



# A DEGREE OF CONTROL

A GUIDE TO SCALP COOLING

**Caution:** Federal law (USA) restricts this device to sale by or on the order of a Physician.

**PAXMAN**<sup>o</sup>  
PIONEERS IN SCALP COOLING

Hello. We're Paxman,  
and we have helped  
tens of thousands  
of people like you  
keep their hair during  
chemotherapy.  
You're in safe hands.

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*Am I going to lose my hair?  
It's the first question that  
people generally ask when  
they initially find out they  
need chemotherapy.*

Paxman is a family business that was born when our chairman's wife started losing her hair during chemotherapy for breast cancer. We know firsthand that this is often devastating.

We also know that many people consider hair loss the most feared and common side effect of chemotherapy treatment. The emotional effect is considerable and can have a dramatic impact on self-esteem.

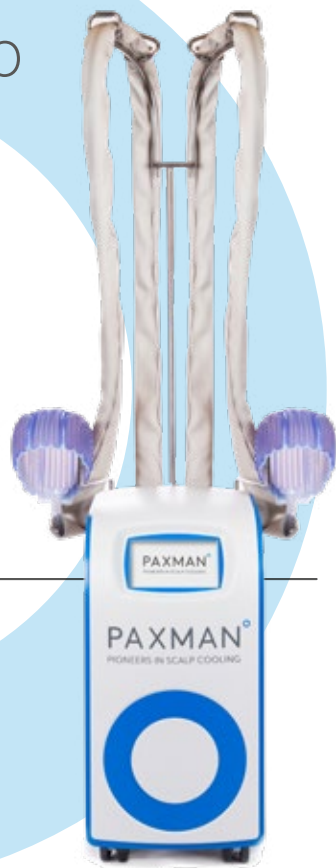
But there is something that can be done.

Scalp cooling can be used during chemotherapy to prevent or reduce hair loss, known as chemotherapy-induced alopecia. Treatment with scalp cooling can positively impact the confidence, sense of control, and hope of people who use it.

Patient care is at the heart of everything we do at Paxman. It's our goal to ensure that all applicable cancer patients, no matter where they are in the world, can keep their hair during chemotherapy.

**It's time for you to take back some control.**

We are the leading global experts in scalp cooling, a clinically proven treatment available throughout the world.



#### **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 [PaxmanUSA.com](http://PaxmanUSA.com).

# Will scalpcooling work for me?

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

## 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.
- 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:

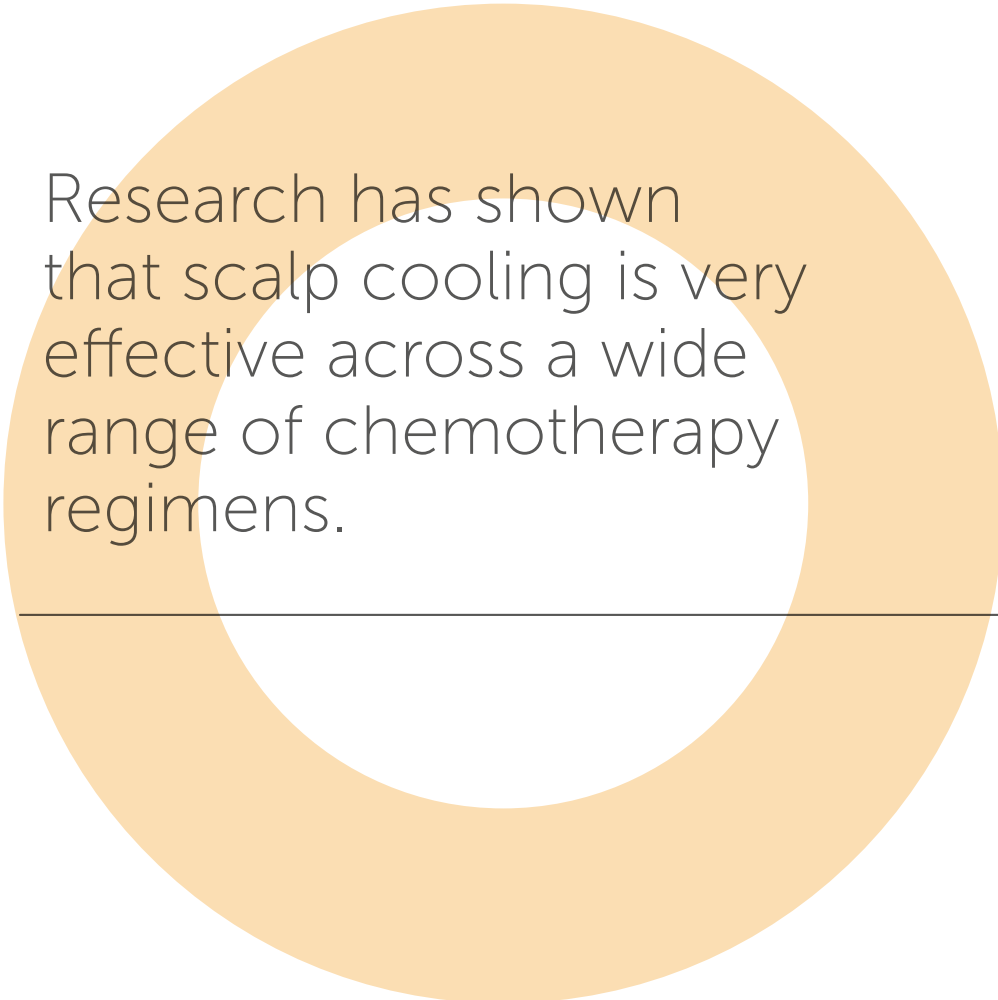
Clinical studies have successfully demonstrated the effectiveness of the Paxman Scalp Cooling System in the prevention of chemotherapy-induced alopecia, or hair loss, with widely used chemotherapy dosages and regimens for solid tumor cancers. Hair retention rates are variable, however, since successful 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](http://PaxmanUSA.com).

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



Research has shown that scalp cooling is very effective across a wide range of chemotherapy regimens.

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.

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

<sup>1</sup> Lemieux J, Maunsell E, Provencher L. Chemotherapy-induced alopecia and effects on quality of life among women with breast cancer: a literature review. *Psycho-Oncology* 17:317–328 (2008).

<sup>2</sup> Udrea, A. Scalp cooling system in preventing chemotherapy-induced alopecia: a pilot study on 108 patients –a Romanian oncology –day

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.<sup>2/3</sup>

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.

hospital experience. *Medisprof Oncology. Psycho-Oncology* 23 (Suppl. 3):169-254 (2014), P1-0062.

<sup>3</sup> 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).

