

PAXMAN^o

Clinical Efficacy Brochure

The Paxman Scalp Cooling System



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This brochure provides a concise overview of the **clinical efficacy and safety** of The Paxman Scalp Cooling System, using a range of studies across Europe, Asia, South America, North America and Australasia.

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REDUCING CHEMOTHERAPY HAIR LOSS

Chemotherapy-induced alopecia is one of the most visible and distressing side effects of cancer treatment.

Globally, 6.4 million patients will lose their hair every year as a result of chemotherapy.^{1,2} It is predicted that by 2040, that figure will be over 9.7 million people.³

Loss of hair can be traumatic, debilitating, and can have an understandably profound effect on a patient's identity, privacy and confidence, making strategies for managing this side-effect crucial.

The Paxman Scalp Cooling System is an innovative solution designed to reduce hair loss during chemotherapy. It is indicated for patients with solid tumours undergoing chemotherapy, including but not limited to, breast, prostate, uterine, ovarian, lung and gynaecological cancers.

A cold cap, which comes in two sections - an inner cap and an outer cover - is worn by the patient and is attached to a mobile, compact refrigeration system. It circulates coolant continually between the system and the cap, extracting heat from the patient's scalp and maintaining it at the optimum temperature for scalp cooling.

By lowering scalp temperature before, during, and after infusion, the system helps to minimise damage to hair follicles, giving patients the opportunity to maintain their sense of identity throughout treatment. Cooling the scalp induces vasoconstriction, and reduces drug uptake, hair follicle cell division, and metabolic activity - all of which lead to reduced hair loss.⁴

Clinical studies and real-world evidence have consistently shown that follicle protection via scalp cooling provides short, medium, and long term benefits.

Scalp cooling = follicle protection

Reduction in CIA
SHORT TERM

Faster hair regrowth
MEDIUM TERM

Supporting the prevention of PCIA
LONG TERM

With proven safety and tolerability, scalp cooling can also enhance patient quality of life

For some patients, the emotional and psychosocial benefits are also experienced beyond chemotherapy and into recovery.



Extensively studied and widely adopted

With over 100 studies and discussions on scalp cooling available in our online library, the Paxman Scalp Cooling System (PSCS) has a substantial level of clinical evidence and is now a firmly accepted side effect management device in clinical practice.

As a result, the PSCS is included within various national and international oncology care guidelines:

- National Comprehensive Cancer Network® (NCCN®)
- European Society for Medical Oncology
- ONS Guidelines (US)
- AGO (Arbeitsgemeinschaft Gynäkologische Onkologie e.V.)
- UK Oncology Nursing Society
- Cancer Australia
- Japanese Association of Supportive Care in Cancer
- Breast Cancer Guidelines by V&VN (Netherlands)
- German Guideline Program in Oncology
- France AFSOS (Association Francophone pour les Soins Oncologiques de Support)



Scan to access our Scalp Cooling Studies Library

scalpcoolingstudies.com

EFFICACY AND RETENTION

There are a large number of studies conducted over the last 20 years into the efficacy of scalp cooling and levels of hair retention. These levels are normally measured according to an alopecia scale (such as WHO, Ludwig, DEAN and CTCAE V 4.0). In most cases, 50% hair retention and above is clinically considered a success.

The table opposite demonstrates a range of selected studies from 2012 to 2025, reporting rates of successful hair retention across multiple cancer types and chemotherapy regimens, using varying alopecia evaluation methods.

A REPRESENTATIVE EXAMPLE OF EFFICACY

This selection provides a strong and consistent representation across various countries and populations (USA, South Korea, India, Japan, Mexico, Germany, The Netherlands and Italy) and therefore multiple ethnicities and practice settings. There is a common misconception that scalp cooling is only for female breast cancer patients and as such, this selection also ensures a range of solid-tumour cancer types and chemotherapy regimens are presented in both male and females.

With data ranging from 2012 to 2025 and a total number of 8,484 patients, these 14 studies present consistent evidence of hair retention due to scalp cooling.

One of the studies within the selection resulted in US FDA clearance, highlighting the level of clinical significance, methodological rigour and safety standards within the evidence.

Some studies were not limited to a single cooling system and the selection includes varying measures of efficacy on grading scales such as CTCAE, DEAN and WHO, demonstrating objective methods.

Each of these studies measured scalp cooling success as 50% hair retention, with the majority presenting over 50% of participants achieving success. The mean average success rate across all 14 studies was 60%.

Many of the studies had a longer follow-up period, which allowed assessment of both long and short-term hair preservation.

Inclusivity of patient-reported outcomes on factors such as quality of life, self-image and satisfaction adds an important dimension of efficacy beyond the clinical scoring.

Finally, patient and treatment-related variables across different clinical settings may influence the efficacy of scalp cooling in real world practice. In a study by Gianotti et al., it was noted that all nursing staff included within the trial had at least 1 year of experience with the procedure. It was hypothesised that more experience in administering scalp cooling contributes to better scalp cooling outcomes.⁵

8,484

Patients across 14 studies worldwide

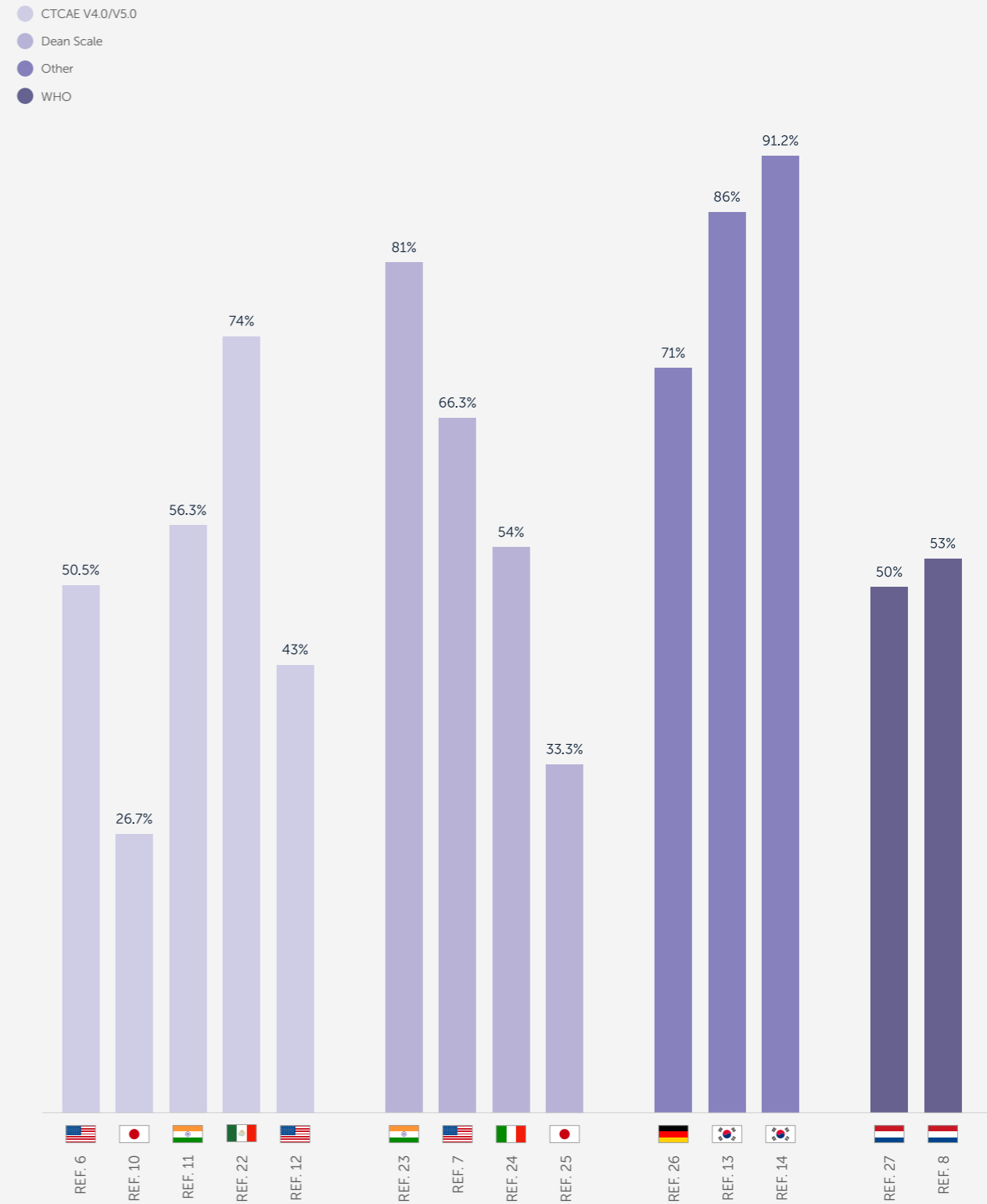
2012-2025

Studies ranging across a 14 year period

60%

Mean average success rate across all 14 studies

Percentage of Patients that had Scalp Cooling Success Defined by 50% or more Hair Retention



KEY HIGHLIGHTS

This section highlights three selected studies as the most compelling evidence of scalp cooling efficacy. Two of these studies secured FDA clearance, recognising the treatment's safety and efficacy. The third study stands out for its scope, offering the world's largest real-world dataset on scalp cooling and demonstrates that the benefits observed in clinical trials translate to everyday practice and across a large patient population.

