the dependency on the type of chemotherapy administered, the limited timeframe, and the sensitive nature of engaging with cancer patients and their acceptance of the device. Despite these limitations, the study yielded an acceptable rate of hair protection.

Hair loss was compared through actual observation under physician supervision, utilizing pictures taken before and after the sessions using the cap, and compared the hair loss between the three chemotherapy groups, depending on the type of chemotherapy and its severity in causing hair loss.

Figure 12. Patient starts treatment with grade (0), grade (1) after the first session, grade (2) after the second session, and grade (3) after the third session, wearing the cap cooling system for three sessions

Figure 13. Patient starts treatment grade (0), grade (1) after the first session, grade (2) after the second session, wearing the cap cooling system for two sessions

Figure 14. Patient starts treatment grade (0), grade (1) after the first session, grade (2) after the second session, wearing the cap cooling system for two sessions

4. DISCUSSION

The present cooling system is lightweight, thin, and flexible, with a controlled smart touchscreen, making it efficient and comfortable. It was built using available components, resulting in an economical final design. The proposed system differs from traditional cooling systems in several ways. First, a Peltier and a radiator replaced the compressor and condenser, facilitating a transition from a mechanical to an electronic working principle, a feature not previously utilized in the manufacturing of such devices. Second, it monitors the temperature of the scalp skin non-invasively using sensors, ensuring the skin temperature remains within an acceptable range.

The instrument was applied to patients who were administered different types of chemotherapy drugs such as Taxol, Taxotere, and Anthracyclines, and were monitored for 2-3 sessions. Through actual observation under physician supervision, it was found that the patients receiving Taxol were protected from 89% hair loss after three sessions of using the cap cooling system, a finding confirmed by before and after session photos. Similarly, patients receiving Taxotere were shielded from an 89% hair loss after two sessions, while those administered Anthracyclines Adriamycin saw a 59% protection from hair loss over two sessions.

Hair loss in cancer patients typically manifests twenty-one days after the first session, thus these experiments were conducted after three sessions for some patients and two sessions for others. The technique proved effective in reducing chemotherapy-induced alopecia; the percentage of hair protected, either completely or partially, depended on the type of chemotherapy drug used. It is imperative that the cap is utilized from the first chemotherapy session to prevent hair loss, as the effects become noticeable twenty-one days post the initial session. Therefore, to safeguard against hair loss, it must be used from the first session and continued until the last session. Finally, the system's compact and portable size makes it suitable for hospital and house use.

5. CONCLUSIONS

In this paper, several key conclusions have been drawn from the results; they are as follows:

1. The primary objective of the current system is to prevent hair loss, a prevalent and distressing side effect experienced by cancer patients undergoing chemotherapy.

2. The developed system is sterilizable with alcohol before the patient wearing the cap and after wearing out, so any risk of infection is negligible. It employs modern software technology with smart touch-screen that transfers the results fast and easy, featuring a non-invasive sensing instrument. Additionally, the device is lightweight, thin, compact, and flexible, making it efficient and comfortable. It also boasts a low-cost final design and is easy to handle.

3. The cooling cap proved effective in reducing hair loss for patients undergoing various types of chemotherapy, with different levels of success based on the specific drug administered.

4. The technique significantly mitigated chemotherapy-induced alopecia; the percentage of hair protected from loss varied depending on the type of chemotherapy drug used.

5. The cap should be utilized starting from the first chemotherapy session to prevent hair loss, as hair loss

becomes noticeable twenty-one days after the initial session. Therefore, to protect against hair loss, it must be used from the outset and continued through to the final session. Based on what was observed, the system's effectiveness is evidenced by the significantly reduced levels of hair loss.

6. The open system device can be easily developed further by incorporating wireless biomedical sensors, which might offer greater comfort for the patient, although these sensors tend to be more expensive. Nonetheless, the results obtained were promising, showcasing no adverse side effects, a low-cost final design, and easy handling capabilities.

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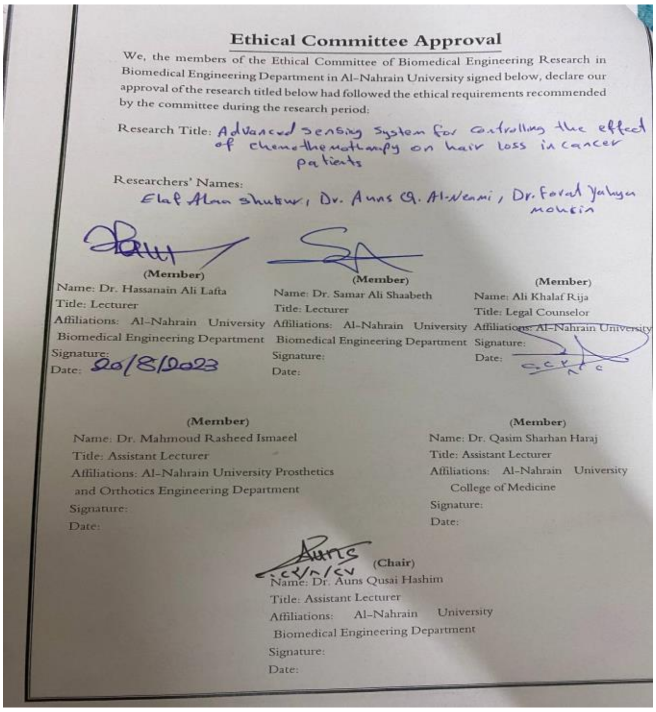
APPENDIX



Ethical Committee Approval

We, the members of the Ethical Committee of Biomedical Engineering Research in Biomedical Engineering Department in Al-Nahrain University signed below, declare our approval of the research titled below had followed the ethical requirements recommended by the committee during the research period:

Research Title: Advanced sensing system for controlling the effect of chemotherapy on hair loss in cancer patients

Researchers' Names: Elaf Alaa shukur, Dr. Auns Q. Al-Neami, Dr. Farad Yahya mohsin

(Member)
Name: Dr. Hassanain Ali Lafta
Title: Lecturer
Affiliations: Al-Nahrain University Biomedical Engineering Department
Signature:
Date: 20/8/2023

(Member)
Name: Dr. Samar Ali Shaabeth
Title: Lecturer
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(Member)
Name: Ali Khalaf Rija
Title: Legal Counselor
Affiliations: Al-Nahrain University
Signature:
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(Member)
Name: Dr. Mahmoud Rasheed Ismaeel
Title: Assistant Lecturer
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(Member)
Name: Dr. Qasim Sharhan Haraj
Title: Assistant Lecturer
Affiliations: Al-Nahrain University College of Medicine
Signature:
Date:

(Chair)
Name: Dr. Auns Qusai Hashim
Title: Assistant Lecturer
Affiliations: Al-Nahrain University Biomedical Engineering Department
Signature:
Date:

Appendix A1. Ethical Committee Approval