Science First

Volume 4, Issue 1
2017

Full-arch solutions
Treatment options for edentulous patients and patients with failing dentition

Nobel Biocare®

Cover picture
Offering meaningful innovation, Nobel Biocare has set the standard for integrated solutions for the treatment of edentulous patients and patients with failing dentition. Shown here are overlay renderings of four full-arch restorative options on 3D images, clockwise from the upper left: NobelZygoma™ implants in the maxilla combined with two anterior conventional implants, the All-on-4® treatment concept, two implants for locator-retained overdenture restoration of the mandible, the Trefoil™ system prefabricated framework over three implants in the mandible. Choose the best solutions for each of your patients, taking into account the remaining bone volume, esthetic requirements, the patient's financial situation and their ability to maintain their restoration.

Contents

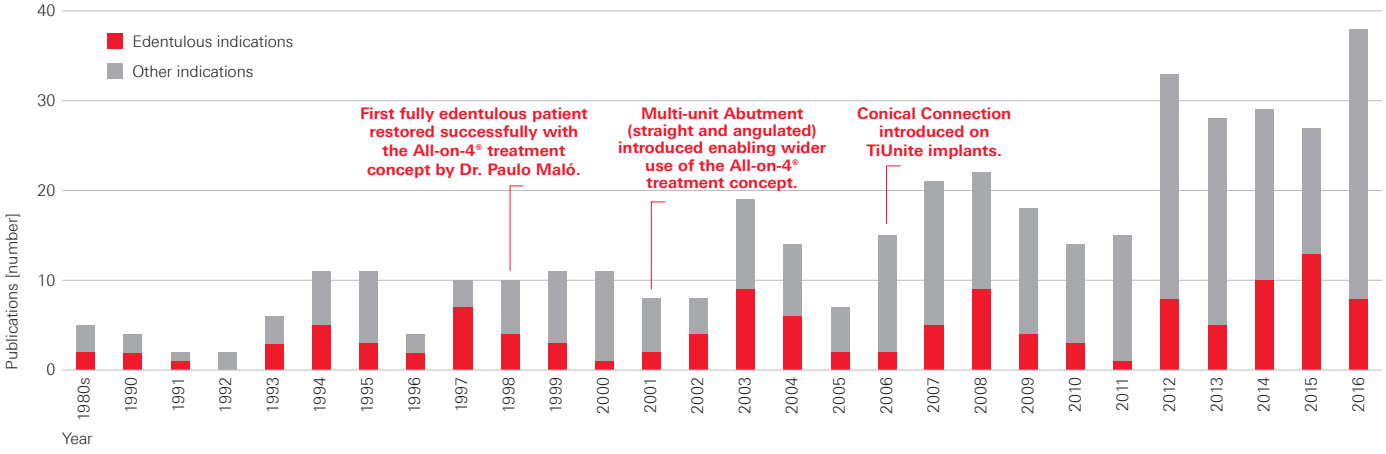
Nobel Biocare – commitment to innovation based on scientific evidence

At Nobel Biocare, we understand that dental professionals need high-quality clinical evidence to help them give quality of life back to their patients. To meet this need, Nobel Biocare is committed to the highest standards of scientific proof in the spirit of our pioneers. All treatment concepts shown in this issue of Science First are supported by clinical evidence. When managing edentulous patients and patients with failing dentition, you can choose Nobel Biocare products and solutions with confidence.

Nobel Biocare's commitment to evidence-based oral health

Every year, Nobel Biocare invests significantly in conducting – and reporting – our latest research, to enable our customers to choose our products with confidence. Nobel Biocare is committed to the highest standard of scientific evidence and recognizes the value of preclinical research and clinical studies. Since the beginning, Nobel Biocare has supported research published in peer-reviewed journals, providing evidence for the treatment of edentulous patients, as well as many other indications.

Studies supported by Nobel Biocare and published in peer-reviewed journals



Nobel Biocare, data on file. Nobel Biocare's electronic library, subject to audits by a notified body, was searched for publications labeled "supported by Nobel Biocare" or "supported by CR". Search performed December 14, 2016.

