THE DESIGN OF MEDICAL LASER SURGERY DERMATOLOGY HANDPIECES FOR RADIATION CONTROL AND DIRECT EXTRACTION OF INFECTIOUS LASER GENERATED PLUME

Paper 1303

Matthew Jones[1], Jack Edwards[1], John Tyrer[1], Lewis C. R. Jones[1], Alan Beswick[2], Delphine Bard[2], Jason Britton[3]

[1] Wolfson School and Mechanical, Electrical and Manufacturing Engineering, Loughborough University, Loughborough, Leicestershire, LE11 3TU, UK
[2] Health and Safety Laboratory, Harpur Hill, Buxton, Derbyshire, SK17 9JN, UK
[3] Medical Physics Department, Leeds General Infirmary, Leeds, LS1 3EX, UK

Abstract

Surgical skin treatments such as; laser ablation, laser scalpels, hair removal, tattooed removal etc can all generate direct and secondary optical radiation hazards, however, because they are designed to intentionally destroy human tissue, they also generate gaseous and particulate emissions. This second family often referred to as; surgical smoke, surgical smoke plume and surgical fume, have now been identified as producing viable bio-active aerosols, these by-products now pose infectious hazards to the patient and staff of the operating room. Local extraction is sometimes used to try and reduce the airborne concentration of these by-products though in virtually all cases the smell of the process is detectable by all. The optical radiation hazard usually dictates the wearing of protective eyewear to provide some level of personal protection. A major health concern to all medical and cosmetic facilities is that of infection control. Surgical smoke is usually overlooked as a source of infection within the operating environment and it has been known since the mid-1980s that the particulate can carry with it live pathogens from the patient which can now be in skin contact or respired by the operating staff. A paper presented by the authors in the Medical Session here at ILSC provides possibly the first quantitative analysis of the hazards the surgeon and other staff are subject to.

This paper examines the practical limitations of the existing approaches and provides some simple practical control measures that provide complete radiation containment as well as enable complete particulate and gas extraction without any reliance on any form of personal protection for the patient and operating staff. These designs have now been tested and are shown to offer 100% effective plume extraction and radiation containment.

Introduction

Lasers are commonly used in treatment and procedures for the ablation of hair and soft-tissues. These procedures can range from the removal of small skin cancers, to leveling skin that has been significantly scarred, for example in cases of acne or lacerations, to the removal of so-called port-wine stains. These procedures tend to be carried out of a number of sessions, both due to the irritation caused to the local area causing the patient and the inaccurate delivery of the laser causing imperfect results. Common to these procedures is the use of a handpiece which contains the laser beam delivery mechanism and allows the operator to manually position the device.

This paper presents safety issues related to optical and fume hazards commonly generated by existing laser handpiece design and proposes engineering solutions to these issues. Experimental results are shown to verify the control systems.

Current handpiece hazards

When talking about laser beam precision and repeatability in a surgical environment, key issues have been identified with existing handpiece design: Laser beam position and repeatability; Optical radiation hazards; Fume and bio-aerosol hazards.

Laser beam position and repeatability

Firstly, the distance between the skin in a laser procedure is absolutely critical. This is due to the precise nature of the Rayleigh length of the laser sources and handpieces used, with a typical working range of ±2mm. Currently, this distance is controlled using a stand-off probe, see Figure 1, that presses on the skin to provide the distance.

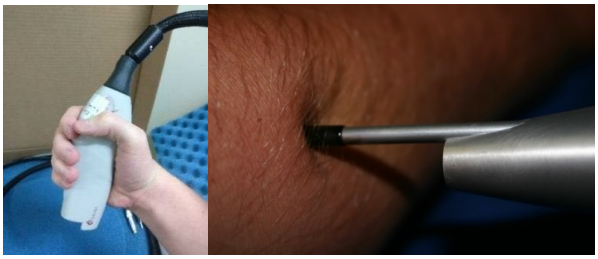

Figure 1. Typical handpiece and stand-off probe showing skin deflection.