## Chemotherapy Drugs Most Likely to Cause Hair Loss<sup>1</sup>

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
Alkylating agents	Amsacrine	8-9
	Cyclophosphamide	5-9
	Ifosfamide	4-8
	Busulfan	2.8-3.9
Antimetabolites	Melphalan	Variable
	Lomustine	72
	Cytarabine	Biphasic: 0.16, 1-3
	Gemcitabine	0.7-1.57
Antimicrotubule agents	5-FU	0.13-33
	Docetaxel	0.07, 0.6, 11
	Paclitaxel	52.7
	Vindesine	24
	Vinorelbine	>40
	Vincristine	15-155
Vinblastine	Triphasic: 0.58, 0.88, 19	

<sup>1</sup> 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).

Patients treated with certain chemotherapeutic agents, including AC, DAC and Irini 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.

## 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).

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, randomized clinical trial that Paxman conducted in the United States for FDA clearance, only 6 participants of 142 patients discontinued scalp cooling because of intolerance.

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.<sup>1,2</sup>

1. 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.
2. 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).

## 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.



# What Can I Expect Using the Paxman System?

Tolerance of the cold feeling experienced while having scalp cooling varies widely from person to person. Patients often have an intense feeling of discomfort or pain from the cold in the first 10 to 15 minutes of treatment. This is transient and is likely to go away as you get used to the cold.

Deep breathing can help at the initial stages of scalp cooling. The benefits can include immediate relaxation as well as an improved ability to handle stress and calm down.

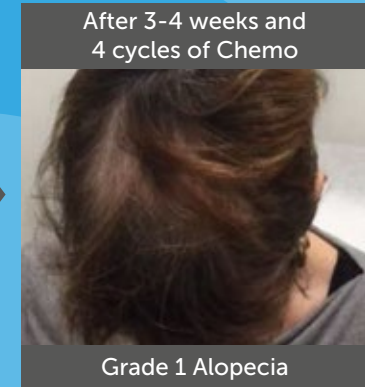
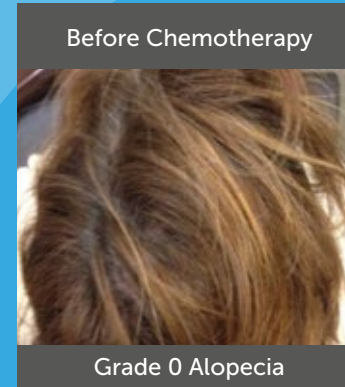
Please continue to breathe deeply throughout treatment. Also be sure to dress warmly-in layers-even in warm weather.

If after the first 20 minutes of scalp cooling you are still finding the cold hard to bear, consult your healthcare professionals about taking a mild pain reliever, which may reduce your discomfort.

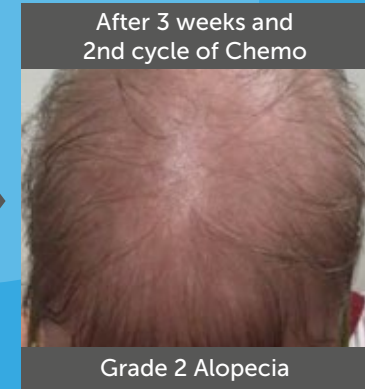
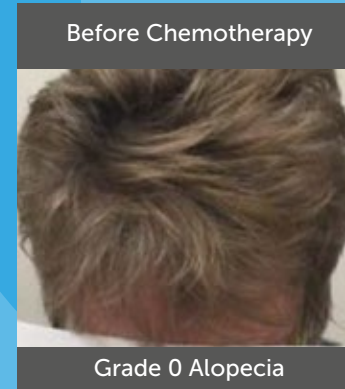
You should prepare yourself that you will see hair loss even with scalp cooling, especially in the first and second Chemotherapy cycles.

The rate of hair retention varies from patient to patient and although it cannot be guaranteed that you will not lose any or all of your hair, many people still feel that scalp cooling is successful when losing 50% or sometimes more of their hair.

Scalp Cooling Example 1



Scalp Cooling Example 2



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# The Paxman Scalp Cooling System & Kit

The Paxman Scalp Cooling System consists of a compact refrigeration unit containing a coolant that is circulated through a specially designed, flexible silicone Paxman Cooling Cap. The lines containing the coolant are supported by a raised adjustable arm to offer maximum comfort.

For treatment to be successful, the scalp needs to be maintained at a constant temperature. This is achieved by correctly fitting the most important feature of the Paxman Scalp Cooling System: the lightweight Paxman Cooling Cap, which you will own and keep. The soft, flexible silicone cap provides a close fit to the head.

As coolant passes through the cap to extract heat from the scalp, inline temperature sensors ensure that the temperature of the scalp is kept at an even, constant temperature.


A neoprene cover is provided (it fits over the cap) and assists in the efficient operation of the system. The cover, which you will also own, insulates the cap and protects it from high room temperatures. It also absorbs condensation and ensures good contact with the scalp.



## Designed for flexibility

People who use the Paxman Scalp Cooling Cap find it is light, yet flexible and strong, and easy to use. After extensive research regarding head shapes, 3 different cap sizes were developed to meet the needs of all women. Your Paxman Scalp Cooling Cap should provide a close fit around the head.

### Each Paxman Personal Cap Kit will include:

- ✓ Your own Paxman Scalp Cooling Cap
  - ✓ Your personal neoprene cooling cap cover.
  - ✓ The cap cover has an icon that is color-coded to your size
- 
- ✓ Headband to be placed below the ears, to reduce discomfort
  - ✓ Spray bottle to moisturize hair prior to putting on cap
  - ✓ Tangle Teezer The Original detangling hairbrush
  - ✓ Shampoo and hair conditioner
  - ✓ Patient brochure with instructions and specific hair care-related information
  - ✓ Towel to dry the hair and to dry the cap after the session
  - ✓ Pay-for-use token (which is explained by the Paxman Hub case manager)

## Connects and disconnects easily

The Paxman Cap easily attaches to the Paxman Scalp Cooling System. If you need to use the restroom, the cap is simple to disconnect and then reconnect. Please be sure to contact a healthcare professional for help with this. Once the treatment is finished, a healthcare professional can disconnect the cap from the coolant line.

