



Cancer and hair loss: innovation to improve psychological well-being

Summary of the results of the pilot study carried by Salute Donna Onlus and the National Cancer Institute of Milan

Assessment of body image, psychological well-being and level of satisfaction with the use of the CNC® prosthetic system in patients with recurrence of breast cancer and recurrent alopecia induced by chemotherapy

OBJECTIVES

1. assessment of the CNC® prosthetic system impact in patients with recurrence of breast cancer with CIA on body image and psychological well-being, investigating any differences compared to the degree of satisfaction experienced during the previous use of traditional wig;
2. assessment of the general satisfaction of women wearing the CNC® prosthetic system, identifying its strengths and weaknesses and highlighting any corrective measures for its optimal use.

STUDY DEVELOPMENT

The study consisted of the following 6 phases:

Phase 1 _ Enrollment and signing of informed consent

Phase 2 _ T0 evaluation (after participation acceptance): presentation of the following rating scales:

- the Body Image Scale (**BIS**), asking patients direct comparison to the previous experience wearing traditional wigs;
- the Psychological well-being scale (**PWB**) asking patients to refer to the current situation.

Phase 3 _ Technical parameters, production and integration of the device.

Taking technical parameters is necessary for the realization of the CNC® prosthetic system which requires a time span of about 30-40 days.

Phase 4 _ T1 evaluation (3 months from CNC® integration)

- The BIS referring to the current situation
- The PWB referring to the current situation

Phase 5 _ T2 evaluation (6 months after CNC® integration):

- BIS referring to the current situation
- PWB referring to the current situation

Phase 6 _ Focus group with the participation of patients who completed the evaluation process. The goal of this Focus Group was to assess the subjective experience of using the CNC® prosthetic system highlighting its strengths and weaknesses and identifying any operational indications for the better management during oncological treatments causing alopecia.

QUANTITATIVE STUDY

From October 2017 to July 2019, the Complex Structure of Medical Oncology 1 of the IRCCS Foundation National Cancer Institute of Milan, enrolled 21 patients with breast cancer recurrence and CIA, respecting the following criteria:

1. previous use of traditional wig
2. age above 18

3. absence of clinically evaluated cognitive disorders
4. absence of anxiety and/or pathological depression
5. general availability to wear the prosthetic system take part to the study.

Objectives were evaluated using the following scales:

- **Body Image Scale (BIS)** for the primary body image evaluation objective,
- **Psychological Well-Being Scale (PWB)** for the psychological well-being evaluation.

QUALITATIVE STUDY

The subjective experience of the CNC[®] prosthetic system use was investigated during a Focus group aiming to detect the level of satisfaction due to the use of the prosthetic device, while identifying its strengths and critical points and any eventual corrections for optimal use.

The focus group was conducted following a semi-structured outline designed to deepening the following aspects:

1. initial expectations related to the CNC[®] prosthetic system;
2. comparison between the traditional wigs and the CNC[®] prosthetic system;
3. perception and evaluation of the CNC[®] prosthetic system;
4. any problems with the CNC[®] prosthetic system;
5. willingness to purchase the CNC[®] prosthetic system.

RESULTS

The quantitative analysis showed a statistically significant decrease at 3 months and 6 months from the moment of acceptance to participate in the study, only at the level of the average scores on the BIS scale (p-value <0.001). This result translates into a global improvement in the body image perceived by patients over time.

On the other hand, there was no statistically significant difference over time or at the level of the perception of the importance of hair or at the level of the individual sub-scales of the PWB.

In the following table the BIS median score decreases from 18 (interquartile range (IQR) \pm 11) to 7.9 (IQR \pm 9.8), while the Mean score decreases from 20.3 (standard deviation (SD) \pm 7.0) to 9.8 (SD \pm 7.1).

Time	Patiens	Median	IQR	Mean	SD
T0	16	18	11	20.3	7.0
T2	16	7.9	9.8	9.4	7.1

The Wilcoxon-Mann-Whitney test, suitable for populations with a low sample size, supports this result, comparing the total score of the BIS scale at T0 and T2. These results are represented graphically through the boxplots of Figure 1 which also contains the individual trajectories.

