2021 43rd Annual International Conference of the
IEEE Engineering in Medicine & Biology Society (EMBC)
Oct 31 - Nov 4, 2021. Virtual Conference

Quantifying Accuracy of Self-Tapping Screw Models

Jack Wilkie[1], Paul D. Docherty[1,2], Thomas Stieglitz[3], and Knut Möller[1]

***Abstract*— Correct torquing of bone screws is important to prevent fixation failures and ensure positive patient outcomes. It has been proposed that an automatic model-based method may be able to determine the patient-specific material properties of bone, and provide objective and quantitative torquing recommendations. Models have been previously proposed for identifying the bone material properties, but have not been experimentally tested for accuracy. Here we used these models to perform parameter identification on experimental data using a variety of materials (rigid polyurethane foams) and screws. The identified values were then compared to the values from the datasheet, and matched with a reasonable accuracy for medium-density foam. It was found that for the lower-density foam, the model slightly under-predicted the strength, and for the highest density foam there was a large under-prediction. This suggests that with appropriate calibration, this method is good, but may only be applicable to lower-to-medium strength materials. More thorough testing is required to confirm this and determine the reliable density range.**

Clinical relevance: **Accurate material property identification is required to provide effective torque recommendations for bone screws. This work quantifies the accuracy of two proposed models for material property identification.**

I. Introduction

Orthopaedic screws are used in many surgical procedures, primarily to fix implants in bone, or for stabilising fractured bone to facilitate natural healing. Incorrect torquing of bone screws through under-/over-tightening can result in screw loosening [1] or thread stripping [2], which may cause implant failure and/or tissue damage [3]; these can be costly and risky remedy with revision surgery.

Surgeons currently torque screws in an *ad-hoc* manner. While experienced surgeons can achieve good results, the potential for error remains [4]. Wilkie *et al.* [5] proposed that an automated system for bone screw torque limitation could provide more intelligent control over bone screw torquing, leading to better patient outcomes. This system could operate by monitoring signals from the screwing process such as torque and angular displacement over time. These signals would be used to fit a model of the screwing process. The model would have unknown parameters for the bone material properties, hence fitting the model would determine these properties. The bone properties could then be combined with known information about the screw, hole, and implant geometry to estimate the optimal torque for the screw. This optimal torque could then be used through a torque indicator or limiter to allow optimal screw torquing.

Previous work has focused on creating models for this screwing process [6] [7], and testing for identifiability using simulation [5] [8]. While useful, these identifiability tests do not confirm the physical accuracy of the models. This paper focuses on partially testing the physical accuracy of the models presented in [9] (which has been previously expanded-upon in [6]) and [7]. To test the accuracy, experimental data from polyurethane(PU) foam bone substitutes [10] was used with these models to identify the PU foam strengths. These strengths will be compared with the datasheet values to evaluate the accuracy of these models for determining material properties.

II. Methods

A. Data Collection

Three types of polyurethane foam were used with varying densities/strengths shown in Table I. These were cut into strips with approximately 30x50 mm² cross-section. 3 mm holes were drilled completely through the 30 mm wide face, 8 mm from the long edges (As required by the test rig [11]), with 10 mm spacing along the long axis, and min. 10 mm space from the ends of the long axis; as in Fig 1. After drilling, the holes were inspected for defects (such as non-round holes from drill 'wandering' during initial insertion), these were marked with a cross, and not used for testing (Fig. 1). An HB 6.5 cancellous screw, and and HA 4.5 cortical screw were used for testing (Specified in ISO 5835:1991[12]).

The screw insertion was performed with the test rig described in [11] (Shown in Fig. 2). This consisted of a stepper-motor powered screwdriver with torque and rotation measurement, mounted on a sliding platform with linear displacement measurement. The platform was inclined to balance the friction of the bearings and give a small axial load pushing the screw (Shown in Fig. 1).

