

Effect of bone density on the drill-hole diameter made by a cannulated drill bit in cancellous bone

Utomo Andi Pangnguriseng, MD^{1,4}, Shinji Imade, MD, PhD^{1,*}, Satoshi Furuya, PhD², Koichiro Nakazawa², Kazuma Shiraishi, PhD², Masaya Sato, MD¹, Toshihiko Kawamura, PhD³, and Yuji Uchio, MD, PhD¹

¹Department of Orthopaedic Surgery, Shimane University Faculty of Medicine, Shimane, Japan

²Department of Manufacturing Technology, Shimane Institute for Industrial Technology, Shimane, Japan

³Division of Medical Informatics, Shimane University Faculty of Medicine, Shimane, Japan

⁴Department of Orthopaedic, Faculty of Medicine, Universitas Muslim Indonesia, Sulawesi Selatan, Indonesia

***Corresponding author:** Dr. Shinji Imade, Department of Orthopaedic Surgery, Shimane University Faculty of Medicine, 89-1 Enya, Izumo, Shimane 693-8501, Japan

Tel.: +81-853-20-2242

Email: imades@med.shimane-u.ac.jp

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ABSTRACT

Background: When a pilot hole is made prior to a screw's insertion into bone, the same drill bit is used irrespective of the bone quality. However, osteoporotic bone is fragile and this may affect the hole diameter, which is of particular concern in cancellous bone. In this study, the relationship between bone density and drill-hole diameter was investigated assuming a pre-drilling process in screw-only osteosynthesis in the metaphysis and epiphysis.

Methods: Two types of drill bit (triple-flute [T] and quadruple-flute [Q]) with different shapes and diameters were prepared: type T bits with 3.5 mm and 4.4 mm diameters, and type Q bits with 3.5 mm and 4.2 mm diameters. Drilling was performed manually in simulated bones with four densities: 5, 10, 15, and 20 pounds per cubic foot. We measured the hole diameters with a coordinate measuring machine and analyzed the relationship between the drill-hole diameters and the densities of the simulated bones. We then compared the screw pull-out strength between the two 3.5-diameter drill bits.

Results: In all cases, the diameters of the drill holes were larger than those of the drill bits. The relationship between the drill-hole diameters and the bone densities was a negative linear correlation. Enlarging the hole diameter decreased the screw pull-out strength.

Conclusions: For cannulated drill bits of 3.5, 4.2 and 4.4 mm diameter, the diameter of the drill hole in cancellous bone obtained by the manual drilling technique tends to be larger in

low-density (e.g., osteoporotic) compared to high-density (e.g., healthy) bone.

Keywords: bone density, hole diameter, osteoporosis, drill bit, cancellous bone, manual drilling technique

Introduction

Bone drilling is an essential technique in orthopedic surgery for skeletal disorders [1–5]. When osteosynthesis is desired, a pilot hole is made prior to a screw's insertion into the bone. Since bone is a fragile material, the use of a drill bit made of a hard material such as metal is likely to cause damage to the wall of the drill hole. Such hole-wall damage contributes to subsequent screw loosening. Investigations of this damage have focused on the use of solid drills [4–6], although a cannulated drill has been more commonly used for medical purposes, such as for drilling a pilot hole for a cannulated cancellous screw (CCS). CCSs are used for a variety of applications, but one of the main uses is screw-only osteosynthesis at the metaphysis and epiphysis [7]. We have searched for but found no published study concerning the hole-wall damage that occurs with a cannulated drill. Although cannulated drills are controlled by guide pins, it is still possible to damage the hole wall, depending on the bone quality. For example, surgeons have often observed that in patients with osteoporosis, sufficient screw fixation strength cannot be obtained when bone fragments at metaphysis and epiphysis are fixed with a CCS, making treatment difficult.

The numbers of individuals with osteoporosis are increasing globally, particularly in rapidly aging societies such as Japan [8]. Osteoporosis is characterized by bone loss and microarchitectural deterioration, and osteoporotic bones become fragile and easily fractured

[9,10]. The pull-out strength of screw fixation in osteoporotic bones is reduced, and the screws are easily loosened [11–14]. In addition, it has been reported that the pull-out strength of a screw in osteoporotic cancellous bone is significantly lower than that of the same screw inserted into healthy cancellous bone [15]. The main reason for this screw-loosening phenomenon is thought to be the fragility of the bone itself. However, an additional potential factor should be considered: the pilot hole that is made for the screw may be larger than expected in osteoporotic bone, contributing to the screw-loosening phenomenon. It has been demonstrated that the pull-out strength in screw fixation in osteoporotic bone can be improved by reducing the pilot-hole diameter [16,17]. In other words, there may be some relationship between osteoporosis and the pilot-hole diameter, but this relationship is unclear.

With the increasing number of osteoporotic patients, the issue of bone fragility and screw fixation strength is expected to become an even more important clinical issue in the future. Knowledge of the precise relationship in cancellous bone between bone fragility and pilot-hole diameters made with a cannulated drill will provide important information for the development of methods that can be used to resolve the problem of screw-loosening in osteoporosis, such as newly designed screws and drills. We hypothesized that the drill-hole diameters in cancellous bone would be enlarged in osteoporotic bone compared to healthy bone, even with the use of hollow drills. The aim of this study was to clarify the relationship

in cancellous bone between bone density and drill-hole diameters made by cannulated drills.

Materials and Methods

Drill bits

Two types of surgical cannulated drill bits that have different tip shapes were prepared. The drill bits with a triple ("T") flute (Teijin Medical Technologies, Osaka, Japan) (Fig. 1A) were designated the Type T drill bits. The Type T1 drill bits were 3.5 mm in diameter, 30 mm in flute length, and 150 mm in total length, and the Type T2 drill bits were 4.4 mm in diameter, 33 mm in flute length, and 230 mm in total length. The drill bits with a quadruple ("Q") flute (Meira Co., Aichi, Japan) (Fig. 1B) were designated the Type Q drill bits. The Type Q1 drill bits were 3.5 mm in diameter, 17 mm in flute length, and 100 mm in total length, and the Type Q2 drill bits were 4.2 mm in diameter, 17 mm in flute length, and 220 mm in total length.

Simulated bone

Polyurethane foam blocks (Sawbones, Vashon Island, WA, USA) with a density of 5, 10, 15, or 20 pounds per cubic foot (pcf) (0.08 g/cm³, 0.16 g/cm³, 0.24 g/cm³, and 0.32 g/cm³, respectively) were used as simulated bone. As described by the manufacturer, 10-pcf foam density mimics osteoporotic bone, 15-pcf foam mimics an intermediate condition, and 20-pcf

foam mimics normal cancellous bone [18]. We prepared 5-pcf-density foam blocks ($40 \times 130 \times 180$ mm) as samples representing severe osteoporotic bone. Composite blocks minimize inter-specimen variability and meet the American Society for Testing and Materials (ASTM) standard #F1839-08.

