The illuminance of laryngoscopes at two central hospitals

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Declaration

I, Gwyneth Ann Davies, declare that this research report is my own work. It is submitted for the admission to the degree of Master of Medicine in Anaesthesiology by the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

…… (Signature of candidate)

29/11/2018

Abstract

Background

Direct laryngoscopy and successful endotracheal intubation require optimal illumination of laryngeal structures. The International Organization of Standardization (ISO) describes minimum adequate laryngoscope illuminance as 500 lux after 10 minutes, and further describes optimal dimensions of the illumination field. Laryngoscope light is subjectively assessed by the anaesthetist as part of theatre preparation. This study sought to describe the illumination of laryngoscopes at two academic hospitals, to compare illumination of incandescent and fibreoptic laryngoscopes and to compare the accuracy of a mobile phone application (app) to a lux meter.

Methods

A prospective, contextual, descriptive study was conducted, testing the illumination of 43 laryngoscopes with a lux meter, as well as a mobile phone app. The illumination field size of each laryngoscope was determined.

Results

The ISO Standard for illumination was met by 8 (18.6%) of laryngoscopes, and 11 (25.5%) had an adequate illumination field. Only 4 (9.3%) laryngoscopes met both criteria. The mobile phone app readings were significantly different to those obtained with a lux meter ($p = 0.0008$). After battery replacement 23 further laryngoscopes demonstrated an adequate illuminance. No significant difference was found between incandescent and fibreoptic laryngoscope illuminance ($p = 0.86$).

Conclusion

The findings are in keeping with other studies as well as subjective opinion of poor laryngoscope illuminance. The mobile phone app lux measurements were found not be comparable with those obtained with a lux meter. Routine objective illuminance testing as well as regular battery changes are suggested to be implemented.

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List of abbreviations

ISO	The International Organization for Standardization
LED	Light emitting diode
UV	Ultraviolet
App	Application
min	Minutes
Wits	University of the Witwatersrand
CHBAH	Chris Hani Baragwanath Academic Hospital
CMJAH	Charlotte Maxeke Johannesburg Academic Hospital
SASA	South African Society of Anaesthesiologists

Section 1: Literature review

1. Introduction

Direct laryngoscopy allows for the inspection of airway structures, removal of foreign bodies, and intubation of the airway (1). Despite the availability of sophisticated equipment such as video laryngoscopes and flexible fibre optics, the rigid laryngoscope remains popular due to its simple design and ease of use (2).

The laryngoscope is required firstly to physically retract the tongue and pharyngeal structures, providing a linear view between the observer and the vocal cords, and secondly to provide adequate illumination of the airway. It is essential for the anaesthetist to be able to visualise the vocal cords and insert an endotracheal tube within seconds, which may be a challenge, even under ideal situations. There are a number of factors that influence visibility with a laryngoscope.

The view in laryngoscopy is monocular, implying a potential deficit in the perception of depth and colour (3). A study by Levitan et al. (4) used principles outlined by the Illuminating Engineering Society of North America, which states that "task visibility is determined by four factors:

- the size of the task components
- the contrast of the task detail against its background
- the amount of time available to see the detail
- the luminance of the detail and its background."

When this principle is applied to endotracheal tube insertion, one can reasonably assume that the best lighting possible should be available to facilitate the task (4).

A functioning laryngoscope is listed in the South African Society of Anaesthesiology (SASA) Airway Guidelines (5) as an essential theatre tool. Furthermore, it is stipulated in the SASA

Practice Guidelines of 2013 (6) that it is the anaesthetist's responsibility to ensure the adequate functioning of all theatre equipment, which includes the laryngoscope. The laryngoscope is usually visually inspected for any damage or contamination, and the illuminance is subjectively assessed.

Most anaesthetists are familiar with laryngoscopes that have inconsistent and variable functionality. Howes (7) describes in an audit of laryngoscopes in a theatre department of Southmead Hospital, Bristol, that five of the 16 reusable laryngoscopes failed to light on at least one occasion with repeated testing. A second study of laryngoscopes in the theatres associated with Eastern Virginia Medical School found that 7% of 691 laryngoscopes failed to light at all (8). No studies assessing the illuminance of laryngoscopes in a South African hospital could be identified.

2. History of the laryngoscope

The invention of the laryngoscope came about by the need to inspect and surgically manage upper airway pathology and therefore does not follow a linear timeline by one key inventor. Rather, many contributors in various parts of the world, with some innovations occurring simultaneously, led to the current laryngoscope design (9).

Bozzini, a German physician, first developed a metal tube he named a "light conductor" which could be used to visualise any body cavity, including the airway. His device derived illumination from a candle or the sun, reflected into a metal tube using mirrors (9). In 2004, Cooper (10) reviewed a number of papers written in the 1800s using such devices to indirectly visualize the airway, including those written by: Babington, a medical student, Türck, a Viennese neurologist, as well as Garcia, who was a professor of singing at the Royal academy of music. Garcia later received an honorary medical degree as he was known at the time as the "father of laryngology". Garcia had an absent gag reflex and thus he performed much of his research on himself. Czermak from Budapest, also made use of mirrors, but derived his light source from table lamps. Avery in London used a head mounted mirror to reflect the light from a candle onto a mirrored speculum (10).

Direct laryngoscopy was not yet widely available, therefore intubation during the 1800s was usually performed blind using various metallic devices (10). Local anaesthetic drugs had not yet been discovered, therefore patients had to be trained to control their gag reflexes. Added to this discomfort was the fire hazard of candles and table lamps in the presence of flammable volatile anaesthetic agents. The discovery of muscle relaxants, later on, assisted in optimising the conditions for airway manipulation (11).

The first direct laryngoscopy was performed by Kirstein in 1895 (2). He modified an oesophagoscope to create a rigid laryngoscope with the light source on the handle, directed to the airway structures by means of a prism. Later Jackson modified this laryngoscope design by applying a tungsten bulb more distally. In 1913 Janeway developed a battery operated laryngoscope similar to the ones used today (10). Janeway helped pioneer the delivery of volatile anaesthetics directly to the lungs in order to improve operating conditions for surgery in the mouth and nasopharynx. His laryngoscope incorporated a blade with a component that the operator could slide out to allow room for passage of an endotracheal tube, and a curved blade tip to increase the likelihood of successful intubation (11).

Various modifications of the laryngoscope blade occurred over time, improving previous designs. The most well recognised, and still used today are the Miller and the Macintosh blades, both developed in the 1940s and named after their creators. The Miller blade (figure 1) is a long, straight blade with a slight curve of the distal tip. It is inserted deeply into the pharynx, is used to lift the epiglottis to allow for visualisation of the vocal cords and is mainly used for neonates and small children. The Macintosh blade (figure 2) is curved, and is inserted into the vallecula to lift the airway structures instead of directly mobilising the epiglottis. Compared to a straight blade, a curved blade is less likely to cause vagal stimulation as it should have minimal contact with the epiglottic mucosa. The curved blade is generally used for adult patients (2, 10).

Figure 1: Miller blade

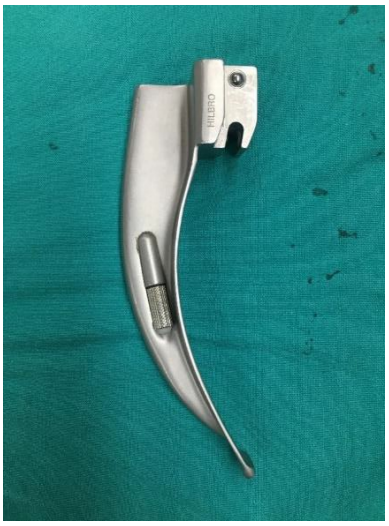

Figure 2: Macintosh blade

More recent innovations in laryngoscope design focussed on indirect visualization of the vocal cords for management of difficult airways. In 1995, Bullard introduced a rigid fibreoptic laryngoscope that did not require alignment of the oral and pharyngeal structures, and included a wide port for oxygen insufflation during airway instrumentation (12). Pacey, a vascular surgeon with an interest in video retractors used for surgery, invented the Glidescope® in 1999, which was the first video laryngoscope available (13). Many other video laryngoscope devices with various modifications have been patented, and are divided into 3 groups based on the shape of their blade: Macintosh (Storz®C-Mac), angulated (Glidescope®) and anatomically shaped with a guide channel (Airtraq®). However, the newer devices have not yet replaced the laryngoscope design of the 1940s, owing to their cost, and high level of skill and operator experience required for their successful use (14). These devices are recommended for use in adult patients with anticipated difficult airways (15), and evidence is emerging for their use in the paediatric population (16).

3. Laryngoscope principle design components

A laryngoscope consists of a handle, an affixed blade, a light source, and an electrical circuit(2). The required dimensions of each part of the laryngoscope are outlined in the International Organization for Standardization (ISO) 7376: 2009 Standard (17). Laryngoscopes are required to be made of biologically safe materials, the majority of

reusable laryngoscopes are made of stainless steel, with some disposable versions made of plastic (17).

The handle is made to be held in the left hand, so that instrumentation of the airway occurs with the right, as the majority of the population is right hand dominant. Right-handed laryngoscopes can be specially ordered for use by left-handed operators, patients with right-sided facial pathology and for intubation in the right lateral position (17). The laryngoscope is usually powered by batteries, which are housed in the handle (18). Handles of varying lengths and diameters are available. The standard size handle houses C batteries, while a slimmer paediatric handle (also referred to as a penlight) requires 2 AA batteries (19).

The most commonly available laryngoscope lighting mechanism types are the “bulb-on-blade”, also called conventional or incandescent type, or the “bulb-in-handle” or fibreoptic type (2). Both types are available with various shapes of blades, such as the Miller and Macintosh blades, and in various sizes. The blades may be reusable or disposable. Certain disposable versions have the blade fixed to the handle. The handles and blades of the incandescent and fibreoptic blades are not interchangeable, so the fibreoptic handle and blade are usually indicated by the manufacturer, for example, by a green stripe on both blade and handle (17).

3.1 Incandescent laryngoscopes

The incandescent laryngoscope (figure 3) remains one of the most widely used types of laryngoscope in the clinical setting. It has a light source or lamp mounted onto the blade. When the blade is affixed to the handle via the hook-on connection, the electrical contact on the blade completes the electrical circuit between the batteries and the bulb, and the bulb lights up (17). The advantage of this type of connection (in comparison to the bulb-in-handle laryngoscopes) is that it is far more robust and less likely to malfunction with repeated use (2).

Figure 3: Incandescent laryngoscope

Although many curved blades are classified as “Macintosh” blades, the design, dimensions of the flange, and angle of the curve may differ depending on the manufacturer. The literature refers to the blade design by the country of origin, namely German, English or American. The various designs place their incandescent bulb at different places along the shaft of the blade, which has implications in the illuminance of the laryngoscope (4).

