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Effects of Repeat Cleaning and Steam Sterilisation on Additively Manufactured Nylon PA2200 (SLS), With and Without Vapour Smoothing

Corresponding Author

Nick Bridgman - Design Group Manager, R&D

Co-Authors

Peter Guite - Design Engineer, R&D

Richard Timbrell - Senior Design Engineer, R&D

Contribution

Richard Timbrell and Peter Guite conducted the investigation, analysis, and report documentation. Nick Bridgman assisted in review of analysis, documentation and wrote this summarised manuscript.

Contributing Partners (Acknowledged)

Prototal Group - Additive Manufacturing Partner

Gloucestershire Royal Hospital - Sterile Services Department

Executive Summary

Nylon PA2200 (Polyamide 12) is widely used in powder-bed additive manufacturing, notably Selective Laser Sintering (SLS) and Multi-Jet Fusion (MJF). For medical applications, such as reusable surgical guides, handling tools, and instrument bodies, the material's ability to withstand repeated cleaning and steam sterilisation is essential.

This study evaluates the geometric stability, tensile properties, and flexural properties of PA2200 printed via SLS, both as printed and after vapour smoothing, following 1, 2, 5, 10, 20, 50, and 100 cleaning + sterilisation cycles in an NHS hospital environment.

Key findings:

- Mechanical properties degraded to ~70% of original tensile strength and ~80% of flexural stiffness by 100 cycles, with most of the change occurring before 20 cycles.
- Geometric dimensions remained stable, with all changes falling inside nominal manufacturing tolerances.
- Vapour smoothing showed no statistically significant impact, positive or negative, on stability or degradation rate.

These results demonstrate that SLS PA2200 withstands up to 100 cleaning and steam sterilisation cycles while maintaining geometric stability within standard manufacturing tolerances.

A measurable reduction in mechanical properties occurs primarily within the first 20–30 cycles, after which performance trends stabilise. From a design perspective, this indicates that the material is suitable for reusable medical device applications, provided appropriate safety factors are applied to account for predictable mechanical degradation and potential dimensional drift in small internal features.

1. Introduction

Nylon PA2200 (polyamide-12) is a versatile additive manufacturing (AM) powder used across industrial, consumer, and medical sectors. In healthcare, additively manufactured nylon is increasingly used in both patient-specific and reusable devices due to its strength, chemical resistance, and design flexibility.

Two powder-based manufacturing methods dominate the use of PA2200:

- Selective Laser Sintering (SLS): A laser fuses powder into solid layers.
- Multi-Jet Fusion (MJF): Binder agents and infrared energy fuse layers uniformly.

Both methods can be further refined via vapour smoothing, a chemical process that melts and seals surface asperities, producing a smoother, less porous finish that is hypothesised to improve steam-sterilisation resilience.

This research was commissioned to support an ongoing internal project at Summit Medical, in which a reusable medical device (cement gun body) may be produced in PA2200. Because NHS equipment undergoes strict cleaning and steam sterilisation cycles, material performance after repeated exposure is critical.

This white paper summarises the testing conducted under an in-house design test protocol (DTP356) and provides a scientifically supported assessment of the suitability of SLS and vapour smoothed SLS PA2200 for repeated sterilisation.

2. Objectives

The study aimed to:

- Assess geometric stability of PA2200 (SLS) after repeated cleaning + steam sterilisation.
- Quantify tensile property changes across sterilisation cycles (ISO527-2).
- Quantify flexural property changes across sterilisation cycles (ISO178).
- Evaluate the effect of vapour smoothing on PA2200's ability to resist degradation.

3. Scope

The test does not validate any single product or regulated medical device. Instead, it evaluates PA2200 behaviour to inform risk reduction and design decisions for development projects, with findings applicable to additive manufactured components of similar material, thickness, and geometry.

