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Title:

A Novel mechanical inclinometer device to measure acetabular cup inclination in total hip arthroplasty.

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Abstract:

It is well recognised that acetabular cup orientation influences patient function and implant survival post-THR. Reliable intra-operative determination of cup orientation remains a challenge. Innovators have described the use of digital inclinometers or mechanical alignment guides (MAGs). However, difficulties with sterilization and practicality remain. We describe the design and testing of a novel mechanical inclinometer to measure intra-operative acetabular cup inclination.

The aim was to design a generic inclinometer to measure acetabular inclination to within +/- 5^o without requiring modification to existing instrumentation while remaining easy to handle & visualise, be robust/reusable, and sterilizable. The device was drafted using computer aided design software, prototyped using a 3D printer and constructed using stainless steel.

Two experiments were undertaken to test accuracy: 1) the absolute accuracy of the prototype device was tested against against a digital device 2); placement of an acetabular component using the device was compared to the standard freehand technique using a sawbone pelvis. 18 surgeons (6 expert, 6 intermediate, 6 novice) were asked to place an uncemented acetabular cup in a saw bone pelvis to a target of 40^0.

The average root mean square error for the device was 1.1^0 (SD: 0.9$^{0)}$. Comparison of the inclinometer to the freehand technique showed that with the freehand component placement 50% of the surgeons were outside the specified range of 35^0-45^0. Inclinometer use resulted in all participants to achieving placement within range. Expert surgeons were more accurate at achieving the target inclination than less experienced surgeons both with free hand as well as whilst using inclinometer.

This work demonstrates that the design and initial testing of a mechanical inclinometer is suitable for use in determining the acetabular cup inclination in THR. Experimental testing showed that the device is accurate to within acceptable limits and allowed surgeons to improve their accuracy reliably.

Introduction:

The angle of acetabular inclination is an important measurement in total hip replacement (THR) procedures. It is recognised that acetabular cup inclination impacts directly on the mechanics of the joint and influences joint function postoperatively(1–4); Acetabular component malposition can result in dislocation (5,6), increased wear (7–9), impaired muscle function (10), reduced range of motion (ROM)(11), impingement (12–14), bearing-related noise generation (15,16), poor functional outcomes (17), limb length discrepancy (18), and loosening and cup failure (19–21). The ideal inclination of the acetabular cup continues to be the subject of debate (22). The concept of a ‘safe zone’ between 30^0-50^0 of inclination described by Lewinnek et al. (6) is well recognised. However more recently an emphasis has been directed toward the multifactorial factors that contribute to dislocation. The concepts of combined anteversion (acetabular and femoral component) and functional range of motion recognising the interrelationship of the lower lumbar spine are not yet fully understood but have been shown to be more accurate than the “safe zone” described by Lewinneck et al. (6,40). The wide range suggested by Lewinnek as “safe zone”,especially with the use of hard-on-hard bearings, has been questioned and a cup inclination of 40^0 is considered optimal(39). Despite the ongoing debate as to the ideal position for the acetabular component in THR it remains important for surgeons to achieve their intended orientation accurately intra-operatively.

Determining the acetabular cup orientation reliably intra-operatively remains a challenge for surgeons. A number of tools are used by surgeons to help determine intra-operative component inclination, including: mechanical alignment guides (MAG), digital and mechanical protractors, computational and robot assisted navigation systems, and inclinometers (23). Freehand and mechanical alignment guides, though simple and cost effective, are least reliable relying on visual referencing by the surgeon alone. Computational and robotic navigation methods (23,24) are the most accurate method to achieve optimal component placement but come with added complexity, as well as considerable expense and can be time consuming. Over the last decade an increasing number of innovators have described inclinometer type devices to assist the surgeon more accurately achieve their intended cup inclination (2,22,25–30).

An inclinometer or clinometer is a device used for measuring angles relative to gravity. Inclinometer based devices offer a more accurate means of determining inclination angle than freehand and MAG techniques while being more cost effective than navigation systems. Mechanical devices, bubble inclinometers, and electronic devices have been used in determining intra-operative cup inclination (2,22,25–28,30). However the use of inclinometers, though showing promising results, has not been fully explored and the devices described are not without limitations; the majority of devices described cannot be autoclaved and need to be placed in sterile containers or bags and the mechanical devices raise some concerns with regard to their practicality.

