BIOMECHANICAL SCREW RESISTANCE ANALYSIS: DEVELOPMENT OF A QUALIFYING METHODOLOGY

Wiedenhoft, Aldoni G., aldonig@yahoo.com.br
Amorim, Heraldo J., amorim@mecanica.ufrgs.br
DEMEC UFRGS, 425 Sarmento Leite st., Porto Alegre, Brazil

Griza, Sandro, sandro@demet.ufrgs.br
Strohaecker, Telmo R., telmo@demet.ufrgs.br
DEMET UFRGS, 9500 Bento Gonçalves av., Porto Alegre, Brazil

Abstract. Human orthotic device components must be comfortable, able to execute the expected functions and, most of everything reliable. The focus of this work is the development and application of an orthotic screw resistance analysis methodology. For this, a mechanical apparatus, consisting of a torque actuator and a data acquisition system was developed. The actuator, composed by an electric engine and reducer, applied torque on the tested screw, who transfers it to a load cell, especially developed, and thus to the data acquisition system. Cortical titanium and cannulated stainless steel bone screws were tested, from different manufacturers, with tests done. Results were obtained for insertion and removal torque, rupture angle and maximum torque. Cortical titanium screws were not tested for the former. Despite all tested screws followed the indicated standards, it was found signifficant dispersion among the results, what can indicate manufacturing or material supply problems. Particularly high dispersion was found for titanium samples. Concerning cannulated stainless steel screws, removal torque was always higher than insertion torque. This is not a desirable effect, once problems may come to happen after the healing of the patient, or even on the occasion of a substitution. The analysis showed the efficiency of the methodology developed, and opens a point of discussion on orthotic reliability.

Keywords*: cannulated screw, cortical screw, screw resistance, rupture angle, insertion and removal torque.*

1. INTRODUCTION

This study comes towards to needs both of suppliers and manufacturers, to fulfill exigencies of ANVISA (National Sanitary Vigilance Agency) on direction of qualification and standardization of screws for human implants. Also, it is necessary to attain the ASTM F 543-02 standard, which states that maximum torque, insertion and removal torque and rupture angle tests must be carried out, in order to properly qualify these products.

According Shimano, 2005, these tests presents several implementation difficulties, such as the reading of angular deformation, torque data recording, maintenance of ortogonality between tested screw axis and applied force and the obtaining of constant speed. Tavares, 2003, has found significant variation on torque values measured by different commercial torque gages. Literature shows an interaction of clinical factors that can cause screw to loosen, losing up tension or pre load (Haack et al., 1995). Collinge et al., 2000, evaluated breaking up torque, and fracture area. Abel & Sum, 1998, developed a torsion mechanism, but found difficulty on reading and recording test data. Other methodologies were used by Glauser et al., 2003, which have used a drilling machine, connected to an load cell, what allowed torque application without rotation speed variation. However, this methodology does not exactly reproduce routine tests carried out by implant screws manufacturers. In front of these challenges, it was necessary the development of an apparatus which accomplished the ASTM F 543-02 standard, and were also able to carry out torque and breaking angle tests, with rotation control and adequate data acquisition system.

Browner et al., 2003, had shown that insertion torque applied by surgeons during screw insertion vary from 2.95 to 5.98 N.m, enough to fracture a 2.92 mm inner diameter screw. There can happen of applied torque to be bigger than the maximum supported by the tested components. Even than the quick relieve of tensions verified spare the screw (or even the bone) from fracture, this overload can happen to compromise functionality and screw life.

The goal of this work is to develop and test an apparatus which attends the ASTM F 543-02 standard and allows simultaneous measuring of applied torque and screw angle, once routine tests carried out by manufacturers did not attend standards exigencies.

2. EXPERIMENTAL PROCEDURE

Tests were done concerning properties of cortical titanium micro-screws and cannulated stainless steel surgical screws, according ASTM F543-02 standards. The titanium screws used in this paper were manufactured by a local surgical material supplier, on an 1/8" bar, according to NBR ISO 5832-2, annealed and then grinded. Screw profile is machined on a CNC lathe, then cold rolled, and the external thread is then laminated. By the end, screw's head is finished through mechanical polishing. Figure 1 shows titanium screw profile and dimensions.