### Paxman Personal Cap Kit



## Features

- Easy-to-read touchscreen visual display with clear system status graphics
- One-touch switch operation for simple ease of use
- Scientifically developed, low-temperature, nonviscous coolant with ultra-efficient heat transfer properties
- Instant cooling capability once connected to the system to allow immediate use
- Visual and audible alarms for restricted and no-flow coolant conditions
- Countdown timer with touchscreen access and visual display
- System diagnostics access for operators, including coded access for engineers
- High-ambient-temperature warning alarm
- Small, compact, easy-to-manuever size
- Soft silicone caps, which mold to individual head shapes
- Three cap sizes to ensure optimized fit
- Caps can be easily disconnected from the system by quick-release, nondrip plastic couplings to enable short breaks
- It is nearly impossible for the Paxman Scalp Cooler to overcool. However, for added safety, the system employs visual warnings to alert the user if the coolant temperature is not within operating conditions and has an automatic shutdown feature to prevent significantly cold temperature from being reached

# Hair Preparation & Use of the Paxman Scalp Cooling System

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## Preparing the hair

**RECOMMENDATION:** Prior to fitting the cap, dampen the hair with lukewarm water and apply a small amount of hair conditioner to the dampened hair. This improves scalp contact and reduces the insulation effect of hair.

Comb hair back using your Tangle Teezer The Original detangling hairbrush, provided in your Paxman Personal Cap Kit. You can also use a wide-tooth comb or your fingers. Be sure that the front hairline is visible. This is especially important if you have bangs.

Position the elasticized headband (included in your kit) below each ear and on the forehead to create a barrier between the edge of the cap and your skin. This will reduce discomfort.

To see how simple it is to prepare your hair and fit the cap, watch the instructional videos at [PaxmanUSA.com](http://PaxmanUSA.com).

**NOTE:** If you have long hair, you do not need to dampen the full length of the hair, just the hair covering the scalp.

## Cap fitting

Effective cap fitting is crucial to successful outcomes. It is therefore important to ensure the correct cap fit is achieved during the chemotherapy consultation appointment. The cap needs to fit around the entire hairline at the back and must be tight.

Good overall contact between the cap and the scalp is essential; any gaps should be eliminated as this could have a detrimental effect on hair retention.

The Paxman Scalp Cooling Cap will be fitted to your head for 30 minutes before the infusion of your chemotherapy drugs. The cap will remain in place during the infusion and for a maximum of 90 minutes (depending on your therapy) after completion of the infusion.

## Starting scalp cooling

Once the cap is correctly fitted, scalp cooling can begin. The Paxman Scalp Cooling System is operated by a member of your healthcare team, and you will use the same cap during each chemotherapy treatment. It is important to know that you will wear the cap for 30 minutes preinfusion, during the chemotherapy infusion, and for a maximum of 90 minutes after the infusion.

## When chemotherapy ends but scalp cooling continues

Sometimes when a center needs the chemotherapy chair for another patient, it may be necessary to move you to another area to continue your scalp cooling. It is fine to disconnect from the machine for a brief period. Paxman works with busy centers, so there should be enough machines for scalp cooling to be continued.

## Completion of treatment

Most people will have a maximum of 90 minutes (depending on therapy) of cooling time, and then your cap can be disconnected from the Paxman Scalp Cooling System. The cap must be left in place on the head for 5 more minutes to allow your scalp to warm up. This makes cap removal more comfortable. Be sure to work with your healthcare professional if you have any questions about cap removal.

The cap should be removed by gently rocking it from side to side, so as not to pull the hair. If you can feel the hair pulling during cap removal, stop and leave the cap on the head for 5 more minutes before reattempting to remove the cap.

Once the cap has been removed, wait 5 minutes before standing up to give yourself time to adjust to the temperature change and the long period of sitting during the treatment.

**NOTE:** It is important that the conditioner used during the scalp cooling treatment is rinsed from the hair at the earliest opportunity. This product is not a leave-in conditioner.

# Cleaning Your Paxman Cap

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## Here are the steps for cleaning the Paxman Scalp Cooling Cap after each use:

- Remove cap cover from the silicone cap
- Wash the internal and external surface of the silicone cap with warm soapy tap water (100°-110°F)
- Rinse the silicone cap with tap water to remove soap residue
- Dry the silicone cap thoroughly with a lint-free cloth. Do not put the silicone cap in a dryer as it may reduce how long you can use the cap
- Use a 70% isopropyl alcohol (IPA) wipe to thoroughly wipe down the silicone cap
- Allow the silicone cap to air-dry

## Cleaning the cap cover:

- Use warm soapy water
- Let air-dry; never put in the dryer
- Always store your cap in your Paxman Scalp Cooling Kit



# A Degree of Control

## 13 things you should know about scalp cooling

### Before and during scalp cooling

1. Be proactive. If you feel the cap isn't tight enough on your scalp, ask your healthcare professional to adjust it.
2. The cap should touch the crown of your head.
3. You should have the feeling that the cooling is occurring evenly throughout your scalp. If you do not, let your healthcare professional know right away.
4. You may use a blanket or neck scarf to help with the cold feeling; drinking plenty of warm liquids also helps.
5. Consult with your healthcare professional about pain relief before your scalp cooling if you are concerned you may get a headache.
6. If you have thick braids or hair extensions, please remove them before your scalp cooling.

### After each scalp cooling session

7. You may see ice on your hair after scalp cooling.
8. Avoid harsh hair treatments like coloring, extensions, braiding, curling, and straightening during and for a short while after your chemotherapy and scalp cooling.
9. Brush your hair gently with your Tangle Teezer The Original detangling hairbrush or a wide-tooth comb, and shampoo less often and with a perfume and color free shampoo; style with your fingertips. Follow the hair care suggestions on page 25.
10. Moderate hair loss (30% to 50%) is expected after using the cap.
11. If you don't feel you have to wear a wig, a head scarf, or a headcover during chemotherapy treatment, the scalp cooling is considered a success.
12. You may experience hair regrowth while having scalp cooling during chemotherapy treatment.

### Side effects

13. Common side effects patients have experienced during scalp cooling:
  - Coldness/cold-related discomfort
  - Headaches ranging from mild to severe
  - Heavy feeling on the head
  - Forehead pain
  - Neck pain that comes and goes
  - Lightheadedness or dizziness (during scalp cooling and/or following removal of the cap at the end of scalp cooling)
  - General discomfort

For more information, visit [PaxmanUSA.com](http://PaxmanUSA.com).



Chemotherapy can cause the scalp skin to become sensitive and irritated. It can also cause the hair to become more dry, brittle, and difficult to manage.

