

Alpha-Bio Tec Drills

Scientific Overview



 **Alpha Bio** TEC
Simplantology

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Alpha-Bio Tec **Advanced Drill Line Overview**

Alpha-Bio Tec Introduces a new and advanced drill line

In this document, Alpha-Bio Tec scientifically demonstrates best possible design supported by design features that reduce heat and enhance bone preservation

Introduction

When designing dental drills, all characteristics and properties should be adjusted to create minimal temperature rise during the drilling process. One of the main causes of failure in dental implant osseointegration is the increase of bone temperature above 47 °C during bone drilling resulting in irreversible osteonecrosis^[1,2]. Having a necrotic area surrounding the implant reduces the efficiency of the osseointegration process, leading to loss of rigid fixation. The thermal damage at the drilling site inhibits the regenerative response in bone healing, damaging the osseointegration process and potentially resulting in the implant's lack of secondary stability.

Drill design plays a significant role in controlling the heat generated during drilling and several design features should be considered. A combination between surgical tools and optimal implant site preparation will result in enhanced osseointegration and reduced failure rate.



Key Design Features

① Use of Coolant

The use of coolant is the most influential factor on bone heating which significantly decreases the temperature induced during the drilling process^[3-7]. Cooling is supplied by one of two methods - internal or external. In an internal cooling system, the coolant passes through an internal drill hole and exits through the drill flutes. The cooling mechanism is a combination of heat transfer between drill, coolant and bone. In addition, the coolant provides lubrication and irrigation. Lubrication reduces the friction during drilling, thereby reducing heat. Irrigation effectively removes chips and debris produced during the drilling process, prevents clogging of flutes and allows bone extraction which reduces the heat. In an external cooling system, the coolant is induced from an external nozzle onto the drill's external surface reducing heat through convection mostly on the exposed drill portion and the upper cortical bone. When examining the various effects of these two methods, we first recognized that both methods significantly reduce bone temperature during drilling.

Matthews and Hirsch^[4] studied the coolant effect when drilling through human cortical bone and found that cooling is highly effective in reducing the maximum temperature received. They used water at room temperature with flow rates of 300, 500 and 1000 ml per minute. They also concluded that increasing the irrigation rate reduces bone temperature developed during drilling and further, that the temperature never increases above 50°C at the irrigation rate of 500 ml/min or above (Figure 1).

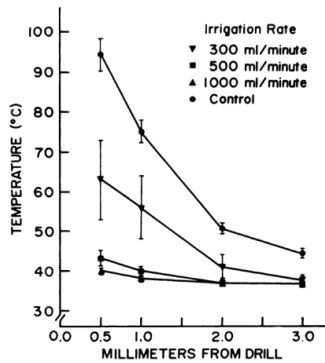


Fig 1

Effect of cooling rates on average maximum cortical temperatures recorded at specific distances from the drill^[4]

Augustin *et al.*^[8] investigated the performance of internally cooled step drill during the drilling of porcine femora and found that the cooling system produces bone temperatures significantly below the threshold for thermal osteonecrosis.

When comparing internal and external cooling systems, the internal cooling system is more efficient in depth, while the external cooling system is more efficient on the surface^[6,9]. The internal cooling system effectiveness increases as the depth increases.

Sener *et al.*^[10] studied bovine mandible heating during drilling with coolant and observed that more heat is generated on the surface of the drilling cavity as compared to the bottom surface. As a result, they recommended external irrigation as a sufficient cooling system during drilling. Further, field experience showed blockage of the internal irrigation lumen when using internal irrigation cooling systems.

② Heating generation overview

There are several drilling parameters considered to be significant for controlling heat generation during drilling, including spindle speed, feed rate, drilling sequence and drilling depth. Understanding the effect of each parameter will enable better control of the temperature generated and will avoid necrosis during drilling^[11-16].

Lee *et al.*^[11] studied the effect of spindle speed and depth of drilling on the temperature distribution during the drilling of cortical bovine femur and found that the maximum temperature increases with increasing spindle speed and independently decreases with the increasing feed rate (Figure 2).

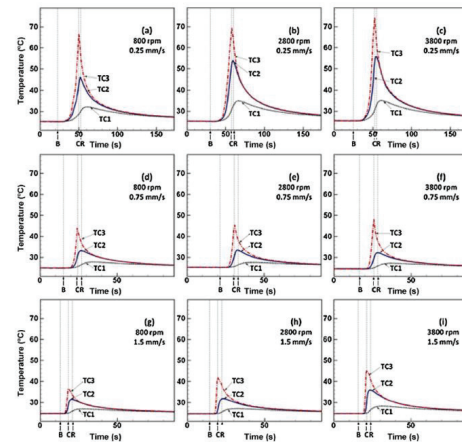


Fig 2

Thermal history for thermocouples located at radii locations of 0.5 mm (TC3), 0.81 mm (TC2), and 2.78 mm (TC1) from the center of the drilled hole; maximum drilling depth of 7 mm (Animal A)^[11]

Lee *et al.* also showed that as the drilling depth increases, the temperature increases (Figure 3).

