NobelActive™

The NobelActive™ technical story

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NobelActive™ origins

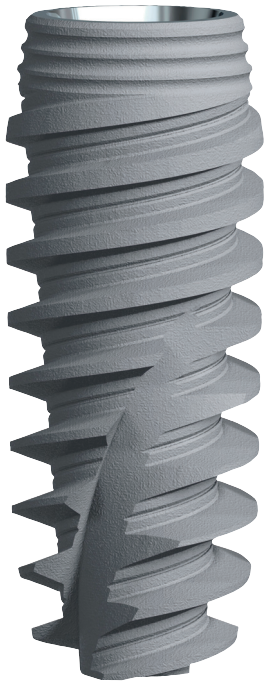
The life cycle of NobelActive began following years of research and development on a self-drilling and bone-condensing implant by the Israeli dental implant company AlphaBio$_{TEC}$ Ltd. After AlphaBio$_{TEC}$ presented their design and clinical data, Nobel Biocare decided to develop a new implant based on their design. Additionally, this new implant would feature current Nobel Biocare technology, such as TiUnite® and Groovy, as well as a new versatile prosthetic offering (Figure 1).

Figure 1: NobelActive

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.



Implant development

General implant development should consider both surgical and restorative requirements.

Clinicians want an implant system with maximum flexibility, both for placement and restorability. Depending on the application, surgeons want the option to place implants in two-stage, one-stage, and immediate loading procedures, all of which should be possible with a minimum amount of preparation in all qualities of bone.

Restorative clinicians want the choice of a variety of prosthetic options such as titanium and zirconia standard and custom abutments to screw-retained restorations on implants; or abutment-level restorations using short-span or full-arch bridges in titanium and zirconia.

NobelActive design

Looking at this implant design from the top down, the first challenge was combining the back-tapered coronal portion with the clinical need for titanium and zirconia fixed abutments and implant-level Procera® Implant Bridges.

To achieve this with NobelActive, a conical prosthetic connection was chosen. This connection combines compact size, high strength, and a very tight fit. The flat surface surrounding the conical connection yields a 1/4 mm wide built-in Platform Shifting™ around the abutments.

The horizontal surface also serves as a platform for implant-level Procera® Implant Bridges Titanium and Zirconia, and eliminates the use of abutments for these restorations, resulting in cost savings for the patient.

For each NobelActive implant diameter, the size of the dual-function prosthetic connection is large enough for zirconia abutments, simultaneously the walls of the implants are thick enough to hold up to the fatigue stresses placed upon the implant.

Material selection

Material selection depends on intended component use. Table 1 displays the materials Nobel Biocare uses in its implant components.

The strongest standard grade, commercially pure titanium is ASTM Grade 4 with a 0.2% yield strength of 480 MPa. This yield strength, however, was not adequate for the NobelActive design. In actuality, Nobel Biocare uses specially processed Grade 4 Titanium for all of its TiUnite® implants.

Table 1: Nobel Biocare Implant System Materials

Component	Material
Implants	Commercially Pure Titanium
Standard Abutments & Procera® Abutments	Ti 6Al 4V Titanium Alloy & Zirconium Oxide
Procera® Implant Bridges	Commercially Pure Titanium & Zirconium Oxide
Abutment Screws	Ti 6Al 4V Titanium Alloy

NobelActive ∅4.3 and ∅5.0 implants are made from the MTA 009 material and the ∅3.5 implants are made from the MTA 010 material, which has almost the same yield strength as the titanium alloy (Table 2).

These material strengths are required for the fatigue strength and thin cutting thread design of NobelActive.

Table 2: Titanium Yield Strengths

Titanium Designation	0.2% Yield Strength (min, MPa)
ASTM Grade 1	170
ASTM Grade 2	280
ASTM Grade 3	380
ASTM Grade 4	480
Nobel Biocare MTA009*	680
Nobel Biocare MTA 010*	750
Ti 6Al 4V-ELI (Titanium Alloy)	760

*Internal Nobel Biocare material designation

Fatigue testing

Fatigue testing is used to evaluate the strength of implant and abutment designs.

In 1992, Nobel Biocare developed an internal standardized protocol for fatigue testing endosseous dental implants which is very similar to the International Standard (ISO 14801) standard that is used today.

