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Technical and Economic Analysis of the Process of Surgical Bone Drilling and Improvement Potentials

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Abstract

Surgical bone drilling is an important preparative procedure for osteosynthesis. Every year, Austrian surgeons drill around 220,000 holes into human bone. The quality of drill holes affects the stability of the fixation after bone fractures. Excessive heat generation during drilling can cause cell death (thermal necrosis) which again weakens the holding strength of the implant. As a result, post-operative complications can compromise the patient's recovery and cause additional economic costs.

The aim of this thesis was to analyse and improve the process of manual surgical bone drilling. For the technical analysis, related research literature has been reviewed. Hence, the most influential factors for the drilling temperature were identified. Furthermore, discarded surgical drill bits from the operation theatre were investigated with the stereo microscope. For the economic analysis, the consequences of thermal necrosis were determined from a biomechanical and economic perspective. For this purpose, interviews with involved people and statistics were used. Surgical bone drilling requires pre- and post-drilling tasks. The overall process was analysed with specific methods from business economics to determine possible weak points.

The investigated surgical drill bits from the operation theatre showed excessive signs of wear. The study showed that both geometry and material of common surgical drill bits have room for improvement. Alternative materials with adequate corrosion and wear resistance as well as improved geometrical parameters are recommended. Cooling is the most influential cutting parameter to decrease the bone temperature during drilling and has to be applied wherever possible. Furthermore, a simple practical guideline was developed to improve the drilling process. Also the economic consequences are remarkable, i.e. complications due to inadequate bone drilling increase the economic costs significantly. These results, and more importantly the safety of the patients justify additional efforts to improve the process of surgical bone drilling.

Kurzfassung

Chirurgisches Knochenbohren ist ein wichtiger Vorgang während der Osteosynthese. Jedes Jahr werden ca. 220.000 Bohrungen in Österreich an menschlichen Knochen durch Chirurgen vorgenommen. Die Qualität der Bohrungen beeinflusst die Stabilität der Fixierung der Knochenfraktur. Übermäßige Wärmeentwicklung während des Bohrens verursacht das Absterben von Zellen (thermische Nekrose), was wiederum die Haltefestigkeit des Implantates verringert. Die daraus resultierenden postoperativen Komplikationen beeinträchtigen den Patienten und verursachen zusätzliche volkswirtschaftliche Kosten.

Das Ziel dieser Arbeit war es, den Knochenbohr-Prozess zu analysieren und zu verbessern. Für die technische Analyse wurde die entsprechende Forschungsliteratur studiert. Daraus wurden die Haupteinflussfaktoren auf die Temperatur während des Bohrens bestimmt. Des Weiteren wurden aus dem Operationssaal ausgeschiedene Knochenbohrer mit dem Stereomikroskop untersucht. Für die wirtschaftliche Analyse wurden die biomedizinischen und volkswirtschaftlichen Auswirkungen auf Grund von thermischer Nekrose untersucht. Dafür wurden Interviews mit involvierten Personen und relevante Statistiken verwendet. Chirurgisches Knochenbohren erfordert Tätigkeiten vor und nach dem Bohren. Der Gesamtprozess wurde mit speziellen wirtschaftswissenschaftlichen Methoden erfasst und daraus mögliche Schwachstellen ermittelt.

Die untersuchten Knochenbohrer aus dem Operationssaal zeigten starke Verschleißerscheinungen. Die Untersuchungen ergaben, dass gebräuchliche Knochenbohrer hinsichtlich der Geometrie und des Materials nicht optimal sind. Alternative Materialien können sowohl korrosions- als auch verschleißbeständig sein. Kühlung ist der wichtigste Einflussfaktor, um die Knochentemperatur während des Bohrens zu senken und sollte daher bei jeder Gelegenheit eingesetzt werden. Weiters wurde eine einfache Richtlinie für die Verbesserung des Knochebohr-Prozesses entwickelt. Die volkswirtschaftlichen Auswirkungen sind bemerkenswert: Komplikationen auf Grund von unzureichender Knochenbohrungen erhöhen die volkswirtschaftlichen Kosten maßgeblich. Deshalb rechtfertigt nicht nur die Patientensicherheit weitere Anstrengungen um den Prozess des chirurgischen Knochenbohrens zu verbessern.

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LIST OF ABBREVIATIONS

AISI	American Iron and Steel Institute
AO/ASIF	Arbeitsgemeinschaft Osteosynthese/Association for the Study of Internal Fixation
AUVA	Allgemeine Unfallversicherungsanstalt (engl. Austrian Workers' Compensation Board)
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (engl. Federal Institute for Occupational Safety and Health)
BPMN	Business Process Model and Notation
CAD	Computer Aided Design
DLC	Diamond-Like Carbon
FSW	Friction-Stir Welding
HSS	High Speed Steel
IBL	Institut für Industriebetriebslehre (engl. Institute of Industrial Management and Innovation Research)
ICD	International Statistical Classification of Diseases and Related Health Problems
IWS	Institut für Werkstoffkunde und Schweißtechnik (engl. Institute of Materials Science and Welding)
KAGes	Steiermärkische Krankenanstaltengesellschaft m.b.H.
LKH	Landeskrankenhaus (engl. federal state hospital)
P-FMEA	Process-Failure Mode and Effects Analysis
PMMA	Polymethylmethacrylate
RPN	Risk Priority Number
SEM	Scanning Electron Microscope
TiBN	Titanium Boron Nitride
TiN	Titanium Nitride
UKH	Unfallkrankenhaus (engl. accident hospital, trauma center)
UTS	Ultimate Tensile Strength
WIFO	Österreichisches Institut für Wirtschaftsforschung (engl. Austrian Institute of economic research)

σ	Point angle
γ_f	Helix angle
γ_0	Rake angle
α	Clearance angle
n	Spindle speed, drilling speed
v_c	Cutting speed
f	Feed
v_f	Feed rate
F_D	Axial drilling force
t_D	Drilling time

1 INTRODUCTION

The first chapter gives an overview of the fundamentals of osteosynthesis and surgical bone drilling. Furthermore, the main objectives of this thesis and the chosen approach will be described.

1.1 The Process of Surgical Bone Drilling

Bone drilling is not an invention of the modern medicine. Some human skeletons from early civilizations show surgically produced holes in their sculls. For example, Fig. 1 shows holes produced by a Peruvian healer in South-Central Peru during the early Late Intermediate period (approx. AD 1000-1250, Kurin, 2013). Around 1850, bone drilling became part of the fracture fixation procedure with screws. There has been no methodical research on the development of a suitable drilling tool until Bechtol (1956). He presented a modified hand drill based on his experiences in surgery and provided further drilling recommendations (Fig. 2). Since then, the twist drill became the standard tool for bone drilling. (Augustin et al., 2012b; Saha et al., 1982)

Fig. 1: Holes in a human skull produced with a hand drill (Kurin, 2013)

In modern medicine there are two main approaches for bone fracture treatment, according to Udiljak et al. (2007). The conventional approach requires the immobilization of the fractured parts. After the reduction of the fracture, it is immobilized from the outside by a cast. Osteosynthesis, on the other hand, is a direct approach. By definition, osteosynthesis is the operative stabilization of a fracture with implants (Hirner, 2008, p.232). A standard procedure is the internal fixation of the fracture using screws, plates, nails and wires (Fig. 3). Fast patient recovery and exact alignment of the fractured parts are two advantages compared to the conventional method (Milberg and Fuchsberger, 1984). Osteosynthesis temporarily fixes the fractured bone - permanent stabilization is provided by the natural healing of the bone (Hirner, 2008, p.232).

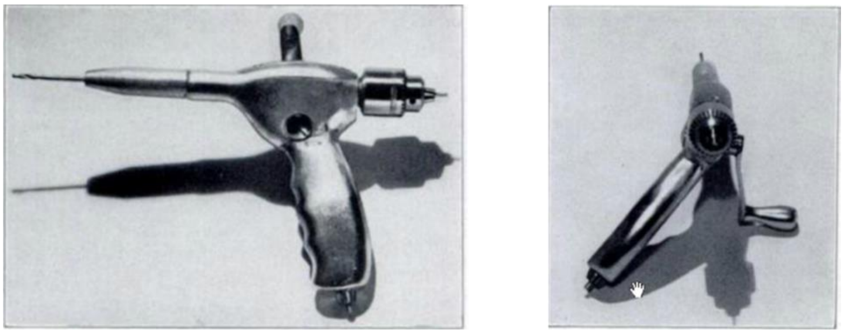


Fig. 2: Modified hand drill for surgical treatment (Bechtol, 1956)

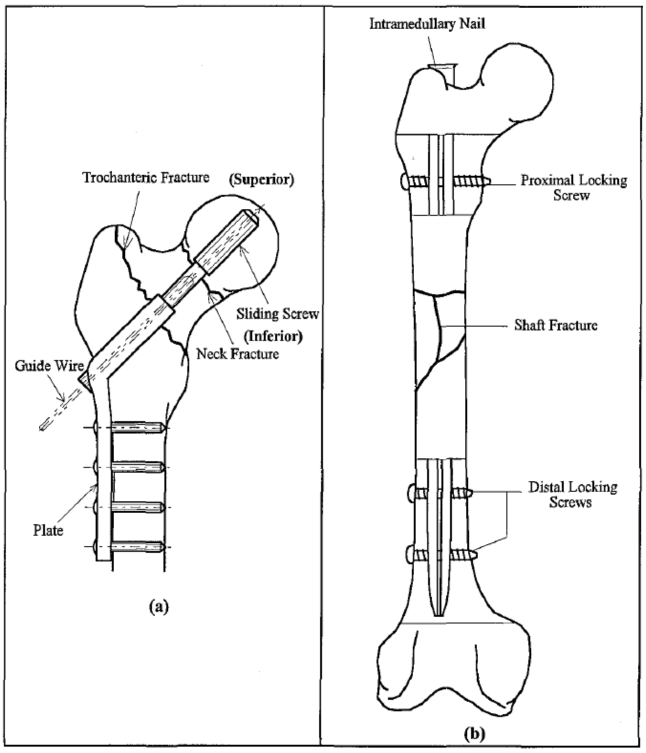


Fig. 3: Fracture fixation of a femur (Bouazza-Marouf et al., 1995, cited in Ong, 1998, p.152)

The fixation of bone fragments with screws and plates requires drilling of the bone. Therefore, surgical drill bits are used by the operating surgeon for the preparation. During the drilling process, the major part of the mechanical energy is transferred into thermal energy (Fuchsberger, 1986). A number of researches (Matthews and Hirsch, 1972; Eriksson and Albrektsson, 1983; Milberg and Fuchsberger, 1984 and Schmelzeisen, 1990) have reported that temperature rise of bone could lead to bone necrosis – the irreversible death of cells. In this thesis, the term "thermal necrosis" will be used to refer to bone necrosis caused by thermal energy. A key issue, therefore, is how the bone temperature during drilling affects the quality of the drill holes.

Generally, the surgical drill bits for drilling human bone are made of martensitic stainless steel for surgical instruments and have a particular geometry. Both, the material and the geometry, as well as the cutting parameters during the drilling process influence the performance of the drill bit in the operation theatre. In addition, the human factor should not be underestimated: the quality of the drill hole and a subsequent stable osteosynthesis depends mainly on the skills of the medical staff.

Osteosynthesis is one of the most frequently performed surgical treatments. In 2013, there were 55,913 documented operative procedures in Austria (Statistics Austria, 2014). In Germany, osteosynthesis was in the Top 10 of the most frequent operations in the same year (Federal Statistical Office, 2014). As previously mentioned, drilling of bone is a necessary step before the fixation of the bone fragments. Although the number of drill holes varies between different osteosynthesis procedures, a rough estimation can be made: based on an average of four holes (according to a specialist for trauma surgery, personal communication, 20 October 2014) for each procedure, more than 220,000 holes were drilled by Austrian surgeons in 2013. This number underlines how important surgical bone drilling is, not only from a patient safety perspective but also from an economic aspect.

1.2 Problem Statement

Thermal necrosis associated with drilling of bone is a very complex topic. First of all, it depends on the maximum level and on the exposure time of the thermal load during drilling. This relationship has been established by numerous researchers (Mortiz and Henriques 1947; Fuchsberger, 1986; Schmelzeisen, 1990; Bachus et al., 2000; Pandey and Panda, 2013). On the other hand, there are several technical and human factors which influence the heat generation while drilling.

Fig. 4: Loosened implant (red) after a femoral fracture (provided by Hans Clement, MD, Medical University of Graz, Department of Traumatology, 23th October 2014)

From a technical perspective, it seems that the design of actual surgical drill bits is not optimized to minimize thermal load. Not only the geometry, but also the material of common surgical drill bits appears to have potentials for improvement. Eriksson et al. (1983), Natali et al. (1996) and Allan et al. (2005) found that worn drill bits cause an increase of drilling temperature. Recent research on the Institute of Materials Science and Welding (IWS) has reported that excessive wear of drill bits occurs even after few drill holes. Even though the problem of blunt drill bits in operation theatres seems to be widespread, there is no general monitoring process established in Austrian hospitals.

The relationship between thermal necrosis and the loss of stability of fixation has been reported by several authors (Matthews and Hirsch, 1972; Schmelzeisen, 1990 and Kyu-Hong 2011). The resulting consequences are severe, i.e. medical complications, unplanned surgeries and an extended duration of the recovery process compromise the patient additionally (Fig. 4). Furthermore and from an economic aspect, absenteeism, the loss of value creation and increased health expenditures lead to high costs. Most prior research has been limited on the technical perspective, but has failed to provide sufficient insight into the economic impact of surgical bone drilling.

1.3 Research Aims

The aim of this thesis is to analyse and improve the process of manual surgical bone drilling. The term "process" implies that this present work focuses not only on the single event of drilling. It examines also pre- and post-drilling processes like quality control, reprocessing or disposal.

This thesis should investigate the optimal geometry, material and cutting conditions for surgical drill bits under present circumstances. It analyses the process of bone drilling in detail to determine possible weak points. As a result, improvement measures are deduced. In the end, a guideline for the optimization of the whole process of bone drilling should be provided. A presentation of this guideline in relevant institutions like hospitals or statutory health insurances should be aspired to make this information available for the medical staff. The expectation is that by applying the guideline, thermal necrosis could be prevented and the amount of well drilled bone holes would rise. This will not only save costs but also – and more importantly – increases the patient safety in long terms.

1.4 Methodology

In this thesis, a number of methods were used to analyse the process of surgical bone drilling.

For the technical part in chapter 2, a detailed research on the literature has been conducted. Since drilling of bone is affected by multiple fields of research (medicine and engineering), the existing literature is widespread. Previous research at the IWS has concentrated on the relationship between the drill bit wear and the drilling forces. Therefore, the focus of this thesis lies on the drilling temperature and its influence by different drilling parameters. Based on the reviewed literature, clear recommendations on drill bit specifications and cutting conditions should be obtained. This this study includes theoretical and practical research. Fig. 5 provides an overview about different types of surgical drill bits which have been investigated for this thesis. With one exception, all of them were already in use in the operation theatres of the state hospital of Graz (Landeskrankenhaus (LKH) Graz).

Fig. 5: Different types of surgical drill bits
1: Synthes 315.33[1], ø3.2 mm; 2: Synthes 310.290[1], ø3.2 mm
3: Synthes 310.23[1], ø2.5 mm; 4: Synthes 310.350, ø3.5 mm (new)
5: Synthes 310.25[2], ø2.5 mm, 6: manufacturer unknown[2], ø3.2 mm

For the economic analysis (chapter 3), several interviews with persons involved in the process of bone drilling from different sectors (medical staff, implant manufacturer, reprocessor etc.) have been carried out. The questionnaire was designed to provide complete insight into the process. Due to the individual points of interest which were discussed with the participants, the questionnaire was not standardized. In the next step, the process was analysed with different economic techniques. The current state is illustrated according to the specifications of Business Process Model and Notation (BPMN). An Ishikawa diagram (cause-and-effect diagram) has been created to determine possible causes for inadequate bore holes and high thermal loads during drilling. Based on the BPMN-model, a Process Failure Mode and Effects Analysis (P-FMEA) has been carried out to determine potential weak points in the process more accurately. Afterwards, improvement potentials for the whole process were developed. Furthermore, statistics about osteosynthesis have been worked out to highlight the importance of well performed surgical bone drilling from an economic point of view.

[1] Provided by Mositech Medizintechnik GmbH, Schwefel 93, 6850 Dornbirn, Austria; surgical drill bits originally from LKH Graz
[2] Provided by the Department of Medical Engineering of LKH Graz

2 TECHNICAL ANALYSIS

This section is about the technical aspects of surgical bone drilling. Since bone is a complex material, biomechanical characteristics will be covered too. The primary focus here is the investigation of drill bits used in operation theatres. Based on the findings from the literature, factors that determine the thermal load during drilling are described. Finally, clear recommendations about drill bit geometry, material and cutting conditions will be provided.

2.1 Biomechanical Basics

As already mentioned, thermal necrosis is a serious issue during the process of surgical bone drilling. In this part, thermal necrosis and its threshold is discussed. Moreover, bone as an anisotropic material is specified in this chapter.

2.1.1 Thermal Necrosis

Thermal necrosis is cellular death due to excessive thermal load. Pandey and Panda (2013) describe it as a result from the loss of blood supply to the bones, which causes the death of bone tissue and further the bone to failure. There have been several studies about the temperature threshold for thermal necrosis. Thermal damage to the bone depends on the temperature level and its duration of impact. This relationship has been studied by a number of authors. In their study on rabbit tibias, Eriksson and Albrektsson (1983) found out that even temperatures at 47 °C could harm bone tissue. Heating up to 53 °C for 1 minute causes even greater injury of bone, according to another study (Eriksson et al., 1984). Moritz and Henrique (1947) demonstrated the inverse relationship between the intensity of a thermal exposure and time required to produce cutaneous burn (Fig. 6). Lundskog (1972, cited in Pandey and Panda, 2013) determined a temperature of 55 °C for 30 s for the irreversible death of bone cells in his studies on rabbits. Pandey and Panda (2013) summarize that there is an average temperature of 47 °C for 1 minute as threshold for the occurrence of thermal necrosis of human bone.

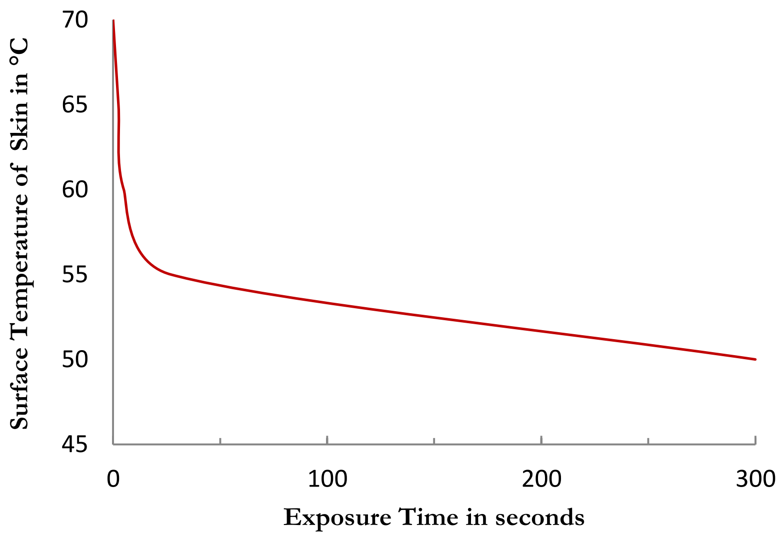


Fig. 6: Time - surface temperature thresholds at which epidermal necrosis of porcine skin occurs (adapted and modified from Moritz and Henriques, 1947)

2.1.2 Physical and Mechanical Properties of Bone

In the field of mechanical engineering, drilling is a well-known manufacturing process. Depending on the workpiece and its material, suitable drilling tools and cutting parameters are chosen by the manufacturer. Mechanical properties of engineering materials can be determined by different methods of testing.

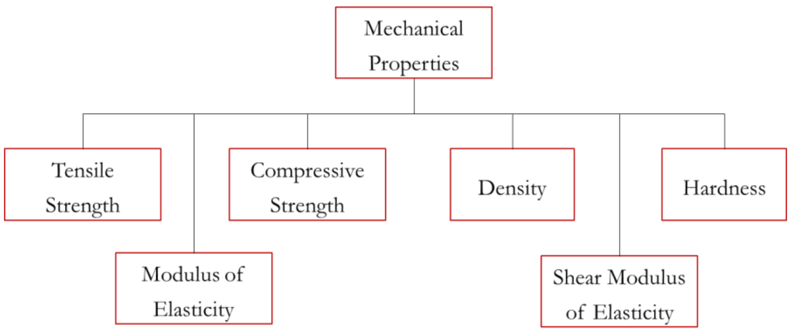


Fig. 7: Mechanical properties of bone (adapted and modified from Ong, 1998, p.36)

For instance, a tensile test provides the stress-strain-diagram and furthermore the modulus of elasticity for a specific material. Although bone is an anisotropic material, the mechanical properties (Fig. 7) are determined by similar testing procedures used for engineering materials (Evans, 1969). Nigg and Herzog (1999) listed selected properties of bone and compared them to selected other materials (Table 1).

Table 1: Selected physical and mechanical properties of bone and selected other materials (adapted and modified from Nigg and Herzog, 1999, p.73)

Variable	Comment	Magnitude	Unit
Density	cortical bone steel aluminium water (at 4 °C)	1700-2000 7850 2700 1000	kg/m³ kg/m³ kg/m³ kg/m³
Mineral Content **Water Content**	bone bone	60-70 150-200	% kg/m³
Elastic Modulus	femur (cortical) aluminium steel	5-28 70 210	GPa GPa GPa
Tensile Strength	femur (cortical) tibia (cortical) fibula (cortical)	80-150 95-140 93	MPa MPa MPa
	steel (S235JR) steel (42CrMo4)	>340[3] 800-1300[3,4]	MPa MPa
Compression Strength	femur (cortical) tibia (cortical)	131-224 106-200	MPa MPa
	wood (oak) limestone granite	40-80 80-180 160-300	MPa MPa MPa
Thermal Conductivity	bovine cortical bone[5] PMMA[6] stainless steel (20 °C)[6]	0.53-0.58 0.16-0.19 15-25	W/mK W/mK W/mK

Anisotropy is the directional dependence of properties. Therefore, the strength of bone is related to the positon of the applied load. In Nigg and Herzog (1999), the differences in mechanical properties for different collagen fibre orientations (longitudinal, alternating and circumferential) are noted (Table 2).

[3]Ultimate Tensile Strength (UTS), source: Stahlschlüssel, 2007
[4] hardened and tempered
[5] Davidson and James (2000)
[6] VDI, 2006; PMMA - Polymethylmethacrylate

Table 2: Mechanical properties of different types of osteons (adapted and modified from Nigg and Herzog, 1999, p.76)

Loading mode	Type of osteons	Ultimate stress in MPa	Elastic modulus in GPa	Ultimate strain in %
Tension	longitudinal	114	11.7	6.8
	alternating	94	5.5	10.3
Compression	longitudinal	110	6.3	2.5
	alternating	134	7.4	2.1
	circumferential	164	9.3	1.9
Shear	longitudinal	46	3.3	4.9
	alternating	55	4.1	4.6
	circumferential	57	4.2	4.6

But anisotropy is not the only influence factor on the properties of bones. Osteoporosis, a serious bone disease, decreases the strength and stiffness of bones (Dickenson et al., 1981). Also less energy before fracturing can be absorbed by osteoporotic bones, which can be observed at the smaller area under the stress-strain curve of the osteoporotic samples (Fig. 8). The experiments have been carried out with femoral cortical bones of 22 elderly women, which died at the age between 67 and 91 years. For the tensile tests, identical bone specimens have been created from the bones. They were attached in a hydraulic servo-controlled testing machine with an extensometer (Fig. 9). (Dickenson et al., 1981)

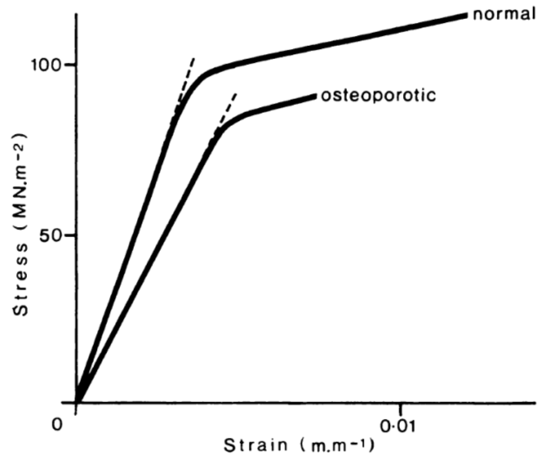


Fig. 8: Stress-strain curves of normal and osteoporotic bone based on the average values from the testing results (Dickenson et al. 1981)

Fig. 9: The clamping of the testing machine with the extensometer in position (Dickenson et al. 1981)

Ong (1998) draws attention to the difficulties of bone specimen for mechanical testing. On the one hand, common testing procedures are carried out in vitro, which means under controlled non-living boundary conditions. On the other hand, the size of the bone specimen influences the reproducibility and the accuracy of the results from the mechanical testing. In his research, Ong (1998, p.40) examined densitometry as a second method for the evaluation of bone strength. Bone densitometry is a medical procedure for the determination of the bone density, which is essential for the diagnostics of osteoporosis. Because of the positive relationship between bone mineral density and strength, densitometry is a suitable method for the determination of bone strength.

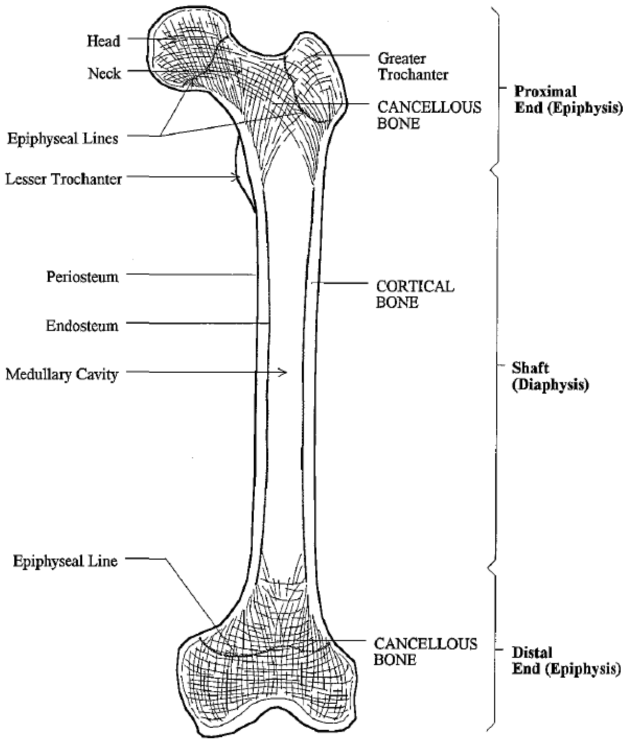


Fig. 10: Bone structure of a femur (Ong, 1998. p.164)

For the performance of osteosynthesis, it is important to take the condition of the patient's bone into account. As a part of osteosynthesis, surgical bone drilling is also affected. As mentioned at the beginning of this chapter, drilling in mechanical engineering depends on the workpiece. This is also true for medicine. In surgery, bone is the workpiece (Fig. 10). Therefore, its properties should also be considered for the process of bone drilling. For instance, drilling into the cortical bone (high hardness) increases the wear of the drill compared to the drilling through medullary cavity or cancellous bone (low hardness). Nigg and Herzog (1999) reported much higher ultimate stress levels for cortical bone in comparison to cancellous (trabecular) bone based on their collected data (Fig. 11). Moreover, drilling into compact bone is the major challenge for surgical drill bits.

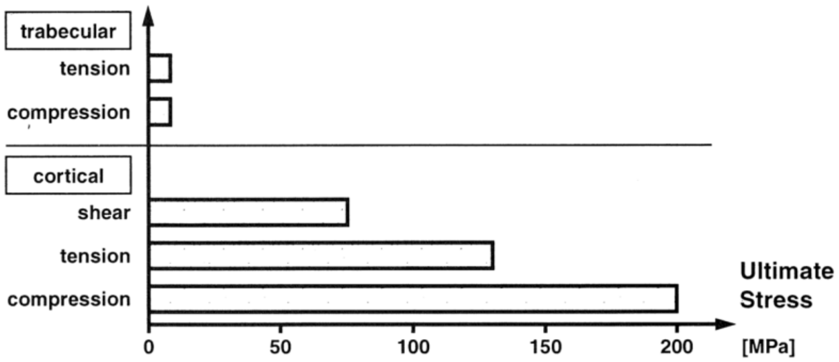


Fig. 11: Differences in mechanical properties of trabecula and cortical bone (Nigg and Herzog, 1999, p.75)

In clinical settings, one measure for well-performed drill holes could be the choice of the right drill bit. Additionally, the adjustment of the cutting conditions according to the patient is important too. In the hospitals, bone drilling is primarily a manual process with special medical instruments. Therefore, limitations in the adjustability are obvious. In the following chapters, relevant technical parameters are described in detail.

2.2 Fundamentals of Drilling

Drilling is a manufacturing process with a rotational cutting motion and chip removal. The tool (drill bit) performs a feed motion in direction of the rotation axis (Grote and Feldhusen 2014, p. 52). The twist drill is the most frequently used drill bit not only in the industry but also in the operation theatre. Fig. 12 shows common drilling procedures.

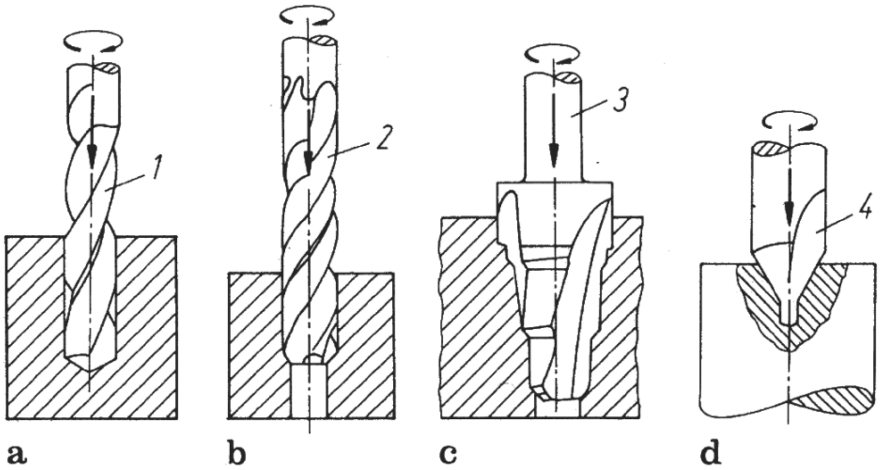


Fig. 12: Typical drilling procedures (Grote and Feldhusen 2014, p. S 53)
a) Drilling; b) Reaming; c) Countersinking, counterboring; d) Center drilling

2.2.1 Geometry

A twist drill has in general three main elements, called shank, body and drill point. Fig. 13 shows the specifications of a typical twist drill. The shank is usually cylindrical (straight) or tapered. In surgery and orthopaedics, the AO/ASIF-quick coupling as a special shank type is widely used (Fig. 17). The geometry of the body and the tip is more complex. It can be modified according to the particular task. The main parameters are web thickness, helix angle, point angle, flute geometry and drill point style. In chapter 2.3 they will be discussed in detail with regard to their importance for surgical bone drilling.

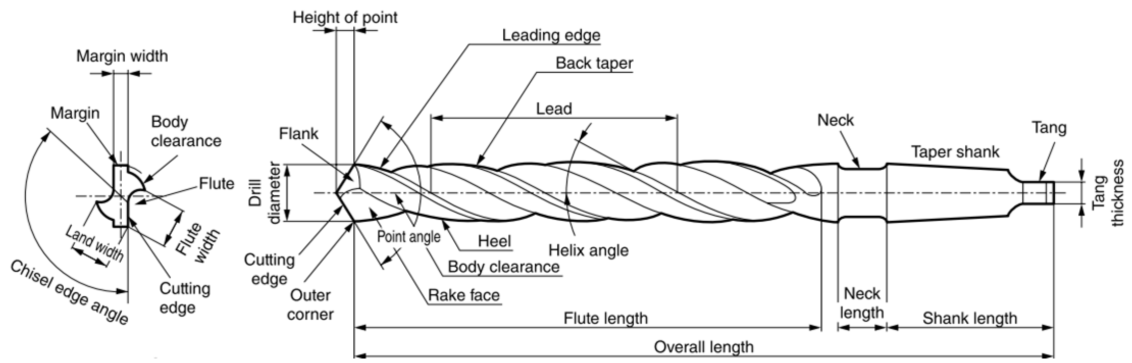


Fig. 13: Drill specifications (Sumi Tool, 2014)

Cutting tools remove material from the workpiece with one or more cutting edges through plastic deformation of the chips. A simple cutting edge and its geometrical specifications can be seen in Fig. 14. The cutting angles depend on the workpiece and the particular task of the tool. This is also true for drill bits (Fig. 15).

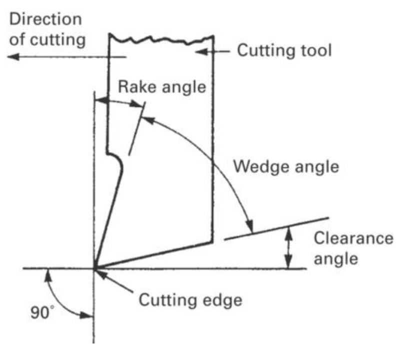


Fig. 14: A simple cutting face of a tool (Natali et al., 1996)

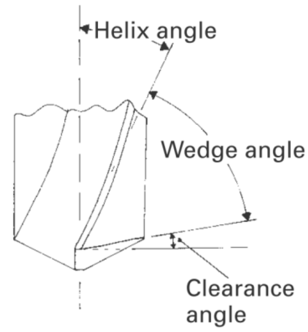


Fig. 15: Basic cutting angles of a drill bit (Natali et al., 1996)

Although there is a large amount of information available for the field of engineering, the ideal cutting edge for surgical drill bits is not fully developed yet. In chapter 2.3, this will be discussed in detail.

2.2.2 Drilling Forces

In this section, the main drilling forces and moments will be described according to Grote and Feldhusen (2014). Fig. 16 shows the chipping situation and the drilling forces of a two-fluted twist drill bit. The axial drilling force applied by the surgeon creates forces on the cutting lip. They can be split into the components F_c, F_p and F_f. The cutting forces $F_{c1,2}$ and the lever arm r_c create the cutting moment M_c. If the drill bit is symmetric, the passive forces F_{p1} and F_{p2} neutralize each other. Otherwise, F_{p1} and F_{p2} produce an additional force which negatively affects the quality of the drill hole.

◊ $M_c = (F_{c1} + F_{c2}).r_c$ F1

◊ $F_{c1} = F_{c2} = F_{cZ}$ F2

◊ $M_c = F_{cZ}.2r_c$s F3

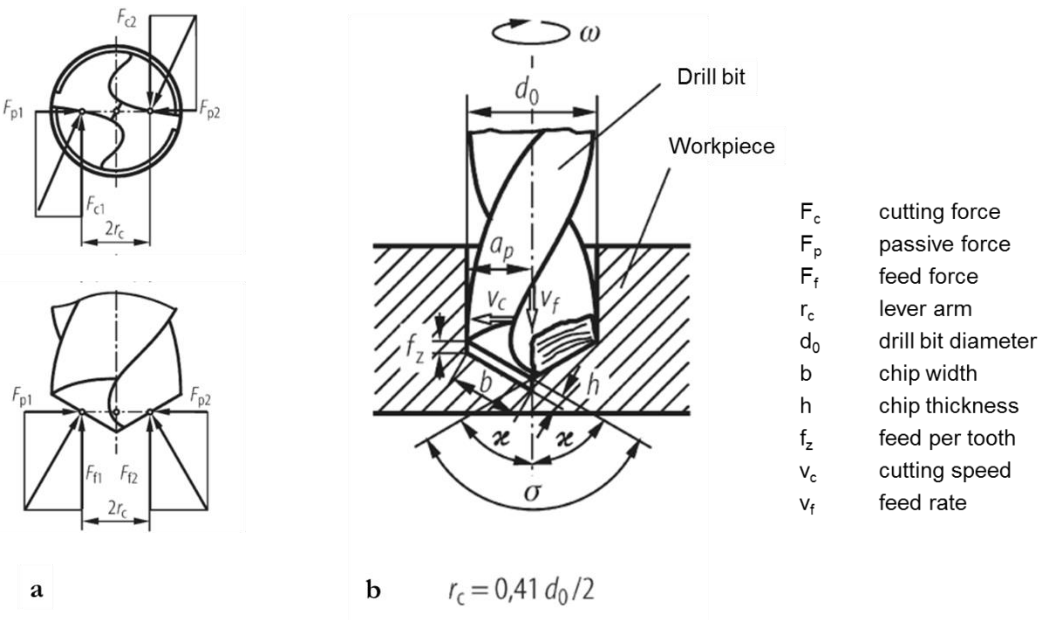


Fig. 16: Drilling forces (a) and chip geometry (b) (adapted from Grote and Feldhusen, 2014, p.54)

2.3 Surgical Drill Bit - Geometry

It is well established that the geometry of a surgical drill has great impact on the drilling process. Drilling force, -torque and -temperature are just three parameters which are affected by the geometry. In this chapter, all relevant specifications concerning the geometry of surgical drill bits will be reported. Although this topic has been studied by several authors, there is no general agreement about the optimal geometry.

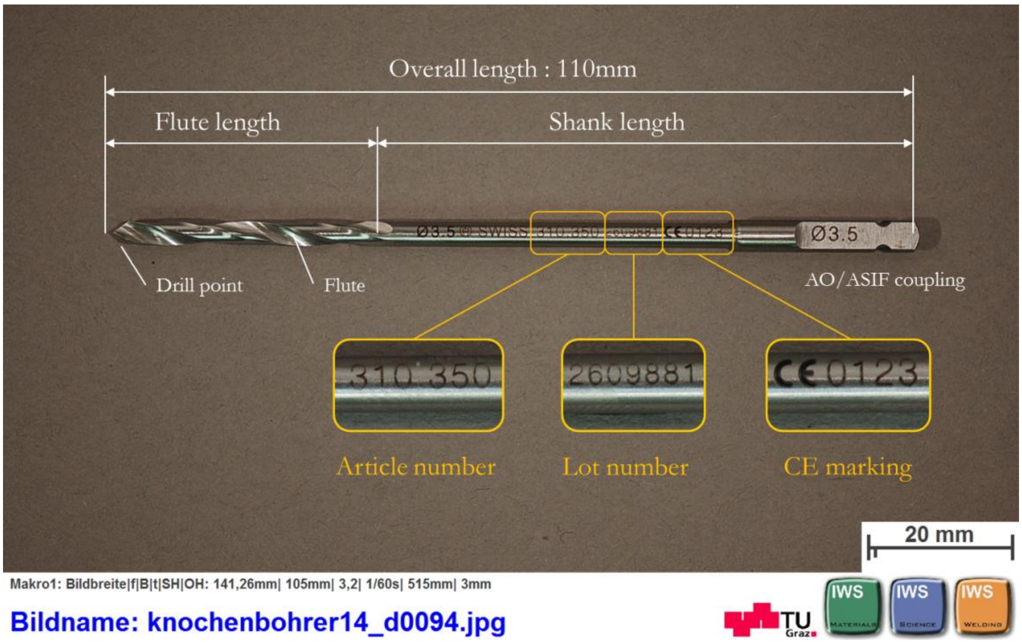


Fig. 17: A Synthes 310.350 surgical drill bit (lot number 2609881)

Fig. 17 shows a common ø3.5 mm surgical drill bit from Synthes[7] with an overall length of 110 mm. Next to the diameter, there is further information visible. The article number is for the clear identification of the drill bit. The lot number allows the traceability relating to the manufacturing process of the product.

