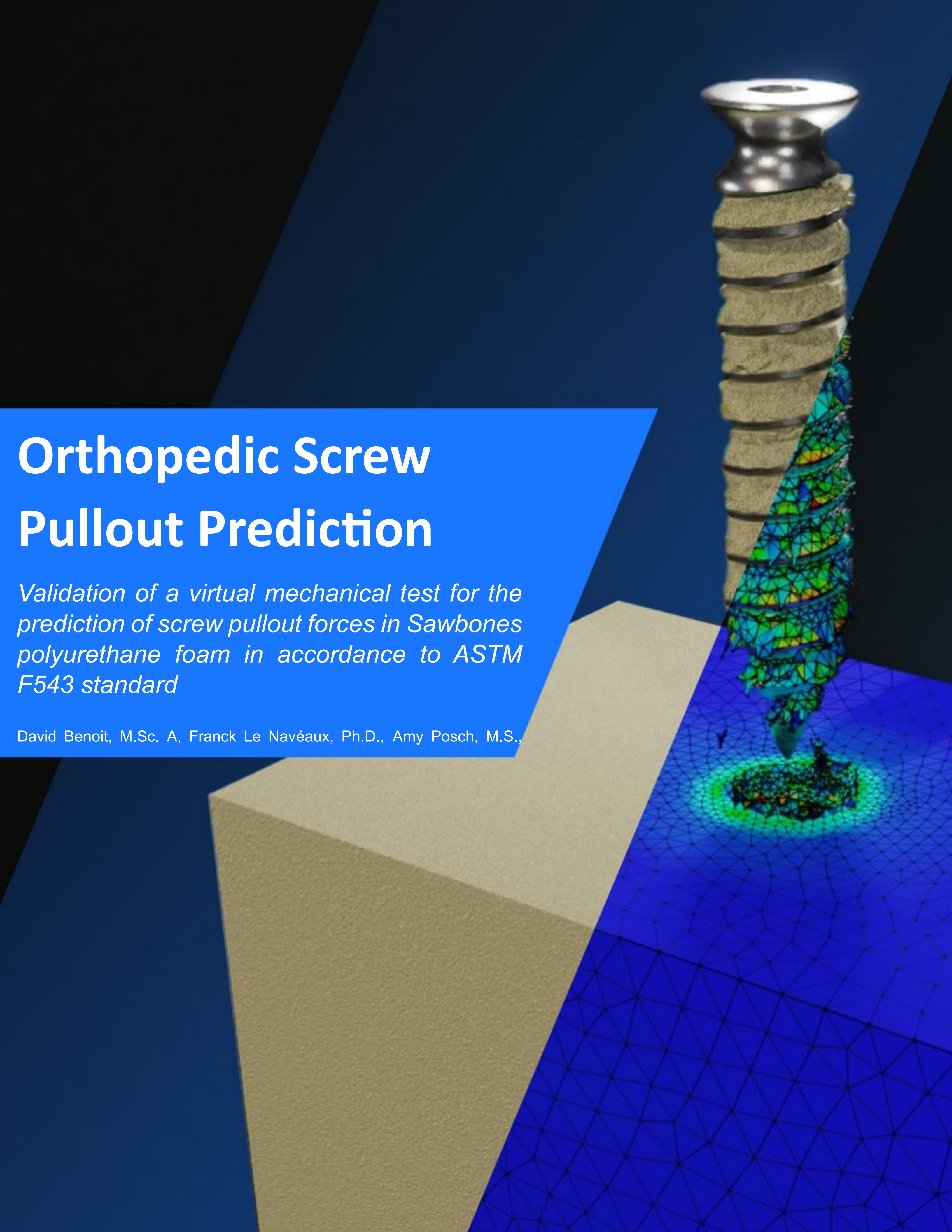
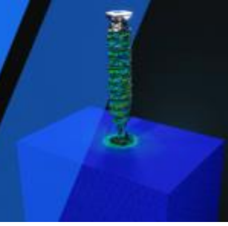


Orthopedic Screw Pullout Prediction

Validation of a virtual mechanical test for the prediction of screw pullout forces in Sawbones polyurethane foam in accordance to ASTM F543 standard

David Benoit, M.Sc. A, Franck Le Navéaux, Ph.D., Amy Posch, M.S.,



Introduction

Achieving optimal screw anchoring performance is crucial in orthopedic implant surgery as it directly impacts the stability and strength of bone fixation, whether used alone or in combination with cage, plate, and rod systems. Screw loss of fixation, known as screw loosening, cutout, or pullout, is a complication that can arise during or following surgery. In spinal surgery for instance, this complication occurs in about 10% of patients (Bredow et al., 2016; Soroceanu et al., 2015), with a higher incidence in patients with osteoporosis (Galbusera et al., 2015). The consequences of this complication can include significant morbidity and decreased patient quality of life, as well as the need for revision surgeries.

