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Title:
Relationship between thread depth and fixation strength in cancellous bone screw

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Abstract

Background: Clarifying the effect of each parameter of screw design on **its** fixation strength is critical **in the development of any type of screw**. The purpose of this study was to clarify the relationship between the thread depth and fixation strength of metal screws for cancellous bone.

Methods: Nine types of custom-made screw**s** with **the** only changed variable being the thread depth were manufactured. Other elements were fixed at a major diameter of 4.5 mm, a thread region length of 15 mm, a pitch of 1.6 mm, and a thread width of 0.20 mm. The pull-out strength and insertion torque of each screw were measured for each of two foam-block densities (10 or 20 pcf). The correlation between the thread depth of the screw and the mechanical findings were investigated with single regression analysis.

Results: Regardless of the foam-block density, the pull-out strength significantly increased as **the** thread depth **increased** from 0.1 mm to 0.4 mm; after that, **the increase** was more gradual ($p<0.01$, respectively). The relationship between **the** thread depth and insertion torque was similar. In addition, **the** insertion torque tended to be more strongly affected by screw depth than **the** pull-out strength (2.6 times at 20 pcf and 1.4 times at 10 pcf).

Conclusions: **The** pull-out strength of 4.5-mm-diameter metal screws in a cancellous bone model **was found to be biphasic, although linearly correlated with the change in screw depth in both phases. The boundary of the correlation was 0.4 mm regardless of the density of the bone model, with the effect of screw depth on pull-out strength beyond that being small in comparison.**

Keywords: Cancellous bone screw, Screw thread depth, Pull-out strength, Insertion torque

Introduction

Screws are widely used as fixation devices for the surgical treatment of fractures. Fractures involving the articular surface can damage the integrity of the articular cartilage and articular surfaces, so **that** even simple fractures require surgical fixation to reduce the rate of post-injury disability; in such cases, metal screws are more often used than screw-plate systems [1]. The fixation strength of screws required for stable internal fixation clearly needs to be maintained until the fracture is clinically healed [2-4]. Pull-out strength is one of the most important parameters to judge the fixation strength of a screw [5,6].

Unfortunately, there is no known “gold standard” for bone screw shape, but the pull-out strength of screws tends to increase with a wider major diameter [7,8], narrower pitch [9], and deeper thread depth [10,11]. The relationship between pitch and thread depth is one of the most important factors; **the two changes in inverse relationship** when other aspects of thread design (thread width, flank angle, etc.) are kept uniform. In other words, a shallower thread depth is required at **narrower** pitches. Therefore, “thread shape factor” (TSF) has been proposed as a concept **integrating both measures** [12].

In designing screws for different purposes, it is important to know the effect of individual changes in each element on the screw fixation strength. Several authors have reported empirical test results on the effect of screw depth on screw fixation strength [10-14], but **these studies** are comparisons between existing products, and the **other** screw elements are non-uniform**, suggesting** only the relative effect of screw depth on pullout strength. To our knowledge, no experiments have been reported with only screw depth as a variable. We hypothesized that screw depth and screw fixation strength are positively correlated. Therefore, our hypothesis was that there would be a linear relationship between the screw thread depth and the fixation strength of the screw. In order to investigate this question, we fabricated custom-made screws with the only changed variable being the thread depth and conducted a demonstration test on the pull-out strength. The purpose of this study was to clarify the relationship between the thread depth and fixation strength of metal screws **designed specifically** for cancellous bone.

Materials and Methods

Preparation of experimental screws

A brass (C2801) rod with a diameter of 6 mm was cut into shorter rods with lengths of 50 mm using a disc grinder. Experimental screws were made from those short rods using a numerical control lathe (MTS4, Nano System Solutions, Yokohama, Japan). Most elements of the screw had fixed values: a total length of 40 mm, a screw head length and diameter of 10 mm and 6 mm, a shaft length and major diameter of 15 mm and 4.5 mm, a thread region with a length of 15 mm, a pitch of 1.6 mm, and a symmetrical thread with a thread width of 0.20 mm. Only the minor diameter was changed from 4.3 mm to 2.7 mm in 0.2-mm increments (Fig. 1). Each minor diameter was converted to a thread depth measurement and given a name from TD0.1 to TD0.9 (Fig. 2 A-I). **The** screw with a minor diameter of 4.3 mm was **called** TD0.1. All screws were measured using a 3D multisensor measurement system (SmartScope® Vantage™ 450, Quality Vision International Inc., Rochester, NY). Using this system, the major diameter, minor diameter, pitch, and thread width of each screw were verified and recorded (Fig. 3 A-I).

Simulated bone

Polyurethane foam blocks (TANAC Co. Ltd., Gifu, Japan) with densities of 10 and 20 pounds per cubic foot (PCF), 0.16 and 0.32 g/cm^3 respectively, were used as simulated bone. Synthetic blocks allow **the** researcher to minimize inter-specimen variabilities respecting the regulations ASTM F1839-08, and the chosen foam densities mimic **those of** osteoporotic bone and normal cancellous bone, respectively [5]. The blocks were cut to 40 × 20 × 20 mm, with 90 small blocks prepared at each density. A 20-mm-long hole parallel to the long axis was pre-drilled into the center of the bottom surface of the block using a drilling machine. For each screw, the diameter of the pre-drilled hole was the same as the screw's inner diameter.

Pull-out test

To measure the fixation strengths of screws, a pull-out test was performed 10 times for each screw. The screw was inserted into the **pre-drilled** hole by self-tap, up to 15 mm from the tip of the screw (**the** overall length of thread part). Two custom-made fixtures were connected to a mechanical loading machine (model 5565, Instron, Canton, MA) (Fig. 4 A,B). The upper fixture had a hole with a diameter of 5.0 mm (smaller than the diameter of the head), and it fixed the screw head. The lower fixture **had** a 90 x 30 x

8 mm stainless-steel plate with an 8-mm-diameter hole in the center, and the pull-out strength was measured by passing a screw through that hole and hooking the bone block on the stainless-steel plate. After applying a 5-N preload, the screw pull-out test was performed in the direction parallel to the screw axis at 5 mm/min as indicated by ASTM F543. The pull-out strength was defined as **the peak force before pull-out**.

Insertion torque

Each screw was inserted into the pre-drilled hole by self-tap using an automatic rotating torque screw-driver (NTS-6-S10; Sugisaki Seiki, Ibaraki, Japan). As a bushing support, a wood block (30 x 30 x 15 mm) with an 8-mm-diameter hole in the center was installed and the screws passed through that hole. The insertion torque was measured under the conditions of a load less than 10 N and 18 rpm in a rotation speed and was recorded every 0.01 sec. The maximum value recorded during the initial four revolutions of the specimen was selected as the value.

