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To interview Julie Rani Nangia, contact Julia Gunther at [julia.gunther@aacr.org](mailto:julia.gunther@aacr.org) or 267-250-5441. For a photo of Nangia, click [here](#). For photos of the cooling cap, click [here](#) or [here](#). Photo credits: Baylor College of Medicine.

Editor's note: This updated version of the press release replaces the word "approval" with "clearance" and "approved" with "cleared" to describe FDA action on the scalp-cooling systems made by Paxman and Dignitana.

## **Scalp-cooling System Reduced Hair Loss in Many Breast Cancer Patients Receiving Chemotherapy**

*Manufacturer is now seeking FDA clearance*

SAN ANTONIO — A system designed to prevent hair loss in chemotherapy patients by cooling the scalp was safe and effective in more than half the breast cancer patients tested in a prospective, multicenter, randomized clinical trial, according to data presented at the 2016 [San Antonio Breast Cancer Symposium](#), held Dec. 6–10.

“Adjuvant chemotherapy decreases the risk of breast cancer recurrence. However, it is associated with distressing side effects, including hair loss,” said the study’s lead author, [Julie Rani Nangia, MD](#), an assistant professor of medicine at the Lester and Sue Smith Breast Center, part of the Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine in Houston. “In Europe, scalp-cooling technology has helped many patients avoid hair loss and maintain their quality of life, and there is a great deal of interest in scalp-cooling in the United States.”

Nangia said the technology has been slower to catch on in the United States, partially due to concerns over cost and potential metastasis to the scalp. In December 2015, the U.S. Food and Drug Administration (FDA) gave clearance to DigniCap, a scalp-cooling system made by Dignitana Inc.

In this trial, the world’s first prospective, randomized trial of scalp-cooling, researchers evaluated the Orbis Paxman Hair Loss Prevention System (OPHLPS), which would compete with the Dignicap if it receives FDA clearance.

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Researchers enrolled 235 women with stage 1 or stage 2 breast cancer who were planning to undergo at least four cycles of either anthracycline- or taxane-based chemotherapy. Participants were randomized in a 2:1 ratio to either receive scalp cooling or no cooling. Those who received the scalp-cooling treatment used the OPHLPS before, during, and after chemotherapy sessions. Independent evaluators assessed hair loss based on published [criteria](#).

At the time of interim analysis, 95 patients in the cooling group and 47 patients in the no-cooling group were evaluable and had completed four cycles of chemotherapy. Among them, 48 patients in the cooling group (50.5 percent) had hair preservation, compared with zero patients in the non-cooling group. Side effects were mild and included discomfort and headache.

The results surpassed the superiority boundary, prompting researchers to stop the study and release the data, according to Nangia. Paxman is now seeking FDA clearance for the system.

Nangia explained that chemotherapy fights cancer by attacking rapidly dividing cells. However, since hair cells also divide rapidly, chemotherapeutic drugs target them as well, leading to hair loss. Scalp-cooling technology lowers the temperature of the scalp, which reduces blood flow to the hair follicles and has been shown to reduce hair loss.

Like some competing products, the OPHLPS features a “cold cap” that is fitted to a patient’s head while he or she is receiving a chemotherapy treatment. Nangia said that compared with some cold caps that are already on the market, the OPHLPS maintains a more constant temperature, allows the patient to wear one cap rather than several during a session, and allows the patient to move around more.

Nangia said this trial enrolled breast cancer patients because they are primarily female. “Although hair loss affects both men and women, women are often more emotionally affected,” she said.

Scalp-cooling technology has been used for other solid-tumor cancer types in other countries, Nangia added. It is not recommended for patients with blood cancers, such as leukemia or lymphoma, because it involves constriction of blood vessels.

Nangia said that preventing hair loss may improve patients’ emotional well-being during chemotherapy and may allow them to maintain a degree of privacy while undergoing cancer treatment. She said the women in this study will be followed for the next five years to monitor overall survival, recurrence of cancer, and potential metastasis to the scalp.

Nangia said the study’s main limitation was variability in how well the device was fitted to patients’ scalps. She said that as the trial went on, the nurses or other staff members became more skilled with using the device, increasing its effectiveness. She also cautioned that most patients will experience some thinning of their hair.

This study was funded by Paxman Cooling. Nangia declares no conflicts of interest.

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**Presentation:** Friday, Dec. 9, General Session 5 – Hall 3, 9:45 a.m. CT

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The mission of the 2016 San Antonio Breast Cancer Symposium is to produce a unique and comprehensive scientific meeting that encompasses the full spectrum of breast cancer research, facilitating the rapid translation of new knowledge into better care for patients with breast cancer. The [Cancer Therapy & Research Center](#) (CTRC) at The University of Texas Health Science Center at San Antonio, the [American Association for Cancer Research](#) (AACR), and [Baylor College of Medicine](#) are joint sponsors of the San Antonio Breast Cancer Symposium. This collaboration utilizes the clinical strengths of the CTRC and Baylor and the AACR's scientific prestige in basic, translational, and clinical cancer research to expedite the delivery of the latest scientific advances to the clinic. For more information about the symposium, please visit [www.sabcs.org](http://www.sabcs.org).