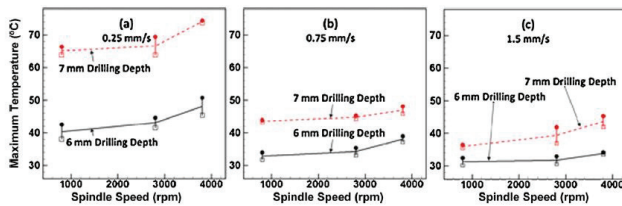


Fig 3

Maximum temperature at 3 mm depth (TC3) as a function of the spindle speed for hole depths of 6 mm and 7 mm, and for an initial temperature of 26°C^[11]

Cordioli and Majzoub^[12] examined bovine femurs by drilling with 1500 rpm and external irrigation and reached higher temperatures at 8 mm depth as compared to 4 mm depth, regardless of the drill diameter and the presence of cooling.

Bachus *et al.*^[13] examined cadaveric femur and found that the maximum temperature decreases with increasing axial thrust force at 820 rpm. Sharawy *et al.*^[14] measured the heat generated from different drilling speeds (1225, 1667, and 2500 rpm) and found that the mean rise in the temperature, decreases as the drilling speed increases.

Chacon^[15] measured heat generation of three implant drill systems and found a decrease in maximum temperature when increasing the number of drills in the drilling sequence as a result of smaller bone volume excavated at each step. As substantial amounts of bone have already been removed in the preceding sequences with smaller diameter drills, the larger diameter drills are subject to cut less bone, therefore, resulting in smaller temperature increases^[16].

In addition, it is recommended to interrupt the drilling procedure at least every 5 s for at least 10 s and apply saline to the bone. Using this sequence will significantly decrease the time of elevated bone temperature^[14].

③ Mechanical Features

i Drill Flutes

Flutes are grooves created on the drill surface for two main functions (Figure 4). The first, is creation of the cutting edge and determination of the number of cutting edges. The second, functioning as an exit path for chips and debris produced during the drilling process.

Bertollo *et al.*^[17] tested two- and three-fluted surgical drills and concluded that a three-fluted design has superior bending stiffness. In further studies, Bertollo *et al.*^[18] also concluded that the cutting efficiency of a three-fluted design is greater than that of the two-fluted drills. However, when trying to establish this theory while measuring the maximum drilling temperature of the two, no significant differences were observed between two- and three-flutes drills. Further, additional flutes in the design may narrow the channels of the flutes that act as a path for bone chip removal, eventually resulting in impaired cutting efficiency and elevated frictional heat. Additional research is required on the optimal number of flutes and its effect on stability, cutting efficiency and frictional heat.

ii Helix Angle & Rake Angle

Helix angle of the drill is defined as the angle formed by the edge of the flute with the line parallel to the drill center line (Figure 4). Rake angle is defined as the angle between the cutting edge and the plane perpendicular to the work-piece (Figure 5).

Helix angle and rake angle are interrelated, as a larger helix angle results in a larger rake angle. The helix angle provided on the drill bit can be slow, standard or quick, depending upon the helix angle^[19].

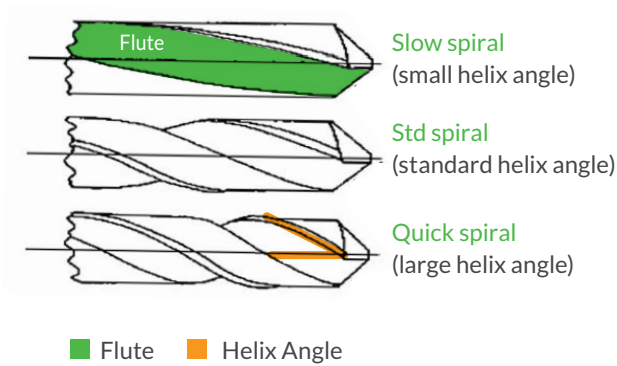


Fig 4

Slow (small helix angle), Standard and quick helix^[19]

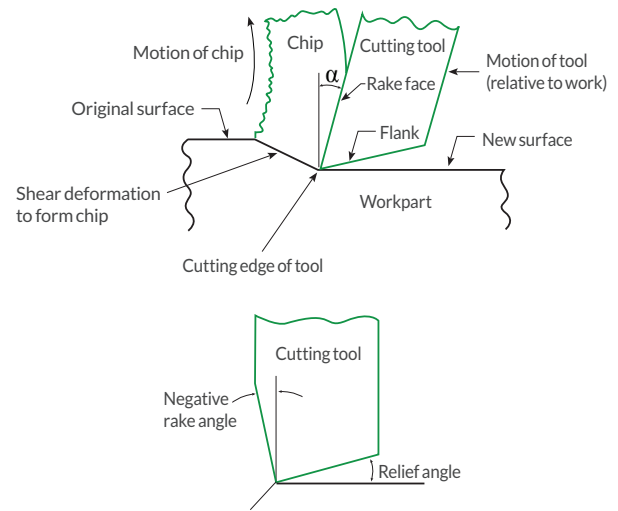


Fig 5

Illustration

Helix angle is defined in such a way that there is a compromise between the strength of the cutting edge and efficient chip ejection through the flutes^[20]. When increasing the helix angle, cutting efficiency is reduced, however, a higher feed rate is achieved and drill propagation reduces the drilling time.

