Berend Linke
Head Research Services
AO Research Institute
Clavadelerstrasse
CH-7270 Davos, Switzerland

Tel: +41 (0)81 414 24 52
Fax: +41 (0)81 414 22 88
E-mail: berend.linke@aofoundation.org
Website: www.aofoundation.org/ari

Mechanical Testing Report

Project: **MT_2004_EXT_01**

Customer: **SYNBONE AG, Karlihof, CH-7208 Malans**

Partner: **Thomas Parkel (Synbone AG)**
Berend Linke (AO Research Institute)

Subject: **Pull-Out and Strip-Out strength of cancellous bone screws in artificial 'Osteoporotic generic bones' (Synbone AG)**

---

1 ABSTRACT

A new product called 'Osteoporotic generic bone' was launched in order to train the correct amount of force required during screw placement in osteoporotic bone without over tightening. However, no data is presently available characterizing the pull-out or strip-out strength of a cancellous bone screw in the new foam material. The objective of this study was to determine pull-out force, strip-out force and strip-out torque of a cancellous bone screw of specific dimensions in samples of 'Osteoporotic generic bones'.

Three specimens of 40mm length were obtained from four 'Osteoporotic generic bones'. Six specimens were used for pull-out and six for strip-out testing. The methods applied in this study are similar to an earlier study about holding strength of different kind of screws in cancellous and cortical bone samples from cattle (Linke et al.). A screw-rig machine was used for the insertion of all screws (cancellous bone screw, ∅4mm). All screw holes were pre-drilled and pre-tapped.

For the strip-out test the screw was inserted at 10RPM until the head got in contact with an axial roller bearing. The insertion process was continued until the screw stripped out and both the axial force and the insertion torque dropped. Strip-out force and strip-out torque were recorded. The pull-out tests were performed in displacement control using a material testing machine. Force as well as displacement were measured at the mobile crosshead of the test machine. Pull-out strength was defined as the force at the first peak of the force-displacement curve.

Strip-out torque was 0.293±0.052Nm (range: 0.138Nm), strip-out force was 0.323±0.023kN (range: 0.069kN) and pull-out force was 0.360±0.033kN (range: 0.093kN). Strip-out force was significantly smaller than pull-out force ($p=0.048$).
The variations of the results have to be attributed to porosity variations of the foam material. In order to investigate if the material simulates osteoporotic bone conditions further tests should be performed using human cancellous bone.

2 BACKGROUND

SYNBONE has received requests from surgeons to develop osteoporotic bone training models. A new product called 'Osteoporotic generic bone' was launched in order to train the correct amount of force required during screw placement in osteoporotic bone. According to the product description, the artificial bone material is appropriate for screw testing and demonstration in osteoporotic-like situations.

Some surgeons are interested to know how well the product simulates the properties of real osteoporotic bone. However, no data is presently available characterizing the mechanical properties of the product. SYNBONE is now interested to get some mechanical properties of the product, even if these can not be related to a certain in vivo stage of osteoporosis.

The methods applied in this study are similar to an earlier study about holding strength of different kind of screws in cancellous and cortical bone samples from cattle (Linke et al.).

3 OBJECTIVE

The objective of this study was to determine pull-out force, strip-out force and strip-out torque of a cancellous bone screw of specific dimensions in samples of 'Osteoporotic generic bones'.

4 MATERIALS

4.1 Osteoporotic generic bones (SYNBONE)

- Osteoporotic generic bone (Nr: 0080, SYNBONE)
- Material: Modified PUR
- Size: 397mm length, 25mm diameter
- Quantity: 4

4.2 Screws:

- Cancellous bone screw (REF: 206.060, Synthes®)
- Material: Stainless steel
- Size: 4.0 × 60mm
- Quantity: 12

Tapping instrument: Nr. 311.340, Synthes®

5 METHODS & EXPERIMENTAL DESIGN

3 specimens of 40mm length were obtained from both ends and the middle part of every ‘Osteoporotic generic bone’ using a precision saw (Figure 1).

