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. On the other hand, 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).

Different Agilus-based materials – namely Agilus 30 Clear, AgilusWhite and AgilusMagenta – were tested in both medium (MS) and high strength (HS) configurations.

Code	*Preset*	*Thickness*	*Coating*		*Infill*	
AgClear - MS	Medium Strength	1mm	0,2mm	92% Agilus Clear 8% Bone Matrix	0,6mm	65% Agilus Clear 35% Tissue Matrix
AgClear - HS	High Strength	1mm	0,2mm	85% Agilus Clear 15% VeroPure White	0,6mm	65% Agilus Clear 35% Tissue Matrix
AgWhite - MS	Medium Strength	1mm	0,2mm	92% Agilus White 8% Bone Matrix	0,6mm	65% Agilus White 35% Tissue Matrix
AgWhite - HS	High Strength	1mm	0,2mm	85% Agilus White 15% VeroPure White	0,6mm	65% Agilus White 35% Tissue Matrix
AgMagenta - MS	Medium Strength	1mm	0,2mm	92% Agilus Mgn 8% Bone Matrix	0,6mm	65% Agilus Mgn 35% Tissue Matrix
AgMagenta - HS	High Strength	1mm	0,2mm	85% Agilus Mgn 15% VeroPure White	0,6mm	65% Agilus Mgn 35% Tissue Matrix

***Table 1**: Tested samples' composition and features.*

Fondazione IRCSS Policlinico San Matteo
Padiglione DEA
Strada Privata Campeggi, 40
27100 Pavia, Italy

Mail: info@3d4med.eu
Website: www.3d4med.eu
Phone: +39 0382.503276

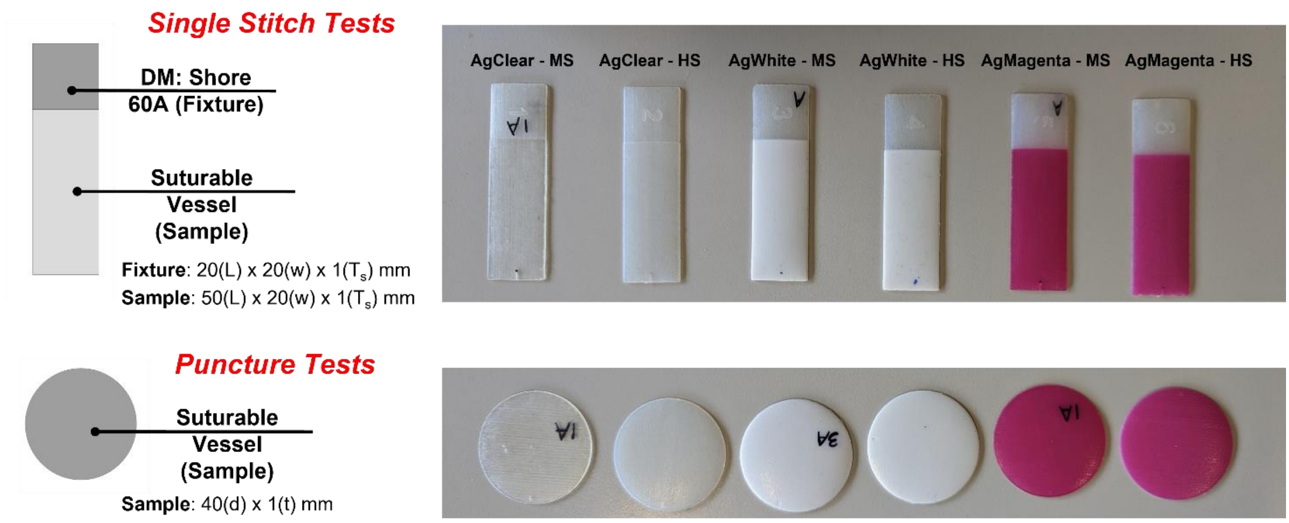


***Figure 1**: Tested samples for single stitch (UP) and puncture (DOWN) tests.*

Results

A total of 6 material combination were tested both for puncture and single stitch tests. For each material combination 6 samples were analyzed, for a total of 72 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 highest displacement 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).

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

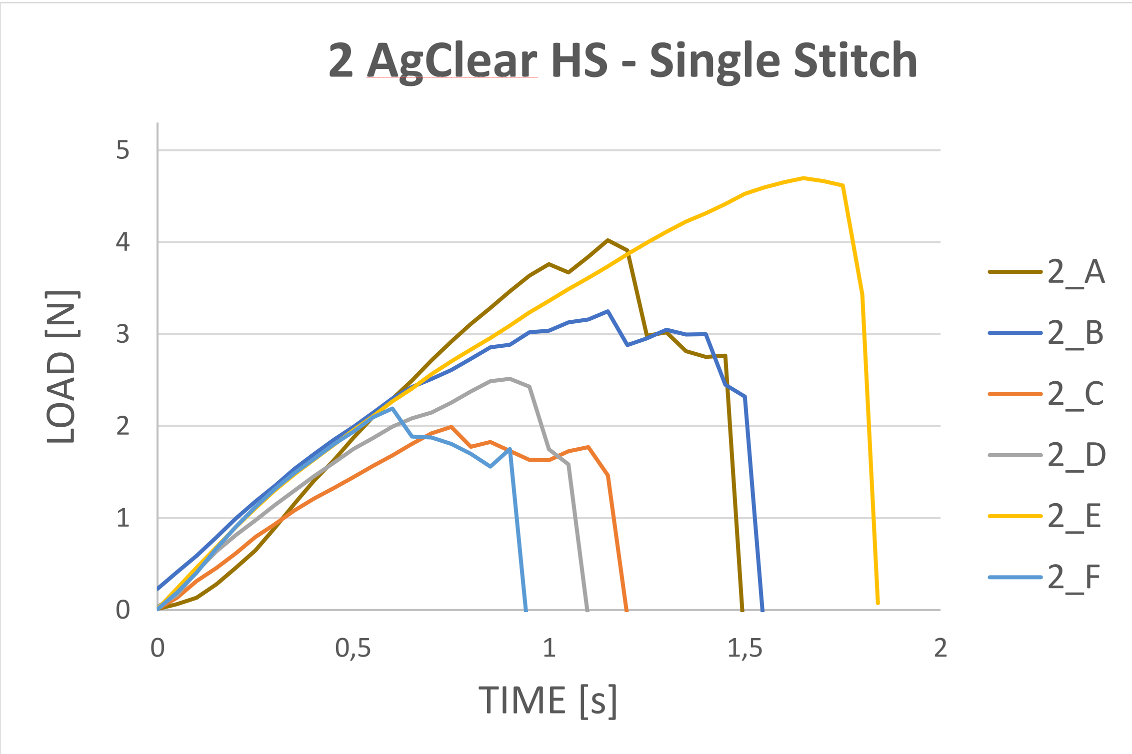
  The highest displacement acquired during the single-stitch test divided by the product of the distance of the stitch from the border (D_b) and the thickness of the sample (T_s).

