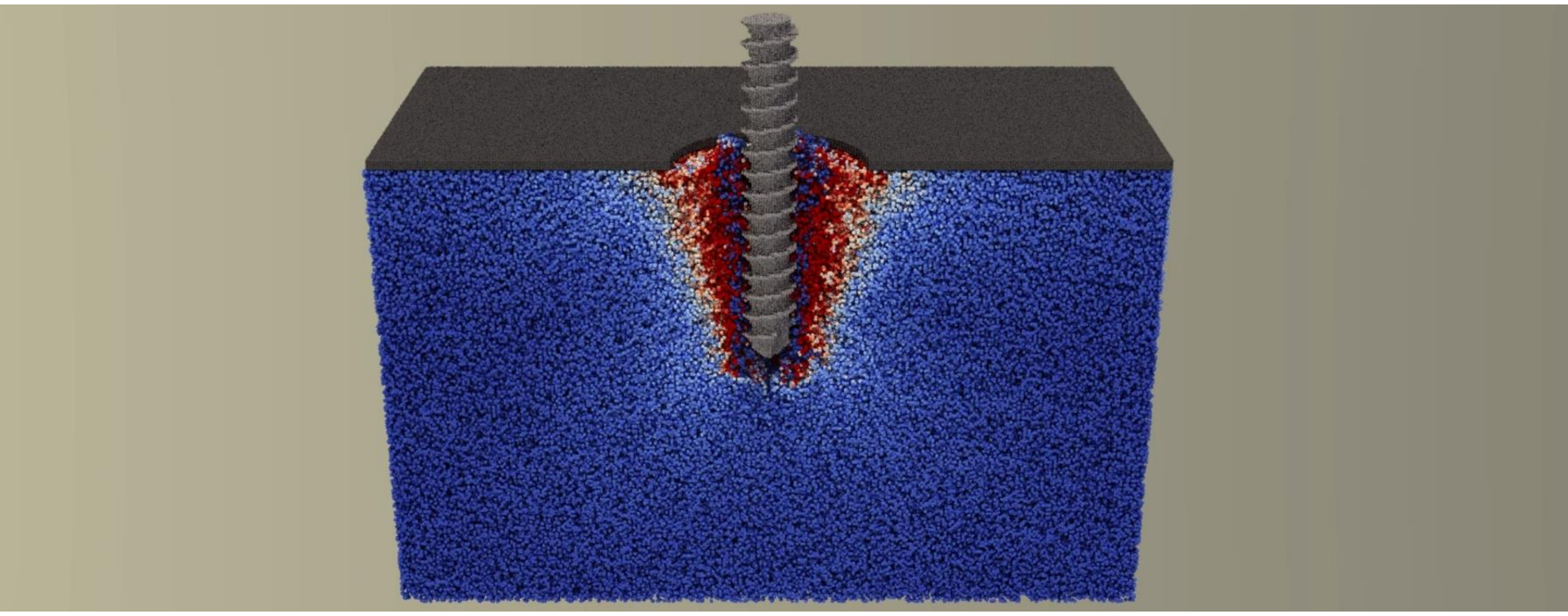
Validation of screw pull-out in Alfonso™: ASTM F543-17 A3

Non-Confidential Technical Whitepaper – 10 April 2023

Experiments and Analysis: Janice Oentaryo, PhD; Rezaul Tharim; Sloan Kulper, PhD; Erica Ueda Boles, PhD
Visualizations: Abbas Alvi and Eka Tjong



Abstract

Computational models of ASTM F543-17 A3 (screw pull-out) were generated using the particle-based simulation system *Alfonso* and its predictions were compared to physical experimental test results. Generic HA 3.5, HA 4.0, and HA 4.5 bone screws were fabricated (316L stainless steel, ISO Fine tolerance, n=3 each), inserted into pilot holes in the PU foam, and then pulled out while recording force vs. displacement data. Blocks of solid rigid polyurethane foam measuring 58 x 65 x 40 mm were prepared from 20 PCF foam (n=3 for each screw design), and 15 PCF foam (n=3 for HA 4.5 screw only). Models of the implant and foam blocks were constructed in *Alfonso* at a resolution of 200 μm/particle and simulated pull-out tests were performed. The maximum peak pull-out loads of the HA 3.5 screws from 20 PCF foam were 692 N (average) and 706 N in the physical and simulated tests , respectively. For the HA 4.0 screws the maximum pull-out loads were 816 N (average) and 713 N from 20 PCF foam in the physical and simulated tests, respectively. For the HA 4.5 screws the maximum peak pull-out loads were 509 N (average) and 508 N from 15 PCF foam in the physical and simulated tests, respectively; maximum pull-out loads were 798 N (average) and 820 N from 20 PCF foam in the physical and simulated tests, respectively. The average CCC (concordance correlation coefficient) between simulation and experiment maximum pull-out loads was >0.90, suggesting excellent concordance, however the simulations over-predicted loads following the peak. *Alfonso* can accurately predict the maximum pull-out loads of several typical orthopedic screws in two common PU foam grades.

Background and Objectives

ASTM F543-17 A3 describes a test used to evaluate the axial pull-out strength of orthopaedic bone screws (e.g., under FDA product code HWC). It is typically part of a battery of tests required to demonstrate that a study device is substantially equivalent to a legally marketed predicate device in a 510(k) premarket submission. *Alfonso*'s particle-based ASTM F543-17 A3 model can be used to quickly predict the likelihood that a candidate design will pass, all without needing a physical prototype. To test the validity of *Alfonso's* predictions, we compare them to physical results of screw pull-out from industry-standard 15 and 20 PCF solid rigid polyurethane foam.

Materials and Methods

Preparation and testing of physical specimens

Generic HA 3.5, HA 4.0, and HA 4.5 bone screw designs were modelled in CAD (Solidworks 2021) and manufactured (n=3 per design) in polished 316L stainless steel per the dimensions and tolerances stated in tables A5.1 and A5.2 of ASTM F543-17, and in ISO 5835-1991 (Figure 1 and Table 1). Type HA screw classification is defined in ASTM F543-17 as screws with a solid head and solid core and shallow, asymmetrical buttress thread, deep screw head, and spherical under-surface of the head. These screw types were selected for validation as it is in common clinical use and is offered by various manufacturers.

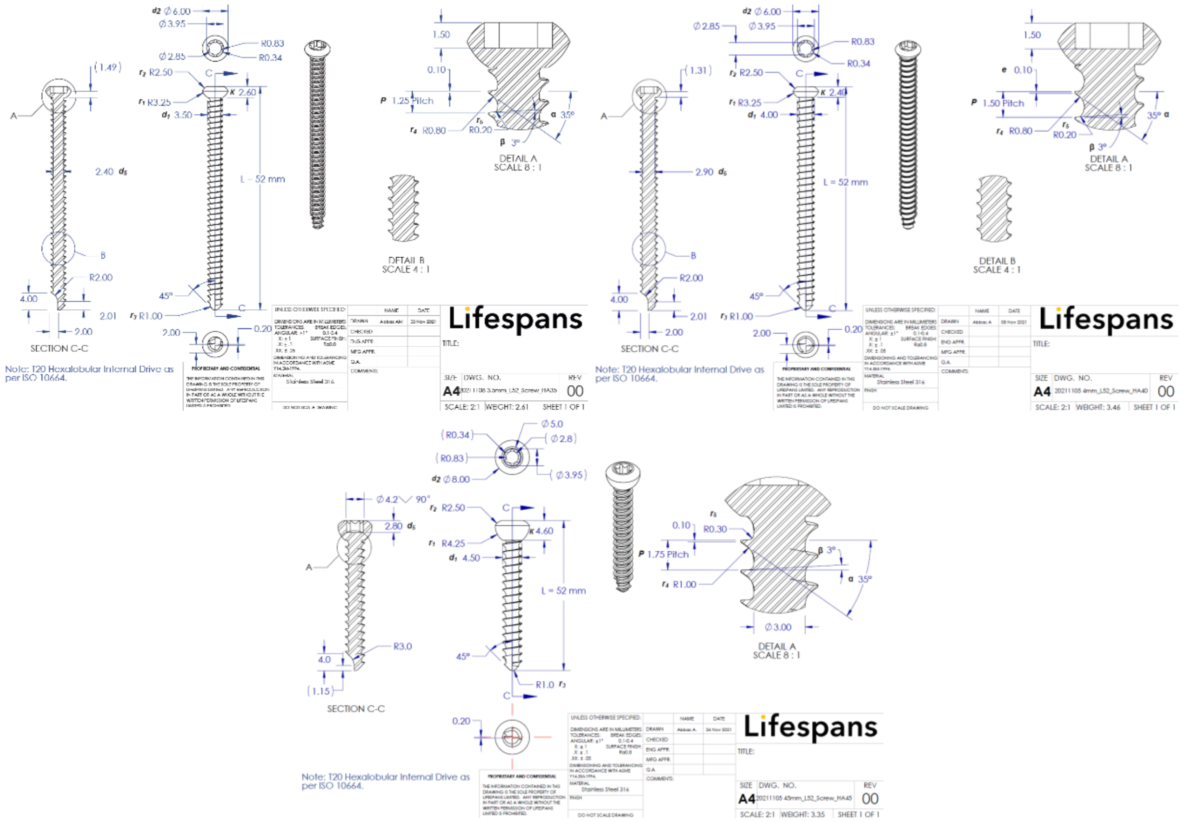


Figure 1. Engineering drawings of the HA 3.5, HA 4.0, and HA 4.5 bone screws, L52 mm

