44

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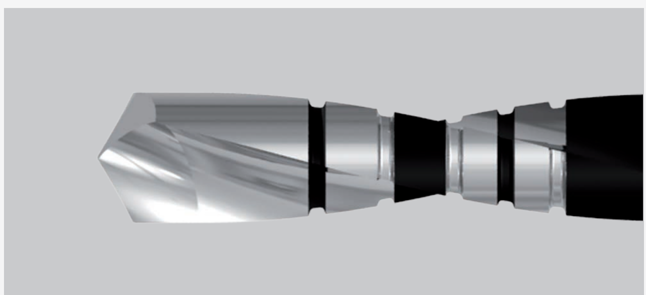
Drill Performance: Erosion and Corrosion Tests Summary



MIS®
MAKE IT SIMPLE

Drill Performance: Erosion and Corrosion Tests Summary

Introduction

MIS® fully stands behind the quality and durability of its drills. In order to demonstrate that, we've done extensive corrosion and erosion testing on drills from various MIS® implant systems including M4, SEVEN®, C1, and V3.

Abstract

A drilling performance evaluation benchmark test was designed in order to validate the durability of these drills. The benchmark test goals were to validate the MIS® recommendation of 30 uses, by means of the maximal measured developed torque in a pre-defined sequence during 60 drills and to compare drilling properties of "straight drill" vs. "step drill", by means of maximal measured developed torque and force in a pre-defined sequence with various diameters.

Materials and Methods

Cutting substance - An artificial substance, representing bone type 2 in its hardness/ toughness properties was used for drilling in order to standardize the examinations. During the test, V–rotation speed and P-feed (progress speed) were set and defined in accordance with MIS® drill site preparation protocols, and M-required torque and F-required force were measured.

Rotational / tangent speed:

Rotation speeds were set according to MIS® site preparation protocols. Due to the fact that while the drill rotates its blades move along the cavity's wall, which may lead to blade erosion and an increase of required torque, the effects of the drill's rotation speed is considered when the tangent speed is calculated and compared. This is done in order to analyze which drill is at a greater risk to develop erosion.

Volume of removed substance:

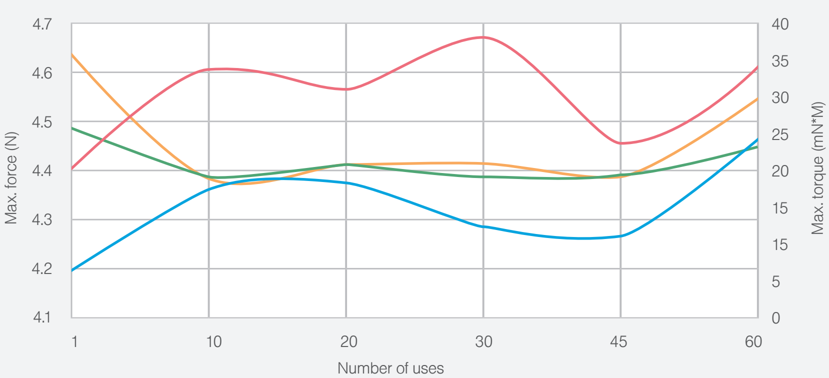
The substance is removed out from the bottom of the cavity. The debris travels along the drill flutes on its way out. While most of the debris finds its way out, some clings onto the drill's blades and gets clamped between the drill blade and the cavity. The combined effect of compressed debris and the extracted debris and therefore flow along the drill flutes, may affect the drill's cutting ability, and therefore theoretically analyzed.

Results

Following are the results of the various testing done.

Figure 1

Demonstrates maximum values of torque and force for step pilot drills and straight pilot drills within tested number of uses.



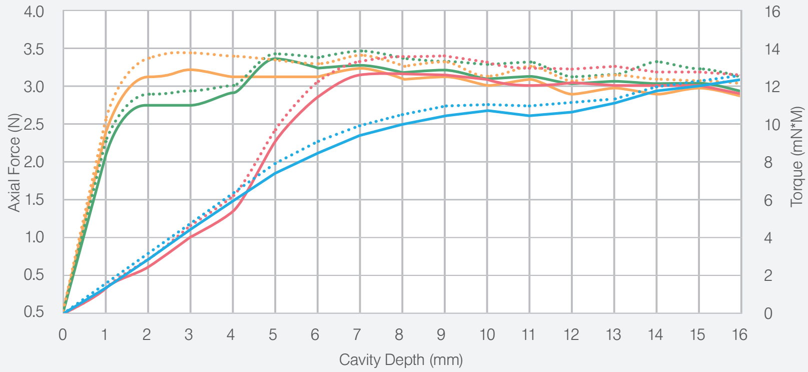
MT-P2416 / CT-P2416	Step Pilot Drill	Straight Pilot Drill
Max. axial force		
Max. torque		