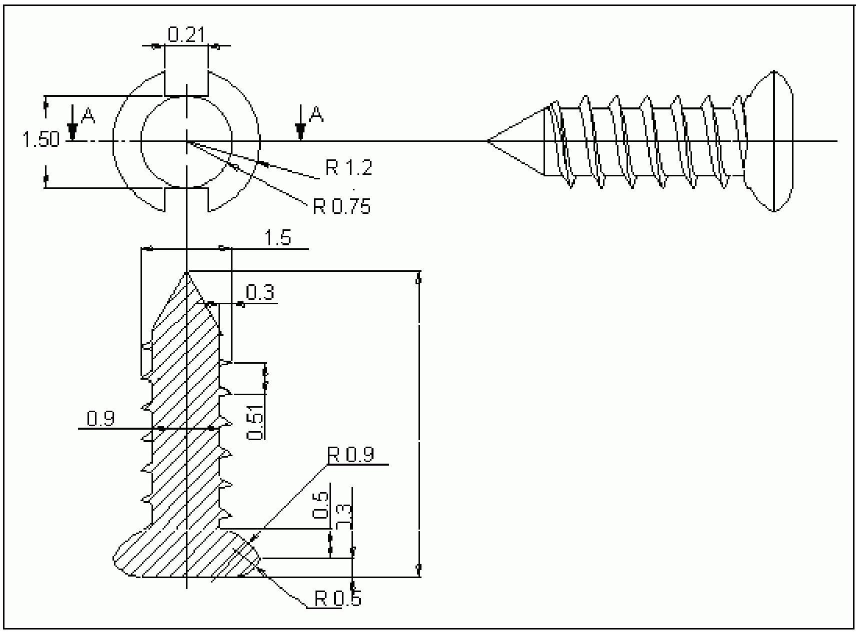

Figure 1. Titanium screw profile and dimensions.

Three different cannulated stainless steel screws were tested. These screws are so called because of their hollow shaft (Fig. 2), and have many advantages over other surgical screws, which involve its high compressive capacity and the precision and easiness of fixation. While the former advantage provides good fixation and reduction of fractures, the others act both on preventing errors and reducing surgical time. Samples of three different cannulated screws were tested, and all of them were inspected with no kneaded, notch, burr or scratch been found.

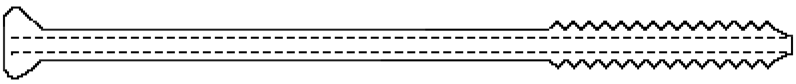
Figure 2. Cannulated screw representation.

Table 1 shows the dimensions of each tested screw, its material and the designation adopted on this work.

Table 1. Tested screws and their characteristics.

Screw Id	Material	Type	Thread	Dimensions (mm)
A	Stainless Steel	Cannulated	Partial	ϕ7.0 x L 80.0
B	Stainless Steel	Cannulated	Partial	ϕ4.5 x L 62.0
C	Stainless Steel	Cannulated	Partial	ϕ3.0 x L 42.0
D	Titanium	Cortical	Entire	ϕ1.5 x L 3.0

The Test device must be supported on a robust and solid base, to absorb mechanical vibrations, which can influence the data acquisition. The torque system is constituted by a mobile plate guided by four axles of 19 mm diameter, and slides on linear rollers, avoiding abrasion. This system has an axial force of 1.4 N that compresses the screw on the test body. This plate is helped by flexible steel cables with sheaves and connected to masses, in order to win inertia. To guide the screw, an interchangeable clamps system, adaptable to the form of each screw head was made. The clamps had been constructed in M2 steel and had received thermal treatment (quenching and tempering).

The standard recommends the tests to be made by random sampling, as a function of production rate. Moreover, it recommends measuring of average torque on four first turns both on insertion and removal of screw.