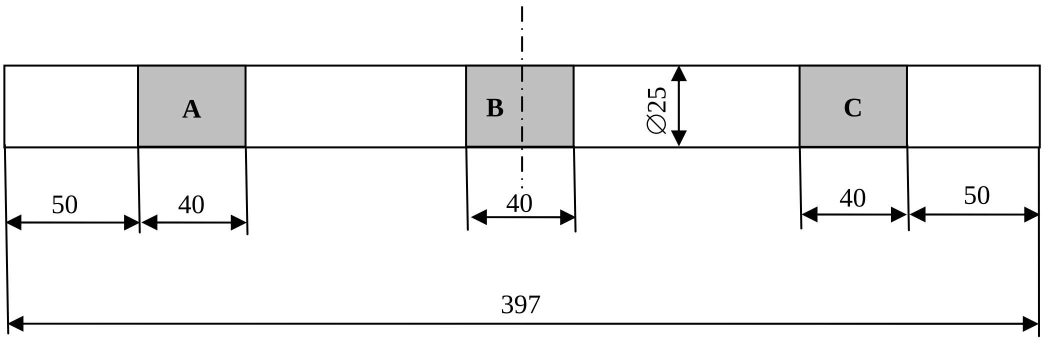

Figure 1: Location of the specimens A, B and C obtained from the ‘Osteoporotic generic bone’. Specimen A was located at the foam inlet site with respect to the manufacturing process. Dimensions in mm.

All specimens obtained from two randomly chosen ‘Osteoporotic generic bone’ samples were assigned to the pull-out test, the remaining specimens to the strip-out test.

A screw-rig machine (MS-TTS-10, Rischag Messtechnik GmbH, Liestal, CH-4410, Switzerland) was used for the insertion of all screws (Figure 2). It is an electrically driven device that operates with constant angular velocity, constant axial force and optional torque limiter. Maximum capacity: 1000RPM, 14Nm, 1000N.

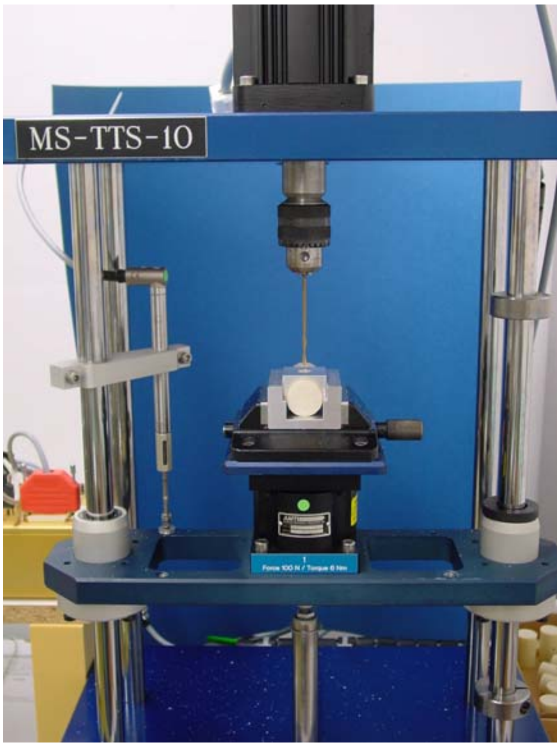

Figure 2: Screw-Rig machine MS-TTS-10.

All screw-holes were pre-drilled (∅2.5mm) at a rotational speed of 300RPM and pre-tapped using an appropriate tapping device (Nr. 311.340, Synthes®). The screws were inserted completely through the specimens (stick out length about 5mm) at 10RPM with an axial force of 10N. For all steps the aforementioned screw-rig machine was used (Figure 3).

