

1. Summary

1.1. This report is a summary of various initial evaluations performed in order to determine the feasibility of SLS (selective laser sintering) parts in the manufacturing of the Glia tourniquet. Initial evaluation shows SLS has several disadvantages and limitations that make it impractical for producing parts such as those used in the Glia tourniquet.

2. Purpose

2.1. The report is composed of early testing that does not comprehensively evaluate the material or manufacturing process. This report should not be considered a validation and should be used to inform decisions related to further testing and formal validation. Testing was carried out across multiple institutions using different test methods, tools and data. Some results are de-identified and should be considered anecdotal.

3. Scope

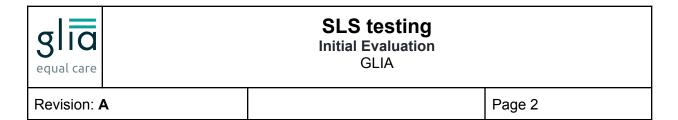
3.1. Testing was performed across multiple institutions and locations with different sample sizes, test methods and reporting methods. This report details the overall evaluation actions and results.

4. <u>Test participants</u>

- 4.1. OpenWorks- A community maker space located in Baltimore MD (https://www.openworksbmore.org/)
- 4.2. FormLabs
- 4.3. Unnamed medical research institution
- 4.4. Baltimore, Maryland fire department

5. <u>Testing Results</u>

- 5.1. Open Works
 - 5.1.1. OpenWorks assembled thirty-eight Glia tourniquets approximately 25 MAY 2022. The SLS components were made using FormLabs PA12



nylon powder on a Fuses 1 printer. Upon review of images sent from OpenWorks several deviations in the work instructions were identified.

- 5.1.1.1. Counter to the work instructions the inner belt is exposed due to feeding the inner and outer belt assembly down through the buckle instead of up.
- 5.1.1.2. Cross stitch at the start of the belt is missing.
- 5.1.1.3. Time piece velcro is black instead of white
- 5.1.1.4. Two-sided rivets are missing
- 5.1.2. OpenWorks tourniquets were tested using the University of Western Ontario tourniquet tester [1]. The tourniquet did not break or deform and provided similar readings to FDM tourniquets produced at Glia.
- 5.2. Unnamed Medical Research Institution
 - 5.2.1. Unknown number of tourniquets were assessed using a "trauma dummy" of unknown make and model and by application to a living subject and verifying full occlusion using a pulse oximeter. Both test cases resulted in acceptable performance according to the evaluator.

5.3. FormLabs

- 5.3.1. Testing was performed on an unknown number of units produced by OpenWorks. These units were affected by the same deviations as outlined in section 5.1.1. A tensile test machine was used to evaluate the overall tensile strength of the assembled units. (PASCO Scientific ME-8236).
- 5.3.2. Failure occurred at 800N (fig 1.) where the buckle and backplate broke. (fig 2, fig 3.)

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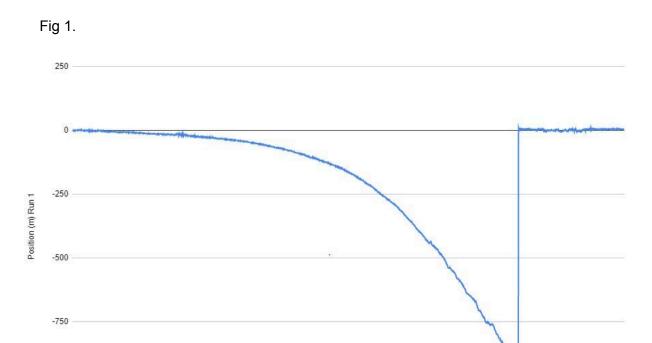


Fig 2. Fig 3.

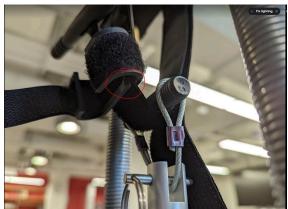
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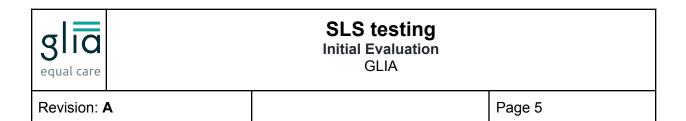




6. Results

- 6.1. SLS has several limitations that make use in the Glia tourniquet impractical.

 Rapid prototyping is a constantly changing field and further evaluation should be considered as methods and technologies evolve. This initial evaluation should be used as a starting point when considering using SLS as a production method.
 - 6.1.1. Cost- SLS machines are significantly more expensive than FDM [2]. Rapid prototyping as a production method for devices such as the Glia tourniquet are generally selected due to lack of capital or infrastructure needed for more traditional methods such as injection molding. The cost of SLS printers is realistically unachievable for community level production organizations.
 - 6.1.2. Material characteristics- Nylon SLS has been considered to be generally more durable and stronger than ABS parts produced using FDM. However studies have shown FDM is stronger [2]. Nylon as a material has higher tensile strength, durability and UV resistance compared to ABS but is susceptible to moisture absorption and may not benefit from the tensile advantages due to the manufacturing process of SLS. Due to the high probability of tourniquets being transported and used in diverse outdoors environments, incorporating a raw material that absorbs



moisture and thus affects downstream clinical operation would be ill-advised.

7. References

- 7.1. [1] Liu, Dawei, et al. "Distributed manufacturing of an open-source tourniquet testing system." *HardwareX* (2023): e00442.
- 7.2. [2] SOFU, Mehmet Mahir, et al. "Comparison of Strength, Surface Quality and Cost of Different Additive Manufacturing Methods." *İmalat Teknolojileri ve Uygulamaları* 4.1: 25-36.

8. Definitions

- 8.1. SLS- Selective Laser Sintering
- 8.2. FDM- Fused Deposition Modeling