#### Hair care for women having scalp cooling

- Be gentle at all times with your hair
- Don't be afraid to brush your hair. Use a good-quality brush; poor-quality brushes will snag and tear your hair
- Avoid permanents and coloring or dyeing your hair while receiving chemotherapy treatment
- Avoid using excessive heat on the hair; dry gently and do not use hair straighteners
- Wash your hair using lukewarm water and a mild shampoo. The scalp can become sensitive to the perfumes and preservatives in cosmetic shampoos. When washing your hair, keep it out straight. Never pile your hair on top of your head after shampooing or conditioning. After washing, use plenty of conditioner each time
- To manage tangles, use a lot of hair conditioner, then brush with your Tangle Teezer The Original detangling hairbrush or a wide-tooth comb while you're in the shower. It also helps to hold the hair above the tangles so that it does not stress hair roots

To ensure the least amount of stress on your hair, do not go to your hair stylist or hairdresser while you are having scalp cooling. However, if you feel you have to go to the hairdresser to feel better, please bring along this brochure so your hairdresser can learn about scalp cooling and the need to minimize stress to the hair.

Following completion of chemotherapy and scalp cooling, you should be cautious and continue to be gentle in caring for your hair. The main reason to avoid hair coloring during treatment is that scalp skin sensitivity is often heightened by chemotherapy drugs. This increased sensitivity can last for a while after treatment completion. We recommend the guidance of an experienced hair stylist or hairdresser, who can do a skin patch test for scalp skin sensitivity prior to coloring your hair.

You may find it useful to read the experiences or watch video testimonials of people who have used the Paxman Scalp Cooling System. Visit the Paxman website: [PaxmanUSA.com](http://PaxmanUSA.com).



# Information for Your Hair Stylist or Hairdresser

While you are having chemotherapy treatment and scalp cooling, it is important to have the least amount of stress to the hair as possible. Paxman recommends that those people having scalp cooling try to avoid going to their hair stylist or hairdresser, but if they do go, please comply with these 5 points:



1

Avoid harsh hair treatments such as coloring, extensions, braiding, curling, and straightening.



2

Use the Tangle Teezer The Original detangling hairbrush provided by Paxman or a good-quality brush and brush hair gently. Poor-quality brushes can snag and tear hair.



3

Wash hair using lukewarm water. Use a mild, perfume and color free shampoo. While undergoing chemotherapy, the scalp can become sensitive to the perfumes and preservatives in shampoos. When washing hair, keep it out straight. Never pile hair on top of the head after shampooing or conditioning. Always use plenty of conditioner.



4

Style hair with your fingertips. To manage tangles, use a lot of hair conditioner, then brush with the Tangle Teezer The Original detangling hairbrush, which is provided, or a wide-tooth comb. It also helps to hold the hair above the tangles so that it does not stress hair roots.



5

Avoid using excessive heat on the hair; dry gently, and do not use hair straighteners.



Once you have completed your chemotherapy and scalp cooling, we suggest you continue with overall gentle hair care. The main reason we advise against hair coloring during treatment is that scalp skin sensitivity is often heightened by the chemotherapy drugs. This increased sensitivity can last a while after treatment completion. We recommend that an experienced hair stylist or hairdresser do a skin patch test for sensitivity prior to coloring the hair.

# Summary of a Recent Clinical Study

An important study was recently published in the *Journal of the American Medical Association*, or *JAMA*, evaluating scalp cooling to prevent chemotherapy-induced alopecia, or hair loss.

## How effective was scalp cooling?

Scalp cooling prevented significant hair loss in about 50% of women.

- Higher success rates were shown in patients receiving taxane-based regimens
- Scalp cooling was generally well tolerated, with no severe adverse events. In a minority of patients, scalp cooling was associated with headache

## There were 7 trial sites across the US:

- Baylor College of Medicine
- Cleveland Clinic
- Memorial Sloan Kettering Cancer Center
- Hematology & Oncology Associates of Northern NJ (now Summit Medical Group-MD Anderson Cancer Center)
- Baylor Sammons Cancer Center
- Texas Oncology-Medical City Dallas
- Texas Oncology-Houston Memorial City

## Adverse events

There were 54 adverse events reported in the cooling group: 46 anticipated adverse device events and 8 unanticipated adverse device events. There were no serious adverse device events. All adverse events were considered relatively mild, noted as grade 1 (n=46) or grade 2 (n=8), and these included chills, dizziness, headache, nausea, paresthesia, pruritus, sinus pain, skin and subcutaneous tissue disorders, and skin ulceration.

Based on the comfort scale, most patients were comfortable, reasonably comfortable, or very comfortable while wearing the device, with an average rating of reasonably comfortable.

In the study, participants were to use the Paxman Scalp Cooling System device (for the prescribed time of 30 minutes prior to chemotherapy, during chemotherapy, and for a maximum of 90 minutes after chemotherapy).

Nangia J, Wang T, Osborne C, et al. Effect of a scalp cooling device on alopecia in women undergoing chemotherapy for breast cancer: the SCALP randomized clinical trial. *JAMA*. 2017;317(6):596-605.

Comfort scale: the average rating was reasonably comfortable

very uncomfortable



uncomfortable



comfortable



reasonably comfortable



very comfortable



## Conclusion

Among women with stage I to II breast cancer receiving chemotherapy with a taxane, an anthracycline, or both, those who underwent scalp cooling were significantly more likely to have less than 50% hair loss after the fourth chemotherapy cycle compared with those who received no scalp cooling.

Nangia J, Wang T, Osborne C, et al. Effect of a scalp cooling device on alopecia in women undergoing chemotherapy for breast cancer: the SCALP randomized clinical trial. *JAMA*. 2017;317(6):596-605.

