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

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2           geometric platform through simulated bench-testing.

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7    Abstract

8    Absorbable metallic stents (AMS) are a newly emerging cardiovascular technology which has  
9    the potential to eliminate long-term patient health risks associated with conventional, permanent  
10   stents. AMS developed to date have consisted of magnesium alloys or iron, materials with  
11   inferior mechanical properties to those used in permanent stents, such as stainless steel and  
12   cobalt chromium alloys. However, for AMS to be feasible for widespread clinical use it is  
13   important that their performance is comparable to modern, permanent stents. To date, the  
14   performance of magnesium, iron and permanent stent materials have not been compared on a  
15   common stent platform for a range of stent performance metrics, such as flexibility, radial  
16   strength and recoil. In this study this comparison is made through simulated bench-testing, based  
17   on finite element modelling. The significance of this study is that it allows potential limitations  
18   in current AMS performance to be identified, which will aid in focusing future AMS design.  
19   This study also allows the identification of limitations in current AMS materials, thereby  
20   informing the on-going development of candidate biodegradable alloys. The results indicate that  
21   the AMS studied here can match the recoil characteristics and radial strength of modern,  
22   permanent stents; however, to achieve this, larger strut dimensions are required. It is also  
23   predicted that the AMS studied are inferior to permanent stents in terms of maximum absolute  
24   curvature and longitudinal stiffness.

25   Keywords: finite element analysis, biodegradable iron, biodegradable magnesium, absorbable  
26   metallic stents

27

## 28 Introduction

29 Coronary stents are small, cylindrical scaffolds used in the treatment of atherosclerosis. The  
30 primary role of the stent is to prevent elastic arterial recoil following vessel dilation with an  
31 angioplasty balloon (Serruys et al., 1994). Typically coronary stents have been considered to be  
32 permanent implants, consisting of high-strength, corrosion-resistant alloys such as stainless steel  
33 (316L) and cobalt chromium L605 (CoCr). However, stents that are gradually absorbed in the  
34 body are now attracting much interest (Peuster et al., 2006). This is due to the possibility of  
35 eliminating the risk of late-stent thrombosis, associated with the long-term presence of the stent,  
36 and also reducing the need for prolonged anti-platelet therapy (Waksman, 2007).

37 Absorbable metallic stents (AMS) have shown promise in preliminary clinical trials (Erbel et al.,  
38 2007), however in order for AMS to be accepted into widespread clinical use it must be proven  
39 that their performance can at least match that of modern, permanent stents. As shown in Fig. 1  
40 and Table 1, the mechanical properties of typical bioabsorbable metals developed to date are  
41 generally inferior to those of permanent stent materials, such as 316L and CoCr. This makes the  
42 design of AMS more challenging than that of permanent stents (Deng et al., 2011) and leads to a  
43 question on the ability of current AMS to match permanent stent performance in terms of stent  
44 radial strength, recoil and flexibility.

45 Simulated bench-testing based on finite element (FE) modelling is commonly used in contrasting  
46 the performance of different permanent stents (Etave et al., 2001; Migliavacca et al., 2002;  
47 Mortier et al., 2011). This study employs a similar approach in investigating the ability of AMS  
48 to match the performance of permanent stents over metrics such as radial strength, recoil and  
49 flexibility. To date, a small number of FE studies have investigated the performance of  
50 magnesium alloy stents (Wu et al., 2010; Gastaldi et al., 2011; Grogan et al., 2011) with  
51 predicted device stresses, strains and recoil reported. However, to the authors' knowledge, this is  
52 the first study in which the performances of magnesium alloy, iron and permanent stents have  
53 been directly contrasted on a common stent geometry over a range of performance metrics, such  
54 as radial strength and flexibility. Also, to the authors' knowledge, this is the first computational  
55 study in which stent resistance to longitudinal compression is compared over a range of  
56 materials, with the ability of coronary stents to resist longitudinal compression recently emerging  
57 as a concern in device design (Prabhu et al., 2011). The significance of the study is that it

58 facilitates the identification of current limitations in AMS performance and also allows  
59 recommendations to be made on how current biodegradable metals can be improved to allow  
60 AMS to more closely match the performance of permanent stents.

61 The adoption of a common geometric platform across materials in this study allows a direct  
62 comparison of a material's performance in a stent application with that of established stent  
63 materials. However, given that AMS designs used in *in-vivo* studies to date (Erbel et al., 2007;  
64 Peuster et al., 2001) differ somewhat from the common geometry used here, and that some may  
65 be designed based on the mechanical properties of a specific alloy, it is useful to also consider  
66 the performance of designs representative of those tested *in-vivo*, alongside that of the common  
67 geometry.

68 As such, the specific goals of this study are: 1) to compare AMS and permanent stent  
69 performance using: i) a common stent geometry and ii) representative stent geometries, through  
70 FE modelling, 2) to identify current design challenges facing AMS development, based on model  
71 predictions, and 3) to make recommendations toward the on-going development of candidate  
72 biodegradable metals for improved AMS performance.

### 73 Methods

74 Stent bench-testing was simulated using the Abaqus/Explicit commercial FE code (DS  
75 SIMULIA, RI, USA), assuming finite deformation kinematics. The performances of candidate  
76 biodegradable alloys were assessed on a generic stent geometry (geometry A in Fig. 2), allowing  
77 a direct comparison of material performance across a common geometric platform, and also on  
78 geometries representative of those used in previous *in-vivo* experiments on magnesium alloy  
79 stents (Erbel et al., 2007) and iron stents (Peuster et al., 2001). Information on the studied  
80 geometries is given in Fig. 2 and Table 2.

81 Six stent materials were studied in each bench-test. Conventional stent materials stainless steel  
82 316L and cobalt chromium L605 were studied on generic geometry A, described in Table 2, with  
83 L605 also studied on geometry A1, which has the same underlying design as geometry A, but  
84 strut dimensions similar to those of many modern 'thin-strut' stents. Magnesium alloys AZ31  
85 and WE43, which is the alloy used in the clinical trials of Erbel et al., (2007), were studied using  
86 generic geometry A and also geometry B, which is representative of the 'Magic' stent geometry

87 used in the trial of Erbel et al., (2007). Two forms (denoted T1 and T2) of annealed pure iron,  
88 which has been used in the *in-vivo* studies of Peuster et al., (2001), were considered in this study,  
89 with different mechanical properties arising from different annealing heat treatments. The  
90 performance of the pure iron was assessed on the generic geometry A and geometry C, which is  
91 representative of the 'PUVA' stent used in the study of Peuster et al., (2001).

92 Stress-strain data for each material was taken from the literature, as detailed in Table 1 and Fig.  
93 1. Each material was modelled using a rate-independent elastic-plastic material description, with  
94 elasticity assumed linear in terms of finite deformation quantities, in particular Cauchy stress and  
95 Lagrangian strain, (DS SIMULIA, 2010), and plasticity described using  $J_2$  flow theory with non-  
96 linear isotropic hardening. The finite element meshes used to discretise each geometry, shown in  
97 Fig. 2, were chosen based on the results of preliminary solution mesh dependence studies. In  
98 order to ensure a negligible influence of inertial effects when using the Abaqus/Explicit code, the  
99 ratio of kinetic energy to internal energy of less than 0.05 was maintained in all simulations.

100 Four bench-tests were simulated for each material and geometry, as detailed in Fig. 3. In the first  
101 test, stent deployment and recoil were simulated through the expansion to 3.0 mm and  
102 subsequent contraction of a rigid cylindrical shell, as shown in Fig. 3. This approach has been  
103 used in a number of previous studies (Gervaso et al., 2008; Wu et al., 2011) and has been shown  
104 by De Beule et al. (2008) to give an accurate prediction of the final, deployed stent geometry for  
105 unconfined, straight stent expansions relative to that achieved in more computationally expensive  
106 wrapped balloon simulations, such as those of Mortier et al. (2010) and Grogan et al. (2011). For  
107 this study the extra control over final stent diameter afforded by cylinder deployment for each  
108 material and geometry also proved advantageous.

109 The quantities of interest in the first test are peak von-Mises stresses ( $\sigma_\theta$ ), max principal  
110 logarithmic strains ( $\epsilon_{mp}$ ) and stent recoil. Von-Mises stresses are chosen as a simple measure of  
111 maximum device stress in this case, given the ductile nature and large plastic deformations of the  
112 metals considered in this study, with alternative measures such as maximum principal stresses  
113 also giving similar overall trends in terms of device performance. In order to facilitate a  
114 comparison of peak stresses and strains across each material, an appropriate comparative  
115 indicator is required. For this study a straight-forward approach was chosen in comparing  
116 materials, through the definition of respective stress and strain based factors of safety,  $\eta_\sigma$  and  $\eta_\epsilon$ .

117 In determining each factor of safety, predicted peak stresses and strains in the stent were  
 118 compared with estimates of true stress and strain at the point of ultimate tensile stress (UTS) in  
 119 each material's engineering stress-strain curve. A conventional conversion of engineering to true  
 120 stress and logarithmic strain measures (Callister et al., 2007) was used, based on UTS ( $\sigma_{UTS}$ ) and  
 121 engineering strain at UTS ( $\varepsilon_{UTS}$ ) data for each material, given in Table 1. This gave the following  
 122 factor of safety definitions:

$$\eta_{\sigma} = \frac{(1 + \varepsilon_{UTS})\sigma_{UTS}}{\sigma_e} \quad (1)$$

$$\eta_{\varepsilon} = \frac{\log_e(1 + \varepsilon_{UTS})}{\varepsilon_{mp}} \quad (2)$$

123 In quantifying stent recoil a conventional approach was taken (Migliavacca et al., 2002), with  
 124 recoil given by:

$$\text{Recoil} = \frac{D_1 - D_2}{D_1} \times 100\% \quad (3)$$

125 where  $D_1$  is the stent internal diameter at max expansion and  $D_2$  is the stent internal diameter  
 126 following rigid cylinder contraction.

