



The Hybrid Video Registry: Safety and Efficacy of the Hybrid Approach in Coronary Chronic Total Occlusion Percutaneous Coronary Intervention

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8 3 The Hybrid Video Registry: Safety and Efficacy of the Hybrid Approach in
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10 4 Coronary Chronic Total Occlusion Percutaneous Coronary Intervention

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10 59 Abstract:
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15 61 Objectives: The aim of the Hybrid Video Registry (HVR) is to assess the acute
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17 62 safety and efficacy of the Hybrid Approach in comparison to other contemporary
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19 63 methods of CTO PCI. Background: Recently, multiple techniques in
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21 64 Percutaneous Coronary Intervention (PCI) for coronary Chronic Total Occlusions
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23 65 (CTO) have been synthesized into a method referred to as the “Hybrid Approach”.
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25 66 Methods: 194 video taped timed live cases from CTO PCI training workshops
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27 67 were analyzed by independent data abstractors and compared to three
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29 68 contemporary CTO PCI registries stratified by case complexity on the basis of
30
31 69 the J-CTO score. Results: Overall procedural success was 95% of all cases
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33 70 attempted with an excellent safety profile. In the most complex lesion subset,
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35 71 which made up 45% of all HVR cases, success was 92.8%, which was
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37 72 significantly higher than either the Royal Brompton (78.9%), or Japanese-CTO
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39 73 (73.3%) registries, $p = 0.04$ Hybrid vs. Royal Brompton, $p = 0.006$ Hybrid vs.
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41 74 Japanese-CTO). The Hybrid Approach was also associated with shorter
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43 75 procedure times and lower contrast utilization. Conclusions: In a real world
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45 76 angiographic registry of complex CTOs, the Hybrid Approach to CTO PCI is safe,
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47 77 and may be superior to other contemporary approaches to CTO intervention with
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3 78 respect to procedural success and efficiency among a diverse group of operators
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12 82 Introduction:

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17 84 Percutaneous Coronary Intervention (PCI) for coronary Chronic Total Occlusions

18 85 (CTO) is associated with improvements in quality of life, left ventricular function,

19 86 and perhaps survival (1-3). Despite this evidence, many patients are not offered

20 87 CTO-PCI as a therapeutic strategy (4). We developed a systematic approach to

21 88 CTO-PCI called the “Hybrid approach”, which has been described in detail

22 89 elsewhere (5). To date, there is a paucity of data on the success rate and

23 90 efficacy of the hybrid approach. In the current study we abstracted angiographic

24 91 data from video recorded CTO-PCIs performed by hybrid operators to create the

25 92 Hybrid Video Registry (HVR). Here we present acute success rate and

26 93 procedural efficiency of the Hybrid approach and compare these outcomes to

27 94 other published series of CTO-PCI.
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96 Methods:

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98 The hybrid approach refers specifically to an algorithmic analysis of the CTO

