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# **Evaluation of the effect of medical gloves on dexterity and tactile sensibility using simulated clinical practice tests**

Peter Mylon<sup>1</sup>, Roger Lewis<sup>1</sup>, Matt J Carré<sup>1</sup>, Nicolas Martin<sup>2</sup>

<sup>1</sup>Department of Mechanical Engineering, The University of Sheffield, UK

<sup>2</sup>School of Clinical Dentistry, University of Sheffield, UK

## **Corresponding Author**

Peter Mylon, Eurolens Research, The University of Manchester, Carys Bannister Building, Room 1.017, Dover Street, Manchester, UK, M13 9PL.

Email: [peter.mylon@manchester.ac.uk](mailto:peter.mylon@manchester.ac.uk) Tel: +44 161 275 5574

# **Evaluation of the effect of medical gloves on dexterity and tactile sensibility using simulated clinical practice tests**

## **Abstract**

Understanding the effect of medical gloves on manual performance is critical for improving glove design and mitigating the impediment to surgical performance caused by gloves. Existing test methods do not correspond well with clinical and surgical tasks. Based on interviews with clinicians, two new tests were proposed: locating a pulse in a simulated blood vessel, and placing and tying sutures in simulated tissue. A pilot study was carried out using 19 clinicians employed at Sheffield Teaching Hospitals. Subjects performed each test three times, with latex and nitrile examination gloves, and without gloves, the order being randomised. In addition to objective test scores, subjects' perception of their relative performance in each condition was recorded. In the Pulse Location Test, performance was found to be significantly better without gloves, while differences between gloves were not statistically significant. Perceived performance correlated well with measured performance. In the Suturing Test, no statistically significant performance differences were found between the three hand conditions, although subjects perceived ungloved performance to be significantly better than with either the latex or nitrile gloves. The Pulse Location Test showed promise as a clinical performance evaluation tool, and could be used to improve medical glove design for better tactile performance. The discrepancy between subjects' perceived and measured performance in the Suturing Test needs further investigation to determine whether the perceived differences translate into genuine clinical performance differences that were not able to be measured using the current method, or whether the difference is purely psychological.

*Relevance to Industry:* The test methods outlined will allow manufacturers to understand the effect of gloves and glove properties on manual performance in medical tasks and improve the design accordingly. Reducing the inhibiting effect of gloves will improve safety and reduce the need to remove gloves for clinical tasks.

## Highlights

- Two new tests simulating clinical tasks (pulse location and suturing) are proposed.
- They are used to assess performance of medical gloves against ungloved performance.
- Latex and nitrile gloves significantly reduced performance in the pulse location test, in agreement with user perceptions.
- Suturing performance was perceived to be better without gloves.
- However, gloves did not have a significant effect on suturing speed.

## Keywords

Tactile sensation, dexterity, medical examination, gloves, surgery, product test

## 1. Introduction

The primary function of medical gloves is to prevent the transmission of pathogens between clinicians and patients. Therefore, the main consideration in glove design and evaluation has rightly been barrier integrity – the ability of the glove to remain intact during use (BSi, 2000) – as well as the obvious need to minimise cost. More recently, the allergenic properties of the glove have also been a significant consideration and have led to major changes in glove properties (NHS Plus, 2008). However, the effect of the gloves on manual performance, i.e. dexterity and cutaneous sensibility, has only recently begun to be explored. Outside of the medical field, glove effects on performance have been studied for a number of years, since it is recognised that manual performance has an impact on both safety and efficiency. Early studies focused on thick gloves for cold weather (Griffin, 1944) or chemical protection (Robinette, Ervin, & Zehner, 1986), which tend to cause substantial reductions in manual performance. However, in clinical situations, where manual errors could lead to injury or increased time in surgery, for example, small differences in manual performance may be significant in terms of safety and efficiency.

A number of recent studies (Johnson et al., 2013; Shih, Vasarhelyi, Dubrowski, & Carnahan, 2001) have attempted to quantify the finer effects of medical gloves on clinical performance. However, these studies have generally been limited to test methods such as the Purdue Pegboard Test and the Semmes-Weinstein Monofilaments that assess general manual ability (of industrial job applicants or those with sensorimotor deficiencies, for example) rather than performance in a clinical context.

In order to understand and quantify the effect of gloves on clinical performance, it is necessary either to evaluate the gloves within a clinical environment, or to establish that performance measures used in the laboratory adequately replicate the requirements of clinical practice. The difficulty with evaluating gloves in clinical practice is in creating a repeatable, objective measure of performance, since every case varies, even when performing a routine task. It also introduces a number of ethical issues that would make large-scale evaluation of glove properties and performance very difficult. For this reason, clinical studies of manual performance have generally been restricted to subjective assessments (e.g., Chua, Taylor, & Bagg, 1996), which are limited in their ability to inform design for better performance.

If laboratory tests can be shown to reproduce the manual performance requirements of clinical practice, they offer a more practical solution in which glove properties could quickly and safely be varied and the effects on performance usefully assessed. In order to determine the elements of manual performance most relevant to clinical practice, a study of clinicians (Mylon, Lewis, Carré, Martin, & Brown, 2014) was conducted, in which they were asked to identify the clinical tasks they performed that required most dexterity and tactile sensibility, and those that were most adversely affected by gloves.

An evaluation of existing tests (Mylon, Carré, Lewis, & Martin, 2011) relevant to medical glove design found that the manual performance required for some of the tasks mentioned (particularly a number of orthopaedic tasks that involve inserting or removing pins

and screws) is adequately simulated by tests such as the Bennett Hand-Tool Test (Bennett, 1965) and the Crawford Small-Parts Dexterity Test (Crawford & Crawford, 1956). However, two of the tasks most commonly perceived as being adversely affected by gloves in the study of clinicians (Mylon, et al., 2014) were: location and palpation of blood vessels for the purpose of cannulating, taking blood or measuring a pulse; and suturing, including knot-tying. Neither of these are well simulated by existing tests.

Two new test methods were therefore proposed for evaluating the effect of gloves on manual performance in clinical practice. The first was to be based around the location of a pulse in a simulated blood vessel, while the second would involve placing and tying sutures in simulated tissue.

## **2. Simulated Pulse Location Test development**

Cannulating involves palpating vessels to determine the quality of the vein (does it bounce, does it drain normally?) and whether it pulsates (i.e., is it a vein or an artery?), and inserting a needle into the vessel. The task involves tactility (both through the fingers and through the needle), dexterity, and active haptic sensing (the use of sensors in muscles, tendons and joints). Official teaching (e.g., Ronis, 2008) tells medical students to don gloves after initial palpation of the vessel, but many practitioners perform the whole procedure without gloves because they cannot feel the vessel or the pulse (Mylon, et al., 2014), thus increasing the risk of bloodborne infections being transmitted. Reducing the impact of gloves on the performance of such tasks, particularly on cutaneous sensibility, is therefore critical to improving compliance with universal precautions.

Any test to assess the effect of gloves on location and palpation of blood vessels would need to involve hidden pressurised vessels, preferably with the ability to pulsate the fluid. Such an apparatus has been designed for training purposes and initial examination suggested that the concept could be replicated in the lab using a simplified rig.