TABLE I

Elastic modulus, tensile strength, and compressive strength of the test materials, and bone for comparison.

Material name	E(MPa)	σ_{uts}(MPa)	σ_{ucs}(MPa)
SikaBlock®M150[13]	65	2.2	1.6
SikaBlock®M330[14]	150	5	4
SikaBlock®M600[15]	750	18-20	16-18
Trabecular Bone[16], [17]	<344-1475	-	0.15-21
Cortical Bone[18], [17]	6900	63-101	-

*This work was partially supported by grants “CiD” and “Digitalisation in the OR” from BMBF (Project numbers 13FH5E02IA and 13FH5I05IA).

[1]Jack Wilkie, Paul D. Docherty, and Knut Möller are with the Institute for Technical Medicine (ITeM), Hochschule Furtwangen, Jakob-Kienzle-Straße 17, Villingen-Schwenningen, Germany wij@hs-furtwangen.de

[2]Paul D. Docherty is also with the Centre for Bioengineering, University of Canterbury, 20 Kirkwood Avenue, Christchurch, New Zealand

[3]Thomas Stieglitz is with the Department of Microsystems Engineering, University of Freiburg, Georges-Köhler-Allee 102, Freiburg, Germany

978-1-7281-1178-0/21/$31.00 ©2021 IEEE

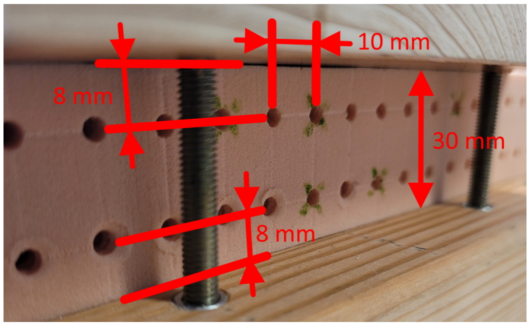

Fig. 1. Example of test sample piece mounted in test rig with hole placement locations, miss-drilled holes are marked with a cross.

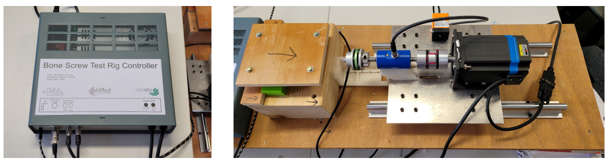

Fig. 2. Test rig used to insert screws into test samples while recording torque and rotational/angular displacement. Detailed description in [11].

The methodology here is similar to [19] with a few changes to improve consistency and meet the goals of this research. All screws were inserted at 30 RPM. Each screw was inserted 8 times each into each material (2 screws x 3 materials x 8 repetitions = 48 tests). A previously unused hole was used every time. The HB 6.5 screw was inserted 8 revolutions (22 mm) and the HA 4.5 screw was generally inserted 16 revolutions (28 mm) except for when it was used in combination with the M150 material, when it was inserted 10 revolutions (17.5 mm) because screws had previously been inserted halfway from the other side, and a shorter insertion was required to avoid interference with existing threads.

To get accurate linear displacement measurements, two steps were taken. The gap between the torque-sensor shaft and screw bit holder was reduced to zero so that the flexible coupler could not compress; hence the position of the platform/displacement sensor was directly coupled to the position of the screw, and could be used in the model as the main independent variable (instead of the rotation, which is susceptible to slippage while the screw initially engages). Then, to find an accurate and consistent zero-point for the displacement before each test, a thin, flat, piece of stainless-steel metal (measured as 1.0 mm thick with vernier calipers) was placed over the test hole, and the tip of the screw (already loaded onto the screw bit) was pressed against the metal; this 1.0 mm offset was subtracted in the data processing, and the larger surface area of the metal strip resulted in negligible indentation in the test material, compared to placing the pointed screw tip directly against the exposed material for zeroing. For consistent zeroing, the screw was pressed against the metal sheet until it returned to the same linear displacement after removing a force that resulted in a 0.1mm elastic linear displacement.

