# Designing a Biodegradable Biliary Stent for Treatment of Biliary Stricture

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## Background:

### The Problem

Biliary stricture is an abnormal narrowing of the bile duct and can lead to inflammation of organs as well as bacterial infections within the liver. Current treatments use metal or plastic stents but require repeated ballooning procedures to ensure the continuous expansion of the duct over several months and a final surgery to remove the stent. This significantly hampers patient quality-of-life and increases their risk to post-operation complications.


**Figure 1:** Boston Scientific WallFlex Biliary RX Stent System with Guidewires. Left (red) is collapsed state of stent. Right is expanded state of stent

### Our Solution

We propose the use of a biodegradable stent made of a WE43 Magnesium-based alloy wire. We **hypothesize** that our stents should maintain structural integrity but show some color change as a physical indication of degradation.



**Figure 2:** WE43 Braid Provided by Fort Wayne Metals

## Design Requirements:

Self-Expanding: ~50-75% increase in diameter

- Relieves biliary stricture

Biodegradable: Slow degradation over 8-12 months

- Negates the need for surgical removal following recovery

Good Mechanical Properties: Must maintain constant radial force

- Necessary to dilate bile duct to aid biliary stricture

## Methods:

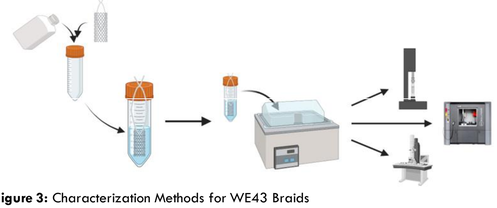

**Figure 3:** Characterization Methods for WE43 Braids

## Results:

### Degradation Behavior

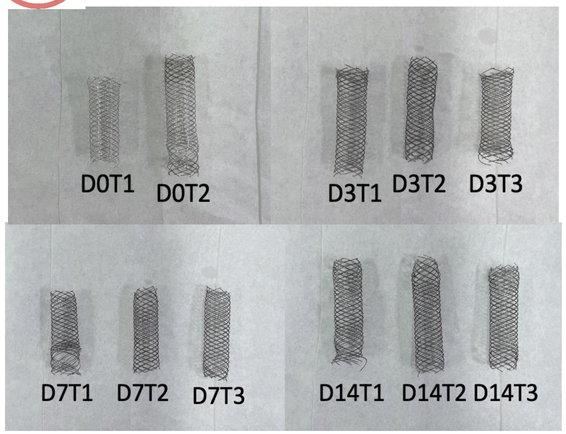


**Figure 4:** WE43 Braids after Day 0, 3, 7, and 14 of Corrosion
*Braids are in expanded state

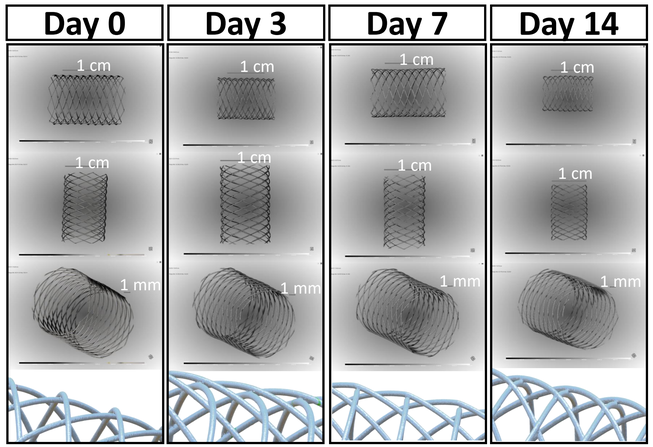


**Figure 5:** Reconstructed µCT Images of WE43 Braids after Corrosion
*Braids are in expanded state

### Tensile Testing

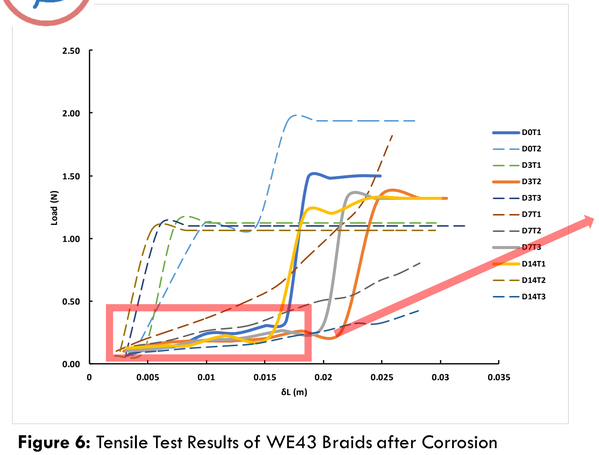


**Figure 6:** Tensile Test Results of WE43 Braids after Corrosion
*Dashed data sets show irregular patterns, which may be from limitations of tensile tester Mark-10 ESM303