## 2.1. Study of existing technology

The heart pumps blood around the body by peristalsis – the contraction of the muscles in a wave that forces the blood around the system. The pressure in the system increases when the left ventricle contracts to pump blood out (this higher pressure is known as the ‘systolic pressure’) and decreases when the right ventricle relaxes to allow blood back in (this lower pressure is known as the ‘diastolic pressure’). The difference between these two pressures is known as the ‘pulse pressure’. Because of the elastic nature of blood vessels, this variation in pressure results in a variation in diameter of the vessels, which is what is felt as a pulse in the arm.

Training equipment has been designed to allow medical trainees to practise palpating the pulse and drawing blood samples. A Life/form Arterial Puncture Arm (Nasco, Fort Atkinson, WI) was examined to determine how the pulse was created. The pulse simulation equipment consists of latex tubes which are filled with liquid. At each end is a reservoir. After the tubes are filled, one end is clamped off, and a squeeze bulb is used to create a pressure pulse. The tubes sit in grooves in the polymeric core of the arm which means the pulse cannot be felt except for at two designated locations where the firm polymer is replaced with low density foam that squashes on palpation, allowing the pulse to be felt.

While this is an effective training tool, it has some limitations as far as testing is concerned. Since the location of the pulse cannot be varied, the participant will know after the first attempt where to expect the pulse. This makes it much easier to detect, and makes verification of detection harder. Furthermore, the squeeze bulb does not allow accurate, controlled variation of the pulse pressure, which is necessary to find the threshold of detection for a given hand condition.

To overcome these problems, a new design was proposed in which the pulse could be sent through any one of a number of ‘vessels’, and in which the pulse pressure and rate could

be controlled. For consistency of flow, it was proposed to use a peristaltic pump (EYELA Micro-Tube Pump MP3) to create the pulse.

## **2.2. Final apparatus**

The final test apparatus can be seen in Figure 1. The artificial vessels are made from latex tubing, which is flexible enough to cause palpable changes in diameter with pressure changes. The diameter was chosen to match the existing Arterial Puncture Arm, but is also close to the diameter and thickness of the radial artery (Adbdulahad, 2006). The tubes sit in v-section grooves cut into a block of low-density rigid polystyrene foam, so that they just protrude above the surface. The tubes are then covered in a 1.5mm sheet of neoprene sponge, which was chosen for its low stiffness that gives more of a flesh-like feel than stiffer rubbers such as silicone or vinyl (used in the Arterial Puncture Arm) and allows enough compression to feel the vessels beneath it.

A case was constructed from medium-density fibreboard (MDF) through which the latex tubes are fed from the peristaltic pump via a five-way ball valve switch, which allows the pulse to be directed down any of the five vessels individually. After passing through the foam, the tubes are clamped through a flexible plate which is bolted to the casing and allows each tube to be opened and closed individually (Figure 1). An aluminium lid was manufactured to hide the workings (where fluid flow could be seen) from the subject, and to improve the aesthetics. The five-way switch was connected to the peristaltic pump via a stiffer plastic tube. To set up the apparatus, the cover and rubber sponge sheet were removed, all five valves were opened and the system was filled with water from the pump end (by placing the loose tube end in a jar). The clamp was released and water was allowed to flow through the 'vessels' until a steady flow was achieved and no bubbles could be observed in the tubes. The clamp was then tightened and the pump end clamped with a plastic crimp to seal the system. The lid and neoprene sponge sheet were replaced.

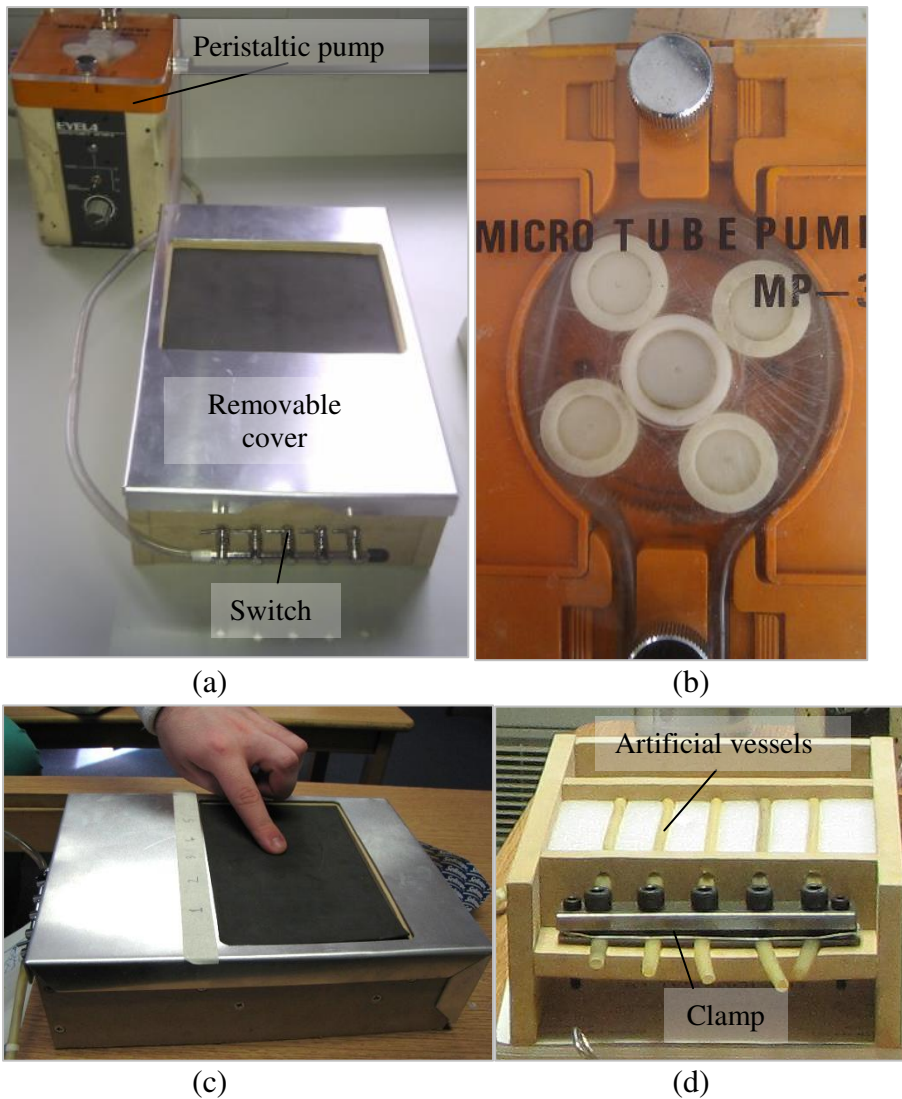


Figure 1. Pulse Location Test: (a) with cover; (b) pump configuration; (c) location technique; (d) cover removed

*Calibration.* The aim of the test was to simulate as closely as possible the feel of a human pulse. The pump motor speed could be varied, and the number of pulses per revolution could be altered by changing the number of cogs that squeeze the tube (Figure 1). This had the additional effect of changing the pulse pressure, which could also be varied by screwing in the two halves that formed the outer walls of the pump, thus increasing the constriction of the tubes by the cogs.