Torque measuring is done through interchangeable load cells, one for each torque range. The load cells use strain gages as sensors, and were developed on site. The possibility of using different load cells is necessary, in order to provide the necessary accuracy for the different tested screws and their torque ranges. For so, three different load cells were developed for measuring applied torque (Tab. 2). Due to the need to measure with accuracy the rupture angle of tested screws, there were necessary an angular controller, and the necessity of perform both insertion and removal tests on same equipment, with controlled speed had made necessary the use of a speed reducer and reverser key.

Table 2. Operation range of the load cells used on the experiments.

Load Cell	Operation range (N.m)
1	0.01 – 0.50
2	0.50 – 3.50
3	3.50 – 6.50

Figure 3 (a) illustrates the suggestion of ASTM F 543-02 for the equipment for maximum torque and breaking angle tests. Figure 3 (b) shows the developed equipment, during the test. It is possible to identify the cannulated screw and the load cell used.

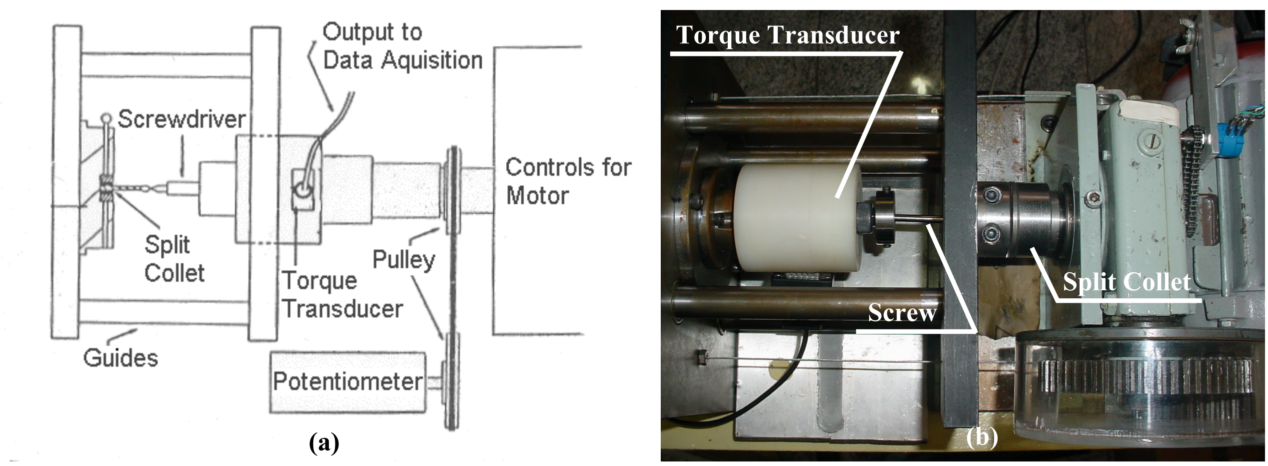

Figure 3. (a) Apparatus according ASTM F 543-02; (b) developed equipment .

2.1. Rupture angle and maximum torque tests

Tree different stainless steel and one titanium screws were tested for maximum torque and rupture angle. These tests were carried out according ASTM F 543-02 standard.

The rupture angle test is used on the evaluation of yield resistance in torsion, maximum torque and rotation angle on fracture of bone screws over conditions established on standard. These results doesn't aim the establishment of necessary torque to insert or remove screws on human or animal bones, but evaluate the uniformity of tested products, comparing similar screws characteristics.

On the beginning of each test, the screw is fixed on a split collet, in such a way that any rotation is avoided. In all cases, at least one turn of the thread is left exposed. Table 3 shows test parameters adopted, concerned to the portion of each screw to be exposed.

Table 3 positioning of tested screws.

Screw	A	B	C
Test length (mm)	53.4	29.3	19.5
Inserted length (mm)	14.0	14.0	7.0
Exposed length (mm)	12.5	18.5	15.5

Yield limit under torsion was determined from displacement method (displacement equal to 0,02%), using the torque versus rotation angle. Rupture angle is identified as the point where torque starts to decline (Fig 4).

