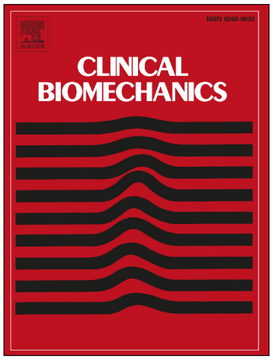
Citation for published version:
Fletcher, J, Neumann, V, Wenzel, L, Gueorguiev, B, Richards, RG, Gill, R, Whitehouse, MR & Preatoni, E 2020, 'Variations in non-locking screw insertion conditions generate unpredictable changes to achieved fixation tightness and stripping rates', *Clinical Biomechanics*, vol. 80, 105201. https://doi.org/10.1016/j.clinbiomech.2020.105201

DOI:
10.1016/j.clinbiomech.2020.105201

Publication date:
2020

Document Version
Peer reviewed version



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PII: S0268-0033(20)30320-X

DOI: https://doi.org/10.1016/j.clinbiomech.2020.105201

Reference: JCLB 105201

To appear in: *Clinical Biomechanics*

Received date: 13 March 2020

Accepted date: 19 October 2020

Please cite this article as: J.W.A. Fletcher, V. Neumann, L. Wenzel, et al., Variations in non-locking screw insertion conditions generate unpredictable changes to achieved fixation tightness and stripping rates, *Clinical Biomechanics* (2018), https://doi.org/10.1016/j.clinbiomech.2020.105201

Variations in non-locking screw insertion conditions generate unpredictable changes to achieved fixation tightness and stripping rates

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Word count:

Abstract – 247

Manuscript – 3470

Abstract

Background

Screws are the most commonly inserted orthopaedic implants. However, several variables related to screw insertion and tightening have not been evaluated. This study aimed firstly to assess the effect of insertion variables on screw tightness, secondly to improve methodologies used by researchers when testing screw insertion techniques and thirdly to assess for any learning or fatigue effects when inserting screws.

Methods

Two surgeons tightened a total of 2280 non-locking, 3.5 mm cortical screws, with 120 screws inserted to what they felt to be optimum tightness whilst varying each of the following factors: different screwdrivers for measuring torque, screwdriver orientation, gloves usage, dominant/non-dominant hand usage, awareness to the applied torque (blinded, unblinded and re-blinded), four bone densities and seven cortical thicknesses. Screws were tightened to failure to determine stripping torque, which was used to calculate screw tightness – ratio between stopping and stripping torque.

Findings

Screw tightness increased with glove usage, being blinded to the applied torque and with denser artificial bone and with thinner cortices. Considering all the insertions performed, the two surgeons stopped tightening screws at difference values of tightness ((77% versus 66% (p<0.001)). A learning effect was observed with some parameters including sterile gloves usage and non-dominant hand application.

Interpretation

Different insertion conditions frequently changed screw tightness for both surgeons. Given the influence of screw tightness on fixation stability, the variables investigated within this study should be carefully reported and controlled when performing biomechanical testing alongside practicing screw insertion under different conditions during surgical training.

Keywords
Screw, tightness, stripping, non-locking, torque

1. Introduction

Screws are the most commonly used orthopaedic implants (Glauser et al., 2003). Biomechanical and clinical investigations into the techniques used for their insertion, and how successful these are, have shown that more than one in four non-locking screws have irreparably damaged (stripped) the surrounding bone on tightening (Fletcher et al., 2020b). Poor screw insertion can have considerable ramifications, as screw hole stripping leads to a reduction in pullout strength of more than 80% (Fletcher et al., 2019; Fletcher et al., 2020c; Wall et al., 2010), contributing to fixation failures (Broderick et al., 2013). Several basic variables related to screw insertion have not been evaluated with regards to changes in the tightness created by a surgeon or the incidence of screw hole stripping. For example, little is known on the impact of cortical thickness, glove usage or bone density on screw tightness.

