The Paxman Cool Cap Systems can be your solution to prevent chemotherapy induced hairloss.
Features

• Available with one or two scalp cooling caps, which can be used independently

• Colour coded, lightweight silicone caps with insulating neoprene cap covers to ensure effective insulation of the cooling cap

• Caps available in a wide range of sizes to suit all varying individual patient head sizes

• The cap moulds to the shape and contours of the patient's head, improving chances of success

• Refrigeration unit compact in size for easy storage

• Touch screen visual display with system status graphics

• Simple switch operation, with no complicated programming and controls

UK observational study reports an **89% success rate** following use of the Paxman System in breast cancer patients, with **only 11% with severe hair loss** requiring wigs.

**Results**

**Alopecia prevention**

- Of patients receiving chemotherapy (n=94), grade 3 hair loss was observed in 5 patients and grade 4 hair loss in one patient (only 11% of patients required wigs).
- 5 /94 patients discontinued scalp cooling treatment
- Of patients receiving FEC specifically (n=62), grade 3 hair loss was observed in 2 patients and grade 4 hair loss in one patient (only 13% of patients required wigs)

**Patient comfort, acceptability and side effects**

Patients reported high comfort and acceptability levels with low numbers of withdrawals from scalp cooling

- 85% of patients reported they were comfortable, reasonably comfortable, or very comfortable during the scalp-cooling period.
- 12% of patients reported they were uncomfortable with an additional 3% very uncomfortable
- Only 5% of patients discontinued scalp cooling before the end of chemotherapy treatment, with discontinuation because of discomfort seen in one patient
- Headaches at some time during treatment cycles were reported in 32% of patients
Methods

- 94 breast cancer patients being treated with chemotherapy in the adjuvant or palliative setting
- Open, non-randomised, observational study conducted at 8 UK sites between 1997 - 2000
- Chemotherapy regimens include:
  - Epirubicin (60 – 75 mg/m2) regimens as monotherapy (10 patients) or the FEC combination therapy regimen used 1997-2000 (62 patients)
  - Doxorubicin as monotherapy or combination administered to 11 patients (doses ranging from 30 - 60 mg/m2)
  - Docetaxel single agent (75 – 100 mg/m2) (n=5) CMF** (n=5)
- Scalp cooling times:
  - Pre-infusion cooling time of 15-20 minutes
  - Cooling was maintained during the infusion period
  - Post-infusion cooling time of 120 mins for majority of patients
  - Hair loss graded according to criteria in table below

<table>
<thead>
<tr>
<th>Hair Loss Grade</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No significant hair loss</td>
</tr>
<tr>
<td>Grade 1</td>
<td>Minor hair loss not requiring wig</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Moderate hair loss but not requiring wig</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Severe hair loss requiring a wig</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Total alopecia</td>
</tr>
</tbody>
</table>

Patient age range 28 – 61 years, mean age 44
Patients completed questionnaires related to comfort and acceptability of scalp cooling

For full details of this study please contact Paxman at: info@paxman-coolers.com or +44 (0) 1484 349 444
Norwegian observational study reports a 92% success rate following use of the Paxman System in 54 breast cancer patients treated with FEC/FAC or paclitaxel.

Results

Hair loss

Evaluation of Hair Loss - All Patients

- Authors concluded that scalp cooling is an effective method for avoiding alopecia in patients receiving FEC or weekly paclitaxel

Patient comfort, acceptability and side effects

89% of patients described scalp cooling as acceptable, with minimal discomfort caused by the longer treatment period.