Table 1. Design specifications of the three different HA screws (according to ASTM F543-17 Table A5.1 Dimensions for HA Screws and Table A5.2 Dimensions for HA Screw Thread)

Dimensions	Screw Type and Size		
	HA 3.5	HA 4.0	HA 4.5
According to ASTM F543-17 Table A5.1 Dimensions for HA Screws			
Head diameter, d_2 (+0.00/-0.15 mm)	6.00	6.00	8.00
Head height (mm), k	2.60	2.40	4.60
Bottom head radius, r_1 (+0.000/-0.075 mm)	3.25	3.25	4.25
Top head radius, r_2 (mm)	2.50	2.50	2.50
Tip radius, r_3 (mm)	1.00	1.00	1.00
According to ASTM F543-17 Table A5.2 Dimensions for HA Screw Thread			
Thread diameter, d_1 (+0.00/-0.15 mm)	3.50	4.00	4.50
Core diameter, d_5 (+0.00/-0.15 mm)	2.40	2.90	3.00
Crest width, e (mm)	0.10	0.10	0.10
Thread pitch, P (mm)	1.25	1.50	1.75
Leading edge radius, r_4 (mm)	0.80	0.80	1.00
Trailing edge radius, r_5 (mm)	0.20	0.20	0.30
Leading edge angle, α (°)	35	35	35
Trailing edge angle, β (°)	3	3	3

All the physical solid rigid polyurethane foam specimens (n=3 each of 15 or 20 PCF density per screw design) were prepared by cutting manufacturer-supplied blocks (130 x 180 x 40 mm) into blocks measuring 58 x 65 x 40 mm. The direction of foam rise was noted to ensure that foam rise always aligned with the axis of pull-out motion. Material properties for the PU foam grades tested are listed in Table 2.

Table 2. Description of Various PU Foam Grades from the Manufacturer's Datasheet and Reported Material Properties based on ASTM D1621 Compressive Tests

Foam grades	Samples per screw design	Dimensions (mm)	Density (kg/m^3)	Volume Fraction	Manufacturer's REF number (original block)	Compressive (based on ASTM D1621)		Speed of sound **c** (m/s)
						Strength (MPa)	Modulus (MPa)	
15 PCF	3	58 x 65 x 40	240	0.20	1522-02	4.9	123	871
20 PCF	3	58 x 65 x 40	320	0.27	1522-03	8.4	210	986

Foam blocks were pre-drilled with pilot holes 0.1 mm smaller than the screw's core diameter and screws were manually inserted to a depth of 20 mm. A pull-out fixture was fabricated in stainless steel and attached to the loadcell of the hydraulic press as shown in Figure 2. Each foam block was then slid into the pull-out fixture, the screw was aligned with a chamfered pull-out slot, and the screw was removed at a rate of 5 mm/min while recording force. The speed of sound c of each foam grade was calculated to set a theoretical upper bound of rate of motion for simulation (Table 2):

$$c = \sqrt{\frac{(K_f + \frac{4}{3}G_f)}{\rho}}$$

Where for each foam grade, K_f is the bulk modulus, G_f is the shear modulus, and ρ is the density (kg/m^3) of the material.

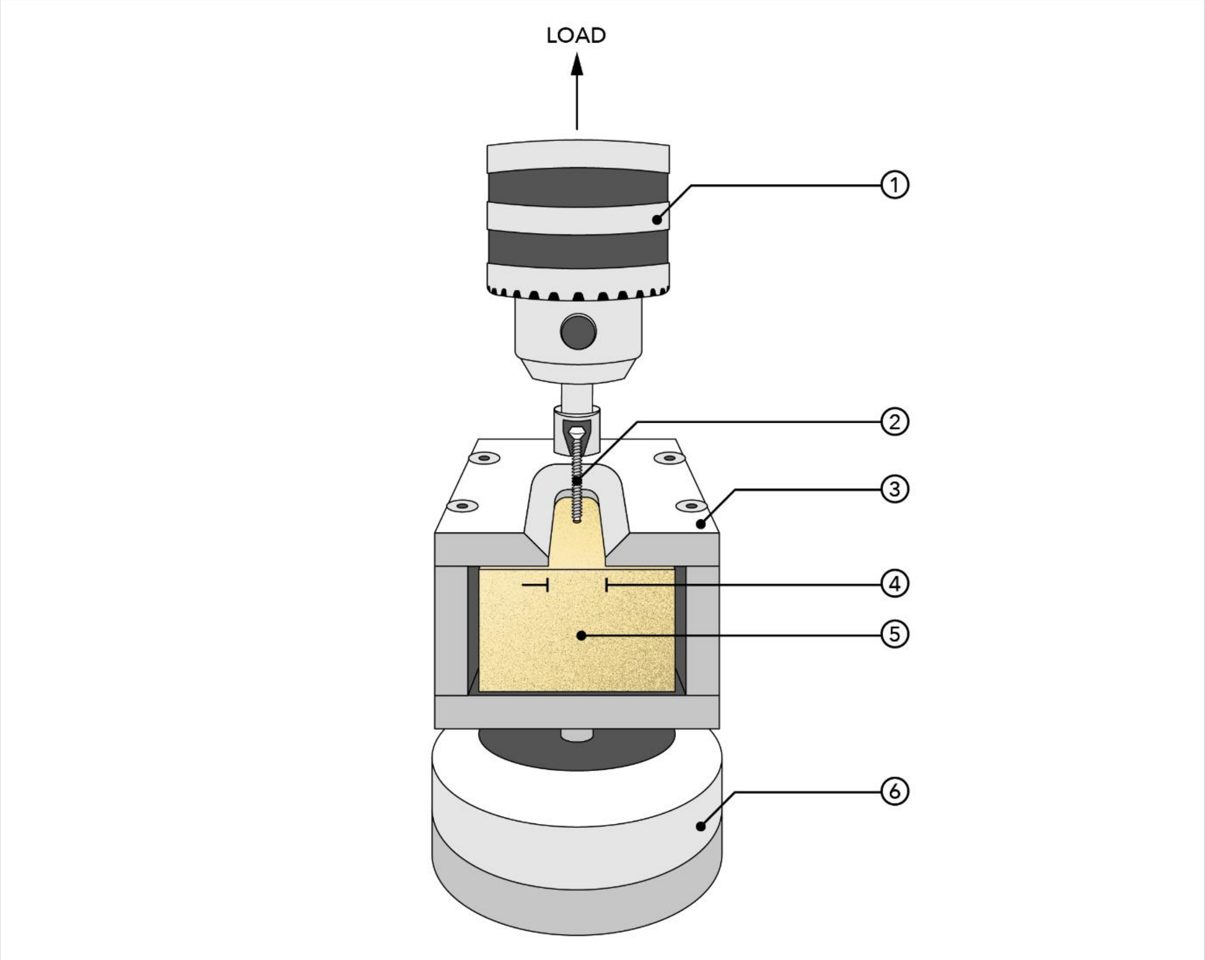


Figure 2. Physical test setup: 1. MTS 858 Mini Bionix hydraulic press, 2. Screw in chamfered slot, 3. Stainless steel pull-out fixture, 4. Gap in pull-out fixture allowing insertion of foam block, 5. Solid rigid PU foam block (58 x 65 x 40 mm), 6. Loadcell (10 kN) clamped to pull-out fixture. Illustration by Eka Tjong

Preparation and testing of simulated specimens

CAD models of the generic HA 3.5, HA 4.0, and HA 4.5 bone screws and a representative model of the pull-out fixture top plate were exported to STL format using a fine mesh (<1 μm deviation from mathematical surface) and developed into a particle-based model in *Alfonso* at a resolution of 200 μm per particle. Simulated solid rigid polyurethane foam specimens (58 x 65 x 40 mm) were prepared by generating particle-based models of 15 and 20 PCF foam grades, likewise at 200 μm per particle (see "Appendix I: Notes on foam models particle-based methods in *Alfonso*" and [1] for further detail). The particle-based bone screw models were positioned at 20 mm depth in the foam blocks, with intersecting foam particles removed through a Boolean operation. The rigid top plate was fixed in position atop the foam block, with the sides and bottom of the foam block bounded by fixed walls and ground plane as shown in Figure 3. Simulations were run with symmetry along the YZ-plane for significantly faster simulation runtime, given that the accuracy of the results was not jeopardized due to the concept of symmetry (see "Appendix II: Validation of symmetric screw pull-out simulation model").