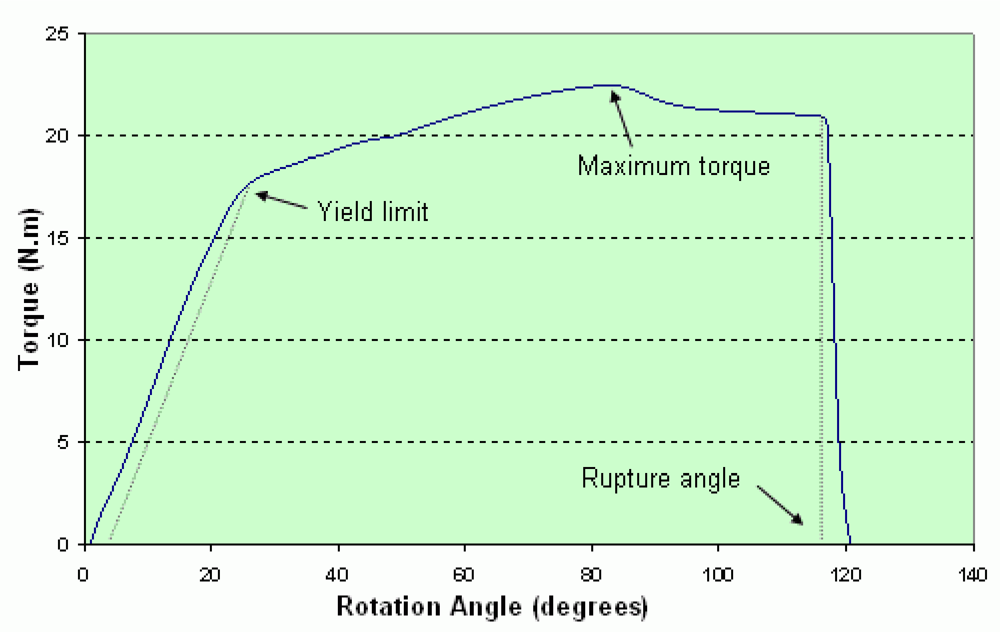

Figure 4. Typical result for breaking angle and maximum torque tests.

2.2. Insertion and removal torque tests

Insertion and removal torque tests are used to determine the necessary effort to turn a bone screw on determined material. Results obtained through this test are does not establish direct correlation with necessary torque on human or animal bones, but are used to evaluate uniformity of tested products.

ASME recommends the use as test body of a material with mechanical properties closed to the human bone as test body, in order to simulate proper use. Those test bodies are produced on expanded polyurethane, and had drilled guides, in order to facilitate screw insertion. For each test, a test body was prepared, with 20mm thickness, and whose diameter had at least ten times the tested screw diameter. It is rigid enough to avoid deformation under test conditions. The screws, partially inserted, were turned on the test bodies, and adapted to the clamp, according to the screw cap. Only cannulated stainless steel screws were tested for insertion and removal torque.

Insertion torque was then obtained through the fastening of the screw, and the adopted result was the highest value measured over four turns. Removal torque tests were so carried out on the same conditions. Axial load used was 1,14 N.m.

3. RESULTS AND DISCUSSION

Once screws of different material and types were used in this paper, it is convenient to present the results separated.

3.1. Results obtained for titanium cortical screws

Results were obtained for titanium cortical screws, concerning maximum torque and breaking angle test. Table 4 shows the results for maximum torque and yield angle. Due to the high plasticity of titanium, the breaking angle is not accurate, and thus not adequate for statistical comparison. Comparison is, then, carried out on maximum torque and yield angle.

Table 4 Maximum torque and yield angle for titanium micro-screws.

Sample	1	2	3	4	5	6	7	8	9	10	Mean	δ
Torque (N.m)	4,0	5,0	3,5	7,0	4,0	6,0	3,0	4,5	6,0	3,0	4,6	1,34
Yield angle (degrees)	2,0	2,5	3,0	3,0	4,0	4,0	2,0	3,5	4,0	2,0	3,0	0,849

Figure 5 shows results obtained for torque versus angular displacement. Despite the good behavior of each sample under the test, significant dispersion was found for titanium screws.

