Reprocessing of single-use electrosurgical pencils: modification of surface characteristics after different number of reuses

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INTRODUCTION and AIM

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, where there are 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 (EPs) is a widespread practice. Safety and efficacy issues are associated to EPs 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 [1] that showed good potentials for tracking modifications during the device lifecycle.

This study aimed at applying this multi-techniques approach to monitor the surface characteristics of single-use electrosurgical pencils subjected to multiple clinical use and in-hospital 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 uses (aesthetic 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 cleaning of external device surfaces with moistened gauze
- manual brushing of the tip with sand paper
- rinsing of the whole device in filtered water
- drying with compressed medical air
- packaging in thermo-sealed pouches
- sterilization by ethylene oxide (38°C, 0.089 Mpa for 120 min)
- degassing for 60 min in vacuum.

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

- #1 cutting surface of the tip
- #2 metal-polymer 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.

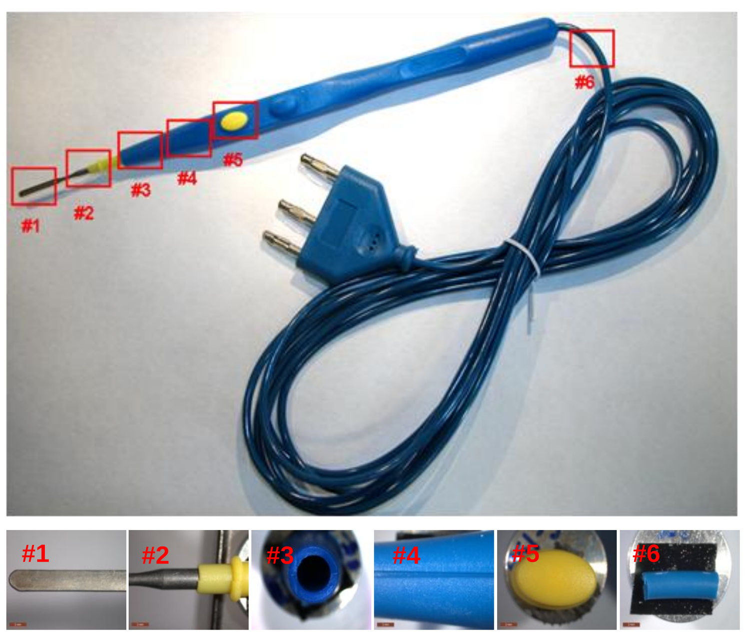

FIGURE 1. Electrosurgical pencil assessed in the study. *In red are indicated the 6 regions of interest subjected to the multi-technique evaluation*, reported below at higher magnification.

Optical Stereomicroscopy (OM)

OM was performed with a S8APO stereomicroscope equipped with a DFC420 CCD camera (Leica, Germany). One high resolution color 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-#6 were pooled 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, Nederland) environmental Scanning Electron Microscope in low-vacuum mode (0.9 torr water pressure) with no conductive coating. A set of 32 images per each EP at 100x and 500x magnification was obtained by collecting the backscattered electron signal. Collected images were pooled and blindly evaluated for the presence (yes/no) of microcracks and for the amount (scored semi-quantitatively from 0 to 4) of surface debris, pitting or scratches as detailed in Table 1.

Energy Dispersive X-rays Spectroscopy (EDXS)

EDXS was performed on the proximal side of the tip (ROI#1) in order to evaluate the surface composition of the following elements: C, O, Na, Al, Si, S, and Cl. 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 applied to characterize thermal properties of the polymeric handle (ROI#4) and power cord insulating polymer (ROI#6) in the temperature range from -20 to 150°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 (10±1 mg) were obtained respectively from the handle and the insulating power cord of each EP by scraping the surface with a scalpel. Collected DSC thermograms were analyzed for obtaining temperatures of endothermic transition peaks (Tmi).

Thermo-gravimetric analysis (TGA)

TGA analysis was applied to evaluate thermal stability of the handle polymer (ROI#4) and of the power cord insulating material (ROI#4) by measuring the amount and rate of weight loss at increasing temperature. TGA analysis was performed from room temperature (@24°C) up to 600°C in nitrogen atmosphere at a heating rate of 10°C/min using a TGA 500 (T.A Instruments). Data were analyzed to determine the degradation temperature (Td) as the maximum in the derivative of the weight vs. temperature curve. Moreover, the percent of weight loss at 600°C was also calculated.

Data analysis and statistics

Categorical variables were expressed as percentages. The results for normally distributed continuous variables were expressed as mean±standard deviation, and variables that did not have a normal distribution were presented as median and interquartile range (IQR). EP device was the statistical unit.

The median (or mean) values between groups were compared to elicit any trend (increase, decrease or no change) of the variables of interest. Significance of differences between study groups were tested with Student-t test or Mann-Whitney U test (according to data normality) and Fisher-exact test for dichotomous variables. Two-sided tests with a significance level of p<0.05 have been considered after *post hoc* correction for multiple comparison according to Holms method.

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 fibers 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 five 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.

