Cost-reduced engineering of functional biomedical products in Kenya: a case study on electrocautery pens

Conference Paper · December 2021

DOI: 10.1109/IHTC53077.2021.9698920

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Cost-reduced engineering of functional biomedical products in Kenya: a case study on electrocautery pens

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***Abstract*—This paper provides details on a case study conducted into the low-cost production of electrocautery pens in Kenya. Kenya's healthcare system is burdened by unaffordable biomedical products, tools and devices. As as consequence, preventable diseases and mortality strain the country. Kenya not only has a poorly equipped health care system, but the country is unable to maintain the imported equipment it has as a result of skills shortages in biomedical engineering in the country. The objective of this paper is to determine the feasibility for manufacturing cheaper biomedical engineering devices in Kenya, with a focus on electrocautery pens. Our method is based on an electro-mechanical design, materials selection, manufacture and testing. While our work is still in-progress, this paper elucidates the feasibility for manufacturing electrocautery devices at low-cost, while acknowledging the challenges in sourcing raw materials within the country.**

***Index Terms*—Biomedical Engineering, Electrocautery Pen, Cautery, Hackerspace, Electro-Mechanical Design, Materials Selection**

I. INTRODUCTION

Targets 3.1-3.6 of the UN Sustainable Development Goal 3, "Good Health and Well Being", are focused on reducing the rate of mortality whilst improving the effectiveness of treatments for both communicable and non-communicable diseases, while Targets 3.c and 3.d of Goal 3 focus on strengthening the healthcare capacity and on the development of the healthcare workforce in low and low-to-medium income countries (LMICs). Kenya has a disease-burden [1] and is neither able to meet its demand for biomedical equipment [2], nor is it able to maintain existing equipment due to skills shortages in biomedical engineering [3]. Major suppliers of medical equipment to Kenya include China, Germany, India, the USA and the Netherlands. Kenya invests ca. 230 million GBP each year in importing equipment from these countries. Biomedical equipment in Kenya is 100% imported (with the exception of Non-Pharmaceuticals (gloves, syringes, needles) products, which are 80% imported). This constitutes a significant economic weight on Kenyan society, and is a preventable deficiency within the healthcare system.

According to the World Health Organisation, between 50% and 80% of all Kenyan medical equipment remains non-functional [4], the most commonly cited reason for this being a skills shortage for the engineering and maintenance of medical equipment. Creating a framework to address these skills shortages is therefore of importance if positive, affordable healthcare is to be made available to a larger percentage of Kenyan society. A framework of this form would include the development of knowledge and skills in the design and manufacture of biomedical products, tools and devices within Kenya, which would reduce Kenya's dependence on costly international imports while conjointly enabling a new stream of income as Kenyans produce and export their own biomedical tools.

This paper details the design considerations, manufacturing and testing of a low-cost re-usable electrocautery pen. We hypothesised that the construction of cautery pens would not require any specialist equipment that would prevent them from being produced in Kenya, and that a simple design could be created to allow fabrication with minimal skill required at a far lower cost than importing devices to fulfil the same purposes. Our aim is to show the feasibility of designing and manufacturing biomedical engineering products in Kenya.

II. ELECTROCAUTERY DEVICES

Heated surgical tools have a number of benefits depending on the place of application and the temperature at which the

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heated tool is used. Electrocautery uses DC current to generate heat through a conductive wire, which is then used to apply localised heating to a relevant area of surgical importance. Electrocautery devices can be used on a broad range of tissues (skin, eye, internal-dermal, blood vessels, tumors), and the operating temperature at which an electrocautery device is used will depend on the type of operation undertaken, and the level of permissible damage that can be sustained by a specific tissue. An electrocautery device can be used to coagulate, dry (dessicate) or cut through tissue, and may utilise a variety of tips to enable the different types of operations including scalpel tips, pin-ends. Coagulation for example, is a procedure that destroys tissue locally and is used to seal e.g. blood vessels, wound openings, and lesions. Since it effectively destroys tissue, coagulation is also used to treat skin cancers, tumors, and pyogenic granuloma. Tissues disintegrate at temperatures of 60°C [5] and above, and as such, coagulation surgery in sensitive areas that can be badly damaged under high temperatures (e.g. the eye, cartilaginous tissue, or areas close to nerve endings) can be conducted at low temperatures. Tonsillectomy for example, is a process ordinarily conducted by cold-blade, after which electrocautery is used to decrease intra-operative bleeding [6]. However, postoperative pain and other complications are reported to occur as a result of the high temperatures used (400-600°C) and thus lower temperature tools have been developed, such as the Harmonic Scalpel and the PlasmaBlade. These work at lower temperatures than common electrocautery operating temperatures but still enable coagulation from temperaturs of 60°C as they can operate at temperature ranges between 40-70°C and 40-100°C, respectively [7].