The variance in the deflection of skin, as a result of patient fat and muscle tissue and the force applied by the operator, may result in significant differences in the offset distance and area of target with each laser application. This offset device creates an inconsistent target for the operator making aiming of the small focus area unnecessarily difficult. As the skin deflects, it is likely that the beam would no longer be centred on the intended location. As the Raleigh length is short this will result in large variations of laser focus during procedures leading to ineffective or dangerous use of the laser. The mechanism tip therefore requires a more reliable method for positioning the laser relative to the target.

Optical radiation hazards

Laser handpieces present direct and indirect optical radiation hazard. The Nd:YAG and Fibre lasers typically used are Class 4 sources (IEC 60825-1:2014) which present the maximum retinal and skin hazard category to the patent, surgeon and other people in proximity of the procedure. It is clear from the stand-off probe method shown in Figure 1 that no optical radiation protection is provided by the handpiece. Risk is managed only by Personal Protective Equipment (PPE) eyewear and operator training.

While the purpose of the handpiece is to expose specific tissue of the patient to laser radiation, they require protection from accidental triggering of the beam and from any scattered radiation. PPE should not be the first and only protection for staff and publics in the vicinity of the procedure. For the case of the UK, this requirement is in provided by law [1], [2].

It should be practicable to redesign the handpiece tip area to meet the Class 1C requirements for laser safety for handpieces which would complete remove the risks to staff. Engineering controls would also eliminate the human errors related to maintaining and adherence to PPE. Elimination of the optical hazard risk at source would also remove the cost of PPE procurement and maintainance.

Fume and bio-aerosol hazards

Surgical smoke generated during procedures also presents a large group of hazards, with over 500 000 workers currently exposed to laser and electrosurgical procedures each year. Laser generated plumes include debris presenting respiratory issues, poisonous chemical substances, and critically, viable cellular materials presenting infection risk [3]. There have been reported cases of surgeons being infected by the plume generated laser procedures [4].

This surgical smoke is controlled through an extraction funnel which must be position nearby to the source of the process. However, there is still a route for the smoke to enter the environment. Anecdotally it has been reported that a foul smell is generated by this process in combination with the smoke [5] and a survey has shown that the use of extraction systems is not guaranteed [6]. This shows that the smoke is not completely captured by the current control methods.

People in the room are also typically wearing surgical masks. In some scenarios, a filtering facepiece (FFP) mask may be suitable in order to provide protection for the theatre staff to protect them from the larger particles. However, due to the nature of the operating theatre, it they are not effective against infectious aerosols [7].

As fume and bio-aerosols present such a significant risk there is an opportunity to integrate extraction into the handpiece design in order to mandate its use through engineering control and provide at-source extraction.

Redesign of the laser handpiece

When looking at the new handpiece design 4 main objectives must be considered based on the presented hazard analysis in order to improve on the safety and accuracy of the device:

I. The device must have an accurate way of locating the device on the skin.
II. The device must have a consistent way of measure the distance between the patient's skin and the laser.
III. The device must enclose optical radiation to reduce danger to the surgeons and patients.
IV. The device must fully extract all fumes at source.

The new device is comprised of two main sections. Section A (shown in blue on the Figures below) is a permanent housing for the laser and main cooling airflow as well having a slot for an endoscope to be inserted into. Figure 2 shows the location of these parts. The small endoscope will allow for a surgeon to see the area where the surgery is taking place, meaning that

they are substantially less likely to fire the laser into the wrong place.

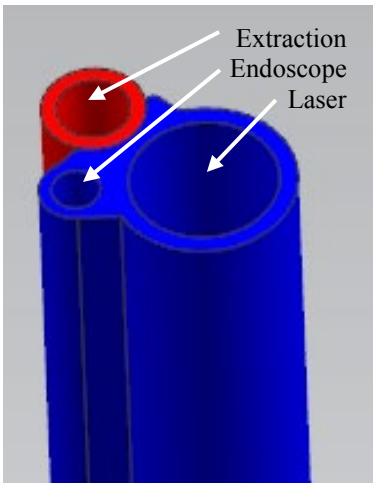

Figure 2. Sections of the handpiece

Section B of the design (in red) is where the flow of fume is collected. Because of the design of the nozzle, it is not possible for the fume to flow up the tube into section A. This is expected to reduce the chance of fume coming into contact with the laser's fibre delivery mechanism.

