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Paper

INVESTIGATION OF THE AWIJ-DRILLING PROCESS IN CORTICAL BONE

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ABSTRACT

So called “interference screws” are state of the art of bone-tendon-bone fixation in Anterior-Cruciate-Ligament (ACL) reconstruction. Theses screws normally consist of materials like different polyactic acids because of their biodegradablility. However, these screws have some disadvantages like frequently reported breakage during insertion and degeneration of bone tissue during the degradation process caused by the chemical reaction products. In contrast, bone material as an implant has the advantage to be fully biocompatible and absorbable by the body. Due to the fact that the AWIJ could already be proven to be a cold cutting process as well in medical aspects, it is possible to machine bone by the AWIJ without any structural damage. Therefore the feasibility to machine a whole bony interference screw by the means of the AWIJ including the bore, the screw thread and the inner contour for the screw drive could be shown in previous works.

This study is focused on the AWIJ drilling process in cortical bone. Therefore a reference model in PMMA and a model for cortical bone were established empirically. As a result the drilling depth as well as the bore diameter can be predicted by our model in respect to the parameters abrasive flow rate, pressure and time. Obviously the mean variance of our bone drilling model (depth: σ = 2.87 mm; diameter: σ = 0.20 mm) was much higher than for the model for the PMMA (depth: σ = 0.59 mm; diameter: σ = 0.14 mm) model caused by the inhomogenity of the bone material. Furthermore the quality of bore was investigated in reference to the German Standard DIN ISO 1101 with the value of the cylinder shape tolerance. The minimal cylinder shape tolerance was determined to z = 0.21 mm.

1. INTRODUCTION

The anterior cruciate ligament (ACL) is the major stabilizing ligament of the knee joint. It is approximately 2 cm long and 10 mm thick and is located in the centre of the knee joint. It runs from the femur (thigh bone) to the tibia (shin bone), through the centre of the knee. The disruption of the anterior cruciate ligament can cause a chronic instability. In cases of active and young patients an operative treatment is recommended. In this operation, a strip of tendon, usually taken from the patient's knee (patellar tendon) or hamstring muscle is used. It is passed through the inside of the joint and secured to the thighbone and shinbone. In the early postoperative period, graft fixation is the weak link within the entire system [1]. On account of their favourable biomechanical properties, patellar tendon autografts are most widely used for autogenous ACL reconstruction [2]. Metallic interference screws became, because of their high initial fixation strength and their early osseous integration, the standard fixation device for bone-patellar tendon-bone (BPTB) implants. Due to the fact that metallic interference screws distort magnetic resonance imaging scans, compromise revision surgery and present a risk of graft laceration during screw insertion, biodegradable interference screws begin to be used intensively in ACL surgery. These screws provide a secure initial fixation of the bone blocks comparable with that of metal interference screws, while allowing degradation followed by replacement of the host tissue. The most frequently reported complication associated with the use of biodegradable interference screws is the breakage during insertion [3]. Furthermore the degradation of the polymers is based on the chemical hydrolysis. During this chemical process organic acid arises, which can influence the tissue to degenerate instead of to build up more cells [4].

The disadvantages of implants made of other materials results that researchers put a lot of commitment into research to use bone as implant material [5-12]. They aimed good results in respect to stability and resorption of these bony implants, but in time of Aids and Creutzfeld-Jakob disease, it was not possible to be aware of contraction of diseases. Recently, the company Tutogen (Tutoplast®) was able to guarantee bone implants free of prions, so that this problem is solved.

Another problem is the manufacturing of bony implants. Bone reacts very sensitive to high temperature. At temperatures between 40 and 60 degrees enzymes, proteins (especially the collagen matrix) as well as minerals like the framework of the bone, the hydroxyapatite, are destroyed irreversibly in dependence of the residence time. This represents a problem when machining the bone with conventional machines for drilling, turning and milling because the friction causes high temperatures [6] and destroys the organic and anorganic matrix, which is responsible for the biomechanical strength of bone.

In recent research studies it could be proven, that the effect of thermal damage can be avoided by the use of an AWIJ to cut bony material [13, 14] and that the possibility to machine a whole screw geometry including the cutting, drilling, milling and turning process by the multifunctional waterjet is generally possible [15]. Anyway for the reproducibility of the screws' geometry the process steps to machine bone by AWIJ have to be determined more precisely. Hence in this paper our results about the drilling process in cortical bone are introduced.