The pulse rate was set to approximately 90 bpm, which falls within the range of normal pulse rates for adults at rest (Zieve, Eltz, & Vorvick, 2012). Experiments were then carried out to determine the range of pulse pressures that could be achieved. It was found that

adjusting the screws did not give a satisfactory range of pressures – the adjustment was very fine and within half a turn the pulse could go from fairly strong to non-existent. This would not allow for measuring the threshold pressure at which a pulse could be detected.

*New pressure adjustment system.* A number of possibilities for providing pressure adjustment were explored, but the only one that was found to be viable was a method based on changing the volume of fluid in the system. The clamps at each end of the tubes ensure that the system is closed, i.e., there is no fluid flow in or out. This means that when the peristaltic pump squeezes the tube, it simply compresses the fluid down the line, which creates a temporary pressure increase that is relieved when the cog runs off the tube. This pressure increase is felt as a pulse, the strength of which depends on the amount of compression of the fluid. Thus, for a given stroke volume, decreasing the volume of fluid in the system will increase the pulse pressure.

The variation in fluid volume was achieved by attaching a length of the latex tubing to the end of the five-way switch. The tube was marked with tape at 11 locations, 45mm apart. To set the pressure, the tube was pinched at a mark using thumb and forefinger. The apparatus can be seen in Figure 2.

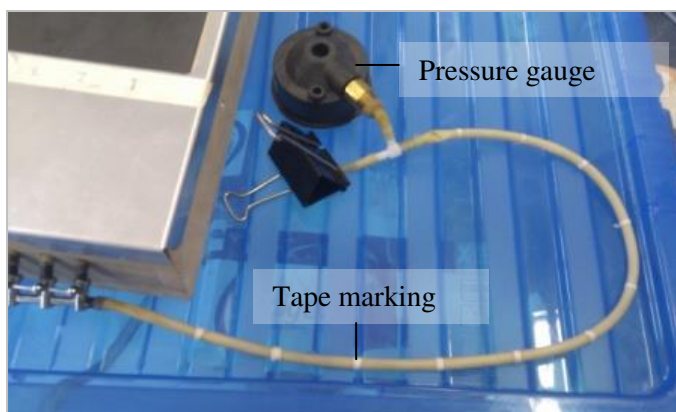


Figure 2. Pressure adjustment mechanism for Pulse Location Test

Attempts were made to measure the pressure using a 60in.H<sub>2</sub>O gauge, attached as shown in Figure 2, but the fluctuations were too high, and even with the pump turned off, the gauge did not seem to read a consistent pressure. This is something that would be worth

exploring if the test is developed further to enable quantification of the pressure threshold. It was discovered during preliminary testing that while the tube provided enough volume change to differentiate between gloved and ungloved threshold, variation between candidates was larger. It was therefore necessary to calibrate the starting pressure by adjusting the screws as described so that the candidate could definitely feel the pulse at the highest pressure and definitely not feel it at the lowest pressure. The calibration was done ungloved as the expected most-sensitive condition, making sure that the highest pressure was some way above the threshold to allow for loss of sensation with gloves.

### **3. Suturing Test development**

#### **3.1. Research and apparatus selection**

Gnanaswaran et al. (2008) designed a suturing task in which the time taken for subjects to stitch a circular pattern on a plastic sheet with latex and vinyl examination gloves was compared to bare-handed performance. However, results showed no significant effect of hand condition (gloved or ungloved, glove type) on completion time. Furthermore, the plastic sheet does not replicate the properties of human tissue well.

For knot-tying practice alone, Bishu et al. (1993) designed a test using different sizes of rope. They found that gloved performance was much worse than bare-handed, but that there was no significant difference between gloves or between rope sizes. Similar tests are used to train surgeons. These involve threading suture material through a magnetic weight and tying a knot while attempting not to lift the weight from the surface of the rig (simulating the need to avoid tearing tissue in a real operation). This adds a level of realism to the task, but is a fairly expensive arrangement.

Simulation of surgical suturing, including knot-tying, is used in training of medical or dental students. The Basic Surgical Skills course of the Royal College of Surgeons uses a multi-layered skin pad (Limbs & Things, 2012) that aims to replicate the elastic properties of

the epidermis, dermis and fat layer. It has also been used in surgical skills testing (Khan, Bann, Darzi, & Butler, 2007). While this model is undoubtedly realistic, the unit cost is prohibitive for large-scale glove testing. Dubrowski et al. (2005) used an “artificial artery model resembling real tissue” to assess suturing ability, but no further details of the apparatus are given.

Other common and cheaper practice materials include orange or banana skins (RCS Medical Student Liaison Committee, 2009) and meat (University Hospitals of Leicester NHS Trust - Clinical Skills Unit), however these have the disadvantages of being messy and inconsistent in mechanical properties.

A simpler technique is used in the School of Dentistry at the University of Sheffield for training undergraduate dentists (Figure 3). A sheet of latex dental dam (a sheet placed in the mouth to prevent debris falling down the throat) is stretched over a plastic pot using a rubber band. The bottom of the pot can be attached to a fixed surface using sticky Velcro pads (Velcro Industries Inc., Willemstad, Netherlands Antilles) allowing limited movement to simulate real tissue operating conditions. An incision is then made in the dental dam and the student attempts to close the incision by suturing. Because of the cost considerations, and because medical professionals who had used the dental dam rig were satisfied that it constituted a fairly realistic simulation of surgical suturing, it was decided to use this apparatus for the glove testing.



Figure 3. Suturing test

### 3.2. Procedure design

Suturing requires three basic surgical tools: needle holders, tissue forceps and scissors, as well as the needle that is included in each pack of suture material. These are shown in Figure 4. A curved needle is generally used, which comes attached to a length of silk, nylon monofilament or other material. In basic suturing (suturing at depth is different), the needle is passed through the top of the tissue and out of the side of the opening. It is then passed through the other side and out the top. Tissue forceps are used to grasp the tissue when inserting the needle. The thread is then pulled through to leave a short amount protruding from the other side.

There are two basic suture patterns – continuous and interrupted. Continuous suturing is somewhat like conventional sewing, where the suture material is knotted only at the beginning and end of the opening, so that the suture material forms one continuous thread. In interrupted suturing, the suture is tied and cut after each pass across the opening, leaving a number of individually tied sutures. This requires more suture material than continuous suturing and takes more time.



*Figure 4.* Equipment used in suturing: (a) needle holders, (b) tissue forceps, (c) scissors and (d) curved needle

There are also two basic styles of knot-tying: instrument and hand tying (which can be one- or two-handed, but one-handed is most common). In instrument tying, needle holders are used to grasp and manipulate a curved needle, creating square knots (four per suture is standard practice). Tissue forceps may be required to manipulate the tissue. The suture is then trimmed using the scissors (usually by an assistant). In hand tying (one-handed), one end is held tight using a hand or needle holders, while the other hand manipulates the thread.

Hand tying requires more dexterity than instrument tying, takes longer and uses more suture material. Because of the complexity of hand tying, inexperienced surgeons tend to be more familiar with instrument tying. Since time, participants and suturing material were all limited, the instrument tying technique was selected for the testing. Interrupted sutures were preferred to continuous suturing as the knot-tying element of the task was thought to involve the most dexterity.