This paper describes the design of a mechanical inclinometer intended for use in the intra-operative measurement of acetabular cup inclination. The absolute accuracy of this mechanical device is tested against a digital device to determine whether it would be fit for purpose and subsequently the accuracy was compared to the freehand technique.

Materials & Methods:

Inclinometer design:

The aim was to design an inclinometer that could be used to measure acetabular inclination without requiring modification to existing instrumentation.

The prototype device was drafted using computer aided design (CAD) software (FreeCAD; www.FreeCAD.org). Subsequently a prototype was constructed using a 3D printer for inspection and testing prior to establishing the final format (*figure 1*). The final device was CNC machined from SAE 304 medical grade stainless steel.

The device consists of an eccentrically weighted wheel mounted on two W16002-2RS roller bearings which were pressed into near symmetrical (asymmetry only in that one side threaded and other counter sunk to accommodate hex bolt heads) housing components (*figure 2*). The weighted wheel was engraved with calibrated markings corresponding to its orientation relative to the centre of mass of the wheel. The functioning of the device is dependent on gravity maintaining the weighted wheel in a fixed orientation relative to the gravitational field while the housing can adapt to the to be measured surface allowing for the corresponding measurement read off the calibrated markings on the weighted wheel.

The device was designed to meet essential design criteria which are listed below with the reasoning and description of how these criteria were met:

1. Ease of use:
   The device is 60×60×30mm in size to easily fit in the average hand. The calibrations can be visualised on the upper surface of the device which does not require adjustment of head or body positioning to visualise a measurement.

2. Versatile:
   The device can be used with majority of instrumentation kits without requiring modification or fittings. Three of the four sides can be used as measuring reference surfaces with grooves to enable improved contact with rounded surfaces. The device can also be used in conjunction with MAGs.

3. Autoclavable:
   The design has open sides to allow for thorough cleaning (all bearings exposed) while maintaining adequate grip surfaces for handling without compromising the movement of the weighted wheel. This means it is also easily washable intra-operatively (e.g. pulse lavage) if

the mechanism were compromised by blood. All components are stainless steel which can withstand repeated washing and autoclaving as well as other sterilization methods.

4. Robust:
   The components are constructed from medical grade stainless steel meaning that the device can withstand impacts, washing, autoclaving and transporting with no impact on the function.

Device Accuracy:

The accuracy of the prototype device was compared against a digital angle finder (0^0 - 255^0 digital protractor). The digital angle finder was used to create an angle on a flat surface (a spirit level was used to establish that the surface was level).The digital angle finder allowed for an angle to be created which was then locked and placed on the flat surface prior to measuring the created angle with the inclinometer device (*figure 3*). Having measured the established angle with the inclinometer device (user blinded to digital reading) the angle was compared to the digital reading.The experimental setup is shown in *figure 3*. Thirty individual blinded measurements taken by two users (angles were changed between readings) were recorded.

Inclinometer vs. Freehand:

The accuracy of the device compared to the standard freehand technique was assessed using a sawbone pelvis. The pelvis was mounted to simulate the lateral decubitus position at 300mm from the edge of the table.

18 surgeons (6 experts, 6 intermediate trainees and 6 novice trainees) were asked to place an uncemented acetabular cup on a standard inserting handle (Medacta International, Switzerland) in a sawbone hemi-pelvis model to a target of 40^0. A custom made digital inclinometer was attached to the insertion handle to measure the final inclination accepted by the participant. The inclinometer made use of a 9-axis Absolute Orientation Sensor (Bosch BNO055) connecter to microcontorller board (Arduino UNO R3). Reading were communicated to a laptop computer using a serial port connection and the data interpreted using the Arduino integrated development environment (*IDE*). The experimental setup is shown in *figure 4*.

All participants were asked to place the acetabular component at 40^0 of inclination; first freehand and then repeat the cup placement using the novel inclinometer device.

Results:

Device Accuracy:

Comparison between the mechanical and digital devices showed that the mechanical device had an average root mean square error of ~~the~~ 1.1^{0} (SD 0.9^{0}, range 0.1^{0} to 3.3^{0}). The average error was -0.2^{0} (SD 1.5^{0}, range -3.3^{0} to 2.6^{0}). *Figure 5* shows a graphical comparison of the mechanical measurement to the digital measurement. The Pearson correlation coefficient was 0.99.

