Bioabsorbable metal stents: properties, modeling and open questions

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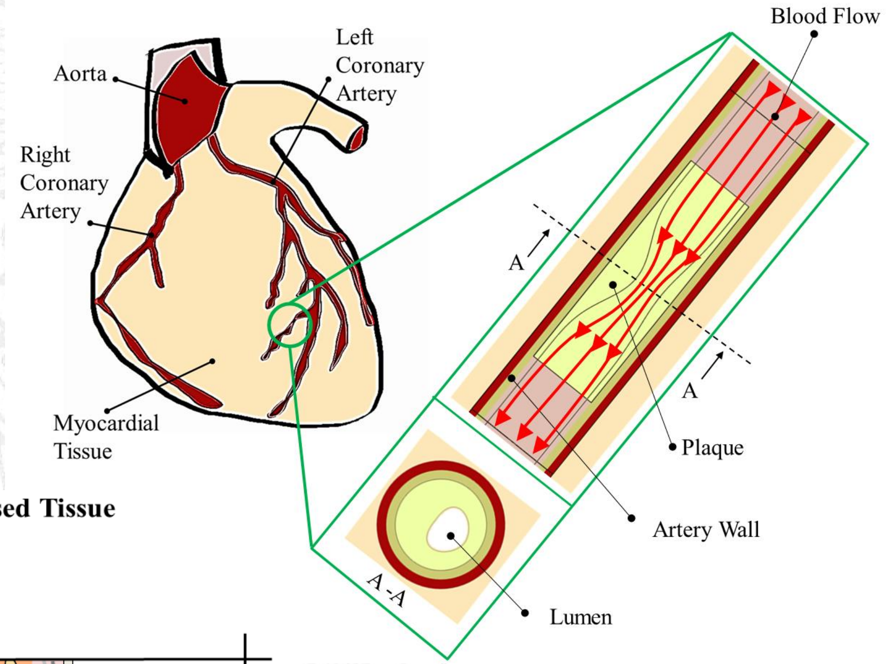
Presentation outline

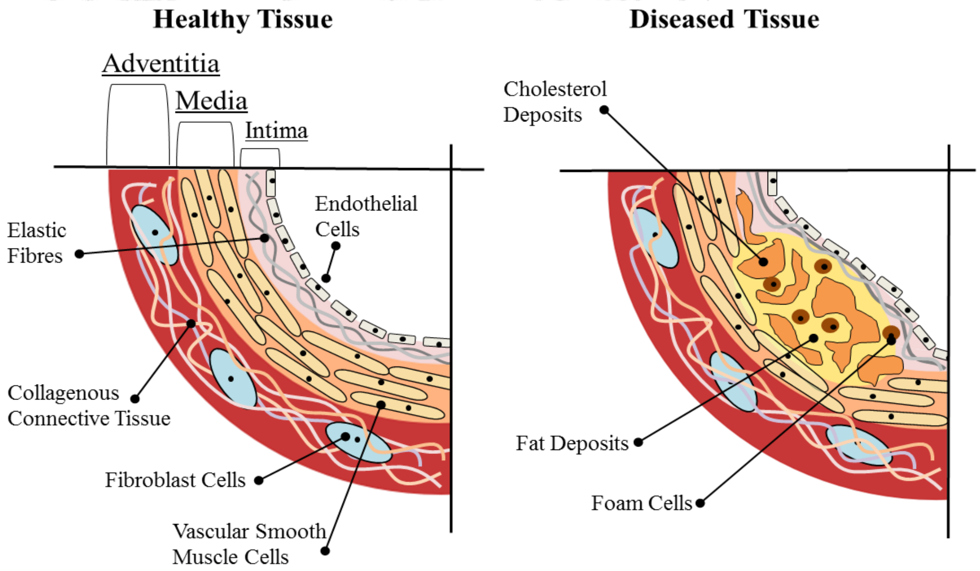
- Motivation and background
- Mechanical Performance of Permanent and Absorbable Metal Stents
- A Phenomenological Corrosion Model for Magnesium Stents
- Designing an Optimum Bioabsorbable Metal Stent
- Conclusions

Motivation and background

ISCHAEMIC HEART DISEASE:

condition characterized by restricted blood supply to the heart muscle.