Edentulism – still a challenge today

Edentulism impacts patients in several important ways, including residual ridge resorption, impaired masticatory function, social handicap and poor quality of life. Despite significant advances in implant dentistry over the last fifty years, demographic changes are expected to maintain high overall numbers of edentulous patients.[6] Implant-based rehabilitation offers improvements to the oral and general health of patients who are edentulous or who have failing dentition, as well as their quality of life.

Edentulism today

Edentulism is an oral health impairment caused by the loss of all natural teeth. Edentulism hinders fulfillment of essential functions of the stomatognathic system including mastication, mimics and phonation.[2–4] The global burden of edentulism and severe tooth loss is increasing.[1] Between 2005 and 2015, the worldwide prevalence increased by 27 % and currently exceeds 275 million cases.[1]

Health-related impairments associated with edentulism

Tooth loss is much more than a dental problem. Considerable changes in facial morphology[5–7] and function are associated with the condition.[8] As an immediate effect, the periodontal ligament and the tactile function arising from its mechanical receptors, which plays an important role in informing patients about chewing force and food consistency, is lost.[9–11] Unfavorable loading or disuse atrophy are causes of jaw bone resorption, which may in turn lead to further tooth loss, unfavorable intermaxillary relationships[12, 13] and decreased jaw bone quality.[14]

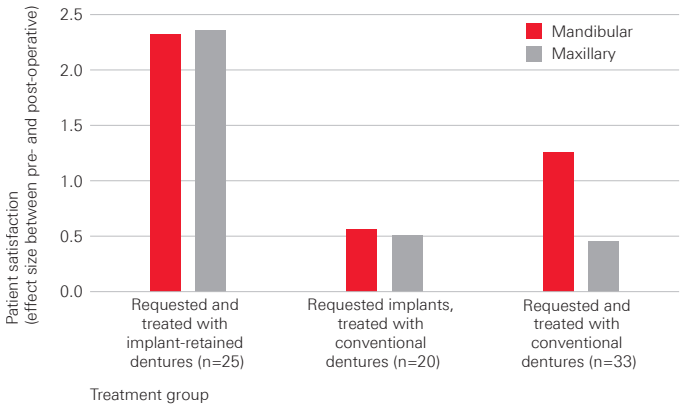
Treatment modalities to rehabilitate edentulous patients

For decades, complete dentures were the only treatment option for edentulous patients. However, complete dentures are often associated with impaired quality of life resulting from unsatisfactory function and stability, poor esthetics, impairment of speech and decreased self-esteem.[15–20]

The alternatives to dentures

Substantially changing lives by addressing the burdens faced by edentulous patients, Prof. Per-Ingvar Brånemark applied the discovery of osseointegration to develop fixtures for (tissue-integrated) dental prosthesis for edentulous patients and published the results in the seminal paper, “Osseointegrated implants in the treatment of the edentulous jaw. Experience from a 10-year period”.[21] Implant-based treatment of edentulism has subsequently evolved to be a first-choice prosthodontic regimen.[22] The application of implants in edentulous patients, to carry or retain a fixed or removable dental prosthesis, delivers significant improvements in quality of life compared to conventional dentures.[23]

Greater improvements in patient satisfaction with implant-retained versus conventional dentures



Patients rated on a Likert scale on aspects of satisfaction with their maxillary and mandibular dentures; namely retention, comfort, stability, appearance, the ability to speak and occlusion, as well as general satisfaction. Effect size (mean pre-operative minus mean post-operative) / SD pre-operative) quantifies the change in satisfaction following treatment in each group. n = number of patients.[23]

Edentulism – treatment options and their impact on function, esthetics and patient satisfaction

With the advent of dental implants, numerous treatment concepts have been described as alternative solutions to complete dentures. As a result, today's clinicians can tailor restorations to the patient's medical condition, their anatomy, socioeconomic situation, as well as their expectations and anticipated compliance.[24]

Choosing the right treatment modality for each patient

Decision making on individual patient treatment should strive to attain a tailored solution that meets the patient's expectations and with which they can readily accept and comply.[25] However, many patients who are dissatisfied with the functionality and esthetics of complete dentures are fearful of implant surgery.[16] It is therefore important to carefully communicate the benefits and risks of implant-supported restorations to increase patient knowledge, informed consent, and acceptance of such a procedure.[16,26]