## **4. Methods**

### **4.1. Simulated Pulse Location Test procedure**

The subject was seated in front of the test, with the five-way switch facing away from them, hidden from view. After following the set-up and calibration procedures described in Section

2, the researcher selected a random 'vessel' for the first test (unseen by the subject). The valve connected to this vessel was left open while the other four were closed. The vessels had been numbered 1 - 5 for ease of identification. The pump was switched on and the researcher pinched and held the pressure adjustment tube at one of the marks (usually starting with the one closest to the switch). The subject was then asked to state the number of the vessel in which they could feel a pulse, if any.

The procedure for determining the pressure threshold was based on the Rapid Threshold Procedure™ (Weinstein, 2010) used in the Weinstein Enhanced Sensory Test, with a slight modification to save time. Each time the vessel number was correctly identified, the pressure was reduced to a lower mark; after an error or non-identification, the pressure was increased. The location of the pulse was then changed to one of the other four vessels, randomly selected, and the test repeated. The first mark at which both a successful and an unsuccessful attempt were made was taken as the 50% threshold pressure. The number of the division was recorded (1 being the closest to the switch and hence the highest pressure, 11 being the furthest and hence lowest).

#### **4.2. Suturing Test procedure**

A fresh sheet of dental dam was stretched over the pot, the tension being made as even as possible across the surface. Three incisions were made using a scalpel, each approximately 40 millimetres long and equally spaced around the pot. The pot was attached to a table using the Velcro® tabs. Because the location varied and was often improvised while participants waited to go into surgery, the height of the table and seat were not always ideal (for example a coffee table and sofa). The three instruments shown in Figure 4 were placed on the table along with a sachet containing a single Ethicon MERSILK, size 3-0, silk suture (Ethicon Endo-Surgery, Norderstedt, Germany).

Before the timer was started, the subjects were allowed to remove the suture and grasp it with the needle holders. They were instructed to place four interrupted sutures in one of the incisions using instrument tying, and were told that this would be timed, but asked to perform as they would in normal operating conditions. They were allowed to use as many 'throws' as they felt appropriate, but were asked to be consistent throughout the tests. The timer was started when they began the first suture and finished when the final suture was cut.

### **4.3. Experimental design**

*Subjects.* 19 volunteers took part in the tests. They were recruited from Sheffield Teaching Hospitals (STH) staff. Subjects were required to be generally healthy and have no known sensorimotor deficiencies and a basic ability to suture. This meant that all the subjects were practising doctors, ranging from House Officers with less than two years' experience to Consultants with more than twenty. Ten subjects were male and nine were female. All subjects were currently using nitrile examination gloves, and some had previously used latex ones.

*Gloves.* The gloves used were ambidextrous examination gloves: Finex PF™ latex and Finite P Indigo AF nitrile (POLYCOHealthcare, Enfield, UK). Nitrile examination gloves are widely used in hospitals, and are currently used throughout STH. The comparison with latex (which was previously the standard for medical practitioners) is one that many practitioners made in the interviews (Mylon, et al., 2014) and is therefore of interest.

*Variables.* The within-subjects factor in both tests was hand condition, consisting of three levels: 'No Gloves', 'Best-Fit Latex' and 'Best-Fit Nitrile'.

*Glove selection.* Examination gloves are available in five sizes, from Extra-Small to Extra-Large. The subjects were allowed to choose the size of glove that fitted them best, usually the size they used on a regular basis. One subject used a larger size for the nitrile

gloves as they found their usual size too tight, but the remainder used the same size for both glove types.

*Statistical design.* The limiting factor in the design of the test session was the time available with doctors. Initial consultation with the STH local contact (a general surgeon) suggested that the maximum time staff could be expected to give during work time (when recruitment would be easiest) would be 15-20 minutes. There was therefore no time to allow some opportunity to practise before recording the results. The order of the three hand conditions was therefore randomised to reduce the effects of learning on the overall mean scores.

*Location.* To increase the availability of medical practitioners, the tests were performed at STH hospitals (apart from one participant who was tested at the University of Sheffield) in a location that was practical for the participant – usually a coffee room or office, during working hours. Because medical practitioners are often called away at short notice, two of the participants were unable to complete the Pulse Location Test in all conditions, and one of those not completing the Suturing Test. Their results were excluded from the relevant data analyses.

#### **4.4. Perception analysis**

Clinicians have previously expressed strong views on the relative effects of latex and nitrile gloves on manual performance, with the vast majority preferring latex (Mylon, et al., 2014). In order to determine whether these views translate to a perceived difference in performance of specific tasks, and whether there is a correlation between perceived and measured performance in the two tasks, clinicians were asked to rate their performance using a modification of the magnitude estimation method (Stevens, 1971), which is normally used for sensory perception testing.

Subjects were asked to assign a numerical score to each result that corresponded to the perceived level of performance. They were allowed to set their own scale for each task, with any positive, non-zero value allowed, so that a score of twice as much represented performance that was twice as good. The ratings were recorded after they had completed both tasks in all hand conditions, and they were not shown their objective scores.

## **5. Results**

### **5.1. Simulated Pulse Location Test**

Since for each subject the apparatus was re-calibrated and the absolute value of pressure could not be obtained, absolute scores would have little relevance. Therefore, only the difference in performance of each gloved condition to the ungloved condition was calculated (performance being defined as the pressure threshold as measured by number of divisions from the switch). The mean differences for latex and nitrile are shown in Figure 5 as a percentage of mean 'No Gloves' score, with 95% confidence intervals.

Although the results are displayed as a percentage to enable easier comparison with other tests, it should be noted that, since pressure could not be measured absolutely, a 50% reduction in 'performance' should not be taken to mean that the pressure threshold was twice as high, or that the cutaneous sensibility was half as much. It can, however, be seen that the mean pressure threshold was much lower (i.e. performance was better) when ungloved than when wearing examination gloves, and latex performed slightly better than nitrile.

