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MANUFACTURING AND ANALYSIS OF COST-EFFECTIVE SCALP COOLING SYSTEM

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ABSTRACT - Scalp cooling or hypothermic caps work towards reduction of alopecia caused as an effect of chemotherapy. Scalp-Cooling reduces the temperature resulting in reduced blood flow to the scalp area so that less chemotherapy drug such as anthracyclines and taxanes reach the hair cells. However, the success rate of this method varies with drugs and also precise medication is still unknown. The system consists of a refrigerating unit, an electronic control system and a cooling cap which together functions for the effect of alopecia. A circulating coolant serves the cooling purpose to the entire scalp area. This paper intends to provide a cost effective system which otherwise compromises the need to resolve alopecia during chemotherapy. The objective is to provide a cost-effective scalp cooling system for patients.

Keywords - Alopecia, Scalp cooling, Refrigeration unit, coolant.

I. INTRODUCTION

Cancer particularly breast cancer and ovarian cancer, are the most invasive cancer worldwide affecting nearly 12% of women population. Breast cancer comprises 24.5% of all invasive cancers, thereby contributing a significant share. A literature review of the effects of chemotherapy induced alopecia on the quality of life confirms that alopecia is a growing concern among women undergoing chemotherapy.^[1] During the medication of cancer, predominantly drugs such as cyclophosphamide with doxorubicin is used. Some taxanes drugs such as docetaxel is added to the regime ^[2]. Mostly these drugs work by destroying rapidly growing or rapidly replicating cancer cells. Hair follicles, the structure in the skin filled with blood vessels makes it one of the fastest growing cells in the body. Administration of chemotherapy induces toxicity in these matrix cells. The root sheaths may become necrotic, or, in less severe cases, form a weak, constricted hair shaft that then easily breaks.^[3] Some drugs cause hair loss particularly the ones' given during radiation whereas the oral medication advised in small doses are less likely to

cause hair loss but affect the hair by thinning them. Hair loss from breast cancer is temporary but in rare cases may be long or permanent causing societal unacceptance for the patients.

Hair fall is closely linked to person's identity. Women have described baldness as a sign of weakness which leads to low self - esteem and a constant societal stigma of indifferent; it is also a constant reminder of the cancer diagnosis causing further stress to deal ^[4].

Scalp cooling is a simple technique proven effective in combatting chemotherapy induced hair loss caused by certain drugs and increase the opportunity of retention capability of hair follicles to avoid its loss during the treatment either fully or minimise the hair loss. For the patients, it is like an opportunity to regain control, maintain self- integrity and encourages a positive attitude towards the treatment which otherwise causes psychological stress which may lead patients to reject potentially curative treatment ^[5].

The technique of scalp cooling works by extracting heat generated during chemotherapy. The current hypothesis for the mechanism to reduce hair loss is that blood perfusion is reduced. This reduces the total amount of cytotoxic drugs available to reach the matrix cells. In addition, reaction rates decrease with lower temperature thereby reducing chemotherapy uptake.^[6] This causes shrinkage of hair follicles in the scalp, hence preserving the hair. The extent of success on a patient depends entirely on the individual diagnosis and other miscellaneous conditions such as psychological factors, prescribed drug dosage and the effect of drug on the patient. The effect of scalp cooling cannot be generalised and is entirely based on trial and error depending on the individual level. There are two ways of preventing hair loss with scalp cooling. Firstly, use of cold caps which consists of a cooling gel which once cooled needs to be placed on the scalp of the patient. The other method is by circulating a coolant; this is done by passing the coolant through a refrigeration setup wherein the coolant is made



to reach the required temperature and circulated by means of a pump through the entire cap covering the scalp. A study showed that the temperature of the coolant should be around 3°C to achieve a subcutaneous temperature < 22°C and is possibly effective in reducing alopecia.^[7]

II. LITERATURE REVIEW

Pliskow et. al^[8] (2016) gives a description on the preferred operating temperatures based on experimental analysis and data from previous researches. By referring to the marketed caps by Dignicaps and Paxman, the work assuming conduction as the mode of heat transfer and no obstruction from the hair layer, empirically and more accurately derives the optimal temperature of the scalp and the working medium. The paper also incorporates the effect of a flowing fluid. A 3-D, transient analysis is performed for the analysis of the cap.

