

DR GAVIN QUAIL

MBBCH (WITS) BCOM (UNISA)

**THE EFFECT OF CLOTH STOMA COVERS ON THE
TRACHEAL CLIMATE OF LARYNGECTOMISED
PATIENTS**

UNIVERSITY OF CAPE TOWN

MASTER OF MEDICINE (MMED) IN
OTORHINOLARYNGOLOGY

The research in this report is based on independent work performed by the candidate and neither the whole work nor any part of it has been, is being or is to be submitted for another degree to any other university. The same mentioned research has not been published prior to registration for the abovementioned degree.

The copyright of this thesis vests in the author. No quotation from it or information derived from it is to be published without full acknowledgement of the source. The thesis is to be used for private study or non-commercial research purposes only.

Published by the University of Cape Town (UCT) in terms of the non-exclusive license granted to UCT by the author.

**The Effect of Cloth Stoma Covers on the Tracheal Climate of
Laryngectomised patients**

Principal Investigators

Dr G Quail

Dr O Raynham

Professor JJ Fagan

Division of Otolaryngology

Medical School

University of Cape Town

Observatory

Cape Town

7925

Tel: 021 4066420

Fax: 021 4488865

Cell: 0728907755

gavinquail@gmail.com

TABLE OF CONTENTS

Summary	6
Part A - Introduction	8
Motivation for the study	10
Part B - Literature Review	11
Objectives	11
Literature search strategy	12
Summary of Literature	14
Part C - Aims and Objectives.....	19
Materials and Methods	20
Design of Sensor Module and Data Collection.....	22
Study Location	25
Study Design.....	25
Study Period.....	25
Study Population	26
Inclusion Criteria.....	26
Exclusion Criteria	26
Data Analysis	27
Ethical Considerations.....	29
Part D - Results.....	30
Discussion of statistical analysis.....	33
TEMPERATURE	34
RELATIVE HUMIDITY	35
ABSOLUTE HUMIDITY	36
Discussion Of Results	37
Limitations of the study.....	38
Part E - Conclusions and recommendations.....	39
Part F - References	41
Appendix.....	44
Consent to act as a subject in a clinical study	47
Ethics and Hospital Approval	48

Acknowledgements:

Henri Carrara - Analytical epidemiologist/Biostatistician, Faculty of Health Sciences, University of Cape Town for assistance with statistical analysis.

Lester John - Electronic & Biomedical Engineer, Department of Human Biology, Faculty of Health Sciences, University of Cape Town for assistance with designing and building the sensor module and software used.

List of figures

<i>Figure 1: HME device with stick over the stoma base plate (left) and close-up of HME device (right)</i>	8
<i>Figure 2: Locally produced cloth stoma cover (top left) with close-up view of fabric (top right) and Buchanan Bib (bottom left) with close-up view (bottom right)</i>	9
<i>Figure 3: Patient analysis being done with no Stoma Cover (left), a Cloth Stoma Cover (middle) and a HME device with the sensor tip passed through the device (right)</i>	22
<i>Figure 4: Thermocouple temperature sensor within the sample line (left); Relative Humidity sensor (middle); Housing for relative humidity sensor and temperature sensor (right)</i>	25
<i>Figure 5: Box Plot comparison of temperature, relative humidity and absolute humidity achieved with Bibs and HME devices (Dry/Wet SA = Dry/Wet South African Locally made Stoma Cover, Dry/Wet Buc = Dry/Wet Buchanan Bib, HME Moist = Heat moisture exchanger extra moist, HME Flow = Heat moisture exchanger extra flow</i>	32

List of tables

Table 1: Raw data summary of Temperature, Relative Humidity and Absolute Humidity.....31

List of Definitions

Heat and moisture exchanger: “**HME**”

Locally produced cotton islet fabric Cloth Stoma Cover: “**Stoma Cover**”

Commercially produced Cloth Stoma Cover: “**Buchanan Bib**”

SUMMARY

Patients that have undergone a laryngectomy lose the normal heat-moisture-exchange functions of the nose and upper airways. Breathing unconditioned air can cause irritation of the tracheal and bronchial mucosa and lead to chest complaints such as irritating coughing and excessive mucus production and mucus plugs.

Disposable HME's that cover the tracheostoma and are stuck to the skin with adhesives are believed to improve the condition of inspired air for laryngectomy patients. HMEs work by accumulating heat and moisture during exhalation and reciprocally warming and humidifying inspired air. Due to the cost of HMEs they are not affordable to the general population in South Africa and many other countries.

Stoma Covers are simple devices made of a single fabric or combinations of fabrics that are fastened around the neck with the cloth covering the tracheostoma. They are relatively inexpensive to manufacture and can be washed and re-used. No research has been conducted to date regarding the effect of using simple Stoma Covers to improve the tracheal climate in laryngectomy patients.

Commercially produced Buchanan Bibs have not been compared to HMEs or to cheap locally produced Stoma Covers.

The practice of wetting Stoma Covers or Buchanan Bibs to improve tracheal climate has not been analyzed.

Temperature and humidification data from breaths of laryngectomy patients were acquired by means of a purpose built sampling device. The results prove that simple Stoma Covers are effective in heating and humidifying inspired air of laryngectomy patients. Stoma Covers compare favorably with HME devices. There is no benefit in using a commercially produced Buchanan Bibs over a cheap locally produced Stoma Cover. The practice of wetting either a Stoma Cover or a Buchanan Bib to improve airway climate was shown to be counterproductive.

Use of cheap and effective Stoma Covers to improve breath temperature and humidity is of benefit to laryngectomy patients in developing world countries where financial resources are limited.

PART A - INTRODUCTION

Laryngectomy patients lose the normal heat-moisture-exchanging function of the nose and upper airways. Breathing unconditioned air can cause irritation of the tracheal and bronchial mucosa and lead to chest complaints such as irritating coughing and excessive mucus production¹ and mucus plugs.

HMEs are known to improve the condition of inspired air of laryngectomy patients (*Figure 1*). HMEs work by accumulating heat and moisture during exhalation. Inspired air is reciprocally warmed and humidified by the HME. HMEs are designed to be disposable.²



Figure 1: HME device with stick over the stoma base plate (left) and close up of HME device (right)

Stoma Covers are simple devices made of a single fabric or combinations of fabrics that are fastened around the neck with the cloth covering the tracheostoma (*Figure 2*). Even though Stoma Covers have been used for many decades, no research has been reported regarding the effectiveness of Stoma Covers to improve the tracheal climate in laryngectomy patients. There is no available research regarding the effect on tracheal climate of commercially produced Buchanan Bibs or locally produced cheap Stoma Covers.