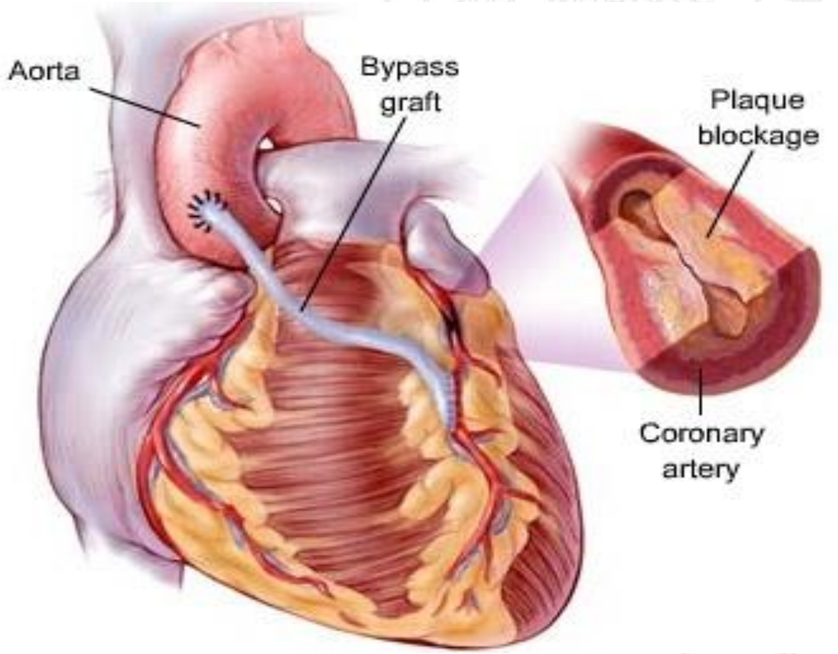




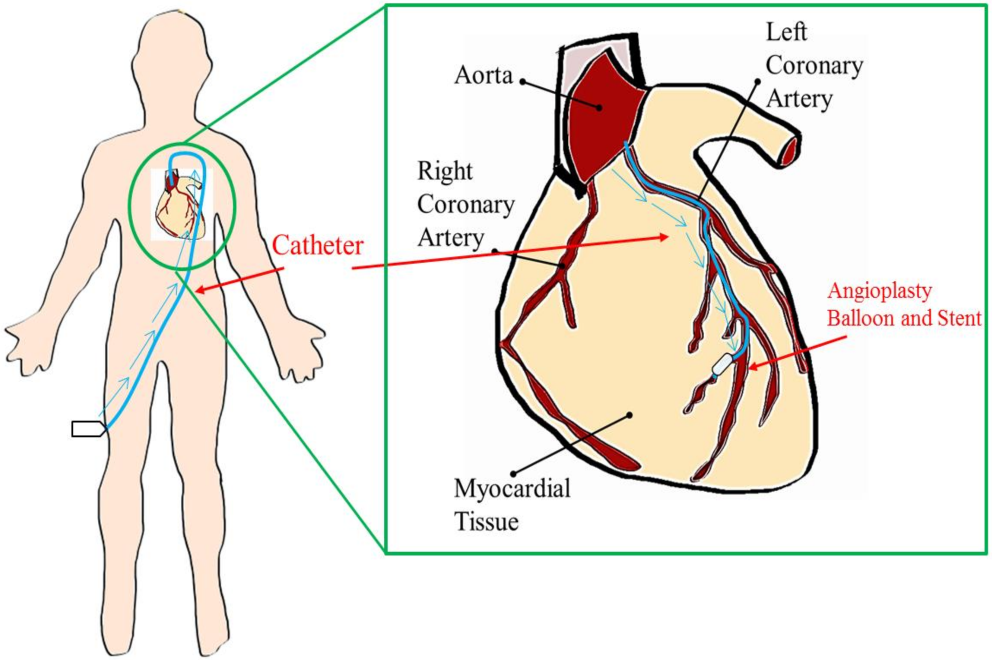
Motivation and background

TREATMENT OPTIONS FOR ISCHAEMIC HEART DISEASE:

Coronary Artery Bypass Grafting:
surgical creation of a new path that enables blood to reach the heart by flowing around (bypassing) the blocked portion of the diseased artery.