The bulb itself may have a tungsten filament in a halogen gas or xenon gas environment. Alternatively, a light emitting diode (LED) may be used as the light source. The glass casing, which may be frosted or clear, may also affect the illuminance. The bulb is typically replaceable, and is screwed into a water tight socket. Unfortunately, this may be the source of poor contact, and if loose the bulb is at risk of falling off. Smith et al. (20) describe a case of a 17 year old patient where the bulb became a foreign body. The anaesthetist was not at first worried when the light of the laryngoscope failed during intubation of the patient. It was only some time later that it was noted that the bulb of the laryngoscope was missing. Luckily, the bulb migrated down the patient’s oesophagus and was passed enterally without any complications. Some manufacturers have created a bulb that is fused to the blade, mitigating the potential for loss of the bulb. However, this has the disadvantage of the entire blade needing to be replaced when the bulb fuses (2).

3.2 Fibreoptic laryngoscopes

The fibreoptic laryngoscope (figure 4) has a light source located in the handle, superior to the batteries. As the blade is engaged by connecting the hinge to the handle hinge pin, the spring loaded light source is depressed, completing the circuit and lighting the bulb. Glass or acrylic fibres conduct the light from the handle to the distal portion of the blade. The glass fibres conduct light more efficiently, but are more expensive (2). The fibres may be broken by dropping the blade or damaged during the cleaning process (21). The type of bulb used is the same as in the incandescent blade, and it may also incorporate a reflector.

Figure 4: Fibreoptic laryngoscope with acrylic fibre bundle

4. The physics of light applicable to laryngoscopes

Luminance and illuminance are principles of photometry (optics). Photometry differs from the more familiar principles of radiometry, which is the study of emitted light energy in terms of absolute power. Photometry (optics), in contrast, is the study of the perception of brightness by the average human observer (22).

Figure 5 illustrates the general principles and conventional terms of photometry. The wavelength of the light determines the perceived colour of the light, typically expressed as a range in nanometer units (10^{-9} meters). The intensity of the light or luminous flux of the light from the source, is measured in lumens. A lumen is the SI unit of luminous flux, equal

to the amount of light emitted per second in a unit solid angle of one steradian from a uniform source of one candela. (22).

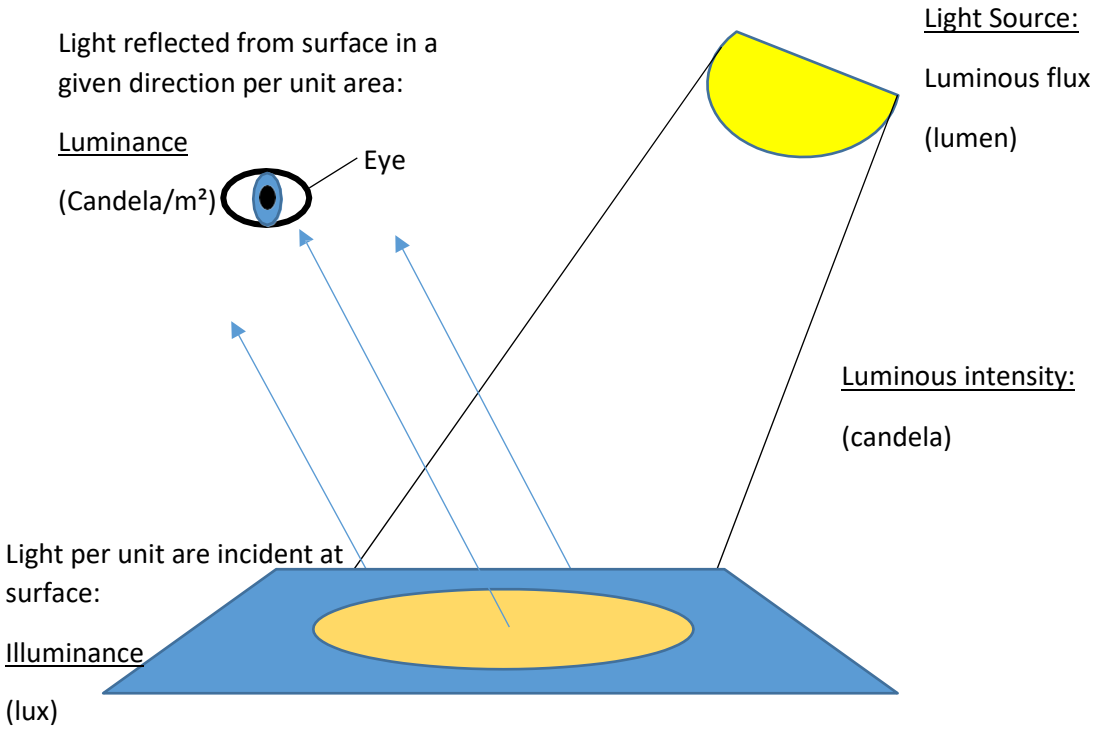

Figure 5: Photometric units of emitted and reflected light

Luminance is defined as the apparent brightness of an object, or the luminous flux emitted from a surface. It is measured in candelas per square meter. Luminance measurements are constant, because as the intensity of light decreases with distance, the area of incidence will increase proportionately.

Illuminance is the amount of light falling on a particular object, measured in lumens per square meter, or lux. Illuminance is affected by 2 laws; the inverse square law, and the cosine law (22).

Figure 6 shows the inverse square law (with regards to light waves) which states that the intensity of light falling on an object is inversely proportional to the square of the distance between the object and the source of the light (2).

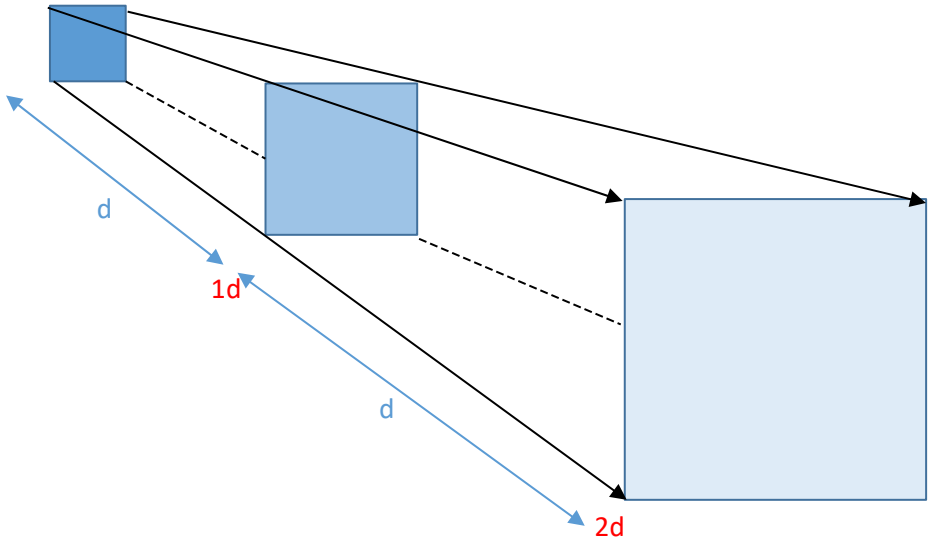

Figure 6: Inverse square law, where intensity = 1/distance²

With regards to laryngoscopes, the inverse square law becomes important in incandescent laryngoscopes made by different manufacturers due to the relative positions of the light source to the blade. A study by Levitan et al. found that the American blades, with the light bulb positioned more proximally, had inferior illuminance to the German blades with the light bulbs located distally (4).

Figure 7 illustrates the cosine law, which states that illuminance of an object will decrease as a function of the cosine of the angle of incidence of illumination. In explanation, a torch is shone perpendicularly to a surface, creating a circular area of light. If the distance between the torch and surface is kept constant, but the angle of incidence is moved away from the perpendicular, the area of the light shone onto the object will change shape, increasing the area, and decreasing the density of light. As illuminance is lumens per square meter, logic dictates that the larger the area, the less illuminance. Commercial lux meters have functions that compensate for the cosine law (22).

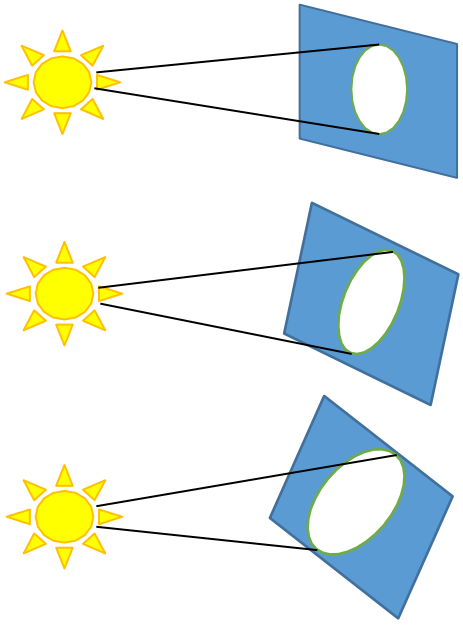

Figure 7: Cosine law

5. Factors affecting laryngoscope illuminance

5.1 Cleaning and decontamination

Laryngoscopes may become soiled with blood, mucous and various other bodily fluids. Decontamination guidelines such as those used by the American Society of Anesthesiology, as well as those specified by the manufacturer, are widely available. Most facilities have their own cleaning protocols available, and manufacturers will guarantee the functioning of a blade per number of cleaning cycles. Steam sterilization reliably decontaminates laryngoscope blades and has a wider margin of safety. However, repeated steam sterilization has been shown to decrease the light intensity of the laryngoscope by causing physical damage to the blade (21, 23, 24).

A study by Bucx of 300 cycles of cleaning on 18 fibreoptic blades from various manufacturers compared the effect of mechanical cleaning plus thermal disinfection at 90 degrees Celsius, to cleaning with added steam sterilization at 134 degrees Celsius. Their findings showed that the illuminance was relatively constant in the group subjected only to thermal disinfection, but majority of the blades undergoing steam sterilization underwent roughly a 90% reduction in light intensity (24).

Another study by Nishiyama (21) had similar findings, with significant deterioration of laryngoscope illuminance after repeated steam sterilization. These studies may have cost implications for institutions, as maintaining sterility of laryngoscope blades may require more regular replacement of blades due to wear and tear. Disposable laryngoscopes may negate the need for cleaning, but they too are expensive, and have inferior illuminance to the reusable type.

5.2 Type of light used

Studies have shown the superiority of the fibreoptic laryngoscopes to older incandescent types. Another important factor is the effect of clear versus frosted glass of the lightbulb, which has been shown to affect the illuminance of American blades (8, 25). Newer xenon and LED bulbs both produce whiter and bluer light (2). A study by Volsky et al. (25) resulted in their department exchanging all of their older incandescent laryngoscopes for LED devices.

5.3 Battery power

Many studies on laryngoscope illumination mention battery type and life as an important factor, but few measure this as part of their audit. Alkaline batteries have a gradually declining discharge curve, which translates to a light becoming slowly dimmer throughout the battery life. This characteristic is important to keep in mind, as a laryngoscope that seemed to have adequate illumination during the morning theatre preparation may be found to have inadequate light by the last case of the day with frequent use (2).