99 angiogram and subsequent initial as well as provisional strategies to most

100 efficiently perform CTO PCI. Specifically, lesion length less than 20 mm are

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3 101 approached with a wires escalation strategy as these lesions have been shown
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5 102 to have a high success rate with this approach (4). Lesions greater than 20 mm
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7 103 are treated with an intention to perform dissection and re entry given the lower
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9 104 likelihood of efficient wire escalation leading to CTO crossing. If the proximal cap
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11 105 is clear and the distal landing zone just beyond the distal cap is an adequate
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13 106 target, an antegrade approach is initially selected. If either an ambiguous
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15 107 proximal cap or a poor distal landing zone exists, a retrograde approach is
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17 108 initially selected provided adequate interventional collaterals exist. Utilizing this
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19 109 Hybrid approach, 194 Video taped, timed live case demonstrations were
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21 110 compiled from 25 two to four day CTO PCI training workshops across the United
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23 111 States and the United Kingdom between January 2011 and June 2013. 28
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25 112 Hybrid operators performed the cases at 9 centers. 10 operators had > 10 years
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27 113 of PCI experience, 15 had 5-10 years and 3 operators had < 5 years of
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29 114 experience performing PCI. No patients were excluded on the basis of
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31 115 angiographic characteristics. The video footage including fluoroscopy,
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33 116 hemodynamics, and audio commentary were transferred to digital media and
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35 117 randomly distributed to 9 independent data abstractors not involved in the
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37 118 performance of the cases. A database including 61 data elements was
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39 119 constructed and populated from review of the cases. Success was defined as
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41 120 TIMI \geq 2 flow and < 30% residual stenosis, the same definition used in the
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43 121 European CTO (ERCTO) registry. TIMI 3 flow, which is considered an optimal
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45 122 outcome, was analyzed and additionally reported. Patients gave informed
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47 123 consent, and all recordings were de identified. Data from the Royal Brompton,
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3 124 Japanese CTO, and ERCTO registries were abstracted from the published works
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5 125 (6-8). The J-CTO score, a previously described index of CTO lesion difficulty,
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7 126 was calculated for each case in the HVR⁸. Case time was defined as the time
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9 127 from the first guidewire or device to be introduced into the target vessel to the
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11 128 final angiogram. Techniques for CTO PCI included antegrade and retrograde
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13 129 wire escalation, and antegrade and retrograde dissection and re-entry. Wire
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15 130 escalation is defined as the use of increasingly aggressive guidewires as needed
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17 131 to ultimately cross the CTO segment into the true lumen. Dissection and re-entry
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19 132 makes use of the sub intimal space within CTO segment with ultimate re-entry
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21 133 into the true lumen (5). Categorical variables were analyzed using Chi Square or
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23 134 the Fischer's exact test where appropriate. Scalar variables were analyzed using
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25 135 the student's t test. All p values were 2 tailed and a p value of < 0.05 was
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27 136 considered statistically significant. Statistical analysis was performed using
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29 137 SPSS version 21.
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142 Results:

143 Angiographic and procedural characteristics:

144 194 CTO lesions were included in the analysis. Table 1 contains the baseline
145 angiographic characteristics of the hybrid video population and the comparator
146 registries. The target vessel was the right coronary artery (RCA) in 62%, left

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3 147 anterior descending (LAD) in 23%, and left circumflex (LCX) in 13% of cases of
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5 148 the HVR cases. J-CTO score was higher in the HVR as compared to either the
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8 149 Japanese-CTO or Royal Brompton registries (2.33 ± 1.11 vs. 1.71 ± 0.068 vs.
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10 150 1.87 ± 1.2 respectively $p < 0.001$ for HVR vs. both Japanese-CTO and Royal
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12 151 Brompton). There was a higher frequency of prior CABG in the HVR as
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15 152 compared to the J-CTO registry. The case complexity in the HVR was high with
16
17 153 a J-CTO ≥ 3 in 45%, which was similar to the Royal Brompton registry 37%, p
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19 154 0.08, and higher than the Japanese-CTO registry 27%, $p < 0.001$.

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24 156 Four initial techniques were used in the HVR including antegrade wire escalation
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26 157 (AWE) in 28%, antegrade dissection and re-entry (ADR) in 49%, retrograde wire
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28 158 escalation (RWE) 8%, and retrograde dissection and re-entry (RDR) in 15% of
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30 159 cases. The initial strategy attempted was successful in 67% of cases, or 1/3 of
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32 160 cases required a switch to a different technique. Final successful strategy was
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34 161 AWE in 25%, ADR in 45%, RWE in 7%, and RDR in 13%. 26% of cases that
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36 162 were started with an intention to utilize the retrograde approach ultimately
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38 163 required an antegrade strategy, the majority of which was ADR.

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44 165 The overall procedural success rate was 95%. Final TIMI 3 flow was present in
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46 166 95% of successful cases. Overall 87% of successful cases had TIMI 3 flow in all
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48 167 left ventricular side branches ≥ 2 mm in diameter.