Statistical analysis

The data were analyzed with JMP 16 (SAS Institute, Cary, NC, USA). The relationship between the true value of the thread depth and the pull-out strength or the insertion torque on each screw was analyzed using simple regression analysis. *P*-values less than 0.05 were considered to indicate significance.

Results

Screw size

The mean values of the constant elements were 4.514±0.026 mm in major diameter, 1.592±0.001 mm in pitch, and 0.213±0.001 mm in thread width. The minor diameter of each screw was machined with an accuracy of 0.06 mm. Details are shown in Table 1. There were no unintended thread breaks or cracks after the experiment.

Pull-out strength

The pull-out strength significantly increased from TD0.1 to TD0.4; after that, it largely plateaued, regardless of the density of the simulated bone (Fig. 5). The mean pull-out strength and stiffness of each screw are shown in Table 2.

Based on the above results, we divided the graph into two parts. Part A was from TD0.1 to TD0.4 and Part B was from TD0.4 to TD0.9. In the scatter plot of the true values of the thread depth and the pull-out strengths, a prediction formula was established for each part. In all parts, a significant positive correlation was found between the thread depth and the pull-out strength (Fig. 6-A,B). In the 20-pcf foam, the coefficient of part A was 1386, but that of part B was 97, which was only 7% of part A

(Fig. 6-A). In the 10-pcf foam, the coefficient of part A was 443, but that of part B was 86, which was 19% of part A (Fig. 6-B).

Insertion torque

Insertion torques could be measured for all screws in the 20-pcf foam. The scatter plot of the true value of **the** screw depths and insertion torques was similar to the scatter plot of **the** screw pull-out strengths. From TD0.4 to TD0.9, there was a mild correlation between the thread depth and the insertion torque (Fig.7-A). On the other hand, for the 10-pcf foam, the insertion torques for TD0.1, TD0.2 and TD0.3 could not be measured because the torque generated was below the detection power of the measuring machine. In the measurable range, there was a mild correlation between thread depth and insertion torque, as with the 20-pcf foam (Fig.7-B).

Relationship between pull-out strength and insertion torque

For the pull-out strength and insertion torque from TD0.4 to TD0.9, the rate of increase per 0.1-mm thread depth from each baseline (constant term) was calculated. At 20 pcf, the pull-out strength increased by about 1.7% and the insertion torque increased by about 4.4%, and the effect on the insertion torque was appr. 2.6 times higher than that on the pull-out strength. At 10 pcf, the pull-out strength increased by about 5.5%, and the insertion torque increased by about 7.7%; the effect on the insertion torque was approx. 1.4 times higher than that on the pull-out strength.

Discussion

As we predicted, a linear relationship was found between the screw thread depth and the fixation strength of the screws. Additionally, this relationship was biphasic: the pull-out strength increased significantly from a thread depth of 0.1 mm to 0.4 mm and then more gradually after that. The relationship between the insertion torque and the pull-out strength also showed a similar relationship to thread depth, but it seemed to be more greatly affected by the thread depth than was the pull-out strength.

Many studies have been conducted on factors related to screw fixation strength. In general, there is a consensus that screws that are thicker in diameter, greater in length, and with a higher TSF tend to have a greater screw fixation strength. Among them, TSF is a complex factor calculated as the relationship between the mean thread depth and the pitch, given by

$$\mathrm{TSF} = (0.5 + 0.57735\, d/p),$$

where d is the thread depth, and p is the pitch of the screw [12]. A deeper thread depth and a narrower pitch leads to greater screw fixation strength in the calculation. In other words, these two factors have a contradictory relationship. Therefore, the relationship between the screw fixation strength when the thread depth and screw pitch are individually changed is an important piece of information when considering the optimal screw shape.

There are two main methods for studying screws: empirical testing and finite element methods (FEM) analysis.

With regard to empirical testing, Chapman et al. tested the pullout strengths of 12 types of commercially available cancellous bone screws (thread depth range; 0.50-1.75 mm) and reported that **the** experimental pullout force was highly correlated to the predicted pullout force, which is controlled by the major diameter of the screw, the length of **the** engagement of the thread, and the TSF [12]. Migliorati et al. investigated the maximum insertion torque and pull-out strength of three types of commercial temporary anchorage devices (thread depth range; 0.114-0.345 mm) and concluded that they are statistically related to the depth of the thread of the screw and to TSF [11]. Additionally, Falco et al. measured the effects of implant macro-geometry (thread depth range; 0.25-0.35 mm) on primary stability and found that a deeper thread was **advantageous** [10]. These findings indicated that the TSF or thread depth affected the screw fixation strength. However, in these past studies, other factors such as major diameter, pitch, and so on were not uniform, and the investigated range of **the** thread depth were narrow; therefore, the true effect of thread depth on screw fixation strength has been unknown.

In contrast, FEM analysis can exclude other factors deliberately and hence can **theoretically** isolate the effect of thread depth on fixation strength. Some previous studies have described the stress distribution of implants with different thread depths using FEM analysis [15-17]. To summarize these results, FEM analyses have suggested that a screw depth of around 0.4 mm is the optimum value in terms of stress dispersion. However, FEM analysis has been found to have limitations as a screw design tool because it is prone to errors due to subtle differences in methodology and can produce misleading results [18,19].

Abuhussein et al. reviewed the factors that may affect implant stability, and showed that implants with smaller pitch, more threads, deeper threads, a decreased thread helix angle, a longer implant and/or a wider diameter may be beneficial for stability, but also emphasized that the effect of a single feature could be washed out by those of other elements of the design for any selected implant [20]. Therefore, in order to accurately understand the effect of thread depth on screw fixation strength, an empirical study in which the screw depth is the only variable and other factors are kept as uniform as possible **seemed** ideal. To our knowledge, our study is the first empirical study to investigate the effect of thread depth as a single variable **in metal screws for**

cancellous bone. Our results were almost consistent with those of the previous literature [10-12]. In other words, we confirmed that the deeper the screw depth, the greater the strength of the screw fixation, a relationship that becomes especially pronounced in the osteoporosis model. **In addition,** what we newly found was a change in the linear relation after a thread depth of 0.4 mm. As mentioned above, previous **works performing** FEM analyses have shown that a thread depth of around 0.4 mm may be optimal, and we believe that our results are consistent with this.