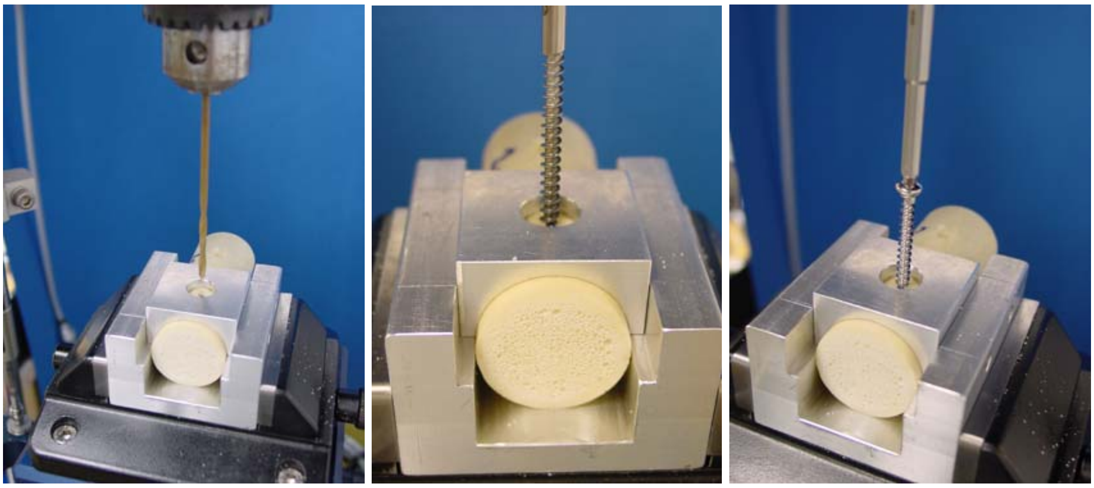

Figure 3: Pre-drilling at 300RPM (left), pre-tapping at 10RPM (middle) and screw insertion at 10RPM (right).

For the strip-out test the specimen was clamped to the base plate and the screw was inserted until the head got in contact with the axial roller bearing. The insertion process was continued until the screw stripped out and the insertion torque dropped. Six tests were performed using a new specimen and a new screw for every single test.

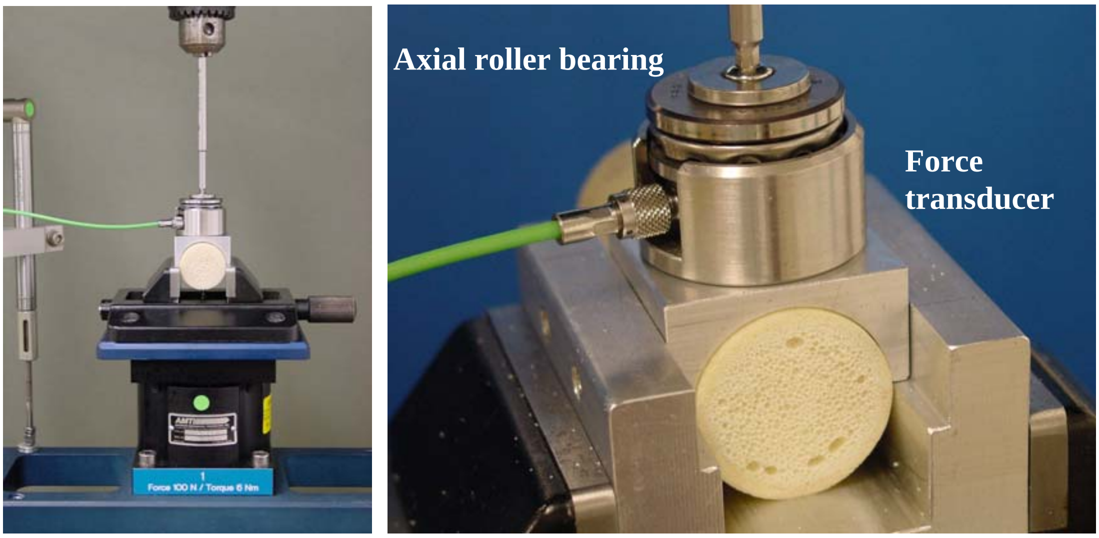

Figure 4: Setup for the strip-out test.

The axial force was measured at a sampling rate of 1000Hz by a ring force transducer (Piezo 9011A, SN 570356, Kistler Instrumente AG Wintherthur, Switzerland) that was mounted in between the axial roller bearing and the specimen (Figure 4). The strip-out strength was defined as the maximum force recorded. The insertion torque was measured by an internal transducer of the screw-rig machine at a sampling rate of 100Hz in order to specify torque at strip-out.