To further increase consistency as there may be some effects related to screw temperature or surface contamination (e.g. with skin oil, which may lubricate the screw [19]), the screws were washed in cold tap water between each test for 10 s. They were thoroughly dried with clean paper towels, and care was taken to minimise touching the threads when setting up the test. The insertion was started within 3 minutes of washing the screw.

For each test, the torque, angular displacement, and linear displacement were sampled at 1000Hz. The data was sent over a USB-serial connection, and a custom program was used to save the data in labelled, timestamped, files, while also allowing control and configuration of the test rig.

B. Data Processing

First the data must be pre-processed. Because only the time period of screw insertion is useful, the data was trimmed to this period. Also, because the incremental encoders used for linear and rotational displacement have no zero-point, their offsets must be determined. The linear displacement and angular displacement values were initially zeroed at the start of the screw insertion period. Due to the extra steps to ensure a consistent linear displacement in comparison to [19], the linear displacement was used as the input variable during the parameter identification (and converted into an angular displacement), instead of the rotational displacement (which is susceptible to slip when the screw initially engages in the hole).

For each set of data, the parameter identification was performed twice. Once using the simple model derived from [9], with only friction and cutting components included. And once using the model from [7] with the simplest (step-function only) model of σ. Both models are based on the sum of thread-cutting torque and friction torque which change as the screw advances into a hole; the model from [9] assumes a triangular thread, and ignores the elasticity of the material, whereas [7] improves the geometric representation of non-triangular threads, and can take material elasticity into account. Both parameter identifications used a simple linear least squares fit, as the material strength could be directly factored out of the total torque values of the models. As the screw thread profiles were not perfect triangles as modelled in [9], the thread angle (2β) was set to the total thread angle from [12] ($\alpha + \beta$); the major diameter was used as-is. For [7], the thread definitions from ISO 5835:1991 [12] were used to create a fully-defined sketch in SOLIDWORKS 2020, and the parameters of the lines in SOLIDWORKS were used to create a parametric function ($[r, z] = \vec{f}(t)$) in MATLAB R2020a. For both cases a hole diameter of 3.1 mm was assumed, as drill vibrations during sample preparation would have resulted in slightly larger holes than the drill bit size, especially due to the soft and compressible nature of the material.

III. Results

The distributions of the results of the parameter ID are shown in figures 3 and 4. In both figures, the identified values have lower coefficients of variation and initially the means rise closer to the datasheet values as the material strength

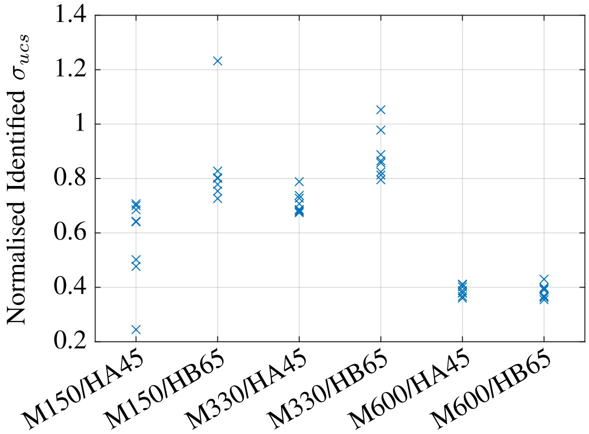

Fig. 3. Parameter identification distributions for each combination of material/screw. Using the model from [9]. Normalised with datasheet σ_{ucs}.