Patient dissatisfaction with complete dentures

Patients are often dissatisfied with complete dentures[17] and complain about instability, decreased chewing ability, limited social contact and impaired quality of life.[18] In the maxilla, complete dentures can often be fabricated with sufficient stability; however, palatal coverage regularly causes speech impairment and dysfunction. Mandibular dentures may be even more problematic, with the limited denture-bearing area and instability.[19]

Implant-retained restorations

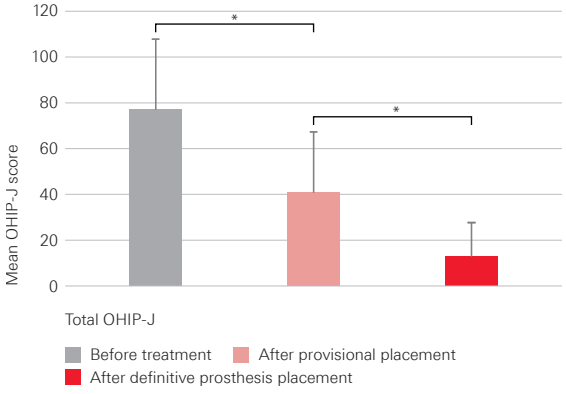
In 2002, an expert consensus concluded that overdentures supported by two implants are the first-choice standard of care treatment for the edentulous mandible.[22] Use of implants for retention of a prosthesis has been shown to improve function, facial esthetics, comfort and quality of life,[20] despite higher costs for this treatment modality when compared with complete dentures.[27]

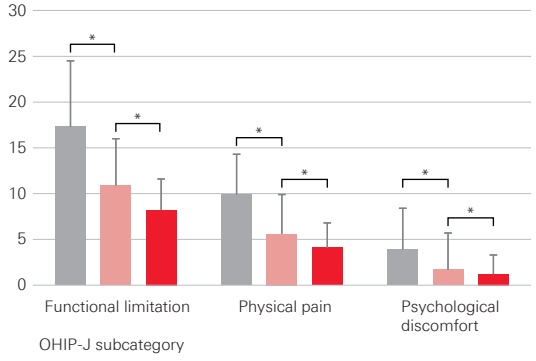
Implant-supported fixed restorations for patient comfort

Implant-supported fixed restorations provide enhanced comfort for the edentulous patient.[28–29] Various concepts with respect to implant number and suprastructure design are available for individualized therapy. Modern approaches such as the All-on-4® treatment concept reduce the number of required implants for fixed solutions, limit the need for bone augmentation and show a highly predictable clinical outcome at a reduced cost compared to conventional implant treatments.[29-32]

For optimized, prosthetically driven implant placement and esthetics, hard and soft tissue augmentation is frequently required, increasing treatment time and risks for the patient. New treatment concepts involving four to six implants avoid critical anatomical structures such as nerves or sinus. Such concepts aim to fully utilize the available native bone and maximize anterior–posterior spread, often applying image-based flapless guided surgery.[28]

Significantly reduced impairment in oral health-related quality of life following full-arch rehabilitation on 4–6 implants.





Patients' benefits following flapless guided surgery for complete-arch maxillary rehabilitation in a clinical study of 50 patients treated with NobelProcera implant bridges supported by NobelActive implants. Lower scores indicated better oral health-related quality of life.
* $p \leq 0.05$; Scheffé test. OHIP-J, Japanese version of the Oral Health Impact Profile.[28]

Implant-supported restorations – fixed versus overdenture solutions

Solutions tailored to patient needs

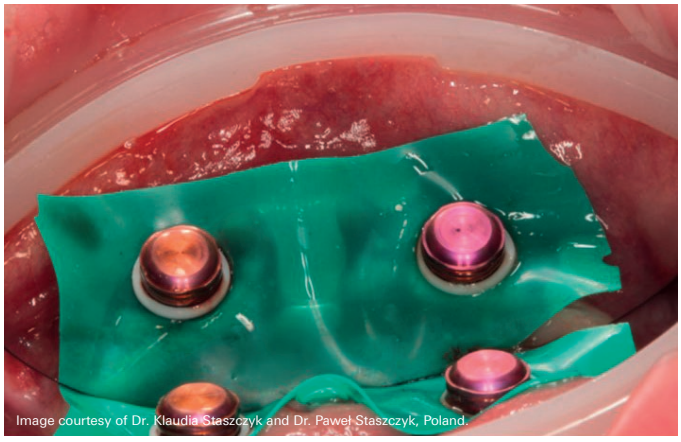
The suitability of a restorative solution for a given patient will depend on their preferences, financial means, oral hygiene and anatomy.[33] When considering restorations for edentulous patients and patients with failing dentition, clinicians may deliberate between fixed and overdenture solutions.[33]

While both fixed and overdenture restorations can be highly successful, reliable and satisfactory modalities for the rehabilitation of edentulous jaws, both have benefits and limitations that are important to consider.

