A novel table-mounted MIS platform: a non-inferiority study of the Revolve Surgical System v1.0

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Introduction

- Robotic-assisted laparoscopic instruments offer improved dexterity and stabilization, and greater range of motion[1-4]
- Sophisticated robotic-assisted laparoscopic devices although beneficial can be costly and increase operating times significantly
- ***Revolve Surgical***, a Canadian startup, aims to provide advanced robotic capabilities to laparoscopic surgery while minimizing cost and impact on OR workflow

Revolve Surgical System (RSS) v1.0 offers the following functions (**Figure 1**):

1. 2-degrees of freedom at tool tip: jaw and roll
2. Joint-braked retraction and countertraction
3. Innovative handle design: customizable & swappable

- The innovative handle design of the RSS is seen in **Figure 4**

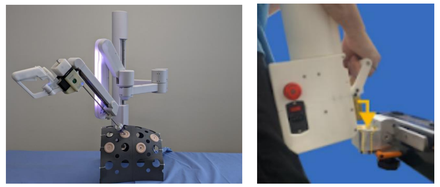


Figure 1: RSS v1.0 mounts to the OR table. Size: 96 (height) x 127 (width) cm. Weight: 18 kg.

Objectives

1. Assess the **performance** of RSS, in comparison to Manual Laparoscopic Systems (MLI) using standardized Fundamentals of Laparoscopy tasks
2. Evaluate user-satisfaction with **workload and ergonomics** of the RSS and handle design

Methods

Participants: medical students, residents, and staff, n=20

Study design: non-inferiority, single center, benchtop

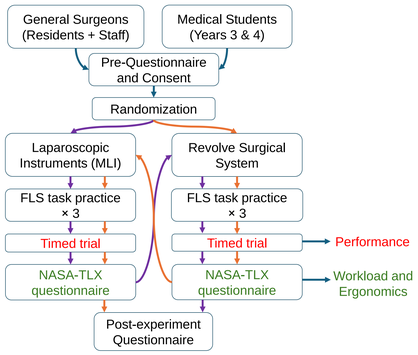
Outcome measures:

- Performance evaluation using Fundamentals of Laparoscopic Surgery (FLS) metrics
- Ergonomic and Workload Testing using validated NASA-Task Load Index (NASA-TLX) questionnaire

Data analysis: comparison between MLI and RSS using FLS outcome metrics and NASA-TLX subjective scores

Statistical Sig.: $p<0.05$ (Wilcoxon Signed-Rank Test)

Procedure Flowchart:



Results

Table 1: Participant Demographics (n =20)

Level of training	Medical Student		2
	Resident	*PGY3*	5
		PGY4	1
		PGY5	3
		PGY6	2
	Fellow	*PGY7*	1
	Attending		6
Handedness	Right		20
	Left		0
Familiarity with FLS	None		2
	Some		7
	Proficient		11
Box trainer hours	0		2
	1-20		6
	20+		12
Total laparoscopic cases	0		2
	1-100		4
	101-250		2
	250+		12

Table 2: Comparison of completion time between RSS and MLI

Completion Time (seconds; median [IQR])	RSS	MLI	p-value
Peg Transfer	87 [79, 108]	76 [53, 105]	**0.012**
Endoloop	22 [15, 31]	18 [15, 26]	0.161
Intracorporeal Knot Suturing	100 [84, 142]	83 [56, 104]	**0.003**

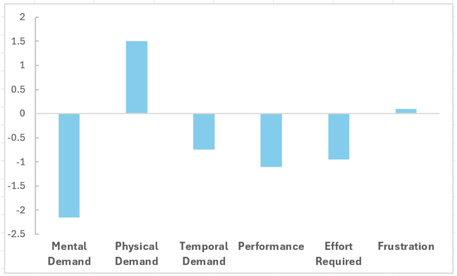


Figure 5: Average of NASA-TLX score differences between MLI and RSS. Positive values represent lessened workload for the RSS v1.0.

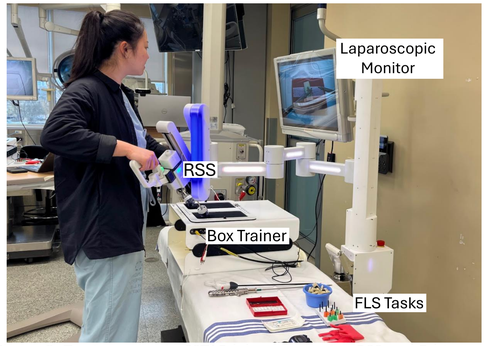


Figure 2: Testing setup in CSTAR laboratory using RSS and Ethicon Box trainer.

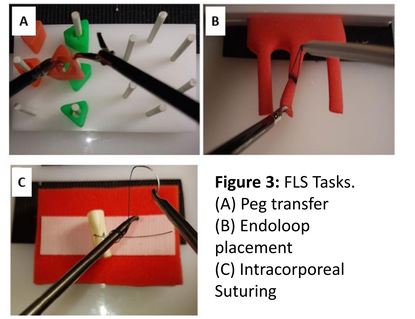


Figure 3: FLS Tasks. (A) Peg transfer (B) Endoloop placement (C) Intracorporeal Suturing

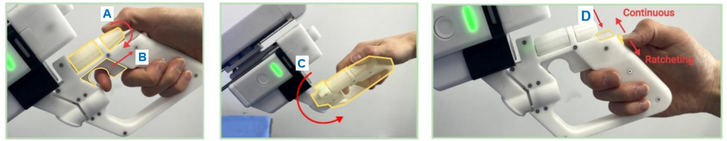


Figure 4: RSS v1.0 handle design: (A) roll via knob, (B) jaw actuation trigger, (C) roll via wrist, (D) ratchet release and mode enabling button.

Discussion

- Learning curve and task complexity may be contributing factors to the increased completion time seen for these tasks in the RSS group
- No variance observed between groups for other FLS metrics of task quality (i.e., errors, accuracy)
- Ergonomically, the RSS was considered less physically demanding thus offering potential benefits of easier adoption and less workplace related injuries

Conclusion

- The RSS v1.0 offers ergonomic benefits over MLI without compromising quality of laparoscopic tasks
- Future RSS enhancements (e.g., wristed instrument) may improve task performance and ergonomics
- Future works: assess learning curves, OR workflow

References

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