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# Quality of Life and Respiratory Performance in the Laryngectomized Patient. Role of the HME Filters during Physical Activity

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**Summary:** The physical: psychological, and quality-of-life effects of the laryngectomee patient have been known for a long time. The concept of patient rehabilitation is increasingly important and must be taken care with a global manner, and this type of rehabilitation requires multidisciplinary. The aim of this study is to evaluate the impact that different types of stomal filters have on the respiratory performance of patients and on their quality of life.

**Abstract: Background:** Permanent tracheostomy because of total laryngectomy surgery entails great consequences for the patient regarding respiratory physiopathology such as the filtering, humidifying, and heating function of the air by the nose is lost. The use of special stomal filters can determine adequate protection of the trachea-broncho-pulmonary system with a reduction in respiratory pathologies. In fact, in most cases laryngectomee patients are first cigarette smokers who for this reason already have also respiratory diseases such as chronic obstructive pulmonary disease (COPD). Despite the availability of tracheal filters, multiple times, as reported in the literature, the patient tends to limit their use due to reported breathing difficulties, especially in conditions of intense breathing. **Methods:** The objective of this clinical study was to evaluate the most suitable stomal filter for the laryngectomee patient during physical activity. The filters studied were an INHEALTH device (Blom-Singer SpeakFree HME); two ATOS devices (Provox® Life™ Energy HME and Provox® Life™ Home HME); and an FAHL device (Laryvox HME Sport). **Results:** For this purpose, the performances of 31 laryngectomee patients, subjected to medium-high physical effort, were analyzed through a standardized pneumological test, the Six Minute Walking Test (6MWT) which involves a sustained walk lasting six minutes, with evaluation , every 60 seconds, heart rate, oxygen saturation and meters travelled; furthermore, it examines two subjective indices, namely, the basal and final dyspnea index and the initial and final muscular fatigue index.

**Keywords:** laryngeal cancer; total Laryngectomy; rehabilitations; sport; HME filter; 6MWT

## 1. Introduction

Laryngeal cancer represents 30% of head and neck cancers and 2% of malignant tumors. Despite progress in surgical and medical techniques, total laryngectomy is still today the operation of choice in the case of advanced forms of laryngeal cancer or in the case of salvage surgery. [1–6]

The creation of a permanent stoma has profound psychological and physical consequences on the patient.[7]

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The loss of vocal ability, a devastating experience for the relational life of the laryngectomee patient.[8]

The need to breathe from the tracheostoma involves a series of problems such as: the loss of the heating, humidifying, and filtering function of the air by the nasal mucosa. This exposes the tracheobronchial tree of patients already compromised by smoking to recurrent respiratory infections. The loss of respiratory resistance caused by the larynx alters the normal functioning of the pulmonary alveoli, compromising gas exchange. Loss of smell due to loss of nasal breathing. [9,10]

In a healthy subject, the air inspired from the external environment at a temperature of 22°C and with a humidity of approximately 4% is heated at the level of the nasal passages reaching 29°C with a humidity that can reach 70%. Finally, at the level of the subglottic region, a further increase in temperature occurs which reaches 32 °C and a humidity of 100%. In the small airways the air temperature is the same as body temperature. In the laryngectomee patient, the air inspired by the tracheostoma reaches the lower airways at a temperature of 27-28 °C with a humidity of 50%. This has an important impact on the activity of the cilia of the respiratory system which progressively reduce their movements until they remain immobile. [11–13] All this, combined with the lack of the filtering action exerted by the nose, determines an increased risk of developing recurrent respiratory infections, an increase in coughing, an increase in mucus production. These symptoms express themselves significantly in the first 6 months and then stabilize around 30 months after surgery. All these respiratory symptoms negatively affect fatigue, sleep quality and social relationships. For this reason, in addition to respiratory rehabilitation, it is important that the patient uses heat and humidity exchangers (HME) early[14].

HMEs filters are also called artificial noses and have three fundamental characteristics: heat and humidity exchange capacity; resistance; particle filtering capacity.

The heat exchange occurs thanks to the retention of water by the filter. In fact, it is made up of a foam sponge treated with calcium salts and placed inside a plastic housing. This composition allows the air to be heated and at the same time to exchange water particles during breathing. [15] Furthermore, the stomal filter is capable of partially restoring the resistance offered by the larynx with a positive effect also on the blowing noise produced at the stoma level, reducing it considerably. [16] The filtering capacity instead depends on the size of the pores that make up the spongy structure of the filter.[17]

## 2. Materials and Methods

A prospective study was conducted on 31 consecutive patients who were enrolled at the U.O.C. of Otolaryngology of the A.O.U. Federico II of Naples from November 2023 and February 2024. All patients were informed regarding the methods, aims, and scope of the study.

27 men and 4 women aged between 41 and 80 (average 63 years). All the patients enrolled had undergone phonatory rehabilitation using a trachea-esophageal prosthesis: in 9 patients it was inserted during the total laryngectomy operation, in the others subsequently. The time since total laryngectomy was less than 3 years in 4 patients; between 3 and 5 years in 6 patients; greater than 5 years in 21 patients. 26 patients were smokers before total laryngectomy; 18 patients used to consume alcoholic beverages. 26 out of 31 patients consistently use stomal filters. All patients stated that they carried out physical activity: 24 constantly, 7 occasionally.

The following were excluded from the study: patients with severe cardiac or bronchopulmonary pathologies; disease recurrence and ongoing adjuvant medical therapy.

The filters we tested in our study were:

- Bloom- Singer SpeakFree HME Hands Free Valve (Figure 1 A): produced by the InHeath company, it is a system that does not require manual closure to speak, allowing hands-free phonation. It is an adjustable device, capable of adapting to the activity of the individual who can choose between hands-free or digital occlusion. The filter with which the valve is equipped is EasyFlow ® HME which allows you to breathe more freely to satisfy the subject's activity level and pulmonary needs.

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- Laryvox HME Sport (Figure 1B): produced by the Fahl company, designed to allow the practice of sport in laryngectomee patients and is useful in situations that require a greater need for air.
- Provox ® Life ™ Energy HME (Figure 1C): produced by the Atos Medical company, it provides good air humidification and low breathing resistance. It is designed for physically active individuals and features a diameter of 23mm, slightly larger than its competitors. This increase in size is designed for optimal performance by ensuring the right balance between moisture-wicking, breathability, and size.
- Provox ® Life ™ Home HME (Figure 1D): produced by the Atos Medical company, it offers the highest level of humidification compared to previous HMEs and is ideal for use at home or in activities that do not require deep breathing.


**Figure 1.** HMEs filters.

All enrolled patients underwent the Six Minute Walking Test (6MWT) which allows you to measure the distance a person simply and reliably can walk in six minutes, walking as fast as possible on a flat surface. [18,19]

Each patient performed the 6MWT with all four types of HME filters object of our experimentation which were applied on the stomal adhesive in random succession, taking care that the type of filter was not recognized by the laryngectomee patient. The following parameters were evaluated before, during and after the effort: blood oxygenation, heart rate, any dyspnea complained of, muscle fatigue, distance traveled during the duration of the test.

