TECHNICAL REPORT

Single Stitch Traction and Puncture Tests on Suturable Vessels' Presets

Stratasys – 3D4Med Joint Project

Tests' Description

Puncture tests were performed to measure the force required to pierce the target material with a suitable surgical needle. Uniaxial traction tests were performed on samples with a single stitch applied for **resistance to stitch** evaluation.

All the mechanical tests were performed through an MTS Insight Testing System® with a 250N load cell, an acquisition rate of 20Hz and a crosshead speed of 5mm/s. The development of the various components of the experimental set-up was based both on the available scientific literature [1-14] and on the ASTM F1342/F1324M-05 (2013) standard related to the resistance to penetration of materials for protective clothing [15]. All the components were designed on Autodesk Inventor® CAD software and 3D printed.

For the measure of the **puncture force**, cylindrical samples - 40 mm diameter and thickness of 1 mm - were produced and tested through the *ad hoc* experimental set-up. Rectangular samples (100x20x1 mm) were used for **single stitch** tests with a single stitch made approximately at 1,7 mm from the margin; the actual distance was then measured with a caliper and recorded.

To correctly perform the **puncture test** with the MTS Insight, it was necessary to use a rectilinear needle; a Trusilk USP 4/0 with a rectified 19mm cylindrical needle was selected. On the other hand, a Prolene 5/0 was used for **single stitch traction tests**. Further information about the tests' technical aspects and set-up can be found in the whitepaper "*Quantitative Assessment of 3D Printed Blood Vessels Produced with J750™ Digital Anatomy™ for Suture Simulation*" (2022) [16].

Suture presets were tested in both Medium (MS) and High Strength (HS) configurations on the J5 Digital Anatomy (DA) printer, replacing the Agilus30™ [17] with Elastico™ Clear [18]. Presets' composition is reported in Table 1. Sample configuration for the two tests is reported in Figure 1.

Code	*Suturable Vessel Wall Preset*	*Sample Thickness*	*Coating*		*Infill*	
Clear – HS | J5 DA	High Strength	1mm	0,2mm	85% Elastico™ Clear 15% VeroPure White	0,6mm	65% Elastico™ Clear 35% Tissue Matrix
Clear – MS | J5 DA	Medium Strength	1mm	0,2mm	92% Elastico™ Clear 8% Bone Matrix	0,6mm	65% Elastico™ Clear 35% Tissue Matrix
Clear – HS | J750 DA	High Strength	1mm	0,2mm	85% Agilus 30™ Clear 15% VeroPure White	0,6mm	65% Agilus Clear 30™ 35% Tissue Matrix
Clear – MS | J750 DA	Medium Strength	1mm	0,2mm	92% Agilus Clear 30™ 8% Bone Matrix	0,6mm	65% Agilus Clear 30™ 35% Tissue Matrix

***Table 1**: Suturable vessel wall presets composition on the different 3D printing machines.*

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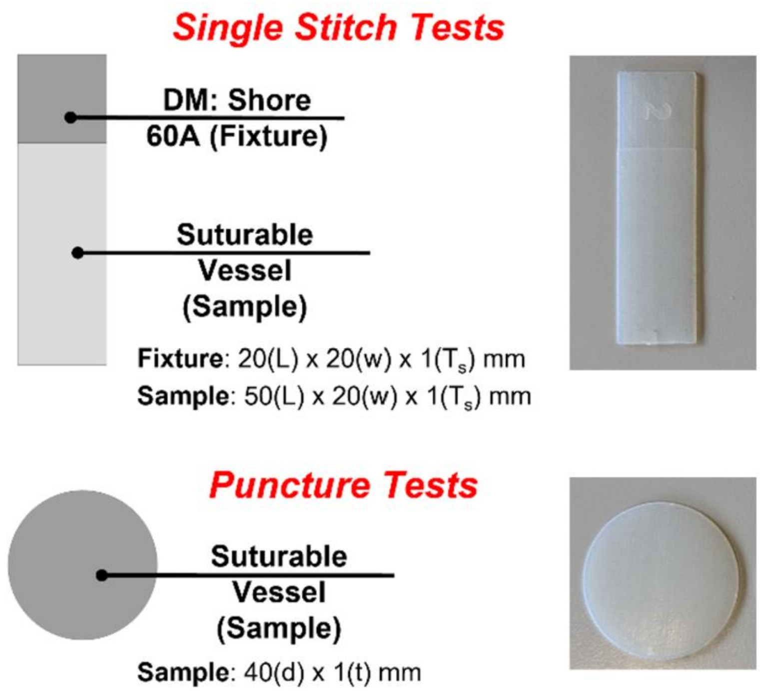

Figure 1: *Tested samples for single stitch (UP) and puncture (DOWN) tests.*

Samples were produced at Stratasys premises (Rehovot, Israel) on 31/03/2024 and shipped to our laboratory (Protolab, Department of Civil Engineering and Architecture, University of Pavia) where the support structure was removed and they were cleaned and finished for the testing on 03/04/2024, always following the protocol reported in [16]. Tests took place on 05/04/2024, thus ensuring at least 12h of drying after the cleaning and finishing.

Results

A total of 2 material combinations (Clear HS and Clear MS) were tested both for puncture and single stitch tests. For each material combination 10 samples were analyzed, for a total of 40 mechanical tests.

