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Evaluation of Trackability Test Method for Intracranial Aneurysm Flow Diverter System Using Simulated Neurovascular Model

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Abstract: A simulation model is a testing model, that mimics the operation of an existing or proposed system, providing evidence for decision-making by being able to test different scenarios or process changes. Trackability refers to the measurement of the force required to advance the device through a tortuous anatomy with or without the assistance of a guiding accessory such as a guide wire and guide catheter. Simulation is becoming increasingly important in medical device development, because its main objective is to lower the development cost by improving device's performance and dependability, eliminating bench top tests clinical trials, and accelerating the regulatory approval process. It could be challenging to compare the performance of several devices because each manufacturer might employ a different "Simulated Neurovascular Model". To reduce the risk of device failure and patient's injury during clinical use, it is important to adequately examine these devices. As a result, "Simulated Neurovascular Model"" is used in the present work, to understand the performance of testing for 'Intravascular devices' meant to access the 'Neurovasculature'. This test process intends to examine or determine the trackability of "Intracranial Aneurysm Flow Diverter System" by using" "Simulated Neurovascular Model". A flow diversion operation is used to treat a number of unruptured brain aneurysms. Sterilized "Intracranial Aneurysm Flow Diverter Stent" samples are used in the present research work.

Keywords: Simulated Neurovascular Model, Intracranial Aneurysm Flow Diverter System, Trackability Test

1. Introduction

Trackability is the capacity to track an object as, it passes through a process. It describes the capacity to track and trace a specific product or device throughout the development process. Flow diversion is a procedure where your doctor inserts a stent (a supple, flexible mesh tube) into the blood vessel where an aneurysm has developed using a catheter. By doing this, the blood flow is immediately redirected away from the aneurysm. A stent, which is a soft, flexible mesh tube, is inserted into the blood vessel where an aneurysm has developed using the flow diversion procedure by a surgeon using a catheter. The blood flow is immediately changed away from the aneurysm by this procedure.

It takes more sophisticated modeling and testing tools to create medical devices that are more complex [1]. Never before, there have been more opportunities for medical device designers to innovate and overcome the difficulties associated with new device development [2, 3]. Design-related failures, which continue to be the main reason for device recalls, can be found and prevented with the help of simulation [4, 5]. It can improve the performance, safety, and dependability of a product [6].

The simulated model is utilized when pre-conditioning or testing in simulated anatomy is advised [7, 8]. In order to accurately depict a difficult vasculature for the patient population that will be treated, the anatomical model should be tortuous [9]. The following factors should be taken into account while building anatomical models: lumen diameter, bend radii, bend reversals, number of bends, tracking length,

and co-efficient friction of tracking materials such as polyurethane, silicone, teflon, glass latex, native vessel, etc. [10-12].

To accurately depict the human anatomy, it is advised that the anatomical model have all pertinent pathway features [13]. Rather than a three-dimensional model, a two-dimensional anatomical model is adopted [14]. Every characteristics of the natural pathway needs to be maintained and represented within the model. The FDA is better equipped to assess and evaluate the performance of intravascular medical devices because it has a standardized simulated model that is reflective of the neurovasculature [15, 16].

In the present work, trackability test of the medical device "Intracranial Aneurysm Flow Diverter System" is performed using the "Simulated Neurovascular Model". Furthermore, the "Simulated Neurovascular Model" simulates the intricate nature of the neurovasculature. The force required to track stent system along the "Test Tracking Fixture" / "Simulated Neurovascular Model" is measured. The trackability test parameters, engineering schematics and images have been mentioned for better understanding. The main agenda of the present study is to properly evaluate the performance of neurovascular medical devices through simulation in order to reduce the risk of device failure and patient injury during clinical use.

2. Materials and Method

The device's performance may be better understood therapeutically by using it in a "Simulated Neurovascular Model" along with other interventional devices, when necessary. This is superior than isolated bench top performance testing. A "Simulated Neurovascular Model" using the Neurocity CT Scan data is used. In accordance with the directions for use, the device is used in conjunction with auxiliary tools such as, an introducer and a guiding catheter, and it is repeatedly tracked using a "Simulated Neurovascular Model". "Simulated Neurovascular Models" are used to make recommendations for the creation of anatomical models. The report is written with observations regarding the device's mobility through the Simulated Neurovascular Model, adequate setup, and compatibility with ancillary equipment. It also reflect the device's integrity before, during, and after use for kinking, impaired push ability.

