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COMPARATIVE STUDY AND ANALYSIS ON THE MECHANICAL PROPERTIES OF 3D PRINTED SURGICAL INSTRUMENT FOR IN-SPACE APPLICATIONS

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***ABSTRACT**: The goal of this study is to optimize the mechanical properties and the design of a 3D printed surgical needle holder for in-space applications. The needle holder, used by a surgeon to hold the needle during suturing, is an integral part of a basic surgical kit. Commercially available needle holders were analysed and a digital model was produced. Requirements were ranked based on their importance and these were then translated into precise technical specifications through quality function deployment tool (QFD). A finite element analysis was executed to analyse stress distribution and the model's geometry was optimized accordingly for the 3D printing process. Six commercial thermoplastic filaments were tested to examine their suitability for the needle holder fabrication such as ABS, PLA, PETG and Nylon filaments and from composite PLA-Stainless Steel and Nylon-Fiber Glass materials, in both horizontal and vertical position. Simulation studies were conducted on the optimized digital model to examine its structural integrity when fabricated from the materials tested.*

***KEYWORDS**: 3D printing, Quality Function Deployment, Finite Element Method*

1 INTRODUCTION

Future, long-duration missions in space are expected to occur in constrained, austere, remote, isolated, prolonged, and alien environments (European Space Agency, 2013). During these missions surgical emergences are expected to occur, however it is not possible to provide a full surgical capability because of several uncertainties and constraints such as mass, volume, skills and cost as well as surgical disorders (Campbell, 2002). 3D printing could prove useful for in-space manufacturing of surgical instruments during long-duration missions (Dunn et al., 2010).

3D printing, also known as additive manufacturing (AM) or digital fabrication, is an established technology that builds objects of a wide variety of shapes, layer by layer, out of plastic, metal, or other materials (Lipson, 2012; Syed et al., 2018). 3D printing is being applied in a range of customized medical applications including prosthetics, implants, tissue engineering scaffolds, and image-based anatomical models. The primary advantage of 3D printing for space missions is localized manufacturing.

Fused Deposition Modeling (FDM) is a 3D printing process that uses a continuous filament of a thermoplastic material. Along with Electron Beam Freeform Fabrication (EBF3) (Hafley et al., 2007). FDM is a promising AM technology for in-space manufacturing according to tests performed in zero-g environment (Prater et al., 2017).

Future objective is expected to be the development and combination of manufacturing technologies and processes as well as control tools required to provide on-demand (in-transit and on-surface) efficient systems and solutions for in-space applications such as recycling, printed electronics [combination of materials and processes (Singh Bedi, 2018; Koidis and Logothetidis, 2015)], printable satellites, etc. (Werkheiser, 2015; Bradley, J.S, 2018).

A previous work focused on assessing the layered printing process with acrylonitrile butadiene styrene (ABS) plastic (Wong and Pfahnl, 2014). According to the results it is feasible to 3D print ABS thermoplastic surgical instruments on Earth. The ideal 3D printing material to fabricate surgical instruments for in-space applications would a) be reliable, durable, and sterilization capable; b) have minimal off-gassing, toxicity, and no carcinogenesis potential; and c) be compatible with on-board 3D printers. In addition, FDM 3D printer installed in space should be properly sealed to protect the integrity of the spacecraft environment from the emitted particles (Stephens, et al., 2013).

In particular for sterilization, although there are no standard sterilization procedures for plastics such as ABS, it appears that the heating of the thermoplastic filament during the FDM printing process could sterilize the printed instrument (Rastogi, et al., 2013).

The current study provides comparative results on a) the mechanical properties of 3D printed thermoplastic surgical instrument (i.e. needle holder) using 3D printing materials, b) the material selection process for in-space medical applications and c) straight forward Finite Element Analysis modelling procedures for the efficient simulation of instrument's mechanical behavior.

2 MATERIALS AND METHODS

A needle holder, also called needle driver, is a surgical instrument like a hemostat, used by doctors and surgeons to hold a suturing needle for closing wounds during suturing and surgical procedures. Commercially available Stainless-Steel needle holders were analysed and the digital model of the instrument was produced, using Solidworks CAD software (Dassault Systemes), considering instrument's characteristics/ergonomic issues (Pinsolle et al., 2005; Francis et al., 1992; Chu and Fraunhofer, 1997; Chen et al., 1991; Acker et al., 1986; Abidin et al., 1989; Towler et al., 1991). The driving dimensions were derived from the technical drawing of a standard 20cm, Stainless Steel needle holder (Apexian Care™).