To test fatigue strength, an implant with standard length abutment is mounted in a fixture with a 30° off-axis orientation, then a cyclic force is applied at a frequency of 14 Hz (Figure 2).

Figure 2: 30° Off-axis Fatigue Testing

The implant/abutment combination is tested at a range of forces to determine the maximum force at which it will survive for five million cycles (Figure 3).

Endurance strength

From fatigue testing results, the endurance strength of an implant/abutment combination can be established.

Nobel Biocare used both titanium and zirconia abutments to determine the endurance strengths of NobelActive.

Figure 3: NobelActive NP Fatigue Testing

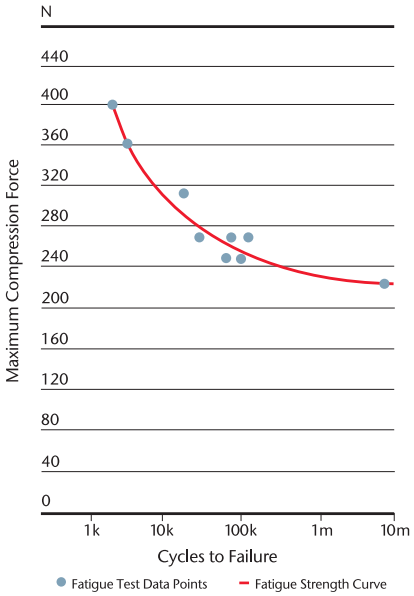


Table 3 displays the established endurance strengths for the tested implant/abutment combinations

These strengths are the maximum loads that the implant/abutment combinations can withstand for at least five million cycles.

Table 3: Implant/Abutment Endurance Strength

Implant/Abutment Combination		Maximum Load (N) @ 5M cycles
Abutment Material	Implant Diameter	
Titanium	∅3.5	222
	∅4.3	355
Zirconia	∅3.5	178
	∅4.3	225

The point where the curve flattens out in Figure 3 represents the safe level of combined occlusal loads which can be placed on the implant/abutment combination. When the combined occlusal loads placed on the implants are above this level, premature breakage of the components can occur.

For this reason, NobelActive NP implants and zirconia abutments are not recommended for use in the molar region, where the occlusal loads are highest; mean occlusal forces in young males can range from 222 N in the incisor region to 522 N in the molar region. [Blamphin et al 1990]

When the NobelActive and titanium abutment combination was tested to failure (at loads above the endurance strength), the fracture normally took place in the implant body. Alternately, when the NobelActive and zirconia abutment combination was tested to failure, the fracture normally took place in the zirconia abutment.

The results shown in Table 4 are the residual torque on the abutment screw; this data demonstrates that the screws and the abutments were tight and stable at the conclusion of the very rigorous fatigue testing.

Table 4: Abutment Screw Removal Torque Following Fatigue Testing

Implant/Abutment Combination		Average Removal Torque (Ncm)	
Abutment Material	Implant Diameter	Test	Control
Titanium	∅3.5	14	27
	∅4.3	15	21
Zirconia	∅3.5	20	31
	∅4.3	23	24

For reference, Nobel Biocare used the original Brånemark System® ∅3.75 ASTM Grade 1 titanium implant with standard titanium abutment to benchmark implant strength in 1992. The endurance strength for this implant/abutment combination was 185 N.

Torque strength

During NobelActive development, torque strength was also an important design parameter. Nobel Biocare needed to know that NobelActive could easily tolerate the torque experienced during its insertion (Figure 4).

Figure 4: Torque Strength Testing

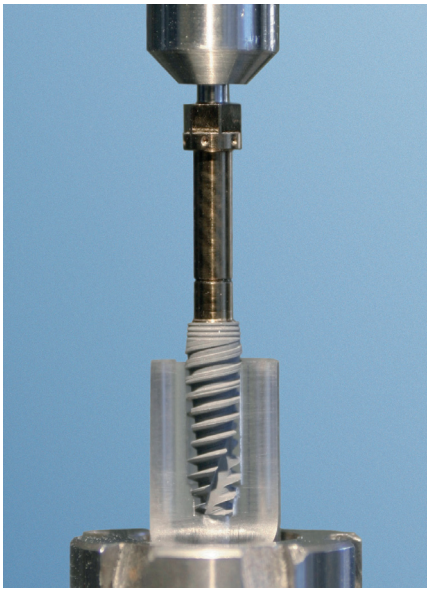


Table 5 displays the maximum implant torque strength for NobelActive implants.