Percutaneous Coronary Intervention:
non-surgical procedure that relieves narrowing and obstruction of the coronary arteries through the use of a balloon-catheter



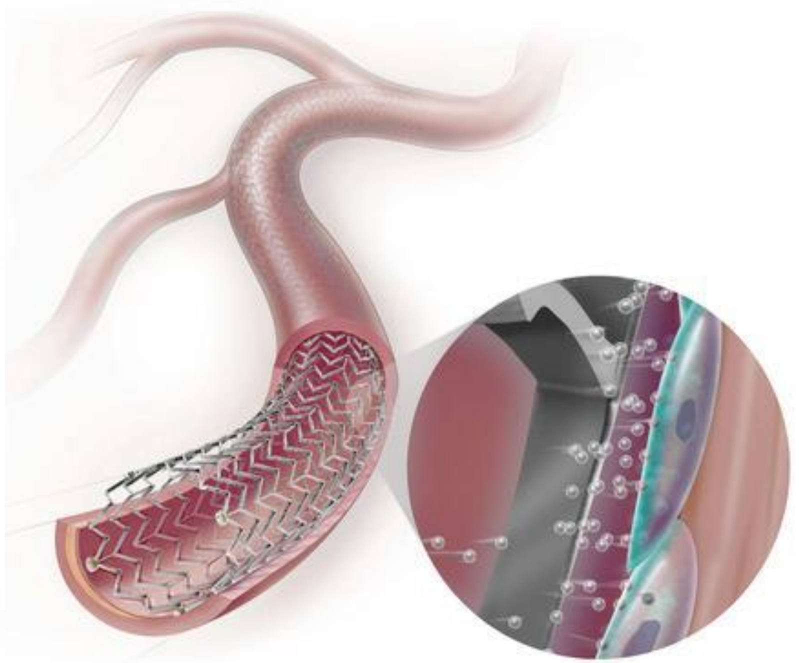
Coronary Artery Bypass Grafting or Percutaneous Coronary Intervention?

Motivation and background

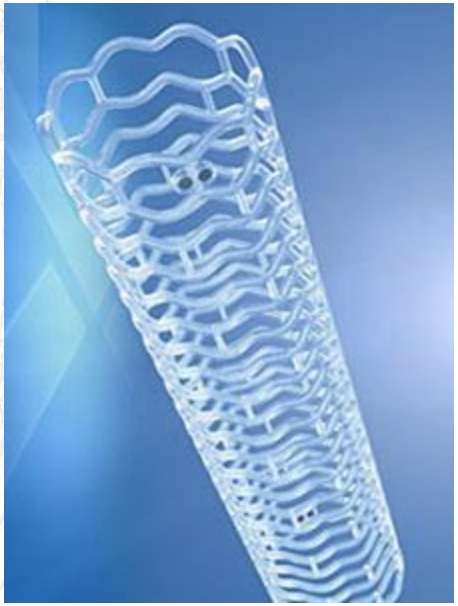
CORONARY STENTS:

Bare Metal Stents

Drug Eluting Stents



Bioabsorbable Stents



❖In-stent restenosis (ISR)