III. MATERIALS AND METHODS

A. Initial Calculations

All electrocautery pen models share a similar design: batteries, a switching system, electrically conductive but thermally insulating rods used to prevent thermal conduction to batteries and a resistance wire tip to generate the high temperatures required to cauterise. Considering only the electronic/thermally active internals, this can be reduced to a simple circuit, Fig. 1.

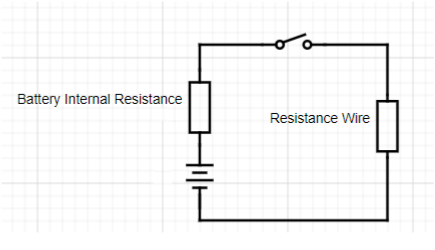

Fig. 1. Simple circuit diagram for most cautery pen models.

The thermal behaviour of the pen tips was first modelled via a time-stepped system. An initial resistance wire (Kanthal A) was selected, and its properties were recorded as follows: specific heat capacity 740 J/(kg · K), diameter 0.0008 m, length 0.06 m, density 7.15 g/cc, resistivity 1.45 $\mu\Omega$/m, emmisivity 0.88 (dimensionless), and thermal conductivity 29 W/(mK). Additionally, two double A batteries (assumed to have negligible internal resistance at this point) were used as a voltage source, for a total supply of 3V. Input variables for wire geometry were also included in order to allow for variation of tip wire gauge/length for easy iteration.

The relationship $P = I^2Rt$ was used to find the thermal power generated in the resistance wire tip. This incoming power was balanced by the heat transfer out of the tip via convection and radiation to find a rough estimate of the expected tip temperatures. While this simplification ignored conduction, it was sufficient to be used to verify the usefulness of the time-stepping method and to inform further design choices. Here, R is the resistance of the wire tip (Ohms), I is the current in the wire tip (Amps), t the time step length (seconds) and P is the thermal power/the radiative heat transfer (Watts), Eq. 1 [8], where ϵ is emissivity, σ is the Stefan-Boltzmann constant $\frac{W}{m^2K}$, A is the surface area (m^2) and T is the temperature difference from the ambient temperature (K). Convection coefficients were calculated for the resistance wire, the brass section and the batteries using Nusselt correlations.

$$P = \epsilon\sigma AT^4 \tag{1}$$

Given the high temperatures of the tip, a brass section was added between the tip and the battery contact point in order to protect the batteries and pen body from heat conduction. Similar sections were observed in many market leading devices, such as the Bovie pen [9], with the goal of preventing batteries overheating or pen chassis melting. This adjusted system required an updated model, including conduction between the resistance wire and the chosen brass section. Using the updated model, the average temperature of a brass section of specified geometry was calculated at each time-step. However, the increasing complexity of the system required a different approach to avoid over-complication.

B. CAD Modelling and Thermal Transfer Simulations

A design for the electrocautery pen was developed using Solid Edge 2021 (Siemens Digital Industries Software). A model of the design is shown in Fig. 2. Subsequent heat transfer simulations were conducted using the finite element method. $P = I^2Rt$ was used to calculate the thermal power generation terms, and after selecting the appropriate materials from the software database the transient thermal behaviour was simulated. Transient thermal simulations were performed over a 20 second period, allowing the system to reach steady state. The device was modelled as only a single battery, the brass section and the resistance wire tip. The battery was modelled as a solid steel element for simplicity.

This model was then used, along with the thermal energy generation and convection terms found in the initial calculations, to perform thermal analyses. At this point in the design, the power generated by the battery internal resistance was

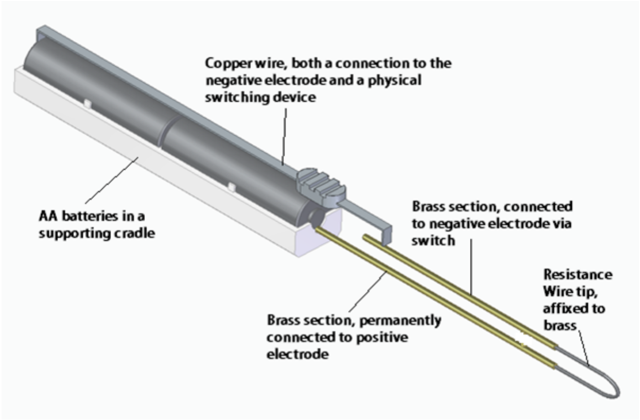

Fig. 2. 3D CAD model of the electrocautery device design.

included in the design process, with thermal power generated according to $P = I^2Rt$. These analyses were used to inform further iterations related to the length of the brass section required to sufficiently insulate the batteries from the heated tip.

