Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Device Description

What is scalp cooling?

Scalp cooling is a simple treatment that can prevent hair loss caused by certain chemotherapy drugs. The use of scalp cooling has been proven to be effective in preventing chemotherapy-induced alopecia, or hair loss, and can result in people retaining much of the hair. Some people retain all of it.

For people receiving chemotherapy, scalp cooling can mean the opportunity to regain some control, ensure some privacy, and maintain a positive attitude toward treatment.

Why does chemotherapy make hair fall out?

Chemotherapy works by targeting all rapidly dividing cells in the body. Hair is the second fastest dividing cell, which is why many chemotherapy drugs cause hair loss. Chemotherapy damages hair follicles (at the root of the hair), resulting in hair loss about
2 weeks after the start of chemotherapy.

Does hair always fall out with chemotherapy?

Many chemotherapy drugs used to treat solid tumor cancers, including taxanes and anthracyclines, cause alopecia, or hair loss. Ask a member of your healthcare team if your specific chemotherapy drugs cause this side effect.

How does scalp cooling work?

Scalp cooling reduces the damage that chemotherapy causes to hair follicles. It does this by lowering the temperature of the scalp immediately before, during, and after chemotherapy. This in turn reduces blood flow to the area around the hair follicles, which may prevent or minimize hair loss.

The Paxman Scalp Cooling System has excellent heat extraction technology, making it the most comfortable and tolerable scalp cooling method. In addition, the Paxman Scalp Cooling System is administered by healthcare professionals during chemotherapy.

How long does scalp cooling take?

If you choose to have scalp cooling during chemotherapy, you will wear the Paxman Scalp Cooling Cap for 30 minutes preinfusion, during chemotherapy infusion, and for a maximum of 90 minutes afterward (depending on your therapy).

It is important to continue with scalp cooling each time you go for chemotherapy to get the full benefits of hair preservation.

For more information and to watch instructional videos, please visit coldcap.com

Indication for Use

Who should use the Paxman Scalp Cooling System?

The Paxman Scalp Cooler is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in cancer patients with solid tumors.

Intended use

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 in pediatric patients. Scalp cooling is contraindicated in patients with:

- An existing history of scalp metastases or the presence of scalp metastasis is suspected.
- Cancers of the head and neck.
- CNS malignancies (either primary or metastatic).
- Cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, cold migraine, cold urticaria, and post-traumatic cold dystrophy.
- Hematological malignancies (leukemia, non-Hodgkin and other generalized lymphomas) or hematological malignancies that are being treated for cure.
- Imminent bone marrow ablation chemotherapy.
- Imminent skull irradiation.
- Previously received, or scheduled to undergo skull irradiation.
- 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, tumor cells that have seeded in the scalp might not receive adequate chemotherapy during hypothermia, thus allowing them to grow at a later date.
- Severe liver or renal disease from any etiology who may not be able to metabolize or clear the metabolites of the chemotherapeutic agent.
- Skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma.
- Small cell carcinoma of the lung.
- Solid tumors that have a high likelihood for metastasis in transit.
- Squamous cell carcinoma of the lung.

Warnings and Precautions

- Scalp and/or cutaneous metastases have been reported in patients with non-small cell lung cancer, colon cancer, renal cell carcinoma, ovarian cancer, and bladder cancer. Patients with advanced forms of these tumors may be more likely to experience scalp metastases with the scalp cooling system.

- It cannot be guaranteed that scalp cooling will prevent all patients undergoing chemotherapy from losing any or all their hair. The success rate of scalp cooling in reducing chemotherapy-induced hair loss varies from patient to patient and according to the chemotherapy regimen administered.
- Long-term effects of scalp-cooling and scalp metastasis have not been thoroughly studied.

PAXMAN

CHANGING THE FACE OF CANCER

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.

- Use of Scalp Cooling in the palliative setting in patients with metastatic cancer may also increase the risk for scalp metastases.
- Use of scalp cooling with Taxanes plus anthracyclines when used together or in sequence has not been shown to be successful in preventing chemotherapeutic drug induced alopecia. The Paxman Scalp Cooler should not be used in these patients.
- The effectiveness of this device in patients who have received previous chemotherapy has not been evaluated.
- Clinical studies have demonstrated variable success rates in patient reduction of chemotherapy-induced alopecia with scalp cooling since the outcome is dependent on multiple factors including chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism, and concomitant comorbidities. 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.
- The Paxman Scalp Cooler 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.