An approach to evaluate the mechanical fixation strength of orthopedic screws is to conduct screw pullout tests in cadaveric bone. However, the mechanical properties of bone can vary significantly based on factors such as age, gender, health, and skeletal site, which can make it difficult to generalize findings and compare results across different studies. Synthetic bone (Sawbones, Pacific Research Laboratories, WA, USA) made of rigid polyurethane foam, are commonly used to evaluate the fixation strength of orthopedic screws as they allow for standardized testing conditions and consistent mechanical properties (Peck et al., 2021). The polyurethane foam is designed to mimic the mechanical properties of trabecular bone (Calvert et al., 2010) and has been shown to be a reliable and accurate predictor of screw pullout force in bone (Nagaraja & Palepu, 2016). Furthermore, the polyurethane foam that meets ASTM F1839 specification is a standard bone substitute material used for mechanical evaluation of orthopaedic implants and instruments, as such it is utilized in several medical device ASTM test methods.

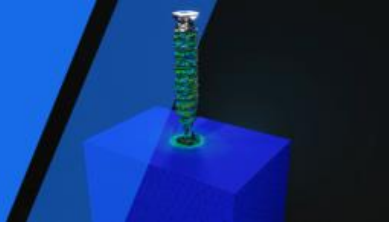
Within industry, considerable efforts are being made towards improving the mechanical performance of orthopedic screws, but the iterative process of designing, prototyping, testing and refining screw designs is costly and time-consuming, hindering engineers' capability to reach optimal design. Furthermore, traditional experimental testing is limited in assessing the effect of screw design feature changes on performance due to the possibility of variability arising from multiple rounds of tests at different time points, which can complicate the analysis of the results.

The Chapman's analytical formula (Chapman et al., 1996) has been proposed as an alternative approach to estimate screw pullout forces by considering screws main geometric features such as major diameter, thread depth and thread pitch. This Formula is utilized in the FDA guidance: "*Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*" as an analytical way to estimate and qualify screw designs. However, this formula has multiple limitations, as it only considers a limited set of screw geometrical features which can be subject to varying interpretations by different users, as well as an over simplified material characterization for the bone substitute which does not account for the cellular nature of polyurethane foam.

As an enhancement to experimental testing, Computation Modeling and Simulation (CM&S) is a tool that addresses issues related to efficiency within the design cycle of orthopaedic implants and, more specifically, can be used to predict the fixation strength of screws. The Screw Pullout Model, a Finite Element Model (FEM) was created to accurately simulate the interaction between a screw and Sawbones polyurethane foam during pullout tests, following ASTM F543 test methods. A thorough validation study was undertaken to assess the predictive capabilities of the FEM regarding screws anchorage strength measured in experimental testing and compare its capabilities to the Chapman equation.

Objectives

To evaluate the Screw Pullout Model accuracy and precision in predicting screw pullout force from Sawbones rigid polyurethane foam



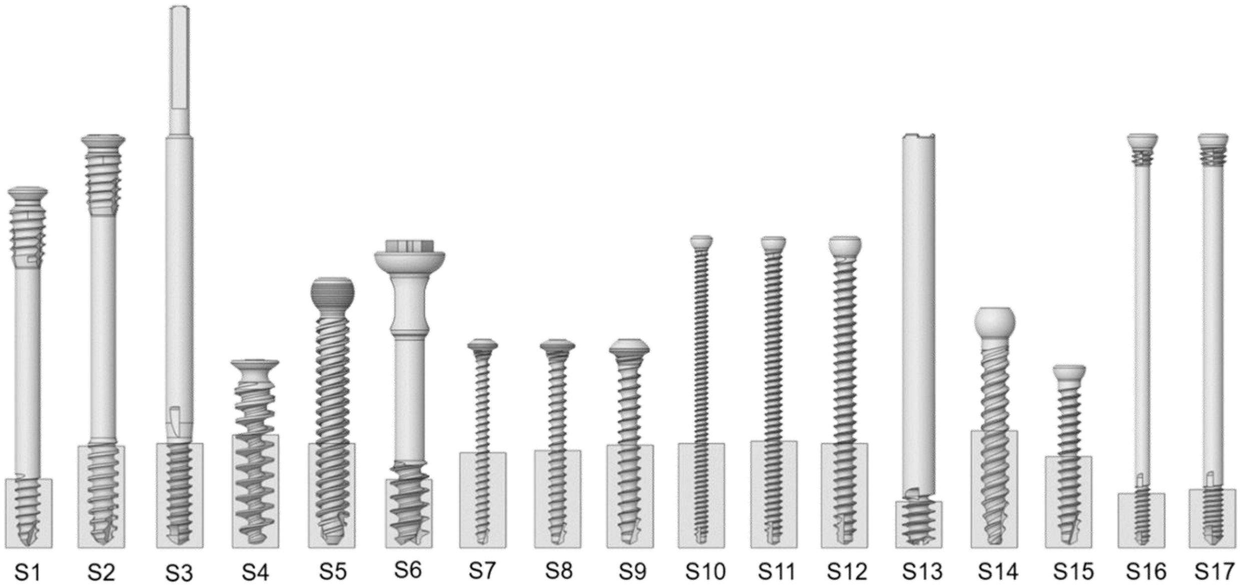


Figure 1: Sample of orthopedic screws included in the validation study. Gray box represents insertion depth in rigid polyurethane foam blocks.