❖Very late stent thrombosis

❖Reduced radial strength

Motivation and background

FUTURE DEVELOPMENTS IN CORONARY STENTS

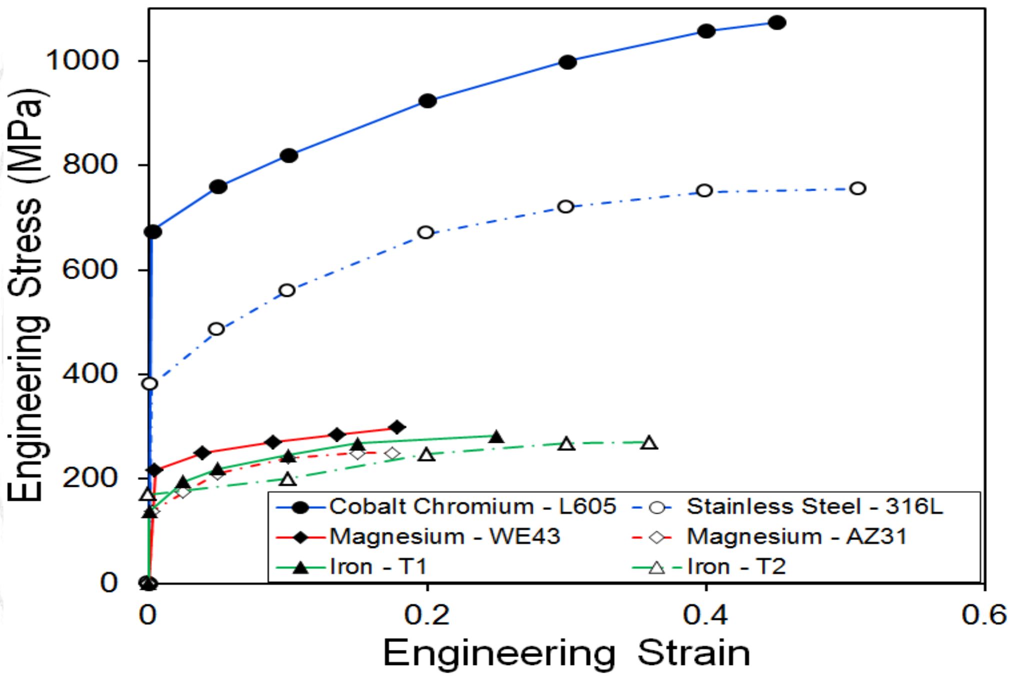
- **Stents with thinner struts**

- **Bioabsorbable metal stents**

The goal of Grogan’s work, on which this relation is based, is to analyze the design and the mechanics of this next generation of coronary stents to improve the current understanding of this device.

Mechanical Performance of Permanent and Absorbable Metal Stents

Mechanical properties of typical bioabsorbable metals developed to date are generally inferior to those of permanent stent materials.



Engineering stress-strain curves for each material modelled in Grogan's study.

Comparing coronary stent material performance on a common geometric platform through simulated bench testing

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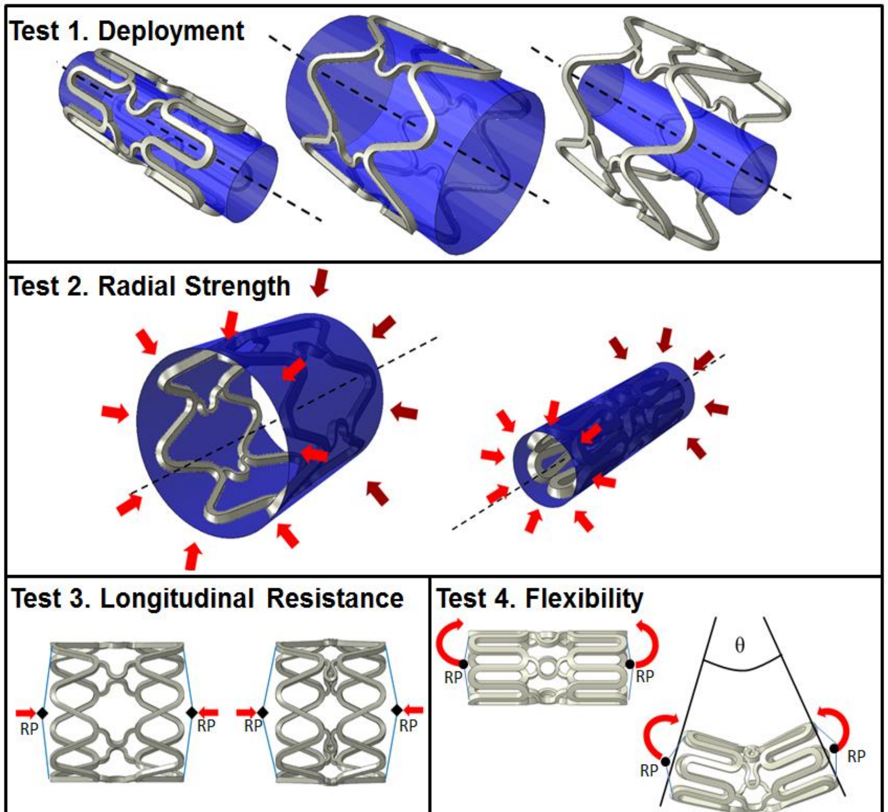
Mechanical Performance of Permanent and Absorbable Metal Stents

Mechanical performance of stents consisting of a range of permanent and bioabsorbable alloys are compared using simulated bench-testing