Maria Janssen et. al.^[9] (2005) quantifies the contribution of the putative mechanisms by which scalp cooling prevents hair loss and with this possible option for improving effectiveness of current day scalp cooling protocols have been investigated. A computational model has been developed based on the current hypothesis of the mechanisms of scalp cooling.

Sheikholeslami et. al^[10] (2015) studies how a cooling cap is used to cool the scalp in which the coolant fluid is adjusted to the desired temperature in flow state by a cooled reservoir. To lower the scalp temperature, the fluid in this system is circulated with specific temperature and flow rate in the cap; therefore, heat is scavenged from the patient's scalp. The brain heat transfers through free convection and evapotranspiration, while heat generation occurs from two perfusion and metabolism sources. The study provides a 3D human head model and a cooling cap to examine the heat transfer between the coolant and the skull, scalp and meningeal layers.

R. P. Gregory^[11] (1982) investigates the relation of the scalp skin temperature obtained with hypothermia to the degree of hair loss. Scalp cooling was undertaken in 24 patients with breast carcinoma. Scalp temperature in the 24 patients varied from 18.5°C to 28.5°C. In each individual patient, however, a consistent temperature was obtained on repeated measurement. Maximal cooling occurred after 20-30 minutes of hypothermia, which was maintained for 30-40. All these patients suffered slight hair loss but not sufficient for them to require a wig. The degree of alopecia was temperature dependent.

Yablonskiy et. al.^[12] (2007) studies the framework of the analytical model of temperature distribution in the brain, and demonstrates that a mild hypothermia can be successfully induced in neonates by means of external head cooling devices if two necessary conditions are fulfilled i.e, sufficiently low cerebral blood flow and sufficiently high value of the heat transfer coefficient

describing the heat exchange between the head surface and the cooling device.

The first condition establishes an eligibility criterion for using head cooling devices for achieving mild hypothermia therapy. The second condition imposes technical requirements on the cooling device.

Diao et. al.^[13] (2001) develops a theoretical model to examine the brain temperature gradients during selective cooling of the brain surface after head injury. The head was modelled as a hemisphere consisting of several layers, representing the scalp, skull and brain tissue, respectively. The dimensions, physical properties and physiological characteristics for each layer, as well as the arterial blood temperature, were used as the input to the Pennes bioheat transfer equation to simulate the steady-state temperature distribution within the brain. Depending on the head surface temperature, a temperature gradient of up to 13°C exists in the brain tissue. The results have shown that the volumetric-averaged brain tissue temperature T_{bt} , avg for adults and infants can be 1.7 and 4.3°C, respectively, lower than the temperature of the arterial blood supplied to the brain tissue.

Liang Zhu^[14](2000) evaluates the capacity of the heat loss from the carotid artery in the human neck and thus, to provide indirect evidence of the existence of selective brain cooling in humans during hyperthermia. A theoretical model is developed to describe the effects of blood flow rate and vascular geometry on the thermal equilibration in the ca-rotid artery based on the blood flow and the anatomical vascular geometry in the human neck. It is shown that the cooling of the arterial blood can be as much as 1.1 °C lower than the body core temperature. The model also evaluates the relative contributions of counter-current heat exchange and radial heat conduction to selective brain cooling.

David Wyatt^[15] (2014) provides an inexpensive and mobile cap design to carry out light weight and self-contained cooling system to be easily handled by patients in process of the therapy. The modelled figure of cooling cap consists of central head bonnet, middle flap, side flaps, upper surface and lower surface and an ice water circulating channel with a starting system consisting of electric supply, pump and cooling system.