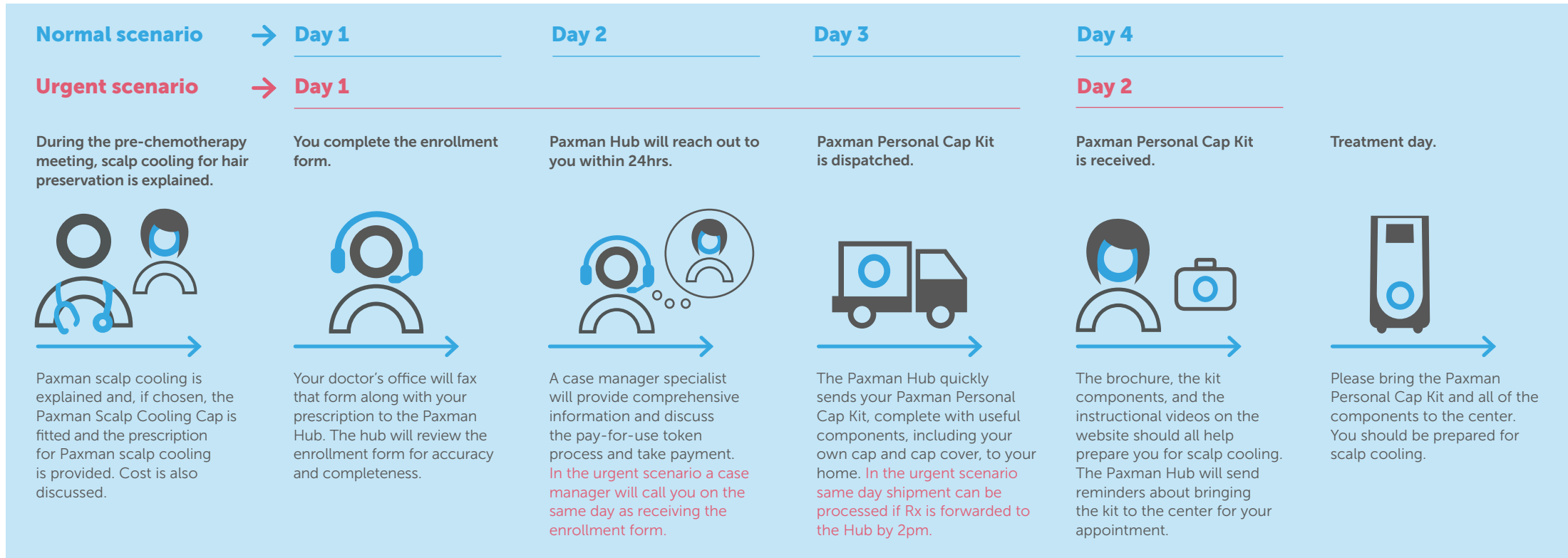


# THE PAXMAN HUB:

**How it works.** The Paxman Hub will send you your Paxman Personal Cap Kit.

The Paxman Hub is a call center with specially trained case managers who will work with you and discuss your situation. They will quickly create your account and send out your kit. A payment system will be set up and the pay-per-use token will be explained. You will also be encouraged to continue with your scalp cooling throughout treatment to get the benefits of hair preservation.

The Hub specialists are there for you with information on scalp cooling and other relevant information.



# THE PAXMAN HUB:

**Pricing.** Details on how much your Paxman Scalp Cooling will cost.

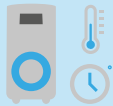


## Paxman Pricing Matrix (Payment can be made per cycle)



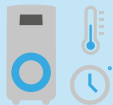
Paxman Personal Cap Kit

**\$500**



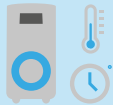
Cycles **1-4**

**\$200** Per Cycle



Cycles **5-6**

**\$150** Per Cycle



Cycles **7-12**

**\$100** Per Cycle

Pricing per patient is capped at **\$2200**

## Cost Example 1

Your chemotherapy treatment consists of eight cycles.

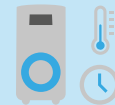


x8

Cap Kit	\$500
(4 x \$200)	\$800
(2 x \$150)	\$300
(2 x \$100)	\$200
<b>TOTAL</b>	<b>\$1800</b>

## Cost Example 2

Your chemotherapy treatment consists of twelve cycles.



x12

Cap Kit	\$500
(4 x \$200)	\$800
(2 x \$150)	\$300
(6 x \$100)	\$600
<b>TOTAL</b>	<b>\$2200</b>

## Refund Policy

### Non Refundable

If a cap has been used for patient treatment it is then non-refundable.



### Refundable

Any unused treatment cooling credits are refundable following completion of an enrollment form by the treating physician.





### A DEGREE OF **CONFIDENCE**...

"I started chemotherapy the day after my 44th birthday during Christmas week. It was amazing to see people's faces when I would tell them I was going through chemotherapy. No one knew I was being treated for cancer because I still had my hair. I am so grateful I was in the Paxman scalp cooling trial. Losing my hair would have been a constant reminder to everyone that I was sick, but the reality was, people did not see me as a cancer patient when they looked at me. They saw me for who I was as a person. And the best part of it all was that I could go anywhere and no one would know what I was going through unless I said something."

**Nelia, 45**  
Healthcare professional, Dallas, TX

To learn more about Nelia's story, visit [PaxmanUSA.com](http://PaxmanUSA.com).



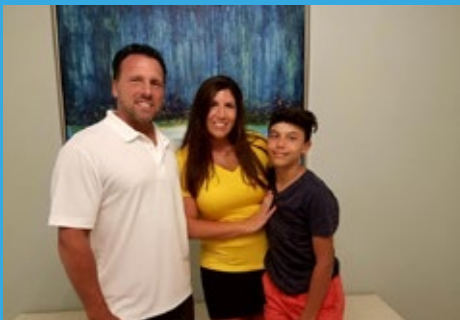
### A DEGREE OF **PRIVACY**...

"Having my hair while getting chemo, I realized for the first time that my Paxman scalp cooling cap gave me such confidence. With my life changing so dramatically and with no control over it, it was a good feeling to have my hair! I recall when my friends found out that I was being treated for breast cancer and they'd look at my face, feeling sad for me, and then they'd say, 'But you still have your hair!' I would smile and tell them all about the Paxman cold cap!"

**Shawna, 60**  
Retired teacher, Arlington, TX

To learn more about Shawna's story, visit [PaxmanUSA.com](http://PaxmanUSA.com).





"It was my surgeon that told me all about the Paxman Scalp Cooling System and how scalp cooling could help stop me from losing my hair during the chemotherapy. The process of ordering my Paxman cap was very simple and I received my cap within 2 days.

Fourteen days after my first treatment it felt like I had lost a lot of hair. As treatments went on the amount of hair I was losing lessened; but it never stopped. Post-treatment I lost approximately 50% of my hair.

To read more experiences, visit [PaxmanUSA.com](https://www.PaxmanUSA.com).

I did have one bald spot on the top of my scalp and it was very thin to bald on each side behind my ears. At first, I thought I was going to need a wig because of how much I lost after the first treatment, but it slowed down so I didn't.

Overall, I was extremely happy with my Paxman Scalp Cooling experience and it was amazing to be able to keep most of my hair! I have an 11-year-old son and worked full time throughout my chemotherapy treatment so being able to keep my hair helped me look better than I actually felt. I would absolutely recommend scalp cooling to others. It helps you feel better whilst you are going through a really difficult time"

**Amber, 33**  
Service Manager & Business Owner,  
Pecatonica IL

"I was diagnosed with breast cancer in February 2017 and underwent chemo from July to September. I had originally heard about cooling caps in my support group, but although my new business was growing it was not enough to supplement chemotherapy, radiation and scalp cooling. This is when my long-term friend stepped in and set up a crowdfunding page on 'Go Fund Me' to help pay for my treatment. Unfortunately, in spite of scalp cooling, I lost the majority of my hair 2 weeks after my first round of chemo, however I would still absolutely recommend Paxman Scalp Cooling.