Additionally, each patient was administered the Borg scale before and after the 6MWT. [19] The patient is invited to provide a value between 1 and 10 to express their respiratory and muscular fatigue, considering this perception an important element in the evaluation of physical performance together with the physiological measurements taken during the test.

This study was conducted in accordance with relevant guidelines and regulations. It was approved by the institutional review board committee of the Federico II University of Naples, Naples, Italy (2023/2092).

## 3. Results

### *3.1. Statistical Analysys*

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The data collected during the experimentation were examined using statistical analysis, in order to evaluate the presence of any significant differences between the four filters examined. The sample size was N=31. For each numeric, sortable and mutable variable, tables of absolute frequencies, relative percentages and cumulative percentages have been created. Additionally, means and standard deviations were determined for each variable. Any differences observed between means of each variable for dependent samples were carried out through the one-way ANOVA procedure, the Bonferroni multiple test, the test of homogeneity of variances through Levene's statistics and Dunnett's T3 test to test the possible homoscedasticity of variances. Significance was set equal to 0.05. 95% confidence intervals were determined. The bivariate correlation matrix was calculated.

To verify the presence of any significant correlations, the linear correlation coefficient was determined according to Pearson, complete with the one-tailed (with the level of sig.=0.05) and two-tailed (with the level of sig.=0.01) significance test . To facilitate reading, diagrams of the regression line interpolating the observed data have been produced.

The processing was carried out with the multifactorial and multidimensional statistical analysis program IBM SPSS statistics, ver.28.0.1.1.

### *3.2. Data Interpretation*

The parameters recorded for each individual patient included instrumental data, therefore objective (saturation, heart rate, meters travelled) and subjective data (basal and final Dyspnea Index and basal and final Fatigue Index), the latter being the result of the patient's subjective perception and measured referring to the Borg CR10 scale.

By placing the saturation parameter as the dependent variable, a multiple comparison was carried out between the four filters studied. As can be seen from the Bonferroni test (Table 1) in terms of saturation, a significant difference can be seen between the Provox® Life™ Home HME filter and the Blom-Singer SpeakFree HME filter and between the Blom-Singer SpeakFree HME filter and the Laryvox HME Sport filter. The Provox® Life™ Energy HME filter does not show significant differences with the other filters considered.

A major correction was carried out with the Dunnet test, which assumes that the variances are not equal, but, nevertheless, what has just been described was verified (Table 1).

**Table 1.** Multiple comparisons. Dependent variable: saturation.

| | (I) Filter | (J) Filter | Mean's difference (I-J) | STD error | Significance | Confidence interval 95% | |
|---|---|---|---|---|---|---|---|
| | | | | | | Lower limit | Upper limit |
| Bonferroni | HOME | SPEAK | -0,502* | 0,144 | 0,003 | -0,88 | -0,12 |
| | | SPORT | -0,069 | 0,144 | 1,000 | -0,45 | 0,31 |
| | | ENERGY | -0,373 | 0,144 | 0,058 | -0,75 | 0,01 |
| | SPEAK | HOME | 0,502* | 0,144 | 0,003 | 0,12 | 0,88 |
| | | SPORT | 0,433* | 0,144 | 0,016 | 0,05 | 0,81 |
| | | ENERGY | 0,129 | 0,144 | 1,000 | -0,25 | 0,51 |
| | SPORT | HOME | 0,069 | 0,144 | 1,000 | -0,31 | 0,45 |
| | | SPEAK | -0,433* | 0,144 | 0,016 | -0,81 | -0,05 |
| | | ENERGY | -0,304 | 0,144 | 0,210 | -0,69 | 0,08 |
| | ENERGY | HOME | 0,373 | ,144 | 0,058 | -0,01 | 0,75 |
| | | SPEAK | -0,129 | 0,144 | 1,000 | -0,51 | 0,25 |
| | | SPORT | 0,304 | 0,144 | 0,210 | -0,08 | 0,69 |
| T3 di Dunnett | HOME | SPEAK | -0,502* | 0,139 | 0,002 | -0,87 | -0,13 |
| | | SPORT | -0,069 | 0,149 | 0,998 | -0,46 | 0,32 |
| | | ENERGY | -0,373 | 0,156 | 0,100 | -0,79 | 0,04 |
| | SPEAK | HOME | 0,502* | 0,139 | 0,002 | 0,13 | 0,87 |
| | | SPORT | 0,433* | 0,131 | 0,006 | 0,09 | 0,78 |
| | | ENERGY | 0,129 | 0,139 | 0,927 | -0,24 | 0,50 |
| | SPORT | HOME | 0,069 | 0,149 | 0,998 | -0,32 | 0,46 |
| | | SPEAK | -0,433* | 0,131 | 0,006 | -0,78 | -0,09 |
| | | ENERGY | -0,304 | 0,149 | 0,223 | -0,70 | 0,09 |
| | ENERGY | HOME | 0,373 | 0,156 | 0,100 | -0,04 | 0,79 |

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| | | | | | | |
|---|---|---|---|---|---|---|
| | SPEAK | -0,129 | 0,139 | 0,927 | -0,50 | 0,24 |
| | SPORT | 0,304 | 0,149 | 0,223 | -0,09 | 0,70 |

*. Mean difference is significance at 0,05.

Considering the average of the saturation parameter (Table 2) it can be seen that the Blom-Singer SpeakFree HME filter was the best performing with respect to the parameter considered (Figure 2).

**Table 2.** Preliminary summary statistics relating to saturation data.

| | | N | Medium | Standard Deviation | Standard error | Middle Confidence interval 95% Lower limit | Upper limit | Minimum | Maximum | Components variance |
|---|---|---|---|---|---|---|---|---|---|---|
| HOME | | 217 | 94,83 | 1,628 | 0,111 | 94,61 | 95,05 | 91 | 98 | |
| SPEAK | | 217 | 95,33 | 1,251 | 0,085 | 95,16 | 95,50 | 92 | 99 | |
| SPORT | | 217 | 94,90 | 1,462 | 0,099 | 94,70 | 95,09 | 91 | 98 | |
| ENERGY | | 217 | 95,20 | 1,629 | 0,111 | 94,98 | 95,42 | 90 | 99 | |
| Total | | 868 | 95,07 | 1,512 | 0,051 | 94,96 | 95,17 | 90 | 99 | |
| Model | Fixed effetcs | | | 1,501 | 0,051 | 94,97 | 95,17 | | | |
| | Casual Effects | | | | 0,120 | 94,68 | 95,45 | | | 0,047 |

Note: N= 31 people x 7 times= 217.