2.3.1 Drill Diameter and Predrilling

The relationship between drill diameter and thermal load on the bone is well reported in the literature. In a recent study, Augustin et al. (2012a) conducted drilling experiments on pig diaphysis. Thereby, he compared an internally cooled drill and a two-step drill with different diameters. Additionally, the feed rates, cutting speeds and the cooling situation have been varied in the experiments. According to Augustin et al. (2012a), the drill diameter is the second most influential parameter (after cooling) on the increase of bone temperature (Table 3). Kalidindi (2004, p.38f.) reported similar results from his experiments.

[7] Synthes is part of Johnson & Johnson since 2011/2012. The company name is now DePuy Synthes. Headquarter Austria: Synthes Österreich GmbH, Karolingerstraße 16, 5017 Salzburg

Table 3: Influence of specific parameters on increase in bone temperature (Augustin et al., 2012a)

Bone temperature (°C)

Parameter	SS	Degrees of freedom	MS	F
Cooling	11606	1	11606	1626.3
Drill diameter	1008	3	336	15.30
Feed	791	4	198	8.87
Cutting speed	57	4	14	0.61
Drill geometry	0	1	0	0.01

SS sum of squares, *MS* mean square, *F* indicator of influence

They attributed that to the size of the cutting lip. If the diameter increases, the contact surface between the drill and the bone increases too. Further on, this raises the friction during drilling which results in higher bone temperatures. That can be demonstrated with Fig. 16. The size of the chip is determined by its thickness (h) and width (b):

◊ $h = f_Z \sin\frac{\sigma}{2}$ F4

◊ $b = \frac{d_0}{2\sin\frac{\sigma}{2}}$ F5

The chip size increases if the feed rate and/or the diameter increase. As mentioned, Augustin et al. (2012a) used newly designed two-step drills for his studies. The idea of step-drilling is related to predrilling of the bore hole. The body of a two-step drill has two different diameters. The smaller diameter starts at the drill point and predrills the hole for the larger diameter (Fig. 18). Augustin et al. (2012a) had not found that their step-drills create lower bone temperatures compared to a classical drill bit of the same diameter. However, Udiljak et al. (2007) reported a difference of 17 °C for the benefit of the two-step drill at low cutting speeds (6.53 m/min).

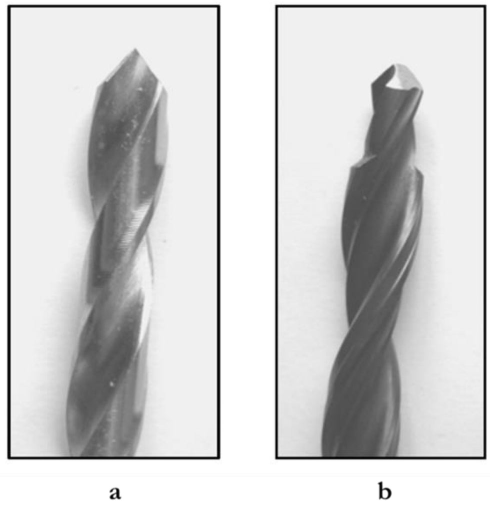


Fig. 18: A classical surgical drill and a two-step drill (Udiljak et al., 2007)

Predrilling is the other option to reduce the bone temperature. Predrilling means drilling in multiple steps to get the final diameter of the drill hole. Since the drill diameter is gradually increased the friction between drill bit and bone is decreased. Matthews and Hirsch (1972) reported the positive effect of predrilling in their in vitro study on human-cadaveric bone (Fig. 19). The holes were predrilled with 2.2 mm drills and enlarged to 3.2 mm afterwards. Compared to the single-step drilling with 3.2 mm, the maximum temperatures were greatly reduced with predrilling. The temperatures were measured with thermocouples at specific distances from the drill. A guide block was constructed for the controlled location of the drill bit and the thermocouples (Fig. 20).

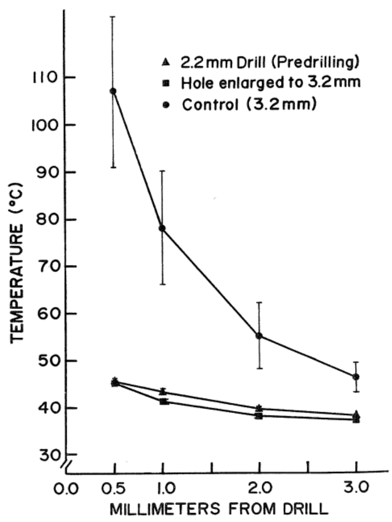


Fig. 19: Effect of predrilling - average maximum cortical temperatures
n = 885 rpm, F_D = 60 N (Matthews and Hirsch, 1972)

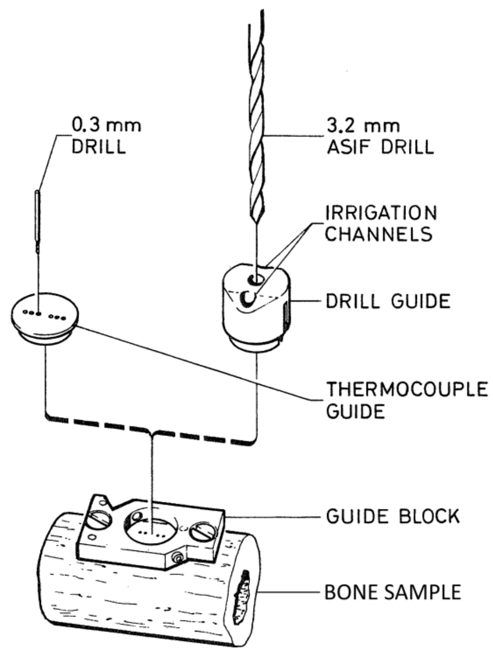


Fig. 20: Guides used for the location of the thermocouples and the drill holes (Matthews and Hirsch, 1972)

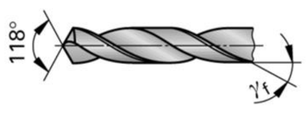
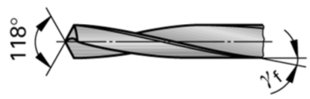
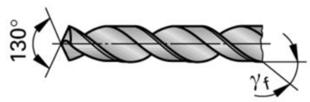
Kalidindi (2004) has also investigated the effect of predrilling on artificial bones (PMMA-Polymethylmethacrylate). The results show less thermal load on the specimen using predrilling. The author argued that the time gap between predrilling and drilling could lead to a decrease of temperature since the specimen has additional time to cool down. In a recent study, Karaca and Aksakal (2013) also concluded that the temperature increases when the drill diameter increases (up to 4.5 mm, see Fig. 42).

To recap, it is well established that the drill diameter has substantial influence on the drilling temperature. This should be considered in terms of thermal necrosis. Predrilling could be an appropriate method to decrease the thermal load during drilling - most notably for large diameters. But it should be noted that predrilling requires additional time which extends the operation time. A fact which should be taken into account for further recommendations.

2.3.2 Point Angle (σ)

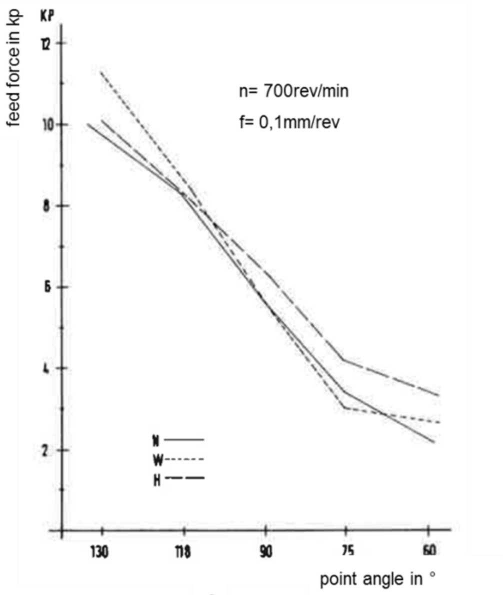
Pandey and Panda (2013) defined the point angle as *"the angle formed by the projection of the cutting edges on to a plane passing through the longitudinal axis of the drill."* Fig. 24 shows the point angle of a Synthes 310.350 (lot number 2609881) surgical drill bit which is approx. 78°. In mechanical engineering, DIN 1414-1 provides information about the appropriate point angle with regard to the material of the workpiece (Table 4). As mentioned in chapter 2.1.2, bone is an anisotropic material which is influenced by several different factors. Therefore, the determination of the ideal point angle according to DIN 1414-1 is not possible for bones.

Table 4: Tool application groups and their specifications[8]

tool application group[9]	for materials	σ (±3°)	d in mm	γ_f (±2°…5°)
N 	**Type N**: normal strength and hardness materials: soft steels, cast steels, brass	118°	1…3.15 3.15…5 > 5	20° 22° 25-30°
H 	**Type H**: hard and brittle materials, short chipping: high-strength steels, laminates		1…3.15 3.15…5 > 5	10° 12° 13°
W 	**Type W**: soft materials, long chipping: copper- and zinc-alloys, aluminium	130°	1…5 5…32 > 32	30° 35° 40°

Although there is no general agreement about the ideal point angle, it seems that small point angles (70-90°) are established in the operation theatre nowadays. Schmelzeisen (1990, p.39-40) investigated the relationship between point angle and feed force on the human tibia (Fig. 21). The author found that small point angles create less feed force, but did not find any significant differences between the drill bit types H, N and W.

[8] Classification according to DIN 1836, information from Dillinger (2007, p.127) and Reichard (2003, p.153)
[9] Figures adapted from Dillinger (2007, p.127)



a

σ 130° (N)	9,8	9,8	9,9	10,0	10,1	10,1
σ 130° (W)	11,0	11,1	11,2	11,5	11,6	11,6
σ 130° (H)	10,0	10,1	10,1	10,1	10,2	10,2
σ 118° (N)	8,1	8,1	8,2	8,2	8.2	8,3
σ 118° (W)	8,5	8,7	8,8	8,8	9,0	9,2
σ 118° (H)	8,2	8,2	8,3	8,3	8,4	8,5
σ 90° (N)	5,4	5,4	5,5	5,6	5,7	5,7
σ 90° (W)	5,4	5,5	5,5	5,6	5,7	5,8
σ 90° (H)	6,0	6,1	6,2	6,4	6,4	6,4
σ 75° (N)	3,4	3,4	3,5	3,6	3,6	3,6
σ 75° (W)	2,9	2,9	3,0	3,0	3,1	3,1
σ 75° (H)	3,9	3,9	4,0	4,2	4,2	4,3
σ 60° (N)	2,0	2,0	2,1	2,1	2,1	2,1
σ 60° (W)	2,3	2,3	2,5	2,3	2,7	2,7
σ 60° (H)	3,1	3,1	3,4	3,4	3,4	3,5

b

Fig. 21: a) Effect of the point angle on the feed force at constant drill speed and feed rate
b) Feed force (in kp) and drill bit geometry (adapted from Schmelzeisen, 1990, p.39)

Saha et al. (1982) designed a new surgical drill bit to improve surgical drilling. They pointed out that there is no clear argument for the well-established 90° point angle from history. In their work, they calculated the torque and the required energy of a 60° surgical drill bit and a 118° standard drill bit. The 118° drill bit showed lower values of torque and energy. Saha et al. (1982) also reported that a large point angle lead to higher temperatures on the cutting face. As a compromise, they recommended a point angle of 118° in their work.

Natali et al. (1996) performed studies on the improvement of orthopaedic drill bits. They investigated five different drill bits with 2.5 mm diameter and found that a point angle of 118° is well-suited for bone drilling.

On the other hand, Milberg and Fuchsberger (1984) emphasised the role of a small point angle. Fig. 22 shows the influence of the point angle on the temperature, torque and drilling time. According to their study, the main advantages of small point angles are low temperatures and short drilling times. Wandering (or walking) is the unwanted change of the positon of the drill bit before drilling into bone. A small point angle can prevent wandering. Some doubts may be raised as to whether this is true for drill bits with a large chisel edge. That will be discussed later in chapter 2.3.5. The disadvantages of small point angles are that the drill bits do not run that smoothly and have less wear resistance. (Milberg and Fuchsberger, 1984)

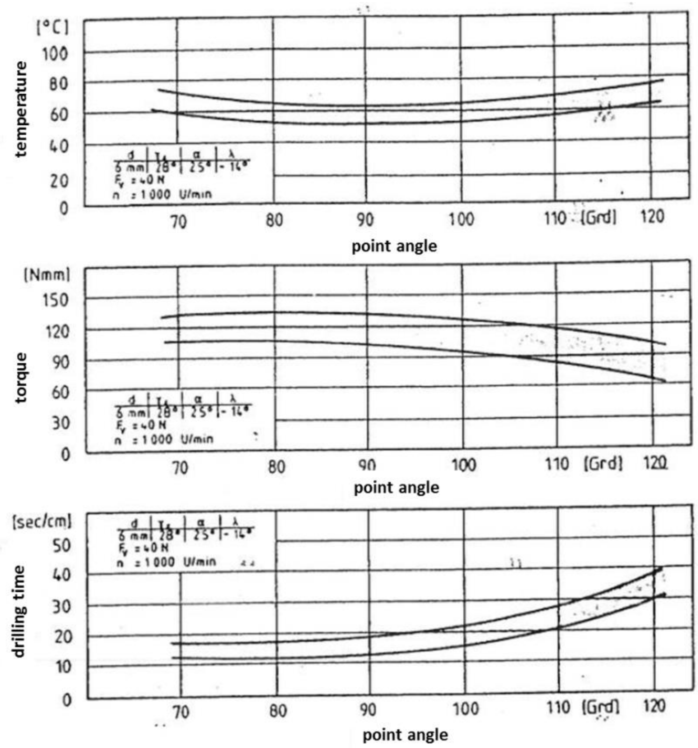


Fig. 22: Influence of the point angle (in °) during drilling of bone (adapted from Milberg and Fuchsberger, 1984)

Augustin et al. (2008) performed drilling experiments on cortical femoral specimen from porcine and canine bones. Different point angles (80°, 100° and 120°) were tested but no significant influence on the bone temperature during drilling has been observed. Hillery and Shuaib (1999) carried out drilling tests on human and animal bone with point angles of 70°, 80° and 90°. No significant difference has been noted in the temperatures by the authors.

To sum up, the relevance of the point angle has been studied by several researchers. However, the ideal point angle for bone drilling has not been established yet.

2.3.3 Helix Angle (γ_f) and Rake Angle (γ_0)

The helix angle determines the lead and the rake angle of the drill bit. Pandey and Panda (2013, p.23) define them as follows:

- Rake angle: *"It is defined as the angle between the cutting edge and the plane perpendicular to the workpiece."* (Fig. 14)
- Helix angle: *"Helix angle of the drill is defined as the angle formed by the edge of the flute with the line parallel to drill centre line."* (Fig. 15)

A larger helix angle generates an increased rake angle and decreases the wedge angle of the cutting face, which is good for the drilling forces. Saha et al. (1982) showed this interrelation in formula F6.

◊ $$\tan \gamma_{0i} = \frac{\left(\frac{d_i}{d}\right) \tan \gamma_f - \tan[\sin^{-1}(\frac{d_0}{d_i}) \sin \kappa] \cos \kappa}{\sin \kappa} \qquad \text{F6}$$

Where

- d_i any intermediate diameter
- d drill diameter
- γ_f helix angle
- $\varkappa$ half of point angle
- γ_{0i} orthogonal rake angle at any intermediate position
- d_0 chisel edge length

It can be seen that:

- The orthogonal rake angle is not constant along the cutting edge of a drill bit.
- A large chisel edge decreases the rake angle and the influence on the rake angle is rather small for common point angles (90-120°).
- The rake angle is mainly affected by the helix angle.

An optimal rake angle improves the cutting efficiency. Therefore, the helix angle should be fully considered when it comes to design a surgical drill bit.

In the literature, the terms of slow and fast helix come up frequently. Slow or low helix drills have a large lead and long flutes. In contrast, high or quick helix drills have a short lead and short flutes. Fig. 23 shows a comparison between these types.

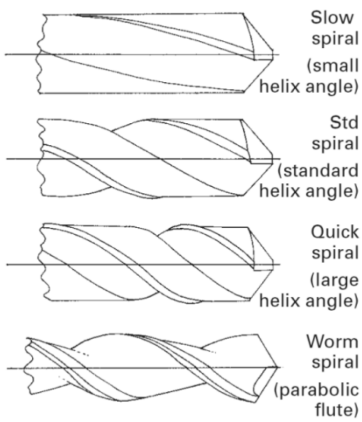


Fig. 23: Variations in helix angle and a worm spiral bit (Natali et al., 1996)

The DIN 1414-1 standard also provides information about the helix angle (Table 4). Depending on the material of the workpiece, a proper drill bit can be chosen. It should be noted that this DIN standard is suitable for engineering materials. Therefore, a classification for bone according to this standard is not meaningful. For hard materials like high strength steels, the helix angle should be in the range of 10-19°. For this configuration, the rake angle is small and the wedge angle large, which results in a high stability of the cutting edge but has disadvantages in terms of the cutting efficiency. Furthermore, a slow helix drill bit is used for short chipping materials like cast iron, because the chips are evacuated easily. Common surgical drill bits like the Synthes 310.350 (lot number 2609881, Fig. 24) have a helix angle of approx. 14°. Some doubts can be raised as to whether such a small helix angle is appropriate for surgical drill bits. On the one hand, mechanical properties of bone are not comparable with hard materials like high strength steels. Large wedge angels are not strictly necessary for drilling bones.

On the other hand, bone is not always short chipping. It becomes wet during surgeries (blood, marrow fat, irrigation). This makes the evacuation of the bone chips difficult and the flutes can get clogged easily. For such materials, quick helix drill bits (large helix angles) are far more suitable for the effective clearance. (Natali et al., 1996)

To conclude, a large helix angle has definite advantages when it comes to surgical drill bits. This has also been reported in the literature. The favourable cutting forces and the good cutting efficiency are two benefits from larger helix angles. Another main advantage is the good clearance of bone chips. As noted in Table 1, bone has a low thermal conductivity and the thermal load during drilling is concentrated mainly around the bore hole. Thus, the effective removal of bone chips is essential to lower the maximum temperature since the heat is primarily evacuated by the chips. Although there is a general agreement about the importance of larger helix angles (20-35°), surgical drill bits seem to neglect this issue to a large extend.

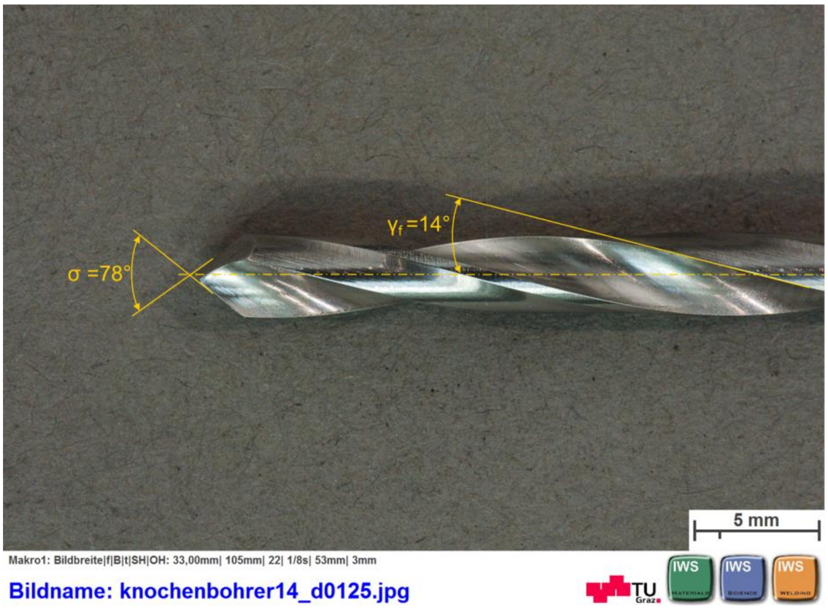


Fig. 24: Point angle (σ) and helix angle (γ_f) of a Synthes 310.350 surgical drill bit (lot number 2609881)

2.3.4 Clearance Angle (α) and Flank

The flank is a surface area on the tip of the drill bit (Fig. 13). It creates friction during drilling if it is not designed properly. Therefore, the contact between the flank and the bone should be as small as possible to keep the friction and temperature low. Relief-grinding is an appropriate method for this. It generates a clearance between the tool (drill bit) and the workpiece (bone). The measure for this is called clearance angle (α) or lip clearance in terms of drill bits (Fig. 15). There are recommendations in the literature about the ideal clearance angle, depending on the workpiece material. Small clearance angles are used for hard materials, because of the necessity of a stable cutting edge. Saha et al. (1982) suggested a clearance angle of 15-18° for surgical drill bits based on their hardness comparison of bone with soft materials. Pandey and Panda (2013) reported clearance angles of approx. 15° from their literature review. Natali et al. (1996) recommended a special drill point style, called split point. It has two different clearance angles along the surface which further decreases the friction (see Table 5). Chacon et al. (2006) investigated three different systems of drill bits which are used for dental treatment. They found that the temperatures during drilling were significantly higher for drill bits from the system B, which had no relief angle (synonymously used for clearance angle). But they pointed out that more research would be necessary to establish the correlation between relief/clearance angle and increased temperature.

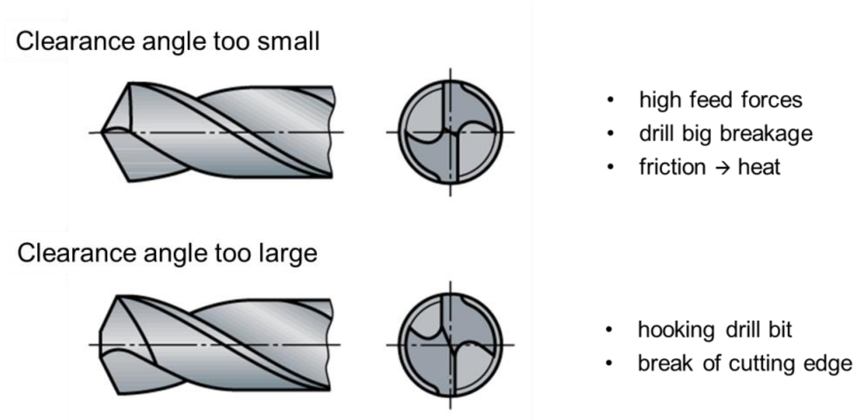


Fig. 25: Effects of wrong clearance angles (adapted from Dillinger et al., 2007, p.128)

The role of the clearance angle should not be underestimated. Grinding failures can cause relevant drilling problems (Fig. 25). The clearance of the Synthes 310.350 surgical drill bit (lot number 2609881) seems to be different from general recommendations. There is practically no relief-grinding on the drill tip, which can be seen in Fig. 26. Therefore, the clearance angle is also very small (approx. 4°). This fits to the observation that the flank is plain and not curved, which would be more usual.

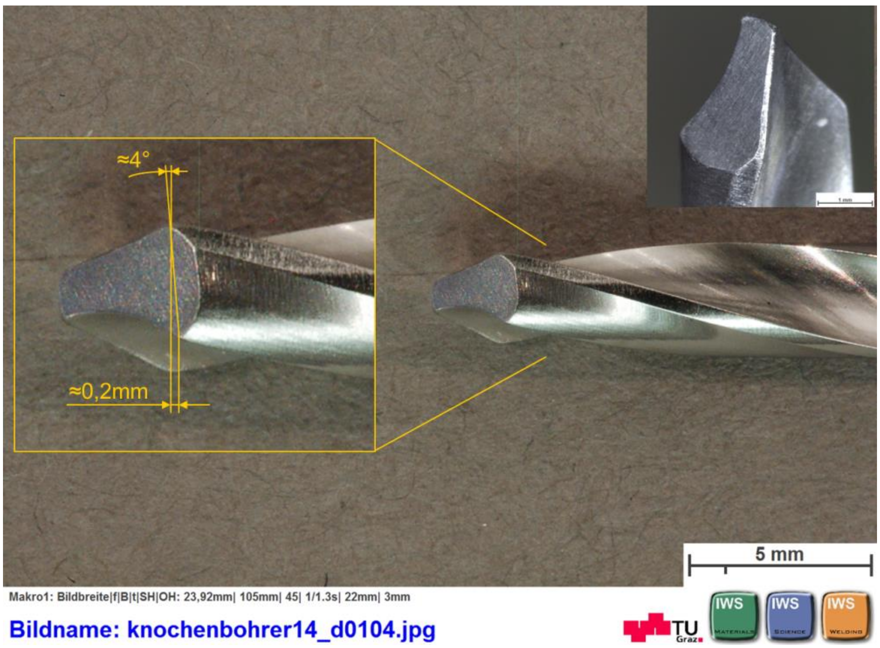


Fig. 26: Clearance angle and relief-grinding of a Synthes 310.350 surgical drill bit (lot number 2609881)

Another Synthes 310.350 surgical drill bit (lot number 9138656) has been investigated. The drill bit has been manufactured in 09/2014 according to the information on the packaging. Apparently, the lip relief and the clearance angle are different to the previous Synthes drill bit. As shown in Fig. 27, the clearance angle is obviously larger on this drill bit. Same specifications have been observed on three other Synthes 310.350 drill bits with the same lot number 9138656. Whether Synthes has changed their grinding process in the long term has not been investigated so far, but this configuration better meets the recommendations from the literature.

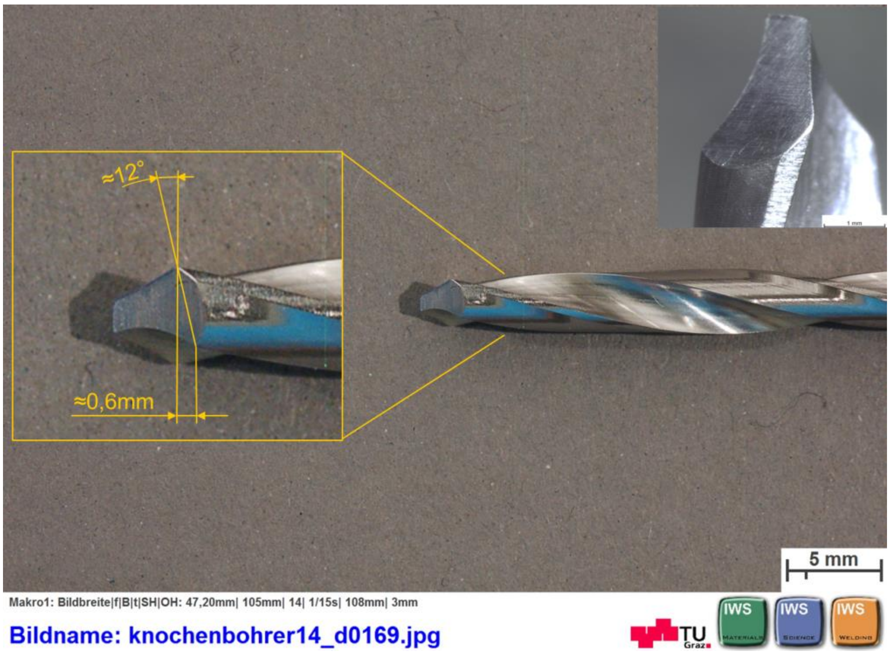


Fig. 27: Clearance angle and relief-grinding of a Synthes 310.350 surgical drill bit (lot number 9138656)

It has been shown that the clearance angle influences the drilling forces and the temperature during drilling. Hence, an appropriate angle for surgical drill bits should be determined. Based on the findings from the literature, angles in the range of 12-15° seem to be suitable. The first examined drill bit from Synthes does not fit to this result because of the small clearance angle. As a consequence, higher drilling forces and additional thermal load can occur.

2.3.5 Chisel Edge

The chisel edge connects the cutting edges on the tip of the drill bit (Fig. 28). It is well known that the chisel edge mainly affects the thrust force during drilling. This is because it does not take part on the cutting process. The chisel edge only quenches the material, while the cutting edges cut the material and produce the chips. Saha et al. (1982) noted that the chisel edge increases the thrust significantly, due to the low cutting speeds and the negative rake angle. Therefore, the ratio of the chisel edge to the cutting edge is important. Saha et al. (1982) further conducted interesting experiments. They performed drilling tests on bone and bone cement to evaluate the influence of the chisel edge on the thrust. In their experiments, they predrilled holes with a diameter equal to the length of the chisel edge (1.5 mm) of a larger drill bit (ø6.35 mm). After that, the hole was widened with the ø6.35 mm drill bit. In the next attempt, the holes were drilled with the ø6.35 mm without predrilling. The drilling experiments were performed with a constant feed rate of 0.128 mm/rev and a drilling speed of 940 rpm. The thrust load was measured with a dynamometer. The results were similar for the bovine bone and the bone cement: predrilling with a small diameter equal to the chisel edge has reduced the thrust load by about 45 %. It can be seen from this experiment that the modification of the chisel edge is substantial for cutting efficiently.

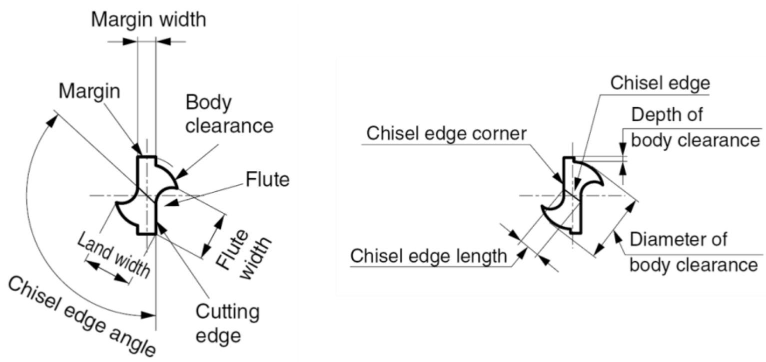
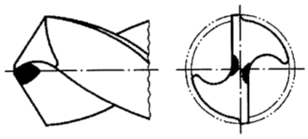
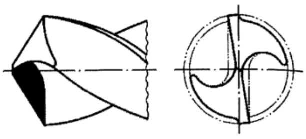
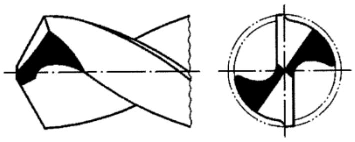
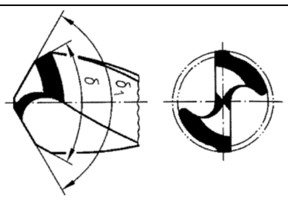


Fig. 28: Drill point specifications (Sumi Tool, 2014)

But thrust load is not the only issue related to the chisel edge. Surgical bone drilling is basically a manual process, since the surgeon uses a hand drill to create the bore holes. For a well-performed osteosynthesis, the locations of the bore holes are essential. But in surgical treatment, it is not always easy to drill a hole exactly at the desired position. On the one hand, the surface of bone is curved which makes the positioning of the drill bit difficult. On the other hand, a large chisel edge is also a typical reason for drill bit walking (Saha et al., 1982). For a high drilling accuracy, a modification of the drill tip is necessary. Natali et al. (1996) reported the advantages of a split point drill bit, which increases the clearance angle along the flank. This further separates the chisel edge and influences its rake angle positively, which allows the chisel edge to take part in the cutting process. Additionally, the friction during drilling is also decreased.

Due to the particular task, there are further drill point modifications according to DIN 1412 (Table 5).

Table 5: Drill point styles for twist-drill bits according to DIN 1412

Drill point (DIN 1412)	Description[10]
	**Form A - Point Thinning** The chisel edge is decreased to about 10 % of the drill bit diameter + lower feed force (axial drilling force) + self-centering
	**Form B - Point Thinning + Modified Cutting Edge** Modification of the helix angle (γ_f) in the area of the cutting edge + no "hooking" of the drill bit + shorter chips, better heat transfer
	**Form C - Split Point** Separated chisel edge and flanks + good centering and lower feed forces + for drill bits with large web
	**Form D - Double Angle Points** The corner of the cutting edge is removed + prevention of breakouts + good evacuation of the heat

The potential of various drill bit styles should be considered also for surgical drill bits. For surgeons, a precise location is essential. For instance, a self-centering drill bit prevents from walking. A modified chisel edge is not only good for the location but also for the thrust load (axial drilling forces). From a theoretical point of view, the point styles DIN 1412 A and C should be taken into account for an improved surgical drill bit design.

[10] Information from Dillinger (2007, p.128) and Reichard (2003, p.156)

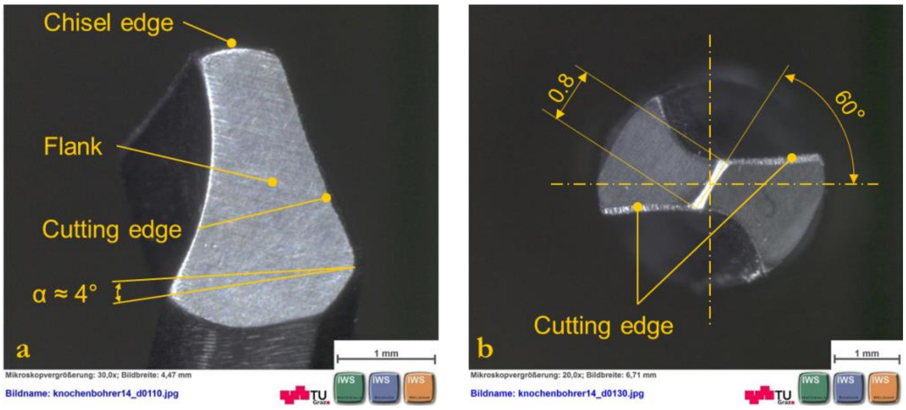


Fig. 29: Synthes 310.350 (lot number 2609881)
a) Specifications; b) Chisel edge width (0.8 mm) and chisel edge angle (60°)

Compared to the information in this chapter, the chisel edge and drill point style from the Synthes 310.350 (440A) with the lot number 2609881 appears completely different. The chisel edge angle is related to the relief grinding and to the lip clearance angle. In mechanical engineering, a chisel edge angle of approx. 55° is characteristic if the clearance angle is grinded properly. The chisel edge angle of the Synthes drill bit is about 60° (Fig. 29) which indicates eventually a small clearance angle. This relationship between chisel edge angle and clearance angle is shown in Fig. 25. Furthermore, the chisel edge width is approx. 0.8 mm. It can be expected that such a large chisel edge causes large axial drilling forces and increases the probability of drill bit walking.

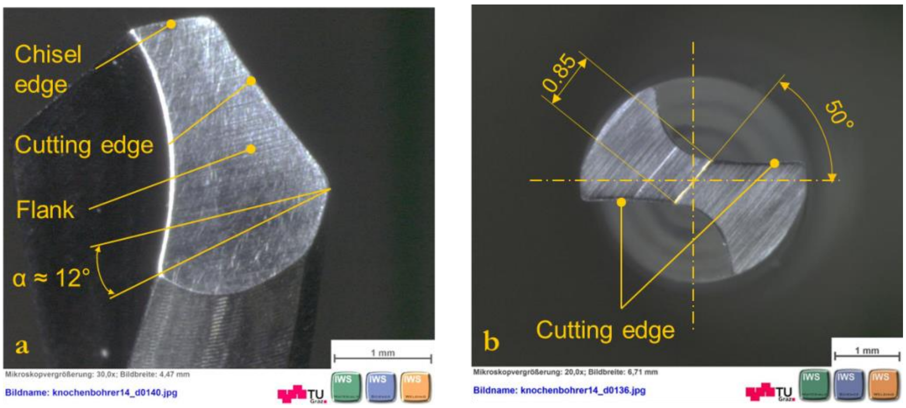


Fig. 30: Synthes 310.350 (lot number 9138656)
a) Specifications; b) Chisel edge width (0.85 mm) and chisel edge angle (50°)

As already mentioned in chapter 2.3.4, the Synthes drill bit with the lot number 9138656 is different in terms of clearance and relief. Also the chisel edge angle (50°) is smaller and the chisel edge width is slightly bigger, which can be seen in Fig. 30. Therefore, drill bit walking and higher thrust load could be expected from this drill bit too. Both aspects are unwanted during surgical treatment.

2.3.6 Flutes

The flute is a groove which twists around the drill bit. There can be one or more flutes, but the two-flute drill bit is the most common type. In this thesis, the focus is clearly on two-flute twist drills, which are frequently used in surgery and orthopaedics. But in this chapter, a comparison to a three-flute drill bit is provided too. Flutes are necessary to transport the bone chips out of the bore hole. According to Bertollo and Walsh (2011), the bone chips evacuate approx. 60 % of the thermal energy out of the bore hole during drilling. This emphasises the importance of an effective clearance where the flutes do not clog. Fig. 31 shows the cross sectional area of a Synthes 310.350 drill bit.

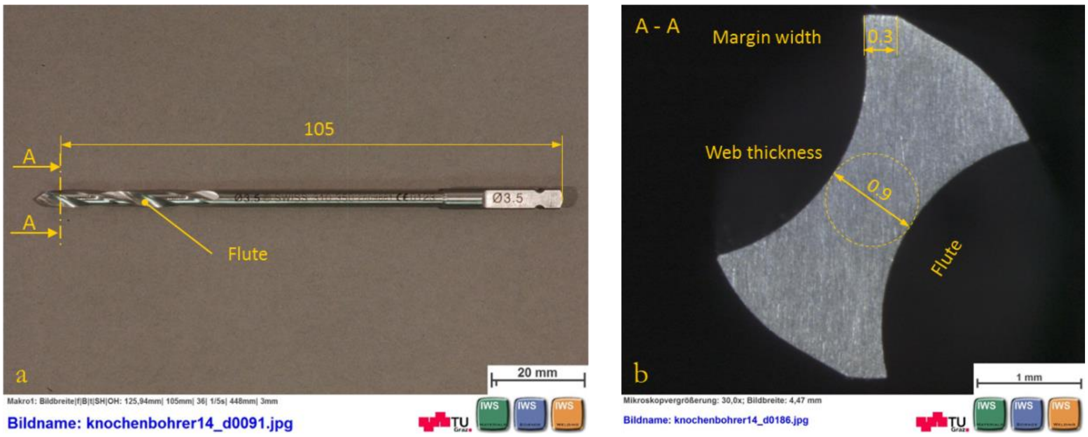


Fig. 31: Flute specifications of a Synthes 350.310 drill bit (lot number 2609881)

Natali et al. (1996) performed drilling tests with five different 2.5 mm drill bits on fresh cadaver tibia. The temperature was measured at several distances (0.5, 1.0 and 1.5 mm) from the drill hole. Fig. 32 shows the importance of clear flutes and an appropriate evacuation of bone chips. The AO surgical drill bit with blocked flutes caused the highest mean bone temperatures.

