WHITEPAPER

Scapa Healthcare

Identification of Adhesive Formulations Minimally Effected by E-Beam Sterilization

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ABSTRACT/EXECUTIVE SUMMARY

A selection of medical/skin adhesives were coated onto substrates and physical properties (Shear, Adhesion to Release, 180° Peel and MVTR) tested before and after exposure to e-beam sterilization of 27 and 40 kGy. Of the four adhesives tested, two displayed a much lower effect from e-beam exposure than the others.

INTRODUCTION

Healthcare products often require sterilization when the indication includes “use on broken skin”. Historically the two most common methods have been ethylene oxide gas and gamma irradiation. Recently there has been more use of e-beam sterilization. E-beam is sometimes preferred when non-permeable packaging is indicated and when lower exposure times are desired.

E-beam irradiation has been known to affect acrylics through both the formation of cross-links and through bond/chain breaking. It is expected that different formulations of acrylic adhesives may experience lesser e-beam effects on physical properties than others.

In an effort to identify adhesives that may be less effected by e-beam irradiation, Scapa Healthcare has examined the effect of two different doses of e-beam sterilization (27 and 40 kGy) on the physical properties of four different commonly used skin adhesives (I to IV).

STUDY METHOD – MATERIALS, TESTING AND RESULTS

The four adhesives were transfer coated via knife over roll onto a 76 pound single side silicone coated liner. Each adhesive was laminated onto a 2mil thick PET film and a 45gsm non-woven PET fabric. The physical properties of the adhesive laminates were tested prior to e-beam exposure and after both 27 and 40 kGy radiation.

180° Peel

A strip measuring 1”x7” was cut from the PET film laminate and ~6 inch length was adhered to a stainless steel plate. The laminate was pressed onto the plate using a 2kg roller and allowed to rest for 20 minutes before being removed at an angle of 180° at a rate of 12in/min. The average peel was measured in lbf/in.

ADHESIVE	DOES (kGy)	VALUE PRE	VALUE POST	% CHANGE
I	27	2.93	2.72	-7.3%
I	40	2.45	2.14	-12.6%
II	27	3.46	3.08	-11.0%
II	40	3.64	3.38	-7.1%

ADHESIVE	DOES (kGy)	VALUE PRE	VALUE POST	% CHANGE
III	27	1.76	1.73	-1.6%
III	40	1.76	1.53	-13.5%
IV	27	3.44	2.88	-16.1%
IV	40	3.44	2.88	-25.0%

4.4psi Static Shear

A strip measuring 1”x3” was cut from the PET film laminate and was adhered to a stainless steel plate such that an area of ½”x1” of laminate was contacting the plate. The laminate were pressed onto the plate using a 2kg roller and allowed to rest for 20 minutes. A 1kg weight was hung from the bottom of the laminate strip and the time until the adhesive released from the plate was measured in minutes.

ADHESIVE	DOES (kGy)	VALUE PRE	VALUE POST	% CHANGE
I	27	190	711	274%
I	40	209	4404	2006%
II	27	689	684	-0.8%
II	40	516	781	-7.1%

ADHESIVE	DOES (kGy)	VALUE PRE	VALUE POST	% CHANGE
III	27	741	403	-46%
III	40	741	376	-49%
IV	27	13	498	-3830%
IV	40	13	715	-5546%

Adhesive Release (AR)

A strips measuring 1”x7” was cut from the PET film laminate and the non-adherent side of the PU film was adhered to a stainless steel plate using 6 inch length of double sided tape. The liner is removed at an angle of 135° at a rate of 300in/min. The average peel was measured in g/in.

ADHESIVE	DOES (kGy)	VALUE PRE	VALUE POST	% CHANGE
I	27	51	112	121%
I	40	38	135	256%
II	27	32	62	96%
II	40	33	67	107%

ADHESIVE	DOES (kGy)	VALUE PRE	VALUE POST	% CHANGE
III	27	60	112	89%
III	40	60	141	138%
IV	27	28	75	170%
IV	40	28	106	278%

MVTR

Moisture Vapor Transmission Rate was measured by cutting out 3 inch diameter circles of the non-woven PET laminates and placing them onto upright Thwing-Albert Vapometer MVTR cups containing 100mL of water. The cups were then placed into a chamber at 98.6°F/10%RH and weighed after 1 and 24 hours to calculate MVTR in $g/24hr/m^2$.