Material and methods

The predictive capability of the Screw Pullout Model was evaluated and compared to both experimental tests and the Chapman equation estimation, across a wide variety of orthopedic screw designs. Each method used to evaluate screw fixation strength (experimental, numerical, and analytical) was performed by three distinct operators.

Orthopedic screw samples

Seventeen orthopedic screws (S1 to S17) and their associated 3D models were obtained from various implant manufacturers (Figure 1). The screws were selected to encompass a wide range of geometric features and designs among orthopedic screws (Figure 2), allowing an extensive assessment of the predictive capabilities of the method. Screws core and outer thread diameters varied from 1.8 to 4.69 mm, and 2.7 to 7.7 mm, respectively, while pitch varied from 1 to 3 mm. The thread profiles of the screws varied between standard buttress threads, variations of rounded V-thread, and fastener thread. S1, S2 and S14 screws had a tapered core diameter, while other screws had a cylindrical core diameter. S4 screw required a tap in addition to the pilot hole before insertion, while all others were self-tapping.

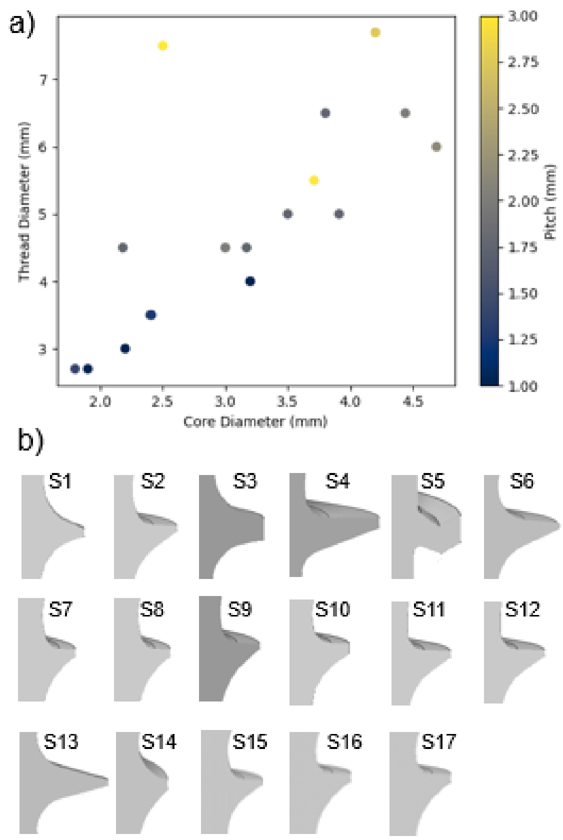


Figure 2: a) Screw geometric features design space. b) Screw thread profiles (scaled).

Experimental testing

The protocol for evaluating the pullout strength of the screws was conducted following ASTM F543 methods. Solid polyurethane foam blocks of grade 20 PCF density were obtained from Sawbones (Sawbones, Pacific Research Laboratories, WA, USA) and the apparent density of each block was determined according to ASTM D1622.

Pilot holes were drilled in the blocks, with diameters slightly smaller than the core diameter of each respective screw. Screw insertion was performed perpendicularly to the blocks using a motorized torque test stand (Mark-10 TSTM-DC-1) at a rotation rate of 3 RPM (Figure 3). A vertical force was initially applied on the screws to ensure it was properly engaged in the foam block and a 7N axial load was maintained throughout the remainder of the insertion process. Insertion depth was measured after each insertion. To ensure the pullout results were not affected by potential temperature increase during screw insertion, a waiting period of 10 minutes was implemented before pullout tests (Fredericks & Nuckley, 2021).

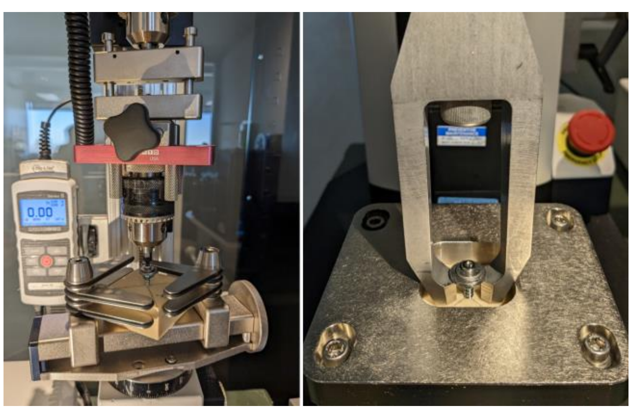


Figure 3: Screw insertion with Mark-10 TSTM-DC-1 (left) and screw pullout with Mark-10 ESM303 (right).

The screws were then pulled out of the block in the axial direction using a motorized tension test stand (Mark-10 ESM303, Force Gauge M5-1000: 20Hz, Accuracy ±5N) at a rate of 3 mm/min (Figure 3). The force-displacement curve was measured, and the pullout strength was determined as the maximum force from the curves. Pullout tests were repeated five times per screw to account for experimental variability, for a total of 85 pullout tests.

