MINUTE POROSITY OF 3D PRINTED SPLINTS AND CASTS MAY ALLOW WATER ENTRY

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Abstract

PURPOSE: Splints and casts are Class 1 medical devices regulated by FDA. Optical scanning and additive manufacturing of these immobilizing devices allow for custom fit without padding. Therefore, this technology has the potential to allow patients to improve hygiene, comfort and lifestyle activities during recovery. However, no studies have evaluated waterproofing of 3D printed immobilization devices. We hypothesized that water may enter the interior of these devices unless strict manufacturing process controls are followed and claims of waterproofing are verified. METHODS: Patient specific ABS polymer casts manufactured using fused filament fabrication methods with 100% infill by ActivArmor were evaluated for water penetration and retention. Manufacturing parameters were evaluated with respect to welding effectiveness between layers. Finished devices with visually smooth unbroken surfaces were immersed in fresh water in depths from 1 to 25 feet for periods ranging from 5 to 30 minutes. Change in gross weight was used to determine the quantity of water retained within the 3D printed article. Examination of surface features was evaluated by digital optical microscopy and internal structure by micro computed tomography. RESULTS: Some fully finished casts that appeared completely sealed admitted water at depths as little as one foot, increasing up to 16% of dry weight at depths of 25 feet. Small changes in manufacturing reduced water entry to 3% of dry weight, while increasing extrusion diameter completely waterproofed prints. Optical microscopy revealed fenestrations in lamination at acute angles in geometry of prints in devices that retained water. Micro computed tomography was notable for 17 micron gaps in smooth straight sections of water absorbing prints. CONCLUSIONS: Clinical claims of improved hygiene and earlier return to normal lifestyle activities associated with custom 3D printed immobilization devices are based upon absence of padding and waterproofing. Visual inspection of 3D printed devices is not sufficient to verify watertight integrity of device surfaces. Retained water inside the print may support bacterial colonization. However, application of appropriate manufacturing process controls and verification procedures enable custom 3D printed devices support claims of improved hygiene and waterproofing.

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Methods

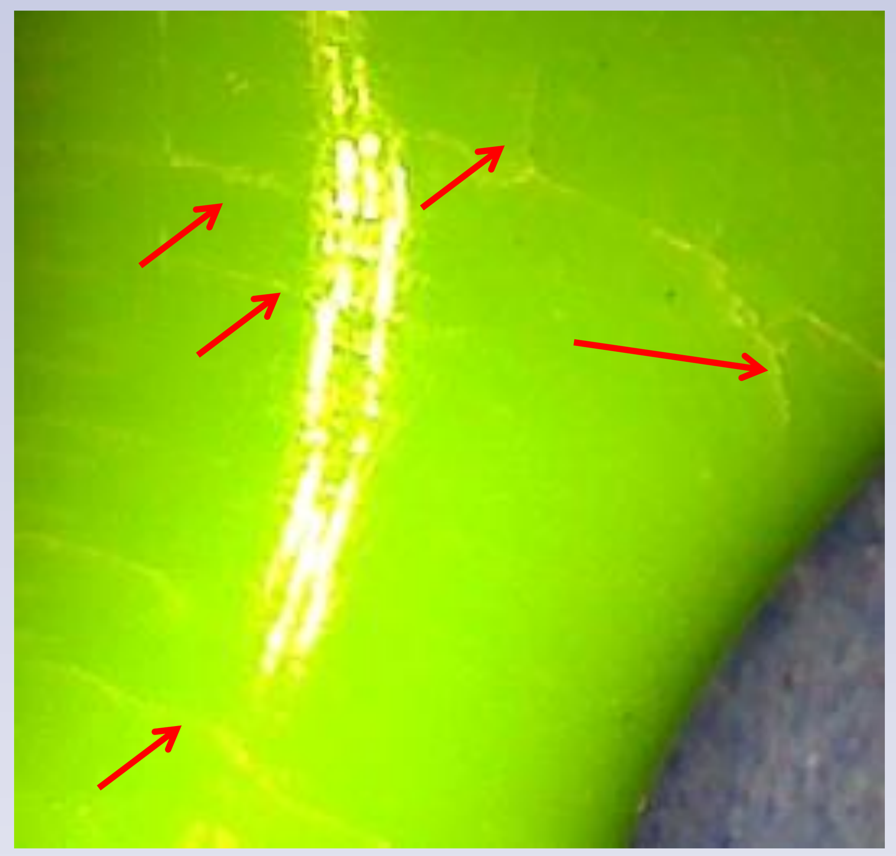
Final, finished 3D splints and casts were photographed for surface fenestrations using light microscopy at 20-200x. Minute cracks or fissures were considered to have potential for unwanted water entry. Micro-computed tomographic 17.5 µ slices of 1 cm print segments further indicated that surface defects occasionally penetrated into the interior of 3D prints.

