

**TITLE: Novel System and Method for Orthopaedic Surgery Training****ABSTRACT:**

This disclosure relates to a system comprising haptic augmented and virtual reality for Orthopaedic Surgery. The system is used together with the Orthopaedic Surgery performance data for competency-based surgical training. We propose to be the first to provide Orthopaedic trainees a 3-dimensional record and analysis of their surgical performance.

**BACKGROUND****Background of Invention****The problems with current surgical education**

Research has shown that surgeons who are not adequately trained will have longer operation time, higher complications and increased mortality rates (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5023056/>). In many countries, improved training of surgeons means increased accessibility to healthcare and a higher living standard. Thus, surgical training has seen a marked transformation in the last 20 years (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6462560/>). The curriculum has become increasingly structured and educationally robust. However, the amount of time a trainee has to spend in the Operating Room (OR) is a fraction of what they used to spend (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3699140/>). Many countries have passed laws to limit residents to a maximum of 80 working hours per week (<https://psnet.ahrq.gov/primer/duty-hours-and-patient-safety>). At the same time, there is a fall in number of surgical cases in teaching hospitals (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4283080/>). Therefore, the opportunity for training is reduced significantly and there is a massive impact on the structured healthcare system.

There is a need to maximize the limited time residents have for training. However, the traditional training workshops are inadequate due to the lack of realistic feedback and the ability to test intra-operative decision-making skills. One such supplementary method is training on cadavers (the deceased body). While it is a common practice, this method is costly and exposes trainers and trainees to a range of ethical and health issues (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4299292/>). In many countries (such as Sweden and Japan), there have been bans on the use of cadaver for clinical trainings (verbal). Besides, residency programs also incorporate mannequins (physical models) into training. However, the use of such consumables (cadavers and mannequins) is costly, presents trainees with very limited scenarios and training opportunities, and provides very limited data for collection (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5023056/>). Tracking trainees' improvement in dexterity skills and general performance is very crucial in determining if they are ready for clinical practice.

Hence, there is a gap in current training for a method that is cost-effective, enhances patient safety, and provides multiple practices in a safe learning environment, tracks and analyses training data. Residents can benefit from new ways to supplement training, making their time spent in hospital more efficient and receive greater educational benefit from the limited number of surgical cases they can perform.

**Orthopaedic Residency Training**

Current Orthopaedic residency is a 5-year program in most parts of the world. Surgical residents go through a small number of lectures, theory discussions during this period. However, the majority of trainee's time is spent on hands-on training: Workshop and In-OR training.

Cadaveric or synthetic bone workshops are rare and expensive to organize. Throughout their entire residency, most residents have only 1 opportunity to practice the 5 most common Orthopaedic procedures (Knee Replacement, Hip Replacement, Arthroscopy, Spine Surgery and Trauma) in workshops (PI Dr Gavin NUHS, Singapore). The focus of the current training curriculum lies mostly in In-OR training.

As aforementioned, this time-based training method has proved to be insufficient in most residencies worldwide. The head of Orthopaedic residency at NUH reports to have operated on approximately 3000 cases during his residency, whereas current trainees are only operating on 1000 cases each in their residencies. This calls for innovation in our training method, moving from time-based training to competency-based training: focused approach to train and evaluate the most critical Orthopaedic skills.

Working closely with NUH's Orthopaedic Department, we have identified the critical competencies required in Orthopaedic Surgery (Hip Arthroplasty in particular):

- *Familiarity with the procedure*
- *Knowledge of anatomical landmarks - for pre-surgical positioning*
- *Pre-operative planning experience*
- *Ability to plan surgical steps in advance*
- *Skills in soft tissue approach*
- *Skills in identifying key anatomical structure (muscles, nerves, tendons, ligaments)*
- *Ability to identify and restore center of rotation, offset and leg length*
- *Intra-operative assessment of your trial implants (Offset of Center of Rotation to Greater trochanter, stability, anteversion, leg length)*
- *Manage complexities and unforeseen incidents*

## Field of Invention

### Our proposed solution

aPlasty, (first of the many plasty hence nplasty) our pioneer product built on this platform, is a Virtual Reality (VR) Medical simulator, a comprehensive system which allows Orthopaedic trainees to acquire the cognitive knowledge & psychomotor skills. aPlasty will complement the traditional Theory Lectures, Workshops and In-OR Training. By creating more training opportunities, aPlasty enables residents to reach a higher competency standard.

