Radiation Processing of Personal Protective Aprons: A comprehensive analysis

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Abstract

Personal protective equipments (PPE) play a key role in the fight against COVID-19 pandemic. Aprons, a major constituent of PPE, are designed for single-time use. COVID-19 may create a temporary, but huge setback in normal demand-supply of PPE aprons. A possible solution would be the sterilization of the PPEs for reuse. It is well known that high energy radiation has high efficacy for killing pathogens. Unlike UV radiation, gamma rays penetrate deeper into matter. Its effect on family of corona viruses is also well proven. However, the possible adverse effects of irradiation on PPE aprons has not yet been reported. The article reports extensive work carried out to develop a radiation processing protocol that assures desired Sterility Assurance Level (SAL) while maintaining acceptable physicomechanical properties in radiation-processed indigenously manufactured PPE aprons. The aprons were evaluated for their mechanical properties, blood penetration resistance and morpohological characteristics. Finally, protocols for radiation processing of PPEs, performance evaluation and their use in the real setting were developed and submitted to the Union Ministry of Health & Family Welfare.

Introduction

The COVID-19 pandemic may result in a short supply of single personal protective equipment (PPE) on account of demand-supply imbalance [1]. As aprons are among the major components of PPE, demand for them is expected to rise. Thus, globally there has been an impetus to investigate the reusability of PPE post adequate sterilization [2]. Two major considerations for re-use of these PPE aprons are: i) the sterilization method should effectively kill pathogens ii) the functional requirement is fulfilled after sterilization. Plasma gas sterilization, vaporized H_2O_2 sterilization, dry heat sterilization, chemical sterilization, steam sterilization and radiation sterilization are the major sterilization methods for treating medical products. Among them, radiation sterilization has its distinct advantage as it is carried out at room temperature with the possibility of sterilization in sealed units. A dose of 25 kGy is recommended for sterilization of medical products. Gamma radiation-induced inactivation of viruses of the SARS-COV family has been extensively documented [4]. The sterilization dose for the virus is a function of initial viral load, D10 value, and the type of virus. It has been recently reported that gamma radiation dose of 10 kGy is sufficient to reduce titers by 4-5 log10 and a dose of 20 kGy is sufficient for complete inactivation of the virus. Further, they suggest a dose of 30 kGy is sufficient to inactivate MERS-CoV in most laboratory cell cultures or tissue-based assays [5]. The same has been validated by studies of Hume et al. on RNA-viruses with a reported dose of 30 kGy for achieving sterility assurance level (SAL) of 10^{-6} [6]. However, there is no report available on the possible adverse impact of high energy radiation on the mechanical integrity and performance of PPE aprons and its fabric. This report presents a systematic study on effects of radiation on physico-chemical properties and performances of PPE aprons and the development of a protocol for radiation processing of used PPEs.

Methodology

For experimental studies, 6 x 6 inch sized units were cut from aprons and irradiated in the gamma chamber (GC-5000) under a dose rate of 6.2 kGy/hour as determined by Fricke dosimetry. All samples were packed in polyethylene (PE) bags and irradiated at a dose rate of 3.1 kGy/hour using a lead attenuator. For large scale irradiation, the aprons were packed in cardboard cartons and the cartons were placed in Tote boxes for irradiation with proper dose indicator displayed on the walls of cartons. The irradiated aprons were initially evaluated manually and later a piece of size 6” x 6” was cut from the apron and evaluated for mechanical properties using Universal Testing Machine (UTS), equipped with a load cell of 100 N at a head speed of 20mm/min. Fourier transform infrared spectroscopy (FTIR) from Bruker in Attenuated Total Reflection (ATR) mode and Rigaku XRD diffractometer were used for material characterization. Synthetic blood penetration resistance test was carried out using an in-house developed set-up confirming to the guidelines of ISO 16603, ASTM F1670 and JIST 8060 and 8122. The apron fabric was tested in the applied fluid pressure range of 40-300 mmHg. Morpohological changes in the apron fabric were observed through microscopic observations. Table 1 gives the details of the aprons investigated.

