Journal of
Manufacturing and Materials Processing

MDPI

Article

Preliminary Investigation on Biodegradable Ureteral Stents Using 3D Printing

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Abstract: The prevalence of kidney stones, a significant urological health concern, necessitates advancements in the management and treatment methods, particularly in the domain of ureteral stents. This study explores the feasibility and potential benefits of utilizing three biodegradable polymers—Polylactic Acid (PLA), Tough Polylactic Acid (Tough PLA), and Polylactic Acid/Poly-hydroxybutyrate (PLA/PHB)—for the fabrication of 3D-printed ureteral stents tailored to patient-specific needs. Through the integration of CAD and Fused Deposition Modeling (FDM) 3D printing technology, ureteral stents were successfully produced, demonstrating key advantages in terms of biodegradability and mechanical properties. The study involved a rigorous evaluation of the biodegradability, tensile strength, and hardness of the stents. Biodegradability tests performed in a simulated physiological environment revealed that PLA/PHB and Tough PLA stents exhibited higher degradation rates compared to PLA, aligning with the requirements for temporary urinary tract support. Tensile strength testing indicated that while PLA showed the highest strength, PLA/PHB and Tough PLA stents provided beneficial ductility, reducing the risk of blockage due to material breakage. Hardness assessments classified PLA/PHB stents as medium soft, optimizing patient comfort during the stenting period. These findings demonstrate the potential of using biodegradable polymers to produce ureteral stents that could eliminate the need for removal procedures, thereby enhancing patient recovery and comfort.

Keywords: ureteral stent; 3D printing; biodegradable

Academic Editor: Steven Y. Liang

Received: 5 January 2025
Revised: 30 January 2025
Accepted: 4 February 2025
Published: 6 February 2025

Citation: Chetan, C.; James, S. Preliminary Investigation on Biodegradable Ureteral Stents Using 3D Printing. *J. Manuf. Mater. Process.* **2025**, *9*, 52. https://doi.org/10.3390/jmmp9020052

1. Introduction

Kidney stones are hard deposits of minerals and salts inside the kidneys [1]. They can develop when urine becomes concentrated, allowing minerals to crystallize and stick together. Depending on their size, kidney stones can pass through the urinary tract on their own with minimal discomfort, or they may cause severe pain, urinary blockage, and complications if they become too large to pass [2]. The symptoms often include sharp pain in the back and side; pain that radiates to the lower abdomen and groin; pain during urination; pink, red, or brown urine; nausea; and vomiting [2]. Factors such as diet, excess body weight, certain supplements, and medical conditions can increase the risk of forming kidney stones [3].

Ureteral stents have significantly impacted the field of urology, turning many procedures that would have required overnight stays in the hospital into outpatient procedures [4]. It was not until the double-pigtail and double-J stent configuration was introduced in 1978 that stents were regularly used without experiencing major problems [5].

Ureteral stents are devices implanted to hold open the ureter, allowing urine to flow physically. The utilization of ureteral stents can be broadly grouped into five categories: (1) alleviation of cancerous obstruction; (2) in conjunction with kidney stone therapy; (3) placement during the perioperative period; (4) management of urine leakage; and (5) alleviation of ureteral stricture. Among various clinical applications, the primary use of ureteral stents is to facilitate the treatment of kidney stones [6]. They are strategically placed to maintain ureteral patency, alleviating obstructions caused by stones, thus allowing for smoother passage of urine and smaller stone fragments and reducing the risk of complications such as hydronephrosis and severe pain.

The urinary system consists of the kidneys, ureters, bladder, and urethra, and its primary function is to remove waste (e.g., uric acid, creatinine, ammonium, ions, sulfates, phosphates, and oxalates) [7] from the bloodstream and convert it into urine. Urine travels down the ureters into the bladder, where it is stored. Voiding urine through the urethra via the coordinated relaxation of the external urethral sphincter and bladder smooth muscle contraction, forcing the urine out of the body [8]. The kidneys are bean-shaped organs that filter waste out of the blood through 1 million tiny units called nephrons [9]. Each nephron contains a glomerulus with fenestrae that filters small molecules while retaining larger red blood cells. The resulting filtrate, combined with water, forms urine, which flows through a tubule to the collecting duct. The ureter then transports urine to the bladder [10]. The ureters are roughly 26 cm long and allow peristalsis to transport urine from the kidney to the bladder. The wall of the ureter is composed of three layers: the mucosa, muscularis, and adventitia. Unlike other transport systems, such as the GI tract, the ureter lacks a connective tissue layer called the submucosa [10]. Blood supply to the ureter is provided from the branch of the nearest artery (e.g., renal arteries, aorta, common iliac, or internal iliac arteries), and drainage is performed from companion veins. It has been observed that the ureter has three physiological narrowings. First, the point where the ureter connects to the kidney is called the ureteropelvic junction. The second occurs as it crosses over the iliac vessel. Finally, the third narrowing is at the ureterovesical junction, where the ureter connects to the bladder. The ureteropelvic and ureterovesical junctions are where stones are most likely to be trapped [11].

Kidney stones, among the most excruciating urological conditions, are not exclusive to modern life. Regrettably, they remain one of the most prevalent disorders affecting the urinary tract. A large number of people are suffering from urinary stone problems all over the globe [12]. This condition, known as nephrolithiasis or urolithiasis, remains a significant challenge in healthcare and affects a substantial portion of the global population. Epidemiological studies have been crucial in revealing this disease's evolving patterns and increasing burden, focusing on identifying modifiable risk factors. For instance, the National Health and Nutrition Examination Survey (NHANES) data indicate a rising trend in kidney stone prevalence, from 3.8% in the late 1970s to over 10% in recent years. Similar increases are observed in Europe, with countries like Germany, Spain, Italy, and France reporting significant growth in prevalence rates. This escalation highlights the need for continued research and innovative treatment strategies to effectively manage this persistently troubling health issue. Kidney stones affect approximately one in eleven people in the United States [13]. The prevalence of kidney stones has been increasing in the U.S. and other parts of the world over the past few decades [13]. Among men, the prevalence of stones was 10.6% (95% CI, 9.4–11.9), compared with 7.1% (95% CI, 6.4–7.8) among women. Kidney stones were more common among obese than normal-weight individuals (11.2% [95% CI, 10.0–12.3] compared with 6.1% [95% CI, 4.8–7.4], respectively; $p < 0.001$) [13].

Kidney stones, composed of minerals and organic substances, are a prevalent medical challenge impacting many people worldwide. The treatment for kidney stones is similar in

children and adults [14]. Doctors often advise drinking more water to help kidney stones move naturally without surgery. You might also be prescribed medicine that lowers the acidity of your urine, which helps the stones pass more easily [15]. But if the size of the stone is too large, it blocks the flow of urine, or if there is a sign of infection, it is removed with surgery. Kidney stones can be treated in two ways [16]. One is using shockwave. Lithotripsy is a non-invasive procedure that uses high-energy sound waves to blast the stones into fragments that more easily pass out in the urine. The second is with ureteroscopy, where an endoscope is inserted through the ureter to retrieve or obliterate the stone [16]. Even with this, a stenting procedure is required [17]. Rarely, for very large or complicated stones, doctors will use percutaneous nephrolithotomy/nephrolithotripsy [18]. Traditional treatments, such as extracorporeal shock wave lithotripsy and invasive surgeries, often face limitations in terms of invasiveness, extended recovery periods, and potential side effects. Consequently, there is an increasing emphasis on innovative, minimally invasive approaches [19].