A sensitivity analysis was also conducted to confirm the maximum pull-out rate (1 m/s), below which there was no observable change in the force-displacement curve. This rate was well below the calculated speed of sound of the foam material (Table 2). Simulated pull-out was then performed at this rate for both foam grades (see Figure 4). Deviations between physical and simulated testing protocols and the published ASTM standard are summarized in Table 3.

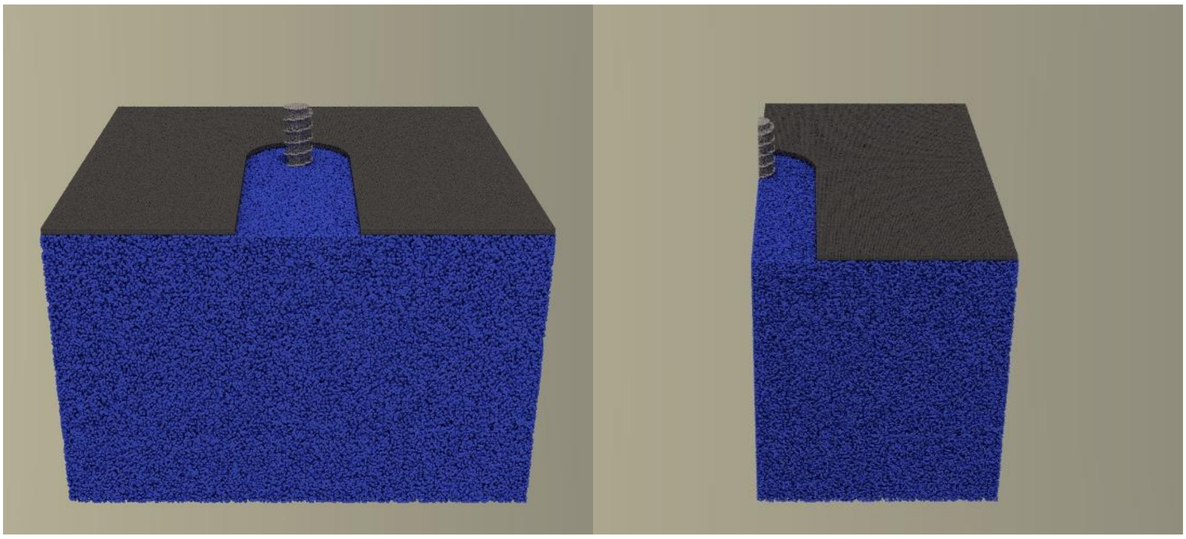


Figure 3. Simulated test setup in Alfonso: Rigid top-plate is fixed in position during analysis, side and bottom surfaces of foam are bounded by walls and ground-plane, respectively for full-sized (left) and half-sized simulations with symmetry across the YZ-plane.

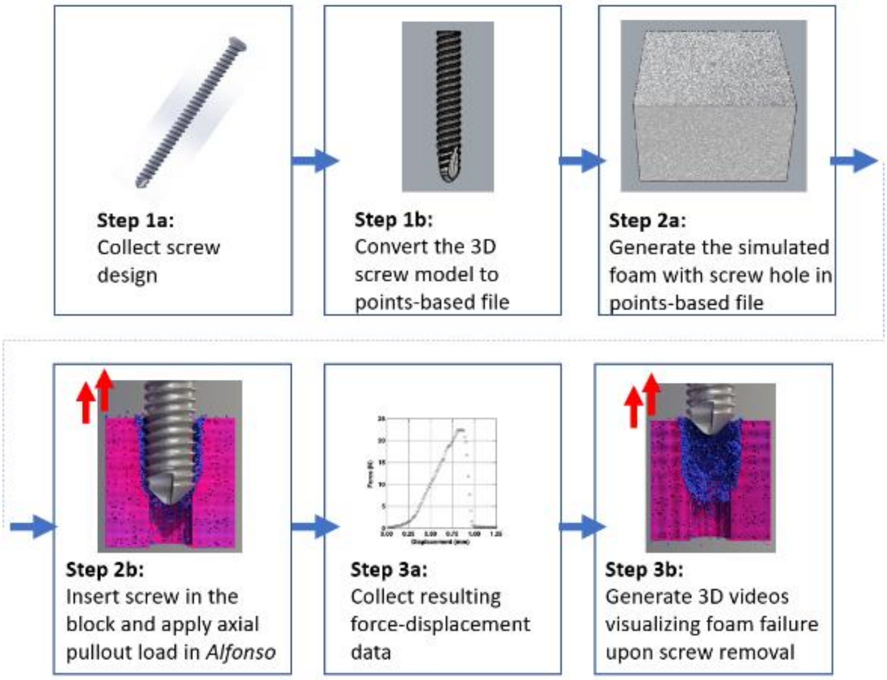


Figure 4. Illustration of the overall ASTM F543-17 A3 axial pull-out simulation procedure in Alfonso.

Table 3. Deviations between physical and simulated testing protocols and the published ASTM standard

Test Setup Parameters/Procedures		ASTM F543-17 A3 standard method	Physical test	Simulation
Test setup procedures	Load fixture	Slot to capture the head of the screw without contact being made with the screw's shaft	Slot to capture the head of the screw without contact being made with the screw's shaft	No simulated load fixture; screw head is removed since only the screw's shaft interacts with the foam
	Test block clamp's grip span	Minimum of five times the major diameter of the bone screw	Minimum of 16 mm	Minimum of 16 mm
	Test block (polyurethane foam in accordance with ASTM F1839)	Discretion of the user	15 or 20 PCF	Scaled according to manufacturer's 15 or 20 PCF compression data
	Foam block size (width x length x height)	Height should be more than 20 mm	58 x 65 x 40 mm	58 x 65 x 40 mm
	Screw insertion	3 rpm into a foam block pre-drilled with a pilot hole using a drill size specified by the screw manufacturer (and tapped if specified)	Manually and slowly inserted the screw into a pre-drilled foam block with pilot hole 0.1 mm smaller than the screw's core diameter	No simulated insertion; Boolean difference operation was performed to create a cavity with the same profile as the screw. The screw model was then positioned in the cavity.
	Screw insertion depth	20 mm	20 mm	20 mm
	Sample size	Usually, n=5 minimum per case	n=3 per case	n=1 per case
Parameters	Tensile load rate	5 mm/min	5 mm/min	1 m/s (Table 2)
	Data collection time interval	Suitable to continuously record load versus load fixture displacement	0.05 s	1×10^{-9} s
	End point (displacement)	The maximum load is reached during the test method	6 mm	6 mm
	Resolution (specific to simulation)	Not applicable	Not applicable	200 μm

Data and statistical analyses

The load–displacement data were normalized such that zero displacement was set at the lowest initial force common for both the physical data and the *Alfonso* simulation data. Stiffness in the initial linear-elastic region of both physical and simulation data was calculated from the load range from 200 to 400 N. The numbers of data points obtained from the physical tests and *Alfonso* simulations varied due to the difference in data collection intervals. In order to directly compare and analyze the load–displacement data for the concordance analysis, Python was used to resample the data sets to the same displacement values and interpolate the load values without changing the load-displacement curves' shape and magnitude. Statistical analyses were performed using an appropriate software such as MedCalc® (MedCalc Software Ltd, Ostend, Belgium).