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 and is available at **PaxmanUSA.com**.

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

Adverse Effects

Known side effects associated with scalp cooling include:

- Chills
- Dizziness
- Headache
- Nausea
- Paresthesia (an abnormal sensation such as tingling, tickling, pricking, numbness, or burning of the skin–a "pins and needles" feeling)
- Pruritus (severe itching)
- Sinus pain
- Skin tissue disorders
- Skin ulceration

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

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.

Ancillaries: Published Clinical Studies of the Paxman Scalp Cooler.

AUTHOR	TYPE OF STUDY/ METHOD	PATIENTS	CHEMOTHERAPY AGENTS	OBJECTIVE	RESULTS (PERFORMANCE & SAFETY)	CONCLUSION
van den Hurk, CJ, et al. (2012) Note: Study data is included 2006-2010 Dutch registry data and Paxman Netherlands Clinical Study of Efficacy/3	Registry, multi-center (28) Nurses and patients completed questionnaires on patients, chemotherapy and scalp cooling; logistic regression analysis was used to examine associated characteristics of the scalp cooling result	n=1411 Male n=50 (4%), female n=1357 (96%), missing n=4 Types of cancer: breast n=1216 (86%), female genital n=65 (5%), gastrointestinal/ colorectal n=63 (4%), lung n=19 (1%), prostate n=27 (2%), other n=16 (1%), missing n=5	A60C600 (AC) (n=74), A60C600/D100 (ACD) (n=16), ACT overall (n=50), D75A50C500 (TAC) (n=66), D overall (n=120), F500A50C500 (FAC) (n=39), FEC overall (n=752), F500E100C500/ D100 (FE100CD) (n=46), TCarbo overall (n=68), T70-90 (42), Irino 250 (n=42), other (n=64)	To estimate the results of scalp cooling for currently used chemotherapies to provide patient information and identify characteristics associated with the results.	Overall, 50% of the 1411 scalp-cooled patients did not wear a head cover during their last chemotherapy session. Patients were satisfied with the results in 8% of cases after TAC chemotherapy and up to 95% after paclitaxel treatment. Besides the type of chemotherapy, higher dose and shorter infusion time, older age, female gender and non-West-European type of hair significantly increased the proportion head cover use. Hair length, quantity, chemical manipulation (dyeing, waving, coloring), wetting hair before scalp cooling, and treatment with chemotherapy ever before did not influence the degree of head covering among patients.	Scalp cooling results as recorded in this open patient registry were positive for most regimens, justifying its use by all eligible patients, except for those needing TAC. Lengthening infusion time may improve the results.
van den Hurk, CJ, et al. (2013)	Review of observational studies, autopsy studies and Munich cancer registry	Studies of skin and scalp skin metastases in patients with breast cancer without scalp cooling: studies of scalp skin metastases in scalp-cooled patients with (mainly) breast cancer	Diverse	Using frequency data on metastases in breast cancer to discuss the risk of whether scalp cooling might facilitate hiding and disseminating scalp skin metastases and thus decrease survival.	The incidence of scalp skin metastases in breast cancer patients seems to be comparable for scalp-cooled (0.04-1%) and for non-scalp-cooled (0.03-3%) patients.	In patients with solid tumors, an unfavorable development of the disease due to scalp cooling has never been documented. Scalp cooling can safely be offered to patients treated with alopecia-inducing chemotherapy.
Lemieux J, et al. (2015)	Retrospective cohort	n=1370 women with non-metastatic breast carcinoma who received chemotherapy in neoadjuvant (n=140) or adjuvant setting (n=1230) n=553 used scalp cooling; n=817 were treated in facilities where scalp cooling was not routinely available	Not reported	To compare overall survival according to whether or not scalp cooling was used during neoadjuvant or adjuvant chemotherapy for non-metastatic breast cancer.	Median follow-up was 6.3 years for scalp-cooled group and 8.0 years for non-scalp-cooled group. No difference in overall mortality was observed between scalp-cooled patients and non-scalp-cooled patients (adjusted hazard ratio 0.89, 95% confidence interval 0.68-1.17, p=0.40).	Among women undergoing neoadjuvant or adjuvant chemotherapy for non-metastatic breast cancer, scalp cooling used to prevent CIA had no negative effect on survival.