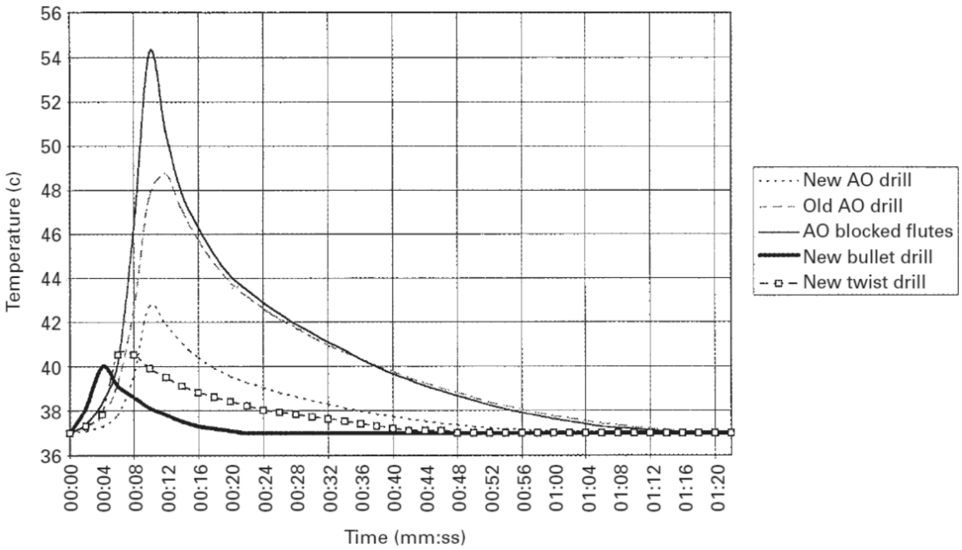


Fig. 32: Comparison of five different drill bits at 0.5 mm from the drill hole (Natali et al., 1996)

In general, the flute is a groove which is determined mainly by the flute width (Fig. 28), the helix angle (γ_f, chapter 2.3.3) and the web thickness. Bertollo et al. (2008) compared two-flute and three-flute surgical drill bits. They found that three-flute drill bits have an advantage in terms of bending stiffness if the measurements between both drill bit types are comparable. Another advantage according to Bertollo et al. (2008) is that the cutting edges of three-flute drill bits tend to coincide in a single point at the tip (Fig. 33), which reduces the chisel edge to a minimum. This allows precise drilling and reduces drill bit walking.

Fig. 33: Comparison of two- and three-flute surgical drill bits[11]
1: Synthes 315.33, excessive wear visible
2: Synthes 310.290, very little wear visible

Although the positive aspects of three-flute drill bits have been highlighted by Bertollo et al. (2008), a lack of evidence about their usage exists in literature (Pandey and Panda, 2013).

2.3.7 Outcome – Geometry

In this chapter, relevant geometric parameters of surgical drill bits were examined. It was found different parameters varies have diverse influence.

It is well established that the drill diameter influences the temperature during drilling. Predrilling is a good method to decrease the temperature for large holes but it increases also the operation time. The positive effect of two-step drill bits have not been stated clearly in the literature. The point angle (σ) has been investigated by several researchers, but there is no general agreement about the ideal angle. Based on the reviewed literature, there is a slight tendency to higher point angles similar to the fields of general engineering. The helix angle (γ_f) also has been in the focus of different studies. Out of it, recommendations on large helix angles can be extracted. They have advantages in terms of cutting forces and cutting efficiency and also facilitate good evacuation of wet bone debris. There is a general agreement in the literature about the effect of the clearance angle (α). The clearance angle is essential for reducing the friction on the contact area between the drill bit and the bone. It further influences the drilling forces and the temperature during drilling. For general engineering applications, the clear-

[11] Both drill bits were removed from operation theatres at LKH Graz, provided by Mositech Medizintechnik GmbH

ance angle is related to the material of the workpiece. Based on reviewed literature, a clearance angle between 12-15° seems to be appropriate for surgical bone drilling.

The effect of the chisel edge has also been analysed in detail. The investigated drill bits from Synthes have a large chisel edge compared to the drill bit diameter. This increases the axial drilling force because of the unfavourable cutting geometry of the chisel edge. Another disadvantage of a large chisel edge is the phenomenon of drill bit "walking" which negatively affects the accuracy. In this connection, various drill point styles have been described. Split point and point thinning are two promising alternatives to decrease the thrust and to provide higher accuracy because of self-centering. The flutes of drill bits are necessary for an appropriate evacuation of the bone chips. Clogging flutes cause high temperatures and have to be avoided. Even though three-flute drill bits have advantages concerning the strength, two-flute drill bits are more common in the operation theatre.

Based on the reviewed literature, it seems that the geometry of common drill bits has potential for improvement. Most of all, the small helix angle (approx. 14°, Fig. 24) and the large chisel edge (approx. 0.85 mm, Fig. 30) differ widely from the recommendations. To sum up, the geometric specifications of surgical drills should not be underestimated. They have a significant influence on various factors such as drilling temperature, drilling forces or cutting efficiency and therefore, have to be well considered.

2.4 Surgical Drill Bit - Cutting Conditions

Beside the geometry of a drill bit, the cutting conditions are essential for the process of drilling. In engineering, information about cutting conditions during drilling is readily available. Depending on the material of the workpiece, the right parameters can be adjusted to keep the temperature and the drill bit wear low. But since bone is a non-homogenous material (chapter 2.1.2), finding proper conditions is far more complex than with simple engineering materials like aluminium or steel. In this chapter, relevant parameters for surgical bone drilling are described and related literature is reviewed. In the end, clear recommendations towards appropriate conditions are provided to prevent thermal necrosis as good as possible.

2.4.1 Spindle Speed (n)

In this thesis, the term spindle speed will be used synonymous with the term drill speed for the rotational speed of the drill bit. It is defined as the number of spindle revolutions in a given time interval. For drilling, a common unit is revolutions per minute (rpm).

Matthews and Hirsch (1972) investigated the effect of spindle speed on the average maximal temperatures during drilling on human cadaveric cortical bone. They could not find significant differences in maximum temperatures at any distance from drill (Fig. 34a). The threshold for the risk of thermal necrosis is 47 °C according to chapter 2.1.1. Due to this, the authors investigated the duration of temperature elevation above 50 °C for different spindle speeds at several distances from the drill (Fig. 34b). The results show significant differences only for the shortest distance (0.5 mm) to the drill.

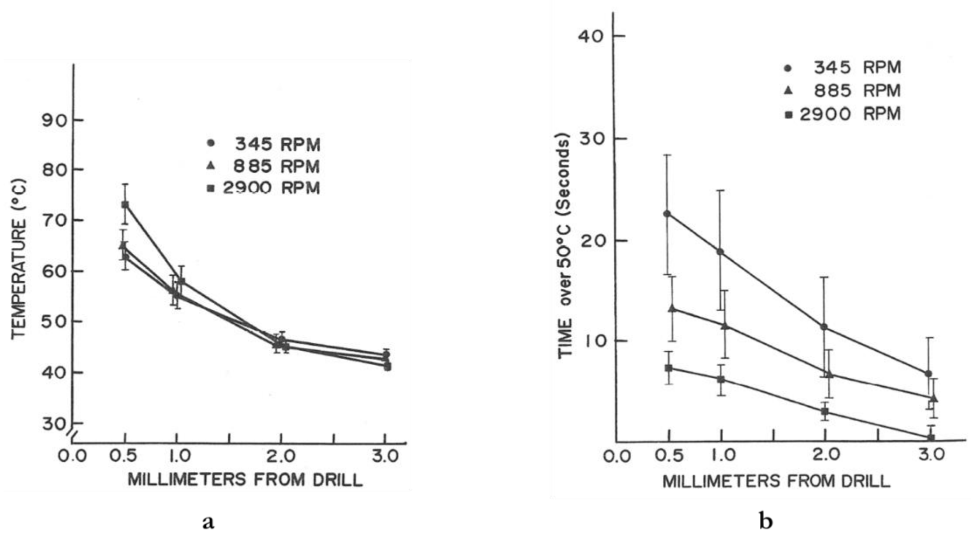
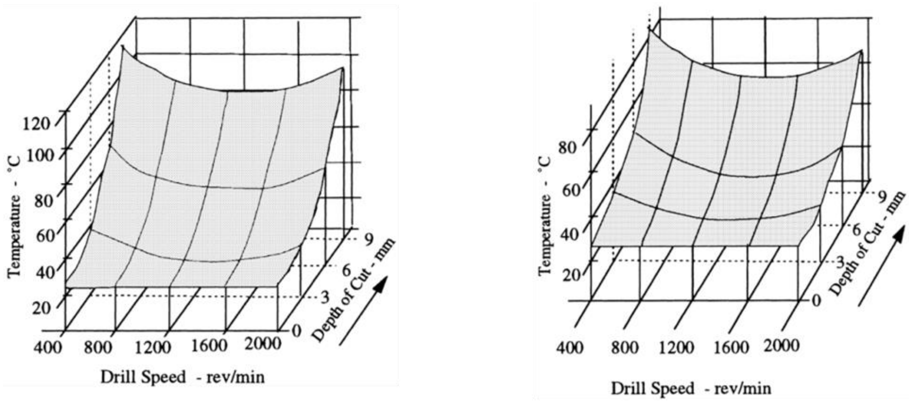


Fig. 34: Spindle speed and thermal load (Matthews and Hirsch, 1972)
a) Effect of spindle speed on the maximum temperature (cortical bone)
b) Effect of spindle speed on the duration of temperature level above 50 °C

Augustin et al. (2008) have found that an increase of the drill speed results in an increase of temperature without external irrigation. Hillery and Shuaib (1999) performed their experiments on human and bovine bones with 3.2 mm drill bits. They recommended spindle speeds of 800-1400 rpm for acceptable temperatures (Fig. 35).



a b

Fig. 35: Temperature vs. speed and depth (Hillery and Shuaib, 1999)
a) Bovine cortical bone; b) Human bone

Reingewirtz et al. (1997) reported a positive correlation between temperature raise and increase of spindle speed in the range of 400 rpm to 10,000 rpm. Pandey and Panda (2013) concluded that there is a general agreement in the literature about the increase of temperature with the spindle speed up to 10,000 rpm. Karaca et al. (2011) performed drilling experiments on bovine tibia. They found that a higher bone mineral density (g/cm²) and an increase in drill speed result in higher bone temperatures.

Lee et al. (2012) presented experimental investigations about several cutting parameters on the temperature of cortical section of bovine femur. In their study, a spindle speed of 800 rpm caused lower temperatures than spindle speeds of 2,800 and 3,800 rpm (2.5 mm drill bit and 26 °C initial temperature). This is interesting since 800 rpm is a common spindle speed for surgical hand drills (Fig. 36).

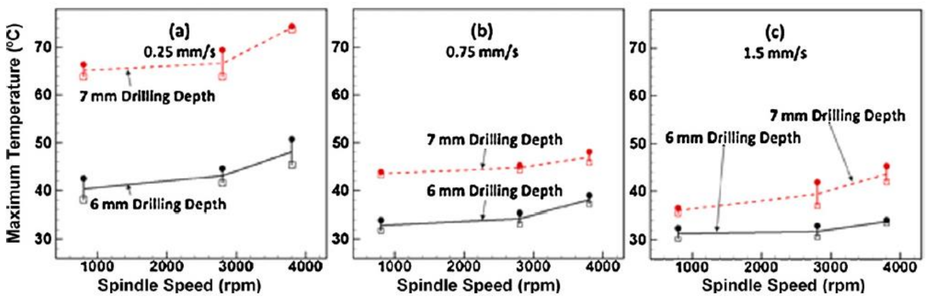


Fig. 36: Maximum temperature at 3 mm depth as function of spindle speed for different feed rates (Lee et al., 2012)

Although the influence of the spindle speed on the bone temperature is well described in the literature, it should not be overestimated. Drilling machines in surgery and orthopaedics are usually hand drills which are electric- or air-driven. For both types, the speed range is limited. Common drill speeds for air-driven devices are 800-900 rpm and there is hardly any adjustability. That makes the question about the optimal spindle speed redundant for drilling bone with ordinary surgical tools. This is a major difference to general engineering where the adjustment of the drill speed is typical. Since drill speed adjustment is not popular for surgical bone drilling, factors like drill bit diameter or bone density are usually left out of consideration.

2.4.2 Cutting Speed (v_c)

The cutting speed v_c (m/min) can be defined as the current speed of cutting motion on the cutting edge (Fig. 37). In the fields of general engineering, the cutting speed is an important quantity. The choice of the right value is essential for the temperature load, drill bit wear and the overall cutting efficiency. Therefore, recommendations about the cutting speed for engineering materials are widely available in technical literature (Table 6).

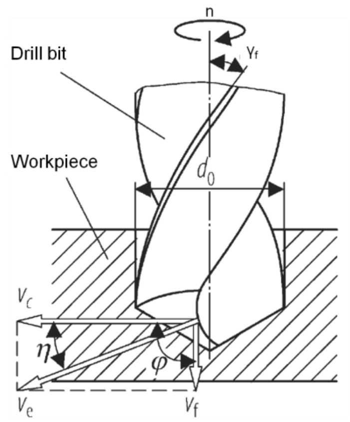


Fig. 37: Cutting speed (v_c) and feed rate (v_f) of a twist drill bit (Grote and Feldhusen, 2014, p. S 53)

There is a simple connection between spindle speed and cutting speed (F7).

◊ $$v_c = \frac{d \times \Pi \times n}{1000}$$ F7

d…diameter in mm
n…spindle speed in rpm
v_c…cutting speed in m/min

For surgical bone drilling, there are no general recommendations for the ideal cutting speed provided. As can be seen in F7, the spindle speed is a main influence factor for the cutting speed. The usual approach in engineering is to determine the right cutting speed according to the literature. With the desired drill diameter, the spindle speed can be calculated easily. But as in chapter 2.4.1 described, the spindle speed is not adjustable for the majority of manual surgical hand drills. Udiljak et al. (2007) performed experiments with 4.5 mm drill bits (classical and step-drill) and found out that the temperatures were higher for low cutting speeds (6.53 m/min ≙ 449 rpm) than for high cutting speeds (140-255 m/min ≙ 9,908-18,038 rpm).

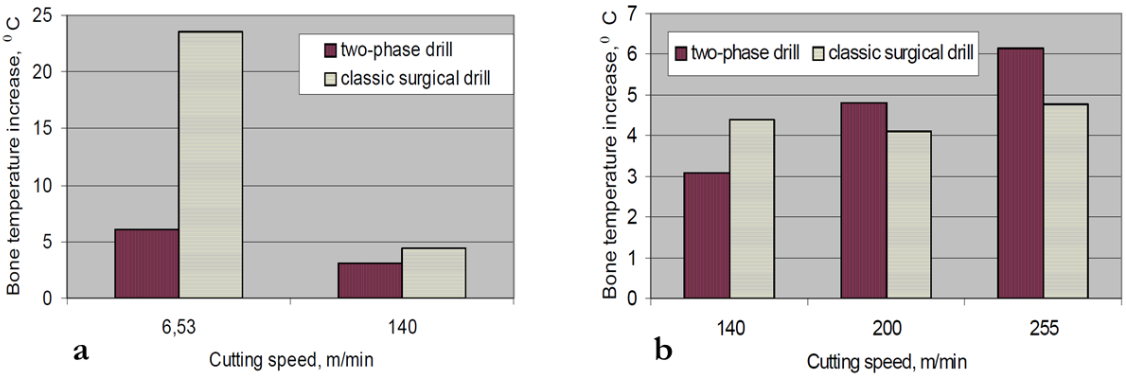


Fig. 38: Bone temperatures for different cutting speeds (Udiljak et al., 2007)
a) Comparison of classical drilling and high speed drilling
b) High speed drilling with a surgical drill and a two-phase step drill bit

Table 6: Recommended cutting parameters for twist-drill bits made of HSS for bore holes up to 3x drill diameter (adapted from Dillinger, 2007, p.126)

Workpiece material	**v_c** in m/min	**f** in mm/rev for drill diameter… 2…5	5…10	10…16
Steel UTS < 700 N/mm²	25…30	0.10	0.20	0.28
Steel UTS = 700…1000 N/mm²	15…20	0.07	0.12	0.20
Steel UTS > 1000 N/mm²	10…15	0.05	0.10	0.15
Cast iron 120…260 HB	25…30	0.14	0.25	0.32
Aluminium alloys short chipping	40…50	0.12	0.20	0.28
Thermoplastics UTS = 40…70 N/mm²	25…30	0.14	0.25	0.36

Fig. 38a shows that the bone temperatures were lower for high speed drilling compared to classical drilling. Furthermore, the positive influence of the two-phase step drill can be seen in the figure. But it should be considered that high speed drilling is more usual to dental treatment whereas in surgery and orthopaedics speeds are typically lower than 1,000 rpm (Bertollo and Walsh, 2011).

In one of their work, Milberg and Fuchsberger (1984) noted the qualitative influence of the cutting speed on the temperature (Fig. 39). Between 20 and 100 m/min, a decrease of temperature of about 20 % can be identified. This is true for steel, cast steel and cast iron at average feed rates.

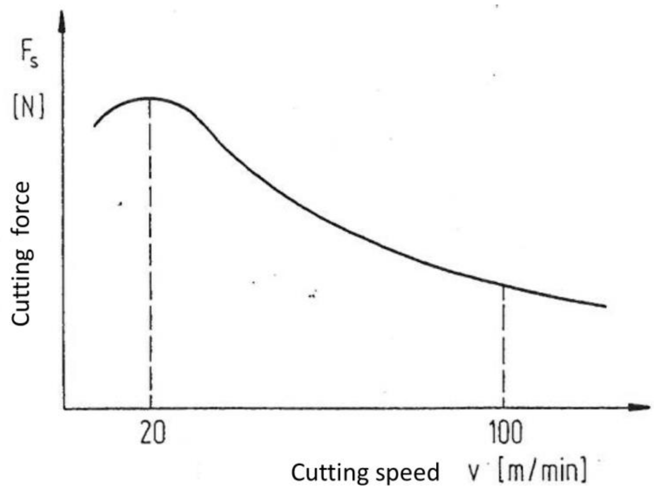


Fig. 39: Qualitative influence of the cutting speed on the cutting force (adapted from Milberg and Fuchsberger, 1984)

In the same study, the authors performed drilling experiments with fresh bovine compact bones. They investigated the influence of the cutting speed on the temperature, torque and drilling time (Fig. 40). In terms of the temperature, it can be seen that there is a small increase if the cutting speed rises. For a cutting speed of 4.7 m/min (n = 500 rpm; d = 6 mm) the temperature is about 60 °C. The peak value of 75 °C can be observed at about 28.3 m/min (n = 1,500 rpm; d = 6 mm). Milberg and Fuchsberger (1984) noted that higher cutting speeds result in more cutting energy which further increases the temperature. Anyway, the influence of the cutting speed on the bone temperature is rather small. This is also true for the torque, as Fig. 40 shows. In their study, the authors referred the drilling time to the drilling depth (normalised drilling time in s/cm). For low cutting speeds, the curve falls sharply and approaches asymptotically 15 s/cm. The interpretation is quite simple: lower cutting speeds cause lower temperatures but further result in longer drilling times. Longer drilling times are unfavourable because they increase the duration of temperature impact on the bone. The drilling time will be discussed in detail in chapter 2.4.5. On the other hand, too high cutting speeds do not affect the drilling time positively and even increase the temperature. Therefore, Milberg and Fuchsberger (1984) recommended cutting speeds between 12 and 20 m/min (approx. 600-1,000 rpm; d = 6 mm) for efficient cutting.

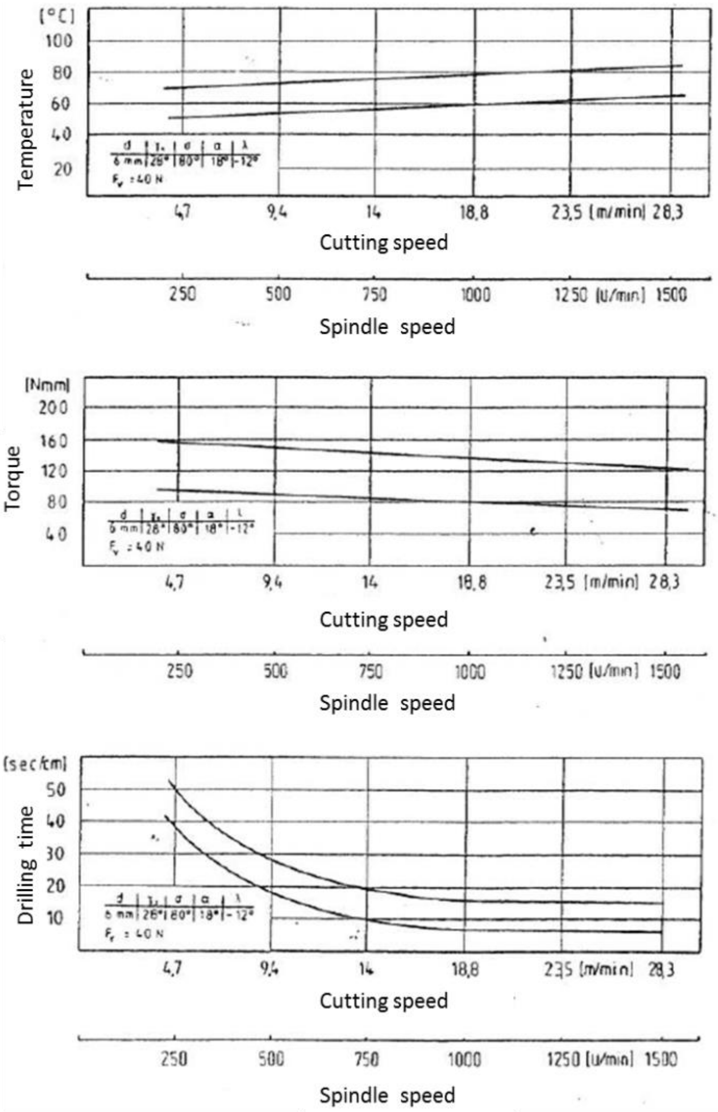


Fig. 40: Influence of the cutting speed during drilling of bone (adapted from Milberg and Fuchsberger, 1984)

In this section, the influence of the cutting speed on the process of surgical bone drilling has been described. Since common surgical drilling tools have practically no possibility for adjustment of related parameters, the provided information is not convertible for surgeons. Furthermore, high speed cutting is not usual in surgical operation theatres. Therefore, the cutting speed should not be overestimated for the determination of the ideal cutting conditions.

2.4.3 Feed (f) and Feed Rate (v_f)

The feed rate indicates the speed of the cutting tool in direction of the feed. For drilling, it is along the axis of the drill bit, which is shown in Fig. 37. Together with the cutting speed, the feed is the second essential parameter for cutting that can be assigned from the literature (Table 6). Feed and feed rate are connected together with the spindle speed (F8).

◊ $$v_f = n \times f \tag{F8}$$

v_f…feed rate in mm/min
n…spindle speed in rpm (rev/min)
f…feed in mm/rev

Again, there are no definite recommendations provided about the ideal feed rate for surgical and orthopaedic drilling. But it should be noted that drilling with constant feed is only possible with automatic drilling devices. As already mentioned, surgical bone drilling is performed by the surgeon with a hand drill. Drilling with constant feed or feed rate is impossible. Therefore, the accuracy and the feed depends most of all on the surgeon. Hillery and Shuaib (1999) have chosen feed rates of 40 to 60 mm/min (≙ 0.67 to 1 mm/s) as appropriate for their experiments. Anyway, the surgeon should be able to control the feed during drilling qualitatively. Rough recommendations can be implemented into the process of surgical drilling for this reason. This is important, because it has been shown that there is a general agreement about the feed rate in the literature. Udiljak et al. (2007) concluded that the feed rate acts inversely proportional to the bone temperature during drilling and proportional to the axial drilling force. Therefore, the feed rate should be as high as possible without damaging the bone with too high axial forces. In their drilling studies on bovine femurs, Lee et al. (2012) also emphasised the role of the feed rate. With increasing feed rates, the maximum temperature decreases even if the shear energy increases. But on the other hand, higher feed rates result in shorter drilling times. So, the time of temperature impact to the bone and also the heat transferred from the drill bit into the bone are reduced. This means good conditions to prevent thermal necrosis.

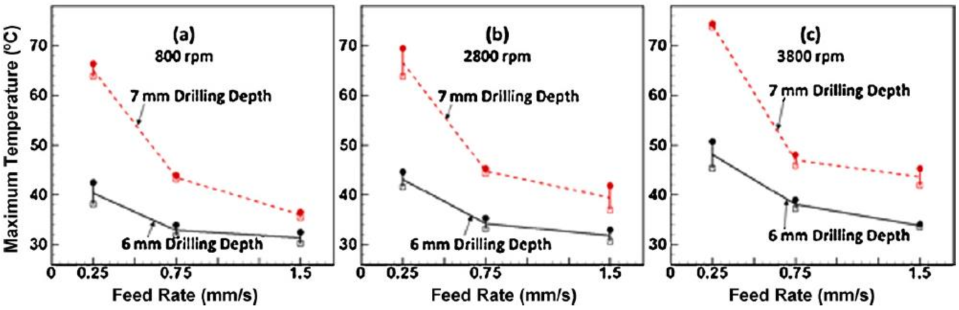


Fig. 41: Maximum temperatures as a function from the feed rate for different spindle speeds (Lee et al., 2012)

Lee et al. (2012) used new 2.5 mm carbide drill bits (σ = 118°, γ_f = 20°) to minimize the effect of drill bit wear. The temperatures were measured with a thermocouple at 3 mm depth in a distance of 0.5 mm to the bore hole. Fig. 41 shows the results from the experiments. It can be seen that the temperatures decrease when the feed rate increases – independently from the spindle speed. At this point it should be considered that the authors did not measure the drilling forces during their experiments. Furthermore, feed rates of 1.5 mm/s are expected to be too fast for surgical drilling by hand. Karaca et al. (2011) also observed that the temperature decreased with increasing feed rate and drilling force for drill speeds from 200 to 800 rpm. This was established again in a recent study by Karaca and Aksakal (2013). To avoid thermal necrosis, they recommended high drilling forces and high feed rates (Fig. 42).

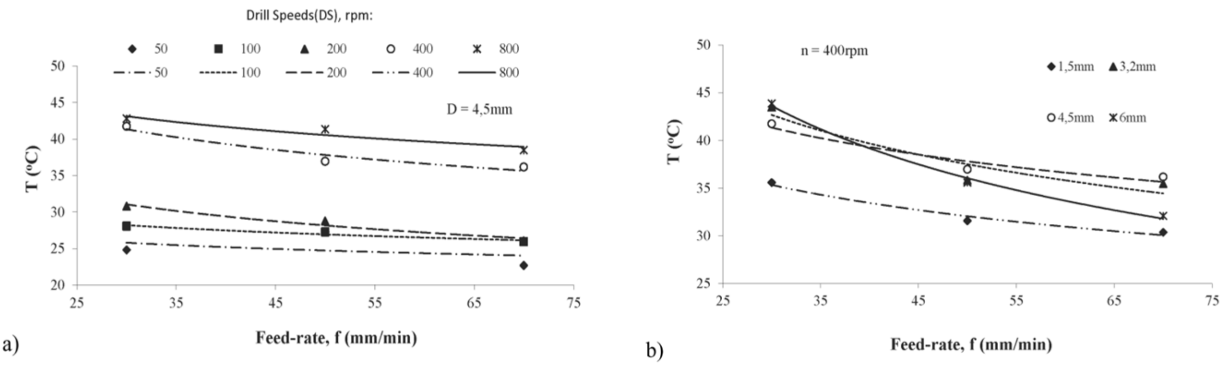


Fig. 42: Effect of the feed rate on the drilling temperature (Karaca and Aksakal, 2013)
a) For different drill speeds; b) For different drill diameters

Augustin et al. (2012a) noted the problem of inefficient cutting which occurs when excessively high feed rates are combined with extremely low cutting speeds. They reported broken bone samples during their experiments under such experimental conditions.

To sum up, high feed rates are desirable for surgical bone drilling with regard to thermal necrosis. It has been shown that the duration of heat impact as well as the maximum temperature of the bone decreases with increasing feed rate. But it should be taken into account that the axial drilling force correlates positively with the feed rate. It depends on the skills of the surgeon, to drill fast enough but also keep the axial load in a harmless range for the bone.

2.4.4 Axial Drilling Force (F_D)

In this thesis, the axial drilling force (F_D) is used synonymously to the feed force (F_f, see Fig. 16) from chapter 2.2.2. It can be seen as a result from the thrust applied by the surgeon in terms of surgical and orthopaedic treatment. In chapter 2.3.5, it has been shown that the length of the chisel edge influences the feed force significantly. This is an important reason for the modification of the drill point. In the previous chapter, the strong interrelation between drilling force and feed (rate) has been stated. In this section, research about the drilling force in the literature will be discussed.

Milberg and Fuchsberger (1984) examined the influence of the feed force on the temperature, torque and drilling time. Their results fit well to the theoretical expectations. As shown in Fig. 43, the temperature curve falls slightly for higher feed forces. Between 10 and 60 N, the temperature decreases by 10 °C. As already mentioned, higher feed forces result in higher feed rates and shorter drilling times. Despite the higher shear energy, the shorter duration of exposure of thermal load lowers the bone temperature. The torque has the tendency to increase almost linearly with increasing feed force up to a maximum value of approx. 200 Nmm. Higher feed rates result in thicker chips which have to be cut at every drill bit revolution (F4). Thicker chips require higher cutting forces which further increases the torque (F1-F3). As Fig. 43 illustrates, the drilling time decreases significantly if the feed force increases. This has already been described in the previous chapter. In the range between 10 and 40 N, the drilling time decreases rapidly. For higher feed forces (40-60 N), the drilling time approaches a horizontal line which indicates only a small decrease in this range. Milberg and Fuchsberger (1984) concluded that a further increase of the feed force will result only in barely noticeable changes of the drilling time. Due to this, they recommend the transition area of the curve between 40-50 N as ideal for drilling into bone.

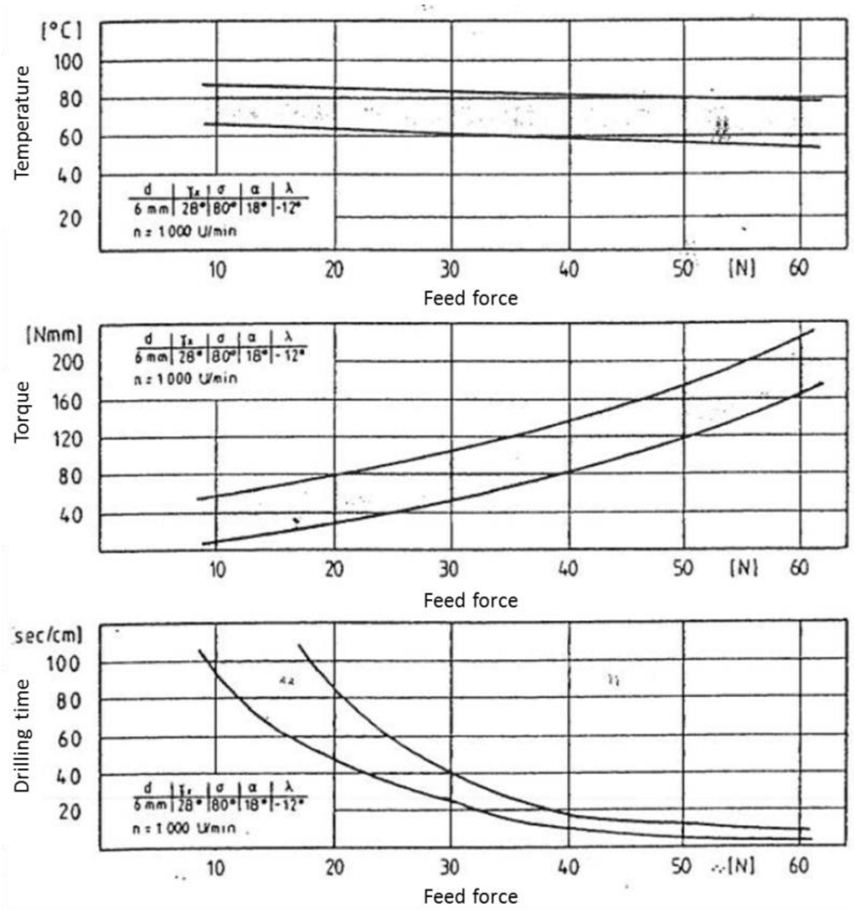


Fig. 43: Influence of the feed force during drilling of bone (adapted from Milberg and Fuchsberger, 1984)

Karaca et al. (2011) also found similar results and pointed out that with increasing drill force, the bone temperature decreases and also the drilling time is shorter. Saha et al. (1982) demonstrated the advantages of their new designed drill bit (σ = 118°, γ_f = 36°, parabolic flute) in terms of thrust load (-45 %) and peak temperature (-54 %). Furthermore, they drew the attention to the negative effect of the chisel edge on the drilling force (chapter 2.3.5). Hillery and Shuaib (1999) reported that the thrust force decreases with increasing spindle speed for a constant feed rate of 50 mm/min.

Bachus et al. (2000) performed an in vitro study on cortical bone specimens obtained from human cadaver femora. Their focus lied on the effects of the drilling force on the bone temperatures and on the drilling duration. The experiments were performed with 3.2 mm Synthes (310.31, 440A) surgical drill bits and the constant applied drilling forces were between 57 and 130 N. The spindle speed was 820 rpm and the specimens were clamped in a water bath (37 °C) to simulate the human body temperature. They concluded that larger drilling forces result in not only lower maximum temperatures (Fig. 44a) but also in decreased duration of harmful exposure times of thermal load (Fig. 44b). They set 50 °C as threshold for thermal necrosis, which fits to the findings from chapter 2.1.1. It can be seen that drilling forces larger than 80 N are useful for the prevention of thermal necrosis. At this point it should be noted that the experimental setup seems to be well chosen in respect of real surgical conditions.

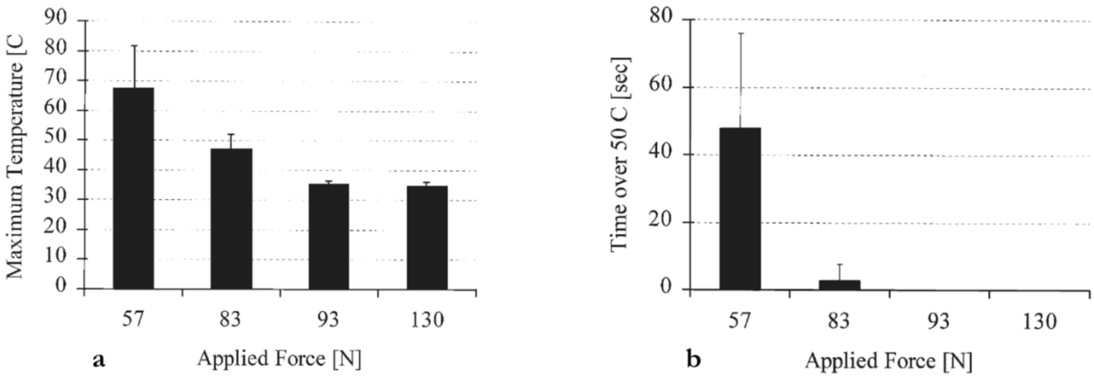


Fig. 44: Influence of the drilling force on the temperature and duration (Bachus et al., 2000)
a) Cortical temperatures at 0.5 mm distance from the drill hole
b) Duration of cortical temperatures above 50 °C

Matthews and Hirsch (1972) also noted the positive effects of increasing drilling forces on the temperature at several distances from the drill bit. Not only the maximum temperature but also the duration of temperature elevation above 50 °C has been decreased with increasing drilling forces.

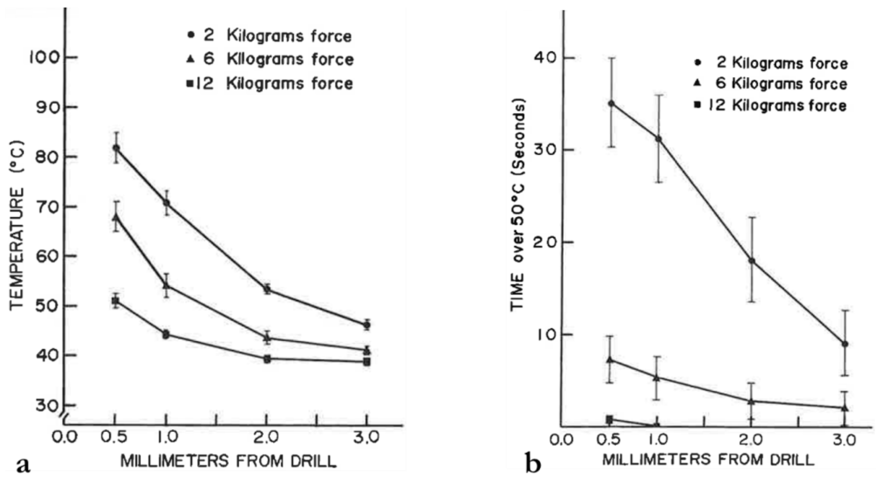


Fig. 45: Effect of the drilling force on the bone temperature (Matthews and Hirsch, 1972)
a) Effect of the drilling force on the average maximum cortical temperature
b) Effect of the drilling force on the duration of temperature elevation above 50 °C

Previous research at the IWS has also focused on the drilling force. In a recent diploma thesis, Stoiber (2014) investigated two typical surgical drill bits from different manufacturers

(Synthes and Brasseler[12]) which are widespread in surgical theatres. In his drilling experiments, holes were drilled into artificial bones and drilling forces were measured (spindle speed 800 rpm, feed rate 70 mm/min). He also modified the drill bits at the drill point: the chisel edge length was reduced, the drill point was changed following DIN1412-Form A (see chapter 2.3.5) and the point angle was increased from 80° to 90° for the Synthes drill bit. It can be seen from the work that the drilling force increased with every new drilled hole for every drill bit. According to Stoiber (2014), the proceeding drill bit wear was the reason for this. But some results were surprising asthe modified Synthes drill bit produced higher drilling forces than the original one (Fig. 46a). This speaks against the positive effect of a short chisel edge length which is described above and in chapter 2.3.5. For the Brasseler drill bit, the modifications lowered the drilling forces as expected (Fig. 46b).