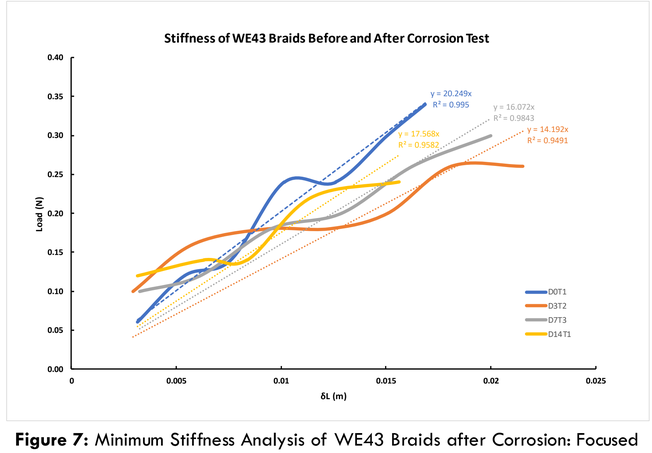


**Figure 7:** Minimum Stiffness Analysis of WE43 Braids after Corrosion: Focused on region that obeys Hooke's Law
* Braid stiffness as measured should increase with displacement

**Table 1:** Minimum Stiffness of WE43 Braids

| Samples | Stiffness (N/m) |
|---|---|
| D0T1 | 20.2 ± 0.6 |
| D3T2 | 14 ± 1 |
| D7T3 | 16.1 ± 0.9 |
| D14T1 | 18 ± 2 |

## Conclusions:

- Through µCT analysis, the degradation study showed no discernible oxidation
  - No increase in diameter after 2 weeks, exemplifies potential for slow expansion over 8 month
- Through tensile testing, minimum stiffness was observed
  - No significant increase or decrease in stiffness
- Aligned with visual/ physical observations
- No change in mechanical properties aligns with µCT results

## Future Directions:

Repeat study

- Longer degradation study, EDS to determine composition
- Convert linear tensile stiffness to radial compressive stiffness
  - Measure resistance against radial deformation of bile duct

Prolonging degradation

- Fluorination pretreatment
- Dip-coating with polymers (PLA, PCL)

Expansion Mechanism

- Test braid expansion in semi-elastic tube that mimics of bile duct
  - Dependence of expansion on degradation time

*In Vitro* Testing

- Mimic flow behavior of bile duct in degradation study

Works Cited

[1] Zhang, Y., Chen, K., Liu, H., Shao, Y., Chu, C., Xue, F., & Bai, J. (2020). A study of a biodegradable braided Mg stent for biliary reconstruction. Journal of Materials Science, 55(36), 17170-17182.
[2] Guo, L., Yu, L., Zhao, Q., Gong, X., Xie, H., Yuan, G., ... & Wan, X. (2021). Biodegradable JDBM coating stent has potential to be used in the treatment of benign biliary strictures. Biomedical Materials, 16(2), 025010.
[3] ASTM G31-21, Standard Guide for Laboratory Immersion Corrosion Testing of Metals, ASTM International, West Conshohocken, PA, 2021, www.astm.org

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