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(Article begins on next page)

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# CORTICAL BONE SCREWS CONSTRUCTIVE CHARACTERISTICS – A COMPARATIVE STUDY

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ABSTRACT

Osteosynthesis is a surgical technique for the treatment of skeletal fractures through the implant of mechanical devices, such as plates and screws, in order to stabilize and fix the injured skeletal segment. It is preferred to the conservative treatment when the fracture requires immediate surgical correction or when, blocking the joints, degenerative changes could occur. Bone screws have different shapes and sizes depending on the intended use. In this study, six types of cortical bone screws were tested to determine the torque transmitted to the bone during the insertion. One Ti6Al4V tapered (Ø 6 mm) and five AISI 316L stainless steel – two straight (Ø 4 and 6 mm) and three tapered (Ø 4, 5, and 6 mm) – screws were used during the tests. Screws have been screwed into Sawbones (Sawbones® Pacific Research Laboratories, Inc., Vashon, USA) solid foam-type cylinders (external diameter 30 mm and thickness 3.5 mm) simulating the cortical bone diaphysis. Each of the 26 screws tested was inserted in a Sawbone cylinder five times, in five previously drawn equally spaced points, without any pilot holes. The experiment design was based on the ASTM standard for medical bone screws; two experienced orthopedic surgeons performed the insertions and removals of the screws using a hand-drill at 1 rev/s, aided by a metronome, and the torque was measured with a torsiometer throughout the tests. The mean and maximum torque resulted to be higher for larger diameter screws. Considering the same diameter, tapered screws showed a higher torque required for the extraction, which indicates stronger retention. However, in some cases, the Sawbones cylinder was fractured during the insertion of screws with a 6 mm diameter. Therefore, the use of medium-size tapered screws might be the most advisable compromise.

*Keywords: Cortical bone screws, Diameter, Extraction torque, Insertion torque, Shape.*

## 1 INTRODUCTION

Nowadays, the use of plating systems and screw fixation has become an established treatment for bone fractures, and the screw-bone interface is the weakest part of the implant. The success of the fixation is therefore related to the stability of the screw. The initial fixation of the screws can be assessed by evaluating the maximum torque during the insertion [1–3], which depends on numerous factors, including the bone mineral density, the design of the screw, and its dimensions [4–7]. Low insertional torque can cause poor compressive force between the plate and the bone [8]. On the other hand, excessive insertional torque can lead to the stripping of the screw, affecting its primary stability [9–11]. High insertional torque is also related to a greater inflammatory response of the tissue near the implant, which can lead to the failure of the implant as well [12]. Therefore, a compromise must be found to ensure fixation stability and avoid screw stripping and excessive tissue damage. Clinically, orthopedic surgeons tighten the screws until reaching the optimal stopping torque by subjective feel basing on their experience [5, 13]. Many studies investigated the optimal insertional

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force for the screw stability as a percentage of the maximum torque, but no consensus has been attained [14]. Using an experimental setup based on the ASTM standard for medical screws (ASTM F543-07), this study evaluated and compared six types of cortical bone screws, assessing the role of screw design in the mean and maximum insertional torque values.

## 2 MATERIALS AND METHODS

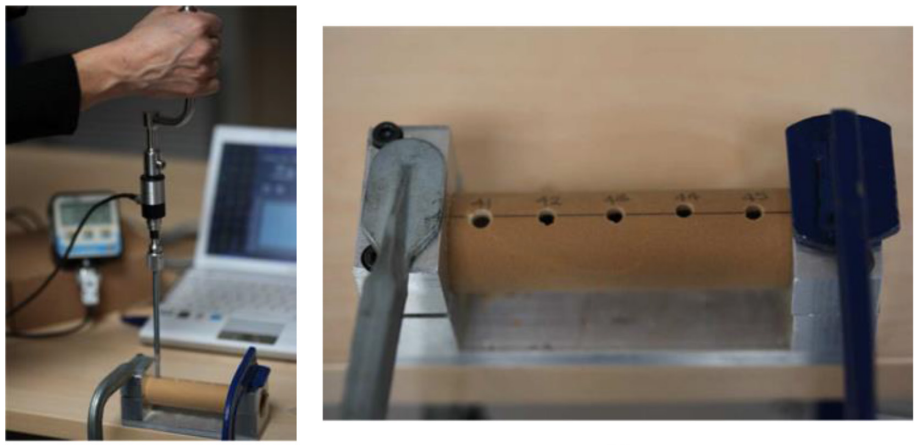
In this study, six types of cortical bone screws (Table 1) were inserted into Sawbones (Sawbones® Pacific Research Laboratories, Inc., Vashon, USA) solid foam-type cylinders (external diameter 30 mm, thickness 3.5 mm) simulating the cortical bone diaphysis.