I have had a hair stylist tell me she has worked with women after chemo and she has never seen this much hair. Although I felt I had to wear something on my head at all times until 2 months after chemo ended I do believe it gives you a head start on the regrowth process."

**Valerie**  
San Diego, California



# Share Your Experience.

There are thousands of women like you around the world receiving scalp cooling right now.

You can read other women's experiences and share your story on the Paxman Facebook page. We welcome feedback and would be delighted to hear about your scalp cooling experience.

**Please complete our satisfaction survey on our website: [paxmanusa.com/survey](https://paxmanusa.com/survey) Password: #PAXMAN**

Our Twitter feed keeps you up to date with news and information relating to our worldwide research into scalp cooling.



[paxmanscalpcooling](https://www.facebook.com/paxmanscalpcooling)



[@scalpcooling](https://twitter.com/scalpcooling)

**Complete our customer survey!**  
[paxmanusa.com/survey](https://paxmanusa.com/survey)  
Password:  
**#PAXMAN**

# Your "To Bring" Checklist

Make sure you bring all of the items in your Paxman Personal Cap Kit to your chemotherapy appointment. Other items to take with you:



Warm clothing



Hat/head covering



Neck scarf



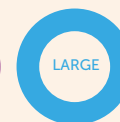
Paxman Personal Cap Kit



Mirror



Keep a note of your cap size by circling it below:



# ANCILLARIES

## Published Clinical Studies of the Paxman Scalp Cooler

AUTHOR	TYPE OF STUDY/ METHOD	PATIENTS	CHEMOTHERAPY AGENTS	OBJECTIVE	RESULTS (PERFORMANCE & SAFETY)	CONCLUSION
<p>van den Hurk, CJ, et al. (2012)</p> <p>Note: Study data is included 2006-2010 Dutch registry data and Paxman Netherlands Clinical Study of Efficacy/3</p>	<p>Registry, multi-center (28)</p> <p>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</p>	<p>n=1411</p> <p>Male n=50 (4%), female n=1357 (96%), missing n=4</p> <p>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</p>	<p>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)</p>	<p>To estimate the results of scalp cooling for currently used chemotherapies to provide patient information and identify characteristics associated with the results.</p>	<p>Overall, 50% of the 1411 scalp-cooled patients did not wear a head cover during their last chemotherapy session.</p> <p>Patients were satisfied with the results in 8% of cases after TAC chemotherapy and up to 95% after paclitaxel treatment.</p> <p>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.</p> <p>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.</p>	<p>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.</p> <p>Lengthening infusion time may improve the results.</p>
<p>van den Hurk, CJ, et al. (2013)</p>	<p>Review of observational studies, autopsy studies and Munich cancer registry</p>	<p>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</p>	<p>Diverse</p>	<p>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.</p>	<p>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.</p>	<p>In patients with solid tumors, an unfavorable development of the disease due to scalp cooling has never been documented.</p> <p>Scalp cooling can safely be offered to patients treated with alopecia-inducing chemotherapy.</p>
<p>Lemieux J, et al. (2015)</p>	<p>Retrospective cohort</p>	<p>n=1370 women with non-metastatic breast carcinoma who received chemotherapy in neoadjuvant (n=140) or adjuvant setting (n=1230)</p> <p>n=553 used scalp cooling; n=817 were treated in facilities where scalp cooling was not routinely available</p>	<p>Not reported</p>	<p>To compare overall survival according to whether or not scalp cooling was used during neoadjuvant or adjuvant chemotherapy for non-metastatic breast cancer.</p>	<p>Median follow-up was 6.3 years for scalp-cooled group and 8.0 years for non-scalp-cooled group.</p> <p>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).</p>	<p>Among women undergoing neoadjuvant or adjuvant chemotherapy for non-metastatic breast cancer, scalp cooling used to prevent CIA had no negative effect on survival.</p>

AUTHOR	TYPE OF STUDY/ METHOD	PATIENTS	CHEMOTHERAPY AGENTS	OBJECTIVE	RESULTS (PERFORMANCE & SAFETY)	CONCLUSION
<p>Nangia J, et al. (2017)</p> <p>Clinicaltrials.gov identifier NCT01986140</p>	<p>Randomized, multi-center (7)</p> <p>A comfort scale was administered after each treatment in scalp-cooling group.</p> <p>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</p>	<p>n=182 women with stage 1 or II breast cancer undergoing chemotherapy from December 2013 to September 2016</p> <p>Randomized to receive scalp cooling (n=119) or no cooling (n=63)</p> <p>Each patient underwent scalp cooling for 30 minutes pre-infusion, during infusion and 90 minutes post-infusion</p>	<p>Planning to receive at least 4 cycles of taxane- (n=91, 64%) and/or anthracycline-based chemotherapy for curative intent (n=51, 36%)</p>	<p>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.</p>	<p>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.</p> <p>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%).</p> <p>Success rate difference was 50.5% (95% confidence interval, 40.5%-60.6%).</p> <p>The trial was stopped early for superiority (p=0.0061).</p> <p>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.</p> <p>54 adverse events (all grades 1 and 2) were reported in the cooling group. There were no serious adverse device events.</p>	<p>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 &lt; 50% hair loss after the 4th chemotherapy cycle compared with those who received no scalp cooling.</p>
<p>Massey C (2004)</p> <p>Note: Data is included in Paxman UK Clinical Study of Efficacy</p>	<p>Open, non-randomized, observational, multi-center (8)</p> <p>Alopecia was assessed using the World Health Organization (WHO) grading system; patient acceptability assessed by questionnaire; results compiled by Scalp Cooling Assessment Groups</p>	<p>n=94 breast cancer patients who underwent treatment 1997-2000</p>	<p>5-fluorouracil, epirubicin and cyclophosphamide (FEC) regimen</p>	<p>To assess the efficacy of scalp cooling to reduce alopecia for women undergoing treatment for breast cancer using the Paxman Scalp Cooler.</p> <p>To assess patient views on the comfort and acceptability of scalp cooling using the Paxman Scalp Cooler.</p>	<p>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.</p> <p>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.</p>	<p>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.</p>
<p>Bini M, et al. (2004)</p>	<p>Observational, single-center</p> <p>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</p>	<p>N=47 breast cancer patients who underwent treatment from June 2013-March 2014</p> <p>Mean age: 53 years (range 35-72)</p> <p>46 female, 1 male</p> <p>80% were treated in the adjuvant setting and chemotherapy naive</p>	<p>70% of patients received anthracycline-based polychemotherapy (AC or FEC 75 every three weeks), and 30% received monotherapy with taxanes on a weekly schedule</p>	<p>To verify effectiveness of Paxman concerning alopecia in the sample group; evaluate patients' expectation and degree of final satisfaction with regard to its use.</p>	<p>Median number of the cooling session: 5 (range 1-12).</p> <p>Alopecia G0 and G1 were registered at the end of chemotherapy in 62% of the patients, irrespective of the type of treatment.</p> <p>100% of patients reported being satisfied in terms of hair preservation during their last session.</p> <p>27% of patients discontinued scalp cooling treatment because of severe alopecia (G2); all these patients were receiving an anthracycline.</p> <p>Scalp cooling was stopped because of intolerance in 11% of patients mainly due to discomfort and longer time of infusion.</p>	<p>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.</p> <p>Lengthening infusion time seems to be the main limit of this system.</p>

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 naive 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.