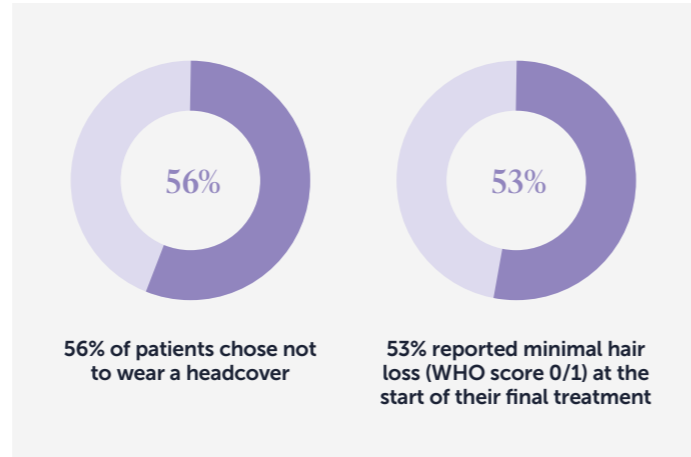
Nangia, J. et al. Effect of a Scalp Cooling Device on Alopecia in Women Undergoing Chemotherapy for Breast Cancer: The SCALP Randomized Clinical Trial. (2017).⁶

- The clinical trial which secured FDA clearance in the United States for Paxman Scalp Cooling.
- A multicentre trial across 7 study sites.
- 119 scalp cooling patients and 63 control, all female with breast cancer.
- Ethnically diverse US cohort: 82% White, 17% Hispanic, 12% Black, 6% Asian.
- Assessed using CTCAE alopecia scale.
- 50.5% average success in hair retention, compared to 0% in control.
- 63% of scalp cooling patients used a wig vs 100% in control.
- Hair preservation is much higher in taxane-based regimens than in anthracycline-based regimens (59% vs 16%).
- Scalp cooling is an effective, safe and generally well-tolerated option for reducing alopecia in early-stage breast cancer.

Rugo, H. S. et al. Association Between Use of a Scalp Cooling Device and Alopecia After Chemotherapy for Breast Cancer. (2017).⁷

- A study using the DigniCap system by Dignitana, Part of the Paxman Group, demonstrating the efficacy and safety of cooling the scalp via mechanical scalp cooling.
- 106 scalp cooling patients, 16 control all with early-stage breast cancer.
- Ethnically diverse US cohort: 77% white, 16% Hispanic, 10.7% Asian, 9.0% Black, 0.9% Multiracial.
- 66.3% success rate vs 0% control via patient assessment.
- 84.1% success rate in independent panel review photo assessment.
- 99% of patients received taxane-based chemotherapy.

Brook, T. S. et al. Results of the Dutch scalp cooling registry in 7424 patients: analysis of determinants for scalp cooling efficacy (2024).⁸



"A strength of this study is the extent of the database with high completeness of data, especially for patient-reported data from multiple centers."⁸

- The largest real-world study into the determinants for scalp cooling efficacy with 7,424 patients.
- 24 different chemotherapy regimens studied.
- Data from 68 hospitals from 2006 – 2019.
- Cancer types included breast, oesophageal, gynaecological, lung, prostate, stomach/colorectal and other solid tumour cancers.
- Assessed success using WHO Alopecia scores and head cover usage.
- 56% of patients did not require a head covering.
- 53% of patients achieved a WHO Score of 0-1, equivalent to less than 50% hair loss.
- Determined that chemotherapy drug was the only ascertainable determinant of scalp cooling success, regardless of lifestyle, age and cancer type, and that male patients should equally be offered the treatment.

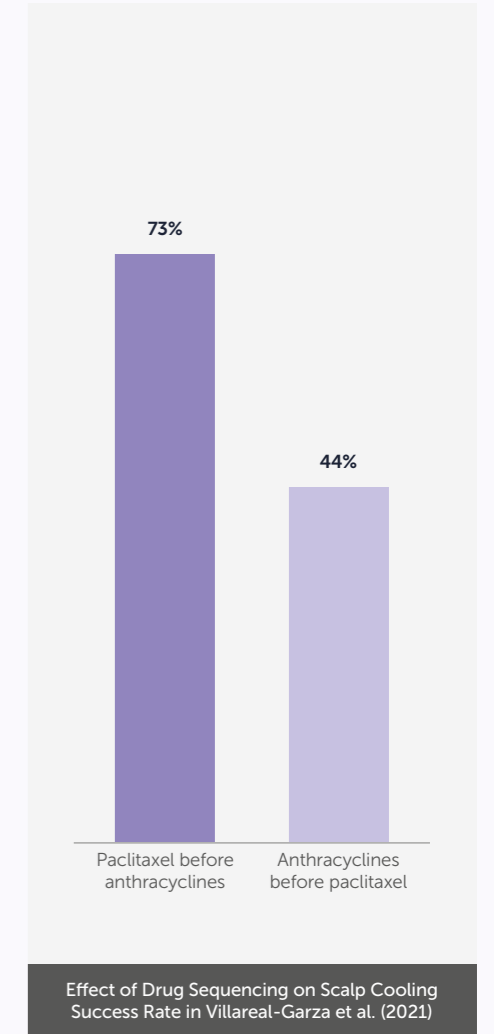
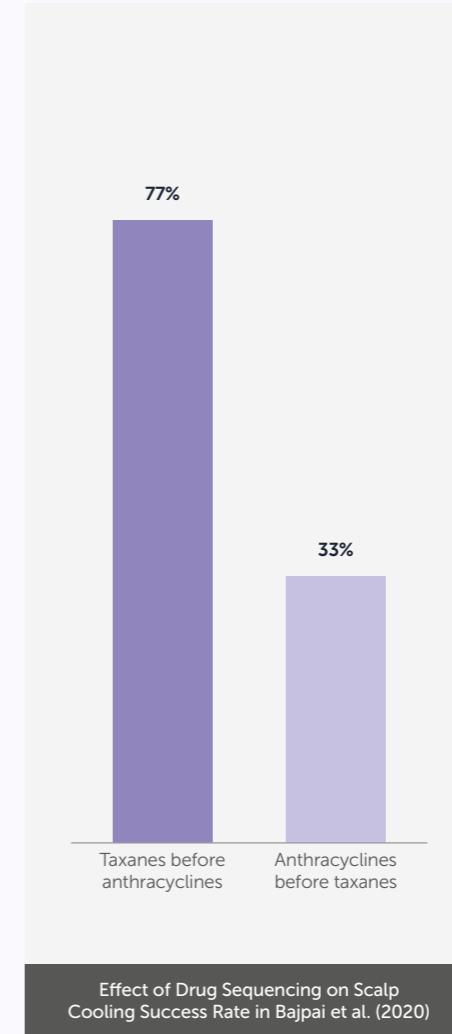
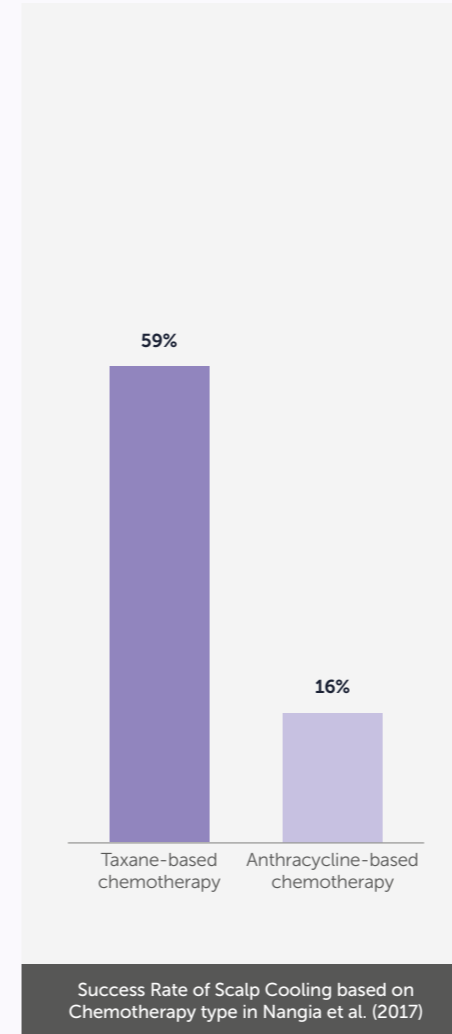
"The most important clinical implication is that medical personnel involved in patient care need to be aware that males are also eligible for and benefit from scalp cooling."

"Scalp cooling is effective for the majority of patients, and it offers patients the opportunity for privacy, identity, and control in their cancer treatment journey."⁸



Scan the QR code to read more about The Scalp Cooling Registry
scalpcoolingstudies.com/scalpcoolingregistry

EFFICACY AND RETENTION



TAXANE VS ANTHRACYCLINE THERAPY

A main factor that affects efficacy is the type of chemotherapy drug administered. It is now generally accepted that patients should anticipate lower hair retention rates when receiving anthracycline-based regimens.

In the Nangia et al. study,⁶ it was reported that only 16% of patients receiving anthracycline-based chemotherapy achieved scalp cooling success compared to 59% for taxane regimens - a trend which is noticeable across a wide range of studies.

However, there are a number of studies that demonstrate a higher-than-typical efficacy rate for this challenging regimen, which could potentially be attributed to nursing staff expertise or strict adherence to protocol.

One example is a study by Gianotti et al. in 220 female early-stage breast cancer patients receiving scalp cooling with the Paxman device.⁵ In this paper, Gianotti et al. reported a **47% hair preservation rate with anthracyclines, compared to 89% in taxanes. The study also reported a 78% hair preservation rate in women receiving both taxanes and anthracyclines in combination.**

The Bajpai et al.¹¹ trial expanded on this even further and explored differences in sequencing depending on which type of drug was administered first. It found that **patients who received taxanes before anthracyclines had 77% successful hair preservation vs 33% in patients who received anthracyclines first.**

This observation was also highlighted in the Villareal-Garza et al. study,²² where sequential chemotherapy that started with paclitaxel followed by anthracyclines was considerably more effective in preventing grade 2 alopecia than when the inverse order was administered (73% vs. 44%).

Importantly, even though success rates in anthracyclines reflect the known higher alopecia-inducing potential of these drugs, scalp cooling still provides a measurable protective benefit compared with no cooling at all. Setting patient expectations early and informing them of the regrowth benefits can help maximise achievable protection, even in higher-risk regimens.



REGROWTH AND PREVENTING PCIA

While the focus of some studies is hair retention directly after chemotherapy, studies with long-term follow-ups demonstrate follicle protection.

Scalp cooling mechanisms mean that despite hair loss, hair follicle cells can be protected, promoting quicker regrowth after chemotherapy.