When loading the pull-out stress to the screw, breakage typically happens on the bone adjacent to the major diameter surface of **the** screw [8,21]. The effect of the captured bone volume into the screw thread is theoretically small if the breakage under pull-out load happens without slipping of the thread. We believe that the increase in screw fixation strength with increasing thread depth in this situation is probably the result of stress distribution against the pull-out load. Ryu et al. reported that thread depth is more critical than other factors for dissipating peak stresses within the bone [22]. Ting et al. investigated the pull-out strength and gripping volume (simulated bone mass captured by the screw thread) and concluded **from statistical analysis** that there was a potential correlation between gripping volume and pull-out strength [23]. In the present study, similar results were obtained for TD 0.4 to TD 0.9. **Conversely**, shallower threads (TD0.1 to TD0.3) may not be able to capture the opposite bone sufficiently and will slip before being broken. We consider that this is the reason why the correlation between thread depth and screw fixation strength is biphasic in our results. The stiffness of the shallower thread screw in our study was lower, and this fact seemed to support the above theory.

In our study, the rate of increase in pull-out strength per 0.1 mm thread depth at thread **depths of** 0.4 mm or more was 5.5% in the osteoporosis model (10 pcf), which was about three times that of the normal bone model (20 pcf), 1.7%. Addevico et al clarified that the density of the host site was the main factor influencing the pull-out strength of the screw [5]. Falco et al. reported that large thread implant designs appeared more suitable in case of poor bone density or inadequate bone amount in order to reach high mechanical anchorage [10]. The reasons for this are not clear, and we believe this is a matter that needs further investigation. In any case, the effect of the thread depth on the pull-out strength changed significantly with TD0.4 as the boundary, independent of bone density. On the other hand, the insertion torque tended to increase as the thread depth increased compared to the pull-out strength. This result is consistent with previous reports [5] and can be explained by the fact that the area of contact between the bone and the screw surface increases with the increase in thread depth; as a result, the frictional force increases. **In terms of clinical relevance, these findings are useful in orthopedic screw design, in cases for example where it is important to increase the strength of the screw itself and reduce the insertion torque while maintaining screw fixation strength. These may be especially important in the design of screws made of bioabsorbable materials whose strength properties are inferior to those of metals.**

Our study has some limitations. First, **the** study was conducted under one condition with only the minor diameter as a variable. If the numerical value of any other element changes, the required thread depth may also change. It is necessary in the future to conduct additional research to see **whether** similar results are obtained when the major diameter or pitch are changed. Second, only **one-time** pull-out tests **were** performed in the long axis direction of the screw in this study; the evaluation did not consider factors such as repetitive load and shear load. **After the screw is inserted into living bone, various stresses other than those measured in this study may be concentrated on the screw.** **Furthermore, the simulated bone models in this study were a uniform material whereas real bone is a combination of cortical and cancellous bone; a more realistic simulation material is a goal for future studies.** This study was performed according to the provisions of ASTM0543 as much as possible. A similar method was used in previously published research on screw-fixing strength [5,6]. **The mechanical characteristics of screws on various conditions would be useful for clinical application, and in the future we hope to investigate them using experimental animals in addition to in-vitro experiments.** Third, brass, which is not appropriate for medical devices, was used as the screw material in this study because of its ease of machinability, ensuring accuracy of the intended thread depths. Titanium alloy (Ti-6Al-4V-ELI), the most common metal for bone screw, has a tensile strength of 932 MPa and a Young's modulus of 109.8 GPa [24]; those of brass (C2801) are 333-578 MPa and 105 GPa [25]. The tensile strength of titanium alloy is greater than that of brass, but the Young's modulus values are almost the same. In addition, the tensile strength and elastic modulus of the simulated bone used in this study were 5.72 MPa and 202.8 MPa in 20-pcf foam, and 2.08 MPa and 60.6 MPa in 10-pcf foam, which were overwhelmingly lower than those of metal. Therefore, although our study is an experiment using brass, we think the results are applicable to actual bone-fixation situations. However, we believe that additional experiments using medical metals such as stainless steel and titanium are necessary for clinical application.

In conclusion, the pull-out strength of 4.5-mm-diameter metal screws in a cancellous bone model was found to be biphasic, although linearly correlated with the change in screw depth in both phases. The boundary of the correlation was 0.4 mm regardless of the density of the bone model, **with** the effect of screw depth on the pull-out strength **beyond that being** small in comparison.

Conflicts of Interest

This research was not supported by any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Figure Captions

Fig. 1. Schema of screw design.

Fig. 2. Macro images of each screw. Images A to I represent TD0.1 to TD0.9. **Commonly used cancellous bone screws have a thread depth around 0.7 mm, as in image G.**

Fig. 3. Micro images of each screw thread. Images A to I represent TD0.1 to TD0.9. **The** scale bar on the upper right indicates 0.2 mm.

Fig. 4. Pictures of custom-made fixtures. A) A simulated bone block with the screw inserted was placed under a stainless-steel plate with an 8-mm-diameter hole, and the screw protruded upward from the hole. B) The upper fixture was divided into two parts, and the screws were sandwiched between them.

Fig. 5. Box plot of maximum pull-out strength for each screw.

Fig. 6-A. Scatter plot of maximum pull-out strength for each screw thread depth (true value) with single regression analysis on 20-pcf foam. The plot was analyzed by dividing it into part A and part B with <u>**a**</u> thread depth of 0.4 mm as the boundary.

Fig. 6-B. Scatter plot of maximum pull-out strength for each screw thread depth (true value) with single regression analysis on 10-pcf foam. It was analyzed as in the case of Fig. 6-A.