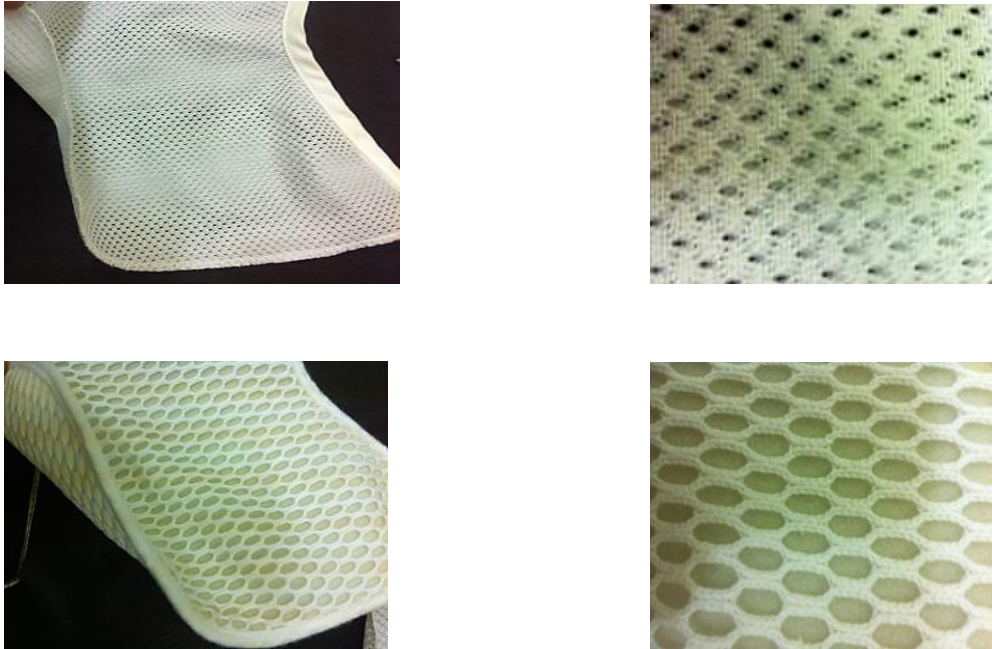


Figure 2: Locally produced Stoma Cover (top left) with close-up view of fabric (top right) and Buchanan Bib (bottom left) with close-up view (bottom right)

In most of the world and specifically in South Africa, HMEs are not affordable for the general population. Annual costs for HMEs conservatively range from the equivalent of US\$ 350 to US\$ 1750 (ZAR 3,500 to ZAR 17,500)^{3,4}. By contrast, Stoma Covers are inexpensive to manufacture and can be washed and re-used for extended periods. Buchanan Bibs (replaced monthly) cost about US\$ 235 (ZAR 2,350) per annum. Locally produced Stoma Covers cost about US\$ 0.5 (ZAR 5) and the annual cost is less than US\$ 2 (ZAR 20).

MOTIVATION FOR THE STUDY

The only commercially available and clinically tested device to improve tracheal climate is the stick-over-the-stoma-type HME device (*Figure 1*). Due to cost constraints, commercially produced HME devices are virtually not used in South Africa. Due to this lack of availability of HME devices, simpler and cheaper solutions for rehabilitation of laryngectomy patients need to be used.

Although many laryngectomy patients report an improvement in symptoms of coughing and the need to clear secretions with the use of laryngeal cloth stoma covers, there is no evidence currently in the literature relating to the efficacy of cloth stoma covers. Commercially produced stoma bib covers are available and marketed under the name “Buchanan Laryngectomy Permanent Tracheostomy Protectors”. There is however no evidence in the medical literature to support the manufacturer’s claims that these devices are beneficial.

Patients with particular problems relating to coughing and excess sputum production have traditionally been advised to wet the Stoma Cover to improve the climate of the tracheal air. Yet the efficacy of wetting the bib has never been reported.

PART B - LITERATURE REVIEW

OBJECTIVES

The objectives of the literature review of previous studies and publications relating to the use of HME devices, Buchanan Bibs and Stoma Covers in laryngectomy patients were to:

- 1) Determine the current understanding of the topic
- 2) To assess where these interventions has been successfully used
- 3) To identify gaps in our current knowledge where this study may prove helpful
- 4) To enable the formulation of a study protocol

LITERATURE SEARCH STRATEGY

A literature search was undertaken of the Pubmed, Medline and Cochrane databases for articles in journals that are listed on Index Medicus. The following keywords were used: "Cloth Stoma Cover", "Bib", "Heat-moisture-exchanger", "HME", "Laryngectomy", "Buchanan bib" and "Buchanan laryngectomy". Inclusion criteria for articles were: Peer reviewed articles, prospective studies and review articles specifically assessing heat and moisture exchanger use following total laryngectomy.

Articles not relevant to the effects of devices on tracheal climate were excluded such as articles that focused on speech rehabilitation rather than changes to tracheal climate; articles relating to HME attachment to the patient; effects of HME on breathing resistance and oxygenation as well as effects of HMEs on microbial colonization.

The quality of the articles was assessed based on the levels of clinical evidence. Meta-analyses and review articles were considered to be stronger evidence; studies with larger patient numbers carried greater weight than those with smaller patient numbers, and controlled trials with outcome-based results were sought out as the results of these might provide more significant clinical evidence.

Numerous articles were found in the literature pertaining to the use of stick-on stoma HME devices. The abstracts were reviewed and assessed according to the questions raised and answered by the paper, the number of patients included in the studies, evidence of statistical significance of the findings and whether they were review articles on the topics. The relevance to this study was also considered with regard to techniques used and methods of data analysis to assist in reporting of the data.

No reports were found that had assessed the effect of Stoma Covers and Buchanan Bibs on tracheal climate in laryngectomy patients.

SUMMARY OF LITERATURE

Patients undergoing a total laryngectomy have to adapt to major physiological and social change. These include excessive sputum production, excessive coughing, the need for forced expectoration along with voice changes or loss of voice, hyposmia, dysgeusia, nasal discharge and swallowing changes.^{1,5}

The permanent disconnection of the upper airways from the lower airways results in the loss of the normal physiological heating, moisturizing and filtering functions that are normally performed by the upper airway.⁶ Toremalm reported a loss of > 500ml of water/day when breathing through a stoma compared with normal nasal breathing.⁷ Significant adverse changes in the pulmonary physiology have been reported as a consequence of total laryngectomy.^{1,8-10}

There are multiple reports in the literature that recommend using “stick over the stoma” HME devices to improve pulmonary physiology.^{1,11,12} An HME device’s function is to heat, moisten and filter inspired air i.e. the functions that are normally executed by the upper airway and are lost in total laryngectomy patients due to the disassociation of the upper and lower airways. HMEs filter air and exchange the high heat and moisture content from expired air with the inspired breath that follows.