ADHESIVE	DOES (kGy)	VALUE PRE	VALUE POST	% CHANGE
I	27	634	603	-4.9%
I	40	498	527	5.7%
II	27	484	518	7.0%
II	40	483	498	3.1%

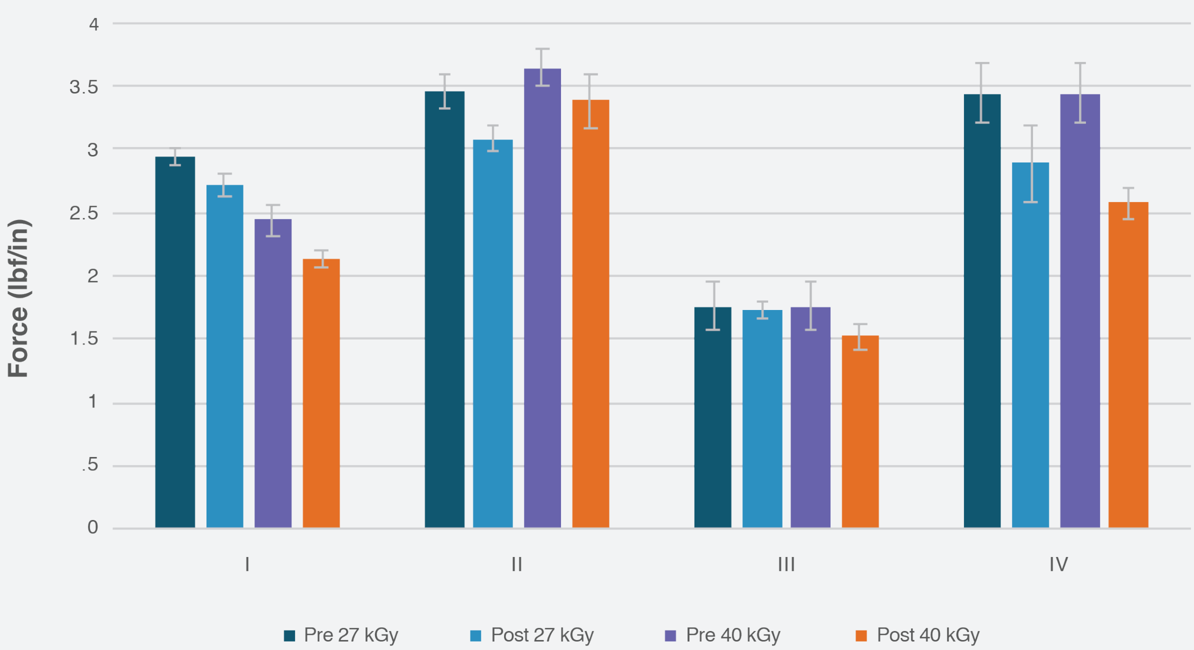
ADHESIVE	DOES (kGy)	VALUE PRE	VALUE POST	% CHANGE
I	27	564	591	4.9%
I	40	564	597	5.9%
II	27	484	589	21%
II	40	484	601	24%

DISCUSSION

180° Peel

All adhesives, accept for adhesive II, displayed a trend of a greater change in peel with increase in e-beam exposure (Graph 1). Adhesive II displayed a reverse of this trend. There was little change (1-13%) in the 180° peel values after e-beam sterilization for adhesives I, II, and III, whether the e-beam exposure was 27 or 40 kGy. Adhesive IV did display a greater decrease in 180° peel value: 16% after 27 kGy exposure and 25% after 40 kGy exposure.