Simulation has already become the standard of training in the aviation industry.. As the medical field deals with countless variations in human anatomy, we aim to reach a ratio of 60% simulation to 40% in-OR training to supplement the curriculum (or approximately 2000:1000 cases in Orthopaedic residency). aPlasty can prepare trainees for the scarce but valuable in-OR experience:

### Description of the Related Art

Multiple research papers have laid out the ground work in Virtual Reality simulation and Medical simulation field. Such papers have been cited and examined in: *Visual Computing in Medicine* (eBook ISBN 9780124159792). These papers provide the base knowledge for our research and development. As public knowledge, they also serve as a protection mechanism.

At the same time, there are relevant patents filed for Virtual Reality medical simulations. Although, there are several patents in the field of Virtual Reality medical simulations, such patents cover other medical fields and are not specific to open surgeries (US20150262511A1, US8527094B2, US8600551B2, and US10108266B2). There are a few patents in Orthopaedics, however, they focus on Arthroscopic surgeries (US8992230B2, US9330502B2, US9424761B2, US20180144550A1, US6939138B2, US6863536B1, US7261565B2, US20180090029A1, US8550821B2, US8388351B2 and US7850456B2). As these are keyhole surgeries, their claims are highly distinguishable to our technical approach to open surgeries - Arthroplasties.

## Brief Description of the Invention

aPlasty includes:

### *- Artificial Intelligence (AI) Trainer's Courseware & Performance evaluation:*

aPlasty's Courseware, presented by an AI Trainer allows trainees to pick up the demanding cognitive knowledge and improve the intra-operative decision-making skills. The procedure is broken down to multiple steps to avoid cognitive overload and enhance learning. Each step includes the instructions, hands-on exercises on the virtual model with haptic feedback, and evaluation of performance.

Trainees' performance is captured and evaluated after each step to immediately strengthen learning: consolidate the right skills and notify the incorrect skills for relearning. This feature is crucial for trainees to learn at their own speed and yield the best result from the practice. The objective assessment of aPlasty's AI Trainer sets it apart from current training methods.

### *-3D virtual environment:*

Orthopaedic anatomy (Hip, Knee, Spine or Shoulder joints) is displayed as virtual anatomical structures. The structures are programmed to demonstrate realistic characteristic of tissues, which trainees can interact with. This virtual environment is displayed through immersive platform (VR Goggles) to allow for the immersive experience

### *-Haptic platform that allows virtual interaction with life-like force-feedback:*

aPlasty replicates the forces surgeons would encounter in Orthopaedic procedures. The haptic feedback is programmed based on physics modelling and actual forces, delivered through a 6 degree-of-freedom haptic system. Understanding the importance of psychomotor skills, we have gone through great lengths with our research and expertise to make sure the surgeons can interact with the haptic control interface in the most natural position, and receive a close-to-reality tactile experience.

Studies have shown that practicing with VR simulators (in areas such as nursing training (<https://www.ncbi.nlm.nih.gov/books/NBK2628/?report=reader>))

, laparoscopy, endovascular skills) improves intra-operative performance (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3577578/>). Similarly, aPlasty aims to solve the skill-transfer problem in Orthopaedic surgery by providing:

*- Data Analysis for competency-based training:*

Performance growth can easily be tracked through our metric system and evaluation algorithm. We collect data and provide feedback on tactile, spatial, procedural, anatomical appreciation. Both learners and trainers can monitor the effect of training, ensuring the required skills have been refined and can be applied in clinical settings.

*- Training without compromising Patient Safety:*

aPlasty gives surgeons more opportunity to train without compromising patients' safety. Before operating on patient for the first time, surgeons who have been trained with simulators would have mastered the cognitive and psychomotor skills to confidently apply it in the OR. This would reduce the time spent in the OR and improve patient outcome.

