Simple Device For Facilitating Surgical Illumination

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Abstract: Ergonomic problems associated with illumination systems in various medical applications including surgeries, dentistry and other diagnostic processes have been the subject of concern for medical professionals. These problems include difficulties in finding a well-lit wound, time to time adjustment of light, illumination intensity, generation of heat and interruption due to formation of shadows etc. Therefore, there is need for improvement in illumination system with major focus on minimizing the need and efforts for repositioning the luminaire. Present work provides user friendly, efficient and greener surgical illumination device. The designed prototype for better illumination provides direct, shadow-less illumination with its proper sterilization using ethylene oxide sterilization. The designed prototype is better used over the gloves as it provides proper intensity and less diffusivity. There are different prototypes designed for different applications including normal illumination ring, illumination ring with a shaft movement of light, a ring with adjustable light intensity etc. The cell viability assay showed no significant impact of light on cells and tissues.

Keywords: Surgical illumination, ergonomics, medical device, cell viability

1. Introduction

Introduction

The ergonomics in various medical applications is an important aspect as it has direct or indirect impact on patients as well as surgeons [1]. The ergonomic problems associated with medical field, majorly in surgeries include visualization, cost of surgical systems, posture of doctors and surgeons, physical and psychological stress, design and setup of the operating room and overall surgical performance [2]. These problems are not only associated with actual surgical procedures but also include user-friendliness of systems, design factors, workplace efficiency and human factors. Despite the increasing attention to ergonomics in healthcare field, the complications in the same are still increasing [3]. The difficulties in visualization during surgeries are considered to be one of the most unresolved ergonomic issues. These difficulties include finding a well-lit wound, heat generation, improper intensity of operation theatre lights and formation of shadow etc., [4, 5].

The existing solutions for the complications related to ergonomics in surgery majorly include use of surgical headlights, operating microscopes and lighted retractors. However, as there are still unresolved ergonomic issues regarding use of current illumination systems including the lack of mobility, time-lengthy & repetitive adjustments, non-optimal illumination, sterilization concerns, unavailability and unaffordability; there is need for the development of a device as an alternative addressing the issues [6]. Therefore, for resolving these issues, the prototype needs to be developed in such a way that the light source can be adjusted according to movement of hands of surgeons without any re-positioning of light. This will help to save 25% of time required in surgeries for re-positioning of operation theatre lights.

2. Materials & methodology

A. Survey for Medical professionals:

For getting insights into various ergonomic problems, medical professionals including surgeons, dentists etc. were interviewed. The responses were recorded for understanding utility of proposed product. The Fig. 1 shows responses of 12 surgeons/ dentists for efficiency of product.

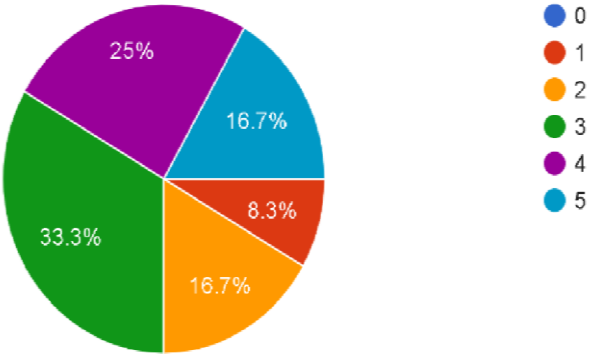

Fig. 1. Responses of 12 surgeons/ dentists for efficiency of product (On the scale of 5).

B. Selection of Materials & Designing of the prototype:

The materials used for product development should possess characteristics suitable for operation theatre environment; specifically including biocompatibility, small size, heat-resistant nature, easy sterilization etc., [7]. The materials used for prototype are mentioned in TABLE I.

Using the materials mentioned in TABLE I., a prototype was designed as a wearable, ring like structure which can be worn over the gloves during surgery and can be re-used by proper sterilization techniques. The Device was developed by using easily available, cost effective materials such as Light Emitting Diodes (LEDs), Teflon Ring and araldite. The prototype was assembled by attaching LEDs on Teflon ring using adhesive followed by insulation of LED using araldite. The LEDs were then connected in parallel for making current value 1 Ampere.

