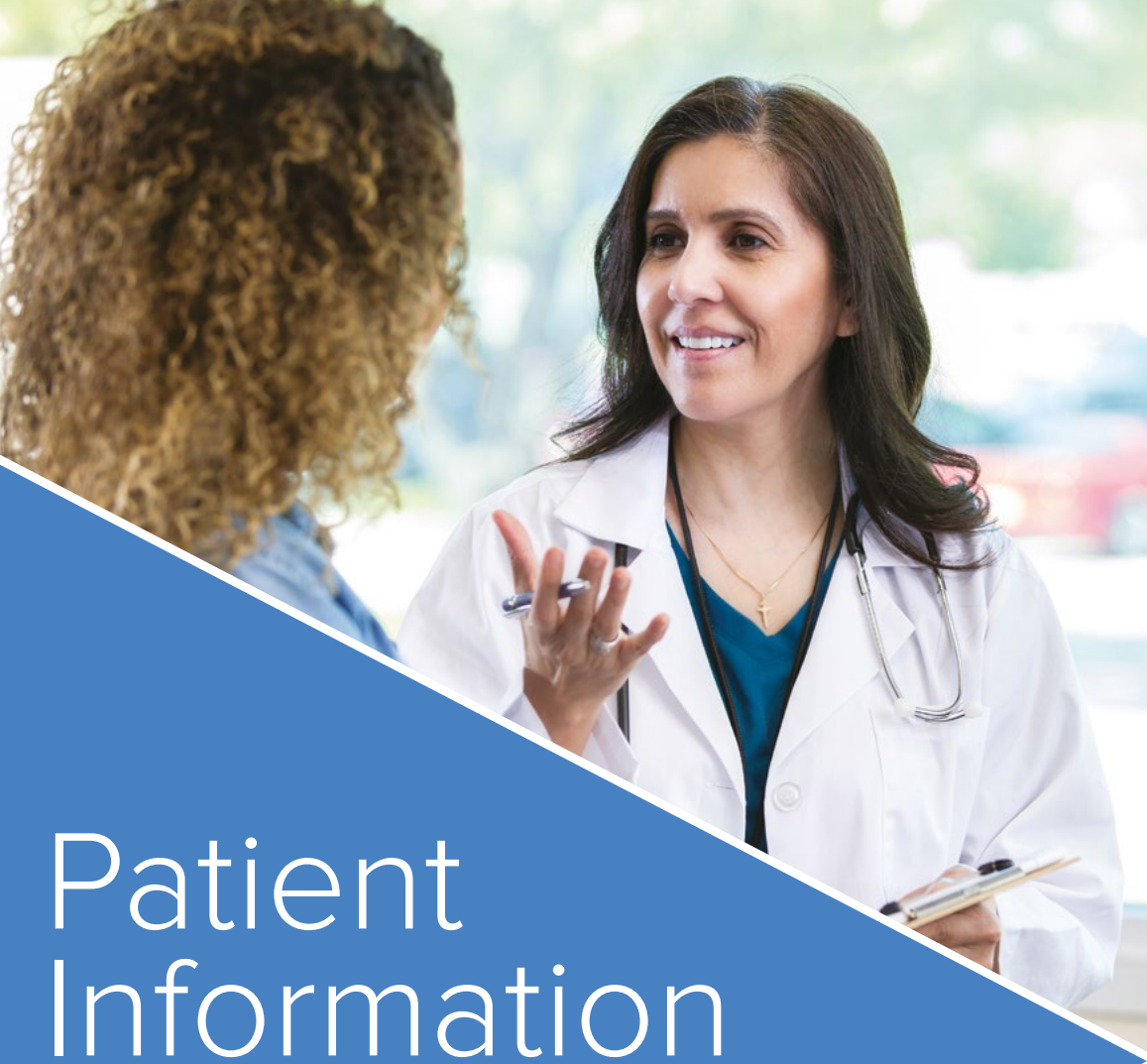

Patient Information

Scalp Cooling with DigniCap Delta®

FDA cleared for patients with solid tumors undergoing chemotherapy

DIGNICAP®

Hair loss is no longer inevitable

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Hair loss is a common side effect of many chemotherapy drugs. The DigniCap® Scalp Cooling System minimizes hair loss from certain chemotherapy treatments for men and women with solid tumors such as those associated with breast, prostate, ovarian, uterine, and other tissues.

The DigniCap Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced hair loss in cancer patients with solid tumors.