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

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

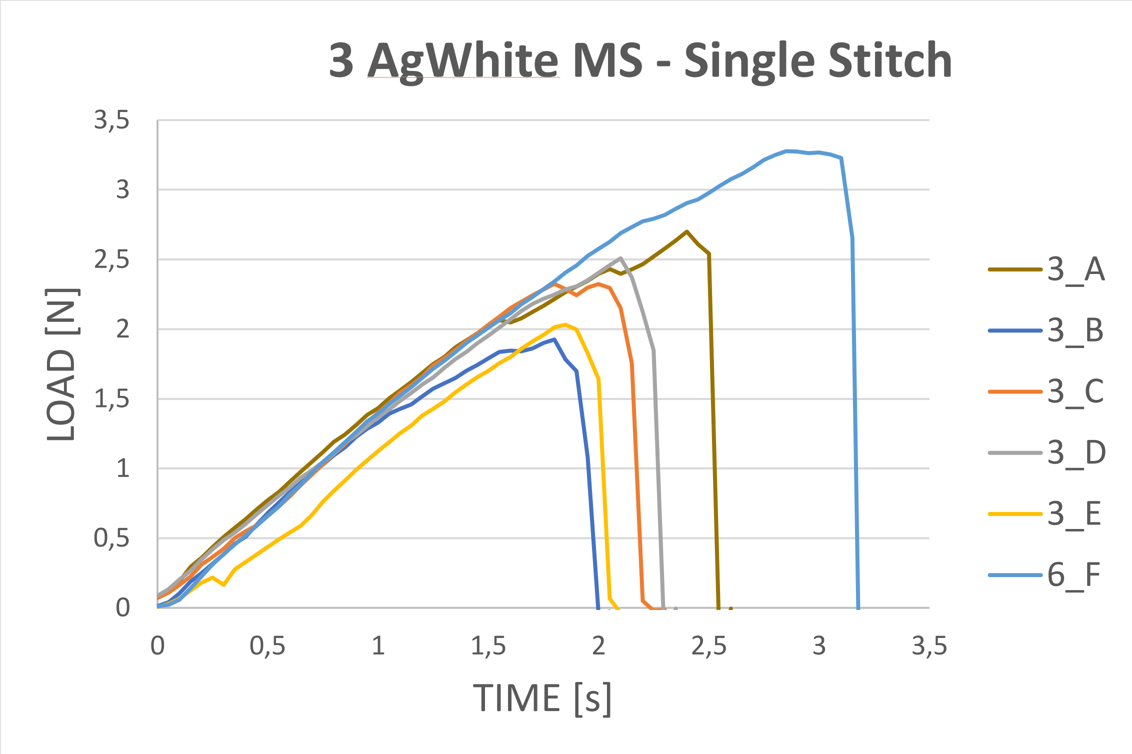
These parameters are computed with the aim of making the result of each test independent from the features of the specific sample.
Further information about the selected parameters can be found in the whitepaper "*Quantitative Assessment of 3D Printed Blood Vessels Produced with J750^{TM} Digital Anatomy^{TM} for Suture Simulation*" (2022).

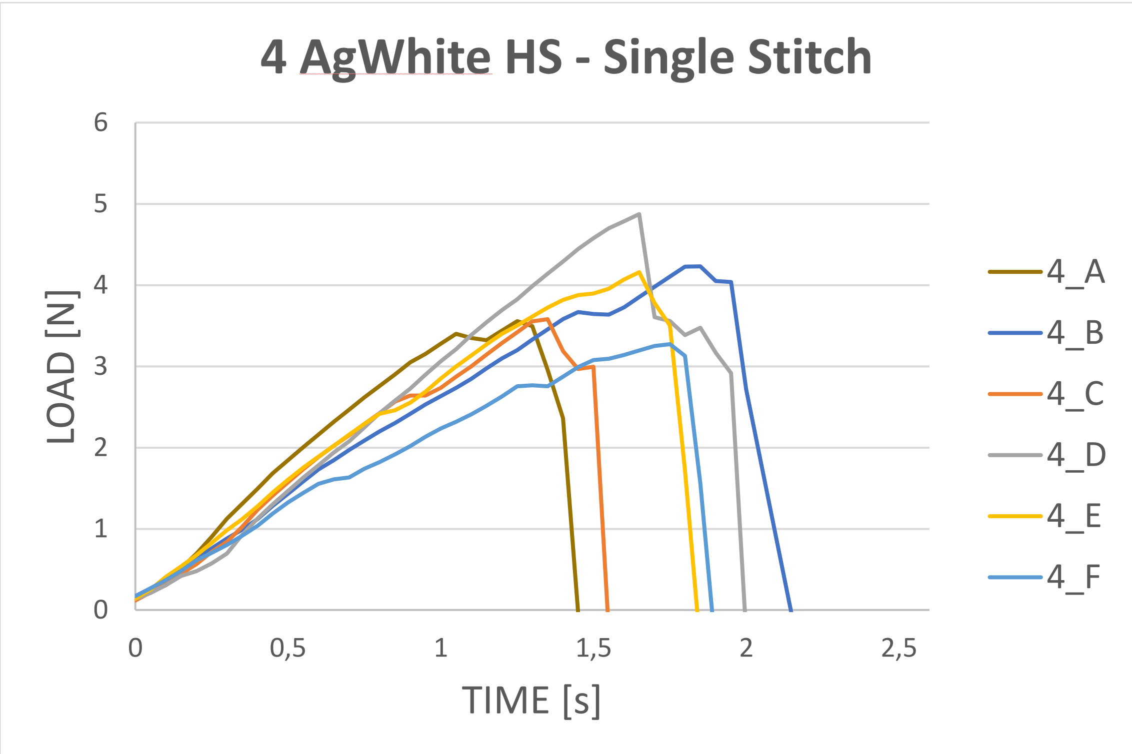
Single Stitch Traction Tests



Fondazione IRCSS Policlinico San Matteo
Padiglione DEA
Strada Privata Campeggi, 40
27100 Pavia, Italy

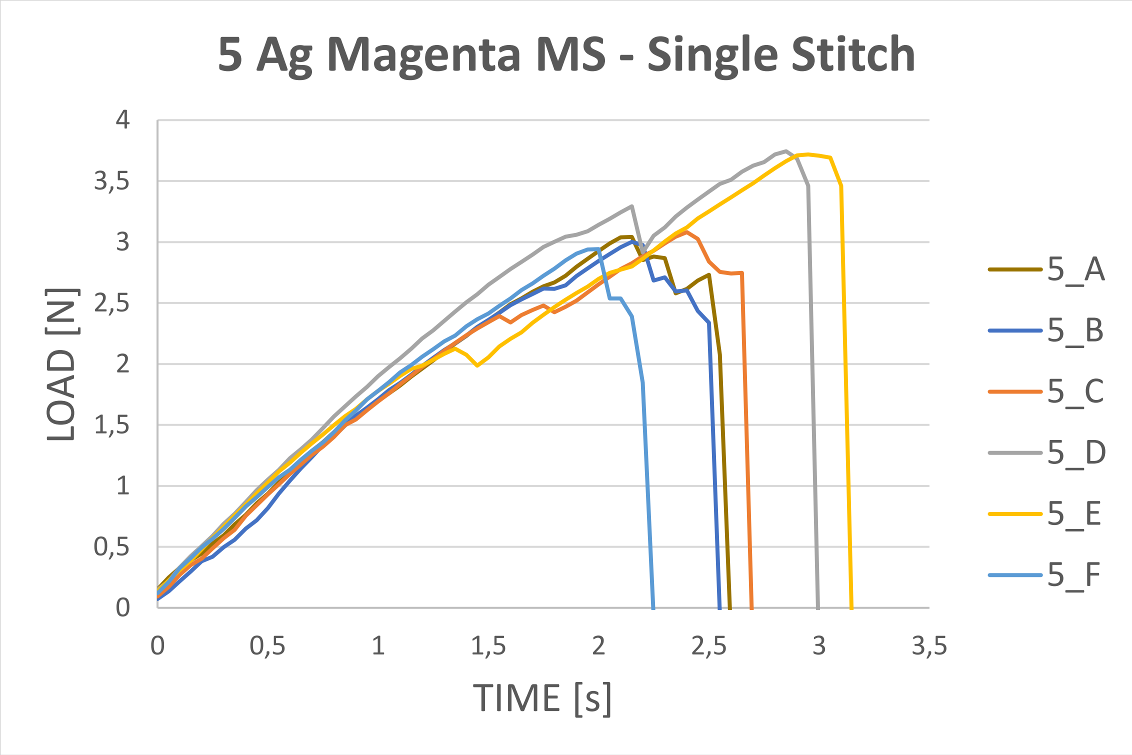
Mail: info@3d4med.eu
Website: www.3d4med.eu
Phone: +39 0382.503276

