BOVINE BONE SCREWS DEVELOPMENT: MACHINING METHOD AND METROLOGICAL STUDY WITH PROFILE PROJECTOR

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SUMMARY

Screws made of bone are little studied in literature. Structural, mechanical and osseointegration/ osteoinduction-related aspects are important research topics to be addressed prior to the use of ***in vivo*** bone grafts. However, the first issue that should be addressed is the machineability of bone tissues. Another relevant issue is regarding the feasibility of building bone screws in pre-determined dimensions. In those researches, screws were made of cortical bone samples removed from the medial-diaphyseal portion of bovine tibiae in a standardized fashion. Bone machining was performed in a horizontal lathe by using two pieces of tool: steel bits and aluminum-oxide tip-mounted grindstone, producing 22 screws. The evaluation of bone screws' dimensions was performed in a profile projector, taking 10 metal screws as reference. In general, the metrological analysis showed no significant changes within bone and metal screws groups. Major dimensional problems found in both screw groups were: very high alpha angles in bone grafts and similar metal grafts presenting a body diameter in a much lower value than expected. We concluded that bone tissue is machineable and the production of screws with pre-defined dimensions was shown to be possible in the bone.

Keywords: Bone screws; Biomedical Engineering; Biomechanics.

INTRODUCTION

Metal is a traditionally used material for screws manufacturing [1]. The search for alternative biomaterials for the manufacture of surgical implants, such as biodegradable polymers, baked clay, and castor oil derivatives, occurs due to problems of biocompatibility, osseointegration, and others related to a too high elasticity module [2-8,].

An osteosynthesis material potential to have the same properties of a bone graft, that is, to be osteoinductive, osteoconductive and to have osteoprogenitor cells, is a very interesting appeal. Furthermore, bone screws will probably favor bone healing, enabling micro movements at fracture line or osteotomy, reducing per-implant osteopenia.

Few studies in literature, most of them experimental, report the possibility of using screws made of homologous or heterologous bone [9-15].

Previously to manufacture bone screws, it is mandatory to check if the bone tissue is machineable, being necessary to select an adequate machine-tool set for producing this kind of implant. Another important point is to evaluate the feasibility of manufacturing bone screws in pre-established dimensions, in accordance to an acceptable quality standard for surgical screws.

MATERIALS AND METHODS

Bone screws manufacturing was performed by using samples removed from the medial-diaphyseal portion of bovine tibia of young animals. Those bone samples were fixed on the horizontal lathe chuck (NDT 650, Nardini®, Brazil), keeping distal end centered at the opposite end. A steel tool (squared bits, of fast steel with 12% cobalt, Steelma Ster®, U.S.A.) used in machining was fixed at lathe's tool support,

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with the tool tip resting approximately at bone piece central level. The wedge, chip output, and main incidence or drift angles were, approximately, 68°, 8° and 14°, respectively. Figure 1 shows these angles. Bone piece was turned (cut movement) at 500 rpm and the lathe operator made the tool to advance against the bone piece (forward movement), being the stroke control performed by means of graded rings (micrometric collars), with progressive removal of bone layers, until a cylindrical piece with 4.5 mm diameter was achieved (Figure 2).

Those bovine bone pieces were used for manufacturing 22 screws (Figure 3).

Threads modeling followed the NBR ISO 5835[16] guideline, of the Brazilian Association of Technical Guidelines (ABNT) (1996), which refers to, among others, for low threaded (thread diameter: 4.5 mm) screws: 1- angles α and β with values of 35° and 3°, respectively; 2 – step of 1.75 mm, and; 3 – 0.1mm-long thread apex (Figure 4).

Thread molding was performed by using a grindstone with a pink aluminum oxide mounted tip (group B-71, Brasilex®, Brazil), in a 35° angle towards cylinder (Figure 5A). That grindstone was attached to a suspension gear (Fava®, Brazil), fixed to horizontal lathe's upper car, being the resulting cutting movement achieved by the cutting motion (produced by the rotation of bone piece) and stroke motion (machine-tool movement), combined to the single-axis rotation of the grindstone. Threads were extended by 22mm in the screws, with an inner diameter of 3 mm.