The more expensive lithium batteries have a fairly constant discharge curve, which means that the light output will be fairly constant through their lifespan until they are exhausted. There are laryngoscopes available that function with nickel-metal-hydride rechargeable batteries, but their availability is limited by cost (2).

6. Standards for measurement of illuminance

In the clinical setting the illuminance of a laryngoscope is merely subjectively assessed by the user. However, standards exist for the minimum illuminance required (17).

A study by Skilton et al. from 1996 is often referred to in the literature as a benchmark study against which many were compared (26). The study used a photometer to determine the minimum luminance of a laryngoscope, and their findings estimated a minimum of 100 candelas per square meter to be adequate. Unfortunately, this study used a small sample of 105 laryngoscopes. A second consideration is that many other studies measured illuminance, and the conversion calculation is complex. One would need to know how the light from the laryngoscope is scattered off of the vocal cords. If one assumed that the vocal cords are Lambertian reflectors; perfectly diffuse, then illuminance would equal luminance divided by 2π. If they are not perfect reflectors then illuminance would equal luminance measured times a diffusion factor, divided by 2π (22).

A study by Cheung et al. used 9 laryngoscopes with measured luminance of 100 candelas per meter squared (as previously outlined by Skilton), then took the average illuminance of three measurements, and found that 100 candelas per meter squared correlated to 867 lux. This value has also been referenced to by various studies as minimum illuminance required (27).

The ISO 7376 Standard describe the performance requirements of a laryngoscope. The document released in 2009 revised the previous standards laid out by the 2003 document. The minimum illuminance which was initially stipulated as being 700 lux has been reduced to 500lux (17). To put this value in perspective, the ambient indoor lighting is between 150 to 500 lux, and light in operating theatres 1000 lux (28).

The ISO 7376 Standard further describes requirements for an adequate illumination field (17). The laryngoscope light should be shone perpendicularly to a piece of paper with the tip of the blade 20mm away. The field may be oval or circular, and the dimensions (measured from the linear shadow cast by the blade tip) should be as follows:

- superior illumination edge to blade tip <3mm
- superior to inferior illumination edge between 30mm and 80mm
- right illumination edge to centre of blade tip between 25mm and 50mm
- left illumination edge to centre of blade tip between 25mm and 50mm.

The ISO 7376 Standard is currently under revision. The new draft article has more practical recommendations on illumination field measurement (29). The new draft has yet to be approved and thus is not yet an official standard.

SASA guidelines do not stipulate the illuminance required for laryngoscopes in South Africa. However, the ISO guidelines are readily available on the South African Bureau of Standards (SABS) website.

7. Measuring equipment for illumination

Illumination of a light is measured with a lux meter. The lux meter needs to be cosine corrected, and must have an accuracy in percentage specified by the manufacturer. The ISO 7376 Standard describe some of the practical aspects when measuring laryngoscope illumination such as positioning of the laryngoscope and distance from the sensor for measurement, and advise that the laryngoscope should be lit for a full 10 minutes to ensure resilience. It is essential to block out ambient light while testing illuminance (17). Various authors of studies created portable devices for this function (8, 25, 30).

Sophisticated equipment such as the lux meter is not readily available in theatre, and the laryngoscope illuminance is merely subjectively assessed by the anaesthetist. There are, however, mobile phone application (app) lux meters available. These apps are mostly intended for amateur photography. Machado et al. conducted a small study comparing illuminance measurements of a Motorola mobile phone app and a lux meter, and found the readings to be similar between the 2 devices, even though the phone manufacturer estimated an accuracy of only 80% (31).

A study conducted by DIAL, a company manufacturing lux meters, compared various apple and android lux meter apps to a professional lux meter, and found a wide discrepancy in readings (32). Despite this result, if a cheap and easy to use phone app were to become available this could potentially provide a more objective assessment of laryngoscope illuminance, and the readings could be used by staff in motivation for replacement of old equipment.

8. Studies on minimum illuminance

Two successive studies by the same set of authors were conducted in Virginia, USA. The first assessed 319 laryngoscopes in their children's hospital, the second larger study of 691 devices were collected from operating theatres, emergency rooms and code carts. Both studies found that roughly one third of laryngoscopes had suboptimal illumination. Furthermore, it was found that all of the xenon laryngoscopes produced more than the minimum illuminance of 500 lux, and the studies thus could be used as motivation for the departments to purchase the more expensive xenon laryngoscopes (8, 25).

Baker et al. (30) initially conducted a pilot study, measuring illuminance of 190 laryngoscopes available, and found their illuminance to range widely from 0 – 4789 lux, with a median of 345 lux. They then conducted a study of 18 laryngoscopes available on a typical day in the operating theatre. These were tested with a 10 minute interval, as stipulated by the ISO guidelines. Two laryngoscopes met the ISO criteria of a minimum of 500 lux, and only one met criteria after 10min. A study in Philadelphia with a comparatively smaller study size of 50 laryngoscopes found that only 13 blades met the study criteria of a minimum lux of 1000 (4).

Howes et al. studied laryngoscopes in a Bristol Hospital in the UK comparing the functioning of reusable to single use laryngoscope blades. The study found the light from the single use blades to be consistently better. However, the light was measured with a galvanometer and gave arbitrary units, making it difficult to quantify any deficit in illuminance (7).

9. Optimal Illuminance

The ISO 7376 Standard describes the minimum light required, and the studies mentioned above focus on minimum illuminance while emphasising the need for optimum lighting, especially in the case of the difficult airway. A study by Baker et al., on the other hand, sought to describe optimum illuminance (33). Study participants included 50 doctors at a tertiary level institution in Auckland, New Zealand. All of the doctors were required to have at least 2 years of experience in direct laryngoscopy, and their vision and contrast sensitivity were tested with wall charts and a Pelli-Robson contrast sensitivity chart respectively, before they were selected for the study itself.

The study itself consisted of the participating doctors reading Sloan near vision charts that were placed in the larynx of a manikin, using a laryngoscope of varying light intensity (the light levels were measured with a lux meter beforehand). The four levels of light were 50, 200, 700 and 2000 lux. The study had an objective measurement, i.e. the logarithm of the minimum angle of resolution (logMAR) score calculated from the number of lines of the vision chart read, as well as a subjective aspect where the doctors would indicate which light level they felt was optimal (33).

The results of the study showed an improvement in vision with increasing illuminance up to a lux of 700, after which there was no difference in visual acuity with 700 or 2000 lux. However, participants felt subjectively that 2000 lux improved their visual acuity (33).

It is important to note that manikin studies differ from in vivo studies, as the illuminance required with the manikin is far less. The authors attempted to correct for this by using a red filter over the field of vision.

10. Conclusion

The laryngoscope is an essential anaesthetic tool. Despite various improvements in airway equipment, much of its design has remained fairly constant. The adequacy of laryngoscope illuminance may be checked daily by the anaesthetist before use, but despite this, various studies have shown that with objective measurements, their illuminance is inadequate when compared to the ISO standard. The illuminance may be affected by multiple factors,

such as incandescent versus fibreoptic lighting, battery condition, electrical connection integrity, cleaning methods and general wear and tear. There are no studies to date describing the illuminance of laryngoscopes in a South African Hospital.

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Section 2: Southern African Journal of Anaesthesia and Analgesia guidelines to authors

Aims, scope and review policy

The SA Journal of Anaesthesia and Analgesia aims to publish original research and review articles of relevance and interest to the anaesthetist in academia, public sector and private practice. Papers are peer reviewed to ensure that the contents are understandable, valid, important, interesting and enjoyed. All manuscripts must be submitted online. SAJAA is accredited by the Department of Education for the measurement of research output of public higher institutions of South Africa (SAPSE accredited). All articles in SAJAA will be peer reviewed.

Article sections and length

The following contributions are accepted (word counts exclude abstracts, tables and references):

* Original research (2800 – 3200 words/ 4-5pages)

* Clinical Reviews (2400 words/ 3-4 pages)

* Drug Reviews (2400 words/ 3-4 pages)

* Case Studies (1800 words/ 3 pages)

* Scientific Letters (2400 words/ 3-4 pages)

* Letters to the Editor (400-800 words)

Please see the journal's section policies section policies for further details.

Full author guidelines

Title page

All articles must have a title page with the following information and in this particular order:

Title of the article; surname, initials, qualifications and affiliation of each author; the name, postal address, email address and telephonic contact details of the corresponding author and at least 5 keywords.

Abstract

All articles should include an abstract. The structured abstract for an original research article should be between 200 and 230 words and should consist of four paragraphs labelled: Background, Methods, Results, and Conclusions. It should briefly describe the problem or issue being addressed in the study, how the study was performed, the major results, and what the authors conclude from these results. The abstracts for other types of articles should be no longer than 230 words and need not follow the structured abstract format.

Keywords

All articles should include keywords. Up to five words or short phrases should be used. Use terms from the Medical Subject Headings (MeSH) of Index Medicus when available and appropriate. Key words are used to index the article and may be published with the abstract.

Acknowledgements

In a separate section, acknowledge any financial support received or possible conflict of interest. This section may also be used to acknowledge substantial contributions to the research or preparation of the manuscript made by persons other than the authors.

References

Cite references in numerical order in the text, in superscript format (Format>Font>Click superscript). Please do not use brackets or do not use the foot note function of MS Word. In the References section, references must be typed doublespaced and numbered consecutively in the order in which they are cited, not alphabetically. The style for

references should follow the format set forth in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org) prepared by the International Committee of Medical Journal Editors. Abbreviations for journal titles should follow Index Medicus format. Authors are responsible for the accuracy of all references. Personal communications and unpublished data should not be referenced. If essential, such material should be incorporated in the appropriate place in the text. List all authors when there are six or fewer; when there are seven or more, list the first three, then ";et al."; When citing URLs to web documents, place in the reference list, and use the following format: Authors of document (if available). Title of document (if available). URL. (Accessed [date]).

The following are sample references:

1. Jun BC, Song SW, Park CS, Lee DH, Cho KJ, Cho JH. The analysis of maxillary sinus aeration according to aging process: volume assessment by 3dimensional reconstruction by high-resolutional CT scanning. Otolaryngol Head Neck Surg. 2005 Mar;132(3):42934.2.

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http://www.journals.uchicago.edu/ICHE/journal/issues/v27n1/2004069/2004069.web.pdf

More sample references can be found at:

http://www.nlm.nih.gov/bsd/uniform_requirements.html"

Tables

Tables should be self-explanatory, clearly organised, and supplemental to the text of the manuscript. Each table should include a clear descriptive title on top and numbered in Roman numerals (I, II, etc.) in order of its appearance as called out in text. Tables must be inserted in the correct position in the text. Authors should place explanatory matter in footnotes, not in the heading. Explain in footnotes all nonstandard abbreviations. For footnotes use the following symbols, in sequence: *,†,‡,§,||,**,††,‡‡

Figures

All figures must be inserted in the appropriate position of the electronic document. Symbols, lettering, and numbering (in Arabic numerals e.g. 1, 2, etc. in order of appearance in the text) should be placed below the figure, clear and large enough to remain legible after the figure has been reduced. Figures must have clear descriptive titles.