No studies were found that assessed changes in the tracheal climate (heat and moisture content) when using a tracheal cloth stoma cover.

Toremalm (1960) first reported on the use of HME devices in tracheostomy patients using an aluminum foil HME which was attached to a tracheal cannula.⁷

HME devices specifically used for laryngectomy patients were prospectively assessed by Hilgers and Aaronson in 1991. They interviewed 42 patients using HMEs and found that symptoms of fatigue and malaise decreased significantly and that social contact had improved; 63% of these patients reported a decrease in sputum volume, frequency of forced expectoration and stoma cleaning¹³.

The same authors published a subjective and objective assessment of 61 patients in 1993. Although there was no statistically significant difference between patients using vs. not using an HME, there was a trend towards improvement in respiratory and psychosocial functioning in the group using the HME. Objectively there was improvement in inspiratory flow and volume on pulmonary function tests in the experimental group using an HME¹⁴. The same group then conducted a multi-institutional prospective study in 1995. They assessed 59 patients using HME devices and showed that forced expectoration, perceived voice quality, social anxiety, social interaction, feelings of anxiety and of depression were improved.¹⁵ A similar multicenter study with 81 laryngectomy patients was reported in 2003 and showed similar pulmonary improvements as well as improvements in voice quality.¹²

Objective measurements of changes in tracheal climate followed from these studies.

McRae et al in 1995 were able to determine the effectiveness of the upper airways to moisturize and heat air by analyzing the breaths of patients with otherwise normal upper airways with tracheostomy tubes in situ. They reported that ideal HME devices should aim to reproduce the physiological functions of the upper airway, i.e. increase stomal resistance, temperature, humidity and be able to filter particulate matter.¹⁶

Laboratory based tests done by Grolman in 1997 with a ventilator attached to a water bath illustrated the moisture-preserving properties of HME devices. Temperature preservation was not assessed in this study.³

Liener and Durr reported an *in vivo* tracheal humidity and temperature system in 2006. This system used a relative humidity sensor and a thermocouple device that was attached to a suction apparatus to sample tracheostomal air. A similar relative humidity sensor and thermocouple were placed outside the stoma to assess inspired air temperature and water content; a stress sensitive belt was placed around the chest to register the phase of the respiratory cycle. The results were recorded electronically. This study device paved the way for future assessments of tracheal climate with and without HME devices.¹⁷

Zuur and Muller coined the term “The Airway Climate Explorer” (“ACE”) when they described their similar intra-tracheal temperature and humidity monitoring device.¹⁸ The ACE device worked in a similar fashion to the device described by Liener and Durr but had a few technical improvements that the authors believed

would increase the accuracy of the results. This ACE device was used in a study published in 2008 by Zuur and Muller to quantitatively assess *in vivo* tracheal climate changes when an HME device was used. Ten patients were recruited in this study. The authors describe multiple technical challenges that occurred with the study but were able to show that tracheal humidity increases, but that the tracheal temperature decreases with an HME device. The authors state that limitations in the thermal capacity and not the moisture retention is the limiting factor in the heat and moisture transfer process performed by HMEs.²

Scheenstra and Muller conducted a further study on the ACE device in 2009 where they assessed intra- and inter-patient variability relating to endotracheal temperature and humidity. They showed that intra-patient variability was a more significant confounding factor, and that the position of the sample tip was the most important variable responsible for this effect. Consequently these authors stated that more measurements on less patients is actually a better way to compare tracheal climate results.¹⁹

The literature review revealed a lack of knowledge relating to laryngectomy Stoma Covers and Buchanan Bibs.

The literature review showed that increasing temperature and humidity of inspired air is beneficial to laryngectomy patients and that these improvements can reduce some of the adverse side effects of a total laryngectomy.

The review shows that the only currently proven way to create these improvements is to apply a stick-on HME device to the stoma. With regards to tracheal climate, HME devices have been proven to improve the tracheal climate with respect to humidity only and not with respect to temperature.

Due to the glaring absence of studies in the literature relating to the effects of Stoma Covers and Buchanan Bibs on changing tracheal climate, it was evident that research on cloth stoma covers is required.

PART C - AIMS AND OBJECTIVES

1. To investigate the efficacy of tracheal Stoma Covers and Buchanan Bibs relating to tracheal climate (specifically humidity and temperature).
2. To compare very cheap locally manufactured Stoma Covers with commercially available but significantly more expensive Buchanan Bibs.
3. To compare the efficacy of Stoma Covers and Buchanan Bibs with commercially produced (but largely unaffordable) HME stick-over-the-stoma devices.
4. To assess the effect of wetting the Stoma Cover and Buchanan Bib on tracheal climate and to determine if the advice to wet the cover/bib is of any benefit.

MATERIALS AND METHODS

Laryngectomy patients were recruited during routine follow up at the Head & Neck Oncology Clinic and at the Speech Therapy Clinic at Groote Schuur Hospital.

A custom-built sensor module (described below) was used to analyze the breaths of laryngectomy patients. From preliminary tests it was determined that 1 minute was more than sufficient time for patient acclimatization to occur and for the breath temperature and humidity readings to stabilize. Each device under investigation was analyzed for 2 minutes to allow for at least 1 minute of recording time after the initial acclimatization had occurred.

The sensor module was first used to obtain a baseline dataset from patients without an HME or cloth stoma cover in place. After the baseline reading was acquired each of the patients was tested in all of the following situations:

- 1) Dry locally manufactured Stoma Cover
- 2) Locally manufactured Stoma Cover wet with 20ml of room-temperature tap water
- 3) Dry Buchanan Bib
- 4) Buchanan Bib wet with 20ml of room-temperature tap water
- 5) Provox Extra Moist HME device
- 6) Provox Extra Flow HME device

To facilitate measuring breath humidity and temperature while using the Provox HME devices, a small hole was punched through the plastic top of the HME cassette and the sample line passed through this hole to reach the tracheal side of the device.



Figure 3: Patient analysis being done with no Stoma Cover (left), a Cloth Stoma Cover (middle) and a HME device with the sensor tip passed through the device (right).