3D prints with and without signs of microscopic signs of cracking were compared to intact prints by changes in weight following timed immersion in fresh water at sequential depths from 1-25 feet. Changes in weight indicated the volume of water entering the splint or cast and subsequent rate of drainage.

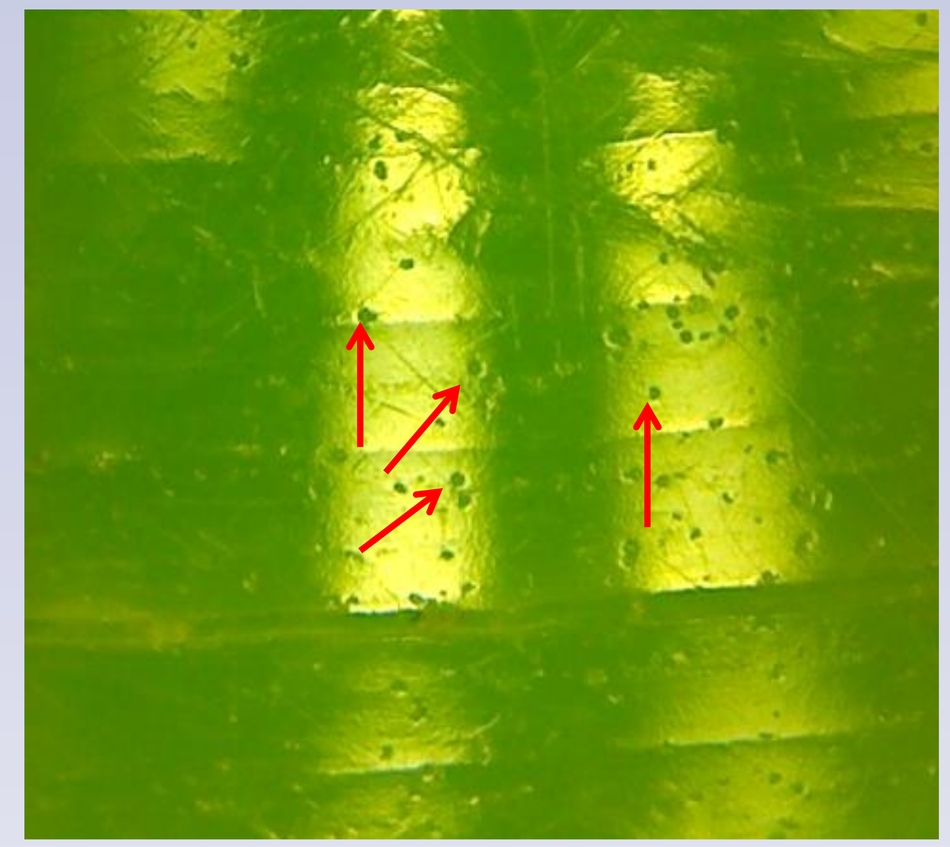
Results

Seven different types of 3D print process controls applied to additive manufacture of splints and casts by fused filament extrusion were evaluated for resistance to water penetration. In all cases, the filament was acrylonitrile butadiene styrene (ABS) extruded at 242^{o} C, deposited serially in vertical layers ascending along the principal axis of the print. Overall geometry was similar among prints, as they were composed of branching struts approximately 1 cm in length and 0.5-1 cm thick.

Resistance to Water Entry into 3D Printed Casts/Splints Depends on Manufacturing Process Controls



Surface cracks are most frequently aligned with layers of lamination, but may extend across layers.



Microporosity on print surface are not necessarily correlated with boundary layers of lamination.

VOI	X	Y	Z	Mean/Density [mg HA/ccm]
Position [p]	846	275	18	of TV (Apparent) −96.7429
Dimension [p]	900	688	929	of BV (Material) −65.9255
Element Size [mm]	0.0172	0.0172	0.0172	

Direct (No Model)		TRI (Plate Model)		Anisotropy	
TV [mm³]	1039.0455	TV [mm³]	–	|H1| [mm]	–
BV [mm³]	711.4162	BV [mm³]	–	|H2| [mm]	–
BV/TV [1]	0.6847	BV/TV [1]	–	|H3| [mm]	–
Conn. D. [1/mm³]	–	BS [mm²]	–	DA [1]	–
SMI [1]	–	BS/BV [1/mm]	–		
Tb.N* [1/mm]	–	Tb.N [1/mm]	–	Segmentation:	0.8 / 1 / 26
Tb.Th* [mm]	–	Tb.Th [mm]	–	Operator Meas.:	Srinidhi Nagaraja
Tb.Sp* [mm]	–	Tb.Sp [mm]	–	Operator Eval.:	Srinidhi Nagaraja