4. Methods

4.1 Manufacturing

Prototal Group produced all SLS samples in PA2200, see Figure 1:

- ISO178 Flexural bars
- ISO527-2 Tensile bars
- A Vapour-smoothed versions as well

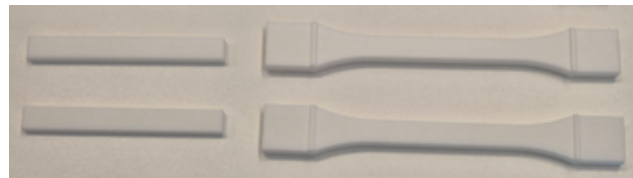


Figure 1 - Sample Bars Supplied from ProTotal

Each material/process combination provided 8 sample sets of 6 parts corresponding to sterilisation cycle counts labelled reprocessing cycle 0 (R0) to reprocessing cycle 100 (R100): R0, R1, R2, R5, R10, R20, R50, R100.

Rationale for 6 replicates followed guidance from the International Conference on Harmonisation (ICH) [1], Section 5.1 to achieve stable estimates of mean and variance.

4.2 Cleaning and Steam Sterilisation

Performed at Gloucestershire Royal Hospital Sterile Services Department using:

- Belimed WD290 washer–disinfectors
 - pH-neutral enzymatic detergent
 - Thermal disinfection $\geq 90^{\circ}\text{C}$ for 1 minute
 - RO-water
- Belimed HS2 autoclaves
 - $134\text{--}137^{\circ}\text{C}$
 - 3–3.5 minutes sterilisation hold

Parts were separated into labelled trays to maintain group integrity (see Figure 2). Third-party cycle confirmation reports were retained.



Figure 2 - Example Sample Segregation for Sterilisation Cycles, white coloured parts were for this investigation

4.3 Measurements and Testing

4.3.1 Geometry

Length & width: Keyence optical metrology

Thickness: Digital micrometer

Resolution:

Length/width: 2 decimal places

Thickness: 3 decimal places

4.3.2 Tensile Testing – conducted in accordance with BS EN ISO 527-2 [2].

- Tensometer with 5 kN load cell
- Pre-load: 2 N
- Speed: 0.5 mm/min
- Outputs:
 - Ultimate Tensile Strength (UTS)
 - Yield stress
 - Elongation at break

4.3.3 Flexural Testing – conducted in accordance with BS EN ISO 178 [3].

- 3-point bending
- Span: 64 mm
- Speed: 2 mm/min
 - Outputs:
 - Flexural modulus
 - Stress at 3-point loading (no samples fractured)

5. Results

5.1 Geometric Stability

No significant dimensional changes were observed in any SLS or VS SLS sample. Variations across all groups remained within standard additive manufacturing tolerances:

- ± 0.3 mm for features < 100 mm
- $\pm 3\%$ for features > 100 mm

Conclusion: 100 repeat cleaning and steam sterilisation cycles did not measurably distort part geometry.

5.2 Tensile Properties

Comparison of the average tensile properties between the SLS standard and vapour smoothed demonstrated a minor decrease in ultimate tensile strength and a minor increase of elongation, to that of the technical datasheet, see Table 1.

Table 1 - Average Baseline Values at R0 for Samples compared to the Datasheet

Material	UTS (MPa)	Elongation at break
SLS PA2200	44.7	25.40%
VS SLS PA2200	45.1	27.70%
Technical Datasheet	48	24%

Trends

- Ultimate Tensile Stress (UTS) unexpectedly increased slightly at R1, then declined.
- The largest rate of degradation occurred between R1 and R10, with ultimate tensile strength reducing by approximately 15 MPa over this interval.
- After R20, values stabilised.

