

A medical hand tool physical interaction evaluation approach for prototype testing using patient care simulators

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ABSTRACT

The purpose of this study was to develop and test a physical ergonomics assessment approach for medical device handles. The method assesses wrist posture and force of exertion simultaneously by task element. Electrogoniometers and EMG sensors were connected through a data acquisition module for synchronization with video recordings of trials. Task analysis of video recordings was performed offline with Observer XT software. Average posture and force data across several repetitions of individual task elements were calculated and presented in a format suitable for informing product designers of specific issues during a test trial. A handle comfort questionnaire is proposed to survey subjective responses. The evaluation approach was applied to an endoscope needle in sampling a biopsy from the stomach wall using a gastrointestinal track simulator with ten physician surrogates. The results showed that for all task elements the wrist was in extension (33° - 45°). Peak muscle forces ranged from 28% to 68% MVC across the three muscles studied. Muscle peak forces were above ACGIH HAL maximum threshold limits for four of the seven task elements, and above the action limit for all seven task elements for two muscles. The handle comfort questionnaire data also supported the high muscle force findings, and also on force distribution on the handle due to contact stresses. This combined approach could be used to collect and report detailed early stage ergonomics data from user trials on patient care simulators. The approach is proposed for use by medical device designers at the design stage of new products using prototypes, but it could also be used on existing products with real patients.

1. Introduction

1.1 Musculoskeletal complaints in endoscopy work

Endoscopy has been described as a “hazardous profession” (Keate et al. 2006). A technology status evaluation report for the American Society for Gastrointestinal Endoscopy describes three main groups of hazards for personnel performing gastro intestinal endoscopy; namely personal protective equipment, radiation safety and ergonomics (ASGE, 2010). Buschbacher (1994) in a survey of over 300 endoscopists, found that many reported musculoskeletal disorders due to endoscopic procedures, impacting severely on some their careers. In the study, 32% of respondents claimed to suffer from carpal tunnel syndrome, 19% of thumb pain and 15% of elbow pain. A survey of gastroenterologists found that they spent on average up to 43% of their time performing endoscopic procedures (ASGE, 2010). Hansel et al. (2009) performed a controlled study on prevalence and impact of musculoskeletal injury among endoscopists. A group of Gastro Interologists (GI) (n=115) were compared with a group of non procedure orientated internal medicine specialist and sub-specialists (n=230). The frequency of musculoskeletal injury was higher in the GI group (74%) than the non GI group (35%). The most common sites of injury were for the thumb (19%), hand (17%), back (12%) and neck (10%). Of the GI group reporting musculoskeletal injury, 69% reported that they had modified at least one part of their work endoscopic practice to reduce injury risk.

It appears that the high incidence of musculoskeletal disorders among GIs is due to two main issues. Firstly due to the control in use of endoscopes, and secondly due to the awkward body postures adopted to control the endoscope while viewing the camera monitor. Shergill (2009a) gives ergonomics advice to correct gross body posture, through for example, correct monitor location and height, and through the use of an adjustable height bed. However, advice on the design of the equipment to reduce musculoskeletal disorders, especially of the upper limb is lacking, despite the high injury symptom rates.

Endoscopy is a demanding skill requiring combined repetitive motions such as pushing, pulling, and the application of torques and turning of knobs (Siegel, 2007).

The terms “Endoscopist’s Thumb” (Siegel, 2007) and the more specific “Coloscopists Thumb (Cappell, 2006) have been coined to describe DeQuervains syndrome in mainly the left hand of gastroenterologists. For colonoscopy the left thumb controls the head for horizontal or vertical colonoscopic tip deflection for steering (Cappell, 2006). Cappell (2006) describes a case report of a 52 year old male academic clinical GI who performed more than 10,000 colonoscopies and esophagogastroduodenoscopies during the previous 20 years. In the old work system two colonoscopists worked as a pair and the GI in question did not previously report symptoms of upper limb injury. The GI developed DeQuervain’s Syndrome during colonoscopy procedures which was purported to be due to work practice changes where one GI was recently eliminated. The remaining GI (who later became injured) used an alternative scope design which had a pair of wheels for the left thumb to manipulate the scope tip deflection.

Successful application of ergonomics in medical device design can ensure a user centred focus reducing musculoskeletal loading and risk of upper limb musculoskeletal disorders, and also improved usability. Cappell (2006) suggests that a multifaceted strategy is needed to prevent musculoskeletal disorders associated with endoscopic devices. For example, specific to colonoscopy it is suggested to focus on thumb strain, but this dictates design stage changes. However, few ergonomics guidelines are available in the public domain for medical device handle design.

Risk factors for upper limb musculoskeletal injury

The National Institute of Occupational Safety and Health (NIOSH, 1997) performed a review of over 600 studies on risk factors for work related musculoskeletal disorders. They concluded that high force of exertion, deviated upper limb postures and frequent repetitive movements were associated with work related musculoskeletal disorders of the upper limb. These findings are further supported by a review of the work relatedness of musculoskeletal disorders by the National Research Council and the Institute of Occupational Medicine in 2001. The International Standard EN1005 details various techniques which can be used to assess the risk of injury in repetitive work. As such various upper limb injury evaluation methods are available, such as RULA (McAtamney and Corlett, 1993), OCRA (Occhipinti, 1998) and HAL

(ACGIH, 2000). These techniques were developed primarily for use in the evaluation of industrial work, for example on repetitive assembly work in production lines. While there is general consensus on the actual risk factors and their relatedness to injury (force, posture, repetition & grip type), design criteria on acceptable levels of exposure to the risk factors are not readily available for medical device handles. One solution is to use ergonomics evaluation techniques widely used to assess repetitive upper limb work, but a precedent has not been set in this respect and the suitability of such evaluation methods has not yet been defended.

