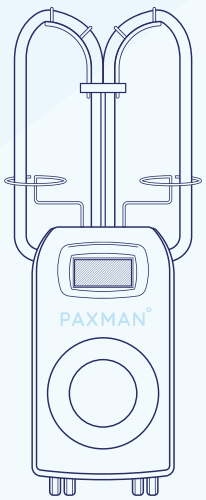
ROW

PAXMAN

SAFETY

Paxman Scalp Cooling System



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Will scalp cooling work?

Many thousands of men and women throughout the world have retained their hair using the Paxman Scalp Cooling System while receiving chemotherapy treatment.

Intended Use

INTENDED PURPOSE

The Paxman Scalp Cooling System is indicated for use to reduce chemotherapy-induced hair loss in cancer patients receiving systemic chemotherapy with alopecia causing chemotherapy agents.

PRINCIPLES OF OPERATION

The PSCS cools the scalp during the administration of chemotherapy which causes vasoconstriction of the capillary blood vessels, reducing the blood supply to the hair follicles; this in turn decreases the amount of concentrated cytotoxic drug reaching the hair follicles, thereby reducing the risk of hair loss.

INTENDED ENVIRONMENT

The Paxman Scalp Cooling System is intended for use in a professional healthcare facility environment by a suitably qualified healthcare professional or a Paxman certified, trained representative.

INTENDED PATIENT POPULATION

For patients receiving chemotherapy treatment.

INTENDED USERS

The Paxman Scalp Cooling System is intended for use by appropriately qualified healthcare professionals who have been trained in correct operation of the device by a Paxman representative.

You should be aware of the following:

- Hair loss is a possible side effect of chemotherapy
- The treatment success rates with the Paxman Scalp Cooling
- System vary from patient to patient and with different drug regimens being administered
- Patients cannot be guaranteed they will not lose any or all of their hair
- Patients may have a headache during treatment
- Some patients may feel cold during treatment
- Some patients may feel lightheaded after the Paxman Scalp Cooling Cap has been removed
- Patients may visit the restroom during treatment

Contraindications

Scalp cooling is contraindicated for:

- The subject has an existing history of scalp metastases, or the presence of scalp metastasis is suspected
- Patients with cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, and post-traumatic cold dystrophy
- Scalp metastases have rarely been reported in the literature, but caution regarding their development has been a limitation for the broad-scale application of scalp cooling during chemotherapy. Theoretically, tumour cells that have seeded in the scalp might not receive adequate chemotherapy during hypothermia, thus allowing them to grow at a later date
- Patients with severe liver or renal disease from any etiology who may not be able to metabolize or clear the metabolites of the chemotherapeutic agent
- Patients with hematological malignancies (leukaemia, non-Hodgkin and other generalised lymphomas)
- Patients with imminent skull irradiation

Warnings and Precautions

It cannot be guaranteed that scalp cooling will prevent all patients undergoing chemotherapy from losing any or all of their hair. The success rate of scalp cooling in reducing chemotherapy-induced hair loss varies from patient to patient and according to the chemotherapy regime administered.

Long-term effects of scalp cooling and scalp metastasis have not been fully studied.

The Paxman Scalp Cooling System should only be used by appropriately qualified healthcare professionals who have been trained in the operation of the device.

Do not allow any liquids to be placed on the scalp cooler or near the touch screen controller, including drips from the cooling caps.

Avoid use in ambient temperatures of over 30°C/86°F.

Do not touch the side ventilation grills whilst the device is in use.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Attention

Clinical studies have successfully demonstrated the effectiveness of the Paxman Scalp Cooling System in the prevention of chemotherapy-induced alopecia, or hair loss, with widely used chemotherapy dosages and regimens for solid tumor cancers. Hair retention rates are variable, however, since successful scalp cooling depends on many factors such as the chemotherapy regimen and dose, duration of drug infusion, metabolism of the chemotherapy drug, and concomitant comorbidities or other conditions. Age, hair type, hair condition, and general health can also affect the results of the Paxman Scalp Cooling System.

It cannot be guaranteed that scalp cooling will prevent all patients undergoing chemotherapy from losing any or all of their hair. The success rates of scalp cooling in reducing chemotherapy-induced alopecia, or hair loss, vary from patient to patient and depend on the chemotherapy regimen administered.

Research has shown that scalp cooling is very effective across a wide range of chemotherapy regimens. You may experience some hair loss and overall thinning of the hair while using scalp cooling, and the normal shedding cycle of the hair will continue. We encourage you to continue scalp cooling even if you experience some hair loss, Many people report hair growth during their chemotherapy treatment while using scalp cooling, as new hair growth is also protected from the chemotherapy drugs.

Based on recent research, it is advised not to buy a wig during scalp cooling. The study suggests that you should wait until a wig

becomes necessary. This study was authored by Dr Van den Hurk and others.[1]

Your healthcare professionals and medical team will let you know if scalp cooling is likely to be successful with your chemotherapy treatment.

Hair loss is very common during chemotherapy for breast cancer as well as other cancers, though some drugs and methods of administration are more likely than others to disrupt hair follicles.

Chemotherapy-induced hair loss is a common and distressing side effect of cancer therapy and is one of the major unmet challenges in cancer management. Scalp cooling can prevent chemotherapy-induced hair loss in some cancer patients with solid tumors receiving certain chemotherapy regimens. Recent evidence indicates that this technique does not increase the risk of scalp metastasis. A reduction in post-chemotherapy infusion duration of scalp cooling and the advancement in cool cap technology may assist clinicians in promoting scalp cooling to cancer patients / to improve the patient experience of chemotherapy-induced hair loss.