2. LITERATURE OVERVIEW – DRILLING PROCESS

For this paper the drilling process shall be understood as machining bores smaller than twice the jet's diameter to establish a border to the AWIJ cutting process. Of course there were already investigations performed in this area which shall be shortly summarised chronologically in the following.

1985 Kim and Sylvia investigated the correlation of drilling time and pressure as well as the influence of different abrasives on the drilling and cutting process [16]. They conclude that the increase of pressure and abrasive mass flow rate causes a reduction of drilling time for certain materials. In the following study Kim et al. determined the influence of different material's properties on the drilling process in 1986 [17]. Meanwhile Yanaguichi et al. searched for a correlation between the drilling time and the upper and lower bore diameters in glass [18]. In their study the lower diameter increased faster than the upper diameter of the bore. In 1992 the hydrodynamic effects in the bore, particularly the erosion effect of the back flushed jet after impact, were described by Ohlsson et al. [19]. For increasing drilling times the bore geometry became more and more bulge. Hashish brought up the problems while drilling small bores (0.5 – 2.5 mm in diameter) in sensitive materials like ceramics in 1994 [20]. He introduces the pressure and abrasive mass flow rate ramps as a solution to minimise the risk of cracking caused by occurring shock waves during the waterjet's impact. 1995 he developed concepts to drill deep holes and discussed the positive effect of a rotating work pieces on the bore depth and bore quality [21]. Investigations on the change of bore diameter in respect to the process parameters pressure, abrasive mass flow rate and standoff distance in ceramic material were conducted by Kwak et al. in 1996 [22]. They figured out an exponential correlation between drilling times and bore depth. Hashish established in 2002 strategies to drill very small holes with diameter smaller than 1 mm in glass, aluminium and steel [23]. Therefore he used orifice/focus diameters of 0.1/0.4 mm. Furthermore he managed to drill bores of 1.5 mm diameter in 75 mm thick steel. Orbanic and Juncar (2004) described the relation of drilling time and drilling depth as a power function [24]. Additionally, the correlation of drilling time and bore diameter were identified as a power function as well.

In summary it can be seen that a lot of work in the area of the AWIJ drilling process is done already and many strategies to avoid damage or to improve the bore quality is given. However, no model could be found which considers more than two process parameters and especially not for drilling of bone material.

3. MATERIAL AND METHODS

3.1 Experimental set up

For the experiments a high pressure intensifier (Böhler, Typ DU 400-4 / PL) with a maximal pressure of 400 MPa and a maximal flow rate of 4 l/min was used. The cutting table consisted of a catcher, a controlled X/Y axis and a Z axis, which can be manipulated manually. The machine, the valves and the abrasive dosing system were numerical controlled by a Berger Lahr NC-control system. The abrasive was injected to the self made cutting head by a rotating wheel. An orifice diameter of 0.3 mm and a focusing tube diameter of 0.8 mm were used. The specimens were clamped in a vise made of brass for the static drilling tests (see figure 1.). For the rotational test a work piece rotator was developed. For each material the drilling experiments were conducted with varying abrasive mass flow rate, pressure and drilling time. The standoff distance was set to 1 mm.

3.2 Specimen preparation

Two different materials, acrylic plastic and cortical bone, were used for the tests. The acrylic plastic specimens were sawed from a bar stock to the required dimensions. The cortical bone specimens were cut out of the thigh bone from cattle. Therefore, both ends of the thigh bone were cut off and only the hollow bones were used after resection of the bone marrow for the experiments. Segments were cut to dimension by a band saw and then frozen at -21°C until the tests. To investigate the crack induction of the AWIJ some of the specimens were processed to bony rods by an AWIJ. For the tests the cortical bone specimens were defrosted in saline solution.

3.3 Measurement technique

3.3.1 Process parameters

To build up a realistic model of the drilling process in bone, it is important to keep the process parameters as constant as possible because of their influence on the raw data. The drilling time could be set very precisely by the NC-control. The abrasive mass flow rate could be proven to be stable. The most critical process parameter was identified to be the pressure due to the known pressure fluctuation. To quantify the pressure fluctuations at certain nominal pressures, preliminary test were conducted. Therefore a high pressure transducer (WIKA, Typ 891.23.610) was placed directly in front of the cutting head. The software DASYLab® was used to analyse the data. The sampling rate was set to 10 Hz. For all tests the pressure fluctuation was measured for 280 s at different nominal pressures.