C. Development of different models of the prototype:

The prototype was modified in different designs for wide range of different applications. Different features of each design of prototype are provided in TABLE II.

D. Testing of designed prototype:

Considering the designed prototype was checked for efficacy and utility using different techniques and parameters that include better light diffusion criteria, sterilization techniques for re-use of the prototype and analyzing the impact of prototype on living tissues and cells.

1) Diffusion of light:

The diffusion of lights on prototype was tested by wearing the prototype inside the gloves and outside the gloves. The extent of light diffused was measured by measuring length of total area lightened by LEDs. The results were compared for use of prototype over the gloves and under the gloves for better application of developed prototype.

TABLE I Materials Used for Prototype Development

Sr. No.	Materials	Image	Characteristics
1.	Teflon ring		Biocompatible Heat resistant Mouldable
2.	LED		Compact size Heat resistant

2) Sterilization of Prototype:

Sterilization of biomedical devices is vital for eliminating the risk of infections microbial pathogens. The sterilization of developed prototype was carried out using different sterilization techniques including alcohol sterilization, flame sterilization, autoclave sterilization and ethylene oxide sterilization etc. The better sterilization technique was selected on the basis of unchanged utility of developed prototype and checked by sterility testing assay [8].

3) Impact of light on living cells and tissues:

The impact of light exposure to living cells was evaluated using *in vitro* cell viability assay of chicken liver cells. The cells were exposed to light for the span of 0 1, 2 hours [9]. The cell viability was checked by hemocytometer by comparing light exposed cells with control cells for 2 hours of continuous light exposure, as indicated in Fig. 2.

4) Energy consumption of developed device:

The overall calculations for power and energy consumption of all the designs of developed device are provided in Table III.

3. Results And Discussion

1) Diffusion of light:

The diffusion of light after adjusting prototype over the gloves and under the gloves was compared by measuring area of light exposure on dark surface. It is observed that prototype should be made in such a way that LED should be placed over the gloves for proper spread of light in an incision; as area of light spread after placing LEDs over the gloves is twice as compared to area of light spread after placing LEDs under the gloves.

Fig.2. Control (Left) and Test (Right) groups for checking impact of light on living cells respectively

TABLE II. Designs Of Protoype Developed

Sr. No.	Prototype design name	Image	Features
1.	Basic ring Design		Normal ring for better visualization during surgeries Surgeries of shorter duration (1-2 hours)

2.	Design With shaft movement		Ring with adjustable shaft Application in Dental surgeries
3.	Rechargeable design		Large mAh battery can be used Rechargeable Longer duration surgeries (8-12 hours surgeries)

TABLE III. Energy Consumption Of Developed Device

Design of the prototypes	Basic ring design	Rechargeable design	Design with the shaft movement
Battery capacity	3000mAh	3000mAh	3000mAh
Battery life	3 hours	3 hours	2.25 hours
Power consumption (P) W = (mAh)*(V)/1000	3.00 W	3.00 W	3.99 W
Energy consumption (E)	3.00 Watt-hours	3.00 Watt-hours	4.00 Watt-hours

**Note- Larger mAh batteries can be used in rechargeable design for longer duration surgeries*

1) Sterilization of prototype:

As basic techniques like flame sterilization and alcohol sterilization are not significant for proper sterilization and only help for partial sterilization. Therefore, sterilization of biomedical devices is majorly carried out using two techniques including autoclave sterilization and ethylene oxide sterilization. After sterilization, prototype underwent sterility testing for checking effectiveness of the technique by detecting presence of any microbial load.

1. Autoclave sterilization: Autoclave sterilization is generally used for sterilization under high pressure usually 15PSI, but after autoclave sterilization of prototype, it was observed that the glue used for developing the prototype is melting which is causing defects in prototype. Therefore, Autoclave sterilization is ineffective for sterilization of developed prototype.

2. Ethylene oxide gas sterilization (EtO Sterilization): The prototype after undergoing this sterilization, remained structurally unchanged and showed proper result for its sterility testing.