C. Prototype Manufacture

Two prototypes were manufactured, one in the UK and one in Kenya. The UK prototype consisted of Kanthal A material wires of varying diameters, subjected to voltages provided by AA batteries connected via crocodile clips to the Kanthal wire. This prototype was used to verify the predicted relationship between wire geometry and temperature reached. The required components included: resistance wire 20GA, AA Batteries, 15cm copper wire, brass rods diameter 1.5mm and length 10cm and PVC piping as housing. Of these, brass rods could not be sourced, even after travel to several cities. These rods aimed to create distance between the hot wire tip and the thermally sensitive batteries/housing material. The Kenyan prototype was a variant of the UK prototype and this was due to the difficulty in sourcing brass for the build. Most sectors specifically manufacturing sector were hit by the COVID 19 pandemic, most of the local industries import their raw materials hence a shortage during the fabrication period. Availability of brass is limited to big cities where its widely used in the manufacturing or due to market proximity. As such, copper wiring was used as a heating element in the Kenya prototype without brass spacers. Using the materials that were available in each country, a basic set-up was manufactured in accordance with Fig. 1.

IV. RESULTS

From the analyses carried out, the construction of cautery pens in Kenya was deemed feasible. The basic model developed as a part of this study as a guide to both UK and Kenyan device manufacture, was found to operate at a steady-state temperature of around 695°C (660°C from initial calculations, 750°C from FEA thermal simulations, Fig. 3). This steady-state temperature was reached within 10 seconds of device being turned on, and maintained performance indefinitely without any foreseeable issues regarding battery or device overheating issues, Figs. 4 and 5.

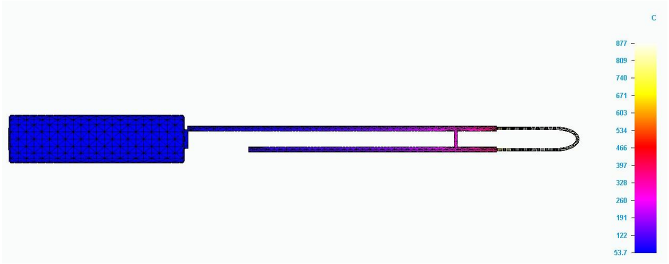

Fig. 3. Simulated temperature distribution of the designed electrocautery pen.

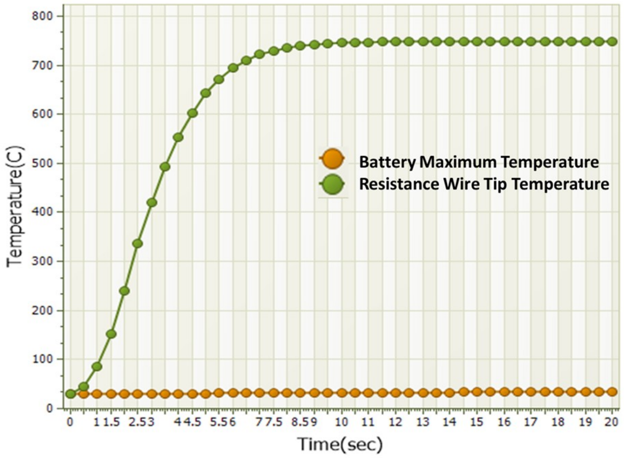

Fig. 4. Simulated behaviour of temperature against time.

Via simple modelling decisions, the device was made to be easily fabricated and assembled; this simplified construction means that little to no expertise is required to construct/maintain the pen, meaning minimal training would be required to maintain working equipment.