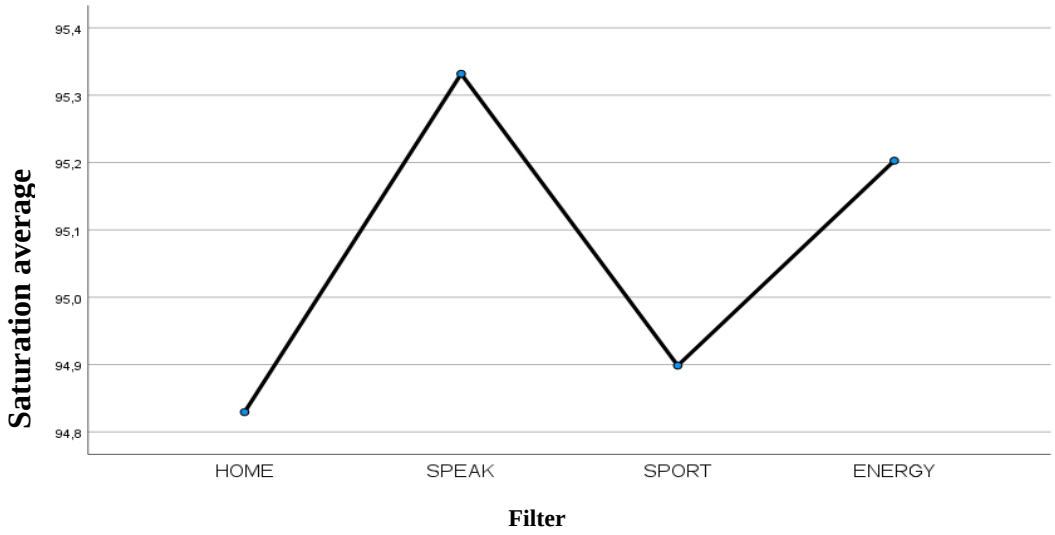


**Figure 2.** Average saturation recorded for each filter.

The saturation values were studied in the six times covered by the test to evaluate whether there were significant differences during the six minutes; this significant difference was observed only in the first minute (Figure 3)

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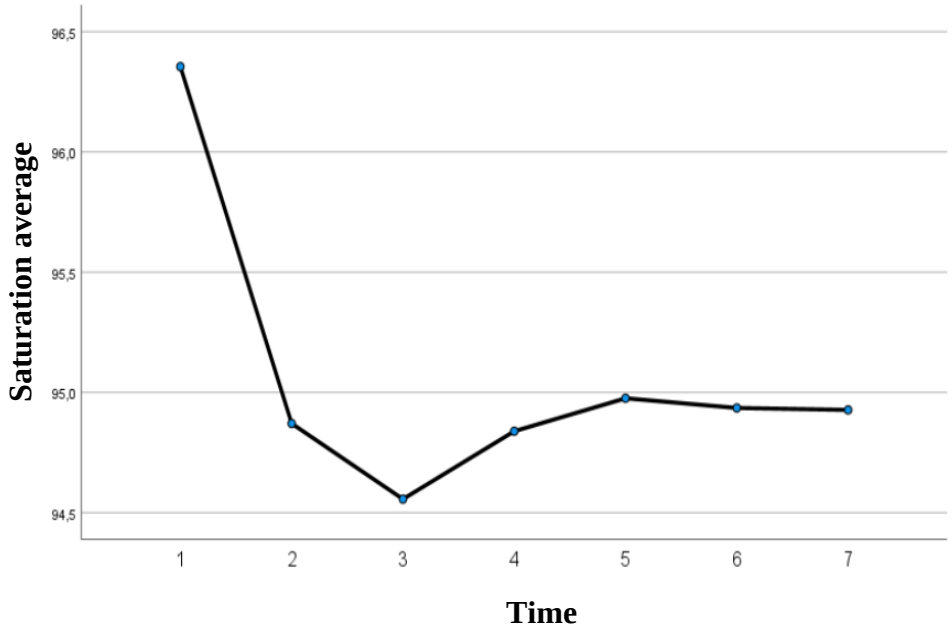


**Figure 3.** Saturation averages' variation over time.

Regarding the study of heart rate (HR) as a dependent variable in the multiple comparison between the four filters studied, the Bonferroni test was applied which did not find any significant difference (Table 3).

**Table 3.** Multiple comparisons. Dependent variable: Heart Rate (HR).

| | (I) Filter | (J) Filter | Mean's difference (I-J) | Standard error | Significance | Confidence interval 95% Lower limit | Upper limit |
|---|---|---|---|---|---|---|---|
| Bonferroni | HOME | SPEAK | 1,032 | 0,863 | 1,000 | -1,25 | 3,31 |
| | | SPORT | -0,705 | 0,863 | 1,000 | -2,99 | 1,58 |
| | | ENERGY | 1,378 | 0,863 | 0,663 | -0,90 | 3,66 |
| | SPEAK | HOME | -1,032 | 0,863 | 1,000 | -3,31 | 1,25 |
| | | SPORT | -1,737 | 0,863 | 0,266 | -4,02 | 0,54 |
| | | ENERGY | 0,346 | 0,863 | 1,000 | -1,94 | 2,63 |
| | SPORT | HOME | 0,705 | 0,863 | 1,000 | -1,58 | 2,99 |
| | | SPEAK | 1,737 | 0,863 | 0,266 | -0,54 | 4,02 |
| | | ENERGY | 2,083 | 0,863 | 0,096 | -0,20 | 4,36 |
| | ENERGY | HOME | -1,378 | 0,863 | 0,663 | -3,66 | 0,90 |
| | | SPEAK | -0,346 | 0,863 | 1,000 | -2,63 | 1,94 |
| | | SPORT | -2,083 | 0,863 | 0,096 | -4,36 | 0,20 |
| T3 di Dunnett | HOME | SPEAK | 1,032 | 0,890 | 0,816 | -1,32 | 3,38 |
| | | SPORT | -0,705 | 0,879 | 0,963 | -3,03 | 1,62 |
| | | ENERGY | 1,378 | 0,844 | 0,479 | -0,85 | 3,61 |
| | SPEAK | HOME | -1,032 | 0,890 | 0,816 | -3,38 | 1,32 |
| | | SPORT | -1,737 | 0,881 | 0,260 | -4,06 | 0,59 |
| | | ENERGY | 0,346 | 0,846 | 0,999 | -1,89 | 2,58 |
| | SPORT | HOME | ,705 | ,879 | ,963 | -1,62 | 3,03 |
| | | SPEAK | 1,737 | ,881 | ,260 | -,59 | 4,06 |
| | | ENERGY | 2,083 | ,835 | ,075 | -,12 | 4,29 |
| | ENERGY | HOME | -1,378 | ,844 | ,479 | -3,61 | ,85 |
| | | SPEAK | -,346 | ,846 | ,999 | -2,58 | 1,89 |

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| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | SPORT | -2,083 | ,835 | ,075 | -4,29 | ,12 | |

If we want to consider the average of the HR parameter (Table 4), from a graphic point of view we observe the higher heart rate with the Laryvox HME Sport filter and the lower heart rate with the Provox® Life™ Energy HME filter, but this has no value statistics (Figure 4).

