

# An Experimental Study to Determine the Optimal Access Route for Renal Artery Interventions

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## WHAT THIS PAPER ADDS

At present there are no reports in the literature that specifically define the critical renal artery take-off angle that should be addressed by an antegrade approach. The goal of this study is to design and implement a set of experiments that could empirically determine the critical renal artery take-off angle at which an antegrade approach should be employed rather than a retrograde approach. This study's result will influence clinical practice by providing a surgeon/interventionalist the data required to correctly plan and implement procedures that involve steep renal artery take-off angles.

**Objective:** The standard approach for endovascular treatment of the renal artery is access via the common femoral artery. However, approximately one in eight patients have a renal artery take-off angle that is less than 50°. In these patients approaching via a femoral access site can be technically challenging. The goal of this study was to design and implement a set of experiments that could empirically determine the critical renal artery take-off angle at which a superior approach would be employed.

**Methods:** An experimental model of the abdominal aorta, iliac arteries and the renal arteries was constructed using averaged CT angiography data from 10 patients. A number of guide catheter and guide wire combinations were advanced into this model and the force/displacement response was established.

**Results:** Our results demonstrate that a renal artery take-off angle less than 30° has a reduced probability of achieving stable guide wire placement in comparison with the base 90° anatomy ( $p \leq .0001$ ). Additionally, our results indicate that the probability of achieving stable guide wire access is increased if the stiffness mismatch between the guide catheter and guide wire is minimised.

**Conclusions:** In conclusion, we recommend a superior approach to the renal artery if the renal artery take-off angle is within the range of 33–38° and a stiff guide wire platform (e.g. an Amplatz stiff) is required to complete the procedure. Finally, we report an equation that can be used to determine the difficulty associated with accessing the renal artery in comparison to the base 90° anatomy.

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## INTRODUCTION

The standard approach for endovascular treatment of the renal artery is access via the common femoral artery.<sup>1</sup> In the majority of procedures, the femoral approach will permit delivery and placement of a stable guide wire platform that will allow subsequent treatment. However, approximately one in eight patients have a renal artery take-off angle that is less than 50°.<sup>2</sup> In these patients, an approach via a femoral access site can be technically challenging and may result in an unsuccessful procedure.<sup>3</sup> To overcome this

hurdle, a brachial approach has been employed, and has been proven to be safe and feasible within a cohort of patients that have a severe renal artery take-off angle.<sup>4</sup> Moreover, a radial approach has also been shown to be an effective approach for patients with acute aorto-renal angles.<sup>5</sup> However, the value of the renal artery take-off angle at which an operator should switch from an inferior approach to a superior approach is unknown, and currently, procedures are planned on intuition rather than empirical evidence. This inexact feature is also reported within the endovascular textbooks, where the decision to use a superior approach is loosely defined as 'when a steep downward angulation of the renal artery [is present]' or 'when the angle of take-off from the aorta is narrow'.<sup>6,7</sup>

At present, there are no reports in the literature that define the critical renal artery take-off angle that should be addressed by a superior approach. The goal of this study is

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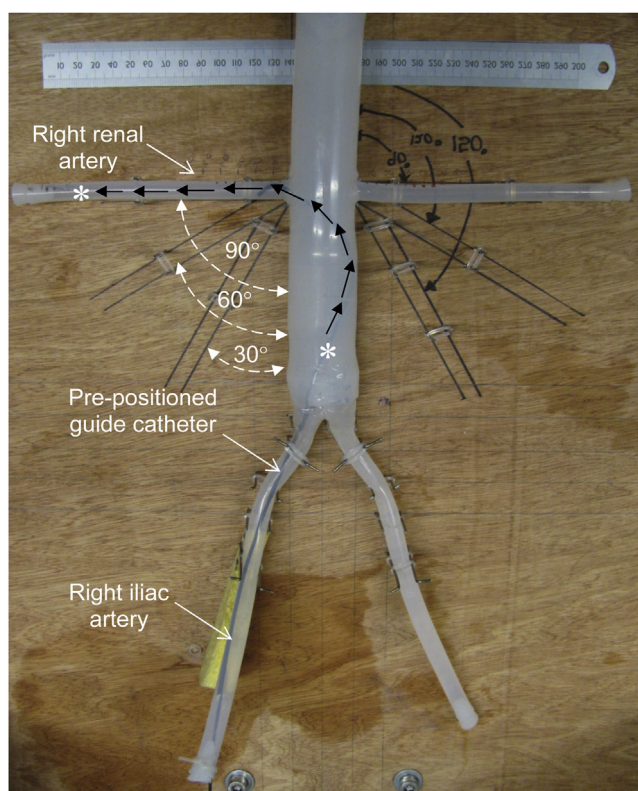
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to design and implement a set of experiments that could empirically determine the critical renal artery take-off angle at which a superior approach should be employed rather than an inferior approach.