Inclinometer vs. Freehand:

An overview of the inclination achieved by both freehand and inclinometer techniques is summarised in *table 1*. The root mean square error (RMSE) was 6.4^{0} (SD 4.4^{0}) in the freehand group and 1.7^{0} (SD 1.0^{0}) in the inclinometer group. The average inclination was 40.1^{0} (SD 7.8^{0}) in the freehand group and 39.4^{0} (SD 1.8^{0}) in the inclinometer group. When comparing the freehand group based on the participants surgical experience an inverse relationship between RMSE and surgical experience is noted. Experienced consultant surgeons had a RMSE of 3.1^{0} (SD 1.2^{0}), trainees 6.5^{0} (SD 5.5^{0}), and novices 9^{0} (SD 3.7^{0}). This trend was also observed in the inclinometer group but to a lesser extent with consultant surgeons achieving an average RMSE of 1.0^{0} (SD 0.8^{0}), trainees 1.6^{0} (SD 1.0^{0}), and novices 2.2^{0} (SD 1.0^{0}).

Of the 36 attempts made 18 (50%) were measured to have an inclination outside of the specified safe zone of 35-45 (40 +/- 5). All the attempts outside of the safe zone were using the freehand method as opposed to all attempts using the inclinometer being within the safe zone (see *figure 6*). Novices were most likely to place the cup outside of the safe zone with 87% of freehand attempts being outliers as opposed to 67% and 0% for intermediate trainees and consultants respectively (see *figure 7*).

Discussion:

Accurate placement of the acetabular component continues to be of a worry to surgeons (2,26,31,32). In this study, we have presented a novel mechanical inclinometer device that was accurate to within 3^0 in 95% of cases (two standard deviations). When using the novel device to assist in placing an uncemented acetabular component in a sawbone model it reduced the number of outliers to 0% when compared to the 50% outliers using the traditional freehand method.

The average root mean square error of the device when compared to a digital inclinometer was 1.1 and there was strong correlation (0.99) with the digital inclinometer readings. The disparity between device measurement and digital measurement occurred owing to the mechanical nature of the device leading to the mechanism experiencing a small amount of stick. It would be impossible to negate all friction however bearing choice and a heavier wheel could reduce this further. A possibility to consider that if the mechanism were contaminated with blood it would "stick" introducing larger errors; However, with this in mind it was designed to be easily washed using a pulse lavage which most surgeons will have available to them during THR procedures. Overall the device was sufficiently accurate for the purpose of assisting surgeons determine the position of the acetabular cup intra-operatively. Comparison of the inclinometer to the freehand technique showed that with the freehand component placement 50% of the surgeons were outside the acceptable range of 35^0-45^0. The use of the inclinometer resulted all participants to achieve placement within the specified safe zone.

A number of studies have described the use of a device used for measuring angles of slope (or tilt), elevation, or depression of an object relative to gravitational orientation. The majority made use of electronic devices positioned on the insertion rod to provide the surgeon with accurate digital readings of the operative inclination angle (2,25–27). Three studies made use of mechanical devices. Darrith *et al. (22)* used a simple spirit level inclinometer placed on the acetabular insertion rod to measure inclination. The other studies used variations of gravity-actuated pendulums attached to the insertion rod (28–30). These inclinometers were scaled at different intervals ranging from 0° to 70° or 0° 180° and could be calibrated to set 0° as parallel to the insertion rod.

Of the studies describing mechanical inclinometers none looked at the absolute accuracy of their devices against a gold standard or another device. As such we are unable to compare the absolute accuracy of our device to those described by other authors. However *table 2* shows an overview of the results for experimental studies looking at acetabular component reported by other authors in comparison to the results for the sawbone testing performed in the current study. In total six other studies compared the se of an inclinometer to freehand techniques; four of these studies were clinical and two were experimental (one using sawbones and one using cadaver). In our study there was no significant difference in means for the two groups which was also the case for half of the other studies. This study showed a standard deviation from the mean of 7.8 degrees in the freehand group compared to 1.8 degrees in the inclinometer group, indicating a reduction in the spread from the target angle, which was also the case in four (2,25,26,28) of the other studies. When comparing the number of outliers (outside of specified target zones) five of the six studies, like this study, showed a reduction outliers when using an inclinometer. The reduction in outliers ranged from 8% (28) to 78% (2) where this study found a 50% reduction in the number of components positioned outside of the specified safe zone.