Results from puncture and single-stitch tests are here presented in terms of the following parameters:

- Ultimate Stress $\left[\frac{\mathrm{N}}{\mathrm{mm}^2}\right] = \frac{Peak\ Force\ [N]}{n * T_f[mm] * T_S[mm]}$

  The peak force acquired during the single-stitch test divided by the surface of the filament in contact with the material. Given the low thickness of the filament used – 0,13 mm – the surface was simplified into a rectangular area computed as the thickness of the filament (T_f) multiplied by thickness of the sample (T_s). n is the number of stitches here equal to 1.

- Normalized Max Displacement $\left[\frac{1}{\mathrm{mm}}\right] = \frac{Displacement\ [mm]}{D_b[mm] * T_S[mm]}$

The maximum displacement acquired during the single-stitch test divided by the distance of the stitch from the border (D_b) and the thickness of the sample (T_s).

- Unit Peak Force $\left[\frac{\mathrm{N}}{\mathrm{mm}}\right] = \frac{Peak\ Force\ [N]}{T_s[mm]}$

  The peak force acquired during the puncture test divided by the thickness of the sample.

These parameters are computed with the aim of making the result of each test independent from the features of the specific sample.
Further information about the selected parameters can be found in [16].

Single Stitch Traction Tests

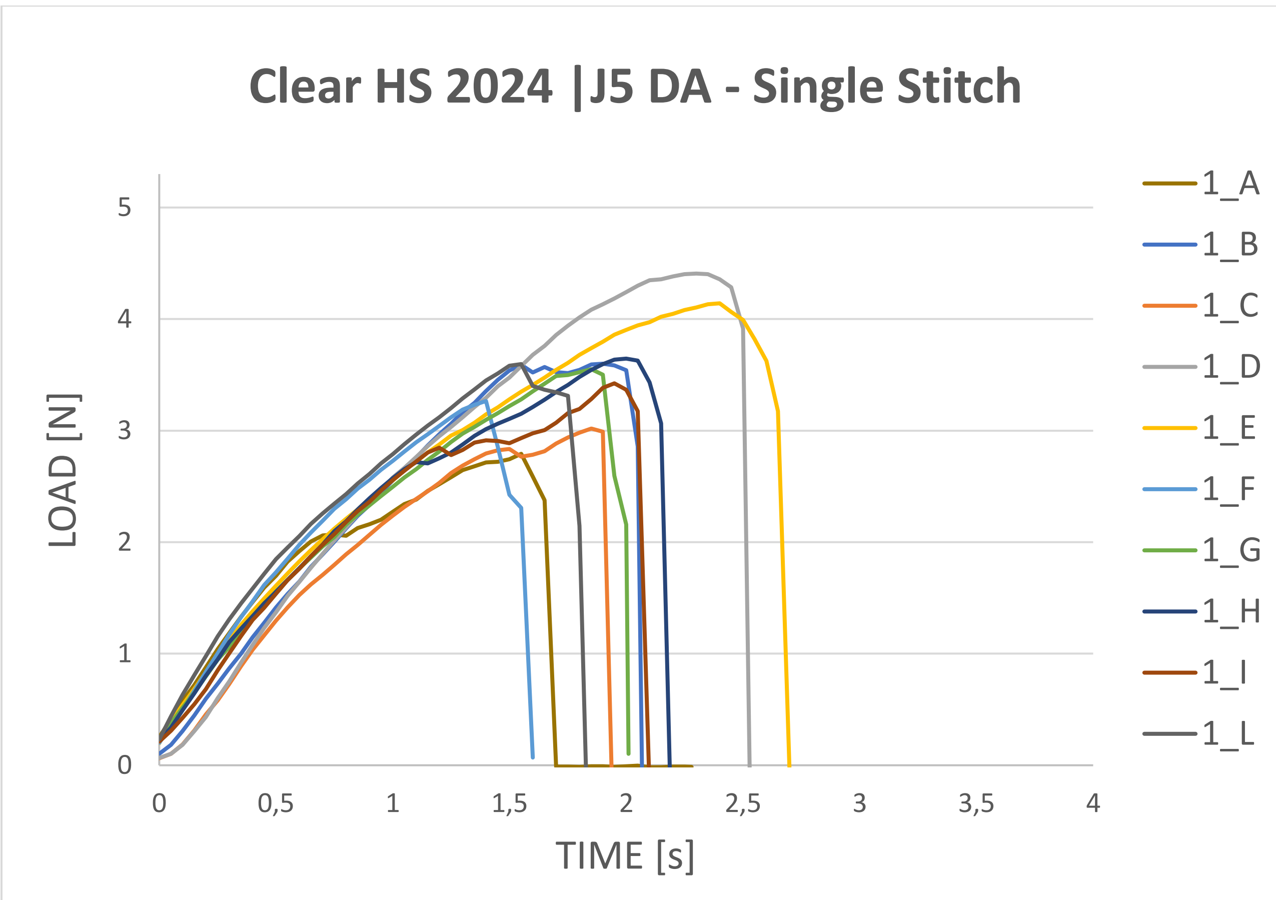

***Figure 2**: Results of single stitch traction tests on the 10 Elastico^{TM} Clear High Strength Suture Preset samples.*