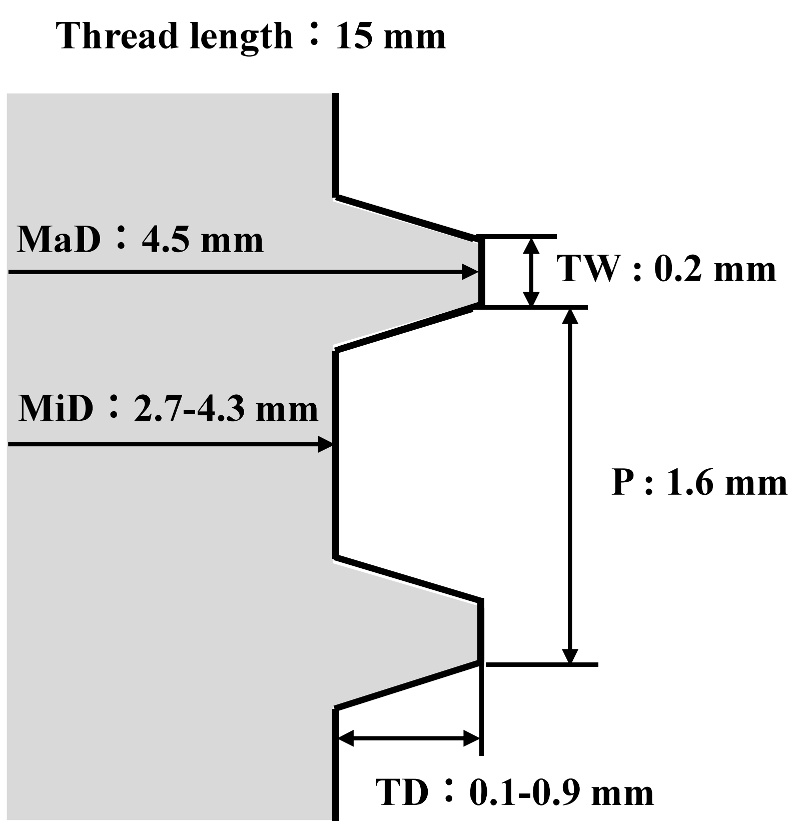
Fig. 7-A. Scatter plot of maximum insertion torque for each screw thread depth (true value) with single regression analysis on 20-pcf foam. Thread depths of 0.4 mm and more were analyzed.

Fig. 7-B. Scatter plot of maximum insertion torque for each screw thread depth (true value) with single regression analysis in 10-pcf foam. It was analyzed as in Fig.7-A.

Table 1. Details of element values for each screw.

Table 2. Details of pull-put strength and stiffness for each screw.

Figure1



MaD, Major diameter; MiD, Minor diameter; TD, Thread depth; P, Pitch; TW, Thread width

