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SPECIAL ISSUE RESEARCH ARTICLE

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3D printed locking osteosynthesis screw threads have comparable strength to machined or hand-tapped screw threads

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Abstract

Additive manufacturing, aka three dimensional (3D) printing, is increasingly being used for personalized orthopedic implants. Additively manufactured components normally undergo further processing, in particular 3D printed locking osteosynthesis plates require post-printing screw thread creation. The aim of this study was to compare 3D printed threads with machined and hand-tapped threads for a locking plate application. Pushout tests were performed on 115 additively manufactured specimens with tapered screw holes; additive manufacture was performed at 0°, 20°, 45°, or 90° build orientations. The screw holes were either machined, hand-tapped or 3D printed. The 3D printed screw holes were left as printed, or run through with a tap lubricated with water or with thread cutting oil. Printed threads run through using oil, with a build orientation of 90°, had comparable pushout force (median: 6377 N 95% confidence interval [CI]: 5616-7739 N) to machined (median: 6757 N; 95% CI: 6682-7303 N) and hand-tapped (median: 7805 N; 95% CI: 7154-7850 N) threads. As printed threads and those run through using water had significantly lower pushout forces. This study shows for the first time that 3D printed screw threads for a locking osteosynthesis plate application have comparable strength to traditionally produced screw threads.

KEYWORDS

additive manufacture, biomaterials, biomechanics

1 | INTRODUCTION

The advent of additive manufacturing, aka three dimensional (3D) printing, has led to a large number of orthopedic applications,^{1,2} ranging from preoperative planning, custom guides and implants which are either personalized or have mechanical properties which not possible to achieve with traditional manufacturing methods.³ A key advantage offered by additive manufacture is the ability to create personalized treatments and devices at a relatively low cost

compared with traditional manufacturing processes. The use of 3D printing for planning of complex surgery is one aspect, Jeong et al ⁴ reported using this technique to perform accurate pre-bending of osteosynthesis plates to allow minimally invasive fracture repair. The other main application is the creation of custom devices, which can reduce operative time and improve outcomes.^{5,6} Additive manufacture using metals is the most relevant for implant fabrication.

However, the popular perception of 3D metal printed components coming straight from an additive manufacturing machine ready

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1560 Orthopaedic Research

for use is not correct. Additively produced components still require postprocessing procedures. In the case of locking osteosynthesis plates the screw threads need to be machined after the component has been printed. The postprocessing operations add to the cost of the component as well as potentially being a source of deviation from the original planned 3D geometry.

As the 3D printing technology improves greater fidelity between the printed component and the source geometry can be achieved. Recently it has become possible to 3D print locking threads. This potentially will allow the production of high fidelity complex parts at lower cost; however it is not known how the performance of printed threads is influenced by 3D build parameters. Orientation is known to influence the mechanical properties of Ti-6Al-4V⁷ the most popular material currently used for additively manufactured implants. Screw threads are a challenging feature to include in additively manufactured parts due to the small size of thread detail in absolute terms as well as in relation to the rest of the part. Additive manufacturing machine parameters are generally optimized to a specific scale and this means they may not be optimal for both the global part and the small thread features. The aim of this study was to evaluate how 3D printed threads compare to those made by five axis machining and by hand tapping in terms of pushout strength.