For the Pull-out tests an Instron® 4302 test machine (Instron series IX automated materials testing system, Instron Ltd., High Wycombe, England) with digital controller and software was used for load application. The load was applied by a spherical notch of a cylindrical pick-up device attached to the crosshead of the loading frame (Figure 5). During pull-out the specimen was held in place by a thrust bearing attached to the base plate of the machine. The tests were performed in displacement control at a crosshead speed of 5mm/min. For every single test a new specimen and a new screw were used. Force as well as displacement were measured at the mobile crosshead of the test machine at a sampling rate of 10Hz. Pull-out strength was defined as the force at the first peak of the force-displacement curve.

The following variables were evaluated by computing descriptive statistics (mean, median, standard deviation, range):

- Pull-out force (Pull-out test)
- Strip-out force (Strip-out test)
- Torque at strip-out (Strip-out test)

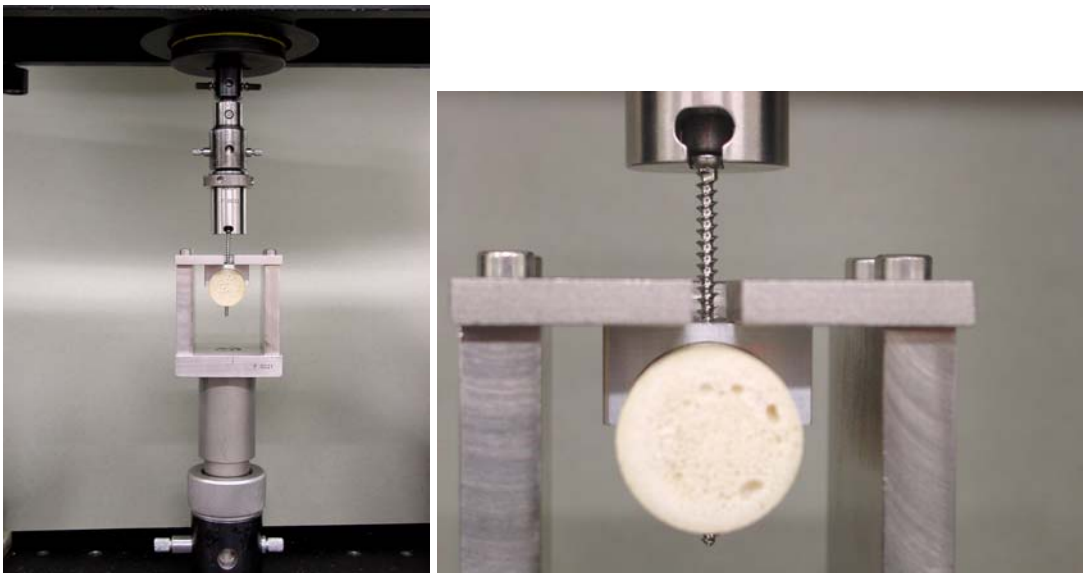

Figure 5: Setup for the Pull-out test.

6 RESULTS

The results of both tests are given in Table 1.

	Mean	Standard deviation	Median	Range
Strip-out torque [Nm]	.293	.0523	.276	.138
Strip-out force [kN]	.323	.0225	.320	.069
Pull-out force [kN]	.360	.0329	.353	.093

Table 1: Mean, standard deviation, median and range of the strip-out torque, strip-out force and pull-out force.

Figure 6, Figure 7 and Figure 8 illustrate the strip-out force, strip-out torque and the pull-out force. The results of every single test are given in Table 2 of the Appendix. Strip-Out force was significantly smaller than pull-out force (p=0.048, unpaired t-test) (Figure 9).

Because the values of the specimens A, B and C were not in the same order for the two bone samples, a clear directional dependency of the results on the location within the bone sample could not be seen.