As a result, there is a clear tradeoff between these two parameters to receive the optimal helix angle. For a surgical drill, the range of 12°-28° helix angle is usually suggested and recommended by several researchers^[20-24]. Increasing the rake angle (α in Figure 5) will result in a decrease of the bone cutting forces^[21,25]. An optimum rake of 20°-30° was recommended by Hillery and Shuaib^[26] as it sufficiently clears the chips and generates very low thrust force.



iii Relief Angle & Body Clearance

Relief angle is defined as the surface adjacent to the cutting edge and below it when the tool is in a horizontal position (Figures 5). Body clearance is defined as the surface that follows behind the edge and up through the drill flute (Figure 6,7). Both relief angle and body clearance reduce the heat generation due to the minimized bone to drill contact during osteotomy preparation [15, 16]. Larger relief angles generally tend to produce a better finish as less surface of the worn flank of the drill rubs against the bone surface [27]. Most dental drills have relief, however, lack body clearance.

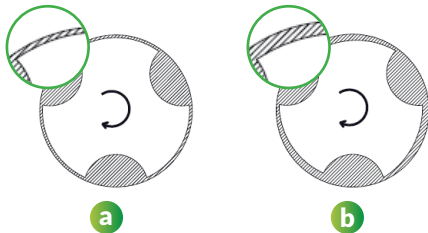


Fig 6

Drill bit without **a** and with **b** body clearance

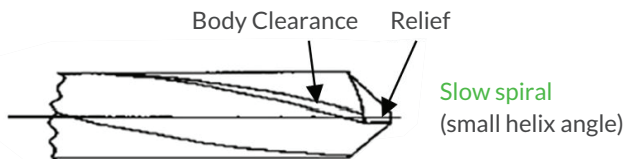


Fig 7

Relief angle and body clearance

iv Point Angle

Point angle is the angle formed between the drill's outer diameter just above the cutting edge and its tip (Figure 8). Larger point angles provide full contact of the cutting lip with the bone as soon as drilling begins, resulting in reduced heat due to faster cutting action along with less acute tip for primary stability which is important for initial drills [28].

For surgical drills, researchers recommend a point angle of 90° for initial drills as they create the first drilled hole [25] and the range of 100° - 130° point angle for all following drills diameters [19,21,24,29].

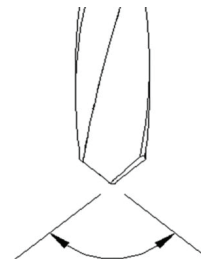


Fig 8

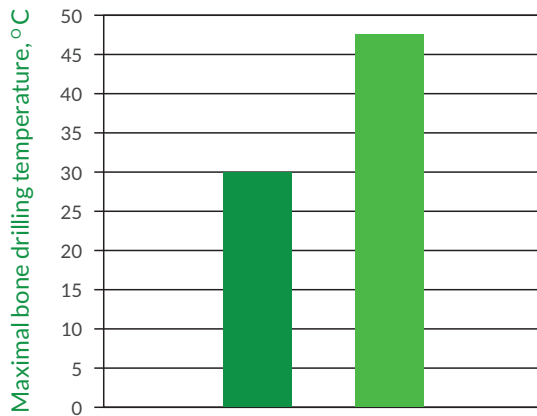
Point angle



v Step Drill Bit

Step drill bit has an effective design that minimizes temperature elevation due to gradual removal of material from the drilling site [30]. Step drill may also assist in centralizing the drilling process. The centralizing feature is due to the lower drill step (small diameter phase) leading the way through the predrilled site.

Udiljak *et al.* [30] examined heat generation with conventional drills and step drills and received lower maximum bone drilling temperature using a step drill as compared to a conventional drill (Figure 9).

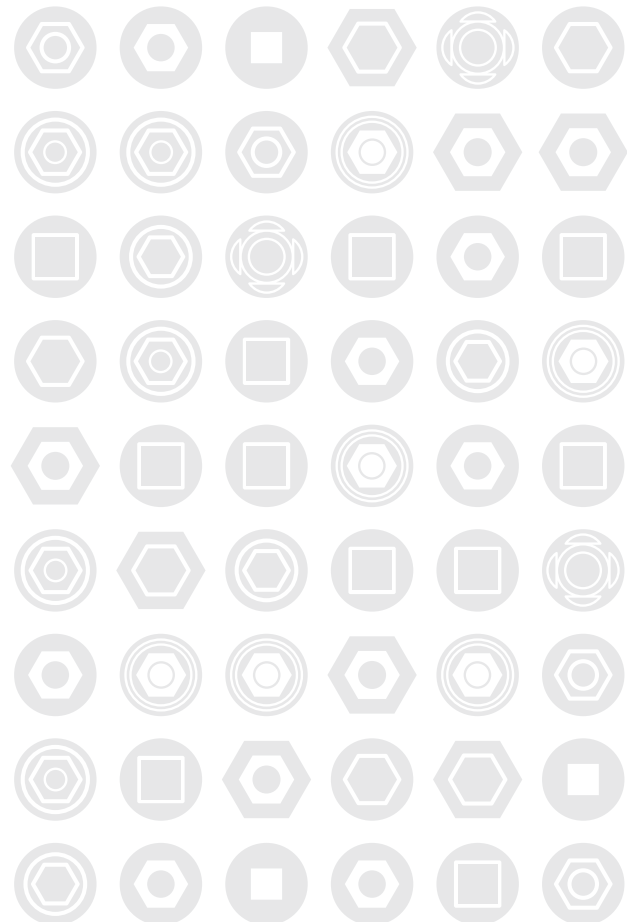


- Step drill
- Conventional Surgical Drill

Fig 9

Maximal bone drilling temperature in dependence on the drilling tool geometry according to Udiljak *et al.* [30].