Approximately 92,000 ureteral stents are implanted every year to maintain urine flow after the treatment of kidney stones, kidney transplants, and urinary incontinence [19]. Most ureteral stents currently on the market are non-biodegradable [20], and the stents are commonly used to facilitate stone passage and relieve obstruction and are effective but with some complications, including discomfort, infection risk, encrustation, and the necessity for a secondary removal procedure [21], highlighting the need for advanced, patient-friendly stent technologies in urological care. The escalating utilization of ureteral stents in managing various urinary tract diseases necessitates a thorough understanding of these devices, their potential consequences, and the severe complications they may entail. The stent's novel coiled shape is intended to provide flexibility and anchor it to the ureter [22]. This highlights the pressing need for improved stent materials and more comprehensive patient management strategies to mitigate the inherent problems associated with traditional ureteral stents [22].

While essential for patient care, the stenting procedure introduces certain challenges and inconveniences. This process consists of two main stages: the initial insertion and the subsequent removal after a 21-day period [23]. The insertion phase is meticulously carried out to ensure both the patient's comfort and the stent's proper placement. However, the necessity of a follow-up procedure for stent removal can be a significant inconvenience. After the healing period, the removal process requires the patient to be under anesthesia once again, introducing potential anxiety and discomfort associated with the use of medical interventions for the removal of the stent to ensure precise positioning and extraction. While it is essential for the success of the treatment, the subsequent use of a cystoscope during the insertion and removal of the stent for precise positioning and extraction adds another level of complication. It may cause discomfort for the patient [24]. These aspects underscore the procedural hassles and physical and emotional strain the patient may experience during the stenting journey, highlighting the need for careful consideration and support throughout the process [25]. Despite their widespread use, these stents are plagued with complications that impede their functionality and patient comfort [26]. Common issues such as encrustation, infection, pain, discomfort due to tissue irritation, and irregular peristalsis are frequently encountered. Moreover, though less common, stent migration and failure occur particularly in cases involving external compression due to malignancies or restenosis [26].

A promising direction in advancing kidney stone treatment involves using biodegradable stents [19], a breakthrough made possible through the development of advanced biocomposites. These stents are engineered from composite biomaterials [19]. Biocomposites in these stents offer the dual benefits of biodegradability and optimized mechanical

properties, ensuring that they maintain structural integrity during their functional period before naturally degrading within the body. This innovative feature of biodegradable stents, stemming from the sophisticated blend of biomaterials, significantly reduces the need for follow-up surgical interventions, thereby transforming patient care. Intense research efforts are currently dedicated to enhancing the degradation profiles of these biocomposites to deliver safer, more effective solutions for patients suffering from kidney stones [27]. Lumiaho et al. explored self-expanding poly-L-D-lactide to fabricate a ureteral stent in a 2009 study [28]. A comparative investigation between poly(lactic-co-glycolic acid) (PLGA) stents and the widely used double-J stent was conducted on eight pigs. Both ureters had a little cystotomy, and the left ureter was stent-filled with segments of PLGA, while the right ureter was stent-filled with double-J stents. The material nature of the double-J stent was not disclosed. Six of the eight PLGA stents had no reflux after four weeks, while the others had mild reflux. Every double-J stent displayed reflux of some kind [28].

Ureteral stents are medical devices used to treat various urinary tract conditions by supporting the ureters, allowing urine to flow from the kidneys to the bladder. Traditional manufacturing approaches for ureteral stents typically involve the following steps:

- Materials Used: The stent material is selected based on biocompatibility, flexibility, and durability. Common materials include silicone, polyurethane, various polymers, and nickel–titanium alloy. Nickel–titanium alloy-based stents such as Memokath^{TM} 051 and Uventa have unique thermo-expandable and shape memory properties that allow them to be flexible and resilient within the dynamic environment of the ureter [29]. To be effective, ureteral stents must be within an acceptable range of physical and mechanical properties. The tensile strength of traditional ureteral stents typically ranges from 3 MPa to 40 MPa [30–33]. This enables the production of thinner ureteral stents with larger internal diameters by facilitating superior intraluminal flow (Hendlin et al., 2006). Hardness is also a significant factor for ureteral stents, with optimal values typically falling within a medium-soft range [34]. Also, recent studies have shown that traditional ureteral stents have shown a degradation percentage of 91.7% within 6 weeks [19,35];
- Molding or Extrusion: The selected material is molded or extruded into the desired shape and dimensions of the stent. This process involves heating and forming the material into the desired shape using molds or extrusion dies;
- Cutting and Finishing: after molding or extrusion, the stents are cut to the appropriate length and undergo finishing processes to smooth out any rough edges and ensure uniformity in size and shape;
- Quality Control: Quality control measures are implemented throughout manufacturing to ensure the stents meet the required specifications and standards. This may involve visual inspection, dimensional measurements, and testing for mechanical properties and biocompatibility.

Challenges associated with traditional manufacturing approaches for ureteral stents include the following:

- Biocompatibility: this ensures that the materials used in the stents are biocompatible and do not cause adverse reactions or tissue irritation when implanted in the body [36];
- Flexibility and Patency: a balance is needed for stents to be sufficiently flexible to navigate the urinary tract while maintaining patency to allow for urine flow [36];
- Infection Risk: ureteral stents can increase the risk of urinary tract infections, so minimizing the risk of bacterial adhesion and biofilm formation on the stent surface is crucial [36];

- Patient Comfort: Ureteral stents can cause discomfort and urinary symptoms in some patients, so optimizing the design and material properties to enhance patient comfort is essential [36]. A softer stent is theoretically more comfortable for the patient [34];
- Migration and Encrustation: stent migration and encrustation (the formation of mineral deposits on the stent surface) are common complications that can occur post-implantation and may require additional interventions [36].

To address these challenges, researchers and manufacturers are exploring alternative materials, coatings, and designs for ureteral stents and incorporating drug delivery systems and antimicrobial agents to reduce infection risk and improve patient outcomes. Additionally, advancements in additive manufacturing technologies, such as 3D printing, offer the potential for more customized stent designs tailored to individual patient anatomy [37]. Biodegradable ureteral stents were crafted by blending the Polylactic Acid (PLA) variants PLLA and PDLLA with a 25% barium sulfate additive for radio-opacity, casting the mixture into films, and then shaping these on a stainless steel wire. These stents, measuring 50 mm in length and 1.4 mm in external diameter, were oven-dried and sterilized, offering flexibility for easier insertion [38].

The advent of three-dimensional (3D) printing technologies has revolutionized various aspects of the biomedical sector, particularly in the realm of medical implants. Its most notable application is fabricating implantable scaffolds, such as stents, where it promises to make significant strides. Several issues that have long plagued the stenting industry are expected to be resolved due to the unique capability of 3D printing to customize and precisely tailor these implants [37]. By allowing the production of stents specifically engineered to fit a unique patient anatomy, this strategy addresses problems associated with inaccurate sizing and design constraints observed in traditional stenting approaches. This work uses 3D printing's complex design and rapid prototyping capabilities to manufacture patient-specific stents tailored to improve efficacy and performance. This innovative application of 3D printing technology to produce customized medical implants is a significant leap in personalized healthcare solutions and patient outcome improvements [37].

Three-dimensional printing, particularly through Fused Deposition Modeling (FDM), has emerged as a transformative fabrication process capable of creating intricate 3D objects by layering materials. Traditionally, FDM printers relied on non-biodegradable materials for filament fabrication [39]. However, with evolving manufacturing strategies and a growing focus on sustainability, there has been a significant shift towards developing biodegradable biofilaments [39]. This shift is environmentally beneficial and addresses the limitations imposed by the cost and availability of petroleum-based filaments. In medical applications such as stent fabrication, using biodegradable biofilaments present a promising avenue, offering potential cost reductions and enhanced sustainability [40].

