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Title: Performance of Cleanroom Garment Fabrics When Processed in an Industrial Laundry, Comparing Irradiation and Autoclave Sterilisation

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Summary

EU GMP Annex 1 requires that "reusable garments should be replaced based at a set frequency determined by qualification, or if damage is identified." [1]

In the UK, most cleanroom garments supplied to the pharmaceutical and healthcare sectors are washed and sterilised by gamma irradiation.

This study compares cleanroom garment fabric performance across the lifespan of multiple fabrics. Previous research has shown that cleanroom garment fabrics terminally sterilised by gamma irradiation remain suitable for use for up to 50 processes, however, these studies often focus on a limited number of samples. This study uses a large sample set, analysing the performance up to 100 processes and compares the performance effects of gamma irradiation vs autoclaving, as an alternative sterilisation method.

Multiple market leading cleanroom garment fabrics were washed and dried using a standard industrial cleanroom laundry process and sterilised by either gamma irradiation or autoclave. They were tested for particle barrier efficiency, abrasion resistance, pore size, and tensile strength as new, then at set process counts throughout their life, 10, 20, 30, 50, 70 and 100 processes. A process is equal to one wash/dry/sterilisation cycle.

The results show that not all cleanroom garment fabrics deteriorate equally and that some market leading fabrics may not provide adequate performance throughout life, even if they are suitable when new. They also show that autoclaving is comparable with irradiation in durability and performance over a fabric's life, in some cases performing better than irradiation above process counts of 50.

Key Words: Cleanroom fabric, autoclave sterilisation, irradiation sterilisation, lifetime, performance

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Introduction

Reusable cleanroom garments are used throughout the pharmaceutical industry, in the development and manufacture of drugs, and in the electronics industry in the manufacture of semiconductors and lenses [1]. The source of microbes within cleanroom air is almost exclusively from personnel within the room. Micro-organisms grow on a person's skin and are dispersed as these skin cells are shed [2]. The purpose of cleanroom garments is to reduce particulate and microbial dispersion from personnel [3].

Reusable garments should be made from fabrics which can perform after multiple decontamination processes, including washing, drying, and sterilisation. To assess the impact this processing has on fabric performance, multiple fabrics were decontaminated up to 100 times. EU GMP Annex 1 requires "reusable garments should be replaced based at a set frequency determined by qualification or if damage is identified."

Garments were selected which were: suitable for use in a Class 4 or GMP Grade B cleanroom environment, a commercially available fabric at a viable price point, comprised of 98% monofilament yarn +2% conductive thread, and made using a non-encapsulated electrically conductive thread to enable the use of surface resistivity in end-use. Four fabrics which met these criteria were selected.

Cleanroom coveralls were produced from each of the fabrics selected, to better simulate the stresses a fabric would typically undergo. Sterilisation by both irradiation and autoclaving was assessed. Four different fabrics, WF5505JG, Fabric B, Fabric, C, and Fabric D (see Table 1), were irradiated 100 times following a standard irradiation process at a Cobalt 60 continuous irradiation facility. Fabrics were irradiated to a validated dose of 25-35kGy. For practicality, the fabrics were washed and dried 10 times, then irradiated 10 times. This was repeated 10 times, until the fabrics reached 100 wash-dry-irradiation processes.

TABLE 1 - COMPARISON OF THE FABRICS PHYSICAL PROPERTIES.

Fabric	GSM	Construction	Weave	Fibre Type
WF5505JG	105	176 x 94	Plain	Polyester
B	98	168 x 100	Plain	Polyester
C	105	*	Plain	Polyester
D	102	165 x 99	Plain	Polyester

(*This information is unavailable due to commercial confidentiality).

WF5505JG, Fabric B, and Fabric C were autoclaved at 121^{O}C for 15 minutes. Garments were washed and dried once, then autoclaved once, up to 100 times. Fabric D was added into the irradiation study later and not included in the autoclave study due to time and space constraints.

The fabric particle barrier efficiency, abrasion resistance, pore size, and tensile strength was assessed at 0, 10, 35, 50, 70, & 100 processes. Particle barrier efficiency and pore size are indicative of a fabric's ability to prevent dispersion of particulate and bioburden into a cleanroom environment. Tensile strength and abrasion resistance are indicative of a garment's durability and can give insights into a garment's performance through life, the risk of a breach during use, and its reusability and therefore cost effectiveness.

Testing Methodologies

Particle Filtration

The fabrics were analysed for their particle filtration effectiveness by the external ISO 17025 laboratory using their determination of barrier ability against airborne particles (ITV-method; VDI 39226-1:2004) test method.

This test method involves the use of a vertically positioned duct with a sample holder built into its wall. A particle disperser is located at the top of the duct, while a suction pump is located at the bottom. A second suction pump pulls a portion of the 'crude gas' produced from the particle disperser though the test sample. Air which has passed through the sample is referred to as the 'clean gas' (see Figure 1). The particle disperser is adjusted to produce a defined particle concentration in the crude gas. The particle concentrations are measured on both sides of the sample simultaneously at certain time intervals using a particle counter. Using these values, a value for the transmitting factor as a function of particle size can be calculated.

The transmitting factor (for every measured particle size) is defined as:

$$Transmitting\ Factor = \frac{Particle\ concentration\ of\ clean\ gas}{Particle\ concentration\ of\ crude\ gas} \times 100\%$$

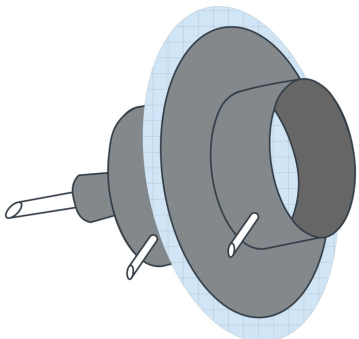
The barrier ability (filtration efficiency) is calculated according to the formula:

$$Barrier\ Ability = 100 - Transmitting\ Factor$$

The lower the transmitting factor, the higher the filtration efficiency of the fabric being tested.