- Only 15% of patients considered coldness to be a major problem
- Only 2% of patients considered headaches to be a major problem
- One patient discontinued treatment because of discomfort
Methods

- 54 breast cancer patients being treated with chemotherapy in the neo-adjuvant, adjuvant or palliative settings in single Norwegian centre between 2000 - 2001

Chemotherapy regimens:
- FEC*/FAC - epirubicin (60 mg/m2)
- Weekly paclitaxel (P) (90 mg/m2)

Scalp cooling times:
- Pre-infusion cooling time
  - FEC/FAC: median 20 mins (range 15-150 mins)
  - P: median 20 mins (range 15 – 120 mins)
- Cooling was maintained during the infusion period

Post-infusion cooling time
- FEC/FAC: median 120 mins (range 120 -150 mins)
- P: median 60 mins (range 60 – 120 mins)

- Patient age range 28 – 61 years, mean age 44
- Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse

*FEC - 5-fluorouracil, epirubicin and cyclophosphamide
*FAC - 5-fluorouracil, adriamycin and cyclophosphamide
** CMF - Cyclophosphamide, methotrexate, 5-fluorouracil

For full details of this study please contact Paxman at: info@paxman-coolers.com or +44 (0) 1484 349 444
Randomised study in the Netherlands shows that a reduction in scalp cooling time to 45 minutes, did not reduce the effectiveness of the PSCS in preventing hair loss in docetaxel treated cancer patients.

Results

Head cover or wig prevention

No head cover or wig required in 88% of patients following 45 mins post-infusion cooling after 3-weekly docetaxel, compared with 74% after 90 mins post-infusion cooling.

Tolerance

Headaches were only reported in 20% of patients, with only 5% of patients discontinuing scalp cooling.

- Visual analogue scale (VAS): mean score = 69 (0 = bad, 100 = good)
- Headache: 80% no headaches; 13% mild headache and 7% moderate / severe headache
- 5% of patients discontinued scalp cooling because of intolerance
Methods

- Trial involving 166 cancer patients from 11 hospitals in the Netherlands, carried out in 2 phases, to determine the effectiveness and tolerance of scalp cooling.

Chemotherapy regimens:

- 3-weekly docetaxel (75 mg/m² or 100 mg/m²)

Scalp cooling times:

- Pre-infusion cooling time 30 mins
- Cooling was maintained during the infusion period
- Post-infusion cooling time: Phase I: 90 mins; Phase II: 90 mins vs 45 mins
- Phase I = non-randomised; phase II randomised
- Effectiveness based on whether patient required head cover or wig

Patients:

- Age range 35-79 years, mean age 44
- Docetaxel 75 mg/m² (39%); 100 mg/m² (61%) 36% male
- Breast cancer (49%), prostate cancer (33%), lung carcinoma (23%)
- Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse
- Tolerance of scalp cooling determined

For full details of this study please contact Paxman at: info@paxman-coolers.com or +44 (0) 1484 349 444
Observational study of scalp cooling in the Netherlands reports a mean success rate of 48% in 1122 patients treated with chemotherapy for a range of different cancer types.

- Scalp cooling has been widely used in routine clinical practice in The Netherlands and most hospitals participate in registration of results.
- Results for 13 different chemotherapy regimens with more than 10 patients up to 2010 are reported.
- The method of scalp cooling is not specified.

Results

- Success rates (no wig or head cover required) varied according to regimen.
- Mean success rate of 48% (range 8 – 80%)*

<table>
<thead>
<tr>
<th>Drug Chemotherapy Regimen</th>
<th>Number Patients</th>
<th>% No Wig or Head Cover</th>
</tr>
</thead>
<tbody>
<tr>
<td>A60C</td>
<td>74</td>
<td>39</td>
</tr>
<tr>
<td>FA50C</td>
<td>38</td>
<td>55</td>
</tr>
<tr>
<td>FE50C</td>
<td>12</td>
<td>67</td>
</tr>
<tr>
<td>F90C</td>
<td>553</td>
<td>52</td>
</tr>
<tr>
<td>FE100CD100</td>
<td>44</td>
<td>48</td>
</tr>
<tr>
<td>FE100C</td>
<td>123</td>
<td>33</td>
</tr>
<tr>
<td>P175 Carboplatin</td>
<td>45</td>
<td>36</td>
</tr>
<tr>
<td>D75 combinations</td>
<td>59</td>
<td>80</td>
</tr>
<tr>
<td>D100 combinations</td>
<td>42</td>
<td>60</td>
</tr>
<tr>
<td>ACT80H</td>
<td>29</td>
<td>48</td>
</tr>
<tr>
<td>ACT175H</td>
<td>21</td>
<td>29</td>
</tr>
<tr>
<td>ACD100H</td>
<td>16</td>
<td>63</td>
</tr>
<tr>
<td>DAC</td>
<td>66</td>
<td>8</td>
</tr>
</tbody>
</table>