2) Impact of light on living cells and tissues:

The chicken liver cells were checked for their viability after direct exposure to LED light using hemocytometer for counting viability of normal and light exposed cells after certain interval of time. After 2 hours, there was no substantial change in the number of viable cells exposed to light as compared to control (unexposed) cells as shown in Fig.3. The percentage cell viability of the normal cells was compared with the light exposed cells, it was confirmed that there is no significant difference in percentage cell viability of the control and the light exposed cells after 2 hours of exposure as shown in Fig.4.

3) Energy consumption of developed device:

The overall power and energy consumption (3-4 W) of all the designs of developed device is relatively less in comparison with the different models and designs of currently used surgical lights (most commonly over 30 - 40 W) [10].

As the developed device is proposed to reduce overall surgery time significantly, the substantial amount of energy therefore can be conserved in spite of using this novel device along with the conventional surgical lights.

4) Impact of developed device on patients:

The advantage of device for reducing the surgery time results in decreasing the risk of patient's life during the surgery. The overall reduction in energy consumption during surgery, due to reduced surgery time will facilitate patient by overall reduction in cost of surgery. The present device will facilitate the illumination during surgeries which will aid in decreasing the time for surgeries.

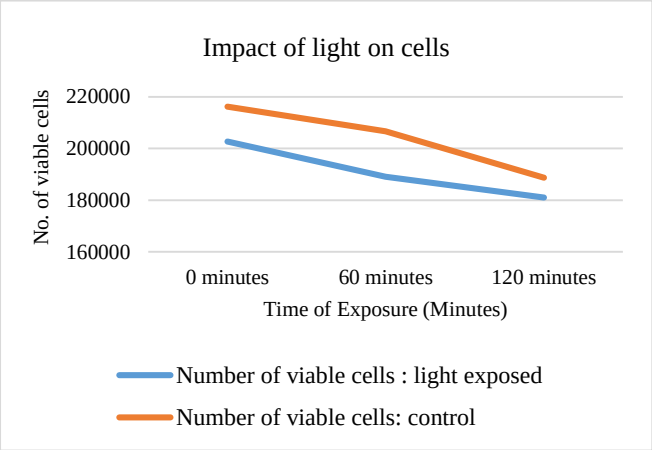

Fig.3.Impact of light on cell viability (Control vs. Light Exposed)

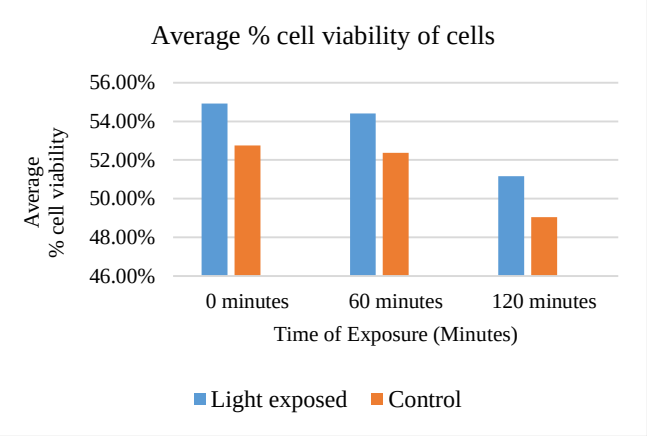

Fig.4. Comparison between average % cell viability of control and light exposed cells

Additionally, the illumination device adds on to the patients' relief during dental surgeries. Time reduction in dental surgeries will decrease the duration of mouth opening during the dental procedure. This will also positively impact the number of patients consulted by the doctor.

Exposure of blue light emitted by LEDs can have adverse effect on the blood cells resulting in cell death during surgeries. However, the use of dimmer for alteration in intensity of light, designing of the prototype in customizable size and coating the hydrophobic materials like parylene coating over the LEDs can help for reducing problems of blocking light due to deposition of blood stains over the LEDs as well as heating [11].

4. Conclusion

The developed surgical illumination device provides direct, shadow-less illumination during surgery which definitely will facilitate the surgeon for reducing the surgery time. It will directly impact power consumption in an operation theatre and contribute towards reduction of the overall energy consumption during surgery. The product also can be easily sterilized and does not adversely affect the tissue cells. This will be potentially beneficial for

solving other ergonomic issues in surgery including betterment of posture as there is no need for time to time re-positioning of light and decreasing both physical and psychological stress in doctors and surgeons.

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