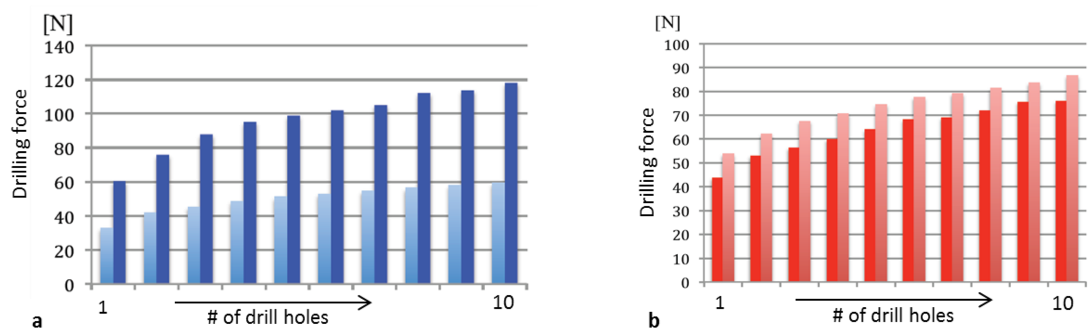


Fig. 46: Drilling force of original and modified surgical drill bits (adapted from Stoiber, 2014)
a) Synthes, original (light blue) and modified (dark blue)
b) Brasseler, original (light red) and modified (dark red)

In another diploma thesis at the IWS, Zopf (2011) investigated surgical bone drilling in detail. Between September 2009 and June 2010, drilling experiments on the Medical University of Graz took place. In this experiments, several surgeons drilled holes into porcine and artificial bones. The thrust (feed force) was recorded over the drilling time. Zopf (2011) concluded that there is no "standardized surgeon" according to the results. The drilling forces and sequences vary from surgeon to surgeon. According to the author, Fig. 47 shows a typical drilling sequence with recorded spindle speed and thrust. It can be seen that the thrust increases until the cortical bone has been drilled through into the cancellous bone. For an easy evacuation of the hand drill, the surgeon activates the hand drill again.

[12] Gebr. Brasseler GmbH & Co. KG, Trophagener Weg 25, 32657 Lemgo, Germany

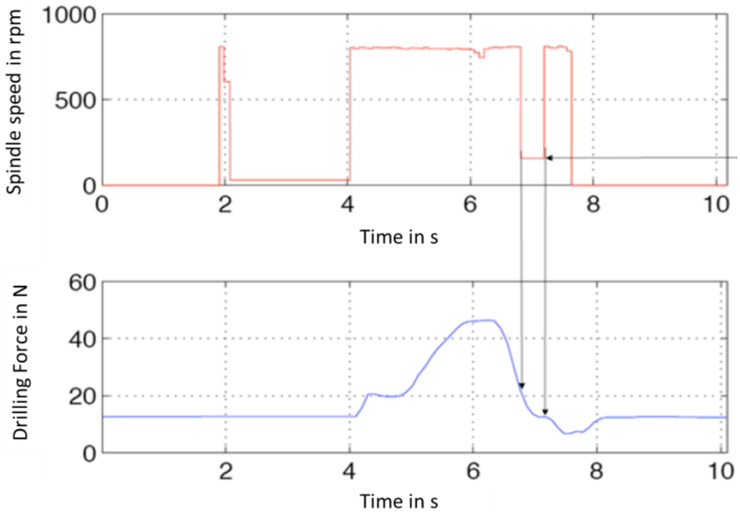


Fig. 47: Typical sequence of drilling by hand (adapted from Zopf, 2011, p.32)

After analysing the results, Zopf (2011) calculated an average maximum feed force of 45 N (±15 N). This would perfectly fit to the recommendations from Milberg and Fuchsberger (1984). One word about the experimental setup of Zopf (2011) and Stoiber (2014) should be added. The drilling temperature has not been measured during the experiments. The detected drilling force can be a measure for the wear and eventually for the geometric specifications of the drill bit – but not for the occurrence of thermal necrosis.

In summary, it has been well established in the literature that there is a positive correlation between drilling force and feed rate. With fast feed rates, the drilling time can be decreased. In terms of thermal necrosis, shorter drilling times are useful since the duration of heat transport into the bone can be reduced. But it should be noted that too high axial forces can cause irreversible bone damage. Therefore, a good feeling of the surgeon for drilling is essential. It is important to understand that efficient cutting needs proper feed rates and drilling forces as well as sharp drill bits. Slow feed rates despite high axial feed forces may indicate a blunt drill bit and drilling should be stopped immediately. Increasing the force in this situation would only harm the bone additionally.

Augustin et al. (2012b) concluded that surgical bone drilling by hand depends most of all on the surgeon's skills and the feeling for it. According to the authors, "*The required core skills are: recognizing the drill endpoint, ability of applying constant, sufficient but nonexcessive feeding rate and thrust force.*" (Augustin, 2012b, p.323)

2.4.5 Temperature and Drilling Time (t_D)

The drilling time and its importance have already been mentioned in the previous chapters. It has been shown that the drilling time negatively correlates with the feed rate. To prevent thermal necrosis, temperature elevation above 47-50 °C for longer duration should be avoided (see chapter 2.1.1). Less drilling time means less heat transfer into the bone which decreases the overall thermal load. Therefore, short drilling times should be aspired in surgical and orthopaedic treatment.

Tu et al. (2010) used a dynamic elastic-plastic finite element model (ABAQUS/Explicit) to simulate the bone temperature during drilling with different influence factors. Fig. 48a shows that the maximum bone temperature and the drilling time decrease with increasing spindle speed. As can be seen from Fig. 48b, the bone temperature and the drilling time further decrease with increasing feed rates. This has already been investigated in several experimental studies (see chapter 2.4.3 and 2.4.4).

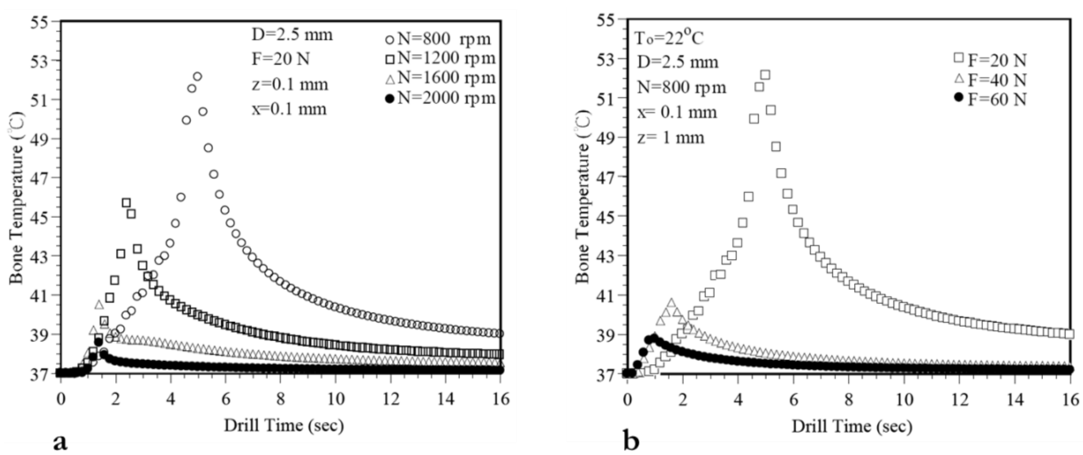


Fig. 48: Results from the FEM simulation (Tu et al., 2010)
a) Changes of bone temperature with drill time for different spindle speeds
b) Changes of bone temperature with drill time for different feed forces

Lee et al. (2012) presented interesting time-temperature relationships for different cutting conditions. They measured the temperature at different locations from the drill hole (TC1 = 2.78 mm, TC2 = 0.81 mm, TC3 = 0.5 mm) as a function of the drilling time. As can be seen from Fig. 49, a spindle speed of 800 rpm and a feed rate of 1.5 mm/s provided the best drilling condition with regard to the maximum temperature. This further supports the findings from the previous chapters.

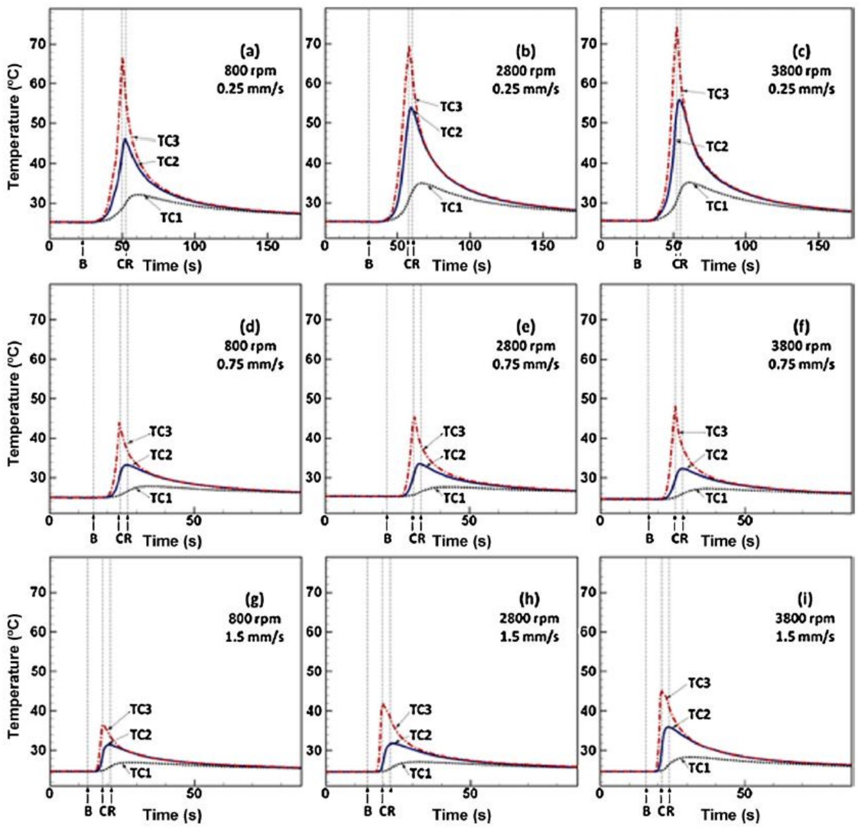


Fig. 49: Drilling temperature as function of the drilling time for different spindle speeds and feed rates (Lee et al., 2012)

In several studies, the relationship between drilling time and temperature has been investigated. The temperature curve rises rapidly during drilling into cortical bone until it reaches the maximum value. After breaking through, a second peak could appear when the drill tip is pulled out of the drill hole (Schmelzeisen, 1990). Then the temperature curve falls and approaches the start temperature asymptotically (Fig. 32, Fig. 48, Fig. 49). Knowledge about these connections is useful for surgical treatment. During osteosynthesis, the surgeon usually has to drill more than one hole. To keep the thermal load in low ranges, there should be a small brake between each drilled hole. This allows the drill bit to cool down additionally.

2.4.6 Cooling

The use of appropriate coolant is essential for efficient cutting. The type of coolant (e.g. emulsion, pressurized air) depends on the workpiece material and is well documented in engineering literature. But also in surgical theatres, the application of coolant is common. Its effect has been investigated by several researchers. It was found that the use of coolant is one of the most influential parameter to decrease the bone temperature during drilling. There are different types of cooling systems which can be divided as shown in Fig. 50:

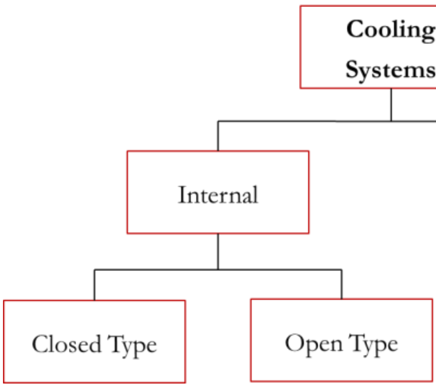


Fig. 50: Different types of Cooling (according to Augustin et al., 2012b)

In internal cooling systems the coolant (cooling fluid or pressurized air) flows through the channels inside the shaft of the drill bit (Fig. 51b). Closed type means that the fluid or air streams up to the tip of drill bit and back again to the cooling container. For the closed type, no contact between coolant and bone takes place. Open type means that the coolant flows through the channels, exits the drill bit at the tip and contacts the bone. Thus, direct cooling of the drilling spot and the drill tip is provided. (Augustin et al., 2012b, Fig. 51)

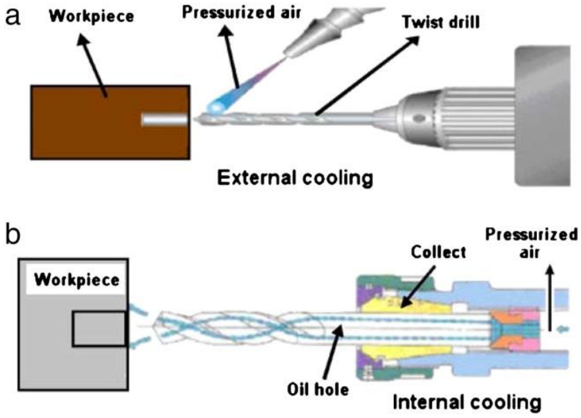


Fig. 51: Different cooling systems (Augustin et al. 2012b), a) External; b) Internal, open type

External cooling means that the coolant is applied on the surface of the drill bit and the bone (Fig. 51a). On the one hand, this can be done automatically where the regulation of the cooling rate is possible. On the other hand, cooling manually takes place with simple syringes. The coolant is usually Ringer's solution or saline solution.

The main task of cooling is to decrease the drilling temperature by thermal conduction. An additional function of the cooling fluid is lubrication, which is necessary for cutting in the fields of engineering. But Augustin et al. (2012b) mentioned that the lubrication properties of coolants in medicine are not scientifically tested. However, a reduction of friction should be possible. Another function of the coolant is the irrigation of the bore hole. As already described, the bone chips evacuate the main part of the thermal energy. Therefore, clogging of the flutes should be avoided. Irrigation helps to clear the bone debris properly, but this seems to be only partly efficient with external cooling. Furthermore, irrigation and lubrication are not possible with closed internal cooling. (Augustin et al., 2012b)

In this chapter, the effect of cooling during drilling of bone should be clarified. Theoretically, external cooling seems to be less efficient than internal cooling for drilling deeper into bone. Since the coolant is applied from the outside, it is difficult to determine how deep it infiltrates the bore hole. If the coolant does not reach the drill bit tip during drilling, both the lubrication and the cooling effect are reduced. Matthews and Hirsch (1972) investigated the effect of external cooling in their experiments with human cortical bones. They found that cooling reduces the maximum temperature of the bone significantly (Fig. 52a). The coolant was applied manually with a 100 ml syringe. They further investigated the influence of the cooling rate (irrigation rate) on the bone temperatures during drilling. The experiments were carried out with a drill guide that allows a constant supply of coolant to the drilling spot (Fig. 20). As can be seen Fig. 52b, the higher the irrigation rate the lower the bone temperature is. For irrigation rates of 500 ml/min and more the temperature stayed below 47 °C. This was also true for manual irrigation. Compared to the control group, both manual and automatic irrigation decreased the thermal load on the bone.

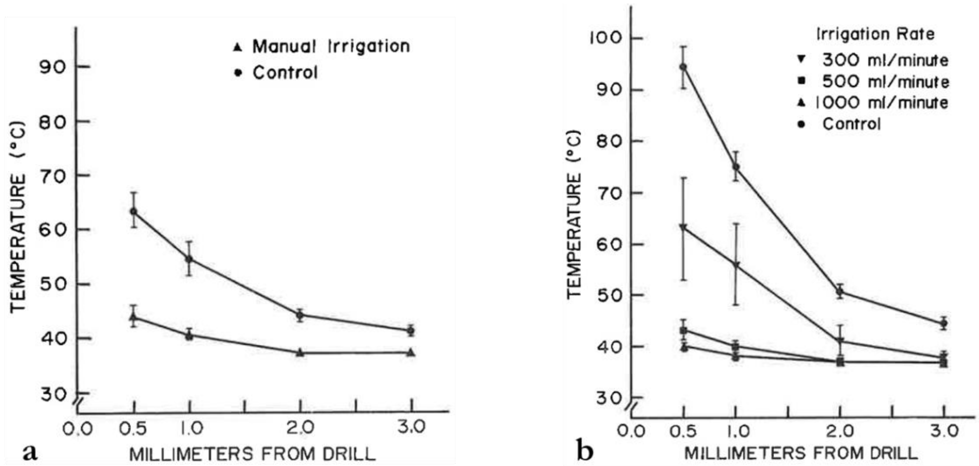


Fig. 52: The effect of cooling (irrigation) on the average maximum temperatures; n = 885 rpm; F_D = 60 N (Matthews and Hirsch, 1972)
a) Manual irrigation; b) Automatic irrigation with different irrigation rates

Augustin et al. (2008) investigated the influence of drill diameter, drill speed and external irrigation (water at 26 °C). Once more, they concluded that external irrigation is the most important factor for decreasing the temperature as a result of three mechanisms:

I. The coolant lowers the temperature of bone by conduction,
II. it further eliminates (hot) bone chips which can cause additional friction
III. and the coolant lubricates the drill bit which lowers the friction.

The authors summarized that external irrigation must be used in operation theatres.

In a later study, Augustin et al. 2012a found that cooling is the most influential parameter for decreasing the temperature during drilling (Table 3). In their experiments, they used open internal cooling with a constant irrigation rate of 10 ml/min. For all experiments under cooling conditions were the maximum temperatures below the threshold of 47 °C. Kalidindi (2004, p.37) also observed that external cooling lowered the maximum temperatures during drilling.

Fuchsberger (1986) investigated the effect of external cooling on different cutting parameters. Fig. 53 shows the dependency of the temperature and torque from the cutting speed for drilling with and without cooling. It can be seen that the temperature has the same tendency over the cutting speed in both cases. But the thermal load and the maximum temperature were lower when coolant was applied. In terms of torque, it seems that cooling has only a small effect at higher cutting speeds.

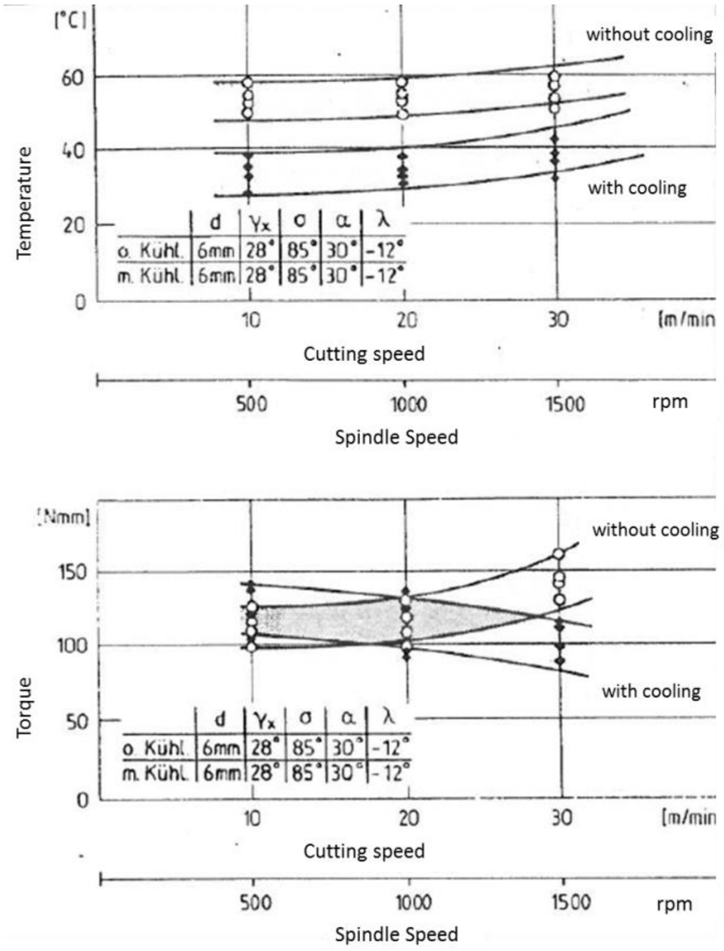


Fig. 53: Influence of the cutting speed on temperature and torque with and without cooling (adapted from Fuchsberger, 1986)

Pandey and Panda (2013) have found from the literature that the effect of cooling during bone drilling is not negligible. But they also concluded that there is no clear recommendation whether internal or external cooling should be preferred. But from theoretical considerations it can be followed that external cooling is more efficient on the surface and for short holes (Fig. 54a) whereas internal cooling is better as the depth increases (Fig. 54b).

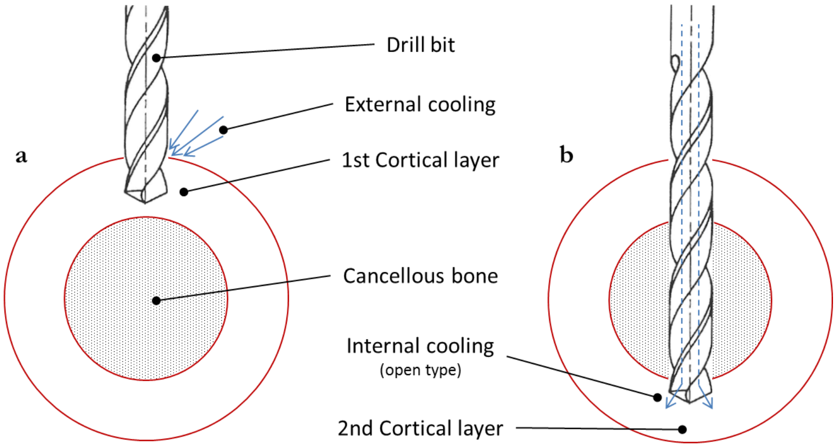


Fig. 54: Different types of cooling (schematic); a) External cooling b) Internal cooling

Schmelzeisen (1990) compared results from vital bone structure and in vitro drilling experiments on sheep metacarpus. The temperature rose slower during drilling into living tissue. Also the maximum temperature was slightly lower compared to the in vivo experiments. Together with Lee et al. (2012), it seems that the cooling effect of blood flow is negligible.

In this chapter, the effect of cooling on the bone temperature has been described. There is a general agreement in the literature that cooling decreases the risk of thermal necrosis efficiently. Anyhow, it seems that the application of coolant is not as common as it should be in operation theatre. Simple external manual cooling could lower the bone temperature but requires more effort from the medical staff at the same time. On the other hand, internal cooling seems to be more user-friendly but the additional equipment increases the clinical costs for the treatment. Anyhow, sufficient external cooling should be considered as an appropriate way to keep the bone temperatures below critical values.

2.4.7 Outcome – Cutting Conditions

Beside the geometry, the drilling conditions are the second important part of the technical analysis. The effect of the spindle speed (n) and the cutting speed (v_c) is described in chapter 2.4.1 and 2.4.2. But since the adjustability of the spindle speed is unusual for common air-driven hand drills, the information is of limited value in the operation theatre. For feed (rate), clear recommendations can be provided. By increasing feed rates the drilling time and further the maximum temperatures in the bone decrease, which helps the prevention of thermal necrosis. Furthermore, there is a positive correlation between feed rate and axial drilling force. It depends on the surgeon, to drill fast enough without overloading the bone. Slow feed rates despite high axial load are signs for blunt drill bits. Thus, an exchange of them has to be assured by the medical staff.

It should be noted that the drilling force is not a good indicator for maximum temperature. High drilling forces paired with sharp drill bits result in fast feed rates which further decreases the thermal load. The question whether coolant should be applied can definitely be answered with yes. Every related study confirmed the positive effect of cooling on the bone temperature. From the literature it appears that internal cooling is more efficient than external cooling, which is easier to provide. In simple terms, any cooling is better than no cooling.

2.5 Surgical Drill Bit - Wear

Previous research at the IWS has shown that wear already occurs after few drilled holes. In this chapter, the fundamentals of drill bit wear are described. Furthermore, the wear investigations of different surgical drill bits are documented.

2.5.1 Causes of Wear

Information about wear is mainly available from the fields of engineering. According to Degner et al. (2009, p.81), the amount of wear depends mainly on the cutting conditions, on the materials (workpiece/cutting edge) and on the time profile. They further define four different causes of wear:

1) **Abrasion**

   Abrasive wear is the mechanical removal of material. It is caused by the friction between tool and chip as well as between tool and workpiece. High surface temperatures can intensify the abrasive wear, because the hardness of the cutting edge usually decreases with high temperatures. Break-outs on the cutting edge are typically caused by abrasion.

2) **Diffusion**

   At high temperatures, atomic particles can wander from the cutting edge into the workpiece and vice versa. Wear caused by diffusion destroys the cutting material from the inside. Special coatings on the tools are a good method to prevent diffusion wear.

3) **Oxidation**

   High temperatures during cutting can cause the oxidation of the cutting material on the contact surface between tool and workpiece. Possible consequences are notches and break-outs on the cutting edge.

4) **Adhesion**

At this, oxygen particles are cold-welded together with the bottom of the chip. It is possible that particles are removed from the cutting material or chips settle down on the cutting edge. This changes the cutting geometry and further increases the cutting forces.

(Dillinger 2007, p.143)

The wear of the cutting edge is always a product of the mechanisms from above. For high cutting speeds, abrasion, diffusion and oxidation appear together. For low cutting speeds, abrasion and adhesion are responsible for wear. Oxidation and diffusion have no effect for low cutting speeds and temperatures where surgical bone drilling is usually located. (Dillinger 2007, p.143; Degner et al. 2009, p.81-82)

2.5.2 Types of Wear for Drill Bits

There are several classifications of wear in the literature. According to Kanai et al. (1978, cited in Sharif et al. 2012) drill bit wear can be classified into:

- Outer corner wear (w)
- Flank wear (V_b)
- Margin wear (M_w)
- Crater wear (K_M)
- Chisel edge wear (C_T and C_M)
- Chipping at the cutting edge (P_T and P_W)

Fig. 55 shows an illustration of these types of wear. Wear begins at the corners of the cutting edges and proceeds along the cutting edges until it reaches the chisel edge. To measure the performance of a drill bit flank wear is suggested as an appropriate criterion. Flank wear is a result of the friction between clearance surface and workpiece. The outer corner wear is suitable to determine the performance of a drill bit because of its close connection to the drill life. (Sharif et al. 2012)

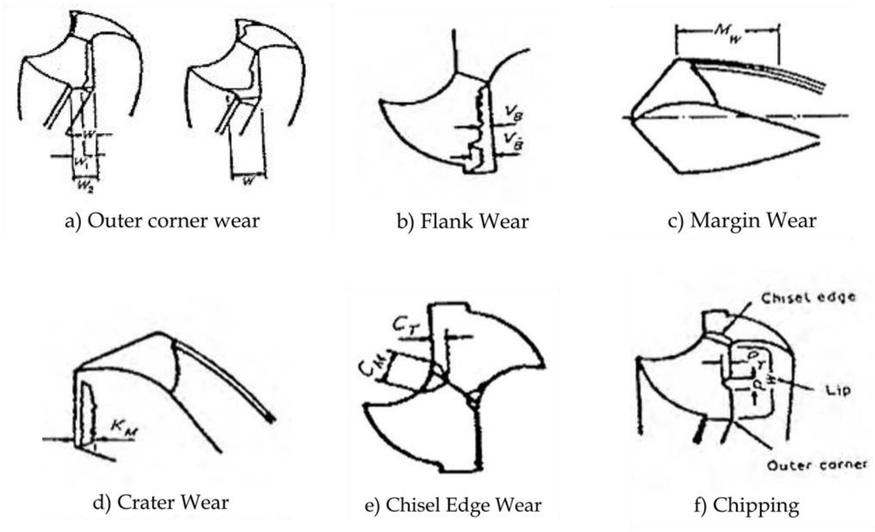


Fig. 55: Types of drill bit wear (adapted from Kanai et al., 1978, cited in Sharif et al., 2012)

Table 7: Types and causes of drill bit wear on hard metal drill bits (adapted from Dillinger et al. 2007, p.129)

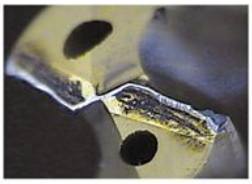
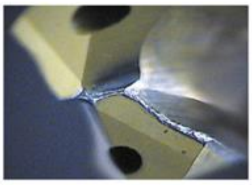
Type of wear	Possible causes
Flank wear 	• inadequate cooling • cutting speeds too high • workpiece too hard
Flank and outer corner wear 	• cutting speed too high • feed rate too low • little wear resistance of cutting material • inadequate cooling
Chisel edge wear 	• cutting speed too low • feed rate too high • chisel edge too small

Table 7 shows typical types of wear on carbide metal drill bits. Wrong cutting conditions accelerate the process of wear which decreases the tool life and influences the cutting efficiency negatively. In the next chapter, the implications of wear on the cutting process are described.

2.5.3 Implications of Wear

According to Degner et al. (2009, p.83) wear directly influences the following cutting parameters (Fig. 56):

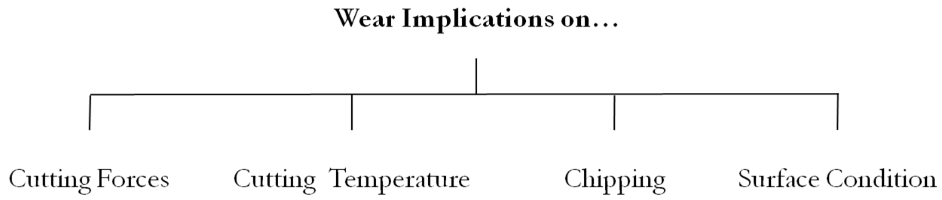


Fig. 56: Wear implications (adapted from Degner et al., 2009, p.83)

Cutting forces: they increase with increasing wear (see also chapter 2.4.4).

Cutting temperature: it increases with increasing wear. This will be explained in detail for surgical bone drilling in chapter 2.5.4. If the temperature rises, the wear will increase further.

Chipping: special types of wear can cause better chip evacuation.

Surface conditions: with increasing wear, the surface roughness increases.

(Degner et al., 2009, p.83)

It can be seen that wear affects important cutting parameters. This is also true for surgical bone drilling. In the next chapter, findings from the literature about drill bit wear in medicine are discussed.

2.5.4 Wear of Surgical Drill Bits – Literature

Drill bit wear in medicine has been reported for different areas of medicine (e.g. dental, orthopaedic or surgery). In this chapter, the effect of drill bit wear on related cutting parameters, first of all on the temperature, is described.

Matthews and Hirsch (1972) compared new drill bits to drill bits which have already drilled more than 200 holes and showed marks of wear on the cutting edge. The results were to be expected: greater maximum temperatures and longer duration of temperature elevation were observed for the worn drill bit (Fig. 57).

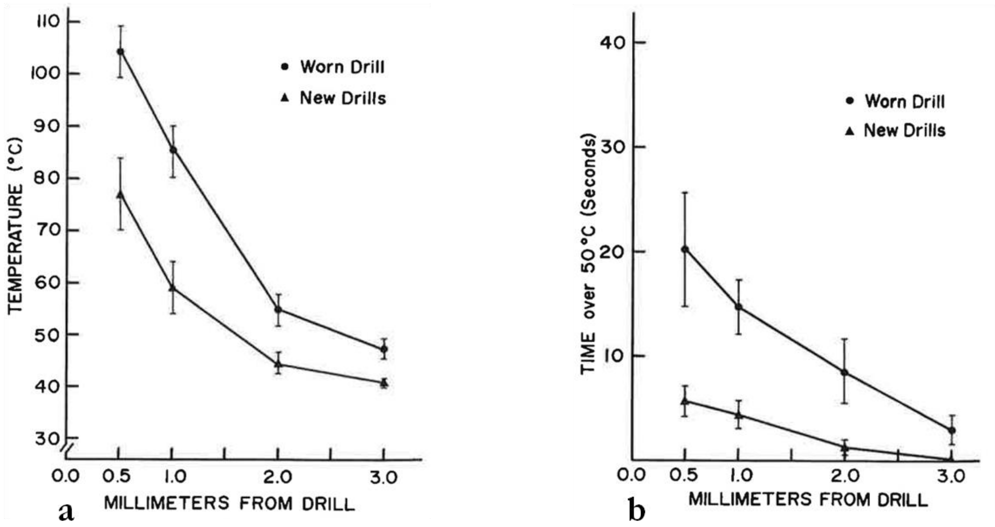
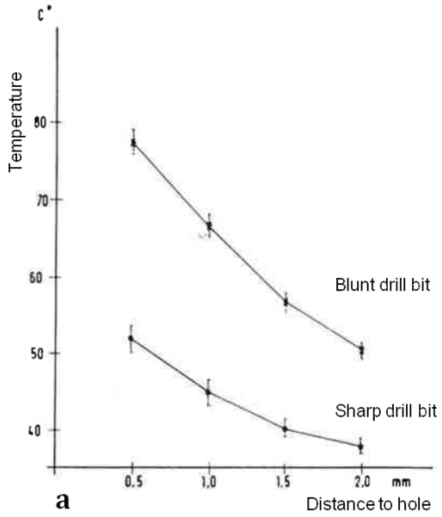


Fig. 57: The effect of drill bit wear (Matthews and Hirsch, 1972)
a) On the maximum cortical temperatures
b) On the duration of temperature elevations above 50 °C

Natali et al. (1996) reported that *"blunt drills are all too common in operation theatres […]"*. In their experiments, they used drills bits which were removed from the operation theatre randomly. The temperature elevation was higher compared to the new drill bit (Fig. 32). Natali et al. (1996) concluded that an additionally increased force is necessary to drill through the bone. This may result in broken drill bits and in injuries of the soft tissue when bursting through the cortex. These results have also been observed by de Pretis (2012) in his bachelor thesis at the IWS of TU Graz.

Schmelzeisen (1990, p.48-51) investigated the effect of blunt surgical drill bits on the bone temperature during drilling into the vital cortex (sheep metacarpus). The absolute temperatures were significantly higher when drilling with the blunt drill bit compared to drilling with the sharp one (Fig. 1, Fig. 58). It can be seen that the temperatures for the blunt drill bits were far above the 47 °C threshold at the close distances to the drill hole.



a

Measuring point	Blunt drill bit	Sharp drill bit
0,5	76 76 77 77 78 80	50 51 52 53 53 54
1,0	65 66 67 67 68 68	44 44 45 45 46 47
1,5	55 56 56 56 57 58	39 40 40 40 41 42
2,0	50 50 51 52 52 52	36 37 38 38 38 39

b

Fig. 58: Comparison of sharp and blunt drill bit (adapted from Schmelzeisen, 1990, p. 51)
a) Comparative illustration; b) Measured temperatures during the vital experiments in °C

Allan et al. (2005) also investigated the effect of worn drill bits on the temperature during drilling. They used porcine mandibles (in vitro) and Leibinger ø1.5 mm drill bits with different wear characteristics: one was new, one had already drilled 600 holes and the last one had been used in the operation theatre (Fig. 59). They observed that the drill bits from the operation theatres created the highest temperature change of the three types (+25 °C approx.). Obviously, the new drill bit performed better than the both worn drill bits (-7.5 °C approx.). It should be noted that cutting conditions were different from ordinary surgical bone drilling. Allan et al. (2005) had chosen a spindle speed of 20,000 rpm and a drilling force of only 12 N. The measurements of the temperature changes were based on a bone temperature of 37 °C.

As can be seen in Fig. 59, the drill bit removed from the operation theatre shows evident signs of wear. Excessive flank wear as well as chisel edge and outer corner wear can be observed easily. It should be emphasized that this drill bit (Fig. 59c) was still in a fragment set in an operation theatre. It is highly questionable whether a surgeon would have drilled adequate holes with it in this condition.

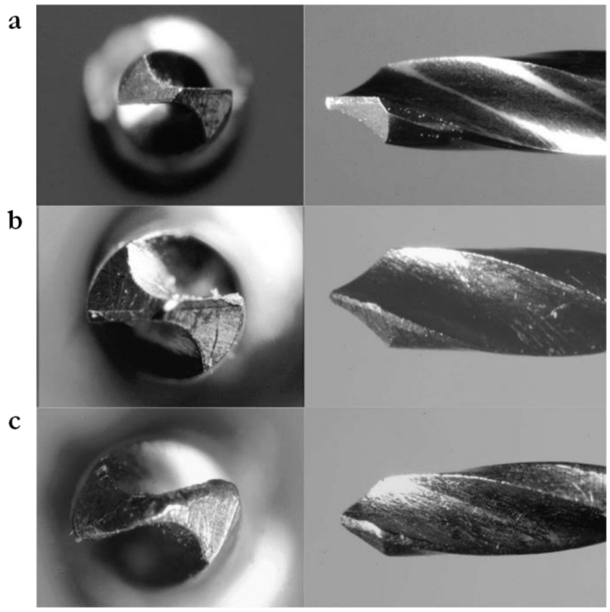


Fig. 59: Photographs of the three ø1.5mm investigated drill bits (adapted from Allen et al., 2005) a) new drill bit; b) worn drill bit (600 holes); c) drill bit from operation theatre

Karaca et al. (2011) compared drill bits with and without coatings. Based on the histopathology results they concluded that the bone quality after drilling with uncoated drill bits was better compared to drill bits with a TiBN (Titanium Boron Nitride) coating. In a further study, Karaca and Aksakal (2013) proved these findings again and added that the temperature was not reduced with coated drills like TiBN. Chacon et al. (2006) found that the temperature increases with multiple-use of drill bits. They performed in vitro experiments on femoral cortical bone specimen and three drill bit systems with different geometries. Additionally, only very little signs of wear were found for all three systems after 25 uses.

Zopf (2011) investigated the wear of surgical drill bits on artificial bones, pig bones and human cadaveric bones (all in vitro, see chapter 2.4.4). In his first series of experiments he varied the constant drilling force for all three bone types (5, 30, 50, 80 and 100 N). The drilling took place on the friction-stir welding (FSW) machine at the IWS TU Graz with common surgical drill bits of the same type. The amount of wear was visually evaluated with a stereo microscope (see Fig. 60 and Fig. 61).

