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Original Article

Orthodontic miniscrews: an experimental campaign on primary stability and bone properties

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Summary

Objective: To evaluate the primary stability of different shaped miniscrews through the acquisition of data regarding maximum insertion torque, pullout force, and a radiodiagnosic evaluation of bone characteristics.

Materials and methods: Sixty fresh porcine bone samples were scanned by computed tomography (CT) and cone-beam computed tomography (CBCT). By means of a dedicated software, CT and CBCT images were analysed to measure the insertion-site cortical thickness, cortical density, and marrow bone density. Sixty miniscrews of 12 different types were implanted with no predrilling pilot hole in the bone samples. Every device was tightened by means of a digital torque screwdriver and torque data were collected. Subsequently, pullout tests were performed. Spearman and Pearson correlations were employed to compare any relationship between continuous variables.

Results: Different types of miniscrews did not show statistically significant differences in their torque value ($P = 0.595$), instead a significant difference was revealed by considering their load measures ($P = 0.039$). Cortical bone thickness resulted strongly correlated both with value of load ($P < 0.001$), and modestly with torque measures ($P = 0.004$). A strong positive correlation was found between CT and CBCT both for cortical density ($P < 0.001$) and marrow bone density ($P < 0.001$).

Conclusion: Bone characteristics play the major role in miniscrews primary stability.

Introduction

Miniscrews are skeletal anchorage devices used to enhance biomechanics during orthodontic treatments (1–3). They are small sized fixtures that may be placed in the alveolar interradicular spaces, in the palatal cortical bone or in the edentulous areas to applicate specific biomechanics (4–7).

Since osseointegration is not required for treatment undertaking and success, primary stability becomes an essential factor. Primary stability is the result of a mechanical interface between the implant and native bone. Nowadays, miniscrews efficiency and their use to obtain more ideal dental movement in patients with low compliance are validated by many studies. Nevertheless, failure rate is still relatively high (8–11): despite variations reported by the literature, it is generally estimated around 15 per cent. Clinical studies have shown that various factors are positively associated with success, such as the diameter of the screw (12), the cortical thickness (12, 13), the lack of tissues inflammation (11, 14), and the distance from the root surface (15).

Recently, the measurement of insertion and removal torque has been proposed as a clinical parameter to predict the stability and the possibility of success for miniscrews. To achieve initial stability, a basal threshold of maximum insertion torque is necessary; however, excessive stress to the bone can cause necrosis and local ischemia and finally result in a diminished holding strength (16). A clinical value in the range of 5–10 Ncm has been proposed as the gold standard (10, 13), even if this criterion is somewhat controversial (17).

The understanding of mechanics underlying primary stability has received a strong contribution by *in vitro* studies, where the resistance to pullout forces has been considered as a measure of the bone-to-implant holding strength (18). Further studies, both on synthetic and natural bone, have been performed in order to understand how insertion torque could be related to screw design and to bone characteristics. These experiments indicate that insertion torque may be increased by some device geometrical characteristics, such as the diameter (19), the thread depth (20), the thread shape factor (20), a tapered shaft (21, 22), and longitudinal fluting (23). On the other hand, miniscrews having a greater pitch show a lower insertion torque (24).

Differences in insertion torque depend on mechanical properties such as bone mineral density and bone microarchitecture (25). Several *in vitro* studies suggest that cortical thickness and cortical density are in a direct relationship with insertion torque (19–21, 26), so that, from a clinical point of view, information on recipient bone quality and quantity would be useful.

Recent studies have investigated and mapped the cortical bone thicknesses at the most frequent sites for mini-implant placement by using computerized tomography and skulls (27, 28). It is known that cortical bone tends to be thicker in hypodivergent than in hyperdivergent subjects (29), while medullary space thickness is largely unaffected by facial divergence (30), but a more accurate and personalized evaluation of cortical thickness and mineral density can be achieved only by means of X-ray generated 3D images.

The standard radiodiagnostic examination to evaluate bone quantity and quality is computed tomography (CT) and the returned Hounsfield units (HU) are a measure of mineral density; however in most orthodontic cases 3D radiodiagnostic images are not indicated. Recently, cone-beam computed tomography (CBCT) has become a valid diagnostic tool in orthodontics, preferred to conventional CT for its lower biologic and economic costs (15, 25). On the other hand, the lower radiation dosage causes a loss of information on mineral density, so that densitometric comparisons are reliable only within the same bone sample.