Interestingly, the two prototypes manufactured in the UK and in Kenya showed variable levels of heat output. While the filament of the UK version was visually noted to glow red-hot, therefore reaching at least the Draper Point of 525°C, the Kenya version did not reach the Draper Point (as it was not seen to glow) but was still noticeably scalding to the touch. The costs were estimated at ca. £3.30 by pricing readily available components found for sale in Kenya, and do not consider possible bulk discounts. The cost of the UK device was estimated at around £4.75. These costs do not take into consideration costs associated with materials, production, regulatory approval, marketing, and distribution, and as such are not comparable against imported mains powered cautery devices, currently costing £525 for each device (excluding shipping).

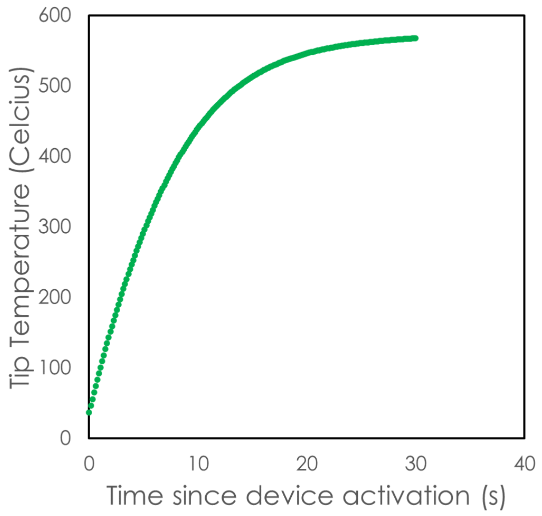

Fig. 5. Calculated behaviour of temperature against time

V. DISCUSSION

The most important properties are the thermal conductivity of the brass used, the internal resistance of the batteries, and the properties of the resistance wire. The brass could not be sourced in Kenya and thus only the copper resistance wire was used to form the circuit. The properties of metals are not standardised across all storefronts in Kenya and therefore, care has to be taken to minimise the impact of metals on the operation of the device. The brass cross-sectional area used in the UK device is of little importance due to negligible electrical resistivity, but its length determines the thermal power transferred from the heated tip into the batteries.

The internal resistance of batteries will control the thermal power generation within the battery itself. This obeys relationship in $P = I^2Rt$, with the resistance being the internal resistance and the current being the circuit current. For a given circuit current (mainly determined by the resistance wire, the larger source of resistance), batteries of differing internal resistance will generate different thermal power. To prevent damage to the battery due to excessive temperatures, the internal resistance should be as low as possible, or the circuit current should be adjusted to a lower value.

Finally, the behaviour of the model was extremely sensitive to changes in the properties of the resistance wire. Power generated in the resistance wire depended on relationship in $P = I^2Rt$, and both the circuit current and the resistance of the resistance wire were controlled by multiple variables. The circuit current was given by the basic relationship $I = V/R$, where I is the current in the wire tip (Amps), V is the supply voltage (Volts), and R is the resistance of wire tip (Ohms). Assuming that total resistance R is the sum of battery internal resistance and resistance wire resistance, this relationship can be expressed as $I = \frac{V}{(R1+R2)}$. Therefore, assuming the constant voltage source also implies a constant battery internal resistance (*R1*), the resistance wire resistance becomes the single variable in control of varying the circuit current. This resistance wire resistance is controlled by the resistivity of the chosen wire type, the length of resistance wire used, L, and the cross-sectional area of the chosen wire, Eq. 2 and 3.

$$R2 = \frac{\rho L}{A} \tag{2}$$

$$P \propto \frac{1}{\left(R1 + \frac{\rho L}{A})^2\right)} \frac{\rho L}{A} t \tag{3}$$

Simplifying this expression, the power generated in the resistance wire tip is shown in Eq. 4.

$$P = \frac{(AL\rho t V^2)}{(AR1 + L\rho)^2} \tag{4}$$

Both the calculated and simulated results show similar behaviours regarding the steady state tip temperatures, however, the built versions in both the UK and Kenya yielded very different temperature outputs. While both the Kenyan and UK builds would still work for different electrocautery operations, there are clearly problems associated with the materials sourced from different countries (at least partially also a consequence Covid 19 pandemic), as understood from the different temperature outputs of each. Possible reasons for why the temperatures were vastly different may include differences in material properties and composition (purity of the metals used), accuracy of measures for the filament materials, and quality and reliability/reproducibility of off-the-shelf batteries. While these are all areas that require further investigation and this is still a work in progress, we have shown that there is feasibility in pursuing pathways to enable greater biomedical engineering development in Kenya.

ACKNOWLEDGMENT

The authors wish to thank the Scottish Funding Council for supporting this work.

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