2 | METHODS

2.1 | Test specimens

Test specimens were designed as rectangular blocks containing either a non-threaded pilot hole or a threaded screw hole suitable for 5 mm diameter locking screws, with a head major diameter tapering from 6.7 mm to 5.9 mm, appropriate for a personalized high tibial osteotomy plate.⁸ The blocks were 16×16 mm with depths of 3.58, 4.08, 4.58, and 5.08 mm corresponding to 3, 4, 5, and 6 threads, respectively (Figure 1). The locking thread had a 14° taper, 0.5 mm pitch, 1.0 mm lead, and 0.3 mm thread height. The test specimens used were additively manufactured using selective laser sintering (Renishaw AM250; Renishaw plc, Wotton-under-Edge, UK) with titanium alloy (Ti-6AI-4V) grade 23.The powder particle size was between 15 and 45 μ m, the laser power was 200 W and the layer thickness was $40 \,\mu$ m.The following laser parameters were used: $80 \,\mu$ m point distance and $50 \,\mu$ s exposure time for borders; $60 \,\mu$ m point distance and $50 \,\mu$ s exposure time for fill hatching. Four borders were used with a hatch offset of $160 \,\mu$ m. Specimens were additively manufactured in different orientations (0°, 20°, 45°, 90°) to examine the influence of this parameter on thread connection strength. The 0°, 20°, and 90° orientations are illustrated in Figure 2. Prior to testing, the supporting scaffold structures (Figure 2) were removed so that all test specimens could be placed flat for testing. The custom blocks were tested in combination with 5 mm orthopedic locking screws made from titanium alloy (Figure 3).

2.2 | Thread production or processing

Five different thread production/processing methods were employed. The test specimens produced with a pilot hole had threads produced either by machining on a five-axis mill (5Axis group) using a v-point cutting tool (Scorpion Tooling UK Ltd, Dursley, UK) or manually (Hand Tap group) using a tapered drill (Scorpion Tooling UK Ltd) and a custom tapered tap (Mercury Tool and Gauge Ltd, Coventry, UK). The test specimens produced with a 3D printed thread were either left as printed (RawPrinted group), or were run through with the custom tap using either water (Printed Tapped Water group) or cutting oil (Rocol Cutting Fluid, Rocol, Leeds, UK) (Printed Tapped Oil group) as a lubricant. Note for these two last groups the tapping operation effectively cleaned/repaired the 3D printed thread rather than creating a new thread. Table 1 lists the combinations of thread type, build orientation and thread count tested as well as the number of specimens per combination. The original intention was to test five specimens for set of considered parameter combinations, however some combinations displayed higher variability during testing and the numbers of specimens were increased for these to the maximum number of specimens available. which varied between 6 and 15.

2.3 | Testing

Prior to commencing the tests, the locking screws were tightened into each test specimen to a measured torque of 14 Nm with an



FIGURE 1 Cross section through the additively manufactured specimen design showing the different depths of the specimen sample depending on the number of threads [Color figure can be viewed at wileyonlinelibrary.com]



FIGURE 2 Additive manufacture build orientations for 0°, 45°, and 90°, showing support structure locations, for the test specimens. Build direction is indicted by arrow

analog torque wrench. Pushout tests were conducted using an electromechanical testing machine (5967 series fitted with a 30 kN load cell; Instron, High Wycombe, UK). The locking screw/specimen construct was held inverted (screw head facing downwards) in spring clamp and placed in contact with a metal block drilled with a clearance hole appropriate for the diameter of the screw head. The testing machine applied a compressive force to the specimens at a constant strain rate of 60 N/s (ISO 4506:2018: hard metals-compression test). The compressive load and the extension of the crosshead was recorded using Bluehills software (v3; Instron, High Wycombe, UK) during the pushout test.

After testing selected samples were CT-scanned (Model XTH225ST; Nikon Metrology Inc, MI) to inspect the geometric fidelity of the thread.

2.4 | Analysis

The maximum pushout force and corresponding extension were extracted from the Instron tests data files using a custom Matlab script (Matlab R2019a; The MathWorks Inc, Natick). The correlation between thread count and pushout force was established for the RawPrinted specimens built at 0° and 90° (Spearman's rho). The difference in pushout force as a function of build orientation was examined for the RawPrinted specimens and for the 5Axis specimens, both groups with a thread count of 5 (Kruskal-Wallis [KW]). The difference in pushout force and corresponding displacement between the thread groups was examined for specimens built at 90° with a thread count of 5 (KW). Differences in pushout between paired combinations of the printed threads were examined