The aim of this experimental *in vitro* research was 1. to evaluate primary stability of different shaped miniscrews through the acquisition of data on maximum insertion torque, pullout force and a CT based evaluation of bone characteristics and 2. to evaluate the agreement on bone density between CT and a specific CBCT acquisition device.

Materials and methods

In this study, 12 devices were tested (Figure 1); the fixtures used in this study were provided for free by the companies that accepted the research protocol. Miniscrews geometrical characteristics are described in Table 1. A 20.00-kV scanning electron microscope (model S-2500; Hitachi, Tokyo, Japan) was used to obtain detailed and calibrated images of the screw's shank, magnifications used were 20, 80, 100, and 500 times. Images were successively imported in IMAGEJ (version 1.47n, http://rsb.info.nih.gov/ij/index.html) to measure the pitch of the miniscrews, the depth, the external diameter, and the initial conical length. The conical length was measured

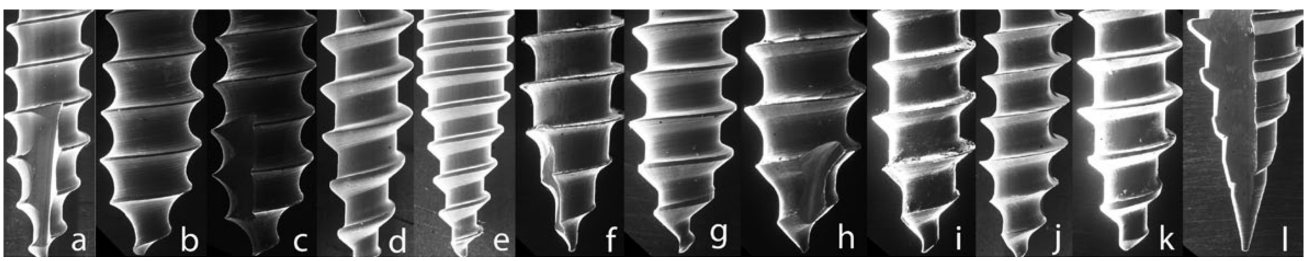

Figure 1. Scanning electronic microscope images of the used miniscrew types a: Thomas, b: Biomaterial Red, c: Biomaterial Pink, d: Novaxa, e: 3M, f: Dewimed, g: Osstem, h: Jeilmed20, i: Jeilmed16, l: Forestadent, m: Aarhus, n: Storm.

Table 1. Miniscrews geometrical characteristics

		Biomaterial Red		Biomaterial Pink										
	To-mas	Large thread	Small thread	Large thread	Small thread	Novaxa	3M	Dewimed	Osstem	Jeilmed 20	Jeilmed 16	Forestadent	Aarhus	Storm
Depth	0.218	0.215	0.208	0.172	0.177	0.265	0.116	0.229	0.222	0.232	0.205	0.346	0.243	0.277
Pitch	0.896	0.674	0.344	0.64	0.348	0.929	0.572	0.686	0.697	0.863	0.746	0.828	0.265	0.682
Thread shape factor	0.243	0.319	0.605	0.269	0.509	0.285	0.203	0.339	0.319	0.269	0.275	0.418	0.365	0.406
Diameter	1.58	1.45	1.45	1.44	1.44	1.65	1.76	1.54	1.67	2	1.59	1.72	1.58	1.99
Length	9.5	7	7	7	7	10	9	9	9	9	9	9	8	9
Conical length	1.335	1.339	1.339	1.221	1.221	1.795	3.647	1.168	1.352	1.360	1.339	1.961	1.335	3.319

along the major axis of the screw, from the tip to the last thread having a diameter less than the largest diameter of the screw. All obtained measurements are expressed in millimeters. Thereafter, the thread shape factor of each TAD was calculated (20, 31). For double threaded screws, only the smallest pitch was considered because of the role of cortical thickness in influencing pullout force (19, 20) and because maximum insertion torque was reached once cervical threads had been interfacing cortical bone.

