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Research Article

A Potential Solution to Minimally Invasive Device for Oral Surgery: Evaluation of Surgical Outcomes in Rat

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The objective of the present research was to investigate the thermal injury in the brain after minimally invasive electrosurgery using instruments with copper-doped diamond-like carbon (DLC-Cu) surface coating. The surface morphologies of DLC-Cu thin films were characterized using scanning electron microscopy and atomic force microscopy. Three-dimensional brain models were reconstructed using magnetic resonance imaging to simulate the electrosurgical operation. In adult rats, a monopolar electrosurgical instrument coated with the DLC-Cu thin film was used to generate lesions in the brain. Animals were sacrificed for evaluations on postoperative days 0, 2, 7, and 28. Data indicated that the temperature decreased significantly when minimally invasive electrosurgical instruments with nanostructure DLC-Cu thin films were used and continued to decrease with increasing film thickness. On the other hand, the DLC-Cu-treated device created a relatively small thermal injury area and lateral thermal effect in the brain tissues. These results indicated that the DLC-Cu thin film minimized excessive thermal injury and uniformly distributed the temperature in the brain. Taken together, our study results suggest that the DLC-Cu film on copper electrode substrates is an effective means for improving the performance of electrosurgical instruments.

1. Introduction

In recent years, there has been considerable concern over the application of electrosurgical instruments in dental surgery. Thermal damage to tissues surrounding the surgical sites is a critical challenge in clinical operations [1–3]. Various methods have been reported to reduce thermal damage caused by electrosurgical instruments, although other evidences indicate that minimally invasive electrosurgery can cause serious injuries to surrounding organs/tissues such as the blood vessels and nerves [4]. The interface between the minimally invasive electrosurgical needle and the tissue is an important factor for reducing thermal injury, but related experimental and mathematical studies are scarce. To investigate the thermal damage caused by minimally invasive electrosurgical instruments, the maximum temperatures and dimensions of the surgical region must be determined.

Finite element method (FEM) is a useful tool for examining the temperature distributions in the tissues surrounding the surgery site including brain tissue [5, 6], and it has been previously used to study biomechanical operations in different medical fields using various boundary parameters [7–10]. In addition, the three-dimensional (3D) FEM has been widely used for the thermal analysis of minimally invasive electrosurgical instruments [11], to investigate the thermal damage to tissues during clinical surgery. Therefore, this method was adopted to investigate and compare the thermal diffusion and tissue injury by novel copper-doped diamond-like carbon (DLC-Cu) coated electrosurgical instruments.

The aim of the present study was to investigate the thermal damage using finite element analysis (FEA) in a rat model of thermal injury. The surface of the electrosurgical instruments was coated with diamond-like carbon using nanostructure surface treatment (DLC-Cu). It was anticipated to reduce the thermal damage in the surrounding tissues during surgery. The nanostructured DLC-Cu surface treatment was applied to the electrosurgical instruments provided by BioEconeer Inc. because the DLC-Cu thin films provide superior physical properties, such as high thermal conductivity, low coefficient of friction, improved hardness, chemical inertness, antichemical corrosion, high impedance, and antibacterial properties [12]. Our animal model was developed to evaluate the decrease in thermal injury from the minimally invasive electrosurgical instruments coated with DLC-Cu film and further accelerate the wound healing process.

2. Materials and Methods

Scanning electron microscopy (SEM; JEOL JSM-6500F, JEOL Ltd., Tokyo, Japan) and atomic force microscopy (AFM; Nanosurf-Mobile S, Nanosurf AG., Liestal, Switzerland) were employed to analyze the surface morphology and thickness of the DLC-Cu deposited instruments. The 3D finite element brain models were rebuilt using magnetic resonance images (MRI, Signa HDx 3.0T, USA). A number of images were obtained to describe the contour of the brain at different parallel surfaces. An edge detection program (AVIZO 7.2, Internet Securities, Inc.) was used to detect all the boundary components of the brain. The thermal properties of the brain tissue, DLC-Cu thin film, and AISI 304 stainless steel (the material used in making the electrosurgical instruments) have been described previously [13–16]. The thicknesses of the DLC-Cu thin films were 0 (SS), 100 (DLC-Cu-SS-1), 200 (DLC-Cu-SS-2), 300 (DLC-Cu-SS-3), 400 (DLC-Cu-SS-4), and 500 (DLC-Cu-SS-5) nanometers. The 3D reconstruction models were simulated using the ANSYS Workbench 12.1 (ANSYS, Inc., Canonsburg, PA, USA) program. The average number of nodes and number of elements in the brain models were approximately 77,000 and 42,000, respectively.