A = adriamycin; C = cyclophosphamide; F = 5-fluorouracil; E = epirubicin; D = docetaxel; P = paclitaxel; H = herceptin

*Please Note –The Dutch study was carried out more recently than the UK and Norwegian studies, and since in general higher doses of chemotherapy may have been used in recent years, this may explain the difference in results (success rates) observed.
Overall Summary of effectiveness and tolerance of the Paxman Scalp Cooling System

• Three independent observational studies have demonstrated the 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, even when post-infusion cooling extended for 2.5 hours

For full details of this study please contact Paxman at: info@paxman-coolers.com or +44 (0) 1484 349 444
### Benefits of Paxman Scalp Cooling System vs Gel Cap System

<table>
<thead>
<tr>
<th>Feature</th>
<th>Paxman System</th>
<th>Gel Cap System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature control</td>
<td>Maintains a constant temperature throughout treatment</td>
<td>None - large fluctuations throughout treatment</td>
</tr>
<tr>
<td>Cap sizes</td>
<td>5 - to cater for various head sizes</td>
<td>One size only</td>
</tr>
<tr>
<td>Weight of caps</td>
<td>Lightweight</td>
<td>Heavy</td>
</tr>
<tr>
<td>Cap changes</td>
<td>None, with any drug regimen</td>
<td>Many / Frequent on all drug regimen</td>
</tr>
<tr>
<td>Cap reusability</td>
<td>Immediately reusable after treatment</td>
<td>Only single use once every 24 hours</td>
</tr>
<tr>
<td>Cap life expectancy</td>
<td>3 years average</td>
<td>Limited -12/18 months</td>
</tr>
<tr>
<td>Nursing time supervision</td>
<td>Minimal throughout treatment period</td>
<td>High demand required throughout treatment period</td>
</tr>
<tr>
<td>Mobility of system</td>
<td>Totally mobile - can be located in any treatment area within the hospital</td>
<td>Limited - within reasonable access of freezer</td>
</tr>
<tr>
<td>Mobility of patients</td>
<td>Limited - but not patient movement</td>
<td>Unrestricted - but have to be available for cap changes</td>
</tr>
<tr>
<td>Additional equipment</td>
<td>None required</td>
<td>At least one freezer</td>
</tr>
</tbody>
</table>
Patient Testimonials

The absolute worst part of cancer treatment for me was the thought of losing my hair. When the Oncologist suggested trying the scalp cooling cap I agreed immediately. I am so glad I did. I had my final chemotherapy session last week and still have a full head of shoulder-length blonde hair. In addition, my hair actually grew two inches, appears thick and glossy and is in far better condition than when I started! I was very gentle with my hair during treatment and did adhere to the tips provided such as using PH neutral shampoo, not using any hair products, sleeping on a silk pillowcase and not using the hair drier, straighteners or heated rollers.

Not losing my hair has made a vast difference to my recovery. I think that because I did not look ill, I didn’t feel so ill and have remained positive throughout. I cannot praise the Paxman scalp cooling cap enough and would definitely recommend it to anyone who would prefer to keep their hair during chemotherapy treatment.

Kind regards
Paula from Suffolk

I underwent chemotherapy after a lumpectomy for breast cancer. I am at last writing to you to praise the scalp cooler machine that The Chiltern Hospital, Great Missenden had installed a short time before my treatment. I followed your instructions to the letter and would suggest I lost no more hair than normal. Consequently, I felt more able to cope with other effects of the treatment; having kept my hair was a great psychological boost.