Patients who experience hair loss (e.g. due to a tough chemotherapy regimen) should be made aware of the regrowth benefits and the potential for preventing persistent chemotherapy-induced alopecia (PCIA).

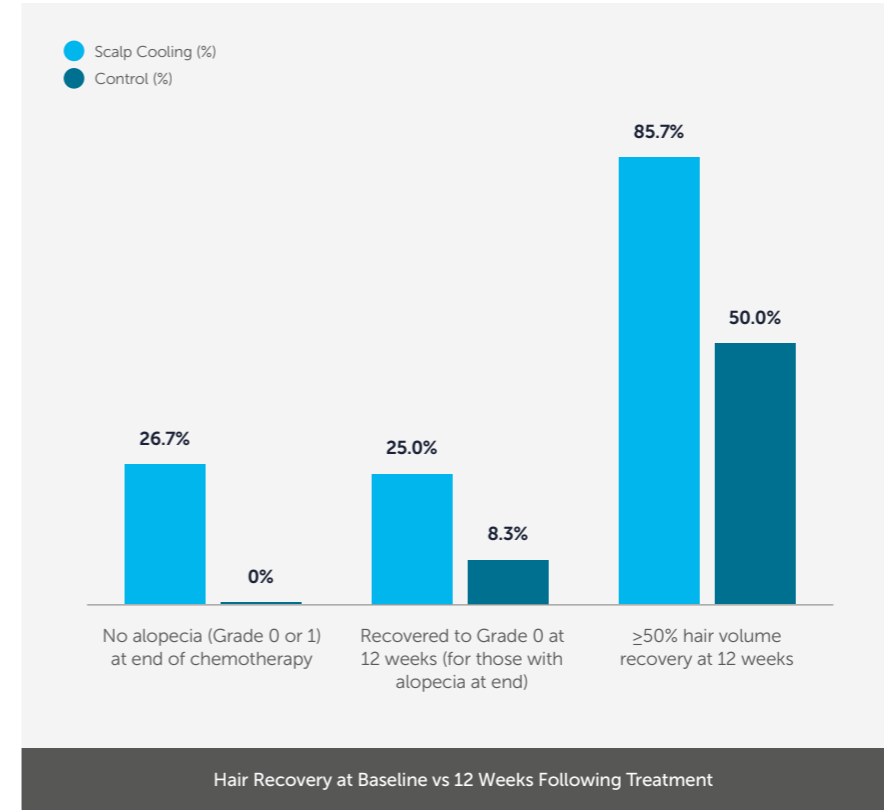
The following studies extended their investigation beyond efficacy and hair retention as primary endpoints. They evaluated patients for a period after chemotherapy (e.g., 12 or 24 weeks) to assess the extent of hair regrowth and the prevention of PCIA following scalp cooling.

These studies consistently demonstrate faster regrowth, greater hair thickness, increased density and reduced incidence of persistent alopecia compared to no scalp cooling, using both qualitative (scalp photography) and quantitative methods (trichoscopic measurements). Importantly, data includes

outcomes from patients on both taxane and anthracycline-based chemotherapy regimens across randomised controlled trials and observational studies.

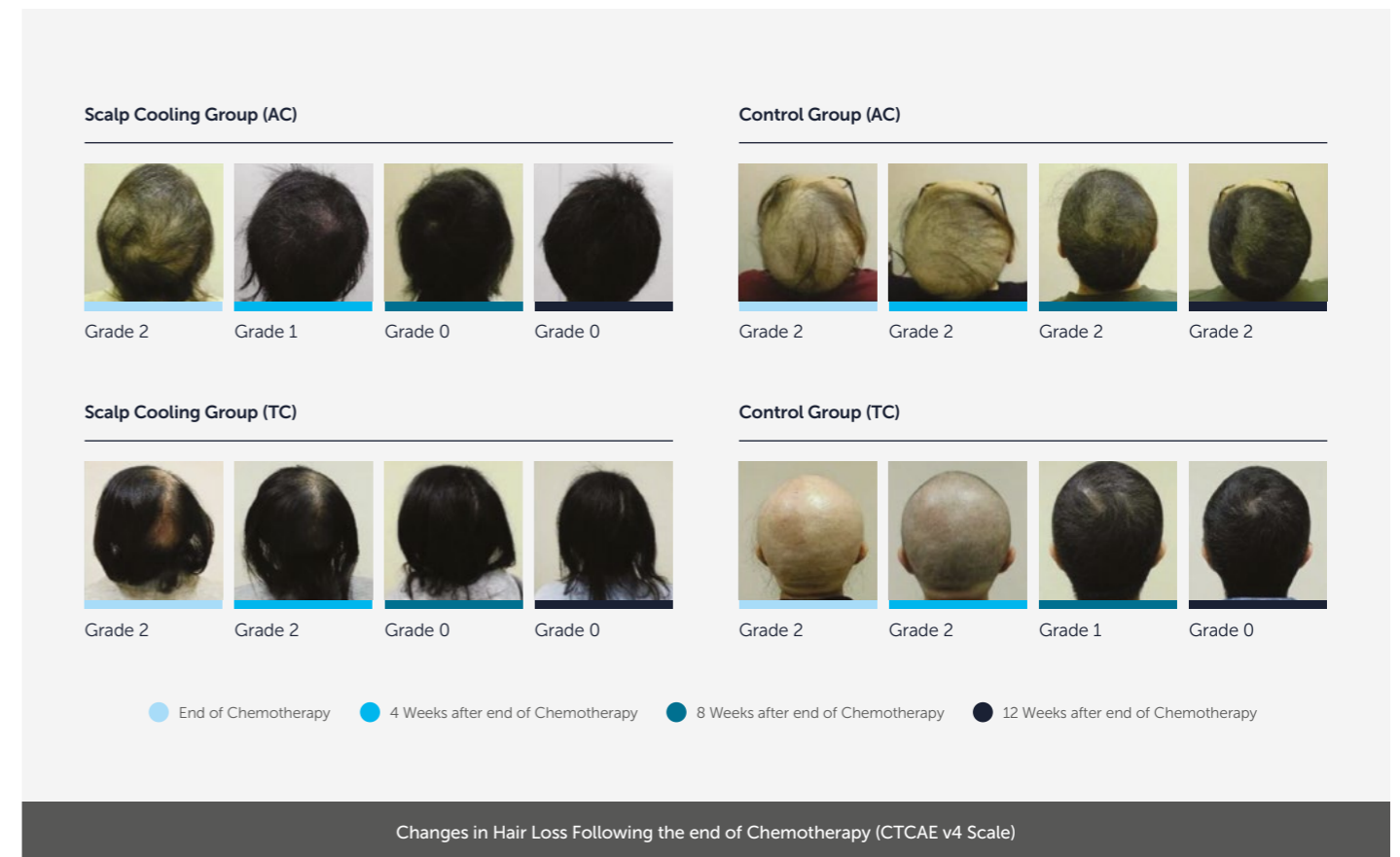
ABOUT PCIA

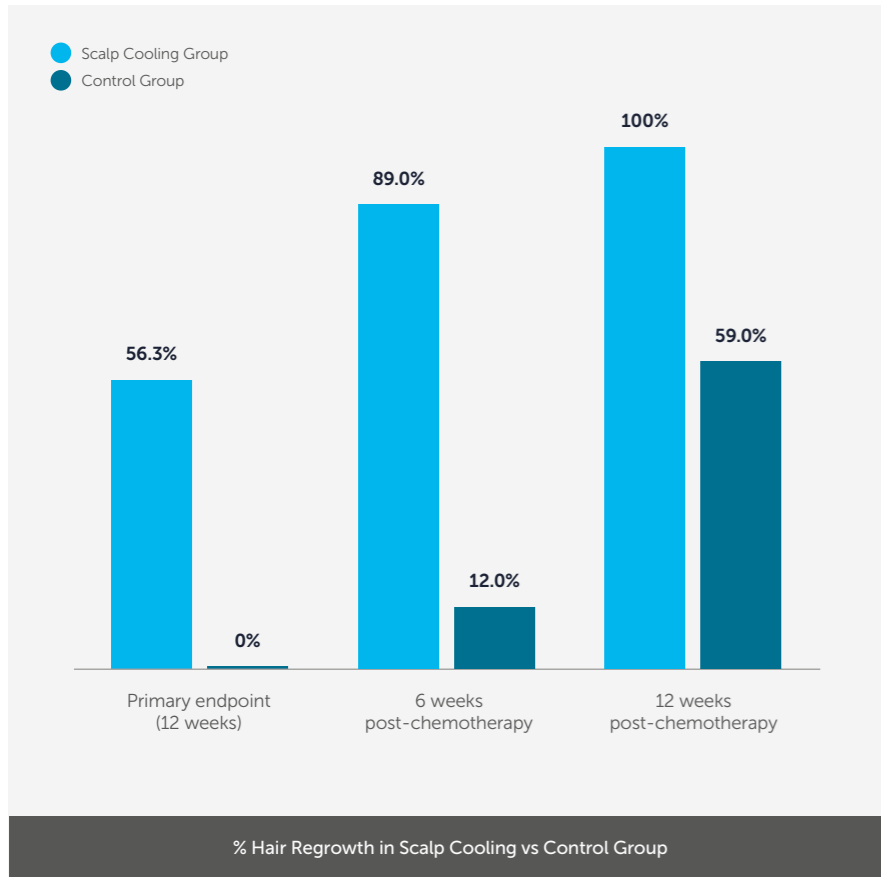
Persistent chemotherapy-induced alopecia, or PCIA, is hair loss that continues for more than six months after chemotherapy treatment ends, and in some cases, it can be permanent.⁹



Kinoshita, T. et al. Efficacy of Scalp Cooling in Preventing and Recovering From Chemotherapy-Induced Alopecia in Breast Cancer Patients: The HOPE Study.¹⁰