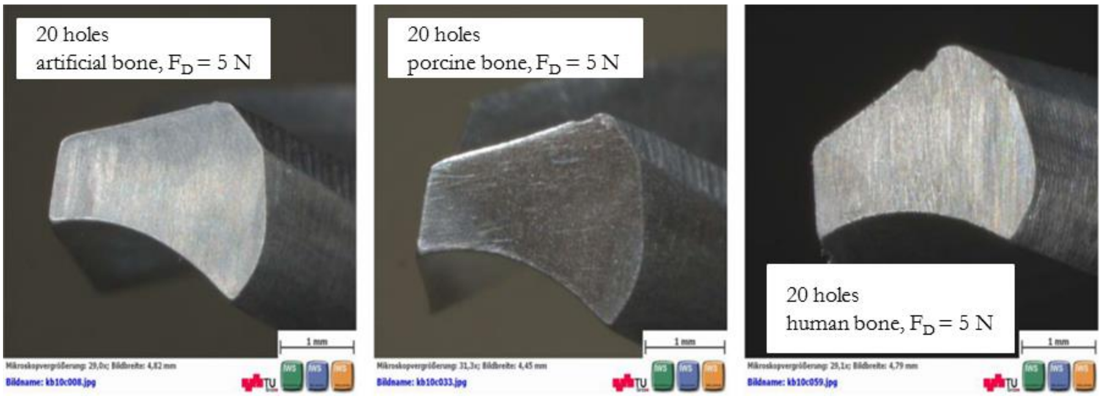


Fig. 60: Drill bit wear depending on bone type and drilling force (F_D = 5 N) (adapted from Zopf, 2011)

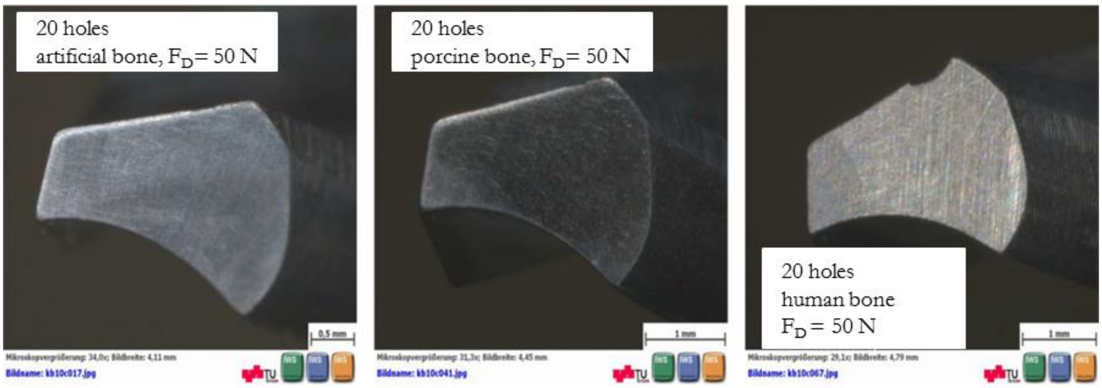


Fig. 61: Drill bit wear depending on bone type and drilling force (F_D = 50 N) (adapted from Zopf, 2011)

Zopf (2011) concluded that the amount of wear increases in the following order: artificial bone, porcine bone and human bone. Chipping at the outer corner of the cutting edge have been observed for the porcine bone and the human bone. Also rounding of the chisel edge and flank wear have been spotted by the author. It seems that the physical properties of human bone are responsible for the highest amount of wear. Zopf (2011) also emphasized the role of the axial drilling force: Higher forces (50 N) created more wear than small forces (5 N). Although drilling was performed automatically, drill bit walking has been observed at the beginning. But there is another important result from the experiments: remarkable signs of wear already occurred after only 20 holes or less.

In the diploma thesis of Zopf (2011), a second series of experiments took place. In these experiments, different types of drill bits with and without coating were tested on human cadaveric bone. The tested drill bit types were:

- Standard surgical drill bit from Synthes made of AISI 440A with a DLC[13]-graphitic coating
- Standard surgical drill bit from Synthes made of AISI 440A with a DLC-titanium coating
- Ordinary and cheap two-flute twist drill bit made of HSS-6-5-2 with a DLC-graphitic coating (not biocompatible)
- Ordinary and cheap two-flute twist drill bit made of HSS-6-5-2 with a DLC-titanium coating (not biocompatible)
- Standard surgical drill bit from Brasseler made of AISI 440B without coating
- Dental three-flute drill bit "CeraDrill" from Brasseler made of ZrO_2

Drilling was done manually with a common electric hand drill machine and automatically with the FSW (feed rate = 150 mm/min, n = 500 rpm). The results showed that manual drilling caused higher amount of wear on the drill bits. Furthermore, there were no clear improvements concerning the wear resistance of the coated Synthes 440A surgical drill bit compared to the uncoated one. But both types showed excessive wear after just 20 drill holes and drill bit walking was also observed. The 440B surgical drill bit from Brasseler performed better than the AISI 440A. According to Zopf (2011), better material properties and surface finish were the reason for this. On the other hand, the cheap two-flute drill bit showed very little wear and also good self-centering characteristics. But clogging of the flutes was investigated during drilling. The CeraDrill from Brasseler showed no wear after drilling automatically. Only after 111 holes drilled by hand, small chipping at the cutting edge have been taken place. (Zopf, 2011, p.139)

Stoiber (2014) experimented with artificial bone and found that the drilling force increases with every repeated use of the drill bit (see chapter 2.4.4). According to the author proceeding wear was the reason for the steady increase of the force which means that drill bit wear is an issue from the very beginning. Also Pandey and Panda (2013, p.25) suggested based on their reviewed literature *"[...] that the drill wear and temperature generated during bone drilling increases with the number of times a drill is used."*

To sum up, the number of uses until the drill bit wears out varies from author to author. Therefore, an exact estimation of the right point of time to exchange the drill bit is hardly possible. It should be pointed out that blunt drill bits are ineffective for cutting and create higher temperature load. This further increases the risk of thermal necrosis for the patient. In the next chapter, surgical drill bits discarded from operation theatres are investigated.

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[13] Diamond-like carbon (DLC), a coating which should provide high hardness and wear resistance

2.5.5 Wear in the Operation Theatre

In this chapter, the issue of blunt drill bits in hospitals is investigated from a technical point of view. For this, discarded drill bits from the operation theatre were collected and evaluated with the stereo microscope (Zeiss SteREO Discovery.V20). All observed drill bits are from the same manufacturer (Synthes), whose drill bits are obviously highly represented in the LKH Graz. No aimed choice and also no preferences have been made by the author.

In the previous chapter, the effect of wear has been described in detail. First of all, Zopf (2011) did intensive research on this topic under laboratory conditions. In this thesis, a different approach was chosen: surgical drill bits, coming directly from the operation theatre, have been documented. Out of it, wear that is developed under real conditions can be observed. The drill bits were discarded at the state hospital of Graz (LKH Graz) and thankfully provided by the Department of Medical Engineering of the LKH Graz or by Mositech GmbH. All drill bits were disinfected before handed out. It should be noted that the reason for the elimination of the investigated drill bits is not known to the author of this thesis. Since there is no recording or monitoring, the number of uses until removing the drill bit is also not known. In Fig. A-1 (appendix), further pictures of discarded drill bits are provided.

First of all, a new and unused drill bit is shown in Fig. 62. Small machining marks from the surface finish on the flank can be seen.

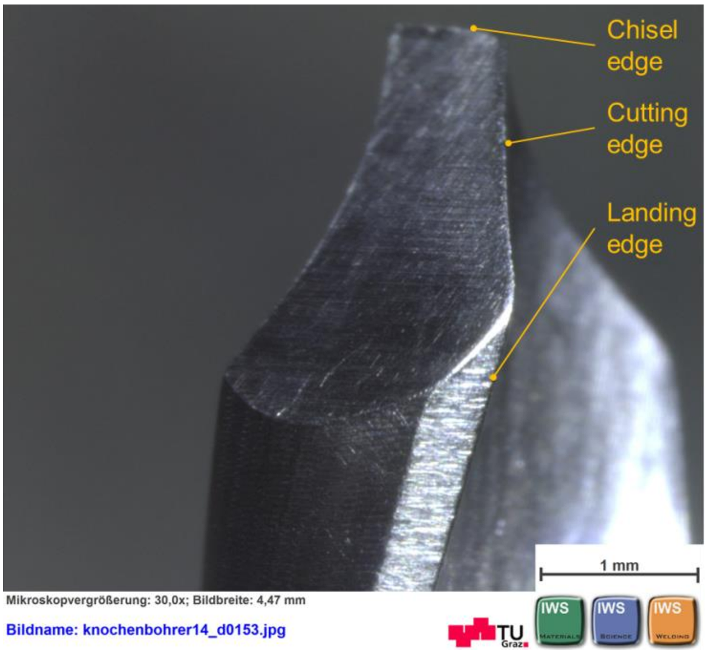

Fig. 62: Unused surgical drill bit ø3.2 mm from Synthes (310.350)

Fig. 63 shows a standard 2.8 mm surgical drill bit with large amount of wear. First of all, the heavy chipping on the cutting edge is remarkable. Along the cutting edge, also typical signs of abrasive wear can be seen. Also the chisel edge is blunt and rounded. The machining marks on the flank are from grinding during the manufacturing process.

Fig. 63: Discarded surgical drill bit (Synthes 310.284, ø2.8 mm) with distinct wear marks

A second drill bit of the same type as above has been investigated (Fig. 64). The wear characteristics are similar compared to the first one. One particular feature should be highlighted: there have been signs of wear observed on the backside of the flank, which is opposite to the cutting edge. Since this part does not take place on the cutting process, wear in this area seems to be unusual. One possible explanation for this could be the reversal of the rotation direction when the surgeon pulls the drill bit out of the finished hole. That results in additional contact between the non-cutting edges and bone which causes signs of wear. Furthermore, deposits on the flanks were found which are expected to be bone residues from drilling which were not removed during disinfecting.

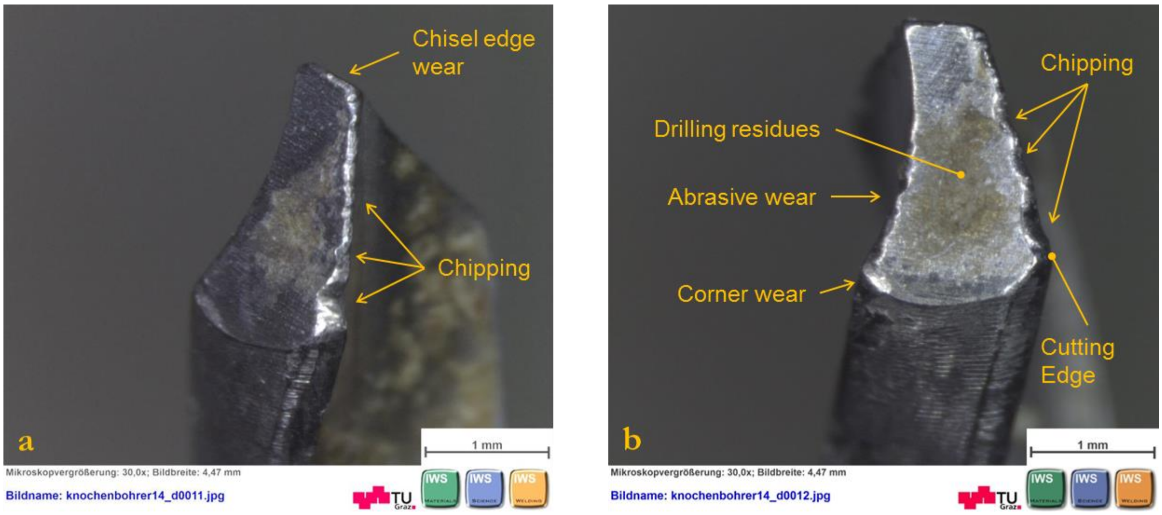

Fig. 64: Discarded surgical drill bit (Synthes 310.284, ø2.8 mm)
a) Excessive wear marks on the cutting edge and chisel edge
b) Wear on the backside of the flank and bone residues

Another two-flute drill bit (2.5 mm, Synthes 310.25) has been documented (Fig. 65). It is coated with TiN (Titanium-Nitride) as it seems from the figures. But on critical locations (e.g. cutting edge, leading edge etc.), the coating has already been relieved. Furthermore, excessive wear can be observed in Fig. 65.

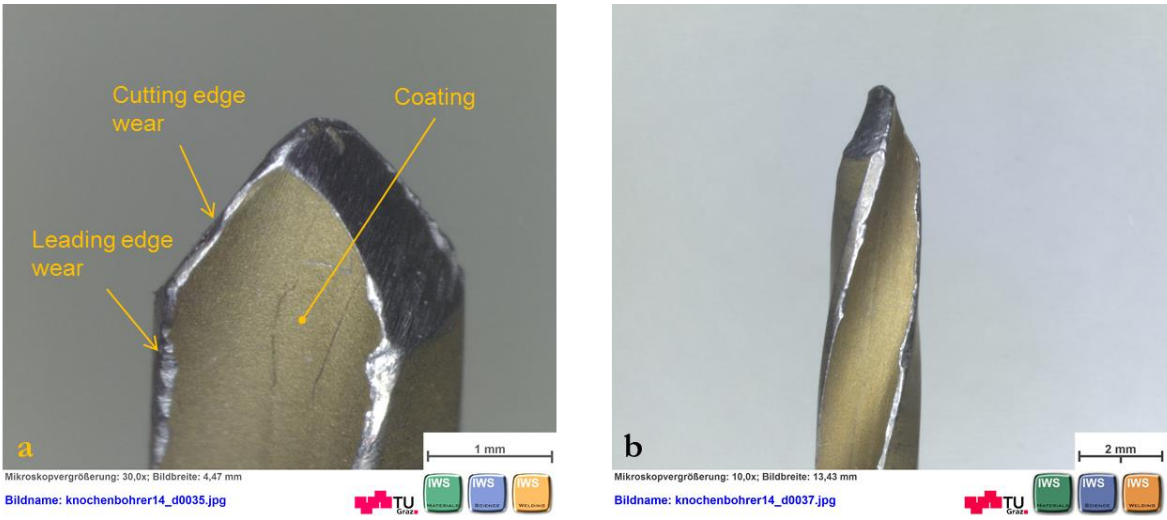

Fig. 65: Coated two-flute surgical drill bit (Synthes 310.25, ø2.5 mm)

For this thesis, also a three-flute twist drill bit has been investigated (Fig. 66 and Fig. 67). The advantages and disadvantages of this type are described in chapter 2.3.6. Not only the drill tip shows significant amount of wear (Fig. 66), but the leading edges seem to be blunt too (Fig. 67). Contact between drill bit and drill guide (if used) could increase this type of wear. The wear of the heels can also be explained with the considerations from above. The wear on non-cutting edges and surfaces could occur when the surgeon changes the rotational direction to pull out the drill bit easily (Fig. 67).

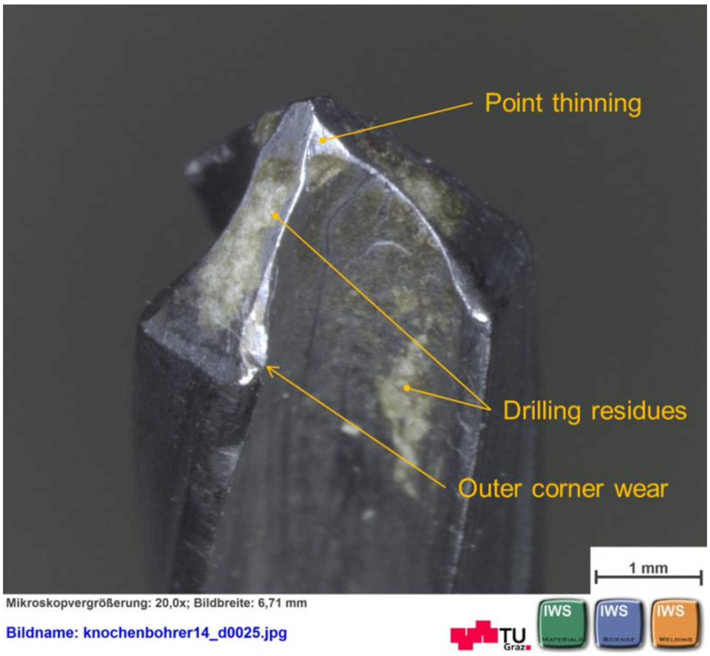

Fig. 66: Tip of a discarded three-flute surgical drill bit (Synthes 324.213, ø4.3 mm)

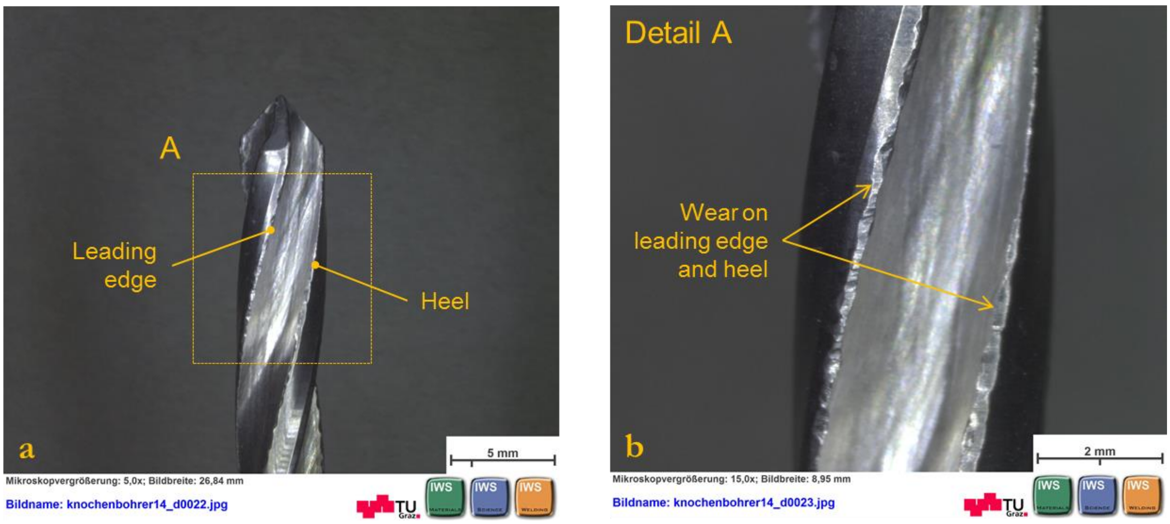

Fig. 67: Three-flute surgical drill bit (Synthes 324.213, ø4.3 mm)

Beside these blunt examples, there were also drill bits which appeared rather new, although they were discarded from the operation theatre. Fig. 68 shows two discarded surgical drill bits. Compared to the drill bits above, only little signs of wear can be observed. Yet, the reason for the removal is unknown.

Fig. 68: Two discarded surgical drill bits with only little wear characteristics
a) Synthes 310.290, ø3.2 mm; b) Synthes 310.370, ø3.5 mm

It can be seen from the figures above, what wear in operation theatres looks like. Obviously, the cutting efficiency suffers from bad drill bit conditions. Unfortunately, there is no monitoring of the wear in the investigated hospitals. Therefore, the removal of a blunt drill bit only depends on the medical staff in the operation theatre and is a subjective decision. This will be discussed in chapter 3.2 in detail.

2.5.6 Outcome – Wear

Wear is a manifold topic for cutting tools. Different causes, types of wear and possible implications are analysed in this chapter. Above all, the increasing temperature with proceeding wear is a problem for surgical bone drilling. This has also been investigated by different researchers. Studies at the IWS have shown that the axial drilling forces increase with increasing wear. The total number of drill holes before the drill bit has to be replaced varies for every reviewed study. Values between 15 and several hundred drill holes are reported in the literature. But since there is no monitoring, these numbers have only an informative purpose. For investigations close to reality, discarded surgical drill bits from the operation theatre have been obtained. They showed excessive signs of wear for the most part, which increases the risk of thermal necrosis. As already mentioned, monitoring of the drill bit wear seems not to be a common practice in the hospitals. Therefore, the medical staff decides subjectively if a drill bit has to be exchanged during or after drilling. But it can be expected that the drill bit could have been blunt a few drill holes before.

Drill bit wear affects the maximum temperatures during drilling which jeopardize the patient's safety. For this purpose, the use of blunt drills in the operation theatre must be avoided. For this, additional monitoring and instructions are necessary to avoid subjective decisions for using and discarding drills. First of all, the patient's safety would benefit from it.

2.6 Surgical Drill Bit - Materials

In the literature, only little research on the materials for surgical drill bits is available. It seems that the material as an important factor is widely underestimated. Basically, drill bit wear has a great effect on the drilling process. With a suitable material, the tool life can be extended. In this chapter, relevant materials for surgical drill bits are compared and discussed. Furthermore, the drill bit wear as an important factor is described. In the end, recommendations on appropriate materials for surgical bone drilling will be given.

2.6.1 Requirements

There are several requirements which cutting materials have to fulfil. This is true for engineering but also for surgical cutting processes. Typical requirements are as follows:

- High hardness and compressive strength.
- High bending strength and toughness: the tool has to resist shock loads.
- High wear resistance: combination of high hardness and good toughness results in proper wear resistance and a longer tool life.
- High temperature resistance: the cutting material has to resist high thermal load without losing too much hardness.
  (Degner et al. 2009, p.60)

There are further requirements for surgical cutting instruments (e.g. for surgical drill bits), which have to be satisfied:

- Biocompatibility: *"[…] the ability to exist in contact with tissues of the human body without causing an unacceptable degree of harm to that body"* (Williams, 2008, p. 2941).
- High corrosion resistance: especially against products during the reprocessing (cleaning, disinfection and sterilization).
- High fracture toughness: drill bit breakage during surgical treatment is fatal.

These characteristics disqualify several common materials like carbon tool steels or high speed steels (like HSS-6-5-2, see chapter 2.5.4) for surgery. The OENORM EN ISO 7153-1 standard (extract in Table 8) determines metallic materials for surgical instruments. Part 1 lists appropriate stainless steels and their composition for surgical drill bits:

Table 8: Steel grades and chemical composition according to OENORM EN ISO 7153-1

Steel grade			Chemical composition in % (martensitic steels)								
Ref. -letter	Sort Nr. ISO 4957	Sort Nr. ISO 683-13	C	Si max.	Mn max.	P max.	S max.	Cr	Mo	Ni	additional Elements
D	-	-	0.42-0.50	1	1	0.04	0.03.	12.5-14.5	-	max. 1	
H	-	-	0.35-0.4	1	1	0.045	0.03	14.0-15.0	0.4-0.6	-	V: 0.1-0.15
I	-	-	0.40-0.55	1	1	0.045	0.03	12.0-15.0	0.45-0.9	-	V: 0.1-0.15
R	-	-	0.80-0.95	1	1	0.045	0.03	17.0-19.0	0.9-1.3	-	V: 0.07-0.12

For the surgical drill bits which have been investigated in this thesis, the materials are known. According to Synthes[14], the following surgical drill bits (Table 9) from their assortment are made of AISI 440A stainless steel:

Table 9: List of surgical drill bits from Synthes made of AISI 440A (type numbers)

356.834	324.213	310.284	310.230	310.350
310.290	310.31	315.31	310.25	310.310

Brasseler, another manufacturer of surgical instruments, changed the material of their surgical drill bits from AISI 440B to AISI 431 during the year 2014. It is not known exactly which article numbers are affected. But the change of the alloy is interesting anyway. To sum up, the material of surgical drill bits should fulfil the following requirements:

- Biocompatibility
- High corrosion resistance
- Balanced ratio of (fracture) toughness to hardness

[14] Information from a Product Manager of Synthes, personal communication (e-mail), September 6, 2014

- High wear resistance

Martensitic stainless steels are clearly the most frequently used material for surgical drill bits. When they are in the right technical conditions, they are able to fulfil all the requirements mentioned above. In the next chapter, basics about heat treatment, microstructure and relating properties are described.

2.6.2 Metallurgic Fundamentals of Stainless Steels

The most important characteristic of stainless steels is their good resistance to corrosion. The reason for this is a thin chrome-oxide layer on the steel. It passivates the surface and inhibits further reaction with oxidative media based on water. This is only possible if the chromium content in the steel is at least 12 %. There are some factors which influence the quality of the oxide layer. For instance, a homogeneous distribution of the chrome atoms in the matrix is necessary to create a resistant layer. (Bargel and Schulze, 2014, p.267)

But also stainless steels with more than 12 % Cr can corrode. These steels build chromium carbides (molecular formula: Cr_3C_2). At higher temperatures, they precipitate from the matrix. Then the chromium content in the lattice can drop below the 12 % limit which eliminates the corrosion resistance on the surface. This phenomenon can be prevented by an appropriate heat treatment of the steel. Stainless steels are generally separated in four main types: (perlitic-) martensitic, ferritic, austenitic and austenitic-ferritic (duplex)-steels. (Verhoeven, 2007, pp.133; Bargel and Schulze, 2014, p.267-269)

For surgical drill bits, martensitic stainless steels are widely used. Because of their higher carbon content, the hardenability is usually good. On the one hand, higher amount of carbon increases the hardness of the steel. But on the other hand, high amount of carbon enhances the effect from above through building large chromium carbides which decrease the amount of Cr in the matrix. For both, adequate hardness and corrosion resistance, the right Cr-C level is important. For knives, Verhoeven (2007, p.142) recommended compositions of 0.6 % C and at least 12 % Cr. The basic steps of the heat treatment are similar to low alloy steels: austenitization, quenching and tempering. During the austenitization, the carbides can dissolve (slowly) in the austenite. Both, proper austenitization temperature and time are necessary for good results. After quenching, the microstructure of the steel usually consists of martensite, carbides and retained austenite, depending on the quenching conditions. Tempering generally increases the toughness and affects the corrosion resistance and hardness. Retained austenite can also be decreased by tempering. Fig. 69 shows the effect of the tempering temperature to the hardness for different types of tool steels exemplarily. Martensitic stainless steels have also a characteristic with a secondary hardness peak, like the curves 1 and 2 in Fig. 69, which can be more or less distinctive.

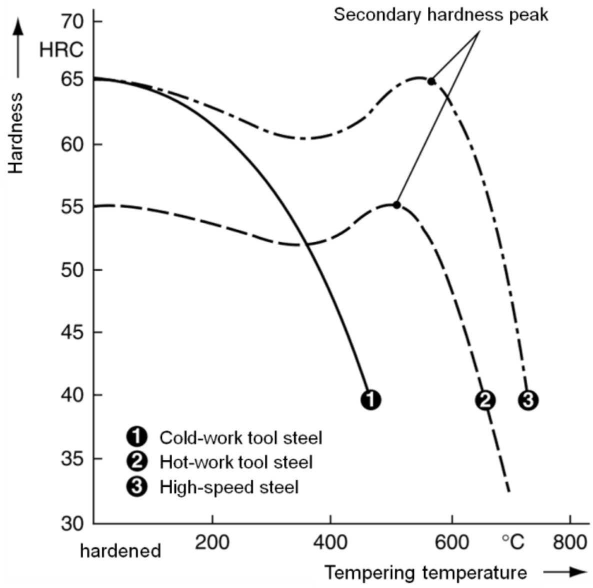

Fig. 69: Effect of the tempering temperature on the hardness (adapted from Bargel and Schulze, p.281)

Landes (2006, p.124-127) compared two different types of heat treatment for the same type of martensitic high alloy stainless steel (austenitization conditions were the same):

1. Austenitization (1065 °C, time t) – quenching – tempering 3x at 540 °C, min. 1h
2. Austenitization (1065 °C, time t) – quenching – deep-freezing 3x at -196 °C – tempering 3x at 200 °C

Although both samples (blades for knives) had the same hardness at the end (60 HRc), the properties were totally different. After the heat treatment 1, high toughness but very little corrosion resistance and stability of the cutting edge were achieved. For heat treatment 2, the corrosion resistance and also the stability of the cutting edge were much better. So it has to be decided due to the specific area of application, if tempering to the secondary hardness peak is necessary and worthwhile.

After quenching and tempering, the microstructure of martensitic stainless steels consists of a martensitic matrix (eventually with retained austenite) and precipitations which are mainly not dissolved coarse carbides. Verhoeven (2007, p.135) differentiate between K_1 (primary) and K_2 (secondary) carbides. The molecular formulas for the carbides are $K_1 = M_{23}C_6$ and $K_2 = M_7C_3$. M means Fe or Cr in Fe-Cr-C alloys, like stainless steels. The primary carbides arise during the solidification out of the melt. They have a high hardness but are very brittle due to its size in the same way. The size of primary carbides depends on the chemical composition of the steel and on the manufacturing process (Sandberg and Jönson, 2002). For high alloy stainless steels (e.g. 440B or 440C), the size of the primary carbides is typically between 15-30 µm. In comparison, the carbides of the low alloy, hypereutectoid 1.3505 (100Cr6) steel are 0.2-2.5 µm in size (Landes, 2006, p.59). Secondary carbides are formed during further steel treatments like forging or tempering. They are usually smaller than primary carbides but have also a high hardness.

The relation between matrix and hard phase (carbides) determines the stability and edge holding ability of the material. If the density of the carbides is too high, their supporting effect in the matrix will be decreased. This is important for cutting tools like knives or drill bits, because the risk of breakouts and chipping is increased. Therefore, a too high amount of carbides is a disadvantage, as well as a weakened matrix. Also the size of the hard phase is important, since carbides are very brittle and tend to break out easily at sharp cutting lips, especially if they are coarser. It can be concluded that fine and homogenous distributed carbides, in the right relation to the matrix are preferable for cutting applications. (Landes, 2006, p.58-61)

In the following chapter, different martensitic stainless steels and their associated surgical drill bits are described.

2.6.3 Investigated Materials

Previous research at the IWS TU Graz has investigated surgical drill bits made of AISI 440A (Synthes), 440B (Brasseler, older models) and 431 (Brasseler, newer models 2014). The relating chemical compositions can be seen in Table 10.

Table 10: Chemical compositions of investigated surgical stainless steels[15]

Steel		C	Cr	Mn	Mo	Ni	P	Si	S	Hard-ness HV[16]	Fracture toughness MPa^0.5[16]	Price €/kg[16]
AISI	Other names											
440A	~1.4109 (X70CrMo15)	0.60-0.75	16.00-18.00	max. 1.00	max. 0.75	—	max. 0.04	max. 1.00	max. 0.03	500-600	17-34	2.21-2.43
440B	~1.4112 (X90CrMoV18)	0.75-0.95	16.00-18.00	max.. 1.00	max. 0.75	—	max. 0.04	max. 1.00	max. 0.03	560-660	13-29	2.24-2.46
431	~1.4057 (X17CrNi16-2)	0.12-0.22	15.00-17.00	1.50	—	max. 2.5	max. 0.04	max. 1.00	max. 0.015	~ 470	—	1.1

In this chapter, these three materials are investigated with regard to their qualification for surgical drill bits. In doing so, wear and corrosion resistance are considered as main criteria. The effect of wear on the drilling forces and most of all on the drilling temperatures have already been described in chapter 2.4.7. Fracture toughness as requirement will be discussed separately in chapter 3.2.4. Since all of the following investigated drill bits are certified for medical treatment, biocompatibility as criterion is presupposed.

The wear resistance is mainly determined by the microstructure of the martensitic stainless steel. Detailed investigations of the microstructure of common drill bits have already been performed at the IWS by several authors (Zopf, 2011; Stoiber, 2014; Funk, 2014). Therefore, additional metallographic specimens of available surgical drill bits have not been prepared for this thesis.

I. <u>AISI 440A:</u>

The AISI 440A is a stainless martensitic steel with a carbon content of 0.60-0.75 %. It has a good corrosion and wear resistance which makes the steel suitable for medical, surgical and dental instruments as well as for general cutting tools. The maximum hardness is 56 HRc (610 HV) after quenching and tempering below 150 °C. (L. Klein, 2014)

Stoiber (2014, p.78-80) measured the microhardness (Vickers, HV0.025) in the centre (web) and in the marginal zone of a 440A surgical drill bit (Synthes, Fig. 70). The mean values were 722.2 HV0.025 (±6.02) for the centre (web) and 705.6 HV0.025 (±11.84) for the marginal zone. The author also investigated the primary and secondary carbides and found broken carbides in the microstructure of new drill bits (Fig. 73). That means that carbides already can

[15] Source: Stahlschlüssel (2007, p.98)
[16] Data from Cambridge Engineering Selector (CES) EduPack 2014, Version 14.3.5, Values for fracture toughness and price are estimates

break during the manufacturing process. Broken carbides in surgical drill bits have been reported by Haubner et al. (2012) as well. According to Stoiber (2014, p.114), the mean size of the coarse carbides for the 440A was 3.3 µm on the marginal zone and 3.0 µm in the centre.

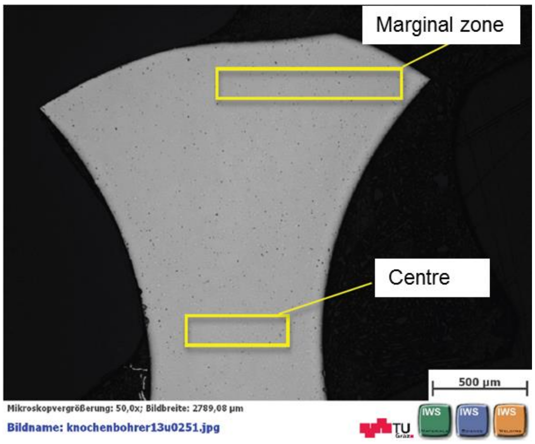

Fig. 70: Measurement areas for the microhardness examinations (Stoiber, 2014, p.80)

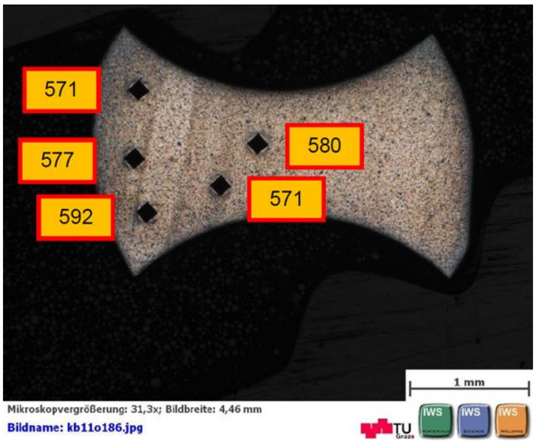

Fig. 71: Measurements of the macrohardness of a Synthes 440A surgical drill bit (Zopf, 2011, p.145)

Zopf (2011, p.145) measured the macrohardness (Vickers, HV10) at several spots on the cross section (Fig. 71). The values were between 571 and 592 HV10 (54-55 HRc). The author also investigated metallographic specimen from 440A drill bits. For the primary carbides, a size of approx. 5 µm was observed (Fig. 72). Funk (2014) found carbides with a size up to 10 µm in the microstructure of a 440A specimen.

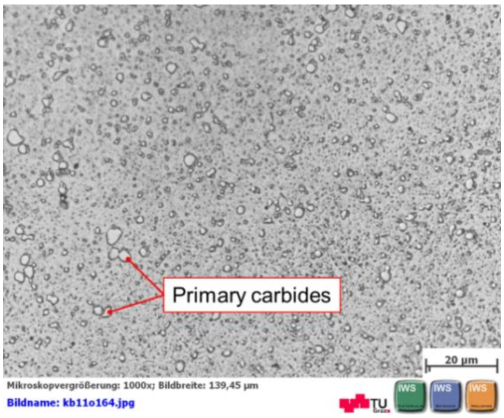

Fig. 72: Microstructure of a Synthes (440A) drill bit (Zopf, 2011, p.142)

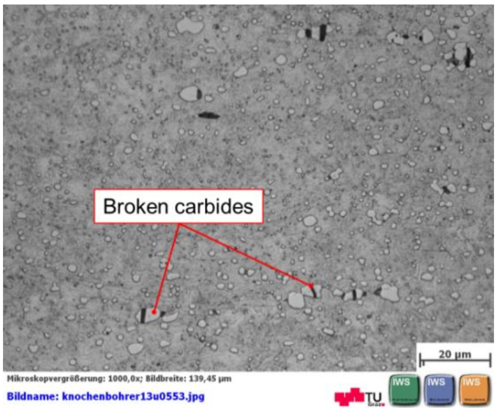

Fig. 73: Microstructure of a new Synthes (440A) drill bit (Stoiber, 2014, p.105)

II. AISI 440B:

The AISI 440B is also a martensitic stainless martensitic steel and close related to the 440A. The main difference is the higher carbon content of 0.75-0.95 %, which is responsible for the good wear resistance and resistance against bluntness and edge-holding abilities, respectively. Because of its good corrosion and wear resistance, this steel is widely used for medical, surgical and dental instruments. The maximum hardness is about 58-59 HRc (650-670 HV) after quenching and tempering below 150 °C. (L. Klein, 2014)

The microhardness (Vickers, HV0.025) measurements from Stoiber (2014, p.79) for the Brasseler 440B showed a mean value of 698.6 HV0.025 (±6.02) for the centre and 713.4 HV0.025 (±7.64) for the marginal zone. The mean size of the primary carbides has been found as 5.5 µm on the marginal zone and 4.7 µm in the centre of the cross section of the drill bit. Broken carbides have also been observed by Stoiber (2014, p. 105) for the 440B microstructure of unused drill bits (Fig. 75).

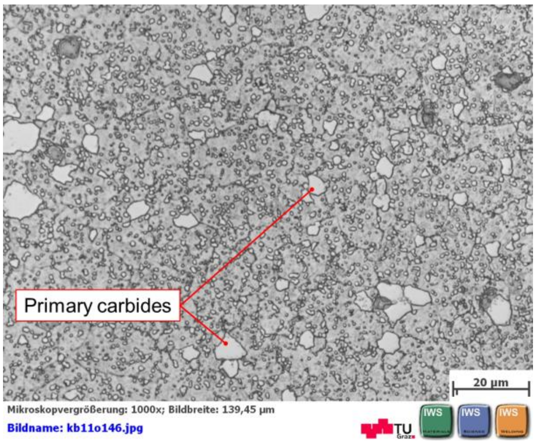

Fig. 74: Microstructure of a Brasseler (440B) drill bit (Zopf, 2011, p.144)

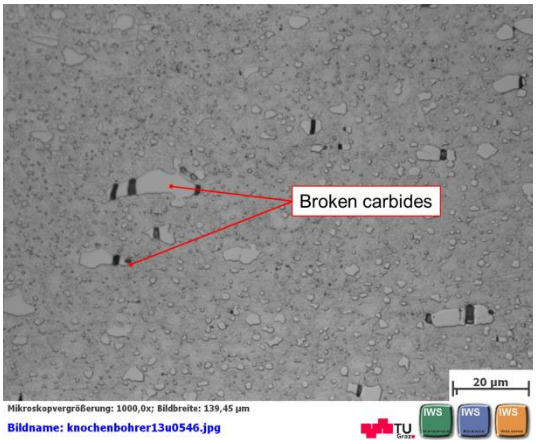

Fig. 75: Microstructure of a new Brasseler (440B) drill bit (Stoiber, 2014, p.105)

Zopf (2011, p.146) also measured the macrohardness (Vickers, HV10) of a Brasseler 440B surgical drill bit in the same way as above. There were slightly different mean values for the centre (580 HV10) and for the marginal zone (590 HV10). The author determined the size of the primary carbides up to 10 µm (Fig. 74). Funk (2014) investigated carbide sizes up to approx. 20 µm.