On the largest side of the block (130×180 mm), 40 small holes (30 mm depth) were drilled as guide pin holes for guide pin insertion perpendicular to the plane, with the use of a machining center. The diameters of the 40 small holes were the sum of the matching guide pin diameter plus 0.1 mm. They were deployed in a grid of 10 longitudinally at 18 mm intervals and four transversely at 30 mm intervals.

Drilling procedure

Drilling was performed manually using a guide pin, following the procedure used in clinical settings. All drilling was performed by a single examiner (PU). Matching guide pins were manually inserted into small holes (40 holes/block) uniformly located in each of the bone blocks simulating one of the four bone densities described above. The diameter of the guide pin was 1.2 mm for Types T1 and Q1, 2.4 mm for Type T2, and 2.0 mm for Type Q2. The drilling was then performed along the guide pin with the use of a rotary tool with a constant rotational speed of 1,900 rpm. Ten holes by each of the four drill bit types in each

simulated bone block of each bone density were made, resulting in 40 holes per simulated bone block (160 holes in total). The drilling depth was standardized at 25 mm from the surface of the simulated bone block.

Measure of drill-hole diameters

Following the method of Singh et al. [5], the diameter of each hole was measured using a coordinate-measuring machine (model UPMC850; Carl Zeiss Co., Oberkochen, Germany). Five measurement points were selected at 2, 5, 10, 15, and 20 mm from the simulated bone surface (Fig. 2A), and measurements were performed once for each hole. Using a 3-mm-diameter probe, we recorded 180 contact points (at every 2° around the hole), and we determined the cross-sectional shape at each measurement point. The diameter of the regular circle inscribed in the shape obtained from the measurement was defined as the diameter at each depth (Fig. 2B), and the average of these values was defined as the drill-hole diameter.

Measure of screw pull-out strength

Screw pull-out strengths were measured for the drill holes made by the Type T1 and Q1 drill bits (n=10 drill holes for each bit). The same cannulated cancellous screw made from titanium alloy was used in all cases. The screw was 4.6 mm in major diameter, 3.1 mm in

minor diameter, and 1.5 mm in pitch, with a 20-mm screw length and 50 mm total length. A 1.2 mm guide pin was used to insert the screw into the drill hole to a depth of 15 mm, and the pull-out strength was measured by a mechanical loading machine (model 5565; Instron, Canton, MA, USA). The method used to connect the machine to the specimen was described previously [19]. A pull-out load was added to the screw at 5 mm/min after a pre-loading of 5 N, and the maximum load achieved without the screw coming loose was defined as the pull-out strength.

Statistical analyses

The data were analyzed with the JMP 16 program (SAS Institute, Cary, NC, USA). A simple regression analysis was applied to examine the relationships between the drill-hole diameters and the density of the simulated bone. Mann-Whitney's U-test was used to compare the drill-hole diameters and screw pull-out strength between the different-type (T1 vs. Q1) drill bits with same diameter in each density of simulated bone. Probability (p)-values <0.05 were considered significant in all statistical analyses.

Results

Drill-hole diameters

In all cases, the diameter of the drill hole was larger than that of the drill bit. The diameters of the holes drilled using the Type T drill bits expanded by 1.3%–12.3% relative to the bit diameter. The diameters of the holes drilled using the Type Q drill were expanded by 1.1%–4.7%, which was less than for the Type T drill bits. These enlargement ratios tended to be greater in the low-density simulated bone (5 or 10 pcf) and showed large differences between the drill types. In contrast, in the high-density simulated bone (15 or 20 pcf), the enlargement ratios were quite low and showed little difference between the drill types. The details of each hole diameter are given in Tables 1 and 2 for the Type T and B drill bits, respectively.

The relationship between the drill-hole diameter and bone density

For all four drill bits, the drill-hole diameter was negatively correlated with the density of the simulated bone (Fig. 3A,B). The regression coefficient indicated the ease of hole enlargement, with the T1 drill bit having the largest value at -0.028 , followed by the T2 drill bit at -0.016 , the Q1 drill bit at -0.009 , and the Q2 drill bit having the smallest value at -0.008 .

Differences between the drill bits

There were differences in the drill-hole diameters between the Type T1 and Type Q1 drill bits, even though they had same diameter (Fig. 4). The drill-hole diameter made with the Type T1 drill bit was larger than that made with the Type Q1 bit, with the diameter difference being 0.267 mm at 5 pcf, 0.204 mm at 10 pcf, 0.027 mm at 15 pcf, and 0.006 mm at 20 pcf. There were significant differences between drill types, with the exception being the 20-pcf simulated bone. In the osteoporosis model, differences in the drill-hole diameters between the drill bits were clearly observed. In the healthy bone model, we observed the same tendency for drill-hole diameter differences, but the differences were smaller and the only significant difference was observed for the 15-pcf bone.

The pull-out strength was lower in the Type T1 cases — which had larger hole diameters compared to the Type Q1 cases, with the exception of the 20-pcf bone (Fig. 5). The pull-out strength with Type Q1 was 2.31 times higher in 5 pcf, 1.21 times higher in 10 pcf, and 1.03 times higher in 15 pcf than that of Type T1. At 20 pcf, the pull-out strength for the drill holes made with the Type T1 bit was higher than that of the drill holes made with the Type Q1 bit.

Discussion

The most important finding of this study is that the density of the simulated cancellous

bone significantly affected the diameter of holes drilled using cannulated drill bits of 3.5, 4.2 and 4.4 mm diameter, with lower simulated bone density resulting in a larger hole diameter relative to the drill-bit diameter.

Although drilling is an important step, it has received little attention because it is performed so frequently and routinely [3]. However, drilling can be destructive at the micro-level because bone is far more fragile than metal drill bits. Bone-drilling experiments using solid drill bits have shown delamination at the entrance and exit of the hole, as well as cracking on the hole wall [5,20]. Fernandes et al. used a finite element model to investigate the stress distribution in bone tissue during drilling, and they reported that high stresses always occur at the interface between the drill bit and the wall of the drilled hole [6]. Their results indicate that the bone around a drill bit may be excessively fractured during the cutting.