Lin's concordance correlation coefficient (CCC)

The Lin's concordance correlation coefficient (CCC) evaluates the degree to which pairs of observations fall on the 45° line through the origin (i.e., the line of equality). [2], [3] The concordance correlation coefficient is calculated as $\rho_c = \rho \times C_b$ ($-1 \leq \rho_c \leq 1$) where:

- ρ is the Pearson correlation coefficient, which measures how far each observation deviates from the best-fit line, and is a measure of precision, and
- C_b is a bias correction factor that measures how far the best-fit line deviates from the 45° line through the origin, and is a measure of accuracy ($0 < C_b \leq 1$; $C_b = 1$ when there is no deviation from the 45° line).

A CCC value of 1 indicates strong concordance, while a value of -1 indicates strong discordance. Borrowing from the standard interpretation of Pearson's correlation coefficient or intraclass correlation coefficients, we assume that positive CCC values <0.20 indicate "poor" concordance, while values >0.80 indicate "excellent" concordance.

Results

The average CCC (concordance correlation coefficient) between the load-displacement curves of the physical and simulated tests across all screw sizes and foam grades was 0.90 (using 26 sample points per curve, see Table 5), suggesting excellent concordance.

The average maximum peak pull-out loads from HA 3.5 screw in 20 PCF foam were 692 and 705 N in the physical and simulated tests, respectively. As shown in Figure 5 and summarized in Table 4, the force-displacement curves of both physical and simulated HA 3.5 screw in 20 PCF foam tests were characterized by initial linear-elastic regions with stiffness of approximately 2.2 kN/mm. The average CCC between the load-displacement curves of the HA 3.5 screw in 20 PCF physical and simulated test pair up to the peak pullout force was 0.89.

The average maximum peak pull-out loads from HA 4.0 screw in 20 PCF foam were 816 and 713 N in the physical and simulated tests, respectively. As shown in Figure 5 and summarized in Table 4, the linear-elastic region of the physical tests had an average stiffness of approximately 2.5 kN/mm. Stiffness was underpredicted in the simulation, with a value of approximately 2.0 kN/mm.

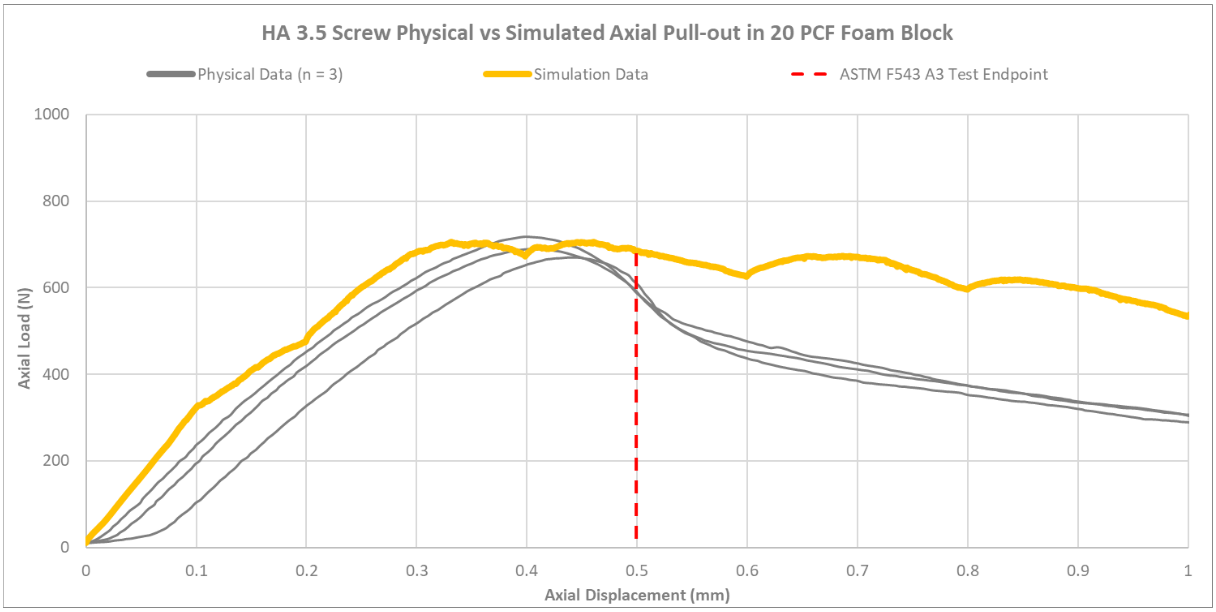
The average CCC between the load-displacement curves of the HA 4.0 screw in 20 PCF physical and simulated test pair up to the peak pullout force was 0.91.

The average maximum peak pull-out loads from HA 4.5 screw in 20 PCF foam were 798 and 820 N in the physical and simulated tests, respectively. In the physical tests, as shown in Figure 6 and summarized in Table 4, the linear-elastic region had a stiffness of approximately 2.0 kN/mm. Stiffness was overpredicted in the simulation, with a value of approximately 2.6 kN/mm. The average CCC between the load-displacement curves of the HA 4.5 screw in 20 PCF physical and simulated test pair up to the peak pullout force was 0.93.

For HA 4.5 screw in 15 PCF foam, the average maximum peak pull-out loads were 509 and 508 N in the physical and simulated tests, respectively. The force-displacement curves of both physical and simulated 20 PCF foam tests were characterized by initial linear-elastic regions with stiffness of approximately 1.3 kN/mm. The average CCC between the load-displacement curves of the HA 4.5 screw in 15 PCF physical and simulated test pair was 0.88.

Table 4. Maximum pull-out load values and stiffnesses at the initial elastic region for the physical versus simulated HA 3.5, HA 4.0, and HA 4.5 screw pull-out in 15 and 20 PCF polyurethane foam blocks

Physical Data versus Simulation Data for Different Screw Sizes	Maximum Pull-out Load (N)			
	HA 3.5 screw	HA 4.0 screw	HA 4.5 screw	
Foam grades	20 PCF foam			15 PCF foam
Physical tests				
Trial 1	717.92	789.44	816.60	470.20
Trial 2	689.47	842.29	746.14	505.84
Trial 3	669.95	817.09	831.61	552.13
Standard Deviation	24.12	26.43	45.63	41.08
Average (Physical tests)	**692.45**	**816.27**	**798.12**	**509.39**
Simulated tests	**705.72**	**713.43**	**819.56**	**508.51**
Physical Data versus Simulation Data for Different Screw Sizes	Stiffness (N/mm)			
	HA 3.5 screw	HA 4.0 screw	HA 4.5 screw	
Foam grades	20 PCF foam			15 PCF foam
Physical tests				
Trial 1	2261.51	2301.27	1891.29	1198.90
Trial 2	2289.92	2561.25	1935.03	1376.23
Trial 3	2110.07	2707.93	2165.49	1489.85
Standard Deviation	96.68	205.94	147.32	146.63
Average (Physical tests)	**2220.50**	**2523.48**	**1997.27**	**1355.00**
Simulated tests	**2294.71**	**1981.01**	**2618.29**	**1325.03**