The tip of the handpiece design is designed to be pressed onto the skin around the area of treatment. This provides three functions. Firstly, the distance of the laser from the skin is significantly more controllable due to the device forming a "drumskin" type effect with the skin (Figure 3). This is a feature that has been adopted in other cosmetic laser treatment product with successful results [8].

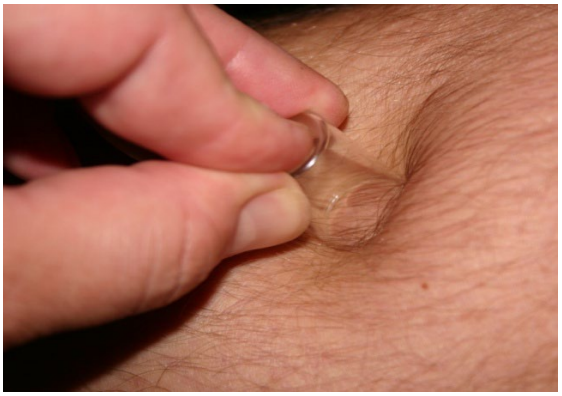

Figure 3. Illustration of the "Drumskin" effect created by handpiece to provide consistent offset distance and surface area.

The annular tip of the handpiece design that creates the "drumskin" is also used to provide a consistent offset distance, shown in Figure 4, between the beam delivery and the skin surface. The fibre beam delivery inside handpiece can be positioned to give the correct focal distance to the target.

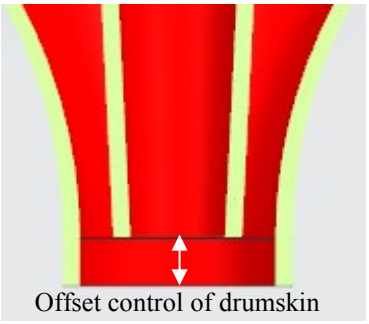

Figure 4. Cross-section of handpiece tip showing offset control and extraction channels.

The second function in pressing the device into the skin is that it provides a seal for the surgical smoke generated, preventing it from entering the environment. The plume produced can then be extracted at source.

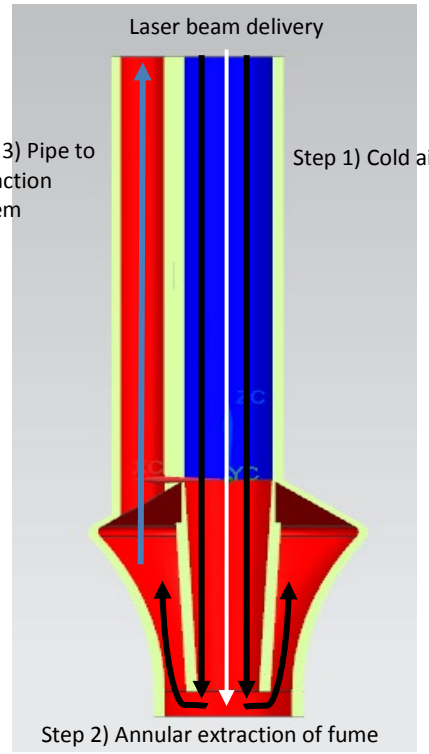

Figure 5. Diagram of airflow within the handpiece to provide extraction of laser generated surgical smoke

Figure 5 shows a cross section of the device with the airflow path illustrated. The central section of the handpiece holds the laser beam delivery fibre and provide positive pressure from the cold air assist gas. The extraction is provided radially around the location of surgical smoke generation. By provide positive

pressure input and negative pressure extraction the path of smoke can be controlled to take it effectively away from the site. It is important that within this chamber atmospheric pressure is kept. This is due to not wanting the device to 'suck' onto the skin if there was a negative pressure gradient, or 'blowing off' the skin if there was a positive pressure gradient. In order to achieve this, the rate of flow into the system must be equal to the flow exiting the system. In a small device this can prove a significant challenge when using purely the input and extraction flows. A solution to this is it intentionally input less flow through the centre than is required by the extraction. The flow rate difference holes shown in Figure 6 allow air in order to maintain the equilibrium. As the air is flowing in there is no risk of the waste being rejected into the operating room. It is also important to note that these holes have a significant lean away from the skin. This not only allows for the flow to be sent more directly to the extract, encouraging other flow to do similarly, but also to prevent the leakage of any optical radiation towards the eyes of the surgeon.