DIGNICAP DELTA®

Scalp Cooling Historical Timeline

1970s — First known use of manual gel caps for scalp cooling

1996 — DigniCap invented in Sweden by nurse Yvonne Olofsson

2001 — DigniCap available in Europe

2009 — Dignitana publicly traded in Sweden

2010 — DigniCap registered in Mexico, Russia and South Korea

2011 — DigniCap registered in Canada and Colombia

2012 — DigniCap registered in Australia and Singapore

2013–2014 — DigniCap US multi-center clinical trial

2015 — DigniCap study presented at ASCO; DigniCap received FDA clearance for women with breast cancer

2016 — Quality of Life data from DigniCap study presented at SABCS

2017 — DigniCap available in Middle East

2017 — DigniCap study published in JAMA; DigniCap received expanded FDA clearance for men and women with solid tumors

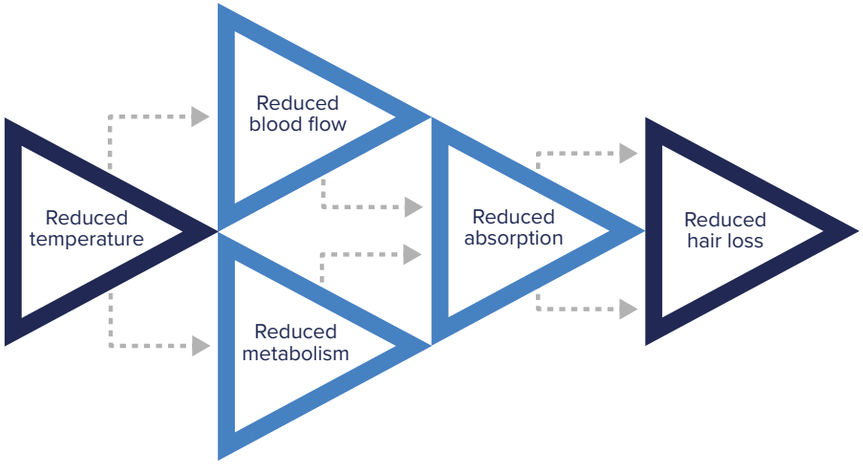
2019 — DigniCap Delta received FDA clearance and CE Mark

What Is Scalp Cooling?

Some chemotherapy drugs can damage your hair. Scalp cooling is a proven approach to reduce chemotherapy-induced hair loss. It has been used successfully by thousands of cancer patients worldwide.

Two reactions occur during scalp cooling:

1. **Reduced blood flow** – Vasoconstriction in the scalp area limits the amount of chemotherapy agent delivered to the hair follicles.
2. **Reduced metabolism** – Lower scalp temperature decreases the reaction rate causing normal cellular activity in the localized scalp area to slow dramatically.

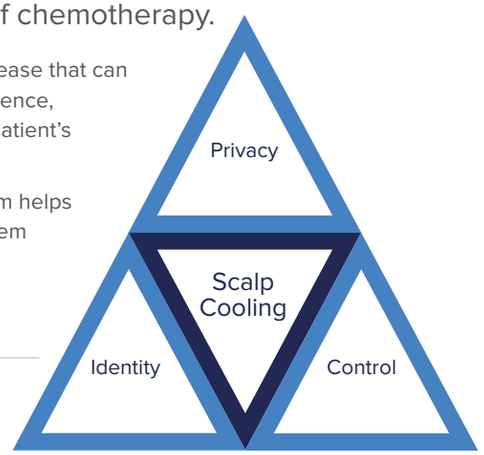


Why Scalp Cooling Matters

Many cancer patients rate hair loss as one of the most devastating side effects of chemotherapy.

It is an unwelcome reminder of disease that can negatively affect self-image, confidence, overall sense of well-being and a patient's attitude toward treatment.

The DigniCap Scalp Cooling System helps patients maintain privacy, self-esteem and control during a critical period of treatment.



My DigniCap Story - *by Donna Tookes, Stamford, CT*

My hair has always been my "signature" feature, ever since I turned prematurely silver at age 25, so when I was diagnosed with cancer at age 59, I was devastated. I knew chemotherapy meant my hair would inevitably fall out. I walked out of the room when the doctors told me. I felt dizzy, weak at the knees, because I just envisioned myself very skinny with no hair, going through chemo.

With the use of the cap, I was able to keep my hair and could choose to stay more private about my battle with cancer. I didn't have to walk into the grocery store and have to explain what I was going through to the same people who had complimented me on my beautiful hair for so many years. I still looked like myself. For some women, losing their hair is a badge of courage, but for me it was a very big issue. I'm so grateful to DigniCap.