Sixty fresh porcine samples 30-mm long were prepared from the same bone region (rib) after removing all periosteum. Thereafter bone samples were singularly packaged in a cellophane envelope and every package was filled with a ultrasound radiolucent gel (Aquasonic clear, Parker laboratories Inc, Fairfield, New Jersey, USA), which prevented the samples from dehydration.

All the bone samples were first scanned by a CT (Asteion Multi; Toshiba, Tokyo, Japan) first and a CBCT (Promax 3D Max; Planmeca Oy, Helsinki, Finland) later. CBCT scans was set with an exposure time of 12.38 seconds, 66 kV, and a voxel size of 100 µm (isotropic), while the CT scans was set with an exposure time of 0.75 seconds, 80 kV. Both examinations were performed at Gazzerro Radiological Centre (Genoa, Italy).

By means of a dedicated software (Romexis, Planmeca Oy), conventional CT images were analysed by an expert operator (F.O.) to measure the insertion-site cortical thickness in millimeters as well as both cortical and marrow bone density, expressed in HU. It was assumed that the border between the cortical layer and marrow bone was the set of points where HU doubled. The same procedure was performed on CBCT images using the same software (Figure 2).

The measurements of cortical density were taken at miniscrew insertion sites, in the middle of the cortical layer. Marrow bone density was measured by describing a cylindrical region of interest laying 3 mm under the apical limit of the cortical layer and by running the function which computes the average density of the indicated volume (this was achieved by simulating the placement of an implant).

Successively, all miniscrews were implanted with no predrilling pilot hole to an intraosseous thread depth of 7 mm by using a dedicated thread locker. Five bone samples were used for each type of temporary skeletal anchorage device, so that the total samples amount was 60. Every device was tightened by means of a digital torque screwdriver (online Supplementary Figure 1: Cedar DID-4, Imada, Northbrook, Illinois, USA) set in a continuous output measuring mode (60 registrations per second) and the output stream was collected by the SW-1SV-USB data acquisition software (Imada, Northbrook, Illinois, USA). The collected data were plotted in a graph (Figure 3).

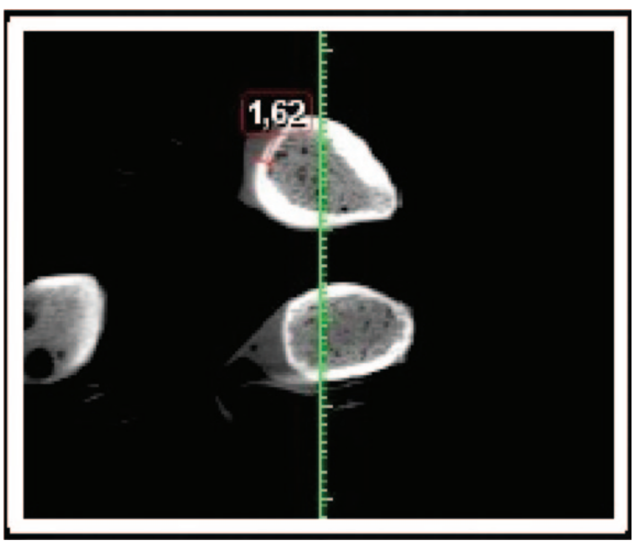

Figure 2. Screenshot of Romexis software (Planmeca Oy) for image analysis.

Perpendicularity of insertion and alignment of miniscrew, bone sample, and load cell were guaranteed by an aluminum frame hosting the thread locker, a hollow steel cylinder to encompass each screwdriver, and a cylindrical steel frame connecting these components to the load cell.

Subsequently, the pullout tests were performed. A universal testing machine (model 8501 plus; Instron, Canton, Massachusetts, USA) with a 10-kN load cell was used for the pullout tests; sensibility of the load cell was 0.0001 kN. The software Plus Windows 98 (series IX, version 8; Microsoft Corporation, Redmond, Washington, USA) was used for data acquisition and processing. A crosshead speed of 2 mm per minute was applied in a controlled environment at 27°C and 70 per cent humidity. The maximum load and screw displacement at peak load were measured.

Statistical Analysis

Normality of data was checked by using the Kolmogorov–Smirnov test.