To the best of our knowledge, this study represents a pioneering effort in the creation of biodegradable ureteral stents using 3D printing technology. While there has been extensive research on both biodegradable and bioresorbable stents, as well as on 3D-printed medical devices, our study uniquely combines these fields to explore the potential of 3D printing in fabricating biodegradable stents. This novel approach allows for the precise customization and optimization of stent geometry and material properties, offering significant advantages in terms of patient-specific solutions and manufacturing efficiency. By integrating 3D printing technology, this study aims to advance the development of ureteral stents, enhancing their functionality and clinical outcomes.

The present study employs advanced 3D printing technology integrated with biodegradable materials to develop custom-sized, patient-specific ureteral stents aimed at significantly enhancing patient comfort and improving the quality of life post-treatment. Our research is dedicated to the detailed development and thorough characterization of

these stents, with a focus on precisely adjusting their mechanical properties and closely monitoring their degradation rates to ensure reliable performance throughout their functional lifespan. By leveraging the rapid prototyping capabilities of 3D printing, we can quickly iterate designs to meet specific patient needs, enhancing the customization process. This approach not only facilitates the tailored sizing of the stents but also makes the production process cost-effective. The evaluation includes extensive in vitro experiments that meticulously assess biodegradation rates, material hardness, and mechanical strength to validate the stents' performance, ensuring that they meet the required standards for clinical use.

2. Materials and Methods

2.1. Material

This study explores the use of filaments made of three biodegradable polymers for the creation of a 3D-printed ureteral stent: Polylactic Acid (PLA), Tough Polylactic Acid (Tough PLA), and Polylactic Acid/Poly-hydroxybutyrate (PLA/PHB) (Make: Ultimaker, Utrecht, The Netherlands, Model: S Series). PLA was chosen due to its biocompatibility, ease of printing, and established use in medical devices. Tough PLA offers improved mechanical properties, making it ideal for stents that need to withstand physical stresses. The PLA/PHB blend combines the advantages of both PLA and PHB, aiming to enhance toughness and biodegradability compared to PLA alone. These materials were selected for their potential to create a biodegradable ureteral stent that combines necessary functionality with optimal safety and breakdown within the body.

PLA is a biodegradable thermoplastic derived from renewable resources like corn starch or sugarcane, making it a sustainable option in 3D printing. Its biocompatibility is a defining feature that allows for medical applications, including the production of medical implants. These implants are designed to dissolve and flow out of the body gradually. PLA's ability to degrade into lactic acid, a substance naturally metabolized by the human body, makes it a preferred material for temporary internal fixation devices, like screws and pins in orthopedic surgery, as well as for controlled drug delivery systems. Its ease of printing and safety profile make PLA a significant choice for innovating and advancing medical treatments and devices.

Tough PLA is a modified version of traditional Polylactic Acid filaments engineered for 3D printing applications that demand higher durability. By incorporating impact modifiers or altering the polymer structure, tough PLA achieves superior toughness and tensile strength compared to PLA without sacrificing its ease of printing and environmental benefits derived from renewable resources. This enhanced material is ideal for producing more durable parts and functional prototypes that require resistance to stress and impact, combining the user-friendly characteristics of PLA with improved mechanical properties for rigorous use.

PLA/PHB is a blend of two biodegradable polymers designed to combine the desirable properties of both materials for advanced 3D printing and plastic applications. PLA provides strength and rigidity, while PHB offers flexibility and enhanced biodegradability. Compared to the individual polymers, this blend aims to improve the overall mechanical properties, such as toughness and impact resistance. The synergy between PLA and PHB results in a material that exhibits improved physical characteristics suitable for various applications. It also maintains environmental sustainability due to its biodegradable nature.

2.2. Computer-Aided Design (CAD) Model

Figure 1 shows the 3D model for a ureteral stent using a Computer-Aided Design (CAD) platform, SOLIDWORKS. This design is strategically chosen for its efficacy in

maintaining the positional integrity of the stent within the ureteral passage [41]. Based on the patient-to-patient method, appropriate stent size selection is fundamental for comfort and preventing migration [37]. Characterized by its distinctive pigtail ends, the double-J stent ensures secure anchorage [19]: one end is affixed to the renal pelvis, while the opposite is connected to the bladder. This configuration is instrumental in stabilizing the stent, preventing displacement, and facilitating continuous urine flow from the kidney to the bladder, demonstrating a critical advancement in urological interventions [41].

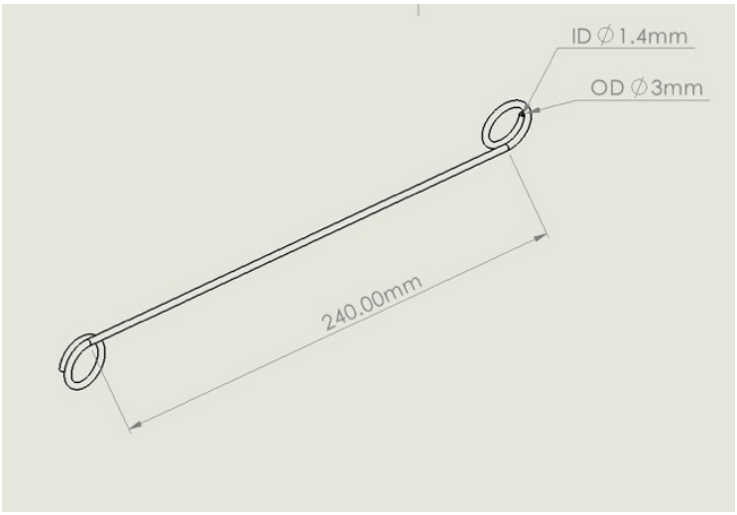


Figure 1. CAD of a ureteral stent.

2.3. Three-Dimensional Printing Process

Figure 2 shows the Fused Deposition Modeling (FDM) 3D printing setup (Make: Ultimaker, Utrecht, The Netherlands, Model: S3) used in this study. This printer's advanced capabilities allow for the use of a wide range of filament materials, enabling us to explore various compositions to optimize the biodegradability and functionality of the stents.

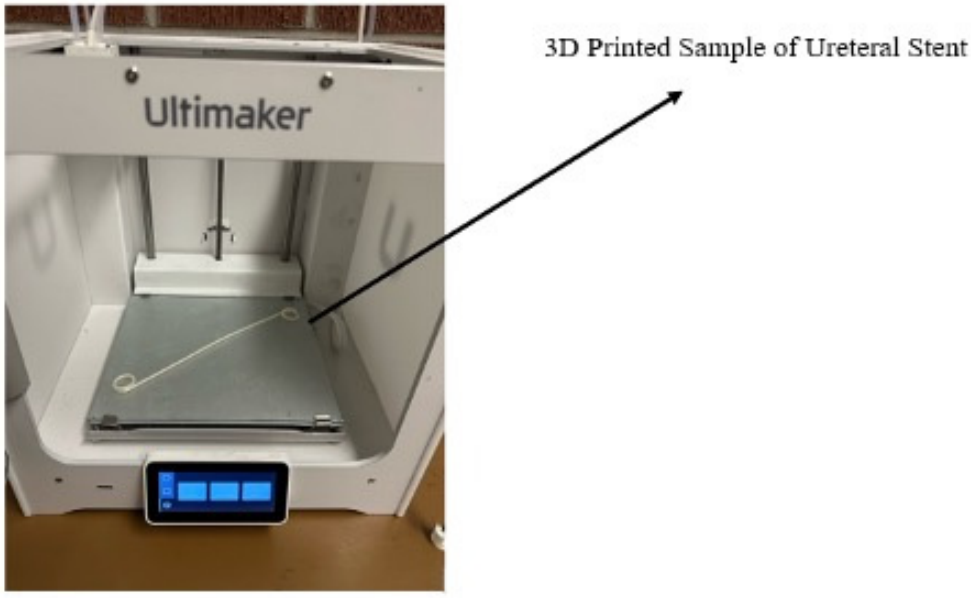


Figure 2. Three-Dimensional printing setup used for fabricating the ureteral stent.

