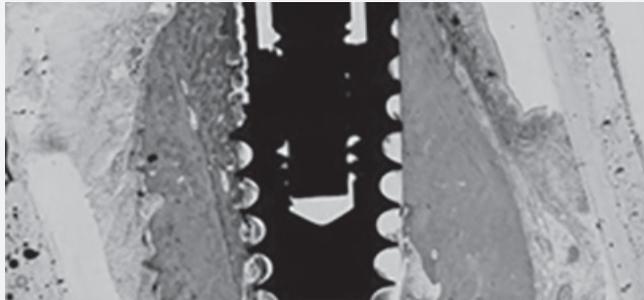


# 41

News No. 41 October 2015

V3 Implant System.  
Research Overview



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# V3 Implant System

Research Overview. June 2015\*

## Introduction:

The V3 implant system was developed with biology in mind, aiming to harmonize with natural biological processes taking place throughout all phases of implant therapy. In order to evaluate and provide scientific evidence for the clinical performance of the V3 implant, several studies are being performed in collaboration with researchers from universities and medical centers worldwide.

The hypothesis of these ongoing studies is that the unique design of the V3 implant will achieve the following:

- Improve hard and soft tissue healing dynamics
- Enhance peri-implant bone quantity
- Preserve crestal bone levels

All of the above factors leading to:

- Better implant survival
- Higher success rates
- Improved aesthetics

This research overview includes preliminary results of two non-clinical and one clinical studies. Additional studies are in early stages of execution and results will be presented at a later stage.

\* Preliminary results were presented in the V3 Implant System Launch event, June 2015.

# Biomechanical Evaluation of Dental Implants with Different Macromorphologies: Removal Torque and Resonance Frequency Analysis in Rabbits. Pre-Clinical Study

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## Objective

To evaluate the dynamics of implant stability during the early recovery phase, comparing implants with different macro-morphologies; and to compare healing dynamics of both cortical and cancellous bones.

## Experimental design

MIS implants with three different macro-morphologies: SEVEN® 3.75/8 mm, C1 3.75/8 mm and V3 3.9/8 mm, were inserted into a proximal part of tibiae and femur of 16 rabbits. Each rabbit had a total of six implants inserted in tibia and femur. Rabbits were sacrificed two and four weeks after surgery and specimens were divided into two groups.

For the immediate healing phase, Implant stability was measured at two weeks by Resonance Frequency Analysis (Osstell) and by removal torque values (Ceder Digital Torque). Same measurements were taken at four weeks for the early healing phase.

## Results

At day 0, comparison between the three implant types showed significant differences in stability values both in Tibia and Femur. The V3 implant showed the highest stability values. At 2 & 4 weeks no statistically significant differences were found. All implants showed an increase in stability values over time. (Fig 2)

Removal Torque measurements in Tibia at 2 & 4 weeks showed higher values in V3 implants compared to the other tested implants. Similar results are demonstrated in the Femur but with no statistical differences. All implants demonstrated increase in removal torque value over time. (Fig 3)

## Conclusions

All implants showed an increase in stability over time, during early recovery phase. The unique design of the coronal part of the V3 implant does not reduce the stability, compared with regular round implants, and even performs better.