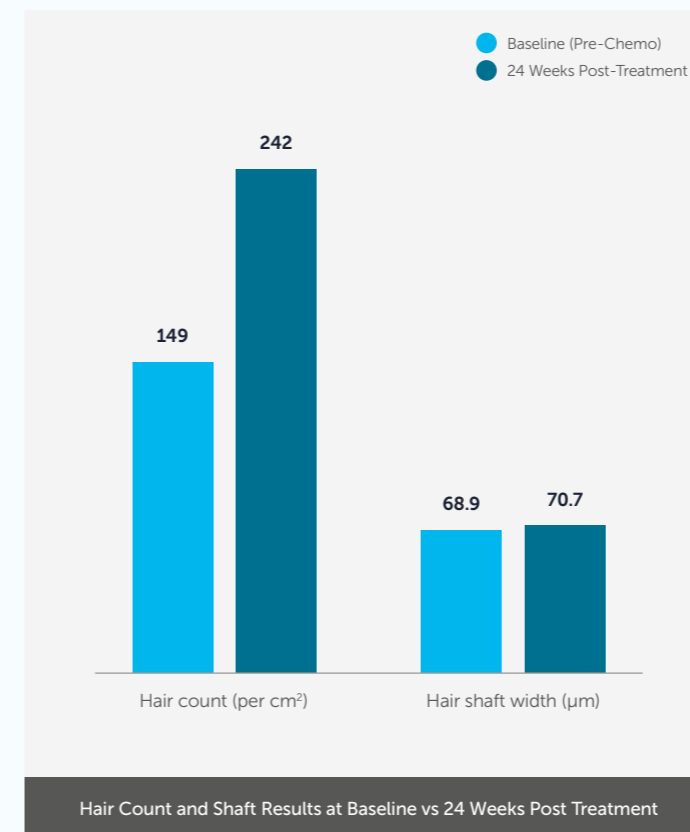
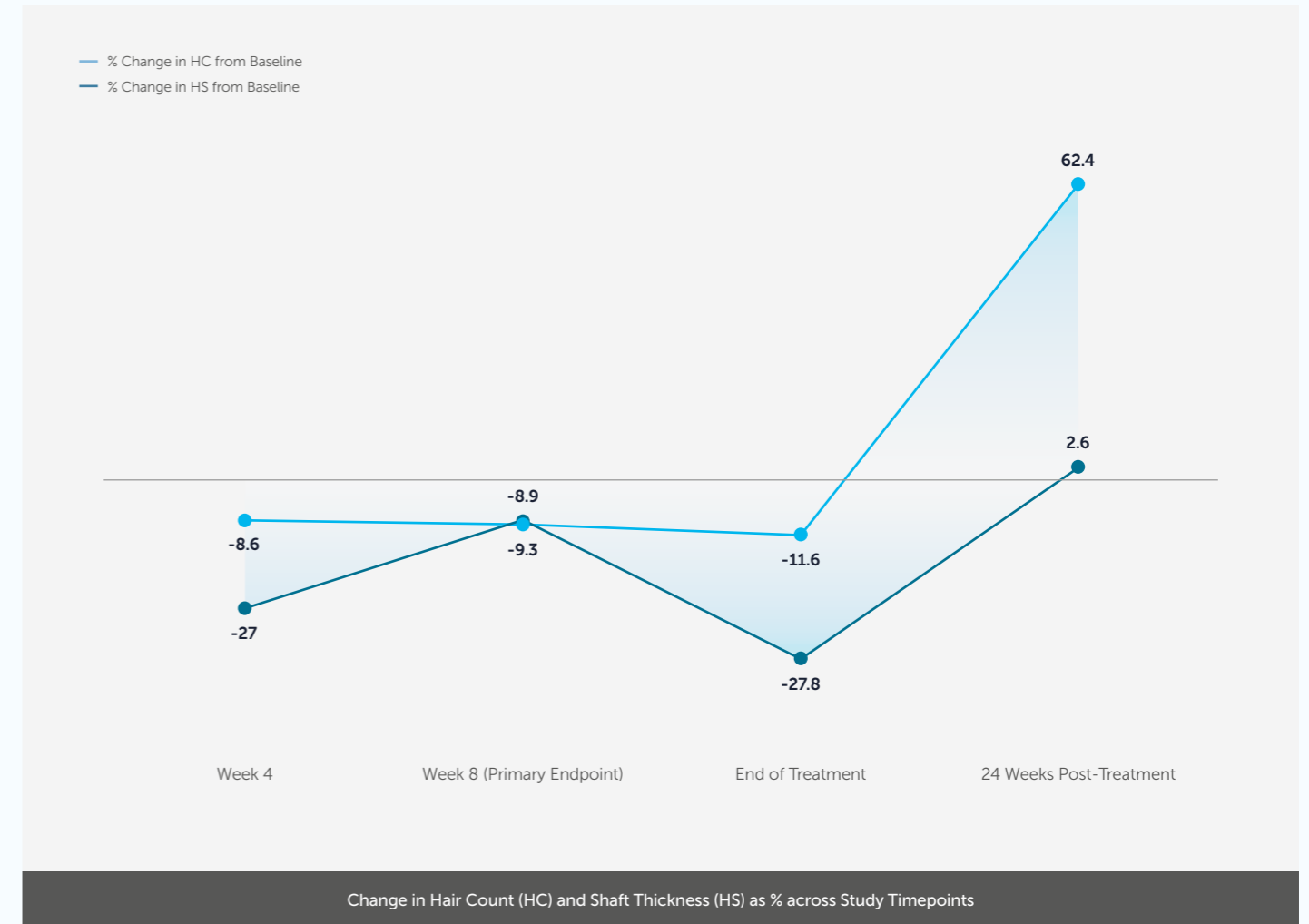
- Although the study only included 48 patients, the findings suggest a meaningful difference in hair recovery following on from chemotherapy treatment.
- Among those who developed severe alopecia, 25% of patients in the scalp cooling group achieved full hair regrowth at the 12 week follow up assessment, compared to just 8.3% in the non-cooled group.
- For those in the scalp cooling group, 85.7% recovered at least half of their hair volume at 12 weeks vs 50% in the control group.
- Even when scalp cooling failed to prevent initial hair loss, it reduced follicle damage enough to accelerate regrowth.
- Patients who cooled are 2 times more likely to regain at least half of their hair and 3 times more likely to fully recover compared to controls.





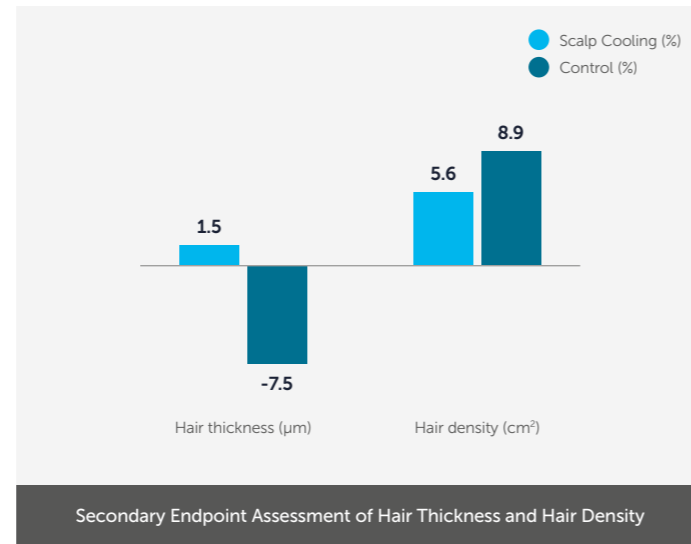
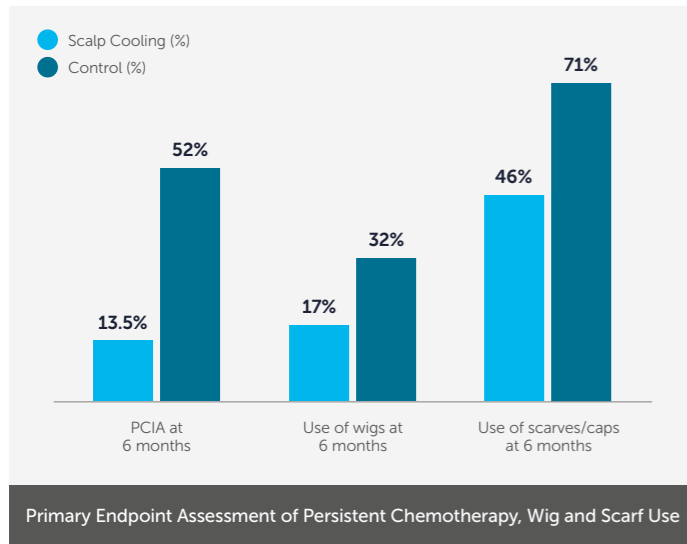
Bajpai, J. et al. "Randomised controlled trial of scalp cooling for the prevention of chemotherapy induced alopecia". (2020).¹¹

- 51 non-metastatic breast cancer patients undergoing (neo) adjuvant chemotherapy were randomised to either the scalp cooling (intervention) group or the control.
- A single-centre study, the primary endpoint was successful hair preservation, (Grade 0 or 1 according to the CTCAE V4.0 scale) assessed clinically and by review of photographs after chemotherapy.
- Hair regrowth (HR), the secondary endpoint, was assessed at 6- and 12-weeks post-chemotherapy.
- At 6 weeks post chemo, 89% of patients in the scalp cooling group showed hair regrowth, vs 12% in the control group. At 12 weeks, this rose to 100% in the scalp cooling group, compared to 59% in the control.
- The study concluded that hair regrowth is significantly higher in scalp-cooled patients on either taxanes or anthracyclines post-chemotherapy in comparison to those in the control group.



