Nexframe

In 2010 Fukaya et al. published that the Nexframe with multitract microrecording for STN DBS still has some problems that need to be resolved. Thus far, they do not consider that this technology in its present state can replace conventional frame-based stereotactic surgery. The accuracy of the system is similar to that of frame-based stereotaxy. However, the narrow surgical field is a disadvantage for multiple electrode insertion. Improvement on this point will enhance the usefulness of the system [1)]

In 2015 The location of 194 (Leksell frame, n = 116; Nexframe, n = 78) DBS leads was determined on postoperative MRI. Obtained stereotactic coordinates were compared with expected intraoperative target coordinates. Resulting absolute errors in the X (medial-lateral), Y (anterior-posterior), and Z (dorsal-ventral) coordinates (x0394;X, x0394;Y, and x0394;Z) were then used to calculate the vector error (VE). The vector error describes the total error in 3-D space and represents our main outcome measure.

Results: The vector error (mean ± SD) was 2.8 ± 1.3 for Nexframe and 2.5 ± 1.2 for the Leksell frame (p = 0.43). For Nexframe, absolute X, Y, and Z errors were 1.4 ± 1.3, 1.7 ± 1.2, and 1.0 ± 0.9 mm. For the Leksell frame, the absolute X, Y, and Z errors were 1.4 ± 1.0, 1.2 ± 1.0, and 1.3 ± 0.9 mm. On the anterior-posterior plane (Y coordinate), the Leksell frame was more accurate than Nexframe (p = 0.04). In contrast, Nexframe was more accurate on the dorsal-ventral plane (Z coordinate) (p = 0.04). There was no difference in accuracy between the two methods on the medial-lateral plane (X coordinate).

Conclusion: This comparison of Nexframe and the Leksell frame shows that both techniques have equivalent overall 3-D accuracy [2)]

Class 1 Device Recall StealthStation DBS Software Nexframe AutoRegistration
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=180357

Medtronic has received reports of entry point and lead placement inaccuracies during deep brain stimulation (DBS) lead implantation procedures using nexframe and the stealthstation auto-registration feature with the o-arm imaging system. This notification is to inform customers of the potential of this type of inaccuracy and to recommend actions that may prevent it from occurring.

Deep brain stimulation (DBS) lead implantation procedures using nexframe and the auto-registration feature with the O-arm imaging system are characterized as not having implanted bone fiducials for manual patient registration and not having rigid head fixation (the patient's head is not pinned), which can lead to undetected patient motion during the O-arm registration scan.

Investigation has shown that minor patient movement may not be initially detected by the user or the software during the O-arm auto-registration scan and could have caused the observed inaccuracies. Potential sources of movement may include: respiration motion, tremor, or other voluntary/involuntary motion. The undetected movement could lead to risks for the patient, including: inaccurate lead placement, delay of surgery, aborted surgery, or additional intervention (including revision of the lead placement and subsequent imaging.

Manual: https://www.fh-co.com/wp-content/uploads/2020/12/L011-500-Rev-A1.pdf

Nexframe™ Stereotactic System using StealthStation navigation

Minneapolis-acquired Medtronic announced that its acquisition of Image-Guided Neurologics (IGN) of Melbourne, Fla., a privately held company that specializes in precision navigation and delivery technologies for brain surgery. S

Medtronic says the IGN product line, which includes the NexFrame disposable, "frameless" stereotactic head frame, offers instruments that simplify the procedure for surgeons and improve patient comfort during surgery. The company added NexFrame replaces a heavier frame with a small, disposable guidance device that is more comfortable, less stressful on the neck and allows the patient to move and change positions during surgery.

Because the frame is disposable, says Medtronic, the need to sterilize and reset the traditional frame system is eliminated, giving surgeons the opportunity to perform multiple operations each day.

Moser et al. described a technique of optimizing the accuracy of frameless deep brain stimulation (DBS) lead placement through the use of a cannula poised at the entry to predict the location of the fully inserted device. This allows real-time correction of error prior to violation of the deep gray matter.

They prospectively gathered data on radial error during the operative placements of 40 leads in 28 patients using frameless fiducial-less DBS surgery. Once the Nexframe had been aligned to target, a cannula was inserted through the center channel of the BenGun until it traversed the pial surface and a low-dose O-arm spin was obtained. Using 2 points along the length of the imaged cannula, a trajectory line was projected to target depth. If lead location could be improved, the cannula was inserted through an alternate track in the BenGun down to target depth. After intraoperative microelectrode recording and clinical assessment, another O-arm spin was obtained to compare the location of the inserted lead with the location predicted by the poised cannula.

The poised cannula projection and the actual implant had a mean radial discrepancy of 0.75 ± 0.64 mm. The poised cannula projection identified potentially clinically significant errors (avg 2.07 ± 0.73 mm) in 33% of cases, which were reduced to a radial error of 1.33 ± 0.66 mm (p = 0.02) after correction using an alternative BenGun track. The final target to implant error for all 40 leads was 1.20 ± 0.52 mm with only 2.5% of errors being >2.5 mm.

The poised cannula technique results in a reduction of large errors (>2.5 mm), resulting in a decline in these errors to 2.5% of implants as compared to 17% in our previous publication using the fiducial-less method and 4% using fiducial-based methods of DBS lead placement [3].

Fifty DBS leads were implanted in 33 patients using the NexFrame (Medtronic, Minneapolis, MN) targeting system. Postoperative thin cut CT scans were used for lead localization. X, Y, Z coordinates of the tip of the lead were calculated and compared with the intended target coordinates to assess the targeting error. Comparative frame-based data set was obtained from randomly selected 33 patients during the same period that underwent 65 lead placements using Leksell stereotactic frame. Euclidean vector was calculated for directional error. Multivariate analysis of variance was used to compare the accuracy between two systems.

Results: The mean error of targeting using frameless system in medio-lateral plane was 1.4 mm (SD ± 1.3), in antero-posterior plane was 0.9 mm (SD ± 1.0) and in supero-inferior plane Z was 1.0 mm (SD ± 0.9). The mean error of targeting using frame-based system in medio-lateral plane was 1.0 mm (SD ± 0.7), in antero-posterior plane was 0.9 mm (SD ± 0.5) and in supero-inferior plane Z was 0.7 mm (SD ± 0.6). The error in targeting was significantly more (P = 0.03) in the medio-lateral plane using the frameless system as compared to the frame-based system. Mean targeting error in the Euclidean directional vector using frameless system was 2.2 (SD ± 1.6) and using frame-based system was 1.7 (SD ± 0.6) (P = 0.07). There was significantly more error in the first 25 leads placed using the frameless system than the second 25 leads (P = 0.0015).

Conclusion: The targeting accuracy of the frameless system was lower as compared to frame-based system in the medio-lateral direction. Standard deviations (SDs) were higher using frameless system as compared to the frame-based system indicating lower accuracy of this system. Error in targeting should be considered while using frameless stereotactic system for DBS implantation surgery [4)]

[1)]
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