Paxman coolers limited^[16] (2016) have designed a heat exchanger cap to conform to a human head consisting of three elements covering the left, right and central portion of the head. The intermediate portion consists of passage for inlet at the beginning of intermediate portion and for outlet of fluid flow at the end of the portion. The work also states the method to manufacture the designed cap.

Freddy Pachys^[17] (1997) selects the elements for the system. The study highlights the design of cap and the various elements included to operate the system to control the temperature of the cap according to the wearer. The work also states about the handling of the temperature of

the setup by pre-defining the temperature for the patient receiving cytokin drugs. The material of the helmet and insulating material are also stated in this study.

Mountford et. al. [18] (1994) works to remove air through suction to reduce moisture content in the evaporator to avoid impedance between the delivery tubing and evaporation orifice for warm incoming air and chilled outgoing air. The study claims to have air as the recirculating medium to provide cooling effect. The effectiveness and highlight of the study being the availability of air and light weight of elements for carrying out the cooling process.

Baldry et.al [19] (2018) studies on how to reduce the metabolic activity of the hair follicle by reducing the temperature below 22°C. This study considers Pennes Bioheat equation and ellipsoidal geometry with simple structural layers of head. The head is modelled in the Numerical Simulation software for female as well as male head sizes. The analysis shows that temperature variation on the various layers of head. The study evaluates the heat transfer amount required to reach the required temperatures through the various layers.

III. PROTOTYPE DEVELOPMENT

A prototype was developed in order to record the temperatures reached and to understand the effect of cooling on human scalp.

Prototype Initiation:

The process of prototype development initiated under the concept of “Designs” Sprint.” during which all the governing parameters to construct a model were listed down and solution categorisation.



Fig 1. Parameters accounted in the Designs ‘Sprint

The parameters accounted for prototype initiation are included in Fig 1. wherein all necessary factors to deliver an effective system were considered. The parameters were the base on which the prototype followed by final model was constructed.

System Design: The system consists of three major components /system assembled together as a single unit.

The basic cooling system or the refrigeration system working on vapour compression cycle; a digital indicator with Copper-Constantan J type thermocouples and the cap unit.

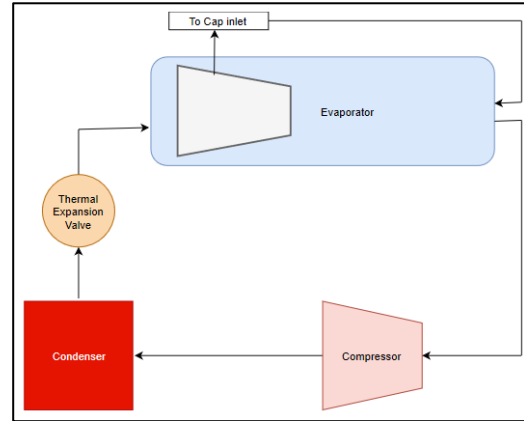


Fig 2. Layout of proposed setup

Prototype Iteration 1: The first iteration for prototype development was carried out using a swimmer cap made of silicone.

Advantage: Flexible

- Disadvantage: 1. Adhesive melted the cap.
 2. Thermally insulating material of cap.

Prototype Iteration 2: A fabric cap was covered with water level tubes wound inside the cap in spiral form and hand stitched to the fabric.



Fig 3: Top view of cap performed under iteration 2



Fig 4: Inside of cap under iteration 2

Refrigeration Setup: The system circulating the cooled liquid through the pipes of the cap works on the concept of vapour compression cycle. The components of the system are - evaporator, compressor of 0.5 TR, air cooled condenser, thermostatic expansion valve. The connection lines are insulated with polystyrene. The system consists of a submersible pump which is accommodated in the evaporator which circulates the coolant which in this case; is water.