The protocols for the present animal models were approved by the Institutional Animal Care and Use Committee of Taipei Medical University (LAC-101-0007). Twelve Sprague-Dawley (SD) rats (200–300 g, BioLASCO, Taiwan) were maintained according to the guidelines for the care and use of laboratory animals. Three rats each were sacrificed on day 0, day 2, day 7, and day 28. Electrosurgical instruments with 500 nm (DLC-Cu-SS-5) DLC-Cu thin film were compared with uncoated stainless steel instruments (SS).

DLC-Cu-SS and SS minimally invasive electrosurgical instruments were powered using an electrosurgical unit (ICC300H, EBRE, USA). The surgical operation was performed under general anesthesia, which was induced by isoflurane inhalation. After adequate skin preparation and sterilization, the brain was exposed through midline laparotomy to avoid surgical injury to the brain. An electrosurgical instrument was inserted into the brain (depth, 3 mm) to create a lesion, using a fixed power setting (40 W) within a fixed surgical time (5 s). The power setting and time were common parameters used in the previous study [17].

Data were expressed as mean ± standard error of the mean. Data were analyzed using the analysis of variance (ANOVA). All statistical analyses were performed using SPSS version 12.0 (SPSS, Inc., Chicago, IL, USA). Values of $p < 0.05$ were considered significant.

3. Results

The samples were observed by SEM and AFM to evaluate the effect of the microstructural variation of the DLC-Cu thin film on the electrosurgical instruments. Figure 1(a) shows a cross section of the nanofilm at a thickness of approximately 500 nm. It was found that a homogenous and smooth film of tiny nano-Cu particles was deposited on the surface of the substrate as depicted in Figures 1(b)–1(d).

Figure 2 shows the temperature distributions for the minimally invasive electrosurgical instruments with and without DLC-Cu thin film. In the control group, the temperature of the brain tissue that was in direct contact with the instrument was > 130°C, while the maximum temperature in the DLC-Cu-SS-5 group was 118.38°C. In addition, the lateral extent of the thermal injury decreased with increasing distance from the instrument in all groups. Figure 3 shows the relationship between the maximum temperature of the brain and the surgical time with varying nanofilm thicknesses on the devices. The maximum temperature of the control group was 130.88°C, and it decreased by 9.55% in the DLC-Cu-SS-5 group.

The thermal temperature with the SS instrument was higher than that of the DLC-Cu-SS instrument as shown in Figure 4. The average temperature of the tissue in the SS groups was 124.9°C and that in the DLC-Cu-SS group was 102.7°C as shown in Figure 4. Histological test of specimens operated with the SS and DLC-Cu-SS electrosurgical instruments showed varying amounts of coagulation and bleeding, indicating varying amounts of heat injury in the brain tissues as shown in Figure 5. When DLC-Cu-SS electrosurgical instrument was used, no obvious bleeding or thermal damage was detected postoperatively in the treated sites. In contrast, thermal damage caused by SS electrosurgical instrument was evident. Hemorrhaging in the SS group was significantly higher than that in the DLC-Cu-SS group, and infections were observed at the operated area after 2 days. The extent of tissue injury caused by the SS electrosurgical instruments was larger than that of the DLC-Cu-SS instruments. The thermal injury areas were reduced in both groups after 7 days, although almost complete recovery after 28 days was seen only in the DLC-Cu-SS group. The area of predominant injury was significantly different for the SS and DLC-Cu-SS minimally invasive electrosurgical instruments. In addition, most apoptotic areas recovered after 28 days in the DLC-Cu-SS group, while the SS group still displayed many apoptotic tissues (see Figure 6).