FIGURE 3 Testing machine set-up showing (A) the frontal view of the screw in the grips and (B) an auxiliary view showing the clearance hole in the lower fixture for the screw head to descend [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Summary of thread groups tested, with details of build orientation, number of threads, and number of specimens

Group	Build Orientation	No. of threads	No. of specimens
5Axis	0°	5	6
	45°	5	5
	90°	5	8
HandTap	90°	5	5
RawPrinted	0°	3	5
		4	5
		5	8
		6	5
	20°	5	5
	45°	5	11
	90°	3	5
		4	15
		5	5
		6	13
PrintedTappedWater	90°	5	7
PrintedTappedOil	90°	5	7
Total			115

(Mann-Whitney U [MW]). All statistical analyses were performed with IBM SPSS Statistics for Windows, version 24 (IBM Corp, Armonk, NY), significance was considered at $P \le .05$.

3 | RESULTS

For the RawPrinted group increasing the number of threads from three to six had a different effect upon pushout force depending upon build orientation (Figure 4). For 0° build orientation there was a significant negative (P = .048) correlation between number of threads and pushout force, Spearman's rho = -0.355. However, for 90° build orientation there was a significant (P = .035) positive correlation with Spearman's rho = 0.297; median pushout force increased from 2378 N (95% confidence interval [CI]: 2305-3084 N) for three threads to 2957 (95% CI: 2480-3934 N) for six threads.

Again for the RawPrinted group, for a thread count of 5, the effective of build orientation had a significant effect (P = .003 KW) on pushout force (Figure 5). The highest pushout force was observed for build angle of 90°, median 3050 N (95% CI: 2631-3377 N), and the lowest for a build angle of 45°, median: 871 N (95% CI: 590-1697 N). Interestingly the pushout force values were higher for build angles of 0° and 20° compared to that of 45°.

Conversely, for the 5Axis group build angle had no significant (P = .220 KW) effect upon the pushout force (Figure 6); median values for 0°, 45°, and 90° were 7419 N (95% CI: 6814-7908 N), 7178 N (95% CI: 6817-7783 N), and 6757 N (95% CI: 6682-7303 N), respectively.

Comparing pushout force between the thread groups for a build angle of 90° and a thread count of 5, there were significant differences (P = .0004 KW) across the five groups (Figure 7). The lowest pushout strength was for the RawPrinted group, median 3050 N (95% CI: 2631-337 N). The median value for the Printed-TappedWater group was 5269 N (95% CI: 4977-7402 N); this was significantly different to that for the RawPrinted group (P = .004 MW). The median value for the PrintedTappedOil group was 6377 N (95% CI: 5616-7739 N); again significantly (P = .038 MW) different to that for the PrintedTappedWater group. There were no significant (P = .086) differences in pushout between the 5Axis (median: 6757 N; 95% CI: 6682-7303 N), HandTap (median: 7805 N; 95% CI: 7154-7850 N) and PrintedTappedOil groups.



FIGURE 4 Pushout force as a function of thread number for RawPrinted group specimens, printed with build orientation of 0° (correlation between number of threads and pushout force, P = .048, Spearman's rho = -0.355) and 90° (correlation between number of threads and pushout force, P = .035, Spearman's rho = 0.297) [Color figure can be viewed at wileyonlinelibrary.com]

FIGURE 5 Pushout force as a function of build orientation RawPrinted group specimens with a thread count of 5. Build orientation had a significant effect (*P* = .003 Kruskal Wallis) on pushout force. Bars and asterisks indicate significant differences (Mann-Whitney *U*) between pairs of orientations [Color figure can be viewed at wileyonlinelibrary.com]









FIGURE 6 Pushout force as a function of build orientation for 5Axis group specimens with a thread count of 5 [Color figure can be viewed at wileyonlinelibrary.com]



Type of Thread



The displacement at maximum pushout force was significantly (P = .002 KW) different between the thread groups; highest for the HandTap group (median: 0.65 mm; 95% CI: 0.64-0.97 mm), which also had the greatest variability, and lowest for the RawPrinted group (median: 0.45 mm; 95% CI: 0.44-0.50 mm).

