Simulation-based Training for Safety Incidents:
Lessons from Analysis of Adverse Events in Robotic Surgical Systems

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ADVERSE EVENTS IN ROBOTIC SURGERY

❖ During 2000–2013, **more than 1.75 million robotic procedures** were performed in the U.S. across different surgical specialties.

❖ We analyzed reports to **U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE)** database.

❖ **10,624** adverse events related to robotic surgery [1]

❖ **1,535 (14.4%)** with significant negative patient impact:
  - ❖ *injuries* (1,391 cases) and *deaths* (144 cases)
  - ❖ *procedure interruptions* (970 cases) to:
    - ❖ Manually reset of the system
    - ❖ Convert the procedure to non-robotic surgery
    - ❖ Reschedule the procedure to a later date

❖ **9,382 (88.3%)** involving device and instrument malfunctions
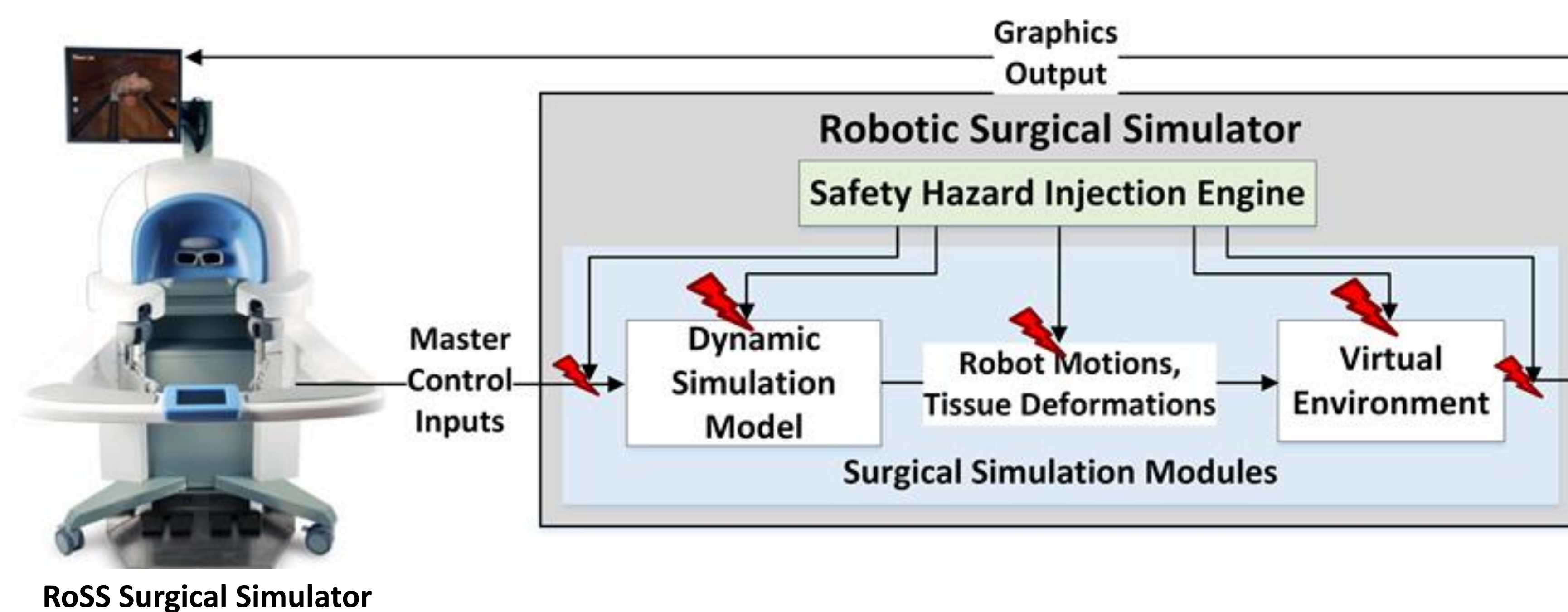
SYSTEM-RELATED SAFETY HAZARDS

Example device and instrument malfunctions

- Master tool manipulator (mtm) malfunctions
- Patient side manipulator (psm) failures
- Unintended operation of instruments (e.g. uncontrolled movements, power on/off)
- Video/imaging problems at the surgeon's console
- Recoverable and non-recoverable system errors
- Burns and holes in tip cover accessories, leading to electrical arcing, sparking, or charring of instruments
- Broken parts of instruments falling into patients

Example inadequate operational practices

- Inadequate handling of emergency situations
- Lack of training with specific system features
- Inadequate troubleshooting of technical problems
- Inadequate system/instrument checks before procedure
- Incorrect port placements
- Incorrect electro-cautery settings or cable connections
- Inadequate manipulation of robot master controls
- Inadequate hand and foot coordination by main surgeon
- Incorrect manipulation or exchange of instruments

