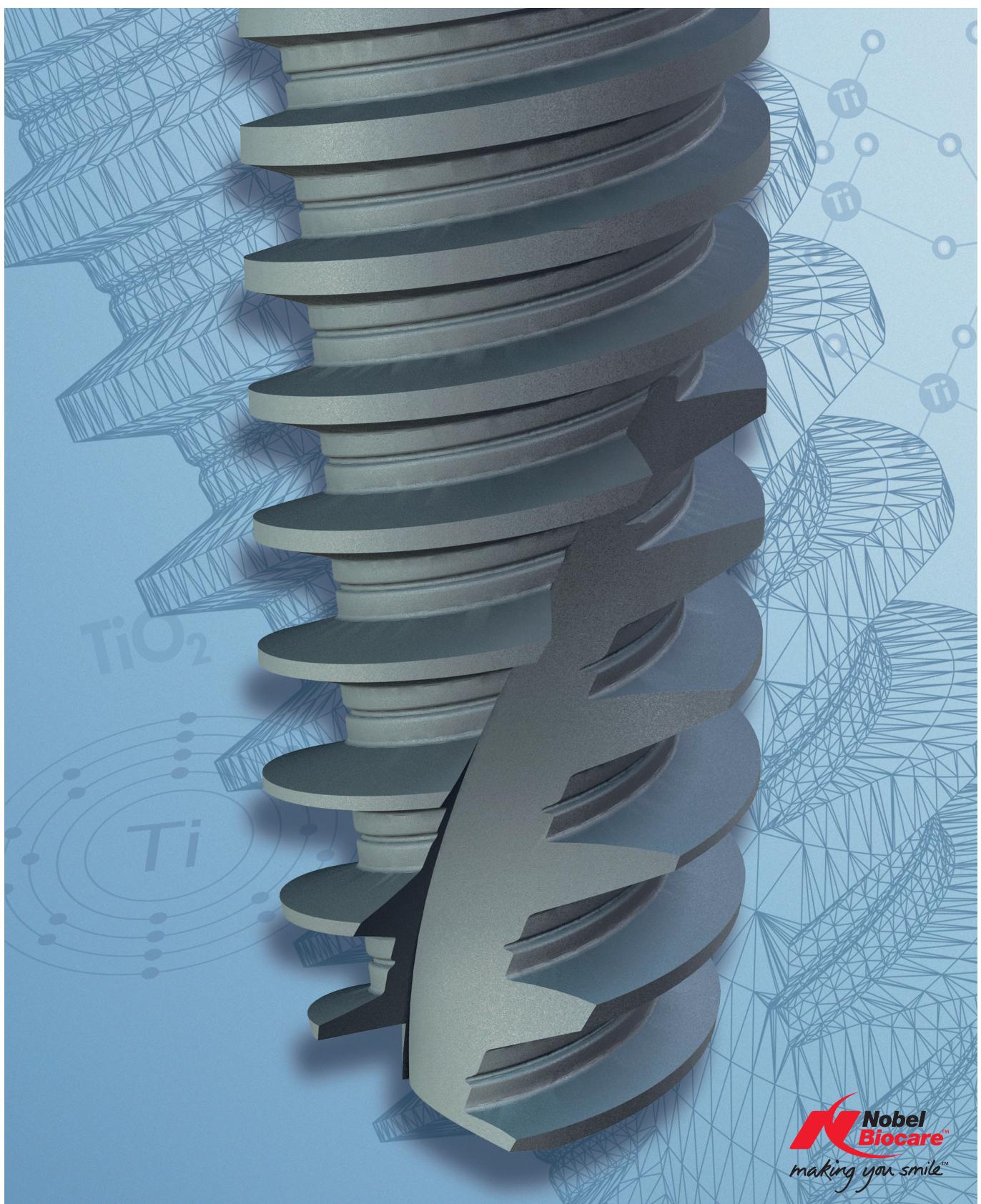


The NobelActive™ clinical story



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Scientific standards

Nobel Biocare is committed to thoroughly researching, testing, and documenting its products and solutions for safety, efficacy and long-term performance, before and after launching.

This commitment is evidenced by a minimum of one-year clinical follow-up data and documented results from mechanical testing, pre-launch activities, and clinical studies at time of launch.

Study types

Randomized controlled

Randomized controlled trials are considered the highest level of evidence in clinical studies. Randomized controlled means that a test treatment group is compared to a control treatment group and that the patients are randomly assigned to the different treatment groups. If designed correctly, this type of study is the perfect tool to find an effect of a specific treatment.

Prospective controlled

Next level of evidence in clinical studies are prospective, controlled studies. This type of study has a lower level of evidence than randomized controlled studies since treatment group assignment is not random and thereby introduces bias into the group assignment. However, in certain cases it might be impossible to assign the patients into study groups by randomization. In these cases the non-randomized controlled study can be a good tool to detect associations and trends.

Prospective uncontrolled

A common type of study in the field of dental implants is the prospective, uncontrolled study. In this type of study all subjects are in the same treatment group and the result is often compared to a literature reference or a historical control. The study population and study protocol in an uncontrolled study usually reflects the day-to-day clinical situation better than a randomized controlled study.

A controlled study has a higher level of evidence than an uncontrolled study, however in many cases it is impossible

NobelActive™ design

All aspects of NobelActive have been balanced to ensure long-term service of the implant and the restoration.