Bubeck *et al.* [31] examined cadavers' bone heat generation comparing step drills versus sequential drilling and found that the maximum heat generation with step drilling and sequential drilling was not significantly different at 60 N and 120 N of drilling force. However, at 80 N, a significant variable of 2.13 °C was found between the two drilling techniques and the time to complete (seconds) was significantly shorter for the holes created by step drilling than by sequential drilling.



Alpha-Bio Tec Advanced Drill Line

Alpha-Bio Tec advanced drills were designed following a comprehensive research process. The advanced drill line took the above mentioned parameters into consideration. To validate drill line performance, Alpha-Bio Tec have designed a system which measures heat generation and mechanical forces (torque & axial force) exerted on the bone during the drilling process.

① System Set-up

- Load cell & Torque meter
- Linear arm
- Thermal Camera
- Bovine bone tissue (Ribs) analog with 2 mm of organic cortical bone which represent a 1200/600 Hunsfield unit bone
- Physio-dispenser
- Optical measurement system

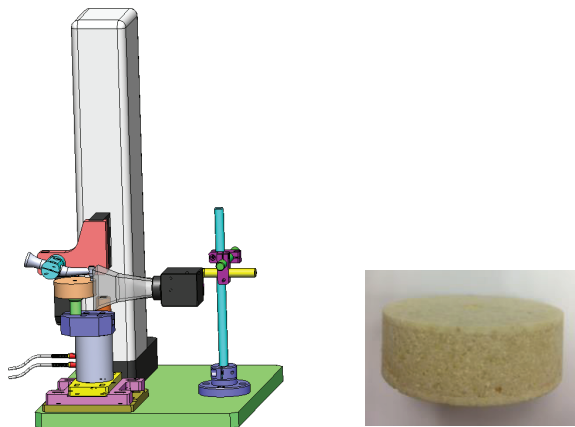


Fig 10

System set-up & Bovine bone

② Experimental Method

- A measurement system was designed to evaluate heat generation, exerted forces (axial and torque) and stability of ABT's new drill line (Step & Straight) by isolating the following design parameters:
 - a. Body clearance
 - b. Step drills rake angle
 - c. Drill flutes
- Contra angle handle of the physio-dispenser was fixed to the linear arm and the drill's position was calibrated to be exactly perpendicular to the bone model surface (Figure 10)
- Constant rotational speed of 1000 rpm was set.
- Axial movement of the linear arm was set to a constant speed creating a constant and unified penetration/retraction of the drill in/out the bone model (= feed rate)
- Drilling depth was set to 11.5 mm
- All tests were performed without irrigation to isolate its effect
- Drills' maximum temperature was measured after drill retraction from the hole and bone temperature isotherm was verified
- Drills' axial forces and exerted torques were continuously recorded
- Drill's temperature performance was verified along 15 drilling repetitions to observe wear properties
- Drill's stability was measured by comparing actual diameter of the drill with the drilled hole diameter



③ Results

Heat generation

Drill temperature was measured after drill retraction from hole. (Figure 11). Testing method was found to be reliable with small deviation.

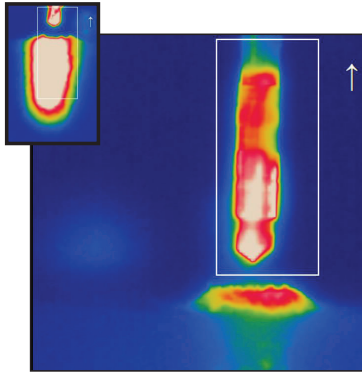


Fig 11

Isotherms of the drill retraction from the bone and the osteotomy

We observed significant heat generation differences between initial drills and the following drills according to the drilling sequence protocol. Maximum temperatures of any initial drills were found to be greater than the maximum temperature of the following drills.

Comparing drills with/without body clearance also showed a significant difference between the two; drills without body clearance generate approximately 15% more heat than those with body clearance. Comparing step drills with Alpha-Bio τ_{ec} improved rake angle against similar drills without this improvement showed significant superiority of the improved rake angle. Step drills without the improved rake

angle generate approximately 10% more heat than the ones with the improved rake angle.

Comparing two- versus three-flute drills did not show significant heat generation superiority of any of the two, however, when comparing torques of large diameters drills ($\varnothing 4.5$ mm and above), the torques exerted by two-flute drills were up to 35% larger than the torques exerted by three-flute drills (Figure 12).