Fig. 1 Experimental design  
Model: Rabbit femur & tibia

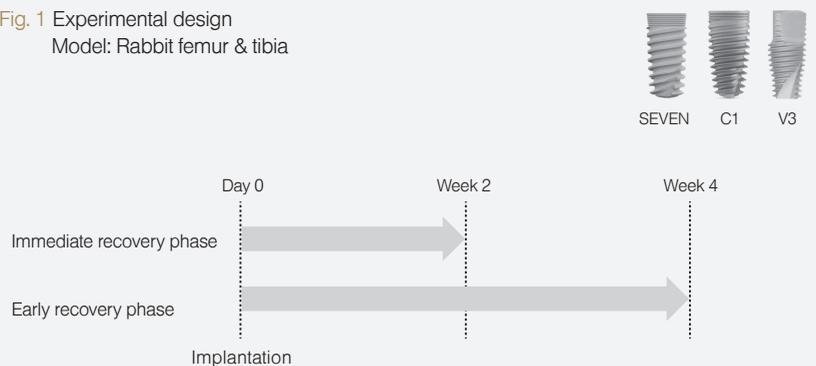


Fig. 2 Implant Stability

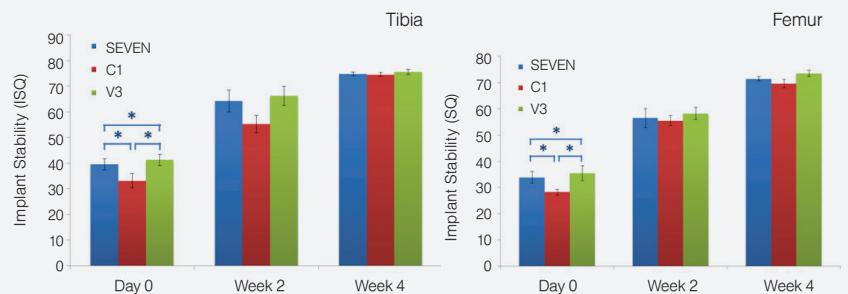
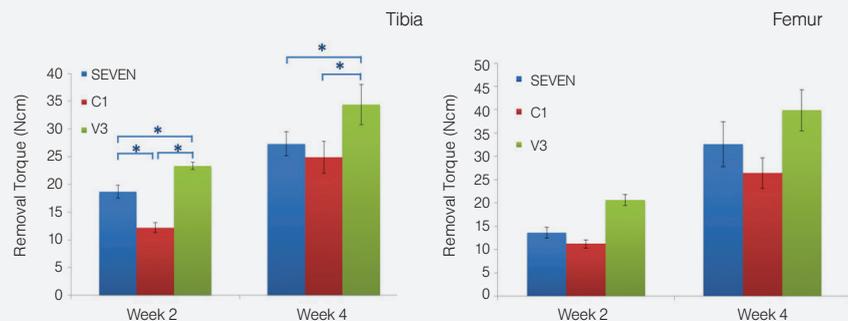


Fig. 3 Removal Torque



# Hard and Soft Tissue Integration of Immediate and Delayed Implants with a Novel Implant Design. An Experimental Research in Beagle Dogs. Pre-Clinical Study

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## Objective

To investigate the influence on both the early and late healing events of hard and soft tissues, comparing:

- V-shape vs. round cervical implant designs
- Delayed vs. immediate placement

## Experimental design

Eight beagle dogs were included in this study. The experimental design provides 4 healed sites and 4 single immediate implant sites per dog, divided into two healing periods: 4 weeks & 12 weeks. Histological Evaluation of de novo bone formation, Alveolar ridge alterations and Morphogenesis of the peri-implant mucosa was preformed at each time point.

## Conclusions

Preliminary results show that the mini-gap in the crestal level is filled with new bone during the healing process.

Further parameters are still in evaluation process and will be presented in due time.

