ABSTRACT
Achieving a controlled corrosion rate is a challenging prospect in the design process of a biodegradable stent. Investigations were conducted to determine the effect of annealing temperature and duration on the corrosion rate. A novel nanostructured biomaterial for stent application was utilized, fabricated using cold gas-dynamic spray technology with iron and stainless steel 316L powders. The results from the static immersion tests indicated that increasing the annealing parameters decreased the overall corrosion rate of the material.

Keywords: biomaterials, corrosion, biodegradable stent, cold spray.

INTRODUCTION
The feasibility of biodegradable stents in a clinical setting is largely dependent upon attaining a controlled corrosion rate. In general, little degradation should occur within the first six months following insertion, with the stent fully degraded within 12-24 months (Serruys, 2006). Attaining this corrosion rate remains a challenge within the design process. One such means to control the corrosion rate is through the use of annealing. Annealing is critical during stent fabrication, in order to achieve the ductility required for stent expansion. Increasing the duration and temperature of annealing can also improve a material’s corrosion resistance (Al-Mangour, 2013). For the material proposed, initial tests determined the corrosion rate to be too rapid for stent application, and therefore must be decreased. The intent of this work is to investigate the ideal temperature and duration of annealing, in order to achieve optimal corrosive properties.

MATERIALS AND METHODS
Cylindrical specimens were fabricated using cold spray (Al-Mangour, 2013), as shown in Fig. 1(a). Iron and stainless steel 316L powders were mixed, with weight percentages of 80% and 20%, respectively. Coatings were sprayed on 5 mm diameter rods, and then annealed at 1150°C for one hour in a tube furnace. The coated substrates were then ground to a thickness of 250 mm, and electrical discharge machining was performed to remove the substrate from the coating. The fabricated tubes varied from 0.6 to 2 cm in length (Fig. 1(b)). Static immersion tests were performed to determine the corrosion rate of the control samples (Fig. 1(c)). Immersion tests were conducted utilizing two solutions: (1) Hank’s Balanced Salt Solution (HBSS), and (2) a modified HBSS, with the inclusion of HEPES buffer in order to maintain physiological pH. Test duration was 7 days at 37°C, after which the specimens were weighed.
Specimens were exposed to additional heat treatment through two processes: (1) a MECO welding torch, and (2) a tube furnace under vacuum with flowing argon for oxidation control. Samples were heated until orange-hot with the MECO torch, and allowed to cool. Samples treated with the tube furnace will be annealed at various temperatures and duration, specifically: 1150°C for two hours, 1175°C for one hour, 1175°C for two hours, 1200°C for one hour, and 1200°C for two hours. Immersion tests will be conducted for all specimens.

RESULTS AND CONCLUSION

Preliminary results indicated that the additional heat treatment resulted in a decrease in the samples’ corrosion rates (Fig. 1(d)). The corrosion rates of the specimens, as well as the total estimated degradation period, are reported in Table 1.

<table>
<thead>
<tr>
<th>Sample</th>
<th>pH Initial</th>
<th>pH Final</th>
<th>Corrosion Rate (mm year⁻¹)</th>
<th>Estimated Degradation Period (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (HBSS)</td>
<td>7.4</td>
<td>9.05</td>
<td>0.1490</td>
<td>119</td>
</tr>
<tr>
<td>Control (Modified HBSS)</td>
<td>7.54</td>
<td>8.03</td>
<td>0.1898</td>
<td>93</td>
</tr>
<tr>
<td>Treatment with Torch (HBSS)</td>
<td>7.40</td>
<td>9.03</td>
<td>0.1135</td>
<td>147</td>
</tr>
<tr>
<td>Treatment with Torch (Modified HBSS)</td>
<td>7.54</td>
<td>8.02</td>
<td>0.1818</td>
<td>97</td>
</tr>
</tbody>
</table>

Data from the experiments utilizing a tube furnace for post-treatment are ongoing. It is expected that the results from these investigations will give further insight into an optimal annealing temperature and duration, in order to increase the degradation period. Overall, the conclusions drawn from this investigation will provide a new annealing approach to optimize the corrosion process of this novel metallic amalgamate used for the fabrication of biodegradable stents.

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REFERENCES