

Refill Port Identification Accuracy of Intrathecal Drug Delivery System Devices with a Raised Fill Port

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Objective

Intrathecal drug delivery is used for the management of intractable pain and spasticity and the intrathecal drug delivery devices (IDDSs) have to be refilled periodically. Difficulties to access the reservoir fill port (RFP) with the needle can lead to patient discomfort and increase the risk of infection and overdose caused by the inadvertent injection of the drug into the pocket surrounding the pump.(1) IDDS design differences may have an influence on the accuracy of localization of RPF. The accuracy of the (template-guided) RFP localization for the IDDS with a Flat Surface design (FS-IDDS) is generally poor, with potential consequences regarding safety.(2) The aim of this study was to assess the accuracy of the manual localization of the RFP for the Raised Septum IDDS (RS-IDDS), and subsequently compare this to previously reported data of 28 patients with a FS-IDDS.

Methods

Nineteen patients underwent two regular refills of their RS-IDDS for the treatment of noncancer pain or spasticity. The primary endpoint was the deviation expressed in millimeters between the needle insertion point and the actual RFP center quantified by fluoroscopic RFP visualization. A distance surpassing that between the center and the margin of the RFP (4 mm for the RS-IDDS, and 3.5 mm for the FS-IDDS) was considered a clinically relevant deviation. A secondary objective was to determine if body mass index (BMI, expressed in kg/m²) had an impact on deviation in identification of the puncture site. Differences of results with the FS-IDDS cohort were tested using Student's t-test. The association between BMI and the deviation was estimated using regression.

Figure 1.

C-arm fluoroscopic image of the Recessed-RFP-IDDS (SynchroMed II, Medtronic Inc, Minneapolis, MN, USA)