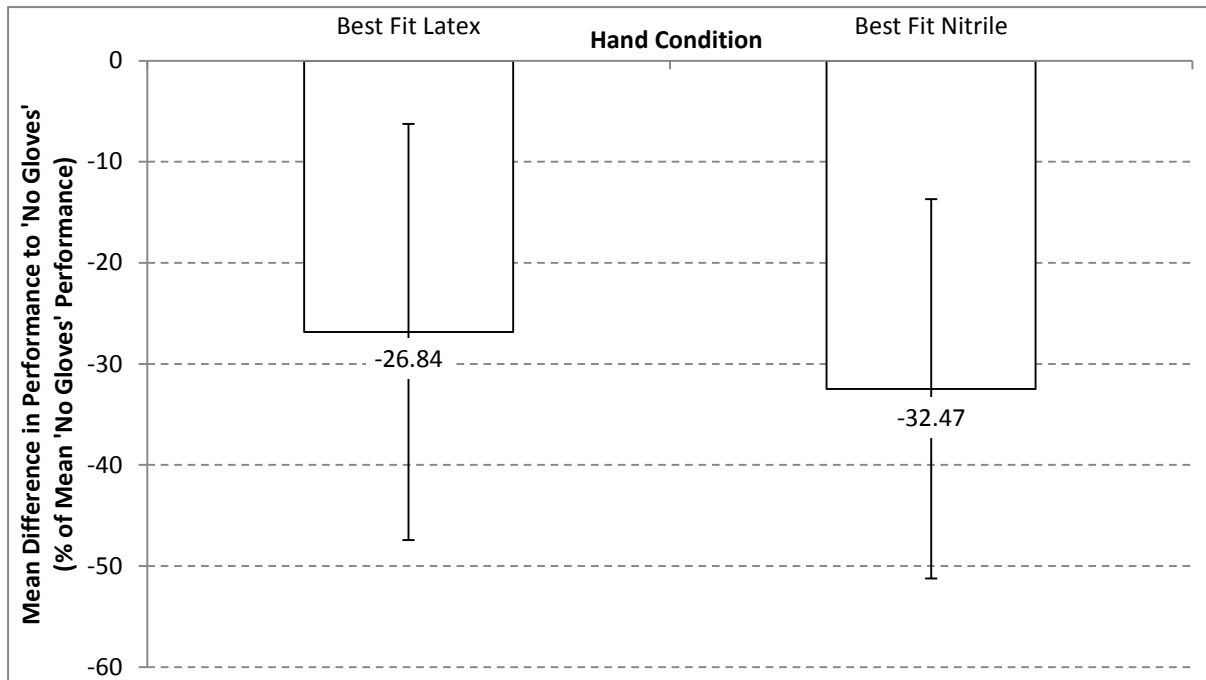


Figure 5. Comparison of latex and nitrile examination gloves performance in pulse test, measuring mean difference to 'No Gloves' score as a percentage of mean 'No Gloves' score, and including 95% confidence intervals

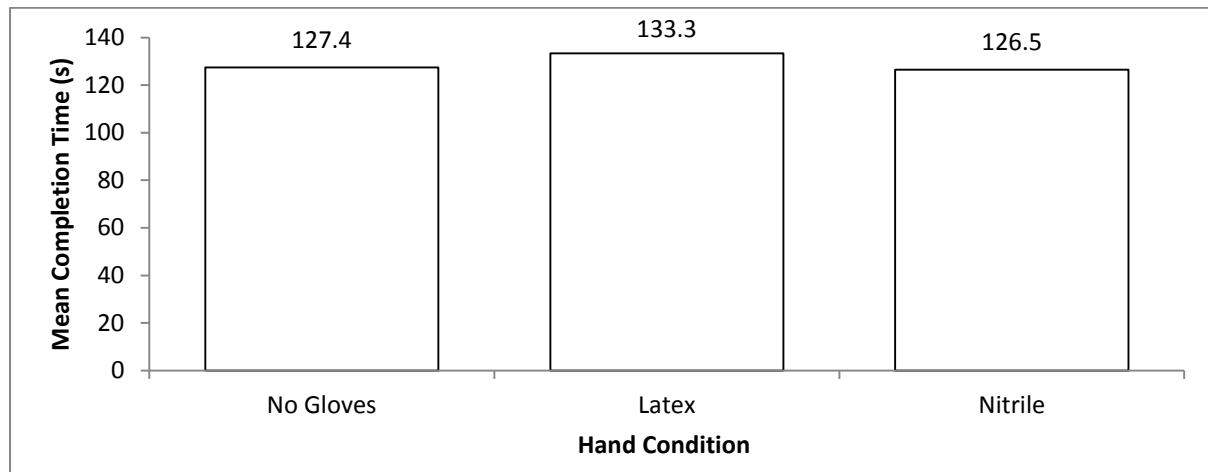
*Statistical analysis.* Results for the three conditions were tested for normality using the Shapiro-Wilk test, and showed no significant deviation from a normal distribution ( $p \geq 0.224$ ). Since the experiment had a repeated-measures design (the test was completed by each subject in all hand conditions) and the results were normal, repeated-measures analysis of variance (ANOVA) was used to analyse the relationship between hand condition and test score. The results showed that hand condition had a significant effect on test score ( $p = 0.014$ ). The significance of differences in mean scores between the individual hand conditions was analysed using paired t-tests, the results of which are shown in Table 1. The ungloved performance is clearly significantly better than gloved performance, but no significant differences between nitrile and latex were found.

*Table 1.* Significance of paired differences in the Pulse Location Test

|           | Latex     | Nitrile    |
|-----------|-----------|------------|
| No Gloves | S (0.021) | S (0.004)  |
| Latex     |           | NS (0.671) |

## 5.2. Suturing Test

The mean completion times for the 18 participants in the suturing test when ungloved and when wearing latex and nitrile examination gloves are shown in Figure 6. The fastest mean completion time was achieved with nitrile gloves, with the slowest being achieved with latex gloves, taking on average 5.4% (6.78 seconds) longer.



*Figure 6.* Mean completion time for three hand conditions in the suturing test (n = 18)

The relative performance of the two gloved conditions to the ungloved condition is shown in Figure 7 with 95% confidence intervals. It can be seen that the confidence intervals are large in comparison to the mean differences between all three conditions, suggesting that the test has not revealed significant differences in performance between hand conditions.

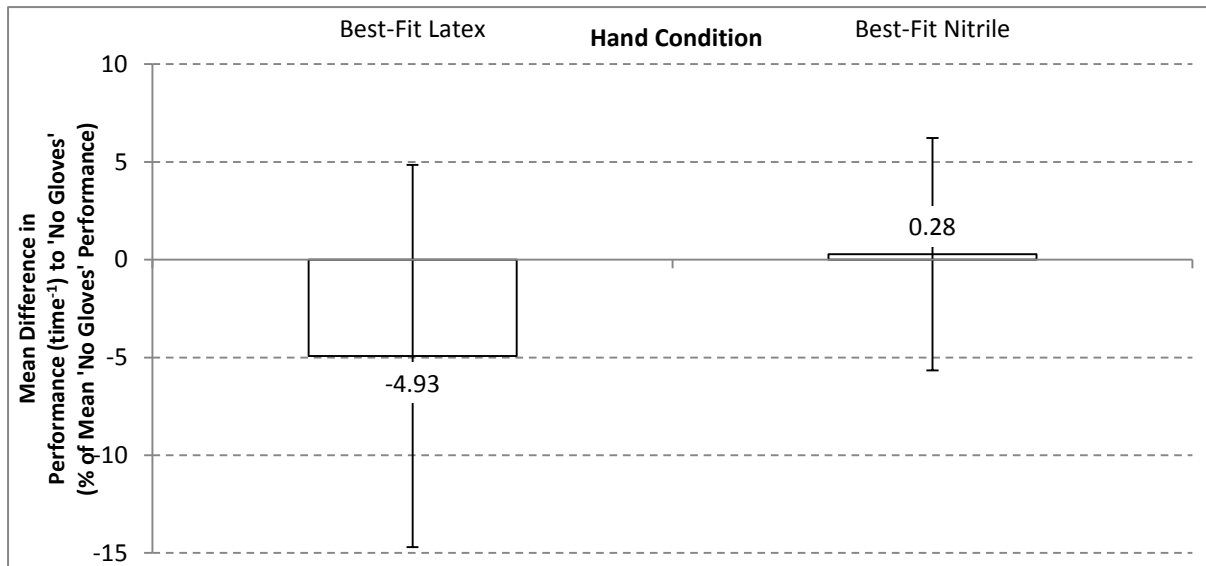


Figure 7. Comparison of performance (time<sup>-1</sup>), relative to the ungloved condition, of latex and nitrile examination gloves in the suturing experiment (with 95% confidence intervals)

None of the three conditions showed significant deviation from a normal distribution ( $p \geq 0.366$ ), but, as expected, repeated-measures ANOVA found no significant effect of hand condition on performance ( $p = 0.374$ ).