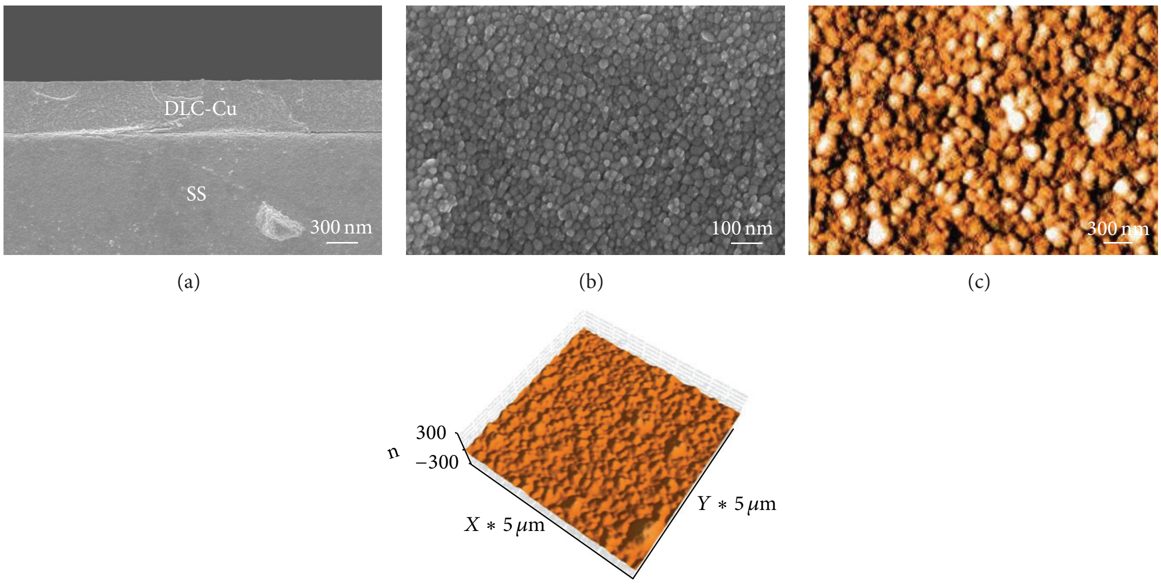

FIGURE 1: (a) SEM cross section, (b) SEM top view, (c) AFM top view, and (d) AFM 3D images of the DLC-Cu thin film.

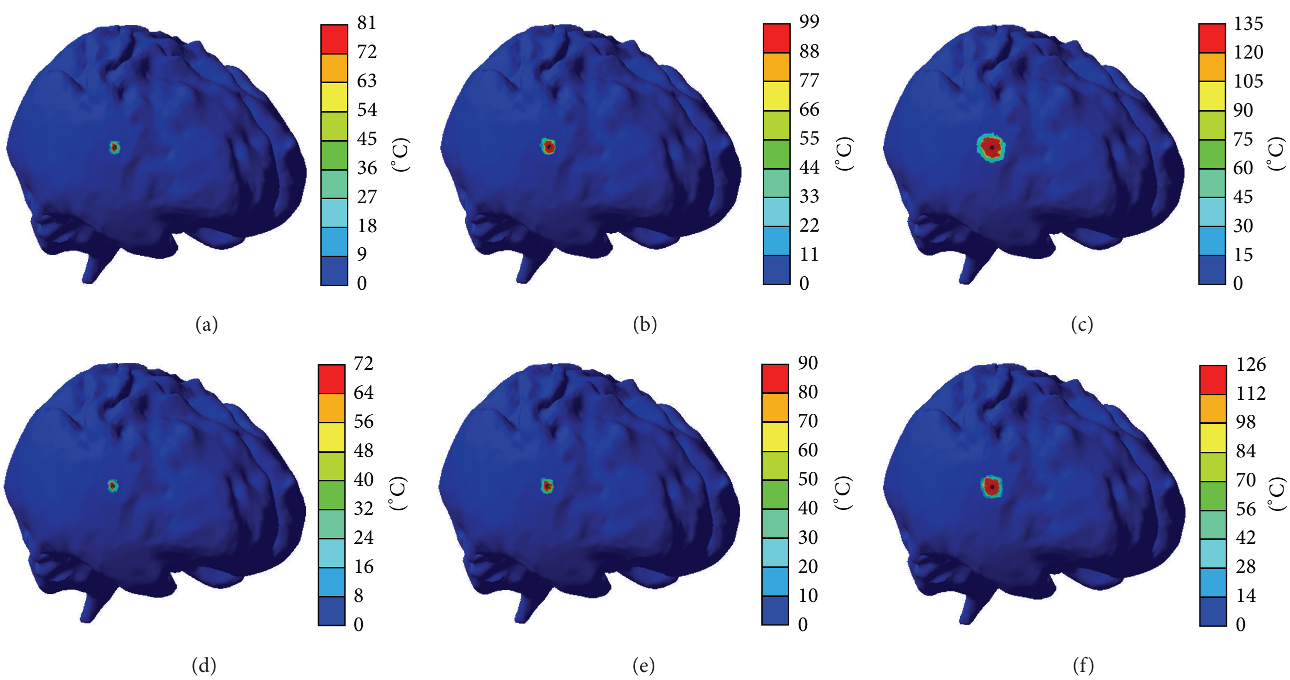

FIGURE 2: Temperature distributions of the brain in the control group at (a) 1, (b) 3, and (c) 5 seconds and in the DLC-Cu-SS-5 group at (d) 1, (e) 3, and (f) 5 seconds.