AUTHOR	TYPE OF STUDY/ METHOD	PATIENTS	CHEMOTHERAPY AGENTS	OBJECTIVE	RESULTS (PERFORMANCE & SAFETY)	CONCLUSION
Nangia J, et al. (2017) Clinicaltrials. gov identifier NCT01986140	Randomized, multi-center (7) A comfort scale was administered after each treatment in scalp-cooling group. Alopecia assessments using CTCAE v4.0 at baseline and after chemotherapy cycle by a blinded clinician, patient's clinician and patient; participants were asked if they needed to use a wig and/or a head wrap	n=182 women with stage 1 or II breast cancer undergoing chemotherapy from December 2013 to September 2016 Randomized to receive scalp cooling (n=119) or no cooling (n=63) Each patient underwent scalp cooling for 30 minutes pre-infusion, during infusion and 90 minutes post-infusion	Planning to receive at least 4 cycles of taxane- (n=91, 64%) and/or anthracycline-based chemotherapy for curative intent (n=51, 36%)	To assess whether use of the Orbis Paxman Hair Loss Prevention System is safe and effective in reducing CIA in woman with breast cancer undergoing neoadjuvant or adjuvant chemotherapy.	Publication reports on interim analysis (n=142 patients); patients will be followed for 5 years for safety (time and site of first recurrence) and overall survival. 48 of 95 (50.5%) in cooling group had successful hair preservation (95% confidence interval 40.7%-60.4%) compared to 0 of 47 (0%) in the control group (95% confidence interval, 0%-7.6%). Success rate difference was 50.5% (95% confidence interval, 40.5%-60.6%). The trial was stopped early for superiority (p=0.0061). No statistically significant differences in changes in any of the quality-of-life (QOL) scales from baseline to chemotherapy cycle 4 were observed between the scalp cooling and control groups. 54 adverse events (all grades 1 and 2) were reported in the cooling group. There were no serious adverse device events.	Among women with stage I to II breast cancer receiving chemotherapy with a taxane, anthracycline, or both, those who underwent scalp cooling were significantly more likely to have < 50% hair loss after the 4th chemotherapy cycle compared with those who received no scalp cooling.
Massey C (2004) Note: Data is included in Paxman UK Clinical Study of Efficacy	Open, non-randomized, observational, multi-center (8) Alopecia was assessed using the World Health Organization (WHO) grading system; patient acceptability assessed by questionnaire; results compiled by Scalp Cooling Assessment Groups	n=94 breast cancer patients who underwent treatment 1997-2000	5-fluorouracil, epirubicin and cyclophosphamide (FEC) regimen	To assess the efficacy of scalp cooling to reduce alopecia for women undergoing treatment for breast cancer using the Paxman Scalp Cooler. To assess patient views on the comfort and acceptability of scalp cooling using the Paxman Scalp Cooler.	Use of the Paxman Scalp Cooler was adjudged a success for 89% of all patients using the WHO grading system for alopecia and for 87% of patients being specifically administered the commonly used 5-fluorouracil, epirubicin and cyclophosphamide (FEC) regimen. When asked about degrees of comfort during the scalp-cooling process, 85% of patients described it as very comfortable, reasonably comfortable or comfortable, with only 15% of patients reporting a description of uncomfortable or very uncomfortable.	Scalp cooling using the Paxman Scalp Cooler was found to be an effective technique with minimal side-effects for patients treated with commonly prescribed alopecia-inducing chemotherapy drugs.
Bini M, et al. (2004)	Observational, single-center Nurses completed questionnaire on patients, chemotherapy and scalp cooling characteristics during each session; results were evaluated indicating the severity of hair loss per CTCAE 3.0 during each chemotherapy session and patient's satisfaction during last treatment	N=47 breast cancer patients who underwent treatment from June 2013-March 2014 Mean age: 53 years (range 35-72) 46 female, 1 male 80% were treated in the adjuvant setting and chemotherapy naïve	70% of patients received anthracycline-based polychemotherapy (AC or FEC 75 every three weeks), and 30% received monotherapy with taxanes on a weekly schedule	To verify effectiveness of Paxman concerning alopecia in the sample group; evaluate patients' expectation and degree of final satisfaction with regard to its use.	Median number of the cooling session: 5 (range 1-12). Alopecia G0 and G1 were registered at the end of chemotherapy in 62% of the patients, irrespective of the type of treatment. 100% of patients reported being satisfied in terms of hair preservation during their last session. 27% of patients discontinued scalp cooling treatment because of severe alopecia (G2); all these patients were receiving an anthracycline. Scalp cooling was stopped because of intolerance in 11% of patients mainly due to discomfort and longer time of infusion.	The Paxman scalp cooler was found to be an effective technique with moderate side-effects for patients treated with commonly prescribed alopecia-inducing chemotherapy drugs. Lengthening infusion time seems to be the main limit of this system.