Goldfarb et al. Efficacy of Paxman scalp cooling system at lower temperatures for prevention of anthracycline associated chemotherapy induced alopecia. (2023).¹²

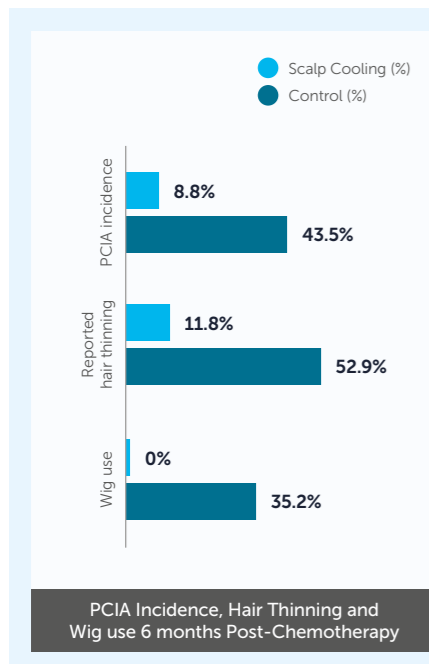
- 34 patients with stage I-III breast cancer were evaluated for hair loss while receiving scalp cooling for anthracycline-based chemotherapy.
- Patients Hair Count (HC) and Hair Shaft width (HS) were assessed using clinical photography and trichoscopy at 5 time points: baseline (pre-chemotherapy), week 4 into treatment, week 8 (primary endpoint), end of treatment and 24 weeks post treatment, to evaluate hair loss during peak alopecia risk as well as long-term regrowth.
- At 24 weeks post-chemotherapy, of patients with available data, 0% had grade 2 alopecia, 23% had no visible hair loss (Grade 0), and 31% had mild hair loss (Grade 1). Hair count increased to 242 hairs/cm² from 149/cm² at baseline, and hair shaft width rose to 70.7 microns (from 68.9 microns)
- This suggests a full recovery of follicles and possible compensatory regrowth.
- These results were based on anthracycline regimens and lower cooling temperatures of -7.5°C and -10°C, suggesting that lower cooling may mitigate severe permanent follicle damage.



Kang et al. Scalp Cooling in Preventing Persistent Chemotherapy-Induced Alopecia: A Randomized Controlled Trial. (2024).¹³

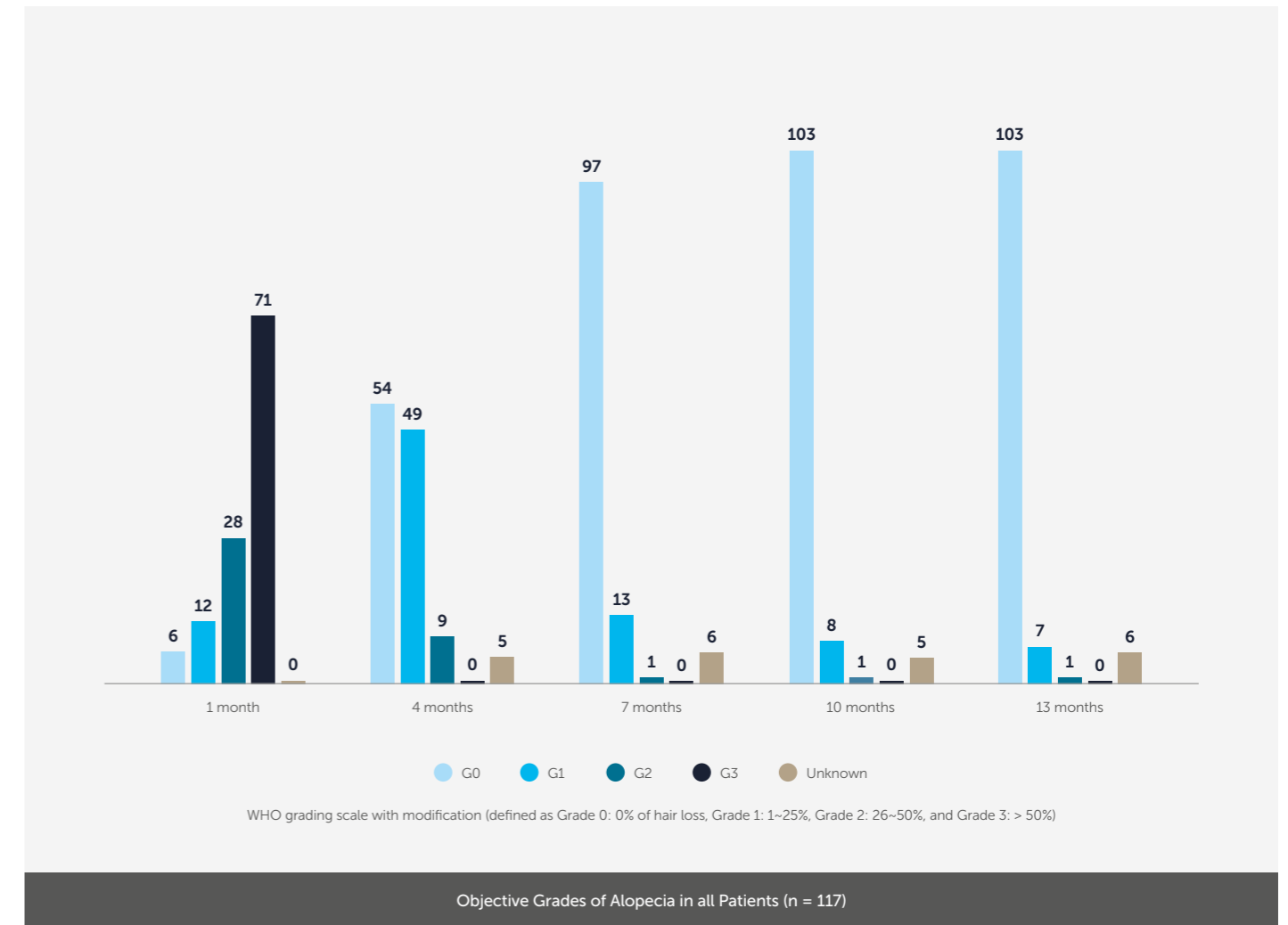
- Conducted at the Samsung Medical Centre in Seoul, South Korea, patients diagnosed with stage I-III breast cancer, scheduled to receive neoadjuvant or adjuvant chemotherapy were randomly assigned to the intervention or control group.
- 139 patients completed the study at a ratio of 2:1.
- 89 patients were assigned to the scalp cooling group and 50 to the control group.
- The study used trichoscopic imaging to measure hair thickness and density up to 6 months after chemotherapy.
- Scalp cooling reduced the initial loss of hair density immediately after chemotherapy, offering early protection.
- From baseline to the 6-month visit, hair thickness decreased by 7.5 µm in the control group and increased by 1.5 µm in the intervention group.
- By 6 months, both groups recovered hair density to near baseline levels: +5.6 hairs/cm² in the intervention group, +8.9 in the control.
- While scalp cooling did not impact total hair count, the main benefit at 6 months is qualitative regrowth, hair thickness, and reduced persistent alopecia.
- This study highlights the importance of follow up with patients and that the primary endpoint (hair retention/loss) is not the sole factor in scalp cooling success.

“In conclusion, this randomized clinical trial showed that scalp cooling reduced the incidence of PCIA, primarily by increasing hair thickness compared with control. Scalp cooling is helpful in promoting qualitative hair regrowth. This effect on hair quality is perceived by the patients and significantly enhances their social and psychological QoL.”¹³



Kang et al. Scalp cooling for preventing persistent chemotherapy-induced alopecia in anthracycline-treated patients: A single-arm trial.¹⁴

- A study of 34 scalp cooling patients, compared to 85 historical controls, on anthracycline-based regimens.
- Quantitative trichoscopy was used to measure hair thickness before, during and up to 6 months after chemotherapy.
- 8.8% of patients in the scalp cooling group had PCIA compared to 43.5% in the controls.
- The study found that fewer patients reported severe thinning (11.8% vs 52.9%) and no wig use (0% vs 35.2%) compared to historical controls: an important indicator of substantial quality of life gains and the return to normality.
- Scalp cooling significantly lowered the risk of PCIA at 6 months, indicating the benefit of scalp cooling - even in anthracycline therapy where efficacy is perceived to be weaker.
- Follow up at 6 months demonstrates that cooling protects follicle stem cells and improves hair shaft quality, leading to significant regrowth and improvement in hair thickness.
- No serious adverse events were reported, and no patients withdrew, aligning with prior data of safety of use.



Ohsumi, S., Kiyoto, S., Takahashi, M. et al. Prospective study of hair recovery after (neo)adjuvant chemotherapy with scalp cooling in Japanese breast cancer patients.¹⁵

- 117 Japanese female breast cancer patients studied who completed planned (neo)adjuvant chemotherapy using the Paxman Scalp Cooling System.
- Patients were evaluated for hair recovery 1, 4, 7, 10, and 13 months after chemotherapy.
- Primary outcomes were grades of alopecia judged by two investigators (objective grades) and patients' answers to the questionnaire regarding the use of a wig or hat (subjective grades).
- 18 out of 117 patients had objective Grade 0 or 1 alopecia after 1 month.
- By 7 months, 97 patients had Grade 0 alopecia, increasing to 103 after 10 months.
- Subjectively, alopecia grades were slightly lower but also improved over time, as with the objective grading, which suggests improvements in self-perception and wellbeing due to regrowth.

“The preventive effects against persistent alopecia by scalp cooling strongly support the hypothesis that it reduces the irreversible damage to hair follicle cells by chemotherapeutic agents.”¹⁵



IMPROVING QUALITY OF LIFE (QoL)

Hair loss is consistently ranked amongst the most distressing side effects of chemotherapy. In a literature review of chemotherapy-induced alopecia and its effects on quality of life among women with breast cancer, patients described hair loss as traumatising, distressing and 'harder than losing a breast'.¹⁶

Chemotherapy-induced alopecia can lead to feelings of anxiety and depression, a loss of identity and confidence, as well as social withdrawal, thus a slower return to normal life.¹⁶

Several studies have analysed the impact of scalp cooling in mitigating the emotional and psychological trauma of hair loss compared with those who did not scalp cool. Because these studies use questionnaires that are not hair loss-specific, other cancer- and treatment-related factors should be taken into account.