4. Discussion

DLC-Cu thin films with high thermal conductivity can distribute thermal energy to the surrounding tissues to prevent concentrated thermal injury under FEA simulation [18, 19]. Furthermore, the lateral thermal diffusion is superior to standard electrosurgery and can decrease the localized heat on the surface of the instruments. Many related studies on thermal modification and damage were evaluated with histological sections in animal models and clinical trials. Different thermal injury patterns with tissue coagulation were displayed depending on the electrosurgical instruments used. The modified bipolar forceps allowed the possibility of achieving different degrees of coagulation on the same tissue under the same power due to the properties of the coated film [20].

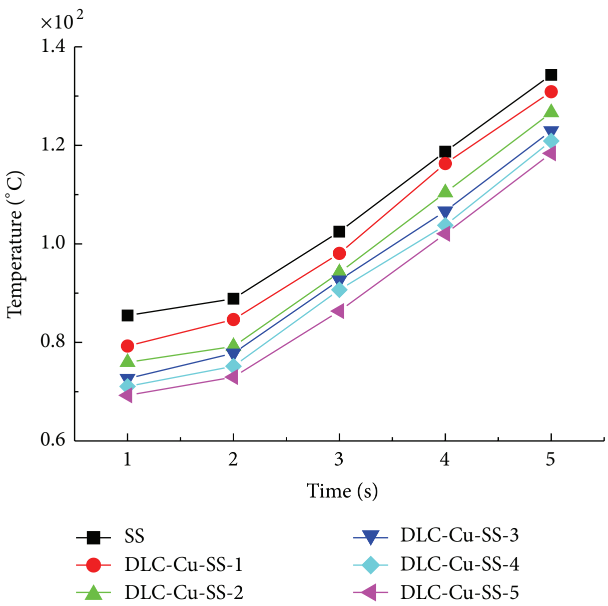

Figure 3: Highest temperatures in different thicknesses of DLC-Cu film groups in brains during 5 seconds.

Increasing attention has recently been given to the industrial applications of DLC-Cu thin films. DLC thin films have been used widely on the surfaces of a number of tools to extend their shelf-life [21]. Before the DLC-treated devices are used for clinical surgery, all processes of manufacturing, packaging, and sterilization need Food and Drug Administration (FDA) 510(k) clearance. Medical device manufacturers design and develop efficient, safe, and reliable medical tools that can affect the lives of many patients. Therefore, these products must pass through stringent tests to ensure safety and functioning of the devices.

Surface treatment can reduce the thermal concentration and incidence of injury due to overheating. The power supply of a bipolar electrosurgical instrument with a surface treatment was controlled during SD rat experiments in 1999 [22]. However, no significant adherence problem was observed, where it could be under low output to achieve the coagulation. Another method used the addition of a small metal tube to bipolar electrosurgical forceps in 1972, which allowed the surgeon to apply double-distilled water during the surgery, which finally resolved the adherence problem. In 1988, 50 μm Teflon was also introduced as a surface treatment for electrosurgical instruments. These two surface coating methods were effective in decreasing the clinical thermal effect of electrosurgical instruments. Therefore, this technology might increase the contact area between the electrosurgical device and the tissue, thereby reducing the quantity of the adhesion and the severity of the thermal wounds.

When the tissue temperature rises over 60°C, the water inside the cell is expelled and desiccation begins; this process continues until the temperature is over 100°C. During clinical surgery, the instant temperature produced by electrosurgical instrument could rise above 200°C, which can result in thermal damage to healthy tissues. However, the specific heat of the DLC is 4.55 times larger compared with that of 304 stainless steel, and therefore, DLC can mitigate the effect of instant temperature increase on the tissue. Moreover, DLC has low electrical resistivity [23], which also generates a lower thermal effect in the brain. Therefore, surface treatment of electrosurgical instruments with DLC is expected to result in significantly less tissue injury.

