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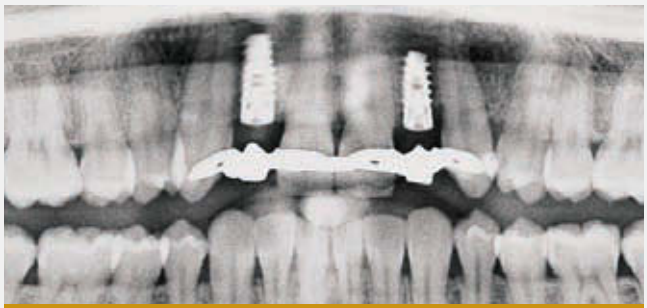
Clinical and Radiographic Evaluation of 7,340 Seven® Implants. Osseointegration Rate and Bone Level Stability: 5 Years Prospective Study.



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Clinical and Radiographic Evaluation of 7,340 Seven® Implants. Osseointegration Rate and Bone Level Stability: 5 Years Prospective Study.

[1] Zabaras D, Bouboulis S, Spanos A, Petsinis V, Gisakis I

Introduction

Millions of dental implants are placed every year worldwide. They have become the most successful prosthetic device and are improving the lives of people every day. Implants are offering a variety of clinical solutions such as reconstruction of a single tooth, fixed bridges and overdentures. The MIS self-tapping Seven® implants (Medical Implant System, Bar Lev, Israel) are especially designed for implantation in a wide range of bone types and bone augmentation procedures. Their innovative geometric design includes dual threads, three spiral channels stemming from the apex, micro rings on the implants' neck, and a changing threads thickness along the implant. All implants are supplied with a single use final drill for reducing the heat produced during drilling, resulting in an improved osseointegration.

Aim

The aim of this paper is to present the results after 1 to 5 years observation of an ongoing clinical and radiographic study regarding: ▪ osseointegration rate ▪ peri-implant bone level changes ▪ survival rate after loading of Seven® implants, used to support fixed prostheses.

Material – Method

The material came from the Dept. of Dental Implants of Hygeia Hospital (Athens, Greece), where this study was conducted. 1945 patients (894 male, 1051 female) participated in the study. In total, 7340 implants were placed. The evaluation period was 12-60 months. All patients underwent detailed clinical and radiographic examination 6 months, or earlier in cases of bruxism, heavy smoking and diagnosed periimplantitis.

Statistical analysis

The analysis was performed using the program IBM SPSS Statistics v.19 (IBM corp, NY, USA). Descriptive statistics were used for patient demographics and analysis of biological complications and failures. The implant survival was calculated using life table analysis (Cutler & Ederer 1958). The threshold value for significance was set at $p \leq 0.05$.

Results

In general, osseointegration was achieved for 7319 implants (99.71%), while only 21 implants failed to osseointegrate (0.29%) ($p<0.001$). Out of them, 13 implants were placed in augmented bone and 8 implants in host bone ($p>0.05$). Marginal bone loss around implants ranged from 0.5mm (±0.05) in cases of host bone, to 1mm (±0.5) in cases of augmented bone ($p>0.05$). Peri-implantitis was revealed in 93 implants (1.27%), mostly after the 24th month. 18 implants (0.25%) were lost after loading during the observation period.

Conclusions

- Seven implant system is reliable and easy to use in all cases of implant placement, both in host and augmented bone
- The results of the study showed exceptional osseointegration rate of 99.71%
- The application of bone regeneration methods does not interfere with osseointegration
- Marginal bone loss around implants was minimal
- Implant survival rate after loading was 99.75%.

[1] Dept Dental Implants & Tissue Regeneration, Hygeia Hospital, Athens, Greece

Table 1: Peri-implant bone measurements

Bone Loss / time	12 months	24 months	36 months	48 months	60 months
0-0.1 mm	2210	2045	1682	903	247
0.11-0.5 mm	41	48	35	24	19
>0.5 mm	21	19	11	9	5
Total observed	2272	2112	1728	936	271

Table 2: Cumulative implants success & survival rates

Year	No. of implants placed	Non-osseointegrated implants	Implant success(%)	No. of implants followed	Peri-implantitis	Implant loss	Implant survival(%)
2006	274	3	98.9	271	0	0	100
2007	943	7	99.3	1207	3	0	100
2008	1733	5	99.7	2935	14	1	99.9
2009	2114	2	99.9	5046	33	6	99.8
2010	2276	4	99.8	7312	43	11	99.7
Total	7340	21	99.7	7312	93	18	99.7

Case 1


Fig. 1


Fig. 2

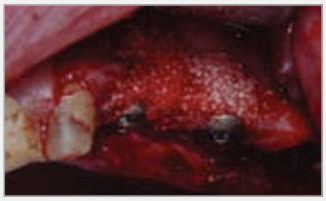


Fig. 3

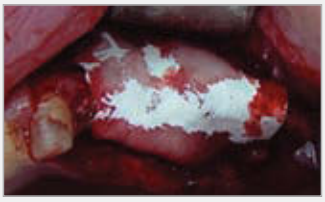


Fig. 4

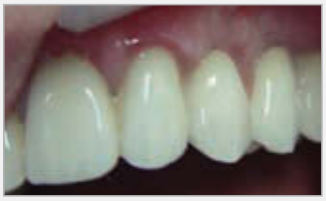
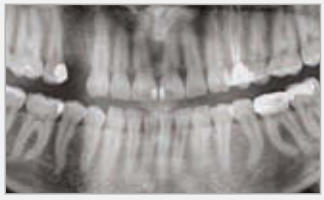


Fig. 5

Case 2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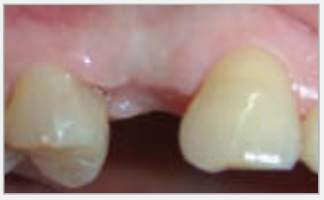
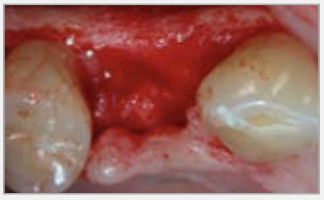


Fig. 2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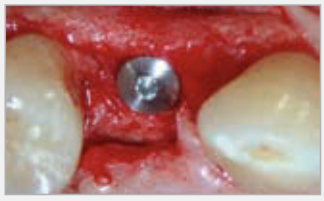
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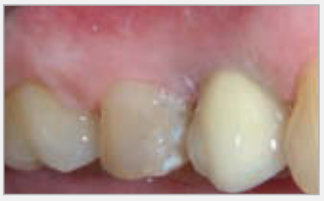
Fig. 5

MIS's Quality System complies with international quality control standards: ISO 13485:2003 - Quality Management System for Medical Devices, ISO 9001: 2008 – Quality Management System and CE Directive for Medical Devices 93/42/EEC. MIS's products are cleared for marketing in the USA and CE approved.

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MIS Implants Technologies Ltd.
www.mis-implants.com