When comparing expert, trainee, and novice surgeons our results showed that expert surgeons were more accurate at achieving the target inclination when compared to less experienced surgeons. Expert surgeons were within the specified safe zone for all attempts as compared to trainees and novices who achieved placement within the target zone 33% & 17% of the time respectively. Other studies have also noted that acetabular component malposition is more likely in inexperienced/low volume surgeons (33–36). This would suggest that the use of an inclinometer will be of greatest benefit to trainees and low volume surgeons. Although the results of the expert surgeons show a reduction in standard deviation and range of angles about the mean, what should be taken into account is that the numbers in this experimental study were relatively low and as such likely insufficient to pick up a true reflection of expert surgeon performance and as such whether they would benefit from the use of an inclinometer. Other studies comparing the use of an inclinometer against freehand and mechanical alignment guide techniques have found an improvement with expert surgeons (22,26,27).

There are a number of limitations to be taken into account with this study. As mentioned in the previous paragraph the number of surgeons assessed was relatively small meaning that definitive conclusions regarding the effect of inclinometer use in expert surgeons cannot be made. The use of a sawbone pelvis can provide an advantage when determining inclination as the influence of the soft tissues is removed. The setup of the sawbone pelvis in this study and the use of an inclinometer assume the positioning of the pelvis in the lateral decubitus position to be parallel to the table. However unrecognised pelvic adduction is common and is an important contributor to unexpectedly high radiographic inclination of the cup (37–39) post operatively. This should be recognised when using an inclinometer intra-operatively and accounted for by careful positioning of the patient and compensating for adduction by modifying the target operative inclination.

This work demonstrates that the design and initial testing of a mechanical inclinometer is suitable for use in determining the acetabular cup inclination in THA. Experimental testing showed that the device is accurate to within acceptable limits and allowed surgeons to improve their accuracy reliably. Regarding future work it remains to test the device in a clinical setting to ascertain whether its use can minimise outliers and improve accuracy in achieving desired acetabular component inclinations.

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Figures:

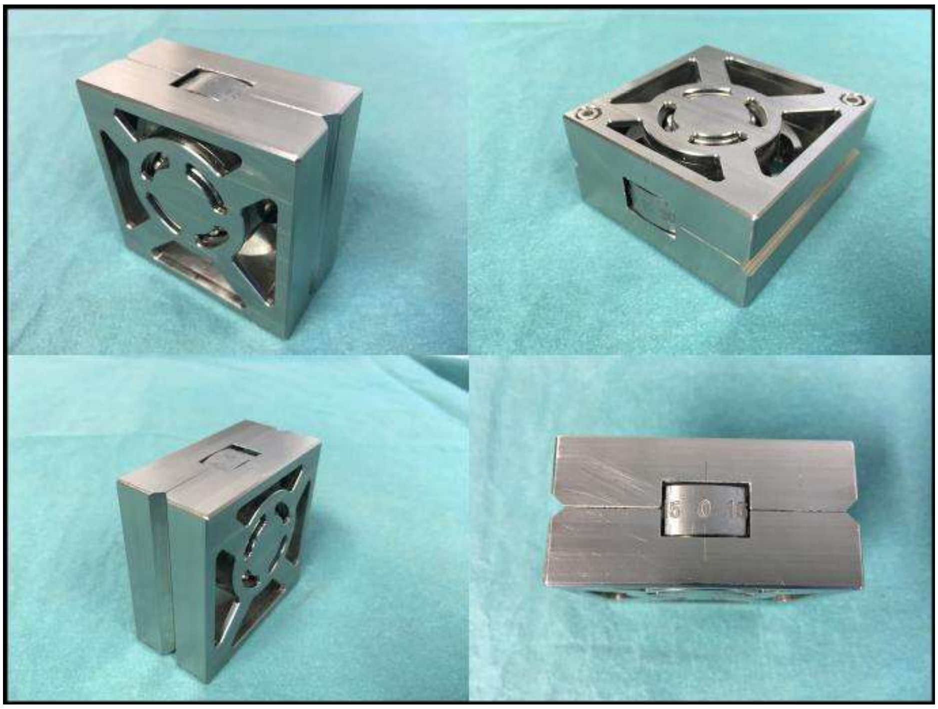

Figure 1: Figure showing the final device manufactured in stainless steel.