Screws heads and the double-headed cylinder heads had a quadrilateral format, with 7mm edges and 10mm long. Head modeling was performed by using two parallel metal saws, 7 mm equidistant.(Figure 5B).

As a reference group, 10 steel screws were used (Figure 6), vastago-type, sourced by Baumer® (Table 1).

For checking quality of threads modeling and of bone standardized dimensions, in comparison to metal models, a medium-sized profile projector (Prazis®, Argentina) from the Laboratory of Mechanical Assays, Paula Souza Technological Education State Center in Ribeirão Preto, with a 10 x magnification glass was used (Figure 7A).

The profile projector had a support where the screws, one by one, were fixed in an accessory enabling the suspension of the portion to be analyzed, which was designed in a round fabric. Screws dimension measurements were taken by means of a 0.001 mm electronic digital reading, with projection accuracy of ± 0.15% and ± 0.10 % for episcopy* and diascopy**, respectively (Figure 7B and 7C). For checking threads bending, a goniometric support with 0.01° electronic digital reading and ± 370° capacity, with segmented reference lines was used.

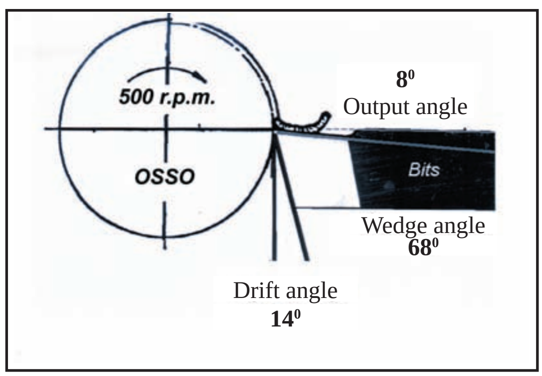

Figure 1 – *Scheme illustration of wedge, chip output, and main incidence or tool drift angles (bits) used for bone machining.*

The following parameters were assessed:

1 - Dimensions:

a. body diameter (proximal non-threaded portion);
b. inner diameter;
c. thread fillet height;
d. step length;
e. thread apex lengths;

2 - Thread bending:

a. alpha angle;
b. beta angle.

3 - Thread surface integrity.

The parameters assessed were obtained by readings in random points of each screw.

Threads surface integrity was assessed by means of episcopy and diascopy, being other parameters evaluated only by diascopy.

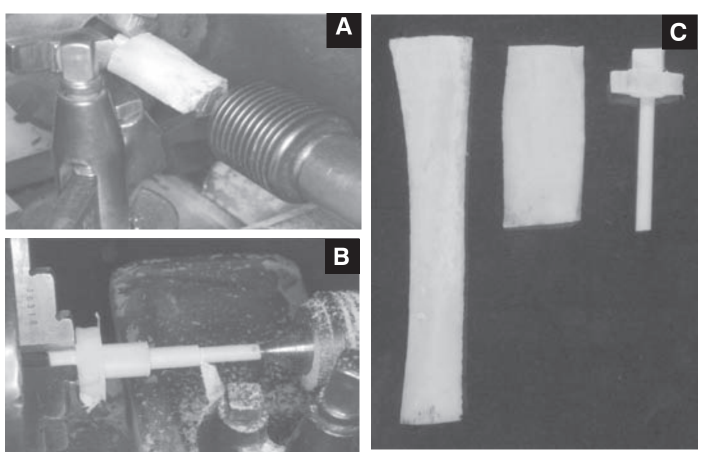

Figure 2 – *Illustration of the main steps for producing screws in lathe. A bone sample was fixed on the horizontal lathe chuck, keeping distal end centered at the opposite end* **(A).** *The steel tool moved towards the bone piece, progressively removing bone layers* **(B)***, until a cylindrical piece with 4.5 mm diameter was obtained* **(C)***.*

Statistical analysis

In the metrological study, the comparison between screw groups (bone x metal) was performed by using

(Footnotes) *Projection of object reflex image. ** Projection of object shadow the *t-test* for independent samples, because in no group and for no variable the data normality hypothesis was rejected.