The following procedure was adhered to for the fabrication of the ureteral stents. Biodegradable polymer filaments were prepared, ensuring that they were dry and free from

impurities, and loaded into the 3D printer according to the manufacturer's instructions. The ureteral stent was designed using the CAD software (SOLIDWORKS 2024) based on patient-specific anatomical data, incorporating features like pigtail ends to optimize placement and minimize migration. The 3D printer parameters, such as extruder temperature printing speed and layer thickness, were set as shown in Table 1 to ensure optimal layer adhesion and structural integrity; the printing process was then started, with monitoring for any errors or malfunctions. After printing, the stent was removed from the build platform; any support structures were manually removed. A thorough quality control check was conducted, with each stent inspected visually and through dimensional measurements to confirm it met the design specifications. Each stent was tested for mechanical strength and biodegradability under simulated physiological conditions.

Table 1. PLA/PHB, Tough PLA, and PLA parameters for the ureteral stent.

Parameters	**Stent**		
Material	**PLA/PHB**	**Tough PLA**	**PLA**
Extruder Temperature (°C)	185	160	220
Layer Height (mm)	0.15	0.15	0.15
Printing Speed (mm/s)	60	60	60
Infill Pattern	Grid	Grid	Grid
Infill Density %	60	60	60
Fan Speed %	100	100	100
Build Plate Adhesive	Yes	Yes	Yes
Diameter of the Stent (Fr)	9	9	9

2.4. Biodegradability Testing

2.4.1. Testing Medium

A phosphate-buffered saline (PBS) solution was used as a testing medium. This solution was chosen to mimic the environment of the urinary tract and kidney, offering a realistic setting for evaluating the stents' degradation behavior, which was kept at a constant 37 °C [42].

2.4.2. Biodegradability Rate Testing

To assess the biodegradability, 63 stents were 3D printed using the three materials, and in the initial phase of biodegradability testing, 21 stents made from a blend of PLA and PHB, alongside 21 stents made from Tough PLA and 21 stents from PLA, were each immersed in the PBS solution. This solution is commonly used for in vitro testing to simulate body fluid conditions. The stents were incubated at 37 °C for 21 days to mimic the human body's internal temperature, providing a consistent environment for evaluating the materials' biodegradability under near-physiological conditions.

Each set of stents, constructed from various filament materials, was accurately weighed before immersion in individual laboratory-grade bottles filled with the PBS solution. These laboratory-grade bottles were consistently maintained at a temperature mirroring the average human body temperature, establishing a controlled and realistic environment for degradation assessment. The stents, designated as S1 through S21 for each material, underwent periodic evaluations to document their physical integrity, weight reduction, and any signs of degradation. This process was designed to accurately measure the biodegradation rate for each type of filament when exposed to simulated bodily fluids. To determine the biodegradability rate, a mass percentage method was used, initially measuring the weight of each stent before submersion in the PBS solution, where it was

also taken into consideration that there was no moisture in it. The stents were labeled S1 to S21 to correspond with the inspection day, from day 1 to day 21, respectively. After every 24 h, the stents were removed from the solution and re-weighed to determine the mass lost for the day, with the findings carefully recorded.

$$Degradation\% = \frac{(M_{Initial} - M_{Final})}{M_{Initial}} \times 100 \quad (1)$$

This equation represents the degradation percentage of each stent. Initially, the weight of each stent was measured after 24 h of incubation to eliminate moisture presence (denoted as $M_{initial}$). Subsequently, daily measurements of the stents' weights (denoted as M_{Final}) were taken by removing the stents from the testing medium, after removing them from the incubator, and drying them inside the incubator for 24 h, ensuring moisture absence before recording the weight.

2.5. Tensile Strength Testing

Figure 3 shows the test setup used for the tensile testing of the sample materials. Tensile testing is a fundamental method for assessing the mechanical behavior of materials used in ureteral stents, crucially determining their tensile strength and ductility. By subjecting stent materials to controlled tension, this testing procedure yields invaluable insights into their ability to withstand the demanding conditions encountered within the urinary tract environment. Understanding the tensile characteristics of stents is essential for ensuring their structural integrity and longevity, especially in scenarios where the stent faces varying levels of urinary flow and pressure. This comprehensive knowledge guides the design and fabrication of stents, facilitating the development of devices that not only offer superior performance and reliability but also prioritize patient comfort. Moreover, enhanced tensile strength enables the production of thinner ureteral stents with larger internal diameters, thereby facilitating superior intraluminal flow Furthermore, the test assesses the material's ductility, a critical attribute that signifies its capability to undergo plastic deformation when subjected to stress. This inherent ductility serves to reduce the risk of sudden failure and subsequent complications, ensuring the stent's reliability and longevity in diverse clinical settings.

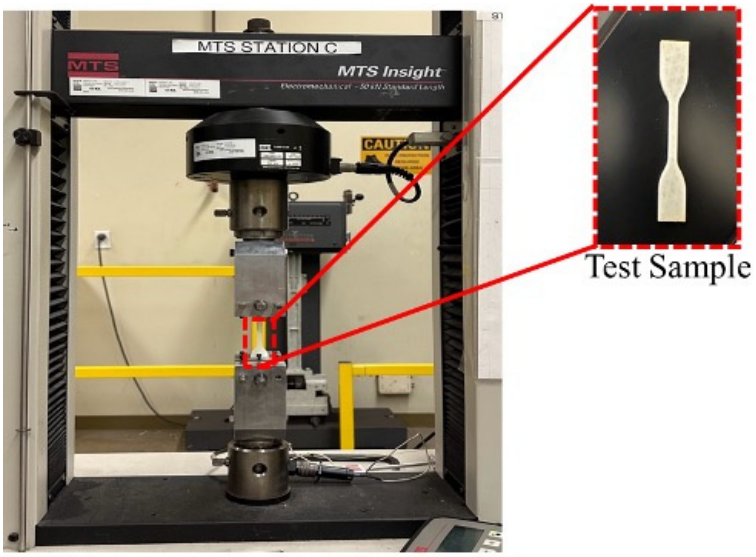


Figure 3. Tensile test setup used (inset shows the ASTM 638D-based tensile test sample).

Initially, standardized specimens are prepared according to specific dimensions and configurations. Specifically, the tensile test specimens measured 115 mm × 19 mm and are fabricated in quantities of 5 to provide a robust dataset for analysis. These specimens are then subjected to a tensile test conducted in accordance with the ASTM D638 standards. The samples are securely clamped onto the MTS Insight universal testing machine during the test. The experimental parameters for the tensile tests included an axial load applied at a constant rate of 1.5 mm/min, with continuous recording of force and deformation until failure. These parameters were chosen to simulate the physiological conditions the stents would experience in vivo, providing insights into their structural integrity and performance. Axial load is then gradually applied to each specimen until it reaches its breaking point, known as failing. Data regarding the applied force and deformation of the specimens are continuously recorded throughout the testing process. These data allow us to analyze the material's behavior under tension and determine its tensile strength, providing valuable insights into its mechanical performance.