Photographs and images

If photographs of patients are used, either the subject should not be identifiable or use of the picture should be authorised by an enclosed written permission from the subject. The position of photographs and images should be clearly indicated in the text. Electronic images should be saved as either jpeg or gif files. All photographs should be scanned at a high resolution (300dpi, print optimised). Please number the images appropriately.

Permission

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Review and action

Manuscripts are initially examined by the editorial staff and are usually sent to independent reviewers who are not informed of the identity of the author(s). When publication in its original form is not recommended, the reviewers' comments (without the identity of the reviewer being disclosed) may be passed to the first author and may include suggested revisions. Manuscripts not approved for publication will not be returned.

Ethical considerations

Papers based on original research must adhere to the Declaration of Helsinki on “Ethical Principles for Medical Research Involving Human Subjects”; and must specify from which recognised ethics committee approval for the research was obtained.

Conflict of interest

Authors must declare all financial contributions to their work or other forms of conflict of interest, which may prevent them from executing and publishing unbiased research. [Conflict of interest exists when an author (or the author's institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her opinions or actions.] * *Modified from: Davidoff F, et al. Sponsorship, Authorship, and Accountability. (Editorial) JAMA 2001: 286(10) The following declaration may be used if appropriate: ";I declare that I have no financial or personal relationship(s) which may have inappropriately influenced me in writing this paper."

Submissions and correspondence

All submissions must be made online at www.sajaa.co.za and correspondence regarding manuscripts should be addressed to: The Editor, SAJAA, Email: toc@sajaa.co.za

Note: Ensure that the article ID [reference] number is included in the subject of your email correspondence.

Electronic submissions by post or via email

Authors with no email or internet connection can mail their submissions on a CD to:

SAJAA, PO Box 14804, Lyttelton Manor, 0140, Gauteng, South Africa.

All manuscripts will be processed online. Submissions by post or by email must be accompanied by a signed copy of the following indemnity and copyright form.

Tips on Preparing your manuscript

1. Please consult the “Uniform requirements for manuscripts submitted to biomedical journals” at www.icmje.org

2. Please consult the guide on Vancouver referencing methods at: http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=citmed.TOC&depth=2

3. The submission must be in UK English, typed in Microsoft Word or RTF with no double spaces after the full stops, double paragraph spacing, font size 10 and font type: Times New Roman.

4. All author details (Full names, Qualifications and affiliation) must be provided.

5. The full contact details of corresponding author (Tel, fax, email, postal address) must be on the manuscript.

6. There must be an abstract and keywords.

7. References must strictly be in Vancouver format. (Reference numbers must be strictly numerical and be typed in superscript, not be in brackets and must be placed AFTER the full stop or comma.)

8. It must be clear where every figure and table should be placed in the text. If possible, tables and figures must be placed in the text where appropriate. If too large or impractical, they may be featured at the end of the manuscript or uploaded as separate supplementary files.

9. All photographs must be at 300dpi and clearly marked according to the figure numbers in the text. (Figure 1, Table II, etc.)

10. All numbers below ten, without percentages or units, must be written in words.

11. Figure numbers: Arabic, table numbers: Roman <="" uk="" in="" proficient=""

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Section 3: Draft Article

The illuminance of laryngoscopes at two central hospitals

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Keywords

Laryngoscope, Direct laryngoscopy, Tracheal intubation, Illumination, Mobile phone app

Abstract

Background

Direct laryngoscopy and successful endotracheal intubation require optimal illumination of laryngeal structures. The International Organization of Standardization (ISO) describes minimum adequate laryngoscope illuminance as 500 lux after 10 minutes, and further describes optimal dimensions of the illumination field. Laryngoscope light is subjectively assessed by the anaesthetist as part of theatre preparation. This study sought to describe the illumination of laryngoscopes at two academic hospitals, to compare illumination of incandescent and fibreoptic laryngoscopes and to compare the accuracy of a mobile phone application (app) to a lux meter.

Methods

A prospective, contextual, descriptive study was conducted, testing the illumination of 43 laryngoscopes with a lux meter, as well as a mobile phone app. The illumination field size of each laryngoscope was determined.

Results

ISO Standard for illumination was met by 8 (18.6%) laryngoscopes, and 11 (25.5%) had an adequate illumination field. Only 4 (9.3%) laryngoscopes met both criteria. The mobile phone app readings were significantly different to those obtained with a lux meter ($p = 0.0008$). After battery replacement 23 further laryngoscopes demonstrated an adequate illuminance. No significant difference was found between incandescent and fibreoptic laryngoscope illuminance ($p = 0.86$).

Conclusion

This study demonstrated that the available laryngoscopes had poor illuminance. A mobile phone app was not comparable to a lux meter. Routine objective illuminance testing as well as regular battery changes are suggested to be implemented.

Introduction

Direct laryngoscopy allows for inspection of airway structures, removal of foreign bodies, and intubation of the airway. Despite the availability of sophisticated equipment such as video laryngoscopes and flexible fibreoptics, the rigid laryngoscope remains the gold standard for direct laryngoscopy due to its simple design and ease of use.

A laryngoscope is required to produce adequate illuminance of the airway structures. A functioning laryngoscope is listed in the South African Society of Anaesthesiologists (SASA) Airway Guidelines[1] as essential as part of the minimum safety requirements. The SASA Practice Guidelines of 2013[2] stipulate that the anaesthetist should check all such theatre equipment. Studies previously conducted have shown that the light produced may be of varying intensity and that the laryngoscopes functionality may not always be reliable.[3-8]

The two most common lighting mechanisms of laryngoscopes are the "bulb-on-blade" or incandescent type, and the "bulb-in-handle" or fibreoptic type. The light source or bulb of an incandescent laryngoscope is mounted on the blade of the laryngoscope. In contrast, the light source of a fibreoptic laryngoscope is encased within the handle, and is conducted to the distal portion of the blade by a glass or plastic fibre bundle.[9] Studies have demonstrated the superior illuminance of the fibreoptic laryngoscopes when compared to the incandescent type.[4, 7, 8]

Factors have been identified which influence the illuminance of laryngoscope light, and include the lighting mechanism (incandescent or fibreoptic), wear and tear of components due to repetitive cleaning and the battery life as well as type of battery used.[9] In addition, a study by Levitan et al.[5] showed that, with regards to incandescent laryngoscopes, the distance between the bulb and the tip of the laryngoscope blade will affect the illuminance of the airway structures. Macintosh, the inventor of the curved blade, did not stipulate the actual angle or dimensions of the blade, as he felt they were not of primary importance in direct laryngoscopy.[10] Hence, although named "Macintosh" laryngoscope blades, the size of the flange, blade curve and bulb placement vary according to manufacturer, and are usually titled by country of origin, namely "American, English or German". Levitan et al.[5] noted the superiority of the shorter distance between bulb and blade tip of the German blade in comparison to a longer distance of the American blades.

In the clinical setting the illuminance of a laryngoscope is subjectively assessed by the user. The International Standard Organisation (ISO) Standard 7376:2009[11] requires a more sophisticated measurement using a lux meter. The Standard specifies a minimum illuminance of 500 lux for at least 10 minutes. In comparison, the ambient indoor lighting is between 150 to 500 lux, and light in operating theatres is typically about 1000 lux.[12] The Standard further describes the required dimensions of the field of light distributed by the laryngoscope. The ISO Standard 7376:2009 is currently in the process of being updated, with more detailed instructions on demarcating the illuminance field described in the draft version.[13] A study by Murphy et al.[7] of 691 laryngoscopes found that 28% did not meet the minimum required 500 lux at 10 minutes. Baker et al.[14] found in their study that only 11% of laryngoscope illuminance audited exceeded 500 lux, and none complied with the dimensions of the illumination field.

With advances in technology and mobile phone applications (apps) the users may have access to sophisticated equipment in their pockets. There are mobile phone lux meter apps available that make use of the mobile phone camera lens as the light sensor. However, not all are accredited. The company DIAL, which produces lux meter devices, conducted a study of various free lux meter apps available in comparison to one of their standard lux meter devices. Their findings showed that the lux meter app readings were variable, and were not consistent with those taken by the lux meter.[15] In contrast, a study by Machado et al.[6] measuring illuminance of laryngoscopes using an app and a lux meter showed that the app was as accurate as a lux meter. The authors describe the type of phone used in the study (Motorola® Moto G XT1068), but not the android app chosen, or if any other accessories were required.

No South African studies were identified that described the illuminance of laryngoscope light. A study was undertaken with the aim to describe the illuminance of the laryngoscopes at two hospitals affiliated to the Department of Anaesthesiology at the University of the Witwatersrand (Wits), Charlotte Maxeke Johannesburg Academic Hospital and Chris Hani Baragwanath Academic Hospital. This study sought to describe the illumination of laryngoscopes at two academic hospitals, to compare illumination of incandescent and fibreoptic laryngoscopes and to compare the accuracy of a mobile phone application (app) to a lux meter.

Methodology

The research design was prospective, contextual and descriptive. Approval to conduct the study was obtained from the Wits Human Research Ethics Committee (Medical) and other relevant authorities.

A total of 43 laryngoscopes and size 3 blades were tested. A convenience sampling method was used. The size 3 blade was chosen as it is most frequently used. The Dr.Meter Digital Illuminance/Light Meter LX1330B was used. The manufacturer specifies an accuracy of within 2%. This meter was chosen because it was the most cost effective. An iPhone 7 was used. The app, Lux Camera 2.0, was selected as it was simple to use, free to download from the South African app store and did not require the purchase of extra accessories. It received a "fair' rating on AppCrawlr.com,[16] and was the only free app that had been rated. A portable dark box was constructed similarly to those in previous studies[4, 8] and was used to minimise ambient light.

The illumination field was traced onto paper and measured as shown in Figure 1 in accordance with the ISO 7376:2009 Standard.[11] The illumination field was either adequate (fulfilled all criteria) or inadequate.

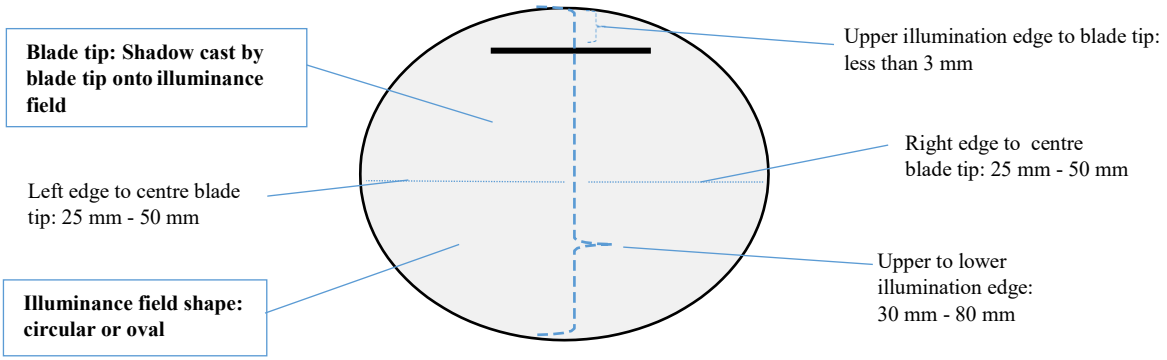

Figure 1: Graphic representation of illumination field and required dimensions

The ISO 7376:2009 Standard[11] requires two sets of illuminance measurements to be taken, the first as the laryngoscope is initially assembled and the light is initially switched on, and the second after the light has been lit for 10 minutes. The Standard is met if an illuminance is initially of over 500 lux, and is maintained above that level for at least 10 minutes.