### 5.3. Perceived performance

*Data analysis.* Because each candidate used their own scale to quantify their performance, and the ratings were based on relative magnitude, the arithmetic mean was not an appropriate measure, as it skews the results towards subjects who gave larger values and greater magnitude differences. Stevens (1971) described a method, adapted by Skedung et al. (2011), that normalises and combines the results for all subjects as follows:

- Calculate the multiplier for each subject by dividing the grand mean of all magnitude estimations by the mean of the individual subject's magnitude estimations
- Multiply each subject's magnitude estimations by their individual multiplier
- Calculate the geometric mean for each case (i.e., hand condition), where the geometric mean of  $n$  estimations is given by

$$\textit{Geometric mean} = \sqrt[n]{x_1 \cdot x_2 \cdot x_3 \dots x_n}$$

95% confidence intervals (CI) were calculated for the geometric mean of the normalised perceived performance scores using:

$$CI_{\text{geometric mean}}(\text{normalised scores}) = \exp\{CI_{\text{arithmetic mean}}[\ln(\text{normalised scores})]\}$$

Significance of differences was tested using t-tests (which analyse differences in arithmetic mean) on the log perception scores.

Similarly, large between-subject variations in test score or completion time were to be expected, which were unlikely to be reflected in the perception data (each subject has their own ‘norm’ in perceived performance, regardless of their actual ability relative to others). This between-subject variation needs to be removed from the analysis in order to have a fair assessment of the correlation between perceived performance and measured test scores. The test scores were therefore normalised, in addition to the perception ratings, using the method above (calculating each subject’s individual multiplier by dividing the grand mean of all test scores by the mean of the individual’s scores) and the Pearson’s correlation coefficient calculated for the whole dataset (all three hand conditions).

*Simulated Pulse Location Test.* The average normalised perception ratings for each hand condition are shown in Figure 8. Two of the three datasets deviated significantly from normality ( $p \leq 0.009$ ), so the non-parametric Wilcoxon Signed Ranks test was used to analyse the significance of paired differences. The results are shown in Table 2.

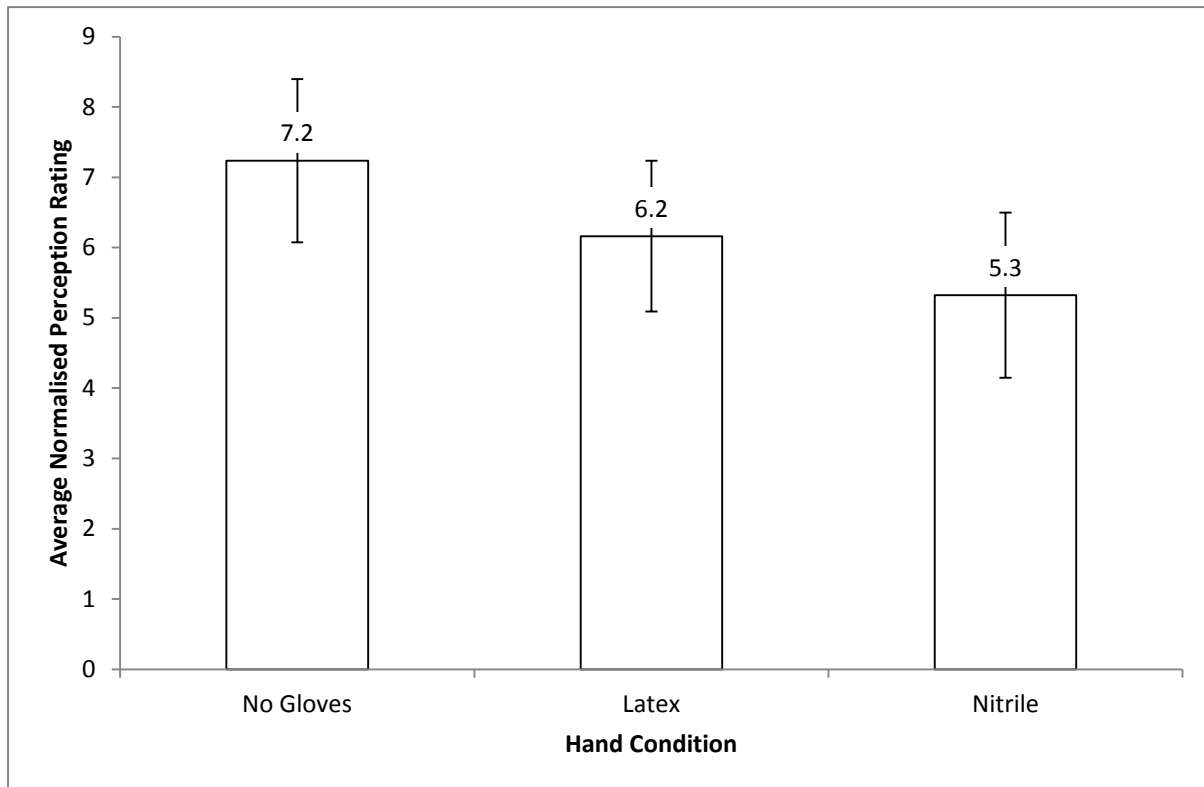


Figure 8. Average normalised perception ratings for 17 subjects in three hand conditions in the Simulated Pulse Location Test (with 95% confidence intervals)

Table 2. Significance of paired differences in perceived performance in the Pulse Location Test

|           | Latex      | Nitrile    |
|-----------|------------|------------|
| No Gloves | NS (0.055) | S (0.038)  |
| Latex     |            | NS (0.276) |

Only the 'No Gloves' and the 'Nitrile' perception scores were significantly different, although the  $p$  value between 'No Gloves' and 'Latex' scores was close to significance. The perception results compare well with the actual test scores, giving the same ranking of the three hand conditions, although the significance of the differences between the ungloved and gloved scores was greater in the objective results ( $p \leq 0.021$ ), while the difference between the gloves was less significant ( $p = 0.671$ ). The relationship between perceived performance and normalised score across all conditions in the Simulated Pulse Location Test is shown in Figure 9. The Pearson's correlation analysis showed a moderate, positive correlation between the variables ( $r = 0.591$ ,  $N = 51$ ,  $p < 0.001$ ).