Five equally spaced points were drawn on each cylinder. No pilot holes were created, regardless of the screw's manufacturer recommendations, in order to avoid bias in the comparison between different screws. The cylinders were placed in custom-manufactured holders and constrained through two bench clamps before the tests.Two experienced orthopedic surgeons inserted 26 screws in as many cylinders by means of a hand drill (Fig. 1a), and five holes were performed with each screw, at a constant rotation speed of approximately 1 rev/s, controlled with a metronome. The screws were inserted until both walls of the cylinders were perforated (Fig. 1b).

The torque value was measured and recorded during each test employing a torque digital indicator (DTR 526, Vetek Weighing AB, Väddö, Sweden) using the TDemo1 software (AEP transducers, Cogneto, Italy). The mean and maximum insertion torque was computed for each test, and the maximum extraction torque was recorded as well, for retention evaluation. In order to establish the statistical significance of the screw geometry and the inter-operator variability of the results, a statistical analysis of variance (ANOVA) was performed on the data considering the following factors: (1) maximum screw diameter (4, 5, and 6 mm), (2) the screw shape (tapered and straight), and (3) the operator which performed the insertion. The analysis was performed considering both the mean and the maximum insertion torque as dependent variables, using a significant level $\alpha$ equal to 0.05.

Table 1: Cortical bone screws. Producers: Citieffe S.R.L. (Calderara di Reno, BO, Italy) and Orthofix S.R.L. (Bussolengo, VR, Italy).

| Quantity | Shape | Diameter [mm] | Pitch [mm] | Material | Producer |
|---|---|---|---|---|---|
| 4 | Tapered | 3 to 4 | 1.2 | AISI316L ASTM F138 | Citieffe S.R.L. |
| 5 | Tapered | 4 to 5 | 1.4 | AISI316L ASTM F138 | Citieffe S.R.L. |
| 4 | Tapered | 5 to 6 | 1.8 | AISI316L ASTM F138 | Citieffe S.R.L. |
| 5 | Tapered | 4 to 6 | 1.4 | Ti6Al4V ASTM F136 | Citieffe S.R.L. |
| 4 | Straight | 4 | 1.3 | AISI316L ASTM F138 | Orthofix S.R.L. |
| 4 | Straight | 6 | 1.2 | AISI316L ASTM F138 | Orthofix S.R.L. |



(a) (b)

Figure 1: (a) Screw insertion, (b) holes in the cylinder simulating a cortical bone diaphysis.

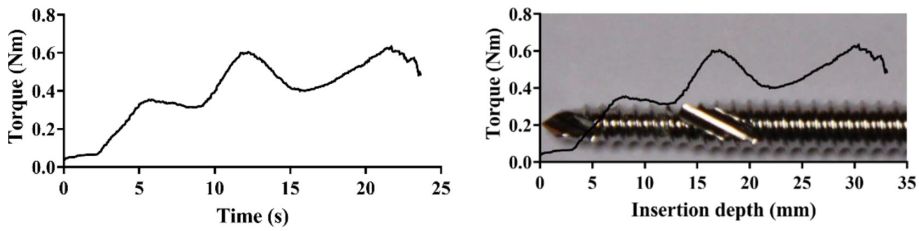
## 3 RESULTS

As previously pointed out, the torque trend over time was recorded during each test. It was used to compute the torque value corresponding to the screw insertion depth following Eqn (1), as shown in Fig. 2.

$$d = p \cdot \omega \cdot t \tag{1}$$

- $d$: indentation depth (mm)
- p: screw pitch (mm/round)
- ω: insertion speed (round/s)
- t: time (s)