Table 5: NobelActive Implant Torque Strength

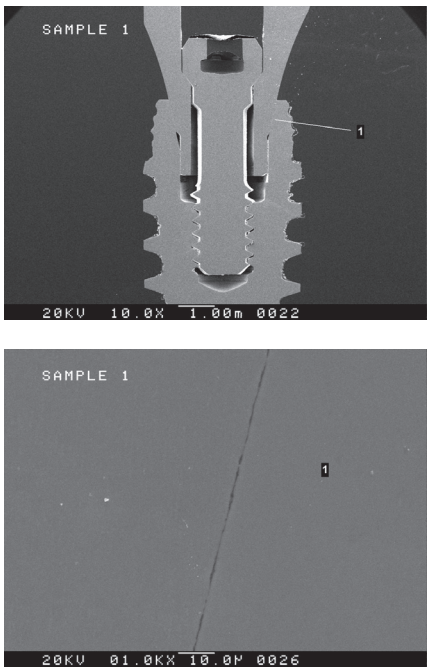
Implant Diameter	Max. Torque (avg, Ncm)	Implant Failure Mode
∅3.5	282	Hex stripped
∅4.3	452	Hex stripped

Dual-function prosthetic connection design

As previously discussed, the dual-function prosthetic connection of NobelActive was designed for compact size, high strength, and a very tight fit.

The specified tolerances for NobelActive and abutments are such that a very tight fit is always achieved at the top of the connection (Figure 5).

Figure 5: NobelActive RP-5 Cross Section



Cross section produced by Photometrics, Inc.

Insertion torque

The torque necessary to insert different implants designs cannot be directly compared. Based on the pre-study development work, it was expected that the torque needed to insert NobelActive implants would be higher than the normally specified 45 Ncm.

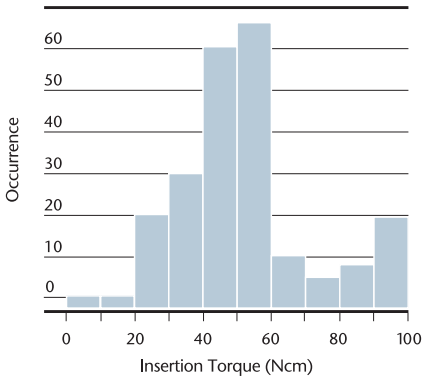
NobelActive implants have 1.2 mm thread spacing with double-lead thread pattern; this means that the implants advance 2.4 mm with each rotation of the implant. By comparison, NobelReplace™ Tapered implants advance approximately 0.7 mm with each rotation.

This higher thread pitch on NobelActive implants requires more torque to insert than the flatter thread pitch of NobelReplace™ implants.

These higher torque values were evidenced in the clinical study of NobelActive.[1] The clinicians were provided with special 150 Ncm torque wrenches so they could measure the actual torque used to place the implants.

The insertion torque values recorded were as high as 100 Ncm and more than 20% of the implants were placed with an insertion torque of 60 Ncm or higher. The mean insertion torque was 51.4 Ncm (Figure 6).

Figure 6: NobelActive Insertion Torque Values



The higher torque required to insert NobelActive, however, does not equate to higher pressure to the surrounding bone and no correlation between insertion torque and implant complications was seen.

From the torque values recorded for NobelActive, and in order to provide a large margin of safety, 70 Ncm was established as the prescribed maximum insertion torque.

NobelActive drilling protocol

The unique self-drilling thread design of NobelActive allows it to be inserted with straight twist drills and without the need for bone taps.

The drilling protocol (Table 6) developed for NobelActive has been validated in clinical study.[1] The surgical parameters identified as necessary to validate during the study were the final drill sizes used and the insertion torque required to place the implants in different bone qualities (as previously discussed).