RESULTS

The results of average measurements of parameters assessed at screws profile projection are shown on Table 2.

It was seen that in seven bone screws height changes occurred in 11 threads, being 8 longer (average 0.066 mm) and three shorter (average 0.064 mm) compared to heights of adjacent threads' fillets. Metal screws did not show differences in thread fillets height for the same screw.

All bone screws showed variations on the average length of its threads' apex, with decimal or centesimal differences in millimeters for threads of a same screw. No differences were seen in this parameter for threads of a same metal screw.

Regarding the evaluation of thread surface integrity, we saw that four bone screws presented with irregularities in one to four thread steps, and metal screws didn't show changes in that parameter. Figure 8 illustrates the rough thread surface of a bone screw.

When comparing bone and metal screws groups, we see statistical differences ($p<0.05$) for the following parameters: body diameter and alpha angle.

DISCUSSION

Machining: operating machines tools used for manufacturing objects may be made of fast steel, hard steel or diamond, and with different geometric formats, and the tool's tip format should vary according to the nature of the work and of the material to be machined. If the tip is not in accordance to the technique, this tool is at risk and the optimal performance is not achieved [17].

In the machining process, we considered the bone, submitted to lathe, as a soft material and, thus, we used a reduced wedge angle and a greater output angle as compared to those usually used for a hard material. If we had worked with a hard material, the wedge angle should have been large enough for the tool to resist, and the output angle should have been reduced, because harder materials loose less fragments than a soft material during machining process. At the lower portion of the machined piece, between that and the tool, a space was left, called drift angle, for avoiding excessive friction with the piece in rotation.

Mora [13] stated that, for bone screws machining, the use of tools with high-quality main edge (such as those of diamond) is not required, since the desirable machined surface to enable osteointegration should probably be wrinkled, which is achieved with low-cost tools.

We considered that the grindstone material (aluminum oxide) used for thread manufacture perhaps is not optimal for that function, because, according to Cunha[17], when aluminum oxide grindstones are used in materials with low tensile strength, they become blunt soon, that is, lose their cutting ability or become plastered.

We made the machining of the bodies of evidence with a cut movement regarded as low (500 rpm) to avoid excessive heating to the bone.

We considered that further studies

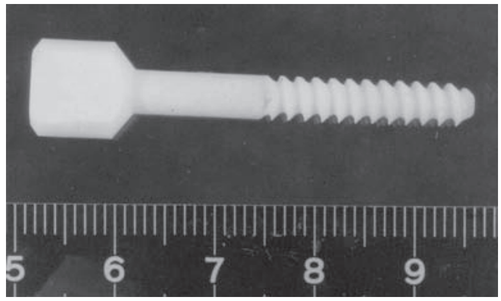

Figure 3 – *Bone screw achieved.*

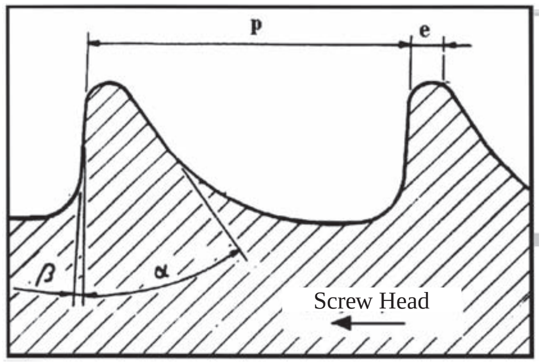

Figure 4 – *Illustration of the angles α (35°) and β (3°), step (p = 1.75 mm) and thread apex length (e = 0.1 mm). Source: ABNT (1996).*