Note

The plot summarizes the maximal values reached in each reference measurement. Using the straight drill resulted in higher values of axial force and torque. The lines are mostly apart due to the scale. When the actual values are taken into consideration we may conclude that both drills perform in a relatively similar manner.

Figure 2

Comparison of drilling behavior parameters during deepening of the cavity, for the 1st and 60th use - step pilot drill versus straight pilot drill



MT-P2416 / CT-P2416		Use #1	Use #60
Axial Force	Step Pilot Drill	—	• • •
	Straight Pilot Drill	—	• • •
Torque	Step Pilot Drill	—	• • •
	Straight Pilot Drill	—	• • •

Note

The compares straight versus step pilot drilling behavior up to 16mm drilling depth in new (1st use) and over-used (60 uses) conditions.

MT-P2416

CT-P2416

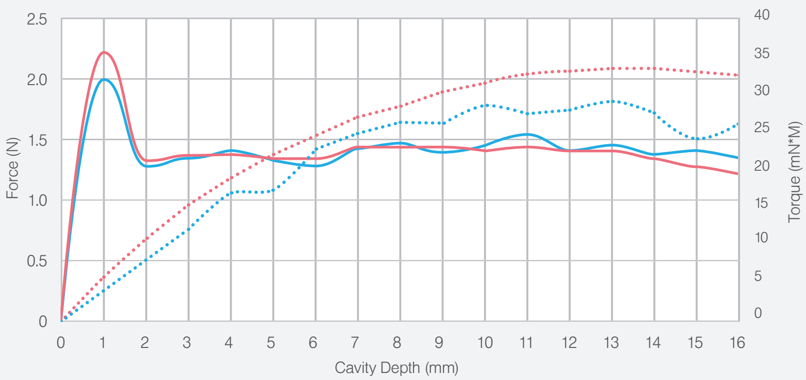
Axial Force

The steep modification of the axial force values after 1mm may be explained by the tip penetration transition effect.

Both drills demonstrate similar axial value behavior at drilling depth over 13 mm. The difference in behavior at lower drilling depths is explained by the difference in drill diameter at the lower portion of the drill.

Figure 3

Comparison of drilling behavior parameters during deepening of the osteotomy, for the use of the widest drill



MT-TDN55	Use #1	Use #60
Force	—	—
Torque	• • •	• • •

Note

The graph compares resulted torque and force behavior at each depth. Graph lines simulate new condition (1st use) and used condition (60 uses). MT-TDN55A is designed as a straight drill with approaching diameter of 5.5mm. The chart presents a predicted behavior of gradual development of the axial force and torque. The steep modification of the axial force values after 1mm may be explained by the tip penetration transition affect.

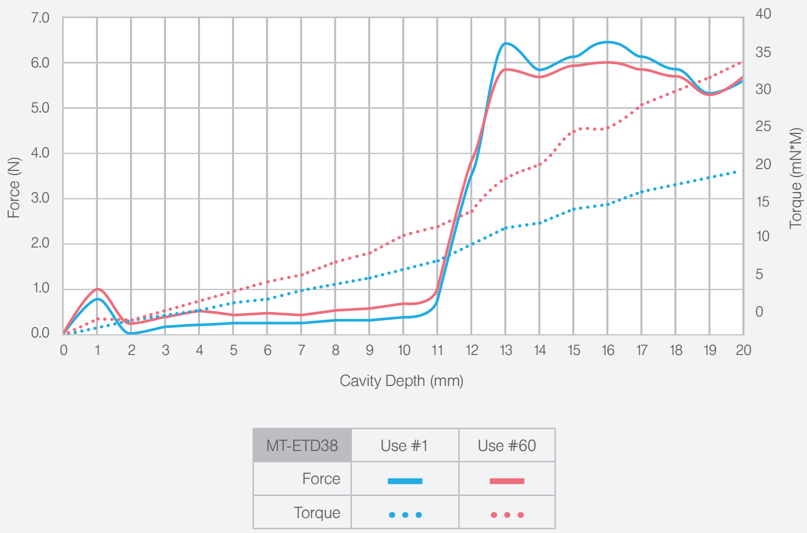
MT-TDN55

Axial Force

The steep modification of the axial force values after 1mm may be explained by the tip penetration transition effect.