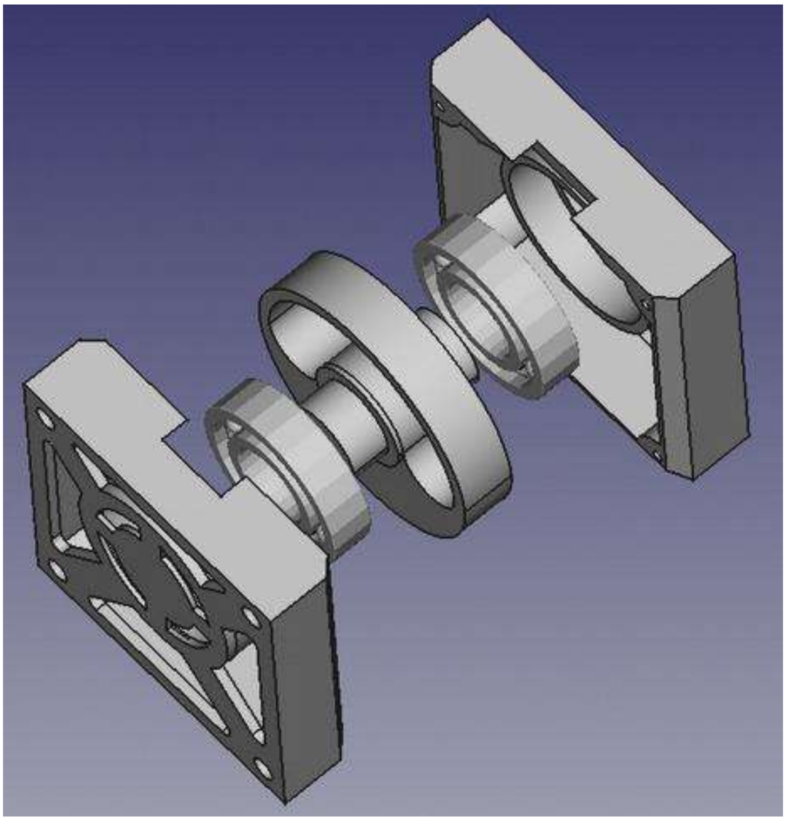

Figure 2: CAD representation of the device showing an exploded view to illustrate the weighted flywheel and bearings mounted within the housing.

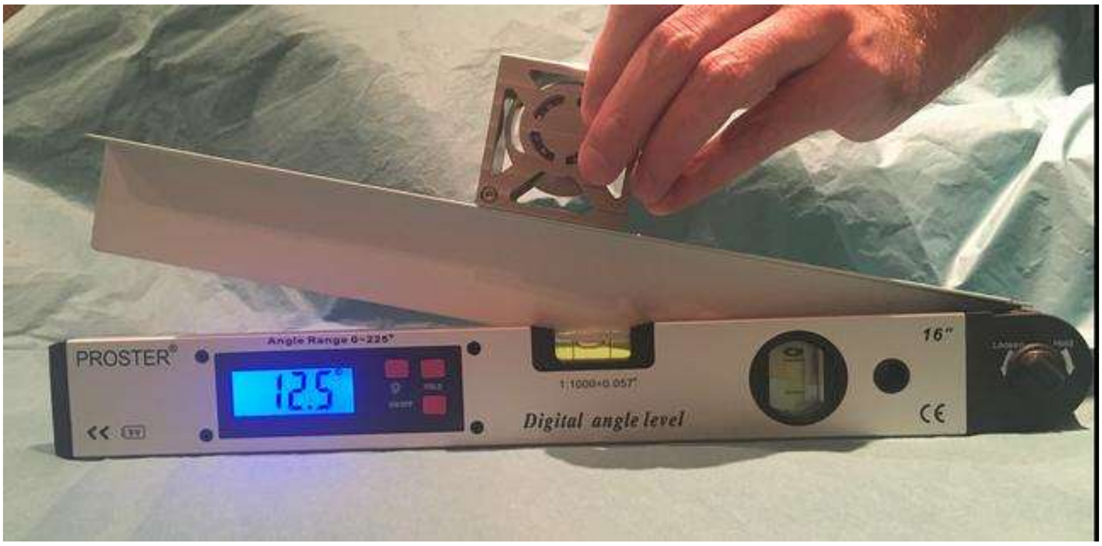

Figure 3: Experimental setup showing the use of the inclinometer device to measure a predetermined angle to establish absolute accuracy.

