

5 Years of Clinical Experience

1000 PALTOP Implants, Up to 5 years outcome



Post-Marketing clinical follow up

Michael Klein, DMD, NY USA | Gil Asafrana, DMD, Tel Aviv, Israel | Henriette Lerner, DMD, Baden Baden Germany
Ronen Bordovski, DMD, Tel Aviv, Israel | Tal Hammer-Topaz, MSc, MBA, | 2017

Purpose:

The purpose of this study was to assess PALTOP Dental Implant outcomes up to 5 years postimplant placement. 2 parameters were evaluated: implant survival rate and bone loss.

The clinical follow up included over 1000 dental implants in a multi-center study.

Study Population:

The study population includes 1007 implants placed in 453 adult patients who are missing at least one posterior tooth in either the mandible or maxilla. The study included 247 females, 206 males; average age 56, sd 14, range 17-92.

The study includes all implants inserted in the chosen dental clinics, including diabetics, smokers and treatment with chronic medication.

Materials:

PALTOP Advanced tapered implants made of Ti6Al4V ELI surface treated with sand blasting and acid etching were used in this study. Implant diameters varied between 3.25-5mm in diameter and the lengths varied between of 6-16mm.

Results:

Figure 6.1: Survival rate in Maxilla vs. Mandible

	Survival	Failure
Maxilla	490 (97.8%)	11
Mandible	511 (97.7%)	12
Sum	1001 (97.8%)	23

Fisher exact test, P=1

Figure 6.2: Survival rate in varying Bone Density

	Survival	Failure
D1	56 (93.3%)	4
D2	486 (98.6%)	7
D3	440 (97.3%)	12
D4	19 (100%)	0
Sum	1001 (97.8%)	23

Chi-square test, P=0.054

Figure 6.3: Survival rate for implant placed into healed bone

	Survival	Failure
One stage	328 (98.5%)	5
Two stage	394 (98.3%)	7
Sum	722 (98.4%)	12

Fisher exact test, P=1

This information was not available for all implants placed

Figure 6.4: Survival rate for implant placement into immediate extraction sites

	Survival	Failure
One stage	220(95.2%)	11
Two stage	44 (100%)	0
Sum	261(96%)	11

Fisher exact test, P=0.38

This information was not available for all implants placed

Figure 6.5: Survival rate for implants placed into healed bone with/without immediate loading

	Survival	Failure
placement into healed bone with immediate loading	81 (98.8%)	1
placement into healed bone without immediate loading	641 (98.3%)	11
Sum	722 (98.4%)	12

Fisher exact test, P=1

This information was not available for all implants placed

Figure 6.6: Survival rate for implants placed into immediate extraction sockets with/without immediate loading

	Survival	Failure
Immediate placement with immediate loading	86 (92.5%)	7
Immediate placement without immediate loading	174 (97.8%)	4
Sum	261(96%)	11

Fisher exact test, P=0.05

This information was not available for all implants placed

Figure 6.7: Survival rate with/without bone graft augmentation procedure

	Survival	Failure
Augmentation	338 (96.3%)	13
No Augmentation	663 (98.5%)	10
Sum	1001 (97.8%)	23

Fisher exact test, P=0.27

The results show overall success rate of 97.8% with 23 failed implants out of 1001 implants placed. Out of the 23 implant failures 11 were in the Maxilla and 12 in the Mandible. In regards to bone density, 4 implant failed in D1 bone, 7 in D2, 12 in D3 and none failed in D4. 96.3% survival rate (13 failed implants) was reported in implantation along with augmentation procedures, while 98.5% (10 failures) were reported for no augmentation.

When examining implants that were placement in healed bone, the results show overall 98.4% success rate, versus 96% survival rate When placing the implants into immediate extraction sites. This data was available for only 983 out of 1001 I implants.

When looking into healed bone, 98.5% survival rate (5 failed implant) was attained in one stage procedure and 98.3% (7 failed implants) was attained in two stage procedure. 98.8% (1 failed implants) success was achieved in immediate loading in healed bone, and 98.3% survival rate (11 failed implants) without immediate loading in healed bone.

When looking into immediate extraction sites the results show 95.2% survival rate (11 failed implant) in one stage procedure and 100% (none failed) in two stage procedure. 92.5% (7 failed implants) success was achieved in immediate loading in extraction site, and 97.8% survival rate (4 failed implants) was achieved without immediate loading in extraction site.

Bone loss was measured in 99 patients. 31 showed some bone loss. 21 showed up to 1 mm bone loss, 8 showed up to 1 - 2 mm of bone loss and 2 showed 2-3mm bone loss. Bone loss was less prevalent in the maxilla.

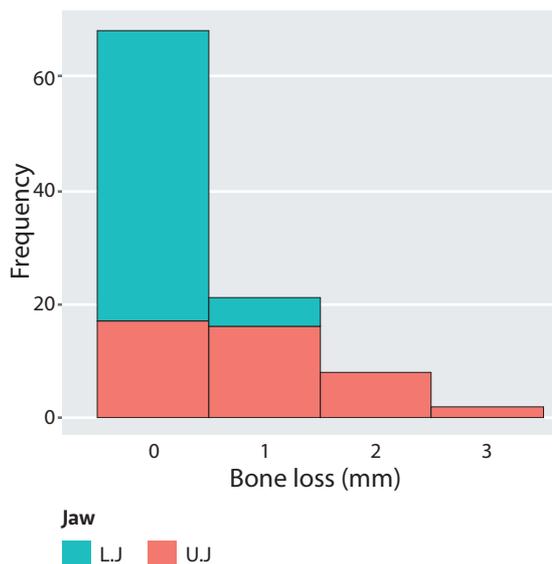


Figure 6.8: Bone loss Vs. Jaw

A Mann-Whitney U test concluded that bone loss is less frequent at the maxilla (p-value= 2.5 10⁻⁸).

Conclusion:

The results of this study show **97.8% survival rate in 1001 implants followed up to 5 years.**

PALTOP implants show excellent results for up to 5 years of follow-up, comparable with proposed standards in the literature ^{6.1, 6.2, 6.3, 6.4}.