2.6. Hardness Testing

The hardness of ureteral stents was carefully evaluated, which is essential for determining whether they are classified as medium, soft, or hard. This assessment was performed using a Shore A durometer, a recognized instrument for measuring the hardness of elastomers. This choice was made due to the specific elastomeric properties exhibited by the Tough PLA and PLA/PHB blends used in this study. These materials demonstrated sufficient elasticity in preliminary assessments, aligning with the Shore A hardness scale. This approach was deemed appropriate for capturing the softer, more flexible nature of the stents, which is crucial for assessing their suitability in terms of patient comfort and adaptability within the urinary tract. While Shore D is conventionally used for harder materials, the application of Shore A in this context provides valuable insights into the stents' performance characteristics. Future studies will include additional hardness testing using the Shore D scale to offer a comprehensive understanding of the material properties and further validate our findings. These standardized specimens were then subjected to a hardness test to measure their hardness by making indentations on four random points on the top face of the sample for all the materials. The tests were repeated five times to ensure accuracy and reliability. This provided critical data for the material selection process for optimal stent fabrication [17]. Hardness was determined using a Shore A type hardness tester (Make: Gain Express Holdings Ltd., To Kwa Wan Kowloon, Hong Kong, Model: 560-10A) according to the ASTM standards. Figure 4 shows the scale for Shore A hardness testing [43].

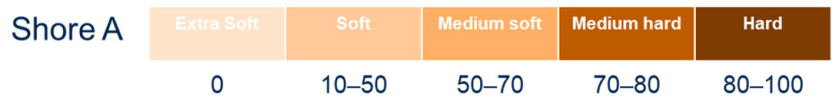
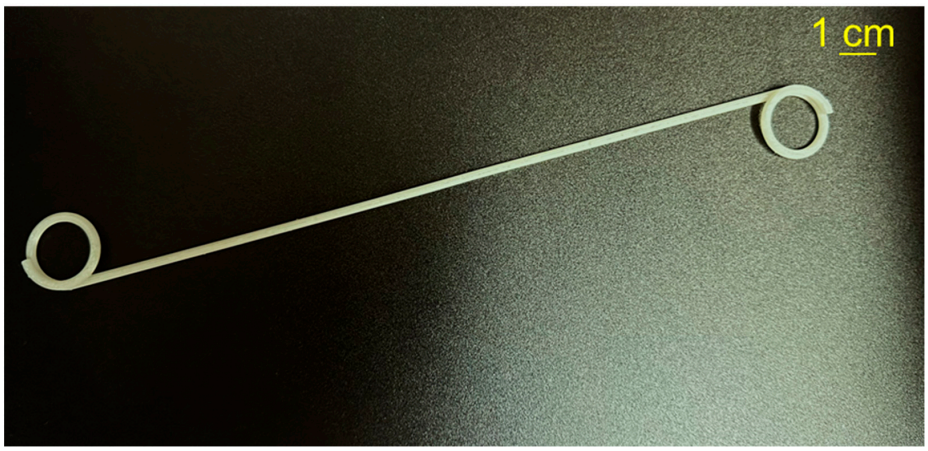


Figure 4. Reference for the Shore A hardness test.

3. Results and Discussion

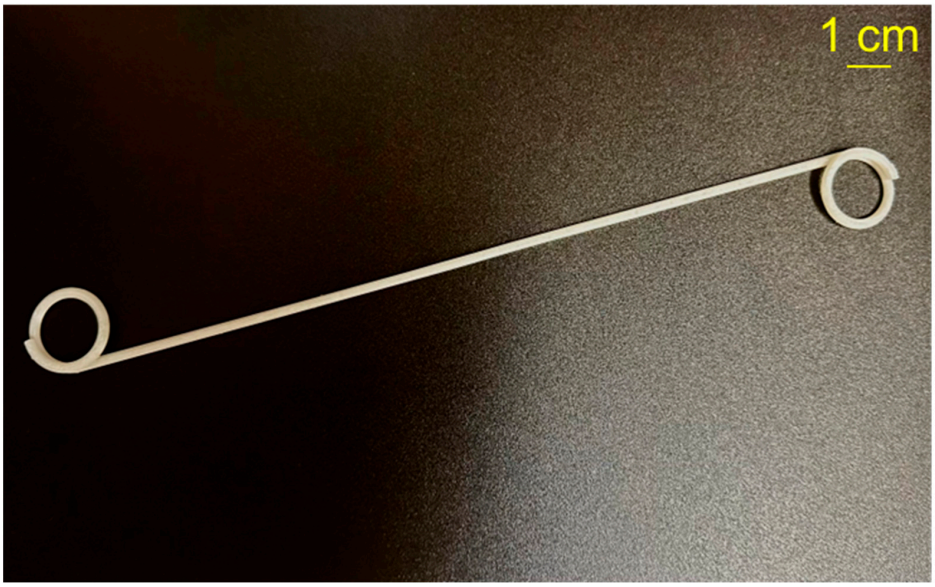
3.1. Three-Dimensional-Printed Part

Figure 5 shows the fabrication of ureteral stents using PLA/PHB, Tough PLA, and PLA, which were printed with the FDM printer. Using a print speed of 60 mm/s, each stent required a fabrication time of 26 min. The chosen parameters minimized the need for support structures, resulting in simplified post-processing. Additional surface treatments, such as acid corrosion, were not required as the 3D-printed samples met the necessary quality standards directly after printing.



(**a**)

(**b**)



(**c**)

Figure 5. Fabrication of 3D-printed ureteral stents from different materials: (**a**) PLA/PHB, (**b**) Tough PLA, and (**c**) PLA.

3.2. Characterization of Stent Degradation

Figure 6 shows the biodegradable rate for 21 days for the PLA, Tough PLA, and PLA/PHB ureteral stents. It is seen that PLA's mass was reduced by 2%, while Tough PLA's and PLA/PHB's masses were 8% and 11%, respectively. The error values for the degradation rates of PLA, Tough PLA, and PLA/PHB over a 21-day period, ranging from ±0.25% to ±1.00%, indicate the precision and reliability of the measurements. The consistent error margins across the testing period suggest that the data are statistically significant, providing confidence in the observed degradation trends and supporting the robustness of the experimental findings. During the initial phase of the degradation test, the masses of the stents made from PLA, PLA/PHB, and Tough PLA exhibited stability. The PLA stent maintained its weight of 2.998 g; the PLA/PHB stent maintained a nearly constant mass of 2.563 g, and the Tough PLA stent remained at 2.678 g. Degradation was first seen in Tough PLA stents after day six and PLA/PHB after day eight. This degradation was characterized by the detachment of small particles, which settled at the bottom of the PBS solution, suggesting the initiation of material degradation.

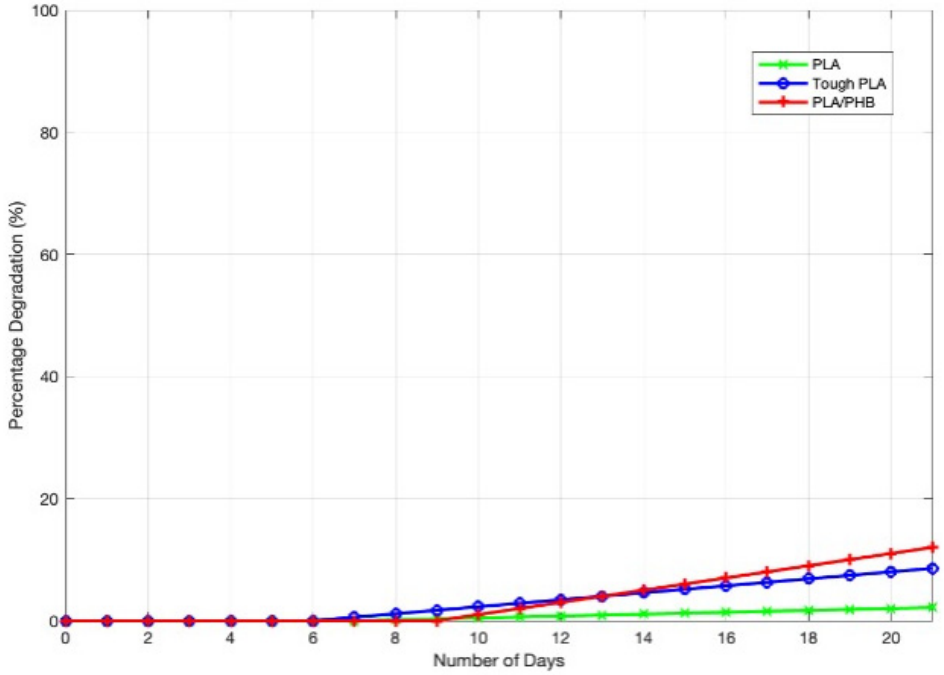


Figure 6. Biodegradability test for the fabrication of ureteral stents.