AUTHOR	TYPE OF STUDY/ METHOD	PATIENTS	CHEMOTHERAPY AGENTS	OBJECTIVE	RESULTS (PERFORMANCE & SAFETY)	CONCLUSION
Falanga M, et al. (2010)	Observational, single-center	n=5 patients with breast or non-small cell lung cancer Patients complete patient priority scale for chemotherapy-related side effects at baseline; patients treated with Paxman Scalp Cooler for 30 minutes pre-infusion and 45 minutes post-infusion; patient questionnaire following each treatment; hair loss evaluated by nurses applying WHO criteria at each chemotherapy cycle	Single agent docetaxel	To determine efficacy and patient compliance of scalp cooler Paxman of patients subjected to single agent docetaxel for breast cancer or non-small cell lung cancer; to report on first Italian experience.	The pilot study is ongoing with 5 patients enrolled to date and 9 chemotherapy cycles with the scalp cooler support. Treatment has been well tolerated, with 1 case of refusal at treatment onset and all others continuing with successive chemotherapy cycles.	Providing a means to reduce alopecia is important for patients for whom this is a distressing and feared side effect, and studies are warranted. Early data on patient acceptance to therapy are encouraging. Data on patient symptom priority, efficacy and further data on tolerance will be presented.
El-saka RO, et al. (2009)	Randomized Paxman Scalp Cooler was applied 20 minutes pre-infusion, during infusion and for 2 hours post-infusion; hair loss assessed using WHO criteria at each cycle and after 6 chemotherapy cycles; QOL was assessed using EORTC QLQ-C30 and BR23	n=120 female breast cancer patients treated in adjuvant setting, July 2007-August 2008 Patients were randomized for scalp cooling during chemotherapy (n=60) or not (n=60)	Doxorubicin (50 mg/m2), 5-FU (500 mg/m2) and cyclophosphamide (500 mg/m2) for 6 cycles	To evaluate the role of scalp cooling in reducing anthracycline-induced hair loss and its impact on QOL.	After 4 cycles, 61.7 % of patients in the scalp cooling group had grade 4 hair loss compared to 81.7 % of patients in control group. After 6 cycles, 85% of patients in scalp cooling group experienced grade 4 hair loss compared to 100% of patients in the control group. 9 patients (15%) in the scalp cooling group developed grade 1-2 hair loss. No significant relation was found between degree of hair loss and liver function tests. 73.3% of patients were comfortable during cooling. QOL scores were comparable between groups except for emotional functioning and body image. In the hair loss group, 71.2% of patients showed severe disturbance of emotional functioning and 54.1% of patients had moderate disturbance in body image. In hair preservation group (9 patients), 77.8% developed moderate disturbance of emotional functioning and all patients had mild disturbance in the body image.	The role of scalp cooling is limited to the total dose of 300 mg/m2 doxorubicin. It may be more effective with fewer cycles or less aggressive drug combination. Hair loss affects various aspects of QOL, especially emotional functioning and body image. More time is needed to assess the long-term effect of hair loss on QOL and the incidence of scalp metastasis in the two study groups.
Betticher DC, et al. (2013) Note: Study data is reported in Paxman Swiss Clinical Studies of Efficacy Clinicaltrials.gov identifier NCT01008774	Open-label, prospective, non-randomized	n=238 patients with solid tumors receiving chemotherapy in a palliative setting Patients allocated per their preference; n=128 Paxman, n=77 cool cap, n=39 no cooling Types of cancer: breast n=76, lung n=38, prostate n=86, other n=38	Docetaxel (55–60 mg/day on weekly therapy, 135–140 mg/day on 3-weekly therapy)	To investigate whether two different methods of scalp cooling can prevent hair loss, i.e. Paxman PSC-2 machine and cold cap. Primary endpoint was incidence of WHO grade III or IV alopecia as assessed by treating physician or wearing a wig. Additional endpoints consisted of discontinuation of initially chosen alopecia prevention method, number of cycles of chemotherapy received in each subgroup, patient perception of scalp cooling procedures, well-being, and tolerability/side effects of scalp cooling systems.	Median number of cycles and median docetaxel doses were similar across groups. Alopecia occurrence under 3-weekly docetaxel • Paxman: 23% • Cold cap: 27% • No cooling: 74%. Alopecia occurrence under weekly docetaxel • Paxman: 7% • Cold cap: 8% • No cooling: 17%. Cooling (Paxman and cold cap combined) reduced alopecia risk by 78% (hazard ratio 0.22, 95% confidence interval 0.12-0.41). 5% patients reported adverse events (most frequently sensation of cold). 30 (13%) patients discontinued cooling measures after 1 cycle.	Both Paxman scalp cooling and cold cap offer efficacious protection against hair loss, in particular when docetaxel is administered in a 3-weekly interval. There appears to be no difference between scalp cooling with Paxman or cold cap in terms of efficacy and tolerability.