127 To assess the ability of the two ring geometries used in this study to capture the  $\eta_{\sigma}$  and  $\eta_{\varepsilon}$  values  
 128 and overall recoil behaviour of each material in a longer stent, a preliminary deployment  
 129 simulation of a four ring **generic** stent, half of which was modelled due to longitudinal  
 130 symmetry, with a wrapped balloon was performed. Results were compared to those from a  
 131 cylinder deployment of a two ring **generic** stent. It was observed that the final stent  
 132 configurations were very similar, as shown in Fig. 4, with only a 1.1% higher peak Von Mises  
 133 stress and a 0.09% lower stent recoil magnitude predicted for the wrapped balloon simulation.  
 134 Such differences result in minor over-estimations in  $\eta_{\sigma}$  (1.1%) and recoil (0.09%) values for the  
 135 cylinder deployment method, but these over-estimations are small relative to the range of values  
 136 each metric takes over the different materials tested in this study.

137 In the second test, stent radial strengths were predicted for each material. Radial compression of  
 138 each stent was simulated by introducing a thin elastic sheath over the deployed stent, as shown in  
 139 Fig. 3. An inward pressure was applied to the outer surface of the sheath and transferred to the

140 stent by contact. The sheath was sufficiently compliant as to not support a significant inward  
141 pressure by itself (Young's modulus,  $E = 0.1$  GPa; Poisson's Ratio,  $\nu = 0.4$ ) and was constrained  
142 to only deform radially with respect to the stent's longitudinal axis. The collapse behaviour of  
143 the stent was quantified through the determination of a pressure-diameter curve, with the stent  
144 outer diameter ( $D$ ) determined for a given applied pressure. Due to there being no obvious point  
145 of global collapse, the pressure for 10% diameter loss, relative to the unloaded stent outer  
146 diameter,  $D_0$ , was taken as a measure of stent radial strength in this study. This diameter loss  
147 corresponds to a clear deviation from linear behaviour in the pressure-diameter curve for all  
148 stents.

149 The third test predicted stent resistance to longitudinal compression. All nodes on each end of the  
150 deployed stent geometry were fixed to control nodes by means of multi-point constraints, as  
151 shown in Fig. 3. The right control node was then moved toward the left control node, which was  
152 fixed in all directions, under displacement control. The resulting reaction force on the right node  
153 was taken as a measure of resistance to a given amount of stent longitudinal compression,  
154 consistent with the measure used in the experiments of Prabhu et al. (2011).

155 The final test predicted the stent's flexibility, in terms of both elastic and plastic deformations.  
156 The approach taken was similar to that commonly used in FE stent flexibility studies (Petrini et  
157 al., 2004; Wu et al., 2007; Pant et al., 2011) and allowed a direct comparison with previous  
158 experimental studies (Mori and Saito, 2005). Similar to the previous bench-tests, only two  
159 circumferential rings of the stent were modelled for stents A and C and three for stent B. This  
160 simplification, which allows improved computational efficiency, can give a good approximation  
161 of the flexibility of a longer stent with the same repeating unit (Petrini et al., 2004). In the  
162 present study, each end of the stent was fixed in all directions to two control nodes via multi-  
163 point-constraints, the right control node was then rotated about the left control node through an  
164 angle  $\theta$ , as shown in Fig. 3. In an approach similar to that of the previously mentioned FE  
165 studies, stent flexibility was determined in terms of the resulting moment-curvature curve, with  
166 the moment given by the reaction moment on the right-control node and the curvature ( $\kappa$ ) given  
167 by:



$$\kappa = \frac{\theta}{L_U} \quad (4)$$

168 where  $L_U$  is the length of the stent unit. Stent flexibility was quantified as the inverse slope of the  
 169 linear (elastic) portion of the moment-curvature curve, allowing a comparison of model  
 170 predictions with the experiments of Mori and Saito, (2005).

## 171 Results

172 Figs. 5(a) and (b) show the respective  $\eta_\sigma$  and  $\eta_\epsilon$  values for each material and geometry. It is  
 173 predicted that all studied magnesium alloy stents have significantly lower  $\eta_\sigma$  and  $\eta_\epsilon$  values than  
 174 the CoCr and 316L stents at maximum expansion. The iron stents are predicted to generally have  
 175  $\eta_\sigma$  and  $\eta_\epsilon$  values closer to those of the permanent stents, with the iron T2 generic stent having  
 176 comparable values to the permanent stents. Predicted recoil for the 316L stent (3.9%), as shown  
 177 in Fig. 5(c), is in good agreement with that measured experimentally for the Cypher stent (3.4%)  
 178 (Menown et al., 2010), while the higher recoil predicted in the thin CoCr stent (6.7%) is  
 179 consistent with experimental measurements of higher recoils in modern thin-strut stents, for  
 180 example the Multilink Vision stent (5.9%) (Lanzer, 2007). The relatively high recoils predicted  
 181 in the magnesium alloy stents (4.7% - 8.6%) are in agreement with reported stent recoil of under  
 182 8% for the Biotronik Magic magnesium alloy stent (Erbel et al., 2007), while the relatively low  
 183 recoils predicted for the iron stents (0.9% - 1.6%) are in agreement with the experimental studies  
 184 of Peuster et al. (2001), who reported a recoil of 2.2%.

185 Figs. 6 (a) and (b) show the predicted pressure-diameter curves for selected stents and the  
 186 pressure required for 10% diameter loss for all stents. Agrawal et al. (1992) have suggested a  
 187 minimum collapse pressure of 0.04 MPa for coronary stents. Modern CoCr stents have typical  
 188 collapse pressures of just over 0.1 MPa (Schmidt et al., 2009), with some older 316L stents  
 189 having collapse pressures as high as 0.21 MPa (Venkatraman, 2003). This range shows good  
 190 agreement with the stent radial strength predictions in this study of 0.08 - 0.15 MPa for 10 and  
 191 50% diameter loss in the 80  $\mu$ m CoCr stent and 0.16 - 0.25 MPa for the 316L stent. The lower  
 192 radial strengths of the magnesium alloy stents predicted in this study (0.06 - 0.14 MPa for 10 and  
 193 50% diameter loss) are in good agreement with the reported collapse pressure of 0.08 MPa for  
 194 the Biotronik Magic magnesium alloy stent (Erbel et al., 2007).

195 As shown in Fig. 7(a), it is predicted that the AMS have greater flexibility than the permanent  
196 stents, including the 80  $\mu$ m CoCr stent. However, as shown in Fig. 7 (b), the curvatures at which  
197 the AMS reach a  $\eta_e$  value of 1.0 are somewhat lower than those of the permanent stents.  
198 Moment-curvature predictions for the 316L stent in this study show good qualitative and  
199 quantitative agreement with those of Pant et al. (2011), who simulated flexure in a similar stent  
200 geometry. Also, considering only the linear portion of the moment-curvature behaviour,  
201 predicted flexibility for the 316L stent ( $0.0062 \text{ N}^{-1}\text{mm}^{-2}$ ) falls within the range of 316L stent  
202 flexibilities experimentally investigated by Mori and Saito (2005) of  $0.0053 - 0.024 \text{ N}^{-1}\text{mm}^{-2}$ .

203 Figs. 8 (a) and (b) shows the predicted resistance of selected stents to an applied longitudinal  
204 compression and the reaction force required for 10% compression of all stents. The predicted  
205 force of 2.8 N required for a 6.5% compression of the 316L stent differs from the force of 0.5 N  
206 for the same compression of the Cypher stent observed experimentally in Prabhu et al. (2011).  
207 This difference is possibly due to the different connecting section geometries of the stent studied  
208 here and the Cypher stent, with stent geometry contributing significantly to device compressive  
209 resistance (Prabhu et al., 2011). Insufficient resistance to stent longitudinal compression is  
210 undesirable as it increases the risk of stent-artery malapposition if the stent comes into contact  
211 with the delivery system following deployment. In this study, it is predicted that the AMS have a  
212 significantly lower resistance to longitudinal compression than the permanent stents. It is also  
213 predicted that reducing the strut dimensions from 120 to 80  $\mu$ m in the CoCr stent resulted in a  
214 significant reduction in resistance.

## 215 Discussion

216 The very low  $\eta_e$  values ( $< 1.1$ ) predicted in this study for both magnesium alloys and the generic  
217 and representative magnesium stent designs, relative to those of the modern CoCr and 316L  
218 stents ( $> 2.6$ ), suggest that considerable effort is required in terms of both device and alloy  
219 design to ensure a comparable fracture risk with modern, permanent stents. Addressing such a  
220 risk is of particular importance considering the nature of the relatively undemanding tests  
221 considered here, where additional deformations due to arterial curvature or irregular lumen  
222 geometry were not considered. Alloy specific device design, through geometric parameter  
223 studies and shape optimization based on finite element analysis seem necessary in the further  
224 development of such stents, with early applications of such an approach showing promise (Wu et

225 al., 2010). Despite this promise, given the large gap in predicted  $\eta_e$  values between the  
226 magnesium and permanent stents, it is likely that improved alloy ductility relative to the AZ31  
227 and WE43 alloys studied here is necessary before comparable performance in this regard can be  
228 achieved. In terms of the pure iron, it is predicted that  $\eta_e$  values more comparable with  
229 permanent stents are achievable (up to 2.1), with it likely that similar performance is possible for  
230 this metric through careful stent design.

231 The low maximum curvatures predicted for both magnesium stent designs and alloys ( $< 0.15$   
232  $\text{mm}^{-1}$ ) relative to the modern, permanent stents ( $>0.75 \text{ mm}^{-1}$ ) also suggest that significant effort  
233 is also required in terms of improved stent design to ensure strains in stent connecting links are  
234 minimized and improved alloy design in terms of increased ductility. This is particularly  
235 important considering typical natural arterial curvatures of up to  $0.066 \text{ mm}^{-1}$  in 90% of the  
236 population (Liao et al., 2004), with variations of  $0.025 - 0.18 \text{ mm}^{-1}$  reported during the cardiac  
237 cycle (Gross et al., 1998). In the case of iron stents, maximum curvatures of up to  $0.33 \text{ mm}^{-1}$   
238 were predicted, which gives an improved performance over the magnesium stents, but may still  
239 require careful design of stent connecting links to allow comparable performance with permanent  
240 stents.