Figure 1

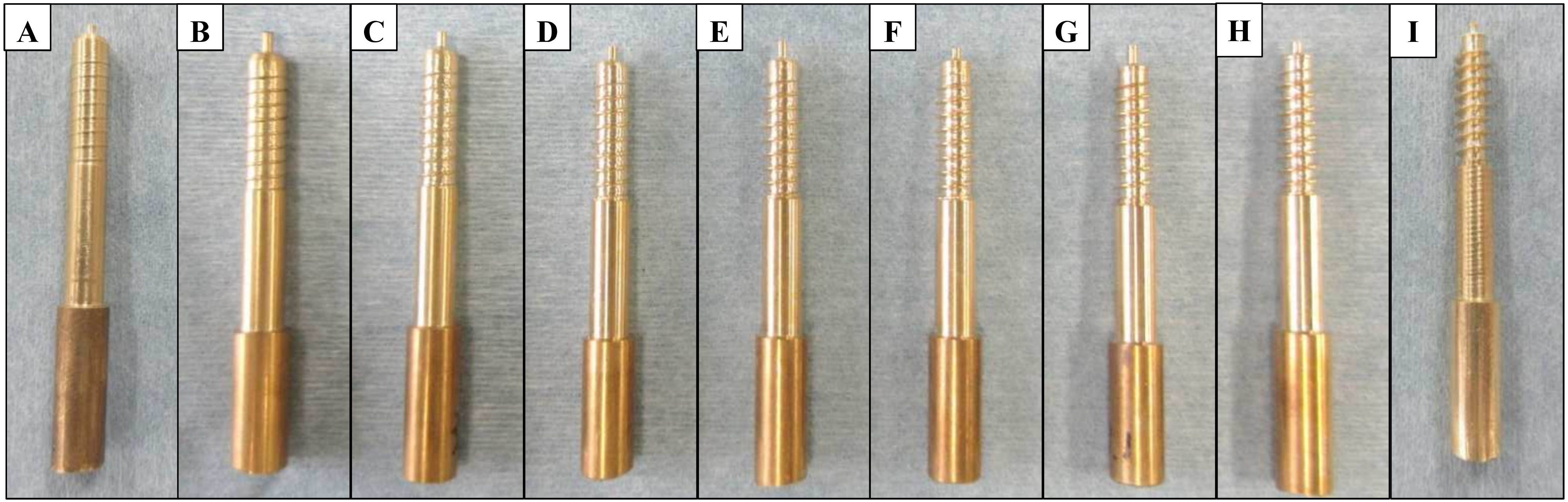


Figure 2

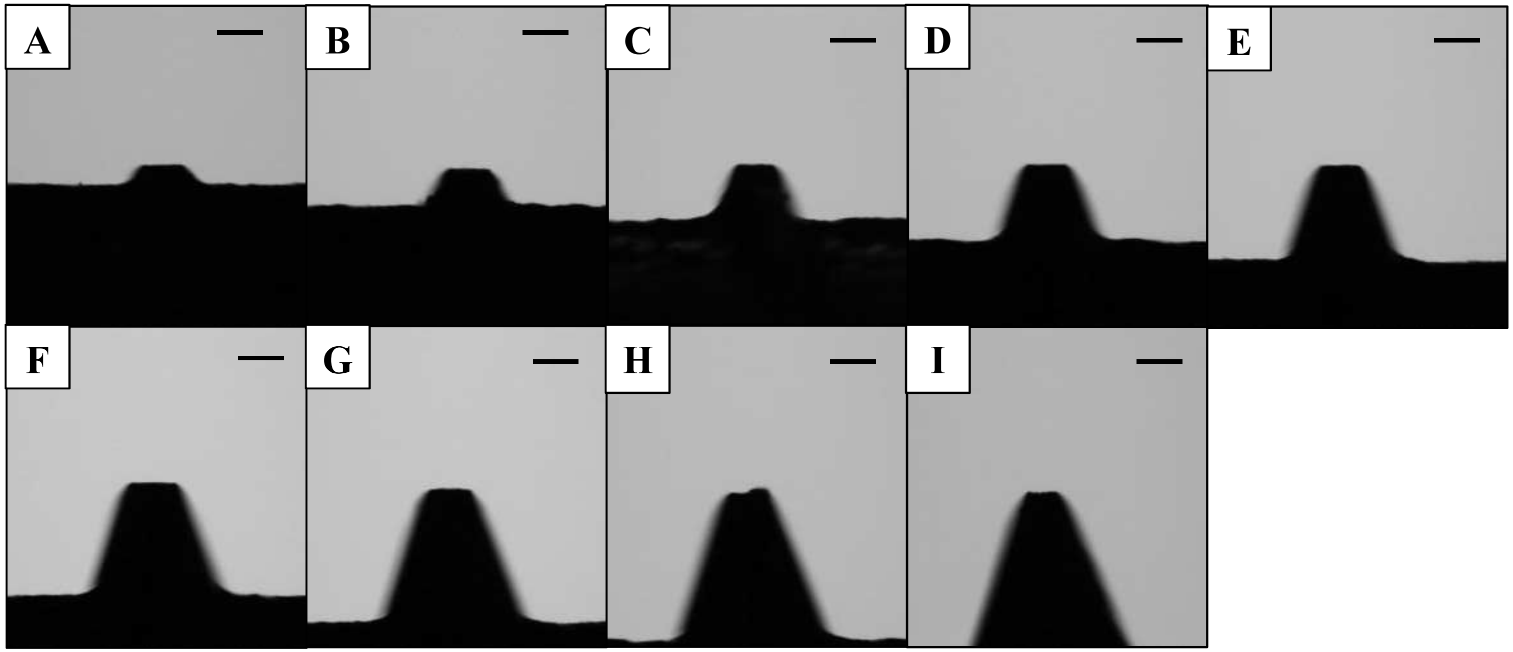


Figure 3

Figure4

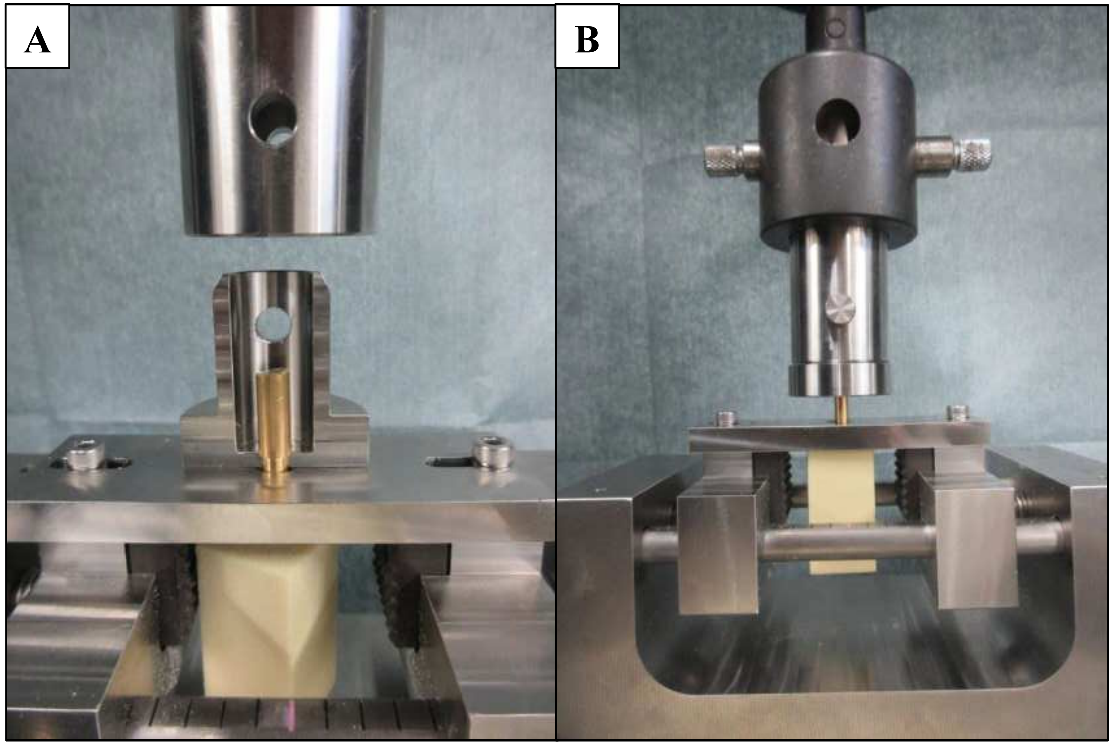


Figure 4

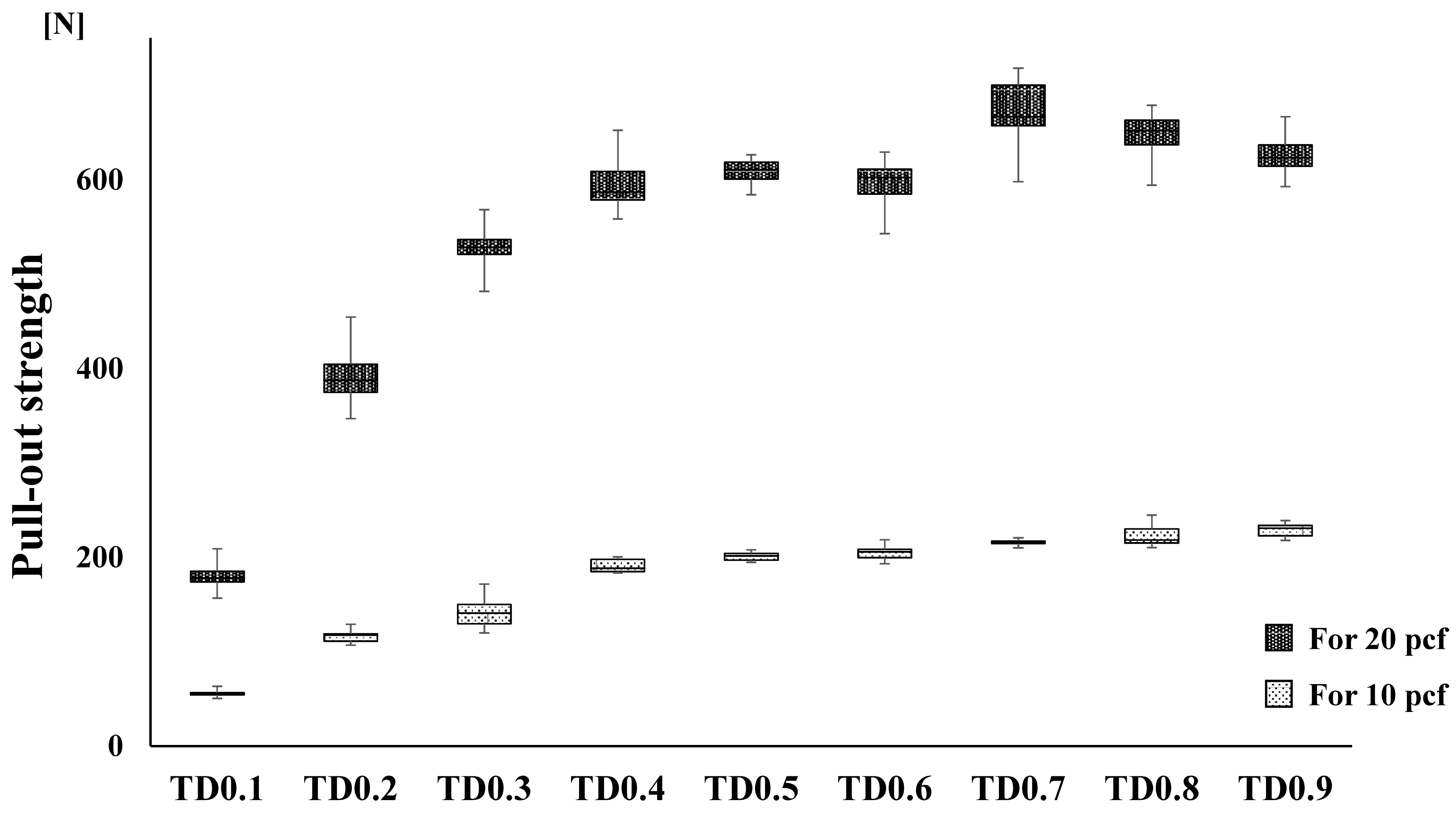

[N]
Pull-out strength
600
400
200
0
TD0.1
TD0.2
TD0.3
TD0.4
TD0.5
TD0.6
TD0.7