AUTHOR	TYPE OF STUDY/ METHOD	PATIENTS	CHEMOTHERAPY AGENTS	OBJECTIVE	RESULTS (PERFORMANCE & SAFETY)	CONCLUSION
Kurbacher CM, et al. (2017)	Retrospective analysis	n=99 female patients who underwent sensor-controlled scalp cooling alongside chemotherapy from 2014-2016 Types of cancer: breast n=78, epithelial ovarian carcinoma n=15, other n=6 Curative intent n=72, palliative setting n=27 Chemotherapy naïve n=66, prior chemotherapy n=33 Pre-menopausal n=48, post-menopausal n=51	Anthracycline-based n=4, taxane-based n=29; AT-based n=51, other n=15	To obtain detailed information about the effectiveness and safety of sensor-controlled scalp cooling using the Paxman system in female patients exposed to CIA-inducing chemotherapy for breast cancer or genital tract malignancies in the clinical routine.	69 (69.7%) patients completed sensor-controlled scalp cooling, of which 58 (58.6%) experienced complete hair preservation (DS 0) and 11 (11.1%) showed partial success (DS 1–2). 30 (30.3%) patients discontinued sensor-controlled scalp cooling. 21 (21.2%) patients discontinued for CIA, 4 (4.0%) headache, 3 (3.0%) local discomfort/"feeling cold", 2 (2.0%) unknown. Side effects were all not severe and resolved completely after cessation of sensor-controlled scalp cooling.	In the clinical routine, sensor-controlled scalp cooling to prevent CIA in patients with breast or female genital tract cancer is feasible, safe, and effective. Study success rate is in good agreement to previous reports although more patients in the palliative setting or with a history of prior chemotherapy have been included.
Silva G, et al. (2016)	Observational Photography and assessment of hair loss by CTCAE v4.0; discomfort was assessed by Pain Visual Analogue Scale	n=20 female patients followed since 2015 Median age: 51 years Types of cancer: breast (90%), n=2 patients had metastatic tumors	Most common treatments were docetaxel-cyclophosphamide (25%) and doxorubicin and cyclophosphamide followed by paclitaxel - AC/T (25%)	To evaluate scalp cooling results in preventing CIA in a private clinic in Brazil, using the Paxman Orbis scalp cooling machine.	7 (35%) patients had success with alopecia G1. 5 (25%) patients discontinued scalp cooling; of these, 3 of 5 patients discontinued secondary to hair loss, all from AC/T group. 7 patients (35%) are still under scalp cooling treatment; 2 of 7 patients with alopecia G2. 56% of patients complained of headache with a median visual analog pain score of 4.	Scalp cooling is tolerable and has been showing good results in preventing CIA in our patients. Patients AC/T receivers remain challenging.
Boyle F, et al. (2015)	Focus group or semi-structured interview Participant perceptions and experiences of scalp cooling were discussed as part of patients' overall chemotherapy experience and a thematic analysis conducted	n=17 women with breast cancer Scalp-cooled (Penguin Cold Caps®, Dignitana Dignicaps® or Paxman Orbis® caps) and non-scalped-cooled participant views were sought	Largely adjuvant TC or FEC-D	To explore breast cancer patients' perceptions and experience of scalp cooling, and their needs for information. Provide first exploration of Australian patient attitudes to scalp cooling.	Scalp cooling was perceived as a proactive way of managing hair loss. 5 main themes: (1) scalp cooling in the context of treatment decision-making discussions (2) hair loss expectations vs experiences (3) treatment expectations vs experiences (4) potential for faster regrowth, and (5) satisfaction with scalp cooling. Accurate information during treatment decision-making was primary factor influencing patient expectations and satisfaction. Faster regrowth was a motivator to continue treatment. Efficacy and tolerability of scalp cooling influenced future hypothetical treatment decision-making for all participants. Information regarding tolerability and hair care during treatment influenced anxiety.	Evidence-based information during treatment decision-making is essential to ensure patient expectations are consistent with current treatment outcomes. Additional information and education tools are needed to assist patients and health care professionals manage scalp cooling, and will be developed.