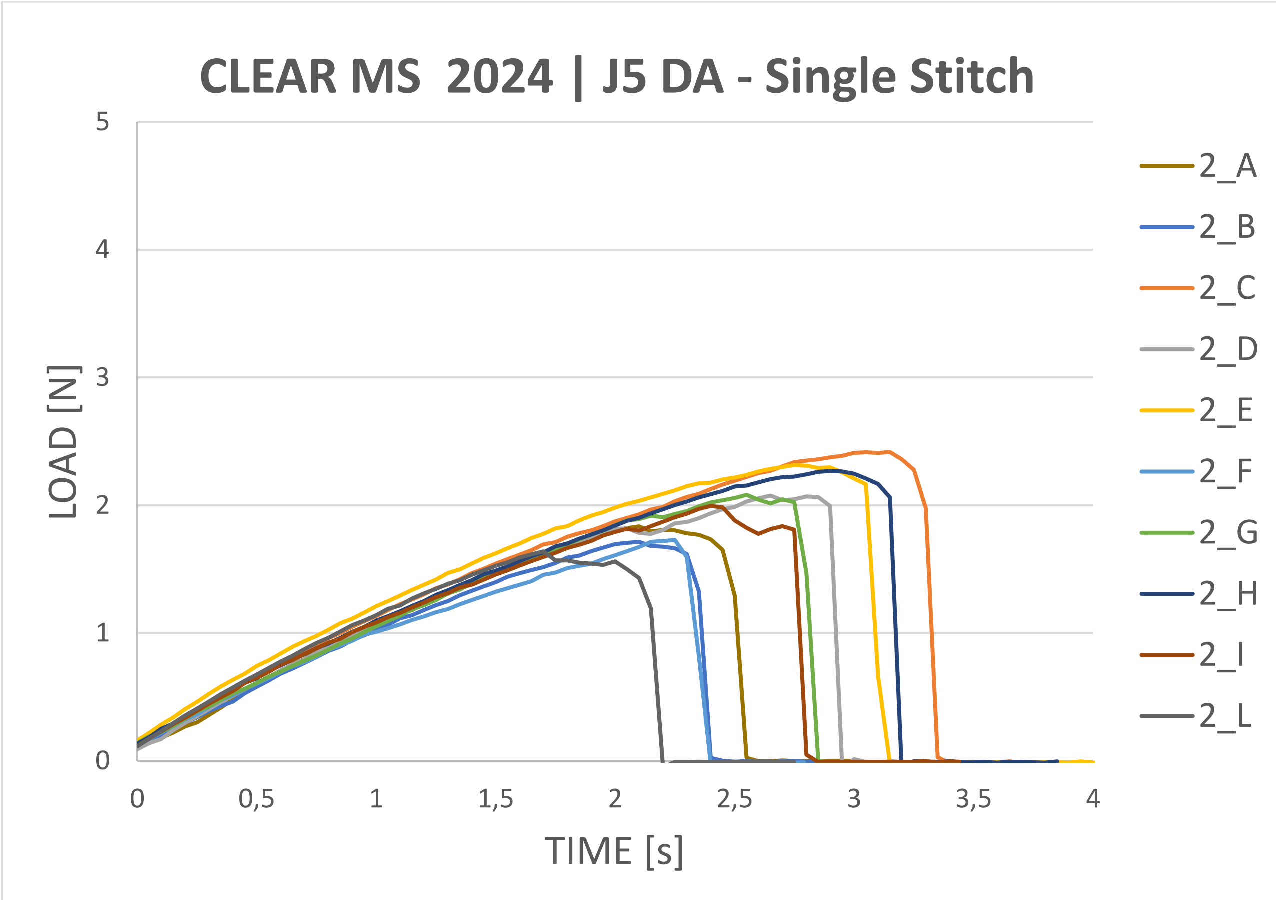

Figure 3*: Results of single stitch traction tests on the 10 Elastico™ Clear Medium Strength Suture Preset samples.*

		Peak Force [N]	Ultimate Stress [N/mm^2]	Max Displacement [mm]	Max Displacement Norm [1/mm]
CLEAR HS 2024 | J5 DA	**MEAN**	3,54	27,26	10,53	6,26
	SD	0,48	3,67	1,81	1,22
	RSD%	13,48%	13,48%	17,22%	19,46%
CLEAR MS 2024 | J5 DA	**MEAN**	2,01	15,44	16,96	9,82
	SD	0,27	2,10	2,71	1,73
	RSD%	13,60%	13,60%	16,00%	17,58%

Table 2*: Single stitch traction test results. Here "Peak Force" refers to the highest value of force registered during the test and "Max Displacement" is the highest displacement register before rupture, not normalized.*