The mean and standard deviation values of the mean and maximum insertion torque were computed for each group of tests performed by the same operator using the same type of screw. The results are shown in Fig. 3. Each label indicates the diameter of the screw – minimum and maximum diameter are indicated for tapered screws – and the operator which performed the insertion. The ANOVA highlighted the statistical significance of the differences obtained between different screws. Indeed, for the first two factors used for the analysis (i.e. the screw diameter and shape), a significance value $p < 0.05$ was obtained. However, no



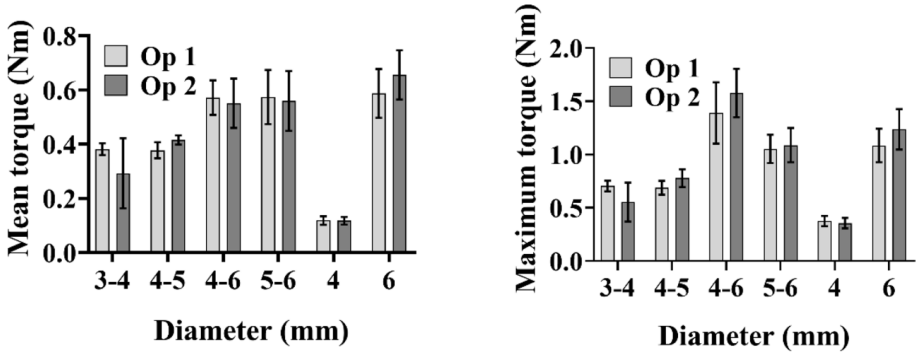

(a) (b)

Figure 2: Torque of the 4-to-5 mm diameter screw. (a) Trend over time, (b) trend over insertion depth, superimposed to the screw profile.

significant differences were detected between the tests performed by the two operators using screws of the same type ($p > 0.05$). For these reasons, the means and standard deviations were calculated for mean and maximum insertion torque obtained with each type of screw (Fig. 4), regardless of the operator which performed the tests.

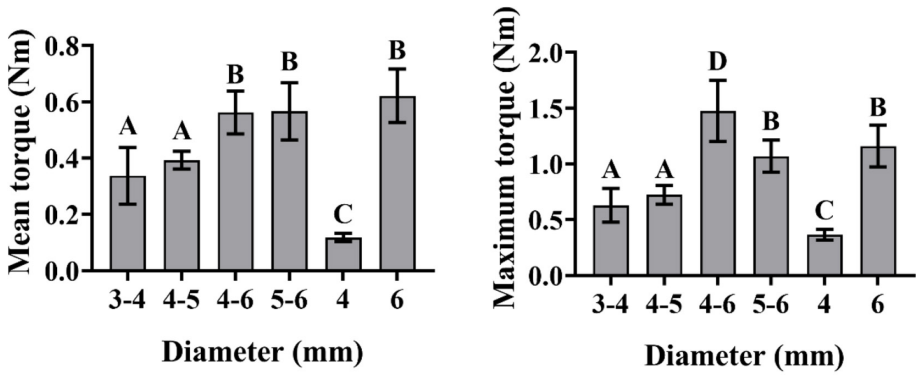
Among the screws with a 4 mm diameter, the straight one achieved the lowest values of insertion torque, while the most tapered (4–6 mm diameter) provided similar results compared with the 5–6 mm diameter tapered screw. Using the screws with the largest diameter (i.e. 6 mm), no significant differences were detected in terms of mean torque. However, during the tests performed with the most tapered one, higher maximum torques were recorded.

The maximum torque during screw extraction was also computed for each type of screw. The results, in terms of mean value and standard deviation, are shown in Fig. 5.




(a) (b)

Figure 3: (a) Mean and (b) maximum torque during screw insertion. The tests were divided according to screw type and operator.




(a) (b)

Figure 4: (a) Mean and (b) maximum torque during screw insertion. The tests were divided according to screw type, and the diameter was considered as the independent variable for the ANOVA. The letters shown above each bar represent the statistical significance of the difference between different screws (bars labeled with different letters are statistically different).