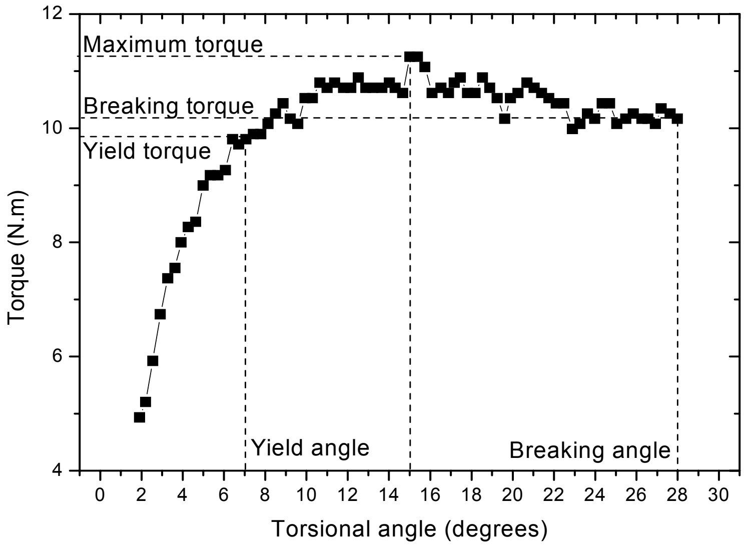

Figure 5. Result for torque versus angular displacement for titanium screw.

Figure 6 (a) shows a titanium screw after torsion test, and Fig 6 (b) shows fractography of its superior portion, obtained through scanning electronic microscopy (SEM). It is possible to observe microcavities coalescence due to shearing forces. Dispersion of results can be related to occurrence of cracks on the bottom of the thread, coarse grains due material annealing, and also lamination marks, due to excessive deformation.

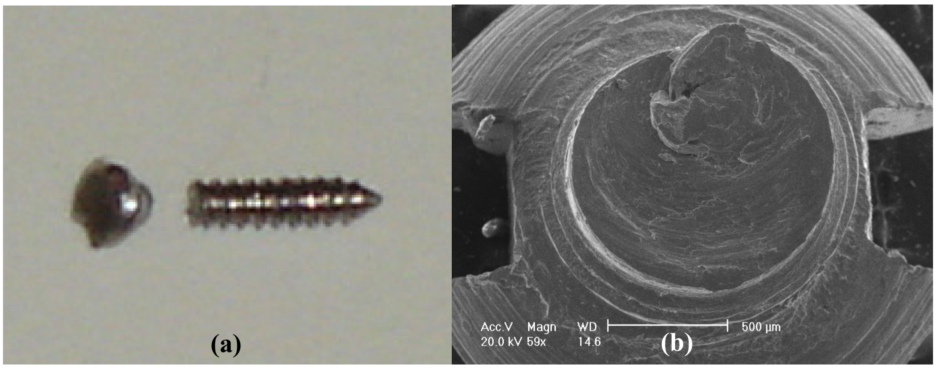

Figure 6. (a) tested titanium screw (b) SEM fractography of upper portion of a tested titanium screw.

3.2. Results obtained for stainless steel cannulated screws

Results were obtained for stainless steel cannulated, concerning maximum torque, breaking angle, and insertion and removal torque tests. Table 5 presents the results for maximum torque and yield angle. Due to the high plasticity of titanium, the breaking angle is not accurate, and thus not adequate for statistical comparison. Comparison is, then, carried out on maximum torque and yield angle. Table 3 shows mean and standard deviation results for the tree studied screws. Statistical analysis has shown significant differences between the different diameters, as expected. Despite some of the tests, such as breaking angle and removal torque, has shown high dispersion, stainless steel cannulated screws behave better than titanium cortical micro-screws. Figure 7 shows fractures observed on samples of A, B and C cannulated screws.

Table 5. Results obtained for stainless steel cannulated screws.