Device component/ROI	Variable of interest	Investigational technique	Variation in respect to new and unused devices — Number of clinical uses and reprocessing cycles				
			1	2	3	4	5
Tip/ROI#1	Brownish residuals?	OM	yellow	yellow	yellow	yellow	yellow
	Foreign bodies?	OM	green	green	green	green	green
	Si (Wt%)	EDXS	red	red	red	red	red
	Biologic C (Wt%)	EDXS	yellow	yellow	yellow	red	red
	Na (Wt%)	EDXS	green	green	green	green	green
	S (Wt%)	EDXS	green	green	green	green	green
	Cl (Wt%)	EDXS	green	yellow	yellow	yellow	yellow
	Ca (Wt%)	EDXS	yellow	red	yellow	red	yellow
Tip/ROI#2	Brownish residuals?	OM	green	green	green	green	green
	Foreign bodies?	OM	yellow	yellow	green	yellow	yellow
	Debris at interface?	SEM	green	yellow	yellow	yellow	yellow
Handle/ROI#3	Brownish residuals?	OM	yellow	green	yellow	yellow	green
	Foreign bodies?	OM	green	green	green	green	green
	Microcracks?	SEM	green	green	green	green	green
	Debris?	SEM	red	red	red	red	yellow
Handle/ROI#4	Brownish residuals?	OM	green	green	yellow	yellow	green
	Foreign bodies?	OM	green	green	green	green	green
	Surface pitting?	SEM	green	green	green	green	green
	Surface scratches?	SEM	yellow	red	yellow	green	green
	Debris in the groove?	SEM	red	yellow	red	red	red
	T_{mI} (°C)	DSC	green	green	green	green	green
	T_{mII}(°C)	DSC	green	green	green	green	green
	T_d (°C)	TGA	red	red	red	red	red
	Weight loss at 600°C (%)	TGA	green	green	green	green	green
Handle/ROI#5	Brownish residuals?	OM	green	green	green	green	green
	Foreign bodies?	OM	green	green	green	green	green
	Surface scratches?	SEM	red	red	red	yellow	yellow
	Debris at the button base?	SEM	red	red	red	red	red
Cable cord/ROI#6	Brownish residuals?	OM	green	green	green	green	green
	Foreign bodies?	OM	green	green	green	green	green
	Debris on surface?	SEM	green	green	green	green	green
	Surface scratches?	SEM	green	green	green	green	green
	Conductor surface oxidation?	SEM	green	green	green	green	green

TABLE 1. Results summary

(green) No difference between reprocessed and new devices

(yellow) Variation between reprocessed and new devices (statistically not significant)

(red) Difference between reprocessed and new devices (p<0,05)