The DigniCap Scalp Cooling System

DigniCap Delta consists of a computerized cooling unit and a Cooling Wrap with temperature regulated coolant continuously circulating through specially designed channels. A Thermal Cap provides insulation and ensures the wrap is in close contact with the head.

The ability to maintain continuous, direct contact between the Cooling Wrap and the scalp for a consistent treatment temperature is a key factor in the effectiveness of DigniCap.

System Features

- System maintains a constant and controlled temperature during the entire treatment period
- Gradual cool down from room temperature provides patient comfort
- Touch screen interface simplifies operation and allows settings to be altered for various chemotherapy regimens

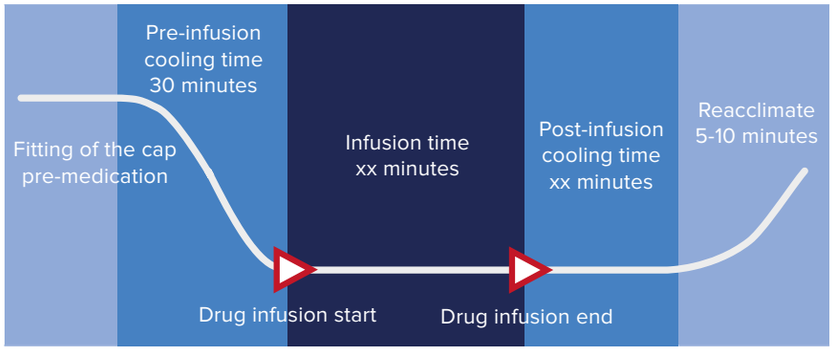
Cap Features

- Single patient use Cooling Wrap and Thermal Cap
- Cap can easily be detached from the cooling unit for restroom breaks
- Inner Cooling Wrap designed for a custom fit
- Outer Thermal Cap maintains direct contact and provides insulation for the ideal treatment temperature

What to Expect During Treatment with DigniCap

DigniCap will be used during each cycle on the day of chemotherapy administration. The Cooling Wrap is connected to the cooling and control unit, so you will need to be connected to the system during treatment. The caps may be disconnected from the system for brief restroom visits. During the break, the Cooling Wrap and Thermal Cap remain on your head.

DigniCap Treatment Cycle



Following the infusion the chemotherapy agent is still active in the bloodstream. Therefore, the scalp cooling treatment continues for a cycle of post-infusion cooling. Depending on drug and dose, this will typically last between 90-180 minutes.

Preparing for Your First Treatment

myDigniCap Patient Portal

The myDigniCap Patient Portal is a convenient place for you to connect with us directly, review your account and share your experience.

As soon as you have scheduled your first chemotherapy appointment, visit mydignicap.com to create your account and purchase a DeltaKit.

Treatment on DigniCap Delta is activated by a DeltaCard and each DigniCap treatment requires a new card. Depending on your provider, you will either purchase cards through myDigniCap or directly from your facility.

Before Your First Treatment

It is important for you to watch the training video located at dignicap.com/patient.

Watch the video several times until you are familiar with the capping process.

Visit mydignicap.com and the DigniCap Patient Support Center for any questions.

Hair Care Recommendations

Recommendations to minimize hair loss during chemotherapy in conjunction with scalp cooling:

- Wash your hair at home prior to scalp cooling/chemotherapy treatments as oily hair may affect the thermal contact. Do not use conditioner on the morning of treatment.
- Wash your hair no more than twice per week.
- Comb your hair with a wide tooth comb or detangling brush twice per day. Always comb your hair before washing to prevent tangles and matting.

- Let your hair dry naturally as much as possible. Avoid using heat tools, such as hair dryers, curling irons, straightening irons, and hot rollers.
- Avoid harsh chemicals that can lead to dry hair, breakage, progressive hair thinning and hair loss.
- Most patients will experience a heavy shedding phase roughly 14-21 days from the first chemotherapy treatment.
- Review the detailed Hair Care Recommendations which can be found in the Patient Guide in your DeltaKit or online at dignicap.com/hair-care.

Share Your Story

Knowing you are not alone in your fight with cancer can be a great source of strength. You may find it liberating to document your journey, and your story may also help inspire others as they face their toughest challenge. Share your story with us at dignicap.com/share

After Chemotherapy

Share your experience with scalp cooling and insurance at scalpcoolingsurvey.org

My DigniCap Story - *by Angela Farino, Irvine, CA*

I had injured my chest last fall when I was in a car accident, but the last thing in the world I expected was a cancer diagnosis. The medical staff was examining the area during an ultrasound when they discovered a tiny lump in my breast that turned out to be cancer.