241 In terms of recoil, a reasonable performance is predicted for the magnesium stents, (4.7 – 8.6%)  
242 relative to the thin CoCr stent (6.7%), however it is important to note the larger strut cross-  
243 sections of the simulated magnesium stents ( $0.0144 - 0.0154 \text{ mm}^2$ ) relative to the CoCr stent  
244 ( $0.006 \text{ mm}^2$ ). Interestingly, the recoil performance of the iron stents (1.6%) is predicted to be  
245 significantly better than even the permanent stents. In terms of radial strength, similar  
246 performance is noted for the magnesium (0.06 – 0.073 MPa), iron (0.06 – 0.09 MPa) and thin  
247 CoCr stents (0.082 MPa), again noting the larger cross-sectional areas of the biodegradable  
248 stents. These recoil and radial strength results suggest that the studied materials have sufficient  
249 yield strengths (138 - 216 MPa) and UTS (245 - 298 MPa) to achieve comparable scaffolding  
250 ability with permanent stents, albeit through the use of designs with larger strut dimensions.

251 It is noted in these comparisons that the iron stents show good potential in terms of achieving  
252 comparable performance with permanent stents across most metrics. However, in the future  
253 development of iron stents it is of interest to reduce strut dimensions insofar as possible, in order  
254 to compensate for the relatively low rate of iron degradation in-vivo (Hermawan et al., 2010). In

255 allowing for such a reduction it appears, based on model predictions, that device radial strength  
256 is the limiting performance metric. As such, the development of higher strength (yield and UTS)  
257 iron alloys would be highly beneficial in the future development of iron stents, with newly  
258 developed alloys such as Fe35Mn (Hermawan et al., 2010) showing much promise in this regard.  
259 Such reductions in device dimensions would also prove beneficial in terms of improvements in  
260 device fracture risk and maximum curvature.

## 261 Limitations

262 Modelling approaches used in this study are either in line with the published literature, or, when  
263 established modelling methods aren't available, predictions are compared directly to results of  
264 *in-vitro* experiments. However, some limitations to the study must be acknowledged.

265 Currently a wide range of magnesium and iron alloys are under consideration for stent  
266 application (Moravej, 2011), only four of which were considered in this study. While the authors  
267 believe the chosen magnesium alloys are representative of the general behaviour of magnesium  
268 alloys in development, it would prove useful in a further study to repeat the simulated tests for an  
269 extended range of candidate alloys, using results presented here as an initial benchmark. In the  
270 case of iron, it would be of interest to compare the performance of pure iron with that of newly  
271 developed iron alloys such as Fe35Mn.

272 Stent struts are small metallic components, with typically only a few metallic grains through  
273 their thickness. As such, continuum plasticity theory and material stress-strain data based on  
274 tensile testing of large-size samples, as used in this study, may not fully capture experimentally  
275 observed ductility size-effects in coronary stent struts (Murphy et al., 2003). Improved predictive  
276 capabilities could be afforded through the use of micro-scale modelling based on crystal  
277 plasticity theory (Harewood and McHugh, 2007). Such a study would be particularly significant  
278 in the case of annealed pure iron, which can have large grain sizes (20  $\mu\text{m}$  for iron-T1 as per  
279 Carson et al., 1968 and 35  $\mu\text{m}$  for iron-T2 as per Islam et al., 2011) relative to those typical of  
280 316L (10  $\mu\text{m}$  as per Murphy et al., 2003).

281 Only short-term stent performance is considered in this study. Over time magnesium and iron  
282 stents will corrode in the body and lose scaffolding ability. The design of these devices and  
283 candidate alloys may be further restricted than indicated in this study by the need to ensure

284 suitable device corrosion behaviour. Such restrictions can be investigated through the application  
285 of FE based corrosion models, such as that of Grogan et al. (2011). Further to this, the risk of  
286 device failure in fatigue should be studied, incorporating the roles device micro-mechanics and  
287 corrosion on fatigue life.

## 288 Conclusions

289 This study presents a computational investigation into the role of material choice on coronary  
290 stent performance for magnesium alloy, iron, steel and cobalt chromium stents, based on generic  
291 and alloy specific geometric platforms. Stent performance was assessed through simulated  
292 bench-testing, using modelling techniques that have either been well established in the literature  
293 or have predictions that can be readily compared with the results of *in-vitro* experiments. The  
294 following are some key conclusions from this work:

- 295 • A significantly higher device fracture risk was predicted in deployment for the  
296 magnesium stents than the permanent or iron stents.
- 297 • Respective maximum allowable device curvatures in the magnesium and iron stents were  
298 predicted to be less than 20% and 50% of those of the permanent stents.
- 299 • Resistances to longitudinal compression in the magnesium and iron stents were predicted  
300 to be less than 50% of those of the permanent stents.
- 301 • The struts of the magnesium and iron stents studied here require cross-sectional areas 2.4  
302 and 1.5 times greater, respectively, than the modern CoCr stent for comparable  
303 performance in terms of radial strength and recoil.
- 304 • In terms of magnesium alloy stent development, the results presented indicate that alloy  
305 ductility needs to be increased by a factor of up to 3 for comparable performance with  
306 modern stents, vis-à-vis predicted fracture risk, with it strongly recommended that the  
307 ductility of alloys proposed for AMS application at least matches that of the AZ31 and  
308 WE43 alloys studied here.
- 309 • For iron stents, future research should focus on the development of higher strength iron  
310 alloys, allowing smaller strut dimensions that are more accommodating of the low *in-*

311 *vivo* corrosion rates of iron and that are comparable to those of modern, permanent  
312 stents.

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444 Tables

Material	Young's Modulus (GPa)	Yield Strength (MPa)	Ultimate Tensile Strength (MPa)	Strain at UTS (%)	Source
Stainless Steel - 316L	190	380	750	51	(Murphy <i>et al.</i> , 2003)
Cobalt Chromium - L605	243	629	1147	46	(Poncin <i>et al.</i> , 2003)
Magnesium Alloy - WE43	45*	216	298	18	(Gu <i>et al.</i> , 2010)
Magnesium Alloy - AZ31	44	138	245	17	(Grogan <i>et al.</i> , 2011)
Pure Iron - Treatment 1	211	138	282	25	(Carson <i>et al.</i> , 1968)
Pure Iron - Treatment 2	211	170	270	36	(Islam <i>et al.</i> , 2011)

445 \* Source: Muller et al., 2009

446 Table 1. Mechanical properties for each material considered in this study, including the sources  
447 of the stress-strain data shown in Fig. 1.

448

Stent	Similar to:	Source:	Strut Width ( $\mu\text{m}$ )	Strut Thickness ( $\mu\text{m}$ )	Length (mm)	FE Mesh
A	Generic	(Pant <i>et al.</i> , 2011)	120	120	3.30	66,000
A1	Generic	(Pant <i>et al.</i> , 2011)	80	80	3.26	108,000
B	Magic Stent	SEM Images (Erbel <i>et al.</i> , 2007)	80	140	3.18	76,000
C	PUVA Stent	Microscope Images (Peuster <i>et al.</i> , 2001)	80	120	2.70	61,500

449

450 Table 2. Stent geometries used in this study. Each geometry has a pre-deployment outer  
451 diameter,  $D$ , of 1.5 mm and is meshed using reduced integration 3D linear brick elements  
452 (C3D8R). The number of elements used in each geometry is shown in the column 'FE Mesh'.  
453 'Width' refers to the circumferential strut dimension and 'thickness' refers to the radial strut  
454 dimension.

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459 Figures

460 Figure. 1. Engineering stress-strain curves for each material modelled in this study. The source  
461 of each stress-strain curve is shown in Table 1.

462 Figure. 2. Stent geometries used in this study and corresponding finite element meshes.  
463 Geometry details are given in Table 2.

464 Figure. 3. Schematic representation of the test cases simulated.

465 Figure. 4. A comparison of von-Mises stresses in the magnesium alloy stent following expansion  
466 by balloon deployment and a rigid cylinder. Very similar stress distributions and overall stent  
467 deformed geometry were predicted for both cases.

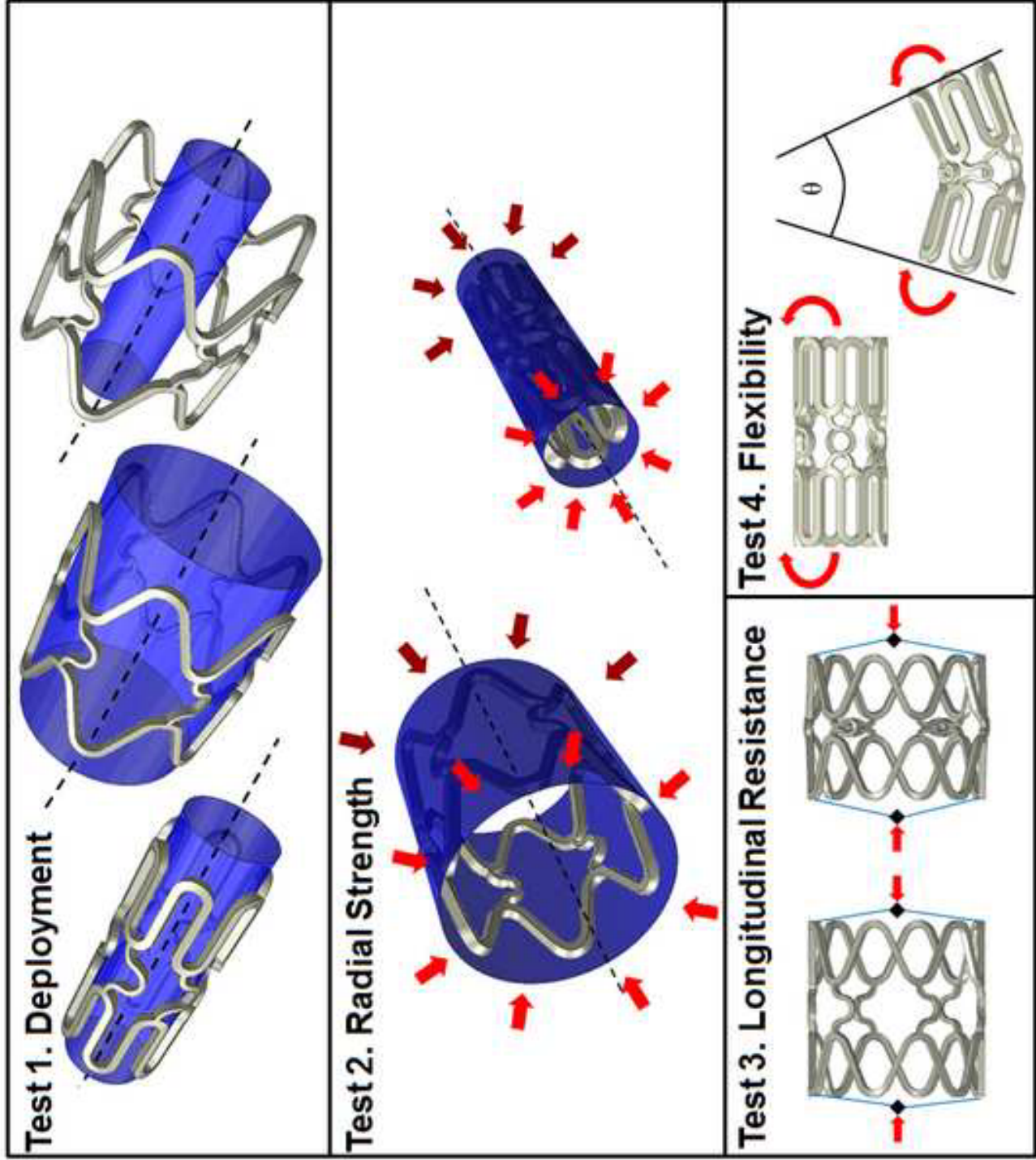
468 Figure. 5. Predicted factors of safety, (a)  $\eta_{\sigma}$  and (b)  $\eta_{\epsilon}$ , for each stent material and geometry. (c)  
469 Predicted elastic recoil for each stent.