Analytical estimation

The Chapman formula was used to estimate the screw pullout force in synthetic bone for each screw. To incorporate the screw thread shape, a thread shape factor (TSF) was defined:

$$\begin{aligned} F_{pullout} &= S_{shear} * A \\ &= S_{shear} * L * \pi * D_{major} * TSF \end{aligned}$$

With,

$F_{pullout}$ = Predicted pullout force (N)
S_{shear} = material ultimate shear stress (MPa)
A = Thread shear area (mm^2)
L = Axial thread length (mm) including only threads that have the nominal major diameter where complete purchase is expected (e.g., excluding the screw tip) of thread engagement in material
D_{major} = Screw major diameter (mm)
TSF = Thread Shape Factor (dimensionless)

$$TSF = \left(\frac{1}{2} + \frac{1}{\sqrt{3}} * \frac{d}{p}\right)$$

p = thread pitch (mm)
d = thread depth (mm)

$$d = \left(\frac{D_{major} - D_{minor}}{2}\right)$$

D_{minor} = minor (root) diameter (mm)

For each screw, the main geometrical features considered in the equation were measured on the CAD models. The axial thread length was calculated by subtracting the screw tip length to the insertion depth measured during experimental tests. The material ultimate shear strength was adjusted by taking into account the actual apparent density of the blocks used in the experiments, using a correlation between the density of the polyurethane foam and its ultimate shear strength.

Screw Pullout Model prediction

The Screw Pullout Model FEM was developed using LS-DYNA explicit solver (Ansys, Canonsburg, Pennsylvania, USA). The polyurethane foam material properties were obtained from compressive (ASTM D1621), tensile (ASTM D1623) and shear (ASTM C273) tests (Figure 4). FEMs replicating each test were then created to calibrate the virtual foam material and failure properties.

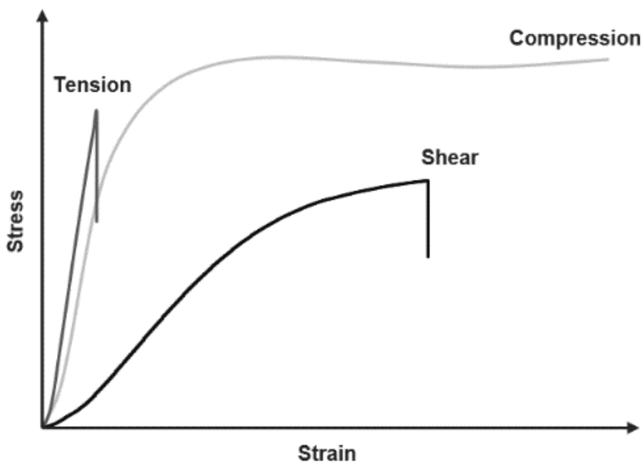


Figure 4: Grade 20 PCF stress strain relationship.

An elasto-plastic constitutive law was utilized to model the nonlinear behavior of the polyurethane foam material, and material properties were calibrated to match experimental test data. Given that the failure strain of the polyurethane foam material is highly dependent on the stress state, a generalized incremental stress state dependent damage model was adopted to simulate material failure by element deletion.

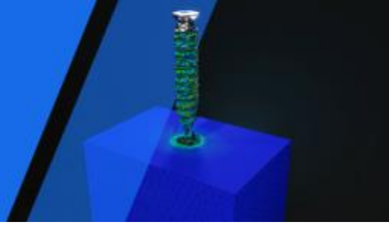
For each screw, a FEM replicating the ASTM F543 pullout experimental set-up was created. The screws were positioned in the blocks according to their respective insertion depth using a Boolean method. The superior surface of the blocks was constrained to prevent any movement, while the screws were restricted to only allow movement in the axial direction. The screws were defined as rigid bodies due to their material properties being orders of magnitude higher than those of the polyurethane foam. The screw-foam interface was modeled using a surface-to-surface penalty method and the active contact segments were updated at every time step to account for the deletion of exterior elements of the foam, as their failure criteria was met during pullout simulation. A ramped velocity was applied on the screw, simulating the tensile force applied by the motorized tension test stand.

A sensitivity analysis was conducted on key FEM numerical parameters. Mesh size was refined through a convergence study to ensure numerical accuracy. Due to the inherent mesh size dependency of failure models caused by strain localization problems, an element size dependent failure strain regularization was defined. This regularization was determined from mesh size sensitivity analysis conducted on the initial compression, tensile, and shear tests models. Contact penalty stiffness was defined as the minimum value at which there was negligeable element penetration and no effect on the force displacement curve. To minimize computational time, a sensitivity analysis was performed to determine the highest pullout velocity at which there was negligeable alterations of the force-displacement curve.

An uncertainty quantification study was conducted on parameters that were difficult to determine experimentally such as screw/foam friction coefficient and geometrical gap between the screw and surrounding foam material. The effect of these parameters on maximum pullout force was found not to be significant. The assumption that the screw can be modeled as a rigid body was tested and was found to have a negligible effect on the results.

Statistical Analysis

Analytical and numerical methods predictions were compared to experimental results in terms of their mean absolute error prediction (accuracy) and 95% confidence interval (precision). Additionally, the reliability of the predictive methods was assessed by calculating Intraclass Correlation Coefficients ($ICC_{(1,1)}$) with respect to the mean of experimental measurements.