Test duration can have an impact on filtration efficiency. The test must be long enough to allow for the particulate to build up on the fabric, resulting in the formation of a filter cake on the sample. In cleanroom fabrics a filter cake forms quickly. Results are, therefore, from test durations of 60 minutes.

FIGURE 1 – PARTICLE FILTRATION EFFICIENCY DRAWING



Determination of Pore Size

Pore size is determined using a bubble point test according to DIN58355 part 2 using a "Coulter Porometer". The specimen is soaked completely with a test liquid then fixed in a sample holder. Air is pumped under the fabric and the pressure is increased gradually. The pressure when the first bubble penetrates through the specimen is recorded. The pore size is calculated automatically from this value.

The method assumes the pores have a circular shape, are homogeneous and have a plane side. This is not typically the case with textiles, the pore size is therefore approximate. [5]

Tensile Strength

Tensile strength measures the force required to break a fabric. In this testing the strip method BS EN ISO 13934-1:2013 was used. A piece of fabric measuring 50mm x 200mm is gripped in the jaws of a tensometer. The tensile force applied is increased until the point at which the fabric breaks. The force required to break the fabric is recorded.

The tensile strength of a fabric is a useful indicator of a fabric's capability to withstand the rigours of repeated use, laundering, and sterilisation. Garments with a lower tensile strength are more likely to result in a breach during use. [6]

Abrasion Resistance

An abrasion resistance test measures a fabric's durability against rubbing and scuffing. This was carried out according to ISO 12947-2:2016 [7].

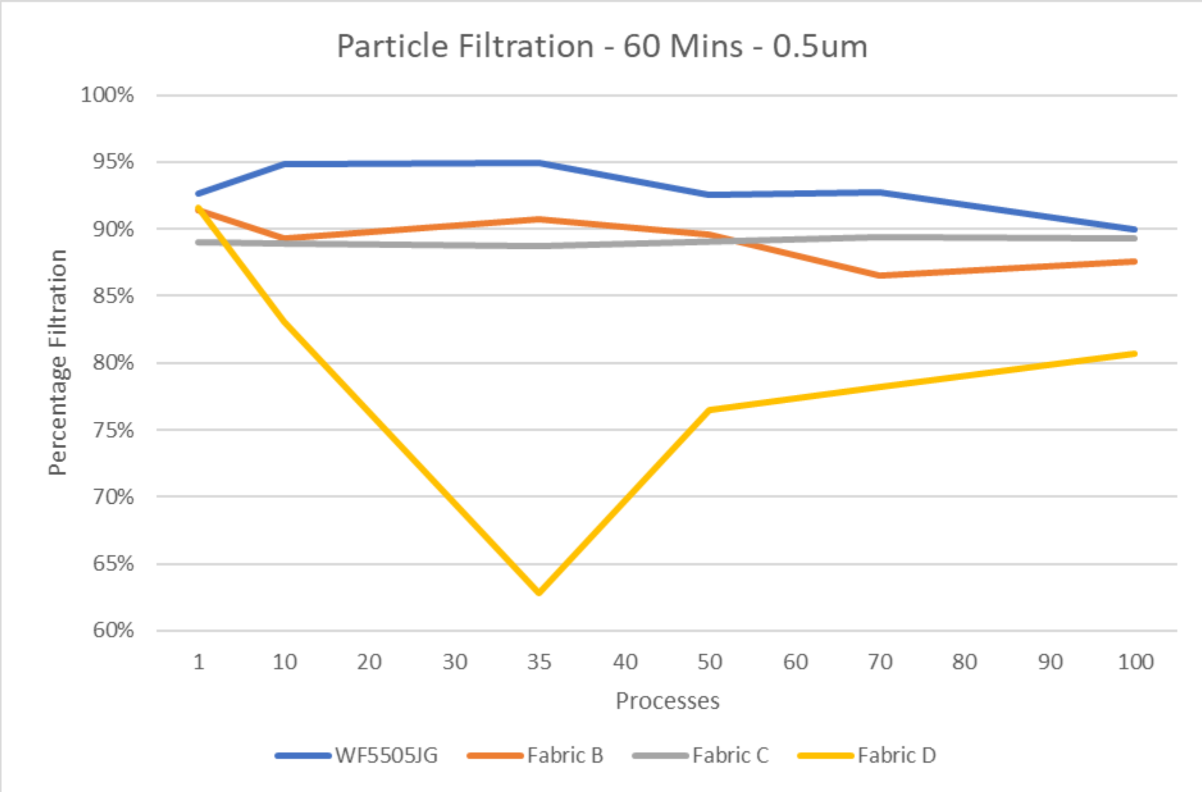
Typically, an abrasion test will involve moving a sample of fabric over a standardised abrasive surface (e.g. sandpaper) in an oscillating pattern and counting the number of cycles the fabric can withstand before showing signs of breakdown. The abrasion resistance of a fabric is a useful indicator of how well the fabric will stand up to the stresses of repeat use. A low resistance to abrasion can indicate risks of rapid fabric degradation.

Irradiation Results & Evaluation

The results in this section are presented with number of processes representing a continuous timeline. Each test was carried out in triplicate and averaged out. Since each test at each process point is on a different garment it is possible for results to deviate from an expected trend.