Botney et al. (2011) detail a comprehensive list of 139 human factors design guidelines for medical hand tools. The guidelines are wide ranging covering context of use issues, such as storage requirements, lighting conditions and vibration dampening, through to handle specific posture, force and grip recommendations. They give accounts of high forces in surgical work, for example the application of 80N in laparoscopy (Evans et al. 2003), but they do not suggest specific limits. Specific to wrist posture, Botney et al. (2011) recommend using neutral postures and slight extension ($<20^{\circ}$) and slight ulnar deviation ($<20^{\circ}$) as derived from data on grip force strength. No detailed wrist posture zones or ratings are given for wrist deviations.

Botney et al. (2011) acknowledge that the more sustained and more frequent a grip the more likely the muscle will be come fatigued and may become injured. Helpful guidance are given on grip types for various types of task based on precision and force demands. For force level they recommend a maximum grip force of 15% Maximum Voluntary Contraction (MVC) for repetitive hand grip work. It is important to consider the variation in frequency of exertion between different hand tools and tasks, as the maximum force permissible may possibly be higher if the exertion frequency is low. The American Conference of Governmental Industrial Hygienists (ACGIH, 2000) Hand Activity Level (HAL) method set action limits and maximum limits for combinations of peak force versus pace of motions (repetitiveness). Shergill et al. (2009b) applied the HAL method in the study of pinch forces and forearm loads during conoloscopy. Peak forearm muscle loading ranged from 12%MVC for scope withdraw for the right Flexor Digitorium to 49% for the left Extensor Carpi Radialis for left colon insertion. Of the five subtasks, stabilising the control section of the

colonoscope, exceeded the ACGIH action limit and maximum threshold limit for the left Extensor Carpi Radialis.

Ergonomics and medical device hand tools

The current study addresses physical interaction in the use of Endoscopic Ultra Sound (EUS) devices as a case study in testing the proposed approach. In 2005 over 1.66 million endoscopic biopsies were performed the USA (DeFrances and Hall, 2007). Such procedures routinely involve the use of an echoendoscope to view ultrasound images through the stomach wall while simultaneously inserting instrumentation through the working channel of the scope to perform specific tasks, such as the sampling of biopsies.

Design of EUS needles and other EUS devices have strict design criteria at the distal portion (the interface with the patient) (Figueredo, et al. 2007). Medical devices are high value added products and a lot of the value is in the innovativeness of their functionality. In many cases little emphasis is placed on the ergonomic design of the proximal interface (the interface with the physician). This offers many opportunities for ergonomics improvement. Cognitive evaluation techniques have been successfully applied to medical devices (Martin et al. 2008) but these need to be complemented with suitable techniques for assessment of physical interaction. It is possible to integrate video recordings of tasks with EMG data collection to extract sub task specific force data, as for example in the study of colonoscopes by Shergill et al. (2009b). However, they did not collect posture data simultaneously. The problem is that there are few commercially available solutions for task analysis level extraction of simultaneous upper limb force and posture data for real tasks or simulations. Patient care simulators have reached a sufficiently high degree of realism for design stage medical device testing (Botney, 2011). The use of an integrated ergonomic approach as part of user testing at the design stage can ensure better medical device design (Buckle et al. 2006) helping to obviate potential injury for patients and discomfort and injury for health care workers (Botney, 2011).

The purpose of this study was to develop a flexible ergonomics design stage evaluation approach for medical device handles. Specifically the objective was to provide ergonomics data on upper limb forces and wrist joint angles specific to individual task elements of medical procedures as collected using patient care simulators.

2. Method

2.1 Measurement and evaluation approach.

BS EN ISO 13407:1999 “Human-centred design processes for interactive systems” details the need for active involvement of users and a clear understanding of users requirements with iterative development of design solutions. As part of a human centred design approach it is of crucial importance to perform design stage testing and to capture user opinions on the physical interaction, on for example prototypes. The proposed solution for medical device handle design evaluation comprises two main steps, a risk measurement step and an evaluation step.

For the measurement step, it is necessary that the approach measures exposure to the key risk factors for work related upper limb musculoskeletal disorders, i.e forces exerted (mean and/or peak), wrist postures adopted and repetitiveness (NIOSH, 1997). For design stage testing of prototypes it is most beneficial if findings, for example high forces of exertion, are related to specific task elements so that design changes can be best targeted. The proposed solution was to integrate measurements on force and posture sensors with video recordings which could subsequently be processed offline to analyse the force and posture data by task element.

Electromyography (EMG) was used to measure muscle forces while electrogoniometers were used to measure joint angles. The EMG and the joint angle data were recorded using different hardware devices so Observer software was used to synchronize the hardware data onto the same time line with the video recordings. The software was also used to perform the task analysis and separate the EMG and joint angle data as per the task elements.