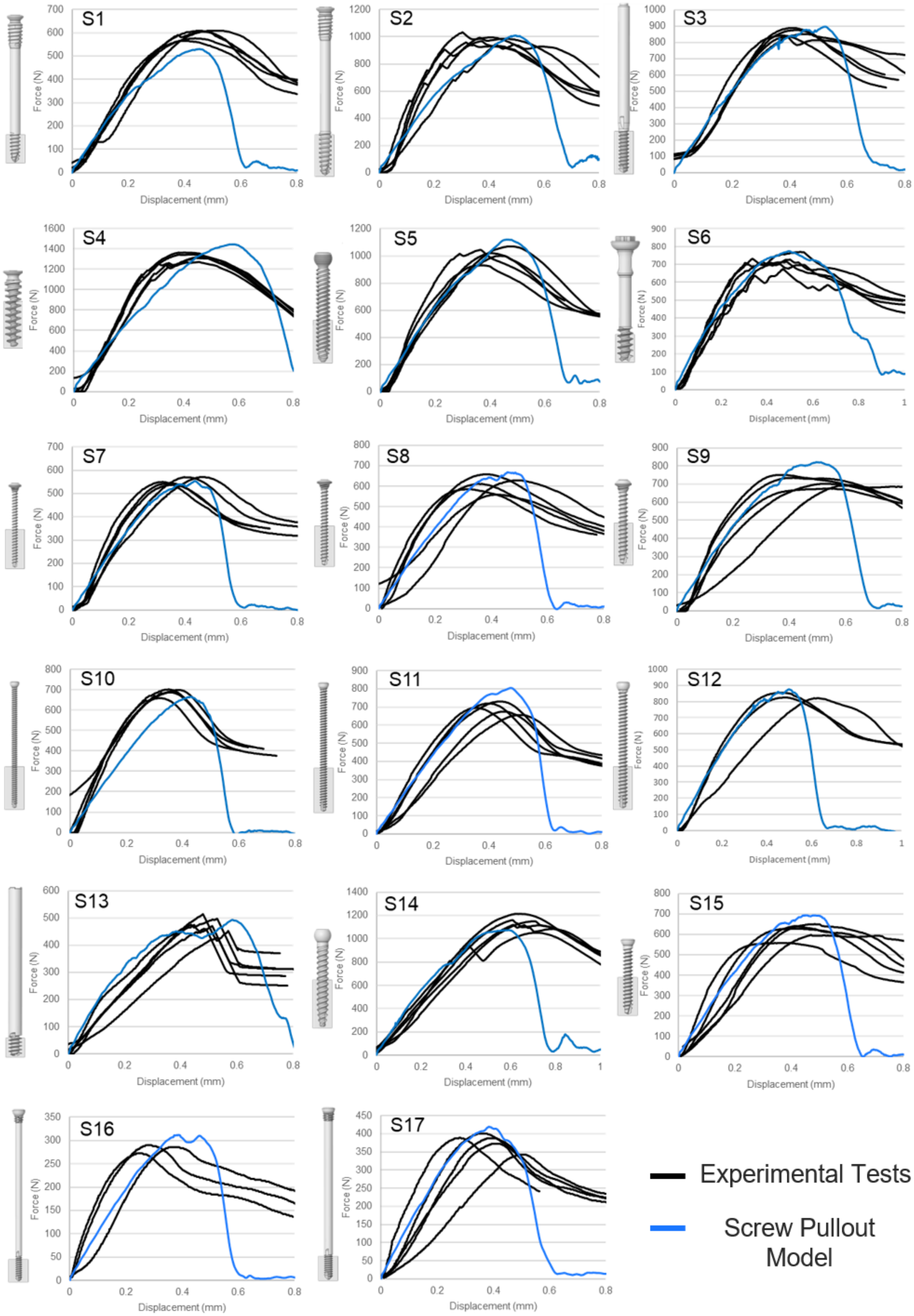


Figure 5: Experimental (black) and simulated (blue) screw pullout force-displacement curves.

Results

Sawbones material characterization

The Sawbones polyurethane foam blocks utilized for the experimental tests had a density of 315.6 kg/m^3 (19.7 PCF), falling within the range of 20 PCF specified by the ASTM F1839 (288.5 to 352.5 kg/m^3). The material ultimate shear strength was defined as 4.2 MPa for the Chapman formula calculation based on Sawbones characterization of mechanical properties relationship with foam density.

Qualitative comparison

The experimental and simulated force-displacement curves exhibited similar behavior for all tested screws (Figure 5). The initial stage of loading displayed linear elastic behavior without any indications of plastic deformation or failure. Subsequently, the stiffness of the construct declined progressively as the material gradually yielded and deteriorated. Finally, the construct reached its peak pullout force and the polyurethane foam failed, resulting in a decrease in the overall stiffness of the assembly.

Failure of the construct occurred at the outer diameter of the screw threads in most cases, except for one screw where the polyurethane foam failed near the distal tip of the screw, which was accurately captured by the numerical model (Figure 6).