**Table 4.** Preliminary summary statistics relating to HR.

| | | N | Medium | Standard deviation | Standard error | Middle Confidence interval 95% Lower limit | Upper limit | Minimum | Maximum | Components variance |
|---|---|---|---|---|---|---|---|---|---|---|
| HOME | | 217 | 96,72 | 9,251 | 0,628 | 95,48 | 97,96 | 70 | 123 | |
| SPEAK | | 217 | 95,69 | 9,287 | 0,630 | 94,44 | 96,93 | 60 | 116 | |
| SPORT | | 217 | 97,42 | 9,059 | 0,615 | 96,21 | 98,64 | 60 | 113 | |
| ENERGY | | 217 | 95,34 | 8,310 | 0,564 | 94,23 | 96,45 | 66 | 118 | |
| Total | | 868 | 96,29 | 9,008 | 0,306 | 95,69 | 96,89 | 60 | 123 | |
| Model | Fixef effects | | | 8,985 | 0,305 | 95,69 | 96,89 | | | |
| | Casual effects | | | | 0,477 | 94,77 | 97,81 | | | 0,539 |

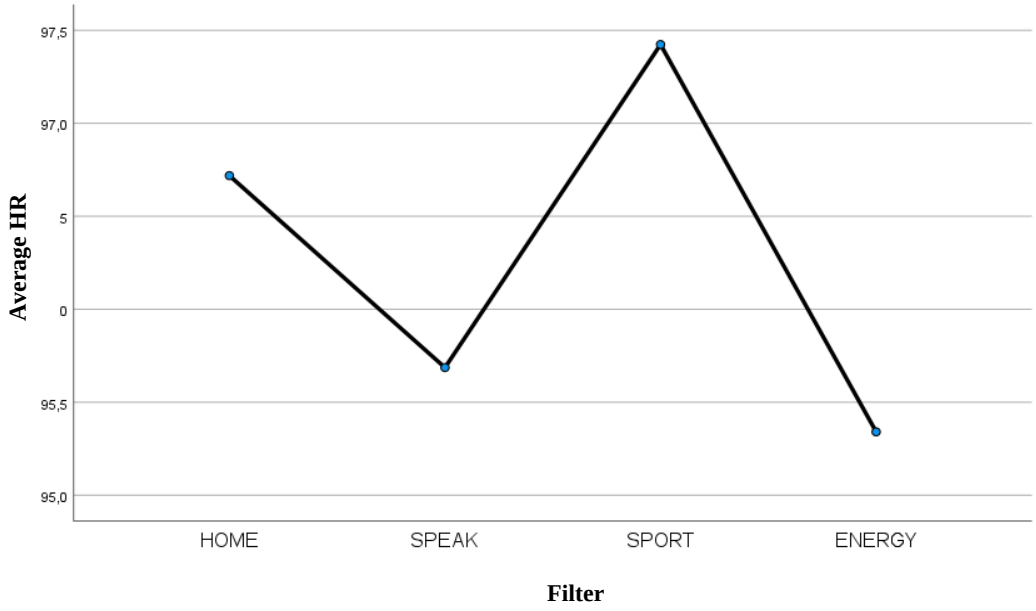


**Figure 4.** Average HR recorded for each filter.

Then, the parameter of meters travelled was examined. The Bonferroni test was applied in the multiple comparison between the four filters studied and it was set as a variable depending on the meters traveled (Table 5); the significant differences found were the following:

- The Provox® Life™ Home HME Filter showed a significant difference compared to the other 3 filters;
- The Laryvox HME Sport filter showed a significant difference compared to the Provox® Life™ Home HME and Blom-Singer SpeakFree HME filters;
- The Blom-Singer SpeakFree HME filter showed significant differences compared to the Provox® Life™ Home HME and Laryvox HME Sport filters;

The Provox® Life™ Energy HME Filter showed a significant difference only compared to the Provox® Life™ Home HME Filter.

The Dunnet test confirms the Bonferroni test (Table 5).

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**Table 5.** Multiple comparisons. Dependent variable: Meters traveled.

| | (I) Filter | (J) Filter | Mean's difference (I-J) | Standard error | Significance | Confidence interval 95% Lower limit | Upper limit |
|---|---|---|---|---|---|---|---|
| Bonferroni | HOME | SPEAK | -31,774* | 4,689 | <0,001 | -44,17 | -19,37 |
| | | SPORT | -14,774* | 4,689 | 0,010 | -27,17 | -2,37 |
| | | ENERGY | -21,871* | 4,689 | <0,001 | -34,27 | -9,47 |
| | SPEAK | HOME | 31,774* | 4,689 | <0,001 | 19,37 | 44,17 |
| | | SPORT | 17,000* | 4,689 | 0,002 | 4,60 | 29,40 |
| | | ENERGY | 9,903 | 4,689 | 0,210 | -2,50 | 22,30 |
| | SPORT | HOME | 14,774* | 4,689 | 0,010 | 2,37 | 27,17 |
| | | SPEAK | -17,000* | 4,689 | 0,002 | -29,40 | -4,60 |
| | | ENERGY | -7,097 | 4,689 | 0,783 | -19,50 | 5,30 |
| | ENERGY | HOME | 21,871* | 4,689 | <0,001 | 9,47 | 34,27 |
| | | SPEAK | -9,903 | 4,689 | 0,210 | -22,30 | 2,50 |
| | | SPORT | 7,097 | 4,689 | 0,783 | -5,30 | 19,50 |
| T3 di Dunnett | HOME | SPEAK | -31,774* | 4,334 | <,001 | -43,23 | -20,32 |
| | | SPORT | -14,774* | 4,404 | 0,005 | -26,41 | -3,13 |
| | | ENERGY | -21,871* | 4,623 | <0,001 | -34,09 | -9,65 |
| | SPEAK | HOME | 31,774* | 4,334 | <0,001 | 20,32 | 43,23 |
| | | SPORT | 17,000* | 4,754 | 0,002 | 4,44 | 29,56 |
| | | ENERGY | 9,903 | 4,958 | 0,247 | -3,20 | 23,01 |
| | SPORT | HOME | 14,774* | 4,404 | 0,005 | 3,13 | 26,41 |
| | | SPEAK | -17,000* | 4,754 | 0,002 | -29,56 | -4,44 |
| | | ENERGY | -7,097 | 5,019 | 0,642 | -20,36 | 6,17 |
| | ENERGY | HOME | 21,871* | 4,623 | <,001 | 9,65 | 34,09 |
| | | SPEAK | -9,903 | 4,958 | 0,247 | -23,01 | 3,20 |
| | | SPORT | 7,097 | 5,019 | 0,642 | -6,17 | 20,36 |

*. Mean difference is significance at 0,05.

Furthermore, considering the average of meters traveled during the 6MWT (Table 6) we observe that the Blom-Singer SpeakFree HME filter was the best performing with respect to the parameter considered (Figure 5).