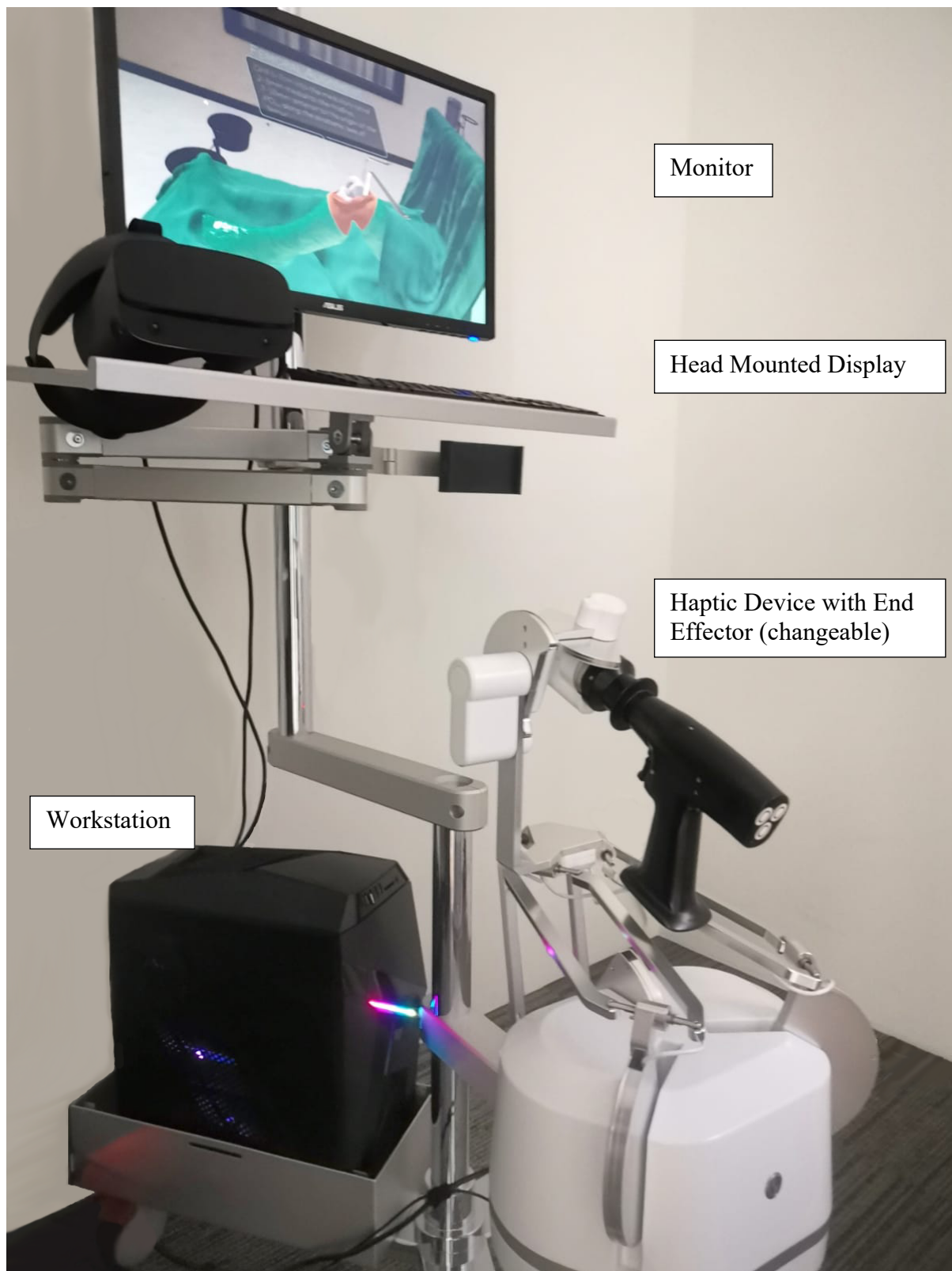
*- Safe learning environment:*

With aPlasty, surgeons can practice multiple times until they are confident with the evaluation results. This poses a strong advantage over other training methods (mannequin, in-OR training) as these resources are limited and stressful to work with. Studies have shown that learning at one's own pace, in less stressful situation will reap better outcomes (<https://rdcu.be/b1a6C>).

aPlasty recognizes the patterns of surgical procedures by the learners and trainers from using the data that we collected from practices. Using these valuable data sets, we have built an Artificial Intelligence (AI) trainer that prompts trainees of common mistakes, their previous unsuccessful attempts, and provide tailored guidance to perfect their skills.