SIMULATION OF SAFETY-RELATED SCENARIOS

RoSS Surgical Simulator

Hazard Scenario	Example System-related Causal Factors	Method to Recreate Hazards	Mutated Simulator Software Module/Function/Input	Simulator Tasks
H1. Master controller malfunctions	Foot pedal does not work, pinch doesn't register	Surgeon inputs get corrupted before being transferred to the robot control	Faulty input stream	Tasks 5 and 6
H2. Slave robot/device malfunctions	Robotic instrument jumps uncontrollably to an unintended location	Slave controller translates the surgeon's commands into incorrect motor and actuator signals	Faulty dynamic simulation model (Faulty motion mapping) or faulty output stream to instruments	Tasks 9 and 10
H3. Console display malfunctions	Camera cable breaks, vision is foggy	Image is lost or obstructed	Faulty graphics (rendering failure) or faulty output stream (image stuck-at blank)	Task 11
H4. Instrument malfunctions	Grasper not opened/closed, instrument not recognized by the system, etc.	Instrument stuck at closed or open	Faulty dynamic simulation model (instrument status stuck)	Task 13
H5. System errors	System freezes: unrecoverable system errors, recoverable system errors	System does not respond to input and displays an error or blank image	Faulty dynamic simulation model (physics engine or motion mapping failure)	Task 16
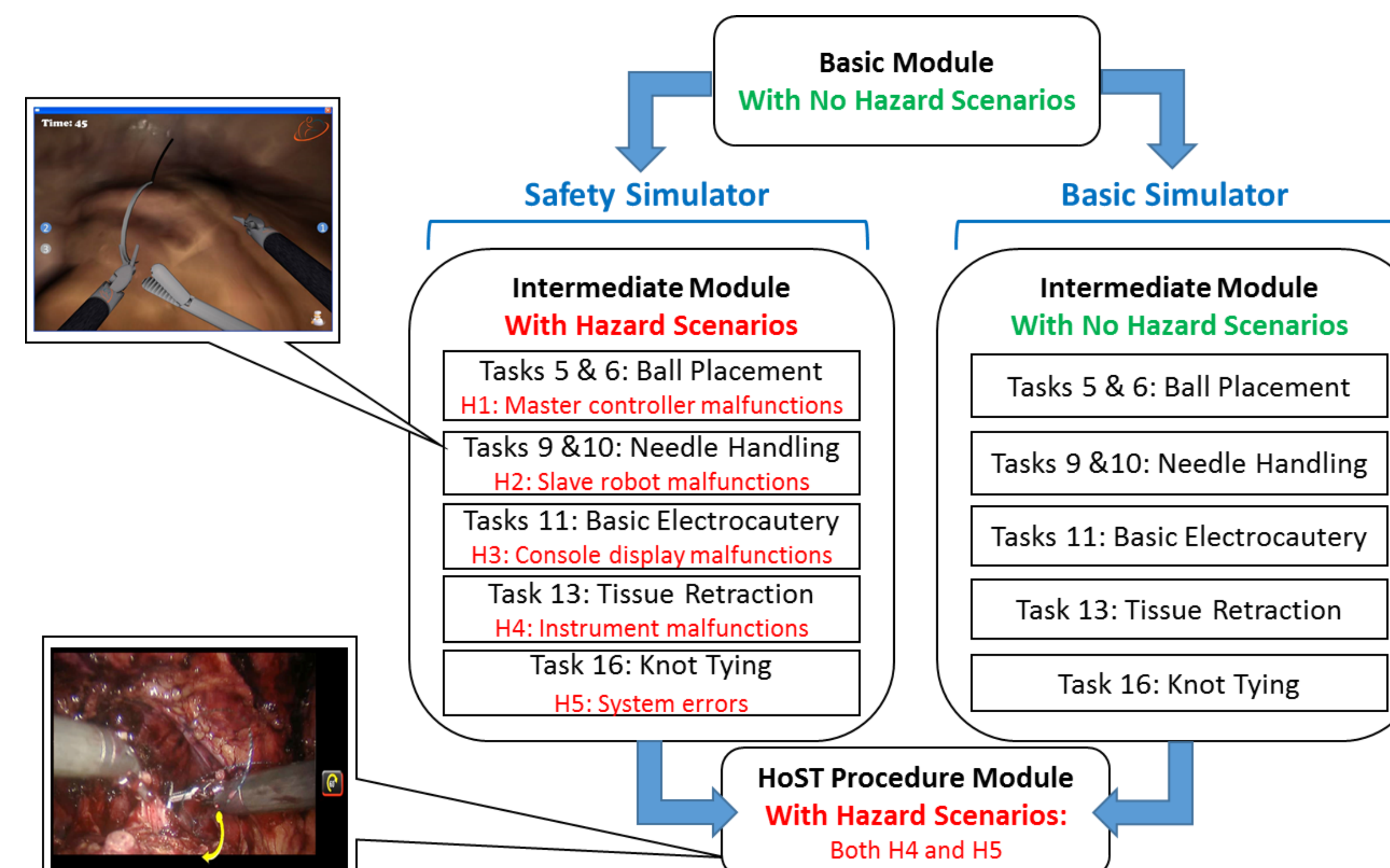
PRELIMINARY RESULTS