This study firstly aimed to identify the effect of several factors on screw tightness and screw hole stripping rates, secondly to establish improved methodologies for testing surgical performance for future studies and thirdly, to assess for any learning or fatigue effect when inserting screws under different conditions.

2. Methods

Seven factors, which in total gave rise to 24 different possible values hereafter called parameters, related to screw insertion were selected for testing (Figure 1): 1) screw orientation (horizontal and vertical); 2) type of screwdriver (both torque measuring: ‘Screwdriver 1’ - DTS101 (Sushma Industries, Bangalore, India) and ‘Screwdriver 2’ - Premier STS103 (Jack Sealey LTD., Bury St. Edmunds, UK)); 3) dominant and non-dominant hand; 4) use of gloves (no gloves, unsterile gloves, single layer sterile and double layer sterile); 5) bone density (artificial bone (10, 20 and 40 pound-per-cubic foot (PCF) (Synbone, Zizers, Switzerland)) and human cadaveric tibiae); 6) cortical thickness (1, 2, 3, 4, 5, 6 and 7 mm); and 7) awareness of applied torque (surgeons blinded to the applied torque, then unblinded by seeing the torque value during insertion, before being reblinded). To investigate these factors, with the exception of the human cadaveric bone tests, a testing frame was developed to mimic the insertion of screws in a clinical situation: a high-density foam base was used onto which the artificial bone sheets were placed. Beneath the high-density foam, a second foam of lower density was used to simulate the reaction of surrounding human tissue during surgical treatment (Figure 2). In the artificial bone sheets, a total of 2160 pilot holes of 2.5 mm were made using a milling machine (FP1, Deckel Maho GmbH, Pfronten, Germany), based on a custom-made template using the screw configuration of 10-hole, 3.5 mm locking compression plate (LCP, DePuy Synthes, Zuchwil, Switzerland). For the human bone tests, a single human cadaveric tibia (female, age 78) was used under local ethical approval. A total of 120 2.5 mm pilot holes were made in the diaphysis of this bone, using an automated bench drill (PDB 40, Bosch GmbH, Gerlingen, Germany). For all tests, stainless steel, fully threaded, cortical screws, outer diameter 3.5 mm (DePuy Synthes, Zuchwil, Switzerland) were pre-inserted until the screw heads were 3 to 5 mm distance from contacting a 3.5 mm, 10-hole limited bone contact dynamic compression plate (LC-DCP).

Two orthopaedic residents were asked to tighten a total of 2,280 screws - 60 screws per surgeon per parameter, to what they felt was optimum tightness. Screw orientation and type of torque measuring screwdriver were investigated initially so that both of these variables could remain unchanged when testing the other parameters. Once orientation and screwdriver were chosen, a further five sub-studies were performed comparing the parameters within each variable group to others in that group but using the same baseline combination of factors (Figure 1). The baseline was tested again after the orientation the screwdriver and were chosen. Only a single parameter would be changed at a time as follows from the baseline condition of: using a surgeon’s dominant hand, wearing unsterile gloves, being blinded to the value of torque applied, tightening to what the surgeon determined optimal for construct stability (stopping torque), into 4 mm thick, 20 PCF artificial bone sheets using Screwdriver 2 in the vertical orientation (Grey boxes in Figure 1). Where the testing set up was duplicated between parameters, i.e. testing 4 mm cortical thickness which had already been indirectly investigated when testing 20 PCF density, only one set of results was used for both situations as these parameters were in the middle of any tested ranges where applicable.