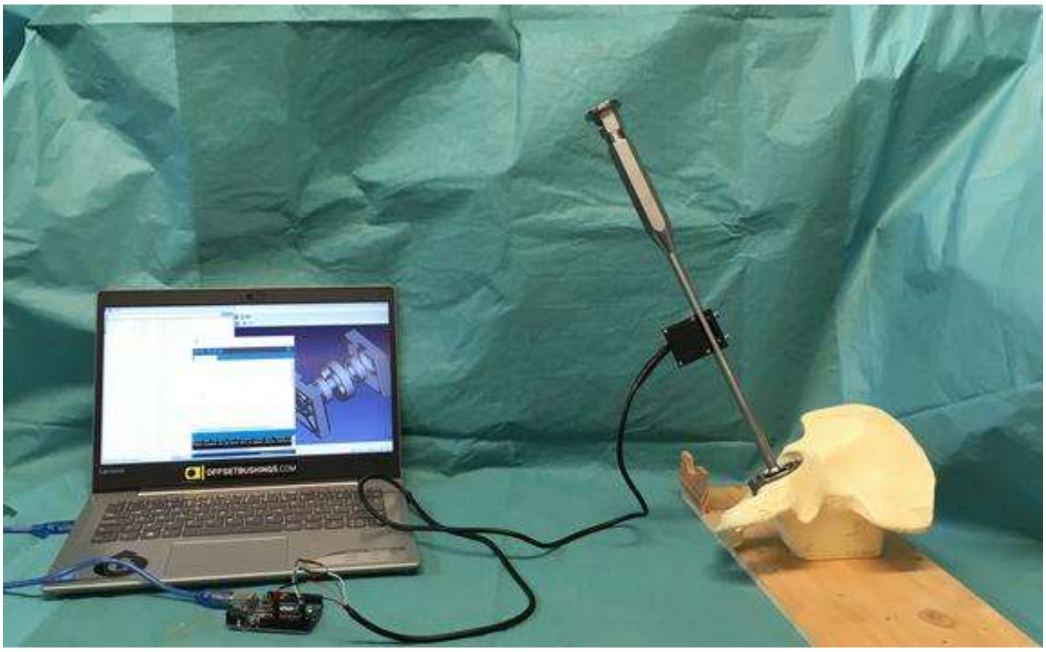

Figure 4: Image showing the experimental setup used in the sawbone cup placement.

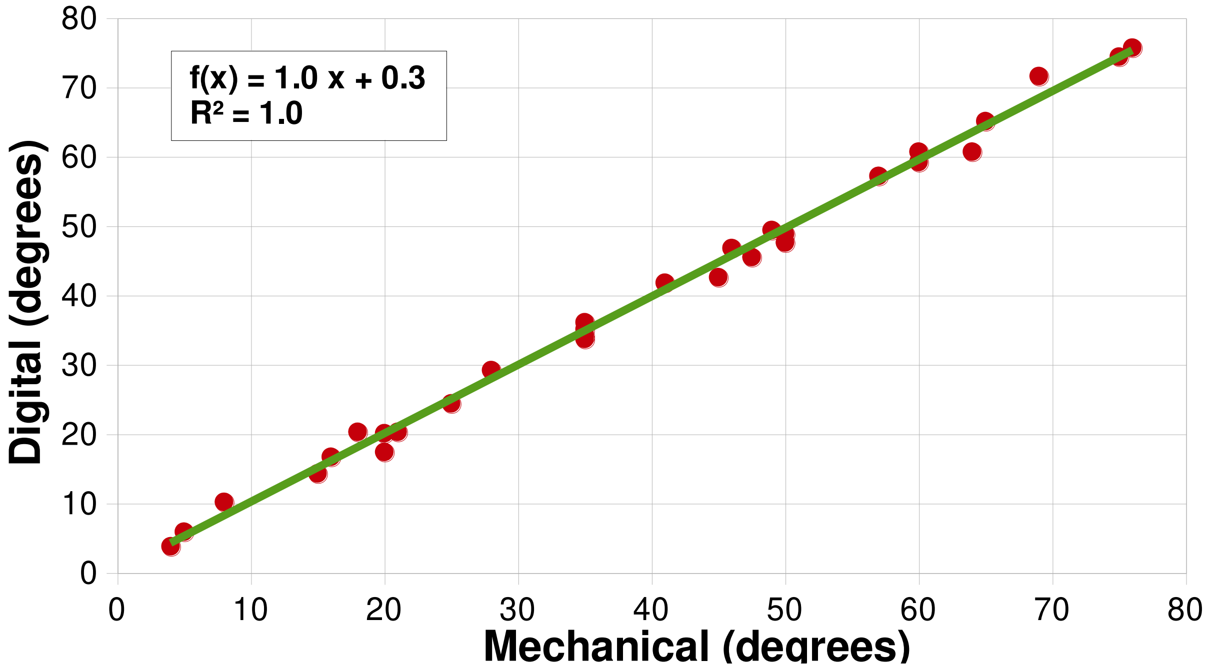

Figure 5: Graph showing the digital (predetermined) measurements plotted against the measurements obtained using the mechanical inclinometer device.