Figure 4

Comparison of drilling behavior parameters during deepening of the osteotomy, for the 1st and 60th use of the extra-long straight drill (20mm)



Note

MT-ETD38A is equipped with 2 different drill diameters. Approaching diameter is 3.8mm and the top diameter is 4mm. Diameter modification appears at 11.5mm height. The diameter modification is noticed in the graph above as a sharp modification of the axial force and a transition effect (0.5N to 9N along 2mm). Torque is not significantly affected by the diameter's modification. Torque is mostly affected by the gradually accumulated bone substance (mostly due to the fact that the test is performed in a single drill without partial retreats).

Axial Force

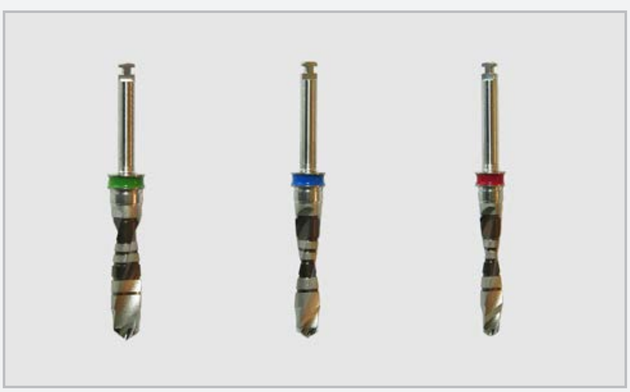
The steep modification of the axial force values after 1 mm may be explained by the tip penetration transition effect.

Corrosion Testing

In order to verify the corrosion resistance of all drill types, test of the influence of repeated autoclave sterilization was conducted. 12 cycles of sterilization cycles were chosen in accordance to ASTM A967 standard, based on the defined number of required repeated water immersion tests. The drills were visually scanned prior to and after 5 and 12 autoclave sterilization cycles. Sterilization was done using a standard Autoclave cycle at 136°. The test was conducted on 2 samples of each drill. No effect was observed on the drills after completing all cycles of sterilization. There are no signs of corrosion of the drills.

Picture 1

Picture 2



Picture 3

Conclusions

In terms of erosion, all drills reached the pre-defined success criteria, operating at very low force and torque values. No significant change in performance or maximum force and torque measurements, from the first to last use, was noticed. MIS® recommends replacing drills after 30 uses, considering a safety factor of up to 60 uses taken during the laboratory test.

Corrosion test demonstrate that repeated autoclave sterilization cycles proved to have no effect on the drills. However cleaning and maintenance of the drills is crucially important for their long-term durability performance. After conducting the various tests, it may be concluded that when prolonged use is in question, the drills perform well in terms of durability and remain resistant to corrosion and erosion.

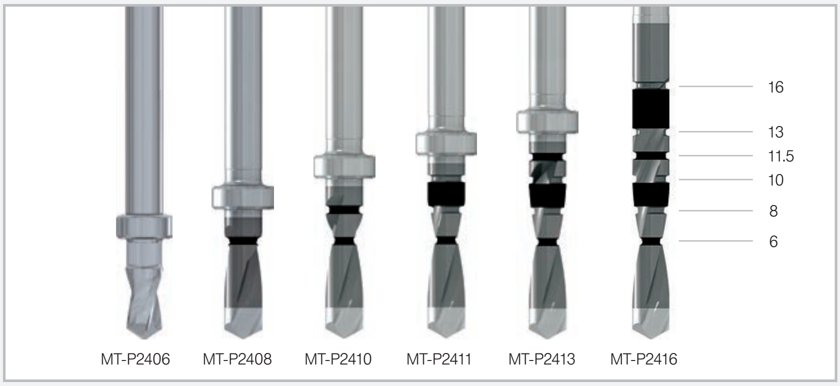
Cleaning and Maintenance Instructions – Key Points

- The drills should be soaked immediately after use in a disinfecting solution.
- Soft nylon-fiber brush should be used to clean under running water.
- In order to ensure continuous cutting ability, contact with other instruments should be avoided during cleaning. Therefore a kit or supporting rack should be used.
- An ultrasonic cleaning system should be used. The drills should be completely immersed in the cleaning solution.
- In order to prevent corrosion, the drills should be dried thoroughly after rinsing.
- Pack in a sterilization pouch and steam sterilize according to the instructions in the user manual.