3.3.2 Specimen evaluation

To evaluate the test results the micro computer tomography (Scanco Medical, SCANCO µCT 80) was used (see figure 2.). Because of the specimens' dimensions the resolution was set to 37 µm. The bore's dimension (bore diameter and bore depth) was quantified by choosing an adequate cutting plane and by measurement with the software integrated drawing tools.

4. RESULTS

4.1 Pressure fluctuation

A pressure fluctuation minimum could be identified at 45 MPa for the used pump (see figure 3). At this pressure the interaction of the high pressure intensifier and the pressure vessel seemed to be optimal. For lower pressures the fluctuation increased significantly caused by the discontinuous movement of the plunger. The increase of fluctuation at higher pressures was probably the result of the variation of speed in the reversal point of the plunger.

4.2 Identification of the domain for the model

The static drilling process was investigated in respect to the process parameters pressure, abrasive mass flow rate and drilling time. Because of the need for a steady process, the parameters can not be verified arbitrarily. A process parameter window had to be determined (see figure 4). The upper pressure limit depends on the material properties. High pressures result in cracking of the material caused by the impact of the water jet which creates shock loading and failure due to shock wave propagation [20]. For the PMMA the pressure limit was reached at 45 MPa. Cortical bone seemed to be less sensitive to the impact pressure. The upper limit could be determined to 75 MPa. The lower pressure limit is given by a minimum pressure to inject the necessary abrasive in the mixing chamber. The abrasive mass flow rate was limited by the dosing system and the maximal abrasive mass flow rate before plugging.

4.3 Variation in drilling depth

The variation in drilling depth was investigated by drilling 13 blind holes in PMMA with constant parameters ($p = 40$ MPa, $\dot{m} = 0.4$ g/s, $t = 60$ s). The mean variation was determined to $\sigma = 0.08$ mm and the maximal deviation to the arithmetic mean was 0.15 mm. Therefore the resolution of the µCT was set to 10 µm for the measurement of the depth. It is obvious that the resolution of 37 µm is sufficient to get adequate results.
To investigate the variation of drilling depth in cortical bone, 12 blind holes in 4 different specimens were machined using the pressure levels of 20 MPa, 40 MPa and 60 MPa ($\dot{m} = 1$ g/s, $t = 60$ s). The mean variations result in $\sigma_{20\,MPa} = 0.41$ mm, $\sigma_{40\,MPa} = 0.48$ mm and $\sigma_{60\,MPa} = 0.77$ mm. By setting the mean variations into relation to the arithmetic mean it can be seen that there are relatively high variation in drilling depth (11.7 % for $p = 20$ MPa, 5.0 % for $p = 40$ MPa and 5.3 % for $p = 60$ MPa) caused by the inhomogeneity of the cortical bone (see figure 5.) in comparison to the homogeneous material PMMA (less than 1 %).

4.4 Results for the drilling depth and hole diameter model for PMMA and cortical bone

The empirical model should allow forecasting the drilling depth as well as the bore diameter at the jet's entry by given pressure, abrasive mass flow rate and drilling time. Therefore a parametric study was performed with varying the process parameters. The results showed the correlation of drilling time and depth as a power function. The relation of drilling depth and abrasive mass flow rate could be polynomial described. For PMMA the drilling depth and bore diameter can be forecast by following formulas:

$$(1.)\ s(\dot{m},p,t) = \left[(-0.05\cdot p + 0.15)\cdot(\dot{m} - (0.0158\cdot p + 0.066))^2 + 0.0416\cdot p + 0.1127\right]\cdot t^{0.445}$$

$$(2.)\ d(\dot{m},p,t) = \left[-0.1\cdot(\dot{m} - 1.6)^2 + 0.0042\cdot p + 0.9375\right]\cdot t^{0.09995}$$

The average stability index for equation 1 was calculated to $R^2_s = 0.994$ (equation 2: $R^2_d = 0.901$) and is therewith significant. The average mean deviation was identified to $\sigma_s = 0.59$ mm in the range of drilling depth from 0 to 20 mm ($\sigma_d = 0.14$ mm; d: 0 to 2.6 mm).
For the inhomogeneous cortical bone, the deviation was determined to a higher value of $\sigma_s = 2.87$ mm for drilling depth between 0 and 36 mm ($\sigma_d = 0.2$ mm, d: 0 to 2.6). Anyway, the mean stability index of the empirical model was still significant with $R^2_s = 0{,}991$ ($R^2_d = 0.926$). Hence the following formula should give adequate values for drilling depth and bore diameter of cortical bone:

$$(3.)\ s(\dot{m},p,t) = \left[(-0.0065\cdot p + 0.3325)\cdot(\dot{m} - (0.0225\cdot p + 0.1375))^2 + 0.0425\cdot p + 0.2125\right]\cdot t^{0.453}$$

$$(4.)\ d(\dot{m},p,t) = \left[-0.1\cdot(\dot{m} - 1.6)^2 + 0.0042\cdot p + 0.9375\right]\cdot t^{0.12}$$