DESIGN OF SENSOR MODULE AND DATA COLLECTION

The Clinical Engineering Department of Groote Schuur Hospital assisted with building of the sensor module. The sensor module consisted of a data acquisition device attached to 5 sensor devices. These sensors were:

- 1) Humidity sensor for humidity of patient's breath
- 2) Thermocouple for temperature of patient's breath
- 3) Room temperature sensor
- 4) Room humidity sensor
- 5) Chest girth monitor to determine the phase of the respiratory cycle

A laptop was attached to the data acquisition device to record the raw data electronically. A laptop was specifically chosen and left disconnected and isolated from the mains electricity to limit any possible electrical risk to the patient. The program was designed to record readings from each sensor at a rate of 10 times per second and written to a pre-labeled data file.

The humidity sensor used was a *Vaisala Humichip 17205* capacitive thin-film humidity sensor (Helsinki Finland) with an accuracy of $\pm 4\%$ at room temperature. The capacitance of a polymer film in the sensor changes with the absorption of water and is a measure of relative humidity.

The thermocouple was a Thermocoax (France) Nickel-Chromium-Nickel aluminium type thermocouple with a stainless steel sheath (diameter of 0.34mm) with an uncertainty of 0.3 degrees Celsius. Its temperature curve is virtually linear and its sensitivity is $41\mu\text{V}/^\circ\text{C}$.

The data acquisition module was a National Instruments (Hungary) Bus Powered USB 6211 device.

The recording software was created using the Labview software suite from National Instruments.

The temperature probe was calibrated against a standard thermometer as well as a digital recording thermometer. The relative humidity probe was calibrated against specifically manufactured standard solutions of MgCl_2 (33% relative humidity) and NaCl (75% relative humidity).

To facilitate sampling of the tracheal air, the humidity sensor chip was built into a plastic housing in such a way that the sample flowed directly over the sensor.

The size of the humidity sensor chip is too large to fit directly inside the tracheostoma. The flow of air was facilitated by a suction device to continuously sample the breath at a rate of 600ml per minute. A short (3cm) sample line with an internal diameter of 3mm was attached to the sensor housing and the thermocouple wire placed inside the sample line to enable temperature sampling at the tip of the sample line.



Figure 4: Thermocouple temperature sensor within the sample line tip (left); Relative Humidity sensor (middle); Housing for relative humidity sensor and temperature sensor (right).

From previous studies by Scheenstra et al ¹⁹ it was noted that the position of the sample line relative to the tracheostoma is of extreme importance. The tip of the sample line was therefore placed in front of, and never inside the stoma and the position of the tip of the sample line was maintained in a constant position between the individual tests for each patient. It was not practical to tape or secure the sample line to the patient, so the operator held the sensor in place.

STUDY LOCATION

A fixed location with still air close to the clinic where the patients were recruited was used for all test subjects. The room measured 5 x 3 meters. There were no windows or artificial ventilation. The patient was seated for the duration of the tests. Each of the cloth stoma covers and HME devices (described above) were used sequentially on each test subject to record a dataset.

STUDY DESIGN

The study was designed and run as a prospective study. There was no observer bias as each patient was recruited and tested sequentially with each Stoma Cover and Buchanan Bib in a dry and wet state and thereafter with the HME devices. The results were automatically generated and recorded electronically.

STUDY PERIOD

Patients were recruited between March and September of 2012.

STUDY POPULATION

25 patients were recruited during the study period. There were 21 males and 4 females aging between 25 and 83 years with an average age of 64.5 years. The average duration following laryngectomy was 4.5 years.

INCLUSION CRITERIA

Healthy, mobile laryngectomy patients that attended the Speech Therapy or the Head and Neck Oncology Clinics were included.

EXCLUSION CRITERIA

Patients that had not undergone total laryngectomy were not eligible for the study. Patients that were too ill or that were not able to move to the study room were not recruited into the study. No patients that were asked to participate in the study declined.

DATA ANALYSIS

To obtain clinically useful data that could be statistically analyzed, the recorded data had to be de-convoluted. The results were imported into Microsoft Excel and viewed graphically. The most significant and critical readings of temperature and humidity during each test are at the end of inspiration. The expiratory breath values are not overtly useful as this would be confounded by the lung's ability to warm and moisten air. Although this data could be used to show changes in expiratory humidity and temperature, it was not considered useful for this study relating to the effectiveness of the HME, Stoma Covers and Buchanan Bibs.

The end inspiratory breath values are the significant values for assessing the changes in tracheal climate from cloth stoma covers or HME devices.

The end inspiratory phase point is at the peak of the chest girth measurement. This point was calculated by determining the turning point of the peak of the graph of the chest girth values. At this point breath humidity and temperature readings were recorded for 5 clinically significant breaths for each Stoma Cover, Buchanan Bib, HME device and baseline value. These values were always recorded after at least one minute of acclimatization and at a point where the temperature and humidity results had plateaued.

Absolute humidity values were calculated using derivatives of the Clausius-Clapeyron and Magnus equations. Between temperatures of -45°C and 60°C this equation has an uncertainty of less than ±0.6% at 95% confidence level.

The formula was obtained from *Introduction to Humidity - Basic Principles on Physics of Water Vapor*, published by Sensirion, a manufacturer of humidity and temperature sensors in Laubisruetistr, Switzerland.

The formula used to make the conversion to absolute humidity was:

$$d_v = 216.7 \cdot \frac{U_w}{100\%} \cdot \alpha \cdot \exp\left(\frac{\beta \cdot t}{\lambda + t}\right) \cdot \frac{1}{(273.15^\circ\text{C} + t)}$$

Where:

d_v = Absolute Humidity (g/m³)

U_w – Measured Relative Humidity % [measured]

α = Pressure constant for a gas above water (hPa) = 6.112

β = Constant for a gas above water = 17.62

λ = Temperature conversion for a gas above water = 243.12

t = Measured temperature of gas (°C) [measured]

And expanded to be used in Microsoft Excel:

Absolute Humidity =

$$216.7 * ((RH/100 * 6.112 * EXP(((17.62 * Temp)/(243.12 + Temp)))) / (273.15 + Temp))$$

ETHICAL CONSIDERATIONS

Permission to conduct the study was obtained from the Research Ethics Committee of the Health Sciences Faculty of the University of Cape Town – see Appendix.

The protocol was accepted by Dr. M Blockman (Chairperson of Ethics Committee) on 18 August 2006 and an updated approval was obtained in May 2013.

Groote Schuur Hospital's Chief Executive Officer, Dr. B Patel, approved the protocol and the use of the facility for the research on 11 October 2006.