The following thermoplastic filaments have been examined as printing materials of the needle holder: ABS standard, PLA (polylactide) standard and PETG (polyethylene terephthalate glycol-modified): EVO (NEEMA3D™), PLA-Stainless Steel (PLA-SS) composite (Proto-pasta™) and Nylon and Nylon-Fiber Glass (Nylon-FG) composite (Markforged™), along with AISI 316L Stainless Steel which was used as a reference. All samples have been printed with 100% infill density to enhance stiffness (Aw et al., 2018). The thickness of each 3D printed layer was 100μm. The flexural properties of the filament materials were investigated on a Testometric M500-50AT (UK) system. The testing samples had dimensions of 8mm x 8mm x 105.74mm. A BCN3D Sigma FDM printer was used for the ABS, PLA, PLA-SS and PETG and a Markforged Mark Two printer for the Nylon and Nylon-FG materials. The 3-point bending tests were conducted according to the ISO 178-2010 standard.

Strength and stiffness of FDM manufactured parts depend on the orientation of the load forces applied, relative to the printed orientation of their layers (Wong and Pfahnl, 2014). For this reason, two sets of samples were 3D printed, firstly, with their layers in a horizontal direction, as printed and, secondly, with their layers in a vertical position, rotated 90o from their printing direction.

Following the Finite Element Analysis of the instrument, static simulation studies of the needle holder were conducted for each material to examine the structural integrity of the instrument under use and optimize its properties (e.g. thickening of key, functional structures, i.e. handles, fulcrum, jaws and ratchets, on which larger stresses are developed).

3 RESULTS AND DISCUSSION

3.1 Mechanical Properties

The calculated flexural strength and flexural moduli of the materials in both vertical and horizontal direction are shown in Figures 1 and 2, respectively. It becomes apparent that the 3D printed samples demonstrate weak mechanical properties when a load force is applied transversely to the 3D printed layers (Wong and Pfahnl, 2014). This implies that 3D printed layer mechanical cohesion and interlayer bonding significantly contribute to the advanced mechanical properties observed during 90-degree testing (Hernandez et al., 2016). As a result, the printing orientation of the parts of the needle holder must be carefully selected to make sure that load forces on the handles and the jaws are applied vertically to the layering direction and maximize the structural integrity of the tool. A noteworthy observation is that the PLA and PLA-SS materials demonstrated brittle behavior and fracturing, a behavior that could cause problems in case of a failure, due to scattered around the suturing area and the cabin in a zero-g environment. Another conclusion is that the glass fiber infill significantly improves the strength of the Nylon, with the flexural yield strength for the Nylon-FG composite material rising to 79MPa from 35MPa, which is the largest among all the materials tested.

The parameters of the materials vertically and horizontally tested are shown in Tables 1 and 2, respectively.

3.2 Simulation Analysis

The user requirements and technical specifications of the needle holder were analyzed to better simulate the process. Requirements were ranked based on their importance and these were then translated into precise technical specifications through quality function deployment tool (QFD) as it is shown in Fig. 4.

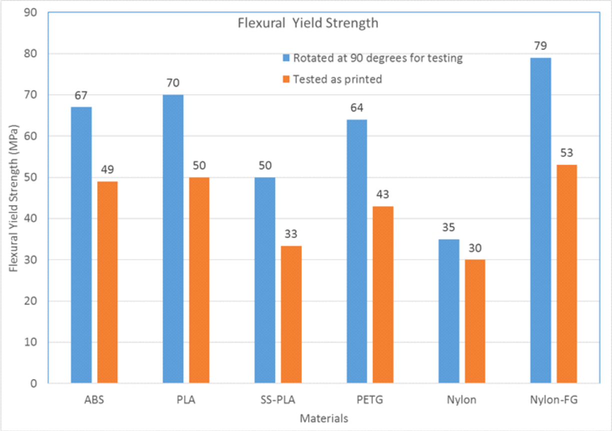


Figure 1. The calculated flexural yield strengths of the materials tested..