Cannulated drill bits are often used in clinical settings, e.g. to make pre-drilled holes when using CCSs for small fragment fixation of epiphyseal fractures. They are used to create a hold along a guide pin; they are thus theoretically more stable compared to solid drill bits. Many orthopaedic surgeons may assume that the diameter of a drill hole is essentially the same as the outer diameter of the cannulated drill bit used to make the hole, but our present results indicate that this is not the case. The outcome of many orthopaedic surgeries depends on the accuracy of the drilling technique [2], and enlargement of the pre-drilled hole diameter

is directly correlated with reduced pull-out strength of the screw [21]. It is thus quite important for orthopaedic surgeons to know the exact diameter of the drill hole.

Osteoporosis is a metabolic bone disease characterized by low bone mass and the microstructural deterioration of bone tissue [9,10]. It is known that implant loosening becomes more likely in patients with osteoporosis [22]. In agreement with this finding, Ogiri et al. reported that the rate of screw loosening was higher in patients with osteoporosis compared to those with healthy bone [12]. Varghese et al. investigated the individual and interaction effects of bone density, insertion depth and insertion angle on pedicle screw pull-out strength and insertion torque, and concluded that bone density contributes most to pullout strength and insertion torque [15]. The relationship between osteoporosis and drill-hole diameters has also been examined; for example, Battula et al. proposed that healthy bone and osteoporosis cannot be treated equally, and they noted that a smaller drill-hole diameter was required to maintain the pull-out strength of screws used for patients with osteoporosis [16]. Stewart et al. compared the effects of the pilot-hole diameter between osteoporotic bone and healthy bone, and revealed that in osteoporotic bone, higher pull-out strength could be achieved by making the pilot hole smaller [17]. In light of these results, it is apparent that reduced bone density due to osteoporosis clearly contributes to screw loosening, and it may be that the pilot-hole diameter is one of the factors that causes screw loosening in osteoporotic

patients. To the best of our knowledge, there are no prior published studies which provide a precise analysis of the drill-hole diameters made by a cannulated drill bit in simulated cancellous bone samples of different density.

With regard to the relationship between drill-hole diameters and pull-out strength, our present findings demonstrated that the larger the drill-hole diameter was, the lower the pull-out strength was in 5-, 10-, and 15-pcf simulated bones. Nagatani et al. stated that the pull-out strength decreased step-by-step when they increased the pilot-hole diameter [21], and this is consistent with our present results. The relationship between thread depth and pull-out strength was investigated by Yu et al., and they observed a biphasic positive linear correlation with a 0.4-mm thread-depth boundary [19]. As the drill-hole diameter increases, the amount of contact between the screw thread and the surrounding bone decreases, and the actual thread depth reflected in the pull-out strength decreases accordingly.

In our present investigation, in order to compare the influence of the hole diameter, we evaluated the pull-out strength of T1 and Q1 drill holes by using titanium screws with a major diameter of 4.6 mm, which is compatible with a 3.5-mm pilot hole. The actual depth of captured cancellous bone by the screw thread (aTD) is calculated by:

$$aTD = (D_{major} - D_{hole}) / 2$$

where D_{major} is the screw's major diameter, and D_{hole} is the drill-hole diameter. In the

osteoporosis model used here, because the Type T1 drill hole had an aTD <0.4 mm, the pull-out strength was significantly decreased compared to that achieved with the Type Q1 drill hole. In contrast, there was little difference in pull-out strength for the 15 pcf specimen, because an aTD >0.4 mm was maintained with both drill-bit types. At 20 pcf, there was a difference in pull-out strength even though the hole diameters were the same. Since the Type Q1 drill-hole diameter is consistently smaller than the Type T1 drill-hole diameter, it may be that in high-density (e.g., 20 pcf) simulated bone, the surrounding bone was compressed due to insufficient cutting and micro-damage occurred, leading to a decrease in the pull-out strength.

We consider that are three possible explanations for the negative correlation between bone density and hole diameter. (i) The drill-hole diameter may be affected by a reduction in the strength of the bone itself. In drilling, the cutting edge cuts the bone to form a hole. The lower the strength of the target bone, the greater the number of fragile fractures occurring at the wall surface, resulting in larger drill holes. (ii) Manual drilling may have induced unintended run-out of the drill bit, resulting in excessive cutting of the wall surface of the drill hole, which may have increased the drill-hole diameter. Basmajian et al. drilled pilot holes with K-wire or a solid drill bit of the same diameter and compared the screw pull-out strength of both [23]. Their results revealed that the pull-out strength of the K-wire holes was higher

than that of the holes made with the solid drill bit. This can be attributed to the absence of a flute in the K-wire's structure, which reduces the unintended run-out of the drill bit to the surface of the drill-hole wall, and thus Basmajian et al.'s report supports this second reason.

(iii) The drill shape may be involved in the negative correlation between bone density and drill-hole diameter. The two types of drill bits with different shapes but the same diameter (Type T1 and Q1) used herein showed a universal tendency for the drill-hole diameter to expand as the bone density decreased, but the enlargement ratios differed. We thus speculate that the shape of the drill may have had an effect. The obvious difference between the two types of drill bits was the number of flutes, i.e., 3 flutes for the Type T and 4 flutes for the Type Q bits. In previous studies on the design and drilling performance of bone drill bits with different numbers of flutes, the results were inconsistent, and there appears to be no optimal design at this stage [1,2,24,25]. However, the results of our study may suggest that, in cases of osteoporosis (10pcf or less), when using a 3.5 mm diameter drill, the 4-flute (Type Q) configuration is recommended over the 3-flute (Type T) configuration for preventing the enlargement of drill-hole diameter.

Many methods have been developed to prevent screw loosening due to osteoporosis [11]. Although there have been reports of the development of implants with novel shapes [26–28], as well as reports describing methods of reinforcing the area around the implant with

materials such as cement or artificial bone paste [29] and methods of reinforcing existing implants in combination [30], there remains no gold standard. We consider that controlling the drill-hole diameter precisely may be a new approach to preventing implant loosening due to osteoporosis. Our observation that drill bits with the same diameter had different hole diameters suggests the possibility of creating a drill bit specifically for osteoporosis.