I started a regimen of surgery, radiation and chemotherapy right away. I wanted to keep my treatment private, but I knew that chemo would cause the telltale sign of hair loss. I heard that DigniCap had been successfully used on cancer patients in Europe for more than ten years and joined UCLA's clinical trial at the Jonsson Comprehensive Cancer Center.

During the process, I tolerated the scalp cooling very well, and my body was kept warm with an electric blanket.

Accepting the fact that I was going to lose my hair was very difficult because I felt as if I would be losing part of my identity. With the DigniCap, it allowed me to have control over something in a process where I really had no control.

Frequently Asked Questions

Why does chemo cause hair loss?

Chemotherapy affects cells that are in the phase of division or growth. All the cells in the body may be affected by chemotherapy, not just the cancer cells. This means that even healthy cells, especially cells with a high growth rate, such as your hair, are likely to be affected by the chemotherapy.

When would I use The DigniCap Scalp Cooling System?

The DigniCap Scalp Cooling System will be used during each cycle of chemotherapy administration. Scalp cooling should begin with the first infusion of any chemotherapy that causes hair loss.

Will scalp cooling work for me?

Scalp cooling is an effective method for reducing the risk of chemotherapy-induced hair loss in men and women with solid tumors. The outcome is dependent on several factors including the chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism and other medical considerations.

Patients experience varying amounts of hair loss while undergoing scalp cooling treatments. We recommend continuing with scalp cooling even if you experience more hair loss than anticipated. Many patients have experienced regrowth while still undergoing chemotherapy with scalp cooling. New growth will continue to be protected if scalp cooling is continued.

Scalp cooling has been evaluated mainly with regimens including taxanes (such as paclitaxel and docetaxel) anthracyclines (such as doxorubicin and epirubicin) and alkylating agents (such as cytoxan and carboplatin). It's not always possible to know how effective the scalp cooling outcome will be until you try it. The effectiveness of scalp cooling with chemotherapy regimens that include sequential anthracycline and taxane chemotherapy in the same infusion day have not been well studied.

Your clinician can tell you if scalp cooling is compatible and likely to be successful with your treatment.

How long does scalp cooling treatment last?

The DigniCap Scalp Cooling System is operated by hospital personnel and will be used during each chemotherapy session. Scalp cooling begins approximately 30-minutes before chemotherapy starts, continues during the infusion and for a set period after the conclusion of treatment. Depending on the chemotherapy drug and dose, post-infusion cooling is typically 90–180 minutes. After completion of the post-infusion cooling time, the cooling cap remains on your head for another 5-10 minutes while you re-acclimate to room temperature.

How does it feel?

Most patients tolerate scalp cooling very well. Common side effects include a feeling of coldness, headache, scalp pain and/or light-headedness. Your doctor can provide a pain reliever if you develop a headache. A warm drink and blanket can also help during treatments.

What should I bring with me to the infusion center on the day of the scalp cooling treatment?

Your clinician can best tell you what you should bring on the day of the treatment. Suggestions are included in the Patient Guide included in the DeltaKit.

Do I need a wig or head covering?

The goal of scalp cooling is to reduce overall hair loss so that a wig, cap, scarf or other head covering is not needed. Any added stress or friction on the scalp and hair follicles may affect the outcome of treatment. However, the use of a wig or head covering may be desirable for reasons other than hair loss. For example, changes in hair color, texture and quality, or for patients experiencing patchy hair loss or thinning.

Some patients have found that wearing a wig causes additional heat and friction on the scalp. If you want to preserve the option to use a wig, you may wish to have a wig fitting before you start scalp cooling treatment to minimize friction on the scalp and hair follicles.

How should I take care of my hair?

Scalp cooling can minimize hair loss during chemotherapy, but chemotherapy could cause scalp irritation, making the hair dry, brittle and more difficult to manage. For detailed hair care recommendations visit dignicap.com/hair-care.

In addition to decreasing hair loss, are there any other advantages to using The DigniCap Scalp Cooling System?

Scalp itching and scaly rash has been shown to be decreased by up to 70% in patients using The DigniCap Scalp Cooling System.

There is evidence that hair regrowth may occur faster if The DigniCap Scalp Cooling System is used.