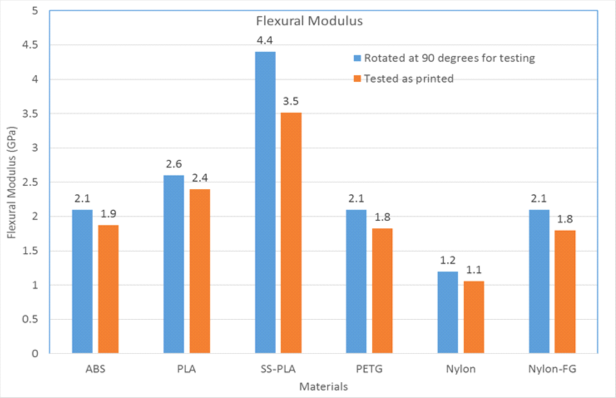


Figure 2: The calculated flexural moduli of the materials tested.

Table 1: Material properties of vertically tested samples.

MATERIAL PROPERTIES-VERTICAL					
	Flexural Modulus (GPa)	Density (g/mm^3)	Flexural Yield Str (MPa)	Poisson Ratio	Ultimate Str (MPa)
ABS	2.1	1.10	67	0.35	73
PLA	2.6	1.25	70	0.35	82
SS-PLA	4.4	1.45	50	0.3	57
PETG	2.1	1.27	64	0.35	75
Nylon	1.2	1.10	35	0.35	60
Nylon-FG	2.1	1.13	79	0.35	105

Table 2: Material properties of horizontally tested samples.

MATERIAL PROPERTIES-HORIZONTAL					
	Flexural Modulus (GPa)	Density (g/mm^3)	Flexural Yield Str (MPa)	Poisson Ratio	Ultimate Str (MPa)
ABS	1.9	1.10	49	0.3	60
PLA	2.4	1.25	50	0.3	74
SS-PLA	3.5	1.45	33	0.3	34
PETG	1.8	1.27	43	0.3	70
Nylon	1.1	1.10	30	0.3	50
Nylon-FG	1.8	1.13	53	0.3	100

Units and target values were also set for each technical specification. The relationships between them were determined along with the correlations among the specifications. “Needle security” and “Stability” are the most important requirements of needle holder and for this reason they were graded with the largest possible score (5) along with “Precision”. It is critical that the instrument can be sterilized, otherwise it cannot be used in a surgery. As a result, “Sterilization” is also graded with (5). “Comfort” and “Durability” are the least important needs in the context of a 3D printed needle holder which can be recycled and reprinted multiple times, thus, they receive a (3). The rest, like “Jaw strength” and “Needle bending protection” fall in between with a (4). Furthermore, needle security is heavily influenced (●) by needle motion and moderately influenced (○) by the locking mechanism, whereas grasping stability is heavily influenced by the locking mechanism and a little influenced (▽) by shape of the handles. Clamping force positively affects (+) the clamping moment but has a negative effect (-) on needle motion (in terms of value).

Similarly, the locking mechanism positively affects the clamping force but has a negative

effect on needle motion. The technical drawing of the optimized model is shown in Fig. 3.