Fig. 1 Experimental design  
Model: Canine Mandible

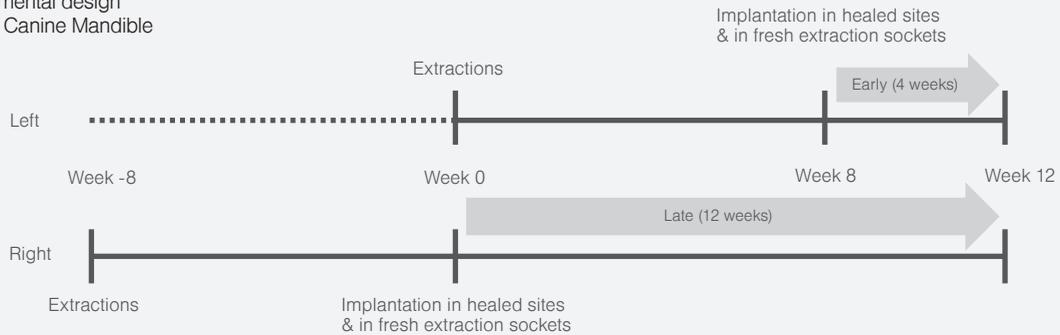
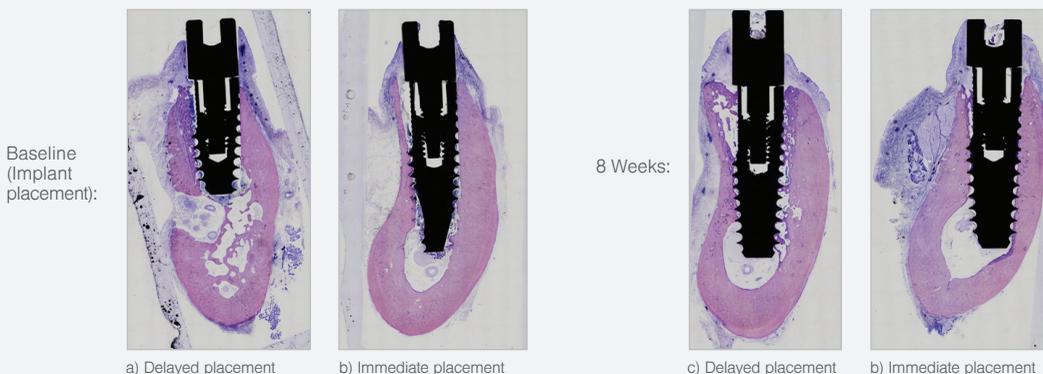


Fig. 2 Histological sections:

V-shape implant design at baseline (a, b) and 8 weeks post implant placement (c, d). At 8 weeks the V3 implant placed in healed ridges demonstrates thick buccal bone on the most coronal aspect. The V3 implant placed immediately in extraction sockets is still healing at 8 weeks.



# Peri-Implant Bone Remodeling in V-shaped Cervical Implant Design. Clinical Study

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## Objective

To monitor the peri-implant bone remodeling post implantation and to examine implant stability at day of implantation, 4 and 12 months later.

## Experimental design

20 patients are included in this study. The implants were covered with healing abutments for trans-gingival healing for a period of 4 months. Immediately after the surgery the patient will perform a CBCT of the treated area. A standard parallel periapical x-ray will be taken, in order to index the level of the implant in the appico-coronal direction.

The following measurements are being performed:

- Width of the buccal bone, measured using cone beam computerized tomography (CBCT) on the day of implantation and 4 months later.
- Crestal bone level in periapical x-rays at day of implantation, 4 and 12 months later.
- Resonance Frequency Analysis (RFA) and implant stability (ISQ) values, measured at baseline and 4 months. ISQ values are measured in two directions: proximal to distal and lateral to medial, and an average of each sample is determined.

## Results

All patients presented appropriate healing during the first week following the surgical procedure and no adverse events. Post-surgical inspections after ten weeks indicate the absence of infection or inflammation. All implants were osseointegrated.

Fig. 1 Experimental design

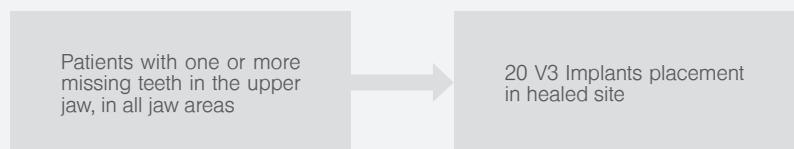
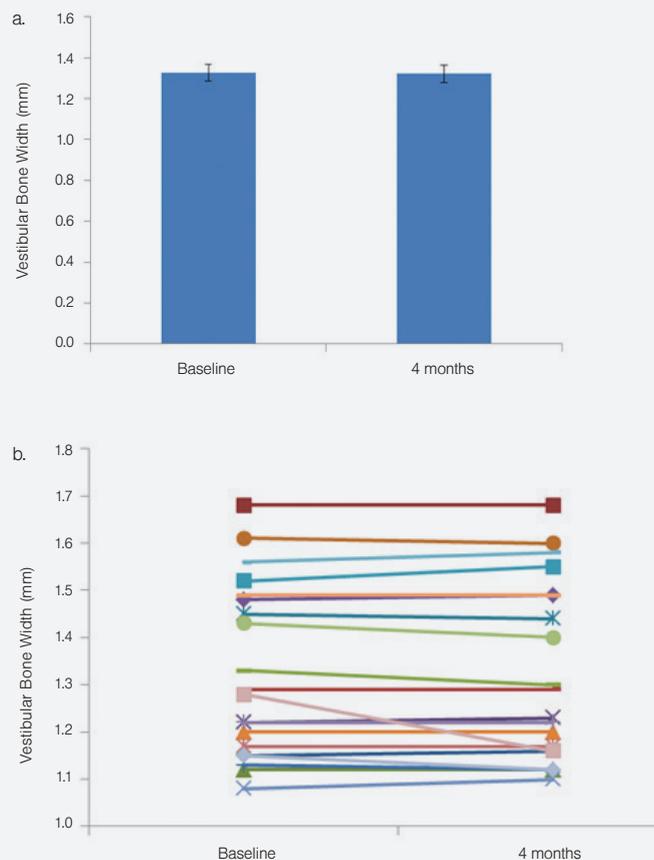