4.5 Improvement of the bore's quality by a dwelling process

Direct after the breakthrough the shape of the bore is usually convergent. To modify this shape to a cylindrical bore the so called dwelling process was used, in which the drilling process is continued a certain time (dwell time) after the breakthrough. In a parameter study the influence of dwell time on the bore quality was quantified. Therefore cortical bone specimens with thicknesses comparable to the length of interference screws (25 to 35 mm) were used. To analyse the quality of bore according to the German standards DIN ISO 1101-4 the cylinder shape tolerance was used. The cylinder shape tolerance is defined as the difference of an outer and inner coaxial cylinder diameter, in which the bore just fit (see figure 6.).
As result the dwell time of 30 s was identified to reach the minimum in cylinder shape tolerance of z = 0.21 mm in average for the used parameter combinations (see figure 7). By increasing the dwell time above 30 s an increasing bulge effect could be detected.

4.6 Optimisation of drilling depth respectively drilling time by rotating the work piece

For a later possible industrial production of bony interference screws, the cost of production has to be considered. Especially the production time of the bony interference screw is relevant in this case. Therefore preliminary test with a rotating work piece should show the possibility of optimising the drilling process (see figure 8.). In case of the static drilling process the return flow of water, abrasive and cutting debris interacts with the incoming jet and weaken the jet. To minimise this effect, tests were performed with a rotating clamping device for the specimens with 500 revolutions per minute. Therewith the back flushing water, abrasive and debris is pushed at the bore wall by the centrifugal force. Thus the interaction of outgoing and incoming process elements is decreased. An increase in drilling depth of approximately 40 % for PMMA and 30 % for cortical bone could be reached compared to the static drilling process.

5. SUMMARY AND CONCLUSIONS

In summary the following conclusions can be drawn:

- For the static drilling process of brittle material like cortical bone and PMMA the pressure influence is of highest importance, because the impinging water jet inducing shock waves which result into cracking of the material above a certain pressure limit.
- These pressure limits could be identified to 45 MPa for PMMA and 75 MPa for cortical bone for the used parameter combinations.
- The deviation in drilling depth is strongly dependent on the materials properties. The mean value of drilling depth in homogeneous PMMA was with $\sigma = 0.08$ mm much smaller than for the inhomogeneous cortical bone material of more than $\sigma = 0.48$ mm.
- It was possible to build up a model to forecast the bore diameter and drilling depth for PMMA and cortical bone with adequate stability indices. The deviation of the model for inhomogeneous cortical bone was much higher than for homogeneous PMMA.
- The shape of the bore could be improved by a dwelling process. The optimal cylinder shape tolerance was reached after 30 s for drilling depth between 25 to 35 mm to $z = 0.21$ in average.
- The drilling depth could be increased up to 40 % for PMMA (30 % for cortical bone) by rotating the work piece during the drilling process.

6. ACKNOWLEDGEMENT

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8. NOMENCLATURE

d	bore diameter
$\dot{m}$	abrasive mass flow rate
p	pressure
s	drilling depth
t	drilling time
R^2	stability index
z	cylinder shape tolerance
σ	mean deviation