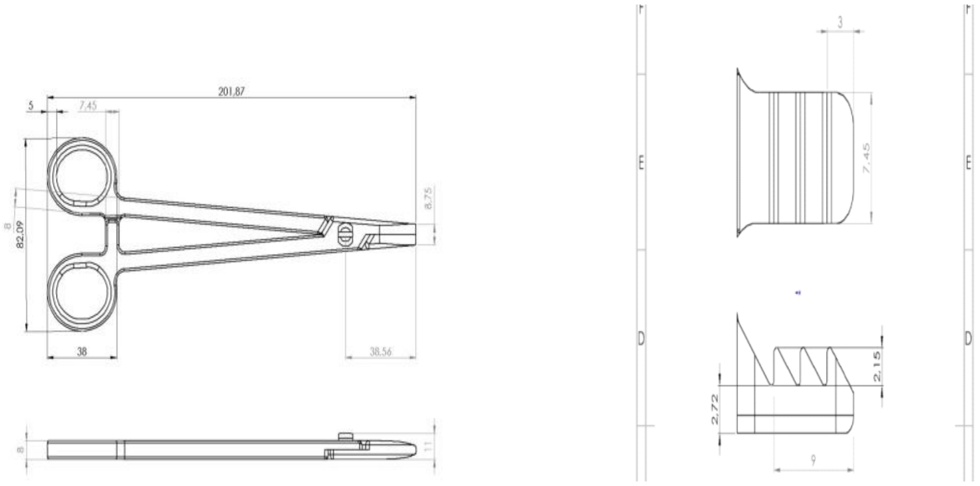
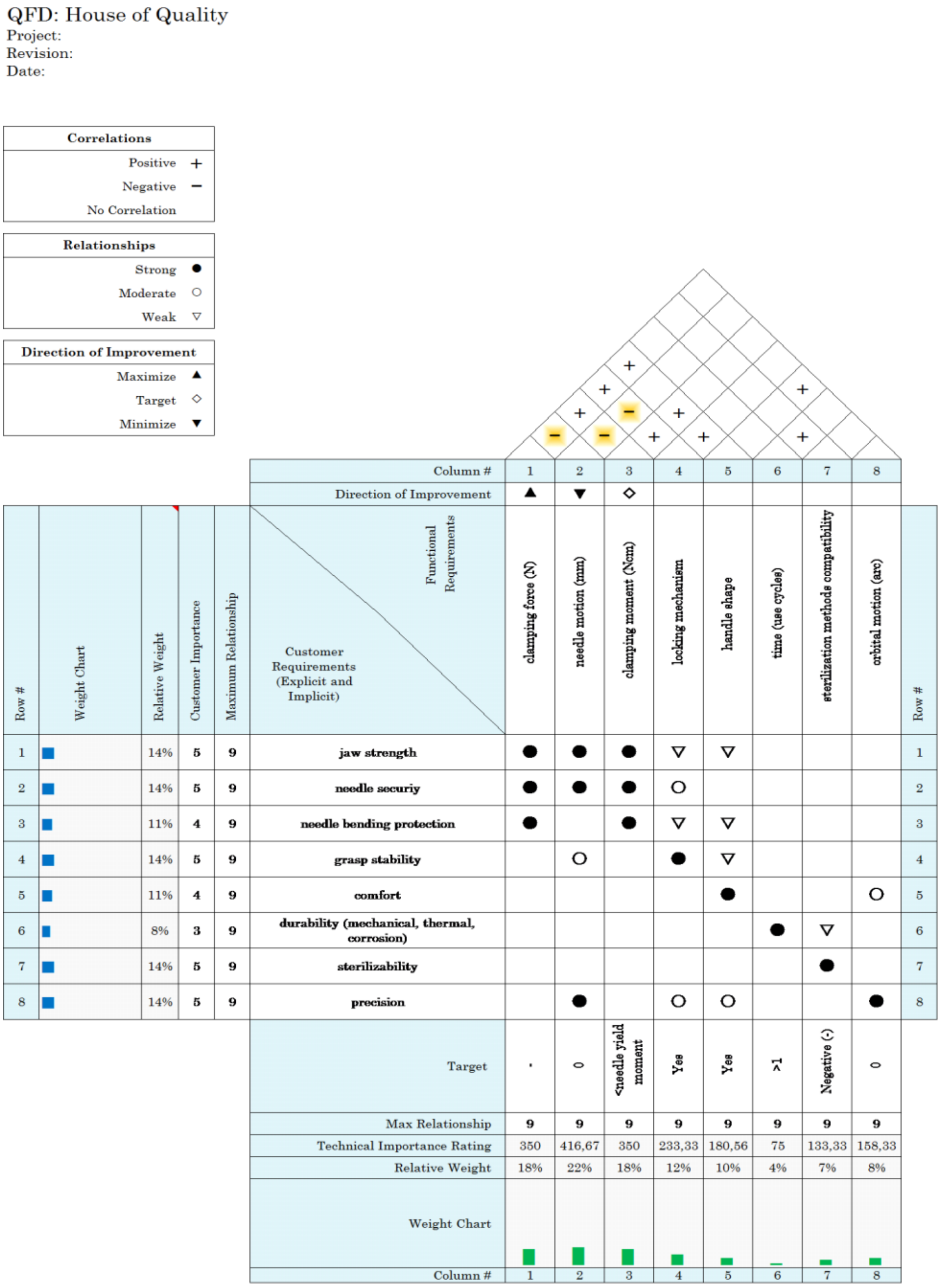


Figure 3: a) Technical drawing of the optimized needle holder. b) Dimensions of the optimized locking mechanism.