AUTHOR	TYPE OF STUDY/ METHOD	PATIENTS	CHEMOTHERAPY AGENTS	OBJECTIVE	RESULTS (PERFORMANCE & SAFETY)	CONCLUSION
Kinoshita T, et al. (2015)	Case review  Hair loss was graded using the WHO classification scheme	n=21 female breast cancer patients  AC therapy n=11, TC therapy n=10	Patients were scheduled to receive 4 cycles of post-operative adjuvant chemotherapy using either AC (60/600mg/m <sup>2</sup> ) or TC (75/600mg/m <sup>2</sup> )	To confirm the efficacy of hair loss prevention and the safety of scalp cooling equipment, and thus enhance patient recovery and QOL.  The primary outcome was the proportion of patients able to complete 4 cycles of post-operative adjuvant AC or TC therapy.  Secondary outcomes were the degrees of comfort, satisfaction, and hair loss prevention, as well as the rates of adverse events and metastases to the scalp in patients who used the scalp cooling equipment, i.e. Paxman Cooler.	9 (81.8%) cases in the AC therapy group and 10 (100%) cases in the TC therapy group completed the protocol.  WHO grades: • AC therapy, Grades 0-4: 0, 3, 2, 5, 1  • TC therapy, Grades 0-4: 0, 3, 3, 4, 0  11 of 21 (52.4%) patients experienced Grade 1-2 hair loss, i.e. 5 of 11 (45.5%) patients in the AC group and 6 of 10 (60%) patients in the TC group.  Scalp cooling resulted in greater hair loss prevention during TC therapy than AC therapy.	We will continue studying the effects of scalp cooling in breast cancer patients undergoing chemotherapy, and work to improve on the design of the original scalp cooling equipment.
Hussain O, et al. (2015)	In vitro testing	Not applicable  HaCaT cells cultured in serum free conditions were treated with chemotherapy agents; drug-induced cytotoxicity following treatment at physiological temperature (37°C) and cooling conditions (max 22°C) was determined at 72 hours post-treatment	Range of concentrations of 5-fluorouracil, epirubicin and paclitaxel; TAC (docetaxel, doxorubicin and cyclophosphamide), FAC [5-fluorouracil (5-FU), doxorubicin and cyclophosphamide] and FEC (5-FU, epirubicin and cyclophosphamide) as combinatorial treatments	To use in vitro keratinocyte models to study the effect of TAC, FAC and FEC on cell viability and determine whether cooling can protect from combinatorial drug-induced cytotoxicity.	Combinatorial drug treatments TAC, FEC and FAC are more cytotoxic in comparison to individual chemotherapy drugs.  Cooling demonstrated the ability to protect very well from individual drug-induced cytotoxicity (e.g. 5-FU associated toxicity), whilst showing differential ability to protect from combinatorial drug-induced cytotoxicity.	The similarity of our in vitro data with clinical observations provides biological support for the cytoprotective role of scalp cooling as well as evidence that, despite their reductive nature, our in vitro models are biologically relevant.
Letchford DB, et al. (2016)	Ongoing prospective cohort  Degree of hair loss was assessed using the WHO and Deans alopecia scale, digital photography and patient self-reporting questionnaire	n=20 consenting patients who underwent scalp cooling using the Paxman Orbis II device during treatment  Each patient underwent scalp cooling for 30 minutes pre-infusion, during infusion and 90 minutes post-infusion	11 varying chemotherapy regimens including FEC, FEC-D, paclitaxel, carboplatin/paclitaxel and TCH	To report preliminary results from ongoing prospective cohort study of scalp hypothermia in the prevention of CIA.	Six patients withdrew due to grade 2/3 alopecia.  3 patients that completed treatment with scalp cooling developed grade 2 alopecia.  6 patients treated so far with FEC (as part of the FEC-D protocol) or weekly paclitaxel developed grade 2/3 alopecia.  4 patients treated with carboplatin/ paclitaxel or TCH completed treatment with either grade 1 or no alopecia.  5 patients withdrew due to discomfort, but otherwise no adverse effects were associated with scalp cooling.	Interim results suggest scalp hypothermia using modern scalp cooling systems represents a safe and effective method of reducing rates of CIA.  Further clinical trials are required to indicate which patients/ chemotherapy regimens will obtain maximal efficacy from scalp hypothermia in preventing CIA.