When necessary and justified, this test is ran in conjunction with other tests. The sample is prepared according to the usage instructions, pre-conditioned as necessary to simulate worst-case scenarios, and each device is followed through a simulated model. The proximal end of the guide wire is rotated while the sample is in the simulated model and the distal end is unrestricted. Rotational input of the resulting distal rotation at 90-degree intervals is reported (with your applied rotation angle determined with reference to the device risk and intended use) and proximal-to-distal rotational ratio for each sample is calculated.

Test procedure:

Sketch of the Tracking model shown in the figure 1. The "Test Tracking Fixture"/"Simulated Neurovascular Model" shown in the figure 2. (manufactured by Endolab Germany) was placed in a constant water bath at (37°C ± 2°C) of "Interventional Device Testing Equipment" (IDTE) (*Procured from: Machine Solution Inc. Model: IDTE 2000-162*) shown in the figure 3.

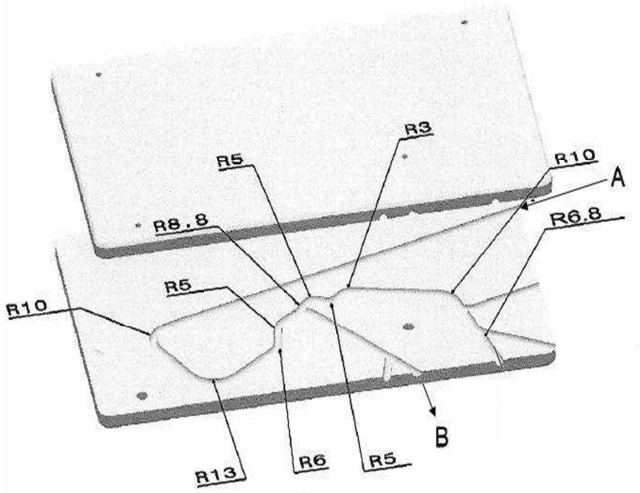

Figure 1. *Sketch of the Tracking Model.*

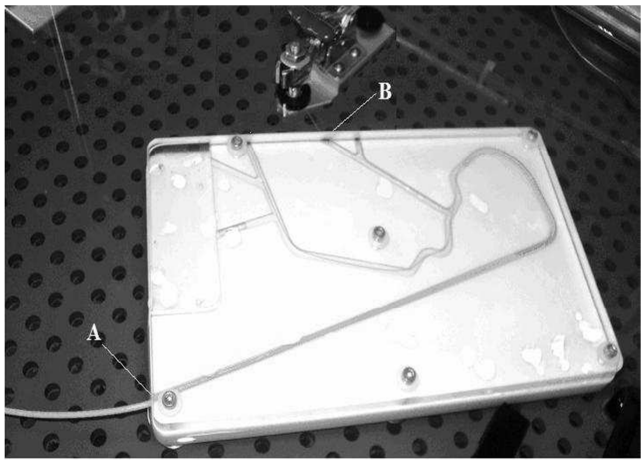

Figure 2. *Experimental set-up for Trackability Testing.*

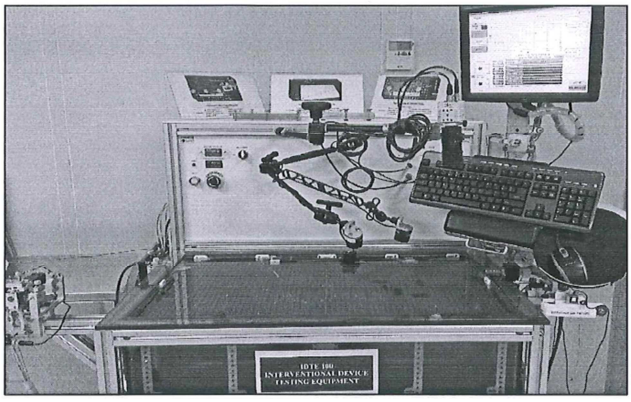

Figure 3. *Interventional Device Testing Equipment.*

Test parameters used for trackability test are given in table 1.