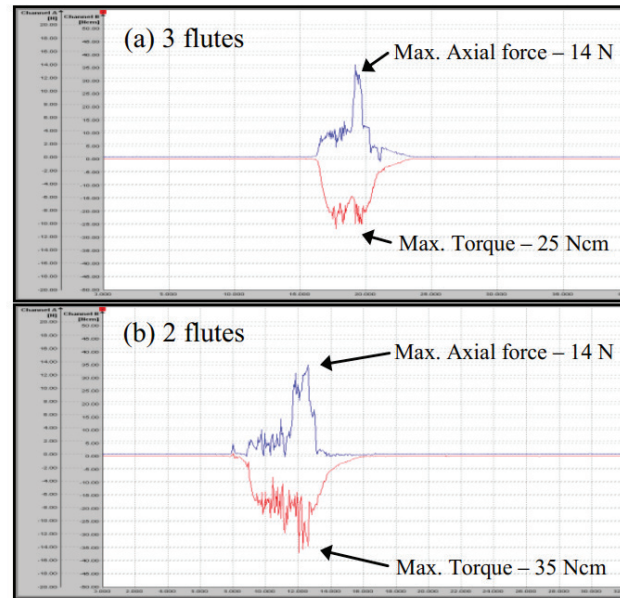


Fig 12

Forces comparison (axial force and torque) of 4.1-4.5 step drills with 3 flutes (a) and 2 flutes (b)

Comparing Alpha-Bio τ_{ec} drills to the main competitors drills, we received a superiority of Alpha-Bio τ_{ec} drills in all tests, generating between 5-25% less heat.

Stability

Comparing the actual diameter of the advanced drill line (Step & Straight drill) to the resulting drilled hole diameter, showed a maximum of 40 μm deviation from the drill's center line using initial drills ($\varnothing 2\text{ mm}$) and a maximum of 20 μm deviation with all other drills (Figure 13). These results indicate superb stability.



Fig 13

$\varnothing 3.2\text{ mm}$ measured hole by our optical measurement system



Summary & Conclusions

Following an extensive research and development process, Alpha-Bio Tec developed an advanced drill line. Each parameter was tested as a standalone and was taken into consideration. Further, a thorough testing method was established to authenticate the company's products. The following table summarizes drill design features:

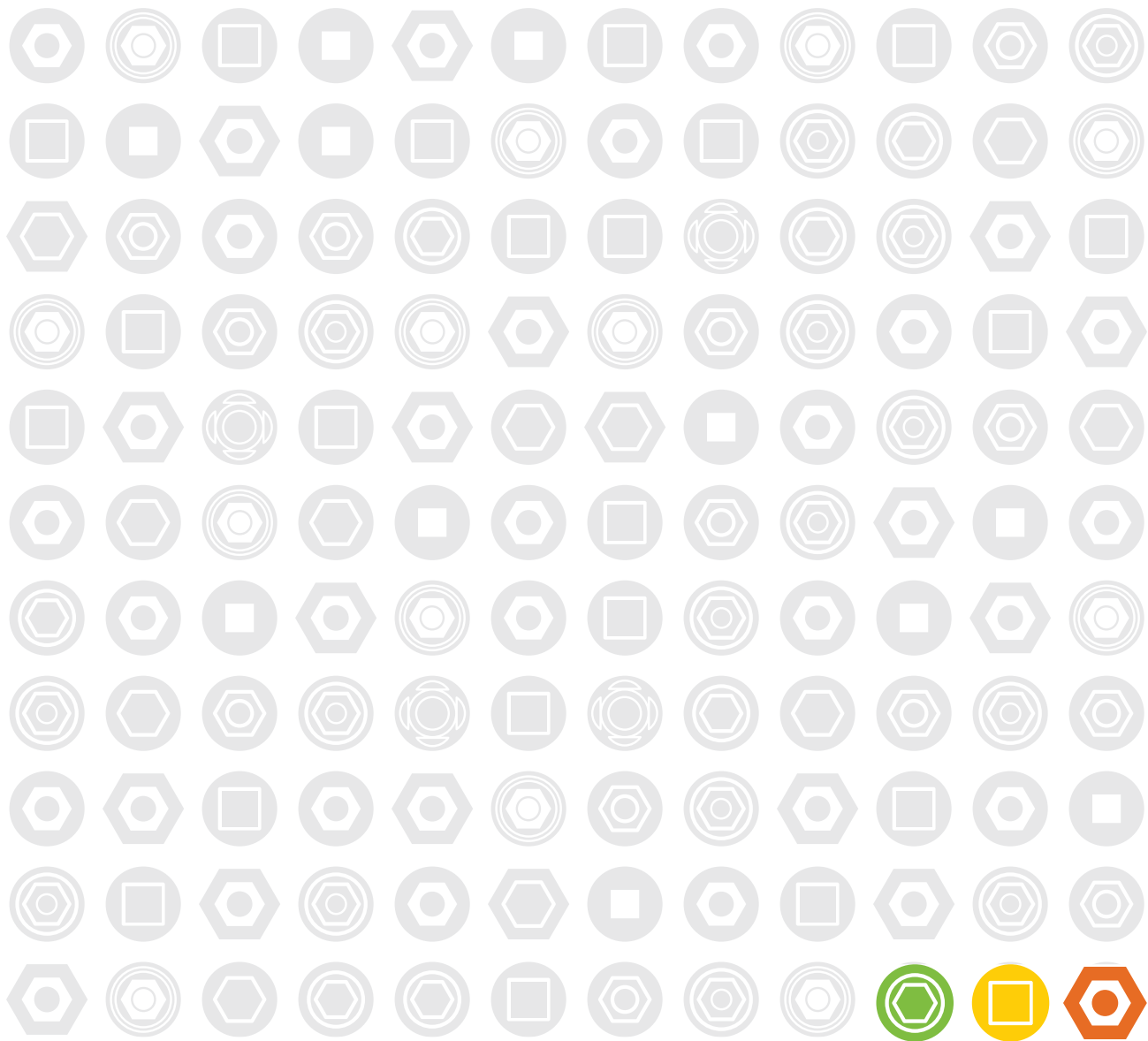
Drill Parameter	Literature Suggested Design	Selection Explanation	Alpha-Bio Tec Drills
Use of coolant	External irrigation	External irrigation is more efficient than internal irrigation on the surface and at the upper section of the osteotomy (dense cortical section). Field experience shows blockage on internal irrigation lumen.	External irrigation
Flutes	3 flutes	Three flutes exhibit superior bending stiffness. Theoretically, they should also exert less heat on the bone due to enhanced cutting efficiency and less torques at larger drill's diameter.	3 flutes design
Helix Angle	10°-30°	For surgical drills, the range of 10°-30° helix angle is recommended to have best cutting efficiency, according to literature and Alpha-Bio Tec's testing.	Within the range