The Hospital Anxiety and Depression Scale (HADS) was used to interpret and compare the psychological and social conditions of patients who scalp cooled and those who did not in a Turkish clinical study by Haksöyler et al. (2018).¹⁸

This particular study found a statistically significant increase in depression scores and antidepressant usage for patients who did not scalp cool. To mitigate the influence of other side effects, such as nausea, weakness or lack of appetite on quality of life, patients were questioned when side effects were expected to decrease.

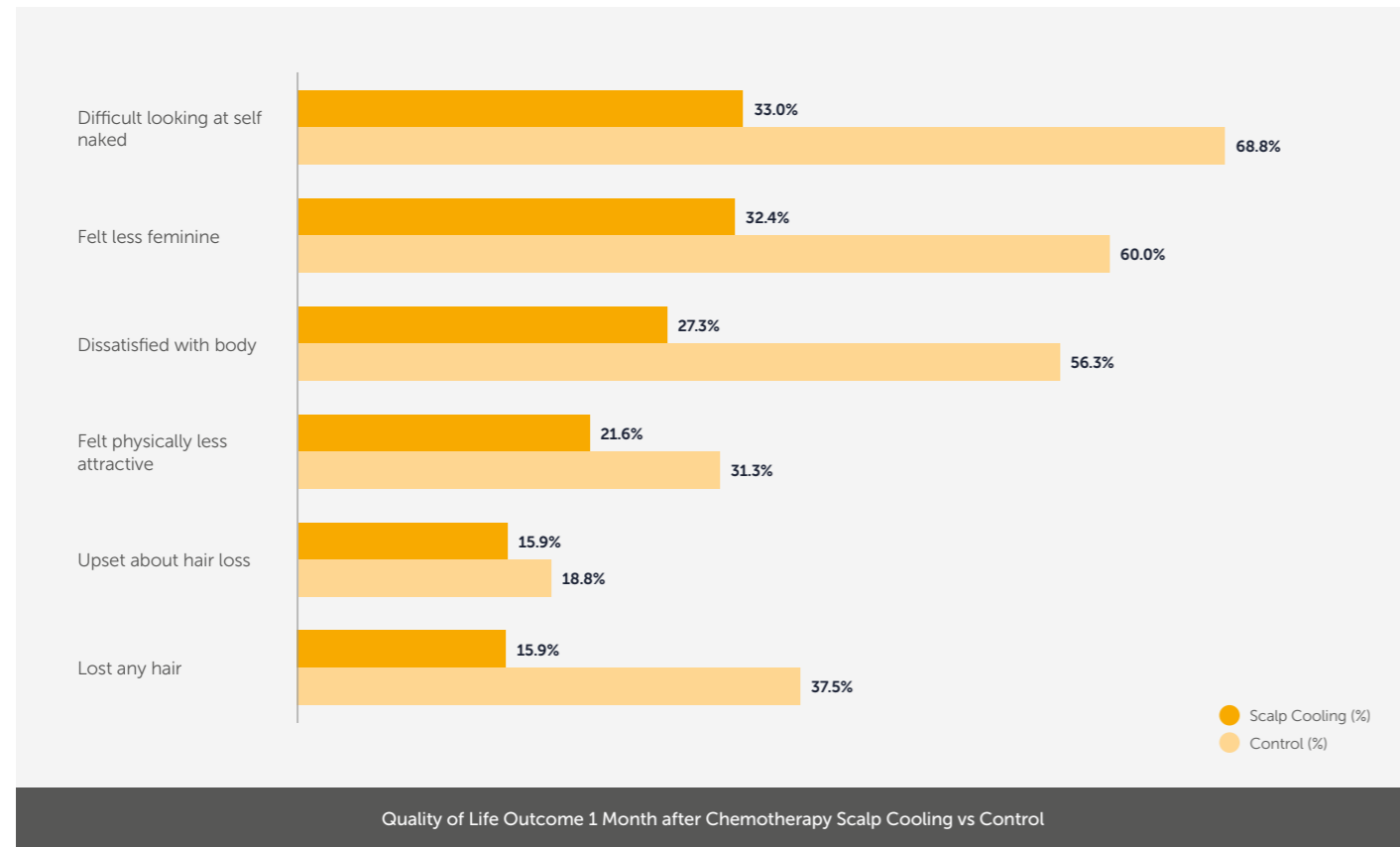
In addition, a patient feedback report of 150 Paxman Scalp Cooling Patients by Clayton et al. (2021) found that 99% of patients reported some impact on their emotional wellbeing and 93% stating that this impact was significant or very significant.²⁸

Although it can be difficult to isolate with certainty the positive effects of scalp cooling among other side effects, there is a positive correlation between scalp cooling and psychological and emotional well-being.

"The benefit of delaying and limiting hair loss put me back in control of my diagnosis and gave me the confidence I so needed while getting treatment."

Rossalyn Abbot Ripper, Maryland, US

KEY HIGHLIGHTS



Rugo, H. S. et al. Association Between Use of a Scalp Cooling Device and Alopecia After Chemotherapy for Breast Cancer. (2017).⁷

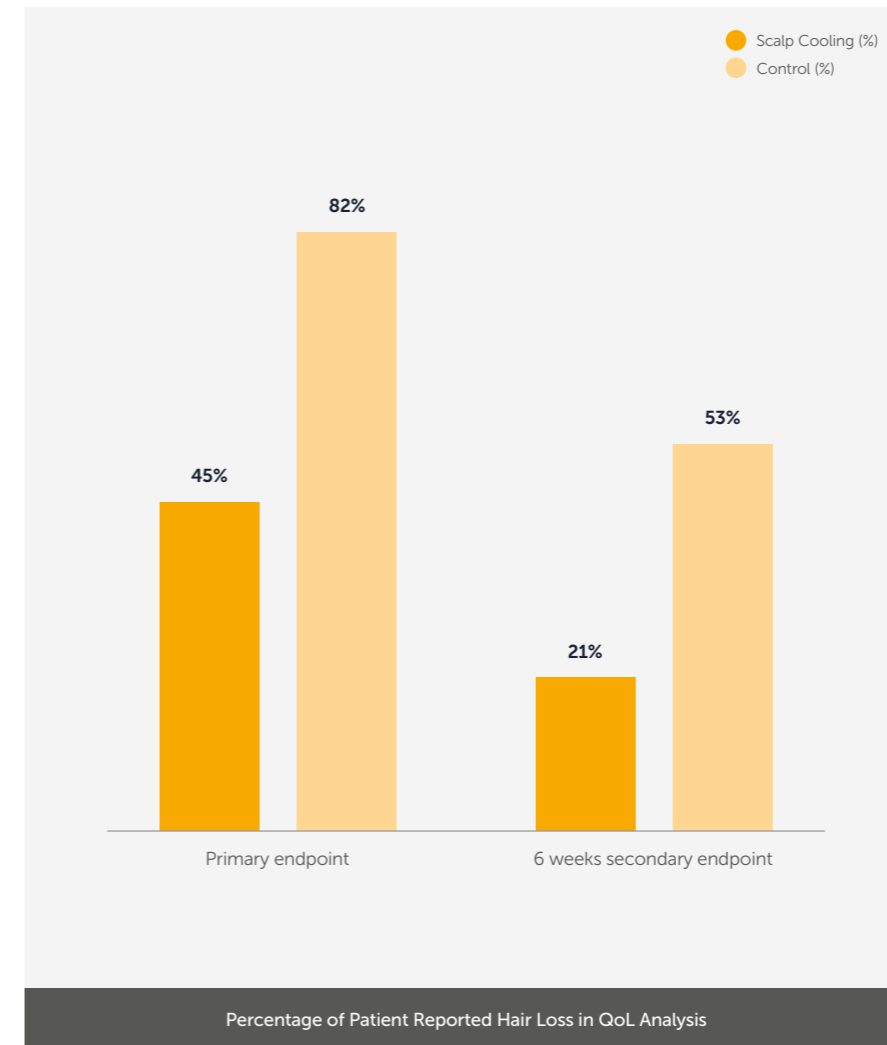
This study assessed patient quality of life factors through EORTC QLQ BR23 questionnaires between scalp cooling and control groups to ascertain the effect of scalp hair retention on quality of life.

- Study in patients with early-stage breast cancer.
- 106 patients scalp cooled while 16 were in the control group.
- Psychological and emotional well-being were positively impacted when scalp cooling successfully reduced alopecia.
- For women who used scalp cooling, 3/5 QoL measures showed statistically significant improvement: Less hair loss distress, feeling more physically attractive, and greater body satisfaction.

“Now 14 months out, I feel like I look like myself again. I could not be happier. Using the Paxman helped my mental health immensely.”

Andrea Billittier, New York State, US

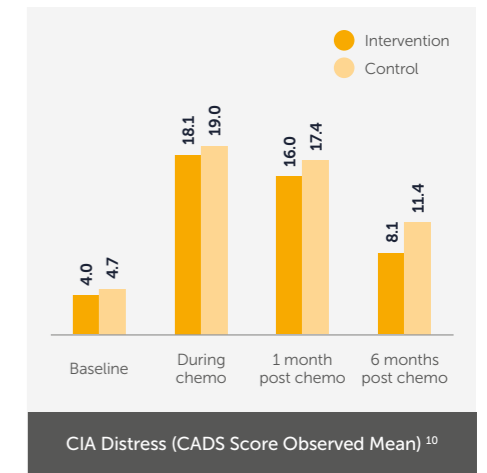
IMPROVING QUALITY OF LIFE (QoL)



Bajpai, J. et al. “Randomised controlled trial of scalp cooling for the prevention of chemotherapy induced alopecia”. (2020).¹¹

In addition to providing valuable data on regrowth, the study by Bajpai et al. used the same EORTC QLQ BR23 questionnaire as the Rugo et al. study to assess quality of life post-chemotherapy.