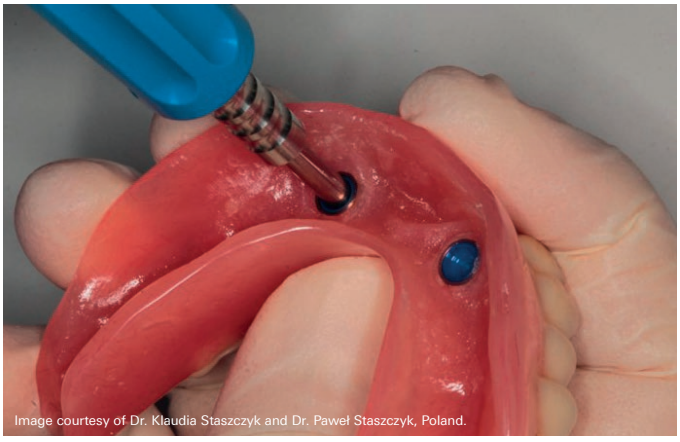
Advantages and limitations of fixed and overdenture restorations

	Fixed restorations[33]	Overdenture restorations[33]
Advantages	Can be made of acrylic or porcelain	Ease of cleaning
	Optimized esthetics	Phonetics
	High bite force	Provision of lip support
	High stability/retention	Ease of production
		Cost effectiveness
Limitations	Number of implants required	Risk of mucosal problems
	Risk of food accumulation	Wear of components

Clinical case – restoration of mandible using a locator-retained overdenture



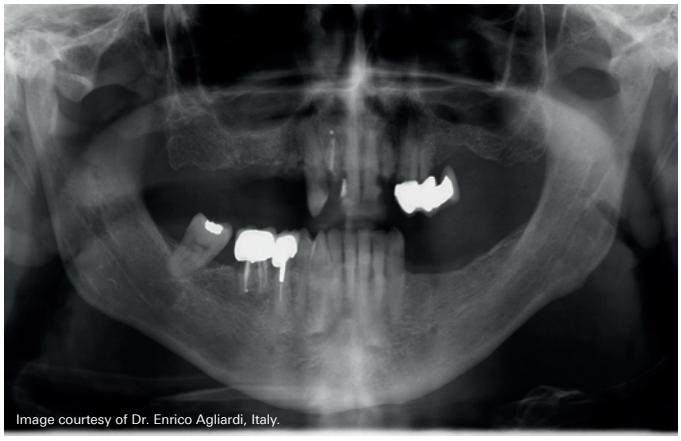
Locators placed intra-orally.



Placing of retention elements in denture.

Intra-oral view of two locator attachments at one-week follow-up.

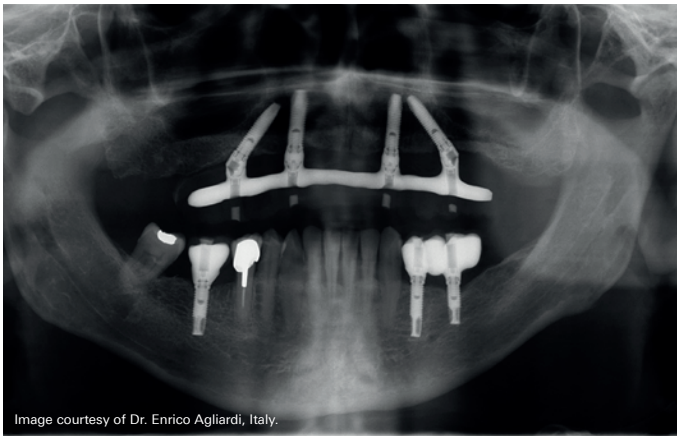
Clinical case – restoration of the maxilla with failing dentition using the All-on-4® treatment concept



Pre-operative panoramic x-ray showing a failing dentition in the maxillary arch with extensive carious lesions on teeth, residual roots and a failing bridge.