Quantitative comparison

The measured and predicted pullout forces are listed in Table 1 and graphically presented in Figure 8. The peak pullout forces for the experimental tests ranged from 272 N to 1362 N with an average variability of ± 5.3% for the five repetitions (3.8% to 18.1%). The mean absolute error prediction for the Screw Pullout Model was 8%, with a 95% confidence interval of -8% to 20% while the mean absolute error prediction for the Chapman analytical formula was 16%, with a 95% confidence interval of -40.0% to 47.8% (Figure 7). The intraclass correlation coefficient with respect to the experimental method was 0.99 for the numerical model and 0.91 for the Chapman equation (Figure 9).

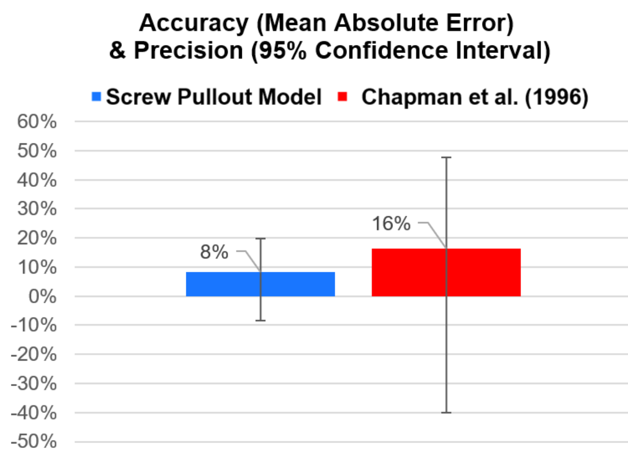


Figure 7: Mean absolute error prediction and 95% confidence intervals.

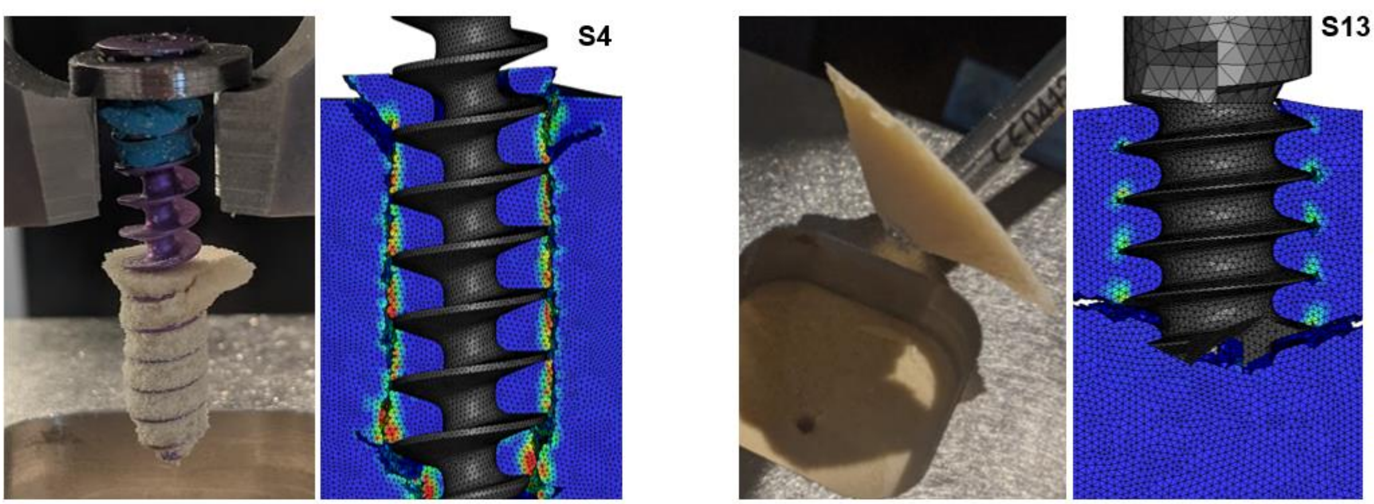
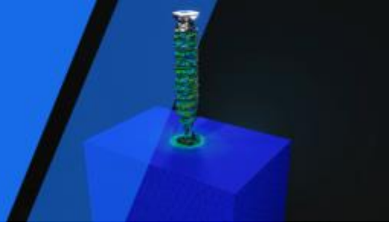


Figure 6: Two distinct modes of failure observed during experimental testing and corresponding Screw Pullout Model prediction.