Drill Parameter	Literature suggested Design	Selection Explanation	Alpha-Bio ^{Tec} Drills
Rake Angle	20°-30°	An optimum rake of 20°-30° was recommended to have best cutting efficiency.	Within the range
Relief & Body Clearance	With both	Both relief angle and body clearance reduce the heat generation due to the reduced bone to drill contact during osteotomy preparation.	Both included
Point Angle	90° (Initial drill)	90° point angle for the initial drills.	90°
	100°-130° (all other drills)	Range of 100°-130° point angle for all following drills diameters.	Within the range
Step vs. Straight	Step	<p>Step drill bit has a highly effective design that minimizes temperature elevation due to gradual removal of material from the drilling site.</p> <p>Step drill assists in centralizing the drilling process due to the lower drill step leading the way through the predrilled site.</p> <p>Step drills increase osteotomy accuracy in cases where drill sequence requires cortical release.</p>	Alpha-Bio ^{Tec} supplies both Step & Straight

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Smart Simplanotogy Solution



Alpha-Bio Tec

Revised Drill Protocol Overview

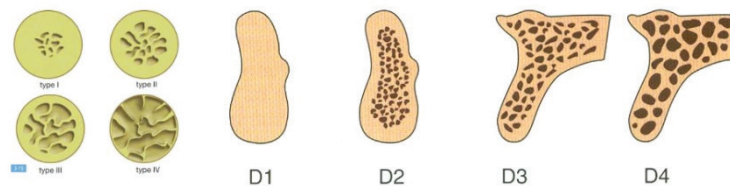
Bone Classification, Drill Protocol and Implant Osteotomy

The high success rate of dental implants has made implants the 'first choice' of dental professionals for the replacement of missing teeth. Alpha-Bio Tec. has become a leader in dental implant design, manufacturing quality implants with a high success rate.

Alpha-Bio Tec's drilling protocol is based on bone type classification. It offers a simplified drilling sequence table, drill heat-reduction features and a unique drill design that are all coordinated with ABT's implant body and core designs.

Bone quality is a collective term referring to the mechanical properties, architecture, degree of mineralization, chemical composition and remodeling properties of bone^[1]. Several classification measures have been developed to assist clinicians in illustrating bone quality using a set of acceptable terms^[2-3], although the most widely accepted system in oral implantology is from Lekholm and Zarb^[2,4,5].

Lekholm and Zarb^[2] classified bone quality into four levels (Types I-IV) according to bone composition (e.g. ratio between compact bone and spongy bone) and subjective bone resistance when drilling. Accordingly, clinical use of the Lekholm and Zarb^[2] classification for the assessment of bone quality and the establishment of a specific treatment plan are based on this property^[6].



Bone Classification

The new surgical drills (straight and step drills) were designed to simplify, and enhance the dental professional's work in order to make it more efficient. The new drilling protocol allows for optimal insertion torque according to bone type and implant design, ultimately ensuring high primary stability with minimal bone stress to enable best possible osseointegration.

The new drilling protocol complies with the Lekholm and Zarb^[2] bone classification, as follows:

Hard bone – bone type I

Medium bone – bone type II + III

Soft bone – bone type IV

The Alpha-Bio Tec. protocols controls and standardizes the preparation of the implant site to achieve optimal values of insertion torque and to avoid excessive compression of the hosting bone. This will maximize the bone remodeling surrounding the implant to increase the Bone to Implant Contact (BIC), and results in the secondary stability of the implant.

Distinguishing between bone type II and type III is particularly difficult. As a result, bones were divided into three separate categories: Hard (type I), Medium (combination of type II + III) and Soft (type IV). By dividing the bone into these categories, dental professionals were given a wider selection of drilling protocols, thereby reducing the risk of error and improving overall drilling protocol accuracy.