While trainees are performing the surgery on aPlasty, we can collect trainee's Tool Orientation, Positioning, Force, and Velocity, thereby, enabling us to predict and simulate the outcome of each surgical step. This information will then be reflected to the trainee after each step, allowing them to quickly spot problems and revise the task with higher accuracy. The AI trainer will follow the trainee's progress and prompt him when necessary.

## **BRIEF DESCRIPTION OF THE FIGURE(S)**



Prototype of the system with a Monitor for viewing by the trainer, Head Mounted Display to be worn by the trainee, Haptic device which mimics the tools used in surgery, interacting with the virtual model. Workstation runs the software controlling the visualisation, simulation and input.

**INVENTIONS' INTENDED USE:**

This invention will be used for training Orthopaedic Surgeons who are unable to get enough practice due to limited resources and avenues available for proper trainings. Alternative uses in other industries would also be explored with time.

**CLAIMS:**

1. A system comprising haptic augmented and virtual reality for orthopaedic surgery
2. The system as defined in claim 1, wherein the orthopaedic surgery is an open surgery
3. A method wherein the system as defined in claims 1-2 is used together with the orthopaedic surgery performance data for competency-based surgical training
4. A method wherein the system as defined in claims 1-2 is used for arthroplasty surgery training

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**REFERENCES:****Patents:**

| <b>Company</b>                           | <b>Patent Number</b> | <b>Status</b> | <b>Patent Name</b>                                                                                                  | <b>Notes</b> |
|------------------------------------------|----------------------|---------------|---------------------------------------------------------------------------------------------------------------------|--------------|
| <b>Intuitive Surgical Operations Inc</b> | US20150262511A1      | Pending       | Systems and methods for medical device simulator scoring                                                            |              |
|                                          | US8527094B2          | Active        | Multi-user medical robotic system for collaboration or training in minimally invasive surgical procedures           |              |
|                                          | US8600551B2          | Active        | Medical robotic system with operatively couplable simulator unit for surgeon training                               |              |
| <b>ImmersiveTouch Inc</b>                | US10108266B2         | Active        | Haptic augmented and virtual reality system for simulation of surgical procedures                                   |              |
| <b>VirtaMed AG</b>                       | US8992230B2          | Active        | Medical training systems and methods                                                                                | Arthroscopy  |
|                                          | US9330502B2          | Active        | Mixed reality simulation methods and systems                                                                        | Arthroscopy  |
|                                          | US9424761B2          | Active        | Medical simulation system and method with configurable anatomy model manufacturing                                  | Arthroscopy  |
| <b>Simbionix Ltd</b>                     | US20180144550A1      | Pending       | System and method for rendering complex data in a virtual reality or augmented reality environment                  |              |
|                                          | US6939138B2          | Active        | Endoscopic tutorial system for urology                                                                              |              |
|                                          | US6863536B1          | Active        | Endoscopic tutorial system with a bleeding complication                                                             |              |
|                                          | US7261565B2          | Active        | Endoscopic tutorial system for the pancreatic system                                                                |              |
|                                          | US20180090029A1      | Pending       | Method and system for medical simulation in an operating room in a virtual reality or augmented reality environment |              |
|                                          | US8550821B2          | Active        | Simulation system for arthroscopic surgery training                                                                 |              |
|                                          |                      |               |                                                                                                                     |              |

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|--|-------------|--------|-----------------------------------------------|-------------|
|  | US8388351B2 | Active | Articulated knee for arthroscopy simulation   | Arthroscopy |
|  | US7850456B2 | Active | Surgical simulation device, system and method |             |

**Non Patent literature:**

1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5023056/>
2. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6462560/>
3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3699140/>
4. <https://psnet.ahrq.gov/primer/duty-hours-and-patient-safety>
5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4283080/>
6. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4299292/>
7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5023056/>
8. <https://www.ncbi.nlm.nih.gov/books/NBK2628/?report=reader>
9. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3577578/>
10. <https://rdcu.be/b1a6C>