9. FIGURES

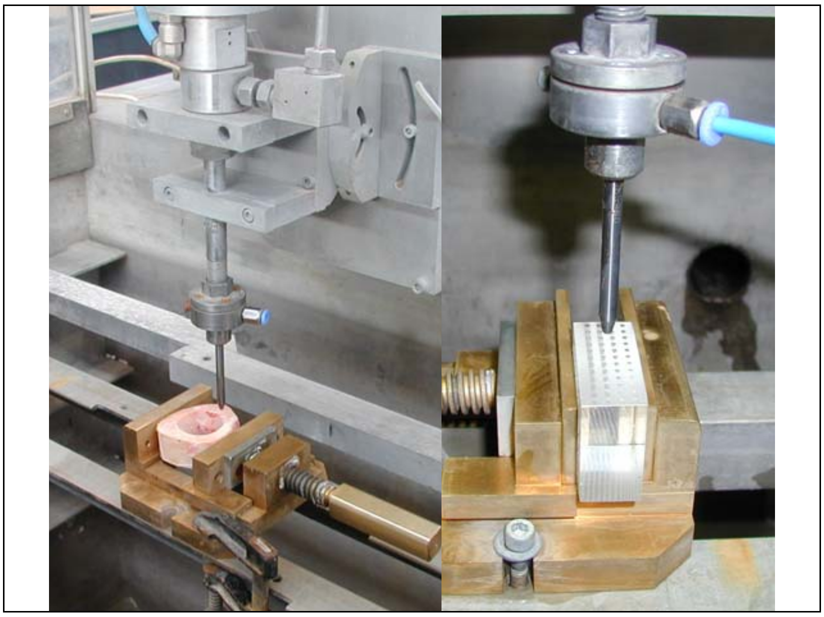

Figure 1. Experimental set up of the static drilling process.

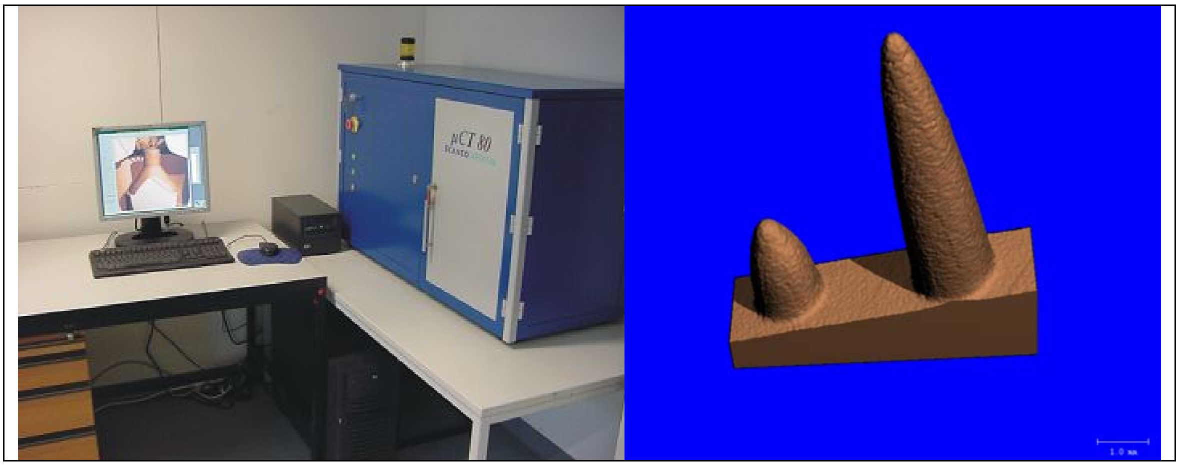

Figure 2. Scanco Medical μCT 80 (left), 3-dimensional view of two blind holes (right)