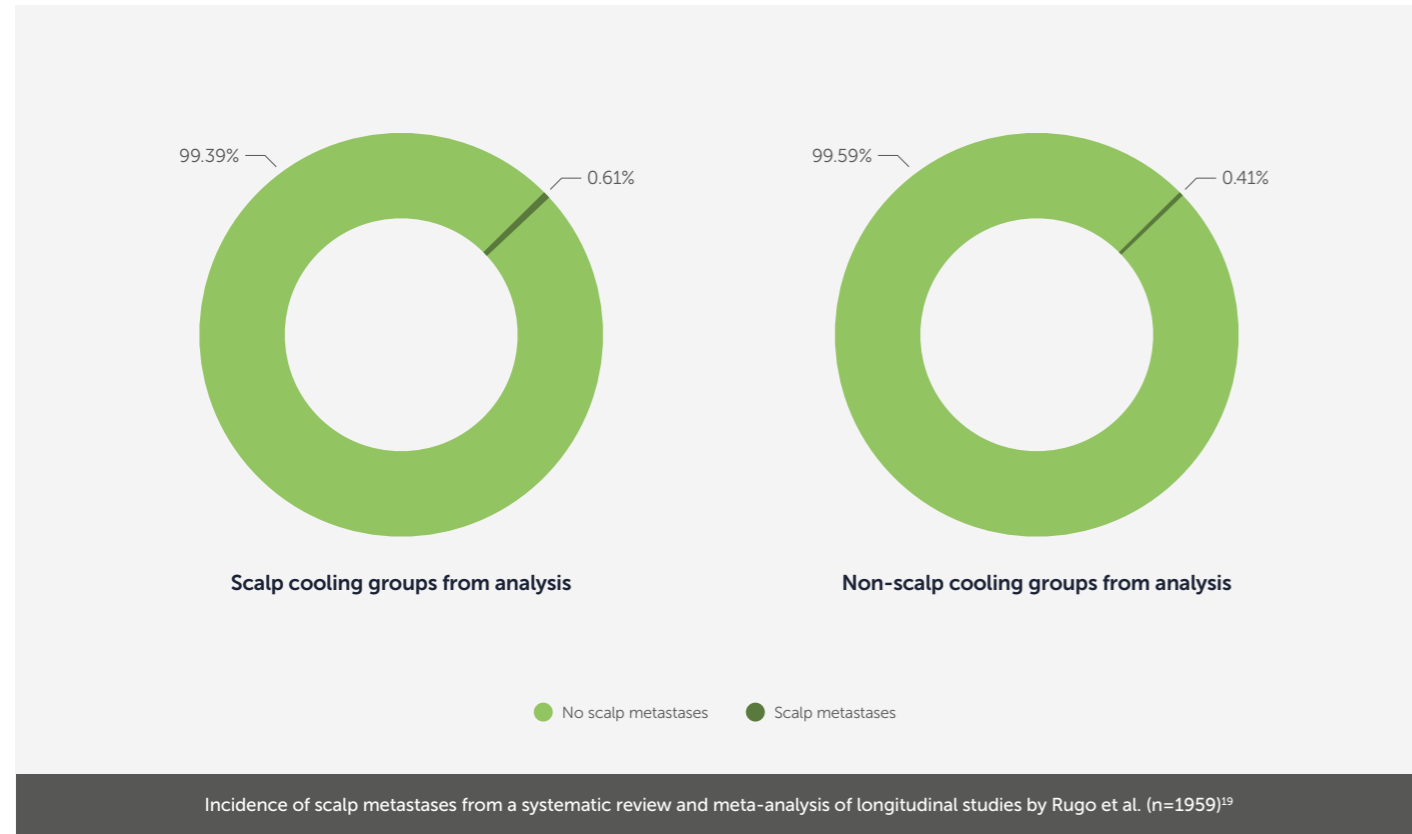
- An investigator-initiated, open label, single centre, randomised trial that recruited consecutive women with non-metastatic breast cancer in India.
- 51 patients planned for curative intent (neo) adjuvant chemotherapy containing both anthracyclines and taxanes in sequential fashion.
- Sample size allocation of 2:1 in the scalp cooling and control arms respectively.
- The questionnaire focused on hair loss, body image, sexual functioning, systemic therapy side effects and future perspective.
- Results showed that scalp cooling significantly reduced distress in the hair loss domain.
- No significant differences were observed between groups within the other 4 domains suggesting scalp cooling specifically provides a meaningful QoL benefit via the reduction of psychosocial distress associated with alopecia.



Kang, D. et al. Scalp Cooling in Preventing Persistent Chemotherapy-Induced Alopecia: A Randomized Controlled Trial. (2024).¹³

Alongside evaluating the effect of scalp cooling on regrowth and the prevention of PCIA, this study measured patient distress due to chemotherapy-induced alopecia. It used the validated and reliable Chemotherapy-Induced Alopecia Distress Scale (CADS) for evaluating the influence of CIA on psychosocial wellbeing and QoL.

- Between baseline and 6 months post-chemotherapy, the scalp cooling group experienced a 4.1 increase in CADS score, compared to a 6.7 increase in the control.
- Data shows a significant 3.3 difference in CADS score 6 months after chemotherapy between the two groups.
- This clinically meaningful difference demonstrates that the intervention group had significantly less CIA-related stress, 6 months after chemotherapy.
- Wig and scarf usage – another identifier in perception of self – was also lower in the scalp cooling group at 46% compared to 71% for the control group.
- It suggests early recovery from alopecia in patients using a scalp cooling device may help improve quality of life.
- Naturally, cancer and chemotherapy are distressing and contribute to a patient’s increased distress score, regardless of hair retention and regrowth. This could explain why both groups did not return to base levels.



SAFETY AND TOLERABILITY

Scalp Metastases

While historically there were concerns among critics that scalp cooling could increase the incidence of scalp metastases, studies have shown that the risk remains low. 100% of studies referenced reported no scalp metastasis.

A systematic review of a meta-analysis of longitudinal studies totalling 1959 patients, undertaken by Rugo, Melin and Voigt, found that the incidence of scalp metastases was low, regardless of scalp cooling.¹⁹

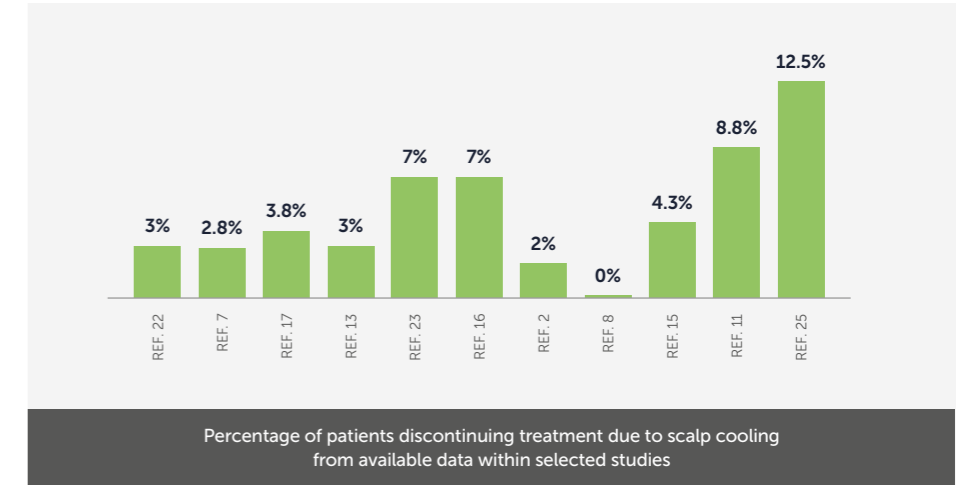
“The possibility that scalp cooling protects the scalp from the beneficial effects of adjuvant chemotherapy has been a concern that has limited the use of these devices in the United States. However, this systematic review and meta-analysis examining patients with breast cancer receiving chemotherapy while using scalp cooling for hair preservation does not support this concern and, demonstrates no statistical difference in the incidence of scalp metastasis between patients using scalp cooling vs. no scalp cooling.”⁷

Tolerability

Scalp cooling is well tolerated by most patients, and its safety is well documented in clinical research. Across studies, minimal numbers of patients report cessation of scalp cooling due to the cold or cold-related side effects.

Of all the studies analysed in the table, the average number of patients who discontinued due to scalp cooling specifically was only 4.93%.

Most studies find that discontinuation of scalp cooling is actually due to perceived hair loss. Patients should be reminded of the potential for accelerated regrowth via protective follicular mechanisms before discontinuing. Patients with significant hair loss can still scalp cool, using protective measures such as theatre caps or gauze.



Despite the use of colder-than-standard coolant temperatures in the study by Goldfarb et al, where the Paxman Scalp Cooling System operated at -7.5°C and -10°C instead of the

typical -4°C, no patients discontinued scalp cooling due to intolerance, indicating that even at lower temperatures, the treatment is safe and well tolerated.

Treatment Adherence

Up to 1 in 7 patients reject chemotherapy outright through fear of hair loss.²⁰

Scalp cooling can help reduce alopecia, however, patients with higher expectations around hair retention may also discontinue the treatment if they experience what they perceive to be significant hair loss.

While 50% hair retention is usually considered clinically successful, individual patients may view this differently, especially when coupled with the other challenges chemotherapy brings.

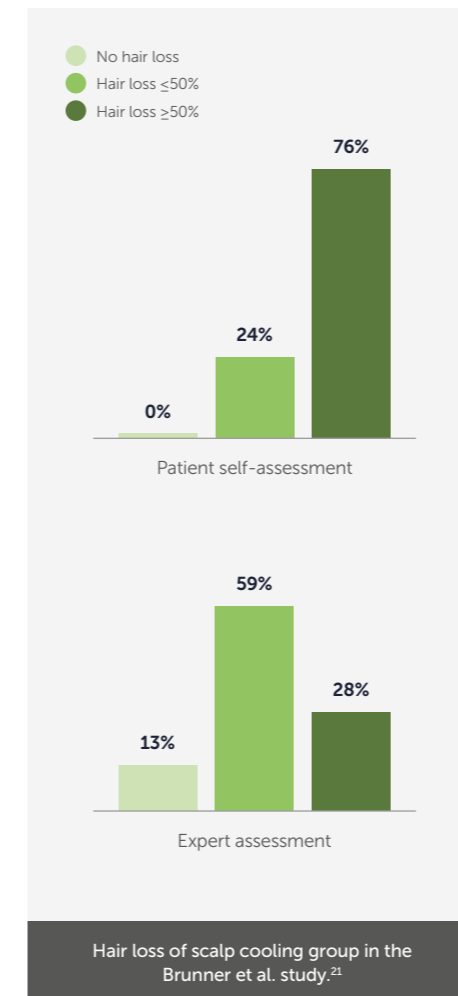
The 2021 Japanese study conducted by Ohsumi et al., evaluated both objective alopecia grades and subjective ones (from patient questionnaires regarding the use of a wig or hat) in two patient groups over 13 months. Group A were patients who received all planned scalp cooling treatments whereas Group B consisted of patients who discontinued.