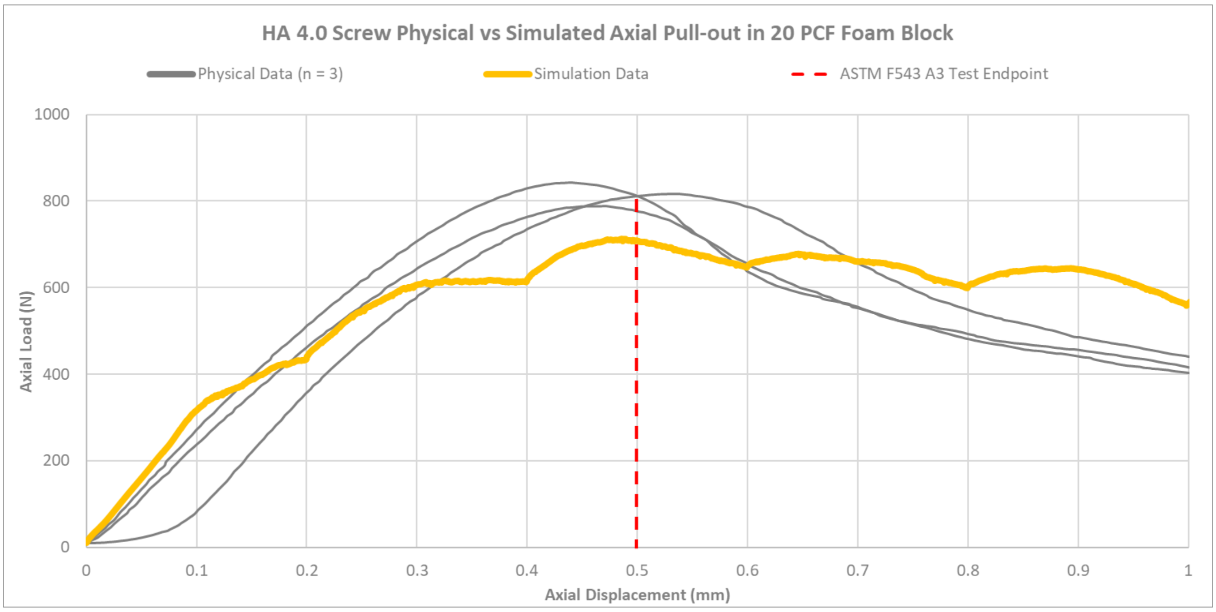
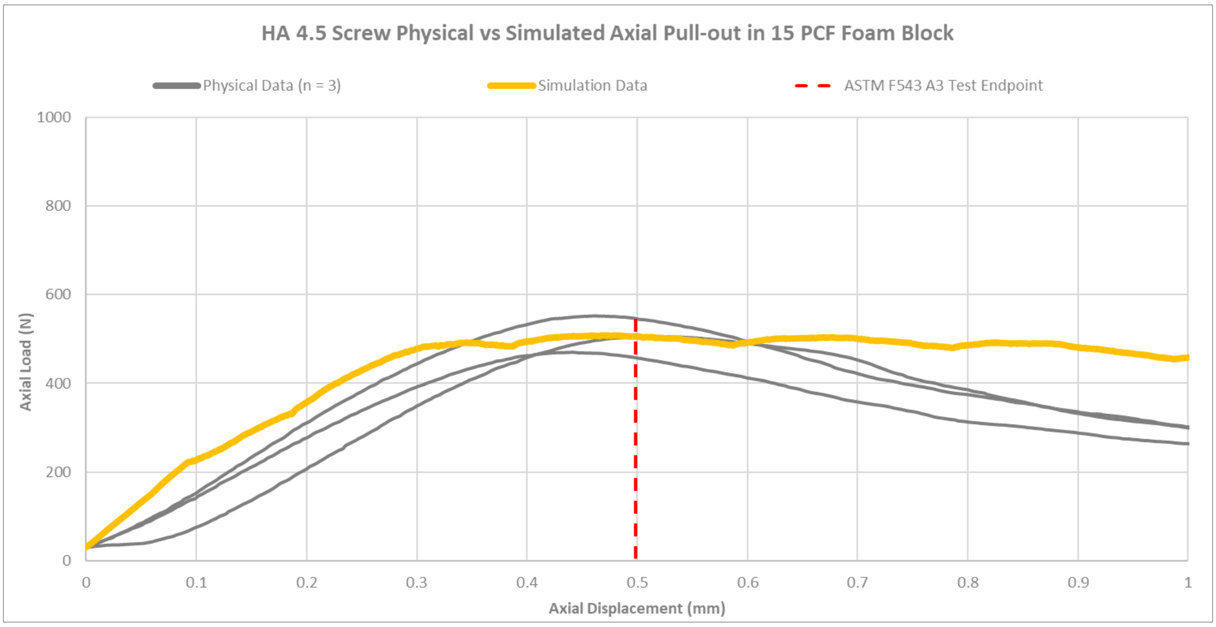


Figure 5. Load-displacement curves from the physical experiment (n = 3) and the simulated (half-sized / symmetric across YZ-plane) axial pull-out tests of HA 3.5 (top) and HA 4.0 screws (bottom) in 20 PCF polyurethane foam blocks up to 1 mm pull-out displacement



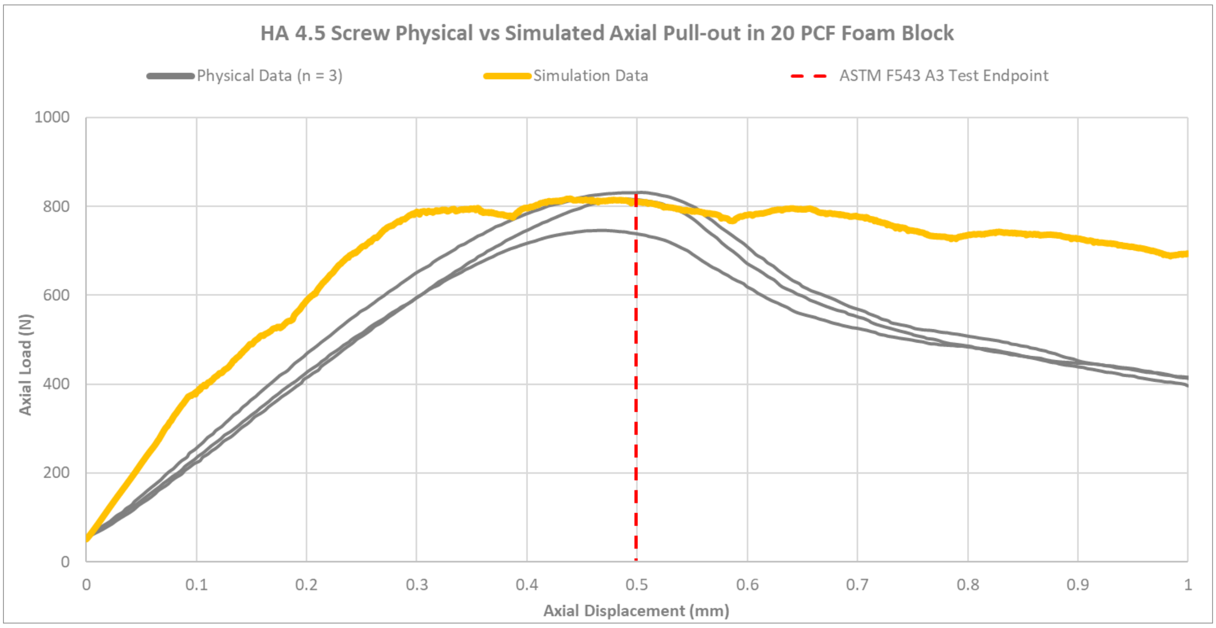


Figure 6. Load-displacement curves from the physical experiment (n = 3) and simulated axial pull-out tests of HA 4.5 screws in 15 PCF (top) and 20 PCF (bottom) polyurethane foam blocks up to 1 mm pull-out displacement

Table 5. Concordance analysis on HA 3.5, HA 4.0, HA 4.5 screw pull-out in 15 or 20 PCF polyurethane foam blocks from the initial displacement to the ASTM F543 A3 test endpoint (0.5 mm displacement) where the maximum pull-out load values have been reached

Variables	HA 3.5 Screw in 20 PCF			HA 4.0 Screw in 20 PCF		
	Trial 1 vs Simulation	Trial 2 vs Simulation	Trial 3 vs Simulation	Trial 1 vs Simulation	Trial 2 vs Simulation	Trial 3 vs Simulation
Sample size (curve data points)	26	26	26	26	26	26
Concordance correlation coefficient	0.9561	0.9216	0.7983	0.9481	0.9055	0.8847
95% Confidence Interval	0.9176 - 0.9768	0.8595 - 0.9569	0.6640 - 0.8827	0.9225 - 0.9654	0.8498 - 0.9411	0.8196 - 0.9272
Pearson ρ (precision)	0.9890	0.9865	0.9559	0.9867	0.9874	0.9634
Bias correction factor C_b (accuracy)	0.9666	0.9343	0.8352	0.9609	0.9171	0.9183
Variables	HA 4.5 Screw in 15 PCF			HA 4.5 Screw in 20 PCF		
	Trial 1 vs Simulation	Trial 2 vs Simulation	Trial 3 vs Simulation	Trial 1 vs Simulation	Trial 2 vs Simulation	Trial 3 vs Simulation
Sample size (curve data points)	26	26	26	26	26	26
Concordance correlation coefficient	0.9047	0.7911	0.9578	0.9088	0.9168	0.9575
95% Confidence Interval	0.8307 - 0.9472	0.6541 - 0.8814	0.92008 - 0.9777	0.8279 - 0.9527	0.8492 - 0.9549	0.9156 - 0.9788
Pearson ρ (precision)	0.9840	0.9373	0.9791	0.9088	0.9833	0.9809
Bias correction factor C_b (accuracy)	0.9194	0.8440	0.9782	0.9391	0.9323	0.9762

The ASTM F543-17 A3 standard also requires reporting of the method of failure (e.g., screw shaft, screw threads, or material failure). The method of failure in all the benchtop and simulated axial pull-out tests for HA 3.5, HA 4.0, and HA 4.5 screws in 15 PCF or 20 PCF foam models was due to failure of the foam material when the screw was pulled out, whereas the screw's shaft and threads remained intact and undamaged. Both the physical test and simulations displayed the foam material getting removed with debris coming out from the foam block when the screw was moved upwards (Figure 7 and Figure 8). *Alfonso* simulations also excel in showing the 3D visualization of the stress distribution in the materials (e.g., around the screw thread inside the polyurethane foam) during and after the screw pull-out.

