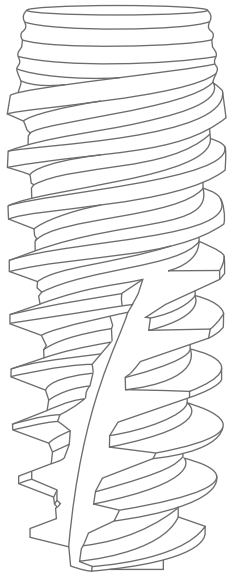
Validating innovation.

NobelActive™ technical and clinical story



Developing NobelActive.

NobelActive origins
The life cycle of NobelActive began following years of research and development on self-drilling and bone-condensing implants. Based on this research Nobel Biocare decided to develop a new implant with leading Nobel Biocare technology, such as TiUnite (titanium oxide implant surface) and Groovy (grooves on the threads), as well as a new comprehensive prosthetic offering.

Surgical and restorative requirements
Implant development should consider both surgical and restorative requirements.

Clinicians request an implant system with maximum flexibility, both for placement and restorability. Depending on the application, surgeons require 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 a comprehensive range of prosthetic options in titanium and zirconia – from standard and individualized CAD/CAM abutments to multiple-unit and full-arch bridges on implant and abutment level.

Maximum soft tissue volume
Built-in platform shifting supports soft tissue interface for natural-looking esthetics.

High initial stability even in compromised bone situations
Expanding tapered implant body with double-lead thread design condenses bone gradually.

Also for minimally prepared sites
Apex with drilling blades enables smaller osteotomy.

Maximum alveolar bone volume
Back-tapered coronal design for improved soft tissue support.

Adjustable implant orientation
Implant design enables experienced clinicians to adjust implant orientation for optimal prosthetic connection.

Dual function connection
Looking at the NobelActive design from the top down, the first challenge was combining the back-tapered coronal portion with the clinical need for titanium and zirconia abutments and implant-level NobelProcera Implant Bridges. To achieve this, a conical prosthetic connection was chosen, which combines compact size, high strength, and a very tight fit.

The flat surface surrounding the conical connection yields a 0.25 mm wide built-in platform shift around the abutment. The horizontal surface also serves as a platform for implant-level NobelProcera Implant Bridges in titanium and zirconia, which can eliminate the use of abutments for these restorations.

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

Testing NobelActive.

Material selection

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

Table 1: Nobel Biocare implant system materials

Component	Material
Implants	Commercially pure titanium
Abutments	Ti-6Al-4V titanium alloy and zirconium oxide
Abutment screws	Ti-6Al-4V titanium alloy
NobelProcera Implant Bridges	Commercially pure titanium and zirconium oxide

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. Nobel Biocare therefore uses specially processed Grade 4 Titanium for all of its implants.

Yield strength

NobelActive ∅ 4.3 and ∅ 5.0 implants are produced from the MTA 009 material and the ∅ 3.5 implants from the MTA 010 material, which has almost the same yield strength as the titanium alloy Ti-6Al-4V (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.*

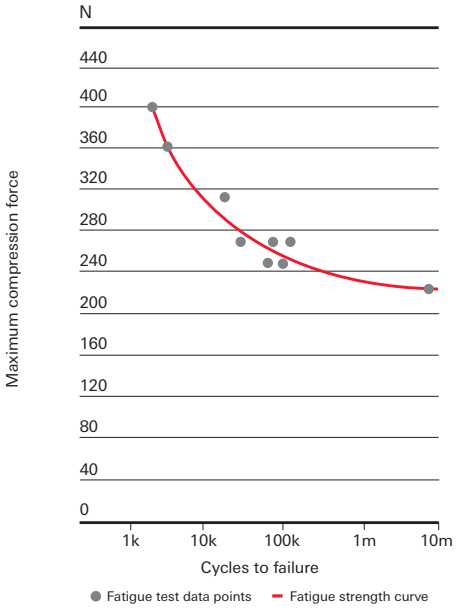
Fatigue strength

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 of endosseous dental implants, which is very similar to the International Standard (ISO 14801) 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 and a cyclic force is applied at a frequency of 14 Hz (Figure 1). 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 2).

Figure 1: 30° off-axis fatigue testing

Figure 2: NobelActive NP fatigue testing



Testing NobelActive.

