Executive Summary

BD scientists completed several in-vivo studies, using fluoroscopy, to investigate the role of catheter geometry in catheter performance during power injection. From these studies, a methodology was developed to quantify catheter stability, or angular deflection, in the vein (Figure 1). Observed angular deflection of the 22 gauge BD Nexiva™ Diffusics™ closed IV catheter system at 6.5 mL/sec and 24 gauge catheter at 3.0 mL/sec was comparable to a standard 20 gauge peripheral IV catheter at 6.5 mL/sec (Figure 3).

Background

Peripheral IV catheters are commonly used for contrast media injection in CT. During power injection, extravasation of the contrast medium into the surrounding tissue is a known risk, but little research exists exploring the main root cause and whether it is related to injection rate and jet velocity, catheter motion, cannula insertion, contrast medium viscosity or catheter gauge.

Methods

An ovine (sheep) model was utilized to provide applicable venous injection sites in the four extremities. The ovine model was useful for measuring catheter motion (angular deflection) based on catheter positioning within venous circulation, morphology of vasculature and surrounding anatomical support structure.

Figure 1. Still frames from the fluoroscopy video were used to graphically compare the position of the catheter in the vein

Catheter Position
Prior to Power Injection

Measurement of Maximum Catheter Motion During Power Injection

Figure 2. A significant relationship was established between increased deflection angle and adverse events

Veins were accessed by trained lab technicians using standard catheter insertion technique (technicians had prior experience inserting both the standard IV catheter and the BD Nexiva Diffusics catheter). The catheters were secured, in accordance with standard clinical practice, using a 3M Tegaderm™ Dressing. Omnipaque® 350 at 22°C was used for all injections.
A total of 468 power injections were performed through a total of 250 devices: (80) 24 gauge BD Nexiva Diffusics catheters, (80) 24 gauge standard IV catheters, (30) 22 gauge BD Nexiva Diffusics catheters, (30) 22 gauge standard IV catheters, (30) 20 gauge standard IV catheters. These quantities were sufficient to provide statistical power in support of key objectives to characterize catheter stability and to establish a relationship between angular deflection of the catheter and adverse events such as catheter “flipping or whipping”, catheter backing out of the vein and extravasation. A statistical link between the degree of catheter angular deflection and these adverse events was established using regression modeling (p-value <0.005). Fluoroscopy (GE 3100 Innova Optima Fluoroscope) was utilized to visualize the injection (catheter and surrounding vasculature).

Still frames from the fluoroscopy were used to graphically compare the position of the catheter in the vein just prior to the injection to the maximum motion of the catheter during the contrast media injection.

**Results**

The 24 gauge (3 mL/sec) and 22 gauge (6.5 mL/sec) BD Nexiva Diffusics catheters were found to be non-inferior to standard 20 gauge IV catheters (6.5 mL/sec) with respect to catheter angular deflection. Figure 3 shows the plotting of each injection at a given flow rate by the maximum angular deflection measured during the power injection. Brackets show 95% confidence intervals of the mean with the median shown in black.

**Conclusion**

The study concluded that at an injection rate of 6.5 mL/sec, the catheter stability of the BD Nexiva Diffusics 22 gauge catheter is equivalent to the standard 20 gauge IV catheter. Also, at an injection rate of 3 mL/sec the catheter stability of the BD Nexiva Diffusics 24 gauge catheter is equivalent to the standard 20 gauge IV catheter at 6.5 mL/sec.

The study also found a significant relationship between the measurement of catheter stability in the vein (angular deflection) and the occurrence of adverse events including catheter back out, catheter flip/whip, and extravasation. Simply stated, these adverse events are more likely to occur as catheter deflection angle increases.