Puncture Tests

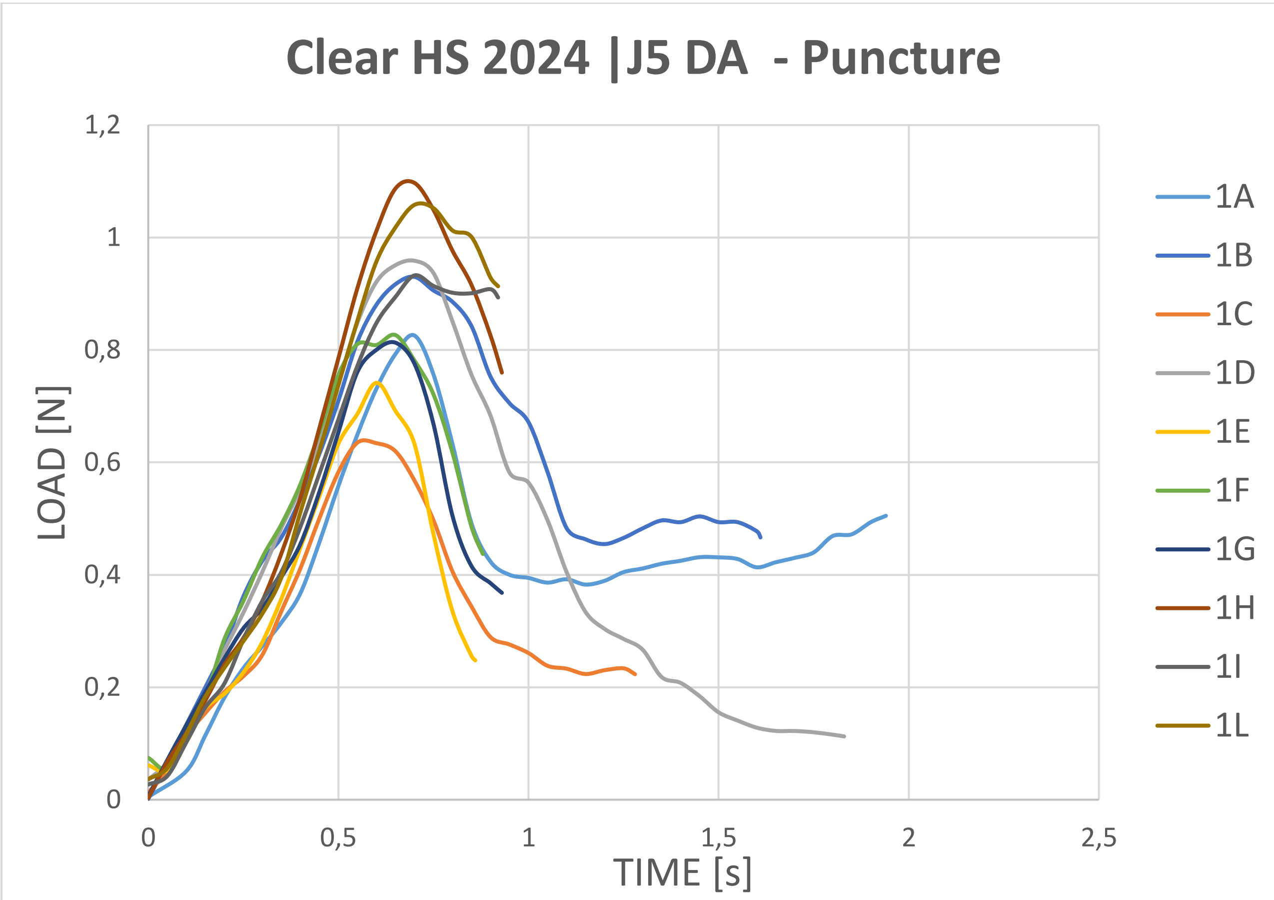

Figure 3: *Results of puncture tests on the 10 Elastico™ Clear High Strength Suture Preset samples.*