Even when objective assessments suggested relatively preserved hair volume, many patients still felt their hair loss was substantial enough to require head coverings. This highlights that patients interpret hair change more emotionally and as a result, managing expectations around scalp cooling is crucial.

A 2022 study by Brunner et al. found a discrepancy in the same vein. Despite 71% of patients achieving more than 50% hair retention, only 24% self-reported that they had preserved enough hair to consider the outcome successful.²¹

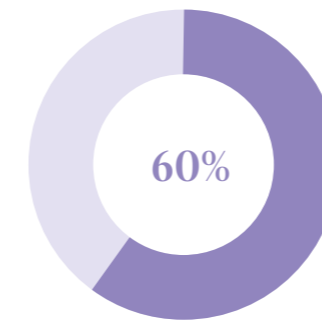
The study also reported that when patients experience increased symptom burden from hair loss, their willingness to continue additional treatments decreased.²¹

It is therefore crucial to establish patient-defined thresholds for what is deemed to be successful hair preservation in order to better support functional health, quality of life, self-image and adherence to treatment. Clear, proactive communication can help align expectations, reduce distress, and support continued adherence to scalp-cooling protocols.



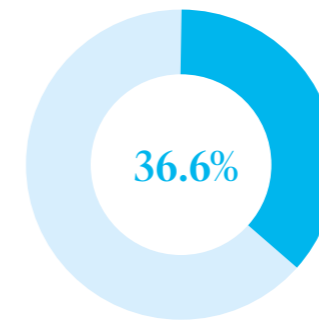


KEY RESULTS FROM THE PUBLICATIONS EVALUATED



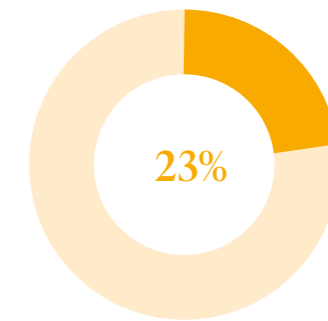
Average hair retention success rate across multiple cancer types, regimens and patient populations

(see graph on page 7)



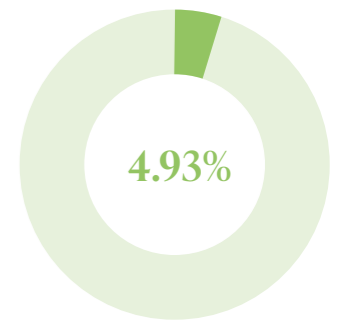
Average reduction in PCIA incidence as a result of scalp cooling

(see Kang et al. 2024 & 2025, page 14)



Average difference across QoL analysis scores between scalp cooling and control groups

(see Rugo et al. 2017, Bajpai et al. 2020, pages 18 & 19)



Average discontinuation rate across selected studies

(see tolerability graph, page 21)

SUMMARY

Clinical evidence demonstrates that the Paxman Scalp Cooling System effectively preserves hair during chemotherapy, with an average hair retention success rate of over 60% across multiple cancer types, regimens, and patient populations.

Beyond hair preservation, scalp cooling promotes faster regrowth and significantly reduces the risk of persistent chemotherapy-induced alopecia (PCIA), even in patients receiving anthracycline-based therapies.

By mitigating visible hair loss, the system also supports improved quality of life, reducing psychological distress and enhancing self-image and confidence throughout treatment.

Extensive studies confirm that scalp cooling is safe and well-tolerated, with no serious adverse events reported and minimal patient discomfort.

Together, these findings highlight that the Paxman Scalp Cooling System is a clinically validated, patient-centred approach to managing one of chemotherapy's most distressing side effects.

OVERVIEW OF HIGHLIGHTED STUDIES

Citation	Study Type	Patients Enrolled	Cancer Types
Bajpai J et al., 2020, Breast¹¹	Randomized controlled trial	51 (34 scalp cooling vs 17 control)	Non-metastatic breast cancer
Brook TS et al., 2024, The Oncologist⁸	Registry-based cohort study	7,424	Various: breast, ovarian, prostate, other solid tumours
Goldfarb SB et al., 2023, Cancer Research¹²	Phase I/II clinical trial	34	Stage I–III Breast Cancer
Kang D et al., 2024, J Clin Oncol¹³	Randomized controlled trial	139 (89 scalp cooling vs 50 control)	Stage I–III Breast Cancer
Kang D et al., 2025, J Am Acad Dermatol¹⁴	Single-arm trial	34	Stage I–III Breast Cancer
Kinoshita T et al., 2019, Front Oncol¹⁰	Prospective cohort study	48 (34 scalp cooling vs 14 control)	Stage I-II Breast Cancer
Ohsumi S et al., 2021, Support Care Cancer¹⁵	Prospective cohort study	117	Breast Cancer
Rugo HS et al., 2017, Breast Cancer Res Treat⁷	Systematic review & meta-analysis	1,959	Breast Cancer
Rugo HS et al., 2017, JAMA¹⁹	Prospective cohort study	122 (106 scalp cooling vs 16 control)	Stage I or II Breast Cancer

Chemotherapy Types	Objective	Primary Endpoint	Assessment Methods
Anthracycline and/or taxane-based regimens	Assess efficacy of scalp cooling in preventing alopecia & promoting hair regrowth	Successful hair preservation after chemo	CTCAE v4.0, EORTC QLQ BR23
Multiple regimens	Evaluate real-world effectiveness of scalp cooling	Successful hair preservation ($\leq 50\%$ hair loss) at end of chemo	WHO Alopecia Scale, head cover usage
Anthracycline-based regimens	Evaluate safety & tolerability of Paxman scalp cooling at lower temperatures	Incidence of adverse events related to scalp cooling	CTCAE v.4.0
Neoadjuvant/adjuvant chemotherapy	Evaluate scalp cooling efficacy in reducing persistent chemo-induced alopecia (PCIA)	PCIA 6 months post-chemo	Quantitative trichoscopy, CIA distress scale (CADS)
Anthracycline-based regimens	Evaluate scalp cooling in preventing PCIA in anthracycline chemo	Incidence of PCIA at 6 months	Quantitative trichoscopy, CIA distress scale (CADS)
Anthracycline and taxane	Evaluate efficacy of scalp cooling in preventing/recovering from alopecia	Proportion with no alopecia at end of chemo	CTCAE v4.0, EORTC QLQ C30
Taxanes (82) & Anthracyclines (33)	Evaluate effect of scalp cooling on hair recovery post chemo	Hair recovery after chemo	WHO Alopecia Scale, head cover usage
Adjuvant & neoadjuvant chemo	Assess risk of scalp metastases with scalp cooling	Incidence of scalp metastases	Review & analysis of existing studies
99% taxane (1 patient anthracycline)	Evaluate scalp cooling association with hair loss & quality of life	Self-estimated hair loss, 4 weeks after last chemo	Dean Scale, EORTC QLQ BR23

GLOSSARY

Alopecia Scales

CTCAE (COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS)

Developed by the National Cancer Institute (NCI) to standardise reporting of adverse events in clinical trials.

Alopecia grading ranges from:

Grade 1: Hair loss <50% of scalp or minor thinning

Grade 2: Hair loss ≥50% or significant thinning, may require wig or covering

Grade 3: Total hair loss or complete alopecia

DEAN SCALE

A numerical scale used to quantify the severity of hair loss, primarily in chemotherapy-induced alopecia.

Grades range from 0 to 4:

Grade 0: No hair loss

Grade 1: <25% hair loss

Grade 2: 25% to 50% hair loss

Grade 3: 50% to 75% hair loss

Grade 4: >75% hair loss

LUDWIG SCALE

Used to classify female pattern hair loss.

Grades:

I: Minimal thinning on the crown

II: Moderate thinning with widening part

III: Severe thinning with sparse hair on the crown

WHO SCALE

Standardised alopecia grading for clinical trials and dermatological assessments.

Typically uses Grade 0–3:

0: No hair loss

1: Mild thinning

2: Moderate hair loss

3: Complete or near-complete hair loss

Quality of Life Scales

EORTC QLQ-C30

European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30: A core, cancer-generic questionnaire used to measure overall quality of life. It covers physical, emotional, cognitive and social symptoms, as well as symptoms of the condition.

EORTC QLQ-BR23

Breast cancer specific module of the EORTC QLQ-C30: Used to assess breast cancer-related issues, including body image, sexual functioning, systemic therapy side effects and hair loss.

HADS SCORE

Hospital Anxiety and Depression Scale: A 14-item screening tool that measures psychological distress, specifically anxiety and depression. The higher the score in the subscale, the higher the rating for depression/anxiety.

BIS SCORE

Body Image Scale: Evaluates body image disturbance, often in cancer patients dealing with visible changes (hair loss, mastectomy, scars etc). Scoring ranges from 0-30, with higher scores indicating higher body image distress.

NPS SCORE

Numerical Pain Scale: A 0-10 pain rating scale where patients self-report the intensity of their pain, where 0 is equivalent to no pain, 10 is the worst pain possible.

CADS SCORE

Chemotherapy-Induced Alopecia Distress Scale: developed to assess the psychosocial impact of alopecia, primarily used in Korean studies.

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