

Comparison Between a Novel Articulating Needle Holder (FlexDex) In 2D and 3D; A Prospective Randomized Trial

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Introduction

Laparoscopic surgery is a task that demands a great deal of manual dexterity, visual acuity and self discipline. New and ever changing technology is constantly being developed to aid clinicians in their struggles of surgery. New 3D vision also shows potential in surgical utility.

The study objective was to compare 2D and 3D visualisation when using a novel needle holder (FlexDex).

Aims

- I. Compare 2D and 3D visualisation in task performance with the novel FlexDex needle holder in surgical novices.
- II. Compare the ease of use when using the FlexDex in 2D and 3D visualisation.

Methods

- Participant recruitment was achieved via recruitment flyers and a Google Document was created for a participant data base.
- Session 1: lecture teaching & Session 2: task assessment
- Two groups: FlexDex+ 2D & FlexDex+3D
- Both groups had 45 minutes task familiarization. FlexDex+3D had additional 2 minute 3D visual adaptation.
- 10 repetitions of the assessment task (LapPass task 1)[1] with error rates and task completion times measured.
- Inter-cohort comparisons between average completion times of attempts 1,2,3 and 8,9,10 and overall error rate.
- A comfort questionnaire was completed at the end by the participants.

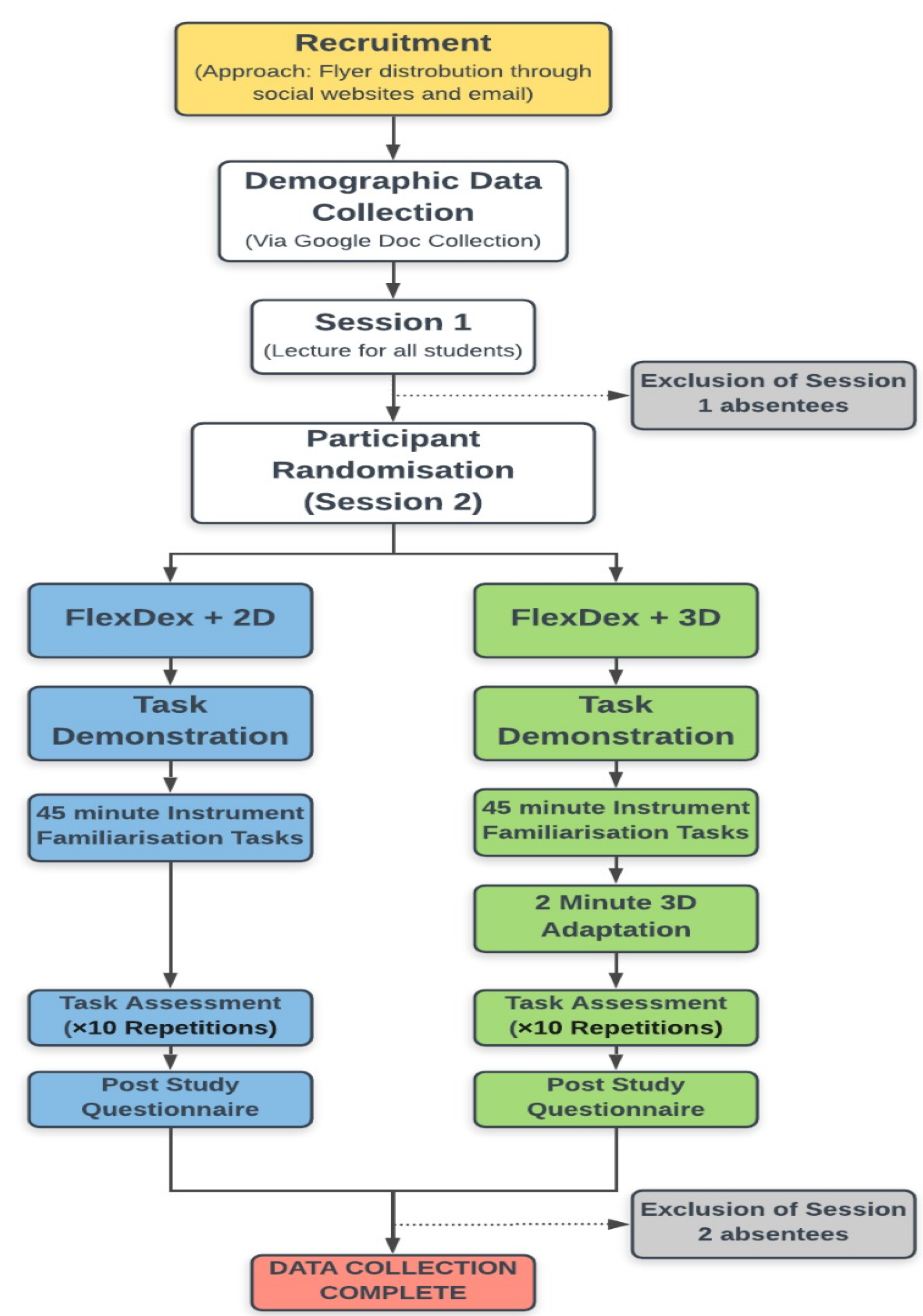


Figure 1. Study protocol diagram.

Results

- There were 20 participants in each study arm.
- Average completion times in the first three and last three attempts were faster in the FlexDex+3D group (statistically significant on both accounts) (Table 2).
- FlexDex+3D group had less errors over the 10 attempts.(not statistically significant with p=0.134)
- FlexDex+2D was easier to use.
- Side-effects of 3D vision were eye strain (95%), fatigue (80%), blurred vision (40%) and general discomfort (40%).

Table 1. Completion times of first and final 3 attempts in the 2 trial arms.

	Attempts 1,2,3			Attempts 8,9,10		
	Average(Sec)	SD(Sec)	Range(Sec)	Average(Sec)	SD(Sec)	Range(Sec)
FlexDex+3D	268.1	96.5	149.0 - 722.9	175.6	45.6	107.6 - 318.2
FlexDex+2D	415.2	145.7	227.9 - 1071.1	283.1	87.6	143.0 - 631.9

Table 2. Inter-cohort comparison of first and final 3 attempts in the 2 trial arms.

Group comparison	Mean time difference (Sec)	P-value
FlexDex 3D and FlexDex 2D Attempts 1,2,3	FlexDex 2D > FlexDex 3D 147.1	P<0.0001
FlexDex 3D and FlexDex 2D Attempts 8,9,10	FlexDex 2D > FlexDex 3D 107.5	P<0.0001

Conclusion

- I. FlexDex+3D was faster in task completion times.
- II. FlexDex+2D was reported as more comfortable.

References

1) LapPass ® [Internet]. ALSGBI. [cited 2019 May 25]. Available from: <https://www.alsgbi.org/lappass/>