Table 1: PPE source & designated code

Make	Sample code
Prime Wear Hygiene (India), Pvt. Ltd. Thane -1	**A**
Not mentioned	**B**
Tyvek-400	**C**
Not mentioned	**D**
Not mentioned	**E**
Not mentioned	**F**
Prime Wear Hygiene (India) Pvt. Ltd, Thane-2	**G**
Fasten Medical Solutions, Cochin	**H**
Aditya Birla Fashion & Retail Ltd., Bangalore	**J**
Shahi Exports Pvt. Ltd., Bangalore	**K**
Aditya Life Science, Ahmedabad	**L**
Hanshil Enterprise, Rajkot	**M**
Pioneer Hygiene products	**N**

Laboratory scale studies

The samples were designated as A, B, and C and irradiated in the gamma chamber for different doses and their mechanical properties were evaluated. All samples showed a systematic decrease in mechanical properties on irradiation. The apron sample C (Tyvek brand) showed minimum decrease while "A" showed maximum decrease in mechanical properties. Figure 1 shows the results of these studies. Based on these studies and as per the values reported in the literature, aprons of PPE sets were consequently irradiated to a dose of ~30 kGy at radiation processing plant (RPP), Vashi, and were later evaluated.

Processing of aprons on a larger scale

The radiation processed aprons were initially subjected to manual evaluation. They were examined for any visible change in color, deterioration in mechanical properties (by physical push-pull), and for any pungent smell. No noticeable color change or pungent smell was observed in any of the aprons. Test samples G and H failed push-pull test. Therefore, unirradiated G and H were also subjected to pull-push test and both of them failed. The response of other irradiated samples to push-pull was

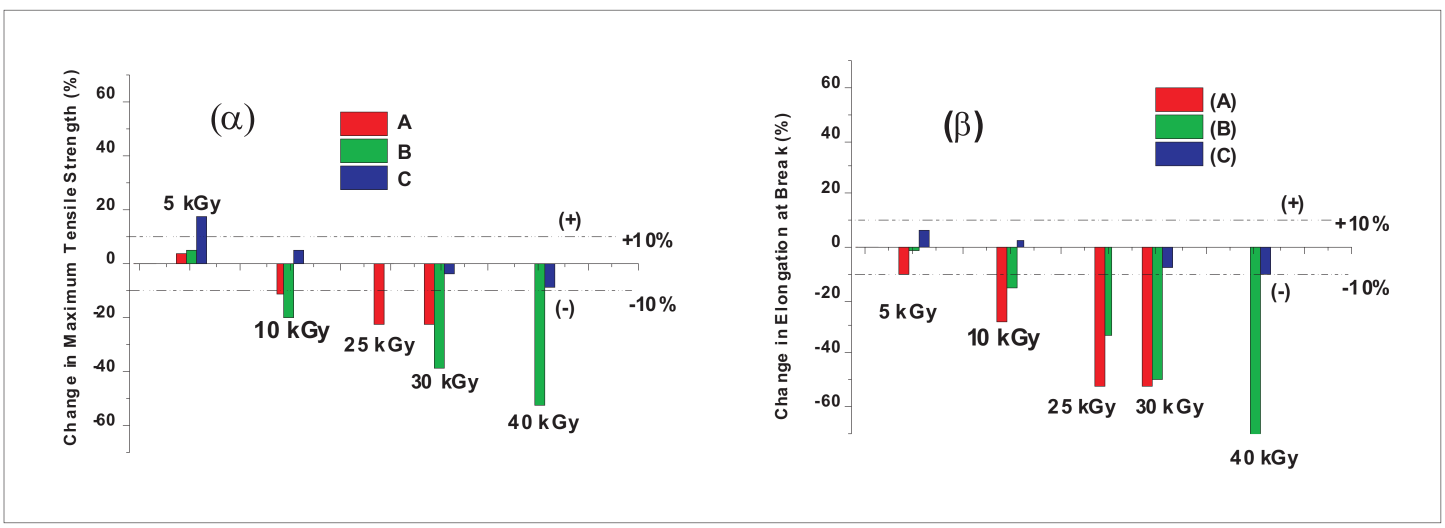

Fig. 1: (α) %Change in maximum tensile strength (β)% Change in elongation at break