A non-parametric Kruskal–Wallis test was conducted to evaluate differences among several types of miniscrew in the torque and load values, in the bone marrow density (both CT and CBCT) measures, and in the cortical bone thickness.

Any difference in the cortical density bone (CT or CBCT) among miniscrews was assessed by applying a parametric one-way ANOVA test.

Spearman and Pearson correlations were employed to compare any relationship between continuous variables: CT versus CBCT Cortical density; CT versus CBCT bone marrow density; all the recorded miniscrew characteristics (depth, pitch, thread shape factor, diameter, initial conical length, load, and torque); and cortical density and load or torque.

Mean differences in density values between CT and CBCT were assessed using a paired-sample *t* test or Wilcoxon signed-rank test within groups, depending on normality.

A *P* value of 0.05 was considered to be statistically significant.

The repeatability of measures of depth, pitch, diameter and bone quantity and density was evaluated with the intraclass correlation coefficient. The intraclass correlation coefficient value for the geometric measurements of the screws was 0.987; that for bone characteristics was 0.971 for cortical thickness and greater than 0.868 for bone density.

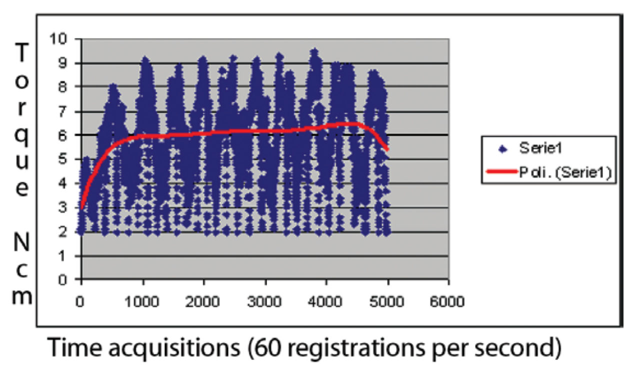

Figure 3. Insertion torque values (Ncm) according to time acquisitions (60 registrations per second).

Results

The groups did not show statistically significant differences in torque values ($P = 0.595$), instead a significant difference was revealed by considering load measures ($P = 0.039$) (Table 2, Figure 4).

Table 2. Differences between miniscrews for torque (Ncm) and load (kN) values

	Torque (Ncm)		Load (kN)	
	Median	25th–75th	Median	25th–75th
Thomas	6.20	4.30–9.40	0.132	0.131–0.178
Biomaterial red	6.50	5.80–8.90	0.137	0.119–0.147
Biomaterial pink	7.20	7.00–9.40	0.146	0.093–0.170
Novaxa	7.30	7.30–9.90	0.105	0.096–0.110
3M	8.60	5.50–14.60	0.316	0.146–0.352
Dewimed	5.60	4.10–7.40	0.150	0.148–0.173
Osstem	6.70	6.30–7.80	0.235	0.180–0.265
Jeilmed20	7.70	6.80–8.80	0.171	0.170–0.249
Jeilmed16	5.80	5.80–6.60	0.171	0.113–0.191
Forestadent	8.90	8.80–12.40	0.212	0.199–0.383
Aarhus	8.05	6.40–9.15	0.165	0.163–0.188
Storm	10.30	6.40–11.20	0.228	0.156–0.241
P value	0.595		0.039*	