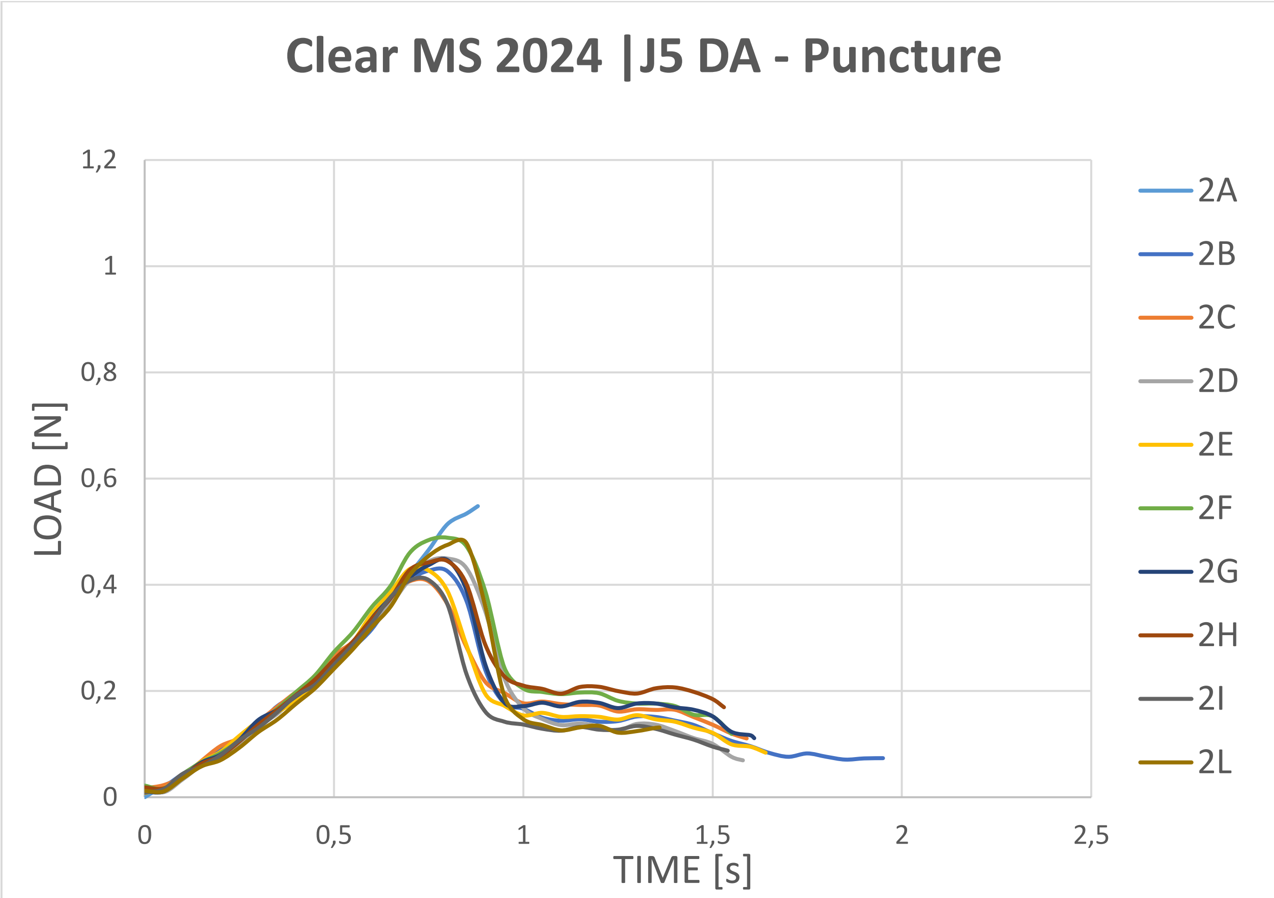

***Figure 4**: Results of puncture tests on the 10 Elastico™ Clear Medium Strength Suture Preset samples.*

		Unit Peak Force [N/mm]
CLEAR HS 2024 | J5 DA	**MEAN**	0,88
	SD	0,14
	RSD%	16,02%
CLEAR MS 2024 | J5 DA	**MEAN**	0,45
	SD	0,04
	RSD%	9,43%

***Table 3**:Puncture test results.*

Overall Results

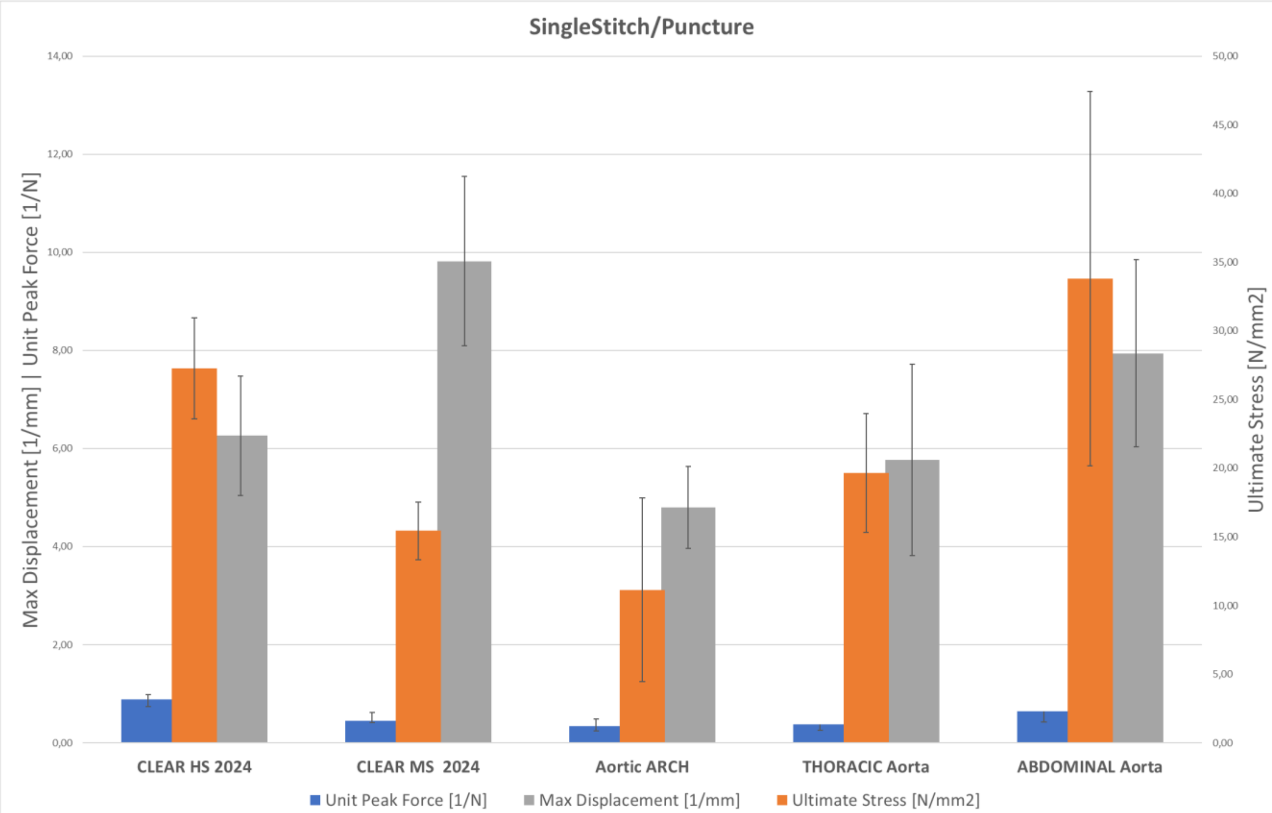

Figure 5*: Overall results of single stitch traction and puncture tests on the 10 Elastico^{TM} Clear High and Medium Strength Suture Preset samples, compared to biological reference values.*