Table 6: NobelActive Drilling Protocol

Implant Size	Soft Bone Type IV	Medium Bone Type II & III	Dense Bone
∅3.5	2.0	2.0 2.4/2.8 (2.8/3.2)	2.0 2.4/2.8 2.8/3.2
∅4.3	2.0 2.4/2.8 (2.8/3.2)	2.0 2.4/2.8 3.2/3.6	2.0 2.4/2.8 3.2/3.6 (3.8/4.2)
∅5.0	2.0 2.4/2.8 3.2/3.6	2.0 2.4/2.8 3.2/3.6 3.8/4.2	2.0 2.4/2.8 3.2/3.6 3.8/4.2 (4.2/4.6)

Drills within brackets (--) denote widening of the cortex only, not drilling to the full drilling depth

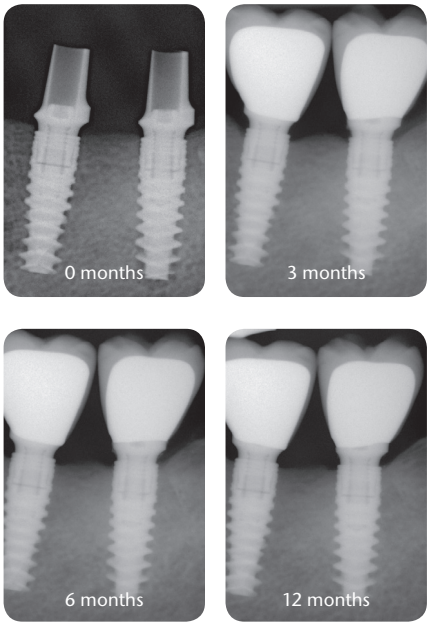
Dense bone

According to the drilling protocol, incrementally larger drills are needed as bone density increases. Using larger drills in dense bone creates a gap between the osteotomy and the minor diameter of the threads.

The radiographs in Figure 7 demonstrate how the bone fills in between the threads of NobelActive with no adverse effects. These NobelActive ∅4.3 implants were placed with a final step drill size ∅3.8-4.2 and were tightened to an insertion torque of 50 Ncm.

No correlation between final drill size and implant complications was seen in the study.

Figure 7: Dense Bone Radiographs



Courtesy of Prof. Dr. Martin Lorenzoni

Clinical validation

Before launching any new implant design, Nobel Biocare validates product safety and efficacy through pre-clinical and clinical studies.

A five-year randomized controlled prospective multi-center clinical study on NobelActive was begun April 2006. The study involves 12 centers in Europe, 177 patients, 199 NobelActive implants, and 126 NobelReplace™ Tapered implants (as control).

The final patient was included May 2007. All implants in the study were placed in healed sites and subjected to Immediate Function™. One-year data demonstrates a cumulative survival rate of 96.5%.†[1]

Additionally, two 3-year prospective multi-center studies are ongoing. These will determine the success of immediate placement of NobelActive in extraction sites:

- 7 centers in the US, 68 patients, and 79 implants; patient inclusion began February 2007 and ended October 2007[2]
- 6 centers in the US and 60 patients; patient inclusion began November 2007 and is ongoing[3]

AlphaBio$_{TEC}$ conducted their own retrospective multi-center study on the SPIRAL implant, which is the design basis of NobelActive. Their study included 648 implants in 251 patients, with up to four years follow-up (Table 7).

The clinical data demonstrated a cumulative survival rate (CSR) of 98.3%.[4]

Table 7: CSR From A Retrospective Multi-center Study On The SPIRAL Implant

Interval	Implants	Failed	CSR (%)
1	648	9	98.9
2	625	1	98.5
3	358	1	98.3
4	110	1	98.3

Conclusion

When developing a new implant system every aspect of the system must be verified and validated. The information shown above demonstrates just some of the steps in the process to ensure long-term clinical success and safety for the patient. ■

†Unpublished data

Clinical references

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2. Evaluation of NobelActive External Implants in Extraction Sites. Ongoing prospective multi-center study in 7 centers, Clinical Research Department, Nobel Biocare Services AG.
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4. Karmon B, Kohen J, Lor A, Gratciany Y, Laster T, Hallel G, Karmon T. Initial report from a retrospective multi-center study on the SPIRAL implant. Presented as a poster at the Nobel Biocare World Conference, Las Vegas, May 2007.

Additional reference

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Tables

Figures