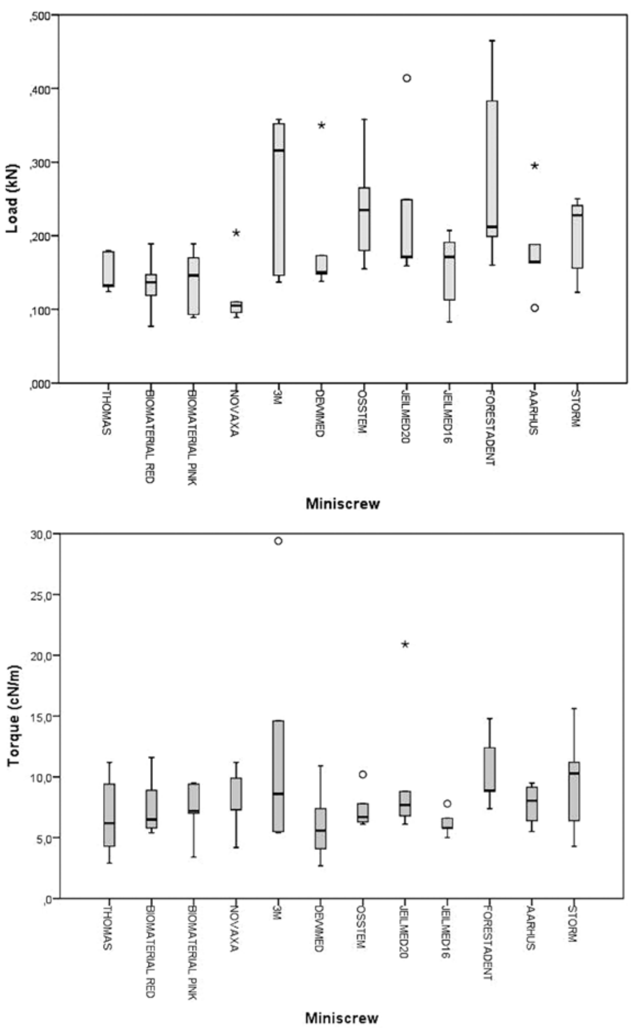

Figure 4. Load and torque values for each type of miniscrew.

No statistically significant differences was found for marrow bone density ($P = 0.574$ for CT and $P = 0.533$ for CBCT), for cortical bone thickness ($P = 0.477$) and for the values of cortical density for CBCT ($P = 0.218$).

Cortical density evaluated by CT revealed a significant difference among groups ($P = 0.026$; Table 3 and Figure 5).

The diameter was the only geometrical characteristic showing a correlation with stability parameters: a significant correlation with load ($P = 0.004$) and a strong positive correlation with torque ($P = 0.055$; Table 4).

Furthermore, cortical bone thickness resulted strongly correlated both with load (rho = 0.708, $P < 0.001$), and modestly with torque measures (rho = 0.370, $P = 0.004$; Figure 6).

Table 3. Differences between miniscrews for cortical density.

	Median	25th	75th
Thomas	1583	1482	1954
Biomaterial red	1963	1547	2025
Biomaterial pink	2145	2069	2254
Novaxa	1834	1759	1955
3M	2079	1904	2385
Dewimed	1645	1574	1783
Osstem	2014	1962	2169
Jeilmed20	1468	1374	1726
Jeilmed16	1631	1421	1696
Forestadent	2270	2024	2340
Aarhus	1909	1756	2025
Storm	1864	1857	2060
P value	0.026*		

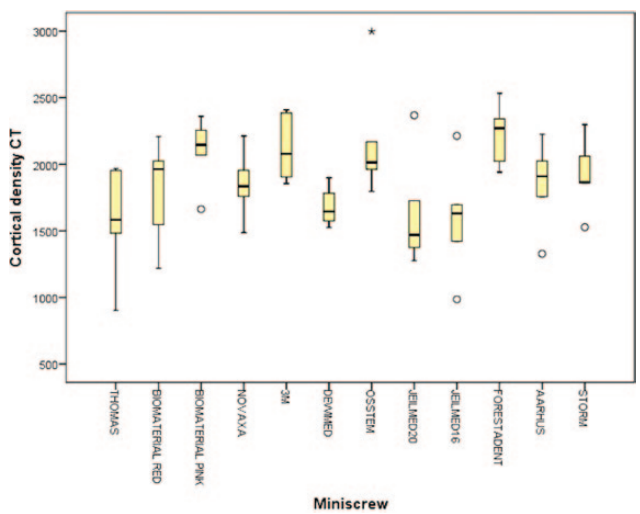

Figure 5. Cortical density (CT) measured for each type of miniscrew.

Table 4. Spearman correlation coefficients for miniscrew geometry.

	Depth	Pitch	Thread shape factor	Diameter	Initial conical length
Load (kN)					
Rho	0.163	0.028	−0.048	0.370**	0.207
P value	0.214	0.833	0.718	0.004	0.112
Torque (Ncm)					
Rho	0.215	0.021	0.102	0.251	0.232
P value	0.102	0.875	0.441	0.055	0.077

Table 5. Correlation between bone features and load or torque tests.