470 Figure. 6. (a) Predicted loss in stent outer diameter ( $D$ ) relative to its unloaded diameter ( $D_0$ ) due  
471 to an external applied pressure for selected stents. (b) The applied pressure required to give a  
472 10% stent diameter reduction for all materials and stents.

473 Figure. 7. (a) Predicted moment-curvature curve for selected stents. (b) Predicted stent curvature  
474 when the  $\eta_{\epsilon}$  value first reaches a value of 1.0 in an element for all stents and materials.

475 Figure. 8. (a) Prediction of the resulting reaction force for a given longitudinal compression for  
476 selected stents. (b) The force required for a 10% stent longitudinal compression for all materials  
477 and stents.

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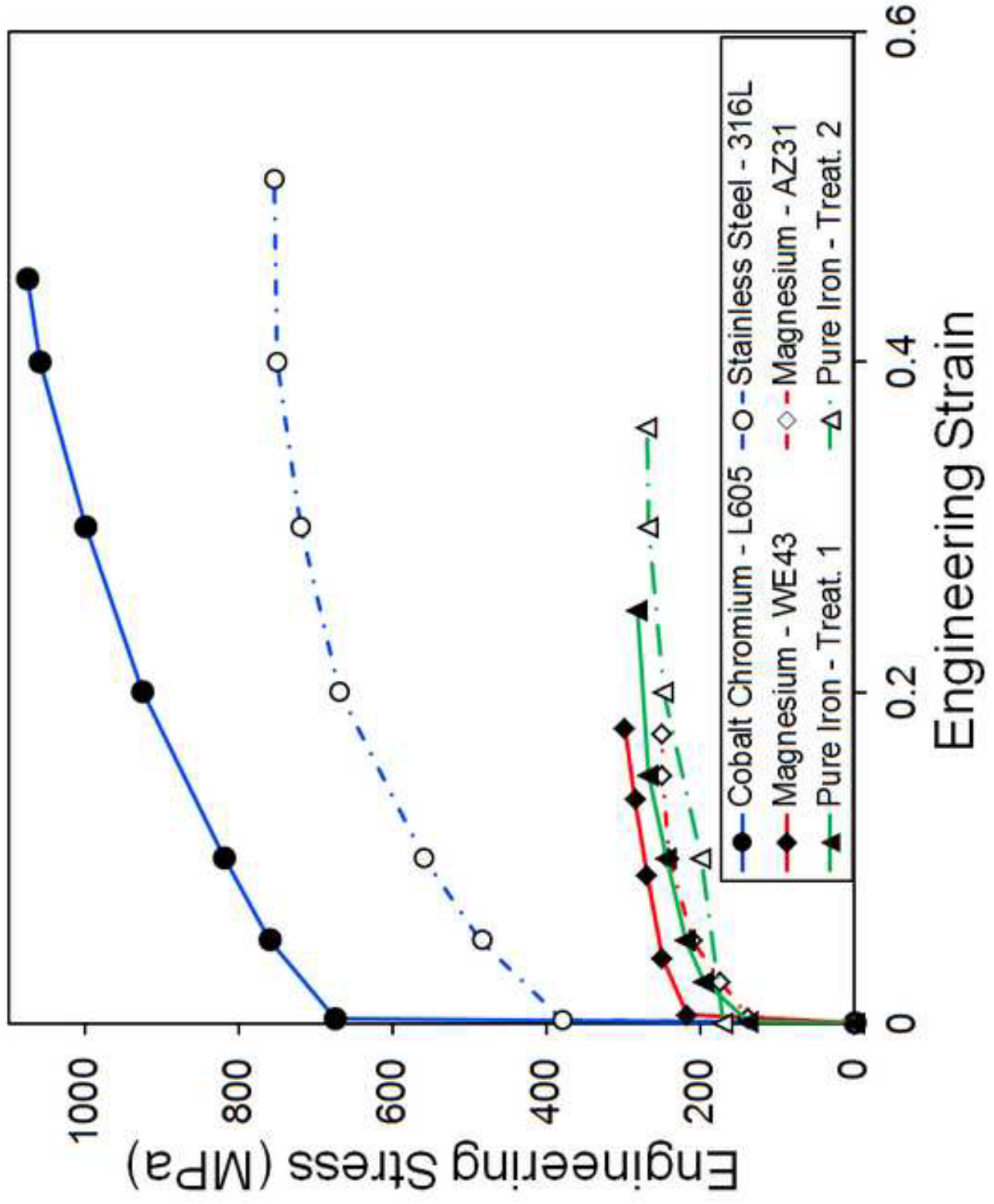


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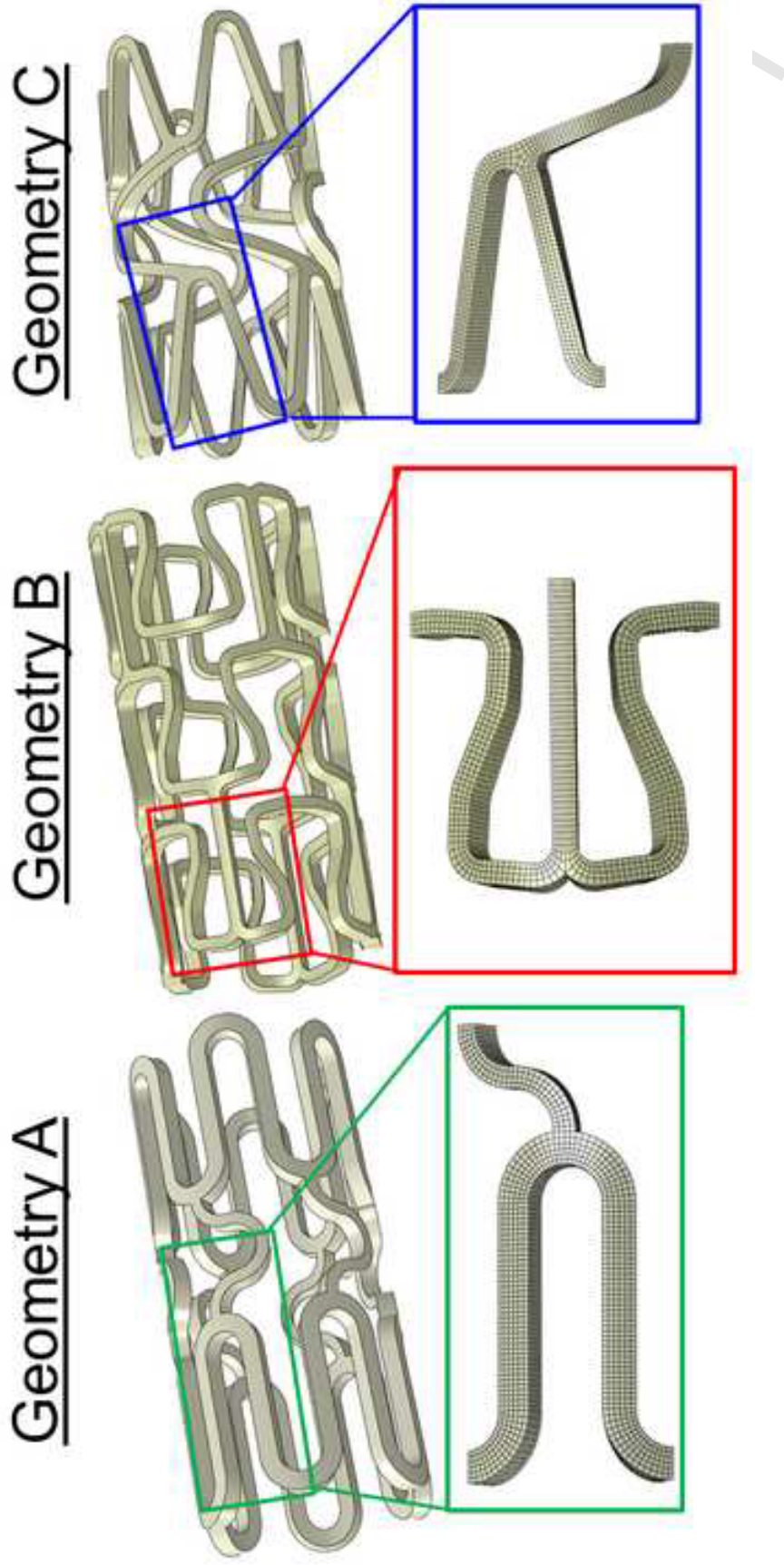