III. AISI 431:

The AISI 431 steel has low C (carbon) and S (sulphur) contents. Together with the Ni-alloying, this steel has a really good corrosion resistance. But the low C content results in lower hardness (max. 47 HRc) compared to 440A/B which further causes lower wear resistance. Because of its good corrosion resistance, the AISI 431 steel is particularly suitable for medical, surgical and dental instruments. But its little wear resistance makes it unusable for cutting instruments. (L. Klein, 2014)

According to Funk (2014, p.42), Brasseler changed the material for their surgical drill bits from AISI 440B to AISI 431 at the beginning of 2014. The author investigated the wear characteristics of three different 3.5 mm surgical drill bits after drilling into artificial bones with the FSW-machine (800 rpm; v_f = 70 mm/min). Funk (2014, p.47) found that the wear characteristics were comparable for the 440A (Synthes) and the 440B (Brasseler, old) drill bits. But the wear results for the 431 (Brasseler, new) were much lower. After only seven holes, clear signs of wear appeared. Chipping and abrasion of the flank as well as abrasion of the chisel edge were observed by Funk (2014, p.47-48). Thus the wear resistance of the AISI 431 was obviously lower compared to the 440A/B drill bits. The author furthermore investigated the microstructure of the steel and found fine carbides (size approx. 1 µm) regularly distributed along the metallographic section (Funk, 2014, p.43).

Conclusion

In this chapter, materials used for surgical drill bits have been described regarding to their mechanical and microstructural properties. The presence of carbides in martensitic stainless steels is essential for the wear resistance and edge-holding abilities. The metallographic specimens from Zopf (2011) showed smaller primary carbides for the AISI 440A steel (Synthes). Furthermore, the distribution of the carbides was slightly more homogenous compared to the AISI 440B from Brasseler. A homogeneous carbide distribution is important for the carbides to build a tight supporting and wear resisting network in the matrix. The higher rate of primary carbides resulted in a higher hardness for the 440B, which can also be explained with the higher amount of carbon in this alloy.

Generally, carbides are very brittle. Broken carbides have been observed by several studies. Since cutting edges have generally thin geometries, break-outs of carbides in those areas are unfavourable they reduce the cutting performance due to the lower edge-holding abilities. Zopf (2011, p.147) investigated heavier break-outs on the cutting edge for the 440A drill bit although the carbides were slightly smaller compared to the 440B (Fig. 76 and Fig. 77). The author ascribed this to the strong machining grooves parallel to the cutting edge of the Synthes 440A drill bit which increased the notch effect.

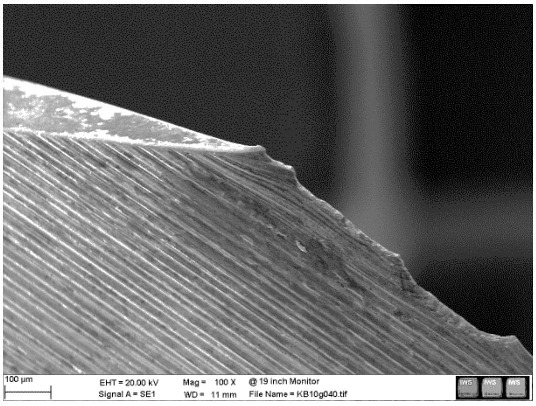

Fig. 76: Machining marks on the Synthes 440A drill bit, SEM x100 (Zopf, 2011, p.148)

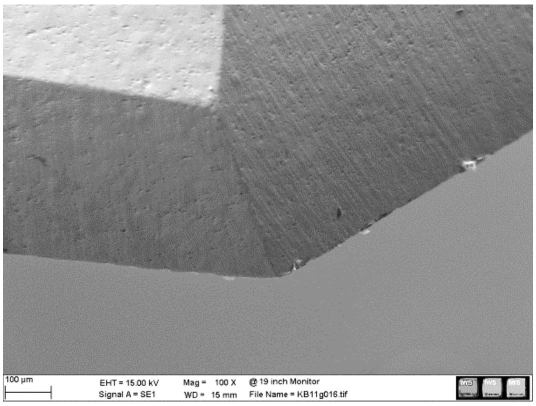

Fig. 77: Machining marks on the Brasseler 440B drill bit, SEM x100 (Zopf, 2011, p.148)

The carbon content is the main factor for the hardness of general tool steels. This is also true for the 440A and 440B. The maximum hardness after hardening and tempering (below 150 °C) is 56 HRc for the 440A and 58-59 HRc for the 440B (L. Klein, 2014). Therefore, the 440B has the potential for the better wear resistance. In terms of the corrosion resistance, the 440A has to be preferred. Less carbides are the reason that the chromium content in the lattice stays higher than the remaining content in the 440B. But as Verheoven (2007) mentioned, the carbon to chromium ratio is decisive. Higher amounts of carbon can be compensated with an increasing content of chromium. With 16-18 % Cr, the 440B should have enough surpluses not to fall below the critical 12 % Cr limit. Furthermore, the 440B has been in use in medicine successfully. This indicates that the 440B withstands the corrosive load during the reprocessing.

Fracture toughness is an important criterion for surgical drill bits. Drill bit breakage during the operation must be prevented as good as possible, although the consequences are not as serious as generally assumed (chapter 3.2.4). Verhoeven (2007, p.139) reported data from the Izod impact test of different martensitic stainless steels (annealed condition). The Izod impact test is similar to the Charpy impact test. It determines the impact resistance of materials which is a measure for their toughness. The absorbed energy was nearly three times higher for the 440A (20 J) compared to the 440B (7 J). Values for the fracture toughness are also provided by the CES (Cambridge Engineering Selector). Table 10 shows that the values for

440A and 440B (both wrought and tempered at 316 °C) differ not that much. The higher toughness of the 440A can be explained with the smaller content of carbon and the smaller carbides. On the other hand, the wear resistance suffers from this.

The AISI 431 appears to be totally different to the AISI 440A/B alloys. It contains only a small amount of carbon (0.12-0.22 %). Hence, the hardness and the wear resistance are really limited. This has also been reported by Funk (2014), who observed excessive wear after only few drill holes. The advantages of the AISI 431 are clearly the good corrosion resistance and the high toughness. Verhoeven (2007, p.139) reported an energy of 68 J from the same Izod impact test. This is approx. 10 times higher than the absorbed energy of the AISI 440B.

Surgical drill bits are single-use or multiple-use tools (see chapter 3.3 for more information), depending on the declaration of the manufacturer. But for the AISI 431, multiple-use seems not to be an option because of its little wear resistance. Multiple-use requires the reprocessing of the surgical instruments. As already mentioned, the main corrosive load to the drill bit appears during this process because corrosive media are used for the disinfection, cleaning and sterilization. Here is the discrepancy of the AISI 431 alloy: its outstanding corrosion resistance is useless because the steel is not an appropriate candidate for reprocessing. "Single-use" means that the drill bit is discarded after the operation without ever reprocessing again. It seems that the AISI 431 is exclusive made for single-use due to its low wear resistance and high fracture toughness, which decreases the risk of drill bit breakage.

To choose between AISI 440A and 440B the main question is whether the corrosion resistance or wear resistance is more important. For multiple-use drill bits, both alloys fulfil these two requirements. In terms of patient safety, corrosion and drilling residues on surgical drill must be avoided. But it should not be underestimated that blunt drill bits cause higher temperatures during drilling which increases the risk of thermal necrosis. If a surgical drill bit with low wear resistance is used multiple times, the risk of drilling with a worn exemplar is rather high. The additional costs for exchanging the drill bit should be taken into account as well (see 3.2.1). One approach could be the development of the full potential of the AISI 440B. Beginning with the manufacturing process, the focus should be on building fine and homogeneous carbides and to avoid coarse primary carbides as much as possible. From the hardness measurements of Zopf (2011), it can be seen that the mean values of the 440B (Brasseler) were nearly the same as for the 440A (Synthes). For further improving the wear resistance and the tool life, the 440B has to be heat treated differently to achieve higher hardness values on the cutting edges. Together with a tough drill bit web, good results could be reached. But selective hardening, which is necessary for this, would be difficult for small drill bits. The surface finishing is important too. Rough machining marks increase the risk of break-outs, first of all at the cutting edge (Zopf, 2011, p.147-148). Therefore, a smooth surface and a low surface roughness have to be aspired after grinding.

To sum up, it seems that none of the materials discussed above is ideal for surgical drill bits from a technical point of view. In the next chapter, alternative materials are critically reviewed.

2.6.4 Alternative Materials

Previous research at the IWS has been mainly focused on three different materials for surgical drill bits: AISI 440A, AISI 440B and AISI 431. It has been also noted that there is potential for improvement. Zopf (2011) tested different coatings on surgical drill bits. He concluded that the hard coating is useless if the drill bit has unsufficient surface finishing quality. The author also performed experiments with a standard HSS-6-5-2 drill bit made for general engineering purposes and do-it-yourselfer. This drill bit showed only few signs of wear but HSS is not a certified material for medical devices because of its lack in biocompatibility.

During this thesis, demands for other alternative materials arose. Since coatings have been already investigated by Zopf (2011) the focus in this work is on uncoated martensitic stainless steels. Two different steels, which fulfil the requirements from chapter 2.6.1, are described in the following section.

I. <u>AISI 440C:</u>

The AISI 440C is a further member in the family of the 440 steels. The idea for the 440C as an alternative came from the knife making branch, where this steel has a good reputation. The chemical composition is similar to the 440A/B. Just the carbon content is significantly higher (0.95-1.20 %). Due to this, a hardness of 60 HRc (approx. 690 HV) can be achieved after hardening which gives the 440C an outstanding wear resistance. The corrosion resistance is acceptable for water and steam as long as the parts undergo the right heat treatment (quenching and tempering at lower temperatures) and are polished and passivated. The primary fields of applications are bearings, cutting tools and medical instruments. (L. Klein, 2014)

From a theoretical point of view, the corrosion resistance is below those of the 440A and 440B. The reason for this is the high amount of (large) chromium carbides. They are responsible for high hardness but also diminish the chromium content of the martensitic matrix.

Therefore, tempering after quenching should be done at low temperatures (around 150-200 °C) where the corrosion resistance is at its best. The disadvantage of this is that the toughness stays at low ranges. Verhoeven (2007, p.139) reported Izod impact test results of 7 J for the 440C which is equal to the 440B. The second issue which arises due to large carbides are possible break-outs at the chisel edge. But a look at the wear characteristics observed on drill bits from the operation theatre (chapter 2.5.5) shows that the abrasion and bluntness is partial widely advanced. For this, small breakouts on the chisel edge are of subordinate importance.

To sum up, the 440C is definitive a candidate for further experimental studies. They have already been planned and should take place in the near future at the IWS. The raw material has been obtained and the datasheet can be found in the Fig. A-5 (appendix). For more information about the experiments, see chapter 4.

I. <u>AISI 420mod:</u>

The AISI 420mod is martensitic stainless steel with a different chemical composition to the AISI 440 steels. Apparently, the nitrogen content of approx. 0.2 % (0.15-0.25 %) is one of the major differences. The corrosion resistance is outstanding and outperforms those of the AISI 440B/C. Hardness levels of about 58-59 HRc can be reached after quenching and tempering, even though the carbon content is moderate (0.37-0.45 %). (L. Klein, 2014)

Perot et al. (2003) presented the X 15 T.N™ as new steel for surgical instruments. The X 15 T.N™ has the same specifications as the AISI 420mod. Other designations are X40CrMoVN16-2 (DIN EN) or 1.4123. Perot et al. (2003) highlighted the nitrogen in the alloy which is added to partly replace the carbon. Furthermore, it ensures a good response to hardening and also improves the corrosion resistance. Compared to the AISI 440 steels, the molybdenum content is higher and vanadium is added to the alloy too. Molybdenum should provide a more stable passive layer: Vanadium builds vanadium carbides which improve the edge-holding stability as well as the high temperature strength. Therefore, hardening up to the secondary hardness peak is possible. Perot et al. (2003) performed experiments with different steels (among others 440C) to show the advantages of the X15TN. Compared to the 440C, decisive advantages were found by the authors:

- <u>Finer carbides:</u> micrographs show finer and homogeneous distributed carbides.
- <u>Better corrosion resistance:</u> far better results for the X15TN compared to the 440C in the salt spray test at same hardness levels (59/60 HRc) and better results in the potentio-kinetic test in sulphuric acid solution as well.

Moreover, the authors mentioned the good edge-holding stability. In a published brochure from Aubert & Duval (2010), differences in the microstructure between 440C and X15TN (420mod) are illustrated (Fig. 78).

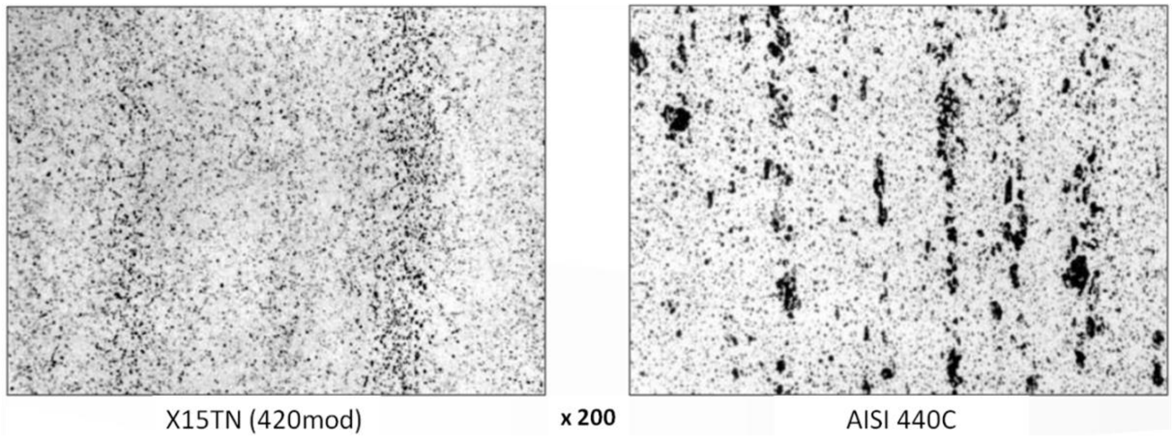

Fig. 78: Comparison of the microstructure, X15TN (420mod) and AISI 440C at magnifications x200 (Aubert & Duval, 2010)

For further research at the IWS, raw materials have already been ordered. Fig. 79 and Fig. 80 show the microstructure of the 420mod and 440C as received from the distributor. The microstructure is as expected:

- Fine and homogeneous distributed carbides are visible in the microstructure of the 420mod. Only a low quantity of broken carbides (dark spots) is visible. The maximum carbide size is approx. 3 µm.
- Larger and more inhomogeneous distributed carbides are visible in the microstructure of the AIS 440C alloy. There are far more broken carbides visible. The maximum carbide size is approx. 8-10 µm.

The chemical compositions of the AISI 440C and the 420mod are listed in Table 11.

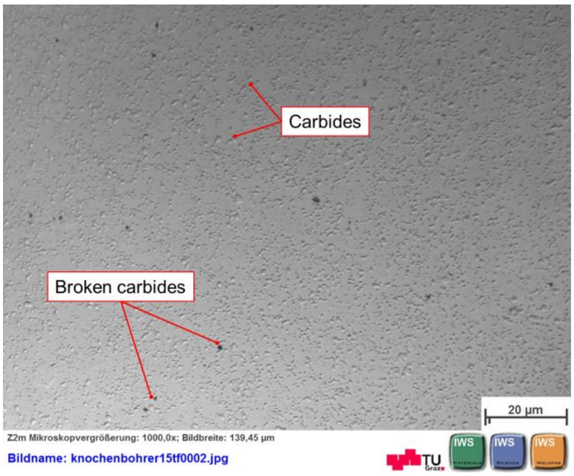

Fig. 79: Microstructure of the AISI 420mod alloy, annealed, ground polished condition, non-etched, magnification x1000

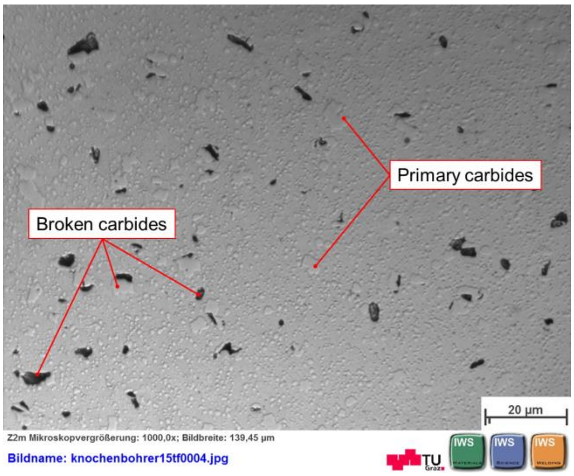

Fig. 80: Microstructure of the AISI 440C alloy, cold drawn and ground polished condition, non-etched, magnification x1000

Table 11: Chemical compositions of alternative surgical stainless steels

Steel		C	Cr	Mn	Mo	Ni	P	N	Si	V	S	Hard-ness HV[17]	Fracture toughness MPa^0.5[16]
AISI	Other names												
440C	~1.4125 (X105CrMo17)	0.92-1.20	16.00-18.00	max. 1.00	max. 0.75	—	max. 0.04	—	max. 1.00	—	max. 0.03	590-690	12-28
420mod	~1.4123 (X40CrMoVN16-2)	0.37-0.45	15.00-16.00	max.. 0.60	1.50-1.90	max. 0.50	max. 0.02	0.16-0.25	max. 0.60	0.20-0.40	max. 0.005	660	—

It seems that the 420mod is the ideal material for surgical drill bits in terms of its mechanical properties. Therefore, this steel should be taken into account for further experiments too.

2.6.5 Outcome – Materials

Materials for surgical drill bits have to fulfil a number of different requirements: they have to withstand corrosion but should be wear resistant in the same way. Beyond that, a high toughness has to ensure that the drill bit does not break during drilling. Previous research at the IWS TU Graz has focused on three different martensitic stainless steels: AISI 440A, 440B and 431. It can be concluded that none of them uncompromisingly fulfils all requirements. 440A and 440B have opposing properties regarding corrosion- and wear resistance. The AISI 431, however, is not suitable for multiple-use. Although its corrosion resistance is outstanding, unacceptable wear resistance must be expected after only a few holes. Therefore, alterna-

[17] Data from Cambridge Engineering Selector (CES) EduPack 2014, Version 14.3.5, Values for fracture toughness are estimates

tive materials have been taken into account: AISI 440C and AISI 420mod (X15TN). AISI 440C, also a martensitic stainless steel, has a very good wear resistance due to the high amount of carbon and the resulting carbide formations. Whereas the corrosion resistance is limited and the fracture toughness is compromised too. The second alternative material, AISI 420mod (X15TN), combines high wear resistance and good corrosion resistance. Therefore this steel appears to be an ideal candidate for surgical drill bits from a theoretical point of view. Further practical tests have to be performed to underline this suggestion.

3 ECONOMIC ANALYSIS

In this section, the economic point of view of the process of surgical bone drilling is described. This is a new approach at the IWS. Up to now, bone drilling has been investigated from a technical view only. Together with the Institute of Industrial Management and Innovation Research (IBL), the process of surgical bone drilling has been analysed and the chosen approach is presented in this chapter. As a result, recommendations for further improvements are provided.

3.1 Background

A broad variety of literature exists on the technical aspects of surgical bone drilling. At the first glance, an economic analyse on this topic seems to be unnecessary because it is only a sub-process during osteosynthesis. But engaging with this topic is important, not only in terms of the patient's safety. Also the economic impact is remarkable.

3.1.1 Statistics of Osteosynthesis

In this chapter, statistics of osteosynthesis are provided. It has been shown that osteosynthetic procedures are one of the most frequently performed operations in Austria and Germany. Since bone drilling is an important part of osteosynthesis, these statistics emphasize also the meaning of research on this topic.

In 2013, 55,913 operative procedures and services related to osteosynthesis were documented in Austria (Statistics Austria, 2014). Furthermore, 23,657 additional services for the removal of osteosynthetic material are noted in the statistics. In Germany, procedures including osteosynthesis (Fig. 81, yellow coloured[18]) are under the Top 10 of the most frequent operations and procedures in 2012 and 2013 (Federal Statistical Office, 2013 and 2014). Further statistics can be seen in Table 12.

[18] engl.: open reposition of a multifragmentary fracture at the joint areas of a long bone including osteosynthesis

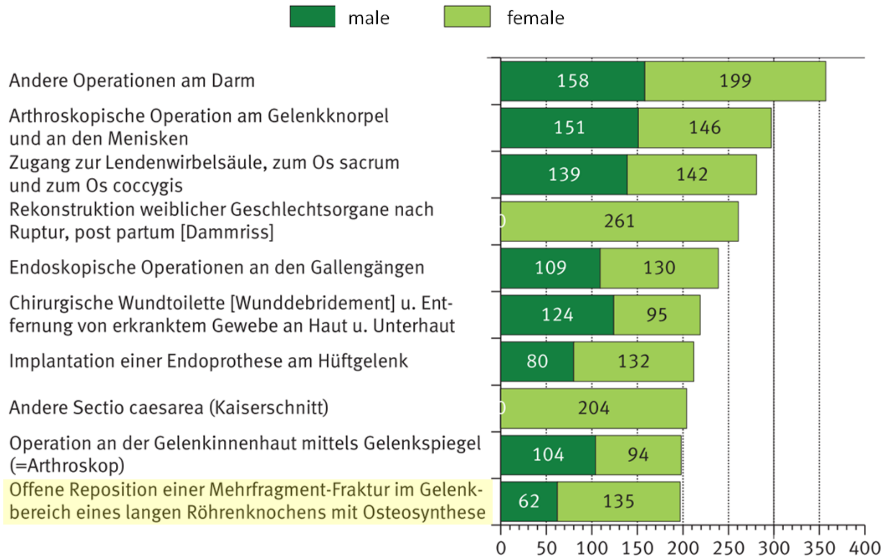

Fig. 81: Top 10 of the most frequent operations (in thousands) in Germany in 2012 (Federal Statistical Office, 2013)

Table 12: Osteosynthesis in Austria and Germany in 2012 and 2013 (Statistics Austria 2014; Federal Statistical Office 2013 and 2014)

Operative procedures and services ...	2012		2013	
	Austria	Germany	Austria	Germany
... associated with osteosynthesis	55,416	583,663	55,913	601,893
... associated with the removal of osteosynthetic material	23,741	182,003	23,657	180,031
... in total	1,218,080	15,714,665	1,233,212	15,818,274

It can be seen from the statistics that there are numerous procedures of osteosynthesis every year. That implies that surgical bone drilling, as a part of osteosynthesis, is also a topic of high relevance. As an illustration, a rough estimate about the total amount of bone holes per year can be made. Not every osteosynthesis requires drilling of bone. But if only four holes are assumed as mean value, Austrian surgeons drill more than 220,000 holes in human bones every year.

Unfortunately, not every osteosynthesis passes off without complications. They can happen during or after the procedure. First of all, complications affect the patient, but they also increase the economic costs. In the next chapters, possible complications relating to osteosynthesis and thermal necrosis are described. Furthermore, an estimate of their economic impact is provided.

3.1.2 Biomechanical Consequences of Thermal Necrosis

The previous chapter has shown that surgical bone drilling is performed frequently in Austrian hospitals. As an accompanying effect, thermal necrosis can occur, depending on the temperature elevation and on the exposure time. This phenomenon has been described in chapter 2.1.1. Thermal necrosis damages the cell tissue irreversibly, which further decreases the stability of the fixation after osteosynthesis.

Schmelzeisen (1990, p.43-45) investigated the holding strength of screws in different bone samples (Fig. 82). The holding strength was decreased for heated bone samples compared to bones without thermal damage. This has also been observed by the author for bone samples drilled with blunt drill holes too. These results emphasize the importance of sharp drill bits.

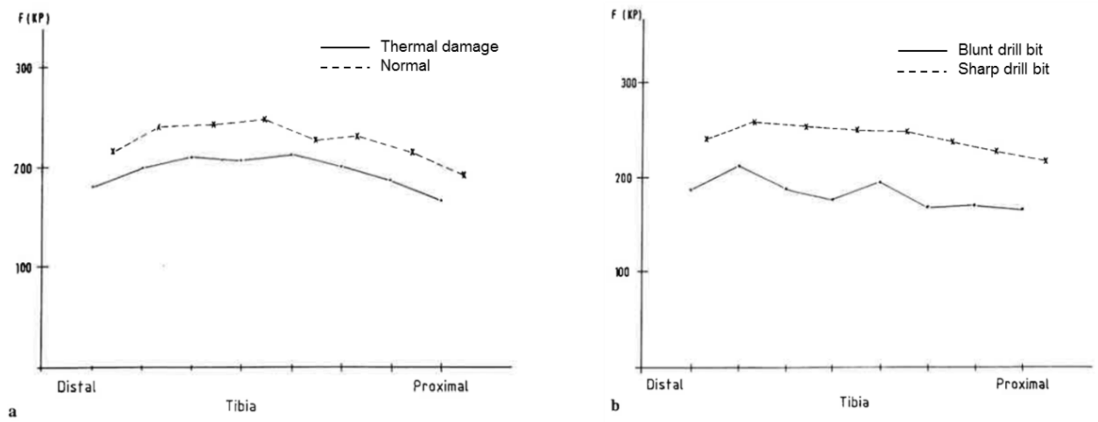

Fig. 82: Holding strength (F in kp) of bone screws (Schmelzeisen, 1990, p.45)
a) Heated and normal bone samples; b) Blunt and sharp drill bits

Schmelzeisen (1990, p.83) concluded that changes of the collages are the reason for the decreased holding strength. Therefore, incorrect surgical bone drilling and/or the use of blunt drill bits can compromise the corticalis in a way that the strength of the implant is decreased. Under stress, this can result in an unwanted loosening of the fixation post-operatively. This has been noted by several other authors (Bachus et al. 2000; Bertollo and Walsh, 2011; Pandey and Panda, 2013; Augustin 2012a).

3.1.3 Economic Consequences of Thermal Necrosis

In the previous chapter, the effect of excessive thermal load on the holding strength of implant screws has been stated. In this chapter, possible consequences for the patient and for the economy are outlined.

It has been described that thermal necrosis reduces the holding strength of fixation screws which further supports loosening of the implant. But the question is what the failure rate of implants is? Is loosening of the fixation a post-operative complication which occurs frequently? Augustin et al. (2008) reported a failure rate for lower leg osteosynthesis of 2.1-7.1 %. As one possible cause, they mentioned bone resorption around the implant screws because of thermal necrosis after preparative drilling. Kyo-Hung et al. (2011) noted success rates for dental implants of 93.9-98.7 % and mentioned thermal necrosis as one of the causes for early implant failure. But none of the studies above quotes a definitive rate of implant failures caused by thermal necrosis.

For this thesis, the goal was to determine the amount of post-operative complications from thermal necrosis caused by surgical bone drilling. Possible consequences of complications, for instance implant loosing, are fatal for the patients:

- additional, unplanned operative procedures,
- extended healing and recovery process,
- absenteeism from work or school.

From an economical point of view, there are further consequences:

- loss of value creation and
- increased health expenditures lead to
- high economic costs.

The chosen approach was to obtain data from statistics. The goal was to find out, how many of the osteosynthesis patients have to undergo unplanned post-operative procedures after complications. But the reasons for complications differ widely and have to be filtered. Only complications due to thermal necrosis should be taken into account (see Fig. 83).

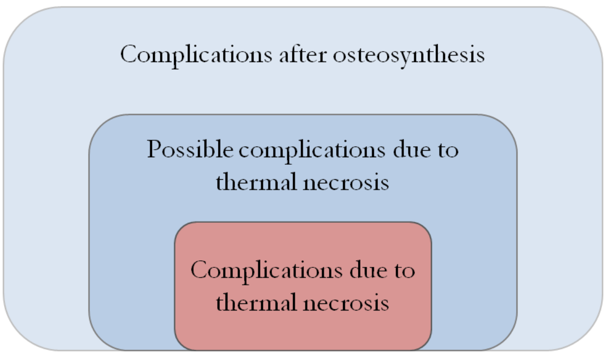

Fig. 83: Selection of relevant complications for the study

For the data, two relevant federal institutions were contacted. The Steiermärkische Krankenanstaltengesellschaft m.b.H. (KAGes) organizes the state hospitals in Styria (among others: LKH Graz). The second institution, the Austrian Workers' Compensation Board (dt. Allgemeine Unfallversicherungsanstalt, AUVA) is the social insurance for occupational risks in Austria. The AUVA is also responsible for seven different trauma centres in the country. For obtaining the statistics, there were three main questions to AUVA and KAGes:

1. How many patients have undergone osteosynthesis procedures in one year?[19]
2. How many of them had to come back because of complications with their implants and fixations?
3. In how many cases was thermal necrosis the cause for the complications with the implants and fixations?

The classification of diseases is based on the ICD-10. The ICD-10 (International Statistical Classification of Diseases and Related Health Problems) is a medical classification list which is used worldwide. The number of patients with osteosynthesis (question no. 1) can be determined easily. But the determination of the cases with complications due to thermal necrosis is far more complex, since the ICD-10 does not provide a special classification code for this. But more important, there is a lack of verifiability whether thermal necrosis was the definite cause for implant failure. Therefore, classification codes have to be found which represent possible complications out of thermal necrosis (Table 13).

Table 13: ICD-10 complication codes for implant failure

ICD-10 code	Name
T81	Complications of procedures, not elsewhere classified
T84	Complications of internal orthopaedic prosthetic devices, implants and grafts
T85	Complications of other internal prosthetic devices, implants and grafts

Both, KAGes and AUVA responded to the enquiry about the statistics via e-mail. The response is concluded in the following paragraphs.

[19] Only osteosynthesis procedures which were performed for the first time on the patient are considered - removal of osteosynthetic materials was not taken into account.

KAGes:

The provided data from KAGes can be seen on Table 14. To determine the complications, only the T84 code was used, which was sub classified into T84.1, T84.2 and T84.6.

Table 14: Statistics about complications after osteosynthesis with complication codes (KAGes)

Operative procedures	2012	2013
Procedures and services with osteosynthesis, overall	3,844	3,810
Procedures and services with osteosynthesis, with complication code*	40	28
Operative procedures, overall	80,518	84,699
Operative procedures on the musculoskeletal system	17,199	17,712
*T84.1: Mechanical complication of internal fixation device of bones of limb T84.2: Mechanical complication of internal fixation device of other bones T84.6: Infection and inflammatory reaction due to internal fixation device (any site)		

From the table above, the complication rate is between 0.73-1.04 %. This is lower than Augustin et al. (2008, see above) noted in their study. On the one hand, the applied complication codes in Table 14 restrict the results tightly. On the other hand, using the ICD-10 codes is partly subjective and depends on the surgeon. If there are additional operations necessary because of post-operative complications, proper coding could become a minor matter.

AUVA:

In terms of comparability, data from the AUVA should be in accordance with the criterions which were used for the KAGes statistics. The results can be seen in Table 15.

Table 15: Statistics about complications after osteosynthesis with complication codes, AUVA

Operative procedures	2012	2013
Procedures and services with osteosynthesis, overall	6,174	6,918
Procedures and services with osteosynthesis, with complication code*	16	30
*T84.1: Mechanical complication of internal fixation device of bones of limb T84.6: Infection and inflammatory reaction due to internal fixation device (any site) no matches for T.84.2		

Unfortunately, there is one vital problem with the data in Table 15: only three AUVA hospitals out of seven appear in the statistics. And the majority of the operation procedures (overall and with complications) took place in only one hospital. According to AUVA, the reason for this could be that in the remaining hospitals the complication code T.84x is not or only barely used. This is possible, since there is room for interpretation for the use of complication codes according to ICD-10. In consultation with the AUVA, the provided statistics is not valid for the determination of complication rates.

To conclude, the absolute number of complications with osteosynthesis procedures due to thermal necrosis is not known. On the one hand, the determination whether a loosened implant was caused by thermal necrosis is effortful and therefore unusual in the daily routine. On the other hand, there is a wide range of using the ICD-10 codes for the medical staff which makes it difficult to obtain definite, reliable statistics.

But a view on the statistics of KAGes and Augustin et al. (2008) should allow making a rough estimate on the economic impact of inadequate bone drilling. For the calculations, it should be assumed that the failure rate for complications due to thermal necrosis and other consequences from careless bone drilling is 0.7 %. This means that for a total number of 55,913 osteosynthesis procedures in Austria in 2013, 391 patients suffer under post-operative complications. To put it simply, every day occurs at least one new case.

Sick leave (absenteeism from work) is not only a personal burden for the employees. It is also a high cost factor for the companies and the economy (WIFO, 2014, p.IV). An estimate of the accruing economic costs in Austria related to accidents and diseases can be separated as shown in Table 16.

Table 16: Estimate of the costs related to accidents and diseases of employees (WIFO, 2014, p.IV)

Costs	in million €
Economic- and economically (business) costs	up to 8,648
Direct costs (continued payment of remuneration and sick pay)	3,248
Indirect costs (losses in value creation)	up to 5,400
Health expenditures	7,782
Direct public costs	5,919
Direct private costs	1,863

On the other side, Austrian employees were absent for 40,363,946 days from work because of illness (including accidents) in 2013 (WIFO, 2014, p.61). With this information, an interesting question can be answered: what does one day of sick leave cost (EC_d)?

$$EC_{d} = \frac{8{,}648 * 10^{6}\ €}{40{,}363{,}946\ d} = \mathbf{214.25\ €/d}$$

From an economic point of view, one day costs up to 214.25 €, not including health expenditures. This result fits well to the calculations from the German Federal Institute for Occupational Safety and Health (BAuA). They determined the costs for production downtimes for each day of sick leave. Depending on the economic sector, the costs were between 138 and 352 € per day in 2012 (BAuA, 2012, p.3). Less days of absenteeism from work would decrease not only the direct and indirect economic costs, but also the health expenditures.

With this information, the effect of inadequate bone drilling during osteosynthesis on the economic costs can be estimated. The following assumptions were made:

Economic costs per day (EC_d):	214 €
Number of patients with complications per year:	391
Percentage of working patients (assumption):	65 %
Days of absenteeism from work per patient (assumption):	30 d[20]

Calculation of the total economic costs (EC) per year:

$$EC = 214 \times 391 \times 0.65 \times 30 = \mathbf{1{,}631{,}643}\ €$$

With each additional day of recovery, the economic costs increase. Permanent disability as worst case scenario is not considered. Health expenditures have also been taken into account for this thesis. With every unplanned complication, the health expenditures have to increase obviously. Additional costs arise for medical staff, surgical instruments, implants and medicine. Since these are patient-specific costs, a different and more general approach for the estimate of the total health expenditures was chosen. The question is: what does one day of in-patient stay in the hospital cost (HC_d)?

Total costs for in-patient care in Austrian Hospitals, 2012: (Statistics Austria, 2012a)	10,739 billion €
Total days of stay in Austrian Hospitals (excl. 0-day stays), 2012: (Statistics Austria, 2012b)	18,102,269 days
Duration of staying in the hospital, mean value, 2012: (Statistics Austria, 2012b)	8 days

$$HC_{d} = \frac{10{,}739 * 10^{9}\ €}{18{,}102{,}269\ d} = \mathbf{593.24\ €/d}$$

Calculation of the total hospital costs (HC) per year:

[20] Mean value for fractures of the upper limbs, personal communication with a trauma surgeon from the LKH Graz

$$HC = 593 \times 391 \times 8 = \mathbf{1,854,904}\ €$$

Calculation of the economic and hospital costs (EHC) per year:

$$EHC = 1{,}631{,}640 + 1{,}854{,}904 = \mathbf{3,486,547}\ €$$

Therefore, the economic impact of surgical bone drilling is considerable. About 3.5 million € of additional costs arise every year in Austria due to related complications, not including out-patient expenditures. Of course, the chosen approach in this chapter is limited. But as a rough estimate, it shows the importance of well performed surgical bone drilling also from an economic point of view.

To get an impression on the specific costs of osteosynthesis, three common procedures are listed below. These costs are lump sums which include for instance the in-patient care and the removal of the osteosynthesis material.

Osteosynthesis of the femur neck (any side)	3677.87 €
Osteosynthesis of the shaft of femur (any side)	4704.55 €
Osteosynthesis of the distal forearm (any side)	1525.32 €

(Data provided by KAGes, as at 2012)

3.2 The Process of Surgical Bone Drilling

The previous chapter has shown that the economic impact of surgical bone drilling is not negligible. Therefore, research on possible weak points and improvement potentials is worthwhile. In the technical analysis (chapter 2), only the single event of drilling has been investigated in detail. In this chapter, the process of manual bone drilling is analysed as a whole. This includes pre- and post-drilling steps, like purchasing, reprocessing or disposal.

3.2.1 Schematic Process

The process of surgical bone drilling has been investigated based on the daily routine of the state hospital of Graz (LKH Graz) and the trauma center of Graz (UKH Graz). For this, interviews with people involved in the process have been conducted. The results can be seen in Fig. 84.

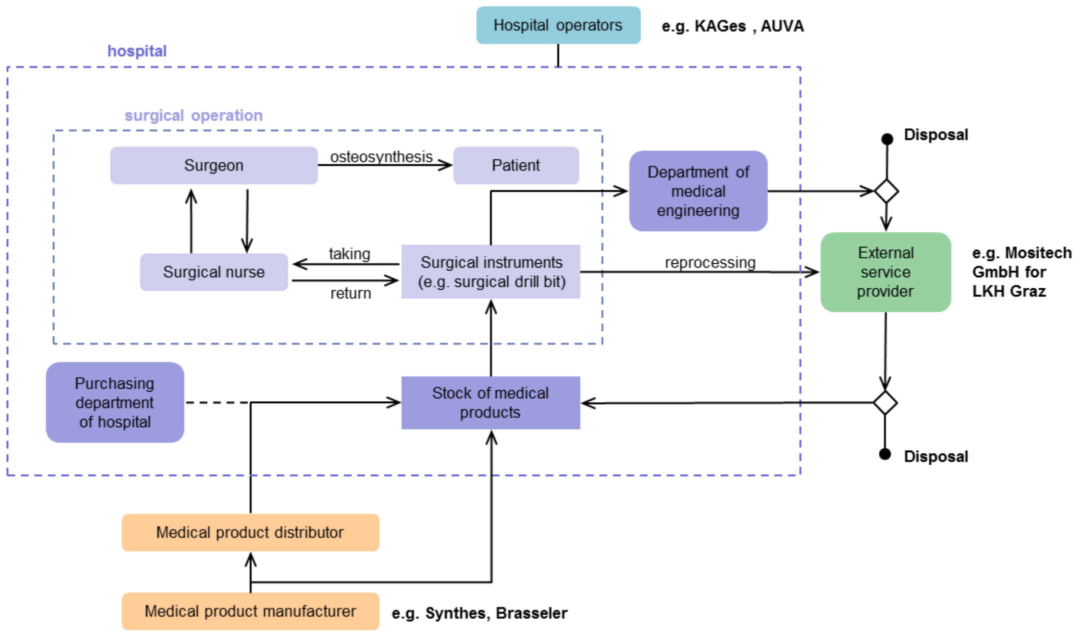

Fig. 84: Schematic process and participants (stakeholder) of surgical bone drilling

The arrows describe the way of the surgical drill bit through the process. The companies and institutions noted in the figure have been or will be mentioned in this work. Of course, there are other participants in this process too.

It was found that reprocessing of the surgical drill bits is mainly done by external service providers. Obviously, drill bits are not the only medical instruments which are reprocessed but in this thesis the focus is clearly on them. From Fig. 84, questions about the process can be generated:

1) How is the selection of the surgical drill bits made?
2) Who performs quality- and functional checks on the drill bits?
3) What are the steps during reprocessing?