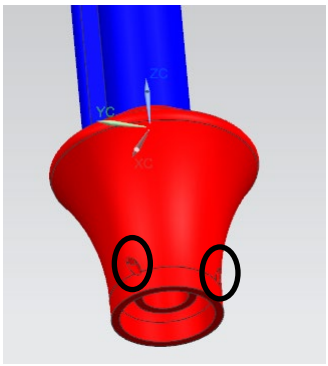

Figure 6. Flow rate difference holes in the handpiece tip allow high flowrate for extraction while maintaining neutral pressure on the patient.

The third feature of the sealing tip is to provide a barrier for optical radiation. The tip should be opaque to the wavelength of the laser to provide this filter. As the tip will only be exposed to scattered radiation this will not be challenging. As the tip is opaque the endoscope can be used to visualise and target the treatment area.

A combination of this opaque sealing device and the potential to include contact sensors on the tip will enable the design to satisfy the Class 1C product requirements.

Fume extraction testing

The ability to seal around the target and successfully extract fume was tested using simulated procedures, see Figure 7. Porcine tissue was laser treated using a 810nm Biolitec diode laser at fluence equal to 15J/cm^2 and a 600µm fibre. Output power of 15W was used, 25 pulses at 0.01s pulse length with a period of 0.5s. Particle concentration was measured for ambient, during processing with extraction and without extraction. Measurements were taken next to the tip and at a typical distance the operator would be from the tip. Particulate measurements were taken using a TSI P Trak ultrafine particle counter. All testing was conducted in the Heath and Safety Labs controlled atmospheric chamber.

The results of particulate extraction testing are shown in Figure 8. The background particulate concentration for the environment was 1012 particles/cm^3. The laser process was initiated at time = 5s. Without any extraction the maximum measurement was 34800 particles/cm^3 at the tip of the handpiece during processing. 25 seconds after the process started a peak of 12800 particles/cm^3 was recorded at the operator location. This shows that surgical smoke can easily spread from the location of treatment.

With the handpiece extraction annulus on the surface of the tissue and the extraction turned on there was no change to the background level of particulate measured. This is a result of 100% extraction of the surgical smoke generated.

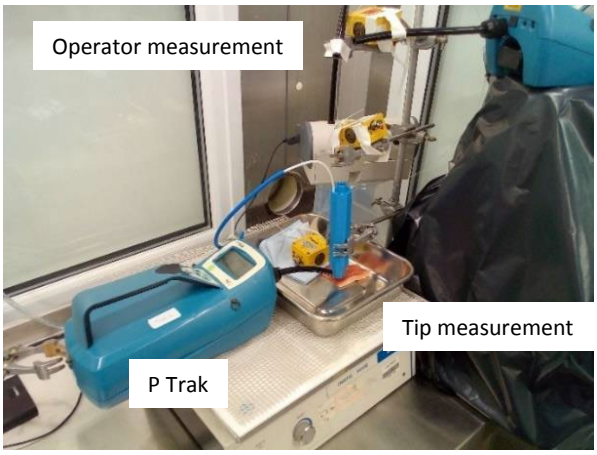

Figure 7. Particulate measurement testing.

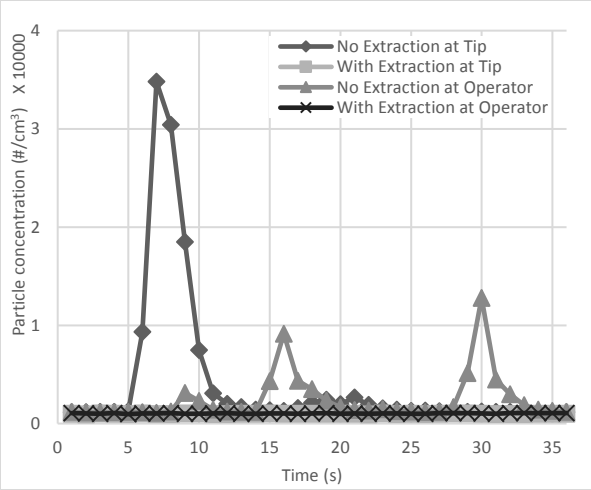

Figure 8. Particle concentration measurements during handpiece extraction testing at tip and operator locations.