Our study has some limitations. Previous studies that performed precise measurement of drill-hole diameters used the cortical bone of bovine femurs [5,6], and to the best of our knowledge, there have been no studies on cancellous bone. We think that the ideal model is biological bone, but it is difficult to control bone density in biological bone. Therefore, in order to qualitatively investigate the relationship between bone density and drill-hole diameter, we used simulated bones in this study; such bones are commonly used in experiments to investigate various aspects of screw performance, including pull-out strength [18]. Although these simulated bones may differ from biological bone, they comply with ASTM F1839-08 and have mechanical properties at the levels reported for human cancellous bone. In addition, Ceynowa et al. compared the compressive strength before and after drilling between the synthetic bone and human cancellous bone, and concluded that although the forces measured in biomechanical studies of synthetic bone cannot be directly equated with those in human bones, the measurement of the changes in the mechanical properties of synthetic bone samples

after drill-induced damage was accurate and was likely a fair approximation of the corresponding changes in human bones [31]. Therefore, we consider that the relations among the drill-hole diameter, screw pull-out strength and bone density of the simulated bone sufficiently mimic those in biological bone. Second, only two types of drill bits (i.e., with triple or quadruple flutes) were compared, and whether a similar trend exists for different drill bits remains to be clarified. Third, only the drill rotation was specified; we did not consider the feed rate. The feed speed contributes the most significant damage around a drill hole during drilling at 84.99%, whereas the drill bit design and spindle speed contribute only 7.33% and 2.41%, respectively [32]. Defining the feed rate in a clinical setting is challenging, and our study reproduced an environment as close to clinical settings as possible. Fourth, this study was performed only on a cancellous bone model because it was mainly designed to replicate the clinical use of screw-only osteosynthesis in the diaphysis and epiphysis regions. The results of this study cannot be applied directly because cortical bone is denser and stiffer than cancellous bone and has significantly different mechanical properties. In addition, cancellous and cortical bone screws have been shown to have different pull-out strengths in either cortical or cancellous bone [33,34]. Whether the bone density of the cortical bone affects the drill-hole diameter and whether the type of screw affects the pull-out strength will be investigated in the future, with appropriate method modifications.

5. Conclusions

At least in the case of cannulated drill bits of 3.5, 4.2 or 4.4 mm diameter, the drill-hole diameters for osteoporotic cancellous bone tend to be larger than those for healthy cancellous bone. Additionally, four-flute drills may achieve smaller hole diameter enlargement compared to three-flute drills. Our findings underscore that drill-hole diameter should be considered for the prevention of implant loosening in osteoporotic bone, and further developments in both implants and related tools such as drill bits are expected.

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 Legends and Table Captions

Fig. 1. The drill bits. *Left:* Frontal view. *Right:* Lateral view. **A:** the Type T drill bit. **B:** the Type Q drill bit.

Fig. 2. **A:** Schema of the drill-hole measuring points. **B:** Measurement of the drill-hole diameters. Measurements were performed once for each hole. *Green ring:* the actual measurement plotted. *Red ring:* the inscribed circle. *White ring:* the diameter of the drill bit.

Fig. 3. Scatterplot of the drill-hole diameter values for each density of simulated bone obtained in the single regression analysis. **A:** the Type T drill bits. **B:** the Type Q drill bits.

Fig. 4. Box-and-whisker diagram of the comparison of the drill-hole diameters produced by the Type T1 and Type Q1 drill bits for each density of simulated bone.

Fig. 5. Comparison of the screw pull-out strengths for drill holes made with the Type T1 or Type Q1 drill bits for each density of simulated bone.

Table 1. Diameter of the inscribed circle of each drill hole by the Type T drill bits and their average values

Table 2. Diameter of the inscribed circle of each drill hole by the Type Q drill bits and their average values

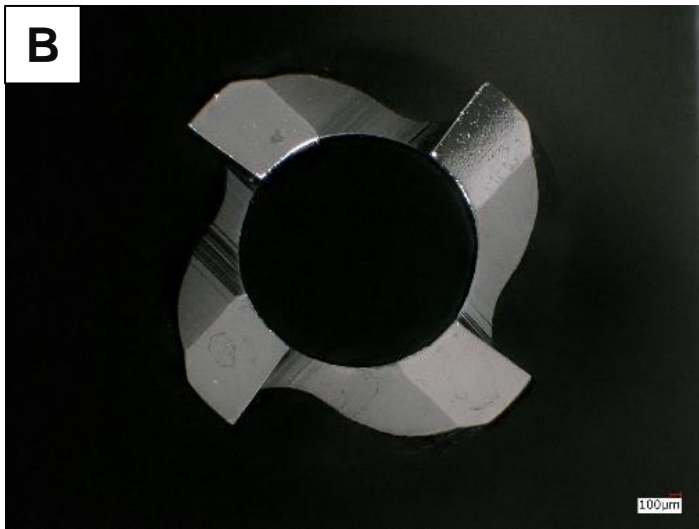
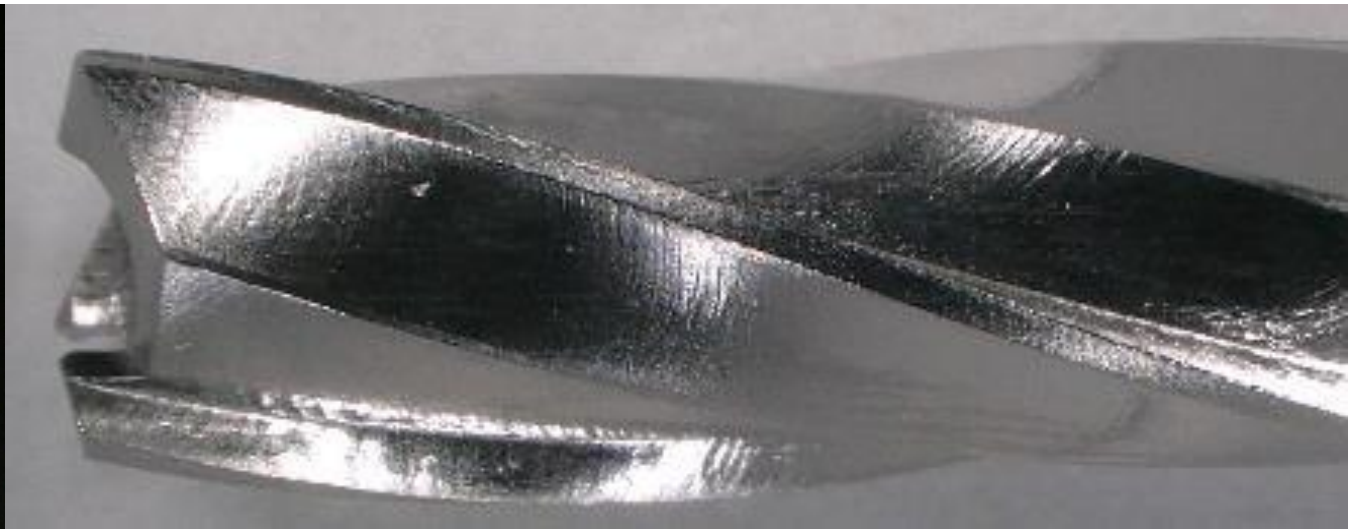
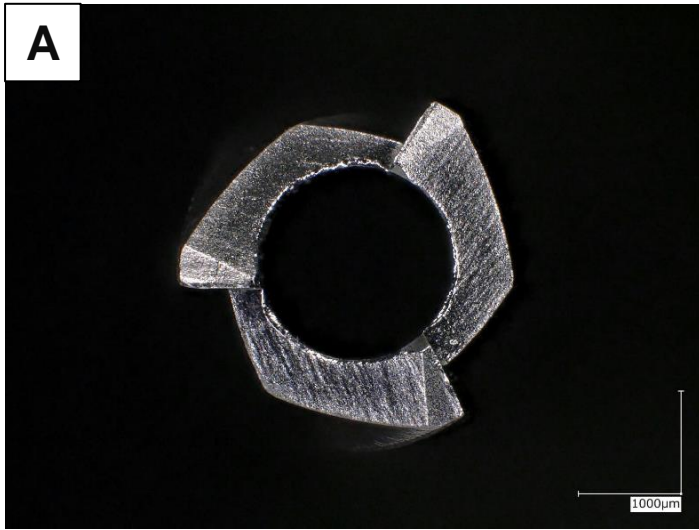