## Non-Published Clinical Studies of the Paxman Scalp Cooler

STUDY DESCRIPTION	TYPE OF STUDY / METHOD	PATIENTS	CHEMOTHERAPY AGENTS		SCALP COOLING TIMES	RESULTS																											
<p>Dutch Registry (presented at 2017 MASCC/ISOO International Meeting)</p> <p>Note: 2006-2010 registry data is included in van den Hurk et al. (2012) and Paxman Netherlands Clinical Study of Efficacy/3</p>	Registry	<p>2006-2010: n=1411 (4% male)</p> <p>2010-2015: n=4864 (14% male)</p> <p>2015-2017: n=827 (19% male)</p> <p>Types of cancer: breast 75%, prostate 8%, ovarian 6%, stomach/colon/liver 5%, lung 3%, other 2%</p>	<p>AC/AC-T/AC-D</p> <p>2006-2010: 140/1411 (10%)</p> <p>2010-2015: 941/4864 (19%)</p> <p>2015-2017: 329/827 (40%)</p> <p>FEC/FEC-D/ FEC-T</p> <p>2006-2010: 798/1411 (57%)</p> <p>2010-2015: 1386/4864 (28%)</p> <p>2015-2017: 66/827 (8%)</p>	<p>Jevtana</p> <p>2006-2010: 0/1411 (0%)</p> <p>2010-2015: 42/4864 (1%)</p> <p>2015-2017: 6/827 (1%)</p> <p>Eribuline</p> <p>2006-2010: 0/1411 (0%)</p> <p>2010-2015: 0/4864 (0%)</p> <p>2015-2017: 6/827 (1%)</p>	Not reported	<p>Results of 2006-2013 registry</p> <table border="1"> <thead> <tr> <th>Chemotherapy agent (s)</th> <th>No. patients</th> <th>Positive result of scalp cooling</th> </tr> </thead> <tbody> <tr> <td>AC/AC-T/AC-D</td> <td>1079</td> <td>61%</td> </tr> <tr> <td>Docetaxel</td> <td>843</td> <td>87%</td> </tr> <tr> <td>FEC/FEC-D/FEC-T</td> <td>2192</td> <td>44%</td> </tr> <tr> <td>FAC</td> <td>101</td> <td>46%</td> </tr> <tr> <td>Taxol(wkl/3wkl)</td> <td>556</td> <td>82%</td> </tr> <tr> <td>TAC</td> <td>167</td> <td>11%</td> </tr> <tr> <td>TCar</td> <td>475</td> <td>57%</td> </tr> <tr> <td>Irinotecan</td> <td>267</td> <td>31%</td> </tr> </tbody> </table>	Chemotherapy agent (s)	No. patients	Positive result of 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%
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<p>Paxman UK Clinical Study of Efficacy</p> <p>Note: Data is included in Massey CS, et al. (2004)</p>	<p>Open, non-randomized, observational, multi-center (8)</p> <p>Patients completed questionnaires related to comfort and acceptability of scalp cooling</p>	<p>n=95 breast cancer patients being treated with chemotherapy in adjuvant or palliative setting between 1997-2000</p> <p>Mean age: 44 years (range 28-61)</p>	<p>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)</p>		<p>Pre-infusion: 15-20 minutes</p> <p>During infusion: cooling was maintained</p> <p>Post-infusion: 120 minutes for majority of patients</p>	<p>5 of 95 (5.3%) total patients observed grade 3 hair loss</p> <p>1 of 95 (1.1%) total patients observed grade 4 hair loss</p> <p>5 of 95 (5.3%) patients discontinued scalp cooling treatment</p> <p>2 of 62 (3.2%) patients receiving FEC observed grade 3 hair loss</p> <p>1 of 62 (1.6%) patients receiving FEC observed grade 4 hair loss</p> <p>11% of 95 total patients and 13% of 62 patients treated specifically with FEC required wigs</p> <p>85% of patients reported that they were comfortable, reasonably comfortable, or very comfortable during the scalp cooling period</p> <p>12% of patients reported they were uncomfortable with an additional 3% very uncomfortable</p> <p>Only 5% of patients discontinued scalp cooling before the end of chemotherapy treatment, with discontinuation because of discomfort seen in one patient</p> <p>Headaches at some time during treatment cycles were reported in 32% of patients</p>																											
<p>Paxman Norwegian Clinical Study of Efficacy</p>	<p>Observational, single-center</p> <p>Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse</p>	<p>n=54 breast cancer patients treated in neo-adjuvant, adjuvant or palliative settings between 2000-2001</p> <p>Mean age: 44 years (range 28-61)</p>	<p>FEC/FAC – epirubicin or paclitaxel</p>		<p>Pre-infusion:</p> <ul style="list-style-type: none"> <li>FEC/FAC: median 20 minutes (range 15-50)</li> <li>Paclitaxel: median 20 minutes (range 15-120)</li> </ul> <p>During infusion: cooling was maintained</p> <p>Post-infusion:</p> <ul style="list-style-type: none"> <li>FEC/FAC: median 120 minutes (range 120-150)</li> <li>Paclitaxel: median 60 minutes (range 60-120)</li> </ul>	<p>8% of patients experienced significant hair loss</p> <p>89% of patients described scalp cooling as acceptable, with minimal discomfort caused by the longer treatment period</p> <p>15% of patients considered coldness to be a major problem</p> <p>2% of patients considered headaches to be a major problem</p> <p>One patient discontinued treatment because of discomfort</p> <p>Authors concluded scalp cooling is an effective method for avoiding alopecia in patients receiving FEC or weekly paclitaxel</p>																											

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: breast 49%, 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 1: 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, C.J, 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
<p>Paxman Swiss Clinical Studies of Efficacy</p> <p>Note: Data is included in Betticher et al. (2013)</p>	<p>Non-randomized, prospective, controlled, multi-center (27)</p>	<p>n=238 patients with several types of cancer including breast, lung, prostate, others who underwent treatment July 2009-October 2011</p> <p>n=128 patients treated with Paxman Scalp Cooling System; n=71 treated with gel caps (cold caps); n=39 received no cooling treatment</p>	<p>All patients except 1 received docetaxel chemotherapy, alone or in combination with other agents</p>	<p>Paxman Scalp Cooling</p> <p>Pre-infusion: 15 minutes</p> <p>During infusion: cooling was maintained</p> <p>Post-infusion: 90 minutes (45 minutes according to amended temperature)</p> <p>Cold cap</p> <p>Pre-infusion: 15 minutes</p> <p>During infusion: cooling was maintained</p> <p>Post-infusion: 90 minutes (45 minutes according to amended temperature)</p> <p>Gel caps have to be exchanged after the first 25 minutes of treatment, after another 45 minutes, and every 60 minutes thereafter</p>	<p>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%</p> <p>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 ± 1.6, gel cap 4.6 ± 1.4, no cooling 4.1 ± 1.9; respective grading marks were similar in the three groups</p> <p>Risk of alopecia is significantly reduced (70%) when using either the Paxman Scalp Cooling System or gel cap compared to no cooling</p> <p>In particular, alopecia is reduced by these two cooling devices when docetaxel is administered every 3 weeks</p>
<p>Paxman Lebanese Clinical Studies of Efficacy</p>	<p>Open, non-randomized, observational, multi-center (10)</p>	<p>n=91 cancer patients who underwent treatment March 2012-April 2013</p>	<p>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</p>	<p>Pre-infusion: 0 minutes</p> <p>During infusion: cooling was maintained</p> <p>Post-infusion: dependent upon drug dosage (range 120-360 minutes)</p>	<p>91.21% overall scalp cooling had excellent results</p> <p>6 of 91 patients underwent treatment with TAC, 6/6 (100%) patients showed no signs of hair loss</p> <p>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</p> <p>Study demonstrates effectiveness of the Paxman Scalp Cooling System on a variety of anti-cancer treatments</p> <p>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</p>

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21. Paxman Netherlands Clinical Study of Efficacy/3
22. Paxman Swiss Clinical Studies of Efficacy
23. Paxman Lebanese Clinical Studies of Efficacy

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