IV. MODEL DEVELOPMENT

The model of the scalp cooling system consists of the same components and additionally, consists of J type Copper-Constantan thermocouples attached at 5 different locations on the system and 1 on the inner side of the cap.

Cap Manufacturing:

An aluminium cap was fabricated from sheet metal of 2 mm thickness. The cap was manufactured using metal shaping process to convert it into hemispherical cap like the shape of the human head. The material aluminium is chosen due to its high thermal conductivity.

Refrigeration Setup: The thermocouples are placed at 1 at evaporator inlet and outlet each, 1 at condenser inlet and outlet each, 1 inserted in the water consisting of evaporator coil and 1 on cap. A digital temperature indicator with a least count of $+0.1^{\circ}\text{C}$ showed the temperature readings. A submersible pump of 2.8 m pressure head was taken to circulate the coolant (water) around the cap, the flow rate was 0.361 litres per minute.



Fig 5: Copper tube winding on the outer surface of the cap



Fig 6: The inner surface of the cap

V. TESTING AND RESULTS

The testing of the manufactured setup was carried out for a duration of 75 minutes on subjects to witness the effects of the system.



Fig 7: The refrigeration setup with the cap

Table 1: Readings from trial I

DBT	32°C	WBT	30°C	Relative Humidity	92%	TC1 Evaporator Outlet	TC3 Condenser inlet	TC5 cap	Date: 13-04-2019
Subject	Akshay	Recorder	Neelam	Time	10:46:00 AM	TC2 Evaporator inlet	TC4 Condenser Outlet	TC6 water temp.	
Water capacity	4.5 litre		Temperatures in °C		Pressure is in psi				
Duration (Mins.)	TC1	TC2	TC3	TC4	TC5	TC6	Suction Pressure	Discharge Pressure	Remark
0	30.4	28.9	29.5	33.4	32.2	26.2			
5	15.1	18.4	64.5	18.7	31.7	12.7	38	160	
10	-2.1	9.1	65.8	22.6	32.4	4.1	15	150	
15	-4.1	6.3	67.4	23.6	31.1	3.6	15	140	Pump started
20	-4.5	5.6	67.8	25	8.9	0.1	15	140	
25	-6.1	5.5	68	25.2	10.6	-0.4	15	140	Cap on subject
30	-2.9	5	68.1	25.6	6.3	-0.4	15	140	
35	-8.3	4.5	68.5	25.8	6.1	-1.5	15	140	
40	-9	2.8	69.1	26.8	6.8	-1.5	15	140	
45	-9.5	2.1	69.4	27.5	7.7	-1.6	15	140	
50	-9.9	1.6	67.6	27.2	7	-1.6	15	140	
55	-10	1.1	65.1	27.1	7.1	-1.4	15	140	
60	-11.2	-0.1	62.5	27.5	6.9	-1.1	15	140	
65	-11.5	-0.4	62.8	27.9	6.8	-1.5	15	140	
70	-12	-1.1	62.1	28.1	6.7	-1.5	15	140	
75	11.3	12.9	25	45.2	12.8	-2.3			system off 5 mins prior

Table 2: Readings from trial II

DBT	32	WBT	30	RH (%)	92%	Date: 15-04-2019			
Subject	Sanket	Recorder	Neelam						
Water Capacity	4.5 litre	Time	11:08 AM						
Time	TC1	TC2	TC3	TC4	TC5	TC6	Suction Pressure	Discharge Pressure	Remark
0	16	13.5	50.8	21.1	31.9	18.3	30	160	
5	11	13.4	63.8	20.4	32.5	14.1	25	160	
10	4	6	65.2	23	32.6	6.1	20	134	
15	-4.7	4.8	66.8	23.5	32.5	5.3	15	140	
20	-6.6	3	70.3	24.5	32.5	5	15	140	Pump started
25	-6	3.4	70.3	25.4	9	-0.5	15	140	cap on subject
30	-5	3.2	67	25.4	8.4	-1	15	140	
35	-1.4	3	66.7	25.3	7.9	-1.8	15	140	
40	-4	1.3	67.8	25.8	7	-2.1	15	140	
45	-10.2	0.7	68.7	26.8	7	-2.1	15	140	
50	-10.9	-0.5	68.5	26.9	6.8	-2.4	15	140	
55	-11.5	-0.6	68.2	27.4	5.5	-2.6	15	140	
60	-12.8	-1.5	69.8	27.5	5.5	-2.6	15	140	
65	-12.8	-2.5	68.5	27.5	5.5	-2.6	15	140	

