Photopolymer Suitability for a 3D Printed Model of the Bile Ducts

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Introduction

Efficient and accurate i*n vitro* testing of biomedical device prototypes, in lieu of large animal studies can decrease the research and development costs of bringing a new device to market [1]. Work in our lab is focused on fabricating an improved i*n vitro* testing system for biliary stents. These stents (see Fig 1) are inserted by gastroenterologists to restore bile draining from the liver when patients have conditions that acutely or chronically impede bile flow through the extrahepatic bile ducts (EHBD) to the small intestine (Fig 2).

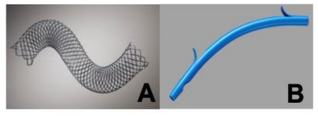

Figure 1. Commercially available biliary stents. (A) Uncovered SEM (Boston Scientific, 2011) (B) Plastic Stent (Cook Medical).

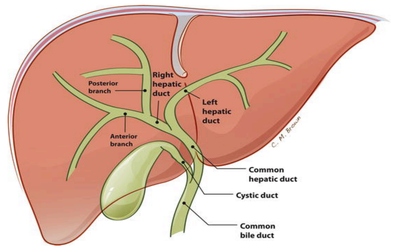

Figure 2. Hepatobiliary System [2]

An anatomically accurate model of the bile ducts will enable rapid evaluation of novel and/or custom biliary stent designs. 3D printing is a relatively inexpensive and timely means to fabricate parts and models. A 3D printed model must be elastic, pliable, and unaffected by long term contact with bile to be suitable for an *in vitro* stent testing system.

A growing number of photopolymers with a variety of mechanical characteristics are commercially available for use in stereolithographic (SLA) 3D printers. In this study we evaluated the mechanical properities and absorption capacities of 3D printed samples of Formlabs Elastic, Flexible and Durable resins that were exposed to water, saline, or bile at 37C for 72 hours.

Methods

3D Printing

Computer aided design (CAD) files of material samples were generated with Autodesk Fusion 360 software. The sample CAD files were modeled with the dimensions of an ASTM D-1708 micro tensile sample (Fig 3A & 3B). Three commercially available Formlabs photoresins were tested, Elastic Resin (FE), Durable Resin (FD), and Flexible Resin (FF).

All samples were printed on a Formlabs Form2 and washed for 20 min in ≥ 90% isopropyl alcohol (IPA) after they were removed from the print platform. Following the IPA wash the samples were cured for 10 min under UV light (395nm) (Fig 3C-E).

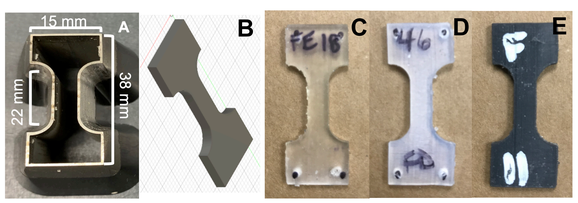

Figure 3: Sample Fabrication for Tensile Testing (A) ASTM D-1708 die, (B) CAD file of ASTM D-1708 sample, (C) Elastic resin sample, (D) Durable resin sample, (E) Flexible resin sample

Methods

Liquid Exposure and Tensile Testing

Prior to liquid exposure the mass of each sample was recorded. One side of each sample was exposed to DI water, phosphate buffered saline (PBS, pH 7.4), or bile (10% m/v solution in DI water, VWR) for 72 hours at 37C (Fig 4A-C). After 3 days of liquid exposure, samples were removed from the liquids, pat dry with a Kimwipe and their masses were recorded. Samples designated for scanning electron microscopy (SEM) were pat dry and dried for 3 hours at 37C. Tensile test samples ($N \geq 6$) were stretched to failure with a Mark-10 ESM303 (Fig 4D). Control and 72 hour liquid-exposed samples ($N \geq 3$) were sent for scanning electron microscopy (SEM) evaluation of surface morphology changes. Statistical analysis was performed with a one-tailed t test.