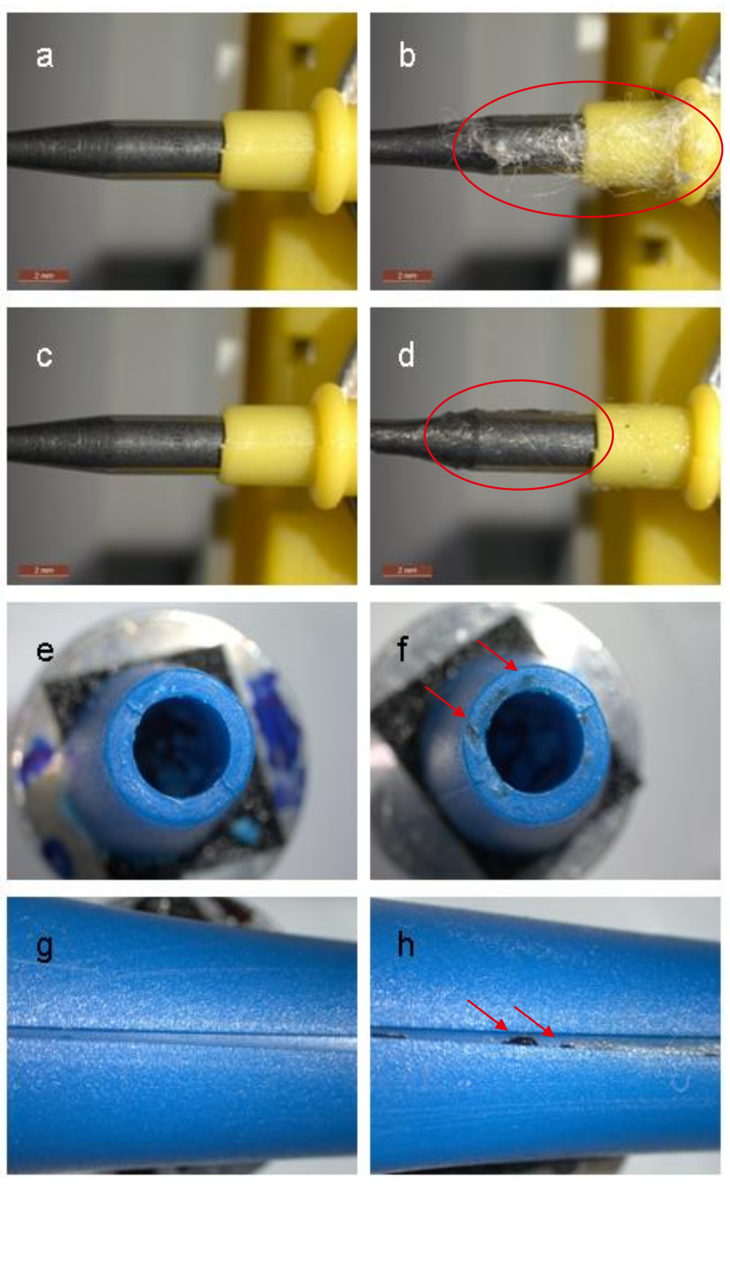

FIGURE 2. Representative optical stereomicroscopy images of areas that showed differences in surface characteristics between new (left column) and reprocessed (right column) EPs. *a-d): ROI#2 (metal-polymer junction of the tip); e,f): ROI#3 (proximal portion of the handle); g,h): ROI#4 (external surface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

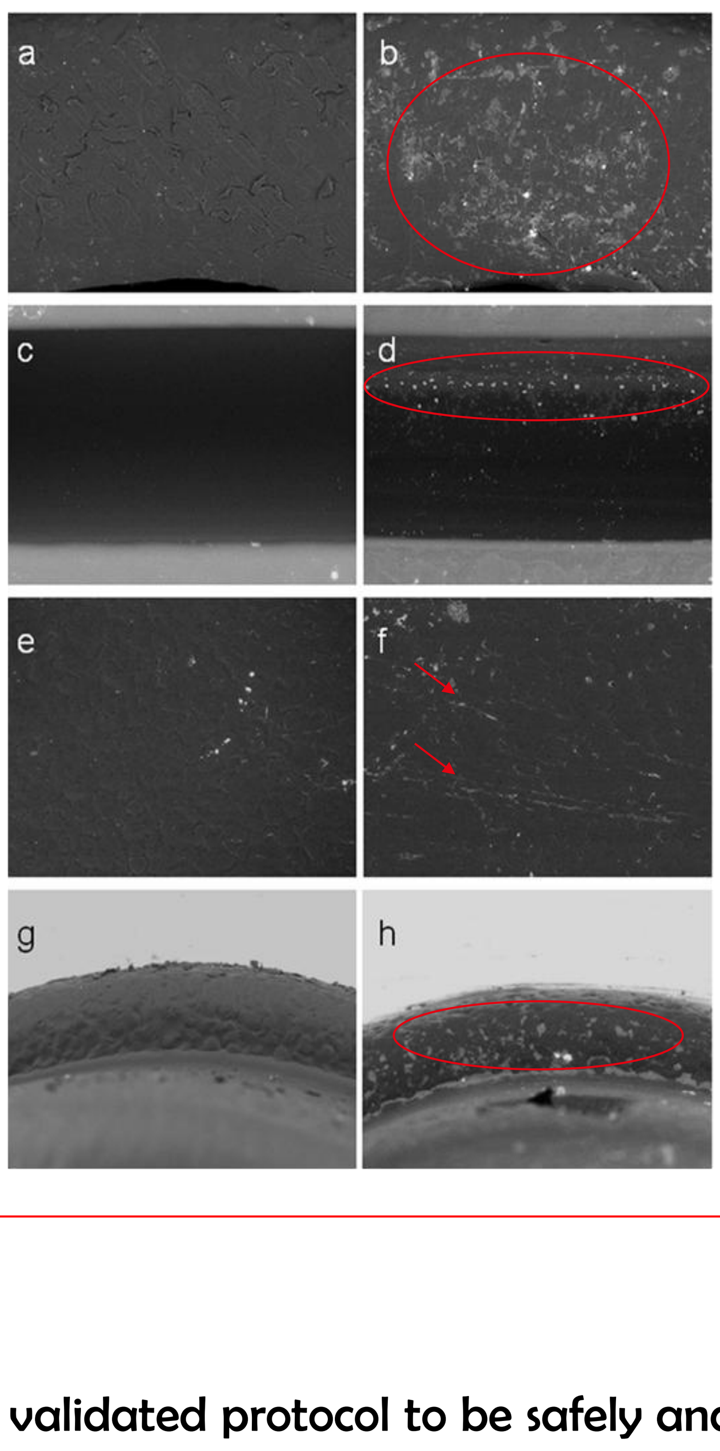

FIGURE 3. Representative SEM images of areas that showed statistically significant differences in surface characteristics between new (left column) and reprocessed (right column) EPs. *a,b): ROI#3; c,d): ROI #4 (longitudinal groove of the handle);e,f): ROI#5 (top surfaceof the "cut" button); g,h): ROI#5 (basement of the "cut" button).*

CONCLUSIONS

EPs are complex devices that require a validated protocol to be safely and effectively reprocessed. The investigation of surface characteristic with OM, SEM, EDXS, 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 have a role in defining the maximum number of reprocessing sustainable by the device.

We recommend not to reprocess and reuse silicon coated EP tips and to check the efficacy of the reprocessing protocol in removing debris from the EP handle with OM and SEM before validating the procedure.

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