PART D - RESULTS

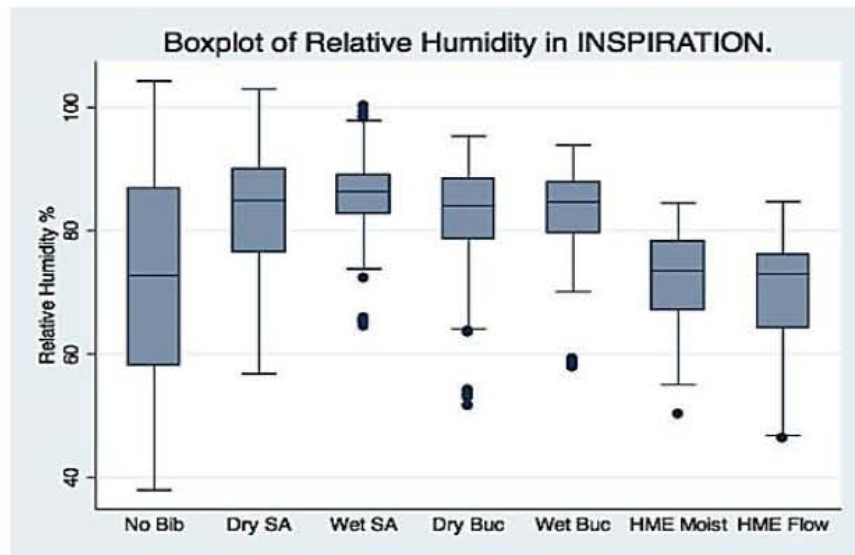
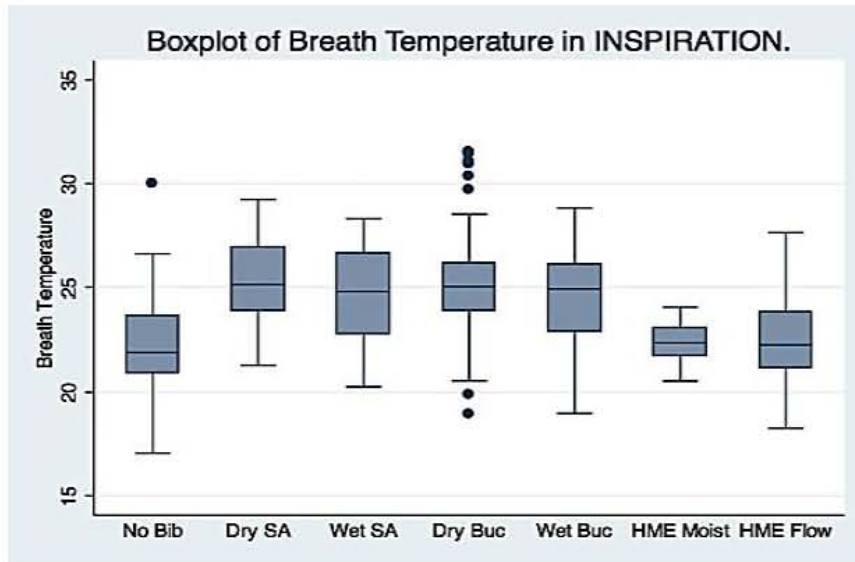
Stata-12 data analysis software was used to analyze the data.

The raw data is summarized in table form below.

	n	Temperature				Relative Humidity				Absolute Humidity			
		min	max	p50	Range	min	max	P50	Range	min	max	P50	Range
No Cover	125	17	29.9	22.1	12.9	37.9	104.3	73.2	66.4	6.4	24	14.1	17.6
Dry Local Blb	125	21.3	29.2	25.1	7.9	56.8	103	84.9	46.2	12.8	28.3	20	15.5
Wet Local Blb	120	20.3	28.3	24.8	8	64.4	100.2	86.3	35.8	13.3	25.8	19.5	12.5
Dry Buchanan Blb	125	18.9	31.5	25	12.6	51.4	95.4	84.1	44	10	27.2	19.1	17.2
Wet Buchanan Blb	120	19	28.8	24.9	9.8	57.9	93.9	84.7	36	12	25.1	18.9	13.1
HME Extra Flow	120	18.3	27.6	22.3	9.3	46.2	84.7	73	38.5	7.9	19.7	14.5	11.8
HME Extra Moist	45	20.5	24.1	22.4	3.6	50.2	84.5	73.5	34.3	8.9	16.9	15.2	8

Table 1: Raw data summary of Temperature, Relative Humidity and Absolute Humidity

Box plots of the raw data are provided to graphically display the results.



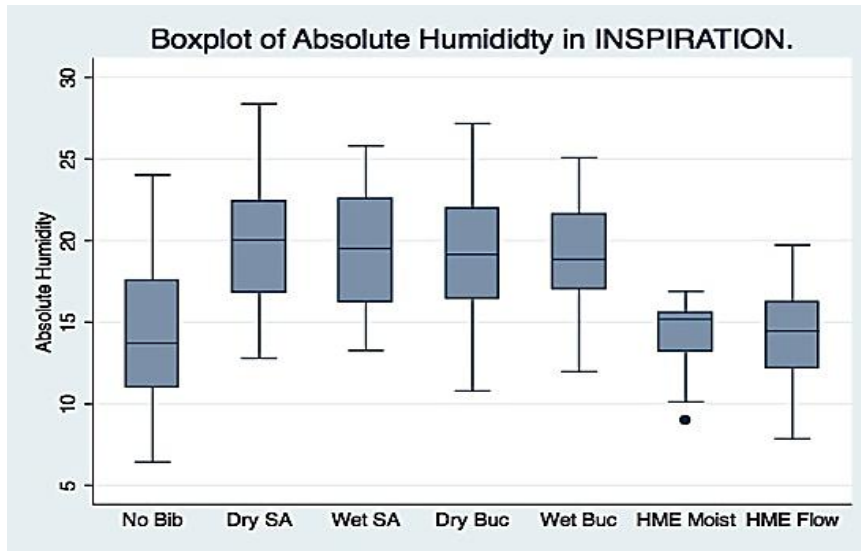


Figure 5: Box Plot comparison of temperature, relative humidity and absolute humidity achieved with Bibs and HME devices (Dry/Wet SA = Dry/Wet South African Locally made Stoma Cover, Dry/Wet Buc = Dry/Wet Buchanan Bib, HME Moist = Heat moisture exchanger extra moist, HME Flow = Heat moisture exchanger extra flow)

DISCUSSION OF STATISTICAL ANALYSIS

Stata 12 was used to analyze the results.

A repeated measures Analysis of Variance was used to compare the means between methods.

Pairwise comparisons using the Bonferonii adjustment was used to determine where differences lie. This test was used to eliminate error from repeated measurements since 5 values were recorded per method (each baseline, Stoma Cover, Buchanan Bib and HME). This effectively eliminates a sampling error that could occur from results *within a set of recordings* being more similar to results *between a set of recordings*.