Pivotal Trial – Summary of Clinical Study in Stage I and II Breast Cancer and Published Literature Experience

Study Design

A clinical study comparing hair loss in 117 breast cancer patients who used and did not use The DigniCap Scalp Cooling System was performed. All patients had either Stage I or Stage II breast cancer and underwent at least 4 cycles of specific chemotherapy regimens. Sixteen of these women did not use the scalp cooling system and 101 patients used scalp cooling.

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 most common chemotherapy regimen was docetaxel/cyclophosphamide for 4-6 cycles (75%, 76 of 89 for 4 cycles), with additional regimens including docetaxel/carboplatin (12%), weekly paclitaxel (12%), and docetaxel (1%). Docetaxel/carboplatin and docetaxel were given with HER2-targeted therapy.

The purpose of this study was to understand how well scalp cooling reduced hair loss. The women in the study evaluated hair loss by comparing before and after photographs of their hair using the Dean Scale.

Dean Scale:

- Grade 0: no hair loss
- Grade 1: > 0 up to 25% hair loss
- Grade 2: > 25 up to 50% hair loss
- Grade 3: > 50 up to 75% hair loss
- Grade 4: > 75% hair loss

Success was defined as a maximum Dean score of ≤ 2 using standardized photographs graded by the patient up to 4 weeks after the last chemotherapy treatment.

Patient satisfaction with using scalp cooling and Quality of Life and Body Image was evaluated with self-reported questionnaires.

Alopecia Self-Report Maximum Dean Score (Evaluable Population)

Dean Score	Patients using DigniCap	Control patients
N	101	16
0 (No Hair Loss)	5 (5.0%)	0 (0.0%)
1 (>0 up to 25% Hair Loss)	31 (30.7%)	0 (0.0%)
2 (>25% up to 50% Hair Loss)	31 (30.7%)	0 (0.0%)
3 (>50 up to 75% Hair Loss)	19 (18.8%)	1 (6.3%)
4 (Greater than 75% Hair Loss)	15 (14.9%)	15 (93.8%)

Of the 101 women in the study who used The DigniCap Scalp Cooling System 67 women (66.3%) lost less than half of their hair, when followed for a month after the last chemotherapy cycle. In comparison all women in the control group lost more than half of their hair.

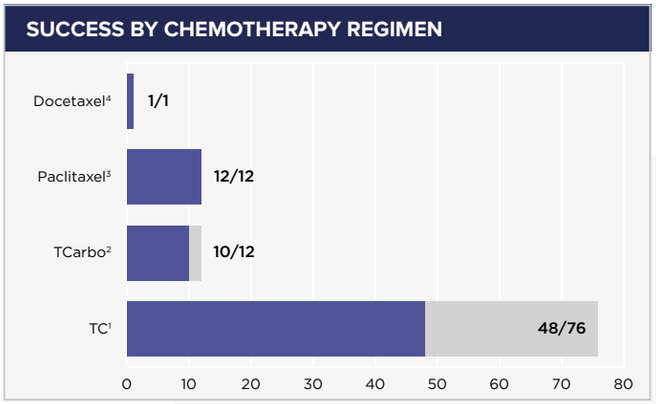
Reduced hair loss was also analyzed by chemotherapy regimen. In patients who used The DigniCap Scalp Cooling System, success was documented in 83.3% (p=0.022) of patients receiving docetaxel/carboplatin, 60.5% (p<0.001) of those treated with docetaxel/cyclophosphamide, and 83.3% (p=0.066) of patients treated with a taxane alone. Success rate did not differ when analyzed by hair thickness, history of previous chemotherapy, median age, median body mass index, use of prior hormone replacement therapy, and menopausal status. At one month after the last chemotherapy treatment, almost half of the women who had used The DigniCap Scalp Cooling System reported that they never used a wig, cap, scarf or other head cover due to hair loss.

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 and hair quality as compared to controls. The patient reported satisfaction score (0 to 100), showed a mean score of 87.5 satisfaction with the decision to use scalp cooling, a mean score of 70.9 for hair quantity and a mean score of 69.1 for satisfaction with hair quality.

In patients using The DigniCap Scalp Cooling System, the Alopecia Self-Report questionnaire results showed thick hair in a mean 0.7 study cycles and no change in hair texture in 1.8 study cycles.

In contrast, the 16 patients in the control group had an average of 1.5 cycles before discontinuing reporting due to hair loss. Patient reported satisfaction score (0 to 100) of 25.6 for hair quantity, and a mean score of 37.6 satisfaction with hair quality. Alopecia Self-Report results indicated 0.9 cycles with no significant change in hair texture.