Non-Published Clinical Studies of the Paxman Scalp Cooler

STUDY DESCRIPTION	TYPE OF STUDY / METHOD	PATIENTS	CHEMOTHERAPY AGENTS		SCALP COOLING TIMES	RESULTS
Dutch Registry (presented at 2017 MASCC/ISOO International Meeting) Note: 2006-2010 registry data is included in van den Hurk et al. (2012) and Paxman Netherlands Clinical Study of Efficacy/3	Registry	2006-2010: n=1411 (4% male) 2010-2015: n=4864 (14% male) 2015-2017: n=827 (19% male) Types of cancer: breast 75%, prostate 8%, ovarian 6%, stomach/colon/liver 5%, lung 3%, other 2%	AC/AC-T/AC-D 2006-2010: 140/1411 (10%) 2010-2015: 941/4864 (19%) 2015-2017: 329/827 (40%) FEC/FEC-D/ FEC-T 2006-2010: 798/1411 (57%) 2010-2015: 1386/4864 (28%) 2015-2017: 66/827 (8%)	Jevtana 2006-2010: 0/1411 (0%) 2010-2015: 42/4864 (1%) 2015-2017: 6/827 (1%) Eribuline 2006-2010: 0/1411 (0%) 2010-2015: 0/4864 (0%) 2015-2017: 6/827 (1%)	Not reported	Results of 2006-2013 registry Chemotherapy agent (s) result of cooling / No. patients / Positive scalp cooling AC/AC-T/AC-D: 1079: 61% Docetaxel: 843: 87% FEC/FEC-D/FEC-T: 2192: 44% FAC: 101: 46% Taxol(wkl/3wkl): 556: 82% TAC: 167: 11% TCar: 475: 57% Irinotecan: 267: 31%
Paxman UK Clinical Study of Efficacy Note: Data is included in Massey CS, et al. (2004)	Open, non-randomized, observational, multi-center (8) Patients completed questionnaires related to comfort and acceptability of scalp cooling	n=95 breast cancer patients being treated with chemotherapy in adjuvant or palliative setting between 1997-2000 Mean age: 44 years (range 28-61)	Epirubicin as monotherapy (n=10), FEC combination therapy used 1997-2000 (n=62), doxorubicin as monotherapy or combination (n=11), docetaxel single agent (n=5), CMF (n=5), not reported (n=2)		Pre-infusion: 15-20 minutes During infusion: cooling was maintained Post-infusion: 120 minutes for majority of patients	5 of 95 (5.3%) total patients observed grade 3 hair loss 1 of 95 (1.1%) total patients observed grade 4 hair loss 5 of 95 (5.3%) patients discontinued scalp cooling treatment 2 of 62 (3.2%) patients receiving FEC observed grade 3 hair loss 1 of 62 (1.6%) patients receiving FEC observed grade 4 hair loss 11% of 95 total patients and 13% of 62 patients treated specifically with FEC required wigs 85% of patients reported that they were comfortable, reasonably comfortable, or very comfortable during the scalp cooling period 12% of patients reported they were uncomfortable with an additional 3% very uncomfortable Only 5% of patients discontinued scalp cooling before the end of chemotherapy treatment, with discontinuation because of discomfort seen in one patient Headaches at some time during treatment cycles were reported in 32% of patients
Paxman Norwegian Clinical Study of Efficacy	Observational, single-center Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse	n=54 breast cancer patients treated in neo-adjuvant, adjuvant or palliative settings between 2000-2001 Mean age: 44 years (range 28-61)	FEC/FAC – epirubicin or paclitaxel		Pre-infusion: • FEC/FAC: median 20 minutes (range 15-50) • Paclitaxel: median 20 minutes (range 15-120) During infusion: cooling was maintained Post-infusion: • FEC/FAC: median 120 minutes (range 120-150) • Paclitaxel: median 60 minutes (range 60-120)	8% of patients experienced significant hair loss 89% of patients described scalp cooling as acceptable, with minimal discomfort caused by the longer treatment period 15% of patients considered coldness to be a major problem 2% of patients considered headaches to be a major problem One patient discontinued treatment because of discomfort Authors concluded scalp cooling is an effective method for avoiding alopecia in patients receiving FEC or weekly paclitaxel