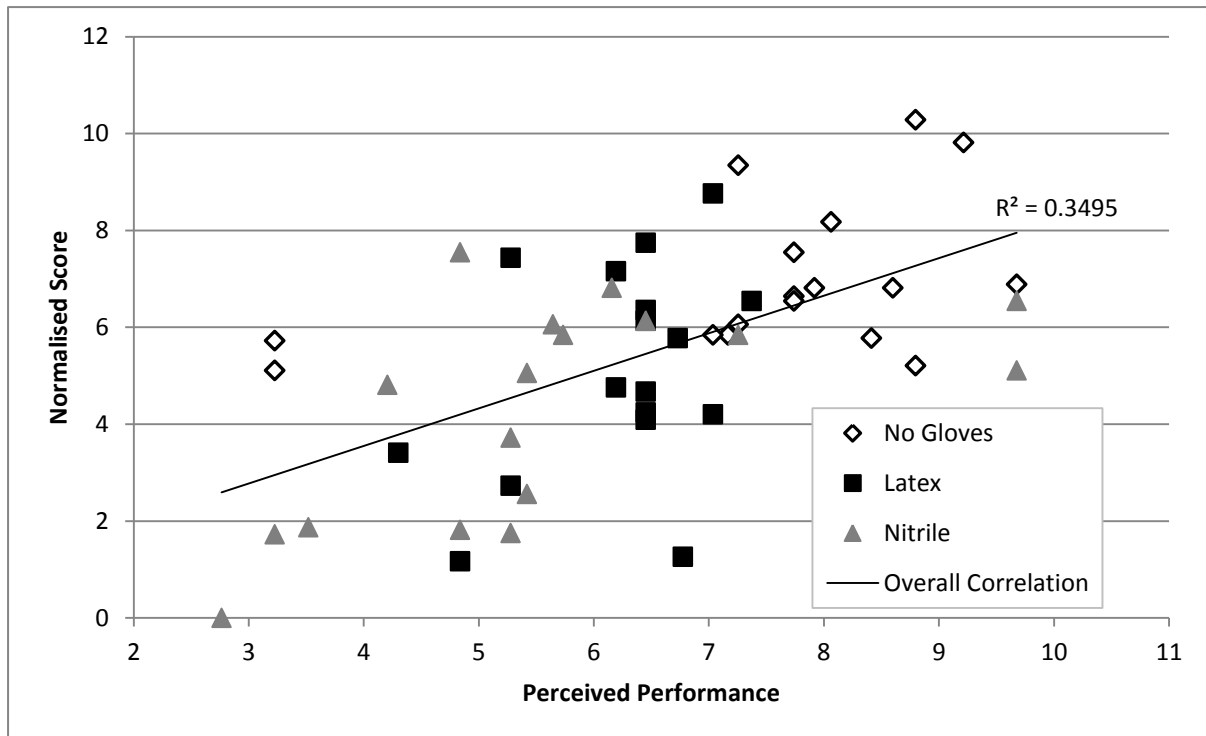


Figure 9. Relationship between score and perceived performance in the Pulse Location Test (normalised scores)

*Suturing Test.* The average normalised perception ratings for each hand condition are shown in Figure 10. Only one of the datasets deviated significantly from normality ( $p = 0.038$ ), so repeated measures t-tests were used to analyse the significance of paired differences between hand conditions. The perceived performance in both gloved conditions was significantly less than in the ungloved condition ( $p \leq 0.009$ ), but the difference between the gloved conditions was not significant ( $p = 0.345$ ). This significant difference in perceived performance between gloved and ungloved is not reflected in the mean completion times for the Suturing Test.

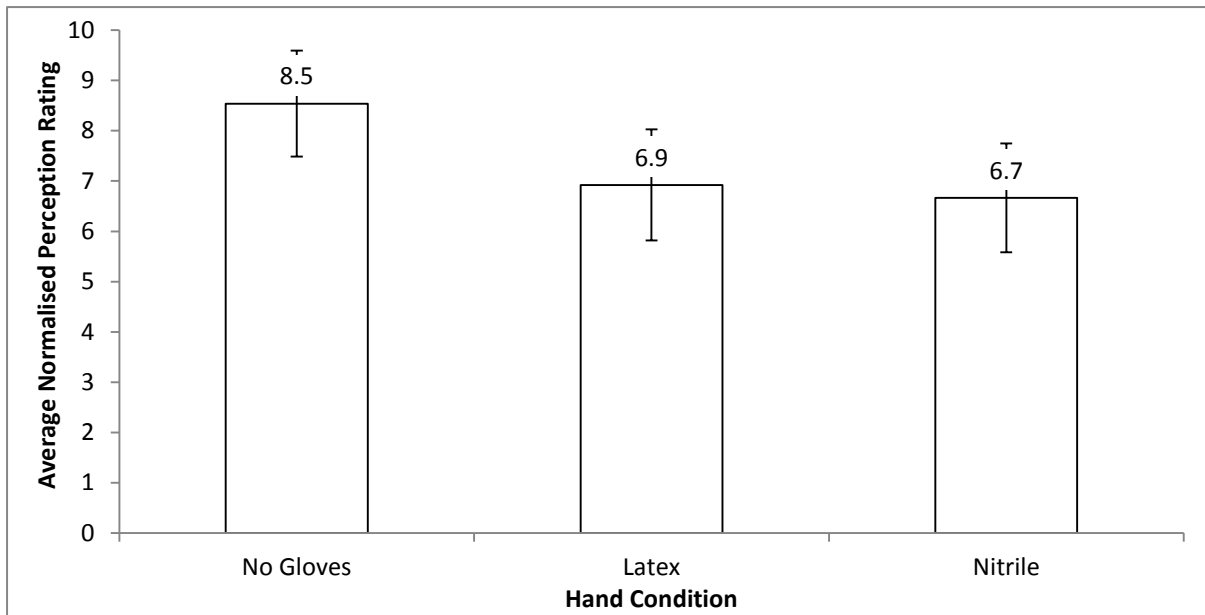


Figure 10. Average normalised perception ratings for 18 subjects in three hand conditions in the suturing test (with 95% confidence intervals)

The relationship between perceived performance and normalised completion time in the suturing test is shown in Figure 11. The Pearson’s correlation analysis showed a weak, negative correlation between the variables ( $r = -0.271$ ,  $N = 54$ ,  $p = 0.047$ ).