**Table 6.** Preliminary summary statistics relating meters traveled.

| | | N | Medium | Standard deviation | Standard error | Middle Confidence interval 95% Lower limit | Upper limit | Minimum | Maximum | Components variance |
|---|---|---|---|---|---|---|---|---|---|---|
| HOME | | 217 | 471,61 | 41,115 | 2,791 | 466,11 | 477,11 | 378 | 546 | |
| SPEAK | | 217 | 503,39 | 48,851 | 3,316 | 496,85 | 509,92 | 378 | 588 | |
| SPORT | | 217 | 486,39 | 50,181 | 3,406 | 479,67 | 493,10 | 378 | 588 | |
| ENERGY | | 217 | 493,48 | 54,295 | 3,686 | 486,22 | 500,75 | 378 | 588 | |
| Totale | | 868 | 488,72 | 50,116 | 1,701 | 485,38 | 492,06 | 378 | 588 | |
| Model | Fixed effects | | | 48,844 | 1,658 | 485,46 | 491,97 | | | |
| | Casual effects | | | | 6,683 | 467,45 | 509,99 | | | 167,644 |

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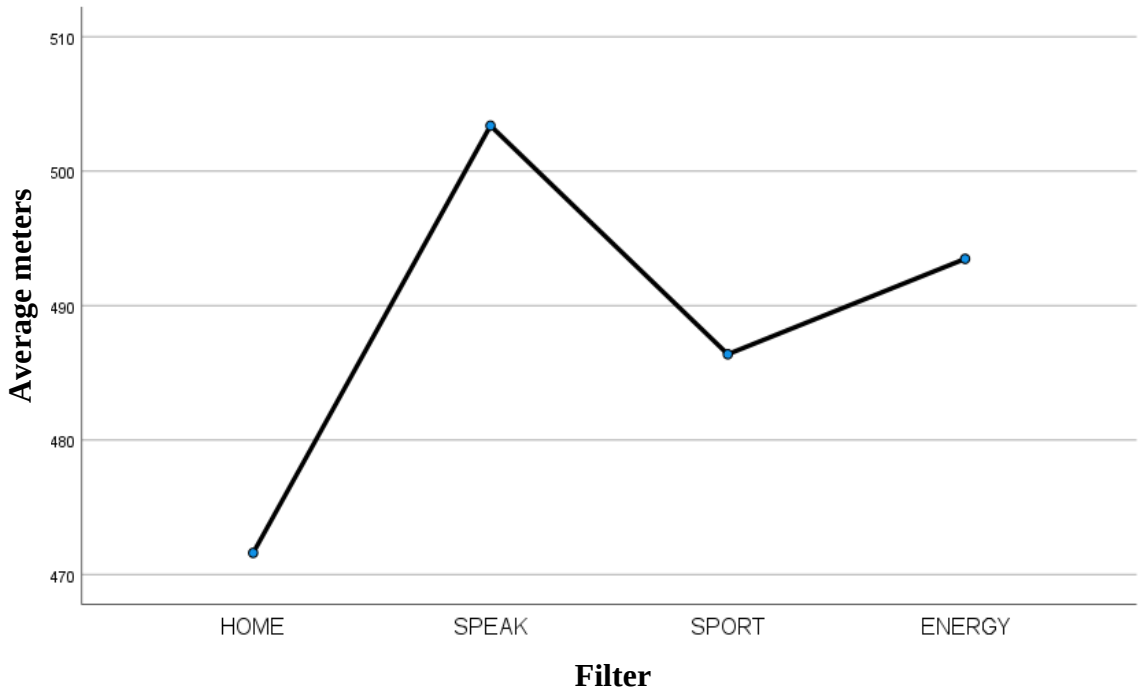


**Figure 5.** Average meters traveled recorded for each filter.

As regards the subjective parameters, placing the final subjective dyspnea index as the dependent variable in the multiple comparison (Table 7) between the four filters examined, a significant difference was found between:

- Provox® Life™ Home HME filter and Blom-Singer SpeakFree HME filter
- Provox® Life™ Home HME filter and Provox® Life™ Energy HME filter
- Blom-Singer SpeakFree HME filter and Provox® Life™ Energy HME filter
- Laryvox HME Sport filter and Provox® Life™ Energy HME filter.

The Dunnet test confirms the Bonferroni test (Table 7).

**Table 7.** Multiple comparisons. Dependent variable: Dispnea index.

| | (I) Filter | (J) Filter | Mean's difference (I-J) | Standard error | Significance | Confidence interval 95% Lower limit | Upper limt |
|---|---|---|---|---|---|---|---|
| Bonferroni | HOME | SPEAK | 0,516* | 0,154 | 0,005 | 0,11 | 0,92 |
| | | SPORT | 0,290 | 0,154 | 0,360 | -0,12 | 0,70 |
| | | ENERGY | 1,387* | 0,154 | <0,001 | 0,98 | 1,79 |
| | SPEAK | HOME | -0,516* | 0,154 | 0,005 | -0,92 | -0,11 |
| | | SPORT | -0,226 | 0,154 | 0,860 | -0,63 | 0,18 |
| | | ENERGY | 0,871* | 0,154 | <0,001 | 0,46 | 1,28 |
| | SPORT | HOME | -0,290 | 0,154 | 0,360 | -0,70 | 0,12 |
| | | SPEAK | 0,226 | 0,154 | 0,860 | -0,18 | 0,63 |
| | | ENERGY | 1,097* | 0,154 | <0,001 | 0,69 | 1,50 |
| | ENERGY | HOME | -1,387* | 0,154 | <0,001 | -1,79 | -0,98 |
| | | SPEAK | -0,871* | 0,154 | <0,001 | -1,28 | -0,46 |
| | | SPORT | -1,097* | 0,154 | <0,001 | -1,50 | -0,69 |
| T3 di Dunnett | HOME | SPEAK | 0,516* | 0,153 | 0,005 | 0,11 | 0,92 |
| | | SPORT | 0,290 | 0,154 | 0,306 | -0,12 | 0,70 |
| | | ENERGY | 1,387* | 0,164 | <0,001 | 0,95 | 1,82 |
| | SPEAK | HOME | -,516* | 0,153 | 0,005 | -0,92 | -0,11 |
| | | SPORT | -0,226 | 0,144 | 0,525 | -0,61 | 0,15 |

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| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | ENERGY | 0,871* | 0,155 | <,001 | 0,46 | 1,28 |
| | SPORT | HOME | -0,290 | 0,154 | 0,306 | -0,70 | 0,12 |
| | | SPEAK | 0,226 | 0,144 | 0,525 | -0,15 | 0,61 |
| | | ENERGY | 1,097* | 0,155 | <0,001 | 0,69 | 1,51 |
| | ENERGY | HOME | -1,387* | 0,164 | <0,001 | -1,82 | -0,95 |
| | | SPEAK | -0,871* | 0,155 | <0,001 | -1,28 | -0,46 |
| | | SPORT | -1,097* | 0,155 | <0,001 | -1,51 | -0,69 |

*. Mean difference is significance at 0,05.

Comparing the averages of the final dyspnea index of the four filters examined (Table 8), it is observed that the Provox® Life™ Energy HME filter was the one best tolerated by patients in the physical effort exerted during the execution of the SMWT (Figure 6).