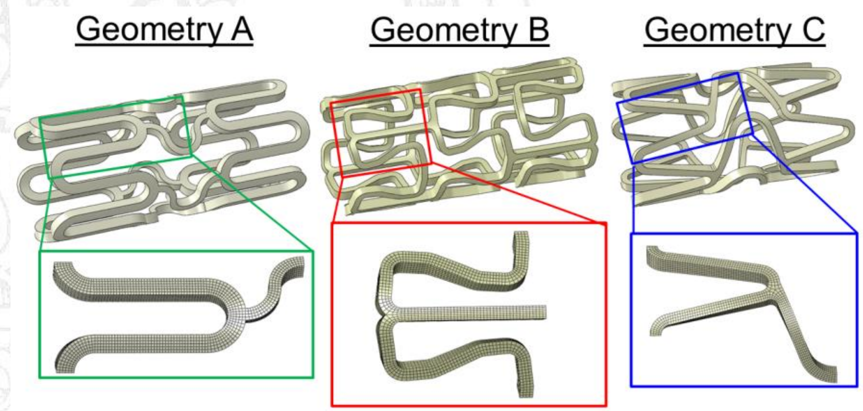
Four bench-tests are simulated for each material and geometry



Schematic representation of the test cases simulated.

Performances of candidate alloys assessed on

- a generic stent geometry (**A**)
- geometries representative of those used in previous in vivo experiments (**B**,**C**)



Stent	Similar to:	Strut Width (µm)	Strut Thickness (µm)	Length (mm)
A	Generic	120	120	3.30
B	MAGIC stent	80	140	3.18
C	PUVA stent	80	120	2.70

Stent geometries used in Grogan's study.

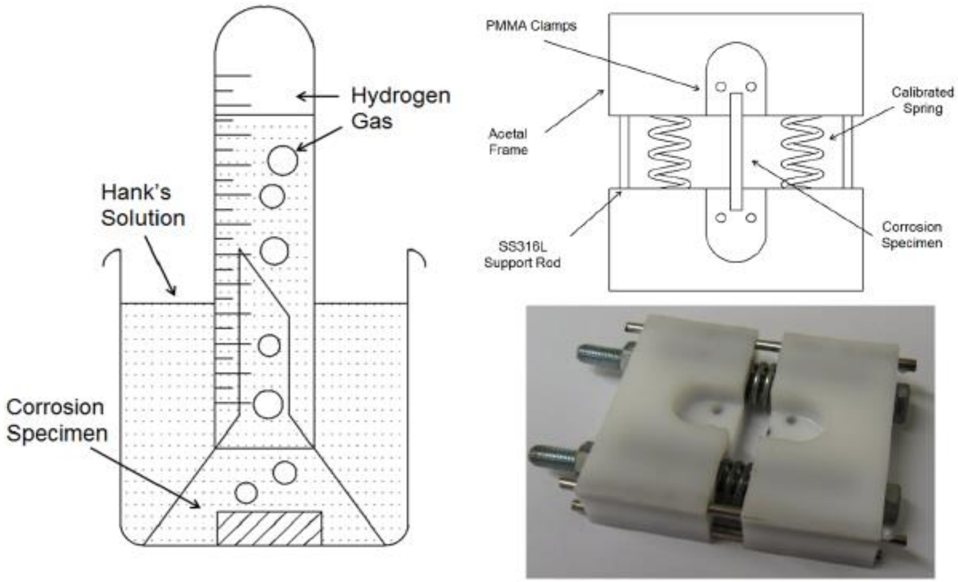
RESULTS

- A significantly higher device fracture risk was predicted in deployment for the magnesium stents than the permanent stents.
- Resistances to longitudinal compression in the magnesium was predicted to be less than 50% of those of the permanent stents.
- The struts of the magnesium stents require cross-sectional areas 2.4 times greater than the permanent stents for comparable performance in terms of radial strength.
- Magnesium alloy ductility needs to be increased by a factor of up to 3 for comparable performance with permanent stents.

A Phenomenological Corrosion Model for Magnesium Stents

In order to comprehensively characterise the corrosion behaviour of the bioabsorbable magnesium alloy, three independent experiments were performed

Experiment	Description	No. of Samples:
A	Determine specimen corrosion rate	5
B	Determine effect of corrosion on specimen mechanical integrity	26
C	Determine effect of mechanical loading on corrosion process	10



(a) (b)

(a) The hydrogen evolution apparatus used in Experiment A.
(b) The constant load test rig used in Experiment C.