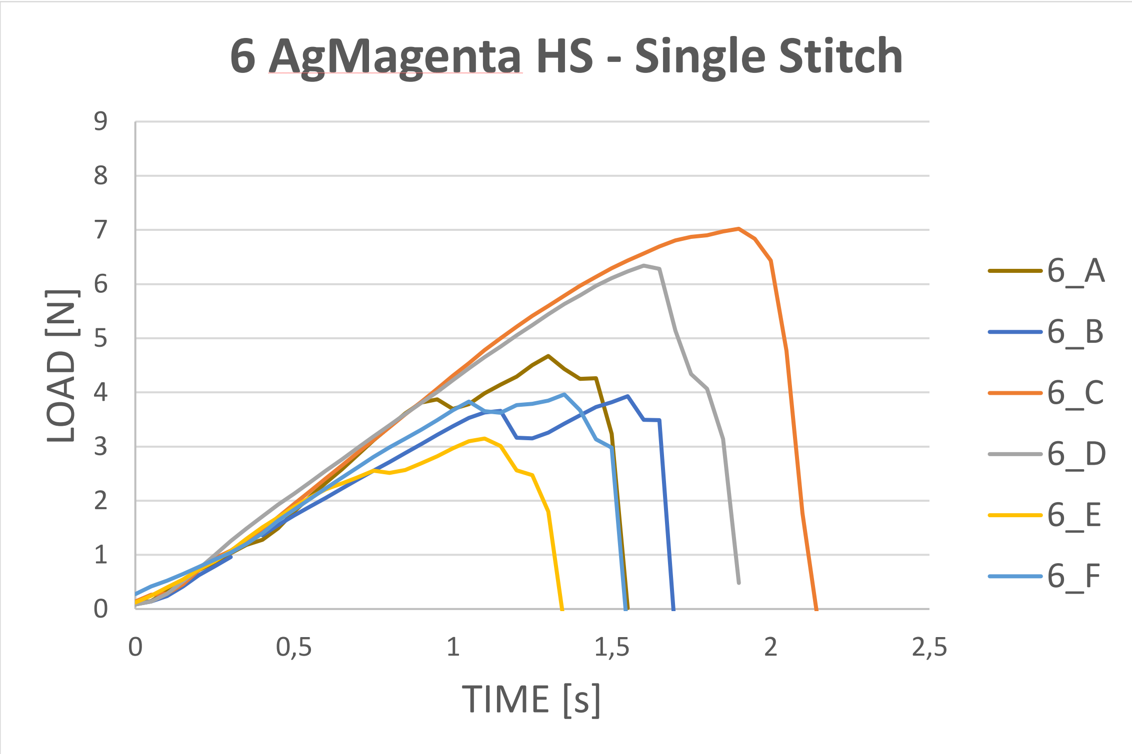




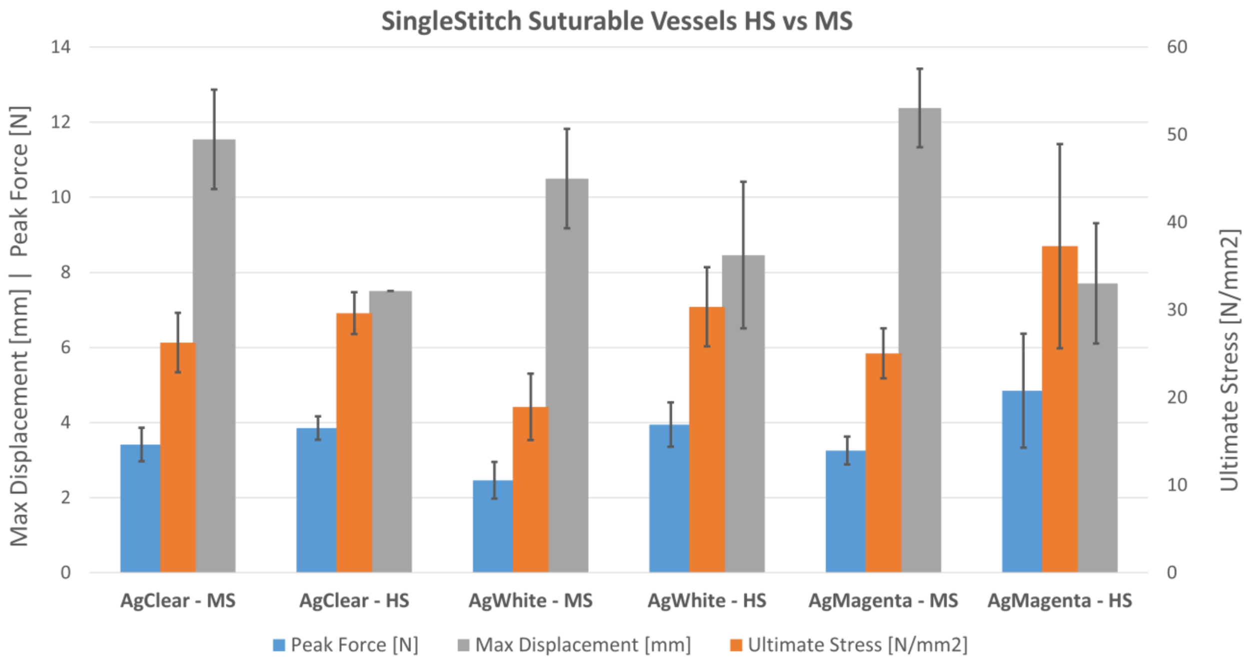
Fondazione IRCSS Policlinico San Matteo
Padiglione DEA
Strada Privata Campeggi, 40
27100 Pavia, Italy