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9 172 Success rate stratified by JCTO score:

10 173 In low or intermediate J-CTO score lesions (score 0-2) there was no difference in

11 174 success rates between the registries. Among cases with a high JCTO score (\geq

12 175 3), the success rate was 92.8% in the HVR, which was significantly higher than

13 176 either the Royal Brompton (78.9%), or Japanese-CTO (73.3%) registries, $p =$

14 177 0.04 Hybrid vs. Royal Brompton, $p = 0.006$ Hybrid vs. Japanese-CTO). (figure 1).

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20 179 Efficiency Analysis

21 180 Mean procedure time in the HVR was 82 ± 53 minutes and 105 ± 58 in the

22 181 ERCTO registry ($p < 0.0001$). No comparison with the Royal Brompton or J-CTO

23 182 registries was possible for this variable because procedure time was not reported.

24 183 Contrast utilization was also lower in the Hybrid registry when compared to

25 184 ERCTO, 238 ± 105 , vs. 313 ± 184 mls ($p < 0.0001$). The J-CTO registry and

26 185 Royal Brompton registries reported contrast, however standard deviations were

27 186 not given so statistical comparisons could not be performed. The absolute

28 187 values were higher than the hybrid registry, 293 and 350 mls respectively.

29 188 Radiation metrics were not uniform and therefore could not be compared among

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35 191 Safety Analysis
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3 192 Safety was similar in all three registries with low rates of major perforation

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5 193 requiring intervention (table 2). Of the 5 perforations in the HVR, 4 required

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8 194 pericardiocentesis, and 4 required a covered stent.

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15 197 Discussion:

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20 199 The main finding of our study was that the Hybrid approach to CTO PCI

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22 200 implemented by a broad spectrum of Hybrid operators is associated with a high

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24 201 success rate independent of case complexity as assessed by the J-CTO score.

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26 202 This differs from other contemporary registries in which escalating J-CTO scores

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28 203 predicted lower success rates. It is notable that with low J-CTO score lesions,

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30 204 expert operators can achieve a high success rate using any of the available

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32 205 techniques. However, among those with a J-CTO score greater than 2, success

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34 206 rate in the other contemporary registries was lower, while among the Hybrid

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36 207 operators success rate continued to exceed 90%.

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41 209 The difference in success rates among high JCTO patients may relate to the

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43 210 higher use of sub intimal techniques. Early prospective use of these techniques

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45 211 may represent the major difference between Hybrid and non-Hybrid strategies.

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47 212 Antegrade or retrograde dissection and re-entry was utilized in 64% of the cases

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49 213 in the HVR, whereas these techniques were used in <26% of the cases in the

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51 214 Japanese-CTO and <38% of cases in the Royal Brompton registries.

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6 216 Sub intimal dissections with a blunt catheter, such as the Crossboss (Boston
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8 217 Scientific, Natick, Ma), or a knuckled guidewire may increase efficiency in
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10 218 complex lesions when compared to traditional techniques, which aim to stay
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12 219 within the intimal plaque. While wire escalation techniques both antegrade and
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14 220 retrograde were employed in the HVR in 60% of cases with a J-CTO score ≤ 1 ,
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16 221 the prospective utilization of subintimal dissection and re-entry was higher in
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18 222 more complex lesions, representing 68% of lesions with a J-CTO score ≥ 2 . In
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20 223 addition, as a provisional strategy for antegrade wire escalation failure,
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22 224 antegrade dissection and re entry with the Stingray device (Boston Scientific,
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24 225 Natick, Ma) has been demonstrated to be safe and effective (9).
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33 227 Additionally, the retrograde approach to CTO intervention is not possible in
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35 228 nearly 20% of cases preselected due to uncrossable collaterals either with the
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37 229 guidewire or support catheter. In these cases, the antegrade success rates are
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39 230 only 60% in a recently reported registry from Japan (10). This limitation of
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41 231 retrograde CTO-PCI can be overcome in many instances with antegrade
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43 232 dissection and re entry. In the Hybrid registry, of the 35 cases that began with a
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45 233 primary retrograde approach, 26% had failure to cross the collateral or failure to
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47 234 cross the CTO retrograde. In these cases, ADR was successful 78% of the time,
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49 235 which exceeds the success rate with traditional techniques cited above. This
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51 236 highlights the utility of ADR as a bailout when collateral crossing is not possible in
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53 237 a procedure initially selected for a retrograde approach.
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5 239 Limitations of our study include the lack of available patient level data from the
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8 240 comparator registries. These data would have allowed for propensity matching
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11 241 to more robustly compare contemporary approaches to CTO PCI. In that case,
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13 242 we might expect the Hybrid approach to compare even more favorably than our
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15 243 study suggests given the significantly higher J-CTO score in our patient cohort.