	#Samples	Unit Peak Force [1/N]		Ultimate Stress [N/mm^2]		Max Displacement [1/mm]	
		Mean	STD	Mean	STD	Mean	STD
CLEAR HS 2024 | J5 DA	**10**	0,88	0,14	27,26	3,67	6,26	1,22
CLEAR MS 2024 | J5 DA	**10**	0,45	0,04	15,44	2,10	9,82	1,73
Aortic ARCH	**4**	0,34	0,10	11,14	6,68	4,80	0,84
THORACIC Aorta	**6**	0,38	0,12	19,65	4,33	5,77	1,95
ABNOMINAL Aorta	**5**	0,64	0,22	33,79	13,63	7,94	1,91

Table 4*: Overall results of single stitch traction (10 samples) and puncture (10 samples) tests on the Elastico^{TM} Clear High and Medium Strength Suture Preset samples, compared to biological reference values.*

Comparison with previous presets

In the following, the results obtained for the two presets printed on the J5 DA using Elastico™ are compared with the already tested variants of the same presets. In particular, the following notation will be used:

- CLEAR HS/MS 2021: Results of the tests on the two presets using Agilus30™ Clear and reported in [16]. The specific preset is reported in Table 1 (Clear – HS/MS | J750 DA). Samples are printed with a J750 DA printer.

- CLEAR HS/MS 2023: Results of the tests on the two presets using Agilus30™ and reported in the Technical Report on the comparison of the two suture presets using Agilus30™ Clear, White and Magenta. The specific preset is reported in Table 1 (Clear – HS/MS | J750 DA). Samples are printed with a J750 DA printer.

- CLEAR HS/MS 2024: Results of the tests on the two presets using Elastico™. The specific preset is reported in Table 1 (Clear – HS/MS | J5 DA). Samples are printed with a J5 DA printer.

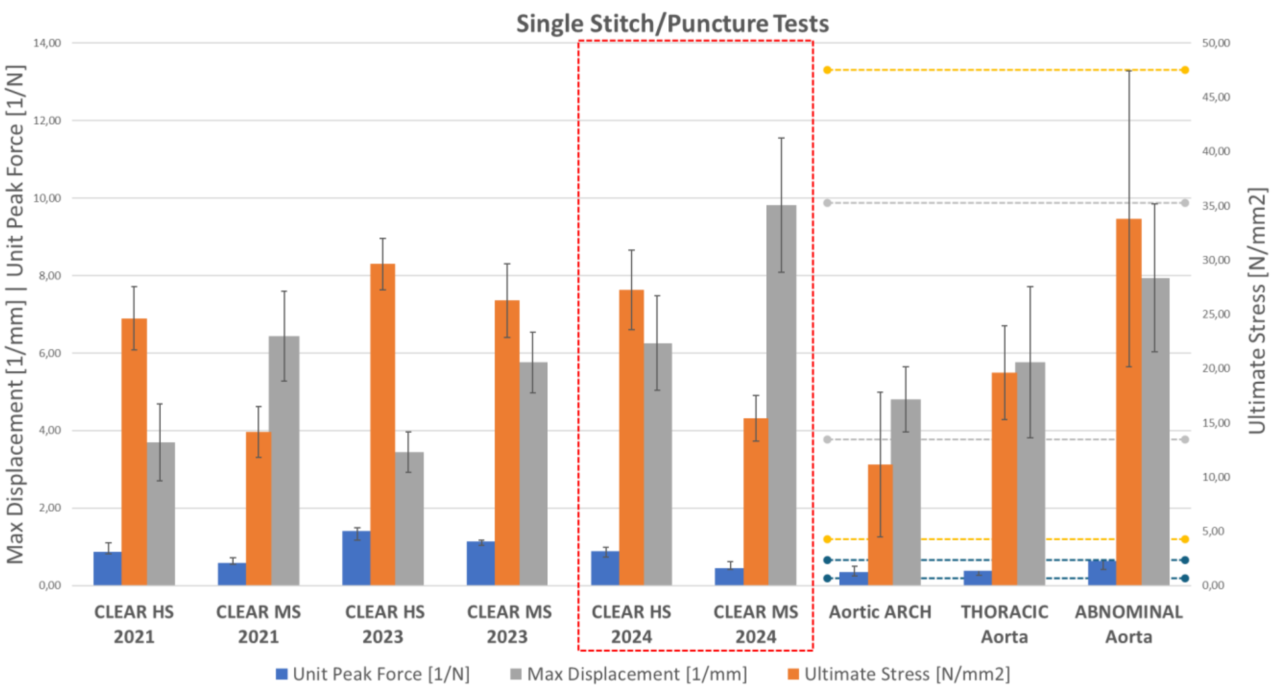

***Figure 6**: Overall results of single stitch traction and puncture tests on the Clear High and Medium Strength Suture Preset samples, compared to biological reference values. Presets using Elastico™ are highlighted in the red dotted box. Horizontal dotted lines identify the intervals of the biological values for the 3 parameters respectively.*