STUDY DESCRIPTION	TYPE OF STUDY / METHOD	PATIENTS	CHEMOTHERAPY AGENTS	SCALP COOLING TIMES	RESULTS
Paxman Netherlands Clinical Study of Efficacy/1	Observational, multi-center (13 of which 2 did not have scalp cooling available) Patients completed questionnaires related to comfort and acceptability of scalp cooling; observational study was scored using the WHO & VAS system	Scalp-cooled (n=160) and non-scalp-cooled (n=86) patients with several types of cancers	Taxane and/or anthracycline-based chemotherapy (n=184) FEC regimen used 1997-2002 (n=62)	Pre-infusion: 30 minutes During infusion: cooling was maintained Post-infusion: 90 minutes for majority of patients	A head cover was used by 51% of scalp-cooled patients 38% of scalp-cooled patients were thought to have purchased a wig needlessly 40% reduction in the use of head covers
Paxman Netherlands Clinical Study of Efficacy/2	Non-randomized (Phase I), randomized (phase II), multi-center (11) Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse	n=166 cancer patients Types of cancer: breast49%, prostate 33%, lung 23% Mean age: 44 years (range 35-79)	3-weekly docetaxel	Pre-infusion: 30 minutes During infusion: cooling was maintained Post-infusion: Phase I: 90 minutes Phase 2: 90 vs. 45 minutes	A reduction in scalp cooling time to 45 minutes, did not reduce the effectiveness of the Paxman Scalp Cooling System in preventing hair loss in docetaxel treated cancer patients No head cover or wig required in 88% of patients following 45 minutes post-infusion cooling after 3-weekly docetaxel, compared with 74% after 90 minutes post-infusion cooling Headaches were only reported in 20% of patients, with only 5% of patients discontinuing scalp cooling Visual analogue scale: mean score = 69 (0 = bad, 100 = good) Headache: 80% no headaches; 13% mild headaches and 7% moderate/severe headaches 5% of patients discontinued scalp cooling because of intolerance
Paxman Netherlands Clinical Study of Efficacy/3 Note: Study data is included in van den Hurk, CJ, et al. (2012)	Observational	n=1411 patients with range of cancer types	A60C600 (AC) (n=74), A60C600/D100 (ACD) (n=16), ACT overall (n=50), D75A50C500 (TAC) (n=66), D overall (n=120), F500A50C500 (FAC) (n=39), FEC overall (n=752), F500E100C500/ D100 (FE100CD) (n=46), TCarbo overall (n=68), T70-90 (42), Irino 250 (n=42), other (n=64)	Not reported	Success rates (no wig or head cover required) varied according to regimen 48% mean success rate (range 8-80%) Study demonstrates effectiveness of the Paxman Scalp Cooling System in the prevention of chemotherapy induced hair loss with widely used chemotherapy dosages and regimens High levels of comfort and patient acceptability were reported in all trials, with low numbers of patients discontinuing scalp cooling Besides the type of chemotherapy, higher dose and shorter infusion time; older age, female gender and non-western European types of hair increased the proportion of head cover Hair length, quantity, chemical manipulation and treatment with chemotherapy ever before, did not influence degree of head covering among patients