SEVEN® / M4

- Straight pilot drills
- Glare reduction effect
- Built in stoppers
- 900-1200 RPM

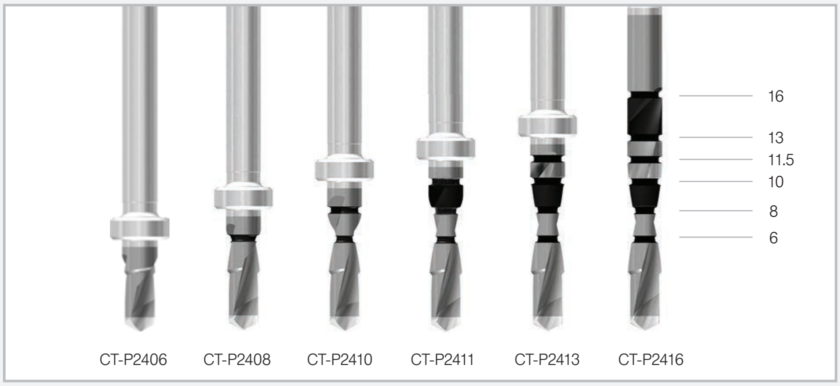
Picture 4



C1 / V3

- Step pilot drills
- Glare reduction effect
- Built in stoppers
- 900-1200 RPM

Picture 5



C1 / V3

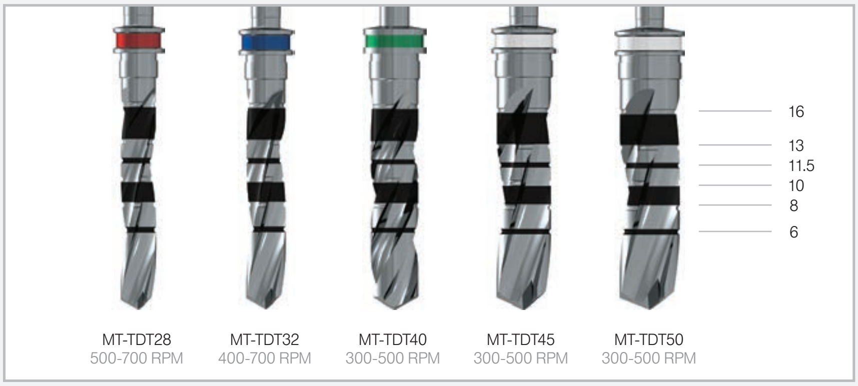
- Step drills
- Glare reduction effect
- Color coded
- Fit with drill stoppers

Picture 6

SEVEN®

- Straight drills
- Color coded
- Fit with drill stoppers

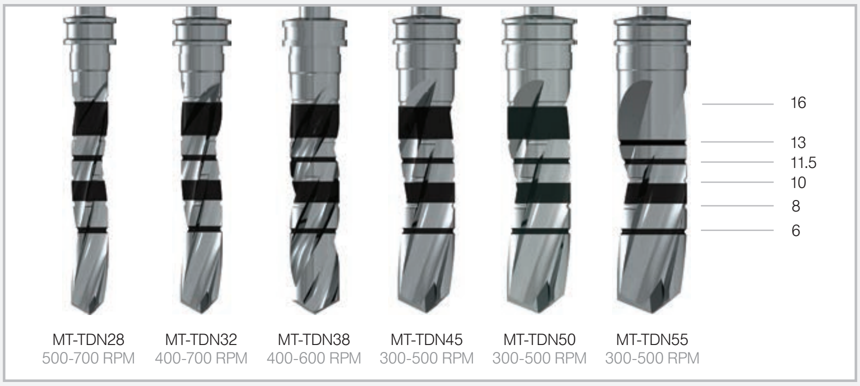
Picture 7



M4

- Straight drills
- Fit with drill stoppers

Picture 8



SEVEN® / M4 for MULTIFIX

- Straight drills
- Extra long

Picture 9

The MIS Quality System complies with International Quality Standards: ISO 13485:2003 - Quality Management System for Medical Devices, ISO 9001: 2008 - Quality Management System and Medical Device Directive 93/42/EEC. Please note that not all products are registered or available in every country or region.

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