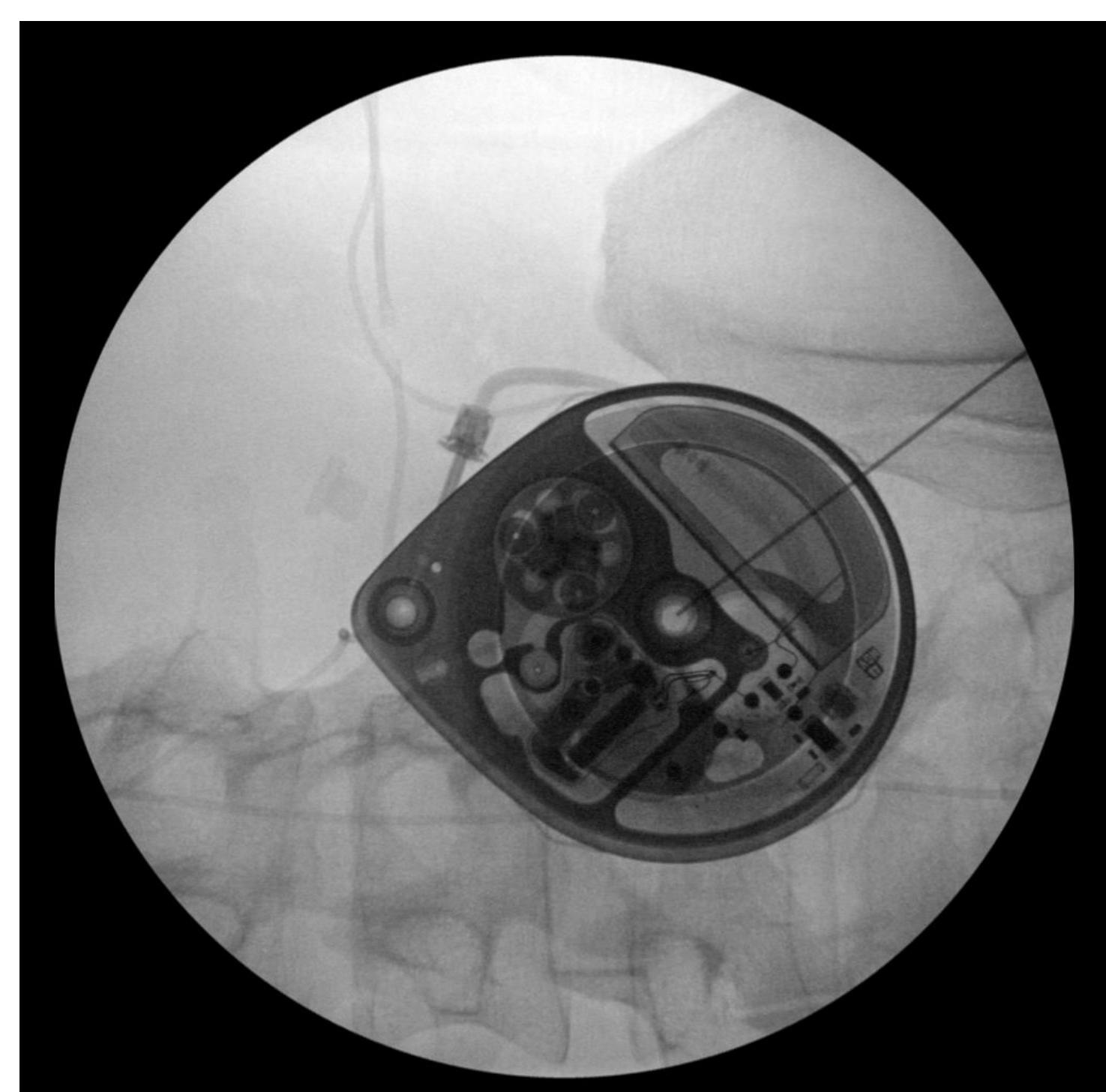
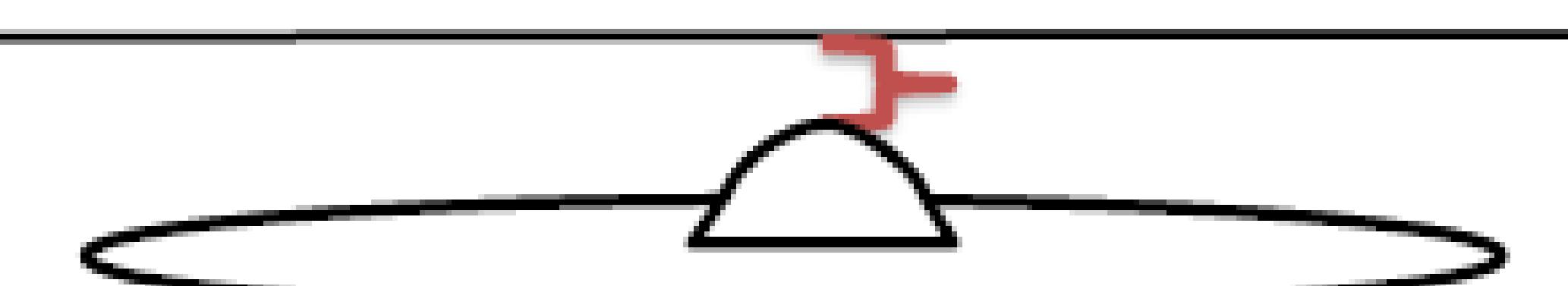
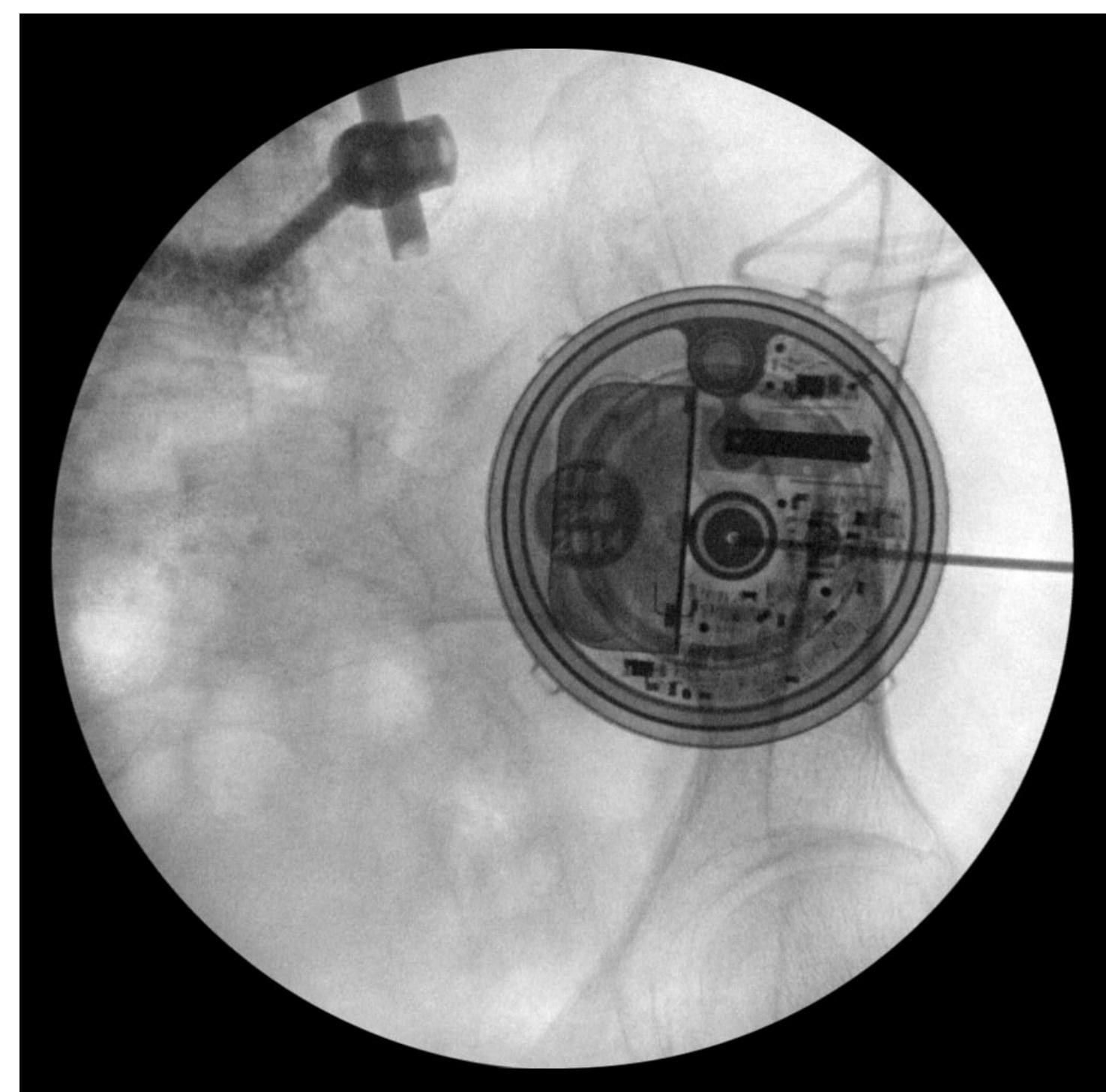


Figure 2.

C-arm fluoroscopic image of the Raised-RFP-IDDS (MedStream, Codman & Shurtleff Inc. Raynham, MA, USA)



Results

The mean deviations in the RS-IDDS cohort were lower compared to the FS-IDDS cohort (first refill procedure 4.0 vs 8.5, p < 0.001, second procedure 5.9 vs 8.1, p = 0.074).

Conclusions

The results of this study suggest that the manual localization of the RFP center for RS-IDDSs is moderately accurate, and that this technique is more accurate compared to the template-guided technique for the FS-IDDS. Therefore, the IDDS with a raised septum design seems to be preferable above the IDDS with a flat surface design.