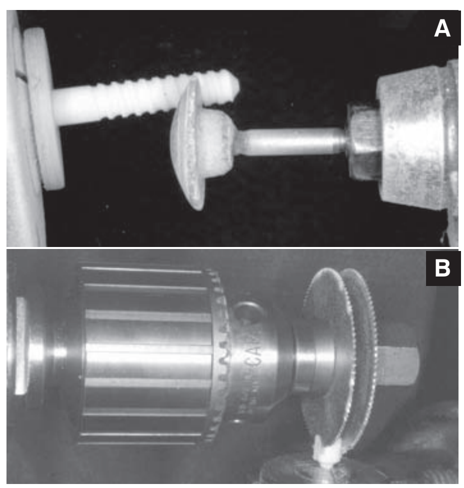

Figure 5 - A – *Thread modeling was performed with a grindstone with aluminum oxide mounted-tip.* **B –** *Screws and cylinders heads with square ends modeling was performed by using two parallel metal saws, 7 mm equidistant.*

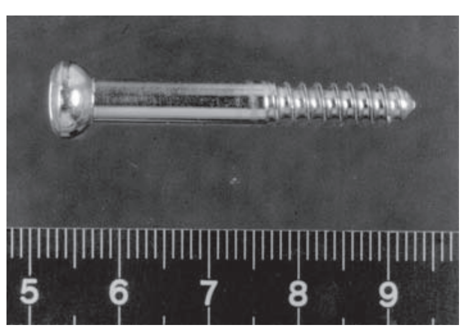

Figure 6 – *Vastago-type low-threaded metal screw.*

are necessary to develop an adequate set of instruments for bone screws manufacturing and that specific guidelines should be created for the production of implants using this kind of material.

Aiming to get further improvement of bone screws, another aspect to be reviewed is the substructure or lathe basis quality, which ideally should have a high stiffness to flexion and torsion, and a low thermal dilatation rate. An important characteristic on the dynamic behavior of machines-tools substructures is correlated to the self-excited vibration created during machining process. Such vibrations foster relative displacement amplitude levels between the cutting tool and the piece that compromise surface fine finishing and dimensional tolerances required on the manufacturing process of a finished piece[18].

Metrologic analysis: we followed the guideline NBR ISO 5835(16) of ABNT (1996) to determine bone screws dimensions due to the lack of specific guidelines for this kind of material. It was not possible to follow every aspects of the guideline, especially those related to the screw head dimension, since it was established for hexagonal wrench-connecting heads. Formatting screws with that kind of head would probably lead to bone fracture during its machining or at insertion with the hexagonal wrench.

Technical measurement is an important process to be performed during or after bone screws manufacturing process, and this can be a form of quality control.

The profile projector was considered as a good measurement instrument, because it assured the possibility of screws dimensions to be measured in a level of accuracy of up to some micrometers (0.001 mm), in addition of being easy to handle. Although accurate measurements were not found, when the dimensions of 32 bone and metal screws were checked and compared, we reported no variations within the limits compatible with literature. Köberle et al.[19], after conducting a metrological evaluation of screws manufactured by several surgical orthopaedic material suppliers, did not find implants presenting all dimensions prescribed by the guideline. Uhthoff[20] found a difference on thread diameters in a same metal screw of up to 70 μm, and of 180 μm among different manufacturers.

In our study, average values for inner diameter and thread step in both groups of screws assessed were very close to the values established by guideline NBR ISO 5835[16]. Adjacent threads fillets heights presented minimal differences, in centesimal millimeters, which were regarded as insignificant.

Both kinds of screws, metal and bone, in the present study, presented values for thread apex length and angle β significantly superior when compared to a theoretically optimal value. According to Belangero and Mariolani[21] the value for angle β should be as close to zero as possible for the upper portion of the screw's thread fillet to have a larger contact area with bone tissue and, thus, a stronger resistance to pull. Those authors, after performing mechanical assays in 4.5-mm metal screws, reported that the screw with the highest angle β resisted most to pull, and regarded

Specifications	Dimensions	
	Bone Screw	Metal Screw
Outer diameter	4.5 mm	4.5 mm
Vastago diameter	4.5 mm	4.5 mm
Inner diameter	3.0 mm	3.0 mm
Head outer diameter	7.0 mm	8.0 mm
Head height	10 mm	4.6 mm
Total length	50 mm	40 mm
Thread length	22 mm	13 mm
Thread bending	*	*
Thread design	*	*