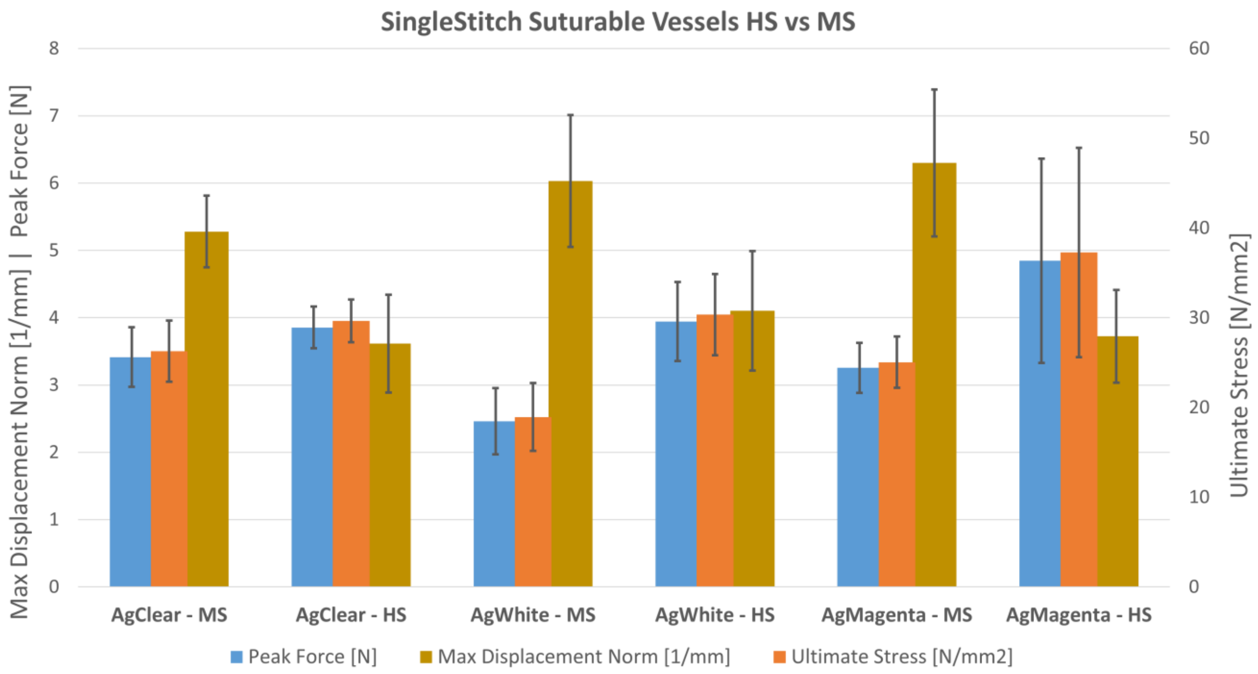
Mail: info@3d4med.eu
Website: www.3d4med.eu
Phone: +39 0382.503276