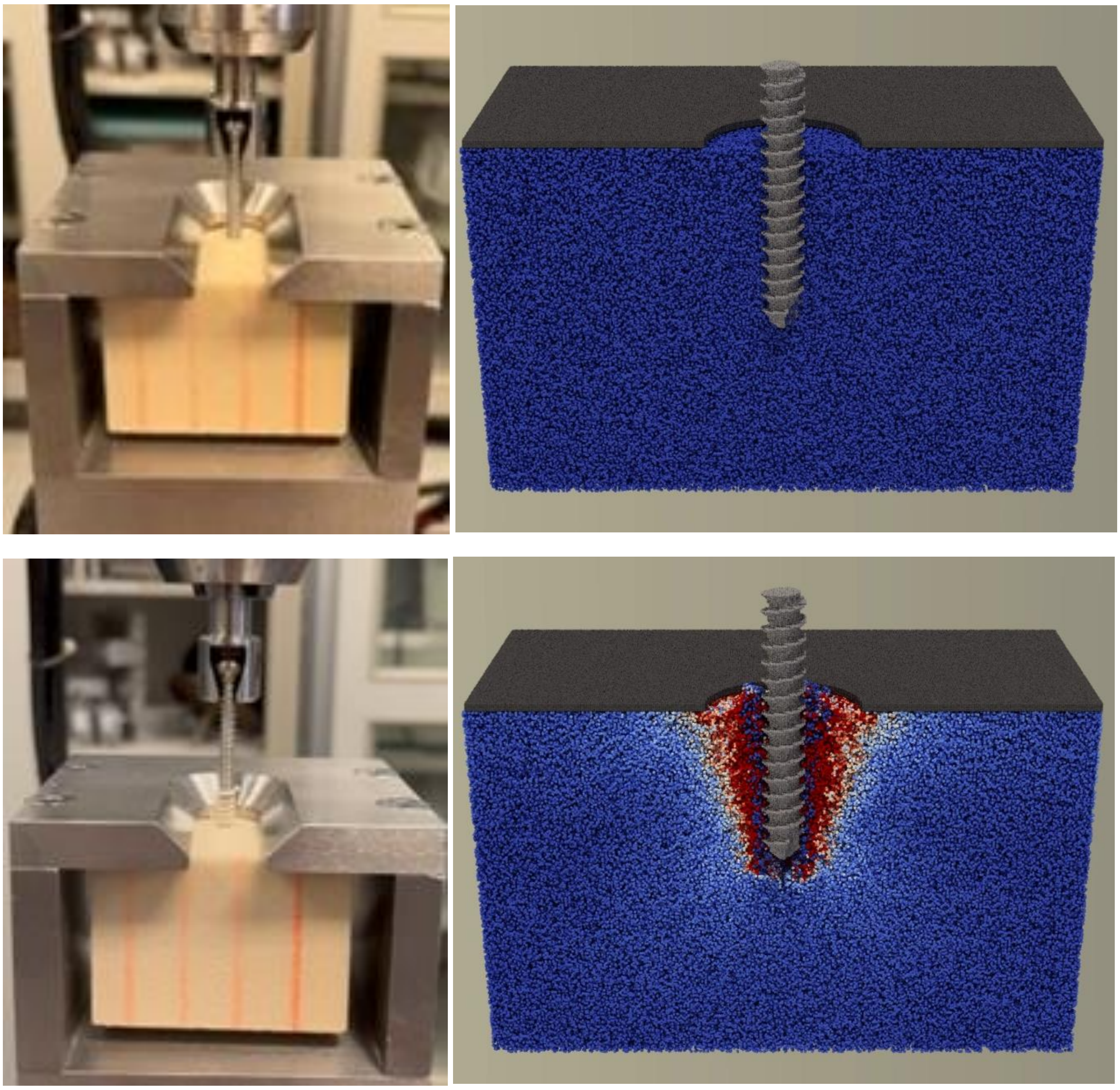


Figure 7. Representative images of the axial pull-out before (top) and after (bottom) 6 mm of axial displacement for a HA 4.5 screw in physical and simulated 15 PCF polyurethane foam

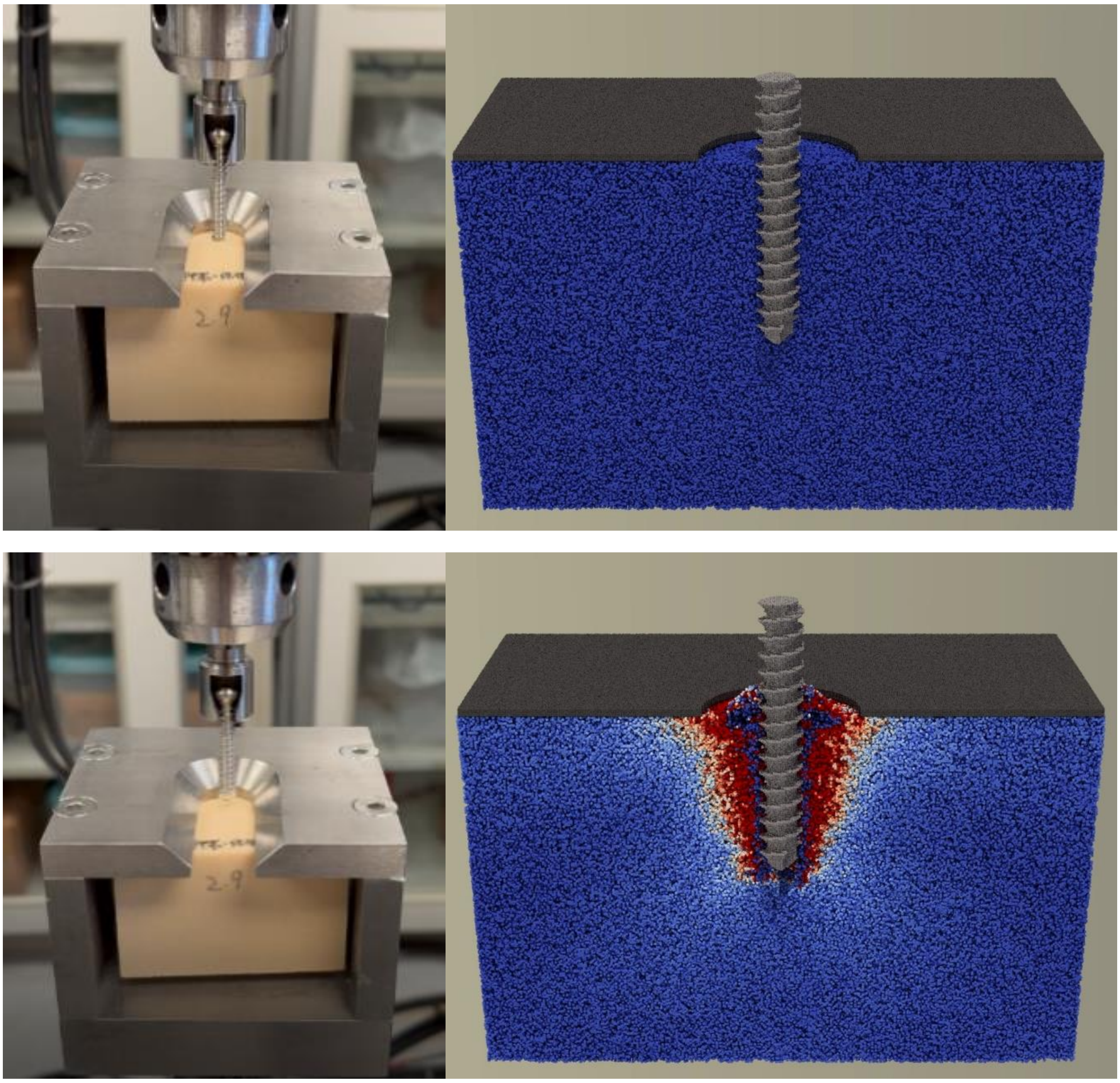


Figure 8. Representative images of the axial pull-out before (top) and after (bottom) 6 mm of axial displacement for a HA 4.5 screw in physical and simulated 20 PCF polyurethane foam

Discussion

According to the ASTM F543-17 A3 standard, the primary result to be reported is the peak axial pull-out force, for which there was excellent agreement between physical experiment and simulated prediction. In the post-peak regions of the force-displacement curves, however, we observed that the simulation generally over-predicted the force values, resulting in a more gradual drop-off than in the physical case. We hypothesize that this discrepancy is the result of the coarse granularity of the simulated foam debris produced as the screw is removed from the block; foam fragments are limited to a minimum dimension of 200 μm as opposed to the real physical case in which fine fragments may serve to lubricate the motion of the screw. The basis of our hypothesis rests on the general trend towards higher friction in coarse versus fine simulations of materials.[4] Improvements to the foam material models in *Alfonso* are ongoing as part of future studies.