Fig. 1

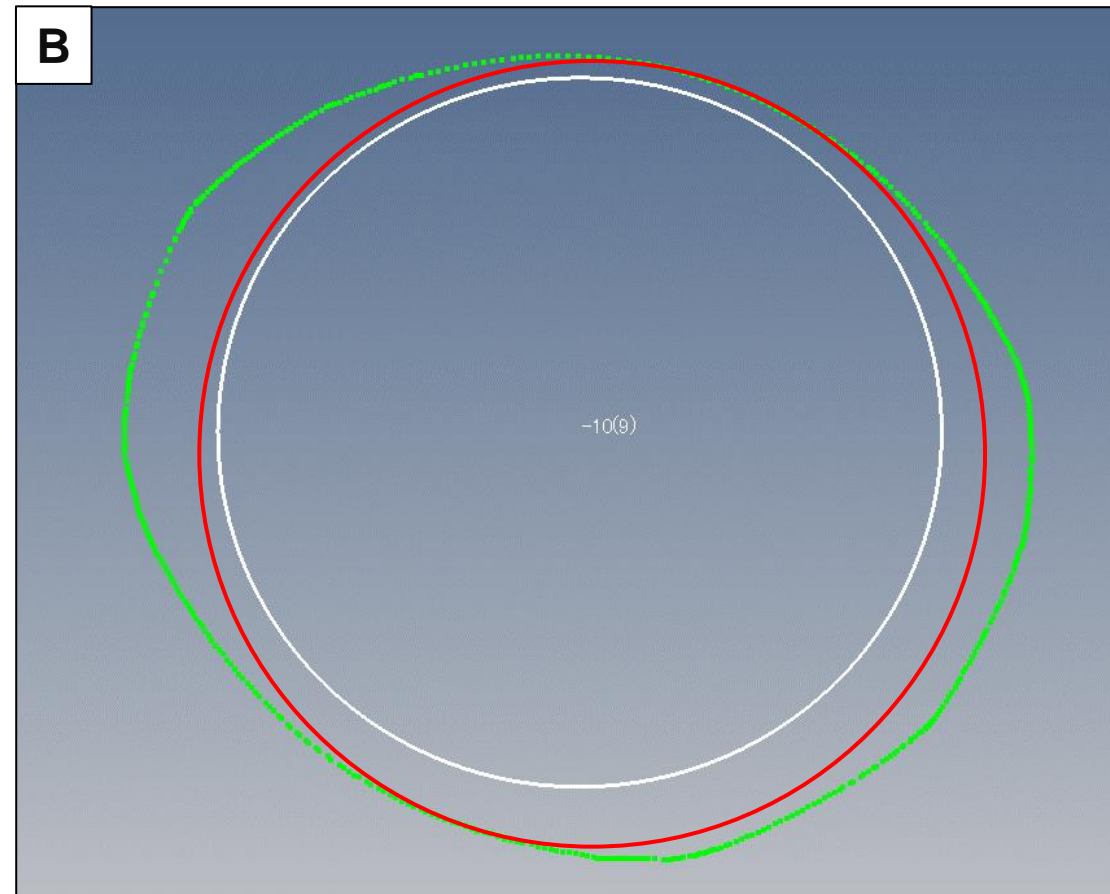
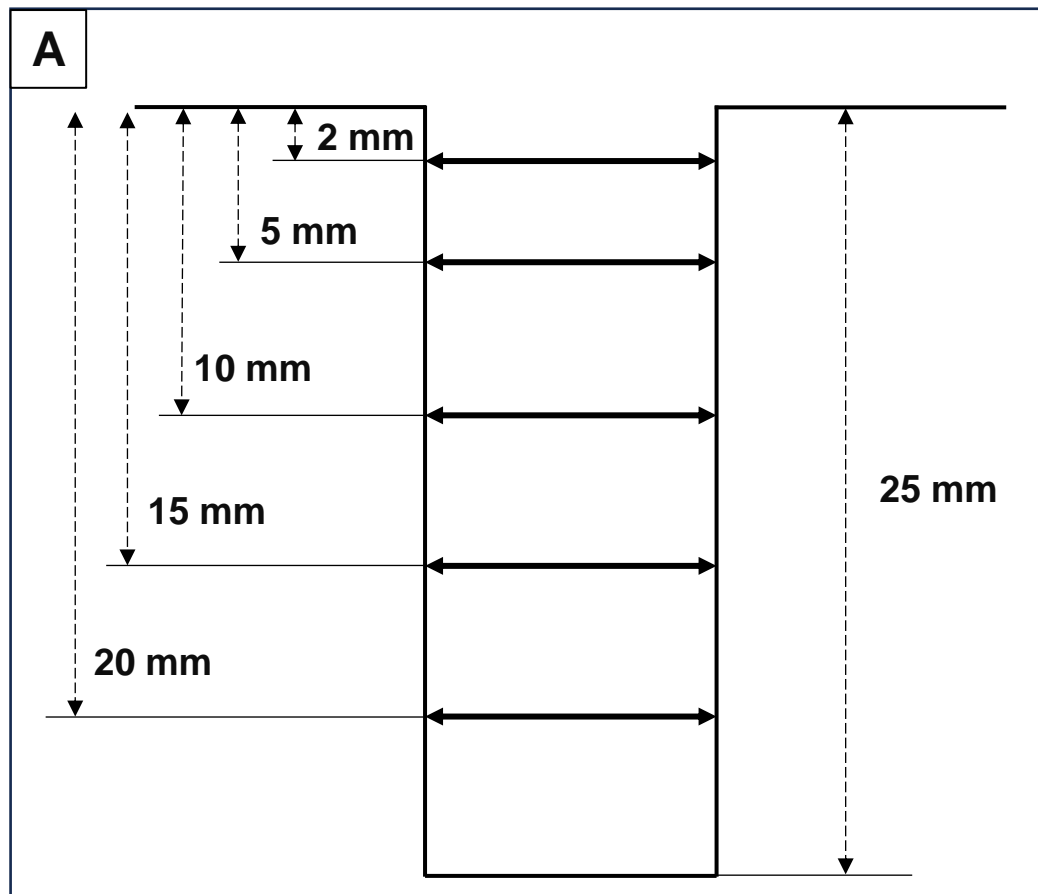