1. TC: Docetaxel/ cyclophosphamide x 4-6
2. TCarbo: Docetaxel/ carboplatin + HER2 targeted therapy x 4-6
3. Paclitaxel: Paclitaxel weekly x 12
4. Docetaxel + HER2 targeted therapy x 4-6

Quality Of Life And Body Image

Compared to patients who used The DigniCap Scalp Cooling System, a greater number of patients in the control group had dry mouth, different than usual taste in food and drink, eyes were painful, irritated or watery, lost hair, upset at hair loss, felt ill or unwell, had hot flushes, had headaches, felt physically less attractive or less feminine due to the disease or treatment from baseline at the last cycle of chemotherapy and the one month follow-up.

Women who used The DigniCap Scalp Cooling System agreed strongly that hair is important for appearance at the baseline (82.2%), last cycle of chemotherapy (80.2%) and one month follow-up (78.7%), while women in the control group agreed strongly that hair is important for appearance at the baseline (50.0%) and the last cycle of chemotherapy (50.0%) and 66.7% at one month follow-up.

Adverse Events

Six women reported 7 adverse reactions caused by The DigniCap Scalp Cooling System. These were headache (4 women), itchiness (1 woman), pain of skin (1 woman) and head discomfort (1 woman); none of these reactions were rated severe and one headache was the only reaction rated moderately severe and the rest were mild.

Three of 106 women discontinued use of scalp cooling because of cold discomfort, while 102 out of 106 women had a feeling of chilliness during the cooling down period.

Less than half of the women (43/106) reported that headaches were triggered or exacerbated by scalp cooling. Although headaches occurred, they were not reported at every cycle of scalp cooling.

Conclusion

Overall, The DigniCap Scalp Cooling System appeared to be safe and well tolerated with only mild discomfort associated with the scalp cooling and effective in reducing the likelihood of chemotherapy-induced alopecia.

Published Literature Experience

Methodology

The efficacy of scalp cooling with the DigniCap System has been reported in 18 clinical evaluations outside of the U.S. These studies investigated the effects of scalp cooling on the incidence of alopecia in patients with various malignancies using a variety of chemotherapy regimens in both the adjuvant and palliative settings. Efficacy has best been demonstrated in chemotherapy regimens containing docetaxel, paclitaxel, cyclophosphamide, and/or carboplatin. These studies did not have long term follow up, and were single armed non-randomized prospective studies. Long-term effects of scalp cooling and scalp metastasis have not been fully studied in the adjuvant setting outside of stage I and II breast cancer. It is not clear whether there is increased risk of recurrence, particularly scalp or skull metastases, based on the data available. Some of the studies did not list the names of the solid tumor malignancies or their frequencies.

A literature review was conducted to address the safety and effectiveness of the DigniCap device. A search in PubMed, EMBASE, Clinical Trial register and Manufacturer and User Facility Device Experience Database - (MAUDE) was performed using the following search terms: DigniCap, Digni and scalp, Digni and alopecia, Digni and hypothermia, and Dignitana. Abstracts and peer reviewed articles of clinical trials covering the majority of the relevance and methodology questions in the appraisal plan of the pivotal clinical trial clinical evaluation report were selected. Due to the literature review method and the design of these studies, safety and effectiveness results presented in these studies may not be accurate. Based on the above published data there is insufficient evidence to assess long term effect. Use of The DigniCap Scalp Cooling System in these patients may increase the risk of scalp metastasis, metastasis elsewhere in the body or impact the natural course of the disease.

Research Overview – Solid Tumors

As published in numerous academic journals, The DigniCap Scalp Cooling System has been shown to be safe and effective in reducing chemotherapy-induced alopecia in cancer patients with solid tumors.

Summary

Of 226 patients with various solid tumors and undergoing different chemotherapies 65% showed no visible hair loss. These findings directly correspond to the results of Rugo et al. study.

As Published

The influence of various parameters on the success of sensor-controlled scalp cooling in preventing chemotherapy-induced alopecia.
Oncology Research and Treatment (Vol. 38. 2015, 489-495)
Schaffrin-Nabe, D, et al.

Research Overview – Scalp Metastases

Metastasis occurs when cancer spreads to other parts of the body. Some patients have asked whether scalp cooling increases the chance of metastases in the scalp.