Fig. 2: Manual evaluation of Aprons

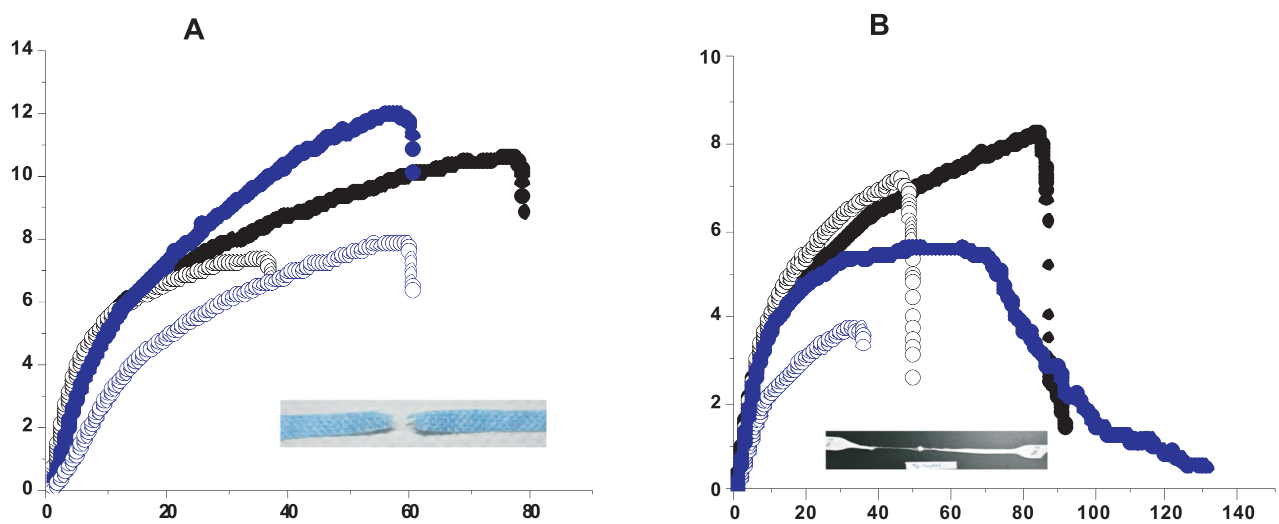

Fig. 3: Stress-Strain profiles for two types of failures (A) Abrupt failure (B) Delayed failure

positive as none of them showed mechanical failure when tested in multiple directions.

The elasticity of the rubbery rubber band at limb ends, the strength of samples at the seam and elasticity of hood lining were also found to be intact, after irradiation. Figure 2 shows pictures of the manual evaluation of aprons. Similar to the laboratory scale studies the aprons after irradiation were evaluated for their mechanical properties. Figure 3 gives representative stress-strain profiles of some of the samples. Mainly, two types of stress-strain profiles were observed. For some samples, the tensile profiles showed an initial elastic region followed by plastic region and then abrupt failure while for others the plastic region was followed by a failure region where the sample slowly deteriorated to failure {Figure 3(B)}. Table 2 shows the results of these studies. It is clear from the table that for all the samples there was a decrease in tensile strength & elongation-at-break (EB) on irradiation though, to different extents. The decrease in mechanical properties to different extents indicted that the aprons were either made of different materials or by different fabrication processes. To the best of our knowledge, no benchmark value for the mechanical properties of PPE aprons has been reported in the literature. Though there is a decrease in mechanical properties for aprons after irradiation, still the data in Table 2 clearly indictes that they are strong enough for reuse. Based on these studies, for a source strength of 680kCi and for an absorbed dose of 30

Table 2: Mechanical properties of aprons

Sample	Tensile strength (MPa)		Elongation at break (%)	
	Unirradiated	Irradiated (30 kGy)	Unirradiated	Irradiated (30 kGy)
D	11.61±1.22	7.43±0.44	63.1±9.21	31.32±1.32
E	12.48±1.01	5.68±0.32	97.82±4.21	18.71±3.72
F	5.12±0.56	3.61±0.25	49.94±14.41	35.41±0.61
G	9.34±0.09	6.66±0.44	48.82±2.04	21.47±1.63
H	8.96±0.23	6.69±0.22	97.45±9.97	46.22±1.58
J	10.01±1.66	7.64±0.51	78.74±21.67	37.34±4.23
K	8.73±0.38	6.58±0.81	80.67±7.67	42.33±7.53
L	8.09±0.01	4.63±0.14	80.27±0.01	43.05±3.31
M	------------	7.82±0.26	------------	33.91±1.43
N	------------	8.62±0.72	------------	83.62±12.12

kGy dose, it was estimated that 3500 aprons can be processed within a duration of 14 hours in RPP Vashi.

Spectroscopic and XRD analysis

Mechanical analysis of aprons indicated that they may be made of different polymers. Therefore, the FTIR analysis of apron material was carried out to ascertain their constituent polymer. The samples which showed delayed failure were analyzed for both the faces. Figure 4 shows representative ATR-FTIR spectra of some of the samples.