Question 1 has been worked out together with the managing partner of a Styrian company. The company is specialized on the development, production and selling of therapy systems for traumatology, orthopaedics and neurosurgery. They also provide instrument and implant sets for the operation theatre. Therefore, the company negotiates directly with the purchasing department about their medical instruments. According to the managing partner, the purchasing department decides on the price which surgical drill bits they buy. Technical effectiveness is secondary, especially if it is not fully proved with studies. But also limited sensitization for technical aspects might reinforce the price as major criterion for the decisions.

The purchase price of a common surgical drill bit is about 30-40 € for the hospital according to a surgeon from the LKH Graz (personal communication). The high price is explained by the price structure. Only a small part concerns the manufacturing process of the drill bit. The major part is for sterilization, certifications and logistics. Medical instruments for the operation theatre have to be available quickly, which makes them expensive in the same way.

But this leads to another consideration: small manufacturing costs compared to the total costs foster the use of better materials. Of course, these materials have to run through clinical studies, to convince the purchasing department of the hospital. But the calculation is simple: what does the drill bit cost and how many holes can be drilled until it has to be exchanged? To compare, the costs per drill hole could be determined. Anyway, the focus should not only be on costs. Drilling temperature and usability should also be taken into account.

To answer question 2 and 3 from above, the process of surgical drilling has been analysed more precisely with Business Process Model and Notation (BPMN), which will be described in the next chapter.

3.2.2 BPMN 2.0 of Surgical Bone Drilling

Business Process Model and Notation (BPMN) is a graphical notation for modelling business processes. A process includes defined activities and tasks done by human or machines, automated or not, to achieve one or more specific goals. BPMN depicts end-to-end processes, to understand the process as a whole. This qualifies BPMN as appropriate method to analyse the process of surgical bone drilling. On the one hand, the process model should be understood by different recipients. That requires an simple graphical representation. On the other hand, the process model has to fulfil formal requirements which can increase the complexity and makes the understanding more difficult. (Freund and Rücker, 2012, pp.1-11).

The Notation – Basic Elements:

BPMN requires defined symbols to depict the business processes which can be associated with one of the basic elements from Fig. 85.

During a process, specific tasks have to be done ("activities") under specific conditions ("gateways") and things can happen ("events"). These three flow objects are connected with "sequence flows" inside a pool or lane. For connections outside the pool, "message flows" have to be chosen. "Artifacts" provide additional information about the process and can be connected with flow objects ("associations"). BPMN 2.0 defines also "data" elements, which includes the creation, processing and storage of information. (Freund and Rücker, 2012, p.21).

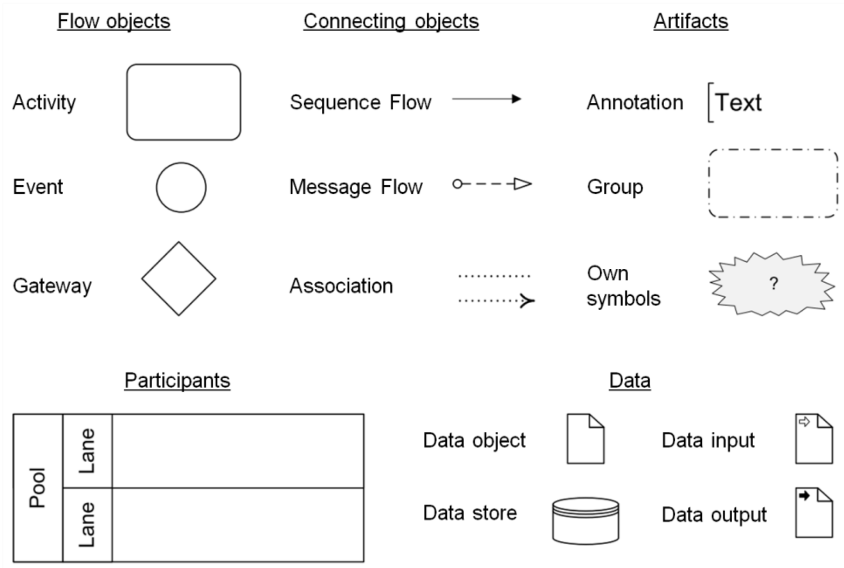

Fig. 85: Basic elements of BPMN (adapted from Freund and Rücker, 2012, p.21)

Based on the conducted interviews, the process of surgical bone drilling has been depicted with BPMN (Fig. 86). The model was created with the freeware software "Bizagi Modeler" (Version 2.7.0.2). As an exemplary process, the fixation of an implant plate with osteosynthesis was chosen. The process begins with "surgery started" and ends with "end reprocessing". Between, two sub-processes describe the bone drilling (Fig. 87 and Fig. 88).

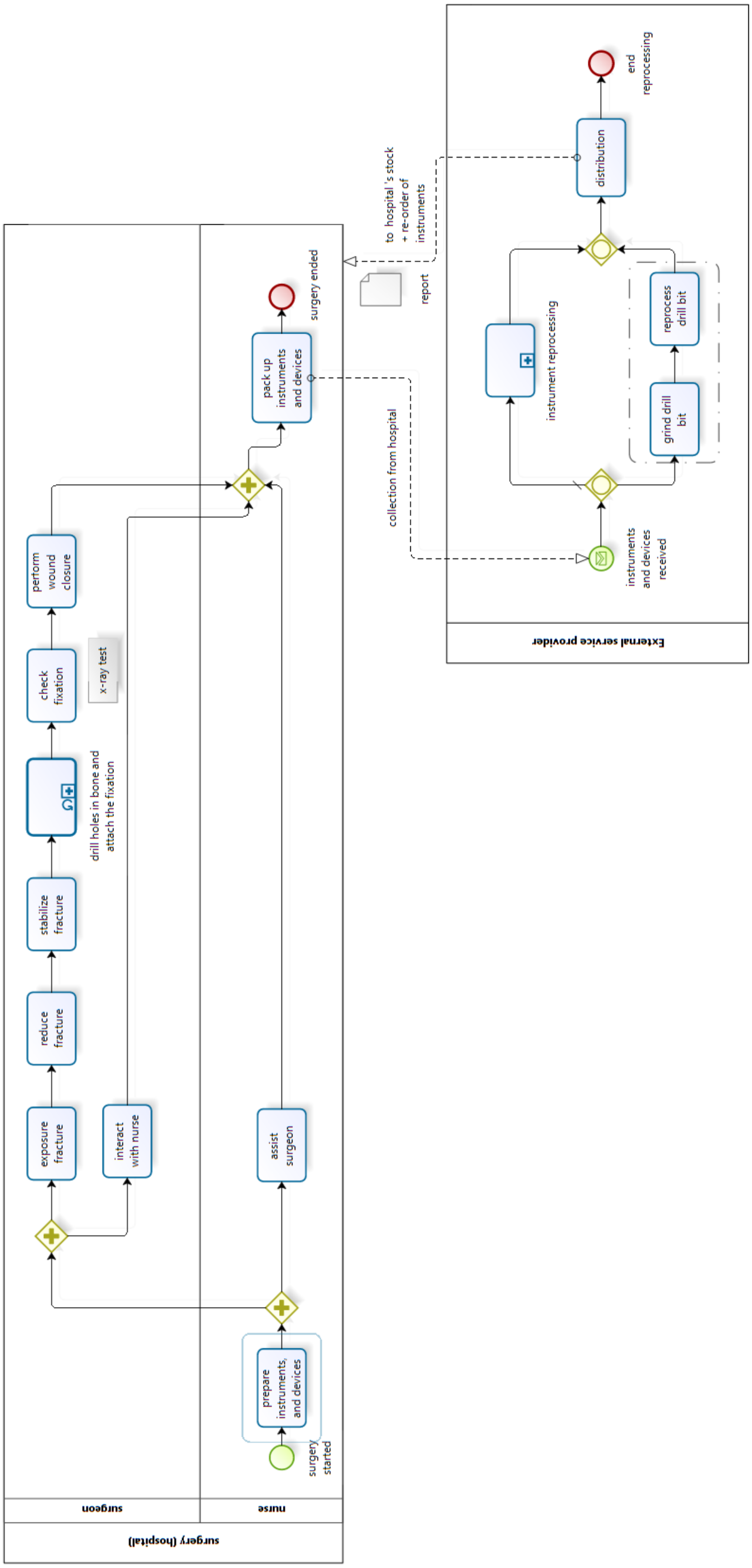

Fig. 86: BPMN process "surgical bone drilling"

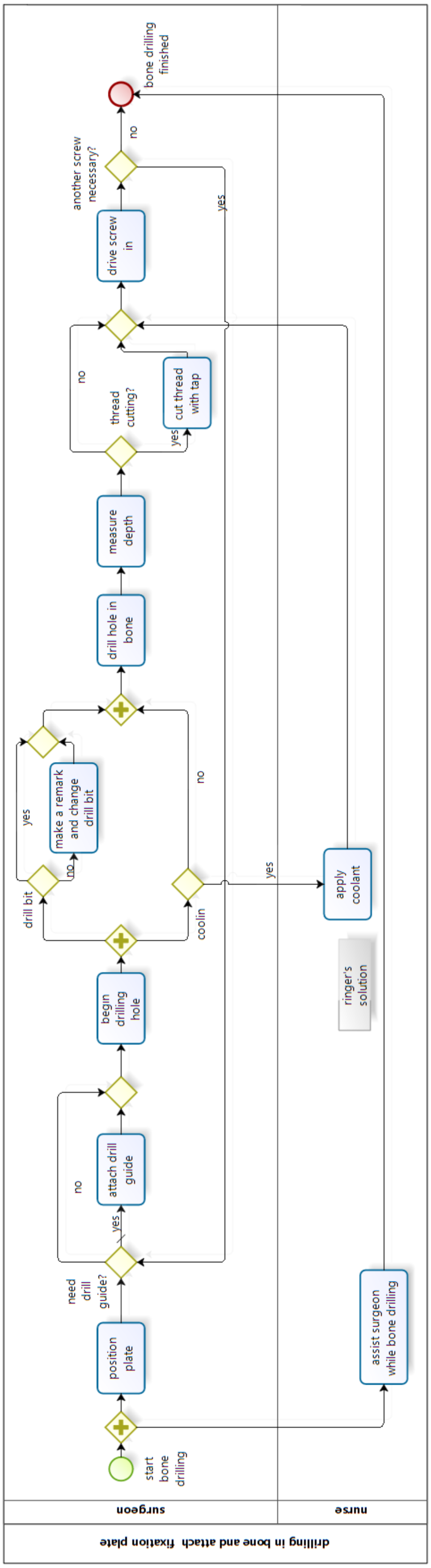

Fig. 87: BPMN sub-process "drill holes in bone and attach the fixation"

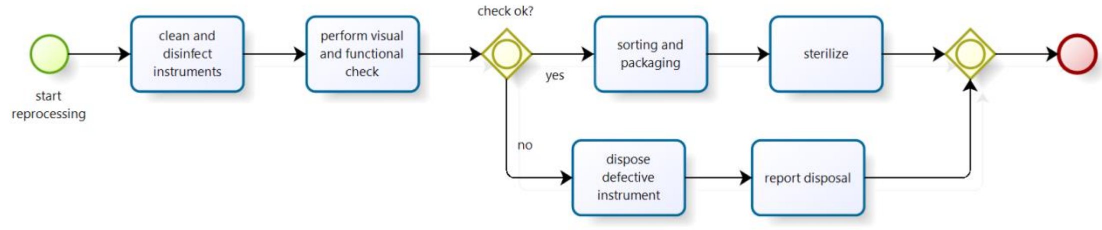

Fig. 88: BPMN sub-process "instrument reprocessing"

The BPMN model depicts the process of surgical bone drilling in detail. Out of it, potential weak points and problems can be worked out. For this, another tool for economic analysis is used: the Ishikawa diagram.

3.2.3 Cause and Effect Analysis (Ishikawa Diagram)

The Ishikawa diagram is a tool for cause-and-effect analysis. Possible causes for a specific effect (problem) can be subdivided into primary- and secondary causes. They are grouped into categories. These can be typical categories like the 5 Ms (Machine, Method, Material, Man Power, and Measurement) or customized categories according to the given case. Ishikawa diagrams are popular in the field of quality management. (Wohinz, 2011, p.8/25)

For surgical bone drilling, "Inadequate bone drilling" is defined as effect (problem) for the Ishikawa diagram. The term "Inadequate bone drilling" includes possible problems related to bone drilling, e.g. thermal necrosis or drill bit breakage. The categories have been adapted to this specific case.

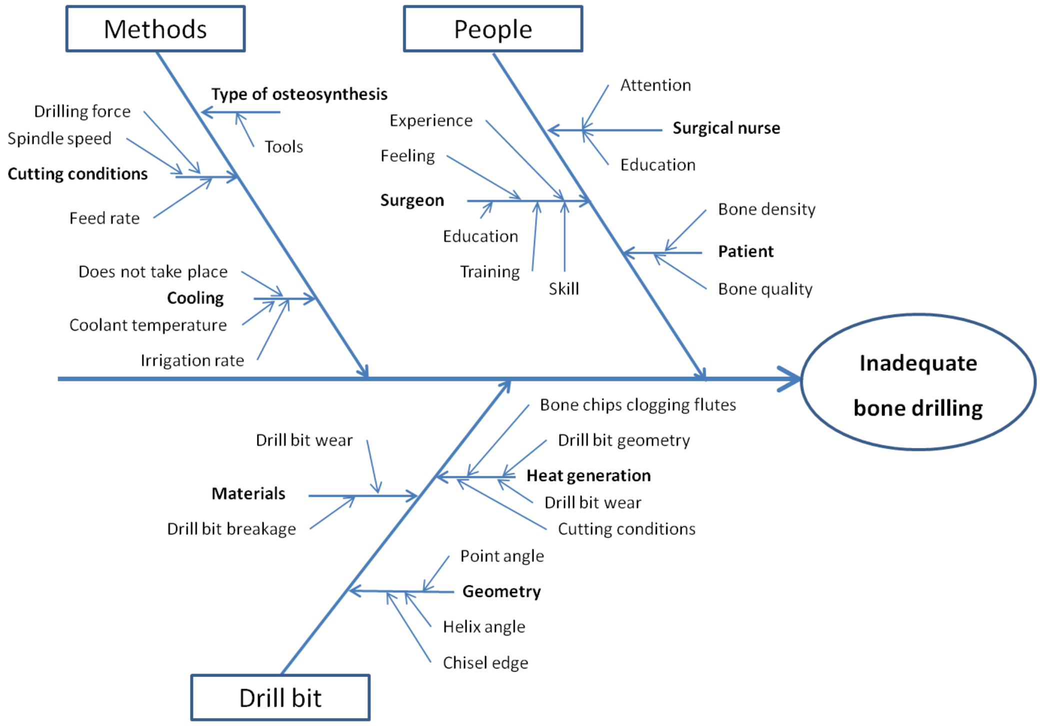

Fig. 89: Ishikawa diagram for surgical bone drilling

Two of the three categories have already been described in the previous chapter. Causes related to the categories "Methods" and "Drill bit" are part of chapter 2, where their effect on bone drilling is accurately described. The third category, "People" deserves a closer look. The skill of the medical staff is a major criterion for bone drilling. Skill can only be developed through training and experience. A surgeon should have a feeling for drilling, which allows to interpret irregularities during drilling. For instance, slow feed rates despite of high thrust might be a sign for blunt drill bits with poor cutting efficiency. Feeling for drilling requires practical experience but also basic understanding of the cutting process. If surgical bone drilling is taken as granted, the implications could be underestimated by surgeons. This leads to another possible cause for inadequate bone drilling: a lack of education and training. It was found that surgical bone drilling is no separate educational objective during the study of medicine. Prospective surgeons come into contact with bone drilling during their specialized medical training after the study. They learn how to drill human bone from their supervising consultant. Two issues come along with this: the first one is about the quality of the transferred knowledge from supervisor to the prospective surgeon. Since there is no general guideline for surgical bone drilling, the realization and also the results can differ widely. The second issue concerns the training for young surgeons. Practicing drilling with artificial- or animal bones is usually not part of the education. Therefore, first attempts are performed on the patient. This is also a kind of "training on the job", exaggeratedly said. Beside the surgeons, also the nurses in the operation theatre have to be focused on their task. During drilling, they have to interact with the surgeon, apply coolant and watch over the drilling process.

Causes related to surgeons and nurses can be influenced, whereas causes related to patients can not. Bone density and quality are specific properties which differ for every human. There are cases where they should be considered for bone drilling. Patients with osteoporosis have to be drilled more carefully than usual because their bones are weaker. Karaca et al. (2011) found that the drilling temperature increases with increasing bone mineral density. This was expected by the authors since the bone hardness correlates positively with the bone mineral density.

To conclude, the Ishikawa diagram shows possible causes for inadequate bone drilling. It was found that major part of them can be influenced. This is obviously for technical parameters like drill bit geometry or cutting conditions. The human factor should not be neglected either. Basic knowledge about the process of cutting and training on artificial- or animal bone could improve the required skills. Both are usually not provided during the medical training of a young surgeon. This thesis does not disparage the ability of surgeons to perform bone drilling. But it should emphasize the importance of a good execution. Due to this, a guideline could provide additional support. As long as drilling into bone is not automated or standardised, it has to be performed manually as good as possible.

In the next chapter, possible failures and their consequences during the process of surgical bone drilling are worked out.

3.2.4 P-FMEA of Surgical Bone Drilling

Failure mode and effects analysis (FMEA) is a systematic method to determine possible failures during a process or product manufacturing in early stages of the development. The result of the FMEA is a ranking of risks based on their potential consequences. There are different types of FMEA (Wohinz, 2011, p.8/18):

- System-FMEA
- Design-FMEA
- Process-FMEA

Every FMEA has three assessment categories (Wohinz, 2011, p.8/18):

- Severity (effect of the failure)
- Occurrence (probability of failure)
- Detection (likelihood of detection of the failure)

The risk priority number (RPN) results from the multiplication of these three categories and allows a ranking of the potential failures.
(Wohinz, 2011, p.8/18)

For surgical bone drilling, a Process-FMEA is used. Considerations about possible failures related to surgical bone drilling were based on:

- BPMN model (Fig. 86)
- Ishikawa diagram (Fig. 89)
- Considerations together with a specialist for trauma surgery and university assistant at the Medical University Graz, Department of Traumatology

In this chapter, possible failures of the process are listed exemplarily (Fig. 90). The complete P-FMEA can be seen in Fig. A- 2 (appendix). Giving recommendations for future improvements is also an important part of the FMEA. Out of it, the RPN should be lowered for the related failure afterwards. It should be noted that the absolute value of the RPN is not meaningful enough. Therefore, a ranking according to the RPNs has to be done to determine the priorities for the removal of errors.

FMEA Failure Mode and Effects Analysis	Name	Surgical Bone Drilling	Date	30	1	2015	SEV	Severity
			Revison				OCC	Occurrence
			Page	1	of	1	DET	Detection
☑ Process-FMEA	Author	C. Höller					RPN	Risk Priority Number

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Effect(s) of Failure	Potential Cause(s) of Failure	Current Process Controls	SEV	OCC	DET	RPN	Recommend Actions	Responsible Person & Target Date	Taken Actions	SEV	OCC	DET	RPN
1	prepare instrument and devices	prepare worn drill bit	high drilling forces	worn drill bit not discarded	none	2	5	10	100	perform visual check	nurse		2	2	10	40
		prepare worn drill bit	high drilling temperatures	worn drill bit not discarded	none	3	5	10	150	perform visual check	nurse		2	2	10	40
2	apply coolant	no use of coolant	bone temperature increases	no order was given	none	3	9	4	108	establish cooling as standard	surgeon and nurse		3	2	4	24
4	drill hole in bone	too heavy bending of drill bit	drill bit brakes	incorrect drill bit handling	none	4	1	3	12							
		too slow feed rate	bone temperature increases	usage of worn drill bit	none	3	5	6	90	additional training for surgeons	hospital, consultant		3	2	3	18
		drilling forces are too high	bone temperature increases	usage of worn drill bit	none	3	7	7	147	additional training for surgeons	hospital, consultant		3	3	4	36
		excessive bone temperatures	thermal necrosis	usage of blunt drill bit		4	3	10	120	visual checks to discard blunt drill bits	nurse		4	1	10	40
				wrong cutting conditions		4	2	10	80	additional training for surgeons	hospital, consultant		4	1	10	40
6	pack up instrument and devices	pack up a worn drill bit (for reprocessing)	worn drill bit in the operation theatre	worn drill bit not discarded		3	5	10	150	perform visual check	nurse		2	2	10	40

Fig. 90: P-FMEA of surgical bone drilling (extract)

The results from the P-FMEA are partly surprising. For instance, the breakage of a surgical drill bit (process no. 4) has a rather small RPN for the process. Pichler et al. (2008) reported an instrument breakage rate of 0.35 % after 11,856 surgical procedures in two hospitals. According to the authors, *"[…] removal of a broken metal drill bit is not indicated routinely if it sticks firmly in the bone and is not near blood vessels or nerves."* (Pichler et al. 2008, p.2653). Fothi et al. (1992) reported a drill bit failure rate of 0.3 % (3 of 1,000). In their study they found that a broken drill bit can be left in the body without extended healing times as long as no implant is involved. But if a drill bit fragment is close to a joint or it can be removed easily, the required efforts should be made. The authors further mentioned the possibility of contact corrosion between implant and drill bit. Since drill bit breakage is less problematic than expected, the topic of fracture toughness comes up. Of course, fracture toughness is an important material property of a surgical drill bit but it should not be overestimated. As already mentioned in chapter 2.6, a good compromise between hardness and fracture toughness should be targeted.

On the other hand, the RPN of failures related to worn drill bits are as expected. During the preparation of the instruments for the operation procedure (process no. 1), also blunt drill bits are (unwittingly) prepared by the nurse. A short visual check on the state of wear would decrease the RPN by discarding blunt drill bits. This could be done by the nurse after she/he has been instructed properly. It has to be clarified, whether these checks should be performed before or after the operation procedure. On the one hand, the nurse has more time for checking the surgical drill bits at the end. Also the replacement can take place easily and the drill bits do not have to be sterile any more. On the other hand, checking before the operation procedure would eliminate the risk that blunt drill bits arrive from the reprocessing and are used again. In this connection, the role of the reprocessor has to be discussed. Performing visual and functional checks is a step during reprocessing. According to an instrument reprocesser in Graz (Austria), visual checks are made on surgical drill bits with a magnifying glass. But it seems that controlling the wear is not a fix part of it. Therefore, it has to be clarified whether the reprocessor or the medical staff has to perform these checks routinely.

Another important point is the application of coolant during drilling (process no. 2). The results from the FMEA showed that cooling is seldom in the operation theatre. Its positive effect has been stated in chapter 2.4.6. Hence, cooling should be established in the operation theatre to decrease the bone temperature and the risk of thermal necrosis.

During drilling into bone (process no. 4), the focus should be on relevant cutting conditions like drilling force. Once more, a blunt drill bit causes an increase of the bone temperature. Slow feed rates and/or excessively high drilling forces can be indicators for advanced wear. Both could be recognized by the surgeons if they are sensitized enough. Additional training would help to affect the occurrence and the detection positively.

The P-FMEA gives insight in possible weak points of the process. The RPN determines the priority for further recommendations. In the next chapter, fundamental considerations about the use and reprocessing of surgical drill bits are discussed.

3.3 Single-use and Multiple-use

Medical instruments are declared as single-use or multiple-use devices by the manufacturer. This is also true for bone drills. Of course, there are pros and cons concerning both types, which will be discussed briefly in this chapter.

3.3.1 Initial Situation

Reprocessing of multiple-use devices after their use is a common and standardized procedure (see Fig. 88). It can be performed by the hospital or by an external service provider. On the other hand, single-use devices are expected to be disposed after the operation. But in reality, this separation becomes indistinctive. The reprocessing of single-use devices is allowed in some countries in Europe, in the USA or in Australia and works generally well there. In Austria, however, the reprocessing of single-use devices is prohibited by law. (Truppe, 2007, p.11)

3.3.2 The Reuse of Single-Use Devices

As already mentioned, the declaration whether a medical instrument is a single-use device determines the manufacturer. According to Truppe (2007, p.26), possible causes for this are:

- The product cannot be used for a second time because of hygienic and functional reasons (e.g. implants or adhesive plasters).
- The manufacturer is not willing to perform required studies to prove the product's qualification for multiple-use.
- The manufacturer generates more income with the selling of single-use devices compared to multiple-devices.

But from a technical point of view it seems that several single-use devices can be reprocessed without damaging. There are also medical products that are sold as single-use in one country and as multiple-use in another. The reason for this is the regulation of the country, like in Austria. (Truppe, 2007, p.26)

This has also been confirmed during this thesis. For example, surgical drill bits can have the same technical specifications (material, geometry, measurements etc.) but can be declared as single- or multiple-use. Only the price is different: the single-use drill costs even more because it is already sterilized and ready to use. (According to a Product Manager of a global manufacturer of medical devices, personal communication, 11th October 2014)

Truppe (2007) investigated the potential of reprocessing single-use devices in Austria. The author found that there are large potentials from an economic and ecological point:

- Reprocessing saves money: approx. 730 million € are spent for medical products in Austria every year. About 60-100 million € can be saved by reprocessing single-use devices.
- Reprocessing protects the environment: about 100 million kg waste is produced by Austrian hospitals every year. Reprocessing reduces not only the waste but also saves energy which is required to manufacture new medical instruments.

  (Truppe, 2007, p.8)

There are also experts and institutions which decline the reprocessing of single-use devices. Eucomed is an organization which represents the medical device industry in Europe. Eucomed is clearly against reprocessing of single-use devices which is rather unsurprising. The major argument is that patient's safety is compromised if reprocessed single-use devices are reused. The reason for this is that inadequate cleaning, decontaminating and sterilization. This can lead to cross infections due to biological residues. Furthermore, the potential failure of the single-use device after repeated use is criticized. (Eucomed, 2009, pp.50-51)

On the other hand, Truppe (2007, p.8) concluded that reprocessing does work on suitable single-use devices. The author noted that an increased risk for the patient after professional and validated reprocessing cannot be deducted from the available studies. But it is not part of this thesis to decide whether the reuse of a single-use device is appropriate or ethically correct. Therefore, surgical drill bits are only investigated concerning their actual classification as single- or multiple-use device in this work.

3.3.3 Drill Bit Specifications for Single-Use or Multiple-Use

The requirements of surgical drill bits differ due to their classification. It is clear that the tool life of a single-use drill bit can be shorter compared to a multiple-use one. On the other hand, the wear- and corrosion resistance of a multiple-use drill bit has to be well developed. Early bluntness and corrosion after reprocessing have to be prevented.

Specifications for improved drill bits depending on their declaration could be:

Single-use

The geometry should be in accordance with the findings from chapter 2.3. As material, a martensitic stainless steel with good corrosion resistance and acceptable wear resistance should be chosen. One candidate could be the AISI 440A which has a good fracture toughness as well. AISI 431 is also a possibility but its hardness can be a problem after only few drill holes during an operation. For example, an implant requires seven screws through both cortical layers for the fixation. Therefore, the drill bit has to drill through 14 cortical layers. As a reminder, clear signs of wear were already visible after drilling seven holes (14 cortical layers) in the artificial bone, which is generally easier to drill than real bone. In terms of process safety, single-use is convenient for the medical staff and the hospital.

Multiple-use

The geometry should also be in accordance with the findings from chapter 2.3. As material, AISI 420mod would fit to the requirements. High wear- and corrosion resistance build a good base for multiple uses and many drill holes. Additionally, a high quality reprocessing procedure and monitoring has to be ensured.

The economic potentials of a multiple-use drill bit are not deniable. But the current situation is unsatisfactory: For example, the 440A seems not to be appropriate for multiple uses because of its limited wear resistance. This affects also the reliability of the process. If the drill bit withstands only 10-20 drill holes, it has to be exchanged after every second or third operation. Thus, the chance of a blunt drill bit in the fragment set is rather high. As already mentioned in chapter 3.2.1, the costs of the raw material are only a small part of the total costs. Therefore, a better material would pay off soon as long as the total costs for reprocessing are below the purchase price of a new single-use drill bit.

4 CONCLUSION AND OUTLOOK

The aim of this thesis was to analyse the process of manual surgical bone drilling from a technical and economic point of view. As a result, recommendations for further improvements have been developed. For the technical analysis (chapter 2), almost every relevant drilling parameter from literature was taken into account. The wear of surgical drill bits has been theoretically and practically investigated. For the economic analysis (chapter 3), the consequences of thermal necrosis were determined. Furthermore, the overall process of surgical bone drilling has been described in chapter 3.2. Out of it, possible weak points and process flaws were determined and discussed. Potentials for improvement were already pointed out in the respective sections but they are summarized as a whole in this chapter.

Surgical bone drilling is an important preparative step for osteosynthesis which involves both medicine and engineering. During drilling, mechanical energy is transformed due to friction into thermal energy which increases the bone temperature. This can lead to thermal necrosis, an irreversible damage of cells, in the area close the drill hole. The threshold for thermal necrosis is between 47-55 °C, depending on the exposure time. In chapter 2.3, the effect of the drill bit geometry on the drilling temperature is explained. Although there is no general agreement about the ideal geometry, changing specific parameters can reduce the drilling temperature. Recommendations for a modified surgical drill bit are provided at the end of chapter 2.3. They are visualized in Fig. 91:

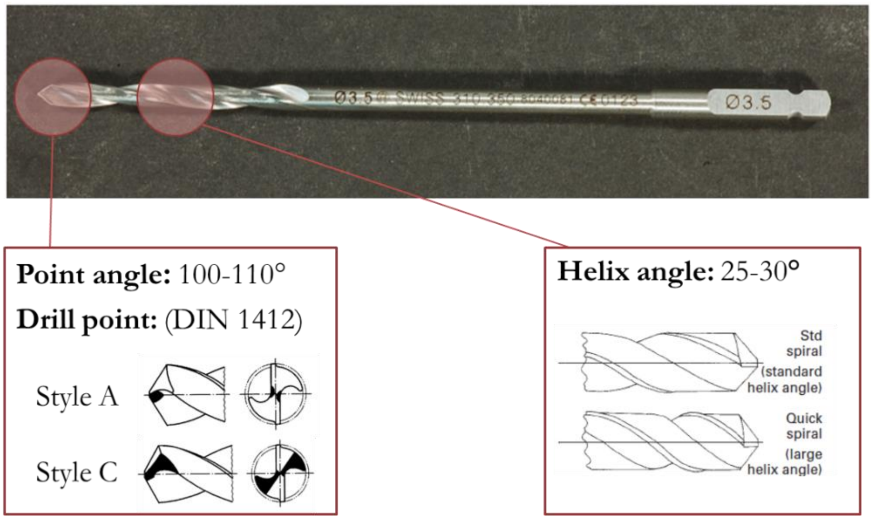

Fig. 91: Supposed improvement of drill bit geometry for surgical drill bits

Beside the geometry, appropriate cutting conditions are essential for efficient drilling. Chapter 2.4 describes the relevant cutting parameters for surgical bone drilling. It was observed that cooling and feed rate have a great influence on the drilling temperature. Spindle speed and cutting speed should not be overestimated, although they affect the temperature as well. The reason for this is that common surgical hand drills are not able to adjust the spindle speed. The drilling force can be an indicator for wear and correlates positively with the feed rate, but it cannot be used for statements about the bone temperature. Drilling should be done with a sharp drill bit and high feed rates, but without excessive axial load on the bone. Together with the application of coolant, the bone temperature will stay in low ranges. Wear is another influential parameter during drilling. In chapter 2.5, the topic of drill bit wear is reported. Because of the general low cutting speeds, adhesion and abrasion are the main causes of wear for surgical drill bits. Proceeding wear increases the drilling force as well as the drilling temperatures. Investigations at the IWS TU Graz have shown that wear occurs after only few drill holes, depending on the bone type. For this thesis, used drill bits from the operation theatre have been observed. The results were alarming: a considerable number of drill bits showed excessive signs of wear. Serious chipping, flank- and outer corner wear were well advanced. But drill bits with hardly any signs of wear have been observed too. This is an indication of the subjective decision whether a drill bit should be discarded or not. It has to be mentioned that the number of drilled holes for discarded drill bits is not known. That makes the prediction of the ideal moment for an exchange impossible. To sum up, wear is a problem in operation theatres because it increases the risk of inadequate drill holes and further on thermal necrosis.

Furthermore, materials for surgical drill bits have been investigated in chapter 2.6. From previous research at the IWS, information about the microstructure of three different stainless martensitic steels is available: AISI 440A, 440B and 431. With regard to essential requirements, it seems that none of them fulfil the expectation totally. Therefore, two alternative martensitic stainless steels have been introduced and analysed: AISI 420mod and AISI 440C. From a technical point of view, the AISI 420mod has a great potential for surgical drill bits. However, the AISI 440C provides high hardness and wear resistance, but its limited fracture toughness and corrosion resistance have to be considered. Further tests and experiments with both steels are planned in the near future to prove their qualification as a multiple-use drills.

On this basis, it can be concluded that surgical bone drilling can be improved from a technical point of view. First of all, a modified drill bit geometry and suitable cutting conditions have the greatest impact on decreasing the maximum temperature during drilling. Alternatively, coated or uncoated materials can increase the tool life and wear resistance to meet the requirements of a good cutting instrument for multiple-uses.

Osteosynthesis is an often performed surgical operation. In 2013, around 56,000 operative procedures and services were documented in Austria. Surgical bone drilling as an important part of osteosynthesis is highly relevant for the quality of the fixation. According to the literature, the failure rate of implants is between 2-7 %. Yet, it is not documented in how many cases thermal necrosis due to inadequate bone drilling was the reason for this. However, to estimate the economic consequences of thermal necrosis, a different approach was chosen. Statistics about complications after osteosynthesis were provided by KAGes. To consider only complications due to thermal necrosis, appropriate complication codes related to ICD-10 were used. Out of this, a complication rate of 0.73-1.04 % can be determined which means that 391 patients were affected in 2013. The consequences are nearly 3.5 million € additional economic costs and health expenditures annually in Austria.

Furthermore, the whole process of surgical bone drilling was investigated further in chapter 3.2. It has been shown that there is potential to improve the process. Beside technical aspects like drill bit geometry or cutting conditions, the human factor is the major criterion for well performed drill holes. To become a skilled surgeon, training and experience is essential. But since surgical bone drilling is not an own part during the theoretical medical education, it has to be learned and practiced under supervision in the operation theatre. Therefore, the achieved knowledge depends also on the medical consultant. A general guideline or instruction for surgical bone drilling would support both, the consultant and the prospective surgeon.

From the Process-FMEA (chapter 3.2.4), other weak points in the process of surgical bone were identified. Blunt drill bits in the operation theatre are the major cause for possible failures during drilling. They cause difficult cutting conditions and increase the drilling temperature. Since there is no monitoring of the bone temperature during drilling, the detection is not possible. Once formation of smoke is visible, the maximum temperatures are definitely high above the threshold for thermal necrosis. Hence, the feeling of the surgeon is even more important. If untypical high drilling forces are required to drill through bone, a worn drill bit is probably the cause. The difference between a sharp and blunt drill bit should be noticeable for the surgeon but requires also experience and sensitization.

However, prevention is better than reaction. Blunt drill bits have to be banned from the operation theatre which requires additional monitoring and control gates. This sounds effortful but it can be realized quite simple. Excessive drill bit wear can be recognized easily (see chapter 2.5.5). Therefore, it is enough to perform short visual inspections with a simple stand magnifier or a hand magnifier. During this thesis, four cheap hand magnifiers were tested. It was found that a magnification of x10 is sufficient to detect the wear on the drill bit. Of course, the nurse has to be trained to decide whether a surgical drill bit should be discarded or not. The other possibility would be to check the wear of drill bits during reprocessing. This process includes the inspection and the functional test of medical instruments. The internal or external reprocessor only has to add wear checks in its process. From a practically point it is not necessary to quantify the wear characteristics to decide about their disposal. Exemplary figures of inadmissibly wear characteristics provide sufficient information. However, visual checks of drill bit wear should be mandatory.

The decision whether a single-use or a multiple-use drill bit should be preferred is debatable. Patient safety and ethical considerations, but also profit maximization of the manufacturer indicates single-use drill bits. On the other hand, economic and ecological advantages can be achieved with multiple-use drill bits. Nevertheless, the actual investigated situation is not satisfying. As an example, a Synthes 440A drill bit can be ordered either as single-use or as multiple-use device with the same technical specifications. The difference is that one is already sterilized and the other not. Previous research at the IWS disqualifies the 440A as well-suited steel for multiple-uses because of its limited wear resistance. A more suitable material, like the 420mod, could take advantage of the economic potential of a multiple-use device. Since the manufacturing costs are only a small part of the purchase price, additional material costs are expected to pay off soon.

In conclusion, the process of surgical bone drilling is quite complex. Both pre- and post-drilling steps have to be considered for good drilling results. Thermal necrosis is an important issue in this context because it causes serious bone damage. The consequences are fatal for the patient: unplanned surgical procedures and extended recovery times are only two possibilities. This leads to a significant increase of economic costs and health expenditures. It has been shown that both, the surgical drill and the overall process, have room for improvement. Recommendations for minimal bone damage according to findings from this thesis are summarized in form of a guideline in Table 17.

Table 17: Guideline for the process of surgical bone drilling

Instruction	Explanation	(Pre)conditions	Reference chapter
Drill with high feed rates (v_f)	Drilling with high feed rates decreases the drilling time and further the time of temperature exposure. Higher feed rates require higher drilling forces. Anyway, overloading the bone has to be avoided.	• Sharp drill bits • Adequate drilling forces	2.4.3 2.4.4 2.4.5
Supply coolant during drilling	Cooling should be applied whenever it is possible. It dissipates heat through conduction. Cooling helps to remove the heated bone chips. Furthermore, if lubrication is provided it can reduce the friction. Provide coolant even if a drill guide is used.	• Availability of coolant (external cooling) • Appropriate instruments (internal cooling) • Sufficient high irrigation rate	2.4.6
Take a short break between each drill hole	A time gap between each drill hole gives the bone and the drill bit additional time to cool down. Drilling intermittently in steps is a good possibility too.	• none	2.3.1
Choose the right surgical drill bit	Drill bit geometry affects the cutting performance: Larger helix angle (quick helix): approx. 25-30°, good for evacuation of bone chips and heat. Chisel edge: A small chisel edge decreases the thrust and increases the accuracy. Split point and point thinning are two possibilities to improve the cutting efficiency.	• Availability of improved surgical drill bits in the fragment set	2.3.3 2.3.5
Perform visual checks before or after the surgical procedure	Blunt drill bits increase the bone temperature during drilling and therefore the risk for thermal necrosis. Unfortunately, worn drill bits are too common in the operation theatre. Short visual checks with simple magnifiers are sufficient to decide about the disposal.	• Instructions and training for the theatre nurse	2.5 3.2
Be aware of uncharacteristic cutting conditions	Worn drill bits require higher drilling forces as usual to create a habitual feed rate. If drilling is more "exhausting" than usual, be cautiously, check for wear and replace the drill bit if necessary. The formation of smoke is a sign for excessive high bone temperatures.	• Experience and "feeling" for drilling of the surgeon • Additional training and instructions	2.4.3 2.4.4 3.2

The improvement potentials of the process of surgical bone drilling have been pointed out in this thesis. The development of drill bits with optimized technical specifications should focus on the geometry and on the material. A wear- and corrosion resistant, multiple-use drill bit decreases the economic and ecologic impact. But a good instrument is nothing without right operating. Therefore, the sensitization of prospective surgeons for drilling should take place during their training. That would decrease the number of complications due to inadequate bone drilling in future and increase the patient's safety. It has been shown that the economic impact is significant: estimated annual costs of 3.5 million € arise out of complications related with thermal necrosis in Austria. For that reason alone, the submission of this thesis at relevant institutions like the KAGes or AUVA is recommendable.