Particle Filtration

Figure 2 – Line Graph of Particle Filtration 60 Minutes

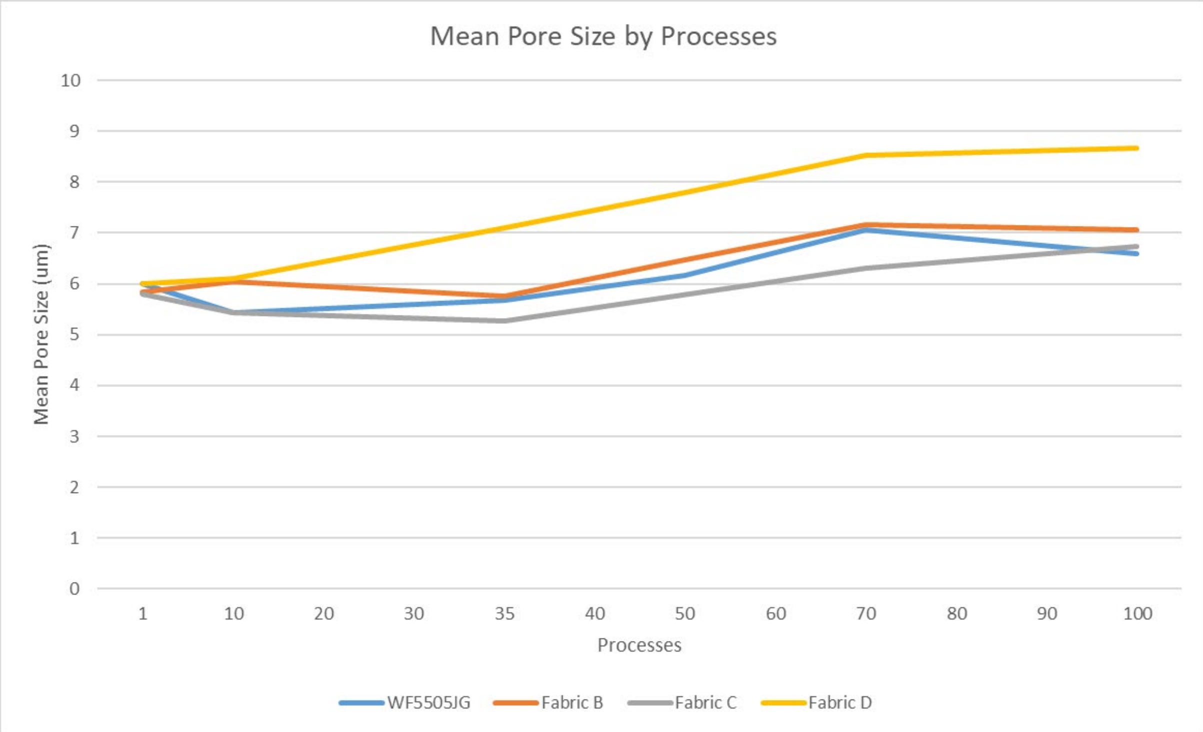


This test measured the particle filtration efficiency (PFE) of the garments.

Figure 2 shows that all four fabrics begin with roughly equal levels of particle filtration efficiency, ranging between 89% and 93%. As the number of cycles increases a slight decline in particle filtration efficiency can be seen in Fabrics WF5505JG and B. WF5505JG retains efficiencies above 89% throughout testing. Fabric B retains >90% efficiency up to 35 processes but sees a decline to 88% by 100 processes. Fabric D sees an immediate decline below the baseline set by Fabrics B and C, reducing to 83% after 10 processes. The 35-process value of 63% is an outlier and assumed to be erroneous, the testing for this process point could not be repeated as the testing is destructive. The fabric continues a downward trend with 77% as the lowest value, 13 percentage points lower than its highest value.

Pore Size

Figure 3- Line Graph of Mean Pore Size - Irradiation



All fabrics begin with a mean pore size between 5.8-6.0µm. At 10 processes, WF5505JG and Fabric C slightly decrease, whilst Fabrics B and D slightly increase. At processes beyond this all fabrics demonstrate a trend towards larger pore sizes.