		Load (kN)	Torque (Ncm)	Cortical bone (mm)	Cortical density CBCT (HU)	Marrow bone density CBCT (HU)	Cortical density CT (HU)	Marrow bone density CT (HU)
Load (kN)	Rho	1.000	0.394**	0.708**	0.634**	0.684**	0.566**	0.681**
	P value		0.002	<0.001	<0.001	<0.001	<0.001	<0.001
Torque (Ncm)	Rho	0.394**	1.000	0.370**	0.206	0.279*	0.211	0.362**
	P value	0.002		0.004	0.118	0.033	0.109	0.005
Cortical_bone (mm)	Rho	0.708**	0.370**	1.000	0.672**	0.580**	0.591**	0.626**
	P value	<0.001	0.004		<0.001	<0.001	<0.001	<0.001
Cortical density CBCT (HU)	Rho	0.634**	0.206	0.672**	1.000	0.577**	0.836**	0.649**
	P value	<0.001	0.118	<0.001		<0.001	<0.001	<0.001
Marrow bone density CBCT (HU)	Rho	0.684**	0.279*	0.580**	0.577**	1.000	0.464**	0.879**
	P value	<0.001	0.033	<0.001	<0.001		<0.001	<0.001
Cortical density CT (HU)	Rho	0.566**	0.211	0.591**	0.836**	0.464**	1.000	0.500**
	P value	<0.001	0.109	<0.001	<0.001	<0.001	.	<0.001
Marrow bone density CT (HU)	Rho	0.681**	0.362**	0.626**	0.649**	0.879**	0.500**	1.000
	P value	<0.001	0.005	<0.001	<0.001	<0.001	<0.001	

CBCT, cone-beam computed tomography; CT, computed tomography; HU, Hounsfield unit.
*$P < 0.05$, **$P < 0.005$.

Any correlation between bone features and load or torque tests are shown in Table 5.

A strong positive correlation was found between CT and CBCT both for cortical density (rho = 0.878, $P < 0.001$) and marrow bone density (rho = 0.879, $P < 0.001$; Figure 7. In relation to comparisons of the mean density values, statistically signicant differences ($P < 0.001$) between CT and CBCT were obtained, both for cortical and for marrow bone (Table 6 and Figure 8).

Discussion

Is there an optimal geometry for stability?

Currently available orthodontic miniscrews have different sizes in order to match the anatomic characteristics of various implantable sites, but even though their bulk is approximately similar, they show different shapes and many other design differences (Table 1). Ideally, clinicians would like to select the shape in order to obtain the maximum primary stability. The objective of this study was to make a stability comparison among 12 mini-implant types through the acquisition of data regarding maximum insertion torque, pullout force and a CT based evaluation of bone characteristics. We found that miniscrews had no significant differences in their torque values; instead a significant difference was revealed by considering their load measures, but the only geometrical feature that was correlated to pullout force was the diameter. This lack of predictability on the way the device design affects torque variations may be attributed to the overlapping of several geometrical factors. Nevertheless, what was found on pullout force seems to indicate that major changes in the bone-to-implant surface are mainly due to changes in the diameter.

Two of the used miniscrews (Biomaterial Red and Pink) presented an additional design variable, which is a dual threaded feature (Figure 9) in the neck region. Dual-threaded design was shown to increase the surface area embedded in cortical bone with regards to a single-threaded design (32) and the importance of cortical holding in primary stability was confirmed by our results. Maximum insertion torque and maximum removal torque were increased too (32). On the other hand, Kim and colleagues (33) reported the decrease in maximum insertion torque for dual-thread miniscrews compared to single-threaded and they proposed that the decreased torque may prevent tissue damage and mini-implant fracture when a small diameter is needed. This disparity in literature findings was attributed to a difference in design between Kim and colleague's dual-thread and Hong's study (32). Particularly, the authors argued that dual-thread design has a thread count that is doubled per unit length in the neck region, instead their thread design has additional overlapping set of threads with the same thread count per unit length as single threading; they called it 'double-thread' (rather than 'dual').

In our experiment, we observed that dual-threaded design did not provide a significantly differerent torque.