$$= 382.99 + 0.794966 \times (13.72)$$

$$= 393.89 \text{ kJ/Kg}$$

$$\text{Entropy at } 1', s_1' = s_1 + C_p \ln\left(\frac{T_2}{T_1}\right)$$

$$= 1.7468 + 0.764966 \times \ln\left(\frac{261}{247.28}\right)$$

$$= 1.7897 \text{ kJ/Kg.K} = s_2$$

Now, entropy at 2', $s_2' = s_2 + C_p \ln\left(\frac{T_2'}{T_2}\right)$
 At 2, $P_2 = 9.65 \text{ bar}$, $T_2 = 40.069^\circ\text{C}$, $s_2 = 1.711776 \text{ kJ/kgK}$, $C_{p2} = 1.12762 \text{ kJ/kgK}$, $h_2 = 418.58 \text{ kJ/kg}$

As $s_2' = s_2 + C_p \ln\left(\frac{T_2'}{T_2}\right) = s_1'$
 $s_2' = s_1' = 1.7897 = 1.711776 + 1.12762 \times \ln\left(\frac{T_2'}{313.069}\right)$
 $T_2' = 335.47 \text{ K} = 62.47^\circ\text{C}$

$$h_2' = h_2 + C_p \Delta T$$

$$= 428.58 + 1.12762 \times (62.47 - 40.069)$$

$$= 443.84 \text{ kJ/kg}$$

At pt 3, saturated liquid phase is present.
 Specific heat for liquid R134a at given conditions is $C_{pl} = 1.4873 \text{ kJ/kgK}$
 $T_3 = T_2 = 40.069^\circ\text{C}$
 $T_3' = 27.5^\circ\text{C}$

Hence, the subcooled liquid is present at pt 3'

Enthalpy of liquid at point 3', $h_{f3}' = h_{f3} - C_{pl}(T_3 - T_3')$
 $= 253.53 - 19.72$
 $= 234.836 \text{ kJ/kg}$

As we know $h_4 = h_{f3}' = 234.836 \text{ kJ/kg}$.
 Now, the cooling effect obtained = $h_1' - h_4 = 159.05 \text{ kJ/kg}$

Compressor work = $h_2' - h_1' = 49.95 \text{ kJ/kg}$
 Co-efficient of performance = $\frac{h_1' - h_4}{h_2' - h_1'} = \frac{159.05}{49.95} = 3.18$

Carnot CoP = $\frac{T_1}{T_2 - T_1} = \frac{247}{313 - 247} = 3.75$

For calculating actual CoP, energy meter constant = 3200 rev/kWh
 Time taken for 10 revolutions = 24.5 sec

Hence, energy consumed = $\frac{10}{3200} \times \frac{3600}{24.5} = 459 \text{ W}$

Actual CoP = $\frac{\text{Refrigeration Effect}}{\text{Energy Consumed}} = \frac{494}{459} = 1.076$

VI. COST COMPARISON

Paxman and Dignicap systems cost varies from \$ 1500 - \$ 3000 which translates to approximately INR 10.5 to 21 lakhs per system. Our system was developed in-house at a total cost of INR 25,000 [20].