## MATERIALS AND METHODS

An experimental model of the abdominal aorta, iliac arteries and the renal arteries was constructed using CT angiography data from 10 patients; these data were used to determine the average diameters of each vessel and the locations of the ostia. The averaged data were matched with available silicone tube sizes, resulting in a model where the iliac arteries had a diameter of 8 mm, the aorta had a diameter of 25 mm and renal artery diameters were 6.4 mm with an ostium diameter of 9.5 mm. The experimental model was designed to be flexible, in order to vary the angle of the renal artery from 90° (i.e. perpendicular to the aorta) to 60° and to 30°. The silicone model of the vasculature was attached to a Zwick materials testing machine (Zwick Roell, Germany), and filled with water prior to commencement of the series of experiments. The test set-up is illustrated in Fig. 1, where the caption discusses the placement of the wire and guide catheter.



**Figure 1.** Illustration of the experimental set-up. During the test set-up, a guide catheter is pre-positioned in the model and placed into the renal artery to a depth of 55 mm, a guide wire is then placed in the guide catheter with its tip at the position of the first white star. Subsequent to this, the guide wire is connected to the load cell and advanced along the course of the black arrows to the second white star, during which the advancing force is recorded. The angle of the renal artery can be varied from highlighted positions at 90°, 60° and 30°.

The study was designed to determine the degree of difficulty encountered when establishing a stable guide wire platform within a mock arterial system. Two phases of the intervention were analysed: (i) advancing a 'soft' guide-catheter over a static floppy wire, and (ii) advancing a wire through a static guide catheter. In each of these situations, the renal artery take-off angle was varied between 90°, 60° and 30°, and the pre-positioned wire or catheter was placed into the renal artery to a depth of 55 mm. The moveable device was advanced at a constant rate of 300 mm/min. All tests were performed wet. The amount of force required to advance the moveable device was recorded at a rate of 1 data-point per mm. The force recorded was used as the key parameter to ascertain the probability of obtaining and maintaining renal artery access.

The experiments that were conducted in the first phase of the study involved pre-positioning a Radifocus wire (Terumo) within the mock renal artery and subsequently advancing a Glidecath (Terumo) over the wire. The force required to advance the Glidecath over the wire and into the mock renal artery was recorded. The test was repeated five times for each renal artery take-off angle.

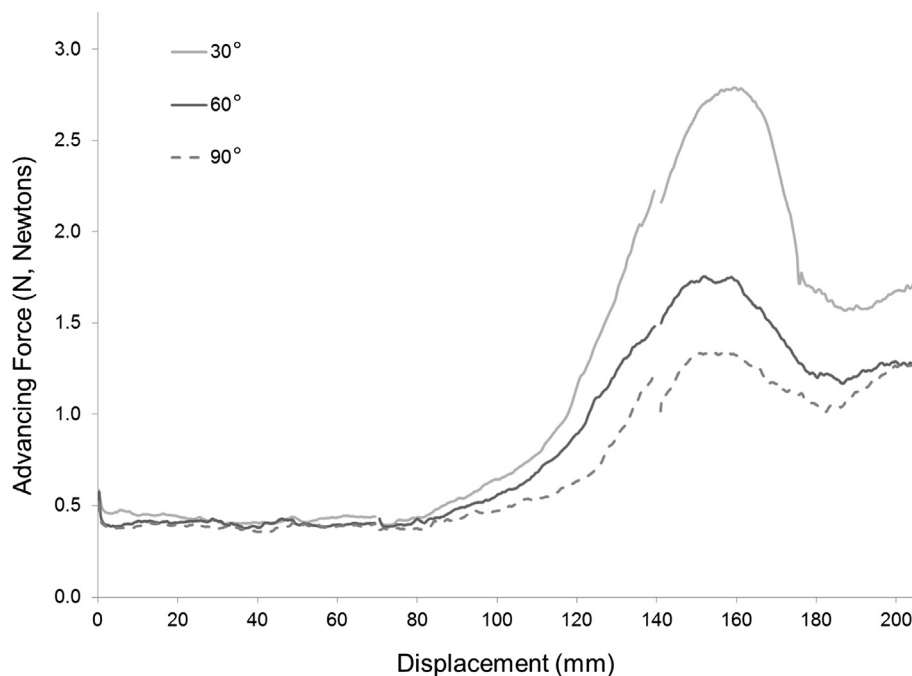
The second phase of the study examined a pre-positioned guide catheter within the mock renal artery and advancing a guide wire through the catheter. The guide catheters that were examined included the Glidecath Angled Taper (Terumo); Torcon NB® Advantage KMP (Cook Medical); Beacon® Tip Van Schie2 (Cook Medical); and the Torcon NB® Advantage VS1 (Cook Medical). Each guide catheter was 5 Fr in size. For each pre-positioned guide catheter, a 0.035" Rosen wire (Cook Medical) and a 0.035" Amplatz Super Stiff (Boston Scientific) wire was advanced through the catheter and into the mock renal artery. The force required to advance the wire was recorded. The test was repeated five times for each renal artery take-off angle.