Table 1. *Test Parameters for Trackability Test.*

Sr. No	Test Parameters	Ranges
1.	Guide Wire	0.36 - 0.46 OD
2.	Insertion Rate	30-40 cm/min
3.	Fluid Test Medium	Purified Water
4.	Temperature	37 °C ± 2 °C
5.	Guide Catheter	0.77 - 0.97 OD

The guiding catheter was placed into the "Test Tracking Fixture"/"Simulated Neurovascular Model" through the introducer sheath until it reached the beginning of the branching. A guide wire was inserted from point "A" into the "Test Tracking Fixture"/"Simulated Neurovascular Model" through the guide catheter till, it exists through point "B". With the use of a distal guide wire clamp, the guide wire was anchored. The distal side of the flow diverter system (Intracranial medical device) was moved along the guide wire from point "A" to "B," with the proximal side of the system being fastened by a gripping mechanism (i.e. Track length). The force required to track stent system along the "Test Tracking Fixture"/"Simulated Neurovascular Model" was measured.

Formula for Average:

$$\frac{(X_1 + X_2 + \text{- - - - - - - - -} + X_n)}{n}$$

Where, n = Total sample size

3. Results and Discussion

The trackability test carried out on the "Simulated Neurovascular Model" reveals increased friction values, if higher force is applied. According to ISO 25539: 2012, the standard test value for the trackability test is between 1.27-1.49 N. If the friction value is excessive, a hydrophilic coating reduces it. The test also examines the product's entire set of quality criteria. As per the acceptance criteria for trackability testing, it is believed that using the advised accessories, the flow diverter system should be able to advanced through the "Test Tracking Fixture/"Simulated Neurovascular Model" to the target site.

In this test, total six sterilized samples of "Intracranial Aneurysm Flow Diverter System" of size 5.00×35 mm were utilized. Force exerted on each samples was tracked while the samples were passing from the "Test Tracking Fixture/ "Simulated Neurovascular Model" through the delivery tool. As shown in the table 2, the force exerted on sample no. 1, 2, 3, 4, 5 and 6 was 1.37N, 1.43N, 1.29N, 1.49N, 1.34N and 1.39N respectively with average force 1.39N and standard deviation 0.07N, which was within the standard test value for trackability test (i.e between 1.27-1.49N). The statistical data is revealed in figure 4.

Table 2. *Results of Trackability Test.*

Sample No.	Batch No.	Stent size (mm)	Stent Sr. No	Maximum Force (N)
1	FDAts07	5.00 X 35	N35FDAts 07007	1.37
2			N35FDAts 07008	1.43
3			N35FDAts 07009	1.29
4			N35FDAts 07010	1.49
5			N35FDAts 07011	1.34
6			N35FDAts 07012	1.39
Average				1.39
Standard Deviation				0.07

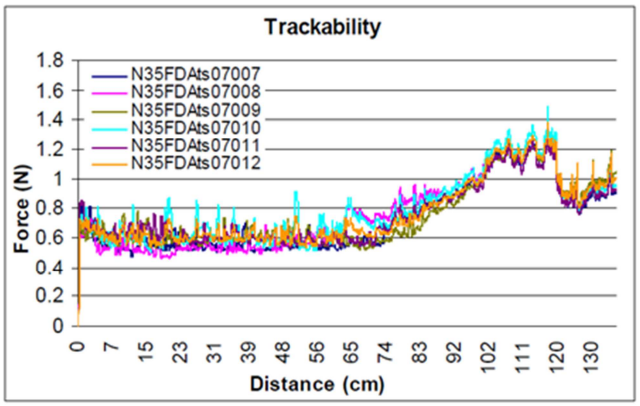

Figure 4. *Force vs. Distance Curve.*

4. Conclusion

The conclusion drawn from the aforementioned data is that, using the recommended accessories, the system was able to advance through the "Test tracking Fixture"/ "Simulated Neurovascular Model" to the target site. The simulation test model provided the better product performance, safety and reliability, as the "Intracranial Aneurysm Flow Diverter System" satisfies the trackability test's acceptance criteria. Also during the execution of the trackability test, no failures such as bending, buckling, or kinking of test samples were reported. This means that, the "Intracranial Aneurysm Flow Diverter System" passes the trackability test and it can be determined that, the aforementioned "Intracranial Aneurysm Flow Diverter System would be relevant for implantation in Neurovasculature.

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