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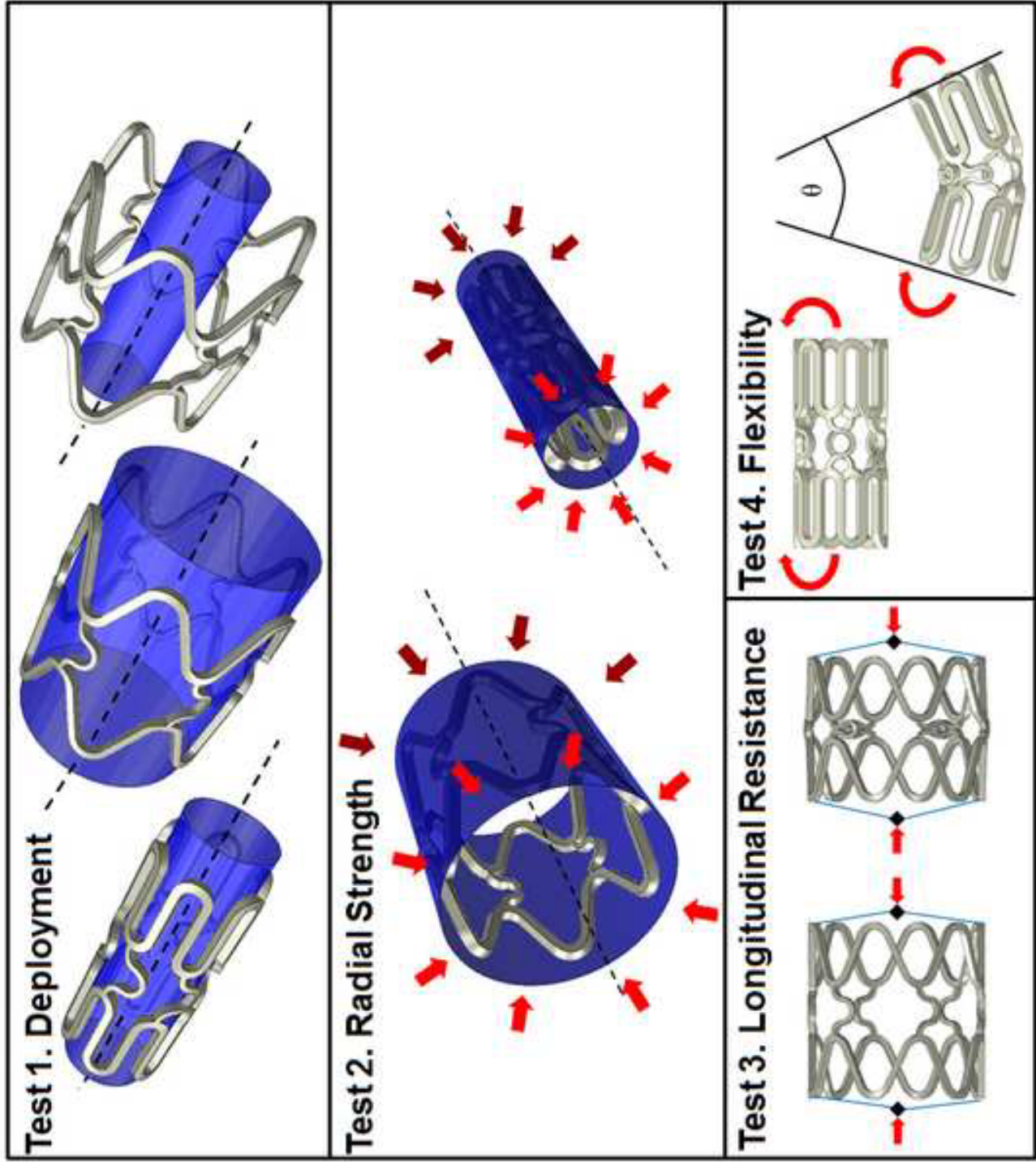
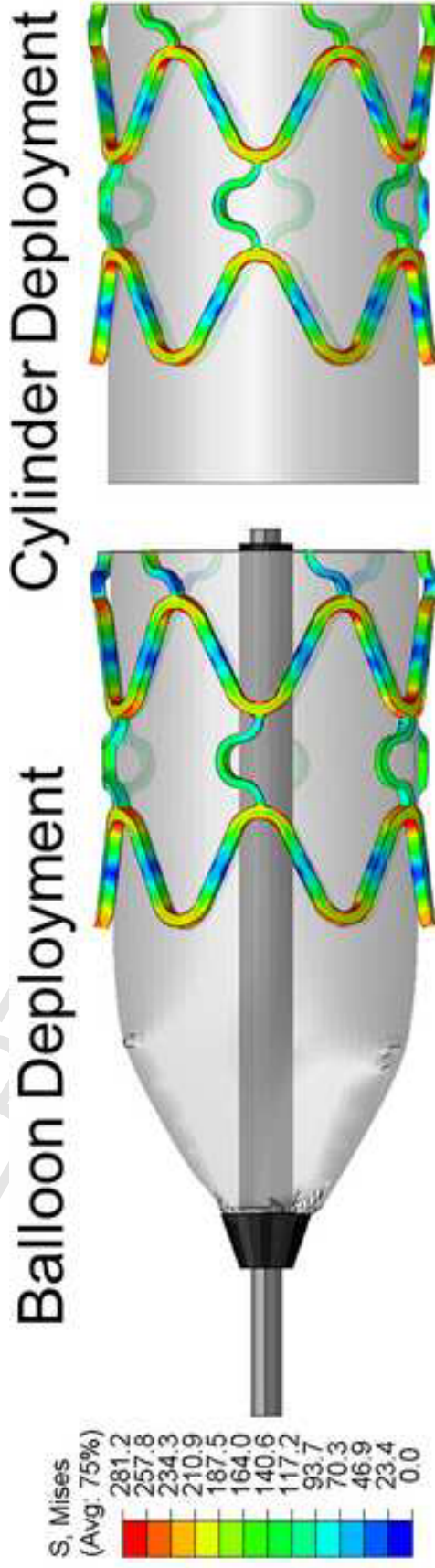


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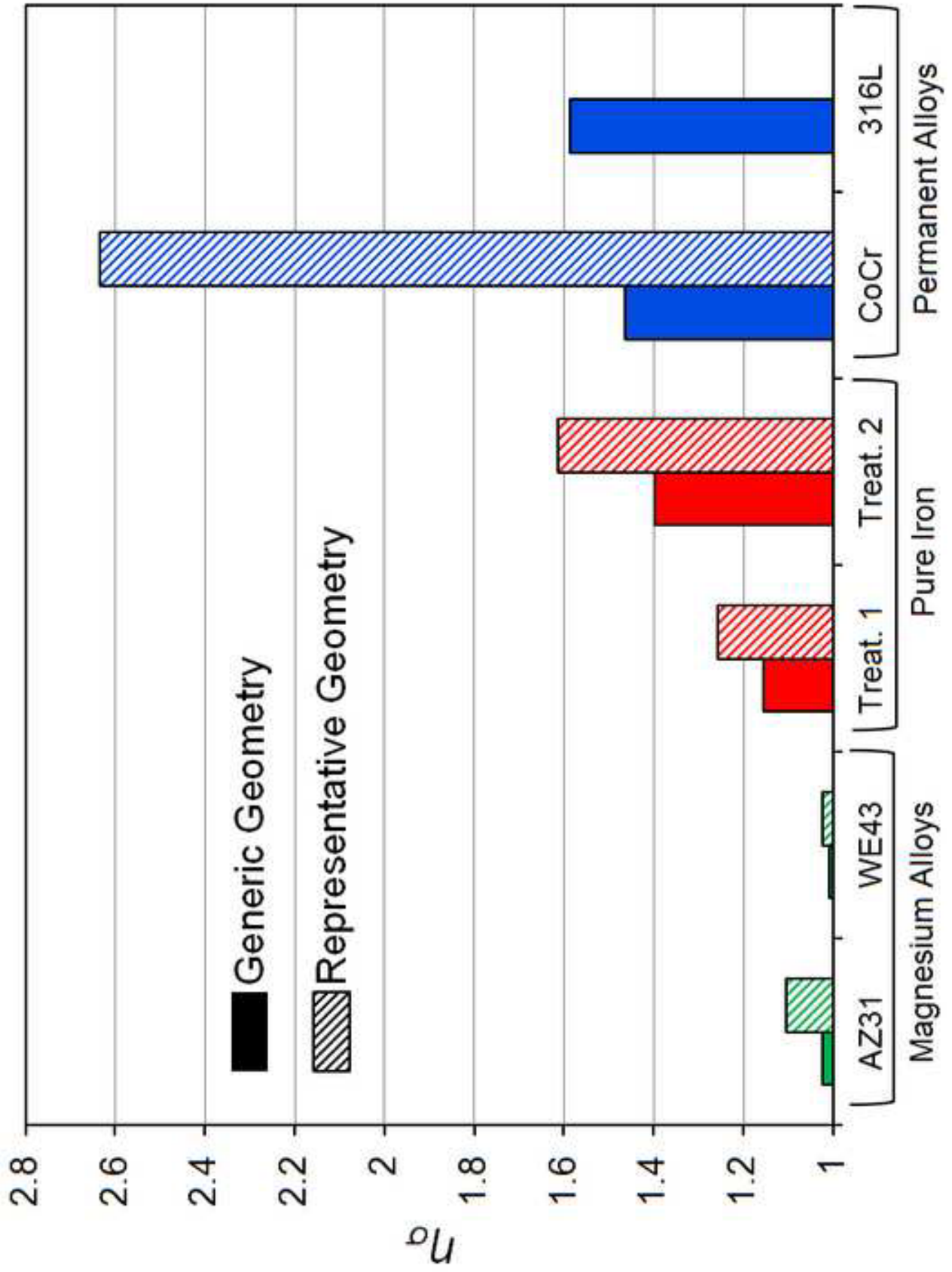