For each test, the moveable device was advanced a total distance of 210 mm in three increments of 70 mm, as per the protocol defined by Kenny and McDermott.<sup>8</sup> Results are presented as means and standard deviations, and where statistical significance is presented between two groups this relates to statistical significance testing utilising a Student's *t*-test.

## RESULTS

The results from the first phase of this study indicate that the take-off angle is not a limitation during catheter delivery over a pre-positioned relatively soft wire. In this case, advancement of a Glidecath (Terumo) over the Radifocus wire (Terumo) is achieved with an advancing force that is negligible (<0.25 N) for a range of renal artery take-off angles between 90° and 30°.

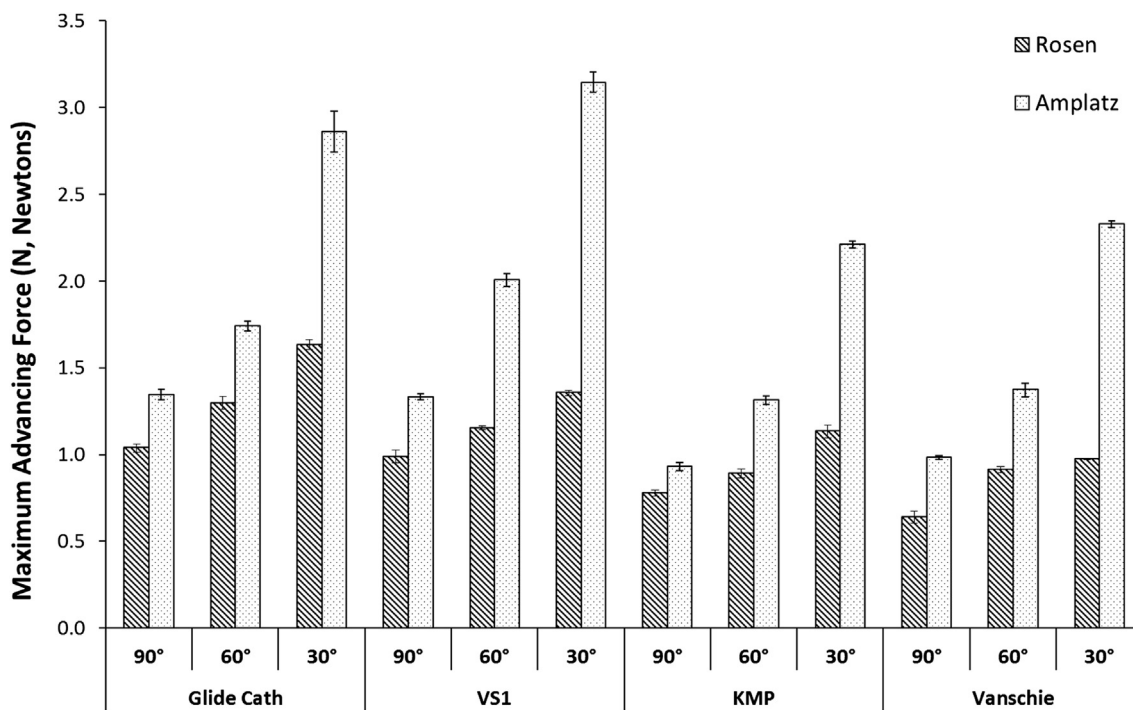
In the second phase of the study, two guide wires, Rosen Curved (Cook Medical) and the Amplatz Super Stiff (Boston Scientific), were advanced through four guide catheters for each renal artery take-off angle. The results demonstrate that the advancement of the wire through the mock renal artery is repeatable for each angle/catheter combination.