None of the samples tested were observed to be made of two different constituent polymers on its two faces. The vibrational modes observed in the FTIR spectra indicated that most of the aprons were predominantly made either of polypropylene or polyethylene and also polypropylene

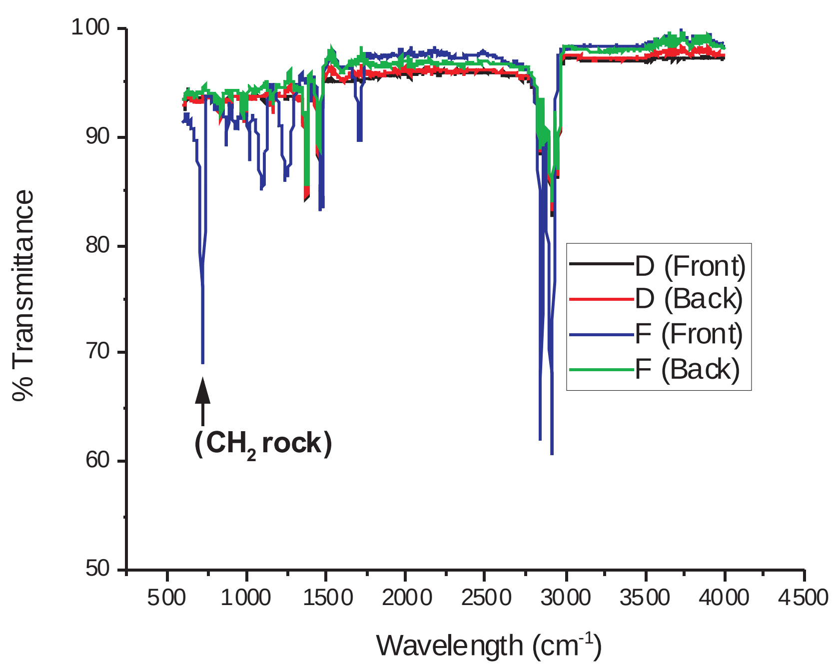

Fig. 4: Representative ATR-FTIR spectra

Table 3: Spectroscopic and XRD identification of apron material

Sample	Major fraction of polymer (ATR-FTIR)	Major fraction of polymer (XRD)
A	PP	PP
B	PP	PP
C	PE	PE
D	PP	PP
E	PP	PP
F	PE	PE
G	PP	PP
H	PP	PP
J	PP	PP
K	PP-PE blend	PP-PE blend
L	PE	PE
M	PP	PP
N	PE	PE

blended with polyethylene in one instance (Table 3). This observation was further supported by the XRD analysis of samples (Figure 5).

Synthetic blood penetration resistance (SBPR) test

The results of the test with respect to the sustained pressure on apron fabrics before and after irradiation are shown in Table 4. On correlating the data in table 3 & 4, it may be concluded that synthetic blood penetration resistance of the apron fabric is not material specific. It seems it also depends on the process used for making the apron cloth.

Morphological changes in apron fabric

Morphological changes in the apron fabric were observed through microscopic observations. Microscopic image of one of the

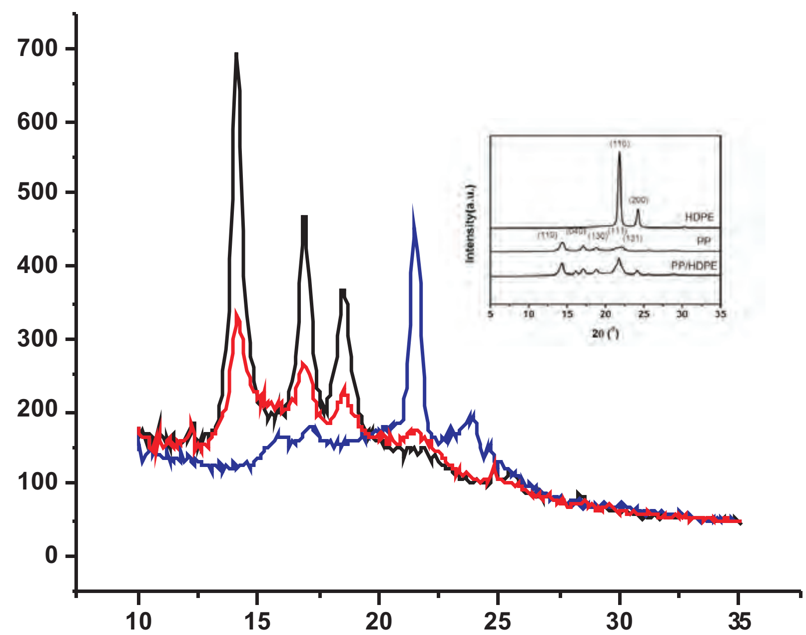

Fig. 5: XRD patterns of samples

Table 4: Blood penetration test

Sample	Tolerance pressure (mm Hg)		JIST8122 classification	Performance of material
	Unirradiated	Irradiated (30 kGy)		
D	<40	<40	Class-1	Low
E	<40	<40	Class-1	Low
F	<40	<40	Class-1	Low
J	>300	>300	Class-6	High
K	>300	>300	Class-6	High
L	>300	>300	Class-6	High