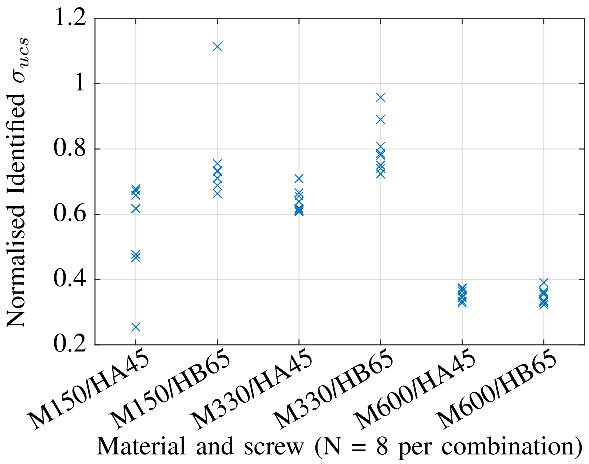

Fig. 4. Parameter identification distributions for each combination of material/screw. Using the model from [7]. Normalised with datasheet σ_{ucs}.

TABLE II

STATISTICS (MEAN, STANDARD DEVIATION, COEFFICIENT OF VARIATION, AND 95% CONFIDENCE INTERVAL OF MEAN) FOR NORMALISED PARAMETER IDENTIFICATION DISTRIBUTIONS USING BOTH MODELS.

Material	Screw	Mean	SD	CV(%)	95% CI
Model from [9]					
SikaBlock®M150	HA 4.5	0.57	0.160	27.78	0.44-0.71
	HB 6.5	0.84	0.161	19.21	0.71-0.98
SikaBlock®M330	HA 4.5	0.71	0.039	5.55	0.68-0.74
	HB 6.5	0.88	0.089	10.02	0.81-0.96
SikaBlock®M600	HA 4.5	0.39	0.019	4.97	0.37-0.40
	HB 6.5	0.38	0.025	6.55	0.36-0.40
Model from [7]					
SikaBlock®M150	HA 4.5	0.56	0.147	26.49	0.43-0.68
	HB 6.5	0.77	0.144	18.74	0.65-0.89
SikaBlock®M330	HA 4.5	0.64	0.035	5.49	0.61-0.67
	HB 6.5	0.80	0.081	10.01	0.74-0.87
SikaBlock®M600	HA 4.5	0.35	0.017	4.89	0.34-0.37
	HB 6.5	0.35	0.023	6.47	0.33-0.37

increases, except for the M600 material where the means drop significantly. Going from HA 4.5 to HB 6.5 the the coefficients of variation generally increase(except with M150 material where they decrease), and the means increase (except with M600 where they are roughly equal). In general the means and coefficients of variation are lower in Fig. 4 than Fig. 3. The summary statistics for these distributions are shown in Table II. It was also noted that in the case of all materials, the peak torque with the HB 6.5 screw was higher than the peak torque of the HA 4.5 screw regardless of the different total insertion depths.

IV. DISCUSSION

From the results, there are a number of trends with respect to the material, screw, and model used. For reference, the ideal result for the parameter identification is for all identified values to fall on the exact value from the datasheet (normalised as '1' here) with zero spread; in practice there will always be some noise and other sources of interference (increasing spread and adding biases), and the singular datasheet value never exactly represents the complex non-linear properties of the material and manufacturing variance.

For the softer materials, there are a larger coefficients of variation than the harder materials. This would be expected because the softer materials require less insertion torque, and this would reduce the SNR of the torque signal, allowing any noise or experimental irregularities to have a larger effect on the final values. By this logic, it would also be expected that because the HA 4.5 screw would require less torque than the HB 6.5 screw, it would therefore similarly have a higher coefficients of variation, this is apparent in the M150 tests, but the opposite is true in the other tests; this odd result is likely because the HA 4.5 screw was inserted further (28 mm) than the HB 6.5 (22 mm) for the M330/M600 tests, resulting in a larger number of data points that counteract the generally lower torque of the HA 4.5 screw thread, while the opposite was true for the M150 test (17.5 mm with HA 4.5, 22 mm with HB 6.5). To compare the accuracy from each screw more carefully in future work, the same insertion/data length should be used, but here we wanted to maximise the accuracy for each test set, so we did not truncate the data. Comparing the models for variance in identified strength, the model from [7] has a slightly but consistently better coefficient of variation than the model from [9] (As CV normalises with the mean, this is valid even though there are systematic differences in the mean identified values).