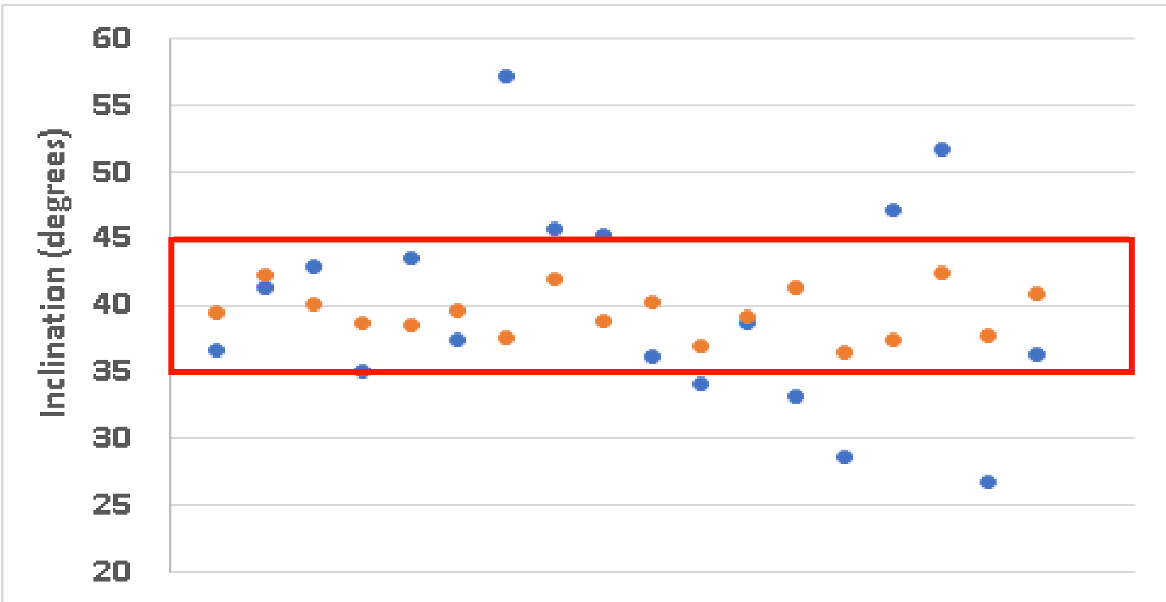

Figure 6: Graph showing the inclination angles achieved for the sawbone experiment. The blue marks represent freehand attempts and the orange with the use of the inclinometer. The area marked by the red dashes represents the specified safe zone.