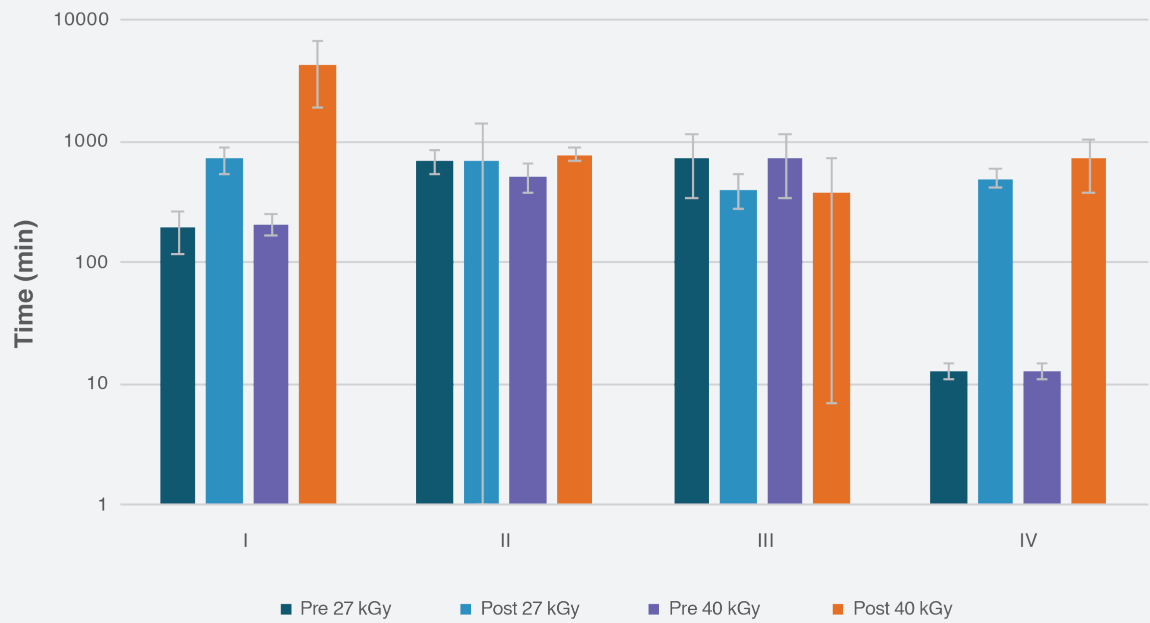
Graph 1 – 180° Peel: Pre and Post 27 and 40 kGy E-beam Sterilization



4.4psi Static Shear

All adhesives accept for adhesive III displayed a trend of a greater change in static shear with increase in e-beam exposure (Graph 2). Adhesive III displayed very little difference in change dependent on the e-beam exposure. There were great differences is static shear for adhesives I and IV: from 274% increase to 5546% increase, while adhesives II and III had much less increase in shear: from a 0.8% decrease to a 51% increase for adhesive II and from a 46% to 49% decrease for adhesive III. In order to be able to observe all of the data on one graph, these values were plotted on a logarithmic scale.

Graph 2 – 4.4lb/in Static Shear: Pre and Post 27 and 40 kGy E-beam Sterilization (Log Scale)

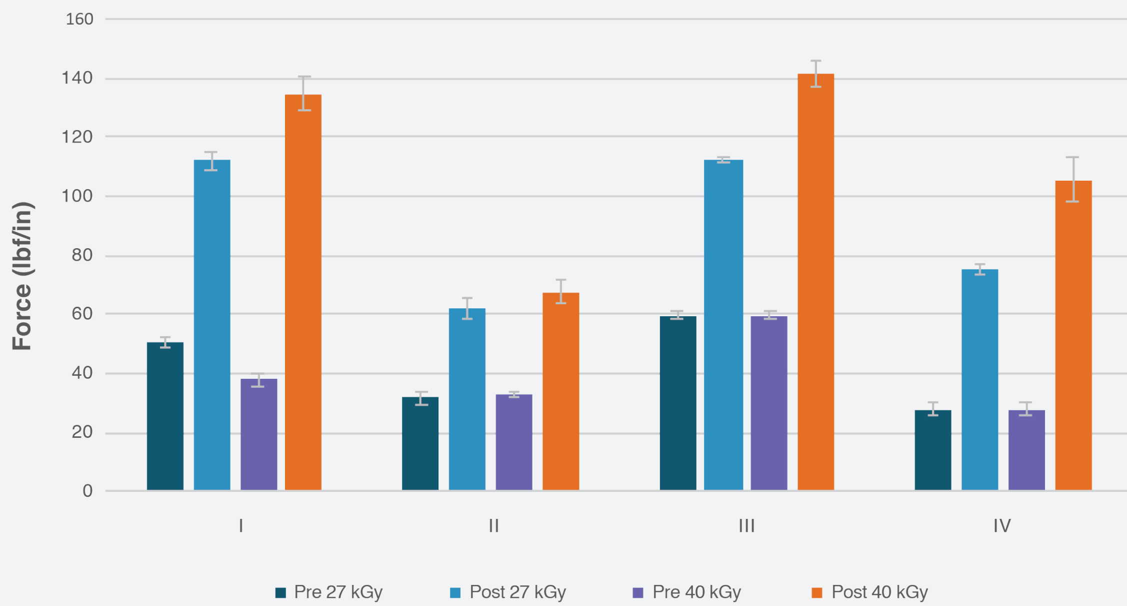


Adhesive Release (AR)