TD0.8
TD0.9
For 20 pcf
For 10 pcf

Figure 5

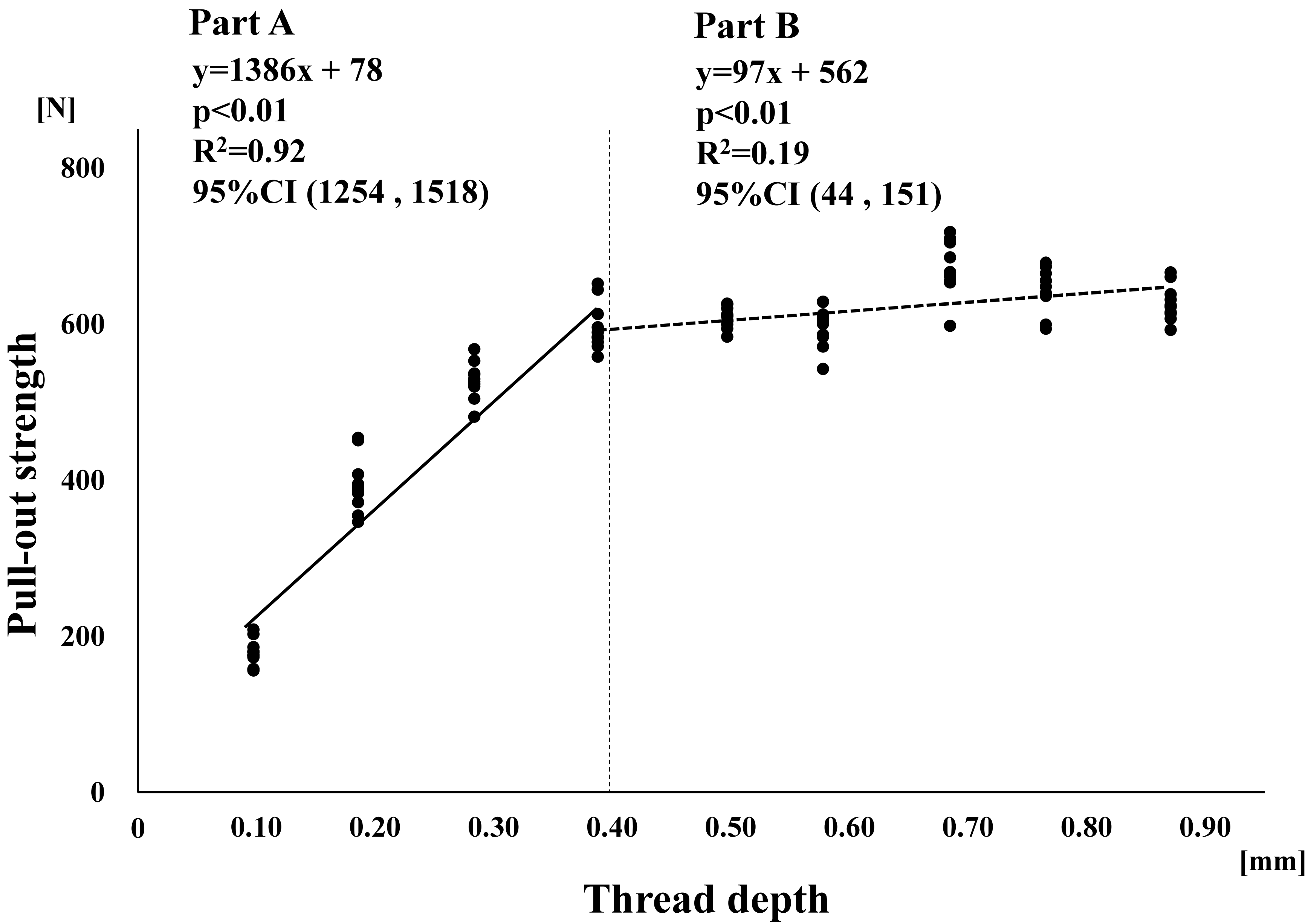

Part A
y=1386x + 78
p<0.01
R²=0.92
95%CI (1254 , 1518)
Part B
y=97x + 562
p<0.01
R²=0.19
95%CI (44 , 151)
[N]
Pull-out strength
800
600
400
200
0
0
0.10
0.20
0.30
0.40
0.50
0.60
0.70
0.80
0.90
[mm]
Thread depth