TEMPERATURE

The Analysis of Variance showed a statistically significant ($p < 0.05$) improvement in temperature when no cloth stoma cover was compared to a local Stoma Cover or a Buchanan Bib, either wet or dry.

There was a statistically significant ($p < 0.05$) improvement in temperature with a Stoma Cover and a Buchanan Bib compared to either of the HME devices.

There was no statistically significant difference in temperature when no Stoma Cover or Buchanan Bib was compared to the HME Extra-Moist or Extra-Flow devices.

There was no statistically significant improvement in temperature between the dry and wet Stoma Cover and Buchanan Bib.

There was no statistically significant difference in temperature between the Extra-Flow and Extra-Moisture HME devices.

RELATIVE HUMIDITY

The Analysis of Variance showed a statistically significant ($p < 0.05$) improvement in relative humidity when a local Stoma Cover or a Buchanan Bib, either wet or dry, was compared to no cloth stoma cover.

There was a statistically significant ($p < 0.05$) improvement in relative humidity with a Stoma Cover and a Buchanan Bib compared to either HME devices.

There was no statistically significant difference in relative humidity when no Stoma Cover or Buchanan Bib was compared to the HME Extra-Moist and Extra-Flow devices.

There was no statistically significant improvement in relative humidity between the dry and wet Stoma Cover and Buchanan Bib.

There was no statistically significant difference in relative humidity between the Extra-Moist and Extra-Flow HME devices.

ABSOLUTE HUMIDITY

The Analysis of Variance showed a statistically significant ($p < 0.05$) improvement in absolute humidity when a local Stoma Cover or a Buchanan Bib, either wet or dry, was compared to no cloth stoma cover.

There was a statistically significant ($p < 0.05$) improvement in absolute humidity with a Stoma Cover and a Buchanan Bib compared to either HME devices.

There was no statistically significant difference in absolute humidity when no cloth stoma cover was compared to the HME Extra-Moist and Extra-Flow devices.

There was no statistically significant improvement in absolute humidity between the dry and wet Stoma Covers and Buchanan Bibs.

There was no statistically significant difference in absolute humidity between the Extra-Moist and Extra-Flow HME devices.

DISCUSSION OF RESULTS

Stoma Covers and Buchanan Bibs significantly improve temperature and both relative and absolute humidity.

There is no difference when a cheap locally produced Stoma Cover is compared to a Buchanan Bib that is purpose-built and significantly more expensive.

No benefit was shown from wetting a Stoma Cover or Buchanan Bib in an attempt to improve tracheal climate, as the drop in temperature associated with a wet cover results in a drop in relative humidity, hence being counterproductive and not improving tracheal climate.

Although no statistically significant improvement was shown with HME devices compared to no Stoma Covers and Buchanan Bibs, there was a decrease in the range of the temperature, relative and absolute humidity readings showing a trend that the HME devices do create some improvement in tracheal climate.

LIMITATIONS OF THE STUDY

The positioning of the tip of the probe of the sample line is of significant importance. In the study the operator held the sample line in place. For future studies a permanent fixture that prevents even the slightest movement of the probe might further increase accuracy.

The Relative Humidity sensor over-read 16 times out of a total sample of 779 readings. The highest over-read was 104% instead of 100%. An attempt was made to correct this error by applying a maximum reading of 100% to these over-reads to assess if any different outcomes of the data would have been reached. The data was analyzed with and without this correction and no change in any final results was found and it can therefore be stated that no different conclusions would have been reached.

The data presented herein is presented without any corrections being made.

PART E - CONCLUSIONS AND RECOMMENDATIONS

Laryngectomy bypasses the heating, humidification and filtering functions of the nose and upper airways. This can cause irritating coughing and excessive mucus production. Warming and humidifying inspired air has been proven to alleviate some of these troublesome symptoms. Thus humidifying and warming inspired air in laryngectomy patients is important. HME devices are expensive in developing countries and many other healthcare settings.

Locally produced Stoma Covers and commercially produced Buchanan Bibs were shown to improve the tracheal climate with respect to humidity and temperature.

Stoma Covers manufactured locally from simple cheap cotton eyelet fabric were found to be at least equivalent to the commercially available, purpose built Buchanan Bibs tested.

Cloth stomas covers, both locally and commercially produced, were found to be superior to the commercially available HME devices tested.

Wetting Stoma Covers and Buchanan Bibs further decreased the temperature and did not yield superior humidification.

Patients should be advised to cover their tracheostoma with a simple, cost-effective cloth cover to improve the tracheal climate and alleviate some of the associated symptoms.

PART F - REFERENCES

1. Hilgers FJ, Ackerstaff a H, Aaronson NK, Schouwenburg PF, Van Zandwijk N. Physical and psychosocial consequences of total laryngectomy. *Clinical Otolaryngology and Allied Sciences*. 1990;15(5):421–5. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/2282704>.
2. Zuur JK, Muller SH, Vincent A, Sinaasappel M, De Jongh FHC, Hilgers FJM. Assessment of tracheal temperature and humidity in laryngectomized individuals and the influence of a heat and moisture exchanger on tracheal climate. *Head & Neck*. 2008;30(8):1072–82. doi:10.1002/hed.20835.
3. Grolman W, Blom ED, Branson RD, Schouwenburg PF, Hamaker RC. An efficiency comparison of four heat and moisture exchangers used in the laryngectomized patient. *The Laryngoscope*. 1997;107(6):814–20. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/9185739>.
4. Mérol J-C, Charpiot A, Langagne T, Hémar P, Ackerstaff AH, Hilgers FJM. Randomized controlled trial on postoperative pulmonary humidification after total laryngectomy: external humidifier versus heat and moisture exchanger. *The Laryngoscope*. 2012;122(2):275–81. doi:10.1002/lary.21841.
5. Ackerstaff a H, Hilgers FJ, Aaronson NK, Balm a J. Communication, functional disorders and lifestyle changes after total laryngectomy. *Clinical Otolaryngology and Allied Sciences*. 1994;19(4):295–300. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/7994884>.
6. Keck T, Leiacker R, Heinrich a, Kühnemann S, Rettinger G. Humidity and temperature profile in the nasal cavity. *Rhinology*. 2000;38(4):167–71. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/11190750>.
7. Nils Gunnar Toremalm. A Heat-And-Moisture Exchanger for Post-Tracheotomy Care. *Acta Oto-laryngologica*. 1960;52(1-6):461–472.
8. Togawa K, Konno a, Hoshino T. A physiologic study on respiratory handicap of the laryngectomized. *Archives of Oto-rhino-laryngology*. 1980;229(1):69–79. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/7469939>.
9. Todisco T, Maurizi M, Paludetti G, Dottorini M, Merante F. Laryngeal cancer: long-term follow-up of respiratory functions after laryngectomy. *Respiration; International review of thoracic diseases*. 1984;45(3):303–15. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/6463394>.