All adhesives displayed a trend of a greater change in AR with increase in e-beam exposure, with adhesive II and III displaying the least change in AR and adhesives I and IV displaying greater changes in AR (Graph 3).

The increase in AR is not unexpected. The exposure of silicone coated liners to irradiation is known to cause the silicone to cross-link, leading to higher release forces. To lessen this effect, it is common to specify an easy-release silicone coated liner for products that are expected to undergo radiation sterilization.

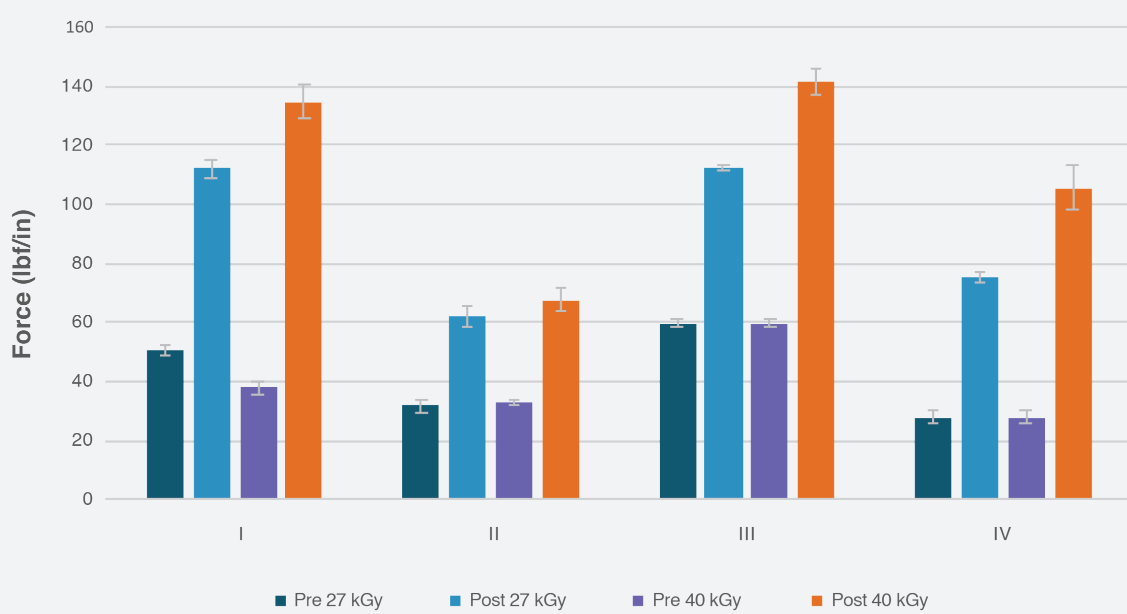
Graph 3 – Adhesion Release from Liner: Pre and Post 27 and 40 kGy E-beam Sterilization



MVTR

All adhesives, accept for adhesive IV, displayed small (<7%) changes in MVTR. Adhesive IV displayed a 21 to 24% increase in MVTR (Graph 4).

Graph 4 – MVTR: Pre and Post 27 and 40 kGy E-beam Sterilization



CONCLUSION

Scapa has performed testing on the effect of e-beam radiation on the physical attributes of 4 different medical acrylic adhesives (I – IV). Two of the adhesives (II and III) show much less effect from e-beam radiation then the others. The main physical test data that set adhesive II and III apart from adhesives I and IV were static shear and MVTR. The MVTR change due to irradiation was not as significant as the difference observed for shear testing. This change in shear testing results could translate into large differences in wear time observed for wearable healthcare products for adhesives I and IV.

Adhesives II and III are expected to work well in applications where acrylic adhesives are exposed to e-beam irradiation, experiencing minimal change upon sterilization.