In-hospital reprocessing of single-use medical devices is present in almost all developing countries of Africa, Asia, Eastern Europe, Central America, and South America. In these countries, shortages of medical supplies and financial resources. The reuse of medium and low-cost devices is also considered and reprocessing of single-use electrosurgical pencils (EP) is a widespread practice. Such high effectiveness is often associated with EP reprocessing, requiring specific methods for assessing the reprocessing protocol. Recently, we proposed a multi-techniques approach to assess surface characteristics of reprocessed single-use electrosurgical pencils and show potential good properties for tracking modifications during the device lifecycle. This study aimed at applying this multi-technique approach to monitor the surface characteristics of reprocessed single-use electrosurgical pencils subjected to multiple clinical use and in-hospital reprocessing.

**RESULTS**

The various ROIs of the reprocessed EP were differently affected from the clinical use and reprocessing. The silicon coating was significantly reduced at the tip surface already after the first reprocessing cycle and remnants of tissue flaps were found on a non negligible number of reprocessed EP. The amount of biological debris at the tip surface increased with the number of reprocessing cycles and was significantly higher in respect to controls after four and five reprocessing cycles. The quantity of debris on the handle surface and at the “cut” function button increased significantly after the first reprocessing, and remained high up to four reprocessing cycles. TGA analysis of the handle polymer showed a progressive alteration of the polymer thermal characteristics with a significant reduction of the degradation temperature. However, the polymer stability at high temperature was not significantly affected. Cable cord show no modification after reprocessing.

**MATERIALS and METHODS**

**Test and Control groups:** A total of 24 single-use-labeled EPs (HT-1, Huatong Medical Appliance Co., Ltd., Jinhua, China) were included in the study and divided in five test groups of four EPs each. Each group was subjected to a different number of clinical use (esthetic surgery interventions) and in-hospital reprocessing, ranging from 1 (single use and single reprocessing) to 5 (5 clinical use and 5 reprocessing cycles).

The following reprocessing protocol was applied:

- **2 min soaking in enzymatic solution at 30°C**
- **manual brushing of the tip with sand paper**
- **washing of the whole device in filtered water**
- **drying with compressed medical air**
- **package in thermostated sealed pouches**
- **sterilization by ethylene oxide (38°C, 0.069 Mpa for 120 min)**
- **degassing for 40 min in vacuum.**

**SIX regions of interest (ROIs) were defined:**

- #1 cutting surface of the tip
- #2 metal-junction of the tip
- #3 proximal portion of the handle
- #4 external surface of the handle
- #5 surface of the “cut” function button
- #6 proximal portion of the cable cord.

**FIGURE 1. Electrosurgical pencil assessed in the study.** In red are reported the regions of interest subjected to the multi-technique evaluation, reported below at higher magnification.

**Optical Stereomicroscopy (OM)**

OM was performed with a BH-2 microscope equipped with a DP2000 camera (Olympus, Japan). One high-resolution raw image at 10x magnification was collected per each ROI. The amount of brownish residuals on ROI #1 was quantified by evaluating 100 points of interest per each side. Images of ROIs #2–#5 were processed and blindly evaluated for the presence (yes/no) of blood/tissue residuals or other foreign bodies.

**Scanning Electron Microscopy (SEM)**

SEM sample investigation was conducted in a XL 30 ESEM FEG (FEI, Netherlands) environmental Scanning Electron Microscope in low-vacuum mode (0.3-0.9 torr) with no conductive coating. A set of 12 images per each EP at 100x and 500x magnification was collected for each ROI, focusing on the backscattered electron signal. Collected images were processed and blindly evaluated for the presence (yes/no) of microcracks and for the amount (scored semiquantitatively from 0 to 4) of surface debris, pits or scratches as detailed in Table 1.

**Energy Dispersive X-rays Spectroscopy (EDXS)**

EDXES was performed on the proximal side of the tip (ROI#1) to evaluate the surface composition of the following elements: C, O, Na, Al, Si, S, and G. The X-rays signal was collected with a Energy Dispersive X-ray Spectrometer (Phoenix, EDAX, USA) integrated into the SEM. Semi-quantitative elemental composition was obtained in low-vacuum mode by acquiring the X-rays spectrum from the surface.

**Differential scanning calorimetry (DSC)**

DSC was characterized thermophysical properties of the polymer (RHOD) and power cord insulating polymer (RBIOD) in the temperature range from -10°C to 90°C. The analysis was performed at a heating rate of 10°C/min in nitrogen atmosphere using a JADE- DSC (Perkin Elmer) apparatus. Tested samples (0.1mg) were obtained respectively from the handle and the insulating power cord for each EP by scraping the surface with a scalpel. Collected DSC thermograms were obtained for evaluating temperatures of endothermic transformation (Tm). The data analysis and statistics

**Thermo-gravimetric analysis (TGA)**

TGA analysis was appreciated of the thermal stability of the handle polymer (RHOD) and of the insulating power cord material (RBIOD) by measuring the amount and rate of weight loss at increasing temperature. TGA analysis was performed from room temperature (30°C) to 600°C at a heating rate of 10°C/min using a TGA 5000 (TA Instruments). Data were analyzed to determine the degradation temperature (Tg), the proportion of mass remaining vs. temperature curve. Moreover, the percent of weight loss at 600°C was also calculated.

<table>
<thead>
<tr>
<th>Difference between reprocessed and new devices (p&lt;0.05)</th>
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<tbody>
<tr>
<td>No difference between reprocessed and new devices (statistically not significant)</td>
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**FIGURE 2. Representative optical stereomicroscopic images of areas that showed differences in surface characteristics between new (left column) and reprocessed (right column) EPs: a,b) ROI#1 (metal-polymer-junction of the tip); e,f) ROI#3 (proximal portion of the handle) g,h) ROI#4 (external surface of the handle).**

**TABLE 1. Results summary**

**FIGURE 3. Representative SEM images of areas that showed statistically significant differences in surface characteristics between new (left column) and reprocessed (right column) EPs: a,b) ROI#1 (metal-polymer-junction of the tip); c,d) ROI#2 (metal-polymer-junction of the tip); e,f) ROI#3 (proximal portion of the handle); g,h) ROI#4 (external surface of the handle).**

**CONCLUSIONS**

EPs are complex devices that require a validated protocol to be safely and effectively reprocessed. The investigation of surface characteristic with OM, SEM, EDXES, DSC, and TGA techniques should be considered in assessing all device components to design the reprocessing protocol according to the device properties. This study evidenced that the EP tip can be significantly affected by clinical use and reprocessing. Moreover debris and scratches can accumulate on the handle surface. TGA analysis could be able to define the maximum number of represencing sustainable by the device. We recommend not to reprocess and reuse silicon coated EP tips and to check for the presence of debris and scratches after each EP use. We recommend to perform EDXES analysis on the EP handle with OM and SEM before validating the procedure.

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