Some of ABT's implants offers convergence in its apical part. Implants that are cylindrical or slightly tapered with convergence in their apical part are suitable for step drill procedures. Step drills allow dental professionals to achieve an optimal osteotomy which is well matched to the implant, resulting in high primary stability.

The step drill stabilizes the drilling and may reduce drilling procedure time, which is not only more efficient but also should decrease the amount of heat produced^[7]. Nevertheless, experienced implantologists should still be able to achieve a perfect match by using the standard straight drill with adaptation of the drilling protocol. Overall drill enhancement, deploying step drills and adhering to the three new categories in drill protocol, contributes to easier, more accurate clinical use of Alpha-Bio Tec's implants for optimal clinical results.

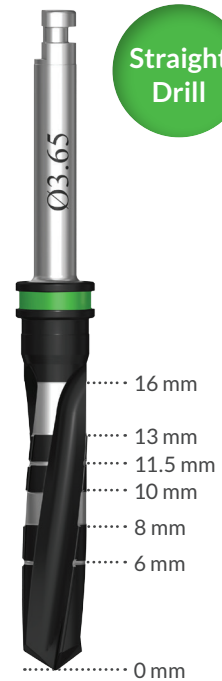
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SPI Drilling Sequence

Straight Drilling Sequence

Ø Implant	Soft bone Type IV	Medium bone Type II&III	Hard bone Type I
Ø 3.3	2.0	2.0 2.8	2.0 2.8 3.2 Cortical
Ø 3.75	2.0 2.8	2.0 2.8 3.2	2.0 2.8 3.2 3.65 Cortical
Ø 4.2	2.0 2.8 3.2	2.0 2.8 3.2 3.65	2.0 2.8 3.2 3.65 4.1 Cortical
Ø 5.0	2.0 2.8 3.2 3.65	2.0 2.8 3.2 3.65 4.1 4.5	2.0 2.8 3.2 3.65 4.1 4.5 4.8 Cortical
Ø 6.0	2.0 2.8 3.2 3.65 4.1 4.8	2.0 2.8 3.2 3.65 4.1 4.8 5.2	2.0 2.8 3.2 3.65 4.1 4.8 5.2 5.8 Cortical



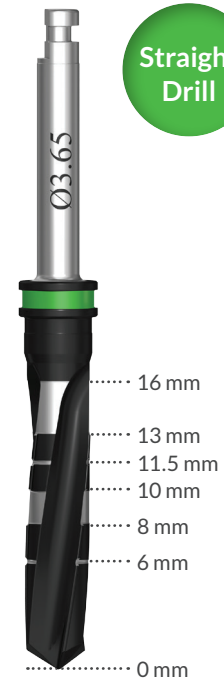
Cortical – Drill through cortical plate



ICE™ Drilling Sequence

Straight Drilling Sequence

Ø Implant	Soft bone Type IV	Medium bone Type II&III	Hard bone Type I
Ø 3.7N	2.0 2.0/2.4	2.0 2.8 2.8/3.2	2.0 2.8 2.8/3.2 3.65 Cortical
Ø 3.75	2.0 2.4/2.8	2.0 2.8 2.8/3.2	2.0 2.8 2.8/3.2 3.65 Cortical
Ø 4.2	2.0 2.8 2.8/3.2	2.0 2.8 3.2 3.2/3.65	2.0 2.8 3.2 3.2/3.65 4.1 Cortical
Ø 4.65	2.0 2.8 3.2 3.2/3.65	2.0 2.8 3.2 3.65 3.65/4.1	2.0 2.8 3.2 3.65 3.65/4.1 4.5 Cortical
Ø 5.3	2.0 2.8 3.2 3.65 3.65/4.1	2.0 2.8 3.2 3.65 4.1 4.5 4.5/4.8	2.0 2.8 3.2 3.65 4.1 4.5 4.5/4.8 5.2 Cortical



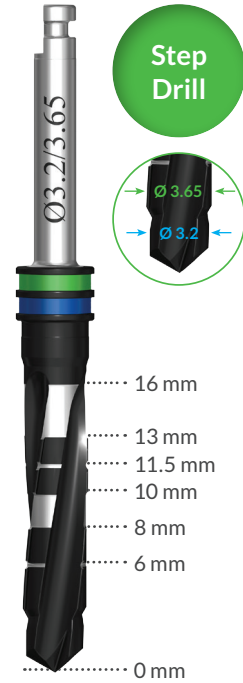
Cortical - Drill through cortical plate
Step drill can be replaced with straight drill by drilling 3mm less



ICE™ Drilling Sequence

Step Drilling Sequence

Ø Implant	Soft bone Type IV	Medium bone Type II&III	Hard bone Type I
Ø 3.7	2.0 2.0/2.4	2.0 2.4/2.8 2.8/3.2	2.0 2.4/2.8 2.8/3.2 3.2/3.65 Cortical
Ø 3.75	2.0 2.4/2.8	2.0 2.4/2.8 2.8/3.2	2.0 2.4/2.8 2.8/3.2 3.2/3.65 Cortical
Ø 4.2	2.0 2.4/2.8 2.8/3.2	2.0 2.4/2.8 3.2/3.65	2.0 2.4/2.8 3.2/3.65 3.65/4.1 Cortical
Ø 4.65	2.0 2.4/2.8 3.2/3.65	2.0 2.4/2.8 3.2/3.65 3.65/4.1	2.0 2.4/2.8 3.2/3.65 3.65/4.1 4.1/4.5 Cortical
Ø 5.3	2.0 2.4/2.8 3.2/3.65 3.65/4.1	2.0 2.4/2.8 3.2/3.65 3.65/4.1 4.5/4.8	2.0 2.4/2.8 3.2/3.65 3.65/4.1 4.5/4.8 4.8/5.2 Cortical