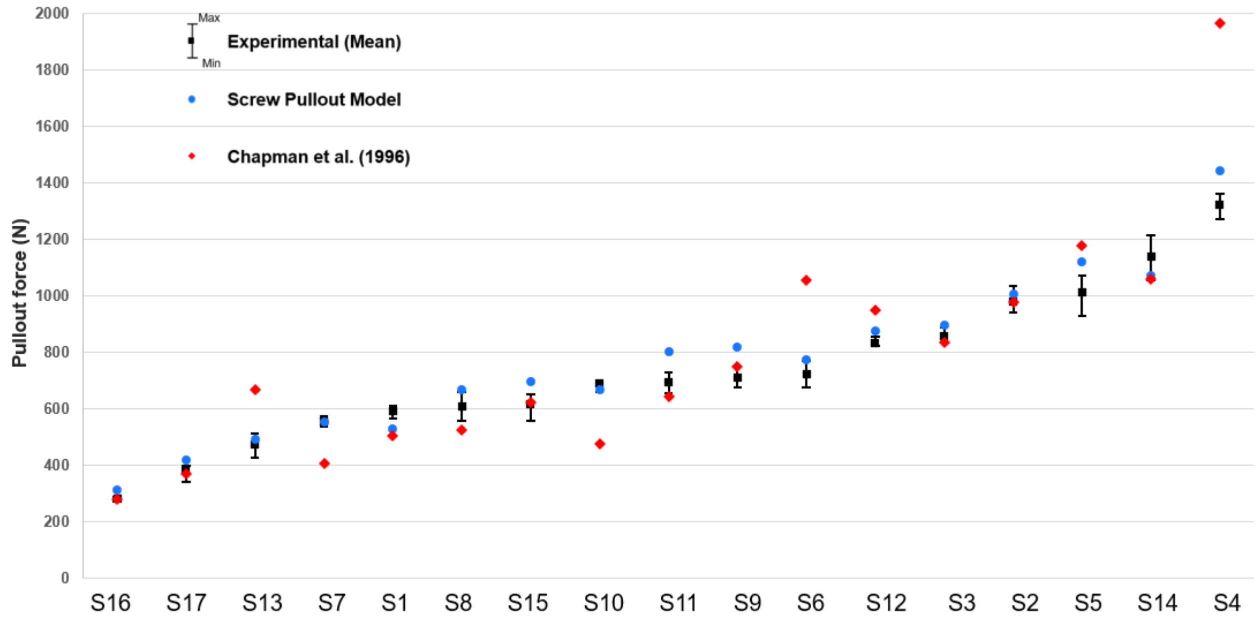
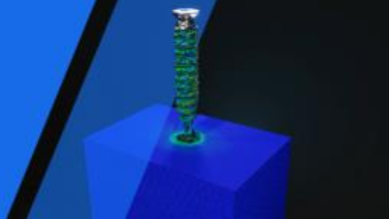


Figure 8: Measured and predicted screw pullout forces. Black bars represent minimum and maximum forces out of 5 repetitions.

Table 1: Measured and predicted screw pullout forces.

Screws	Experimental Pullout Force (N)			Screw Pullout Model		Chapman et al. (1996) Formula	
	Mean n=5	Min	Max	Prediction (N)	*Error (%)*	Prediction (N)	*Error (%)*
S1	593	564	610	531	*-10%*	504	*-15%*
S2	980	942	1034	1008	*3%*	977	*0%*
S3	857	836	888	897	*5%*	836	*-2%*
S4	1323	1270	1362	1445	*9%*	1964	*48%*
S5	1012	928	1072	1120	*11%*	1179	*17%*
S6	724	676	770	774	*7%*	1054	*46%*
S7	556	538	572	554	*0%*	408	*-27%*
S8	608	558	658	667	*10%*	523	*-14%*
S9	710	676	750	820	*15%*	747	*5%*
S10	688	660	702	667	*-3%*	476	*-31%*
S11	695	654	730	804	*16%*	644	*-7%*
S12	833	822	854	877	*5%*	948	*14%*
S13	475	428	514	492	*4%*	669	*41%*
S14	1140	1054	1216	1072	*-6%*	1059	*-7%*
S15	615	558	652	694	*13%*	625	*2%*
S16	283	272	290	313	*11%*	281	*-1%*
S17	378	342	400	420	*11%*	371	*-2%*



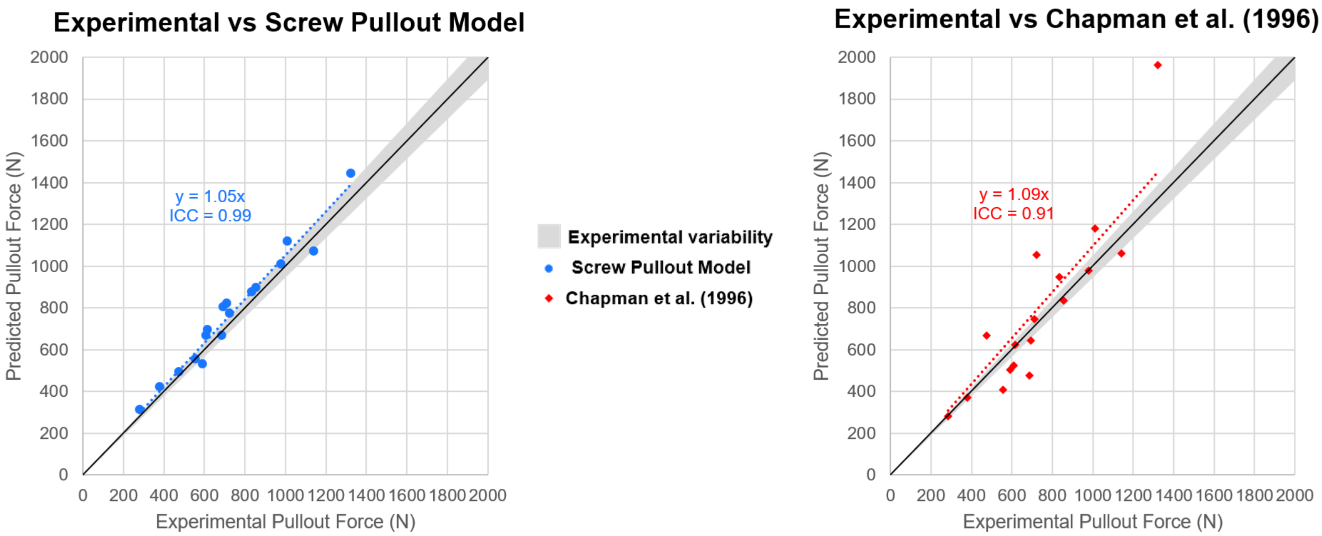


Figure 9: Correlation between experimental and predicted pullout forces.