* according to guideline NBR ISO 5835

***Table 1 –** Technical specifications of bovine bone screws compared to metal screws.*

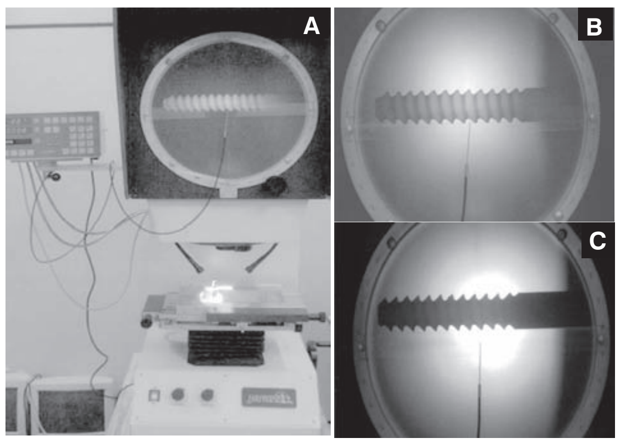

***Figure 7 –** Metrologic evaluation of the screws. Profile projector (A). B – Image obtained by episcopic mode and, C – image obtained by diascopic mode.*

Variable assessed	Screws	
	Bone	Metal
Body diameter (mm)	4.48±0.08	4.38±0.04
Inner diameter (mm)	3.06±0.07	3.01±0.10
Thread fillet height (mm)	0.71±0.07	0.68±0.07
Step length (mm)	1.77±0.06	1.75±0.01
Thread apex length (mm)	0.23±0.09	0.25±0.06
Alpha angle (degrees)	47º65'±1º53'	32º17'±3º74'
Beta angle (degrees)	11º39'±2º75'	12º58'±2º20'

***Table 2 –** Results of some parameters assessed at screws profile projection, with correspondent averages and standard deviations.*

other factors as causative of this controversial result. In our study, metal screws' body diameter were, in average, two tenths of millimeter below the value established by ABNT guideline, which, according to Belangero and Mariolani[21], may influence pull strength. Those authors considered that this mechanical property was significantly superior for the screw with the larger outer diameter. Belangero and Mariolani[21] also reported that threaders and screws with inner and thread diameters different from standards may influence on screw pulling strength.

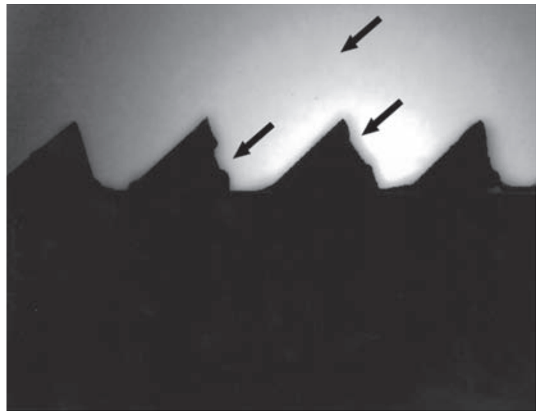

Figure 8 *– Bone screw profile projection in detail, with two adjacent threads showing rough edges (arrows).*

The presence of high α and β angles, out of standards considered as optimal, has shown that the used tool apex (mounted-tip grindstone), probably did not have an ideal format, or has not been optimally angled towards the bone during machining process.

We consider that bone screws manufacturing failures detected in this study, with dimensions slightly out of established values and rough surfaces, would probably be minimized by improving machining process. Nevertheless, dimensional values strictly following guidelines would be hardly achieved. Schnider[22] reports that maintaining angles β and α during metal screws manufacturing process is difficult and requires highly accurate equipment, with a strict quality control. For bone screws, this would probably be even harder to achieve.

We didn't see significant differences in dimensional parameters assessed in the group of screws made of bone and metal, which was corroborated by the low standard deviation of variables measured. However, the verification of dimensional parameters in other places in a same screw could have improved metrological analysis precision, yet not significantly.

CONCLUSIONS

By evaluating the overall results of the profile projection, we considered that the manufacture of screws with pre-established dimensions has shown to be possible in bone, presenting a dimensional quality standard compatible to a similar metal model. Furthermore, in bone screws machining process, we regarded as feasible to copy metal models and follow technical guidelines.

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