Conclusion

In lieu of the physical testing of ASTM F543-17 Annex A3 "Test Method for Determining the Axial Pullout Strength of Medical Bone Screws", *Alfonso* is a novel particle-based simulation model that can accurately predict the axial pull-out performance of 316L stainless-steel bone screws in polyurethane foam blocks of a certain foam grade (e.g., 15 or 20 PCF per ASTM F1839-08(2021)). The measurement outputs from the *Alfonso* simulation of the pull-out tests follow the ASTM F543 A3 test standards, namely the load-displacement curve, the resulting axial pullout strength of the screw (e.g., tensile force required to fail or axially pull out the screw from the foam block), and the mode of failure. In our pilot study, we have shown that Alfonso is a reliable tool to assess the axial pull-out performance of HA 3.5, HA 4.0, and HA 4.5 screws in 15 PCF or 20 PCF foam. Here, we have shown that the physical and simulated screw pull-out tests had comparable maximum peak pull-out load values, excellent concordance of the load-displacement curves with very high CCC values across all trials and samples (>0.84), and similar polyurethane foam failure for various screw sizes and polyurethane foam grades. *Alfonso* can provide 3D visualizations of the simulation showing the mode of screw and/or polyurethane foam material failure, along with the stress and strain in the foam model during screw axial pull-out. Taken together, *Alfonso* serves as a non-clinical assessment tool to assess the screw pull-out performance across various screw designs, particularly in medium-density foam grades.

References

[1] J. Oentaryo, R. Tharim, S. Kulper, and E. A. Ueda Boles, 'Validation of polyurethane foam models in Alfonso^{TM}: Uniaxial compression', 2022.

[2] L. I.-K. Lin, 'A Concordance Correlation Coefficient to Evaluate Reproducibility', *Biometrics*, vol. 45, no. 1, p. 255, Mar. 1989, doi: 10.2307/2532051.

[3] MedCalc Software Ltd, 'Concordance correlation coefficient'. https://www.medcalc.org/manual/concordance.php (accessed May 27, 2022).

[4] A. J. C. Ladd and J. H. Kinney, 'Numerical errors and uncertainties in finite-element modeling of trabecular bone', 1998.

Appendix I

Notes on particle-based polyurethane foam models in *Alfonso*

- Models of solid rigid polyurethane foam in Alfonso are generated with a randomized distribution of pores designed to mimic the generally isotropic structure of the physical material.
- Micro-CT scans of the corresponding physical materials for each foam grade are used as reference to ensure faithful reproduction of the true material structure.
- A review of the literature suggests that coarse model resolutions lead to stiffening when simulating porous compressible solids like bone or foam [4], though the effect size appears to decrease with porosity. To compensate for this effect, an iterative process is used to determine the appropriate material properties required for each simulated foam model to converge with the properties of the physical specimens, given the resolution used in each study.
- Using the stated material properties from the manufacturer as a starting point, a proprietary formula based on porosity is applied uniformly to the modulus, yield, and ultimate strength of each foam grade.
- In general, we do not scale material density (i.e., mass) in *Alfonso*.
- "Resolution" (e.g., 50, 200, 500 μm) in *Alfonso* is typically equivalent to the diameter of the particles in the model, and thereby the minimum distance within which particles begin to interact. The degree of interaction between particles varies continuously as a function of their distance (e.g., in compression, particles repel more vigorously the closer they are to one another, while the reverse is true for tensile forces acting between "bonded" particles of the same object).
- Each particle represents a small volume of mass of an object in the analysis, the material properties of which (elastic modulus, yield, failure, hardening criteria, etc.) dictate the responses of particles to forces applied during analysis.
- While the initial positions of particles are typically spaced in discrete increments of the resolution (e.g., 200 μm), during analysis particles may continuously move in 3D space. For instance, a particle initially at (200, 200, 200) may move to (200.0034, 199.793403, 202.09809823462) during analysis.
- "Bonds" between particles in *Alfonso* are typically formed only at the initial time state, and then only between neighboring particles of the same object. Bonded particles resist both compression and tension, per the homogeneous or heterogenous properties of the material, until the stress or strain failure limits of the material are exceeded, and a crack is formed. Failed particles remain in analysis (e.g., as debris) and continue to interact with other particles, allowing phenomena such as compaction to be faithfully reproduced in *Alfonso*.
- "Unbonded" particles that come into contact after analysis has begun (i.e., particles that move to within the minimum distance of interaction) will not form bonds and will only repel one another.
- (See [1] and "Beyond FEA: Particle-based simulation 101" at https://www.lifespans.net/publications for further discussion of the basics of mesh-free analysis)

Appendix II

Full-sized versus half-sized simulations (symmetric across YZ-plane)

To significantly speed up the simulation time, we tested the concept of symmetry by running the HA 4.5 screw pull-out in full-sized versus half-sized simulations (symmetric across the YZ-plane) (Figure 9). The measured load values were multiplied by a factor of two to consider the half simulation size (Figure 10), resulting in nearly identical load-displacement data between the full-sized and half-sized simulations (Figure 11). Average CCC values between load-displacement curves of the physical and simulated tests were 0.92 and 0.93 for the full-sized and half-sized simulations (using 26 sample points per curve, see Table A1), respectively, suggesting comparable results. The maximum peak pull-out load values of the HA 4.5 screw in 20PCF foam using full-sized versus the half-sized simulations were 819.56 and 817.53 N, respectively. These values were still within the range of the average ± standard deviation of the physical tests as summarized in Table 4. Thus, the results have shown that there are no significant differences between running the simulations in full-sized and half-sized simulations.