A corrosion model for bioabsorbable metallic stents

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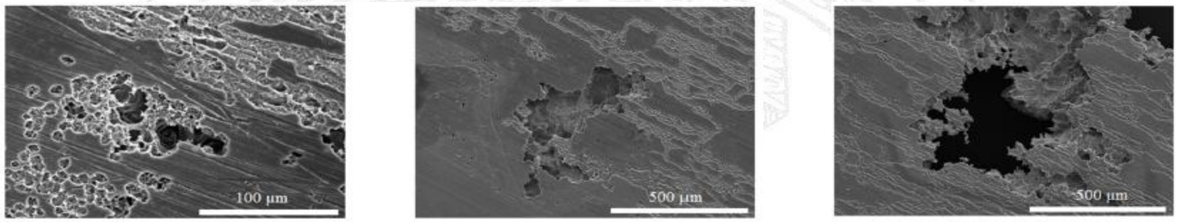
A Phenomenological Corrosion Model for Magnesium Stents

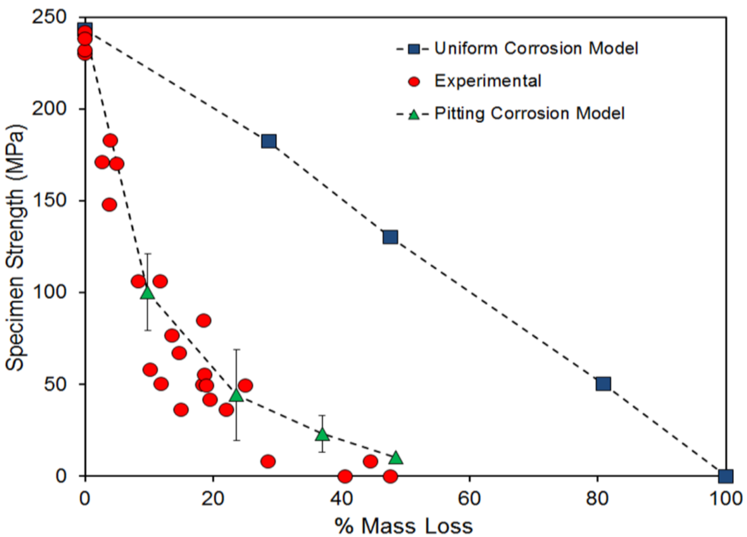
RESULTS



(a) (b) (c)

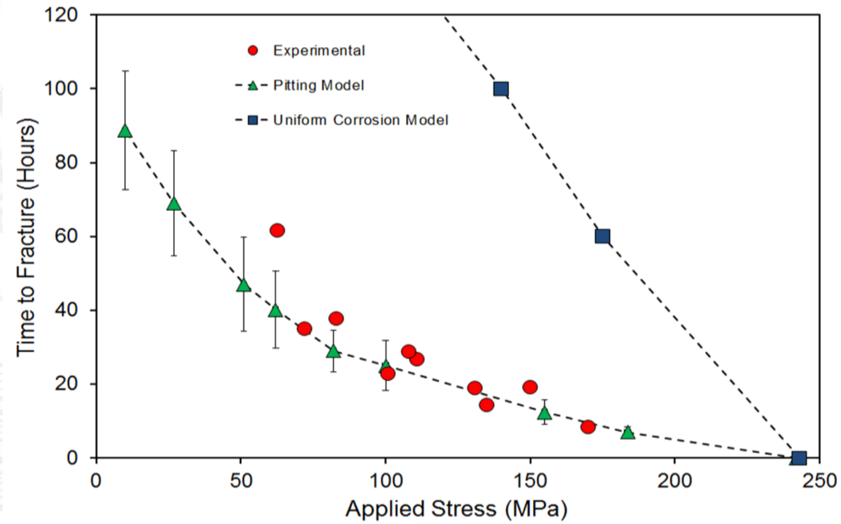
Experiment A:

SEM images of the alloy corrosion surface following (a) 3 hours, (b) 12 hours and (c) 40 hours of immersion in solution.



Experiment B:

a significant reduction in strength (> 25%) is noted for relatively small percentage mass losses (< 5%).