The CT scan images demonstrated that the fidelity of the threads was found to be lowest in the RawPrinted group with the 5Axis and PrintedTappedOil group show much more clearly defined threads (Figure 8).

4 | DISCUSSION

Additive manufacture has been adopted into a number of orthopedic applications^{1,2}; one of the most disruptive applications is the relatively low cost, compared with traditional manufacturing methods, production of personalized implants.⁹ However, 3D printed parts still require considerable finishing processes. In the manufacture of locking osteosynthesis plates this usually includes cutting of screw threads, either by hand tapping or further machining.¹⁰ Additional post-printing manufacturing steps increase production costs and introduce risk of deviation from the original planned component geometry, particularly for anatomic parts lacking readily identifiable datums. In some cases, particularly in veterinary applications, the threads may be too small to be additively manufactured,¹⁰ however, if feasible, printing of threads could substantially reduce the postprocessing effort required. The aim of this study was to assess the pushout strength of 3D printed threads and compare with that of hand-tapped and machined threads.

For unprocessed 3D printed threads build orientation proved to be very important. This was observed firstly in the effect of the number of threads upon the pushout strength. The 0° build orientation led to an unexpected negative correlation between thread number and pushout force (Figure 4); whilst for the 90° build orientation the behavior was as expected with a positive correlation between thread number and pushout force. We believe thread geometric fidelity is dependent upon build orientation, with greater fidelity possible if the build direction is orientated with the axis of the screw thread. For specimens that had a thread count of 5, we were able to evaluate the effect of four build orientations, 0°, 20°, 45°, and 90°. For the particular thread geometry we used, the highest pushout was achieved for the 90° build (Figure 5); again supporting the proposal that highest build fidelity occurs when the thread axis is orientated with the build direction. The fact that build orientation had no effect on pushout force for the 5Axis group (Figure 6) suggests further that it is geometric matching of the corresponding screw faces which is important for pushout strength. This is supported by the CT scans demonstrating that the groups which produced larger pushout forces also had higher geometric fidelity around the threads (Figure 8).

The cleaning/repair of the geometry by running a tap through the printed thread gave rise to increases in pushout force. It was interesting to note that use of thread cutting oil gave a significantly higher pushout force compared with using water. Thread cutting oils are formulated to cool the tool and aid with chip removal; we propose the use of cutting oil will increase the geometric fidelity of the thread. The PrintedTappedOil group managed to achieve comparable pushout strengths to the 5Axis and HandTap groups.

This study used a quasi-static push-out test as a measure of threadinterlock strength; however, the long-term strength of the thread interlock will also be influenced by the cyclic behavior of the printed material. This aspect should therefore be investigated in the future. This study has used pushout force as an indicator of screw thread efficacy. In reality, the thread junction will be subject to a more complex loading environment. However, this approach allowed us to compare the different thread groups in a straightforward manner. To our knowledge this is the first study to assess the efficacy of 3D printed threads compared with traditionally created threads for custom 3D printed osteosynthesis plates.

In conclusion, 3D printed threads created with a build orientation of 90° and cleaned/repaired by running a tap lubricated with thread cutting oil achieve comparable pushout strength to traditional hand or machine created threads.

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CONFLICT OF INTERESTS

Alisdair MacLeod and Kate Mactear are employees of 3D Metal Printing Ltd. Alisdair MacLeod and Harinderjit Singh Gill are named on a related patent.

AUTHOR CONTRIBUTIONS

AML: concept, methodology, experimental planning, supervision, analysis, writing, and reviewing. MP: eperimental work, reviewing. KMT: experimental work, reviewing. HSG: concept, methodology, planning, supervision, analysis, writing, and reviewing.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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