UTS at R100

- **SLS:** 77.6% of R0
- **VS SLS:** 70.9% of R0

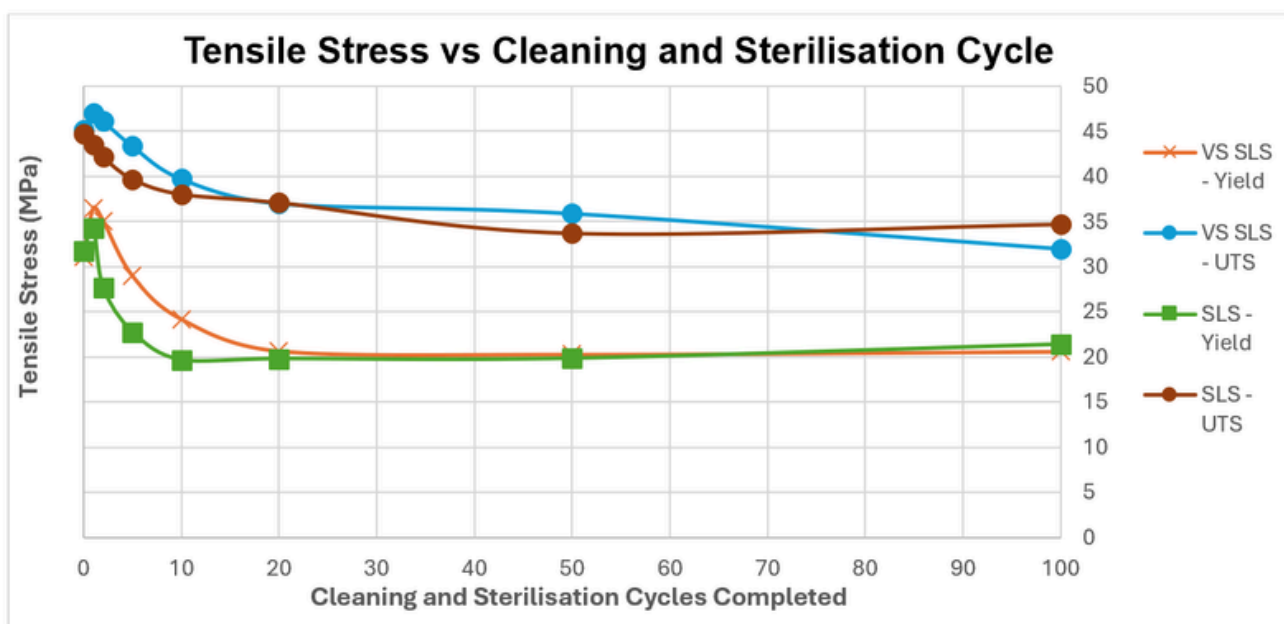


Figure 3 - Graph of Tensile Stress vs Cleaning and Sterilisation Cycle number showing yield stress and UTS for SLS and Vapour Smooth SLS samples

Statistical Analysis

One-way Analysis of Variance testing (ANOVA) revealed:

- Significant differences ($p < 0.05$) among R0–R10 for vapour smooth SLS.
- R20, R50, R100 were statistically indistinguishable (stable) at yield strength, see Figure 4.
- SLS showed progressive decrease but lacked significant separation between all groups.
- A single R2 outlier in standard SLS samples was identified and removed (suspected misalignment loading error).
- For standard SLS samples there is a progressive decrease in means but no statistical difference in the result grouping