5 Ag Magenta MS - Single Stitch
LOAD [N]
TIME [s]
0
0,5
1
1,5
2
2,5
3
3,5
4
5_A
5_B
5_C
5_D
5_E
5_F

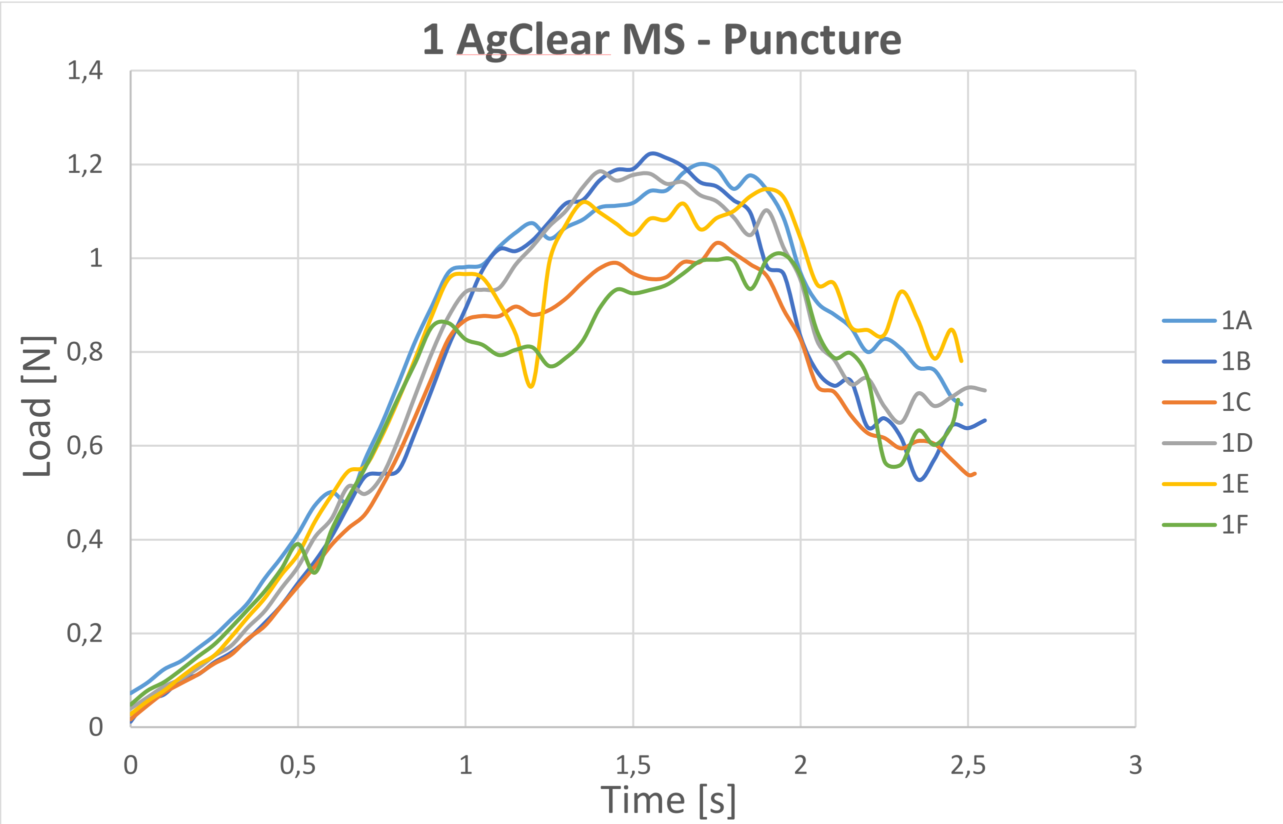

6 AgMagenta HS - Single Stitch
LOAD [N]
TIME [s]
0
1
2
3
4
5
6
7
8
9
0,5
1,5
2,5
6_A
6_B
6_C
6_D
6_E
6_F

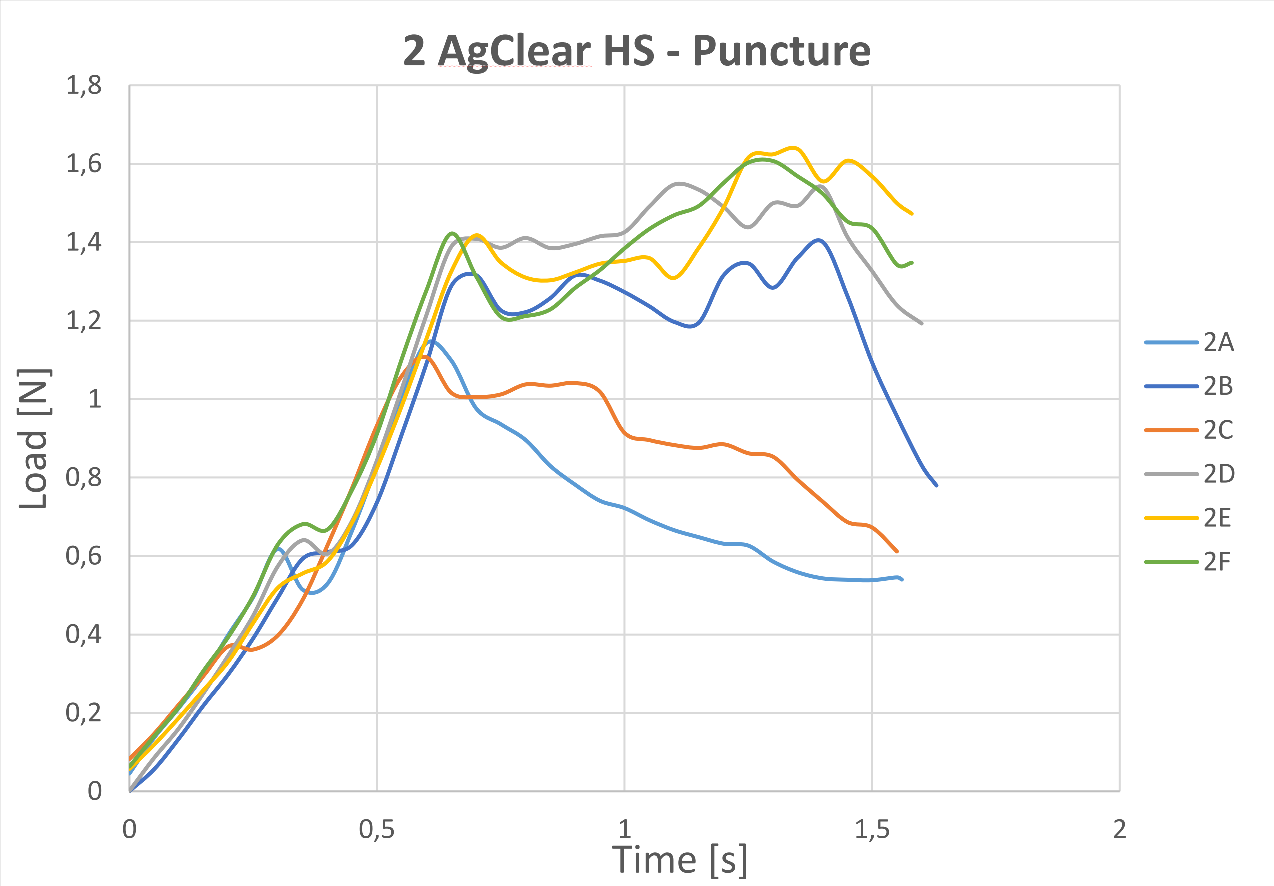
		Peak Force [N]	Ultimate Stress [N/mm^2]	Max Displacement [mm]	Max Displacement Norm [1/mm]
AgClear - MS	**MEAN**	**3,41**	**26,26**	**11,54**	**5,28**
	SD	0,44	3,41	1,33	0,53
	RSD%	12,97%	12,97%	11,50%	10,11%
AgClear - HS	**MEAN**	**3,85**	**29,64**	**7,50**	**3,61**
	SD	0,31	2,38	0,00	0,73
	RSD%	8,04%	8,04%	0,00%	20,14%
AgWhite - MS	**MEAN**	**2,46**	**18,93**	**10,50**	**6,03**
	SD	0,49	3,79	1,32	0,98
	RSD%	20,02%	20,02%	12,60%	16,26%
AgWhite - HS	**MEAN**	**3,94**	**30,35**	**8,46**	**4,10**
	SD	0,59	4,52	1,95	0,89
	RSD%	14,89%	14,89%	23,08%	21,67%
AgMagenta - MS	**MEAN**	**3,25**	**25,04**	**12,38**	**6,30**
	SD	0,37	2,86	1,05	1,09
	RSD%	11,43%	11,43%	8,45%	17,30%
AgMagenta - HS	**MEAN**	**4,85**	**37,27**	**7,71**	**3,72**
	SD	1,52	11,67	1,60	0,69
	RSD%	31,30%	31,30%	20,76%	18,52%