STUDY DESCRIPTION	TYPE OF STUDY / METHOD	PATIENTS	CHEMOTHERAPY AGENTS	SCALP COOLING TIMES	RESULTS
Paxman Swiss Clinical Studies of Efficacy Note: Data is included in Betticher et al. (2013)	Non-randomized, prospective, controlled, multi-center (27)	n=238 patients with several types of cancer including breast, lung, prostate, others who underwent treatment July 2009-October 2011 n=128 patients treated with Paxman Scalp Cooling System; n=71 treated with gel caps (cold caps); n=39 received no cooling treatment	All patients except 1 received docetaxel chemotherapy, alone or in combination with other agents	Paxman Scalp Cooling Pre-infusion: 15 minutes During infusion: cooling was maintained Post-infusion: 90 minutes (45 minutes according to amended temperature) Cold cap Pre-infusion: 15 minutes During infusion: cooling was maintained Post-infusion: 90 minutes (45 minutes according to amended temperature) Gel caps have to be exchanged after the first 25 minutes of treatment, after another 45 minutes, and every 60 minutes thereafter	Kaplan-Meier estimate to reach the combined end point (alopecia WHO III/IV and/or wearing a wig) showing Paxman Scalp Cooling Systems and gel caps have a significantly reduced risk of alopecia by 78% On a six-point scale (1=good to 6=bad) with respect to global impression of therapy, patients at study end reported the following: Paxman 4.5 $\pm$ 1.6, gel cap 4.6 $\pm$ 1.4, no cooling 4.1 $\pm$ 1.9; respective grading marks were similar in the three groups Risk of alopecia is significantly reduced (70%) when using either the Paxman Scalp Cooling System or gel cap compared to no cooling In particular, alopecia is reduced by these two cooling devices when docetaxel is administered every 3 weeks
Paxman Lebanese Clinical Studies of Efficacy	Open, non-randomized, observational, multi-center (10	n=91 cancer patients who underwent treatment March 2012-April 2013	Docetaxel 80-130mg as monotherapy or combination, TAC, AC, Taxotere 100mg + Herceptin, Taxol 120-140mg, Taxol 120mg/Carboplatin, FEC, Alimta 700mg + Carboplatin 300mg, FAC, TCH, VP 16 Etoposide, TCiH, MTX 100mg - Doxorubicin 80mg, AD, Gemzar 1600mg + Carboplatin	Pre-infusion: 0 minutes During infusion: cooling was maintained Post-infusion: dependent upon drug dosage (range 120-360 minutes)	91.21% overall scalp cooling had excellent results 6 of 91 patients underwent treatment with TAC, 6/6 (100%) patients showed no signs of hair loss Severity of chemotherapy-induced alopecia has been reduced greatly by using the Paxman Scalp Cooling System, with only 5 of 91 (5.5%) patients not responding well to head cooling Study demonstrates effectiveness of the Paxman Scalp Cooling System on a variety of anti-cancer treatments It should be noted that the difference in climate, nature of skin and types of hair amongst European and Mediterranean, makes a difference with pre/post-infusion times

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