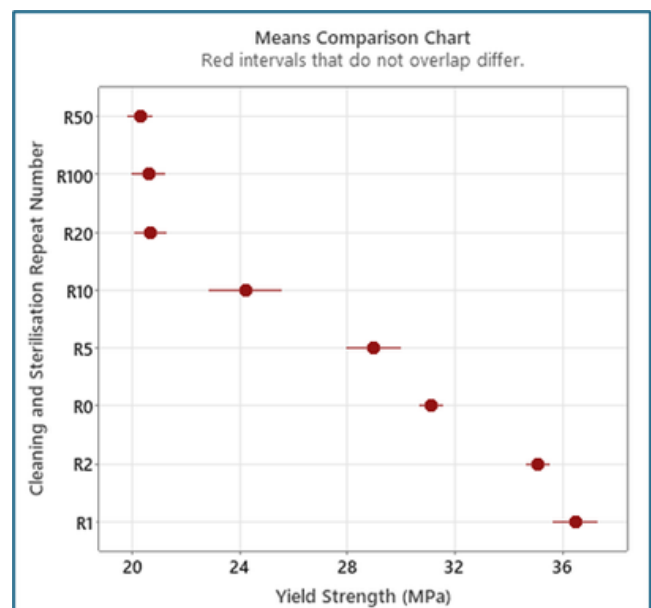
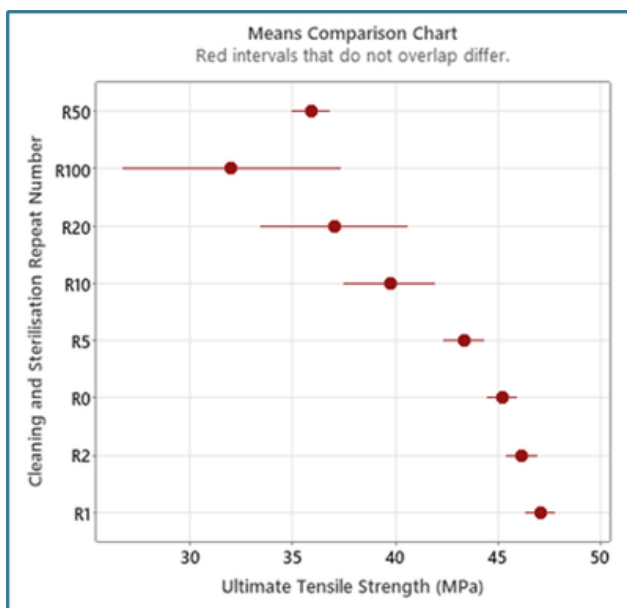


Figure 4 - Means Comparison charts for both UTS & Yield of vapour smoothed SLS as part of the ANOVA test

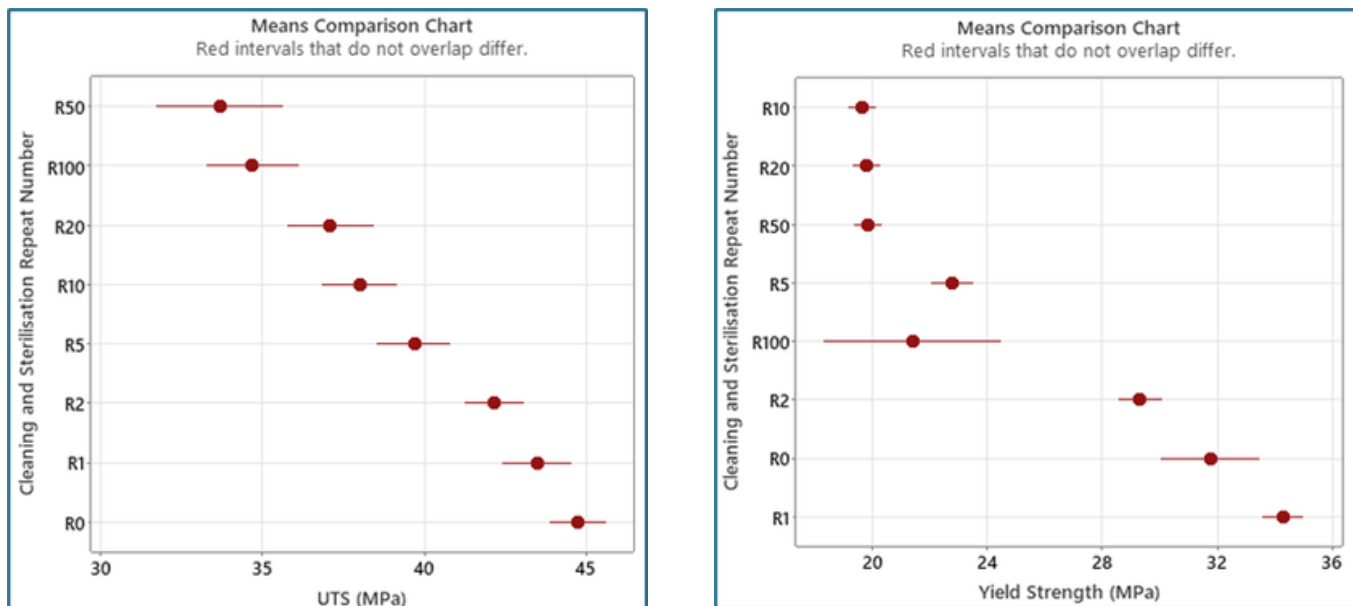


Figure 5 - Means Comparison charts for both UTS & Yield of standard SLS as part of the ANOVA test