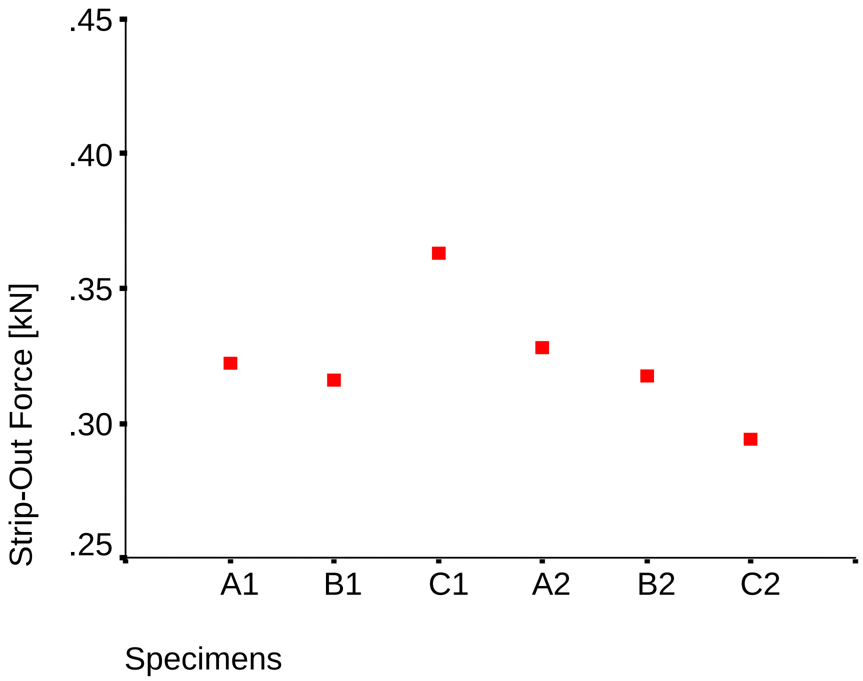

Figure 6: Strip-out forces for all specimens. A, B and C refer to the position within an 'Osteoporotic generic bone' sample and the number indicates the bone sample number.

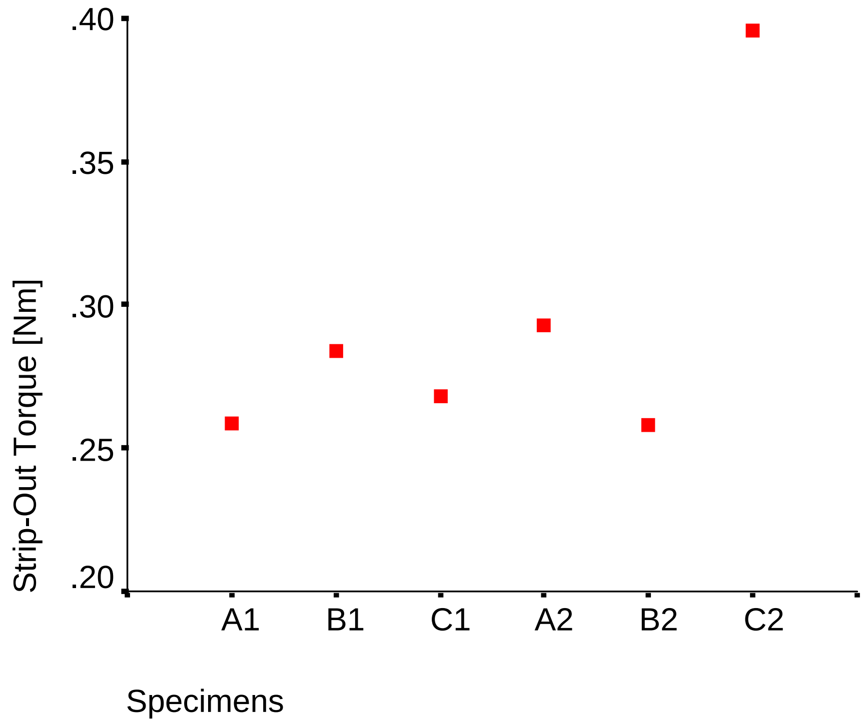

Figure 7: Strip-out torque for all specimens. A, B and C refer to the position within an 'Osteoporotic generic bone' sample and the number indicates the bone sample number.