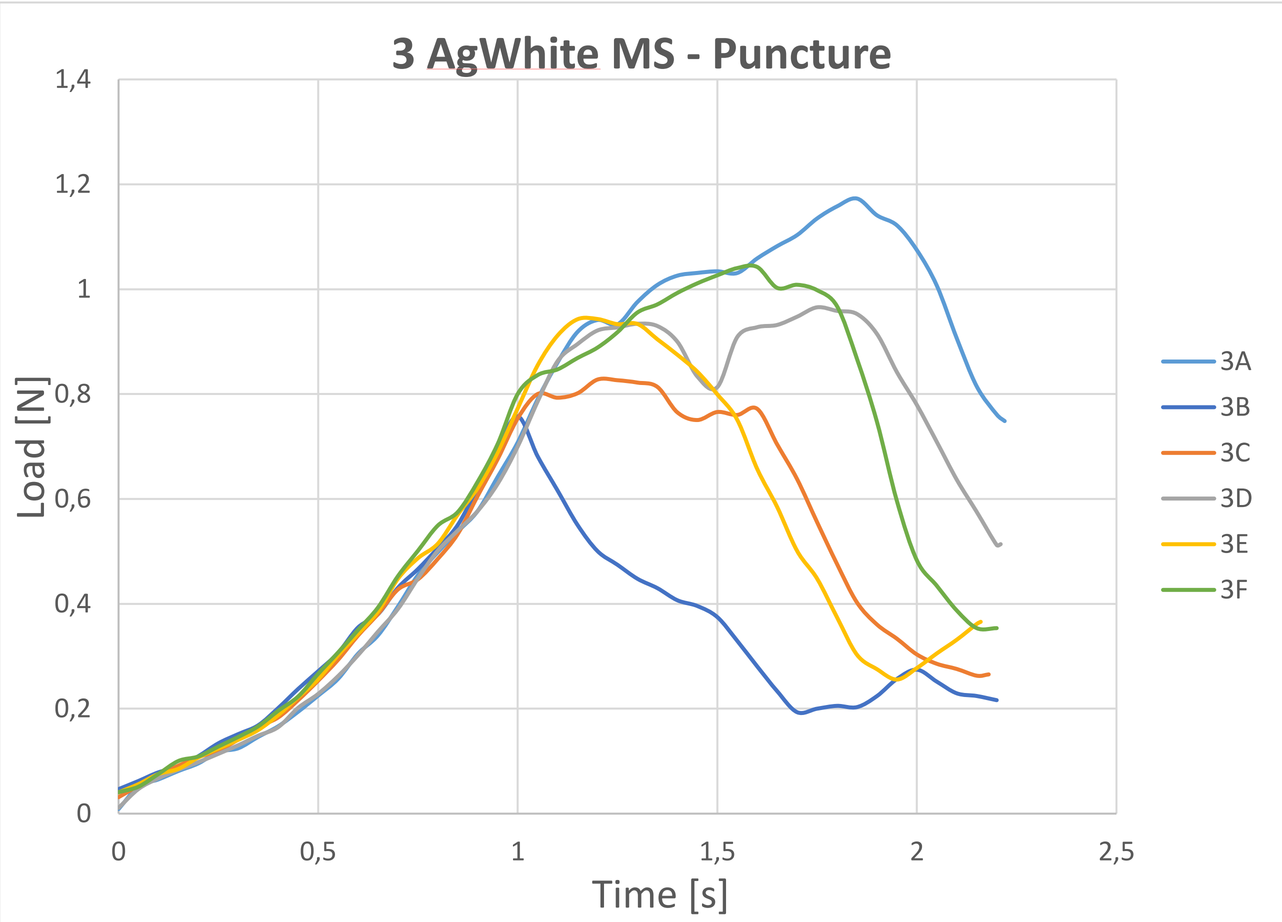


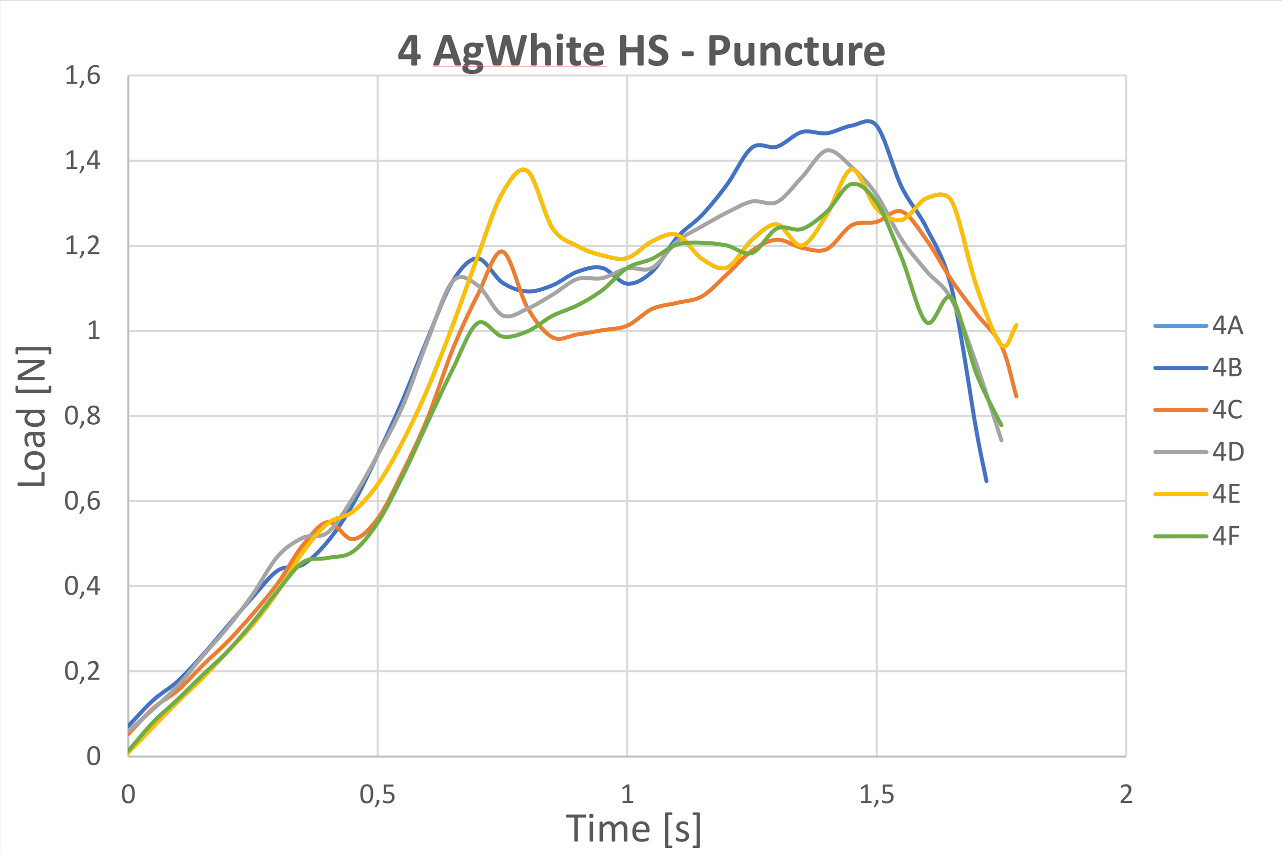


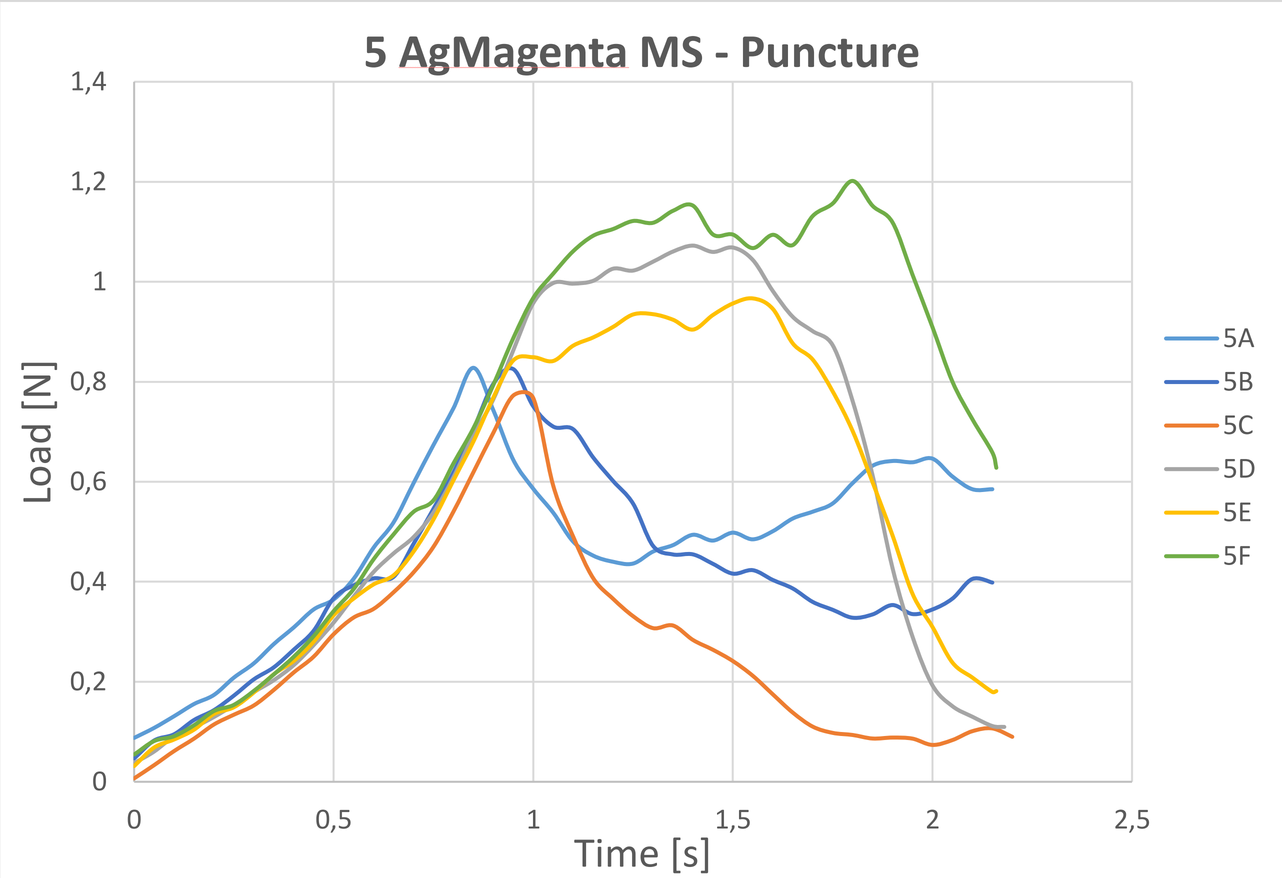
Puncture Tests




2 AgClear HS - Puncture
Load [N]
1,8
1,6
1,4
1,2
1
0,8
0,6
0,4
0,2
0
0
0,5
1
1,5
2
Time [s]
2A
2B
2C
2D
2E
2F