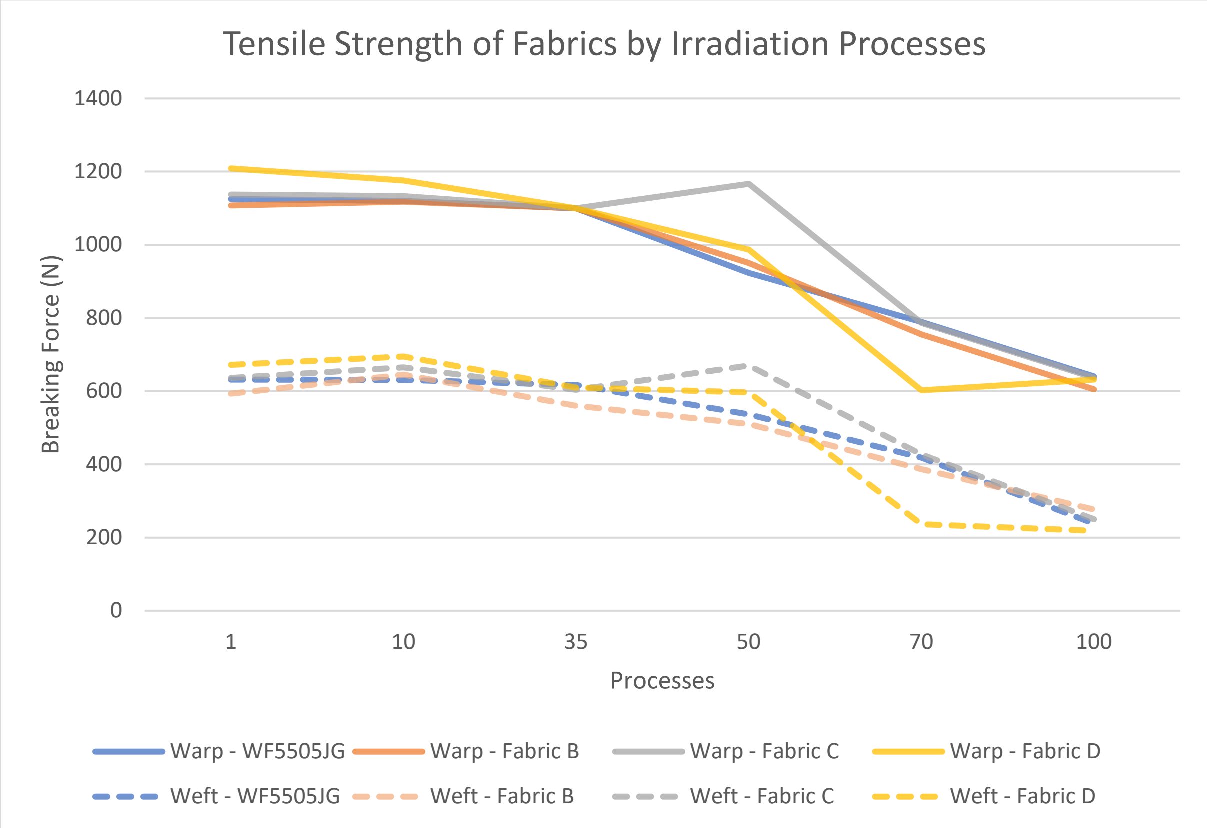
Fabric	Highest Mean Pore Size (µm)	Mean Pore Size Increase (µm)
WF5505JG	7.1	1.7
Fabric B	7.2	1.4
Fabric C	6.7	1.4
Fabric D	8.7	2.7

The highest mean pore size was observed after the maximum number of processes for all fabrics, except WF5505JG.

Table 2 shows that Fabric D saw the highest increase overall with a 2.7µm increase from new to 100 processes. WF5505JG & Fabric B performed similarly.

Tensile Strength

Figure 4 – Tensile Strength – Irradiation

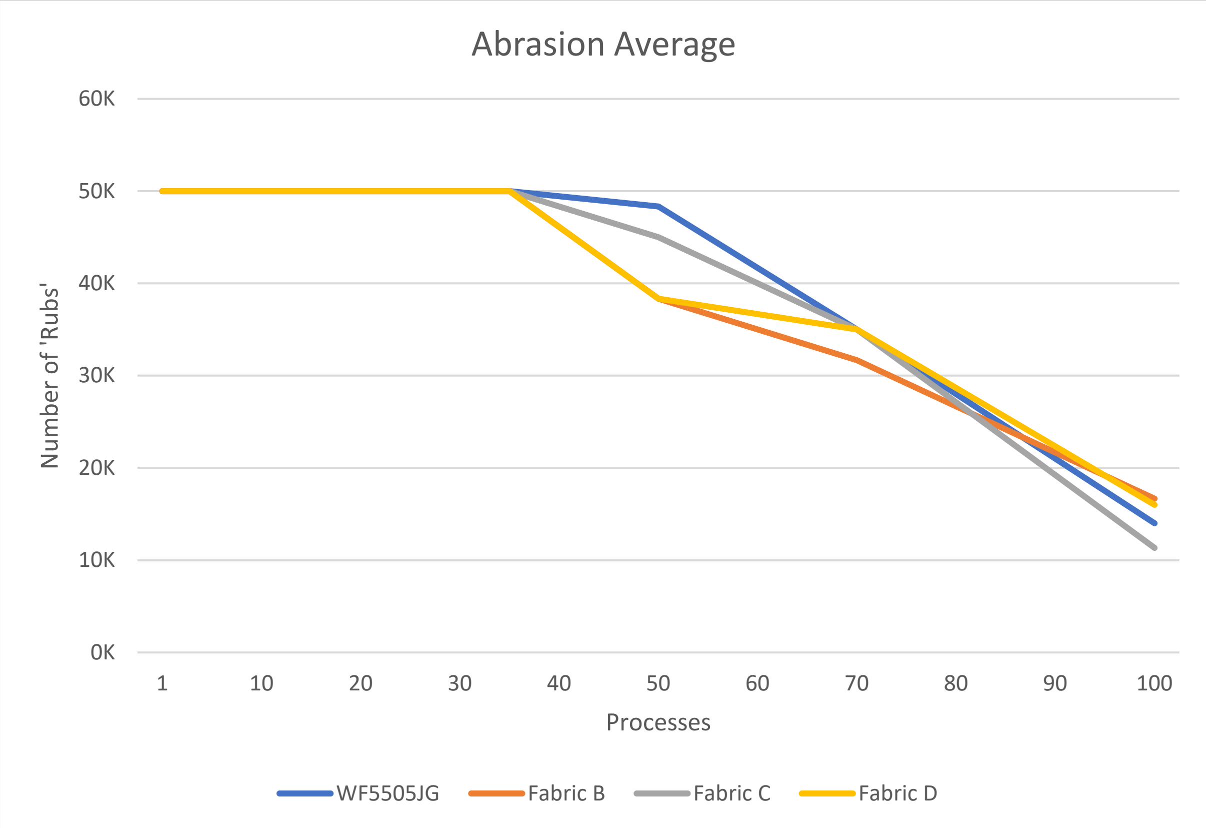


All fabrics exhibit a reduction in tensile strength breaking force as the number of processes increases. 4 shows that the decline in breaking force required, reduces slowly from 1 to 35 processes, but declines more rapidly at 50+ processes.