I am attaching a photograph taken just after my 6th and final session of chemotherapy.

Thank you to your technicians for the development of such a successful piece of equipment.

Yours sincerely,
Liz Wyatt
## Recommended Cooling Times

<table>
<thead>
<tr>
<th>Drug Regimen</th>
<th>Minimum Recommended Pre-Cooling Time</th>
<th>Infusion Time</th>
<th>Minimum Recommended Post infusion cooling time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FEC (Epi 60mg/m²)</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>1 - 1½ hours</td>
</tr>
<tr>
<td><strong>FEC (Epi 75mg-90mg/ m²)</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>1½ - 2 hours</td>
</tr>
<tr>
<td><strong>CMF</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>1 hour</td>
</tr>
<tr>
<td><strong>AC (Dox 60mg/ m²)</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>2½ hours</td>
</tr>
<tr>
<td><strong>MMM</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>2 hours</td>
</tr>
<tr>
<td><strong>Paclitaxel (Taxol) weekly (90mg/ m²)</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>2 hours</td>
</tr>
<tr>
<td><strong>Paclitaxel (Taxol) 3 weekly (175mg/ m²)</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>45 mins</td>
</tr>
<tr>
<td><strong>Docetaxel (Taxotere) (100mg/ m²)</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>1½ hours</td>
</tr>
<tr>
<td><strong>Irinotecan (Campto) (350mg/ m²)</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>2 hours</td>
</tr>
<tr>
<td><strong>Etoposide</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>1 hour</td>
</tr>
<tr>
<td><strong>Epirubicin single agent and combinations 60 mg/ m²</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>1 - 1½ hours</td>
</tr>
<tr>
<td><strong>75mg/ m²</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>1½ - 2 hours</td>
</tr>
<tr>
<td><strong>90mg/ m²</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>2 hours</td>
</tr>
<tr>
<td><strong>&gt;100mg/ m²</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>2 hours</td>
</tr>
<tr>
<td><strong>Doxorubicin single agent and combinations &lt;60mg/ m²</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>1 hour</td>
</tr>
<tr>
<td><strong>60-75mg/ m²</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>2 hours</td>
</tr>
<tr>
<td><strong>80-90mg/ m²</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>2 hours</td>
</tr>
<tr>
<td><strong>&gt;100mg/ m²</strong></td>
<td>30 mins</td>
<td>Time to infuse drugs</td>
<td>2 hours</td>
</tr>
</tbody>
</table>

Recommendations for post infusion cooling times are based on peak plasma concentrations, drug half life, potential interactions, recent trials and the experience of current users of the Paxman Scalp. The docetaxel post-infusion cooling time was based on a randomised comparative study.

It is recommended that patient’s hair is dampened with water, and hair conditioner (ph neutral) is applied to improve scalp contact and reduce the insulation effect of hair.

Where liver function and metabolism of the cytotoxic agent is impaired, scalp cooling may be less effective.

Results with Afro-Caribbean hair are less successful, and it is advisable to increase cooling times by ½ to 1 hour.

The Dutch Scalp Cooling Group are conducting future research to determine optimal cooling times for various chemotherapy regimens.
Warnings and Contraindications

Warnings

• Treatment success varies from patient to patient and with different drug regimens

• Patients cannot be guaranteed they will not lose any or all of their hair

• There is the possibility that some patients may experience headaches or feel cold during treatment

• Some patients may experience light-headedness after the cooling cap has been removed

Contraindications

• Haematological malignancies (leukaemia and other bone marrow malignancies or generalized lymphomas).

• Cold allergy

• Cold agglutinins

• Presence of scalp metastases

• Imminent bone marrow ablation chemotherapy

• Imminent skull irradiation

References

1. Massey SM. A multicentre study to determine the efficacy and patient acceptability of the Paxman Scalp Cooler to prevent hair loss in patients receiving chemotherapy. Eur J Oncol Nursing; 8: 121-130, 2004


4. Van den Hurk CJG, personal communication; publication in preparation