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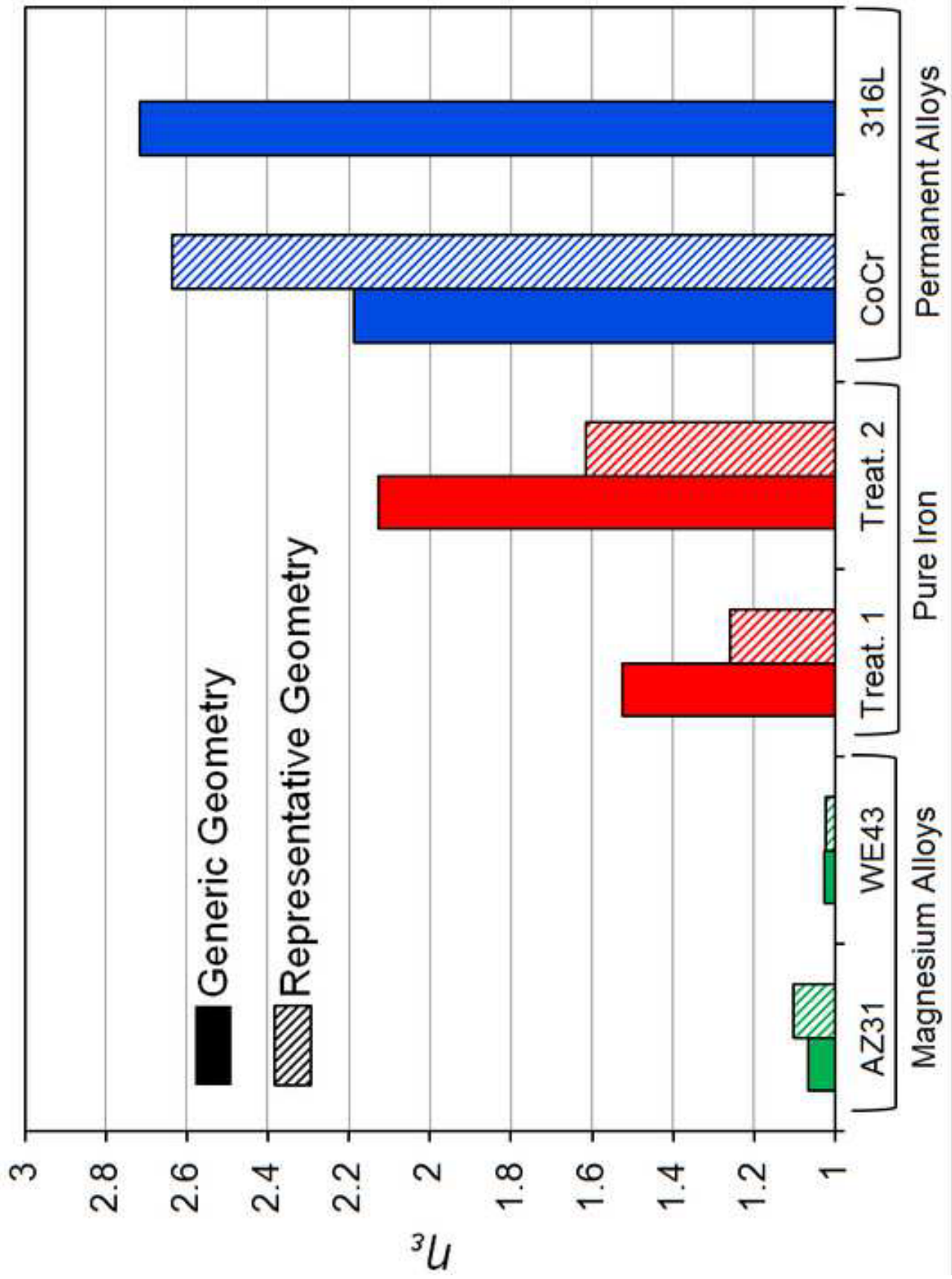


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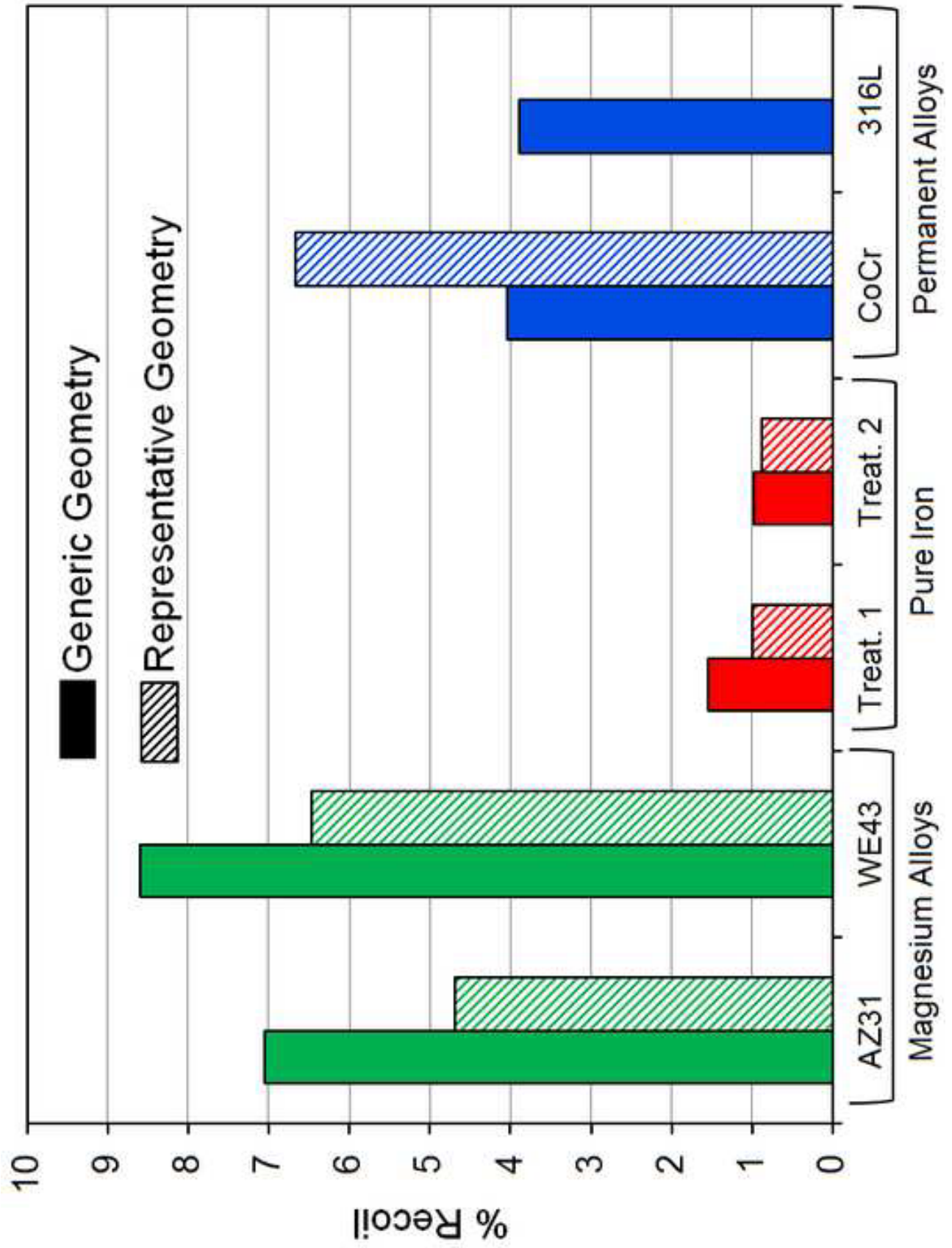


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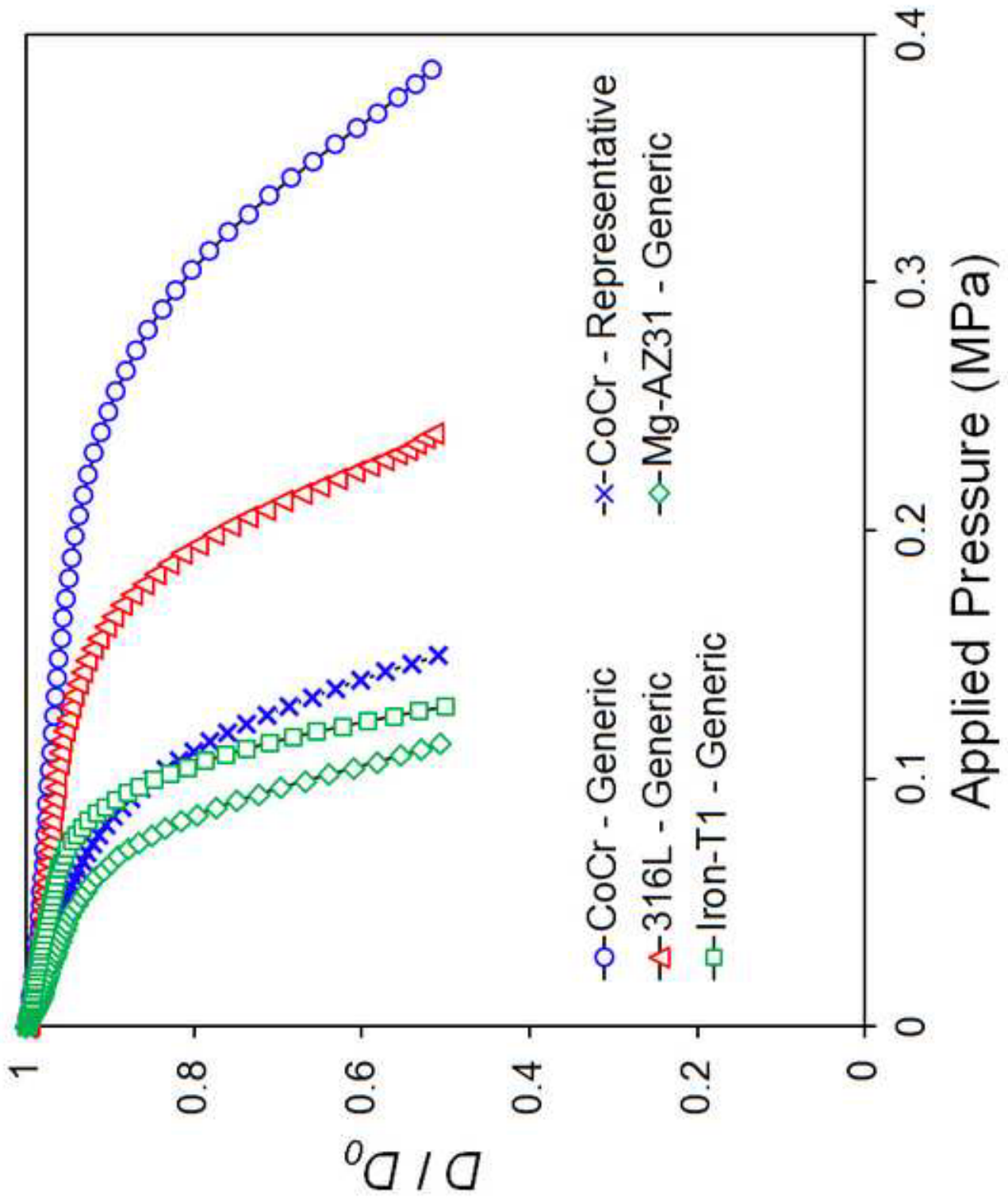