Of course, this thesis is also limited. Additional studies and experiments have to take place to prove and underline the findings from this work. Furthermore, an improved surgical drill bit will be manufactured and validated in an actual bachelor thesis at the IWS. However, this thesis provides recommendations for the geometry and the material which are summarized in Table 18. The drilling experiments will be performed on the FSW machine in vitro with animal and artificial bones. Moreover, the temperature will be measured using thermocouples at specific distances from the bore hole to determine the risk of thermal necrosis. This is a new approach at the IWS TU Graz. Drill bit wear will be investigated utilizing the stereo microscope. The control group consists of common Synthes ø3.5 mm surgical drill bits. The manufacturing quality of the surface finish should be similar to the specifications of certified drills for medicine to make the results comparable.

Table 18: Technical specifications of the improved surgical drill bit

Drill diameter	3.5 mm
Point angle	105° ±2°
Helix angle	27° ±1.5°
Lip clearance angle	13-15°
Web thickness	approx. 0.8 mm
Overall length	110 mm ±5 mm
Point styles	DIN 1412 N, A, and C
Material	AISI 440C and AISI 421mod

This experimental work should be a further step at the IWS towards an optimized surgical drill bit. Future research should also focus on the topic of coatings to investigate their potential for surgical applications. But besides all these technical considerations, the human factor must not be forgotten. Drilling should be performed as good as possible in the operation theatre. This also includes the use of coolant and avoiding worn drill bits.

5 REFERENCE LIST

Research Literature:

Allan, W., Williams, E. D. & Kerawala, C. J., 2005. Effects of repeated drill use on temperature of bone during preparation for osteosynthesis self-tapping screws. *British Journal of Oral and Maxillofacial Surgery*, pp. 314-319.

Augustin, G. et al., 2008. Thermal necrosis and bone drilling parameters revisited. *Arch Orthop Trauma Surg*, Issue 128, pp. 71-77.

Augustin, G. et al., 2012a. Temperature changes during cortical bone drilling with a newly designed step drill and an internally cooled drill. *International Orthopaedics*, pp. 1449-1456.

Augustin, G. et al., 2012b. Cortical bone drilling and thermal osteonecrosis. *Clinical Biomechanics*, 27(4), pp. 313-325.

Bachus, K. N., Rondina, M. T. & Hutchinson, D. T., 2000. The effects of drilling force on cortical temperatures and their duration: an in vitro study. *Medical Engineering & Physics*, Volume 22, pp. 685-691.

Bargel, H.-J. & Schulze, G. eds., 2014. *Werkstoffkunde.* 11. ed. Berlin/Heidelberg: Springer Vieweg.

Bechtol, R. C., 1956. A Modified Hand Drill. *The Journal of Bone and Joint Surgery*, Volume 38, pp. 691-692.

Bertollo, N., Gothelf, T. & Walsh, W., 2008. 3-Fluted orthopaedic drills exhibit superior bending stiffness to their 2-fluted rivals: Clinical implications for targeting ability and the incidence of drill-bit failure. *International Journal of the Care of the Injured*, Volume 39, pp. 734-741.

Bertollo, N. & Walsh, W. R., 2011. Drilling of Bone: Practicality, Limitations and Complications Associated with Surgical Drill-Bits. In: *Biomechanics in Application.* s.l.:Dr. Vaclav Klika.

Chacon, G. E. et al., 2006. Heat Production by 3 Implant Drill Systems After Repeated Drilling and Sterilization. *American Association of Oral and Maxillofacial Surgeons*, 64(2), pp. 265-269.

Davidson, S. R. H. & James, D. F., 2000. Measurement of thermal conductivity of bovine cortical bone. *Medical Engineering & Physics*, 22(10), pp. 741-747.

de Pretis, D., 2012. *Untersuchung des Überbohrens und des Kraftverlaufes bei Bohrungen in die Knochenkortikalis - Einfluss: Bohrertyp und Verschleißgrad.* Graz University of Technology: Bachelor Thesis.

Degner, W., Lutze, H. & Smejkal, E., 2009. *Spanende Formung - Theorie, Berechnung, Richtwerte.* 16. ed. München: Carl Hanser Verlag.

Dickenson, R. P., Hutton, W. C. & Stoot, J. R. R., 1981. The Mechanical Properties of Bone in Osteoporosis. *The Journal of Bone and Joint Surgery*, 63-B(2), pp. 233-238.

Dillinger, J., 2007. *Fachkunde Metall.* 55. Hrsg. Haan-Gruiten: Europa-Lehrmittel.

Eriksson, A. R. & Albrektsson, T., 1983. Temperature threshold levels for heat-induced bone tissue injury: A vital-microscpoic study in the rabbit. *The Journal of Prosthetic Dentistry*, 50(1).

Eriksson, A. R., Albrektsson, T. & Albrektsson, B., 1984. Heat cuased by drilling cortical bone. Temperature measured in vivo in patients and animals.. *Acta Orthop Scand*, Volume 55, pp. 629-631.

Eucomed, 2009. *Eucomed White Paper on the reuse of single use devices.* Brussels: Eucomed.

Evans, G. F., 1969. The Mechanical Proporties of Bone. *Artificial Limbs*, Volume 13, pp. 37-48.

Fothi, U., Perren, S. M. & Auer, J. A., 1992. Drill bit failure with implant involvement — an intraoperative complication in orthopaedic surgery. *Injury*, 23(2), pp. 17-29.

Freund, J. & Rücker, B., 2012. *Praxishandbuch BPMN 2.0.* 3. ed. Müchen, Wien: Carl Hanser Verlag.

Fuchsberger, A., 1986. Die Zerspantemparatur beim Bohren. *Medizinisch-orthopädische Technik*, Volume 2, pp. 54-57.

Funk, J. M., 2014. *Untersuchung des Verschleißverhaltens von chirurgischen Knochenbohrern: Charakterisierung des Verschleißes.* Graz University of Technology: Bachelor Thesis.

Grote, K.-H. & Feldhusen, J. eds., 2014. *Dubbel - Taschenbuch für den Maschinenbau.* Berlin/Heidelberg: Springer Vieweg.

Haubner, R., Strobl, S. & Henke, A.-M., 2012. An Investigation into Porosity in Medical Drills Caused by Broken Carbides. *Practical Metallography*, 49(4), pp. 221-232.

Hillery, M. T. & Shuaib, I., 1999. Temperature effects in the drilling of human and bovine bone. *Journal of Materials Processing Technology*, Volume 92-93, pp. 302-308.

Hirner, A. & Weise, K., 2008. *Chirurgie.* 2 ed. Stuttgart: Thieme.

Kalidindi, V., 2004. *Optimization of Drill Design and Coolant Systems During Dental Implant Surgery.* University of Kentucky: Master's Thesis.

Karaca, F. & Aksakal, B., 2013. Effects of various drilling parameters on bone during implantology: An in vitro experimental study. *Acta of Bioengineering and Biomechanics*, 15(4), pp. 25-32.

Karaca, F., Aksakal, B. & Kom, M., 2011. Influence of orthopaedic drilling parameters on temperature and histopathology of bovine tibia: An in vitro study. *Medical Engineering & Physics*, Volume 33, pp. 1221-1227.

Kurin, D. S., 2013. Trepanation in South-Central Peru during the early late intermediate period (ca. AD 1000-1250). *American Journal of Physical Anthropology*, December, 152(4), pp. 484-494.

Kyu-Hong, J. et al., 2011. Thermally induced bone necrosis during implant surgery: 3 case reports. *Journal of the Korean Association of Oral and Maxillofacial Surgeons*, pp. 406-414.

Landes, R., 2006. *Messerklingen und Stahl: Technologische Betrachtung von Messerschneiden.* 2. ed. Bad Aibling: Wieland Verlag.

Lee, J., Ozdoganlar, B. O. & Yoed, R., 2012. An exprimental investigation on thermal exposure during bone drilling. *Medical Engineering & Physics*, Volume 34, pp. 1510-1520.

Matthews, L. S. & Hirsch, C., 1972. Temperatures Measured in Human Cortical Bone when Drilling. *The Journal of Bone and Joint Surgery*, 54-A(2), pp. 297-308.

Milberg, J. & Fuchsberger, A., 1984. Möglichkeiten zur Verminderung der thermischen Schädigung des Knochens beim Einsatz von Spiralbohrern in der Osteosynthese. *Biomed. Technik*, Volume 29, pp. 309-317.

Moritz, A. R. & Henriques, F. C., 1947. Studies of Thermal Injury II. The Relative Importance of Time and Surface Temperature in the Causation of Cutaneous Burns. *The American Journal of Pathology*, 53(5), p. 695–720.

Natali, C., Ingle, P. & Dowell, J., 1996. Orthopaedic bone drills - can they be improved?. *The Journal of Bone & Joint Surgery (Br)*, 78-B(3).

Nigg, B. M. & Herzog, W. eds., 1999. *Biomechanics of the Musculo-Skeletal System.* 2. ed. Chister: John Wiley & Sons.

Ong, F. R., 1998. *Analysis of bone drilling characteristics for the enhancement of safety and the evaluation of bone strength.* Loughborough University: Dissertation.

Pandey, R. K. & Panda, S., 2013. Drilling of bone: A comprehensive review. *Journal of Clinical Orthopaedics and Trauma*, Volume 4, pp. 15-30.

Perot, N., Moraux, J.-Y., Dichtel, J.-P. & Boucher, B., 2003. X 15 T.N™ : A new Martensitic Stainless Steel for Surgical Instruments. In: G. L. Winters & M. J. Nutt, eds. *Stainless Steels for Medical and Surgical Apllications.* West Conshohocken: ASTM International, pp. 13-27.

Pichler, W. et al., 2008. Frequency of Instrument Breakage During Orthopaedic Procedures and Its Effects on Patients. *The Journal of Bone and Joint Surgery*, pp. 2652-2654.

Reichard, A., ed., 2003. *Fertigungstechnik 1.* 14. ed. Hamburg: Handwerk und Technik.

Reingewirtz, Y., Szmukler-Mocler, S. & Senger, B., 1997. Influence of different parameters on bone heating and drilling time in implantology. *Clinical Oral Implants Research*, Volume 8, pp. 189-197.

Saha, S., Pal, S. & Albright, J. A., 1982. Surgical Drilling: Design and Performance of an Improved Drill. *Journal of Biomechanical Engineering*, Volume 104, pp. 245-252.

Sandberg, O. & Jönson, L., 2002. New generation of tool steels made by spray forming. In: J. Bergström, et al. eds. *The Use of Tool Steels: Experience and Research; Proc. 6th Internat. Tooling Conf.*. Karlsbad, Sweden: Karlstad University, pp. 1147-1158.

Schmelzeisen, H., 1990. *Der Bohrvorgang in der Kortikalis.* Berlin: Springer Verlag.

Sharif, S., Rahim, E. A. & Sasahara, H., 20112. Machinability of Titanium Alloys in Drilling. *Titanium Alloys - Towards Achieving Enhanced Properties for Diversified Applications*, 16 March, pp. 117-138.

Stahlschlüssel-Taschenbuch, 2007. 21. ed. Marbach: Verlag Stahlschluessel Wegst GmbH.

Stoiber, U., 2014. *Bohrkraftmessungen und Verschleiß zweier chirurgischer Knochenbohrer am Markt.* Graz University of Technology : Diploma Thesis.

Truppe, M., 2007. *SUPROMED - Aufbereitung und Wiederverwendung von Einweg-Medizinprodukten unter Nachhaltigsaspekten - Einführung in Österreich,* Wien: Bundesministerium für Verkehr, Innovation und Technologie.

Tu, Y.-K.et al., 2010. Thermal Contact Simulation of Drill Bit and Bone During Drilling. *4th International Conference on Bioinformatics and Biomedical Engineering (iCBBE)*, pp. 1-4.

Udiljak, T., Ciglar, D. & Skoric, S., 2007. Investigation into bone drilling and thermal bone necrosis. *Advances in Production & Management*, Volume 2, pp. 103-112.

VDI-Verein Deutscher Ingenieure, 2006. *VDI-Wärmeatlas.* 10. ed. Berlin/Heidelberg: Springer-Verlag.

Verhoeven, J., 2007. *Steel Metallurgy for the Non-Metallurgist.* Ohio: ASM international.

Williams, D. F., 2008. On the mechanisms of biocompatibility. *Biomaterials*, Volume 29, pp. 2941-2953.

Wohinz, J. W., 2011. *Industriebetriebslehre.* 25. ed. Graz University of Technology: lecture script.

Zopf, C., 2011. *Verschleiß- und Werkstoffuntersuchungen an Knochenbohrern.* Graz University of Technology: Diploma Thesis.

Standards:

DIN 1412:2001-03. Spiralbohrer aus Schnellarbeitsstahl – Anschliffformen; (engl.: Twist drills made of high-speed steel – Shapes of points)

DIN 1414-1:2006-11. Technische Lieferbedingungen für Spiralbohrer aus Schnellarbeitsstahl – Teil 1: Anforderungen; (engl.: Technical specifications fort twist drills of high-speed steel – Part 1: Requirements)

DIN 1836:1984-01. Werkzeug-Anwendungsgruppen zum Zerspanen; (engl.: Groups of tool application for chip removal)

OENORM EN ISO 7153-1:2001-02-01. Chirurgische Instrumente - Metallische Werkstoffe - Teil 1: Nichtrostender Stahl (ISO 7153-1:1991, einschließlich Änderung 1:1999); (engl.: Surgical instruments - Metallic Materials - Part 1: Stainless steel (ISO 7153-1:1991, including Amendment 1:1999))

Documents from websites:

Aubert & Duval, 2010. *X15TN.* http://www.aubertduval.com/uploads/tx_obladydownload/Brochure_X15TN.pdf. [Accessed 6th January 2015].

BAuA (Federal Institute for Occupational Safety and Health), 2012. *Volkswirtschaftliche Kosten durch Arbeitsunfähigkeit 2012.* http://www.baua.de/de/Informationen-fuer-die-Praxis/Statistiken/Arbeitsunfaehigkeit/Kosten.html [Accessed 12th January 2015].

Federal Statistical Office, 2013. *Diagnosis Related Groups ("Fallpauschalenbezogene Krankenhausstatistik").* https://www.destatis.de/DE/Publikationen/Thematisch/Gesundheit/AlteAusgaben/FallpauschalenKrankenhausAlt.html [Accessed 08th January 2015].

Federal Statistical Office, 2014. *Diagnosis Related Groups ("Fallpauschalenbezogene Krankenhausstatistik").* https://www.destatis.de/DE/Publikationen/Thematisch/Gesundheit/Krankenhaeuser/FallpauschalenKrankenhaus.html [Accessed 08th January 2015].

L. Klein, 2014. *Datasheets for stainless steels for surgical instruments.* L. Klein AG
AISI 440A: http://www.kleinmetals.ch/shop/Datenblatt/E/468.pdf
AISI 440B: http://www.kleinmetals.ch/shop/Datenblatt/E/461.pdf
AISI 440C: http://www.kleinmetals.ch/shop/Datenblatt/E/464.pdf
AISI 431: http://www.kleinmetals.ch/shop/Datenblatt/E/455-1.pdf
AISI 420mod: http://www.kleinmetals.ch/shop/Datenblatt/E/467.pdf
[All accessed on 2nd February 2015].

Statistics Austria, 2012a. C*urrent expenditure on health by function of care and provider industry in Austria, 2012*. http://www.statistik.at/web_en/statistics/health/health_expenditure/index.html [Accessed 27th January 2015].

Statistics Austria, 2012b. *Spitalsentlassungen aus allen Krankenanstalten 1989 bis 2013*. http://www.statistik.at/web_de/statistiken/gesundheit/stationaere_aufenthalte/spitalsentlassungen_gesamt/index.html [Accessed 27th January 2015].

Statistics Austria, 2014. *Anzahl der unterschiedlichen medizinischen Einzelleistungen bei Spitalsentlassungen 2009 bis 2013*. http://www.statistik.at/web_de/statistiken/gesundheit/stationaere_aufenthalte/medizinische_leistungen/index.html [Accessed 08th January 2015].

Sumi Tool, 2014. *Technical Guidance – Basics of Drilling.* Sumitomo Electric Industries. http.//www.sumitool.com.sg/catalogues/2013%20-%202014%20generalcatalogue/207%20Technical%20Guidance%20-%20Drilling.pdf [Accessed 02nd February 2015].

WIFO (Austrian Institute of economic research), 2014. *Absence from Work Report 2014. Absences Due to Sickness and Accidents in Austria ("Fehlzeitenreport 2014. Krankheits- und unfallbedingte Fehlzeiten in Österreich").* http://www.wifo.ac.at/en/publications?detail-view=yes&publikation_id=50887 [Accessed 12th January 2015].

6 LIST OF FIGURES

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APPENDIX

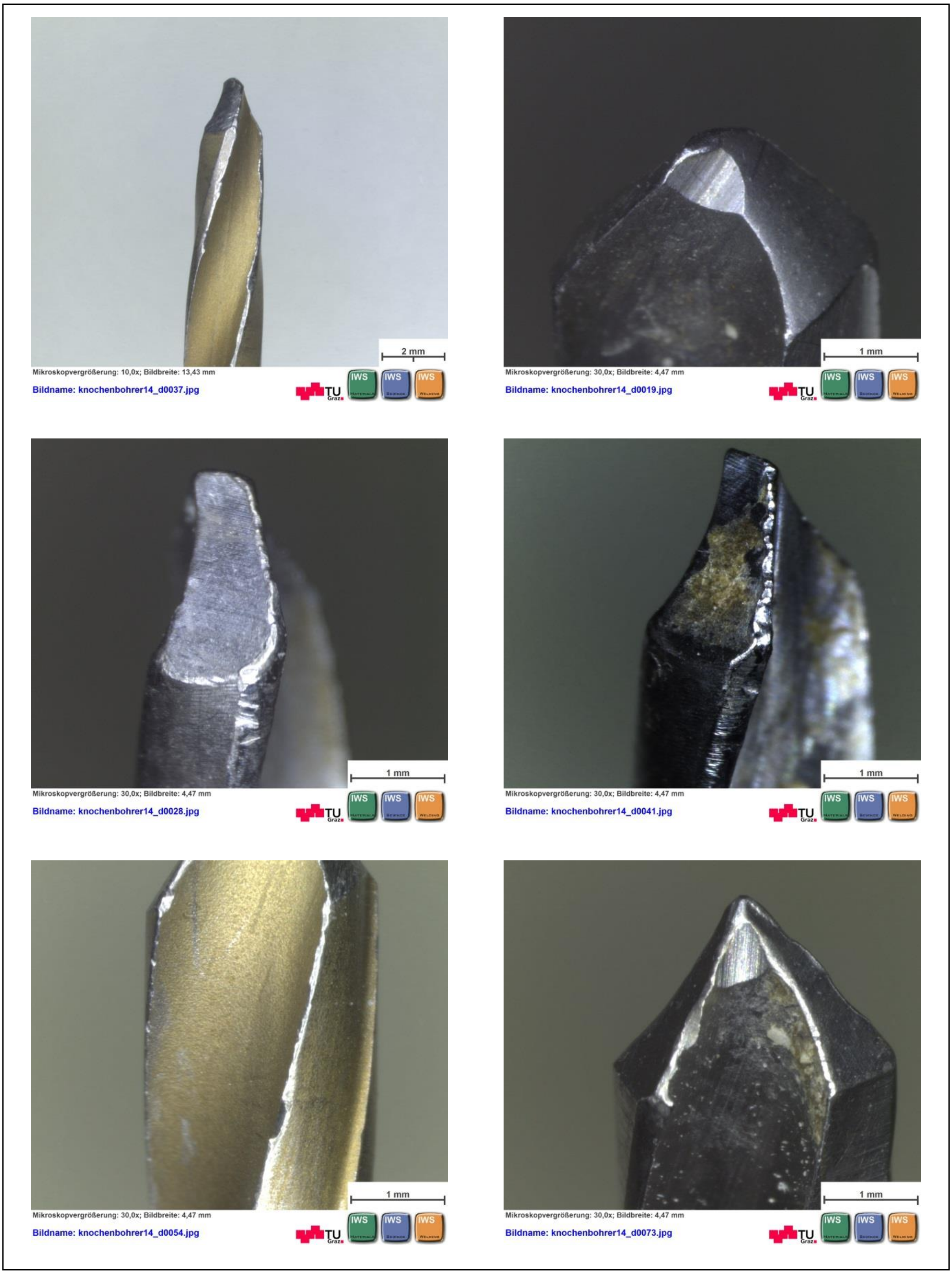

Fig. A-1: Wear characteristics of surgical drill bits discarded from the hospital

FMEA Failure Mode and Effects Analysis	Name	Surgical Bone Drilling	Date	30	1	2014	SEV	Severity
			Revison				OCC	Occurrence
			Page	1	of	1	DET	Detection
☑ Process-FMEA	Author	C. Höller					RPN	Risk Priority Number

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Effect(s) of Failure	Potential Cause(s) of Failure	Current Process Controls	SEV	OCC	DET	RPN	Recommended Actions	Responsible Person & Target Date	Taken Actions	SEV	OCC	DET	RPN
1	prepare instrument and devices	prepare worn drill bit	high drilling forces	worn drill bit not discarded	none	2	5	10	100	perform visual check	nurse		2	2	10	40
		prepare worn drill bit	high drilling temperatures	worn drill bit not discarded	none	3	5	10	150	perform visual check	nurse		2	2	10	40
2	apply coolant	no use of coolant	bone temperature increases	no order was given	none	3	9	4	108	establish cooling as standard	surgeon and nurse		3	2	4	24
		too low coolant rate	bone temperature increases	wrong determination of required amount	none	3	1	2	6							
		no possibilty to use coolant	bone temperature increases	drill guide prevents sufficient cooling	none	3	1	2	6							
3	beginn bone drilling	drill bit walking	wrong position of bore hole	drill bit geometry (chisel edge)	none	3	2	1	6							
4	drill hole in bone	too heavy bending of drill bit	drill bit brakes	incorrect drill bit handling	none	4	1	3	12							
		too slow feed rate	bone temperature increases	usage of worn drill bit	none	3	5	6	90	additional training for surgeons	hospital, consultant		3	2	3	18
		too slow feed rate	bone temperature increases	feed force is too slow	none	3	1	6	18							
		drilling forces are too high	bone temperature increases	usage of worn drill bit	none	3	7	7	147	additional training for surgeons	hospital, consultant		3	3	4	36
		drilling too deep	penetration of joint	lack of drill bit controll	none	4	6	3	72							
		bone chips clogging flutes	less heat transport out of the drill hole	suboptimal helix angle	none	3	3	8	72	drilling intermittently in steps	surgeon		3	2	5	30
										advanced drill bit geometry	manufacturer & purchasing dep.		3	2	8	48

		excessive bone temperatures	thermal necrosis	usage of blunt drill bit		4	3	10	120	visual checks to discard blunt drill bits	nurse		4	1	10	40
				wrong cutting conditions		4	2	10	80	additional training for surgeons	hospital, consultant		4	1	10	40
		bursting through 2nd cortical layer	soft tissue injuries	too high load at the end of drilling	none	4	6	3	72							
5	drive screw in	screw is loose	srew does not fixate implant	bore hole is too big		3	1	2	6							
6	pack up instrument and devices	pack up a worn drill bit (for reprocessing)	worn drill bit in the operation theatre	worn drill bit not discarded		3	5	10	150	perform visual check	nurse		2	2	10	40
7	instrument reprocessing	remaining residues on drill bit	increased risk of infection	insufficient decontamination and sterilization		4	2	9	72							
		reprocessing of blunt drill bit	worn drill bit in the operation theatre	insufficient visual and functional check		3	5	7	105	instructions for visual check	management and checker		3	2	7	42

Fig. A- 2: P-FMEA for surgical bone drilling

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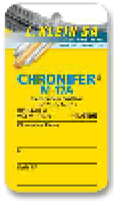

CHRONIFER® M-17A

Hardenable martensitic stainless steel

Attributes and particularities
The CHRONIFER® M-17A steel has remarkable wear resistance in the hardened condition. Thanks to its Mo addition and its high C content, this steel has good response to heat treatment to reach high hardness values. However its corrosion resistance in water and steam can only be secured in the hardened polished and passivated condition. Its machinability is, as for all martensitic stainless steels with the exception of the free machining grades, modest only.

Uses
Thanks to its good wear resistance allied to its also good corrosion resistance, this steel is widely used to make bearings, cutting instruments, medical, surgical and dental instruments, for cutlery and the production of nozzles and valve components.

Normes

Material Number	1.4109
DIN	~X70CrMo15
AISI/SAE/ASTM	AISI 440A, ASTM F899
ISO	7153-1 (S)
Euro Norm EN	~X70CrMo15
Others	UNS S44002

Chemical composition ($\%_{wt}$)

C	Si	Mn	P	S	Cr	Mo	Cu	Fe
0.60 0.75	max. 1.00	max. 1.00	max. 0.04	max. 0.03	16.0 18.0	max 0.75	max 0.50	balance

Dimensions and tolerances
Ø < 2.00 mm ISO h8 for bars
Ø ≥ 2.00 mm ISO h6 (h7, h8) for bars
Ø ≥ 0.80 mm ISO fg7 for coils (for ESCO machines)
Out of roundness: max ½ of tolerance
- Other executions on request

Executions and Delivery conditions
Standard: in bars 3 m (+50/0 mm) and in coils for ESCO
- Bars Ø ≥ 2.00 mm: cold drawn, ground polished, rugosity max Ra 0.4 µm (N5)
  End of bars: Pointed, chamfered,
  eddy-current checked according to EN10277-1, Tab. 1
- Bars < 2.00 mm surface condition: cold drawn execution
- Coils for Escomatic machine: (Ø max size : 6.00 mm)
- SWISSLINE for bars Ø ≥ 6.00 mm
- Other executions on request

Availability
Standard dimensions on stock, see: Sale program

Mechanical properties
Standard delivery condition:
- Strength UTS: 700 - 950 MPa, function of diameter

Hardness after hardening: ≥ 52 HRc,
max 56 HRc, tempering ≤ 150°C

Cutting condition
Machinability: passable
forms longs chips
Cutting speed: $V_c \approx 20 - 30$ m/min.
- Lubricant-cooling fluid i.e.: INOX or ORTHO NFX

The optimal cutting conditions depend on the machine tool, the cutting tools, the chip dimensions (cutting depth and feed), the cutting speed, the lubricant-cooling fluid, as well as the tolerances and surface roughness to be produced.

Modifications will not be adjusted automatically.
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Fig. A-3: AISI 440A datasheet (L. Klein, 2014)

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FINE STEEL AND METALS

CHRONIFER® M-17B

Hardenable martensitic stainless steel

Main features and Particularities

The CHRONIFER® M-17B steel has a low S content and is ESR remelted. It has a good wear resistance and, because of its high C content, it also has a good resistance to bluntness. Therefore it is widely used in the cutlery industry where it substitutes the 1.4034 and 1.4035 grades. Its corrosion resistance in water and its steam is at its best when the parts are previously hardened and tempered, fine ground and passivated. This steel can be mirror polished.

Uses and Applications

This steel is well indicated for the production of medical, surgical and dental instruments. It is also used where a good wear resistance allied to a good corrosion resistance is asked for as i.e. in the agro- and food industries.

Applicable standards

Material Number	1.4112
DIN EN	X90CrMoV18, EN 10088-3
AISI/SAE/ASTM	≈ AISI 440B, ASTM F899, QQS763 (chem. composition)
AFNOR	X90CrMoV18, X 89CrMoV 18-1, (former Z 90 CDV 18)
ISO	7153-1 (R)
NF	S 94-090
JIS	≈ SUS 440B

Chemical composition ($\%_{wt}$)

C	Si	Mn	P	S	Cr	Mo	V	Fe
0.85	max.	max.	max.	max.	17.0	0.90	0.07	balance
0.95	1.00	1.00	0.04	0.03	19.0	1.30	0.12	

Dimensions and tolerances

Ø < 2.00 mm ISO h8 for bars
Ø ≥ 2.00 mm ISO h6 for bars
Ø ≥ 0.80 mm ISO fg7 for coils (for ESCO machines)
Out of roundness: max ½ of tolerance

- Other executions on request

Executions and Delivery conditions

Standard: in bars 3 m (+50/0 mm) and in coils for ESCO

- Bars Ø ≥ 2.00 mm: cold drawn, ground polished, rugosity max Ra 0.4 µm (N5)
  End of bars: Pointed, chamfered,
  eddy-current checked according to EN10277-1, Tab. 1
- Bars < 2.00 mm surface condition: cold drawn execution
- Coils for Escomatic machine: (Ø max size : 6.00 mm)
- Other executions on request

Availability

Standard dimensions on stock, see: Sale program

Mechanical properties

Standard delivery condition: annealed (ø > 2.00 mm)	
Strength UTS:	depends on diameter
	UTS max 925 MPa
Ø > 14.00 mm:	HB max. 265

Cutting conditions

Machinability: satisfactory
forms long chips

- Cutting speed: V_c ≈ 25 - 40 m/min.
- Lubricant cooling fluid i.e.: INOX or ORTHO NFX

The optimal cutting conditions depend on the machine tool, the cutting tools, the chip dimensions (cutting depth and feed), the cutting speed, the lubricant-cooling fluid, as well as the tolerances and surface roughness to be produced.

Modifications will not be adjusted automatically.
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Fig. A-4: AISI 440B datasheet (L. Klein, 2014)

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CHRONIFER® M-17C

Hardenable martensitic stainless steel

Attributes and Particularities
The CHRONIFER® M-17C steel has a low S content and is ESR remelted. Its wear resistance is remarkable. Its corrosion resistance in water and its steam is satisfactory only if the parts have previously been hardened (quenched and tempered), polished and passivated. Thanks to its high C content its hardening capability is high. It gives this steel its characteristic wear resistance as well as its most favorable resistance to bluntness. In the opposite its machinability is fair only.

Uses and Applications
This steel is well indicated for the production of bearings; medical, surgical and dental instruments; cutting tools and nozzles for various industries.

Applicable standards

Material Number	1.4125
DIN EN	X105CrMo17, EN 10088-3
AISI/SAE/ASTM	AISI 440C, ASTM F899, A 276, A 959, AMS5630J, AMS 5880C (chemical composition)
AFNOR	X105CrMo17 (former Z 100 CD 17)
UNS	S 44004
NF	S 94-090
JIS	≈ SUS 440C

Chemical composition ($\%_{wt}$)

C	Si	Mn	P	S	Cr	Mo	Fe
0.95	max.	max.	max.	max.	16.0	0.40	balance
1.20	1.00	1.00	0.04	0.03	18.0	0.75	

Dimensions and tolerances
Ø < 2.00 mm ISO h8 for bars
Ø ≥ 2.00 mm ISO h6 for bars
Ø ≥ 0.80 mm ISO fg7 for coils (for ESCO machines)
Out of roundness: max ½ of tolerance
- Other executions on request

Executions and Delivery conditions
Standard: in bars 3 m (+50/0 mm) and in coils for ESCO
- Bars Ø ≥ 2.00 mm: cold drawn, ground polished, rugosity max Ra 0.4 µm (N5)
  End of bars: Pointed, chamfered,
  eddy-current checked according to EN10277-1, Tab. 1
- Bars < 2.00 mm surface condition: cold drawn execution
- Coils for Escomatic machine: (Ø max size : 6.00 mm)
- Other executions on request

Availability
Standard dimensions on stock, see: Sale program

Mechanical Properties
Standard delivery condition: annealed
Strength UTS, hardness H_B and HRc:
Ø < 14.00 mm: max. 950 MPa
Ø ≥ 14.00 mm: max. 285 H_B
- Hardness after hardening: max. 60 HRc

Cutting conditions
Machinability: low, forms long chips
- Cutting speed: V_c ≈ 20 - 30 m/min.
- Lubricant-cooling fluid: INOX or ORTHO NFX

The optimal cutting conditions depend on the machine tool, the cutting tools, the chip dimensions (cutting depth and feed), the cutting speed, the lubricant-cooling fluid, as well as the tolerances and surface roughness to be produced.

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Fig. A-5: AISI 440C datasheet (L. Klein, 2014)

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FINE STEEL AND METALS

CHRONIFER® M-15

Hardenable martensitic stainless steel

Features

The CHRONIFER® M-15 steel has a high Cr and low S contents. It is ESR remelted. The low C and S contents, as well as the Ni addition promote and support its good corrosion resistance. It is the second best of all martensitic stainless steels after this of the powder metallurgy made CHRONIFER® M-15X steel. However, as for all martensitic stainless steels, it exhibits its best values in the quenched, tempered, polished and passivized condition. In this condition, it exhibits a good resistance to water and water steam (autoclave sterilization). Its high mechanical properties indicate it for various applications in many industries.

Uses

This steel is well adapted for medical, surgical and dental instruments. It is well indicated for the production of parts for many industries, such as i.e. automotive, chemical, oil and petrochemical, paper, agricultural, food, aerospace, instrumentation and precision mechanical engineering, natural energy extractions and conversions.

Standards

Material No.	1.4057
DIN	X17CrNi16-2 (former X20CrNi17-2)
AISI/SAE/ASTM	AISI 431, ASTM F899
AFNOR	X17CrNi16-2 (former Z 15CNi 16.02)
ISO	X17CrNi16-2
Euro Standard EN	X17CrNi16-2 (X21CrNi17)
JIS	SUS 431
Others	NF S 94-090

Chemical composition (%wt)

C	Si	MN	P	S	Cr	Ni	Fe
0.12	max.	max.	max.	max.	15.00	1.50	balance
0.20	1.00	1.00	0.04	0.03	17.00	2.50	

Dimensions and tolerances

Ø < 2.00 mm ISO h8 for bars
Ø ≥ 2.00 mm ISO h6 (h7) for bars
Ø ≥ 0.80 mm ISO fg7 for coils (for ESCO machines)
Out of roundness: max ½ of tolerance
- Other executions on request

Executions and Delivery conditions

Standard: in bars 3 m (+50/0 mm) and in coils for ESCO
- Bars Ø ≥ 2.00 mm: cold drawn, ground polished, rugosity max Ra 0.4 µm (N5)
  End of bars: Pointed, chamfered,
  eddy-current checked according to EN10277-1, Tab. 1
- Bars < 2.00 mm surface condition: cold drawn execution
- Coils for Escomatic machine: (Ø max size : 6.00 mm)
- Other executions on request

Availability

Current dimensions on stock, see: Delivery program

Mechanical properties

Standard delivery condition:	
Ultimate Strength UTS/Rm:	≈ 850 MPa, according to diameter
Hardness after hardening:	≈ 47 HR

Cutting conditions

Machinability:	fair to good, forms long chips
Cutting speed:	V_c ≈ 30 - 40 m/min.
Cooling lubricant i.e.	INOX or ORTHO NFX

The optimal cutting conditions depend on the machine tool, the cutting tools, the chip dimensions (cutting depth and feed), the cutting speed, the lubricant-cooling fluid, the tolerances and surface roughness to be produced, as well as the machinists & users.

Modifications will not be adjusted automatically.
Last update date 07.2014

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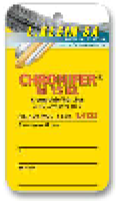
Fig. A- 6: AISI 431 datasheet (L. Klein, 2014)



CHRONIFER® M-15 KL

Hardenable martensitic stainless steel

Features
The CHRONIFER M-15 KL is an ESR remelted N containing hardenable martensitic stainless steel with a low S content. Its corrosion resistant is noteworthy, superior to these of the 1.4112 and 1.4125 grades. It has a good wear resistance and exhibit a particularly good resistance to becoming blunted. It can be mirror polished.

Uses
This steel is most suitable for the production of bearings, drills, taps, milling cutters and other tools, as well as for medical, surgical and dental instruments and general-purpose instruments in medicine.

Standards

Material No	1.4123
DIN EN	X40CrMoVN16-2, EN 10088-3
AISI/SAE/ASTM	420 mod, ASTM F899, AMS5925 chemical analysis
AFNOR	X40CrMoVN16.02, (former Z 40 CDV 16.02)
NF	S 94-090 chemical analysis
UNS	S4025 chemical analysis

Chemical composition (%wt)

C	Si	Mn	P	S	Cr	Mo	Ni	V	N	Fe
0.37	max.	max.	max.	max.	15.0	1.50	max.	0.20	0.15	balance
0.45	0.60	0.60	0.02	0.005	16.0	1.90	0.50	0.40	0.25	

Dimensions and tolerances
Ø < 2.00 mm ISO h8 for bars
Ø ≥ 2.00 mm ISO h6 for bars
Ø ≥ 0.80 mm ISO fg7 for coils (for ESCO machines)
Out of roundness: max ½ of tolerance
- Other executions on request

Executions and Delivery conditions
Standard: in bars 3 m (+50/0 mm) and in coils for ESCO
- Bars Ø ≥ 2.00 mm: annealed, ground polished, rugosity max Ra 0.4 µm (N5)
  End of bars: Pointed, chamfered,
  eddy-current checked according to EN10277-1, Tab. 1
- Bars < 2.00 mm surface condition: cold drawn execution
- Coils for Escomatic machine: (Ø max size : 6.00 mm)
- Other executions on request

Availability
Current dimensions on stock, see: Delivery program

Mechanical properties
Delivery condition: annealed ground polished
- Ultimate tensile strengtha: < 14 mm max ≈ 900 MPa
- Ultimate tensile strength: ≥ 14 mm 265 HB
- Hardness after quenching and tempering: ≈ 58 HRc

Cutting conditions
Machinability: difficult to acceptable/passable
produces long chips
- Cutting speed: V_c ≈ 20 - 30 m/min.
- Lubricant i.e.: INOX or ORTHO NFX

The optimal cutting conditions depend on the machine tool, the cutting tools, the chip dimensions (cutting depth and feed), the cutting speed, the lubricant-cooling fluid, the tolerances and surface roughness to be produced, and, obviously, the experience of the machinist.

Modifications will not be adjusted automatically.
Last update 07/2014

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Fig. A- 7: AISI 420mod datasheet (L. Klein, 2014)