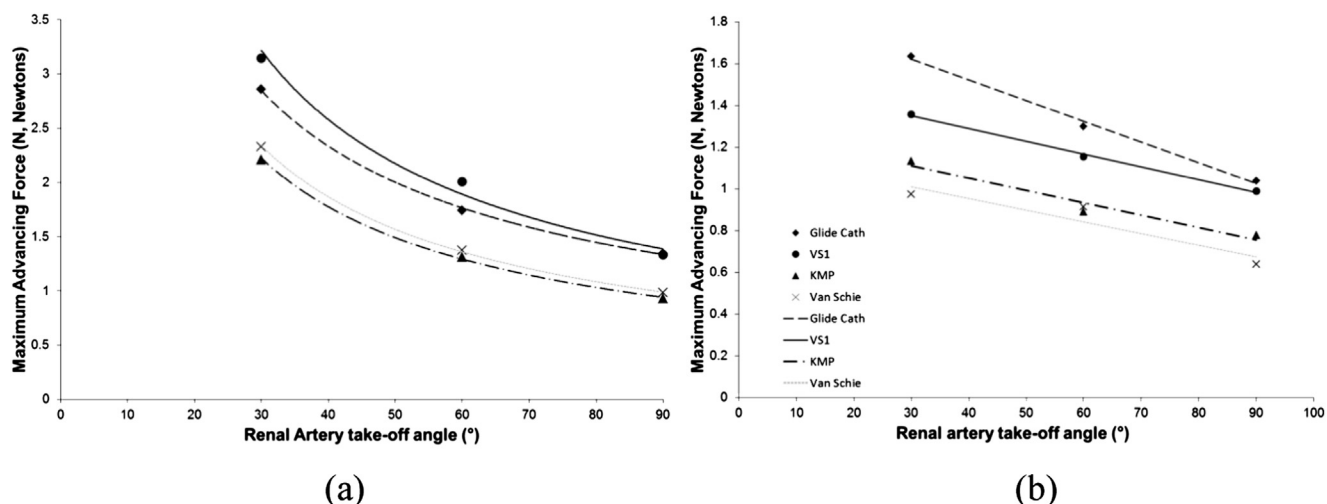
**Figure 2.** Average advancing force values of the three renal artery take-off angles for the Glide catheter/Amplatz combination. Note the large increase in the maximum advancing force from the base 90° case to the 30° case.

The advancement of the Amplatz wire through each of the catheters for the 90° anatomy results in a relatively low maximum force occurring (an average maximum force of 1.15 N). When the angle is decreased to 60°, the average maximum force for the four catheters increases by 40% of the base 90° degree anatomy. Furthermore, when the angle is decreased to 30°, the average maximum force increases substantially by 129% of the base 90° anatomy. An example of this force increase is shown in Fig. 2 for the Glide

Catheter/Amplatz combination. The maximum force values for all catheter and Amplatz wire combinations are shown in Fig. 3. Additionally, it can be noted from Fig. 3 that the stiffness match or mis-match can affect the maximum advancing force. For example, the combination of the Guide Cath (least stiff catheter) and both wires has the greatest largest advancing force, in comparison with the KMP and Vanshie guide catheters which are stiffer than the Guide Cath.