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17 244 Cases were performed in the context of courses focused on teaching antegrade
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20 245 dissection and re entry along with retrograde techniques so those approaches
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22 246 may be over represented in these data, but nonetheless success rates are quite
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24 247 high with a good safety profile. Due to the design of the HVR, rates of ischemic
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27 248 complications post PCI could not be ascertained so complete safety information
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29 249 is lacking. Finally, we did not collect follow up data and cannot assess long-term
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32 250 patency or safety of sub intimal stenting. A report from the J-Proctor
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34 251 angiographic follow-up study suggests that MACE and TVR rates among IVUS
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36 252 adjudicated intimal vs. sub intimal stenting are similar (11).

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39 253 Conclusion:

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41 254 Using a real world angiographic registry of complex CTOs, the Hybrid Approach
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43 255 to CTO PCI may be superior to other contemporary approaches to CTO
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45 256 intervention with respect to procedural success and efficiency among a diverse
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48 257 group of operators and lesion complexity. With increasing lesion complexity, the
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51 258 prospective use of both antegrade and retrograde dissection and re-entry is safe
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53 259 and associated with excellent success rates.

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32 Figure Legend
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34 322 Figure 1: Final success in the Hybrid Video Registry in comparison to the Royal
35 323 Brompton and Japanese CTO registries stratified by J-CTO score.
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37 325 Figure 2: Distribution of J-CTO score as a measure of lesion complexity among
38 326 the three registries.
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Table 1

	Hybrid Registry (N=194 lesions)	J-CTO Registry (N=498 pts, 528 lesions)	Royal Brompton Registry (N=195 pts, 269 lesions)	p
Lesion Length	29.9 ± 24.4	13.5 ± 13.0	22 (IQR 15-32)	* <0.001
Length > 20mm	63%	21%	63.1%	* <0.001 ‡ 0.44
Calcified	61%	58%	50.8%	* 0.036 ‡ 0.72
Tortuosity	31%	45%	22.1%	* 0.002 ‡ 0.06
Blunt Stump	61%	38%	47.2%	* <0.001 ‡ 0.009
Prior Failure	16%	10%	37.9%	* 0.082 ‡ 0.10
Prior CABG	30%	10%	29.2%	* <0.001 ‡ 0.60
J-CTO Score	2.33±1.11	1.71±0.068	1.87±1.2	* <0.001 ‡ <0.001
*Hybrid Registry vs. J-CTO Registry, ‡ Hybrid Registry vs Royal Brompton Registry				

Table 2

	Hybrid Registry (N=194 pts)	J-CTO Registry (N=498 pts)	Royal Brompton Registry (N = 195 pts)	p
Death	0%	0.4%	0%	NS
Any Perforation	6%	10%	4.6%	*0.191 ‡0.625
Perforation requiring Intervention	2%	0.2%	1%	*0.0371 ‡0.654
*Hybrid Registry vs J-CTO Registry, ‡ Hybrid Registry vs Royal Brompton Registry				