10. Ackerstaff a H, Hilgers FJ, Meeuwis C a, Knegt PP, Weenink C. Pulmonary function pre- and post-total laryngectomy. *Clinical Otolaryngology and Allied Sciences*. 1999;24(6):491–4. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/10606994>.
11. Moerman M, Lawson G, Andry G, Remacle M. The Belgian experience with the cyranose heat moisture exchange filter. A multicentric pilot study of 12 total laryngectomees. *European Archives of Oto-rhino-laryngology: Official journal of the European Federation of Oto-Rhino-Laryngological Societies (EUFOS): affiliated with the German Society for Oto-Rhino-Laryngology - Head and Neck Surgery*. 2003;260(6):301–3. doi:10.1007/s00405-002-0576-5.
12. Ackerstaff a. Multicenter study assessing effects of heat and moisture exchanger use on respiratory symptoms and voice quality in laryngectomized individuals. *Otolaryngology - Head and Neck Surgery*. 2003;129(6):705–712. doi:10.1016/S0194-5998(03)01595-X.
13. Hilgers FJ, Aaronson NK, Ackerstaff a H, Schouwenburg PF, Van Zandwijk N. The influence of a heat and moisture exchanger (HME) on the respiratory symptoms after total laryngectomy. *Clinical Otolaryngology and Allied Sciences*. 1991;16(2):152–6. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/2070531>.
14. Ackerstaff a H, Hilgers FJ, Aaronson NK, Balm a J, Van Zandwijk N. Improvements in respiratory and psychosocial functioning following total laryngectomy by the use of a heat and moisture exchanger. *The Annals of Otolaryngology, Rhinology, and Laryngology*. 1993;102(11):878–83. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/8239351>.
15. Ackerstaff a H, Hilgers FJ, Aaronson NK, et al. Heat and moisture exchangers as a treatment option in the post-operative rehabilitation of laryngectomized patients. *Clinical Otolaryngology and Allied Sciences*. 1995;20(6):504–9. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/8665707>.
16. McRae RD, Jones AS, Young P, Hamilton J. Resistance, humidity and temperature of the tracheal airway. *Clinical Otolaryngology and Allied Sciences*. 1995;20(4):355–6. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/8548971>. Accessed August 9, 2013.
17. Liener K, Durr J, Leiacker R, Rozsasi A, Keck T. Measurement of tracheal humidity and temperature. *Respiration; International review of thoracic diseases*. 2006;73(3):324–8. doi:10.1159/000088659.

18. Zuur JK, Muller SH, De Jongh FHC, et al. A newly developed tool for intra-tracheal temperature and humidity assessment in laryngectomized individuals: the Airway Climate Explorer (ACE). *Medical & Biological Engineering & Computing*. 2007;45(8):737–45. doi:10.1007/s11517-007-0217-7.
19. Scheenstra RJ, Muller SH, Vincent a, Sinaasappel M, Zuur JK, Hilgers FJM. Endotracheal temperature and humidity measurements in laryngectomized patients: intra- and inter-patient variability. *Medical & Biological Engineering & Computing*. 2009;47(7):773–82. doi:10.1007/s11517-009-0496-2.

Appendix

Stata-12 data analysis summaries

Stata-12 Summary of Breath Temperature

Method	Summary of Temp Breath		
	Mean	Std. Dev.	Freq.
No Bib	22.296146	2.2813035	120
Dry SA	25.385625	2.0056787	125
Wet SA	24.681005	2.2153433	120
Dry Buc	25.072582	2.2642592	125
Wet Buc	24.541572	2.0966921	120
HME Moist	22.445562	.9411783	45
HME Flow	22.531762	2.0690874	120
Total	24.004367	2.4378275	775

Source	Analysis of Variance				
	SS	df	MS	F	Prob > F
Between groups	1190.42548	6	198.404246	44.69	0.0000
Within groups	3409.4589	768	4.43939961		
Total	4599.88438	774	5.94300307		

Bartlett's test for equal variances: $\chi^2(6) = 39.7610$ Prob> $\chi^2 = 0.000$

Comparison of Temp Breath by Method (Bonferroni)						
Row Mean- Col Mean	No Bib	Dry SA	Wet SA	Dry Buc	Wet Buc	HME Mois
Dry SA	3.08948 0.000					
Wet SA	2.38486 0.000	-.70462 0.190				
Dry Buc	2.77644 0.000	-.313042 1.000	.391578 1.000			
Wet Buc	2.24543 0.000	-.844053 0.038	-.139433 1.000	-.53101 1.000		
HME Mois	.149417 1.000	-2.94006 0.000	-2.23544 0.000	-2.62702 0.000	-2.09601 0.000	
HME Flow	.235617 1.000	-2.85386 0.000	-2.14924 0.000	-2.54082 0.000	-2.00981 0.000	.0862 1.000

Stata-12 Summary of Breath Relative Humidity

Method	Summary of RH Breath		
	Mean	Std. Dev.	Freq.
No Bib	71.993395	16.921909	120
Dry SA	83.522914	10.253186	125
Wet SA	85.468079	7.0913854	120
Dry Buc	81.770058	9.8250806	125
Wet Buc	82.716395	7.3689632	120
HME Moist	72.270926	8.1404639	45
HME Flow	70.291775	9.2627931	120
Total	78.929252	12.022396	775

Source	Analysis of Variance				
	SS	df	MS	F	Prob > F
Between groups	27218.7861	6	4536.46435	41.16	0.0000
Within groups	84653.6229	768	110.226071		
Total	111872.409	774	144.537996		

Bartlett's test for equal variances: $\chi^2(6) = 138.0070$ Prob> $\chi^2 = 0.000$

Comparison of RH Breath by Method (Bonferroni)						
Row Mean- Col Mean	No Bib	Dry SA	Wet SA	Dry Buc	Wet Buc	HME Mois
Dry SA	11.5295 0.000					
Wet SA	13.4747 0.000	1.94517 1.000				
Dry Buc	9.77666 0.000	-1.75286 1.000	-3.69802 0.126			
Wet Buc	10.723 0.000	-.806519 1.000	-2.75168 0.896	.946337 1.000		
HME Mois	.277531 1.000	-11.252 0.000	-13.1972 0.000	-9.49913 0.000	-10.4455 0.000	
HME Flow	-1.70162 1.000	-13.2311 0.000	-15.1763 0.000	-11.4783 0.000	-12.4246 0.000	-1.97915 1.000