After insertion of each screw, the torque value displayed on the screwdriver was recorded (stopping torque), with the surgeon blinded to this (except when specifically testing their unblinded technique). With the exception of the human cadaveric bone tests, once all 60 screws for a parameter had been tightened by a surgeon, a researcher applied the maximum torque to each screw and recorded this as the torque needed to strip the material surrounding the screw (stripping torque). Due to the curvature of the human bone surfaces not allowing consistently flat placement of the plate, the stripping torque was measured after each screw insertion, whilst maintaining surgeon blinding. Tightness was defined as the ratio between stopping and stripping torques. If the stopping torque was greater than the torque achieved when subsequently attempting to strip the material, the screw hole was defined as having been stripped during insertion, this enabled calculation of the stripping rate. Only unstripped insertions were used to calculate the average tightness for a parameter. From preliminary testing, 50 screws were calculated to be needed per test scenario for 90% power at 5% level of significance based assumptions for detection of a 5±10% difference in tightness, with 10 extra tests performed in case of experimental issues.

Following One-Sample Kolmogorov-Smirnov tests for normality of distribution, the difference between the screw tightness and stripping rates for each variable for the combined results of both surgeons were compared using Mann-Whitney U Test tests for variables with two parameters and Kruskal-Wallis test for variables with more than two parameters. For each test variable, to assess for differences in screw tightness due to any learning or fatigue effect, using the Mann-Whitney U test, the first and the last 10 screw insertions were compared against each other. McNemar tests were used to assess for differences in the rate of stripping for each parameter.

Results were considered significant at a level of significance of 0.05, with Bonferroni corrections in cases of multiple comparison and confidence intervals calculated at 95%. Statistical analysis was performed using IBM SPSS Statistics for Windows, version 20 (IBM SPSS Corp., Armonk, N.Y., USA). All data are available in an online repository (Fletcher et al., 2020a).

3. Results

All insertions were performed successfully and included in the overall analysis. There was no evidence against the null hypotheses of there being no differences in screw tightness based on the screwdriver used (p=0.098), the orientation of insertion (p=0.221) or which hand was used (p=0.234). There was a significant reduction in stripping rates when using the second screwdriver (30% to 7%, p<0.001).

Wearing any gloves increased the tightness by 5 to 14% compared to when no gloves were used (p≤0.018), with single layer and double layer sterile gloves decreasing tightness by 9 and 8% respectively compared to unsterile gloves (p=0.012 and p=0.006). There were no changes in the stripping rates (p=0.105-1.000) with glove usage.

When the surgeons were unblinded to the insertion torque, tightness decreased by 9% (p<0.001) with a reduction in the stripping rate of 9% (p=0.009). On being re-blinded to the applied torque, tightness increased by 8% (p<0.001), though the stripping rate remained low (2%) and less than when compared to being initially blinded (p=0.039).

Screws inserted into 20 PCF and 40 PCF artificial bone, being compared to 10 PCF, showed reductions in tightness of 15% and 11% (both p<0.001), with no difference in tightness between 20 PCF and 40 PCF (p=0.846). Stripping rates were also lower in the 10 PCF and human cadaveric bone tests (1 and 3%) compared to the 20 and 40 PCF (10% and 7%, respectively), though there was no overall difference in stripping rates when comparing all artificial tests with human bone tests (p=0.231).

There were few differences in tightness due to cortical thickness, with the exception of 7 mm insertions, where screws were 4-10% less tight (all p<0.050) than in all other thicknesses except when compared to the 4 mm samples (p=0.102). Additionally, 6 mm and 3 mm insertions were both 6% less tight than 5 mm (both p<0.001). The stripping rate for 1 mm was 0% though only significantly less than the rate with 4 mm insertions (p<0.001).

For six parameters, tightness increased as more screws were inserted, with no situations where subsequent groups of screws were less tight than previous (Figure 3).

Screw tightness for all unstripped insertions was 77%, 95% CI [74-79] for surgeon A (n=1034), and 66%, 95% CI [64-69] for surgeon B (n=1110) (p<0.001). All stripping rates were below 10% except for when using Screwdriver 1 (30%) and when inserting screws horizontally (11%). The overall stripping rates were 9% and 3% (p=0.183) for surgeons A and B respectively.