NobelActive features:

- Back-tapered coronal portion to maximize the volume of alveolar bone around the implant.
- Constantly expanding central core that acts like a threaded osteotome.
- Compacts bone outward as the implant is placed to deliver excellent primary stability.
- Unique double-lead thread pattern consisting of deep and widely spaced 35° threads emanating from a pair of very sharp cutting blades at the apex.
- Enables the implant to cut through bone and actively change direction.



to perform a controlled study. This can be due to the lack of a valid control, or there can be ethical issues deeming any other treatment option unusable.

Retrospective uncontrolled

Retrospective uncontrolled studies are often used for long-term follow-up.

The studies with the lowest level of evidence are case series and case reports.

Multi-center

Multi-center studies have a higher level of evidence than single-center studies. By conducting a study at multiple clinics it is possible to discriminate center-specific discrepancies from product-specific ones. Also multi-center studies show if the treatment can be reproduced at multiple centers.

NobelActive studies

NobelActive is currently being investigated in three prospective clinical multi-center studies.

In all three multi-center studies, NobelActive implants are being placed into Immediate Function™. This is a more demanding treatment protocol than a delayed loading protocol, and includes recording baseline bone remodelling measurements at the time of implant placement, instead of at the time of prosthetic placement.

A systematic review of studies where Nobel Biocare implants were placed in Immediate Function has been conducted.

The review contains more than 90 independent publications. The cumulative survival rates in these studies range from 71% to 100%. A complete listing is available for review on the Nobel Biocare website.

First study

The first study is a randomized controlled study that compares NobelActive to NobelReplace™ Tapered implants.

All implants were placed in Immediate Function, which means that all implants were provided with a prosthetic restoration at time of implant placement.

The implants were placed in healed sites, i.e., at least six months after extraction. No major bone augmentation at implant installation was permitted. However, a minor augmentation procedure to cover exposed threads or interproximal/buccal grafting due to deficient sites was allowed. The study has a planned five-year follow-up. Currently, all patients have reached the one-year follow-up. The primary objective of the study was to monitor changes in bone level over time. In addition, implant success rate and soft tissue parameters are evaluated within the study.

The one-year results from the first study are presented in further detail below*. The results from the other two studies will be published when all patients have reached the one-year follow-up.

Study design

A randomized controlled clinical study comparing NobelActive with NobelReplace Tapered. Implants (single or multiple) were placed in healed sites in maxilla or mandible, both anterior and posterior. All implants were subjected to Immediate Function.

Study population

Twelve centers have treated 177 patients and 325 implants in the study. 199 NobelActive implants (both Internal and External) and 126 NobelReplace Tapered implants (control group) were placed.

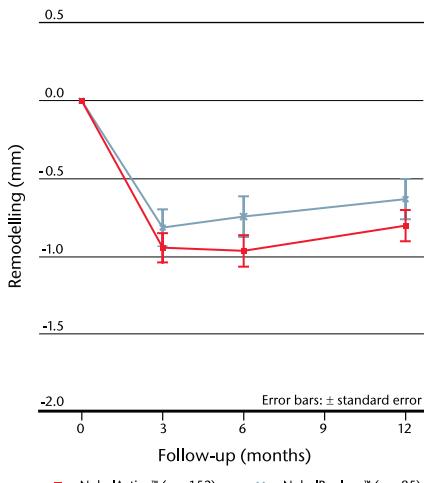
Survival rate

The cumulative survival rates for NobelActive and NobelReplace implants after one year were virtually the same, 96.5% and 97.6%, respectively. No significant differences between the groups were observed.

Marginal bone remodelling

The marginal bone resorption (\pm standard deviation) between implant insertion and the one-year follow-up was 0.8 ± 1.2 mm for NobelActive, and 0.6 ± 1.2 mm for NobelReplace, as seen in Figure 1. No significant differences between the groups were observed.

Figure 1: Marginal Bone Remodelling



All implants with follow-up both at time of insertion and at the one-year follow-up are included in the graph. Data is presented as mean of mesial and distal values \pm standard error.

Soft tissue parameters

The papilla index improved over time in both NobelActive and NobelReplace sites.

Soft tissue variables, plaque and periimplant mucosa, were stable over time for both implant types.

Second study

The second ongoing prospective multicenter study is designed to evaluate a clinical situation where the unique design features of NobelActive are utilized; immediate placement in combination with Immediate Function in extraction sockets. In this three-year study, 79 NobelActive external connection implants have been placed in 68 patients. Patient inclusion began February 2007 and ended October 2007.

Third study

The third ongoing prospective multicenter study has the same overall study design as the second study; immediate placement in combination with Immediate Function in extraction sockets. In this study, 60 patients will receive NobelActive internal connection implants. Patient inclusion began November 2007 and is currently ongoing.

Conclusions

The first study shows:

- Good survival data for NobelActive with a cumulative survival rate of 96.5%. This survival rate is within an expected range for implants placed in Immediate Function.
- Good crestal bone preservation and bone resorption comparable to the NobelReplace control group. No significant differences between the groups were observed after one year.
- Stable soft tissue conditions during the first year in function.
- NobelActive performs well under demanding clinical conditions, i.e., Immediate Function.
- NobelActive performs well in a wide variety of indications (from single tooth to full arch cases), in all positions and in all bone qualities. ■

*Unpublished data