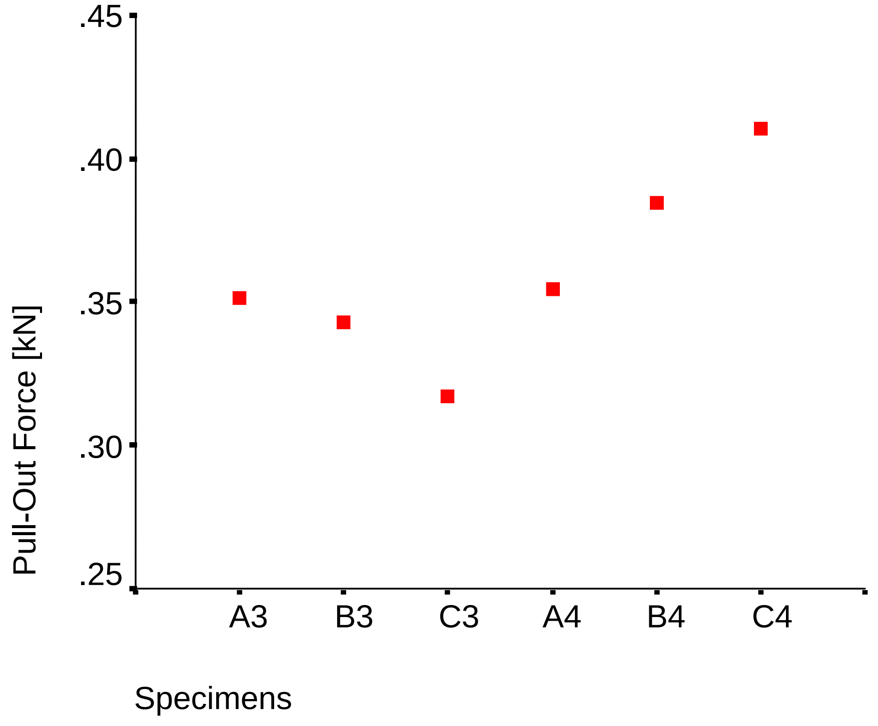

Figure 8: Pull-out forces for all specimens. A, B and C refer to the position within an 'Osteoporotic generic bone' sample and the number indicates the bone sample number.

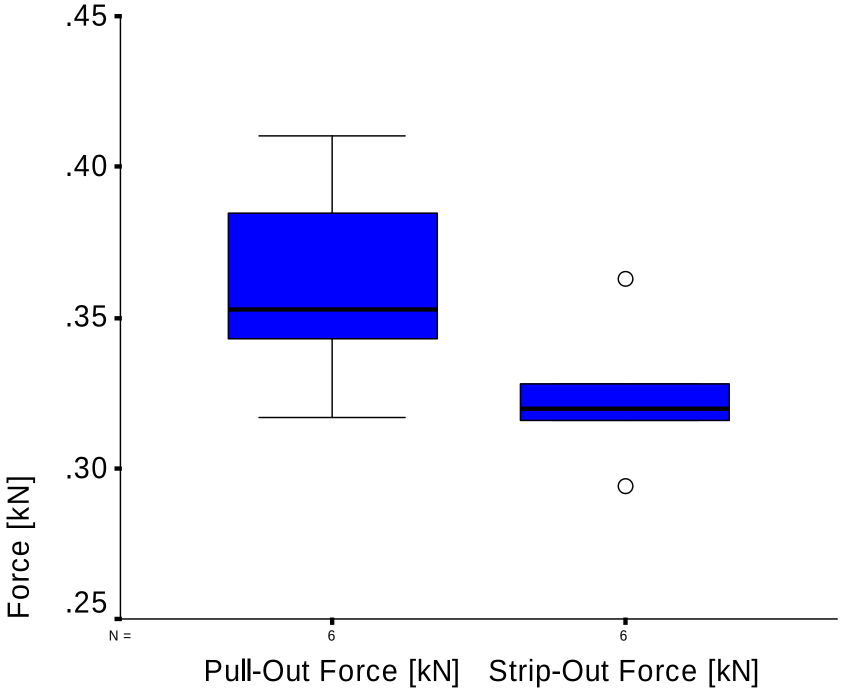

Figure 9: Strip-out and pull-out forces for all specimens.

