Stable bone levels and healthy papilla.

Evaluation of NobelActive™ in extraction sites with immediate temporization: a multicenter clinical trial

Key findings
– Minimal marginal bone remodeling in the first year followed by increasing bone levels.
– Significant increase in papilla size.
– Patient assessment of function, esthetics, and self-esteem showed significant improvement.
– Cumulative survival rate (CSR) after two years: 98.3%

Clinical relevance
– NobelActive is a successful implant even under demanding conditions such as immediate post-extraction tooth replacements.
– Immediate function protocol is an appropriate treatment if the implant tightening torque is at least 35 Ncm.
– Increase in papilla size indicates healthy and esthetic soft tissue.
– The combination of implant design, platform shifting and the surface TiUnite are possible contributors to the favorable bone and soft tissue levels presented in this study.

Clinical evidence
Data from 6 centers, 55 patients and 60 implants.

Minimal marginal bone remodeling followed by increasing bone levels
Graph shows the entire bone remodeling from the day of implant placement to the two-year follow-up.

Increase in papilla size
Papilla scores increased significantly between implant insertion and two-year follow-up, with most of the increase occurring during the first year.

Jemt's Papilla Index*

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
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<tbody>
<tr>
<td>0</td>
<td>No papilla</td>
</tr>
<tr>
<td>1</td>
<td>Less than half of the papilla height</td>
</tr>
<tr>
<td>2</td>
<td>Half or more of the papilla height</td>
</tr>
<tr>
<td>3</td>
<td>Optimal soft tissue contour with papilla filling up the entire proximal space</td>
</tr>
<tr>
<td>4</td>
<td>Hyperplastic papilla covering too much of the restoration and/or adjacent tooth</td>
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</table>

Abstract.

Study title
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Purpose
The purpose of this clinical trial is to evaluate the survival rate, bone remodeling, and soft tissue health surrounding a variable-thread tapered implant (NobelActive) immediately placed in extraction sites.

Materials and methods
60 implants were placed in 55 patients at six centers according to a pre-determined protocol. All implants were placed in extraction sockets and were subjected to immediate temporization and function. Definitive prostheses (58 single crowns and one two-unit fixed bridge) were placed within the first year. Clinical and radiographic examinations were performed at implant placement and after three, six, twelve, and twenty-four months. Measurements of implant stability, papilla index, plaque, perimplant mucosa, and marginal bone levels were recorded at the respective visits.

Results
The cumulative survival rate was 98.3% at the two-year follow-up. One implant failed prior to the three-month follow-up visit. The mean marginal bone remodeling from implant insertion to the one-year follow-up was $-0.22 \text{ mm}$ (SD 1.30 mm, n = 41), followed by an average bone gain of $+0.12 \text{ mm}$ (SD 0.77 mm, n=33) between 12 months and 24 months. Mean marginal bone remodeling was $-0.10 \text{ mm}$ (SD 1.38 mm, n=35) from implant insertion to the two-year follow-up.

Papilla size, as measured by Jemt’s Papilla Index, increased significantly ($p < 0.001$) over the two years. Patient assessments of function, esthetics, and self-esteem, measured on a VAS scale of 1 to 100, also showed significant improvement over the course of the study.

Conclusion
The results, over 24 months, indicate that the variable-thread tapered implant NobelActive can be used safely and effectively under demanding conditions such as an immediate post-extraction tooth replacement.

Radiographs from one case in the study highlighting the increasing bone levels over time (courtesy of Dr M. Kolinski, Chicago, USA).

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1 Private Practice in Periodontics (USA), 2 Private Practice in Oral and Maxillofacial Surgery (USA), 3 Private Practice (USA)