Electrosurgery can be applied in many surgical fields, but its application is limited in neurosurgery. Therefore, the use of the ultrasonically activated scalpel (US) was suggested in place of electrosurgical instruments in 2005. The temperature of a US instruments is required to be lower than 150°C, compared to the temperature of >200°C for electrosurgical instruments. Moreover, electrosurgical instruments produce greater lateral thermal spread and damage. Morphological tests have revealed significantly less thermal injury around nerves using the US device. Compared to electrosurgical instruments, the US technique may be safer for clinical dissection around important nerves.

FEM has been applied in brain research for a long time and has been successfully used in a number of human diseases [24]. However, most FEA reports have analyzed the biomechanical and thermal behaviors of the different materials and have set many assumptions and simplifications [25]. To achieve the correct geometries in our experimental model, we selected a precise resolution of MRI for remodeling. Although MRI data does not describe the contours of the hard tissues accurately (e.g., mandibles or spine), it can be used to obtain information regarding the brain contours without exposing the patients to dangerous radiation. However, as the present study focused on the soft tissues of the brain, MRI was an appropriate resource to use.

Given the differences in the material properties, meshes, electrical powers, and boundary conditions, it would be difficult to accurately compare the present results with those from previous studies. Moreover, various important factors affect the mechanical and thermal properties of experimental animals. Our study considered 3 materials (brain tissue, 304 stainless steel, and DLC), and the FEM could provide useful information to predict the temperature distributions and location of the highest temperature area in the brain and the electrosurgical instrument.

5. Conclusion

Surface treatment technology can promote thermal conduction and decrease the temperature in the tissues around the surgical site during the electrosurgical operation. Our result stated that DLC-Cu-SS minimally invasive electrosurgical instruments have the potential to cause a relatively small amount of thermal damage and lateral thermal effect in the brain. Previous study has found that the surface treatment films provide many benefits, such as decreasing adhesion and promoting homogeneous thermal diffusion successfully. Therefore, surface treatment with DLC-Cu for microsurgery applications is potentially useful for reducing thermal injury, thereby benefiting clinical brain electrosurgery procedures.

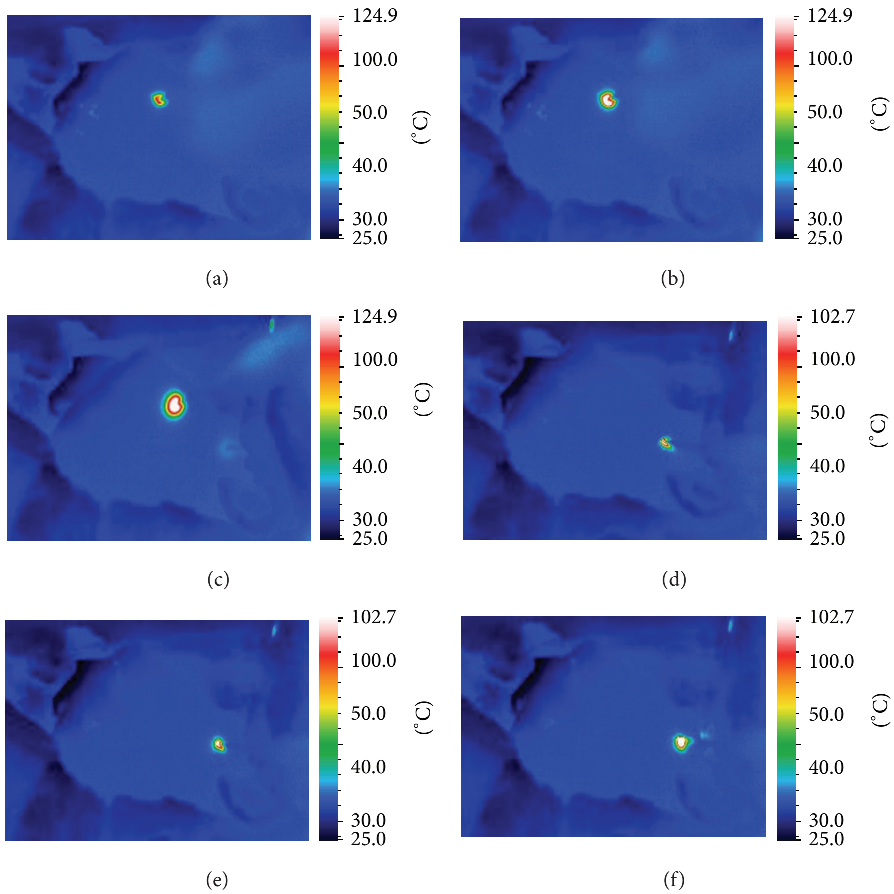

FIGURE 4: Highest recorded temperature in the control group at (a) 1, (b) 3, and (c) 5 seconds and in the DLC-Cu-SS group at (d) 1, (e) 3, and (f) 5 seconds.