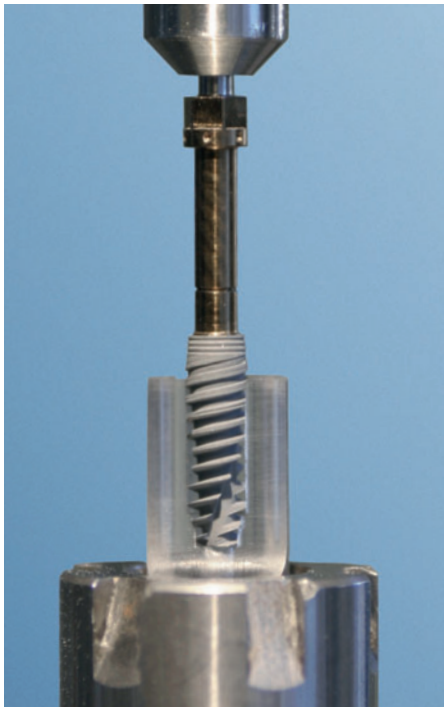
Table 3: Implant/abutment endurance strength

Implant/abutment combination		Max load (N) at 5 mio cycles
Abutment material	Implant diameter	
Titanium	∅ 3.5	222
	∅ 4.3	355
Zirconia	∅ 3.5	178
	∅ 4.3	225

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

Figure 3: Torque strength testing



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.

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. The point where the curve flattens out in Figure 2 represents the safe level of combined occlusal loads which can be placed on the implant/abutment combination. When the combined occlusal loads are above this level, premature breakage of the components can occur.

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. With zirconia abutments, on the other hand, the fracture normally took place in the abutment. For this reason, NobelActive NP implants and zirconia abutments are not recommended for use in the molar region, where the occlusal loads are highest.*

Screw removal torque

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 end of the very rigorous fatigue testing.

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 the development of NobelActive, 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 3). Table 5 displays the maximum implant torque strength for NobelActive implants.

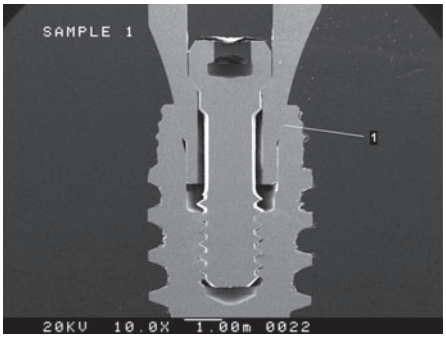
Table 5: NobelActive implant torque strength

Implant diameter	Max torque (avg, Ncm)	Implant failure mode
∅ 3.5	282	Hex stripped
∅ 4.3	452	Hex stripped

Prosthetic connection

The dual-function prosthetic connection 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 4).

Figure 4: NobelActive RP 5.0 cross sections



** Mean occlusal forces in young males can range from 222 N in the incisor region to 522 N in the molar region (Blamphin C N J, Brafield T R, Jobbin B, Fisher J, Watson C J, Redfern E J. A simple instrument for the measurement of maximum occlusal force in human dentition. Proc Instn Mech Engrs, Vol 204, Apr 1990).*

Insertion torque

The torque necessary to insert different implant designs cannot be compared directly. 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, which means that they advance 2.4 mm with each rotation. By comparison, NobelReplace Tapered implants advance approximately 0.7 mm with each rotation. This higher thread pitch on NobelActive requires more torque to insert the implant than the flatter thread pitch on NobelReplace implants.

These higher torque values were evidenced in clinical studies.* The clinicians were provided with special 150 Ncm torque wrenches so they could measure the actual torque used to place the implants. The 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 5).

The higher torque required to insert NobelActive 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 developed for NobelActive (Table 6) has been validated in clinical study.* 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.

Dense bone

According to the drilling protocol, incrementally larger drills are required 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 6 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 ∅ 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 5: NobelActive insertion torque

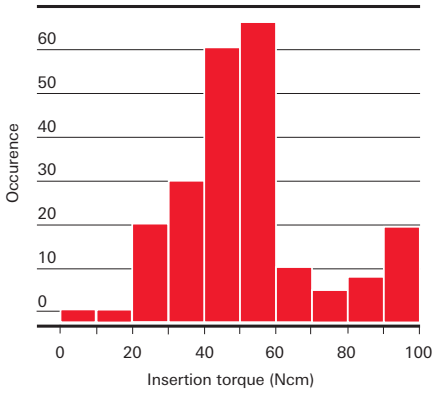
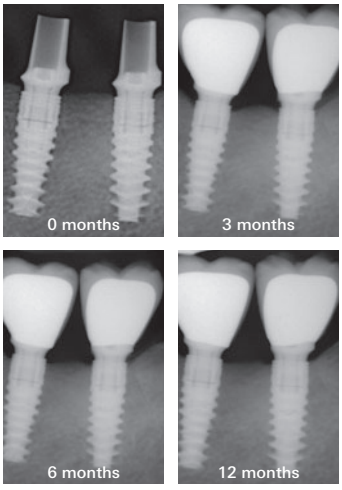


Table 6: NobelActive drilling protocol

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. All data in mm.