7 DISCUSSION

The results can be used in order to characterize the homogeneity of the 'Osteoporotic generic bone' samples with respect to strip-out and pull-out behavior of the specific type of screw which was used in this study. In order to detect a directional dependency upon specimen location within the bone samples a higher number of tests would have been required.

Kock et al. performed pull-out tests in non-osteoporotic bovine cancellous bone specimens using a ∅4mm cancellous bone screw with 26mm length (Art. 206.026, Synthes). Unfortunately, BMD values of the specimens were not specified. Based on 10 measurements a pull-out force mean of 0.73kN was determined, which was about twice as high as the value obtained for the foam material of the present study.

Strip-out force was significantly smaller than pull-out force. This was also observed in a study investigating the holding strength of different kind of screws in cancellous bone of cattle tibiae (Linke et al.). This study also showed that pull-out and strip-out force depend mainly on the outer diameter of the screw. Linke et al. investigated the holding strength of a ∅4mm cancellous bone screw with 28mm length (Art. 406.028, Synthes). Based on these results and assuming a linear regression between BMD and pull-out force, a pull-out force of 0.36kN would correspond to a BMD of about 0.35g/cm^3 for bovine cancellous bone specimens with a thickness of 15mm. However, in order to establish a relationship between the properties of the foam material and human cancellous bone further test would be required.

The composite material tested in this study consisted of inner foam and a thin shell. It could be hypothesized that the values obtained would have been smaller if the specimens would have been tested without the shell.

The variations of the results have to be attributed to variations of the porosity within the foam material. All the specimens obtained from bone sample 3 had smaller pull-out forces compared to the specimens of bone sample 4. As can be seen qualitatively in Figure 10, the porosity of the latter was smaller than for the other specimens.

Figure 10: Cross sections of the bone samples A3, B3 and C3 (left, from top to bottom) and A4, B4 and C4 (right, from top to bottom) at the screw insertion site. Specimens A4, B4 and C4 had a higher pull-out strength because of the lower porosity of the foam material compared to the other specimens.

The values obtained in this study for pull-out force, strip-out force and strip-out torque may serve as an important basis for further discussions with surgeons. Furthermore this data set may be used in order to estimate the effects of material or manufacturing modifications based on further mechanical tests.

8 LITERATURE

Kock H-J., Pokinskyj P., Wenz R., Linhart W. *Screw fixation in cancellous osteoporotic bone – first in vitro results with a novel augmentation material*, European Journal of Trauma, 2001, 5: 250-256.

Linke B., Butscher A., Schneider R., Wahl D., Gasser B. *Holding strength of conventional and locking head screws*, Folia Traumatologica Lovaniensia, 2003, 68-79.

Further Readings:

Thompson JD, Benjamin JB, Szivek JA. *Pullout strengths of cannulated and noncannulated cancellous bone screws.* Clin Orthop., 1997, 341:241-9.

Brown GA, McCarthy T, Bourgeault CA, Callahan DJ. *Mechanical performance of standard and cannulated 4.0-mm cancellous bone screws.* J Orthop Res., 2000, 18(2):307-12.

Chapman JR, Harrington RM, Lee KM, Anderson PA, Tencer AF, Kowalski D. *Factors affecting the pullout strength of cancellous bone screws.* J Biomech Eng., 1996, 118(3):391-8.

Turner IG, Rice GN. *Comparison of bone screw holding strength in healthy bovine and osteoporotic human cancellous bone.* Clin Mater., 1992, 9(2):105-7.

Davos, 19-April-04

Author: ________________ K. Schwieger

Checked by: ________________ B. Linke

Customer Acceptance: ____________________________ Date: ____________

APPENDIX

	Pull-out force [kN]	Strip-out force [kN]	Strip-out torque [Nm]
A1	–	0.322	0.259
B1	–	0.316	0.284
C1	–	0.363	0.268
A2	–	0.328	0.293
B2	–	0.317	0.258
C2	–	0.294	0.396
A3	0.351	–	–
B3	0.343	–	–
C3	0.317	–	–
A4	0.354	–	–
B4	0.385	–	–
C4	0.410	–	–

Table 2: Results of all tests.