Cortical – Drill through cortical plate

Step drill can be replaced with straight drill by drilling 3mm less

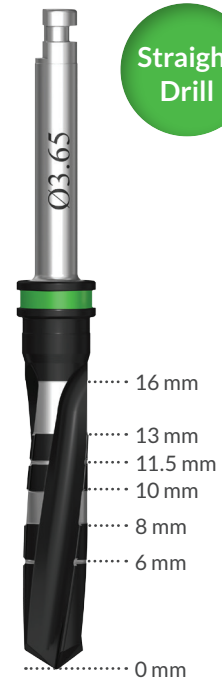


DFI Drilling Sequence

Straight Drilling Sequence

Ø Implant	Soft bone Type IV	Medium bone Type II&III	Hard bone Type I
Ø 3.3	2.0 2.8 Cortical	2.0 2.8	2.0 2.8 3.2 Cortical
Ø 3.75	2.0 2.8 3.2 Cortical	2.0 2.8 3.2	2.0 2.8 3.2 3.65 Cortical
Ø 4.2	2.0 2.8 3.2 3.65 Cortical	2.0 2.8 3.2 3.65	2.0 2.8 3.2 3.65 4.1 Cortical
Ø 5.0	2.0 2.8 3.2 3.65 4.1 4.5 Cortical	2.0 2.8 3.2 3.65 4.1 4.5	2.0 2.8 3.2 3.65 4.1 4.5 4.8 Cortical

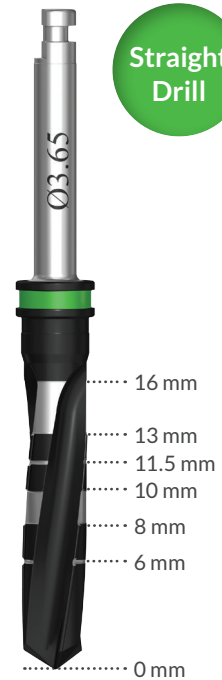
Cortical – Drill through cortical plate



ATID Drilling Sequence

Straight Drilling Sequence

Ø Implant	Soft bone Type IV	Medium bone Type II&III	Hard bone Type I
Ø 3.3	2.0	2.0	2.0
	2.8	2.8	2.8
	3.2 Cortical	3.2	3.2
			3.65 Cortical
Ø 3.75	2.0	2.0	2.0
	2.8	2.8	2.8
	3.2 Cortical	3.2	3.2
			3.65 Cortical
Ø 4.2	2.0	2.0	2.0
	2.8	2.8	2.8
	3.2	3.2	3.2
	3.65 Cortical	3.65	3.65
			4.1 Cortical
Ø 5.0	2.0	2.0	2.0
	2.8	2.8	2.8
	3.2	3.2	3.2
	3.65	3.65	3.65
	4.1	4.1	4.1
	4.5 Cortical	4.5	4.5
		4.8 Cortical	
Ø 6.0	2.0	2.0	2.0
	2.8	2.8	2.8
	3.2	3.2	3.2
	3.65	3.65	3.65
	4.1	4.1	4.1
	4.8	4.8	4.8
	5.2 Cortical	5.2	5.2
			5.8 Cortical



Cortical – Drill through cortical plate.

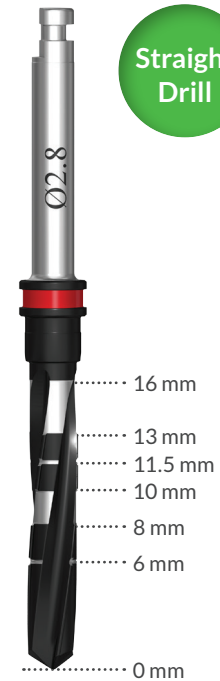


NICE Drilling Sequence

Straight Drilling Sequence

Ø Implant	Soft bone Type IV	Medium bone Type II&III	Hard bone Type I
Ø 3.2	2.0	2.0 2.8 *	2.0 2.8 2.8/3.0

* In cases of thick cortical layer use Ø3.0mm drill only through the cortex
Step drill may be replaced with a straight drill by drilling 3mm less





Alpha-bio Tec Drills

Scientific Overview

Alpha-Bio Tec's products are CE-marked in accordance with the Council Directive 93/42/EEC and Amendment 2007/47/EC. Alpha-Bio Tec complies with ISO 13485:2012 and the Canadian Medical Devices Conformity Assessment System (CMDCAS).

Authorized regulatory representative:

 **MEDES LIMITED**

5 Beaumont Gate, Shenley Hill
Radlett, Herts WD7 7AR, England
T./F. +44.192.3859810

www.alpha-bio.net

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