It can be clearly seen that the high strength M600 material was identified as much lower mean strength than the datasheet value, in comparison to the other materials. This could be in part due to the much higher elastic modulus of the material compared to the others (even normalised by strength); this means that any small undulations in the surface of the screw thread will plastically compress the threads formed in the hole, and after the surface elastically relaxes again, the remaining elastic stress which contributes to friction will be lower than the compressive strength of the material (which it would be equal to if the screw was perfectly smooth), reducing the friction and therefore required torque. Some form of abrasion may also have an effect for less elastic materials. More work is required to investigate and quantify these effects, and to figure out at what elastic modulus threshold these effects become significant (as there is a large gap in material properties between the M330 and M600 samples in this testing).

The normalised mean identified values for M150 and M330 are similar, within 10-20%. The difference is much more pronounced for the HA 4.5 screw; this could be partly due to the lower torque/SNR described above, and additionally due to the insertion distance difference between the two materials for the HA 4.5 screw also described above (while the HB 6.5 was consistent). In general, the identified values for the M330 tests, and with the HB 6.5 screw, were less under-identified(larger relative to the datasheet value) than those for M150 tests, or with the HA 4.5 screw; in this case (ignoring M600) the material/screw combinations with larger torque requirements were identified with higher strength relative to the datasheet value, suggesting that the stronger torque SNR gave more accurate results, however there may be a number of other unknown effects. To enhance testing in the future, a torque sensor with a more relevant range can be used to further improve SNR (in this case a 20 Nm sensor was used while the values did not exceed 1.5 Nm, so a 5 or 2.5 Nm range would be more appropriate), this should reduce the effects of noise and sensor/experimental errors, and help reveal if other factors are impacting these results.

There was also some difference in the identified means between the 2 models tested. Most notable is that the model from [7] gives lower identified strength values (further from the expected value) than the one from [9]. At first glance suggests that [9] could be more accurate, but this cannot be shown conclusively, as the true material strength is unknown. As discussed in [7], the σ_{ucs} is only an approximation of the force that will be present on the screw thread, and taking more care with this approximation may lead to a different result. Additionally, the model from [7] appears to account for the different thread geometries more accurately. For example, the 95% confidence interval for the mean identified values of the two screws using M150 overlap more for the model from [7] than for the one from [9]; the magnitude of this overlap is not statistically quantitative in and of itself, but with the CI used as an indicator of spread around the mean, it indicates that the model from [7] accounts for the variation in thread profile more accurately, and because the coefficient of variation is smaller for the results from [7], it is clear that the spread and therefore overlap should be smaller (not the case here) if the models were equal.

V. Conclusions

The accuracies of two models [9], [7] were tested for identifying the strength of a material from screw insertion torque-displacement data. It was found that the models had the best performance for middle-density foam, slightly under-predicted for low-density foam, and massively under-predicted for high-density foam. There were some differences in the accuracy depending on the screw used, although the model from [7] accounted for this slightly better, and had generally smaller coefficients of variation. Further work is required to more precisely define the parameter space for acceptable accuracy of parameter identification using these models, and/or to expand this parameter space by accounting for other factors.

References

[1] M. Evans, M. Spencer, Q. Wang, S. H. White, and J. L. Cunningham, "Design and testing of external fixator bone screws," *Journal of Biomedical Engineering*, vol. 12, no. 6, pp. 457–462, Nov. 1990.

[2] A. Feroz Dinah, S. C. Mears, T. A. Knight, S. P. Soin, J. T. Campbell, and S. M. Belkoff, "Inadvertent Screw Stripping During Ankle Fracture Fixation in Elderly Bone," *Geriatr Orthop Surg Rehabil*, vol. 2, no. 3, pp. 86–89, May 2011.