Fig. 2

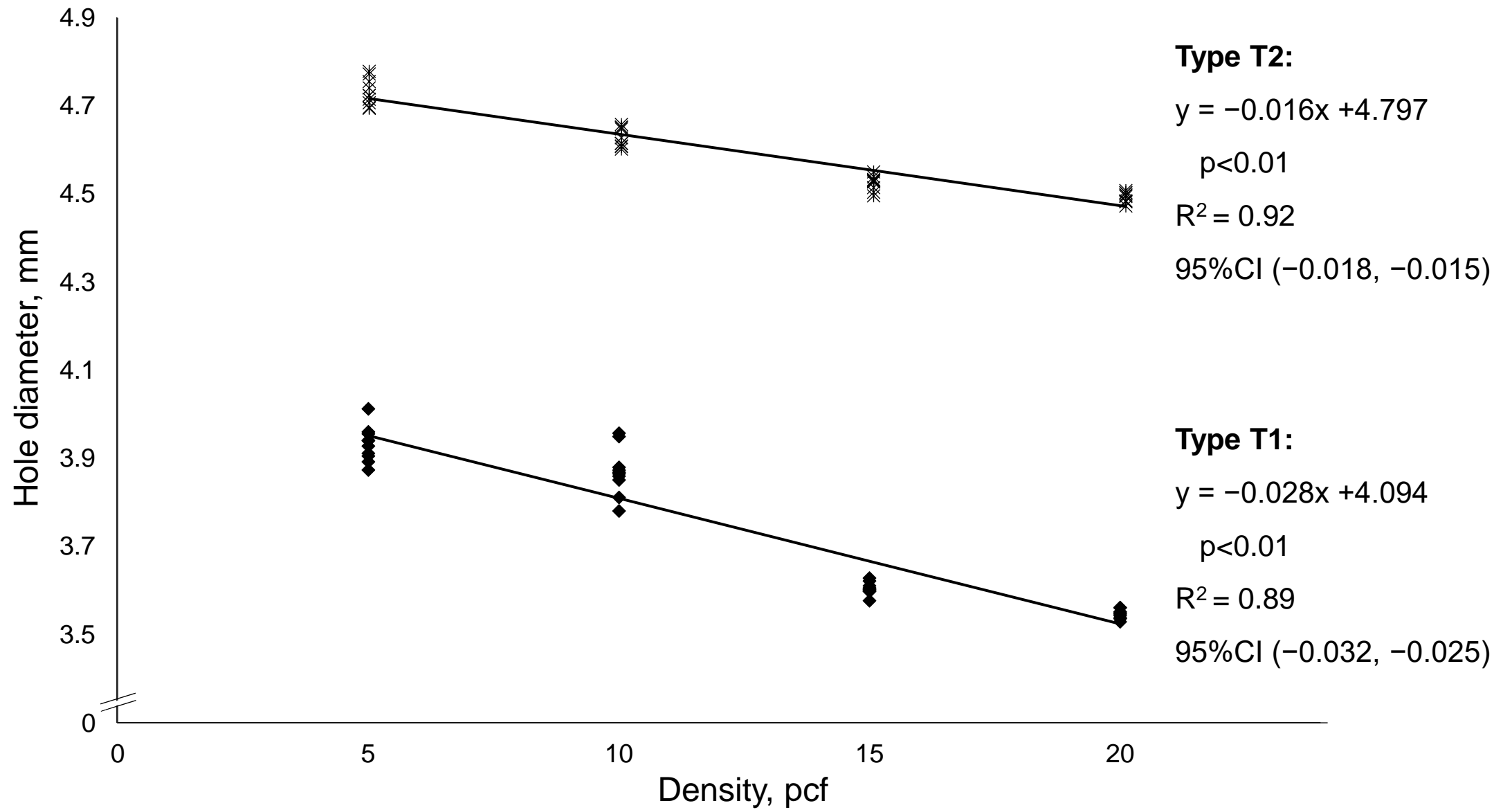


Fig. 3A

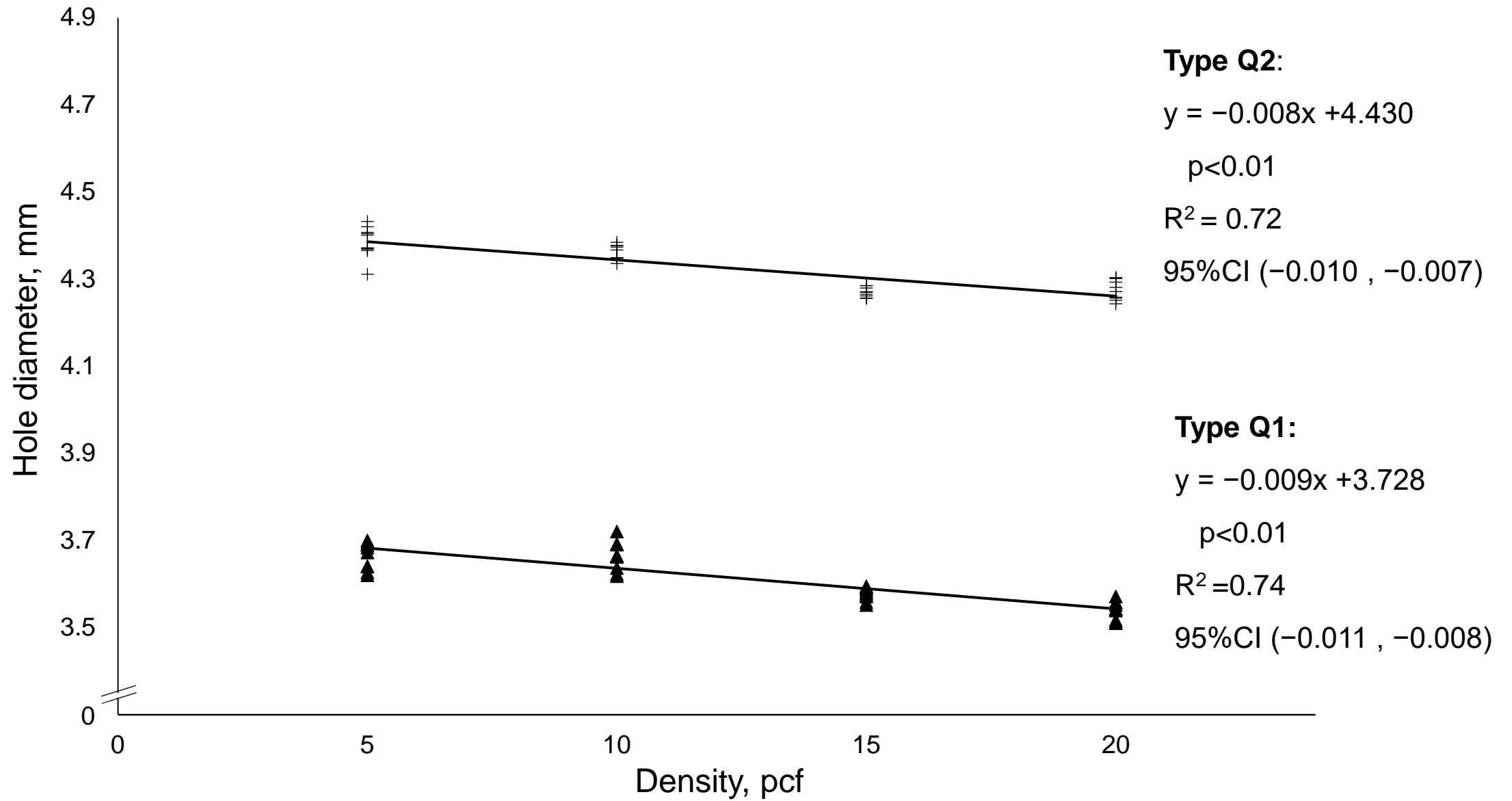


Fig. 3B

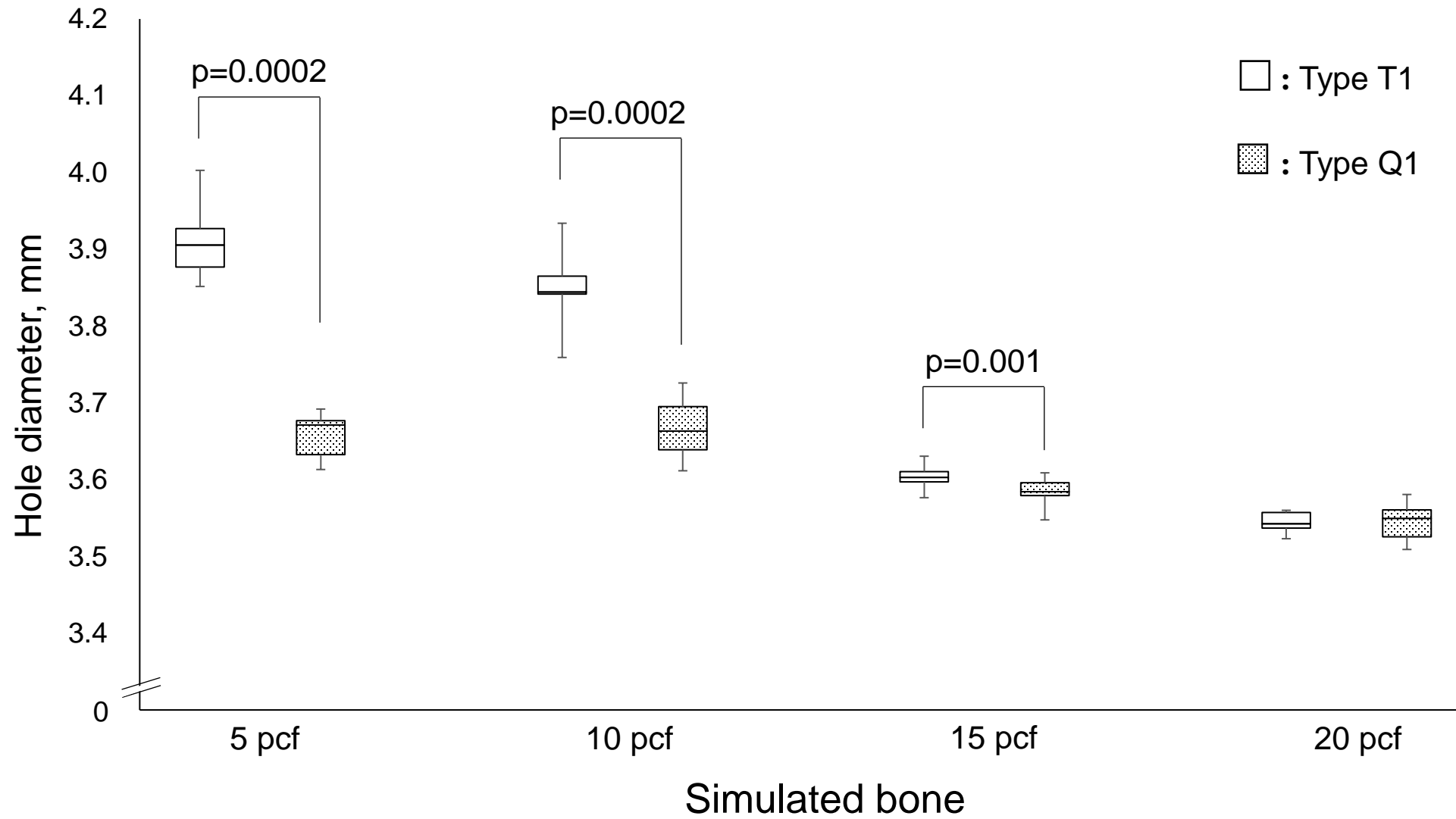


Fig. 4

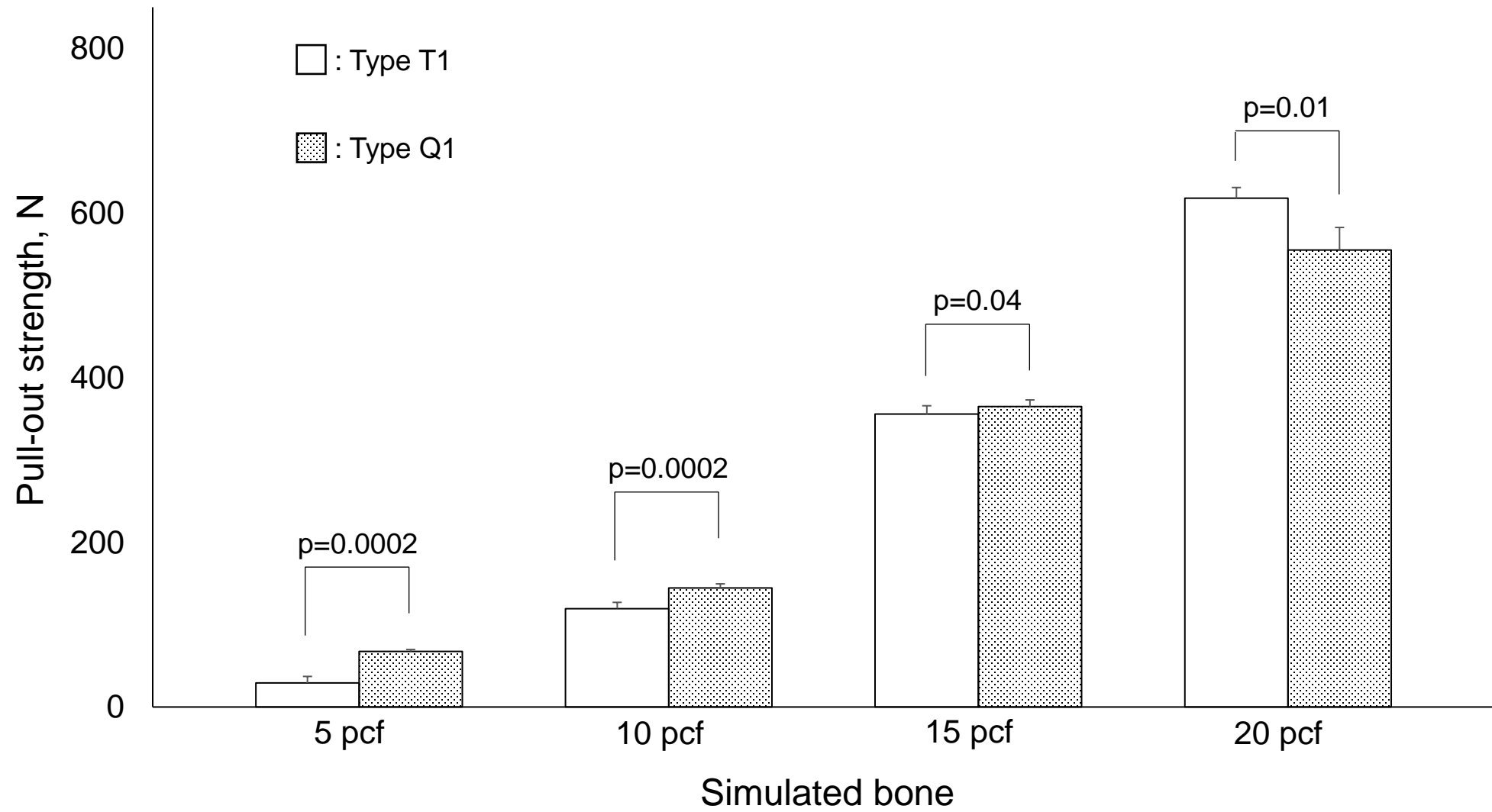


Fig. 5

Table 1

Type T1					Type T2				
No.	5 pcf	10 pcf	15 pcf	20 pcf	No.	5 pcf	10 pcf	15 pcf	20 pcf
1	3.905	3.873	3.599	3.529	1	4.706	4.614	4.530	4.497
2	3.892	3.868	3.577	3.552	2	4.693	4.608	4.549	4.502
3	3.940	3.781	3.603	3.537	3	4.695	4.651	4.514	4.482
4	3.928	3.880	3.606	3.561	4	4.740	4.606	4.529	4.482
5	4.013	3.957	3.621	3.543	5	4.777	4.614	4.532	4.503
6	3.874	3.859	3.604	3.547	6	4.714	4.627	4.495	4.497