The first set of tests with the lux meter and mobile phone app has been referred to as "Test 1". A second set of data was collected after the batteries of laryngoscopes, with illuminance deemed to be inadequate, were replaced with new batteries. This set of data is referred to as "Test 2". All replacement batteries were new Duracell® alkaline 1.5V batteries, either size AA or C (depending on the handle size). All old batteries were disposed of responsibly. Figure 2 shows the process of how the data were collected.

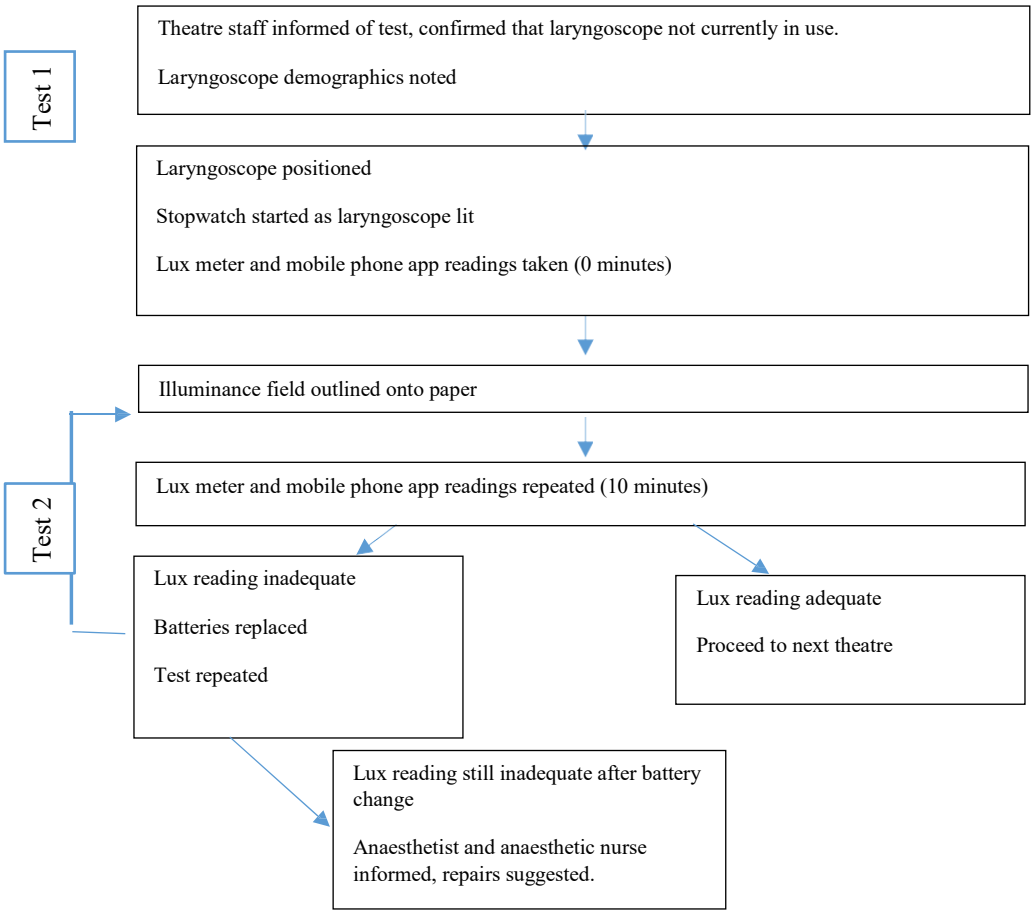

Figure 2: Data collection process

The data were entered onto a Microsoft Excel spreadsheet. Descriptive and inferential statistics using STATA (StataCorp, USA) and Graphpad Prism 7 (GraphPad Software, Inc, USA) were used for analysis. A Wilcoxon signed- rank test was used to compare data, with a $p < 0.05$ considered statistically significant.

Results

All 43 laryngoscopes were of the reusable type. Twenty eight (65.1%) of the laryngoscope handle and blade pairs were mismatched sets not from the same manufacturer, which could possibly contribute to poor electrical contact between the parts and affect illumination (Figure 3). Thirteen (30.2%) laryngoscopes were incandescent and 30 (69.7%) were fibreoptic.

The number of handles and blades made by various manufacturers are shown in Table I. The majority were made by Welch Allyn®, those labelled as "other" included Intubrite®, Sololite®, Vibgyor®, Rheister, Ultra®, Penlon®, Hi-care®, Gale Med®, Mdlunalite®, Rhein, EFF®, and Medicon. One blade, manufactured by Intubrite (Figure 4), had 2 light bulbs; 1 light emitting diode type (LED) and 1 ultraviolet (UV) bulb.

Figure 3: Handle and blade with poor contact.

Figure 4: Intubrite blade with 2 light bulbs.

Table I: Manufacturers of blades and handles.

	Number (percentage)					
Manufacturer	Welch Allyn	Heine	Medisensor	No name	Hilbro	Other
Handle	25 (58)	0 (0)	3 (6.9)	4 (9.3)	3 (6.9)	8 (18.6)
Blade	23 (53)	4 (9.3)	1 (2.3)	5 (11.6)	0 (0)	10 (23)

Fourteen (32.5%) handles were of the paediatric type (using AA batteries), while the remaining 67% were the standard size (housing size C batteries). The batteries were all alkaline and included 27 sets of Eveready®, 9 Energizer®, 5 Excell®, 1 Duracell®, and 1 Super Power®.

Only 11 (25.6%) laryngoscopes had initially acceptable lux readings at 0 minutes, of these 3 (6.9%) were considered inadequate as their readings of above 500 lux were not maintained for 10 minutes. Eight (18.6%) laryngoscopes had an illuminance of over 500 lux after 10 minutes. Three (6.9%) laryngoscopes had adequate illuminance at 0 and 10 minutes when tested with the app. The findings of Test 1 and Test 2 (with new batteries) are shown in Figure 5. The results of testing with the lux meter at 10 minutes are highlighted in Figure 5 as these results comply with the ISO 7376:2009 Standard with regards to illumination after 10 minutes tested with a lux meter.

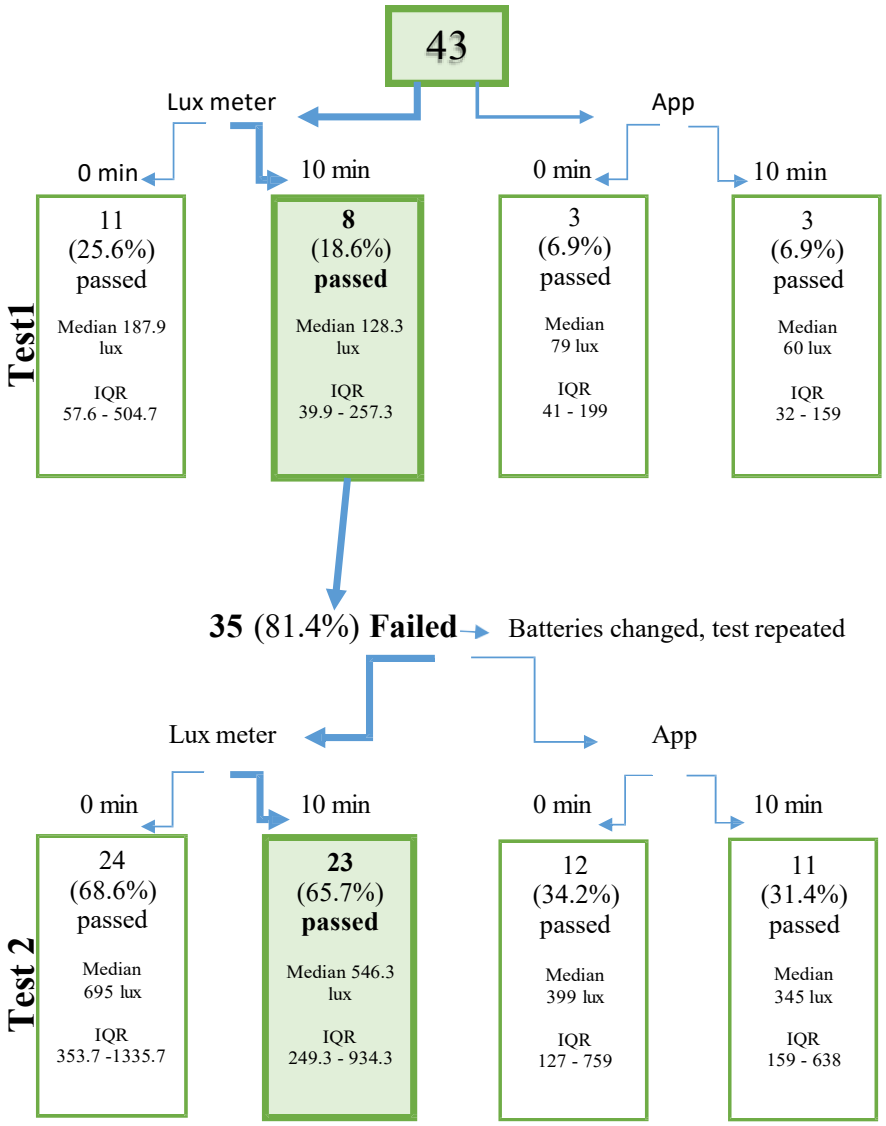

Figure 5: Results of Test 1 and Test 2

Six of the 8 laryngoscopes that met the ISO Standard in Test 1 were matching Welch Allyn handle and blade pairs. Out of the 12 laryngoscopes that did not meet the ISO Standard after a battery change in Test 2, 10 were mismatched handle and blade pairs.

The differences between the illuminance readings on the lux meter compared to the mobile app were statistically significant at 0 minutes ($p = 0.001$) and 10 minutes ($p = 0.008$).

Of the 8 laryngoscopes that met the ISO Standard after 10 minutes, 1 was incandescent and 7 were fibreoptic. The difference between the illuminance of the 2 types of laryngoscopes was found not to be statistically significant ($p = 0.86$).

Eleven (25.6%) laryngoscopes had an adequate illuminance field in Test 1. Only 1 (2.3%) laryngoscope had readings of over 500 lux for both the mobile phone app and the lux meter, as well as having an adequate illuminance field. A further 15 (34.9%) laryngoscopes' illumination fields became adequate after the batteries were changed in Test 2.