Fabric D begins with the highest tensile strength breaking force in both warp and weft directions. The warp starts at 1209N, by 35 processes it is on par with the remaining fabrics at 1100, and by 70 processes Fabric D is at 602N, with the next lowest being Fabric B with 755N.

Abrasion

FIGURE 5 - LINE GRAPH OF ABRASION RESULTS – IRRADIATION



The maximum value in abrasion testing is artificially capped to 50,000 rubs, once a sample reaches this milestone the testing is ceased. Figure 5 shows that the 4 fabrics tested do not exhibit results below this cap until 35 processes. At this process point Fabrics D and B exhibit a reduction in abrasion resistance below 40,000 rubs, whilst WF5505JG, and Fabric C remain above 45,000. At 70 processes WF5505JG and Fabric C see a more rapid decline to 35,000 rubs. Fabric D reduces less than other fabrics between 50 and 70 processes, matching WF5505JG, and Fabric C with 35,000 rubs. At 100 processes the garments see a large decline in abrasion resistance, continuing the trend observed once results are lower than the 50,000 rub cap at 50 irradiation processes.

Autoclave Results & Evaluation

Particle Filtration Efficiency

FIGURE 6 – LINE GRAPH OF PARTICLE FILTRATION – AUTOCLAVE

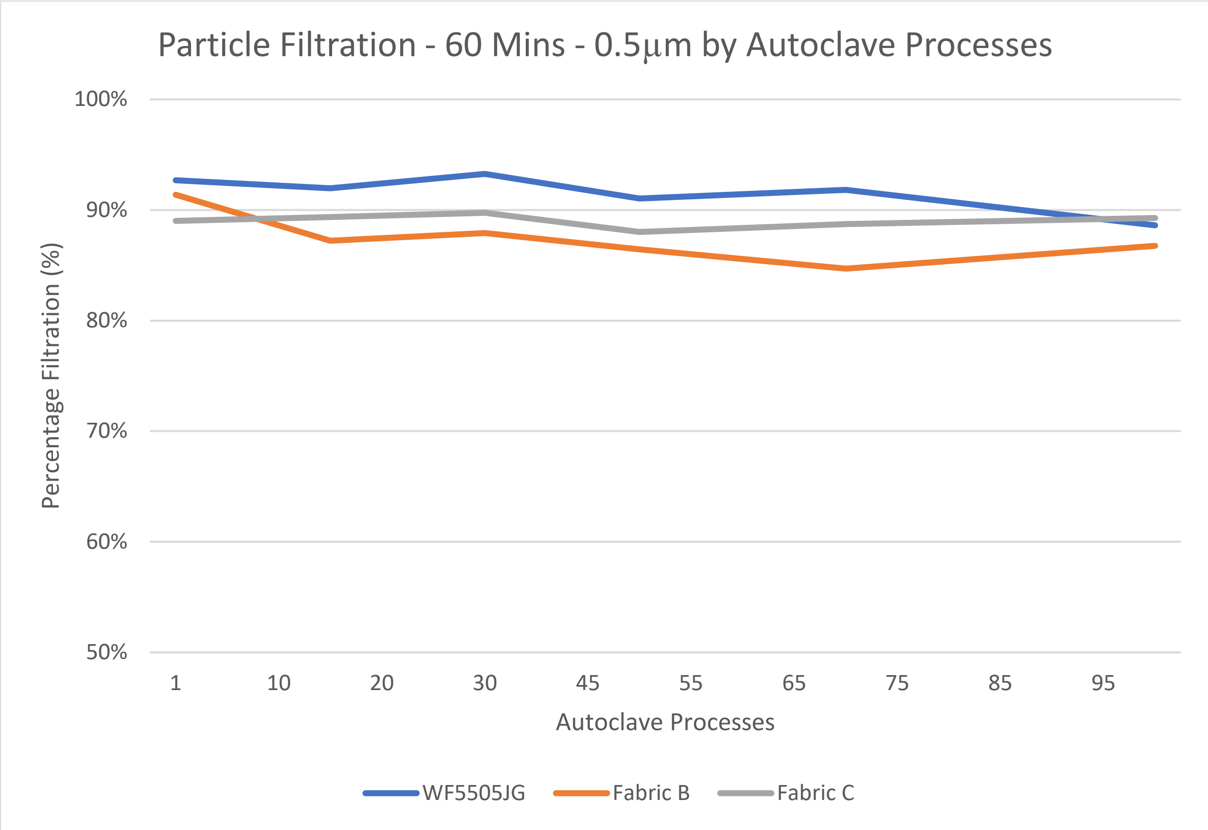


Figure 6 shows that PFE for all fabrics tested remains consistent throughout the entire garment life. WF5505JG begins at 93% PFE when new, falling to 89% at 100 processes. Fabric B begins at 91%, displaying a lowest PFE value of 85%. Fabric C begins at 89% and has a minimum value of 88%.