4. Discussion

Non-locking screw insertion is reliant on the decision making of the surgeon as to when the optimal tightness has been reached for a specific screw in its corresponding screw hole. We have shown that tightness and stripping rates are affected by insertion conditions, that feedback about the applied torque affects the quality of insertion and that many conditions show a learning effect. These findings have implications for research involving screw insertion and potentially impact on guidelines and clinical practice that such studies inform, as these variables should be controlled for and reported more accurately given the potential impact to screw fixation. Furthermore, in clinical practice and when training, awareness of the effects from different insertion parameters and screwdriver torque feedback are needed to optimise insertion techniques and minimise screw hole stripping.

The feedback from the resisting torque from the friction generated by screw thread compression at the bone-screw interface is likely to be the main determinant for how much further rotation of the screw is felt to be required. Prior knowledge of bone density, which influences the shear strength of the material, and cortical thickness, which determines the thread surface area engaged (Chapman et al., 1996), may narrow the expected range of torque values that will prove to be optimal for a screw. Furthermore, following the insertion of the first screw under the same testing conditions, the anticipated optimum torque may be recalibrated by a surgeon based on the proprioceptive feedback of how good the purchase is felt and/or whether the surrounding material was stripped during tightening. Insertions seemed to be controlled further when quantitative values were displayed, allowing screws to be inserted at a value less than a previously stripped insertion. Cordey et al. (1980) suggested that the rate of increase in force against the rate of screw rotation is detected by surgeons and used to predict the optimum tightness (Cordey et al., 1980). However, it is questionable as to how detectable this is given the high incidence of stripped screw holes seen during biomechanical testing and in clinical practice (Fletcher et al., 2020b). Assuming that the rate of increasing force is felt and acted upon, either consciously or subconsciously, which torque value creates the best construct has previously been poorly defined, though recent in vitro work has shown it to be 70 to 80% of the maximum torque (Fletcher et al., 2019; Fletcher et al., 2020c). In addition to ensuring that screws are inserted below the maximum torque to prevent stripping (the primary objective), having an optimum tightness to target introduces a second aspect into the decision making required during screw insertion – making sure that the construct will be fixed at the best tightness (the secondary objective) (Fletcher et al., 2020c). Variables related to creating non-locking screw constructs were found to affect screw tightness and have impact on the quality of the fixation created. If a surgeon’s ability to moderate the torque applied is related to their proprioceptive sensitivity, changes to certain variables may make optimum tightness more difficult to achieve. Visual feedback affected the quality of screw insertion, seen when surgeons were unblinded to the applied torque. This shows the benefit of measuring the applied torque when inserting screws both in clinical situations and during biomechanical testing as knowing the torque changes how tight screws are inserted and reduces stripping rates. Finally, we have shown that in many conditions, there is a learning effect due to multiple repetitions. Thus biomechanical studies with small numbers of screws are potentially not only at risk of being underpowered due to small sample sizes, but that the tightness applied to screws may considerably change as more screws are inserted, which given that insertion torque correlates with the applied compression (Fletcher et al., 2019; Fletcher et al., 2020c), may influence biomechanical testing data.

Two of the factors examined changed the stripping torque due to alterations in the quantity of bone available for purchase by the screw threads through changes in thickness or density (Troughton, 2008). Screw tightness was found to be lowest in the 10 PCF, where extra attention to the risk of stripping may have been employed, as the stripping torques were very low, and could have been anticipated to be easily exceeded; average stripping torque was 0.05 Nm. However, the average stripping torque for the human bone used in this study (0.41 Nm) was between that of the 20 PCF (0.17 Nm) and the 40 PCF (0.55 Nm), yet the tightness in the human bone used in this study was significantly less than both, with a lower rate of stripping. Whilst the theory of extra attention being paid in situations where low stripping torques could be encountered is echoed in the cortical thickness findings, where neither surgeon stripped any screws in the 1 mm samples, this theory does not explain why human bone tests showed low stripping rates, and may be more related to the different mechanical characteristics of human bone testing and the variable cortical thickness of the screw holes in human bone.

