

Novel Kink-Resistant Insulin Infusion Set Causes Significantly Less Subcutaneous Tissue Inflammation Compared with a Straight Teflon Insulin Infusion Set



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BACKGROUND AND AIMS

Capillary Biomedical Inc. (CapBio) has developed an improved, kink-resistant, angled insulin infusion set (IIS) with a softer cannula material and 3 additional side holes for better insulin delivery. This study aimed to compare a regular 90° Teflon IIS (T90) with the CapBio improved IIS.

METHODS

40 T90 and 48 CapBio IISs were inserted subcutaneously (SC) every other day for 2 weeks in 11 swine and connected to an insulin pump (basal/bolus pattern). After 2 weeks, the tissue surrounding the cannulas was excised and kinking within the tissue determined using micro-examined CT. The specimens were processed and stained with Masson's Trichrome to assess the area of inflammation (AI) and thickness of inflammatory layer (LT) surrounding the cannula.

RESULTS

AI and LT were consistently higher using T90, with statistically significant differences after 6 days of IIS wear time. On average, the AI was reduced by 52.6% and the LT by 66.3% using the angled CapBio IIS. While 32.5% (13/40) of T90 IISs exhibited a bend in cannula >90° (kinking), a bend was observed in only 2.1% (1/47) of the CapBio IISs (p<0.001). Bench testing subsequently demonstrated that a >90° bend does not disrupt flow from the CapBio IIS.

CONCLUSIONS

The data suggest that the new cannula design of the CapBio IIS causes less tissue trauma compared to a regular 90° Teflon IIS between 2 days and 2 weeks post insertion and is resistant to kinking. These results are supportive of the objective of extending infusion set wear through changes to the material and mechanical design of traditional IIS cannulas.

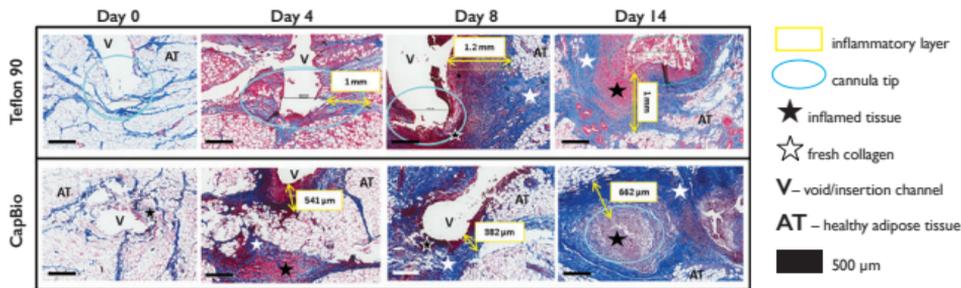


Figure 1. Trichrome stains of cannula-tissue specimens. At 0 days, there is no infiltration of inflammatory cells, but disruption of normal tissue morphology due to insertion trauma. Over time an inflammatory layer consisting of cells, fibrin and fresh collagen builds up around the insertion channel and increases in density over wear-time.

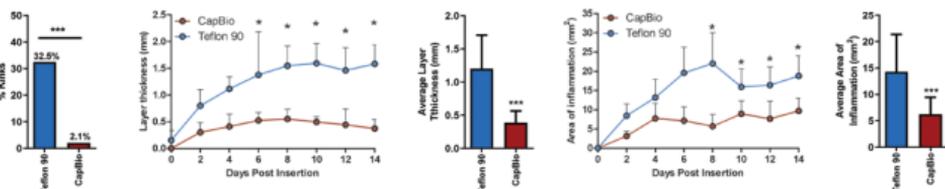


Figure 2. From left to right: Incidence of kinking in T90 and CapBio cannulas; thickness of the inflammatory layer over wear time and averaged over 14 days; area of inflammation around the cannula over wear time and averaged over 14 days. (*p<0.05, ***p<0.001; mean ± SD).

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