Figure 6-A

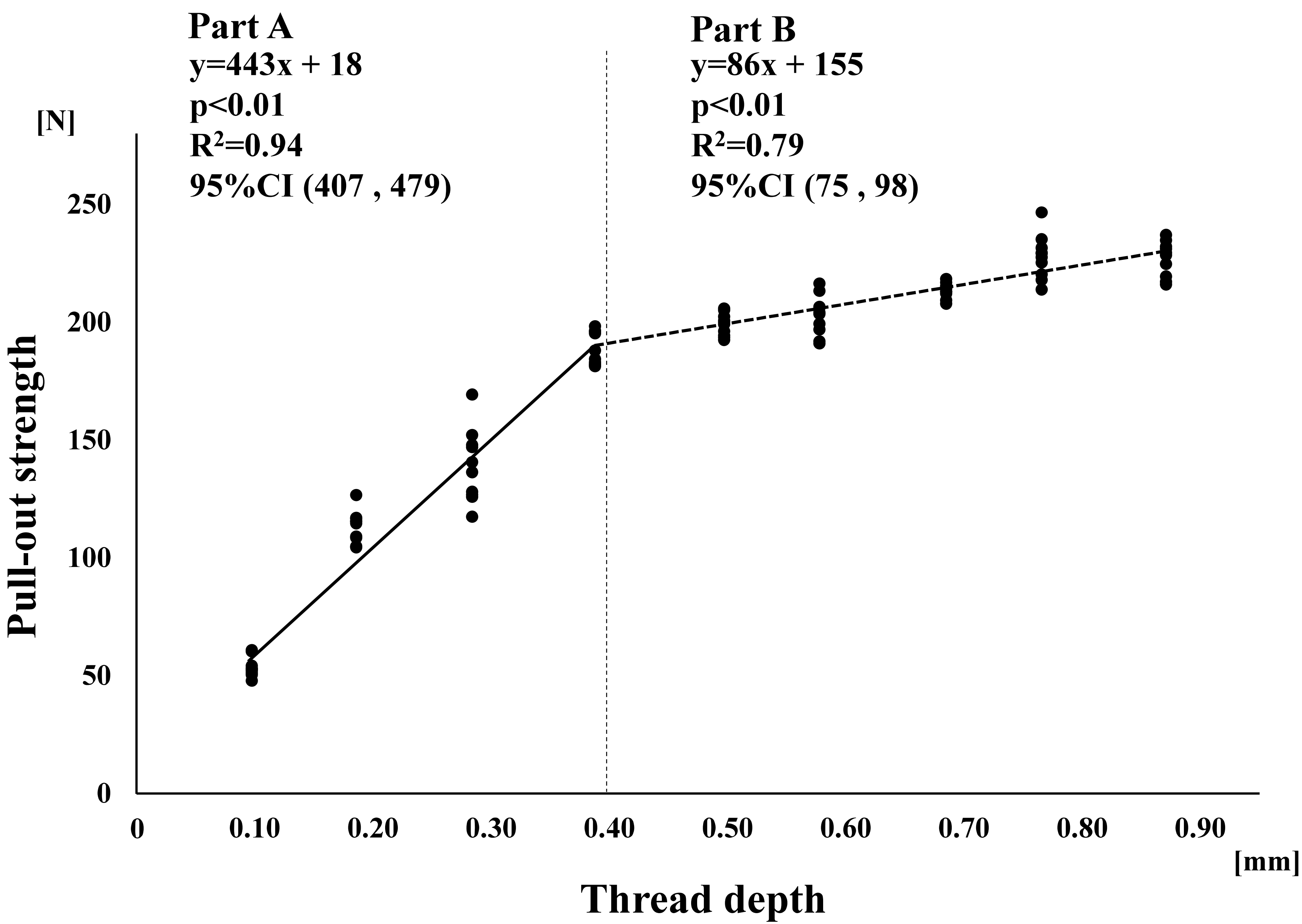

Part A
y=443x + 18
p<0.01
R²=0.94
95%CI (407 , 479)
Part B
y=86x + 155
p<0.01
R²=0.79
95%CI (75 , 98)
[N]
Pull-out strength
250
200
150
100
50
0
0
0.10
0.20
0.30
0.40
0.50
0.60
0.70
0.80
0.90
[mm]
Thread depth

Figure 6-B

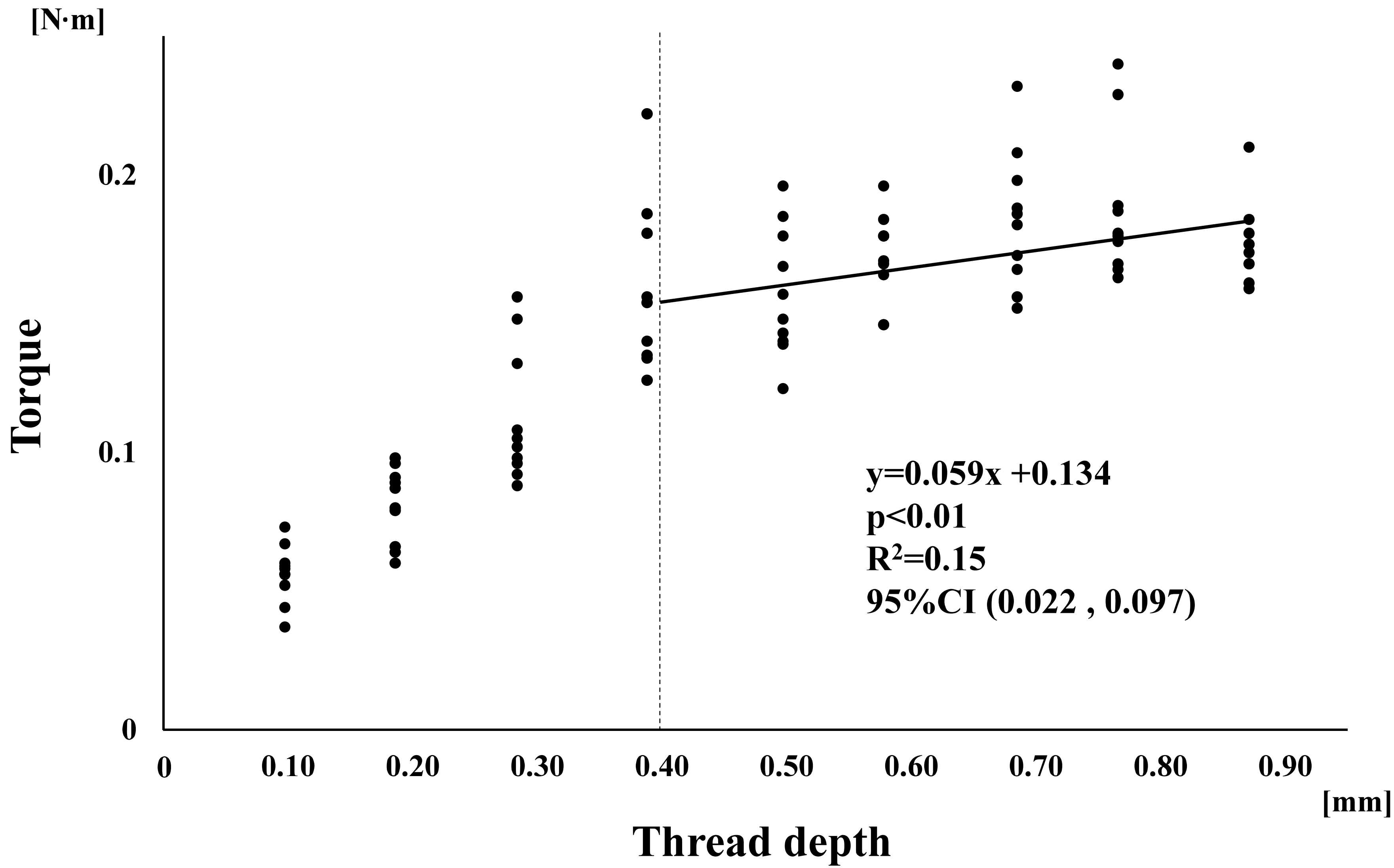

[N·m]
Torque
0.2
0.1
0
0
0.10
0.20
0.30
0.40
0.50
0.60
0.70
0.80
0.90
[mm]
Thread depth
y=0.059x +0.134
p<0.01
R2=0.15
95%CI (0.022 , 0.097)