For the evaluation step, two methods are proposed for the interpretation of the force, motion pace and wrist posture data. The ACGIH (2000) HAL method proposes

Threshold Limit Values (TLVs) for combinations of hand activity (pace) versus peak hand force (Figure 1). If a task is rated above the TLV, task changes are necessary, including engineering (design) controls. A lower Action Limit is also proposed. Tasks rated between the TLV and Action Limit require surveillance and job improvements. It is recommended that tasks are positioned below the Action Limit to reduce the risk of injury. Hand Activity Level (pace) is rated on a scale from 0-10 (Table 1) and Peak Hand Force is normalized on a scale from 0-10, which corresponds to 0-100% MVC. Standard BS ISO 11228-3 (2007) details the actual cutoff values for the TLVs and Action Limits based on the ACGIH (2000) HAL data, as plotted in Figure 1. The limit values are reproduced in Table 2 to assist in interpretation of force value acceptability for each HAL level.

[Figure 1 about here]

[Table 1 about here]

[Table 2 about here]

One limitation of the HAL method is that it does not evaluate posture. Drury (1987) proposed posture zones based on deviations from neutral. Zone 0 was for postures up to 10% Range Of Motion (ROM), Zone 1 for 10-25% ROM, Zone 2 for 25-50% and Zone 3 for postures greater than 50% ROM. Zone 0 is interpreted as exposure to negligible risk due to posture, Zone 1 to low exposure, Zone 2 as moderate exposure and Zone 3 as high exposure. Drury (1987) standardized the zones to angular values based on population averages (Table 3).

[Table 3 about here]

2.2 Equipment (objective data)

2.2.1 Hardware: Wrist posture and force measurement

EMG sensors (Biometrics Ltd., EMG Pre Amplifier SZ230) were attached over three muscles of the dominant forearm: the Flexor Carpi Ulnaris (FCU), Extensor Carpi Ulnaris (ECU) and Extensor Carpi Radialis Brevis (ECRB) in accordance with the SENIAM guidance (SENIAM, 1999). Wrist posture data (flexion/extension) were

recorded using a Biometrics SG65 electrogoniometer. A Datalink module (Biometrics Ltd. Biometrics Data Link DLK900) was used to integrate the data from the electrogoniometers and EMG sensors with Observer, enabling a common time line to be attached to the data. Additional channels, for example for more EMG sensors or postures, are easily accommodated through the module. A thumb switch with the Datalink module, activated in front of the video at the start of the task, inserted a marker in the data file enabling synchronization of the time line of the data file with the video recordings.

2.2.2 *Observer software*

Observer XT software is routinely used in animal behavior and ergonomics usability research where event based activities can be studied through codification of video recordings. In this case the software was used to link behaviour occurrences (task elements) from video recordings to an external data set (posture and EMG data). The software interface comprises a video window, a behaviour definition pane, and event log on a time line, and a graph of the external data (Figure 1). In preparation for the video coding, the raw data files from the Biometrics Datalink system were modified manually in Microsoft Excel to include a column with a time-line based on the sampling frequency of the data streams. EMG data were converted to % MVC values in the modified file in Microsoft Excel. Hence the modified data file included a time-line with three separate channels of EMG data (as %MVC) and one column with the wrist flexion/extension posture data. The modified data file was loaded into the software as an external data source at the start of the evaluation. Both the external data file and the video recordings were synchronized by manually stepping both to the thumb switch marker point datum when it appeared on the screen. The user enters the behaviors to be studied (task elements) and then subsequently steps through the video recording coding the start and end points. The output is a file with the original (external) data accompanied with each task element occurrence.

[Figure 2 about here]

2.3 Patient care simulator

Medical device companies routinely use simulations of medical procedures to perform prototype testing. In this case a gastro intestinal tract simulator, an EUS Scope (used to feed the EUS devices) and the EUS needle with handle were used. The simulator comprised a manikin head with throat and gastrointestinal tract. Simulated sampling of a stomach wall biopsy was performed on an apple at the end of the tract. This involved aspiration of the needle in the EUS device once in position. The equipment was setup to closely resemble use by physicians in the theater. A laptop was used to display the image from the endoscope camera (Figure 3)

[Figure 3 about here]

2.4 Subjective evaluation

The Kuijt- Evers et al. (2007) handle comfort questionnaire was used to obtain user feedback on design and perception aspects of the device. In total eighteen questions are answered on a scale of 1 “Totally disagree” to 7 “Totally agree”. The questionnaire asks the user to make ratings on aspects such as size, functionality, ease of use, force transition, professional impression and hand device contact. The full list of questions is contained in Figure 4.

2.5 Procedure

At the start of testing, the participants gave their informed consent and none reported recent upper limb musculoskeletal disorder. The EMG sensors and electrogoniometers were attached as per the manufacturer’s instructions. Reference isometric maximal wrist flexion and wrist flexion contractions were recorded to determine the maximal electrical activity corresponding to the Maximum Voluntary Contraction (MVC) of the muscles studied.

Participants were trained in the use of the device and they performed at minimum ten practice trials. For testing, each participant performed five trials and they completed the handle evaluation questionnaire after the last trial.

3. Case study on application to EUS needle device evaluation

3.1 Participant and product details

Eight right-handed and two left-handed novice participants performed five simulated biopsy sampling trials with the EUS biopsy sampling device. The EUS needle device involved using a two finger tip pinch type grip, as in using a large syringe, to aspirate the needle. The task involved inserting the EUS needle through the endoscope to take a biopsy sample. Task analysis of the video recordings identified seven task elements (Table 4).

The device tested is commercially available but as the trials were not performed by physicians who are expected to have specific techniques and skills, the results are not generalisable for clinical use without further validation. Therefore the product brand and model are not reported. However, the results are indicative of the data which can be obtained using the approach and the subsequent discussion demonstrates how it could be interpreted for design purposes.