Bone Characteristics

The role of cortical bone on miniscrews stability is well known (13) and finite element analysis showed that when a lateral loading is applied on the screw, the stress distribution is mainly distributed in the neck region, which is embedded in cortical bone (34). Our experiment confirms what was found in a previous study (24), which is a positive correlation between cortical bone thickness and pullout force. Furthermore, it underlined that a correlation between cortical thickness and insertion torque does exist.

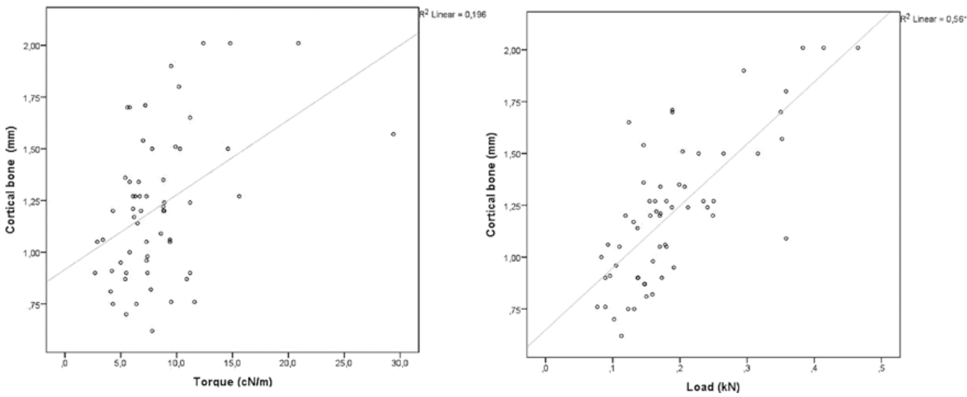

Figure 6. Correlation between cortical bone thickness and load or torque.

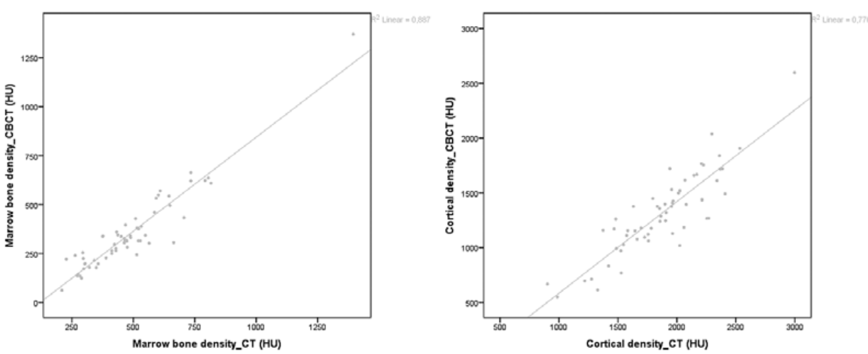

Figure 7. Correlation between CT and CBCT cortical density and bone marrow density.

Table 6. Mean density values for cortical bone and marrow bone.

		CT	CBCT	*P* value
Density values	Cortical bone	1878.38 ± 386.506	1318.45 ± 368.411	<0.001
	Marrow bone	464.00 (351.00–560.25)	313.50 (231.00–394.00)	<0.001

CBCT, cone-beam computed tomography; CT, computed tomography.

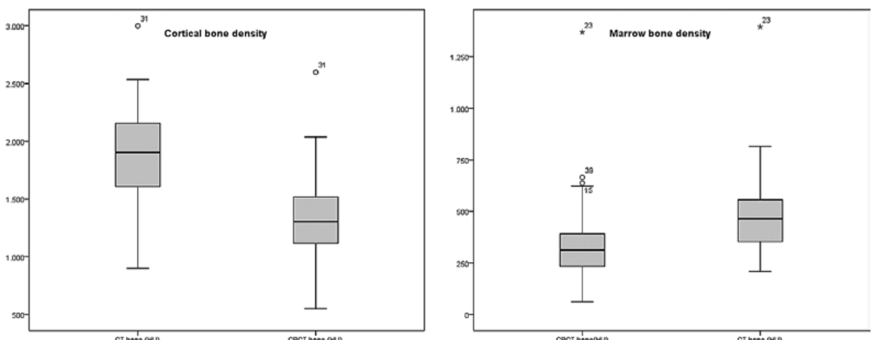

Figure 8. Comparisons of the mean density values between CT and CBCT.