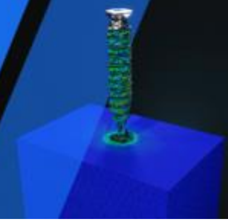
Discussion

The objective of this study was to assess the ability of a computational model of synthetic bone material to predict the anchorage strength of orthopedic screws and compare its capabilities with that of an already established analytical formula. The predictive strength of the numerical method was assessed over a wide design space by selecting screws with diverse sizes and thread features. The goal was to ensure that the numerical model can reliably predict the anchorage strength of any type of metallic screw in the future.

The Screw Pullout Model prediction accuracy fell within experimental test variability and mean absolute error was two times lower than the Chapman formula. In terms of precision, the numerical model was more than 3 times more precise than the analytical formula and had excellent reliability for all tested screws (ICC=0.99). In addition to the prediction of the maximum pullout force, the numerical model was also able to reliably predict the full force-displacement curves, from the initial linear elastic behavior to the initiation of yielding and failure, as well as the correct failure mode of the synthetic bone.

The performance of the Chapman equation tended to be inadequate for screws with either very short or long thread lengths (outer diameter – core diameter), suggesting that the method may not be generalizable to all screw designs. Additionally, this analytical method presents limitations in its applicability to more complex screw designs, such as conical screws, variations in thread profile along the axial direction, or screws with prominent self-tapping features. While some studies have attempted to modify the formula to account for more complex features (Tsai et al., 2009), this approach can increase the complexity of the method by requiring additional measurements and potentially leading to varying interpretations among users and subjectivity when evaluating screw anchorage strength.

The process of experimentally testing screw anchorage strength has certain limitations, including inherent variability in the results observed across different tests, both intra and inter laboratories. This variability can originate from several factors, such as differences in the testing apparatus, protocol, operator, and test specimens. Despite the possibility of significant differences in results when comparing screw performance in polyurethane foam blocks, the ASTM F1839 standard permits a variability of ± 10% in foam density during the manufacturing process. According to a previous study, differences as small as 3.7% in foam apparent



density can result in more than 10% difference in terms of maximum pullout force (Weidling, Wendler, et al., 2022). This discrepancy may even surpass the impact of certain screw features, which complicates the design assessment process. Although increasing the number of repetitions can improve the statistical reliability of results, it also extends the duration of testing, which can be time-consuming and costly.

The Screw Pullout Model FEM offers a consistent and standardized method for evaluating screw anchorage strength by providing a fully controlled testing environment that minimizes sources of variability found in experimental testing. By integrating the exact geometry of the screw and the mechanical properties of synthetic bone material, this model offers a comprehensive evaluation of screw performance and valuable insights into bone damage mechanics. The standardized testing conditions provided by the Screw Pullout Model are ideal for conducting design of experiment types of studies, enabling a clear understanding of the impact of each screw design parameters on performance. Additionally, the use of this numerical model can significantly reduce the time and resources required for prototyping and testing new designs, making it an efficient tool for the optimization of orthopedic screws early in the development phases.

This validation study has some limitations. Although the numerical model performance was assessed over a wide screw design space, additional screws will be added to the validation sample to further demonstrate the model's credibility and its capability to reliably predict the anchorage strength of any type of screws. Additionally, experimental studies have suggested that the level of bone compaction during screw insertion has an impact on anchoring strength (Weidling, Heilemann, et al., 2022). Although the model does not currently account for bone compaction, it still demonstrated precise predictions for all tested screws, including self-tapping and conical screws which may lead to some bone compaction during insertion, suggesting that it has a limited effect on anchoring strength.

Conclusion

This study demonstrates that the Screw Pullout Model is a high-potential tool for evaluating the anchorage strength of orthopedic screws in synthetic bone material. The accuracy and precision of the computational model's predictions were found to be significantly superior to the accuracy and precision of an analytical equation that is currently recognized by regulatory bodies to qualify orthopedic screw designs. The standardized testing environment provided by the Screw Pullout Model can significantly reduce the time and resources required for evaluating new screw designs and could be used as a complementary or surrogate tool to the ASTM F543 bench-top tests. The bone model and testing set-up could be adapted to other ASTM tests conducted on synthetic bone material, expanding its potential applications in the orthopedic field.

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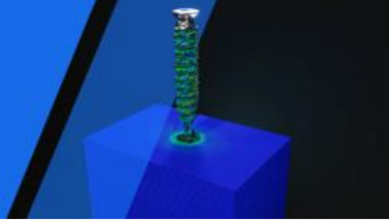

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