[Table 4 about here]

3.2 Physical interaction

Average wrist posture and peak muscle forces by task element averaged across the participants are presented in Table 5. The table includes the evaluation by task element of the wrist postures using the Drury posture zones and of the muscle forces using the ACGIH HAL method. As the participants were surrogates they had, as such, no previous skills or techniques in performing the procedure so their pace is assumed to be unrepresentative of that of a physician. Shergill et al. (2009b) made HAL ratings of 4 for colonoscopy work in a theater and this rating will be assumed to be indicative of the pace of such work in a clinical setting.

[Table 5 about here]

Average wrist postures across the tasks elements ranged from 33⁰ extension for Advancing the Stylet to 46⁰ extension for Advancing the Needle. Hence all task elements involved extension with no flexion. For each of the seven tasks elements the

wrist extension postures were rated as Zone 2 (moderate exposure to risk due to wrist posture).

For muscle force, Tasks 1 and 7 exceeded the TLV for two muscles, while two of the task elements exceeded the TLV for one muscle. For three of the task elements one of the muscle peak forces was below the Action Limit (Task 3 FCU, Task 4 ECU & Task 6 FCU). The remaining task elements were rated between the Action Limit and TLV. By task elements, the findings were as follows. For Task 1 Feeding the device the peak forces for the FCU was 41% MVC (between the AL and TLV) while the forces for the ECU was 53% and the ECRB were 48% (above the TLV). For Task 2 Loosening the Thumbscrew, peak forces in the FCU and ECU were between the limits (43% & 37%), while the peak forces for the ECRB were above the TLV (48%). For Task 5 Pulling Back the Handle, peak force in the ECRB was 54%. Task element Task 3 forces were not as high. The FCU forces were below the Action Limit (28%) while the forces for the ECU and ECRB were between the limits (38% & 36%). Similar general findings were observed for Task 4. Pulling back the handle (Task 5) had two muscles rated between the limits (FCU 38% & ECU 45%) but the ECRB was considerably above the TLV at 54%. Tightening the Thumbscrew (Task 6) involved lower forces for the FCU (36% <AL) and forces between the Action Limit and TLV for the ECU (39%) and the ECRB (46%). As with Task 1, Task 7 forces for two muscle were above the TLV (FCU 55% and ECRB 67%) and one muscle was rated between the limits (ECU 48%).

The general findings were that for Task 1 the wrist extensor forces were above the TLV but for Task 7 both the flexor and one extensor were above the TLV. Of the remaining task elements, Tasks 3 & 4 extensor muscle forces were between the limits but for Tasks 2,5 & 6 both the flexor and one extensor were between the limits.

3.3 Handle questionnaire ratings

The minimum, mean and maximum handle ratings for each of the eighteen parts of the questionnaire are presented in Figure 4. The range of values varied considerably between the ten participants, but that is not unexpected. Explanations for these differences could include, but not be limited to, physical interaction differences in for

example hand anthropometrics and strength, and differences in cognitive aspects, such as inter individual differences in perception of pain and discomfort.

The average ratings for questions 1 through 8 ranged between 3 and 5. The highest average score was for “Looks professional” at 5.1. The lowest average ratings were for “Causes inflamed skin” (2.0) “Causes peak pressures” (2.4) and “Causes blisters” (2.5). Average ratings for “Causes numbness and lack of tactile feeling on hand” was 2.2 and “Causes cramped muscles” was 2.5.

[Figure 4 about here]

3.4 Case study findings

The posture and force data provide very specific information on physically stressful aspects of the task. For example it was clear that for all steps there was a lot of wrist extension (rated as zone 2 moderate risk). In essence the device handle design when used with the endscope dictated the use of an extended wrist for each task element. In deviated postures grip force is lower and hence a higher amount of muscle effort is required to generate the same external force. Furthermore, a greater relative (%MVC) force of exertion compromises precision.

The muscle forces were considerably higher (and above the TLVs for two muscles) for specific task elements, namely Tasks 1 and 7, and this was due to the lateral pinch used to feed and retract the device. Tasks 2 and 5 involved a combination of 1 muscle peak force above the TLV and 2 between the limits. For Task 2 this was most likely due to the pinch and turning forces required to loosen the thumbscrew (c. 8mmn diameter) from the tight position, whereas for Task 5 this was due to the forces required to pull back the handle to aspirate the needle. The remaining task elements contained a mix of forces between the action limit and the TLV, and these can be related also to design aspects. While they are conditionally acceptable, it is preferable that they too are reduced at the design stage to lower the risk of injury and so the physician can apply higher precision.

The handle comfort questionnaire data support the posture and force data. Many of the questions were rated between 3 and 5 indicating design improvement for those factors i.e. ratings closer to 7 for questions 1-11 and ratings closer to 1 for questions 12-18. These ratings, while not particularly severe, do indicate that long term use may lead to problems such as discomfort. Possibly the most informative dimensions from the questionnaire for medical device handles relate to size, ease of use, and details on acceptability of forces and force transition. Trials with physicians and product designers are necessary to test and refine the questionnaire for use on medical devices.

4. Conclusions

Few commercial solutions to task analysis based upper limb ergonomics assessment are available to the ergonomist and this precludes a more widespread use of detailed ergonomics evaluations of medical products at the design stage. This approach used Observer software to simultaneously log multiple data streams from separate devices (EMG and electrogoniometers) with video recordings. In the present study one wrist posture (flexion/extension) any three muscles were studied. But for different products and applications it may well be desirable to include more postures, such as radial/ulnar deviation and supination/pronation. In addition, for some products or for more complex medical procedures, it may be desirable to study more muscles than in the current study to elicit more information on musculoskeletal loading. The method has flexibility to add up to a total of eight posture or EMG data channels (each plane of posture movement is one channel, e.g. flexion/extension).