The findings from this degradation test were crucial to understand the temporal performance of stent materials. For PLA/PHB and Tough PLA, the results suggest 11% and 8% degradation levels, suggesting their suitability for applications where the stent is needed for a limited duration. However, the observed degradation of PLA over the 21-day period, with only a 2% change in mass, indicates a slower degradation process. The test was terminated due to the observed short-term degradation of the PLA/PHB and Tough PLA materials, evidenced by material particles that accumulated at the bottom of the laboratory-grade bottles.

The degradation behavior of PLA, Tough PLA, and PLA-PHB observed in this study can be attributed to differences in their molecular structure and composition. PLA, as a homopolymer, typically exhibits a distinct degradation rate compared to blends such as PLA-PHB, which incorporate PHB to enhance flexibility and toughness. The degradation of PLA is influenced by its homopolymeric structure, while the inclusion of PHB in PLA-PHB blends alters the molecular interactions and degradation pathways [44]. Additionally, the

degree of crystallinity significantly affects the hydrolysis rate, with PLA generally exhibiting higher crystallinity, leading to slower water penetration and degradation. In contrast, the modified crystallinity of the PLA-PHB blend accelerates degradation under similar conditions [45]. Tough PLA, engineered for improved impact resistance and flexibility, incorporates additives that modify its interaction with environmental factors such as moisture, potentially influencing its degradation rate [44].

In clinical settings, the degradation rate of a ureteral stent is a critical factor in determining its functional lifespan and the timing for its replacement or removal. The increased biodegradability observed in PLA/PHB stents, compared to Tough PLA and PLA, indicates a faster breakdown of the material in a physiological environment. This characteristic has both potential benefits and challenges.

The most immediate benefit of the faster degradation rate of PLA/PHB stents is the potential reduction or elimination of the need for surgical interventions to remove the stent. In traditional stent usage, a secondary procedure is often required to remove the stent after it has served its purpose, which can be uncomfortable and costly for patients. Faster degrading stents could dissolve sufficiently within the body over a predetermined timeframe, eliminating this requirement. While faster degradation can be advantageous, it also means that the stent may have a shorter functional lifespan. This could be a limitation in situations where long-term urinary tract support is needed. For patients requiring prolonged stenting, a faster degrading material might necessitate more frequent monitoring and potentially earlier replacement, which could increase clinical visits and associated healthcare costs.

Clinically, the increased degradation rate must be carefully matched to the expected recovery timeline of the patient. If a stent degrades too quickly before the underlying medical issue, such as stone passage or healing post-surgery, has resolved, it could lead to the premature loss of patency in the urinary tract. Thus, careful selection based on individual patient needs and expected recovery times is essential. An additional consideration is the risk of fragmentation due to rapid degradation. If the material degrades unevenly or too quickly, parts of the stent might break off and lead to blockages or require interventions for its removal. Thus, understanding the degradation behavior under physiological conditions is crucial for ensuring the safety and effectiveness of the stent.

3.3. Tensile Strength Results

Figure 7 compares the tensile stress–strain behavior of the Tough PLA, PLA/PHB, and PLA materials used for stent fabrication. PLA exhibits the highest Ultimate Tensile Strength (UTS), reaching 8.3 MPa ($\pm$0.4 MPa Standard Deviation), indicating its superior ability to withstand loads before failure. The PLA/PHB blend (UTS of 5.8 MPa, $\pm$0.2 MPa Standard Deviation) and Tough PLA (UTS of 6.8 MPa, $\pm$0.3 MPa Standard Deviation) demonstrate slightly lower tensile strengths. Notably, the stress–strain curves highlight differences in ductility. PLA's sharp peak and limited extension signify brittleness. On the other hand, the more gradual slopes and extended strain regions of PLA/PHB and Tough PLA indicate enhanced ductility.

The high tensile strength of PLA is beneficial for withstanding initial loading and maintaining structural integrity under static conditions. However, its inherent brittleness, as evidenced by its sharp peak and limited extension in the stress–strain curves, could pose risks under dynamic conditions. This brittleness might lead to sudden failures without significant deformation, potentially causing acute blockages within the urinary tract.

Conversely, the more ductile materials, Tough PLA and PLA/PHB, demonstrate a greater ability to deform elastically under stress. This ductility permits the stent to adapt to the urinary tract's natural movements and pressure variations without fracturing. Stents

made from these materials are, therefore, less likely to break suddenly. The reduced risk of breakage decreases the likelihood of emergency complications, such as blockages or the need for unexpected surgical interventions to remove or replace failed stents. Therefore, while the higher ductility of Tough PLA and PLA/PHB might result in slightly lower initial tensile strengths, this property is crucial for ensuring long-term reliability and safety in the fluctuating environment of the urinary tract.

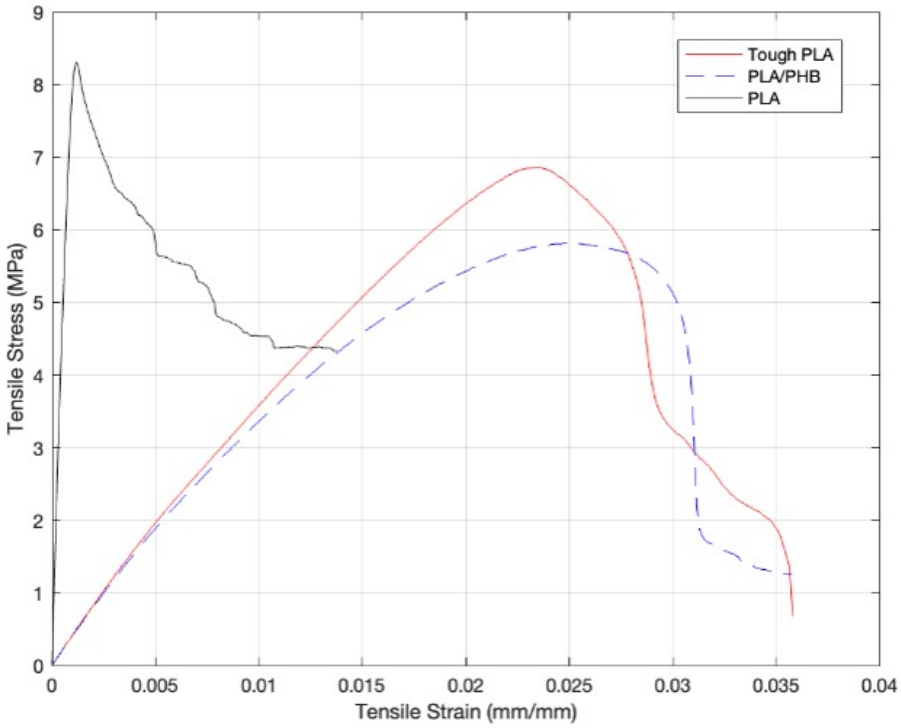


Figure 7. Tensile stress vs. Tensile strain plot for the ureteral stent materials.

The Young's modulus values for the materials used in this study—Tough PLA, PLA/PHB, and PLA—were determined to be 355 MPa, 285.7 MPa, and 1412 MPa, respectively. These values, which measure the stiffness of each material, indicate that PLA is the most rigid, while PLA/PHB is the most flexible among the three materials. The associated measurement errors were ±21 MPa for Tough PLA, ±17 MPa for PLA/PHB, and ±51 MPa for PLA, reflecting the precision of the testing process. This characterization of Young's modulus provides critical insights into the mechanical properties of these materials, informing their potential applications in ureteral stent design and other biomedical uses.