Figure 6: Dense bone radiographs



Courtesy of Prof. Dr. Martin Lorenzoni, School of Medicine (Graz, Austria)

** Kielbassa AM, Martinez-de Fuentes R, Goldstein M, Arnhart C, Barlattani A, Jackowski J, Knauf M, Lorenzoni M, Maiorana C, Mericske-Stern R, Rompen E, Sanz M. Randomized controlled trial comparing a variable-thread novel tapered and a standard tapered implant: interim one-year results. J Prosthet Dent 2009 May;101(5):293-305.*

NobelActive™ in use.

NobelActive is quickly becoming the implant of choice for clinicians looking for improved esthetics and excellent clinical results, especially in challenging indications.

Clinical evidence
Clinical studies have shown that NobelActive is a reliable implant with unique benefits:
- High initial stability, especially in compromised indications
- Excellent survival rates using progressive treatment protocols
- Enhanced soft tissue management and esthetics, due to the unique prosthetic connection design
- Stable bone levels supported and minimized bone remodeling
- Bone condensing osteotome effect enabling implant placement in narrow ridges with exceptional outcome

Ongoing clinical research
NobelActive continues to be the focus of clinical research.

Results demonstrate high cumulative survival rates (95.7–100%), stable bone levels and favorable soft tissue parameters under various clinical conditions and using immediate function protocols.

From an ongoing five-year study, preliminary two-year results demonstrate continued favorable trends from the first year: no soft tissue recession, and stable papillae and bone levels.

During the first year, there was an overall improvement in papilla size, shown by an increase in Jemt's papilla score (+0.63), followed by stable papilla conditions during the second year (+0.06).

Additionally, the majority of NobelActive implants showed improved bone levels during the second year (Martínez-de Fuentes et al 2010).

Clinical research summary
The clinical data summarized in the following tables (grouped by study type) is the result of research conducted in more than 30 clinical centers, involving more than 650 patients and 1700 implants.

Randomized controlled

Primary investigator / year	Follow-up time	No of patients	No of implants	CSR (%)	Key findings
Kielbassa / 2009	1 year	64	117	96.6	NobelActive delivered high survival rates, as well as stable bone and soft tissue levels, after one year.
Gultekin / 2010*	1 year	25	43	97.7	Minimal marginal bone remodeling (0.38 mm) shown around NobelActive.
Martínez-de Fuentes / 2010*	2 years	64	117	95.7	Improved bone levels were observed in the majority of NobelActive cases followed during the second year.

** Conference abstract.*

Prospective

Primary investigator	Follow-up time	No of patients	No of implants	CSR (%)	Key findings
Cherry / 2011*	1 year	55	60	98.3	Stable marginal bone after the first 6 months and minimal remodeling (0.25 mm) during the first year for NobelActive immediately loaded in extraction sites.
Lope / 2010*	6 months	8	16	100	NobelActive is a viable option for immediately loaded mandibular overdentures supported by two unsplinted implants.

Retrospective

Primary investigator	Follow-up time	No of patients	No of implants	CSR (%)	Key findings
Babbush / 2011	up to 29 months	165	708	99.6	All-on-4 immediate function treatment concept using NobelActive is a viable treatment for patients with edentulous arches and/or immediate placement.
Irinakis / 2009a	Short term	84	140	97.9	NobelActive consistently exhibited high initial stability in all bone types, as evidenced by high torque levels (mean 50.8 Ncm).
Irinakis / 2009b	Average 9 months (range 5-13)	**	107	98.1	NobelActive claims of 1) high initial stability, 2) bone condensing and 3) redirection capability were confirmed in this study.
Irinakis / 2011	More than 18 months	49	49***	100	NobelActive can be used successfully in sinus elevation procedures with simultaneous implant placement.
Kutsko / 2010*	6 months	293	1001	98.0	NobelActive can be successfully used in treating partially and fully edentulous patients.
Navarro / 2009*	1 year	138	409	98.0	NobelActive delivered stable hard and soft tissue levels and is optimal in demanding clinical situations.

** Conference abstract.*
*** Not specified in study.*
**** NobelActive and NobelReplace implants.*

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