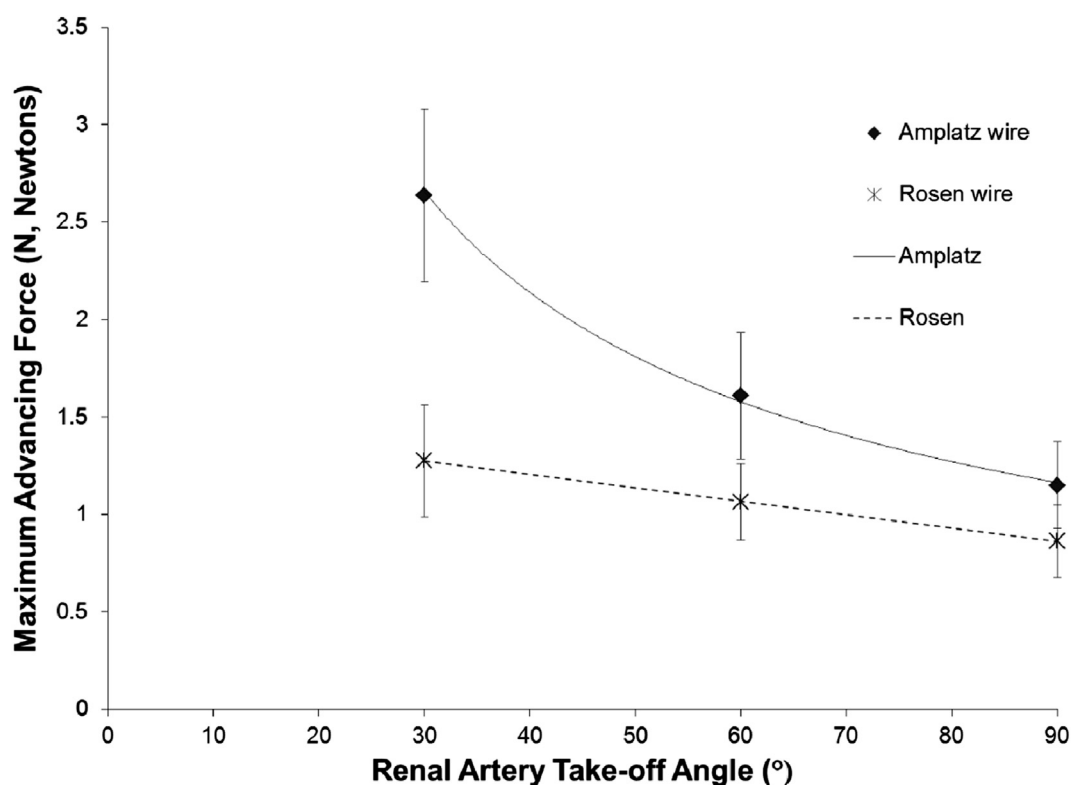
**Figure 3.** Maximum advancing forces for all wire/catheter/angle combinations.



**Figure 4.** Maximum advancing force versus renal artery take-off angle for the four Guide catheters in combination with (a) the Amplatz wire and (b) the Rosen wire.

A similar pattern is observed when the Rosen wire is advanced through each of the four catheters. For the 90° anatomy, a relatively low maximum force is required to advance the wire (an average maximum force of 0.86 N). When the angle is decreased to 60°, the average maximum force for the four catheters increases by 23% of the base 90° anatomy. Additionally, when the angle is decreased further to 30°, the force increases by 47% of the base 90° anatomy. The maximum force values for all guide catheter/Rosen wire experiments are shown in Fig. 3.

For the Amplatz wire, the maximum advancing force through the four pre-positioned catheters increases in a non-linear fashion with a decreasing renal artery take-off angle. However, for the Rosen wire, the force increases in linear like fashion with the same decreasing renal artery take-off angle. The relationship between the maximum advancing force and the renal artery take-off angle for both of the wires through the four pre-positioned catheters is shown in Fig. 4. An exponential trendline was fitted to the Amplatz force data (Fig. 4a), while a linear trendline was



**Figure 5.** Average maximum advancing force of all four guide catheters versus renal artery take-off angle for both Amplatz and Rosen wires.



fitted to the Rosen force data (Fig. 4b). The average maximum advancing force of the four-pre-positioned catheters versus renal artery take-off angle for the Amplatz and Rosen wire and their respective fitted exponential and linear trendlines is shown in Fig. 5. Ultimately, the trendline equations were analysed in order to determine the critical renal artery take-off angle, where a superior approach should be used rather than an inferior approach, which is explained in the following paragraph.

For each guide catheter case, the critical renal artery take-off angle is hypothesized to occur at the instance where it is twice as difficult to achieve a stable platform with a wire in the renal artery. The force at which this degree of difficulty occurs is determined by doubling the maximum advancing force recorded for the base 90° anatomy. This force value is subsequently entered into the trendline equation to determine the critical renal artery take-off angle. The resulting critical take-off angles for each catheter/Amplatz combination are: Glide/Amplatz combination 38°, Van Schie/Amplatz combination 38°, KMP/Amplatz 37°, and VS1/Amplatz 33°. The average critical renal artery take-off angle of the four-pre-positioned guide catheters with the Amplatz wire is 36°. For the Rosen wire, we did not observe a doubling of the maximum advancing force for the base 90° anatomy within the range of experiments we conducted. Therefore, no critical renal artery take-off angle was established for the Rosen wire.

