

# Safety and Effectiveness of PALTOP Drills

Dr. Michael Klein, DDS | Dr. Gil Asafrana, DMD | Mr. Moti Miles B.Sc

## Objective

The purpose of this study was to examine the safety and effectiveness of the design and production of PALTOP drills, based on evaluation of heat production during osteotomy preparation. PALTOP Drilling temperatures were compared to leading implant manufacturer. 3 leading implant companies were selected to be evaluated: Leading Manufacturer "N" | Leading Manufacturer "S" | Leading Manufacturer "I"

## Introduction

Heat production is an objective measurable parameter for bone safety and effectiveness. PALTOP drills were evaluated using a whole sequence of PALTOP burs including the 2 bur/drill types of twist/step drills and spade drill designs, in all diameters produced.

Significance of heat production during osteotomy preparation: temperature of 47 degrees celsius for 1 minute is associated with irreversible cell damage  
5.1, 5.2, 5.3, 5.4, 5.5

## Materials and Methods

Four implant systems were evaluated: PALTOP Advanced; Leading Manufacturer "N"; Leading Manufacturer "S"; and Leading Manufacturer "I".

The drill diameters were as following: PALTOP Advanced spadedrill/starter, 1.5/2, 2.0/2.4, 2.4/3.2, 3.2/3.8, 3.25 final, 3.75 final, 4.2 final, 5.0 final, Leading Manufacturer "N" 4.3mm spade drill, Leading Manufacturer "S" 3.5mm twist drill, Leading Manufacturer "I" tapered implant 4.0mm spade drill.

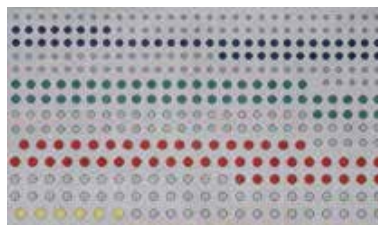
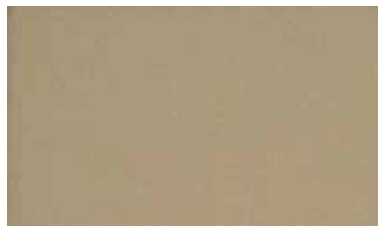
The drilling was done in simulated bone designated as type D1-D2 bone from Sawbone Sweden(#1522-04 30 pcf). The temperature was measured using a Newtron TM-5005 digital thermometer K-type probe.

The drill temperature was measured prior to each osteotomy and the drilling was not begun until the temperature was below 24 degrees centigrade.

50 osteotomies were performed with each final diameter bur with drilling speed of 1500 rpm.

Drill temperatures were measured after completing drilling a 10mm osteotomy. The temperature was measured at the cutting tip of the drill using a thermocouple, Immediately after drill removal.

Figure 5.1: Experiment settings



Simulated Bone Designated As Type D1-D2 With Template



PALTOP Drills



Drilling Testing



## Statistical Analysis

A Wilcoxon Rank Sum Test Was Performed.

Drill Types: when comparing the temperatures of spade and twist drills there is no significant difference: p-value = 0.09708 (although twist drills have a slightly lower temperature).

Correlation Between Drill Diameters and Temperature: Spearman's correlation coefficient test was used. Twist drills - larger diameter drills are associated with higher temperatures. Spade drills - larger diameter drills are associated with lower temperatures

## Results

As can be seen on the figure below, drilling temperature for all PALTOP drills is way under the temperature of 47 degrees Celsius, which is associate with cell damage. PALTOP drilling temperature is similar to those of other leading clinically reliable products.

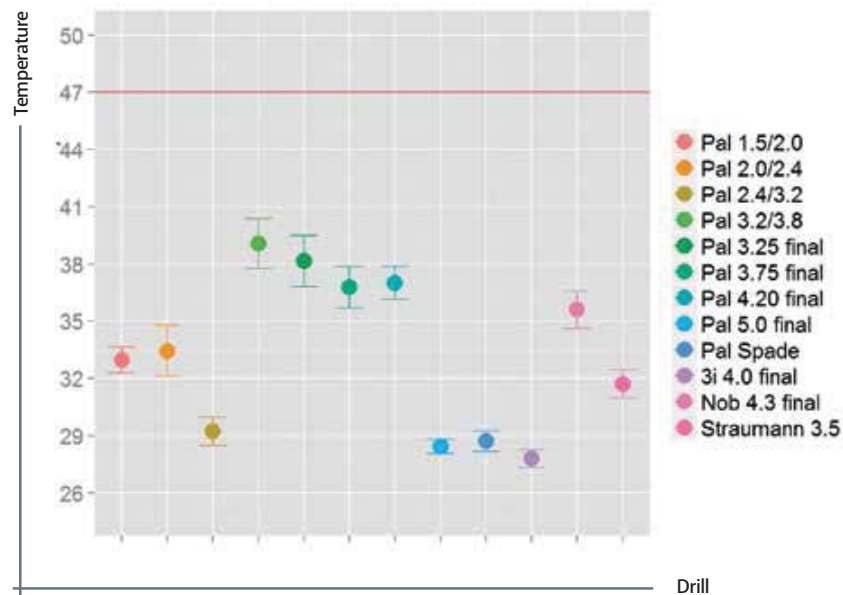


Figure 5.2: Drill Temperatures for PALTOP drills and leading competitors

## Conclusion

All Values Fall Within Clinically Acceptable Range. PALTOP drills are effective and safe for use.