Conclusion

Tensile strength decreases by ~30% after 100 cycles, with most loss by 10–20 cycles. Vapour smoothing did not significantly change this behaviour.

5.3 Flexural Properties

Baseline Flexural Modulus

- SLS: 1579 MPa (datasheet: 1500 MPa)
- VS SLS: 1596 MPa

At R100

- SLS: 82.7% of original modulus
- VS SLS: 84.7% of original modulus

Trend

Similar to tensile results:

- A decline was observed through first 20 cycles
- Results were seen to stabilise between R20 and R100
- One anomalous high R100 result was observed in the vapour smoothed SLS dataset, which contributed to the apparent increase in flexural modulus at this interval. As this behaviour was not observed across the wider dataset and is inconsistent with the overall degradation trend, it is considered an outlier potentially attributable to test variability or operator-related testing error rather than a material recovery effect.

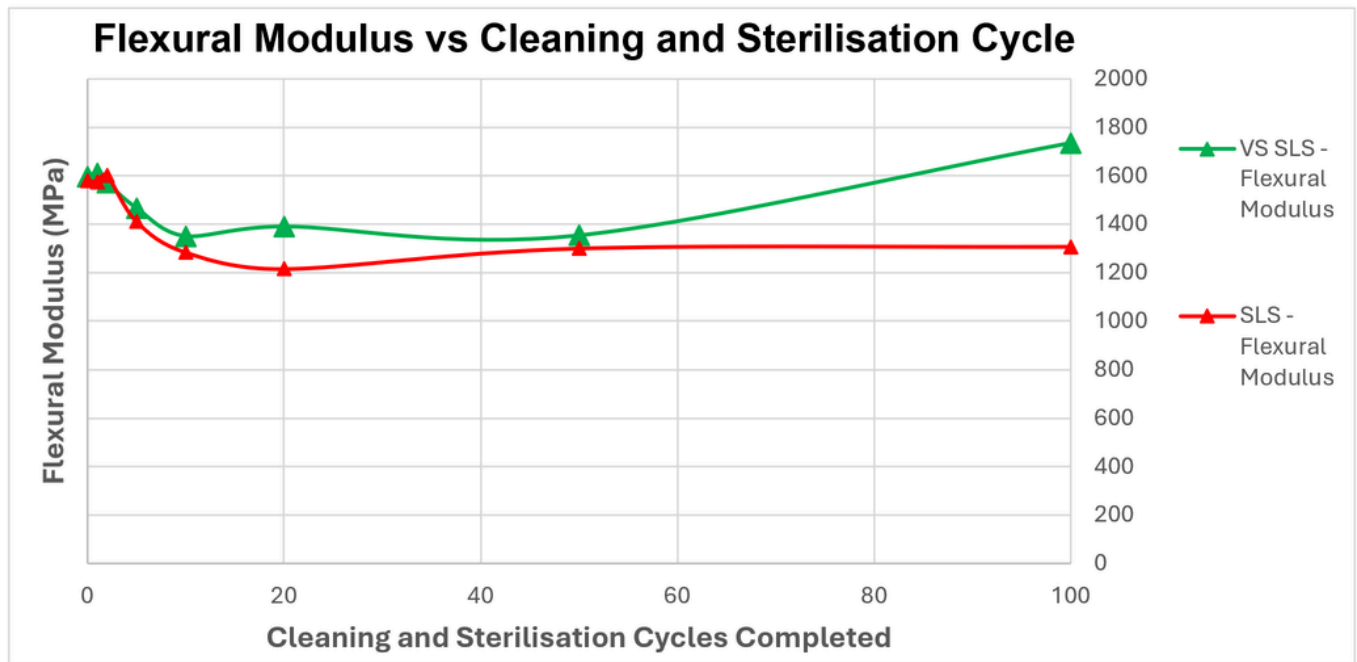


Figure 6 - Graph of Flexural Modulus (MPa) vs Cleaning and Sterilisation Cycle for SLS and VS SLS samples