The increased challenge to optimally insert screws under some conditions could be reflected by the differences between the average tightness of the first 10 screws and the last 10 screws per variable. As more screws were inserted, the average tightness increased for six parameters (p<0.001-0.049), with no decrease in screw tightness seen as more screws were inserted under any of the tested conditions. This may show a learning effect, as increasing knowledge of a screw insertion situation is acted upon, with growing confidence to apply more torque. The learning effect could explain the increased tightness seen with non-dominant hand, double and single sterile gloves, as these were all conditions were there had been a change to the proprioception, either by using a less familiar hand or the thickness and feeling from surgical gloves.

Tsuji et al. (2013) investigated screw tightness in artificial and human bone using cortical and cancellous screws inserted by a single surgeon (Tsuji et al., 2013). They found that in artificial bone, cortical screw tightness decreased (R = -0.63) as density increased from 5 to 50 PCF. The findings from our study contradict this, as there was a significant increase in tightness between the least and most dense samples, however a tighter range of artificial bone densities was used in this study (10 to 40 PCF). Also investigating the effect of density, Stoesz et al. did not find any difference in tightness (p=0.299) or stripping rate (p=0.186) when 10 surgeons inserted 10 cancellous screws into artificial bone blocks of 5, 10 and 20 PCF (Stoesz et al., 2014). Having three contradicting findings for the same factor may reflect the how different surgeons respond to different factors, and/or the underpowered nature of the other studies due to a small number of screw insertions per variable.

Blinding to applied torque

With unblinding of the applied torque during screw insertion, stripping rates reduced considerably. Even without a pre-insertion torque value to target for the optimal tightness, being able to quantitatively know the applied torque seems to have helped the surgeons when tightening screws. Gustafson et al. first used this method of blinding, unblinding and then re-blinding surgeons to the torque they had applied (Gustafson et al., 2016). They also found that stripping rates decreases when surgeons were aware of the quantitative torque being applied, though on re-blinding, the stripping rate they observed returned to the baseline level.

Hand dominance

Screw insertion either clinically or in biomechanical testing studies using a non-dominant hand is uncommon, however the variation in tightness highlights that extra care is needed if this occurs given the increase in tightness seen between the non-dominantly inserted first 10 screws, all 60 screws and last 10 screws (65%, 70% and 85% respectively). One other study has compared tightness when surgeons used both their dominant and non-dominant hands (Acker et al., 2016). Acker et al. did not report tightness data for the non-dominant hand, just that there was a small tightness difference (9%) between each hand for the senior surgeons and that the only individuals with more than 70% difference were first- and second-year residents. However, senior surgeons stripped nearly twice as many screw holes with their dominant hands than first and second year residents, again highlighting that there are two key components to ensuring good screw insertion - firstly not stripping screw holes and secondly achieving optimum tightness - with variation in screw tightness being far less of a consequence than greater stripping rates (Fletcher et al., 2019).

Glove usage

In clinical practice, screws will be inserted with the surgeon wearing gloves, so it is surprising that no biomechanical studies into screw tightness have stated the use of them in their methods; the only paper that is assumed to have used them when investigating screw tightness involved during in-vivo ankle fixation (Andreassen et al., 2004). This is especially important given that no gloves, sterile gloves (either single or double) and unsterile gloves all generated different tightness. In biomechanical testing, glove usage may be inconsistent depending on the contamination risk of the model being used, but it is likely to involve the use of unsterile gloves to reduce costs. Given the difference in tightness when only changing the gloves used for screw insertion, this may impact on the clinical transferability of findings that do not replicate clinical glove usage.

