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Three-dimensional printing surgical instruments: are we there yet?

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ABSTRACT

Background: The applications for rapid prototyping have expanded dramatically over the last 20 y. In recent years, additive manufacturing has been intensely investigated for surgical implants, tissue scaffolds, and organs. There is, however, scant literature to date that has investigated the viability of three-dimensional (3D) printing of surgical instruments.
Materials and methods: Using a fused deposition modeling printer, an Army/Navy surgical retractor was replicated from polylactic acid (PLA) filament. The retractor was sterilized using standard Food and Drug Administration approved glutaraldehyde protocols, tested for bacteria by polymerase chain reaction, and stressed until fracture to determine if the printed instrument could tolerate force beyond the demands of an operating room (OR).
Results: Printing required roughly 90 min. The instrument tolerated 13.6 kg of tangential force before failure, both before and after exposure to the sterilant. Freshly extruded PLA from the printer was sterile and produced no polymerase chain reaction product. Each instrument weighed 16 g and required only $0.46 of PLA.
Conclusions: Our estimates place the cost per unit of a 3D-printed retractor to be roughly 1/10th the cost of a stainless steel instrument. The PLA Army/Navy retractor is strong enough for the demands of the OR. Freshly extruded PLA in a clean environment, such as an OR, would produce a sterile ready-to-use instrument. Because of the unprecedented accessibility of 3D printing technology world wide and the cost efficiency of these instruments, there are far reaching implications for surgery in some underserved and less developed parts of the world.

1. Introduction

Additive manufacturing or three-dimensional (3D) printing has recently shown itself to have some immediate utility in medicine and surgery [1,2]. Surgeons are using patient computed tomography–derived 3D prints to plan surgical approaches [3]. 3D models of patient-specific anatomy such as dental crowns and biological scaffolds are already being used for human implants [4–6]. However, there is scant literature

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discussing the production of surgical instruments with a 3D printer [7].

The first 3D print was reported by Hideo Kodama in 1982. Since the additive manufacturing/3D printing of simple shapes, 3D printers have become much more accessible and are now able to print with a multitude of materials including metals, wood products, and thermoplastics such as polylactic acid (PLA). In addition, there are various techniques for printing solid materials in 3D, including electron beam free-form fabrication, direct metal laser sintering, and fused deposition modeling (FDM), among others.

Within the surgical realm, PLA and polyglycolic acids have been intensely investigated for biodegradable implants and suture material, such as Vicryl (Ethicon, New Brunswick, NJ) [5]. As PLA has been proven to be safe for surgical implantation, we selected it as a cost effective, safe, and environmentally suitable material for printing a surgical instrument.

An instrument, although defined by its form, must also be functional. We sought to produce an instrument capable of tolerating the demands of the operating room on a commercially available 3D printer. An Army/Navy retractor is simple in shape and ubiquitous in all surgical specialties. The retractor must be strong enough to retract human tissue, hypoallergenic, and it must tolerate repeat sterilization. Finally, it must be at least equivalent in cost, strength, and accessibility when compared with a standard stainless steel Army/Navy retractor to be considered as a substitute.

The ability to sterilize a 3D-printed instrument is paramount to its application. PLA is extruded at temperatures well above the 121°C recommended for steam sterilization or even the 170° C recommended for dry heat sterilization [6]. However, research has found that autoclaving compromises the structural integrity of PLA [5,8]. Minimal degradation of PLA polymers has even been shown *in vitro*, when physiological conditions are simulated for days to weeks [9,10]. Although lower temperature methods of sterilization such as ethylene oxide "gas" sterilization did not impact PLA strength, harmful levels of ethylene oxide residue are a serious concern. Alternatively, glutaraldehyde, an effective sterilant at room temperature, has been shown to retain the greatest PLA strength when compared with other chemical sterilants [11]. As we are unaware of works in the medical literature specifically focusing on this area, the purpose of this pilot study was to determine if printed surgical instruments would tolerate chemical sterilization and tension of an operation.

2. Methods

In this project, we used a MakerBot Replicator 2 (MakerBot, Brooklyn, NY), MakerBot MakerWare software to generate G-code by means of slicing via MakerBot Slicer (software products of MakerBot industries) and a PLA substrate to print a prototype replica of a common Army/Navy retractor. The instrument measured 17 cm × 1.5 cm × 4 mm and was printed with 75% infill (the density with which the instrument is printed), six shells of perimeter laid axially, and 100-μm layer height with a hexagonal infill pattern. The replicator 2 printer extruded material at 240°C with a 90 mm/s speed while extruding.

To confirm sterility of the instrument, five replicate samples were taken of each of the following items: the printing environment (desk, keyboard, and so forth); the freshly printed retractor; a "clean catch" 5 cm string of PLA collected on extrusion; 5 cm pieces of PLA before printing; and printed retractor after exposure to sterilant. Sterilization entailed submersion in a 2.4% glutaraldehyde solution with a pH of 7.5 for 20 min at 25° C in accordance with CDC guidelines for critical medical devices [6]. All samples were tested for bacterial load using polymerase chain reaction (PCR) amplification of the V1-V2 region of the 16s rRNA gene as a measure of intact bacterial DNA. Briefly, 200 μL sterile phosphate-buffered saline were added to each sample and vortexed. Two microliters of buffer was used as template in a PCR consisting of 4 min at 98°C followed by 30 cycles of 98°C for 10 s, 68.8°C for 30 s, 72°C for 30 s. PCR reagents were from the Applied Biosystems (Grand Island, NY) real-time PCR Master mix with 2 U of Phusion polymerase (New England bioloabs incorporated, Ipswich, MA). The forward primer sequence was: AGAGTTT GATCMTGGCTCAG and the reverse primer sequence was: CYIACTGCTGCCTCCCGTAG. Two microliters of the resulting PCR product from each reaction was analyzed on an agarose gel to determine if a PCR product had been formed of anticipated size. Negative controls consisting of purified water were included to control for contamination of the reagents. A positive control containing *Escherichia coli* genomic DNA was included to demonstrate success of the procedure.

To test the strength of the instrument, weights were suspended by a 1.5-cm webbing and sequentially hung from the retracting surface of the instrument while it was held perpendicular to the ground by an investigator. Five printed retractors of the same measurements and infill were tested and a one retractor was tested after sterilization with glutaraldehyde.

3. Results

Printing of the Army/Navy retractor required just <90 min. Print times were consistent for all instruments and dependent on G-code generated by the slicing profile settings as well as the printer's capabilities.

The form accurately represented an Army/Navy retractor. This is due in part to accurate computer-aided design, and the 100-μm resolution of our chosen printer (Fig.).

All specimens collected from the environment, the freshly printed instrument, the raw PLA and the gluteraldehyde-processed instrument contained bacterial gene products. The clean catch samples that were collected immediately on extrusion revealed no viable bacterial product.

Strength testing proved that the printed retractor tolerated 11.3 + 0.57 kg of tangential force, began to visually deform at 13.6 + 0.68 kg, and fractured at 15.9 + 0.8 kg. The glutaraldehyde-processed retractor showed no significant difference in tolerances ($P = 0.96$).

Our 3D printer was purchased for $2199 and 1 kg of PLA is available for $27.99 including shipping. Each retractor weighed 16 g. We can make 61 custom retractors/kg, which calculates to $0.46 of PLA per instrument with our settings applied in G-code generation.