Appendix 3: Table I: Validity Assessments

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Simulator | Paper | Study design | Validity | | Participants | | Outcomes | | |
| Subjective or Objective | Face or Content | Number | Experience | Face | Content | Objective |
| Voxel-Man | Khemani S, et al (2012) 1 | Identification and delineation of the sigmoid sinus in 10 minutes. Evaluated by experienced surgeon. | Objective | n/a | 40 | Novice (medical students) |  |  | Experts and intermediates: quicker, fewer injuries, greater bone volume removed, less time bone hidden, less dural force and less efficient than novices. Intermediates - more injuries and less efficient than experts. |
| 15 | Intermediate (registrars, completed 10 dissections and previous TB course) |  |  |
| 10 | Experts (consultants with 100 mastoid procedures as primary surgeon) |  |  |
| Voxel-Man | Varoquier M, et al (2017) 2 | 3 tasks completed with automated feedback provided. 1) opening cortical mastoid bone. 2) Exposing the sigmoid sinus; 3) Exposing the short process; 4) Exposing lateral SCC. Realism and training effectiveness assessed by expert group - Likert survey 1-5. | Subjective + Objective | Face and Content | 58 | Novice (<50 mastoidectomies) | Global assessment 3.4;  Appearance of: anatomical structure 3.5;  Anatomical rapports 4.3;  Drill 3.6;  Haptic feedback 3.1;  Drill control 3.1;  Drill performance 3.9;  Ergonomics 2.5 | Global assessment 4.1; teaching: anatomy 4.7; surgical planning 4.1; hand eye coordination 3.9; curriculum 4.5; transfer to OR 3.1 | Experts outperformed novices (z=3.03, p<0.01) - faster, more efficient |
| 16 | Experts (>50 mastoidectomies) |
| Voxel-Man | Arora A, et al (2012) 3 | 5 tasks:  1) delineate sigmoid sinus + sinodural angle 2) antrostomy 3) identify short process 4) delineate facial nerve and chorda 5) posterior tympanotomy Realism, training effectiveness and global impressions - 5-point Likert scale. Score of 4 or more = acceptable. | Subjective | Face and content | 60 | Referent (trainees, mean ENT experience 2.9 years) | Trainers: appearance of anatomical structure 3.6, drill 3.7, haptic feedback 2.9, ergonomics 3.2, depth perception 3.4, graphics quality 3.5 | Trainers: teaching anatomy 4.5, surgical planning teaching 4.1, drilling technique 3.7, instrument navigation 3.9, hand eye coordination 4.2, overall 4.2 |  |
| 25 | Experienced (>150 mastoid surgeries) |
| Voxel-Man | Linke R, et al (2013) 4 | Antrostomy, wide open antrum, view of short process, dura, sinus, labyrinth, angle of Citelli. 7 minutes. Assessed by expert. | Objective | n/a | 20 | Medical students |  |  | Experts outperformed residents and students: less injuries (p<0.05 residents; p<0.01 students); completed more of the procedure |
| 10 | ENT residents - no experience of mastoid |
| 7 | 6 consultants, 1 resident with experience |
| Voxel-Man | Zhao YC et al (2010) 5 | Performed a canal wall down mastoidectomy. | Objective | n/a | 9 | Novices |  |  | Experts were quicker (P<0.001) and had less injuries (p<0.011) than novices and residents. |
| 6 | Residents |
| 12 | Experts |
| Voxel-Man | Zirkle M et al (2007) 6 | Performed a cortical mastoidectomy on cadaver and simulator, 20-minute limit, recording evaluated by experts. | Objective | n/a | 11 | Novices |  |  | Experienced trainees could be assessed to be ready to operate in theatre compared to novices on assessment of blinded videos by the expert. |
| 8 (2 excluded) | Experienced (at least one 3-month otology rotation) |
| CardinalSim | Compton EC et al (2020) 7, 8 | Cortical mastoidectomy and posterior tympanotomy in 20 minutes then completed a questionnaire. Likert 1-5. Accepted if 4 or greater. | Subjective | Face and Content | 30 | Residents (subdivided to junior and senior) | Sufficient ratings: Appearance of temporal bone, anatomy, and drill; performance of drill; depth perception; overall graphics quality. Mixed ratings: haptic feedback; ergonomics | Median score 5: Teaching anatomy, surgical planning; hand eye coordination, overall utility;  Mixed scores drilling technique, instrument navigation. |  |
| 32 | Practising surgeons (subdivided to high and low volume >10 mastoids/yr) |  |