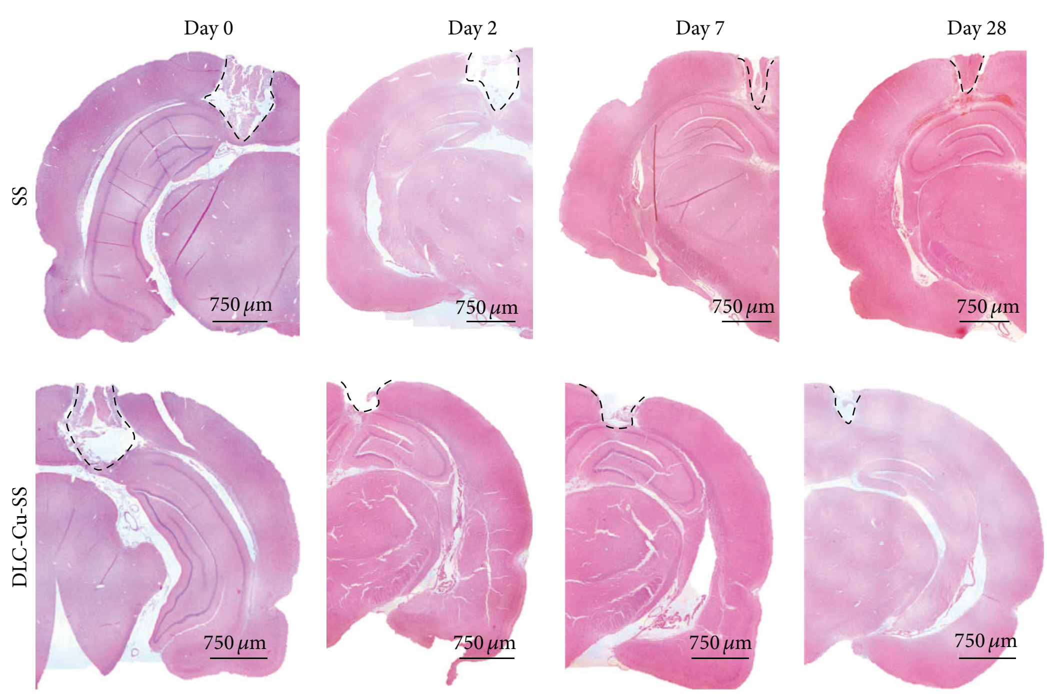

FIGURE 5: Total injury images in the DLC-Cu-SS and SS groups during 28 days.

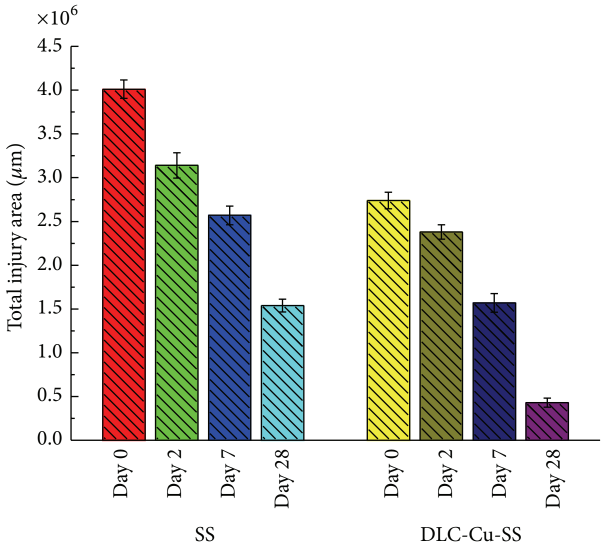

Figure 6: Total injury area statistical analysis between DLC-Cu-SS and SS groups during 28 days.

Disclosure

Li-Hsiang Lin is the co-first author.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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