The Observer XT software package is mainly associated with collecting and analyzing data from video recordings in observational studies. On this basis it lends itself to task analysis of video recordings of simulated trials in ergonomics. In the analysis the software was used to determine the task elements (events on a time line) and this facilitated the analysis of the data streams by individual task element. At the analysis stage the user could also add additional event options, such as grip types used or observer/participant comments. Combining this software with multiple data streams from Biometrics sensors and the Datalink system permitted the measurement of force and wrist posture separately for each subtask, and this is of particular benefit

in performing assessment of specific features of products for specific parts of tasks, as demonstrated in the case study. It should however be mentioned that the use of the software in this manner is time consuming and not practical for infrequent add-hoc use. The main delay is due to manual extraction of data for individual task elements. Software code could possibly be written to automate this.

The Kuijt- Evers et al. (2007) handle comfort questionnaire was a useful method of surveying users perception of the physical interaction with the device. Rephrasing of some of the questions is recommended for use with professionals, e.g. use “device” instead of “tool”. Some of the questions may be redundant if the trials are of only a short duration. For example, “causes blisters” is unlikely to yield much design information if the devices are only used for very short duration trials

It was necessary to develop and test this approach in the laboratory environment in advance of testing on real users’ in real environments, either simulated or with patients. The next phase of this work necessitates validity testing with physicians performing procedures with patient care simulators in advance of testing with real patients. During that phase emphasis will be placed on the validity of the musculo skeletal strain data collected in addition to the validity of the method in conveying specific ergonomics information for use by biomedical product designers.

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5. References

- American Conference of Governmental Industrial Hygienists, 2000, Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, Cincinnati, ACGIH.
- American Society for Gastrointestinal Endoscopy, 2010, Minimizing occupational hazards in endoscopy: personal protective equipment, radiation safety and ergonomics, Technology Status Evaluation Report, 72, 227-235.
- Botney, R., Privitera, M.B., Berguer, R. and Radwin, R.G., 2011, Hand Tool Design, in Handbook of Human Factors in Medical Device Design, eds M. Weinger, M. Wiklund, and D.J. Gardner-Bonneau, CRC Press, Boca Raton.
- Buckle, P., Clarkson, P.J., Coleman, R., Ward, J. Anderson, J., 2006. Patient safety, systems design and ergonomics. *Applied Ergonomics* 37, 491-500.
- Buschbacher, R. 1994, Overuse syndromes among endoscopists, *Endoscopy*, 26:539-44.
- Cappell, M., 2006, Conoscipist's thumb: Dequervains's syndrome associated with overuse during endoscopy, *Gastrointestinal Endoscopy*, 54, 841-843
- DeFrances C.J. and Hall M.J., 2007, National Hospital Discharge Survey. Advance data from vital and health statistics; no 385. Hyattsville, MD: National Center for Health Statistics.
- Drury, C.G., 1987, A biomechanical evaluation of the repetitive motion injury potential of industrial jobs, *Seminars in Occupational Medicine*, 2, 41- 49.
- Evans, A., Vaughan, R.S., Hall, J.E., Mecklenburgh, J. and Wilkes, A.R., 2003, A comparison of the forces exerted during laryngoscopy using disposable and non-disposable laryngoscope blades, *Anaesthesia*, 58, 869-873.
- Figueredo, S.L., Brugge, W.R., and Slocum, A.H., 2007. Design of an Endoscopic Biopsy Needle with Flexural Members. *Journal of Medical Devices* 1: 62-69.
- Hansel, S.L., Crowell, M.D., Pardi., D.S. and Bouras., E., 2009, Prevalence and Impact of musculoskeletal injury among endoscopists: a controlled study, *Journal of Clinical Gastroenterology*, 43, 399-404.
- International Standards Office, 1999, BS ISO 13407, Human-centred design processes for interactive systems, Brussels.
- International Standards Office, 2001, BS ISO EN1005 Safety of Machinery- Human Physical Performance, Brussels.
- International Standards Office, 2007: BS ISO 11228-3 Ergonomics - Manual handling - Part 3: Handling of low loads at high Frequency, Brussels.
- Keate, R., Drden, G.W., Wang, K., 2006, Occupational injuries to endoscopists:
- Kuijt-Evers, L.F.M., Vink, P., de Looze, M.P., 2007. Comfort predictors for different kinds of hand tools: Differences and similarities. *International Journal of Industrial Ergonomics* 37, 73-84.
- Martin J. L., Norris B. J., Murphy E., Crowe J. A., 2008. Medical device development: The challenge for ergonomics. *Applied Ergonomics* 39, 271-283.
- McAtamney. L. and Corlett, E.N., 1993, RULA: A survey method for the investigation of work related upper limb disorders, *Applied Ergonomics*, 24,91-99.
- National Research Council and the Institute of Medicine, 2001, Musculoskeletal Disorders and the Workplace, National Academy Press, Washington DC.