Fig. 2 Peri-implant Bone Remodeling

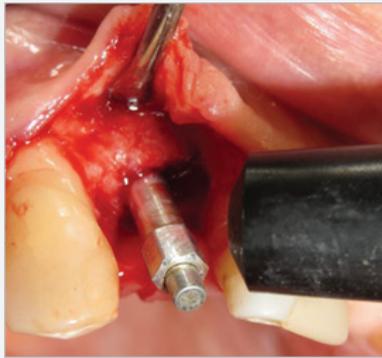


The linear vestibular bone width was measured by CBCT from the more cervical portion of the implant to the vestibular bone cortex (a) mean values  $\pm$  SE. (b) Individual values. No statistical difference were found comparing the two time points.

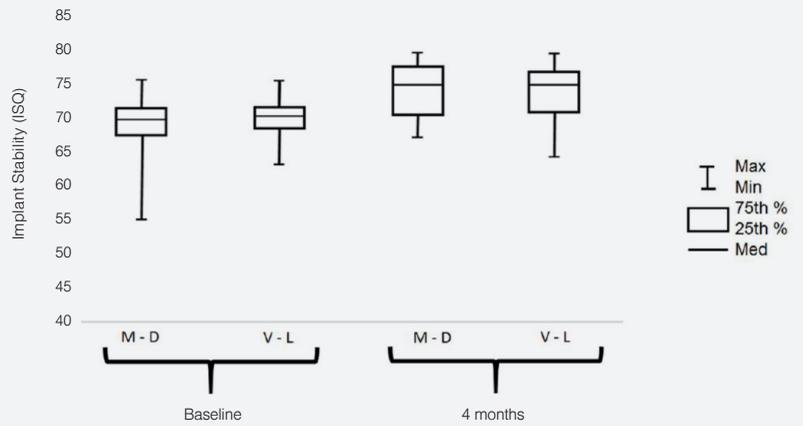
### Conclusions

Comparison of the values measured in the CBCT in the vestibular portion of the crestal area showed no statistical difference between baseline and 4 months after implant placement. The V3 implants, all placed in the maxilla, showed consistent high stability values at baseline and at 4 months post-surgery.

Fig. 3 Implant Stability



a) resonance frequency measured with Osteo.



b) Box plot of measured ISQ values in two directions mesial to distal (M-D) and vestibular to lingual (V-L) at baseline and 4 months after implant placement.

# Summary

To conclude, the preliminary evidence from the pre-clinical and clinical studies presented in this research overview suggests that the stability of V3 is at least as good as the stability of round cervical implants. It was shown that the mini-gap in the crestal level of the V3 is filled with new bone during the healing process and that the width of the buccal wall is preserved over time.

Final results of the presented studies will be published at a later stage. Furthermore, additional studies are in progress and preliminary results will be presented in due time.

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 CE Directive for Medical Devices 93/42/EEC. MIS products are cleared for marketing in the USA and CE approved.

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