QFD: House of Quality
Project:
Revision:
Date:

Correlations	
Positive	+
Negative	−
No Correlation	

Relationships	
Strong	●
Moderate	○
Weak	▽

Direction of Improvement	
Maximize	▲
Target	◇
Minimize	▼

					Column #	1	2	3	4	5	6	7	8	
					Direction of Improvement	▲	▼	◇						
Row #	Weight Chart	Relative Weight	Customer Importance	Maximum Relationship	Functional Requirements / Customer Requirements (Explicit and Implicit)	clamping force (N)	needle motion (mm)	clamping moment (Ncm)	locking mechanism	handle shape	time (use cycles)	sterilization methods compatibility	orbital motion (arc)	Row #
1	🟦	14%	5	9	jaw strength	●	●	●	▽	▽				1
2	🟦	14%	5	9	needle securiy	●	●	●	○					2
3	🟦	11%	4	9	needle bending protection	●		●	▽	▽				3
4	🟦	14%	5	9	grasp stability		○		●	▽				4
5	🟦	11%	4	9	comfort					●			○	5
6	🟦	8%	3	9	durability (mechanical, thermal, corrosion)						●	▽		6
7	🟦	14%	5	9	sterilizability							●		7
8	🟦	14%	5	9	precision		●		○	○			●	8
					Target	-	0	<needle yield moment	Yes	Yes	>1	Negative (-)	0	
					Max Relationship	9	9	9	9	9	9	9	9	
					Technical Importance Rating	350	416,67	350	233,33	180,56	75	133,33	158,33	
					Relative Weight	18%	22%	18%	12%	10%	4%	7%	8%	
					Weight Chart	🟩	🟩	🟩	🟩	🟩	🟩	🟩	🟩	
					Column #	1	2	3	4	5	6	7	8	

Figure 4: The Quality Function Development tool used to define the characteristics of the needle holder.

Figure 5 shows the maximum stress distribution throughout the needle holder made of a)Nylon, b)ABS and c)Nylon-FG using static simulation methods. The max stress is located at the fulcrum, handles and ratchets but is significantly lower than material's yield strength calculated experimentally. Figure 6 represents the max stresses exerted on the needle holder for each filament material. The results of the original AISI 316LSS analysis are also included for comparison. They are located near the fulcrum, but they remain safely below the yield strengths of all the materials.

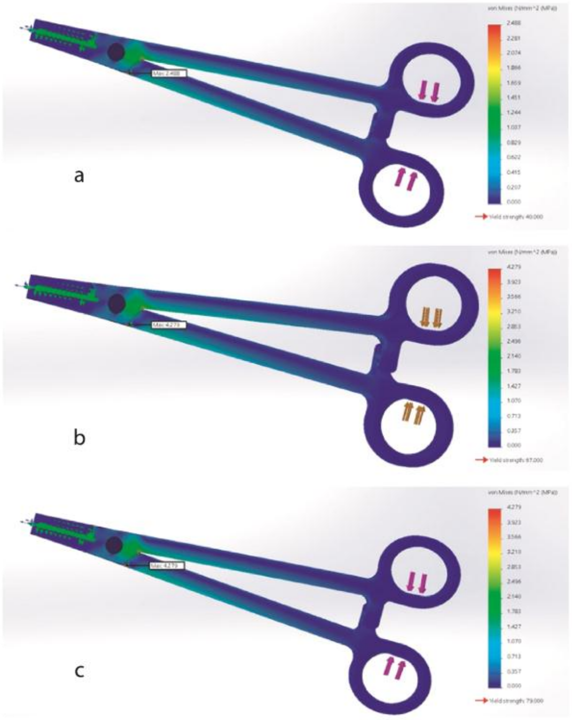


Figure 5: Max stress analysis for a) Nylon, b) ABS and c) Nylon-FG.