Fume Extraction Design

As has been established that it is now possible to extract the fume from the area that the surgery is being taken place on. A fume extraction system has then been designed to not only treat this flow but to get samples so as a pathology lab could potentially take samples of the skin in order to carry out research on other infections taking place in the body.

Firstly, the fumes are put into a cyclone with the aim of collecting large particles from the flow. Collecting these large particles serves 2 main purposes. Primarily, removing these large particles from the flow allows for a lower burden to be place on the processes later in the system, allowing for more efficient operation. The separation of large particles also allows for the potential for these particles to be sent to pathology in order for complete testing to take place if a surgeon/doctor requires.

Using a theoretical analysis of the flow that is entering the cyclone, it is possible to assess how efficient the cyclone may be. For this analysis to take place, 3 main factors must be considered:

- Overall size of the cyclone must be minimized as much as possible to not take up too much room in an operating theatre
- The volumetric flow rate entering the cyclone is largely determined by other factors in the system therefore cannot be easily changed
- Flow should be laminar when entering the cyclone in order to allow for best efficiency

Using these parameters, it was possible to design the cyclone shown in Figure 9.

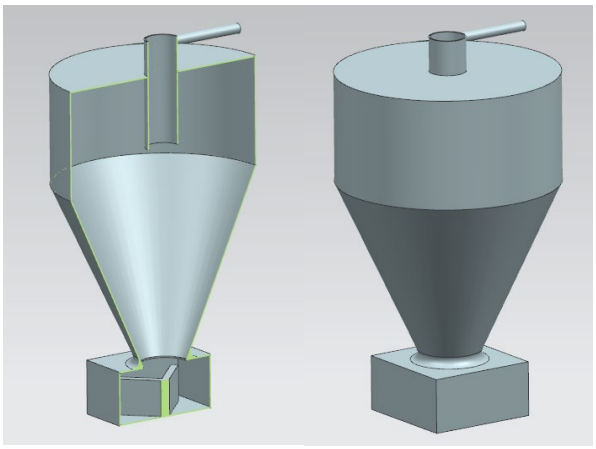

Figure 9. Cyclone design

Using a theoretical analysis of the cyclone [9] Eq , it has been shown that this cyclone design will allow for an approximate 56% efficiency with 1-micron particles and a >80% efficiency for all particles above 2 microns

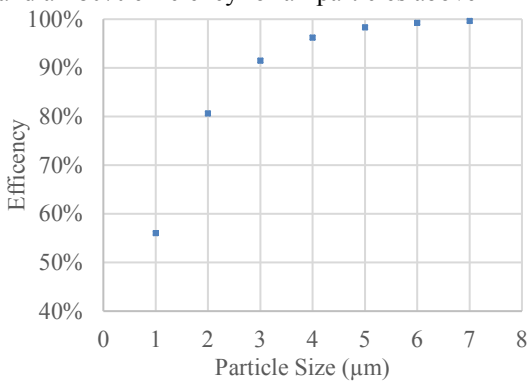

Figure 10. Cyclone efficiency

These numbers derive from the equation :

$$\eta = 1 - \exp\left(-\left(\frac{4d}{3r_{0r}C_D}\right).\left(\frac{\rho_P}{\rho}\right)^{0.5}.\frac{L_{VS}}{a_{0r}}\right) \quad (1)$$

Where:

η	Efficiency
a_{0r}	Average flow width/m
C_D	Drag Coefficient
D	Particle diameter, m
L_{VS}	Vortex Height in Streamwise direction, m
r_{0r}	average radius of particle trajectories, m
ρ	Density of Fluid, kg/m^3
ρ_p	Density of Particle, kg/m^3

This cyclone also allows for the flow entering the cyclone to be at a Reynolds value of approximately 1400. As the flow within the cyclone is expected to decrease in Reynolds value, it can be assumed this is our

"critical value" and therefore the flow can be considered as laminar.

