

Leading the Way in Scalp Cooling Innovation

Pivotal Trial
The DigniCap® Scalp Cooling System

Clinical Study in Stage I And II Breast Cancer

As Published

Association Between Use of a Scalp Cooling Device and Alopecia After Chemotherapy for Breast Cancer
Journal of the American Medical Association (2017;317(6):606-614)
Rugo, H, et al.

Key Findings

The DigniCap Scalp Cooling System prevented hair loss in 66.3% of patients with breast cancer receiving adjuvant chemotherapy, compared to a control group where all patients experienced significant hair loss. Scalp cooling treatment was well-tolerated and no scalp metastases have been observed.

66.3%
of patients using scalp cooling
retained ≥ 50% of their hair.

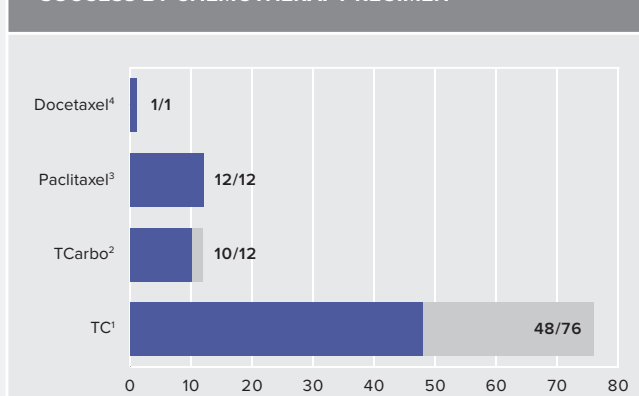
Objective and Method

In a randomized trial, The DigniCap Scalp Cooling System was assessed to determine if the use of scalp cooling was effective in minimizing chemotherapy-induced alopecia in women with breast cancer. The average age of the women was 53.0 years (range 28 -77); 77.4% were White, 10.4% were Black and 9.4% were Asian. The study was conducted at 5 leading cancer centers in the United States. All patients either had Stage I or Stage II breast cancer and underwent at least four cycles of specific chemotherapy regimens. Sixteen women did not use scalp cooling, while 101 patients used scalp cooling. Patients were evaluated 4 weeks after their last chemotherapy session. Results were self-estimated using the Dean scale. A Dean scale score of 0 to 2 (≤ 50% hair loss) was considered treatment success.

Chemotherapy Regimens in Treatment and Control Groups

CHEMOTHERAPY REGIMENS & DOSE	DigniCap N (%)	Controls N (%)
Totals	101	16
Docetaxel 75 mg/m ² & cyclophosphamide 600 mg/m ² every 3 weeks or 4-6 cycles	76 (75%)	10 (62.5%)
Paclitaxel 80 mg/m ² weekly for 12 cycles	12 (12%)	2 (12.5%)
Docetaxel 75 mg/m ² , carboplatin AUC 6 for 6 cycles every 3 weeks, trastuzumab weekly or every 3 weeks, with or without pertuzumab every 3 weeks	12 (12%)	3 (19%)
Docetaxel 75 mg/m ² , trastuzumab & pertuzumab every 3 weeks for 6 cycles	1 (1%)	0
Doxorubicin 60 mg/m ² & cyclophosphamide 600 mg/m ² every 3 weeks for 4 cycles	0	1 (6%)

SUCCESS BY CHEMOTHERAPY REGIMEN



Dignitana – Scalp Cooling Leader

In 2015, DigniCap was the first scalp cooling system to receive FDA clearance in the United States. In 2017, DigniCap received expanded clearance for men and women with solid tumors.

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Patient Satisfaction

Patients in the study filled out an Alopecia Self-Report questionnaire. Results clearly showed that 101 patients who had an average of 3.6 cycles of chemotherapy and used The DigniCap Scalp Cooling System were satisfied with the decision to use scalp cooling and expressed higher satisfaction with their hair quantity as compared to controls.

In contrast, the 16 patients in the control group had an average of 1.5 cycles before discontinuing reporting due to hair loss.

Quality of Life

Women with breast cancer receiving scalp cooling using DigniCap versus the control during chemotherapy:

- Were significantly less likely to lose $\geq 50\%$ of their hair
- Felt significantly more physically attractive
- Were significantly less dissatisfied with their appearance when dressed
- Regarded the importance of hair significantly more

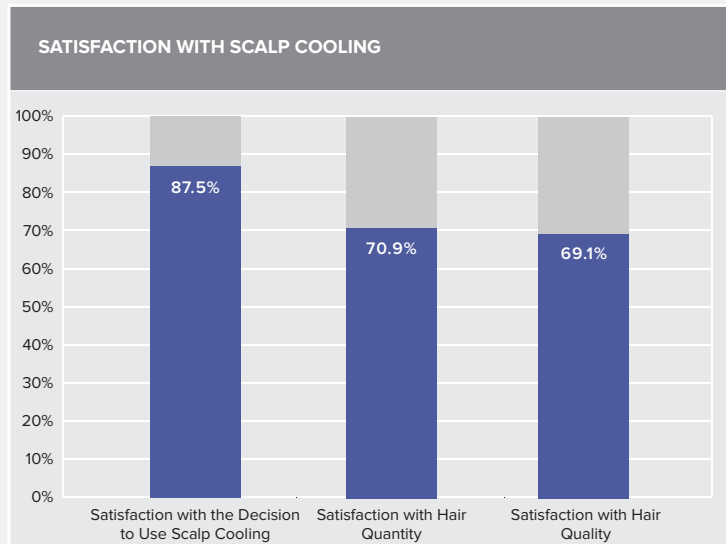
Conclusions

- The DigniCap System is highly effective in reducing chemotherapy-induced alopecia with clinically meaningful benefit.
- The DigniCap System prevented hair loss in 66.3% of patients with breast cancer receiving neo/ adjuvant chemotherapy, compared to the control where all patients experienced significant hair loss.
- Treatment was safe and well tolerated.

Long Term Safety Follow-Up

- 91 patients have follow-up out to 3 years.
- Scalp cooling using The DigniCap Scalp Cooling System in patients with early stage breast cancer receiving taxane based neo/adjuvant chemotherapy is safe and effective.
- 4 year follow-up data collection is still ongoing.

Patient Satisfaction with Using Scalp Cooling



Thank you to the patients and investigators who participated in this trial.

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Wake Forest Baptist Medical Center, Winston-Salem, NC
Weill Cornell Breast Cancer Center, New York, NY
Mount Sinai Chelsea Comprehensive Cancer Center, New York, NY
UCLA Jonsson Comprehensive Cancer Center, Santa Monica, CA*

Read More

"Association Between Use of a Scalp Cooling Device and Alopecia After Chemotherapy for Breast Cancer" JAMA (2017;317(6):606-614) Rugo, H, et al.

"Body image in women with breast cancer using a scalp cooling system to reduce chemotherapy induced alopecia." SABCS Abstract, December 2016 Cigler, T, et al.

"Long-term Safety Follow-Up of Patients with Early Stage Breast Cancer Treated with Scalp Cooling on the Dignitana Scalp Cooling Trial" SABCS Abstract, December 2018 Rugo, H, et al.

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