The distinct mechanical behaviors observed among PLA, Tough PLA, and PLA-PHB can be attributed to variations in their molecular composition and structure. PLA, a homopolymer, is characterized by its high stiffness and brittleness, largely due to its crystalline structure, which contributes to its rigidity and higher tensile strength. In contrast, Tough PLA is a modified version of PLA engineered to enhance impact resistance and ductility through the incorporation of plasticizers or impact modifiers. These modifications result in a more flexible material with lower tensile strength but greater resilience under stress [44]. The PLA-PHB blend combines PLA with PHB, a biopolymer known for its flexibility and toughness. The addition of PHB reduces the overall crystallinity of the blend, enhancing its ductility and impact resistance. This results in a material that balances strength and flexibility, making it suitable for applications requiring both properties. These differences are supported in the existing literature, which highlights the impact of polymer composition and crystallinity on mechanical behavior.

3.4. Hardness Test Results

Hardness significantly influences how a ureteral stent interacts with the body, affecting both patient comfort and stent functionality. According to the hardness test results depicted in Figure 8, PLA/PHB stents, with an average hardness of 65.60, fall into the 'Medium Soft' category. This categorization suggests that PLA/PHB stents are likely to offer a gentler interaction with the ureter, providing a cushioned contact that can reduce discomfort and improve overall patient tolerance during daily activities. In contrast, Tough PLA stents, with a hardness of 84.93, are categorized as 'Hard'. Such stents may lead to increased irritation and discomfort, especially when body movements cause the stent to press against the walls of the ureter. This higher level of hardness can result in a more abrasive interaction with the sensitive mucosal lining, potentially causing trauma such as abrasions or pressure ulcers. Meanwhile, PLA stents, which have a hardness of 72.27, are at the upper limit of the 'Medium Soft' range, approaching 'Medium Hard'. This indicates that they may also pose a risk of discomfort like that of Tough PLA, though potentially to a lesser extent.

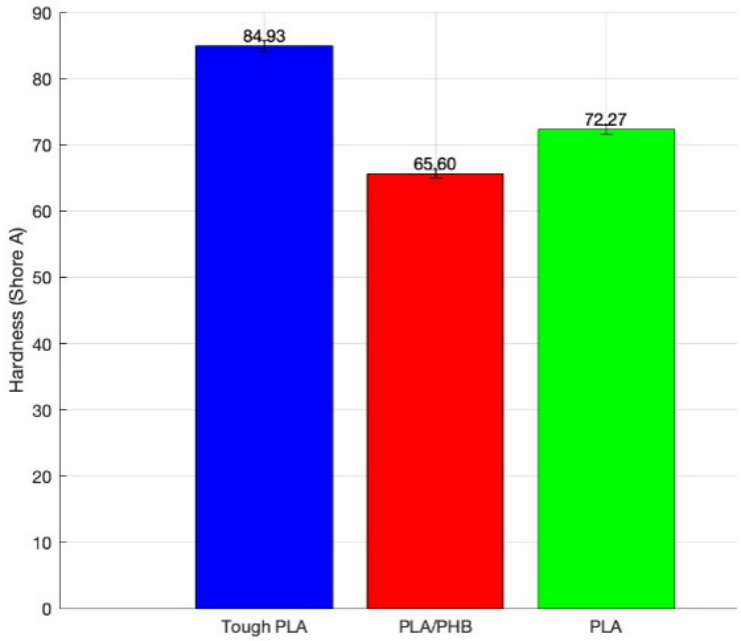


Figure 8. Hardness test results for the Tough PLA, PLA/PHB, and PLA stent materials.

The differences in hardness among PLA, Tough PLA, and PLA-PHB arise from variations in their molecular structure, crystallinity, and the presence of additives or secondary polymers. PLA, a relatively brittle thermoplastic, exhibits higher stiffness and hardness due to its homopolymeric nature and moderate to high crystallinity. In contrast, Tough PLA incorporates plasticizers or impact modifiers that reduce hardness while improving toughness and flexibility. PLA-PHB, a blend of PLA with PHB, balances biodegradability and mechanical properties, with PHB's high crystallinity contributing to brittleness, while the blend results in intermediate hardness due to modified crystallization behavior. Since hardness is closely linked to crystallinity, the dense molecular packing in PLA leads to greater hardness, whereas Tough PLA and PLA-PHB exhibit reduced crystallinity, enhancing impact resistance. Additionally, Tough PLA's elastomeric additives disrupt rigid molecular packing, lowering hardness but increasing flexibility, while the PHB in PLA-PHB blends alters the polymer network, adjusting hardness based on the blend ratio and processing conditions.

It is interesting to note that PLA shows a higher UTS compared to Tough PLA but a lower hardness. The observed higher UTS of PLA compared to Tough PLA, despite its

lower hardness, can be attributed to differences in molecular structure and mechanical behavior. PLA exhibits a relatively high degree of crystallinity, which enhances its stiffness and tensile strength but also increases its brittleness, leading to lower toughness. In contrast, Tough PLA is formulated with impact modifiers or plasticizers that improve ductility and toughness by increasing molecular mobility. These modifications reduce UTS while also lowering hardness, as the disrupted molecular packing results in a more flexible and less rigid material.

The adaptability of a stent to the ureter's natural contours is also crucial for its effectiveness and safety. Rigid stents may not conform well to the ureter's bends and curves, potentially leading to issues such as suboptimal drainage or stent migration. However, the softer PLA/PHB stents can more easily adjust to these anatomical variations, maintaining proper positioning and minimizing the risk of complications. Additionally, the pliability of PLA/PHB allows it to distribute the physical forces from ureteral peristalsis more evenly along its length, preventing localized pressure points that could damage the ureter or cause patient discomfort.

When selecting a stent material, it is important to consider the specific clinical requirements of each case. While the hardness of Tough PLA may be advantageous for maintaining luminal patency in scenarios where external compression is a factor, such as from a tumor, the softer and more flexible nature of PLA/PHB is generally more suitable for standard applications requiring temporary stenting. Balancing structural support with flexibility is essential, as excessive flexibility might compromise the stent's primary role of keeping the urinary passage open. This nuanced approach helps in choosing the most appropriate material to ensure both effective treatment and patient comfort.

3.5. Comparison with Traditional Ureteral Stents

Among the three materials tested, PLA/PHB stands out with the most promising potential for ureteral stent applications, primarily due to its faster biodegradation rate compared to Tough PLA and PLA. This rapid degradation not only reduces the need for surgical removal but also potentially enhances patient comfort and lowers healthcare costs. The material's "medium soft" hardness and relatively high ductility contribute to this potential by minimizing the risk of ureteral irritation and the likelihood of blockage should the stent break. These properties make PLA/PHB stents a more comfortable and safer alternative during the stenting period, improving patient outcomes and satisfaction.

The comparative analysis in Table 2 highlights that the Ultimate Tensile Strength (UTS), hardness, and degradation percentage of PLA/PHB stents align closely with those of traditional ureteral stents. Specifically, the UTS values of the fabricated stents are comparable to traditional stents, reinforcing their structural integrity and suitability for clinical use. The PLA/PHB stents' "medium soft" hardness is particularly notable, as it is well within the range considered acceptable for minimizing discomfort. In contrast, traditional ureteral stents typically show a much higher degradation percentage of 91.7% within six weeks, indicating a slower breakdown. This slower breakdown is consistent with their design for longer-term applications, where gradual degradation is necessary to maintain structural integrity over extended use. This study's biodegradability tests, however, have shown a range of 2% to 11% degradation in just three weeks, indicating a more rapid adaptation to the clinical need for temporary stenting. This rapid degradation aligns with the clinical need for temporary stenting, where the stent is designed to degrade within a specific timeframe to eliminate the need for surgical removal. The rapid degradation observed in our study is a deliberate design feature aimed at providing temporary support. This is beneficial for reducing patient discomfort and minimizing follow-up procedures, a contrast to traditional stents designed for longer-term use.