Figure 7-A

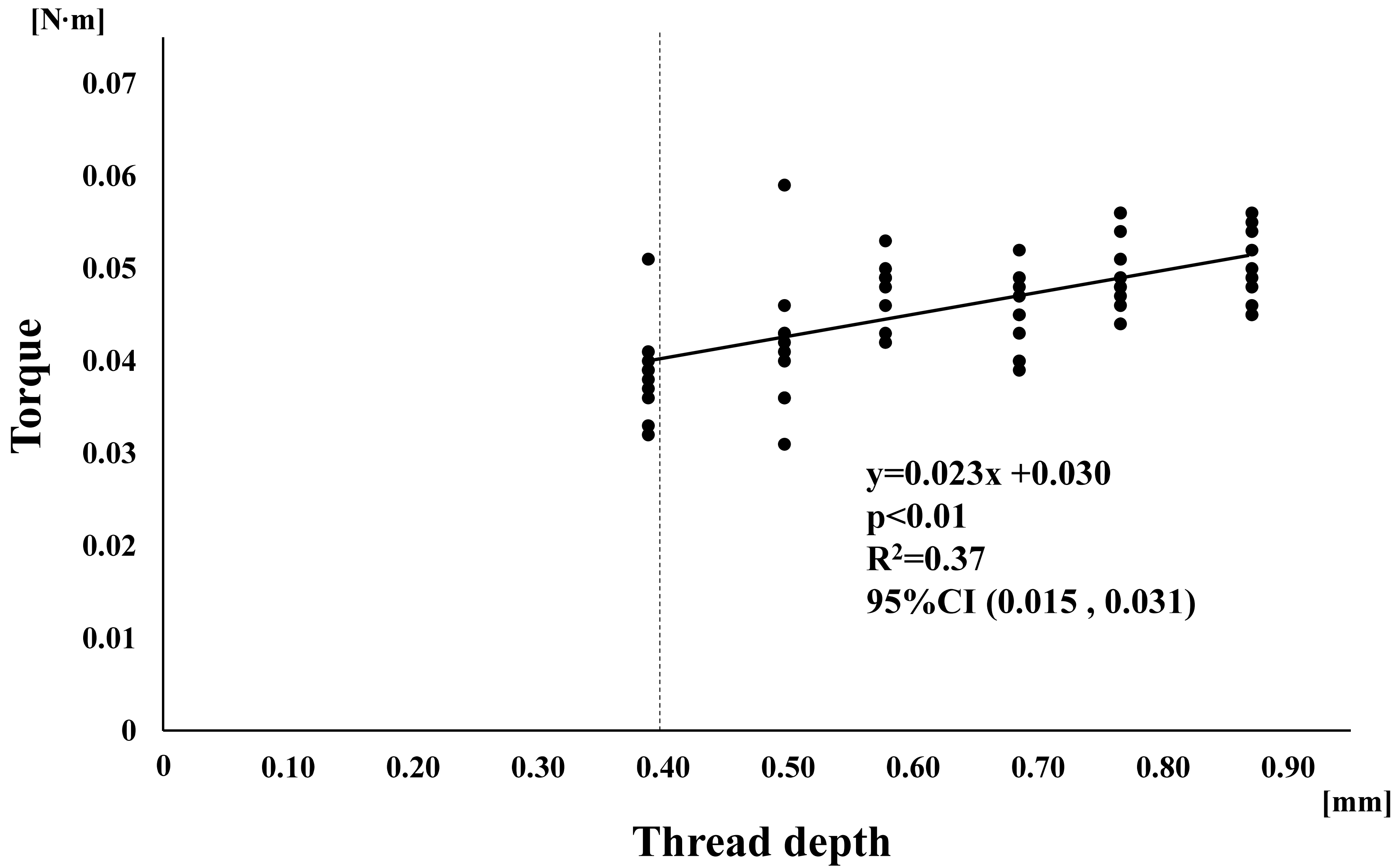

[N·m]
0.07
0.06
0.05
0.04
0.03
0.02
0.01
0
Torque
0
0.10
0.20
0.30
0.40
0.50
0.60
0.70
0.80
0.90
[mm]
Thread depth
y=0.023x +0.030
p<0.01
R2=0.37
95%CI (0.015 , 0.031)

Figure 7-B

	TD0.1	TD0.2	TD0.3	TD0.4	TD0.5	TD0.6	TD0.7	TD0.8	TD0.9
MaD	4.528	4.505	4.525	4.520	4.537	4.555	4.499	4.484	4.476
MiD	4.333	4.133	3.957	3.744	3.542	3.399	3.130	2.952	2.734
TD	0.097	0.186	0.284	0.388	0.497	0.578	0.685	0.766	0.871
P	1.594	1.593	1.593	1.592	1.591	1.591	1.592	1.592	1.592
TW	0.212	0.210	0.210	0.218	0.215	0.222	0.215	0.214	0.207

[mm]

MaD, Major diameter; MiD, Minor diameter; TD, Thread depth; P, Pitch; TW, Thread width

Table 1

		TD0.1	TD0.2	TD0.3	TD0.4	TD0.5	TD0.6	TD0.7	TD0.8	TD0.9
20 pcf										
PS*	Ave.	180	394	528	597	609	597	678	645	628
	SD	17	36	24	31	14	26	36	29	23
S**	Ave.	534	892	1195	1336	1257	1338	1348	1420	1339
	SD	126	228	111	151	144	165	164	72	142
10 pcf										
PS	Ave.	54	113	139	189	199	203	213	221	227
	SD	4	7	15	7	5	8	4	13	7
S	Ave.	247	322	311	414	372	331	412	354	376
	SD	69	66	96	121	80	70	70	84	48

*PS, Pull-out strength [N]; **S, Stiffness [N/mm]

Table 2