Recently, an experimental study on synthetic bone showed that cortical density too has a positive correlation with pullout force and insertion torque (19) and our study on animal bone specimens adds some evidence at least for what concerns pullout force.

Finally, marrow bone density showed a significant correlation with pull-out force and torque values, extending a previous result (24) and answering another issue recently addressed by the literature, whether cancellous bone is related to primary stability (35).

Densitometric Agreement between CT and CBCT.

Agreement results between CBCT and CT scan in this study can not be considered valid for every CBCT device, and even between the same CBCT product line there could be differences in correlation with a CT. In most cases, a significant difference between the mean values of the two density analyses could be expected, both for cortical density and marrow bone density; however in this study the degree of correlation was high. The CBCT analysis underestimated the cortical density value with respect to the CT analysis, with a mean difference value of −559 933 HU and a standard deviation of 187 522. For marrow bone density, the difference between CT values and CBCT values was less than 169 HU in 95 per cent of samples. That could lead to the conclusion that the HU data obtained by the cone beam exposition are a close approximation to real HU obtained from traditional CT scan (Figure 10) and CBCT analysis are a good and reliable opportunity to obtain realistic data from a bone sample.

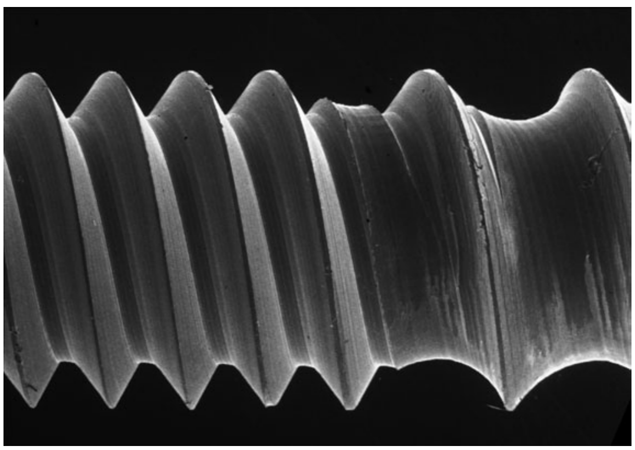

Figure 9. SEM image of double-threaded region in Biomaterial Red and Pink screws.

Conclusions

Our study led to the following conclusions:

1. cortical bone thickness has a significant correlation both with the values of torque and pullout force;
2. cortical bone density has a significant correlation with pullout force;
3. marrow bone density was significantly related to pullout force;
4. miniscrews diameter was the geometrical feature with the strongest consequences on stability;
5. the agreement between the CT and the CBCT system used in this study on bone density was high.

Supplementary material

Supplementary material is available at *European Journal of Orthodontics* online.

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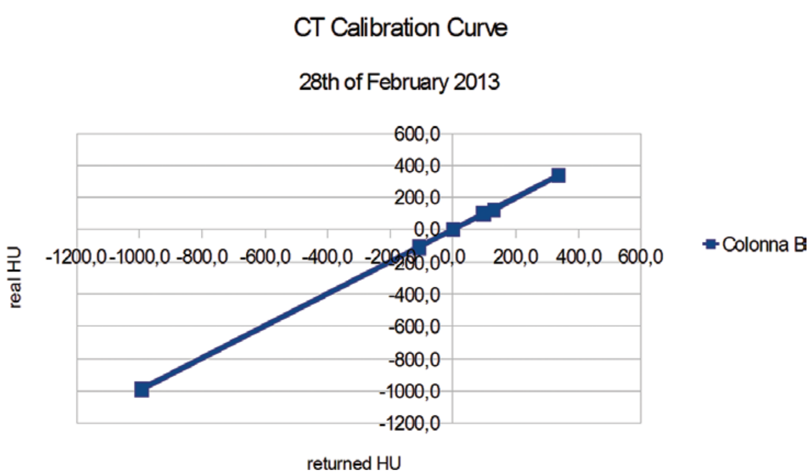

Figure 10. CT calibration curve (scanning objects of known density).

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