Pore Size

Figure 7 – Line Graph of Pore Size by Autoclave Processes

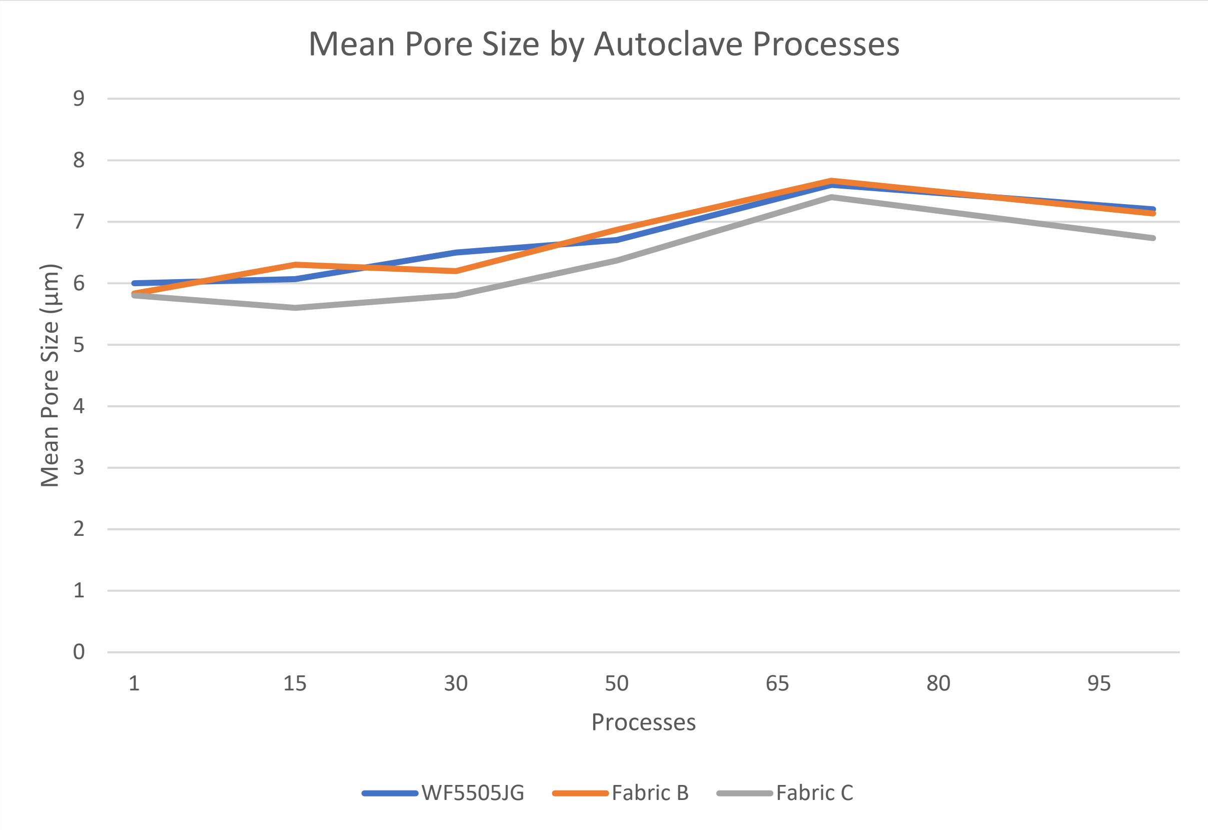


Figure 7 shows all fabrics begin with a mean pore size between 5.8-6.0µm. At 15 processes, WF5505JG and Fabric B slightly increase, whilst Fabric C slightly decreases. Up to 70 processes, all fabrics demonstrate a trend towards larger pore sizes. At 100 processes, the average pore size is slightly smaller than at 70 processes for all fabrics.