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	#Samples	Unit Peak Force [1/N]		Ultimate Stress [N/mm^2]		Max Displacement [1/mm]	
		Mean	STD	Mean	STD	Mean	STD
CLEAR HS 2021 | J750 DA	**10**	0,87	0,06	24,64	2,92	3,69	0,99
CLEAR HS 2023 | J750 DA	**6**	1,41	0,23	29,64	2,38	3,44	0,52
CLEAR HS 2024 | J5 DA	**10**	0,88	0,14	27,26	3,67	6,26	1,22
CLEAR MS 2021 | J750 DA	**10**	0,58	0,03	14,15	2,35	6,43	1,16
CLEAR MS 2023 | J750 DA	**6**	1,13	0,09	26,26	3,41	5,76	0,78
CLEAR MS 2024 | J5 DA	**10**	0,45	0,04	15,44	2,10	9,82	1,73
Aortic ARCH	**4**	0,34	0,10	11,14	6,68	4,80	0,84
THORACIC Aorta	**6**	0,38	0,12	19,65	4,33	5,77	1,95
ABNOMINAL Aorta	**5**	0,64	0,22	33,79	13,63	7,94	1,91

***Table 5**: Overall results of single stitch traction and puncture tests on the Clear High and Medium Strength Suture Preset samples, compared to biological reference values*

The comparison reported in Figure 6 and Table 5 show the presets printed on the J5 DA replacing Agilus30™ with Elastico™ keep the same trend of the previous presets. In particular, the higher Ultimate Stress and Unit Peak Force of the HS preset with respect to the MS and the higher Normalized Maximum Displacement of the MS with respect to the HS.

The values are still comparable with the biological reference. It can be noted how the values of the Unit Peak Force are slightly over the biological interval for HS preset, as happened also in the previous tests. Ultimate Stress perfectly fits the biological range, while Normalized Maximum Displacement goes a little over the biological boundaries. This happens exclusively in the MS preset printed with Elastico™ (CLEAR MS 2024).

This behavior can be explained by the higher elongation at break the Elastico™ [18] features with respect to the Agilus30™ [17]. In fact, the MS preset has a higher percentage of Elastico™ in the coating (92%) with respect to HS preset (85%), thus resulting in an overall higher Normalized Maximum Displacement. Notably, the higher shore of Elastico™ with respect to the Agilus30™ has no evident impact on the Unit Peak force, which is even reduced in MS.

Anatomy Printing and Surgical Simulation

In order to compare the performance of suture presets made with Elastico™ against previous results obtained with Agilus30™, we repeated the surgical simulation as described in [16]. This study focused on kidney transplantation, particularly the anastomosis between donor renal arteries and veins and the recipient's iliac vessels. A specialized 3D printed simulation platform for kidney transplantation [19] was utilized, incorporating anatomical structures reconstructed from CT images of average adult patients to closely replicate the pelvic area's morphology.

Two sets of removable parts, including the recipient's right iliac vessels and the donor renal artery and vein, were printed using the MS Suturable Preset. The recipient vessels were attached via sealing tube-connectors to the simulator's respective fixed proximal and distal vascular segments, while the donor vessels were connected to the kidney parenchyma, accurately simulating the transplantation procedure.

All models were thoroughly cleaned of support material. Gel Support was used as inner support for the vessel lumens, except for the renal arteries and veins, where lite support was employed. The vascular models did not rupture, and only slight tearing of the kidney parenchyma occurred during the removal of the inner support. The cleaning protocol followed was as per [16].

An expert surgeon performed the anastomosis of the recipient and donor vessels using a non-absorbable polypropylene/polyethylene 5/0 monofilament with a 3/8 18mm cylindrical needle [16]. The steps are summarized in the following.

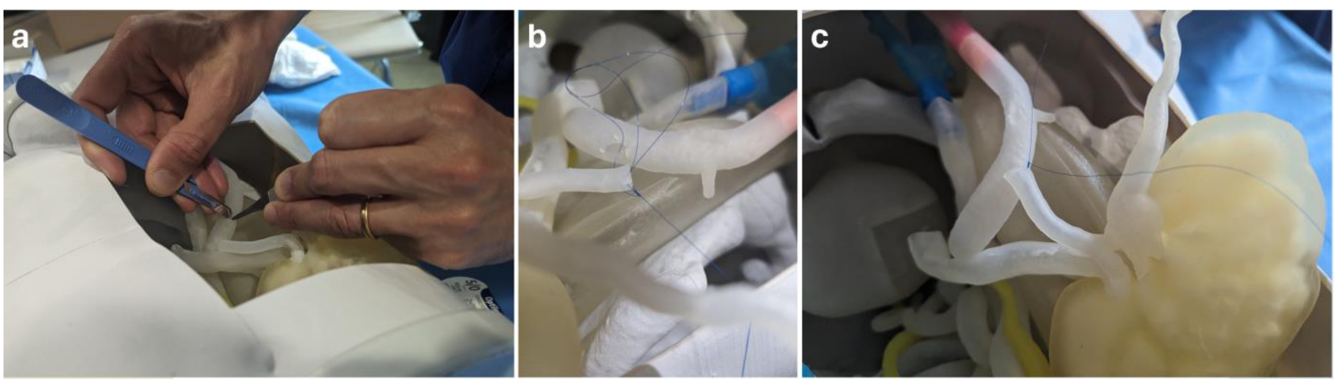

***Figure** 7: Steps of the arterial anastomosis. Opening of the iliac artery (a) and performing the first connection stitch between iliac artery and renal artery (b-c), to then approach the circular suture.*

- Opening of the Iliac Artery (Figure 7a):
  The surgeon begins by making an incision in the recipient's iliac artery. This is a critical step to prepare the site for the connection to the donor renal artery.

- Performing the First Connection Stitch (Figure 7b-c):
  The surgeon places the initial suture to connect the donor renal artery to the recipient's iliac artery. This first stitch anchors the two vessels together, ensuring they are aligned correctly for the subsequent suturing process.