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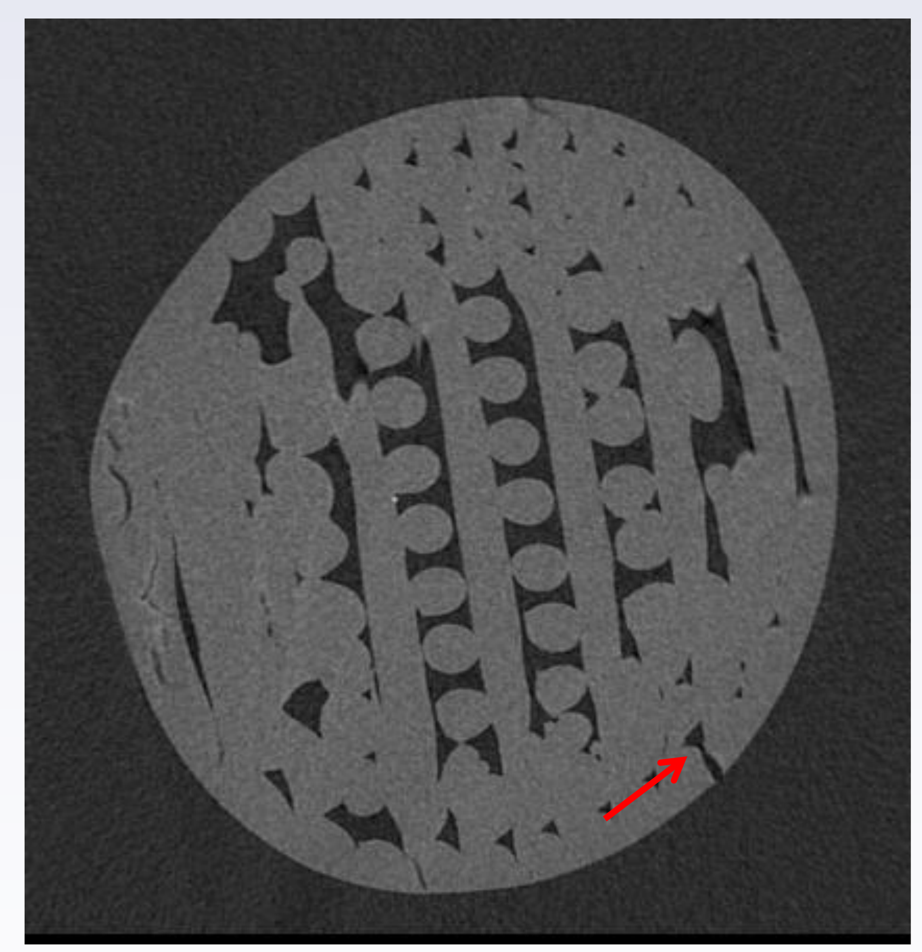
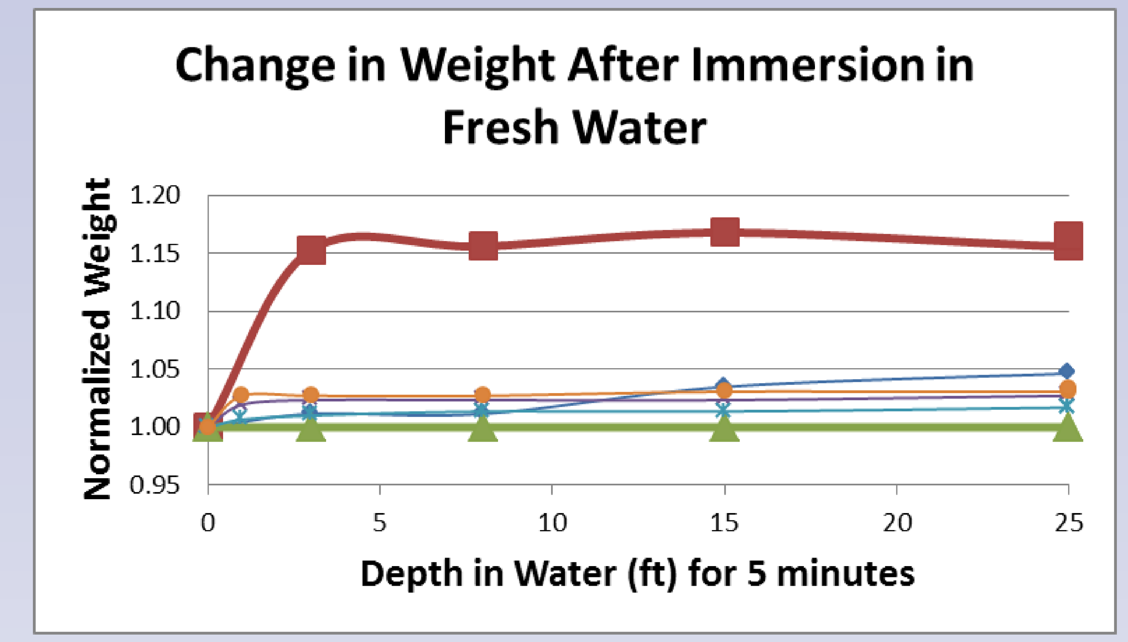
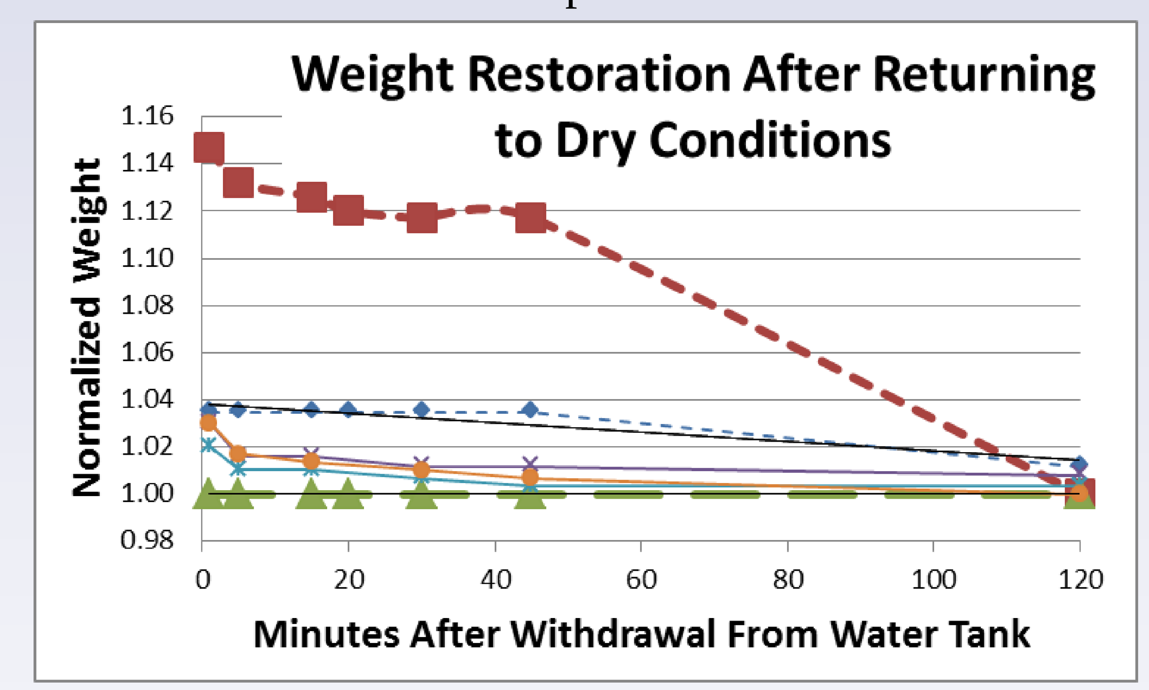


Surface cracks and interior channels are revealed by micro computed tomography. These can occur despite 3D print settings for 100% infill in fused filament prints. Slice by slice examination of 3D Prints (shown above) demonstrate that surface defects can extend beyond exterior shells into the print where they can communicate with longitudinal conduits resulting from incomplete welds or infill.

Immersion Testing of 3D Prints Under Pressure is a Sensitive Measure of Water Permeability



Visually smooth 3D printed casts/splints admitted water ranging from 0% to >15% $\pm$ 1% of print dry weight, depending on process controls. With appropriate 3D print technique, waterproofing was maintained for 30 minutes at depths of 25 feet.



If water enters 3D print, it may be retained for hours. Retained water may serve as a culture medium for microbial growth and subsequent infection of a surgical site or wound underneath the cast/splint.

Conclusion

Claims of waterproofing of 3D printed medical devices should be verified by quantitative pressure tests. Inspection of parts by optical microscopy or micro computed tomography is informative, but subject to sampling error. Surface texture should be carefully inspected for signs of porosity that could hamper hygienic cleaning of medical devices.

References

1. https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM499809.pdf