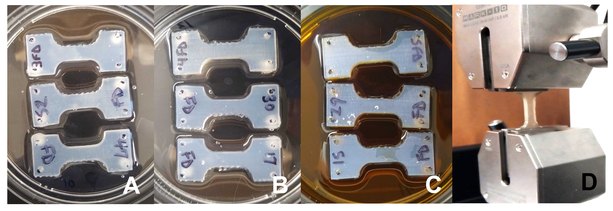

Figure 4. Liquid Exposure and Tensile Testing. (A) Samples in water, (B) Samples in saline, (C) Samples in bile acid solution, (D) Sample undergoing tensile testing

Results

Material Characteristics

Table 1. Elongation of Formlabs Photoresins Pre- and Post-Liquid Exposure. Samples were exposed for 72 hrs at 37 C. Expected values taken from Formlabs material datasheets. N = 6, Avg ± St Dev, * = P < .05.
% Elongation = Distance stretched (mm) / initial length of the parallel zone (mm) * 100

	Expected	Control	Water	Saline	Bile
Elastic	160	134.6 ± 19.0	92.9 ± 17.6 *	111.0 ± 26.9	108.4 ± 27.1 *
Durable	49	95.8 ± 10.5	105.5 ± 8.7	96.0 ± 18.4	102.3 ±21.6
Flexible	75 - 85	66.5 ± 15.2	69.5 ± 19.8	72.2 ± 21.7	86.8 ± 8.2 *

- **Elastic Resin:** The % elongation of control FE samples (134.6% ± 19.0) fell below the expected % elongation of 160%. After exposure to all 3 liquids, percent elongation decreased. This may indicate that heat exposure affects the material characteristics of the elastic resin. We plan to run heat exposure only tests to confirm this observation.

- **Durable Resin:** The FD resin had an increase in percent elongation 95.8% ± 10.5 compared to the expected 49% elongation. Our samples were cured at room temperature for just 10 min in contrast to the suggested 60 min at 60C; the shortened cure time time likely preserves some elasticity. Liquid exposure did not significantly alter the % elongation of our samples.

- **Flexible Resin:** The flexible control samples were below the expected 75 - 85% elongation at 66.5% ± 15.2. These differences are likely due to differences in the duration we UV cured our samples relative to the Formlabs suggested protocols. % elongation of flexible samples was unaffected by exposure to water and saline but we did see a modest, significant increase in % elongation after bile exposure.

Results

Liquid Absorption Capacity

In all three conditions the elastic samples absorbed enough fluid to significantly increase their masses. Formlabs indicates the elastic resin undergoes a 2% increase in mass at 24 hrs. Its unclear if greater duration of exposure would equate to additional absorption.

Table 2. Liquid Exposure Effect on Sample Mass. One side of samples was exposed to liquid for 72 hrs at 37C. Data shown is percent change in sample mass. N = 6, Avg ± St Dev. * = P < .05

	Water	Saline	Bile
Elastic	2.16 ± .15 *	2.44 ± .33 *	3.41 ± .37 *
Durable	2.19 ± .19 *	2.09 ± .34	1.85 ± .33
Flexible	.47 ± .26	.61 ± .51	.47 ± .71

Formlabs durable resin datasheet indicates it absorbs <1 % at 24 hrs in water. Again, we predict the behavior of our samples, i.e. increasing ~2% in mass in all solutions, is due to curing protocol differences.

Conclusions & Future Work

- **Liquid Exposure Effects**

Our data show that elastic resin, aptly named, is the most elastic of the 3 resins we tested. Its liquid absorption capacity and potential changes upon heat exposure must be considered when utilizing it for future experiments. Liquid absorption into the elastic resin may negate any ability to reuse a device fabricated with it.

All liquid absorption capacity studies will be repeated; pre-exposure masses were potentially incorrect due to modifications made to durable and flexible samples to facilitate experimental set up.

- **Additional material characterization**

Control, water exposed, bile exposed, and saline exposed samples were sent for scanning electron micrographs to identify any changes in surface morphology ($N \geq 3$). Additional samples will be liquid-exposed for 1 week ($N \geq 6$) to evaluate if longer exposure to any of the solutions has negative effects on the polymers.

- ***In vitro* stent testing**

These results and other data that we have collected will be used to select the polymer or polymer blend most suitable for 3D printing an accurate model of the extrahepatic bile ducts (EHBD). We plan to test biliary stent prototypes in our EHBD model (see Fig 5).

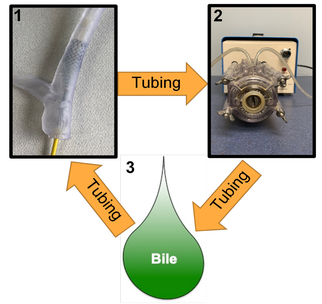

Figure 5: *In Vitro* Stent Testing System (1) stent placed in our *in vitro* model (2) peristaltic pump (3) bile reservoir at 37C

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