## DISCUSSION AND CONCLUSIONS

Therapeutic strategies that involve the renal arteries have become more routine in recent times. For example, the implantation of fenestrated aortic stent grafts has been demonstrated to be safe and effective, and the advent of renal denervation to control blood pressure has demonstrated outstanding early results.<sup>9–11</sup> However, renal artery anatomy can vary significantly and the choice of a superior or inferior approach is a function of the renal artery take-off angle. In this study, we experimentally demonstrated that if the renal artery take-off angle is within the range of 33–38°, a doubling of the maximum wire advancing force will occur (over the base 90° anatomy) when an Amplatz stiff wire platform is advanced through a guide catheter. Additionally, for procedures such as renal denervation, where stable artery wall/probe contact must be maintained, the access route must not compromise probe stability. The results of this study, therefore, can be used to allow the interventionalist to plan the access route for the procedure to ensure that consistent nerve ablations are achieved.

By utilising the normalised exponential equation (Eqn. (1)), one can calculate the approximate % increase in maximum advancing force required for any arterial take-off angle in comparison with the base 90° anatomy and relate this increase to the % increase in difficulty as follows:

$$\% \text{ increase in difficulty} = (1492(\text{artery}^\circ)^{-0.752}) \quad (1)$$

where  $\text{artery}^\circ$  is the renal artery take-off angle. This equation can be used to predict the degree of difficulty to place

a stable Amplatz stiff wire in the renal artery. The resulting answer should enable the interventionalist to make a better informed choice on whether an superior or inferior approach should be utilised. This decision can be integrated into pre-procedure planning. For example, in fenestrated stent graft cases, which routinely have pre-procedure high end imaging such as CT angiography available — potentially fenestrated grafts could be produced to allow superior access if visceral vessels have acute take-off angles.

The above analysis is conducted only for the Amplatz wire; however, the results highlight that significant differences exist between the advancing force responses for the two wires analysed. The results suggest that, potentially, if the intervention can be completed with the use of a Rosen wire or a less stiff wire (in comparison with the Amplatz wire), this should be accounted for when planning the procedure, as a superior approach may not be required, and the potential difficulty in placing a stiff wire such as the Amplatz would be avoided.

The results additionally indicate that matching the stiffness of the guide catheter to the stiffness of the wire is another parameter that should be addressed. For example, for both the Amplatz and the Rosen wire, the Glide Cath (the least stiff catheter) was one of the more difficult catheters to advance a wire through. Moreover, the shape of the tip of the guide catheter influences the degree of difficulty to achieve guide wire placement. Most noticeably, the VS1 guide catheter has the highest advancing force for the Amplatz wire and the second highest maximum advancing force for the Rosen wire.

The use of the maximum advancing force as the key parameter to predict stable access was confirmed by a series of early tests. In these tests, the guide catheter was placed in the renal artery to a depth of only 15–30 mm. When the wire was advanced into the guide catheter and renal artery, a maximum advancing force was observed prior to ‘pop-out’ of the wire and catheter from the renal artery and subsequent loss of access. In addition, we analysed the rate of increase of advancing force as an alternative key parameter, and our findings resulted in a similar result to utilising the maximum advancing force. We therefore continued to use the maximum advancing force as the key parameter. The limitations of this study are: substitution of silicone material for the arterial wall, removal of pulsatile blood flow and renal artery movement associated with breathing. Additionally, we modelled one experimental set-up only: a healthy geometry and an arterial stiffness that represented a non-calcified arterial system. However, in lieu of these limitations, we demonstrated that our test methodology is repeatable and observations during the course of the experiments are routinely encountered during clinical procedures.

In conclusion, we recommend a superior approach to the renal artery if the renal artery take-off angle is within the range of 33–38° and a stiff guide wire platform (e.g. an Amplatz stiff platform) is required to complete the procedure. Moreover, Eqn. (1) can be used to determine the degree of difficulty associated with accessing the renal artery in comparison with the base 90° anatomy. Finally, matching the stiffness of the guide catheter to the guide

wire stiffness and avoiding using tip configurations such as the VS1 will maximise the probability of achieving stable renal guide wire access.

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### CONFLICT OF INTEREST

None.

### FUNDING

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