Alopecia is a common side effect of chemotherapies used in the treatment of cancer. The effects of alopecia on quality of life (QOL) on various aspects of QOL in cancer patients includes anxiety and distress, body image, sexuality, self-esteem, social functioning, global QOL and return to work outcomes.

Hair loss consistently ranked amongst the most troublesome side effects, and is described as distressing, and may affect the body image. The presence and extent of negative effects on chemotherapy-induced alopecia on various aspects of QOL of patients who have had scalp cooling may be worse than those who did not have scalp cooling.

Whether a patient develops hair loss and the degree of hair loss depends on several factors including:

- Dose of chemotherapy
- How often the chemotherapy is given
- The route of administration
- The drugs or combination of drugs received

Chemotherapy-induced hair loss is almost always reversible.

Hair loss often begins around the time of the second chemotherapy infusion, though this varies widely. Some people do not lose all of their hair until they have nearly completed chemotherapy.

Data have shown that women who experience hair loss despite using scalp cooling might have worse quality of life than women who did not have scalp cooling. It is important to select those patients who would benefit most from scalp cooling.[2],[3]

The following table identifies the chemotherapeutics cited as most likely to cause chemotherapy-induced alopecia. The risk of scalp cooling may outweigh the benefits in patients receiving chemotherapeutic agents with a high incidence of inducing alopecia.

Chemotherapy Drugs Most Linekly to cause Hair Loss[4]

Patients treated with certain chemotherapeutic agents, including AC, DAC and Irino mono, as well as patients with Asian or chemically-colored hair may be least likely to benefit from scalp cooling. The risk of scalp cooling may outweigh the benefits in patients that are least likely to benefit from scalp cooling.

Class	Agents	Half-Life (Hours)
Topoisomerase Inhibitors	Doxorubicin	Triphasic: 0.5, 3.3 & 30
	Epirubicin	40
	Daunorubicin	0.75-18.5
	Irinotecan	6-12
	Topotecan	2-3
	Etoposide	1.5
	Teniposide	21.2
	Amsacrine	8-9
Alkylating Agents	Cyclophosphamide	5-9
	Ifosfmainde	4-8
	Busulfan	2.8-3.9
	Melphalan	Varable
	Lomstine	72
Antimetabolites	Cytatarbine	Biphasic: 0.16, 1-3
	Gemcitabine	0.7-1.57
	5-FU	0.13-0.33
Antimicrotubule Agents	Docetaxel	0.07, 0.6, 11
	Paclitaxel	52.7
	Vindsine	24
	Vionrelbine	>40
	Vincristine	15-155
	Vinblastine	TriphasicL 0.58, 0.88, 19

Adverse Effects

Known side effects associated with scalp-cooling therapy include:

- Discomfort due to feeling cold
- Headache
- Light-headedness or dizziness
- Nausea

All of these side effects occur during the scalp cooling process. They are transient or temporary in duration, and are generally recognised as presenting a low risk of harm (although in some cases, patients have discontinued scalp cooling because of, these effects).

The majority of women using the Paxman Scalp Cooling System reported being able to tolerate a high level of cooling. They also reported a high level of comfort and acceptability.

Few people discontinued scalp cooling because of side effects. Most patients were comfortable, reasonably comfortable, or very comfortable while wearing the device; many said they were reasonably comfortable. In the multicenter, randomised clinical trial that Paxman conducted in the United States for FDA clearance, only 6 participants of 142 patients discontinued scalp cooling because of intolerance.

A Potential Long-Term Side Effect

The only known potential long-term side effect of scalp cooling is also the most controversial one; this is that scalp cooling when used on women receiving chemotherapy for breast cancer could lead to an increased incidence of scalp metastases. (This is because the same mechanisms that restrict the effectiveness of the chemotherapeutic agent against hair roots or follicle cells in the scalp can also restrict the effectiveness of the chemotherapeutic agent against cancerous tissue in the scalp.)

The natural incidence of scalp metastases in patients with breast cancer is approximately 1 in 4000. This incidence seems to be about the same in patients who receive scalp cooling and those who don't.

There is no clinical evidence that cooling the scalp during adjuvant and palliative chemotherapy treatment increases the risk of developing scalp metastases. The issue remains a theory or possibility, but it has not been proven.

The Paxman Scalp Cooling System is the leading product found to minimize the risk of hair loss during chemotherapy in women with breast cancer. Your healthcare professionals can advise you if scalp cooling is likely to be successful with your chemotherapy treatment, or whether any other treatments, or the use of a wig, scarf, or headcover, may be more appropriate.

[1] Van den Hurk CJ, van den Akker-van Marle ME, Breed WP, van de Poll-Franse LV, Nortier JW, Coebergh JW. Impact of scalp cooling on chemotherapy-induced alopecia, wig use and hair growth of patients with cancer. Eur J Oncol Nurs. 2013;17(5):536-540.

[2] Udrea, A. Scalp cooling system in preventing chemotherapy-induced alopecia: a pilot study on 108 patients – a Romanian oncology – day hospital experience. Medisprof Oncology. Psycho-Oncology 23 (Suppl. 3):169-254 (2014), P1-0062.

[3] Van der Hurk CJ, Mols F. Impact of alopecia and scalp cooling on the well-being of breast cancer patients. Psycho-Oncology. 19(7):701-9 (2010).

[4] Dunnill CJ, Al-Tameemi W, Collett A, Haslam IS, Georgopoulos NT. A Clinical and Biological Guide for Understanding Chemotherapy-Induced Alopecia and Its Prevention. Oncologist. 23(1):84-96 (2018).