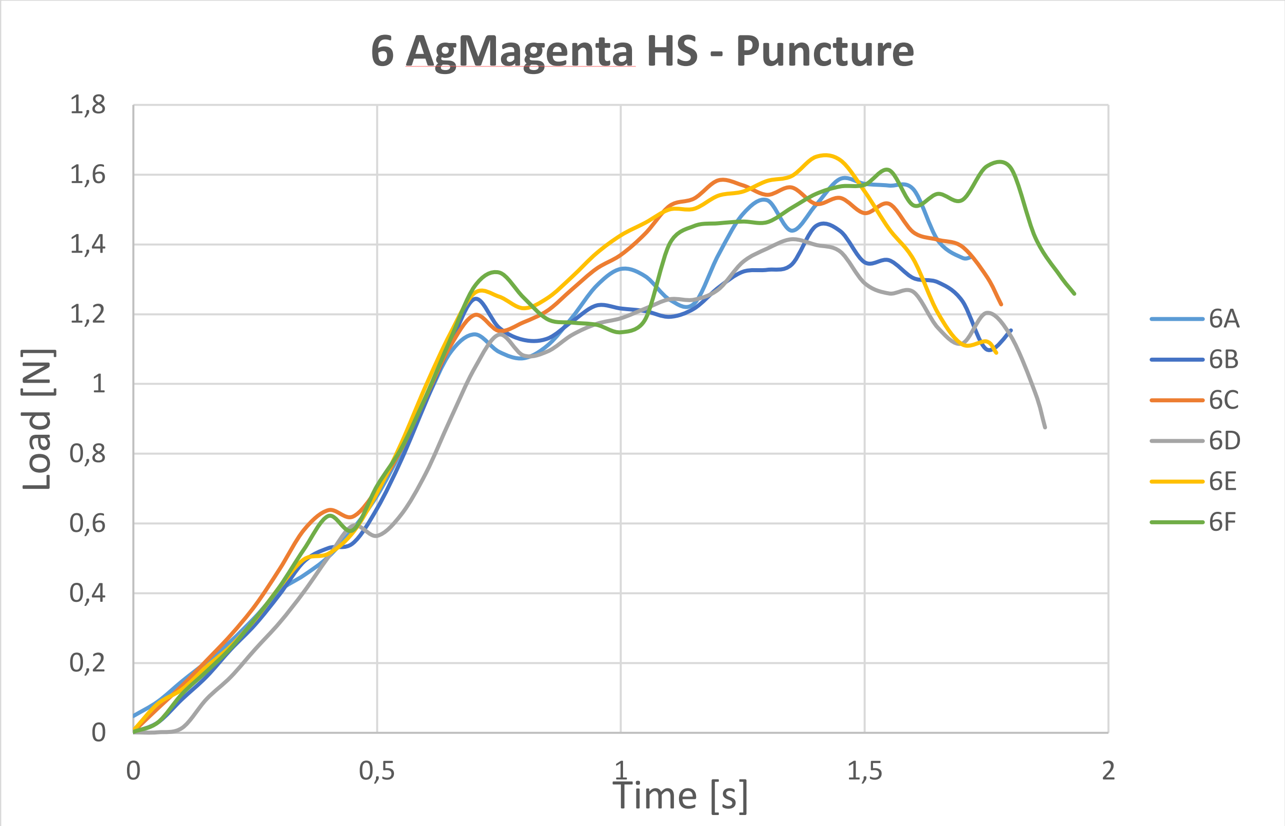

3 AgWhite MS - Puncture
Load [N]
1,4
1,2
1
0,8
0,6
0,4
0,2
0
0
0,5
1
1,5
2
2,5
Time [s]
3A
3B
3C
3D
3E
3F



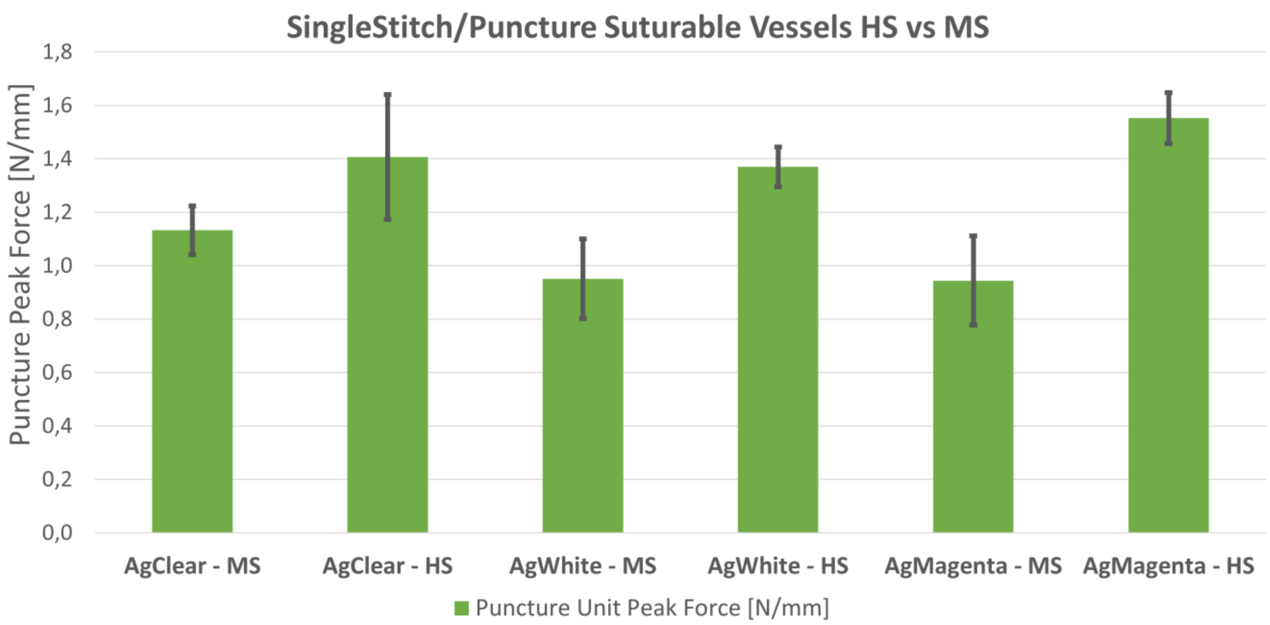


Fondazione IRCSS Policlinico San Matteo
Padiglione DEA
Strada Privata Campeggi, 40
27100 Pavia, Italy