A study published in 2017 reviewed patients with breast cancer receiving chemotherapy while using scalp cooling for hair preservation and found there was no statistical difference in the incidence of scalp metastasis between patients using scalp cooling vs. no scalp cooling. The study concluded that “based on this extensive review and meta-analysis, scalp cooling is highly unlikely to increase the incidence of scalp metastases in patients with early-stage breast cancer receiving adjuvant chemotherapy.”

Summary

The incidence of scalp metastases was low regardless of scalp cooling. This analysis suggests that scalp cooling does not increase the incidence of scalp metastases.

As Published

Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systematic review and meta-analysis.
Breast Cancer Research and Treatment, 2017: 163:199–205
Rugo, H, et al.

Research Overview – Quality of Life

Minimizing hair loss helps patients to preserve personal identity and self-esteem and appear normal as opposed to sick. Protecting privacy and gaining the ability to choose whether to disclose a cancer diagnosis is significant to many patients. Additionally, scalp cooling patients gain a much needed sense of control in an otherwise overwhelming experience.

Summary

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

- Were significantly less likely to lose ≥ 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

As Published

Body image in women with breast cancer using a scalp cooling system to reduce chemotherapy-induced alopecia.
San Antonio Breast Cancer Symposium Abstract, December 2016
Cigler, T, et al.

Research Overview – Anthracyclines

An Italian study published in 2019 assessed the effectiveness of scalp cooling with DigniCap for patients receiving adjuvant chemotherapy with an anthracycline with or without taxanes.

Summary

The DigniCap System was able to prevent significant hair loss in 43% of breast cancer patients receiving adjuvant chemotherapy.

The study had a lower than expected dropout rate with only 7% discontinuation. Among the patients that continued, the success rate was 54%.

None of the patients who participated in the study using DigniCap developed scalp metastases after a mean follow-up of 2.4 years.

As Published

Preventing chemotherapy-induced alopecia: a prospective clinical trial on the efficacy and safety of a scalp-cooling system in early breast cancer patients treated with anthracyclines.
British Journal of Cancer (2019) 121:325-331
Munzone, E, et al.

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Considerations

Who should use and who should not use The DigniCap Scalp Cooling System?

Indication For Use

The DigniCap Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

Contraindications

The use of DigniCap is contraindicated in pediatric patients.

The use of DigniCap is contraindicated in adult patients with:

- Cold sensitivity
- Cold agglutinin disease
- Cryoglobulinemia
- Cryofibrinogenemia
- Cold urticaria
- CNS malignancies (either primary or metastatic)
- Squamous cell carcinoma of the lung
- Small cell carcinoma of the lung
- Cancers of the head and neck
- Skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma
- Hematological malignancies treated with curative intent by chemotherapy
- Solid tumor malignancies with a high likelihood of metastases in transit
- Patients who are scheduled for bone marrow ablation chemotherapy
- Patients who are scheduled to undergo skull irradiation
- Patients who have previously received skull irradiation

Warnings and Risks

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 cancers may be more likely to experience scalp metastases with the scalp cooling system.

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 in combination has not been shown to be successful in preventing chemotherapeutic drug induced alopecia. The DigniCap Scalp Cooling System should not be used in these patients.

Scalp radiation can cause stenosis of small cutaneous vessels decreasing device effectiveness.

The effectiveness of this device in patients who have received previous chemotherapy has not been evaluated.

The risk of scalp cooling may outweigh the benefits in patients receiving chemotherapeutic agents with low incidence of inducing alopecia.

Long-term effects of scalp cooling and risk of scalp metastasis have not been fully studied.

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 in spite of using scalp cooling might have worse quality of life than women who did not have scalp cooling.

There is a potential for cold injury, even when providing cooling within the prescribed treatment settings. Special care should be taken when applying the Cooling Wrap to ensure that there is no direct contact between a patient's exposed skin and the wrap's cooling surface. Individuals who experience any unusual swelling, skin discoloration or discomfort should immediately discontinue the use of the DigniCap System.

Adverse Events

Most patients tolerate scalp cooling with The DigniCap Scalp Cooling System very well. In the clinical study conducted in the U.S. for FDA clearance, three of 101 patients stopped scalp cooling because they could not tolerate the temperature of the cooling.

Approximately half of the patients experienced a mild to moderate headache that was triggered or worsened by scalp cooling using The DigniCap Scalp Cooling System.

Mild scalp pain was experienced by the majority of the patients, but rarely required pain medications to control the pain.

Up to 10% of patients may experience claustrophobia, or a fear of confined spaces while wearing the cooling cap.