- Approaching the Circular Suture:
  After securing the initial connection, the surgeon proceeds to complete the anastomosis by stitching around the circumference of the arterial opening. This circular suturing technique ensures a secure and leak-proof connection between the donor renal artery and the recipient's iliac artery, facilitating proper blood flow post-transplantation.

As observed during the previous tests, the first stitch is confirmed to be the most critical (Figure 7), as it must withstand all the mechanical stresses. Once the initial stitches are made, the load begins to distribute over a wider surface, allowing the circular stitch to be effectively completed without any additional failures (Figure 8).

Conversely, during the tests performed in [16], several stitch failures were reported. This discrepancy highlights the improved performance and reliability of the suturing process in the current study.

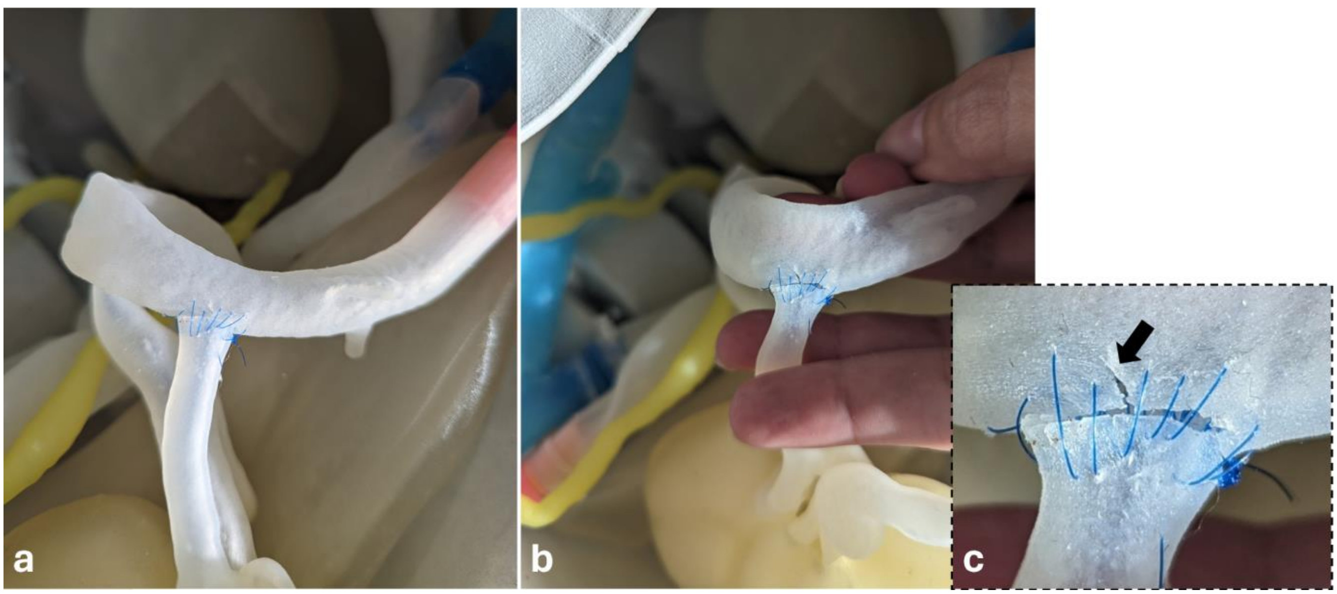

Figure 8*: Final result of the arterial anastomosis without applying any traction of the suture (a) and manually pulling apart the two vascular tracts (b. Upon traction, the arrow in (c) highlights the iliac vessel rupture due to the initial opening with a surgical knife, which is not affecting the surrounding stitches.*

Conclusions

The Suturable Presets made by replacing Agilus^{TM} with Elastico^{TM} remain consistent with the biological reference: Ultimate Stress in the single-stitch traction test perfectly aligns with the biological range, while Unit Peak Force in the puncture test and Normalized Maximum Displacement in the single-stitch traction test slightly exceed the biological boundaries. Compared to the previous tests on the Suturable Presets, the most notable difference is in the values of Normalized Maximum Displacement in the single-stitch traction test. This difference is attributed to the higher elongation at break exhibited by Elastico^{TM} [18] compared to Agilus30^{TM} [17]. Anatomical prototyping confirmed the favorable behavior of the material mixture during cleaning and finishing. The surgical simulation with vascular anastomosis validated the mechanical test results, demonstrating the material's enhanced ability to withstand suturing, with improved qualitative results with respect to the previously tested Suturable Presets. This improvement can be attributed to the higher elongation at break of Elastico™ compared to Agilus30™.

In conclusion, replacing Agilus30™ with Elastico™ enhanced the performance of the Suturable Vessel Wall Presets. Additionally, as with the Agilus-based presets, a subtle coating with latex may further contribute to achieving a more realistic behavior.

Credits

This technical report has been produced thanks to the contribution of the following professionals.

- Samples and models preparation: Leonardo Montaldo, Stefano Serioli
- Mechanical testing and data analysis: Beatrice Rossetti, Gianluca Alaimo PhD
- Surgical Testing: Luigi Pugliese (MD), Valeria Mauri, Mariagrazia Zaccara, Giacomo Zanellati
- Supervisors: Prof. Ferdinando Auricchio, Prof. Andrea Pietrabissa (MD)
- Project management and reporting: Stefania Marconi, PhD

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