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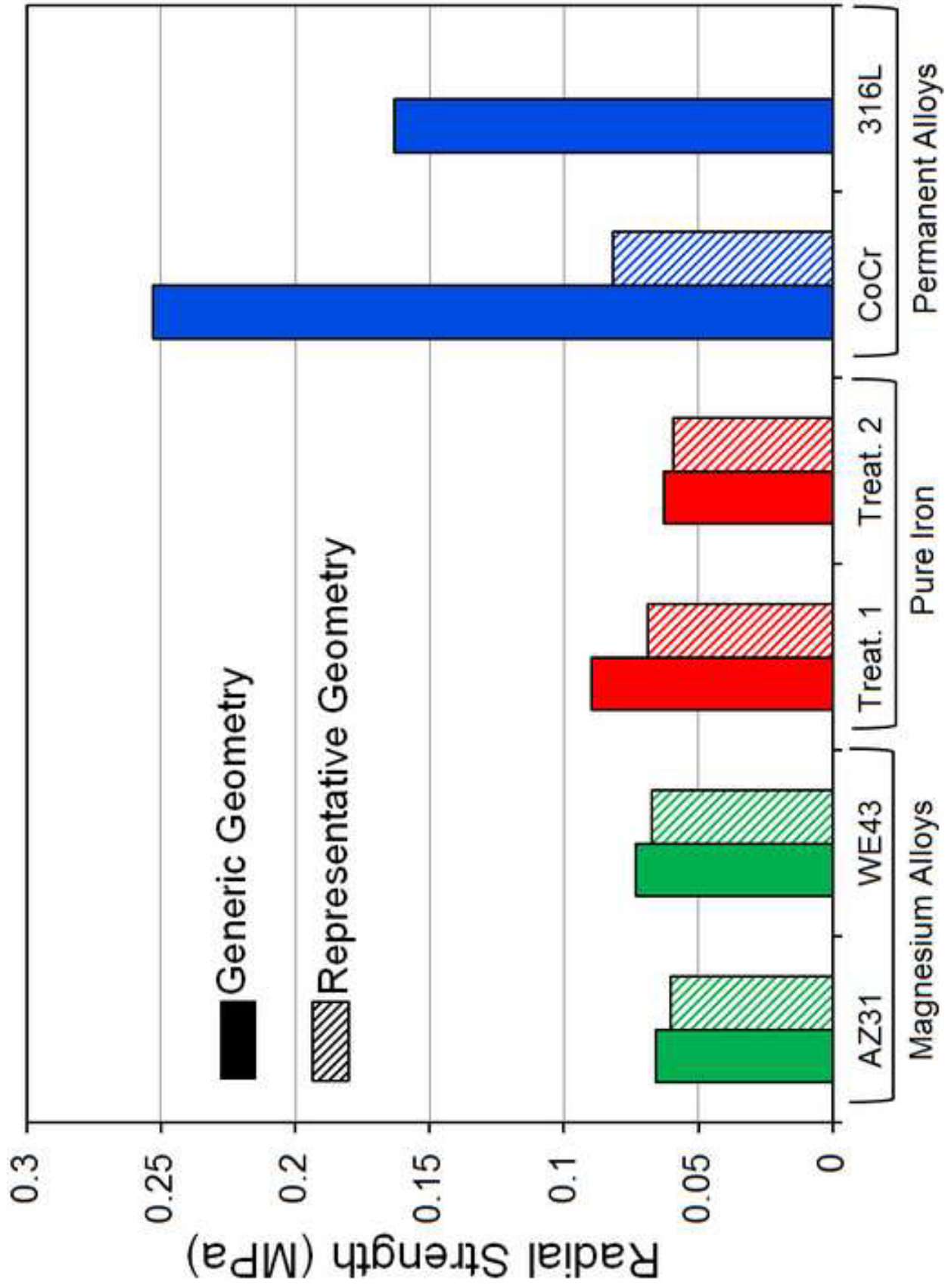


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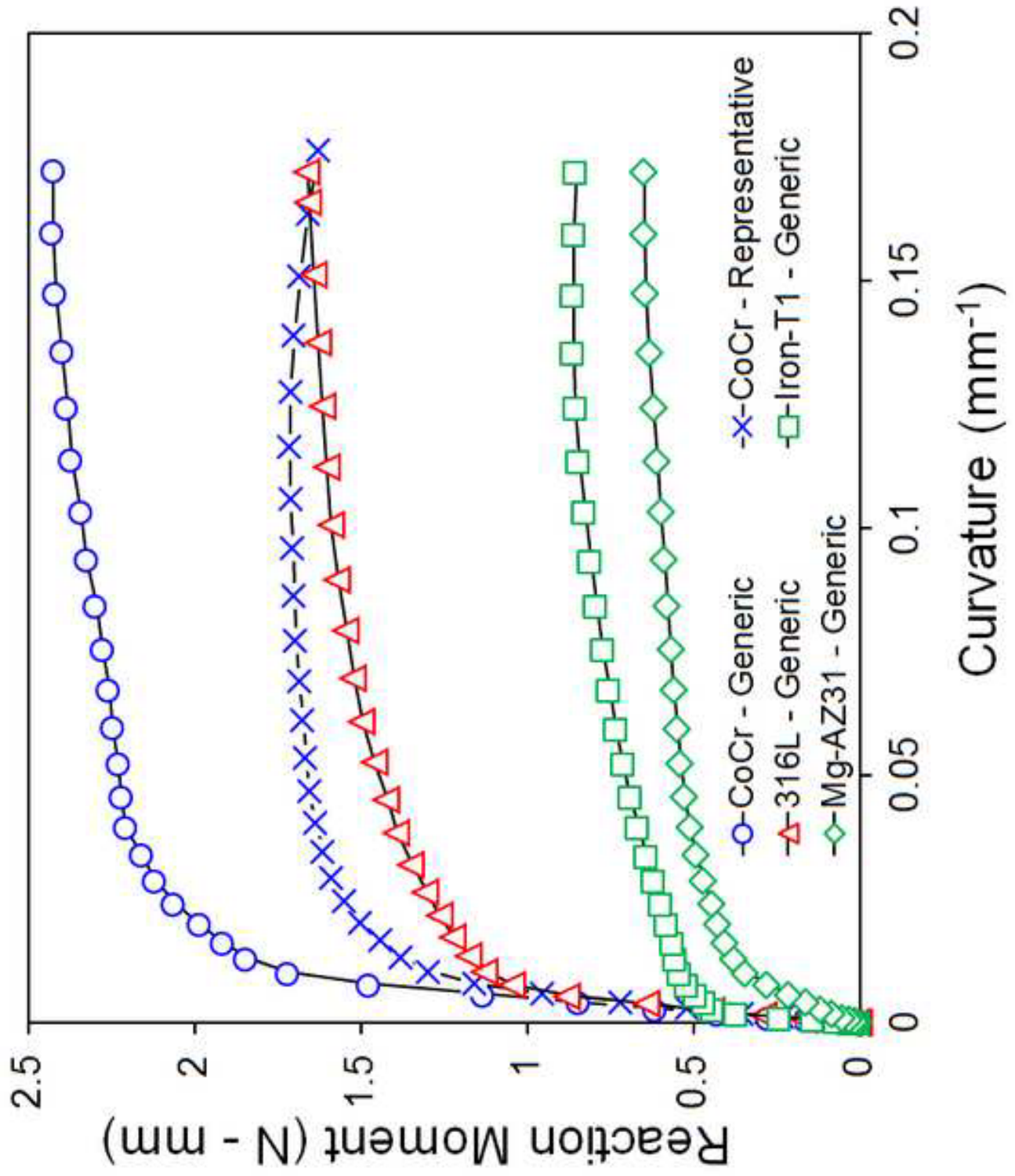