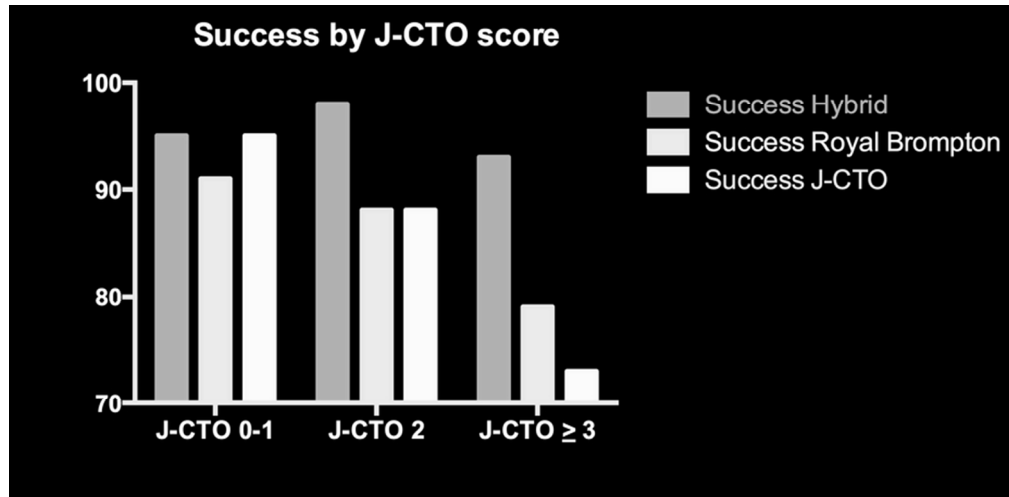
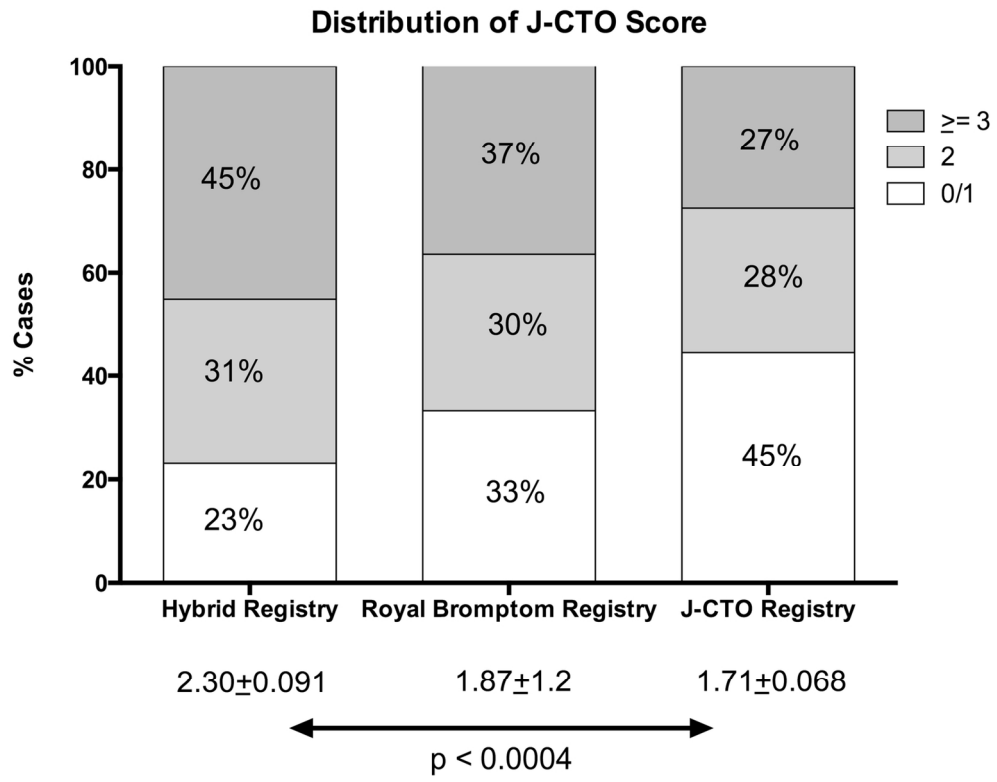


Figure 1: Final success in the Hybrid Video Registry in comparison to the Royal Brompton and Japanese CTO registries stratified by J-CTO score
77x38mm (300 x 300 DPI)

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Distribution of J-CTO score as a measure of lesion complexity among the three registries.
139x119mm (300 x 300 DPI)