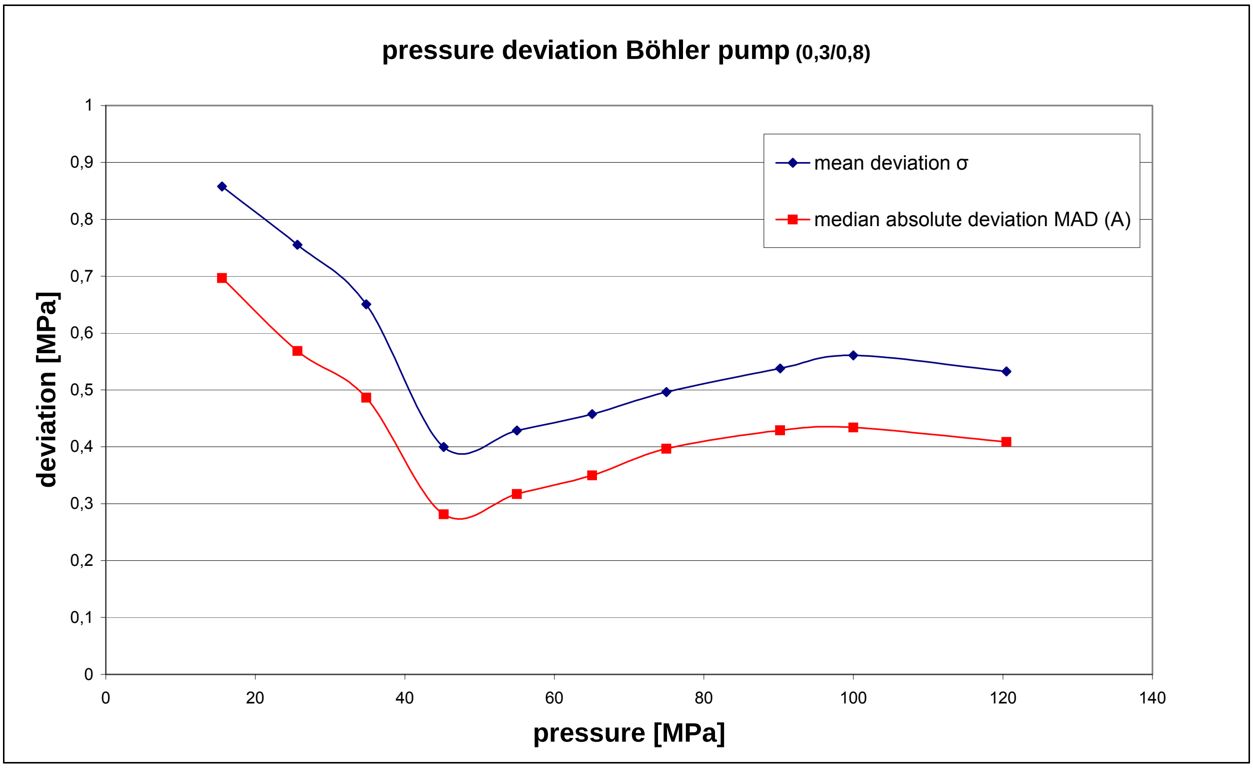

Figure 3. Pressure deviation of the used Böhler pump

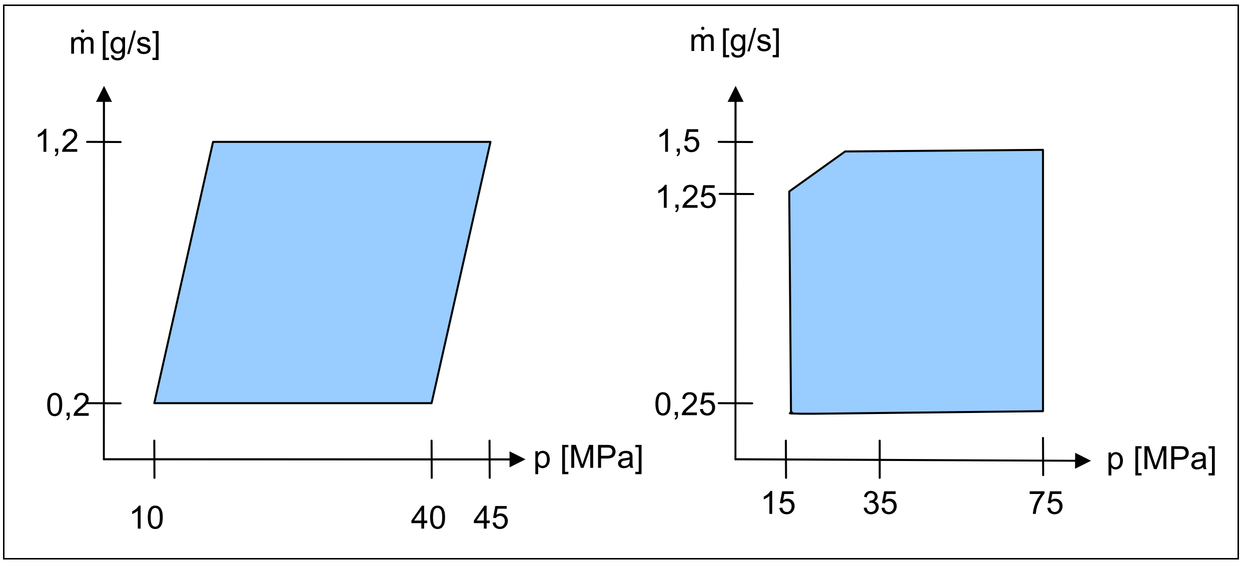

Figure 4. Parametric window for PMMA (left) and cortical bone (right).