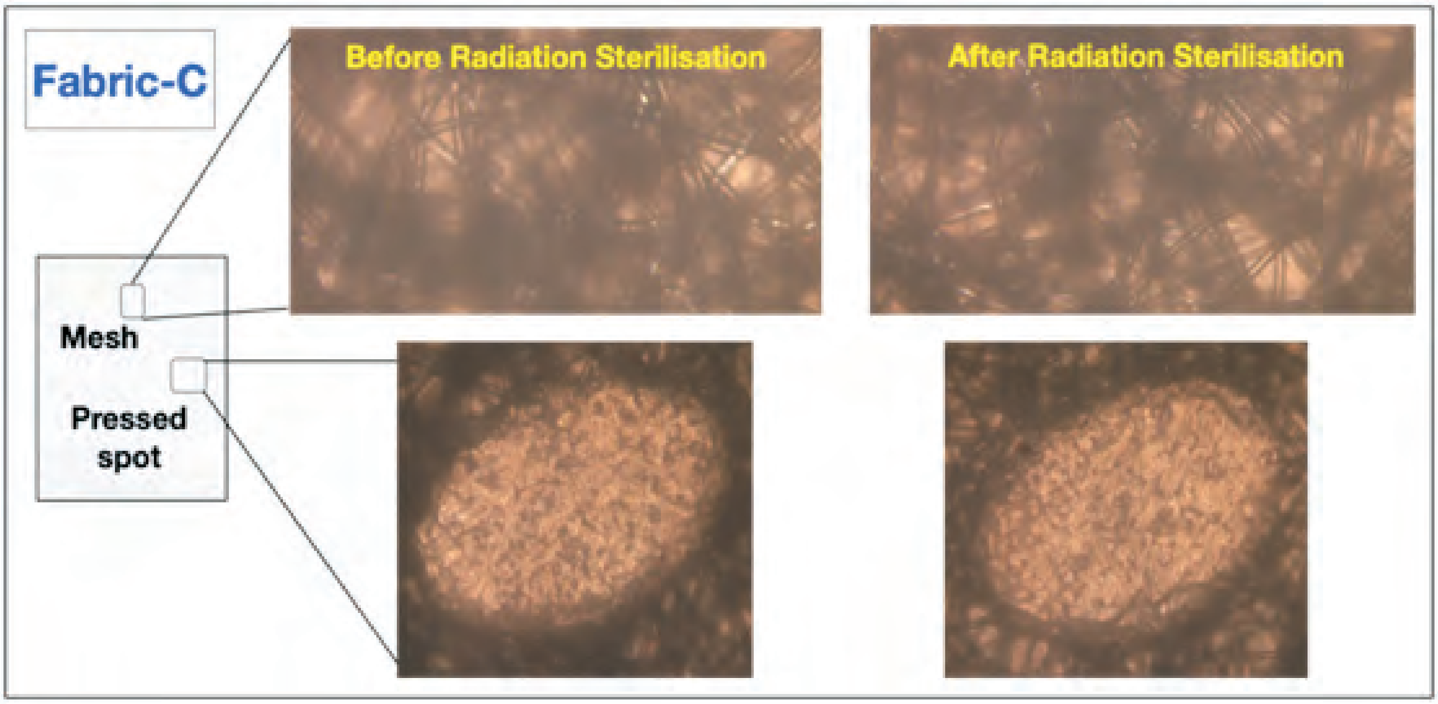

Fig. 6: Microscopic (bright field) image of sample F (Magnification 100 X)

representative sample (sample F) is shown in Figure 6. No observable change in number and size of voids was observed in the pressed or mesh region. For other samples too similar observations were made. Morphological observations were in sync with the SBPR test observations for all samples, where no change in tolerance pressure was observed post irradiation.

Conclusion

Radiation processing is an effective process for enabling the reuse of PPE aprons. Based on the positive outcomes of these investigations, a Standard Operating Procedure (SOP) for radiation processing of used PPE aprons has been prepared and submitted to the Union Ministry of Health & Family Welfare.

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