Tensile Strength

FIGURE 8 - LINE GRAPH OF TENSILE STRENGTH – AUTOCLAVE

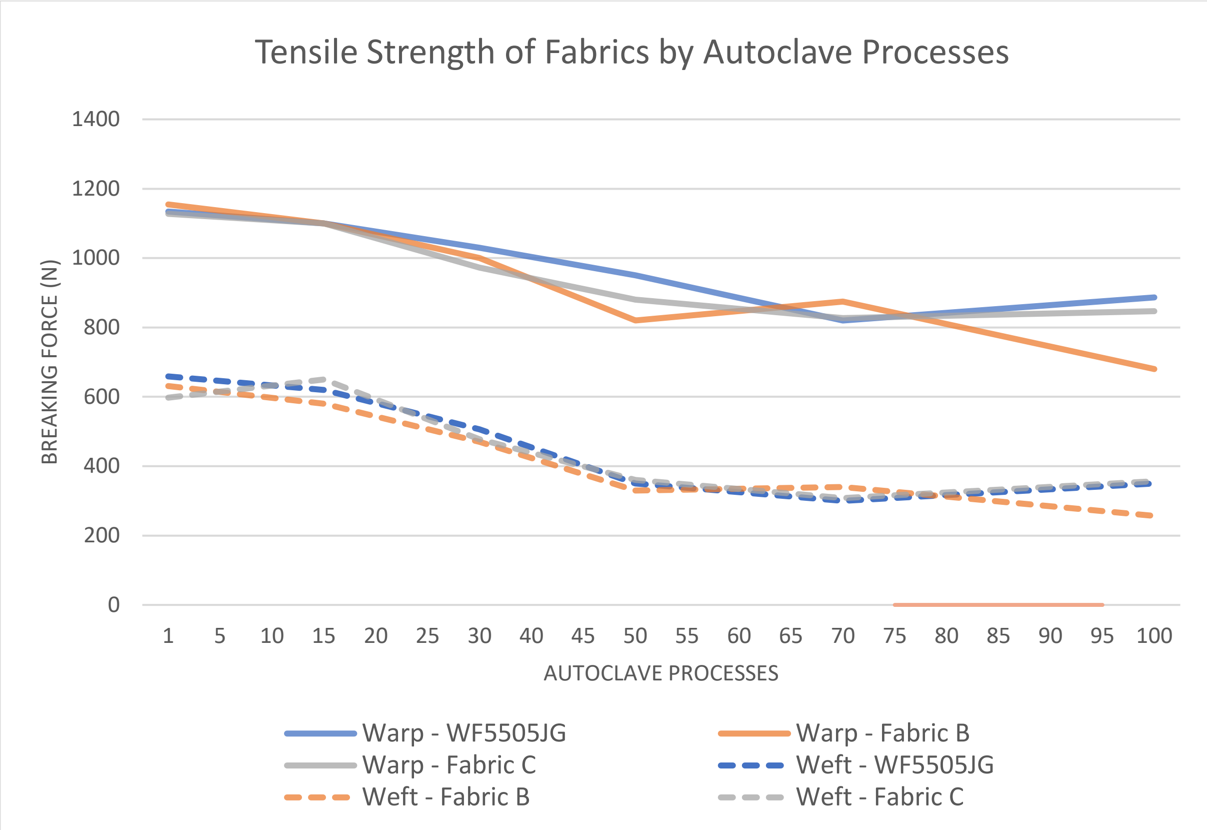
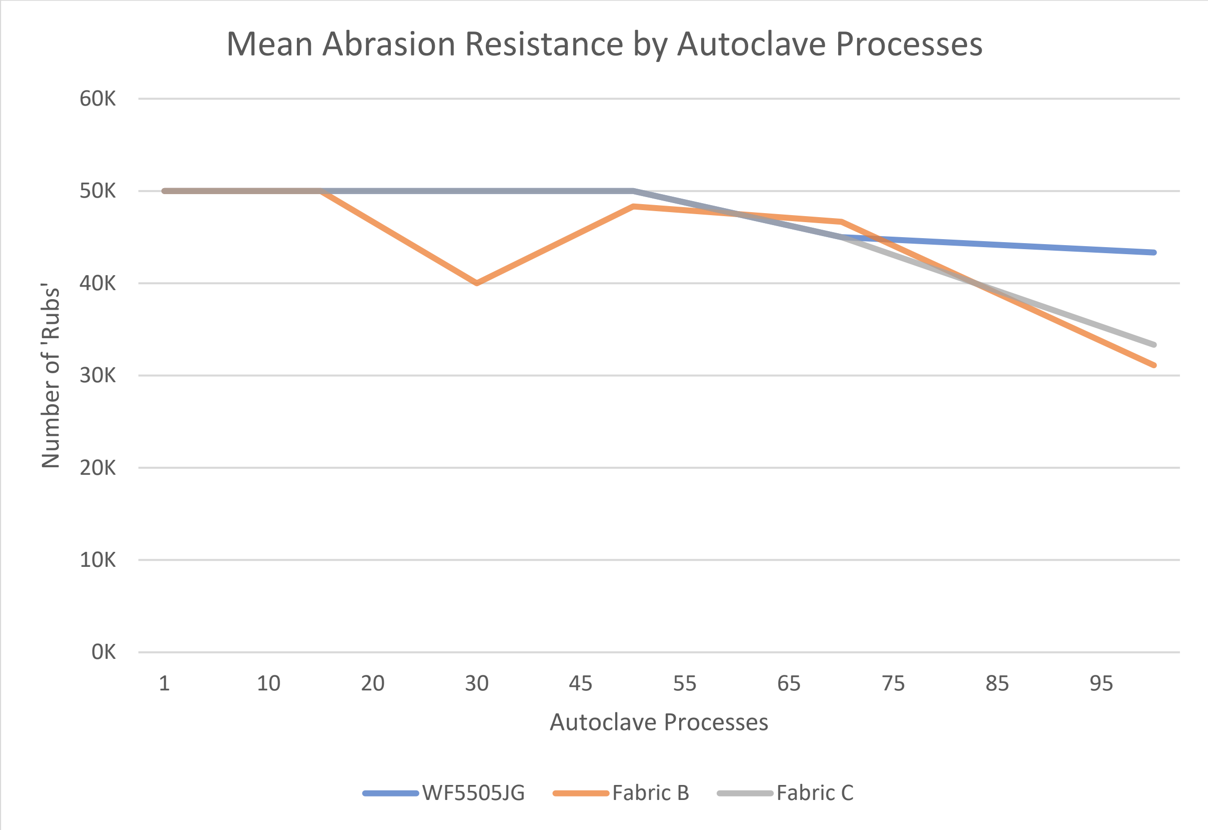


Figure 8 shows that, as with fabrics sterilised by irradiation, fabrics sterilised by autoclave demonstrate a reduction in tensile strength breaking force as the number of processes increases. All fabrics trend downwards towards 800N at 50 processes, from a starting point of 1100-1150N. WF5505JG remain above 800N up to 100 processes, while Fabric B dropped to 700N.

Abrasion

Figure 9 - Line Graph of Mean Abrasion resistance – Autoclave



The maximum value in abrasion testing is artificially capped to 50,000 rubs, once a sample reaches this milestone the testing is ceased. Figure 9 shows that WF5505JG and Fabric C remain at this cap until 50 processes, whilst Fabric B falls slightly below this at 50 processes. All fabrics then demonstrate a steady reduction in abrasion resistance, with WF5505JG remaining above 43,000 average rubs, and Fabrics B and C remaining above 30,000.

Discussion and Conclusions

The tests used in this article are commonly provided in cleanroom garment fabric specifications when new and can be used as an assessment of a fabric's ability to perform as required within a cleanroom environment. This study utilises those tests to evaluate how this performance changes as the garments are washed and dried in a commercial cleanroom laundry, and subsequently sterilised by either irradiation or autoclaving. The impact of a user wearing a garment, made from the fabrics tested, was not investigated, but it is probable that this would have a negative impact on the garment performance over time. The effect of zippers, buckles and push buttons was not included as part of this study. These attachments can vary across garments and this study focused solely on the fabric of the garments, and the fabric's contribution to the performance of the garments.