Screw	Breaking angle (°)	Sd	Yield limit (N.m)	Sd	Maximum torque (N.m)	Sd	Insertion torque (N.m)	Sd	Removal torque (N.m)	Sd
A	114,4	23,92	16,794	2,078	21,966	0,665	0,75	0,088	1,676	0,356
B	691,4	107,69	2,9	0,145	3,804	0,043	0,156	0,018	0,292	0,040
C	930	168,84	0,97	0,052	1,234	0,050	0,046	0,009	0,122	0,057

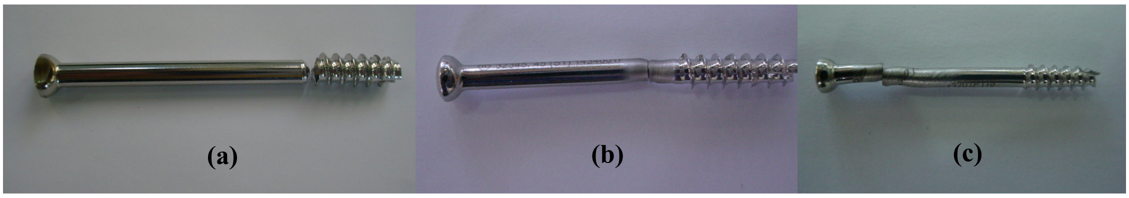

Figure 7. Fracture placement on samples of A, B and C cannulated screws.

4. CONCLUSIONS

Through careful analysis of both the results and the developed equipment, it was possible to reach several conclusions:

The equipment developed had shown itself adequate for insertion and removal torque, maximum torque and breaking angle tests for bone screws, thus satisfying ASTM F-543-02 standard exigencies. The development of equipment with such characteristics was necessary in order to improve quality control in such a vital field as surgical screws.

Screws with bigger diameters presented bigger rupture torque and smaller breaking angle. Such effect goes according the expected, since bigger diameter also means bigger core section, and, for a same material over the same conditions, higher resistance.

Removal torque was higher than insertion torque for all tests done. This is not a desirable effect, once problems may come to happen after the healing of the patient (on the case of removal), or even on the occasion of a substitution.

Considerable dispersion was found between tests carried out on different samples of the same screws, what shows the necessity of better quality control for the manufacturers. This problem was stronger for titanium cortical micro screws. Stainless steel cannulated screws had shown smaller dispersion.

5. ACKNOWLEDGEMENTS

The authors would like to acknowledge the support of the laboratory of machining and automation and the laboratory of physical metallurgy of federal university of Rio Grande do Sul.

6. REFERENCES

Abel, E. W.; Sun, J., 1998, "Mechanical evaluation of a new minimum contact palete for internal fracture fixation". Journal of Orthopedics trauma, Vol 12, No.6, pp. 382-386.

ASTM F543-02; Standard Specification and Test Methods for Metallic Medical Bone Screws. Annual Book of ASTM STANDARDS, Vol 13.1, pp. 112-130.

Browner, B. D, Jupiter, J. B., Levine, A. M., Trafton, P. G., 2003, "Skeletal trauma, basic science management and reconstruction". Ed. Saunders, New York, USA, 2626 p.

Collinge. C. A.; Stern, S.; Cordes, S.; Lautenschlager, E. P., 2000, "Mechanical properties of small fragment screws". Clinical Orthopaedics and related Research. Vol. 373, pp.277-284.

Glauser, C. R.; Oden, Z. .M.; Ambrose, C. G.; Willits, M. B.; Coupe, K. J., 2003. "Mechanical testing of small fracture implants for comparison of insertion and falilure torques". Archives of Orthopaedic and Trauma Surgery, Vol 123, pp. 388-391.

Haack, J. Sakaguchi, R., Sun, T., Coffey, J., "Elongation and preload stress in dental implant abutment screws". Int Journal os Maxilofacial Implants, Vol. 10, pp. 529-36.

Shimano, S. G. N., 2005, "Comportamento mecânico e análise dimensional de parafusos corticais de aço inoxidável e liga de titânio submetidos a ensaios de torção", USP, Brazil, 102 p.

Tavarez, R. R. J, Bonachela, W. C., Xible, A.A., Araújo C. R. P., "Torque Produzido por Quatro Torquímetros Diferentes Utilizados em Próteses sobre Implantes. Estudo Comparativo", Ciência odontológica brasileira, Vol. 6, pp. 82-88.

5. RESPONSIBILITY NOTICE