**Table 8.** Preliminary summary statistics relating dispnea index.

| | | N | Medium | Standard deviation | Standard error | Middle Confidence interval 95% Lower limit | Upper limit | Minimum | Maximum | Components variance |
|---|---|---|---|---|---|---|---|---|---|---|
| HOME | | 217 | 2,84 | 1,691 | 0,115 | 2,61 | 3,06 | 0 | 7 | |
| SPEAK | | 217 | 2,32 | 1,493 | 0,101 | 2,12 | 2,52 | 0 | 5 | |
| SPORT | | 217 | 2,55 | 1,503 | 0,102 | 2,35 | 2,75 | 0 | 5 | |
| ENERGY | | 217 | 1,45 | 1,724 | 0,117 | 1,22 | 1,68 | 0 | 7 | |
| Totale | | 868 | 2,29 | 1,685 | 0,057 | 2,18 | 2,40 | 0 | 7 | |
| Model | Fixed effects | | | 1,606 | 0,055 | 2,18 | 2,40 | | | |
| | Casual effects | | | | 0,299 | 1,34 | 3,24 | | | 0,345 |

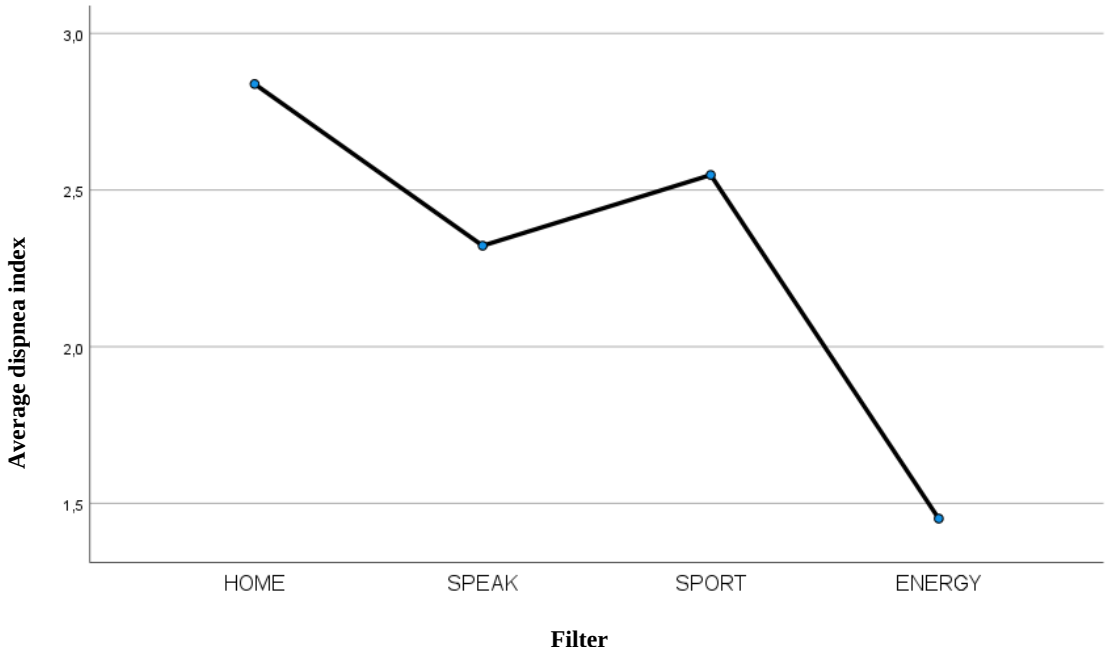


**Figure 6.** Average dispnea index recorded for each filter.

By placing the final subjective fatigue index as the dependent variable in the multiple comparison (Table 9) between the four filters examined, a significant difference was found between:

- Provox® Life™ Home HME Filter and Blom-Singer SpeakFree HME Filter
- Provox® Life™ Home HME Filter and Provox® Life™ Energy HME Filter
- Blom-Singer SpeakFree HME Filter and Provox® Life™ Home HME Filter

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- Blom-Singer SpeakFree HME Filter and Provox® Life™ Energy HME Filter
- Laryvox HME Sport filter and Provox® Life™ Energy HME filter.
- Provox® Life™ Energy HME Filter and Provox® Life™ Home HME Filter
- Provox® Life™ Energy HME Filter and Blom-Singer SpeakFree HME Filter
- Provox® Life™ Energy HME filter and Laryvox HME Sport filter

The Dunnet test confirms the Bonferroni test (Table 9).

**Table 9.** Multiple comparisons. Dependent variable: final subjective fatigue index.

| | (I) Filter | (J) Filter | Mean's difference (I-J) | Standard error | Significance | Confidence interval 95% Lower limit | Upper limit |
|---|---|---|---|---|---|---|---|
| Bonferroni | HOME | SPEAK | 0,323 | 0,132 | 0,090 | -0,03 | 0,67 |
| | | SPORT | -0,129 | 0,132 | 1,000 | -0,48 | 0,22 |
| | | ENERGY | 0,419* | 0,132 | 0,010 | 0,07 | 0,77 |
| | SPEAK | HOME | -0,323 | 0,132 | 0,090 | -0,67 | 0,03 |
| | | SPORT | -0,452* | 0,132 | 0,004 | -0,80 | -0,10 |
| | | ENERGY | 0,097 | 0,132 | 1,000 | -0,25 | 0,45 |
| | SPORT | HOME | 0,129 | 0,132 | 1,000 | -0,22 | 0,48 |
| | | SPEAK | 0,452* | 0,132 | 0,004 | 0,10 | 0,80 |
| | | ENERGY | 0,548* | 0,132 | <,001 | 0,20 | 0,90 |
| | ENERGY | HOME | -0,419* | 0,132 | 0,010 | -0,77 | -0,07 |
| | | SPEAK | -0,097 | 0,132 | 1,000 | -0,45 | 0,25 |
| | | SPORT | -0,548* | 0,132 | <0,001 | -0,90 | -0,20 |
| T3 di Dunnett | HOME | SPEAK | 0,323 | 0,141 | 0,126 | -0,05 | 0,69 |
| | | SPORT | -0,129 | 0,149 | 0,947 | -0,52 | 0,27 |
| | | ENERGY | 0,419* | 0,133 | 0,010 | 0,07 | 0,77 |
| | SPEAK | HOME | -0,323 | 0,141 | 0,126 | -0,69 | 0,05 |
| | | SPORT | -0,452* | 0,132 | 0,004 | -0,80 | -0,10 |
| | | ENERGY | 0,097 | 0,113 | 0,948 | -0,20 | 0,39 |
| | SPORT | HOME | 0,129 | 0,149 | 0,947 | -0,27 | 0,52 |
| | | SPEAK | 0,452* | 0,132 | 0,004 | 0,10 | 0,80 |
| | | ENERGY | 0,548* | 0,124 | <0,001 | 0,22 | 0,87 |
| | ENERGY | HOME | -0,419* | 0,133 | 0,010 | -0,77 | -0,07 |
| | | SPEAK | -0,097 | 0,113 | 0,948 | -0,39 | 0,20 |
| | | SPORT | -0,548* | 0,124 | <0,001 | -0,87 | -0,22 |

*. Mean difference is significance at 0,05.

Comparing the averages of the final fatigue index of the four filters examined (Table 10), it is observed that the Laryvox HME Sport filter was the least tolerated, while the Provox® Life™ Energy HME filter was the most tolerated by patients in the physical effort exerted during the execution of the 6MWT (Figure 7).