[3] N. J. Hallab and J. J. Jacobs, "Biologic effects of implant debris," *Bull NYU Hosp Jt Dis*, vol. 67, no. 2, pp. 182–188, 2009.

[4] M. J. Stoesz, P. A. Gustafson, B. V. Patel, J. R. Jastifer, and J. L. Chess, "Surgeon Perception of Cancellous Screw Fixation," *Journal of Orthopaedic Trauma*, vol. 28, no. 1, p. e1, Jan. 2014.

[5] J. Wilkie, P. D. Docherty, and K. Möller, "A simple screwing process model for bone material identification," *Proceedings on Automation in Medical Engineering*, vol. 1, no. 1, pp. 038–038, Feb. 2020.

[6] ——, "Developments in Modelling Bone Screwing," *Current Directions in Biomedical Engineering*, vol. 6, no. 3, pp. 111–114, Sep. 2020.

[7] J. Wilkie, P. D. Docherty, T. Stieglitz, and K. Möller, "Geometric Generalization of Self Tapping Screw Insertion Model," in *2021 43rd Annual IEEE Conference of the IEEE Engineering in Medicine and Biology Society, In Press*, Guadalajara, Mexico, 2021.

[8] J. Wilkie, P. D. Docherty, and K. Möller, "Model-based bone material property identification," *at - Automatisierungstechnik*, vol. 68, no. 11, pp. 913–921, Nov. 2020.

[9] L. D. Seneviratne, F. A. Ngemoh, S. W. E. Earles, and K. A. Althoefer, "Theoretical modelling of the self-tapping screw fastening process," *Proceedings of the Institution of Mechanical Engineers, Part C: Journal of Mechanical Engineering Science*, vol. 215, no. 2, pp. 135–154, Feb. 2001.

[10] K. L. Calvert, K. P. Trumble, T. J. Webster, and L. A. Kirkpatrick, "Characterization of commercial rigid polyurethane foams used as bone analogs for implant testing," *J Mater Sci Mater Med*, vol. 21, no. 5, pp. 1453–1461, May 2010.

[11] J. A. Wilkie and K. Möller, "Test rig for bone screw insertion modelling," in *15th Interdisciplinary Symposium Automation in Medical Engineering (AUTOMED 2021).*, Basel, Switzerland, 2021.

[12] International Organization for Standardization, "ISO 5835:1991(en), Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions," https://www.iso.org/obp/ui/#iso:std:iso:5835:ed-1:v1:en, 1991.

[13] Sika Deutschland GmbH, "SikaBlock M150 Product Data Sheet," Sep. 2020.

[14] ——, "SikaBlock M330 Product Data Sheet," Sep. 2020.

[15] ——, "SikaBlock M600 Vorläufiges Produktdatenblatt," Nov. 2014.

[16] O. Cornu, X. Banse, P. L. Docquier, S. Luyckx, and C. Delloye, "Effect of freeze-drying and gamma irradiation on the mechanical properties of human cancellous bone," *Journal of Orthopaedic Research*, vol. 18, no. 3, pp. 426–431, 2000.

[17] C. M. Schoenfeld, E. P. Lautenschlager, and P. R. Meyer, "Mechanical properties of human cancellous bone in the femoral head," *Med. & biol. Engng.*, vol. 12, no. 3, pp. 313–317, May 1974.

[18] J. C. Wall, S. K. Chatterji, and J. W. Jeffery, "Age-related changes in the density and tensile strength of human femoral cortical bone," *Calcif Tissue Int*, vol. 27, no. 1, pp. 105–108, Dec. 1979.

[19] J. Wilkie, P. D. Docherty, T. Stieglitz, and K. Möller, "Investigating Torque-Speed Relationship of Self-Tapping Screws," in *2021 43rd Annual IEEE Conference of the IEEE Engineering in Medicine and Biology Society, In Press*, Guadalajara, Mexico, 2021.