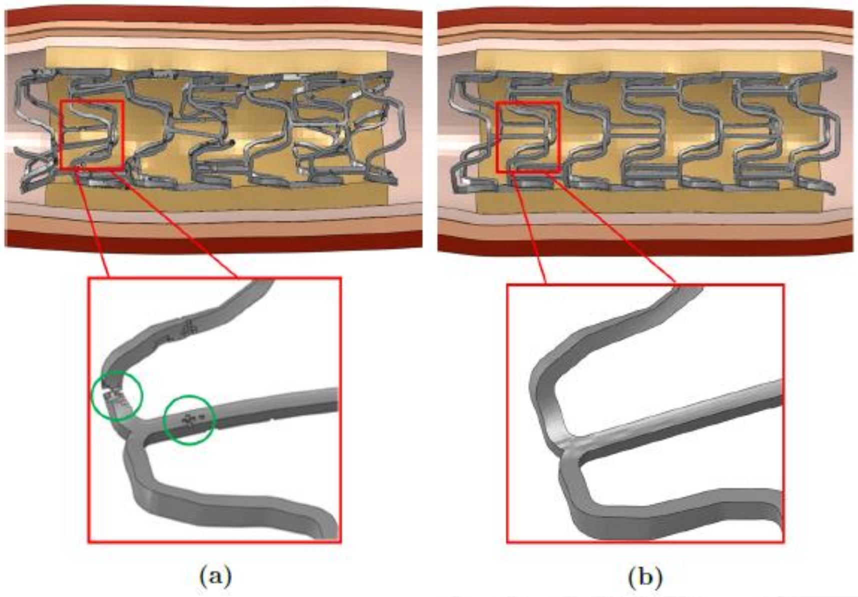


Experiment C:

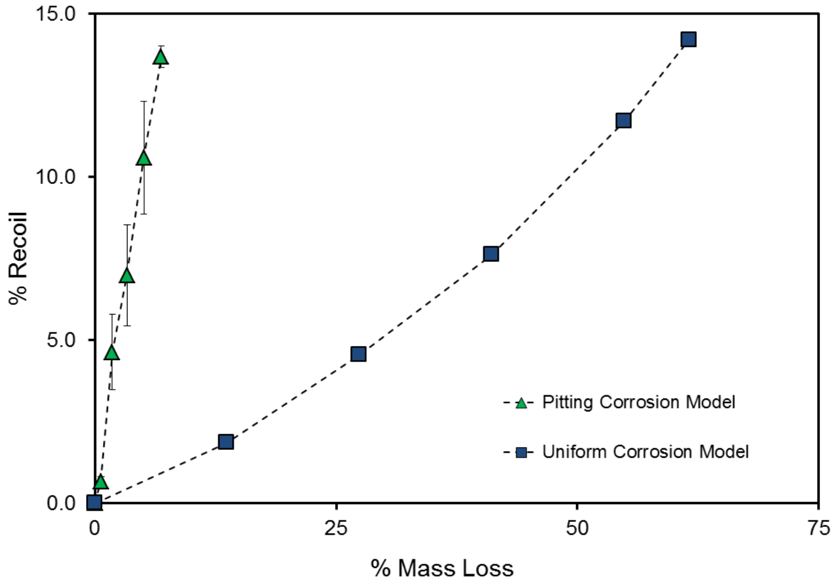
increasing applied stress leads to a significant reduction in the time to fracture for the specimen

STENT APPLICATION

To predict the performance of an AMS, a CAD approximation of the Biotronik MAGIC stent is generated based on SEM images in the literature



(a) pitting corrosion and
(b) uniform corrosion processes in an AMS



% stent recoil due to corrosion.
Pitting corrosion model predicts a significant loss of support with relatively little mass loss compared to the uniform corrosion model.

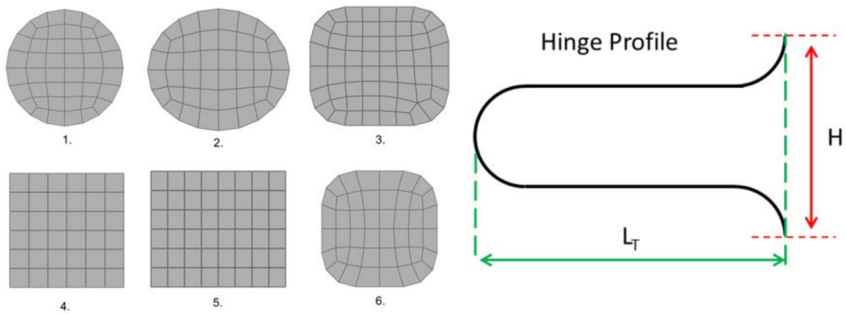
Designing an Optimum Bioabsorbable Metal Stent

A new optimization strategy for AMS, that considers both the effects of corrosion and the limited mechanical properties of the alloy, is developed.