**Table 10.** Preliminary summary statistics relating to final fatigue.

| | N | Medium | Standard deviation | Standard error | Middle Confidence interval 95% Lower limit | Upper limit | Minimum | Maximum | Components variance |
|---|---|---|---|---|---|---|---|---|---|
| HOME | 217 | 1,19 | 1,638 | 0,111 | 0,97 | 1,41 | 0 | 6 | |
| SPEAK | 217 | 0,87 | 1,266 | 0,086 | 0,70 | 1,04 | 0 | 4 | |
| SPORT | 217 | 1,32 | 1,471 | 0,100 | 1,13 | 1,52 | 0 | 4 | |
| ENERGY | 217 | 0,77 | 1,071 | 0,073 | 0,63 | ,92 | 0 | 4 | |
| Totale | 868 | 1,04 | 1,394 | 0,047 | 0,95 | 1,13 | 0 | 6 | |

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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Model | Fixed effects | | 1,378 | 0,047 | 0,95 | 1,13 | | |
| | Casual effects | | | 0,130 | 0,63 | 1,45 | | 0,059 |

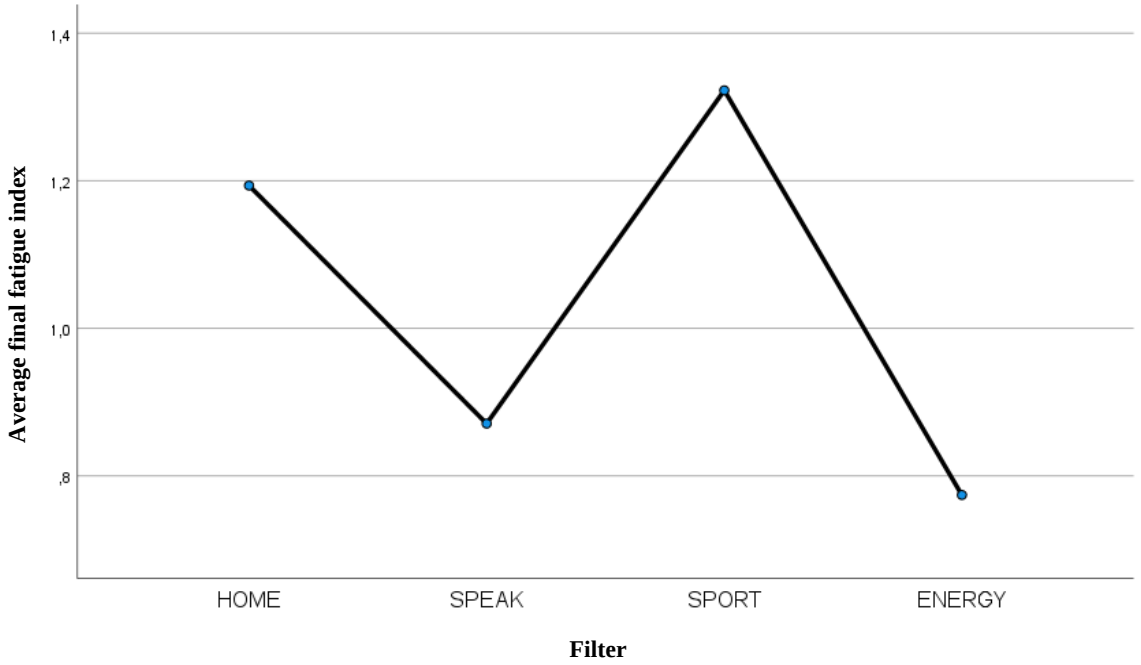


**Figure 7.** Average final fatigue index recorded for each filter.

Upon completion of the investigation, we wanted to evaluate whether there was a statistically significant correlation in between the instrumental and subjective data. As can be seen from Table 11:

- saturation has a significant inverse correlation at the 0.01 level with the baseline dyspnea index: this means that subjects with a reported perception of dyspnea at the start recorded lower saturation values during the execution of the 6MWT;
- the meters traveled have a significant inverse correlation at the 0.01 level with the basal dyspnea index, i.e. the subjects who reported some dyspnea at the start walked fewer meters during the test;
- the final dyspnea index presented a significant inverse correlation at the 0.01 level with saturation (Figure 8) and with the meters traveled and a significant direct correlation at the 0.01 level with the heart rate; this means that the subjects who reported higher values of perceived dyspnea after the 6 minutes of testing recorded, in the instrumental data, lower saturation values and lower number of meters travelled, whereas the heart rate had higher values;
- final work showed a significant inverse correlation at 0.05 level with saturation and a significant inverse correlation at 0.01 level with heart rate; therefore, subjects who reported rilevant tiredness after carrying out the test recorded lower saturation values and fewer meters travelled.

**Table 11.** Data relations.

| | | Saturation | HR | Meters Traveled | Basal dispnea Index | Final dispnea Index | Basal fatigue | Final fatigue |
|---|---|---|---|---|---|---|---|---|
| Saturation | Pearson correlation | -- | | | | | | |
| | N | 868 | | | | | | |

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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| HR | Pearson correlation | -0,185** | -- | | | | | |
| | Significance (two tailed) | <0.001 | | | | | | |
| | N | 868 | 868 | | | | | |
| Meters traveled | Pearson correlation | 0,264** | 0,248** | -- | | | | |
| | Significance (two tailed) | <0,001 | <0,001 | | | | | |
| | N | 868 | 868 | 868 | | | | |
| Basal dispnea Index | Pearson correlation | -0,259** | 0,050 | -0,254** | -- | | | |
| | Significance (two tailed) | <0,001 | 0,144 | <0,001 | | | | |
| | N | 868 | 868 | 868 | 868 | | | |
| Final dispnea Index | Pearson correlation | -0,257** | 0,126** | -0,091** | 0,408** | -- | | |
| | Significance (two tailed) | <0,001 | <0,001 | 0,007 | <0,001 | | | |
| | N | 868 | 868 | 868 | 868 | 868 | | |
| Basal fatigue | Pearson correlation | -0,014 | 0,024 | 0,047 | -0,091** | -0,018 | -- | |
| | Significance (two tailed) | 0,678 | 0,474 | 0,166 | 0,007 | 0,595 | | |
| | N | 868 | 868 | 868 | 868 | 868 | 868 | |
| Final fatigue | Pearson correlation | -0,077* | -0,088** | -0,039 | -0,024 | -0,187** | 0,754** | -- |
| | Significance (two tailed) | 0,023 | 0,010 | 0,250 | 0,484 | <0,001 | <0,001 | |
| | N | 868 | 868 | 868 | 868 | 868 | 868 | 868 |

**. The correlation is significant at the 0.01 level (two-tailed).

*. The correlation is significant at the 0.05 level (two-tailed).