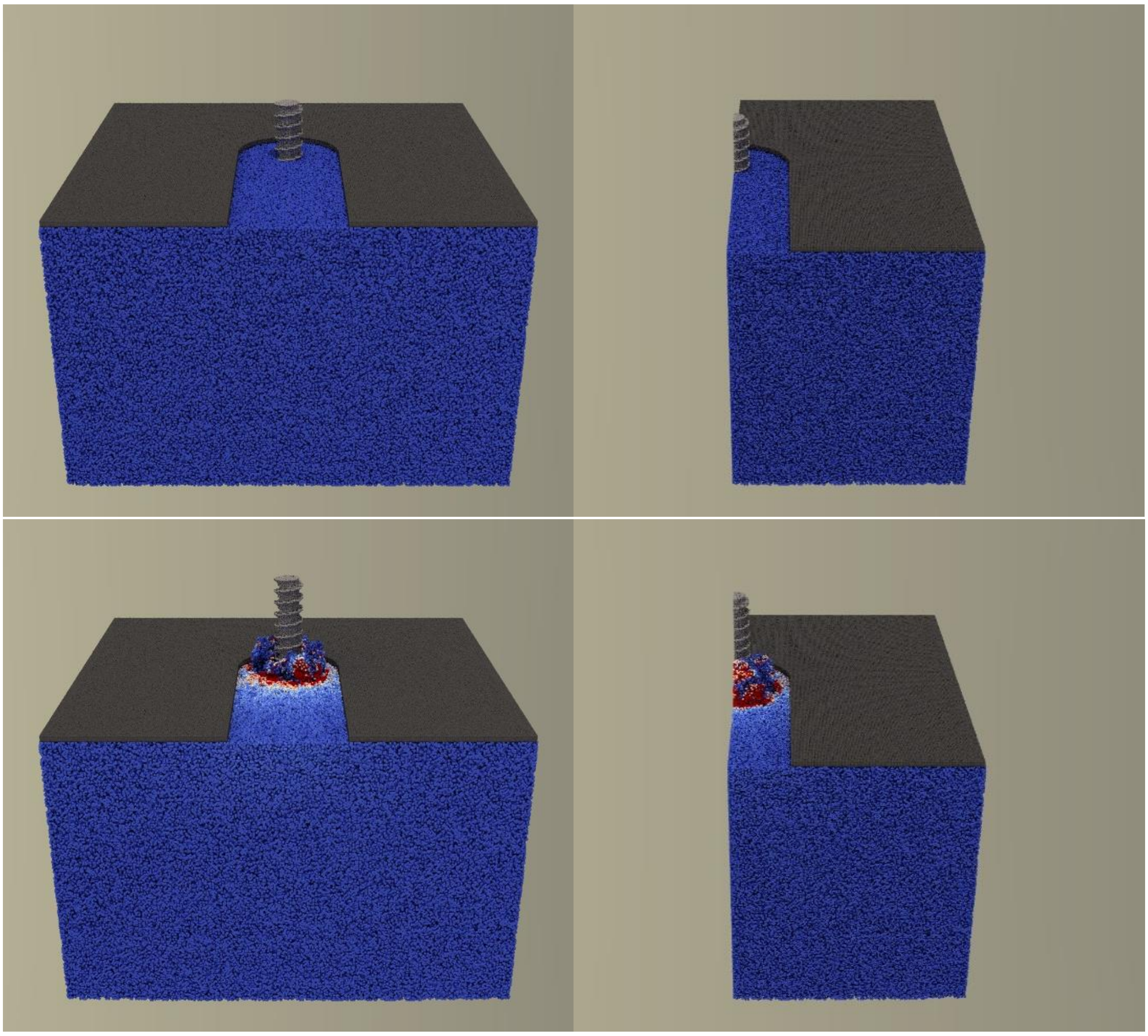


Figure 9. Images of axial pull-out at an initial displacement (top) and after 6 mm of axial displacement (bottom) of a HA 4.5 screw in simulated 20 PCF polyurethane foam using a full-sized (left) and half-sized simulations (right) symmetric along the YZ plane

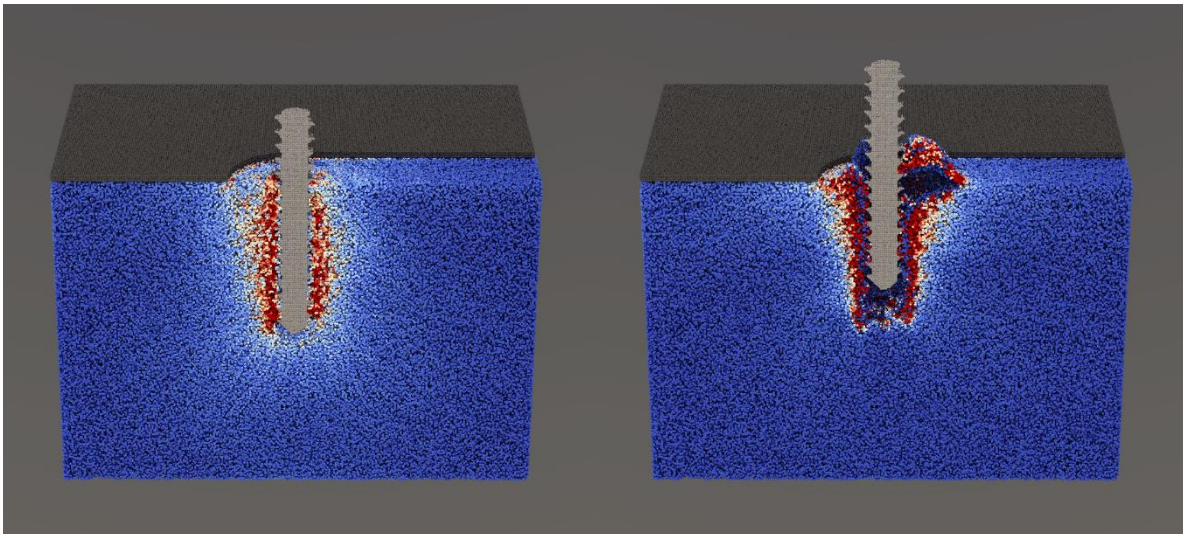


Figure 10. Images of axial pull-out at an initial displacement (left) and after 6 mm of axial displacement (right) for a HA 4.5 screw in simulated 20 PCF polyurethane foam using a half-sized simulations (symmetric across YZ-plane)

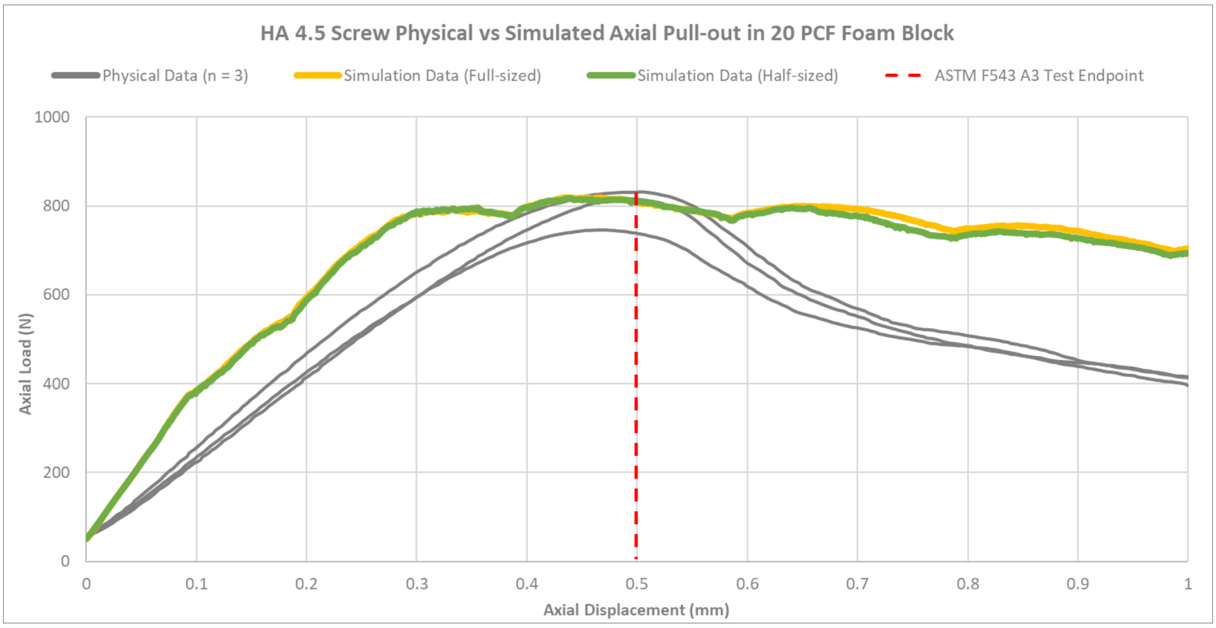


Figure 11. Load-displacement curves from the physical experiment (n = 3) and the simulated axial pull-out tests using full-sized or half-sized simulations of HA 4.5 screws in 20 PCF polyurethane foam blocks up to 1 mm pull-out displacement

Table A1. Concordance analysis on HA 4.5 screw pull-out in 20 PCF polyurethane foam blocks of full-sized and half-sized simulations from the initial displacement to the ASTM F543 A3 test endpoint (0.5 mm displacement) where the maximum pull-out load values have been reached

Variables	Full-sized			Half-sized simulations (symmetric across YZ-plane)		
	Trial 1 vs Simulation	Trial 1 vs Simulation	Trial 1 vs Simulation	Trial 1 vs Simulation	Trial 2 vs Simulation	Trial 3 vs Simulation
Sample size (curve data points)	26	26	26	26	26	26
Concordance correlation coefficient	0.9036	0.9114	0.9540	0.9088	0.9168	0.9575
95% Confidence Interval	0.8191 - 0.9497	0.8401 - 0.9517	0.9090 - 0.9770	0.8279 - 0.9527	0.8492 - 0.9549	0.9156 – 0.9788
Pearson ρ (precision)	0.9665	0.9824	0.9799	0.9088	0.9833	0.9809
Bias correction factor C_b (accuracy)	0.9349	0.9277	0.9735	0.9391	0.9323	0.9762