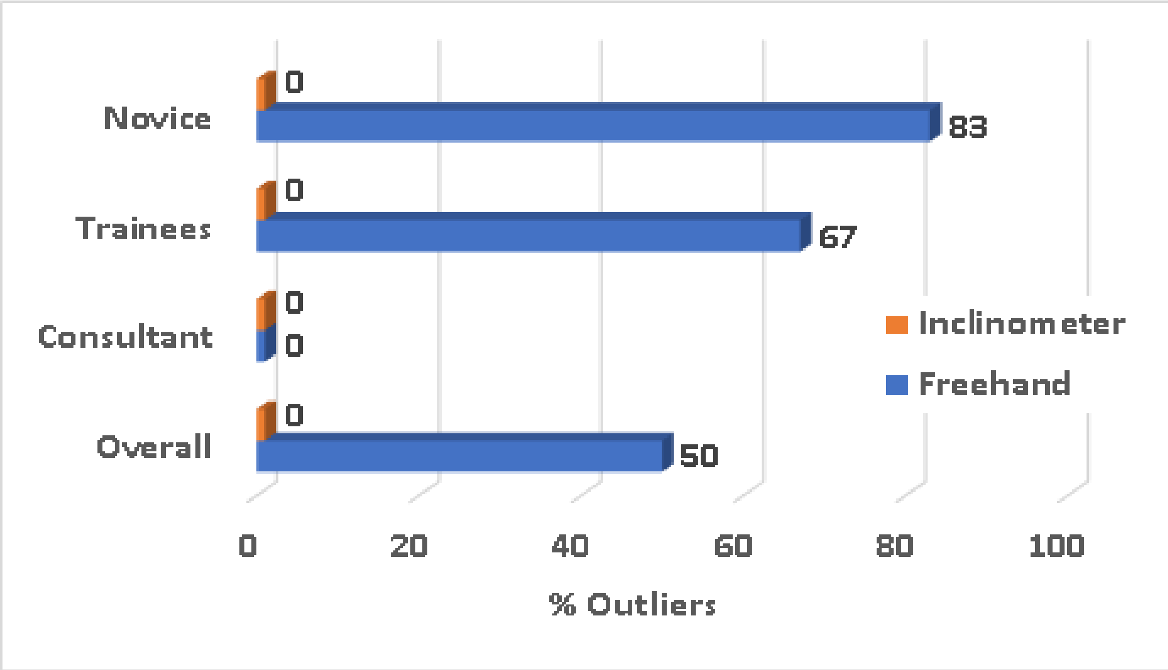

Figure 7: Bar graph showing the number of outliers using both the freehand (blue) and inclinometer (orange) techniques.

Tables:

Group	Freehand Av. Angle (SD) Range	Freehand RMS (SD)	Inclinometer Av. Angle (SD) Range	Inclinometer RMS (SD)
All	40.1 (7.8) 26.7 – 57.2	6.4 (4.4)	39.4 (1.8) 36.4 -42.5	1.7 (1.0)
Experienced	39.5 (3.5) 35.1 – 43.5	3.1 (1.2)	39.8 (1.3) 38.5 – 42.2	1 (0.8)
Trainee	42.8 (8.5) 34.1 – 57.2	6.5 (5.5)	39.1 (1.8) 37.0 – 41.9	1.6 (1.0)
Novice	37.3 (10.1) 26.7 – 51.8	9 (3.7)	39.4 (2.5) 36.4 -42.5	2.2 (1.0)

Table 1: Overview of the average inclination angles achieved and associated root mean square errors (RMS) for the participant groups.

	Study type	Study description	Method	Inclinometer Type	Target RI	Safe Zone	Mean (SD) Inclination	% outliers	P value: comparison of means	P value: comparison of outliers	Comments
Radiographic Inclination (RI)											
Meermans et al.	clinical	cohort	Freehand		40	35-45	38.5(7.0)	28	P = 0.80	P =0.002	
			Inclinometer	Digital	40	35-45	38.3(4.7)	10			
Darrith et al.	clinical	cohort	Freehand		40 (30)*	30-50	46.5(6.3)	21	P = 0.004	P = 0.034	* 30 degrees OI target assuming 10 degrees greater for RI
			Inclinometer	Mechanical	40 (30)*	30-50	42.9(7.0)	13			
Vendittoli et al. '02	cadaver	cohort	Freehand		40	30-55	44.4(11.4)	8	P = 0.83	P = 0.49	
			Inclinometer	Mechanical	40	30-55	42.2 (3.8)	0			
Vendittoli et al. '07	clinical	RCT	Freehand		40-49	30-55	42.7 (6.7)	4	P = 0.56	P =0.536	
			Inclinometer	Mechanical	40-49	30-55	43.6 (6.8)	6			
Operative Inclination (OI)											
O'Niell et al.	clinical	RCT	Freehand		35	32.5-37.5	32.9(2.9)	49	P < 0.001	P < 0.001	
			Inclinometer	Digital	35	32.5-37.5	34.0(1.6)	12			
Sykes et al.	sawbone	cohort	Freehand		*	+/- 2.5	6.2(4.2)**	78	P = 0.001	n/r	* Different target angles from 20°- 55° at 5° increments using each technique ** absolute mean error *** At 35° increment
			Inclinometer	Digital	*	+/- 2.5	0.6(0.5**	0			
Current Study	sawbone	cohort	Freehand		40	35-45	40.1 (7.8)	50	P=0.39		
			Inclinometer	Mechanical	40	35-45	39.4 (1.8)	0			

Table 2: Table showing the findings of other studies comparing inclinometer to freehand techniques. We have included the findings of this study for comparison.