

Initial test results in bone absorption,  
primary stability and torque removal  
value in the SEVEN implant.

Eng. Daniel Baruc, R&D Manager



MIS presenting the initial test results for the SEVEN, the company's new implant based on its proprietary technology. This implant is the result of extensive follow-up, backed by comprehensive studies and tests that were conducted in Israel and in a number of other countries around the world (Italy, Spain, Korea, USA).

The uniqueness of the SEVEN is in the geometrical design and morphology of its surface: Use of dual threads of 2.4 mm, 3 spiral channels that extend along the length of the implant, and micro-rings that are located in the implant's neck.

The combination of these distinctive characteristics gives the SEVEN implant a number of advantages: simple, convenient and successful use, quick and easy insertion, high primary stability and increased prevention of bone absorption at the implant's neck.

In addition, incorporation of the most advanced surfaces available on the market today enables accommodation and recuperation in even the most complex cases and in every area of the jaw. SEVEN implants meet recognized international standards: ISO 9001:2000, ISO 13485:2003, FDA - Clear for marketing, CE.

Upon completion of the development of the SEVEN, MIS initiated a series of comprehensive tests in order to determine the success of the combination of its unique characteristics.

Main Tests Performed on SEVEN Implants:

### International Multi Center Study

covering about 1500 SEVEN implants in 5 countries: Italy, Spain, Korea, USA and Israel. Thirty dental surgeons are participating in this follow-up, which will last about a year. The follow-up data includes reports on surgical implantations, implant exposure, and patient follow-up

during the recuperation period. All interim results were collected by MIS and compiled by Eng. Daniel Baruc, R&D manager. As of July 2005, data was collected from about 1000 implants, clearly showing that these implants are characterized by primary stability and successful absorption in every type of bone. The data received so far corresponds with or exceeds the data appearing in the professional literature that defines between 94%-97% success in dental implants, depending on the jaw.

Number of Implant Reports	960
Number of Exposure Reports	483
Number of Reported Failures	14 (2.89%)
<b>Percentage of Successes</b>	<b>97.11%</b>

### Primary Stability Test

In the framework of the International Multi Center Study (IMCS), results of the primary stability of the SEVEN implant according to Torque test, are as follows:

#### Insertion Torque Data

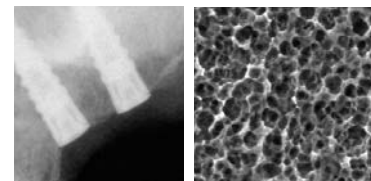
Bone Type	Torque Ncm	Primary Stability
1	40-45	4
2	40-45	4
3	40	4
4	45	3

Primary Stability Key:

- 1 - Poor
- 2 - Moderate
- 3 - Good
- 4 - Excellent

There are strong indications for very good primary stability for various bone types.

The excellent results shown in the above table are consistent with the data that appears in the professional literature regarding the optimal conditions for inserting the implant. The force of the insertion was between 40 N/cm to 45 N/cm for bone types 1-4, with high primary stability.



excellent stability

new surface morphology

### Torque Removal Value

In the framework of the In VIVO research, Torque tests (RTV) were conducted to measure the force required to remove the SEVEN implant. The values for the period between 8-16 weeks from implantation range from 70 N/cm to over 150 N/cm (instrument torque limit). The increase in the values measured over time that were observed in the study is characteristic of good osseointegration.

In order to assure comprehensive analysis, MIS conducted several additional tests. The main ones were: surface roughness (Ra=2µm), surface morphology (SEM), analysis of the surface (XPS), biological test - growth of proteins on the surface characterizing the SEVEN implant, and In VITRO/In VIVO tests.

MIS conducted and continues to conduct comprehensive tests on all aspects that affect the absorption of the implant. In all the tests that were conducted up to now, SEVEN implants have shown a very high success rate, due to the combination of the advanced geometric design and surface morphology.

\* The results of these tests have appeared in the company's marketing materials.