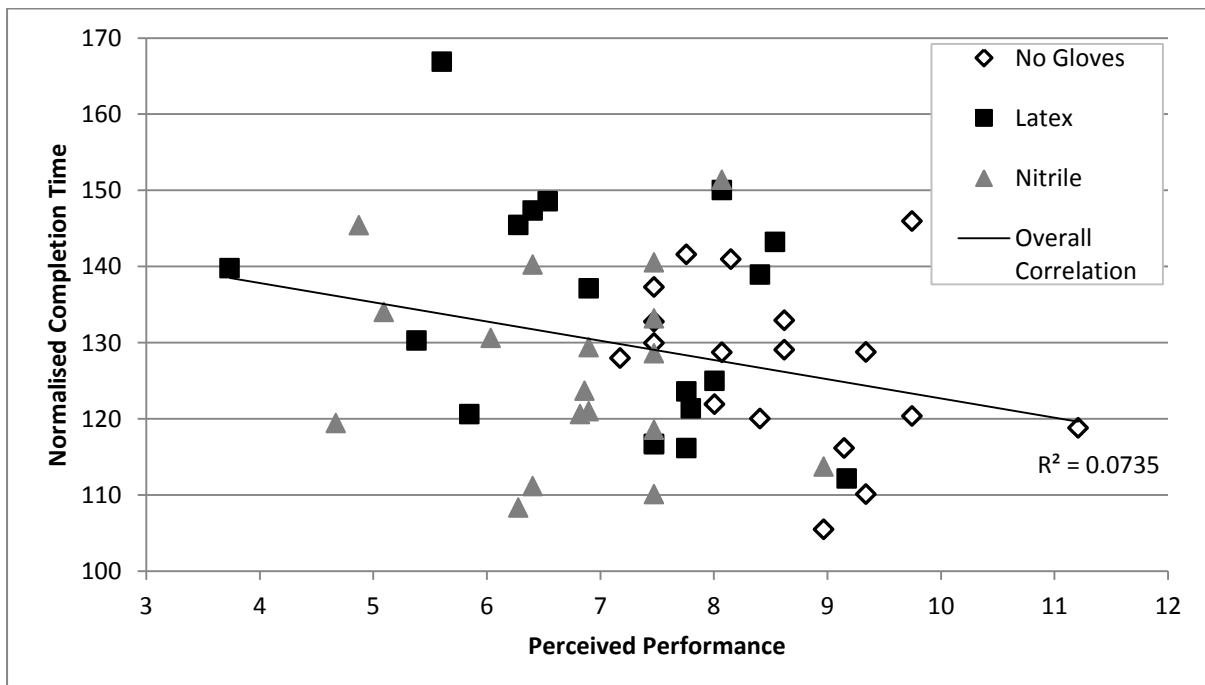


Figure 11. Relationship between normalised completion time and perceived performance in the suturing test (normalised scores)

## **6. Discussion**

### **6.1. Simulated Pulse Location Test**

The results agree with previous studies using the Semmes-Weinstein Monofilaments (Johnson, et al., 2013; Mylon, 2012), which found that ungloved tactile performance was significantly better than gloved, but that single-layer gloves could not be separated. The gloves act as a barrier that attenuates the tactile signals from the pulsating vessel, but the similarity in thickness of the gloves means the attenuation effect is very similar.

Given that significant differences in the ability to locate a pulse were found between the ungloved condition and the gloved conditions, the test shows promise in assessing improvements in cutaneous sensibility for new glove designs with the aim of closing the gap to ungloved performance. Although the results of this initial study replicated those found with an existing test method (Semmes-Weinstein Monofilaments), the ability of the Simulated Pulse Location Test to mimic the more complex tactile aptitude required in real clinical tasks makes it a more useful tool for glove evaluation, and with further optimisation may yet find performance differences that would not be detected with a passive test such as the monofilaments.

The fact that measured performance differences in the test between hand conditions were accompanied by significant differences in perceived performance lends weight to the view that the differences found are relevant to clinical performance and not purely an artefact of the test method. However, it is important for validation of future glove comparisons that absolute values for the threshold are obtained, whether in terms of pulse pressure through a gauge, or in terms of number of divisions on the pressure adjustment tube. In order to achieve the latter, the tube length needs to be increased to give a larger range of pressures.

The pump was not ideal in being limited in speed and pressure adjustment, and the cogs wore fairly easily so that they began to slip, causing the pulse to be irregular. A more

robust and user-friendly pumping and pressure adjustment system could be designed, based on the same principles (peristalsis, variation of fluid volume). Whether it is possible to differentiate the performance of medical gloves is uncertain. With more accurate measurement and finer gradations of pressure, the significance of the differences found might be increased.

## **6.2. Suturing Test**

Although the test is still in the early stages of validation, it does not show promising discrimination between glove types or even between gloved and ungloved performance. However, suturing was identified as one of the common tasks that practitioners felt were adversely affected by gloves (Mylon, et al., 2014), and there were significant differences in perceived performance between the ungloved condition and the gloved conditions.

These perceived differences may relate to real performance differences that are not being measured or may be purely subjective, either an indication of the effect of the gloves on confidence or comfort or a result of preconceptions about gloves. If there are real performance differences, either the test does not have sufficient accuracy and resolution to bring them out, or it is not measuring the relevant performance outcomes. The lack of correlation between perceived performance and completion time supports this analysis.

Khan et al. (2007) used a number of measures when assessing suturing performance, including: tissue and instrument handling and confidence; dimensions and orientation of sutures; appearance and economy of motion. They were able to find significant differences between grades of practitioners. However, this approach required videotaping and observation by three experts, which is time-consuming and difficult to do on a larger scale with non-surgical researchers.

Improvements to the test procedure could yield better results in separating the glove types. Hand tying of the sutures would increase the dexterity requirements and could magnify

any differences that exist. The number of sutures could be reduced to compensate for the increased test time. Difficulties in suturing and differences between gloves may become more apparent in real operating conditions because of lubrication of the gloves and sutures with bodily fluids. This element could be introduced to the test by coating the gloves in lubricants such as water, artificial saliva or fat.

Although medical task-based tests such as the Simulated Pulse Location Test and the Suturing Test have advantages over more general dexterity and tactile sensation assessments such as the Purdue Pegboard Test and the Semmes-Weinstein Monofilaments, in being more immediately applicable to clinical practice, any new test method needs a large body of data to be collected in order to match the validity of more established tests and achieve widespread acceptance as a reliable evaluation tool.

### **6.3. Perceived performance**

Aside from its relevance to the validity of the new test methods, it is worth considering the perceived performance analysis method in its own right. Since one of the aims in improving glove performance is to increase compliance with universal precautions, it is also important that gloves are perceived to perform well, whatever the reasons for that perception.

Significant differences were found in both tests using the current method, even where objective performance differences could not be found. This suggests that the method has some merit as a glove evaluation tool. However, using purely subjective methods could hinder the progress of glove design, since there may be a tendency among users to stick to what they know, and to be biased towards perceiving different as worse.

Coupling the objective and subjective test methods in any future product testing would help to ensure that new glove designs are both objectively better (and hence improve efficiency and reduce the potential for injuries or errors), and more appealing to users, thus increasing the chances of their uptake.

## 7. Conclusion

The Pulse Location Test showed an ability to discriminate between hand conditions, and therefore has potential as a glove evaluation test. However, in order to provide a benchmark for future glove evaluation, the pulse pressure needs to be quantified in absolute terms.

Further development of the apparatus should also include consideration of the manufacturing process to produce a robust, fully sealed system.

In the new suturing test, there were significant differences in perceived performance between the ungloved condition and the gloved conditions, but completion time was not significantly affected by hand condition. Improvements in the method were recommended, as well as testing in lubricated conditions, and with a larger sample size, to determine whether the pattern of perceived differences in surgical suturing performance between gloves can be replicated in objective performance measures.

It was recognised that more data is needed once the methods have been optimised in order to validate them for glove evaluation, and it was recommended that future test regimes incorporate both the objective and subjective performance elements to ensure that any results are relevant to clinical practice.

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