Effects of Corrosion on AMS Performance are investigated through:

- **two parameter studies (P1 and P2),**
- **an optimization study (O1).**

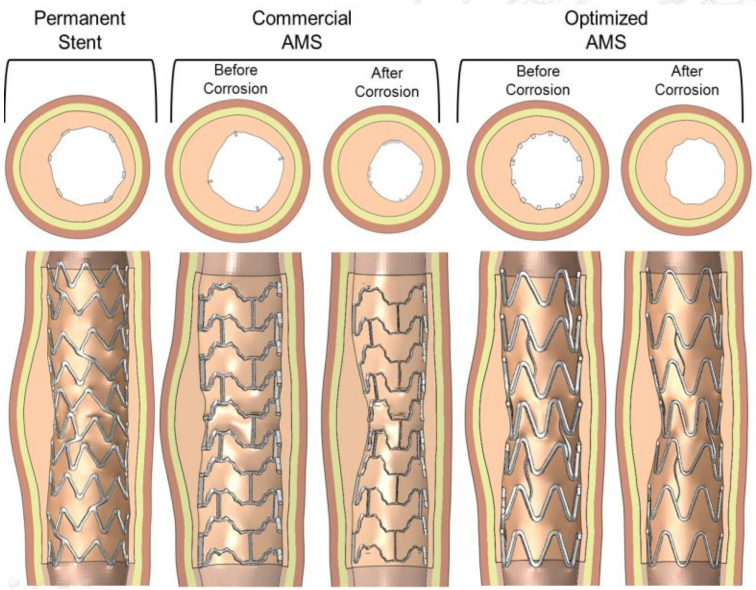
Parameter study P1 focuses on a simple, sinusoidal stent hinge profile with a number of different cross-sections.



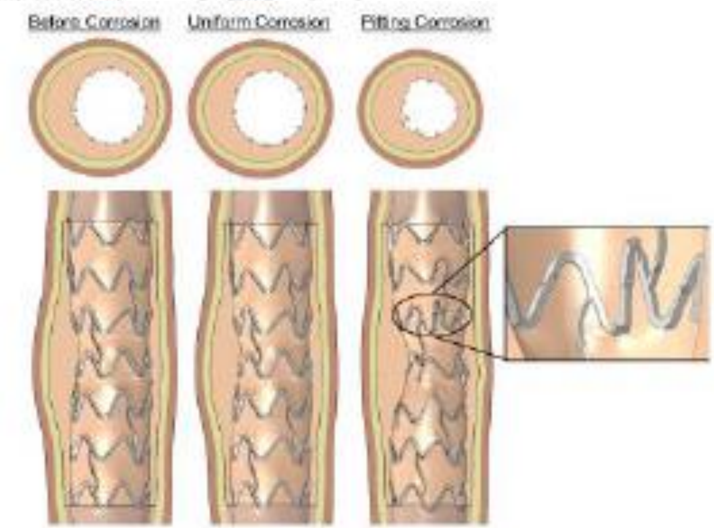
In **Parameter study P2** a range of hinge profiles that are more reflective of those used in commercial AMS's are investigated.

In **optimization study O1** the goal is to maximize hinge radial stiffness after a specific amount of corrosion.

IN-VIVO DEPLOYMENT SIMULATIONS



Cross-sections of predicted stent configurations before and after uniform corrosion .



Artery cross-section showing predictions for uniform and pitting corrosion of the baseline geometry for 15% mass loss.

RESULTS

- The short-term scaffolding performance of an optimized AMS design is predicted to match that of a modern permanent stent in a stenosed vessel.
- An optimized AMS design is predicted to maintain lumen patency approximately 1.5 times longer than a commercial design.

Conclusions

The modelling of absorbable metal stents is a newly emerging field and presents many interesting challenges.

Based on the predictions of Grogan's work, the most important improvements in magnesium alloy performance are:

- increasing their ductility
- inhibiting pitting corrosion.

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Thank you!