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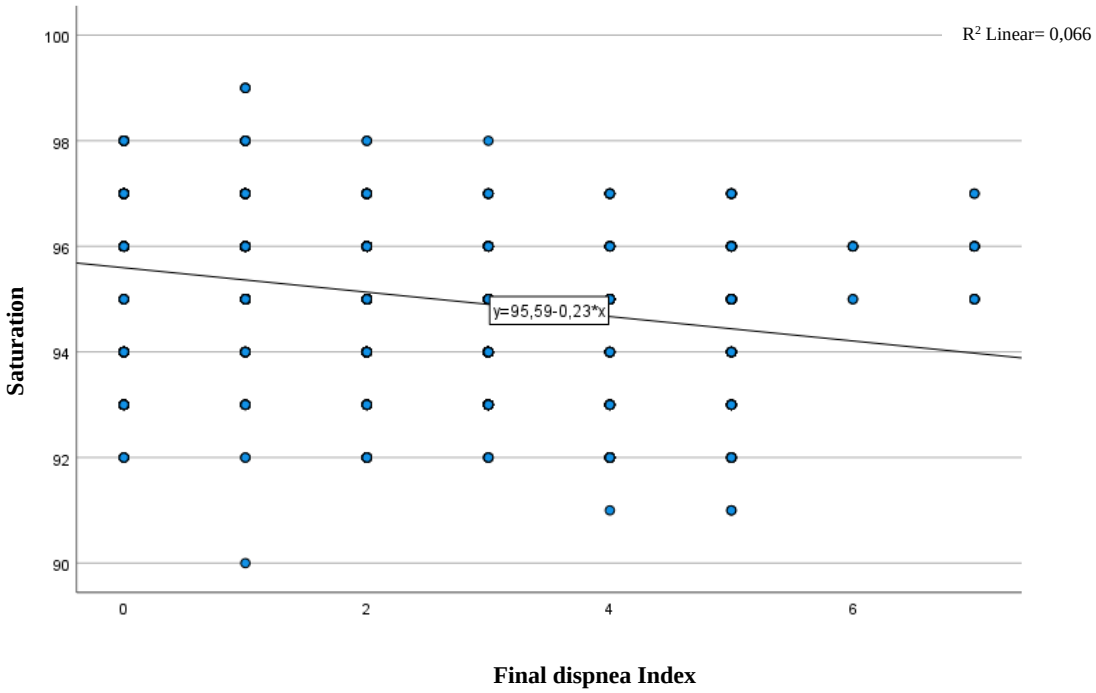


**Figure 8.** Diagram of the regression line interpolating the saturation data and final dyspnea index.

## 4. Discussion

The use of HME stomal filters in laryngectomee patients represents a fundamental pulmonary rehabilitation method to allow the maintenance of a physiology of the respiratory system as closest, as possible to that existing before the surgery, considerably reducing the incidence of inflammatory pathologies, even severe ones.[12,15,20,21] The prevention of respiratory complications is also of great importance during vocal rehabilitation, especially in cases of use of the trachea-esophageal prosthesis; the exhaled pulmonary air as an air current sets the pseudo glottis in vibration, therefore a good pulmonary performance, with reduced trachea-bronchial secretion, is closely related to a satisfactory voice quality.[22–24]

The process of social reintegration of the laryngectomee patient begins with vocal rehabilitation: as the voice is an essential tool in man's life, especially in the relational sphere, although the vocal function is returned, sometimes, no attention is paid to the purpose of welfare information, the importance of having an active lifestyle for social reintegration.[8,25–27] Sport, among other things, represents a vehicle for social inclusion, an important tool for aggregation and interaction which, especially for these patients, can represent an element capable of distancing them from the state of anguish resulting from their state of illness and at the same time a way to feel socially accepted.[6,28–30]

Over the years, various models of HME filters have been proposed to have a device that allows both adequate protection of the trachea-bronchial tree and respiratory resistance suitable for the physical activities carried out by the patient to satisfy the various needs of daily life. [31]The main problems were related to the creation of a filter capable of allowing the practice of more intense motor activities, such as those associated with sport, considering that, unfortunately, many patients are mostly part of younger age group.[17,22] An HME filter suitable for sports practice must have less resistance to air flow; currently the most used ones are:

- Provox® Life™ Go HME
- Laryvox HME Sport
- Provox® Life™ Energy HME
- Provox® XtraFlow HME™
- Blom-Singer EasyFlow HME
- Blom-Singer SpeakFree HME

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- Laryvox® Extra HME

The data obtained in our study reveal that with regards to the objective parameters measured during the 6MWT the best results, which were also statistically significant, were obtained with the Blom-Singer SpeakFree HME filter, despite the subjective perception of the patient when we evaluate the final dyspnea index is the Provox® Life™ Energy HME filter which has received the widest approval from patients.

These results lead to several considerations; first of all, it is a preliminary study, with a limited series of cases and with an instrumental evaluation conducted for a short period of time, a condition which can obviously be different from what the patient experiences during the practice of his physical activities (e.g. cycling, walking, gym, Pilates, etc.).

If the Blom-Singer SpeakFree HME filter and the Provox® Life™ Energy HME filter can be considered apparently equivalent in daily practice and certainly much more suitable for more intense physical activity than traditional filters, however, it is necessary to plan studies that evaluate the same parameters we used in a longer period of motor activity, in order to better define the respiratory resistance characteristics perceived by the patient and compare them with the results obtained by measuring saturation and heart rate.

## 5. Conclusions

Patients undergoing total laryngectomy inevitably experience significant changes in their quality of life, not only due to anatomical and functional variations, which limit the performance of numerous activities, but above all linked to the psychological impact that the oncological pathology and these limitations have on the subject. [7,25,32]The resulting repercussions concern a vast range of aspects; the main problem undoubtedly concerns the area of verbal communication, but there are also food problems, more than anything else, which can be traced back to the reduction of the senses of taste and smell, which determine a lower appreciation of food.[8,33] Furthermore, there is a decrease in strength and physical resistance which leads to difficulty in carrying out strenuous activities and, in more serious cases, even simple daily activities. Concern about one's physical appearance and one's voice is what most affects the psychological well-being of the laryngectomee patient, leading him to maintain a distance from the world around him and to withdraw into himself, thinking that other people find him unpleasant.[34,35]

Consequently, although laryngeal cancer has a good cure rate, it is equally true that it disturbs the patient's psychological balance throughout his life, influencing his habits and constantly reminding him of the cancer experience, due to the permanent presence of the tracheostoma.[20,32,36] Considering this, it is correct to take note of the change in the quality of life of the laryngectomee patient, but, at the same time, also of the current therapeutic and rehabilitative supports, which allow to compensate for this handicap.[6,37] In fact, restoring to the patient a quality of life as similar as possible to the pre-operative one represents an essential objective in the rehabilitation field, unfortunately, it does not seem adequately considered, very often the relationship with the laryngectomee focusing only on the oncological and vicarious vocal aspect. [36,38]

It is the task of the speech therapist, together with the doctor, to illustrate the various aids for the treatment of the tracheal stoma and the importance of using HME filters due to the enormous advantages it provides at a pulmonary and relational level. [20] Even today, many laryngectomees do not use stomal filters and this can essentially be attributed to a lack of information received, therefore, it is the primary task of the healthcare team to inform patients, both pre-operatively and subsequently, of the possibilities that modern technologies offer for the best management of the tracheostoma.[15,22]

In our study, both Blom-Singer SpeakFree HME and Provox® Life™ Energy HME proved to be the most suitable filters for patients' physical performance during testing; the first regarding the instrumental data of better saturation, reduced heart rate values and greater number of meters travelled, while the second one was more appreciated by the patients due to their perception of less dyspnea and fatigue during the test. Whatever the patient's choice, the important thing is that the HME filter is always used as it will guarantee the patient a better physical condition, the possibility

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of returning quickly and satisfactorily to previous activities, even the most demanding ones from the motor, by accepting the new anatomical-physiological condition with much more serenity.

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**Conflicts of Interest:** The authors declare no conflict of interest.

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