- NIOSH. 1997, Musculoskeletal Disorders and Workplace Factors: A Critical Review of Epidemiological Evidence for Work-Related Musculoskeletal Disorders of the Neck, Upper Extremity, and Low Back, 2nd Ed., Publication No. 97-141, U.S. Department of Health and Human Services, OH.
- Occhipinti E., 1998. *OCRA: A concise index for the assessment of exposure to repetitive movements of the upper limbs*. Ergonomics 41,9; 1290-1311.
report from the ASGE Web Survey. Gastrointestinal Endoscopy , 63,AB111.
- SENIAM, 1999, European Recommendations for Surface ElectroMyoGraphy, Roessingh Research and Development, Enschede, The Netherlands
- Shergill, A., McQuaid, K.R. and Rempel., D., 2009a, Ergonomics and GI endoscopy, Gastrointestinal Endoscopy, 70, 145-153.
- Shergill, A.K., Asundi, K.R., Barr, A., Shah., J.N., Ryan, J.C., McQuaid, K.R. and Rempel, D., 2009b, Pinch force and forearm-muscle load during routine colonoscopy: a pilot study. Gastrointestinal Endoscopy, 69, 142-6.
- Siegel, 2007, J.H., Risk of repetitive use syndromes and musculoskeletal injuries, Techniques in Gastrointestinal Endoscopy, 9, 200-204.
- Wallace M.B., Hawes R.H., 2001. Endoscopic ultrasound in the evaluation and treatment of chronic pancreatitis. Pancreas 23: 26-35.

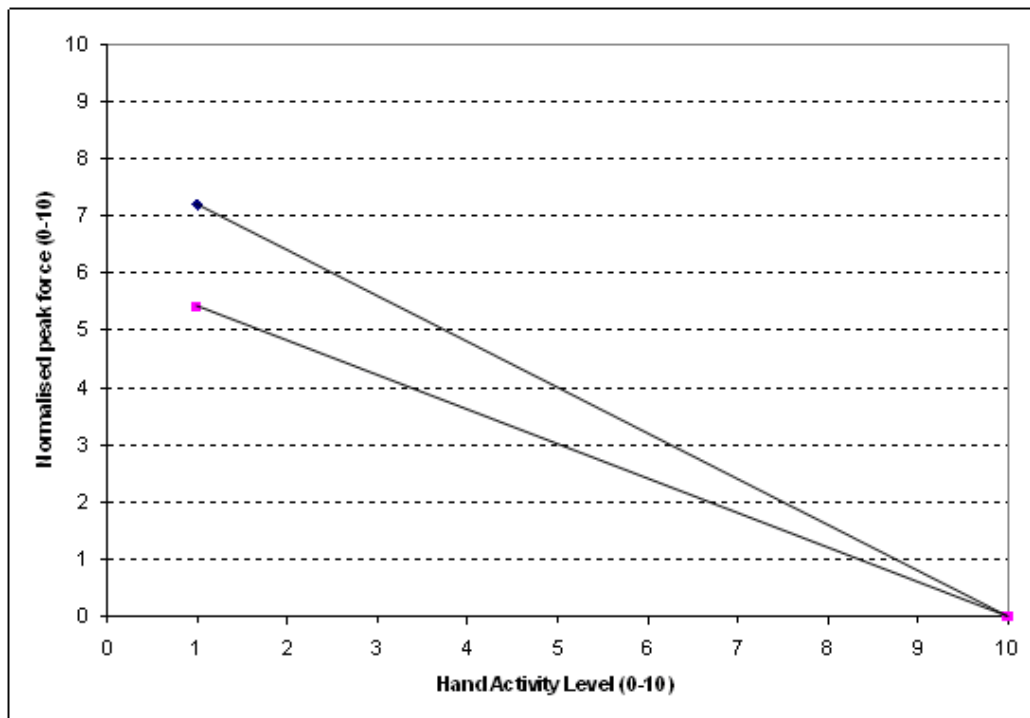


Figure 1 Hand Activity Threshold Limits (ACGIH, 2000)