Conclusion

Flexural stiffness decreased by ~15–20% after 100 cycles, with most loss by 10-20 cycles. Most of the reduction occurring within the first 10–20 cycles before stabilising. No meaningful difference in long-term flexural degradation behaviour was observed between standard SLS and vapour smoothed SLS samples.

6. Established Knowns

The PA2200 material exhibits predictable degradation under repeated cleaning and steam sterilisation:

- Surface heating, moisture ingress, and repeated crystallisation cycles are likely mechanisms driving property change.
- Geometric stability suggests macro-scale dimensional changes are negligible, but smaller internal features may expand, consistent with observations from other project activities.
- Vapour smoothing's lack of significant effect indicates that:
 - Surface sealing does not meaningfully protect against thermal–moisture cycles
 - Mechanical degradation is bulk-material driven, not surface-driven

From a design perspective:

- Loadbearing characteristics of components designed to be manufactured by SLS using PA2200 can be expected to degrade over the first 20 to 30 sterilisation cycles before stabilising.
- For components requiring long-term strength retention, alternative materials (e.g., glass-filled nylon, PEEK, or metal AM) may offer superior stability.

7. Investigation Conclusions

1. Mechanical properties (tensile and flexural) of PA2200 decrease by ~20–30% during 100x repeated cleaning and sterilisation cycles, stabilising after ~20 cycles.
2. Geometric dimensions remain within pre-specified tolerance after 100 cycles.
3. Vapour smoothing does not meaningfully change material response to 100x repeated cleaning and sterilisation cycles.
4. For reusable medical devices anticipated to require repeat steam sterilisation, PA2200 (SLS) is a suitable candidate material. A sufficient safety factor should be introduced to accommodate a reduction in mechanical performance over the product lifecycle.
5. This investigation reflects one representative NHS-compliant cleaning and steam sterilisation process using neutral enzymatic detergent and defined autoclave parameters. Further material testing, verification, and validation would be required to assess performance under alternative reprocessing conditions and prior to implementation within a finished regulated medical device.

8. Acknowledgments

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- **Prototal Group** for manufacturing SLS and MJF PA2200 samples.
- **Gloucestershire Royal Hospital Sterile Services Department** for conducting cleaning and steam sterilisation cycles and providing cycle verification.

Their collaboration was essential to completing this investigation.

9. Cited

- [1] INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH). November 2005. [*Validation of Analytical Procedures: Text and Methodology Q2 R1*](#).
- [2] BS EN ISO527-2. February 2012. Plastics — Determination of tensile properties — [*Part 2: Test conditions for moulding and extrusion plastics*](#)
- [3] BS EN ISO178. April 2019. [*Plastics — Determination of flexural properties*](#)

10. References

- BS EN ISO 15883. November 2018. [Cleaning equipment standards \(Washer–Disinfectors\)](#).
- Health Technical Memorandum (HTM01-01). [NHS England guidance for decontamination of surgical instruments](#)
- EOS - [PA2200 Material Technical Datasheet](#)
- Summit Medical Development Test Protocol DTP356, Issue 02
- Summit Medical Test Report TR1875, Issue 01

11. Disclaimer

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11. Revision History

Revision No#	Date	Change Description	Originator
1	Dec 12, 2025	First issue	Nick Bridgman

Protototal Group

3T Additive Manufacturing Polymers Ltd T/A Protototal UK
Unit 14, Fulton Court, Wofford Way,
Greenham Business Park
Newbury, Berkshire RG19 6HD
United Kingdom