Stata-12 Summary of Breath Absolute Humidity

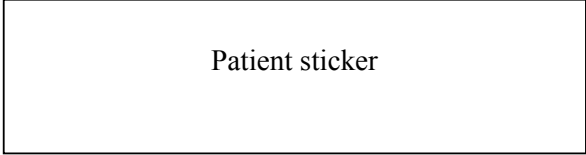
Summary of Absolute Humidity						
Method	Mean	Std. Dev.	Freq.			
No Bib	14.414164	4.3747339	120			
Dry SA	19.798607	3.8385001	125			
Wet SA	19.474894	3.3150574	120			
Dry Buc	19.08012	3.8185681	125			
Wet Buc	18.703554	3.214367	120			
HME Moist	14.404783	1.9487084	45			
HME Flow	14.192292	2.8777041	120			
Total	17.448057	4.2683626	775			
Analysis of Variance						
Source	SS	df	MS	F	Prob > F	
Between groups	4499.02039	6	749.836731	59.97	0.0000	
Within groups	9602.42333	768	12.5031554			
Total	14101.4437	774	18.2189195			
Bartlett's test for equal variances: chi2(6) = 49.2301 Prob>chi2 = 0.000						
Comparison of Absolute Humidity by Method (Bonferroni)						
Row Mean- Col Mean	No Bib	Dry SA	Wet SA	Dry Buc	Wet Buc	HME Mois
Dry SA	5.38444 0.000					
Wet SA	5.06073 0.000	-.323713 1.000				
Dry Buc	4.66596 0.000	-.718487 1.000	-.394774 1.000			
Wet Buc	4.28939 0.000	-1.09505 0.328	-.771339 1.000	-.376566 1.000		
HME Mois	-.009381 1.000	-5.39382 0.000	-5.07011 0.000	-4.67534 0.000	-4.29877 0.000	
HME Flow	-.221872 1.000	-5.60632 0.000	-5.2826 0.000	-4.88783 0.000	-4.51126 0.000	-.212491 1.000

Consent to act as a subject in a clinical study

TITLE: The effect of Cloth Stoma Covers on the Tracheal Climate of Laryngectomised patients

INVESTIGATORS:

Dr G Quail; Prof J Fagan
Address: Dept of Otolaryngology,
Old Main Building, Groote Schuur Hospital,
Observatory, Cape Town, 7925.
Phone. no: 021 406 6420



Ethics Office Tel: 021 4066496

DESCRIPTION

- **You are being asked to participate in this study** to see whether wearing a cloth stoma cover is beneficial compared to not wearing one and whether using a heat moisture exchanger device is beneficial.
- **We ask that you have the following tests done:**
 1. Have your breath analyzed with a purpose built machine while wearing no bib, a locally made bib (wet and dry), Buchanan bib (Wet & Dry) and wearing a HME device
 2. These tests will be carried out at your original visit to the ENT outpatients department or LE32. You will not be required to come back for any further testing

RISKS & BENEFITS

- There are no risks or benefits to you, and the information collected will not be utilised in your hospital management plan. It is for research purposes.
- Should you have any questions, you are welcome to ask them at any time throughout the study.
- You have the right to refuse to participate in this study at any time, and your decision will not adversely affect your care at this institution.
- There will be no additional costs to you or your family.

CONFIDENTIALITY

- The information obtained from this study will be published in the future such that your identity will remain anonymous. Medical records related to this study are confidential, but may be examined by researchers from this institution.

VOLUNTARY CONSENT:

I understand what is stated above and agree to participate in this clinical study.

Patient Signature:

Name:

I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participating in this research study, have answered any questions that have been raised and have witnessed the above signature.

Witness /Researcher: Name: Signature:

Ethics and Hospital Approval



UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
e-mail: preaward@curic.uct.ac.za

18 August 2006

REC REF: 310/2006

Dr OW Raynham
Otolaryngology

Dear Dr Raynham

PROJECT TITLE: THE EFFECT OF "LARYNGECTOMY BIBS" ON THE TRACHEAL CLIMATE OF LARYNGECTOMISED PATIENTS

Thank you for submitting your study to the Research Ethics Committee for review.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please supply the RECs details on the consent form and re-submit a copy for our files.
Please confirm that the above-mentioned study adheres to the Declaration of Helsinki 2000.

Please quote the REC. REF in all your correspondence.

Yours sincerely

signature removed

DR. M. BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

lemjedi

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938)			
This serves as notification of annual approval, including any documentation described below.			
<input checked="" type="checkbox"/> Approved	Annual progress report	Approved until/next renewal date	28/05/2014
<input type="checkbox"/> Not approved	See attached comments		
Signature Chairperson of the HREC	signature removed	Date Signed	21/5/2013
Comments to PI from the HREC			

Principal Investigator to complete the following:

1. Protocol information

Date form submitted	18 Aug 2006		
HREC REF Number	310/2006	Current Ethics Approval was granted until	
Protocol title	The Effect of Laryngectomy Bibs on the tracheal climate of Laryngectomised Patients		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.			
RESEARCH ETHICS COMMITTEE			
Principal Investigator	Dr Oliver Raynham / Dr Gavin Quail		
Department / Office Internal Mail Address	Division of Otolaryngology - University of Cape Town Medical School H-53 Old Main Building, Groote Schuur Hospital Observatory, Cape Town 7925 gavinquail@gmail.com		
FACULTY OF HEALTH SCIENCES UNIVERSITY OF CAPE TOWN			
1.1 Does this protocol receive US Federal funding?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	
1.2 Does this study require full committee approval?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	



Enquiries : Dr B Patel
Telephone : (021) 404-4256
Fax : (021) 404-4304
E-mail : bpatel@pgwc.gov.za
Reference : Research
Date : 11 October 2006



Departement van Gesondheid
Department of Health
ISebe IezeMoilo

Dr O W Raynham
Otolaryngology
Ward F8
GROOTE SCHUUR HOSPITAL

Dear Dr Raynham

RESEARCH: THE EFFECT OF LARYNGECTOMY BIBS ON THE TRACHEAL CLIMATE OF LARYNGECTOMISED PATIENTS

Your recent letter to the hospital refers.

You are hereby granted permission to proceed with your research.

Please note the following:-

- a) Your research may not interfere with normal patient care.
- b) Hospital staff may not be asked to assist in the research.
- c) No hospital consumables and stationery may be used.
- d) Please introduce yourself to the person in charge of an area before commencing.

I would like to wish you every success with your project.

Yours truly

signature removed

DR B PATEL
For CHIEF EXECUTIVE OFFICER

BP/em 11/10/06



Groote Schuur Hospital
Private Bag,
Observatory, 7935
Telephone: 404-9111