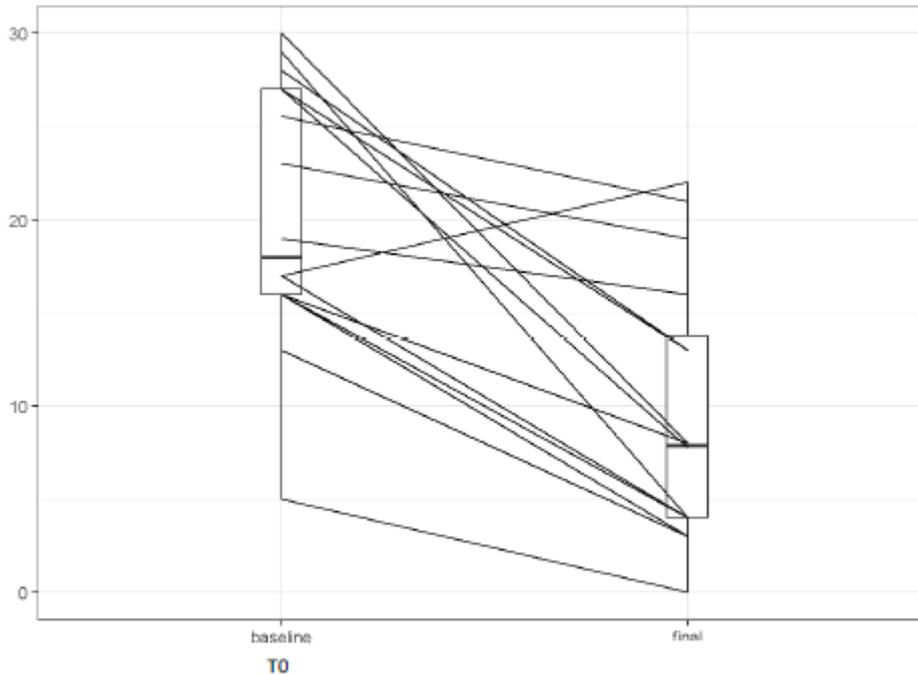


Figura 1

It is possible to observe from the figure that there is a substantial difference between the distribution at T0 and T2. Consistent with the result of the nonparametric model, the Wilcoxon-Mann-Whitney test finds that this difference is statistically significant (p -value < 0.001), thus allowing us to reject the hypothesis that the BIS scale scores at the baseline time are similar to those of T2.

The qualitative analysis through focus groups revealed strengths and weaknesses.

The strengths identified by the patients mainly concern the characteristics of the device itself, but much satisfaction was also expressed for the assistance received by the CRLabs professionals. The most important strength lies in the fact that the device allows patients and people around them not to perceive themselves as sick. This aspect is of fundamental importance both for the management of daily life and for the improvement of life quality.

Regarding the two abovementioned elements, there are four major emerging aspects: 1) "not seen"; 2) "does not move;" 3) the good quality of the hair; 4) no high demanding management of the device. The fact that the prosthetic device is not detectable by other people assumes significant importance, as this feature allows patients to live a life in total "normality", to be able to rediscover what they were "before the disease" (or even during younger age, because the device, sometimes, leads them to see themselves as they were years before), and avoiding discussing about the disease with acquaintances and relatives. The critical issues that emerged from the focus group essentially concern three areas which are related to: a) the device (perspiration, tightness at night, adherence, hair type); b) assistance (Quality of the cut, positioning of the device, waiting times to go to the center); c) feeling comfortable (feeling free to go to another hairdresser, use of the device in water).

Considering the quantitative results, it can be concluded that the CNC[®] prosthetic device, compared with traditional wig, leads to a significant improvement in the perceived body image. This benefit emerges also from the analysis of the focus group which shows a substantial satisfaction. Patients are not embarrassed to look in the mirror, as the device helps maintain a positive perception of their body image. This device becomes, day after day, "part of yourself", thus helping patients to safeguard their femininity and not suffer the social stigma that generally accompanies oncological disease.

The comparison with the traditional wig shows that the latter appears to be an object of the past, while the CNC[®] prosthetic system is configured as something revolutionary. Satisfaction collides, however, with an important limit, namely the poor transpiration of the device which makes it difficult to use, especially in the heat and at night. Perspiration is undoubtedly the point for which patients hope for corrections that can lead to a significant improvement, in order to achieve optimal use of the device.