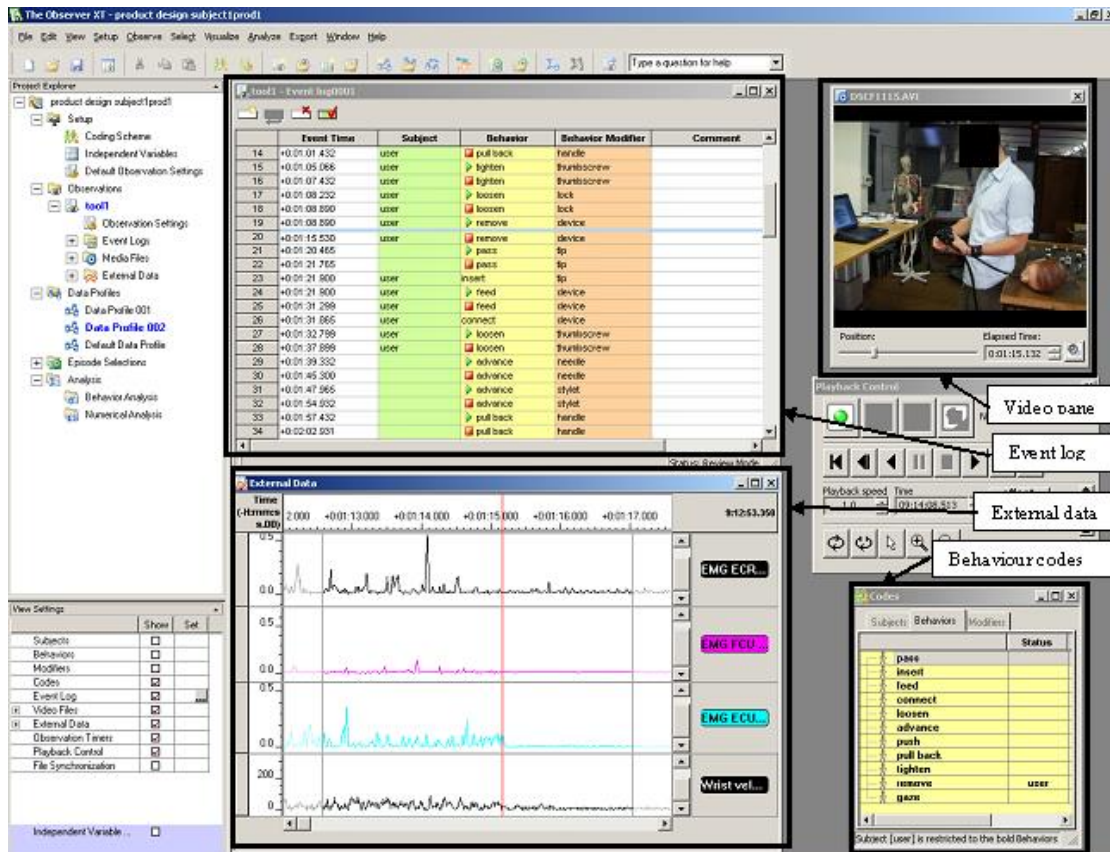


Figure 2 Observer software interface

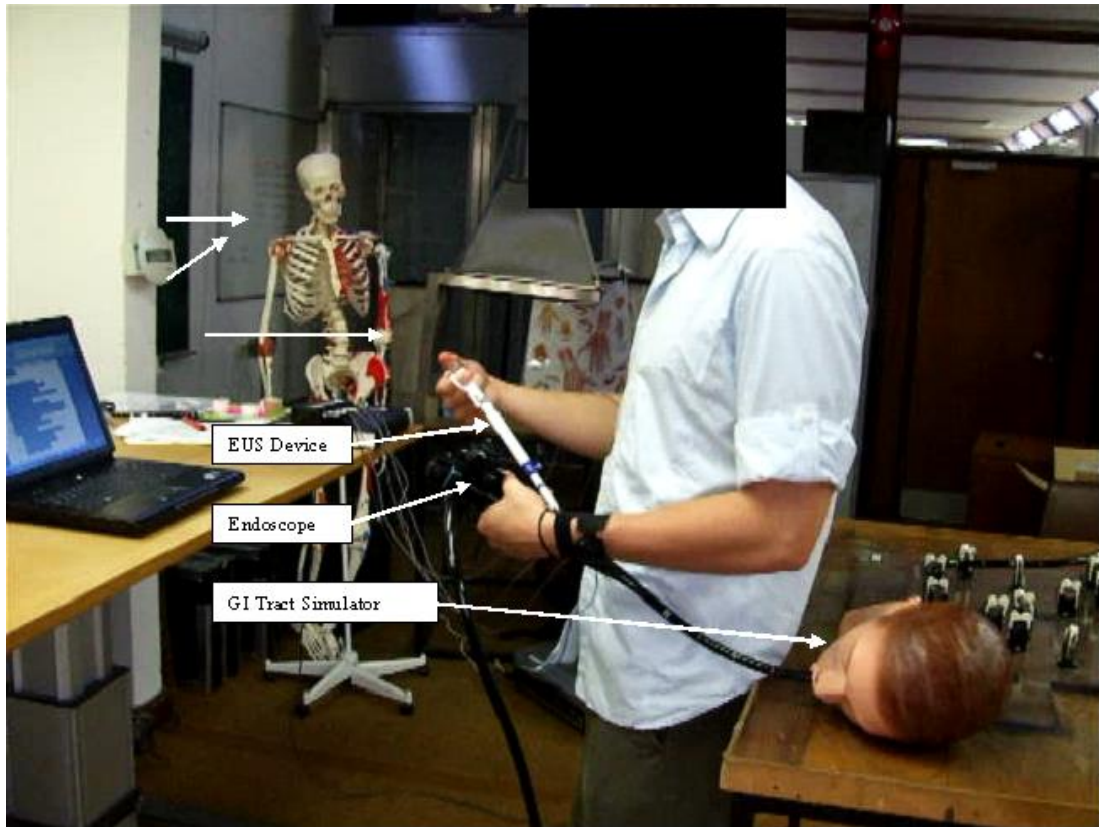


Figure 3 Participant holding using the device with the gastrointestinal tract simulator