The total number of screw insertions performed within this study is 9.5 times larger than the next nearest studies to date into screw tightness under different conditions (Gustafson et al., 2016; Stoesz et al., 2014). With 120 screws inserted per condition, aspects such as learning and fatigue effects could be investigated - factors that may have been overlooked in smaller studies (Fletcher et al., 2020b). Whilst this study was strengthened by being appropriately powered and using more than one surgeon, the different variables affecting the surgeons' performances may highlight the subjectivity of screw insertion. Using more surgeons may have reduced the impact of this limitation and made the specific findings more transferable to other surgeons. However, the purpose of this study was to investigate the differences caused by variations in factors related to screw insertion and finding that all such variables can lead to differences in tightness means that they should all be controlled in testing. A second limitation of this study is that bias may have been introduced by having participants who knew the aims of the project before inserting and knowing that the tightness of their screws would be measured may have changed their behaviour compared to uncritiqued insertions. However, the aim of the research was to compare the effect of different factors rather than detailed analysis of how and why each surgeon tightened their screws. Thirdly, no assessment was undertaken of how the fixation changes as the tightness varied, such as measuring the compression generated or the fixation strength, though previous work has shown that if screw holes are stripped, it reduces compression and pullout strength by more than 80% (Fletcher et al., 2019; Fletcher et al., 2020c; Wall et al., 2010). Fourthly, artificial bone was predominantly used given its highly homogeneous properties especially compared to human models, but the transferability of some of the findings may be limited as human bone may behave differently. Finally, the cortical thickness of the human bone screw holes varied and may have been a confounder to these tests.

5. Conclusion

Variations in conditions related to screw insertion led to significant changes in screw tightness and stripping rates. Given the differences seen, methodologies involving non-locking screws should report the conditions of screw insertion and standardise them throughout testing to control for these potentially confounding factors. Surgical training should incorporate technique assessments for surgeons so that they can safely understand the tightness applied to screws under different conditions.

Acknowledgements

The authors would like to express their gratitude to Dieter Wahl and Erich Zweifel for their invaluable help in producing the apparatus needed for testing.

Funding

This work was generously funded by the Royal College of Surgeons of England. The funder had no role in the collection, analysis and interpretation of data; in the writing of the report; nor in the decision to submit the article for publication.

Conflict of Interest

The authors have no conflicts of interest relevant to this article.

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Figure legend

Figure 1: Flow diagram of the parameters tested. Baseline parameters indicated with grey boxes – i.e. 4 mm thickness samples used when testing all glove variables. The dividing line indicates that the remaining five sub-studies were performed once the screwdriver and screw orientation tests had been analysed. N=60 screws tested per surgeon per variable. # - bone density not quantitatively measured.

Figure 2: Testing apparatus – screw drill holes made following 10-hole, 3.5 mm LCP template, with artificial bone sheet placed into dense foam, on top of a less dense foam – the latter mimicking the stiffness of human tissue.

Figure 3: Significant differences ($p<0.05$) for both surgeons comparing the averaged screw tightness of their last 10 screw insertions against their first 10 screw insertions.

Figure 4: Bar chart of the combined unstripped screw tightness and stripping rates for each variable for both surgeons; mean average indicated by columns and 95% confidence intervals indicated with error bars. Baseline combination of parameters is indicated with red bars, where the same data are displayed five times. Brackets indicate significant ($p<0.05$) differences between screw tightness, # indicate significant difference in stripping rates between screwdriver types and orientations, and * indicate significant differences in stripping rates for remaining tests compared to the baseline.

Conflict of interest and sources of funding

Declarations of interest: none.

This study was performed with the assistance of the Royal College of Surgeons of England, Surgical Research Fellowship (JWAF). This study was supported by the NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol (MRW). The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care. For the remaining authors none were declared. The funding sources had no involvement in the study design, the analysis and interpretation of data, in the writing of the report nor in the decision to submit the article for publication.

Highlights

- Common variables related to screw insertion impact on tightness and stripping rates.
- Awareness of applied torque improves screw insertion and reduces stripping rates.
- The tested variables need to be controlled for and reported during biomechanical testing.