Safety Hazard Scenario	Injected Fault	Target Software Module	No. Manifested/ Injected Faults
H4. Recoverable System Errors	Intermittent master tool manipulator malfunction	Faulty input stream	22/30
H4. Non-recoverable System Errors	Sensor (encoder) reading malfunctions	Faulty input stream	61/64
H2. Unintended Instrument Movements (Sudden jumps)	Patient-side manipulator malfunctions	Faulty Output Stream	10/12
			3/4

Sudden Jump Hazard Scenario emulated by injecting Faulty Output Stream [2]
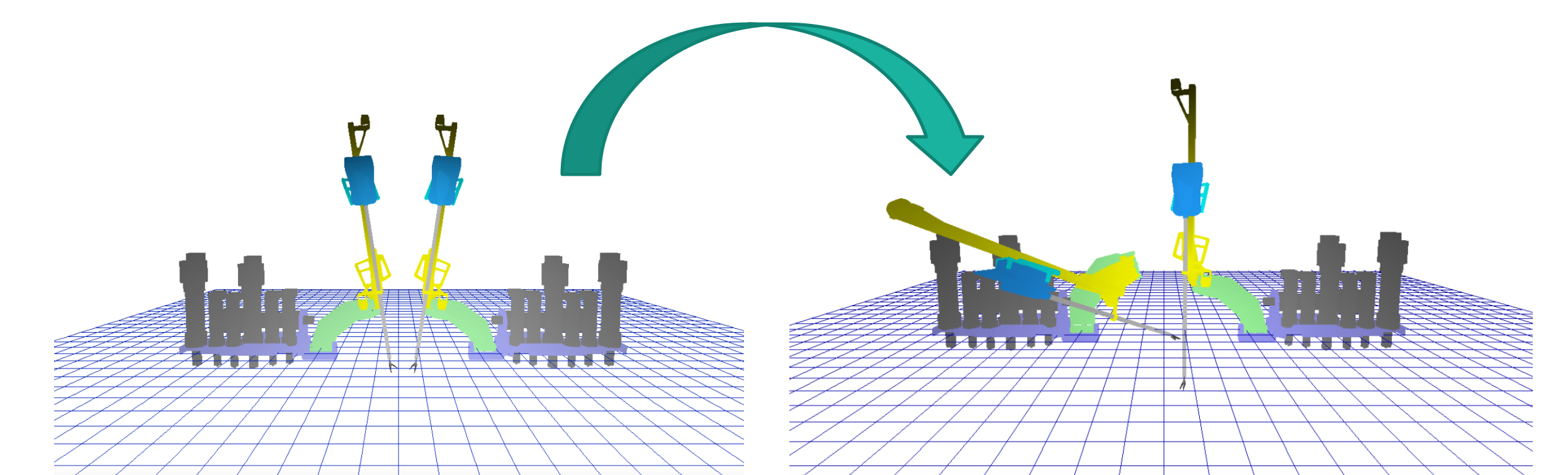
SUMMARY

❖ A simulation framework for creating realistic safety hazard scenarios during robotic surgery training
  - ❖ Prepare surgical trainees for handling safety-critical events

❖ Future work:
  - ❖ Conduct human subject testing on a group of surgical trainees exposed to hazard scenarios in a simulated environment
  - ❖ Evaluate surgical trainee's behavior and performance to obtain feedback on the simulated environment

REFERENCES

1. H. Alemzadeh, et al., "Safety Implications of Robotic Surgery: A Study of 13 Years of FDA Data on da Vinci Surgical Systems," *50th Annual Meeting of the Society of Thoracic Surgeons (STS)*, 2014.

2. "A Software Framework for Simulation of Safety Hazards in Robotic Surgical Systems," H. Alemzadeh, et al., *To appear in the Medical Cyber Physical Systems Workshop 2015, April 2015.*