After the flow has been treated in the cyclone, the air will then pass 2 filters to catch any remaining particles above 0.1 microns (Note: 0.1 microns has been determined as the critical value where there are unlikely to be significant effects due to pathogens). The first of these filters will be in to catch all particles >1 micron with the second catching particles of >0.1 microns. These filters will then be removed and replaced after every surgery, providing the surgeon with a system that is unlikely to clog and become inefficient due to the amount of buildup on the filters. All the particles that are treated in this cyclone will then be deposited into a detachable base which can be transferred.

Conclusions and Recommendations

This paper has presented three hazard categories that are generated by existing laser handpiece designs.

- Laser beam position and repeatability;
- Optical radiation hazards;
- Fume and bio-aerosol hazards.

The existing control measures for reducing the risk of each of these hazards has been found to be unsatisfactory as they are reliant on PPE and human controls. The redesigned handpiece presented in this paper addresses each of these issues and provides engineering solutions to each to ensure that an appropriate hierarchy of control measures are integrated.

- Current devices also do not allow for accurate placement of the handpiece in relation to the skin, both from a distance and location perspective. The integration of a "drumskin" approach, along with the addition of an endoscope in the next gen. design will help solve this, encouraging more accurate surgery. This will also provide a video record of any procedures conducted for auditing.
- Another key area for concern when looking at these surgeries in the potential for the laser the cause harm to the patient or the operator. It is clear that the current devices do not meet the requirements typically used in an industrial setting with the surgeon and the patient required to wear significant PPE in order to make the surgery safe, both an inconvenience and a significant cost. The redesigned device allows for optical radiation to be enclosed within the chamber. If a fail-to-safe measure is added to the handpiece, this will allow for the laser to be operated without any significant specialist PPE.
- When looking at the biohazard potential of the current set up, it becomes clear that current measures are simply not adequate for the potentially hazardous nature of the surgery, risking sickness and long-term health implications to surgeons. The redesigned handpiece negates this by keeping all bioactive material within the chamber, preventing from it being in human contact with practical evidence proving this is a viable solution. This material is then cleared from the chamber and then separated from the flow using a cyclone. This allows for pathologists to look into any material removed in the surgery. The flow is then passed through 2 additional filters in order to make it safe.

To conclude, it is clear to see that the current flaws in the way that this surgery is conducted do not have impossible solutions. The proposed redesign can provide the next generation of handpiece, in collaboration with a fume treatment system allows for this surgery to take place without the potential problems that are exhibited in current procedures.

References

[1] *The Supply of Machinery (Safety) Regulations 2008*. SI 2008/1597.

[2] *The Provision and Use of Work Equipment Regulations 1998*. SI 1998/2306.

[3] E. Alp, D. Bijl, R. P. Bleichrodt, B. Hansson, and A. Voss, "Surgical smoke and infection control," *J. Hosp. Infect.*, vol. 62, no. 1, pp. 1–5, Jan. 2006.

[4] M. Rioux, A. Garland, D. Webster, and E. Reardon, "HPV positive tonsillar cancer in two laser surgeons: case reports," *J. Otolaryngol. - Head Neck Surg.*, vol. 42, no. 1, p. 54, 2013.

[5] NIOSH, "Control of Smoke From Laser/Electric Surgical Procedures," 2014.

[6] B. E. Edwards and R. E. Reiman, "Results of a Survey on Current Surgical Smoke Control Practices," *AORN J.*, vol. 87, no. 4, pp. 739–749, Apr. 2008.

[7] J. Gawn, M. Clayton, C. Makison, B. Crook, and H. Hill, "Evaluating the protection afforded by surgical masks against influenza bioaerosols," 2008.

[8] J. Tyrer, "It is possible to make hand delivered medical / cosmetic laser equipment inherently safe," *Int. Laser Saf. Conf.*, pp. 198–204, 2013.

[9] A. Avci and I. Karagoz, "Effects of flow and geometrical parameters on the collection efficiency in cyclone separators," *J. Aerosol Sci.*, vol. 34, no. 7, pp. 937–955, Jul. 2003.