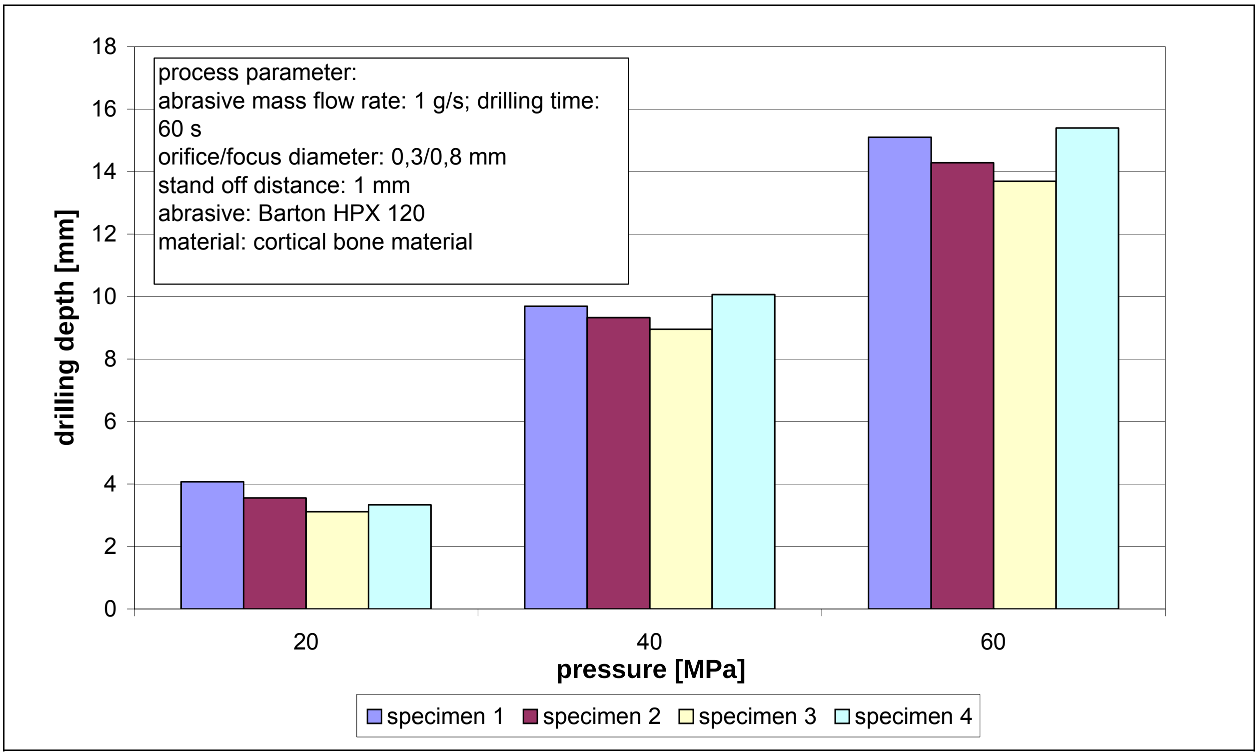

Figure 5. Variation of drilling depth in cortical bone.

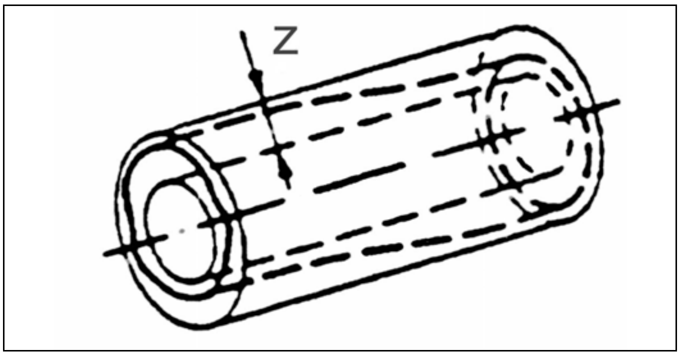

Figure 6. Definition of the cylinder shape tolerance according to the German Standards