7	3.912	3.851	3.628	3.536	7	4.723	4.601	4.538	4.507
8	3.960	3.950	3.598	3.549	8	4.771	4.650	4.526	4.472
9	3.941	3.865	3.600	3.538	9	4.754	4.647	4.528	4.484
10	3.956	3.811	3.611	3.561	10	4.723	4.657	4.503	4.494
Avg. (mm)	3.932	3.870	3.605	3.545	Avg. (mm)	4.730	4.627	4.525	4.492
SD	0.040	0.054	0.014	0.011	SD	0.030	0.022	0.016	0.011
ER* (%)	12.3	10.6	3.0	1.3	ER* (%)	7.5	5.2	2.8	2.1

*Enlargement Ratio

Table 2

Type Q1					Type Q2				
No.	5 pcf	10 pcf	15 pcf	20 pcf	No.	5 pcf	10 pcf	15 pcf	20 pcf
1	3.640	3.662	3.551	3.542	1	4.313	4.351	4.258	4.260
2	3.619	3.691	3.587	3.556	2	4.371	4.375	4.287	4.253
3	3.640	3.622	3.583	3.542	3	4.422	4.379	4.273	4.245
4	3.672	3.664	3.592	3.516	4	4.407	4.351	4.287	4.306
5	3.683	3.662	3.558	3.558	5	4.371	4.379	4.258	4.304
6	3.689	3.617	3.571	3.512	6	4.409	4.350	4.263	4.295
7	3.690	3.691	3.578	3.551	7	4.434	4.369	4.290	4.273
8	3.626	3.690	3.575	3.571	8	4.374	4.386	4.271	4.303
9	3.699	3.720	3.594	3.509	9	4.403	4.338	4.267	4.283
10	3.695	3.636	3.590	3.538	10	4.367	4.351	4.281	4.258
Avg. (mm)	3.665	3.665	3.578	3.539	Avg. (mm)	4.387	4.363	4.273	4.278
SD	0.031	0.033	0.015	0.021	SD	0.035	0.017	0.012	0.023
ER* (%)	4.7	4.7	2.2	1.1	ER* (%)	4.5	3.9	1.7	1.9

*Enlargement Ratio