Table 2. Comparison of properties of fabricated ureteral stents with traditional available ureteral stents.

Property	PLA/PHB Ureteral Stent	Tough PLA Ureteral Stent	PLA Ureteral Stent	Traditional Ureteral Stent
Ultimate Tensile Strength (MPa)	5.8	6.8	8.3	3–40 [30–33]
Hardness (Shore A)	65.60	84.93	72.27	70–85 [46,47]
Degradation (%)	11 (3 weeks)	8 (3 weeks)	2 (3 weeks)	91.7 (6 weeks) [19,35]

It is important to note that the literature references a six-week degradation assessment period for traditional ureteral stents, which typically show a higher percentage of degradation over a longer duration. The shorter assessment period in our study reflects its preliminary nature and serves as an early indicator of the stents' performance. Recognizing the need for a comprehensive comparison, further tests need to be conducted to extend the degradation assessment to six weeks and beyond. These future studies will provide a more detailed evaluation of the long-term degradation behavior of the stents, enabling a consistent comparison with traditional stents and enhancing our understanding of their clinical applicability.

While the biodegradation of 3D-printed stents offers significant clinical advantages, such as reducing complications and avoiding follow-up procedures for removal, there are also inherent drawbacks. The rapid degradation might not be suitable for cases requiring long-term stenting, as premature degradation could lead to inadequate support before the treatment objective is achieved. Additionally, there are limited long-term data available on the efficacy and safety of these newer materials, posing challenges in predicting their performance over extended periods. Manufacturing and regulatory hurdles also complicate the widespread adoption of 3D-printed biodegradable stents, as consistency and compliance with medical standards are crucial yet difficult to maintain. Ensuring the degradation rate matches the specific medical needs precisely remains a technical challenge that can impact clinical outcomes.

Regarding the UTS of the fabricated ureteral stents, it is acknowledged that the values obtained in this study are lower than those reported for traditional ureteral stents in the literature [30–33]. However, it is important to note that the primary requirement for temporary urinary tract support is to maintain patency and prevent occlusion, rather than to withstand high tensile loads. The materials used in this study, while exhibiting lower UTS, offer enhanced flexibility and biodegradability, which are critical for minimizing patient discomfort and facilitating stent removal without surgical interventions. Furthermore, the design and material selection processes prioritize patient comfort and safety, aligning with the clinical requirements for temporary urinary stents. The use of biodegradable polymers allows for gradual degradation, reducing the need for secondary procedures and aligning with the intended use of these stents for short-term applications.

3.6. Future Directions

The findings of this study underscore the promising potential of utilizing biodegradable materials for the fabrication of ureteral stents, signaling a pathway for further exploration and advancement in the field. Moving forward, future investigations should prioritize the implementation of a comprehensive testing program aimed at fully harnessing this potential and optimizing the performance of biodegradable stents for in vivo applications. Key areas of focus could include evaluating the flexibility of the stents and their ability to conform to the unique geometry of the ureter, with the overarching goal of minimizing patient discomfort and mitigating potential tissue damage. While the current study focused on mechanical and degradation properties, future works need to include compre-

hensive in vitro biocompatibility tests. Planned assessments include cytotoxicity assays and hemocompatibility evaluations to ensure the materials do not elicit adverse biological responses, providing further validation of their safety for clinical use. The future research also need to focus on detailed morphological analysis at various degradation times to better understand the degradation mechanisms and their impact on long-term performance.

Moreover, conducting thorough radial strength testing will be instrumental in assessing the stent's resistance to crushing forces, thereby ensuring its ability to maintain an unobstructed pathway for urine flow throughout its intended lifespan. Additionally, fluid flow testing represents a crucial avenue for exploration, providing invaluable insights into the dynamic interaction between the stent and urine flow dynamics within the urinary tract. By elucidating the impact of biodegradable stents on urine flow dynamics, such investigations can inform the refinement of stent designs and aid in the development of strategies to minimize the risk of obstruction, thereby enhancing patient outcomes and overall treatment efficacy.

4. Conclusions

This study demonstrates the feasibility of fabricating biodegradable ureteral stents using 3D printing technology, a significant advancement in urological medical devices. Three biodegradable materials, Polylactic Acid (PLA), Tough Polylactic Acid (Tough PLA), and Polylactic Acid/Poly-hydroxybutyrate (PLA/PHB), were investigated, each offering distinct advantages. CAD facilitated the creation of a stent model conducive to optimal functionality within the ureteral passage, ensuring patient comfort and stability. The Fused Deposition Modeling (FDM) 3D printing process successfully fabricated stents with precise geometry and the necessary structural integrity. Biodegradability tests in a simulated physiological environment showcased the materials' distinct degradation patterns, offering crucial information on their potential lifespan within the body. Furthermore, tensile strength and hardness testing confirmed that the mechanical properties of the fabricated stents aligned positively with those of existing traditional stents, offering critical data for material selection and performance evaluation. The key findings of this study are as follows:

- The study's findings indicate a degradation profile among the studied materials. PLA/PHB and Tough PLA stents are biodegradable, with PLA/PHB showing more mass loss in the PBS solution, indicating progressive breakdown. On the other hand, PLA stents exhibited minimal degradation within the observed timeframe. The use of biodegradable materials was aimed to eliminate the need for a removal procedure in the near future;
- The PLA/PHB blend displayed adequate strength, with a tensile strength slightly lower than 5.8 MPa. Tough PLA withstood a higher tensile strength of up to 6.8 MPa before failing. In contrast, PLA exhibited the highest tensile strength of 8.3 MPa among the tested materials. Importantly, both PLA/PHB and Tough PLA demonstrated ductility, while PLA exhibited a more brittle nature. This ductility is advantageous, as it reduces the risk of creating blockages due to breakage;
- PLA/PHB is categorized as "Medium Soft" using the hardness test, making it perfect for applications compromising comfort and functionality. Classified as "Hard", Tough PLA may have lesser comfort levels but is more durable. Regarding consistency, PLA is positioned as medium soft and is closer to medium hard than medium soft.

This study demonstrates a future for 3D-printed biodegradable ureteral stents in urology. PLA/PHB demonstrates the promising potential for ureteral stent applications due to its faster biodegradation rate, ductility that minimizes blockage risk, and "medium soft" hardness for enhanced patient comfort.

Author Contributions: S.J. contributed to the conceptualization of the study, visualization of the data, reviewing and editing the manuscript, providing resources, supervising the project, acquiring funding, and administering the project. C.C. was responsible for curating the data, conducting formal analyses, carrying out the investigation, developing the methodology, and writing the original draft of the manuscript. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by California State University Fullerton Office of Research and Sponsored Projects (ORSP) Grant.

Data Availability Statement: The original contributions presented in this study are included in the article. Further inquiries can be directed to the corresponding author(s).

Acknowledgments: The authors thank the mechanical engineering department at the California State University Fullerton.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

CAD	Computer-Aided Design
FDM	Fused Deposition Modeling
PLA	Polylactic Acid
PHB	Poly-hydroxybutyrate
NHANES	National Health and Nutrition Examination Survey
CI	Confidence Interval
PLGA	Poly(lactic-co-glycolic acid)
PLLA	Poly(L-lactide)
PDLLA	Poly(DL-lactide)
UTS	Ultimate Tensile Strength
ASTM	American Society for Testing and Materials

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