As a result, following the mechanical testing of the materials and approximations considered for the simulations, it can be assumed that all six materials could be used for 3D printing a functional needle holder, with the Nylon-FG having an advantage due to its higher yield strength. The maximum displacement is typically found on the ringlets as the ringlets move closer to engage the third ratchet. The maximum value for the tested materials can be found in Figures 6 and 7. In Fig. 8 snapshots of the instrument's 3D printing process is shown for PLA. Prototype was fully functional after printing. Further assessment will enable the optimization of instrument's operational characteristics.

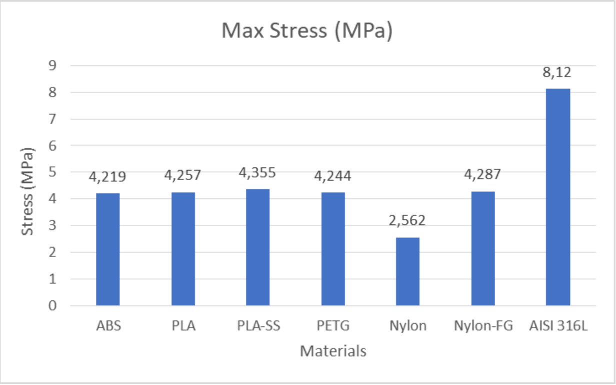


Figure 6: Max stresses of all simulated materials.

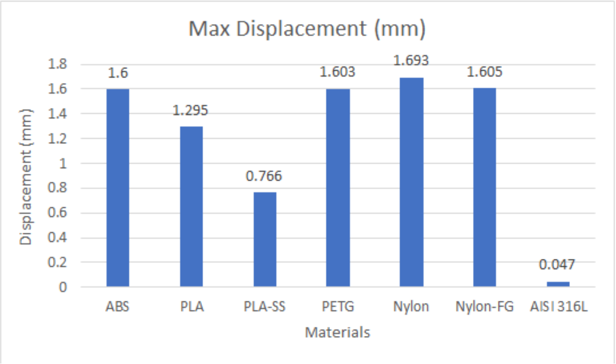


Figure 7: Max displacement of all simulated materials.

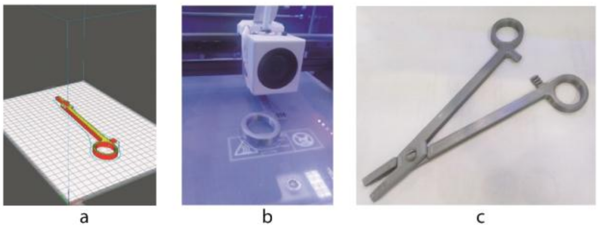


Figure 8: a) Simulation of the 3D printing procedure on the 3D printing software, b) Snapshot during 3D printing of the shank where the handle and ratchet are shown, c) Photo of the final 3D printed needle holder.

4 CONCLUSIONS

Three point bending tests have been performed and revealed a similar trend among the materials tested in a horizontal and a vertical orientation. The vertically placed specimens demonstrated advanced mechanical properties compared to those horizontally tested. Therefore, it is important to carefully select the printing orientation of the needle holder's parts to ensure that the load forces are exerted vertically to the tool layering. PLA and PLA-SS exhibited brittle behavior upon flexing and fracturing. This behavior could pose risks in a zero-g environment since debris could scatter around the suturing area and the cabin in case of structural failure. For this reason, further consideration should be given before using these materials for in-space fabrication.

Finite element analyses were conducted on the optimized needle holder model based on the material properties values from the vertically tested samples. Maximum stresses and strains were found near the fulcrum while maximum displacements were located on the ringlets. The maximum stresses for all the tested materials stayed well below their respective yield strengths. Thus, all materials tested are expected to be safely used for the fabrication of a functional needle holder with approximations considered. The Nylon-FG is a favorable choice due to its higher yield strength.

Further research will be conducted on the topic for the establishment of advanced modelling and printing standardization procedures to safely and cost-efficiently 3D print surgical instruments in space for medical emergencies during future, long-duration space missions.

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