Table 3: Total breakdown of the incurred cost

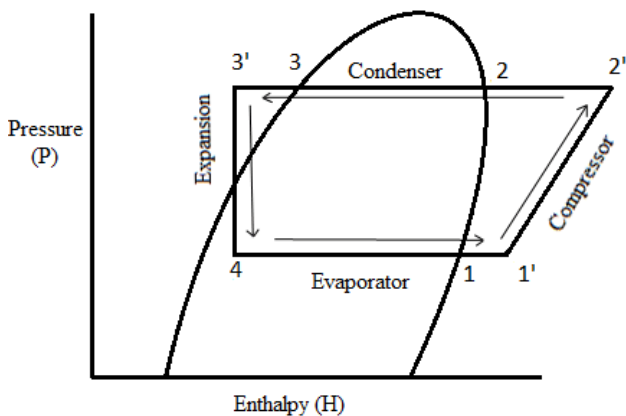


Fig 6: The P-H plot

At $P_1 = 15 \text{ psi} = 1.03 \text{ bar}$, the saturation temperature for R134a is $T_1 = -25.72^\circ\text{C}$
 Actual temperature measured at evaporator outlet is $T_1' = -12^\circ\text{C}$.
 Hence, the vapor is superheated.

Entropy at 1, $s_1 = 1.7468 \text{ kJ/Kg.K}$
 Enthalpy at 1 $h_1 = 382.99 \text{ kJ/Kg}$
 Enthalpy at 1', $h_1' = h_1 + C_p \Delta T = h_1 + C_p(T_1' - T_1)$



Sr. No.	Component	Quantity	Rate per piece (INR)	Total Cost (INR)
1	Hermetically sealed reciprocating compressor	1	4000	4000
2	Air cooled condenser	1	3000	3000
3	Cooling fan	1	1000	1000
4	Pressure gauges	2	200	400
5	Aluminum sheet	3 sq. ft.	40 per sq. ft.	360
6	Filter dryer	1	300	300
6	Copper Tube	20 feet	25 per feet	500
7	Capillary tube	10 feet	100 per feet	1000
8	Thermostatic expansion valve	1	1500	1500
9	PUF insulation	2 Kg	1200	2400
10	Refrigerant (r-134a)	2 kg	800 per kg	1600
11	Hoses with end connectors	2	400	800
12	Orifice	1	500	500
13	Starting Relay	1	240	240
14	Flow switch	2	1600	3200
15	Over load protector	2	900	1800
16	Submersible pump	1	450	450
17	Thermocouple	10 ntr.	45 per metre	450
18	Electric wire	6 ft.	40 per ft.	240
19	3 pin plug	2	60	120
20	FRP enclosure	As per setup size	As per setup size	3000
21	Aluminum cap	1	50	50
Total				Rs. 24,950

VII. CONCLUSION

Prototype conclusion:

The results obtained in prototype are comparable to the results obtained in the actual setups as directive from the literature survey and hence, development is possible for making it cost effective.

Setup conclusion

The observations noted during testing of the setup are comparable to the actual values drawn from the literature survey and hence it can be concluded that the setup meets the required demands. Hence, the primary objective of the setup and the project is satisfied. The refrigeration system of the setup is efficient with an actual CoP of 1.7606. The required temperature of 6°C is reached at the cap end, literature suggesting a requirement of temperatures between 6°C - 9°C and thus, it can be concluded that the setup meets the requirements and can be further iterated and tested. The cost report suggests that the setup is cost effective in manufacturing.

As can be derived from previous works (insert reference to best calculation paper), since the temperature on scalp is < 19 °C, it can be concluded that the cap satisfactorily performs its intended use. From further CFD analysis, it has been determined that the optimum time of application is between 15 – 30 minutes as beyond this time limit, the body fights back to maintain the optimum body temperature. Also, the total cost incurred is 2.5% of what the already commercial systems charge. Hence, it is safe to conclude that the motive of designing and developing a cost-effective was successfully achieved.

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