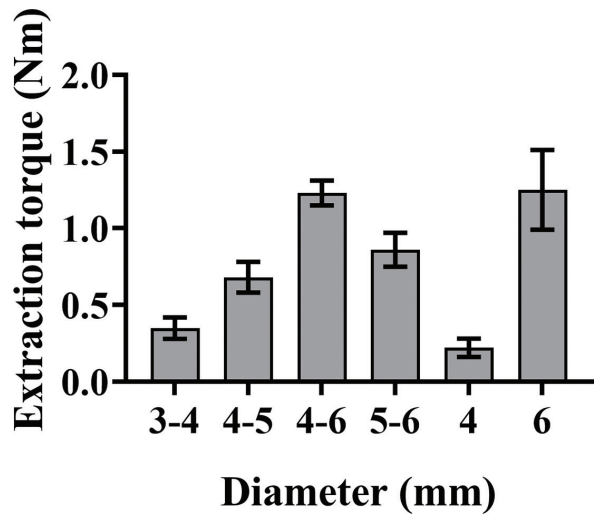



Figure 5: Mean and standard deviation of the maximum torque reached during the extraction of each type of screw.

## 4 DISCUSSION

Insertion torque is considered one of the most reliable indexes of screw stability, which is usually evaluated experimentally through the pullout strength. The inter-operator variability of the obtained torque was also investigated, and it resulted to be negligible among trained orthopedic surgeons (Fig. 2). Another important factor that influences the insertion torque and the stability of the screw is the bone quality, often measured in terms of areal bone mineral density [15]. In this study, the screws were inserted in identical synthetic cortical bone reproduction, which can be considered as a limit of the investigation, although it avoided results bias. Among the factors that were taken into consideration during this study, the influence of the screw diameter was significant, in accordance with previous findings [9]. The shape of the screw influenced the insertion torque as well, as shown in Fig. 4. Going into detail, among the screws with 4 mm maximum diameter, the tapered one provided a higher insertion torque. On the other hand, the shape had a lower influence with larger screws. Indeed, no significant difference was found between tapered and straight 6 mm screws in terms of mean insertion torque, while the maximum insertion torque obtained with the most tapered screw was significantly different from the others. The influence of the screw pitch was previously investigated by other authors, obtaining different results: in some studies, the pitch influenced the insertion torque [16], while it was not significant in other investigations [8]. In this study, the importance of screw pitch was not highlighted, which could be caused by the fact that its influence also relies on bone quality [17]. The maximum extraction torque was recorded during each test (Fig. 5). The comparison between different screws is similar to the one obtained with the maximum insertion torque, except for the 6 mm diameter, straight-shaped screw, which, however, was associated with the highest value of standard deviation.

## 5 CONCLUSIONS

The structural analysis of skeletal body elements and of biomechanical systems consisting of a bone element coupled to a prosthesis, an implant or a fracture synthesis device, can be

performed both numerically and experimentally [18]. There are many examples of clinical problems, which have moved from a qualitative assessment to a quantitative evaluation thanks to the respective modelling [19–39] or to the application of classical experimental methods of structural analysis to the evaluation of the efficacy of procedures or surgical techniques [40–75] or to the evaluation of the mechanical characteristics of the materials used at different scales of investigation [76–92]. Moreover, the structural analysis of medical devices and biological tissues is strictly connected with the in-vivo behavior of their interaction [93, 94].

However, each approach has its own limitations: numerical models can be very complex and consequently need to be validated; experimental tests cannot faithfully reproduce the real conditions and they require simplifications, in most cases. On the basis of these assumptions, both approaches still remain necessary and, in most cases, complementary.

This study aimed to compare the insertion torque obtained with different cortical screws, focusing on their constructive differences (i.e. the shape, the maximum diameter, and the pitch). In light of the results, the authors would conclude that the maximum value of the insertion torque is more capable to highlight the influence of the screw taper rather than the mean value. Moreover, using screws with 6 mm diameter and tapered shape, the specimen underwent unexpected fracture several times, confirming that an excessive insertion torque may cause implant failure. Therefore, a nonexcessive diameter combined with a tapered shape could be the most advisable compromise.

## ACKNOWLEDGEMENTS

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