| CardinalSim | Sewell C, et al (2007) 9 | Performed 2 virtual mastoidectomies. 2 experienced instructing surgeons assigned global scores. | Objective | n/a | 7 | Novices |  |  | For each virtual procedure global score correlated with experience and instructor rating |
| 8 | Experts |
| SurgiSim | de Lotbiniere-Bassett M et al (2022) 10 | Participants tested VR microscope and provided feedback. | Subjective | Face | 2 | Experts | Appearance realistic; weight of the microscope poorly replicates - would easily move during the simulation, difficult to find the handles of the microscope. |  |  |
| 2 | Novices |
| Melbourne | O'Leary SJ at al (2008) 11 | 1 hour lesson on cortical mastoidectomy in the virtual environment with a trainer then completed TB cadaveric dissection |  | Face and Content | 11 | Novices | Not clearly stated on formal evaluation method. Found to be a convincing representation of drilling and exhibits face validity | High level of acceptance of simulated surgery for training, perceived value in specific enhancements of the virtual environment |  |
| Melbourne | Ioannou I et al (2017) 12 | Performed two trials of the surgical approach to cochlear implantation - cortical, skeletonise dura and sigmoid sinus, identify incus, skeletonise facial nerve, open facial recess, preparation of round window niche and cochleostomy. Raw feedback data evaluated alongside videos by expert. | Objective | n/a | 7 | ENT residents |  |  | Experts drilled more efficiently, used larger burrs, applied higher forces, and excised more caution when drilling close to anatomical structures. |
| 7 | ENT consultants |
| Ohio | Wiet GJ, et al (2002) 13 | Demonstrated at a conference and participants provided formative and summative evaluation of the system. | Subjective | Face | 43 | Presumed consultants but not stated | Found to be acceptable to a "varied population" of otologic surgeons; expert and older surgeons would give lower scores on comparison to other methods |  |  |
| Ohio | Wiet GJ, et al (2012) 14 | Participants randomised to 2 groups, 2-week practice with simulator (group 1) or cadaveric bones (group 2), outcomes compared at completing a mastoidectomy with facial recess approach in 30 minutes on simulator and on cadaver. Assessed by otologists. | neither | n/a | 65 | Medical students and residents | No significant difference between groups - doesn't measure validity based on our definition |  |  |
| Ohio | Kerwin T, et al (2013) 15 | 80 residents performed a virtual mastoidectomy on a temporal bone before and after a training course; 80 pre-test and 50 post-test dissections evaluated and compared to experts based on multivolume analysis. | Objective | n/a | 80 | Residents |  |  | Residents can be compared and distinguished from experts. |
| Ohio | Andersen SAW et al (2021) 16 | Completed a cortical mastoidectomy with a facial recess approach completed before completing a questionnaire on accuracy and utility of simulator. | Subjective | Face and Content | 5 | Trainees | 84.6% of simulations rated the overall experience as “good”, “very good” or “excellent”. As with previous simulators the feel of the drill was rated less favourably. | 84.6% of simulations rated the overall experience as “good”, “very good” or “excellent”. As with previous simulators the feel of the drill was rated less favourably. |  |
| 4 | Attendings |
| VES | Andersen SAW, et al (2019) 17 | Performed 3 mastoidectomies on the VES, scores analysed using simulator metrics and final product analysis | Objective | n/a | 37 | Residents |  |  | 17 metrics could discriminate between resident and experienced surgeon. Mainly based on efficiency |
| 11 | Otosurgeons |  |
| VES | Fang TY, et al (2014) 18 | Performed 3 sessions at 1-week intervals.44-point technology acceptance model (TAM) questionnaire rating on a scale of 1 (very untrue) – 5 (very true). | Subjective | Face and Content | 7 | Medical students | Only one question focused on face validity: “the design of the simulation helps me to complete temporal bone dissection smoothly” this was evaluated as 4. |  |  |
| 7 | Otology residents |  |  |

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