Clinical studies have produced variable success rates in patient reduction of chemotherapy-induced alopecia, or hair loss, with scalp cooling. This is because the outcome is dependent on several factors including chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism, and concomitant comorbidities. Increasing age may decrease the effectiveness of the cooling cap. Data have shown that women who experience hair loss in spite of using scalp cooling might have worse quality of life than women who did not have scalp cooling.

Long Term Adverse Events

When using scalp cooling, less chemotherapy is distributed to the hair cells, and cancer cells could theoretically survive locally within the scalp area. In breast cancer patients there has been a concern for scalp and skin metastases with scalp cooling patients. Based on medical literature, scalp and skin metastases are rare occurrences regardless of breast cancer stage (scalp metastases as first sign of recurrence occurs in 1 out of 4,000 patients, and in 1 out of 100 patients who already have other sites of metastasis). The observed risk of scalp metastasis does not seem to differ between patients who have and have not used scalp cooling.

There is a theoretical possibility that the scalp may act as a reservoir for cancers which have a high likelihood of metastases traveling in the blood stream. While the patient wears the cooling cap up to 5 hours, cancer cells in your blood stream may be resistant to your chemotherapy during transit through your cooled scalp and less susceptible to chemotherapy. These cells may then metastasize and alter your prognosis.

Alternative Therapies

The DigniCap Scalp Cooling System was the first device to be granted marketing permission by the FDA to reduce the risk of hair loss during chemotherapy in cancer patients with solid tumors. However, you should discuss with your physician whether any other treatments, or the use of a wig or other head covering, would be more appropriate for you.

Financial Assistance

Insurance

In the U.S., some patients are receiving insurance reimbursement at varying levels. Success with reimbursement varies depending on plan, coverage and location.

Ask your provider for details or visit dignicap.com for more information.

Patient Assistance Programs

Dignitana was a founding partner of HairToStay, a national non-profit foundation that provides subsidies to scalp cooling patients with demonstrated financial need.

DigniCap patients have also received funding from individual medical center foundations, community health funds and other philanthropic entities that work to increase awareness and provide financial assistance to scalp cooling patients in their communities. Listed below are a few of these organizations. Ask your healthcare provider if there are any local or regional organizations in your area such as Cold Capital Fund serving the Washington DC area and Hope for Hair Foundation in North Carolina.

HairToStay
hairtostay.org

hair to stay

Cold Capital Fund
coldcapitalfund.org

Cold Capital Fund
Putting a Cap on Cancer Hair Loss

Hope for Hair Foundation
hopeforhair.org

Hope for Hair Foundation

Testimonials

“If I did not have my hair, my self-image which already has taken a beating from the cancer and the subsequent therapy, would have been much worse. Keeping my hair has given me a sense of normality during one of the worst experiences of my life.”

- Howard, New Port Richey, FL

“After 4 rounds of AC and 12 rounds of Paclitaxel in 135 days, I’ve finished chemo and saved my hair with DigniCap.”

- Monika, Washington DC

About Dignitana

Our mission is to provide cancer patients with dignity and control during a very challenging time. Working directly with both clinicians and patients, we provide an innovative medical device in combination with expertise, education and support throughout the scalp cooling process.

With operations based in Dallas, Texas, Dignitana AB is now a part of the Paxman Group, combining 60 years of clinical experience to serve patients and clinicians with expert and trusted experience Dignitana produces the patented DigniCap Scalp Cooling System to counteract chemotherapy-related hair loss and contribute to improved patient well-being and quality of life.

The DigniCap Scalp Cooling System has been used around the world since 2001. In 2015, after a multi-center clinical trial, DigniCap became the first scalp cooling system to receive FDA clearance in the United States. It is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

DIGNITANA

Part of the **Paxman Group**

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ESPAÑOL Para ver la información del paciente en español, visite dignicap.com/patient

DigniCap is a product of Dignitana AB, a public, Swedish medical device company. DigniCap is a patented scalp cooling system that offers the ability to reduce hair loss during chemotherapy. DigniCap provides continuous cooling with high efficacy, safety and acceptable patient comfort. The company was the first FDA cleared provider of scalp cooling technology.

Dignitana, DigniCap, DigniLife, DigniCap Delta, DeltaCool and DeltaCard are registered trademarks owned by Dignitana AB (publ).

The company is certified under ISO 13485:2016 DigniCap C3 and Delta are FDA cleared and CE certified as Class IIa medical devices.

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