Figure 7a

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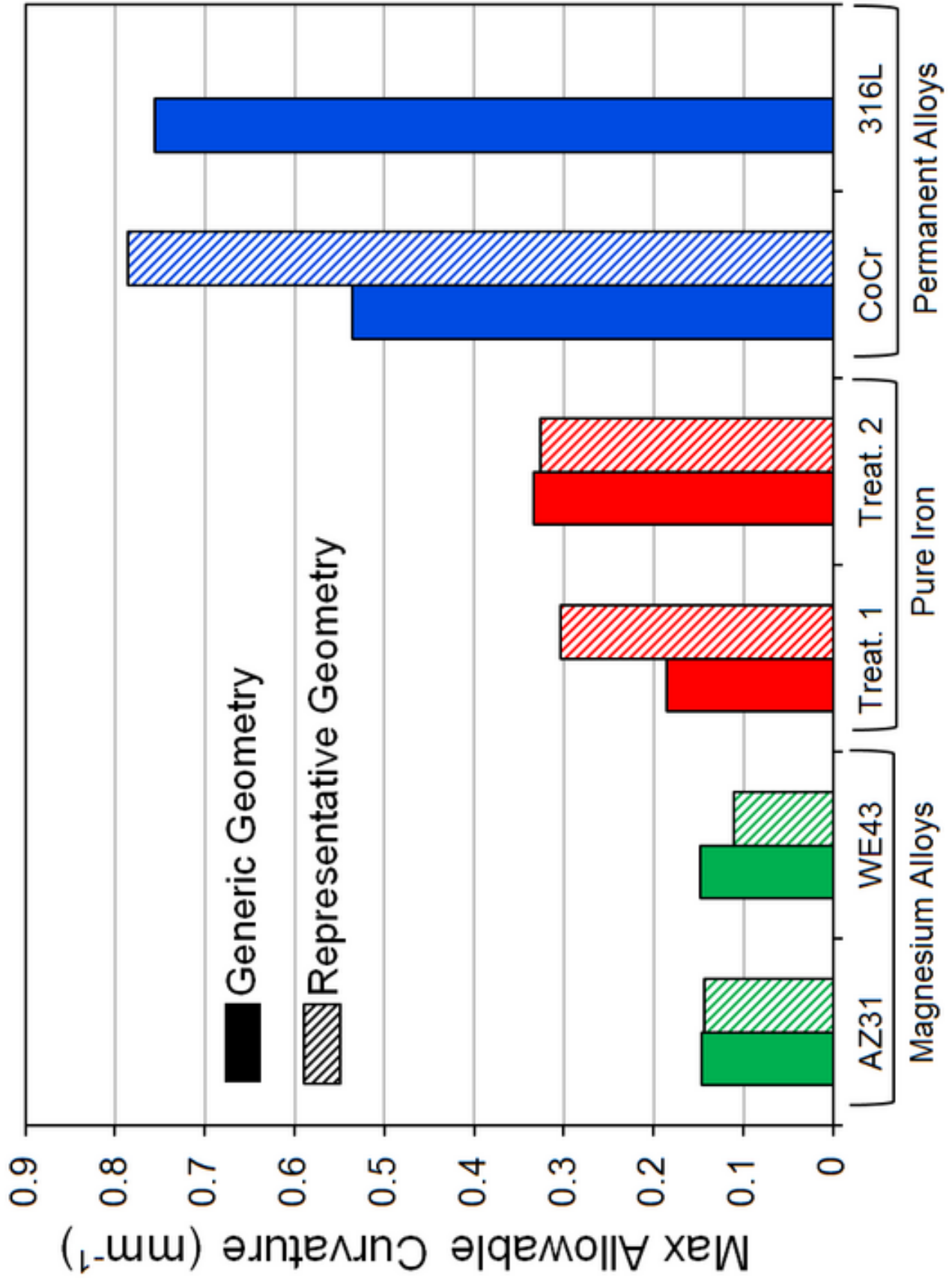


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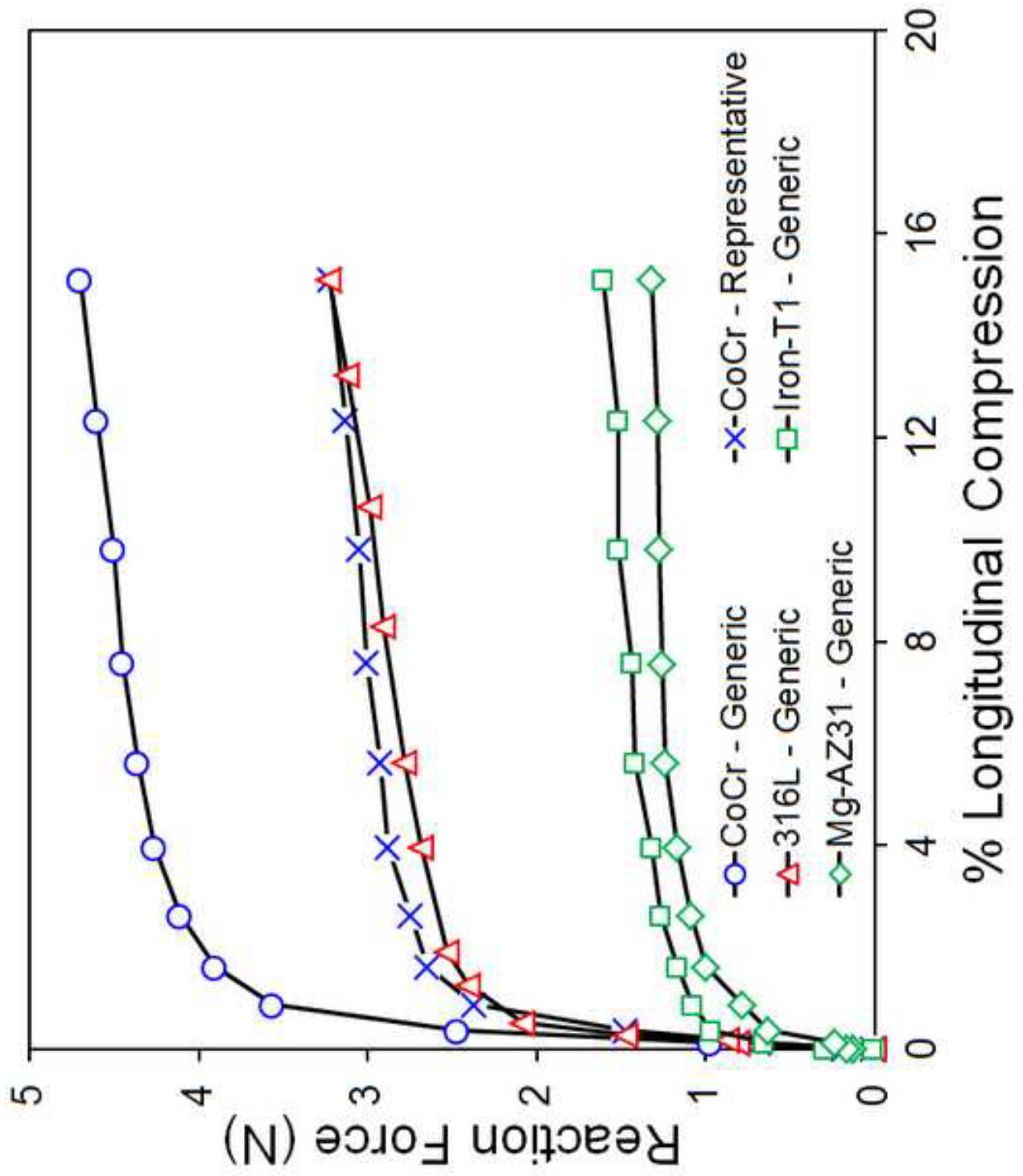


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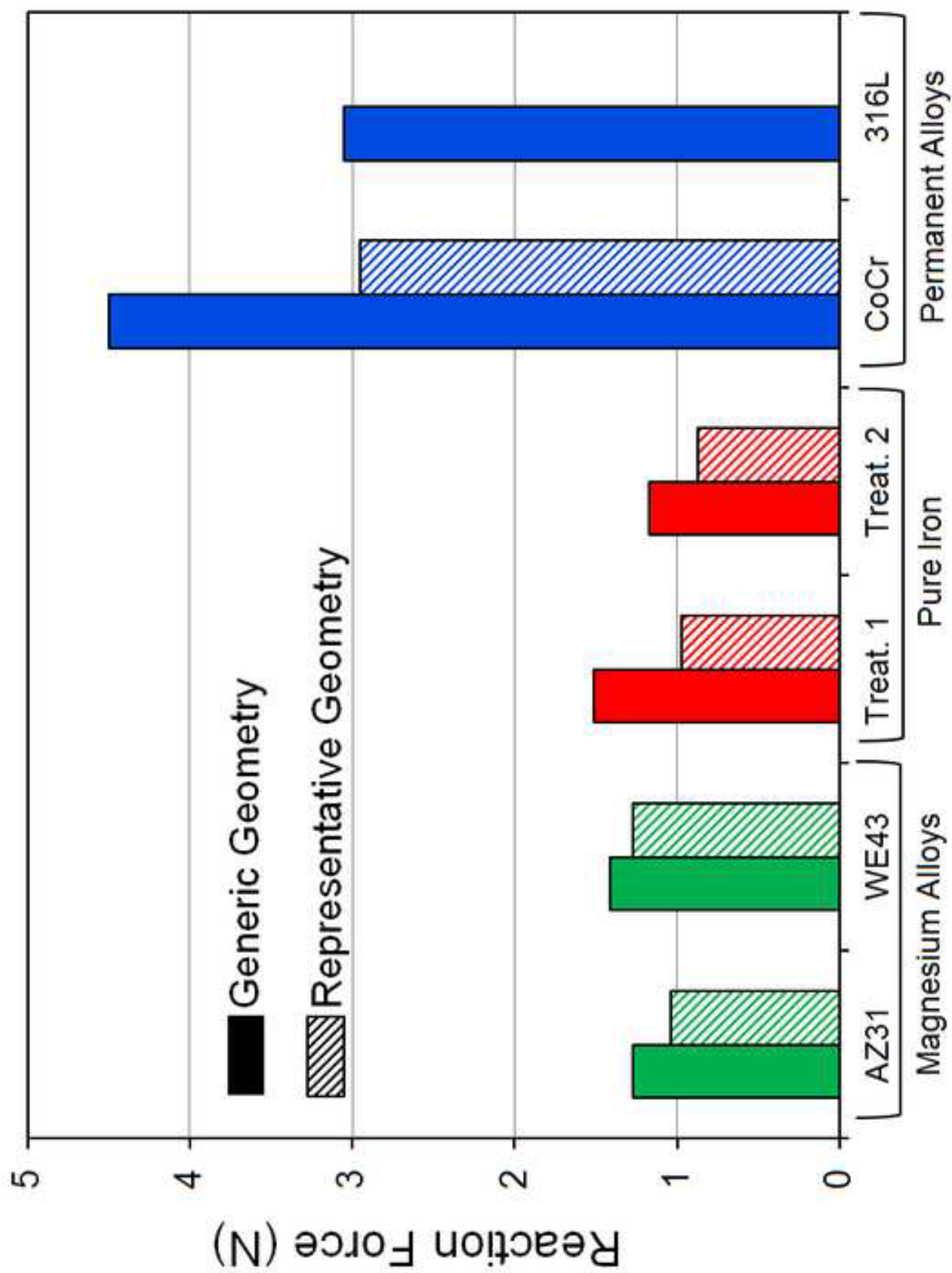


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## **Comparing coronary stent material performance on a common geometric platform through simulated bench-testing.**

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### **Highlights**

- Performance of a range of metals compared on a common stent platform.
- Higher risk of fracture predicted in Mg stents relative to permanent and Fe stents.
- Similar scaffolding for AMS and permanent stents possible through stent design.
- Improvements in Mg alloy ductility important for Mg stents.
- Improvements in Fe alloy strength important for Fe stents.