The force required to break each fabric was observed to decline as the number of processes the fabric had undergone increased. Figure 4 shows that Fabric D has the highest tensile strength when new but has the lowest after 70 irradiation processes highlighting the importance of understanding how a fabric will perform throughout its use and setting appropriate process limits for the fabric's use case. This difference reduces as the fabrics hit 100 processes, with all fabrics having tensile strength results between 615 and 670N.

For WF5505JG, Fabric B, and Fabric C, tensile strength declined more rapidly when the fabrics were irradiated compared with the fabrics which were autoclaved. However, 70 process results display a higher tensile strength when autoclaving rather than irradiating. The results indicate that autoclaved fabrics may retain adequate strength, and therefore remain more durable, for a higher number of process cycles, whereas irradiated fabrics show a progressive decline in strength. This may mean that autoclaved fabrics are more durable over time in comparison with irradiated fabrics.

The particle filtration efficiency of the fabrics was examined and compared when irradiating fabrics. WF5505JG and Fabric C demonstrated the potential for fabrics to consistently retain 'like new' values for PFE throughout 100 irradiation processes. Fabric B performed slightly worse reducing by 4 percentage points by the end of testing. Fabric D continues the trend of starting strong at 92% PFE, dropping by 11 percentage points to 80.7% PFE after 100 processes. Fabric D is a market leading cleanroom fabric and when new, its performance is on par with the other market leading fabrics included in this study, however, it's significantly lower PFE after 100 processes, further reinforces the importance of evaluating a fabric throughout its entire life expectancy rather than relying on specifications when new.

Particle filtration when autoclaving showed a similar consistency up to 100 processes as with irradiation. WF5505JG, Fabric B, and Fabric C reduced by 5, 4.9, and 0.6 percentage points respectively from their highest observed values.

An additional 100 process test was carried out on the autoclave fabrics, these results follow the trend seen for the 1-70 process results.

Assessment of the mean pore size of the fabrics showed that after an initial reduction in pore size for WF5505JG and Fabric C after 10 autoclave or irradiation processes, all fabrics trend towards larger pore sizes as they are processed, overall.

The pore sizes of WF5505JG, Fabric B, and Fabric C were slightly larger when autoclaving rather than irradiating. Pore sizes of garments were 0.5-0.8µm larger for each fabric at each process point when autoclaving. The slight increase in pore size when autoclaving correlates with the slight increase in PFE values when compared with irradiated garments, but care should be taken when drawing conclusions from small pore size changes.

The results indicate that pore size is correlated with particle filtration efficiency. Fabrics that saw the lowest increase in pore size, saw the lowest reduction in their PFE and tensile strength performance as processes increased. The mechanism for this correlation is not clear from this study. Further study into this correlation may give insight into whether pore size can be a good indicator of barrier performance and vice-versa.

Irradiated WF5505JG and Fabric C started to drop below the 50,000 rub upper abrasion limit of the test at 50 processes, while Fabrics B and D dropped below 40,000 rubs. By 70 processes all fabrics had dropped below 35,000 rubs. At 100 processes the abrasion resistance of all irradiated fabrics drops significantly to less than 20,000 rubs. The testing makes clear that typical cleanroom fabrics should have process limits lower than 100 to avoid significant risk of fabric breach during use.

When autoclaved the fabrics retain their abrasion resistance for more processes, with WF5505JG remaining above 40,000 rubs and Fabrics B and C remaining above 30,000 rubs at 100 processes. Alongside improved tensile strength retention this testing suggests that fabrics last longer when autoclaved rather than irradiated.

Overall, the results reinforce that not all cleanroom fabrics are equal and stresses the importance of the EU GMP Annex 1 requirement to understand the performance of garment fabrics throughout their entire usable life, either by carrying out a fabric life study or relying on a garment supplier to provide such data.

References

[1] E. Vozzola, M. Overcash and E. Griffing, “Life Cycle Assessment of Cleanroom Coveralls: Reusable and Disposable,” *PDA Journal of Pharmaceutical Science and Technology,* vol. 75, no. 3, 14 February 2018.

[2] W. Whyte and M. Hejab, “Particle and microbial airborne,” *European Journal of Parenteral & Pharmaceutical Sciences,* vol. 12, no. 2, pp. 39-46, 2007.

[3] W. Whyte and P. V. Bailey, “Reduction of Microbial Dispersion by Clothing,” *PDA Journal of Pharmaceutical Science and Technology,* vol. 39, no. 1, pp. 51-61, 1985.

[4] R. T. Kocaman, S. A. Malik, D. Aibibu, T. Gereke and C. Cherif, “New Method for In-situ Measurement of Pore Size Deformation of Barrier,” *J Textile Sci Eng,* no. 8, 2018.

[5] Deutsche Institute Für Textil -undFaserforschung, “Test Report No. E-0055-TT-18,” 2018.

[6] M. Bide, “Testing Textile Durability,” in *Understanding and Improving the Durability of Textiles*, Woodhead Publishing, 2012, pp. 126-142.

[7] BSI, “Textiles. Determination of the abrasion resistance of fabrics by the Martindale method. Determination of specimen breakdown,” *BS EN ISO 12947-2,* 2016.

[8] European Commision, “Manufacture of Sterile Medicinal Products - Annex 1 Consulation Document,” 2021. [Online]. Available: https://ec.europa.eu/health/sites/default/files/files/gmp/2017_12_pc_annex1_consultation_document.pdf.