Discussion

The findings of this study were in keeping with previous studies,[5, 7, 14] as well as the clinical impression of poor laryngoscope illuminance. Only 8 (18.6%) laryngoscopes of the 43 tested met the ISO Standard after 10 minutes. Compared to theatre ambient and surgical light requirements, a minimum of 500 lux is seemingly low.[12]

The importance of noting the manufacturer of the laryngoscope handles and blades has been highlighted in previous studies.[5] Although the length of the Macintosh size 3 blade is standardised, the degree of the curve, the size of the flange, and the placement of the light bulb/fibreoptic bundle do vary. The latter is suggested to have an effect on the illuminance. The majority of handles (58%) and blades (53%) in use in the two hospitals were made by Welch Allyn, an American manufacturer. It would be difficult to assess which manufacturer had the best illuminance, considering that there were many single handle and blade sets from different manufacturers. Mismatched pairs of laryngoscope handles and blades may lead to poor electrical contact and affect illumination. It is not known whether the Welch Allyn laryngoscopes were purchased more recently, and therefore had not yet been exposed to heavy use and cleaning.

All laryngoscopes tested were reusable. The methods of cleaning and autoclaving of reusable handles and blades has been previously shown to cause wear and tear and ultimately affect their functioning.[17, 18] This study did not take into consideration how the equipment was being cleaned, and it is not known how long each handle and blade had been in use. It may be considered that the laryngoscopes that did not meet criteria after Test 2 were old. Faulty electrical connections, damaged fibre bundles of the fibreoptic blades and exhausted light bulbs are all possible causes of low illuminance,[4] which could be the topic of a future study.

The Intubrite laryngoscope blade (figure 4) had two bulbs, one LED and one UV. This laryngoscope passed the first test with an average illuminance of 827 lux at 10 minutes. This illuminance was not the highest of the study group, as one would assume. This may be because it was paired with a handle from a different company

(Sololite), or perhaps the batteries may have been partially depleted. No second test with new batteries was performed on this particular laryngoscope, as it met the ISO Standard in Test 1. The manufacturer of this particular blade specifies that the quality of light produced allows for better tissue differentiation and less glare, but not necessarily increased illumination.[19]

The reason for the required 10 minute time duration for maintaining an illuminance of 500 lux is not specified in the ISO Standard. It may be to ensure the adequacy of the illuminance in a situation such as a difficult airway where the laryngoscope may be left on for a longer duration. In Test 1, although 11 (25.6%) laryngoscopes had adequate illuminance at 0 minutes, 3 (6.9%) did not maintain adequate illuminance. A possible reason is that the batteries were old and depleted. Test 2 showed that 23 laryngoscopes (65.7% of the repeated 35 tests) met the ISO Standard after new batteries were inserted. A weakness of this study is that the types of batteries were noted, but were not tested with a multimeter to determine their condition.

There was no significant difference found between the illuminance of the incandescent or fibreoptic laryngoscopes ($p = 0.86$), which is in keeping with a study by Volsky et al.[8] In contrast, Murphy et al.[7] found the fibreoptic illuminance to be superior to the incandescent. None of the laryngoscopes in this study were made with bulbs utilising xenon, which the authors of the studies mentioned had found to be superior to incandescent and fibreoptic. A Canadian study[20] found the incandescent light source was superior to the fibreoptic. In their study, that the ISO Standard was not used to determine illuminance. The authors measured the exposure indices of the laryngoscopes, and converted their readings into lux by a complex calculation.

The mobile phone app was not found to be accurate when compared to a lux meter. This is in keeping with a previous comparison of various free apps to a lux meter,[15] but is in contrast to the study by Machado et al.[6] The author specified that the app used would have an accuracy of 80% in the range of 5 – 10 000 lux, but it is not mentioned which app was used, if the app was purchased, and if any other accessories were required to ensure accuracy.

Only 25.6% of laryngoscopes had an adequate illuminance field. This may pose a problem in the case of a difficult airway, where the glottic opening is not directly in front of the laryngoscope blade tip. Potential damage to soft tissue and teeth could occur if the anaesthetist were to repeatedly reposition a blade to bring the glottis into a narrow illuminance field. A further 34.9% of laryngoscopes demonstrated adequate illuminance fields after the batteries were replaced, indicating the importance of using non- depleted batteries.

During this study, if a laryngoscope was still found to have inadequate illuminance after a battery change, the findings were reported to the anaesthetist and anaesthetic nurse assigned to the particular theatre. They were then responsible for reporting faulty equipment and sending the laryngoscope for repairs. The particular theatre could continue operating at the discretion of the theatre staff. This may pose an ethical issue, as the staff may have continued to use the laryngoscope on patients despite the proven inadequacy of their equipment. There are, however, no studies proving the relationship between adequate laryngoscope lighting and successful intubation. It may have been of value to have followed up the faulty laryngoscopes sent for repairs, to determine the cause of their low illuminance, and if they could be returned to circulation after repairs were carried out.

Of the laryngoscopes that were in use, 81.4% had inadequate illuminance, and 74.4% had an inadequate illuminance field. The improvements seen between Test 1 and Test 2 suggest that more regular battery changes may improve illuminance. The increased cost of the batteries is outweighed by the potential improvement in conditions for direct laryngoscopy. Regular audits of laryngoscope illuminance using a lux meter may be of benefit in providing objective data that may be used as motivation to replace older equipment. Furthermore, a cleaning and repair register may be of value. An inexpensive, easy to use, mobile phone app that is comparable to a lux meter was not found by this study.

Conclusion

The anaesthetic complications of failed airway management result in significant morbidity as well as mortality. An anaesthetist should therefore have optimal tools available for successful intubation, such as a laryngoscope with optimal illumination. This study concludes that regular objective audits of laryngoscope illuminance, frequent battery changing and documentation of laryngoscope cleaning and sterilization may assist in improving the illuminance if the laryngoscopes in use at CHBAH and CMJAH.

Conflict of interest

We declare that we have no financial or personal relationships which may have inappropriately influenced us in writing this paper.

Acknowledgements

This research was done in partial fulfilment of a Master of a Medicine degree.

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Section 4: Appendices

Appendix 1: Postgraduate Approval

UNIVERSITY OF THE
WITWATERSRAND,
JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

02 April 2017
Person No: 0401238M
PAG

Dr GA Davies
P O Box 1235
Pinegowrie
2123
South Africa

Dear Dr Davies

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *The illuminance of laryngoscopes at two central hospitals* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 2: Ethics Waiver

Human Research Ethics Committee (Medical)

Golden Jubilee: October 1966 – October 2016

Research Office Secretariat: Faculty of Health Sciences, Phillip Tobias Building, 3rd Floor, Office 301,
29 Princess of Wales Terrace, Partktown, 2193 Tel +27 (0)11-717-1252 /1234/2656/2700
Private Bag 3, Wits 2050, email: zanele.ndlovu@wits.ac.za
Office email: hrec-medical.researchoffice@wits.ac.za
Website: www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/

Ref: W-CJ-161129-3 29/11/2016

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: **Dr Gwyneth Davies (Student No 0401238M).**

Project title: **A study of the illuminance of laryngoscopes at two central hospitals.**

Reason: This study will measure illuminance with a lux meter device and a mobile phone application and readings compared to the International Organisation of Standards (ISO) 7376:2009. There are no human participants

UNIVERSITY OF THE WITWATERSRAND
PROF PE CLEATON-JONES
HREC (MEDICAL)
2016 -11- 29
JOHANNESBURG

Professor Peter Cleaton-Jones

Chair: Human Research Ethics Committee (Medical)

Copy – HREC (Medical) Secretariat: Zanele Ndlovu, Rhulani Mkansi.

Appendix 3: Head of Anaesthesiology Approval

WITS UNIVERSITY

DEPARTMENT OF ANAESTHESIOLOGY
UNIVERSITY OF THE WITWATERSRAND,
JOHANNESBURG
Tel.(011)933-9334/5 / Fax (011)933-1843

FACULTY OF HEALTH SCIENCES

24 July 2017

TO WHOM IT MAY CONCERN

RE : DR GWYNETH ANN DAVIES STUDENT NUMBER 0401238M

I herewith grant permission to Dr Davies to conduct the study titled "The illuminance of laryngoscopes at two central hospitals" in the University of the Witwatersrand Department of Anaesthesiology.

With Kind Regards

Yours sincerely

PROF. A.C. LUNDGREN
CHIEF SPECIALIST AND HEAD
DEPARTMENT OF ANAESTHESIA
UNIVERSITY OF THE WITWATERSRAND

Appendix 4: CHBAH Approval

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 20 July 2017

TITLE OF PROJECT: The illuminance of laryngoscopes at two central hospitals

UNIVERSITY: Witwatersrand

Principal Investigator: GA Davies

Department: Anaesthesiology

Supervisor (If relevant): J Scribante, PC Anamourlis

Permission Head Department (where research conducted): Not yet

Date of start of proposed study: July 2017
Date of completion of data collection: Dec 2018

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 20 July 2017

.....
Approved/Not Approved
Hospital Management
Date: 24/7/17

Appendix 5: CMJAH Approval

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. N. Mzila
Office of the Clinical Director
Tell: (011): 488-4812
Email: Nolwazi.Mzila@gautemg.gov.za
19 February 2018

GP_2017RP49_110

Dear Dr. G. Davies

STUDY TITLE: The Illuminance of Laryngoscopes at Two Central Hospitals

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic Hospital will not anyway incur or inherit costs as result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the HOD and Unit Manager or sister in charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported / ~~not supported~~

Dr. M.L Mofokeng
Clinical Director
DATE: 23/11/2017

Approved/not approved

Ms. G. Bogoshi
Chief Executive Officer
Date: 27 · 11 · 2017

Section 5: Proposal

The illuminance of laryngoscopes at two central hospitals

Gwyneth Ann Davies

0401238M

Supervisor:	Helen Perrie
	Department of Anaesthesiology
Supervisor:	Juan Scribante
	Department of Anaesthesiology
Co-supervisor:	Dr Prodromos Christopher Anamourlis
	Department of Anaesthesiology

Introduction

Direct laryngoscopy allows for inspection of the airway structures, removal of foreign bodies, and intubation of the airway. Despite the availability of sophisticated equipment such as video laryngscopes and flexible fibreoptics, the rigid laryngoscope remains the gold standard for direct laryngoscopy due to its simple design and easy use.

A laryngoscope is required to produce adequate illuminance of the airway structures. A functioning laryngoscope is listed in the South African Society of Anaesthesiologists (SASA) practice guidelines of 2013 (1) as essential as part of the minimum safety requirements. It is also stipulated that the anaesthetist is responsible for checking all such theatre equipment. Studies previously conducted have shown that the light produced may be of varying intensity and that the laryngoscopes functioning may not always be reliable (2-7).