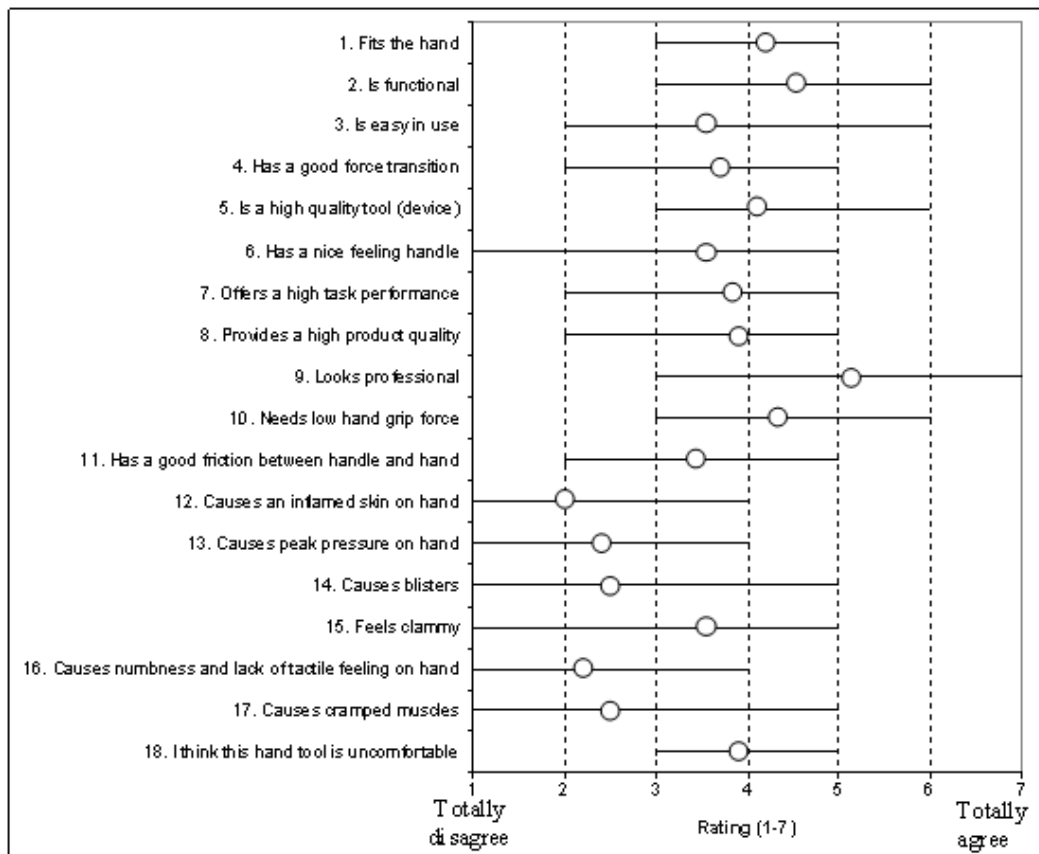


Figure 4 Hand tool questionnaire ratings (minimum, mean and maximum)

Table 1 The American Conference of Governmental Industrial Hygienists Hand Activity Level (HAL) rating scale (ACGIH, 2000)

0	2	4	6	8	10
Hands idle most of the time; no regular exertions	Consistent conspicuous long pauses; or very slow motions	Slow steady motion/exertion; frequent brief pauses	Steady motion/exertion; infrequent pauses	Rapid steady motion/exertion infrequent pauses	Rapid steady motion or exertion; difficulty keeping up.

Table 2 ACGIH TLV and Action Limits as interpreted by BS ISO 11228-3

Hand Activity Level	1	2	3	4	5	6	7	8	9	10
Normalised peak force: TLV	7.2	6.4	5.6	4.8	4.0	3.2	2.4	1.6	0.8	0.0
Normalised peak force: Action Limit	5.4	4.8	4.2	3.6	3.0	2.4	1.8	1.2	0.6	0.0

Table 3 Drury zones for wrist postures (degrees)

Wrist posture	Zone 0	Zone 1	Zone 2	Zone 3
Flexion	0-9	9-23	23-45	45+
Extension	0-10	10-25	25-50	50+
Radial deviation	0-3	3-7	7-14	14+
Ulnar deviation	0-5	5-12	12-24	24+

Table 4 Simulated task elements

Task	Description
1	Feed the device into scope
2	Loosen thumbscrew on the handle (to advance the needle)
3	Advance needle while looking at screen area
4	Advance stylet to aspirate a sample
5	Pull back handle (after aspirating a sample)
6	Tighten thumbscrew at base of handle
7	Remove device from the scope

Table 5 Wrist postures and upper limb muscle peak forces with evaluations by task element

Task Element	Parameter (Wrist posture & MVC)	Posture (degrees) / force values (% MVC)	Posture rating	ACGIH TLV rating
1 Feed device	Wrist extension	41 ⁰	Zone 2	
	FCU	41%		> AL & < TLV
	ECU	53%		> TLV
	ECRB	48%		> TLV
2 Loosen thumbscrew	Wrist extension	39 ⁰	Zone 2	
	FCU	43%		> AL & < TLV
	ECU	37%		> AL & < TLV
	ECRB	48%		> TLV
3 Advance needle	Wrist extension	46 ⁰	Zone 2	
	FCU	28%		< AL
	ECU	38%		> AL & < TLV
	ECRB	36%		> AL & < TLV
4 Advance stylet	Wrist extension	33 ⁰	Zone 2	
	FCU	37%		> AL & < TLV
	ECU	35%		< AL
	ECRB	42%		> AL & < TLV
5 Pull back handle	Wrist extension	45 ⁰	Zone 2	
	FCU	38%		> AL & < TLV
	ECU	45%		> AL & < TLV
	ECRB	54%		> TLV
6 Tighten thumbscrew	Wrist extension	34 ⁰	Zone 2	
	FCU	36%		< AL
	ECU	39%		> AL & < TLV
	ECRB	46%		> AL & < TLV
7 Remove device	Wrist extension	39 ⁰	Zone 2	
	FCU	55%		> TLV
	ECU	48%		> AL & < TLV
	ECRB	67%		> TLV

ACGIH: American Conference of Governmental Industrial Hygienists

TLV: Threshold Limit Value

AL: Action Limit

FCU: Flexor Carpi Ulnaris

ECU: Extensor Carpi Ulnaris

ECRB: Extensor Carpi Radialis Brevis

% MVC = % Maximum Voluntary Contraction