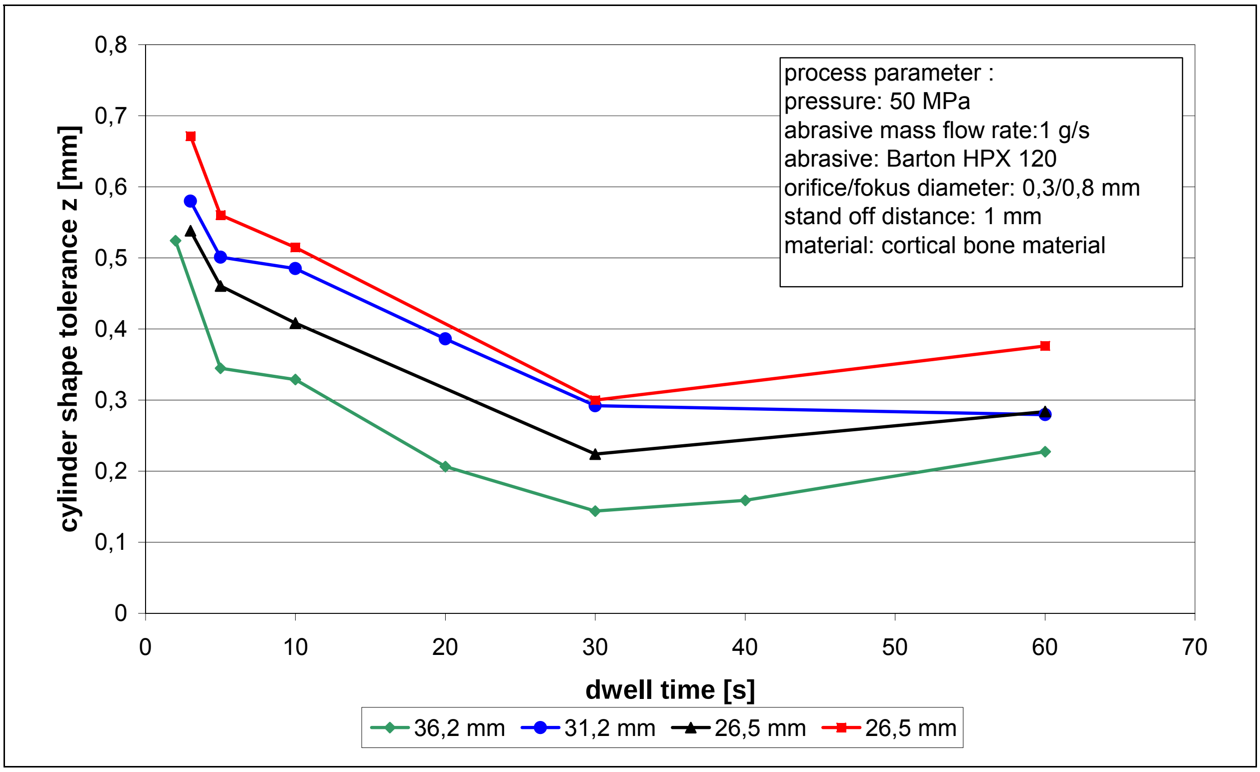

Figure 7. Influence of the dwelling time on the cylinder tolerance shape under variation of the specimens' thickness.

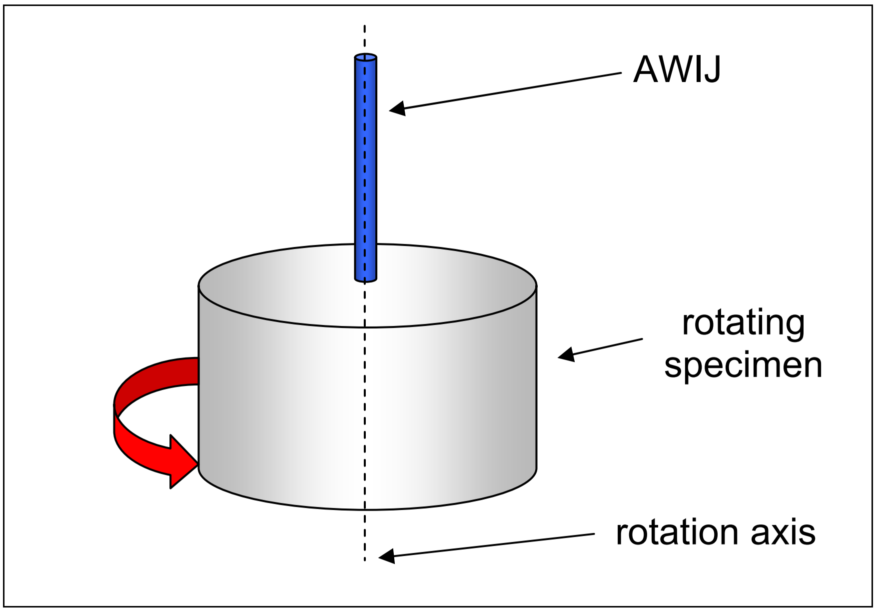

Figure 8. Schematic diagram of the experimental set up for drilling with rotating work piece.