The two most common lighting mechanisms of laryngoscopes are the “bulb-on-blade” or incandescent type, and the “bulb-in-handle” or fibreoptic type. In an incandescent laryngoscope, the light source or bulb is mounted on the blade of the laryngoscope. In contrast, the light source of the fibreoptic laryngoscopes is encased within the handle, and is conducted to the distal portion of the blade by a glass or plastic fibre bundle (8). Studies have demonstrated the superior illuminance of the fibreoptic laryngoscopes when compared to the incandescent type (2, 3, 8).

Factors have been identified which influence the illuminance of laryngoscope light, including:

- the lighting mechanism (incandescent or fibreoptic)
- wear and tear of components due to repetitive cleaning
- the battery life as well as type of battery used (8).

In addition, a study by Levitan et al. (6) showed that, with regards to incandescent laryngoscopes, the distance between the bulb and the tip of the laryngoscope blade will affect the illuminance of the airway structures. The curved or “Macintosh” laryngoscope blades differ slightly, depending on manufacturer. The manufacturers are named by the country of origin, namely “American, English or German”. The study noted the superiority of

the shorter distance between bulb and blade tip (German blade) in comparison to a longer distance of the American blades.

In the clinical setting the illuminance of a laryngoscope is subjectively assessed by the user. The International Organization of Standardization (ISO) 7376:2009 requires a more sophisticated measurement using a device called a lux meter. The standard specifies a minimum illuminance of 500 lux (9). In comparison, the ambient light is 150 to 500 lux. The ISO 7376:2009 further describes the required dimensions of the field of light distributed by the laryngoscope. A study by Murphy et al. (2) of 691 laryngoscopes found that 28% did not meet the minimum required 500 lux. Baker et al. (10) found in their study that only 11% of laryngoscope illuminance audited exceeded 500 lux, and none complied with the dimensions of the illumination field. No South African studies were identified that described the illuminance of laryngoscope lights.

With advances in technology and mobile phone applications (apps) the user may have access to sophisticated equipment in their pockets. There are mobile phone lux meter apps available that make use of the mobile phone camera lens as the light sensor. However, their efficacy requires further testing. The company DIAL, which produces lux meter devices, conducted a study of various lux meter apps available in comparison to one of their standard lux meter devices. Their findings showed that the lux meter app readings were variable, and were not consistent with those taken by the lux meter (11). In contrast, a study by Machado et al. (5) measuring illuminance of laryngoscopes using an app and a lux meter showed similarity in the readings of the two devices.

Problem statement

In order to successfully intubate a patient, using direct laryngoscopy, the laryngoscope must provide adequate illumination and exposure of airway structures. Previous studies have found substandard illuminance in 29% to 100% of laryngoscopes in use, with 5% to 7% not turning on at all (2, 3, 5, 6). These studies also noted the superiority of fibreoptic type laryngoscopes over the older incandescent type (2, 3).

Illuminance is tested with a lux meter, which is not available in the theatre setting. Laryngoscopes are usually checked subjectively by the anaesthetist as part of the daily theatre preparation. There are mobile phone apps available that measure lux, and while they are cheap their accuracy may be questionable (11).

Currently, within the Department of Anaesthesiology at the University of the Witwatersrand (Wits), it is not known how many of our laryngoscopes have adequate illuminance.

Aim

The aim of this study is to describe the illuminance of the laryngoscopes at two hospitals affiliated to the Department of Anaesthesiology at Wits.

Objectives

The primary objectives of this study are to:

- determine the illuminance of the laryngoscopes available in theatre with a lux meter
- determine the illuminance of the laryngoscopes available in theatre with a mobile phone app
- determine the size of the illuminance field emitted from the laryngoscope.

Secondary objectives of this study are to:

- compare the illuminance readings obtained on a lux meter to those obtained with a cell phone app
- compare the illuminance of the incandescent and fibreoptic laryngoscopes.

Research assumptions

The following definitions will be used in the study**:**

Luminance: is the apparent brightness of an object perceived by the observer, or the luminous flux emitted from a surface. It is measured in candelas per square meter (12).

Illuminance: is the amount of light falling on a particular object, measured in lumens per square meter, or lux (12).

Minimum adequate illuminance: according to the ISO 7376: 2009 is 500 lux at 10 minutes (9). The illumination field (when the laryngoscope is shone onto translucent paper with the tip 20 mm away) will have the following measurements:

- from the superior illumination edge and the blade tip on the paper shall be less than 3 mm
- from the superior to inferior illumination edges shall be between 30-80 mm
- from the right edge to the centre of the blade tip shall be between 25-50 mm
- from the left edge to the centre of the blade tip shall be between 25-50 mm.

Incandescent laryngoscope: is a laryngoscope with the light source located on the blade.

Fibreoptic laryngoscope: is a laryngoscope with the light source located in the handle. The light is transmitted to the distal tip of the blade via a glass or plastic fibre bundle.

Demarcation of study field

The study will be conducted in the theatre complexes of Chris Hani Baragwanath Academic Hospital (CHBAH) and Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), both of which are affiliated to the Department of Anaesthesiology at Wits.

CHBAH is a 2888 bed central hospital with 25 theatres and 65 000 cases are done annually. CMJAH a 1200 bed central hospital with 23 theatres and on average 23 000 cases are done annually. The emergency operating theatres function 24 hours a day within both hospitals.

Ethical considerations

Approval to conduct this study will be obtained from the Graduate Studies Committee of Wits. An ethics waiver (Appendix 1) will be applied for from the Human Research Ethics Committee (Medical) of Wits as no human participants will be involved in this study. Approval with be obtained from the Medical Advisory Committee at CHBAH (Appendix 2) as well as the Chief Executive Officer of CMJAH (Appendix 3). The theatre nursing manager will be informed of the study taking place.

A fully functional laryngoscope will be made available to each theatre while that particular theatre's laryngoscope is being tested, in case of an emergency. At the time of the study if a laryngoscope tested is found to be inadequate for use, the anaesthetic staff will be informed of findings, and advised not to continue with theatre cases until the anaesthetic nurse has replaced the laryngoscope. The senior anaesthetist on the floor will be made aware of which theatres do not have adequate laryngoscopes.

The data collected will be stored securely for six years after completion of the study in a password protected computer.

This study does not involve any drug or therapeutic management, and will be conducted by adhering to the South African Good Clinical Practice guidelines (13) and the Declaration of Helsinki (14).

Data collection

Research design

The research design is prospective, contextual and descriptive.

A prospective study is one in which a select population is followed over time, to observe an outcome (15). This study will look at the illuminance of laryngoscopes in use in the operating theatre to determine their adequacy.

A contextual study is one in which the historical and cultural factors of the setting which may have an effect on the outcome, are taken into consideration (16). This study will look at

the particular laryngoscopes available, which is, in part, determined by the financial constraints of the hospital.

A descriptive study is a study "in which phenomena are described or the relationship between variables is examined; no attempt is made to determine cause-and-effect relationships"(15). This study will describe the adequacy of the laryngoscope illuminance in the operating theatres of two central hospitals.

Study population

The study population will comprise the laryngoscopes in the operating theatres at the two hospitals.

Study sample

Sample method

In this study a convenience sampling method will be used. Convenience sampling is the use of a population that is easy to access, that may be representative of a larger population (15). This study will use the laryngoscopes available in theatre on the day of data collection.

Sample size

The sample size will be determined by the number of theatres in use, as each theatre has a laryngoscope handle and at least two blades that are checked preoperatively by the anaesthetist. The sample will potentially consist of 48 laryngoscopes (25 operating theatres at CHBAH and 23 operating theatres at CMJAH). The sample number may be less if certain theatres are not in use during the period of data collection. Each laryngoscope consists of one handle, and a blade. The size 3 blade was chosen as it is the most frequently used blade.

Inclusion and exclusion criteria

All laryngoscope handles, and corresponding size 3 blade that are ready for use on the anaesthetic machine will be included in the study. Extra handles and blades in theatre will be excluded.

Collection of data

Each hospital will be visited on a weekday, when the operating theatres are in use. The theatre nursing manager, as well as theatre staff will be informed of the study to be conducted. The data will be documented on the data collection form (Appendix 4).

The lux meter used will be Dr. Meter Digital Illuminance/Light Meter LX1330B. The manufacturer specifies an accuracy of within 2%. This particular lux meter has been rated second (4.5/5 stars) out of the top ten lux meters (17). This meter was chosen because it was the most cost effective. It consists of a hand held meter device, connected to a circular light sensor by an electric cord. The illuminance is measured by the sensor, with the lux reading displayed on the screen. The app, Lux Camera 2.0 received a fair rating on AppCrawlr.com(18), is free to download and is available on the South African app store. This app is simple to use and does not require one to purchase extra accessories for one's mobile phone.

The ISO Standard requires two sets of measurements to be taken, the first as the laryngoscope is initially assembled and the light is first switched on, and the second after the light has been lit for 10 minutes. The reason for the time duration is not specified. One could assume it is to ensure the adequacy of the illuminance in a situation such as a difficult airway where the laryngoscope may be left on for a longer duration.

The portable dark box is required to minimise ambient light. A photographic dark room could be used, however the screen of the lux meter is not back lit, making observing the lux meter readings difficult in this situation. The portable dark box will be constructed similarly to those in previous studies (3, 19).


Portable dark box with laryngoscope and light sensor in place

Data collection will occur as follows.

- Theatre staff will be informed of the study upon entering theatre.
- The spare, fully functioning laryngoscope will be left in theatre, while the theatre's laryngoscope is taken for testing.
- The lux meter will be calibrated before each reading.
- The characteristics of the laryngoscope will be documented.
- The laryngoscope will be lit, and inserted into the portable dark room. The stop watch is started as the laryngoscope is lit. Distance from blade tip to sensor confirmed (20 mm) with a ruler.
- Three illuminance recordings are taken first with the lux meter.
- The lux meter is replaced with the mobile phone and three recordings are taken with the app.
- The mobile phone is replaced by a sheet of translucent paper and the illuminance field is marked with a pencil and measured with a ruler.
- When the stopwatch indicates ten minutes have passed the illuminance will be again measured three times with the lux meter, and then three times with the app.
- The laryngoscope will be switched off, and removed from the portable dark room.
- The batteries will be removed, and the demographics noted.

- The batteries will be replaced, if necessary, and the tests as above repeated.
- Each laryngoscope handle and blade will then be marked with a small sticker, to ensure that they are not tested twice. This sticker will be placed in such a way as to have minimum chance of compromising sterility of the blade.
- The laryngoscope will be returned to theatre.
- Theatre anaesthetic nurse and anaesthetist will be informed of adequacy of the laryngoscope illuminance.

Data analysis

The data will be entered onto a Microsoft® Excel spreadsheet. Descriptive and inferential statistics will be used for data analysis using Statistica version 12 (Statsoft, USA). Categorical variables will be described using frequencies and percentages. Continuous variables will be described using means and standard deviations or medians and interquartile ranges depending on the distribution of the data.

If the data is normally distributed the comparison between the measurements made with the lux meter and the mobile phone app will be done using a paired t- test, and if not, the Wilcoxon matched pairs test will be used. A p value of <0.05 will be considered statistically significant.