Mail: info@3d4med.eu
Website: www.3d4med.eu
Phone: +39 0382.503276

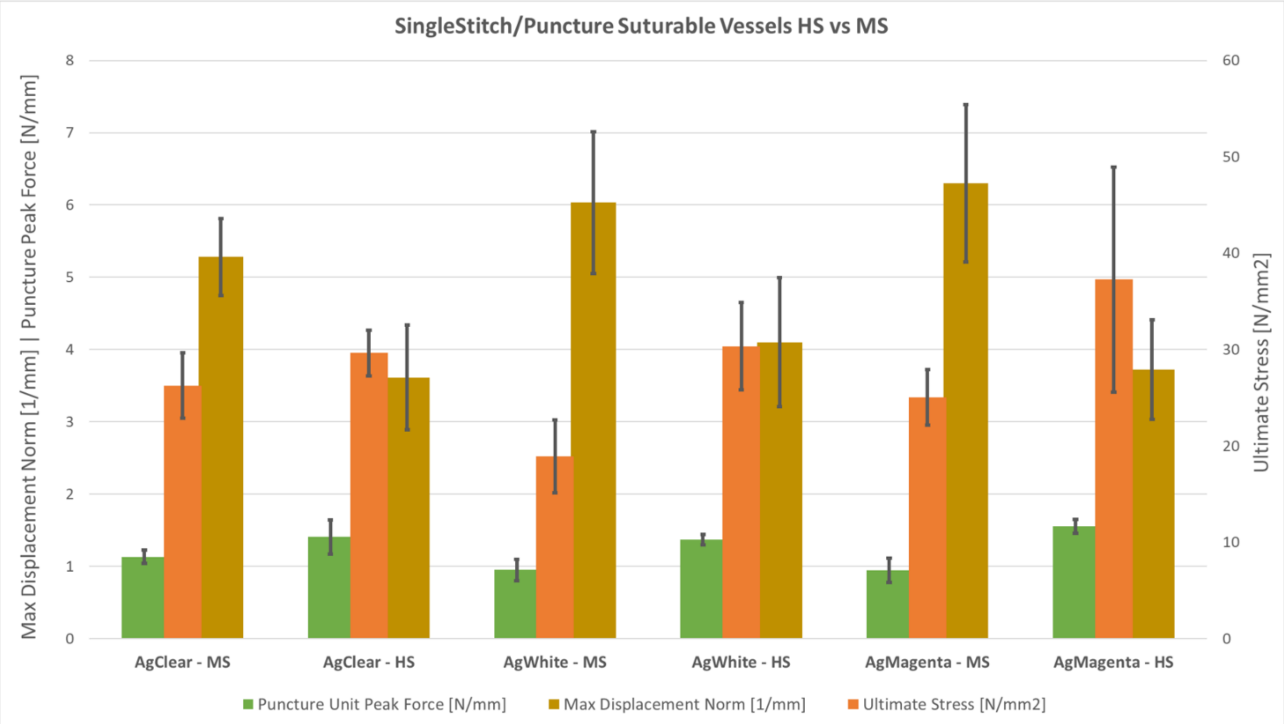

6 AgMagenta HS - Puncture
Load [N]
1,8
1,6
1,4
1,2
1
0,8
0,6
0,4
0,2
0
0
0,5
1
1,5
2
Time [s]
6A
6B
6C
6D
6E
6F

		Puncture Unit Peak Force [N/mm]
AgClear - MS	MEAN	**1,13**
	SD	0,09
	RSD%	8,02%
AgClear - HS	MEAN	**1,41**
	SD	0,23
	RSD%	16,59%
AgWhite - MS	MEAN	**0,95**
	SD	0,15
	RSD%	15,62%
AgWhite - HS	MEAN	**1,37**
	SD	0,07
	RSD%	5,43%
AgMagenta - MS	MEAN	**0,94**
	SD	0,17
	RSD%	17,74%
AgMagenta - HS	MEAN	**1,55**
	SD	0,10
	RSD%	6,17%



Overall Results

		Peak Force [N]	Ultimate Stress [N/mm^2]	Max Displacement [mm]	Max Displacement Norm [1/mm]	Puncture Unit Peak Force [N/mm]
AgClear - MS	**MEAN**	**3,41**	**26,26**	**11,54**	**5,28**	**1,13**
	SD	0,44	3,41	1,33	0,53	0,09
	RSD%	12,97%	12,97%	11,50%	10,11%	8,02%
AgClear - HS	**MEAN**	**3,85**	**29,64**	**7,50**	**3,61**	**1,41**
	SD	0,31	2,38	0,00	0,73	0,23
	RSD%	8,04%	8,04%	0,00%	20,14%	16,59%
AgWhite - MS	**MEAN**	**2,46**	**18,93**	**10,50**	**6,03**	**0,95**
	SD	0,49	3,79	1,32	0,98	0,15
	RSD%	20,02%	20,02%	12,60%	16,26%	15,62%
AgWhite - HS	**MEAN**	**3,94**	**30,35**	**8,46**	**4,10**	**1,37**
	SD	0,59	4,52	1,95	0,89	0,07
	RSD%	14,89%	14,89%	23,08%	21,67%	5,43%
AgMagenta - MS	**MEAN**	**3,25**	**25,04**	**12,38**	**6,30**	**0,94**
	SD	0,37	2,86	1,05	1,09	0,17
	RSD%	11,43%	11,43%	8,45%	17,30%	17,74%
AgMagenta - HS	**MEAN**	**4,85**	**37,27**	**7,71**	**3,72**	**1,55**
	SD	1,52	11,67	1,60	0,69	0,10
	RSD%	31,30%	31,30%	20,76%	18,52%	6,17%



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, Valeria Mauri, Gianluca Alaimo PhD
- Supervisors: Prof. Ferdinando Auricchio, Prof. Andrea Pietrabissa (MD)
- Project management and reporting: Stefania Marconi, PhD

Bibliography

[1] Bao, X. et al. (2016). “Experiment study on puncture force between MIS suture needle and soft tissue”.

[2] Maurin, B. et al. (2004). “In vivo study of forces during needle insertions”. Perspective in Image-Guided Surgery, pp. 415–422.

[3] Okamura, A.M. et al. (2004). “Force modeling for needle insertion into soft tissue”. IEEE transactions on biomedical engineering 51.10, pp. 1707–1716.

[4] Patel, H.B. et al. (2004). “Puncture resistance and stiffness of nitrile and latex dental examination gloves”. British dental journal 196.11, pp. 695–700.

[5] Nguyen, C.T. et al. (2009). “Puncture of elastomer membranes by medical needles. Part I: Mechanisms”. International journal of fracture 155.1, pp. 75–81.

[6] Podder, T. et al. (2006). “In vivo motion and force measurement of surgical needle intervention during prostate brachytherapy”. Medical physics 33.8, pp. 2915–2922.

[7] Pavicic, T. et al. (2019). “Arterial wall penetration forces in needles versus cannulas”. Plastic and reconstructive surgery 143.3, pp. 504–512.

[8] Zhang, G. et al. (2017). “Development of a penetration friction apparatus (PFA) to measure the frictional performance of surgical suture”. Journal of the mechanical behavior of biomedical materials 74, pp. 392–399.

[9] Zhai, J. et al. (2013). “A sensor for needle puncture force measurement during interventional radiological procedures”. Medical engineering & physics 35.3, pp. 350–356.

[10] Urrea, F. A et al. (2016). “Evaluation of the friction coefficient, the radial stress, and the damage work during needle insertions into agarose gels”. Journal of the Mechanical Behavior of Biomedical Materials 56, pp. 98–105.

[11] Jong, T.L. de et al. (2017). “PVA matches human liver in needle-tissue interaction”. Journal of the mechanical behavior of biomedical materials 69, pp.223–228.

[12] Tan, Z. et al. (2018). “Composite hydrogel: A high fidelity soft tissue mimic for surgery”. Materials & Design 160, pp. 886–894.

[13] Casanova, F. et al. (2014). “In vivo evaluation of needle force and friction stress during insertion at varying insertion speed into the brain”. Journal of neuroscience methods 237, pp. 79–89.

[14] Westwood, J.D et al. (2005). “In vivo force during arterial interventional radiology needle puncture procedures”. Medicine Meets Virtual Reality: The Magical Next Becomes the Medical Now. Vol. 111, pp. 178–184.

[15] (2020). url: https://www.astm.org/Standards/F1342.htm (visited on 14/07/2020).