Significance of the study

Previous studies have found that the laryngoscopes at hospitals do not meet the minimum criteria outlined by ISO 7376 (2, 3, 5). To date there have been no South African studies identified looking at the illuminance of laryngoscopes in operating theatres. Adequate theatre safety includes functioning equipment, such as laryngoscopes. An anaesthetist will not be able to intubate a patient without adequate vision of a patient's airway. The study may contribute to the development of a quality assurance program to ensure adequate functioning of the laryngoscopes in the operating theatre.

Validity and reliability of the study

According to Botma et al. (20) validity "refers to the degree to which a measurement represents a true value" and reliability "represents the consistency of the measure

achieved". The validity and reliability of this study will be ensured by the following measures:

- Using an appropriate study design
- Using standardised measuring procedures according to the ISO 7376:2009 (9)
- Using a lux meter that has a four and a half star quality rating and is calibrated according to the manufacturer
- Using the same mobile app for all measurements
- The same mobile dark box as specified by previous studies (3, 19) and measuring apparatus(ruler) will be used for each measurement
- Check every 10th data entry on Microsoft® Excel for accuracy
- Statistics done in consultation with a biostatistician.

Potential limitations of the study

The study is contextual, therefore the finding may not be applied to other settings. The study may also not look at other laryngoscopes that may be available in theatre. The study will make use of the laryngoscopes that are on the anaesthetic machine and are ready for use, however, there may be other laryngoscopes present in theatre that may be called upon during an emergency or if the laryngoscope in use fails. These extra laryngoscopes will not be tested.

Project outline

	Oct 2016	Nov 2016	Jan 2017	Feb 2017	March 2017	April 2017	May 2017
Proposal							
Literature review							
Proposal submission							
Graduate studies committee submission							
Data collection							
Data analysis							
Draft article							
Editing							
Submission							

Financial plan

	Price per unit	Number of pages	Copies	Total
Proposal	R1	15	10	150
Ethics form	R1	10	1	R10
Graduate studies committee	R1	2	6	R12
Completed research report	R1	80	4	R240
Binding	R20		4	R80
Lux meter	R500			R500
Mobile phone app	R0			R0
Portable dark room	R100			R100
			Total	R1092

The department of Anaesthesiology will be paying for the printing paper. The Department of Anaesthesiology research fund will be approached for the funds to pay for the lux meter.

References

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3. Volsky P, Murphy M, Darrow D. Laryngoscope illuminance in a tertiary children's hospital: Implications for quality laryngoscopy. JAMA Otolaryngol Head Neck Surg. 2014;140(7):603-7.DOI:http://dx.doi.org/10.1001/jamaoto.2014.676

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Appendix 1: Request for ethics waver

Dr Gwyneth Davies

MBCHB(Wits) DA(SA)

Cell: 083 498 9938

Email: gwynethad@gmail.com

Date: 2016

Att: Professor Peter Cleaton-Jones

Chair: Human Research Ethics Committee

Re: A study of the illuminance of laryngoscopes at two central hospitals

To Prof Cleaton-Jones

I am a registrar in the Department of Anaesthesiology at the University of the Witwatersrand. The research component of my MMed is a non-human study. I propose to measure the illuminance of the laryngoscopes in the operating theatres of Chris Hani Baragwanath Academic Hospital and Charlotte Maxeke Johannesburg Academic hospital.

The illuminance will be measured with a lux meter device and a mobile phone application and readings compared to the International Organization of Standards (ISO) 7376:2009. The laryngoscopes will be the focus of the study and no patient or medical staff information will be recorded. I would like to request an ethics waiver for this study.

Yours sincerely

Gwyneth Davies

Appendix 2: Letter to Medical Advisory Committee

Dr Gwyneth Davies

MBCHB(Wits) DA(SA)

Cell: 083 498 9938

Email: gwynethad@gmail.com

Date: 2016

The Medical Advisory Committee of Chris Hani Baragwanath Academic Hospital

Dear Doctors

RE: Request for permission to conduct research

My name is Gwyneth Davies, and I am currently a registrar in the Department of Anaesthesiology at the University of Witwatersrand. I am conducting a MMed research study entitled "The illuminance of laryngoscopes at two central hospitals", and I would like your hospital to participate in the study.

The study will describe the illuminance of the laryngoscopes available in the operating theatres. On the day of data collection, the theatre nursing manager as well as the theatre staff will be informed of the study taking place. The laryngoscope handle and corresponding size 3 blade will be taken for testing, and a spare set left in its place in case of emergency in that particular theatre.

The illuminance of each laryngoscope will then be measured with a lux meter and a mobile phone application. The size of the illuminance field will also measured. These will be compared to the standards described in the International Standard of Organisations (ISO) 7376:2009. The batteries contained within the handle will be checked and replaced if necessary.

If any laryngoscope is found to have inadequate illuminance (as outlined in the ISO7376:2009) then the anaesthetic nurse as well as the anaesthetist responsible for that theatre will be informed so that they may seek a replacement device.

An ethics waiver has been granted as no humans are involved in this study. There will be no cost to the hospital. I request your permission to proceed with the study at your hospital.

Yours sincerely

Gwyneth Davies

Appendix 3: Letter to hospital CEO

Dr Gwyneth Davies
MBCHB(Wits) DA(SA)
Cell: 083 498 9938
Email: gwynethad@gmail.com
Date: 2016

The CEO

Dear Mrs Gladys Bogoshi

RE: Request for permission to conduct research

My name is Gwyneth Davies, and I am currently a registrar in the Department of Anaesthesiology at the University of Witwatersrand. I am conducting a MMed research study entitled "The illuminance of laryngoscopes at two central hospitals", and I would like your hospital to participate in the study.

The study will describe the illuminance of the laryngoscopes available in the operating theatres. On the day of data collection, the theatre nursing manager as well as the theatre staff will be informed of the study taking place. The laryngoscope handle and corresponding size 3 blade will be taken for testing, and a spare set left in its place in case of emergency in that particular theatre.

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If any laryngoscope is found to have inadequate illuminance (as outlined in the ISO7376:2009) then the anaesthetic nurse as well as the anaesthetist responsible for that theatre will be informed so that they may seek a replacement device.

An ethics waiver has been granted as no humans are involved in this study. There will be no cost to the hospital. I request your permission to proceed with the study at your hospital.

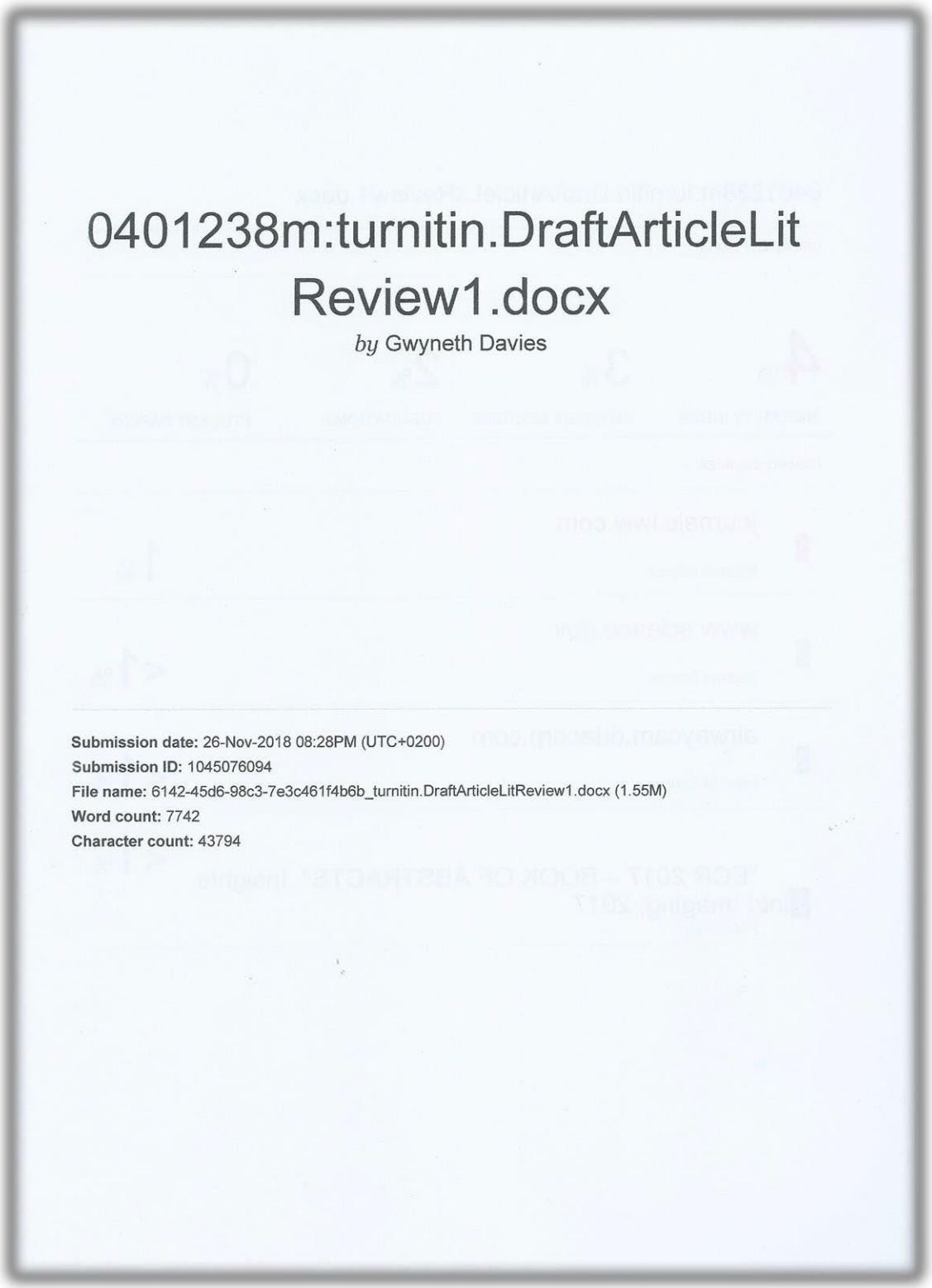
Yours Sincerely

Gwyneth Davies

Appendix 4: Data collection sheet

Laryngoscope demographics			Lux meter: Illuminance at 0 min (lux)			App: Illuminance at 0 min (lux)			Lux meter: Illuminance at 10 min (lux)			App: Illuminance at 10 min (lux)			Illuminated field (mm)				Battery		Action taken
Theatre of origin	Type	Make	1	2	3	1	2	3	1	2	3	1	2	3	Upper edge to blade tip	Upper to lower edge	Right edge to centre	Left edge to centre	Type	Voltage	e.g. battery replaced, send for repairs, returned to theatre
e.g.Theatre 4	*incandescent*	*American*	*600*	*650*	*625*	*500*	*520*	*550*	*400*	*370*	*370*	*380*	*400*	*400*	*3*	*50*	*30*	*30*	*alkaline*	*50*	*Batteries replaced*

Section 6: Turnitin Report



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by Gwyneth Davies

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