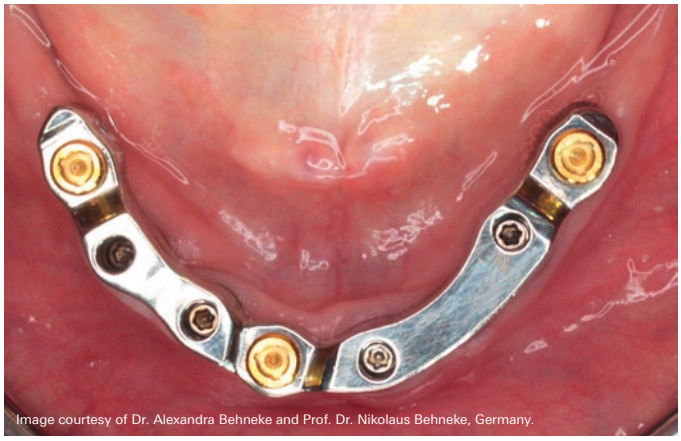
Lateral view of the final NobelProcera zirconia framework veneered.

Detail of the frontal teeth (prosthesis) in lateral view.



3-year follow-up.

Clinical case – restoration of the maxilla with CAD/CAM implant bar overdenture



Occlusal view of the NobelProcera Implant Bar Overdenture on 4 implants at one-year follow-up.

Clinical view at one-year follow-up visit.

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Nobel Biocare: Pioneering implant-supported solutions for the benefit of edentulous patients

Clinical studies with up to 10 years of follow-up confirm excellent performance and consistently high survival rates for Nobel Biocare restorative solutions, which are supported by implants with a TiUnite surface, in edentulous patients.

Key findings

- Clinical outcomes documented for over 28,600 TiUnite-surface implants in more than 5,000 fully edentulous patients in 132 publications representing 111 studies.[1]
- High implant survival rates of 97.9%[A] for over 11,200 implants with follow-up times of up to 10 years (mean 2.4 years[B]) in 48 studies that reported implant survival rate.
- Prosthesis survival rates of up to 97.9%[C] for over 2,700 patients with follow-up times of up to 6 years (mean 2.6 years[B]) in 43 studies that reported of prosthesis survival rate.

Nobel Biocare's pioneering efforts in implant-supported solutions have demonstrated clear patient benefits every step of the way.

First edentulous patient treated with implants

"No one should die with their teeth sitting in a glass of water" Prof. Per-Ingvar Brånemark.

First Brånemark system implants in edentulous patients

96–98% success rate for the mandible and 92% for the maxilla in up to 4 years follow-up of 184 patients.[2]

First Procera implant bridge

Improved potential for fit and minimizing distortion.[4]

Zygoma machined implants

Facilitated successful, long-term rehabilitation of patients with severe atrophic maxillae.[7]

Ball anchors/ Ball abutment

Good retention of the overdenture, low rates of soft-tissue complications and high patient satisfaction.[5]

First fully edentulous patient restored successfully with the All-on-4® treatment concept by Dr. Paulo Maló

Cost-efficient, graftless solution that provides patients with a provisional fixed full-arch prosthesis on the day of surgery.[8,9]

TiUnite® surface

Proven concept with more than 10 years of clinical studies, maintaining the marginal bone levels after the initial bone remodeling phase.[10–13]

1965 1982 1983 1988 1991 1995 1996 1997 1998 2000 2001 2002

Dr. Matts Andersson first presented fully automated industrialized, CAD/CAM dental prosthetic production

High-precision, repeatable manufacturing for individualized dental restorations.

First zygomatic implant introduced by Prof. Per-Ingvar Brånemark for the maxilla

Treatment concept for severe maxillary defects and/or resorption in compromised patients.[3]

Brånemark Novum

Landmark treatment paving the way for a full-arch, fixed and definitive restoration on three implants delivered in one day.[6]

Multi-unit Abutment (straight and angulated)

Restoring multiple teeth using tilted implant placement.

TorqTite prosthetic screws

Total system performance with higher preload of TorqTite coating to avoid screw loosening and/or fracture of the retaining screw and enable long-term stability of the system.[14]

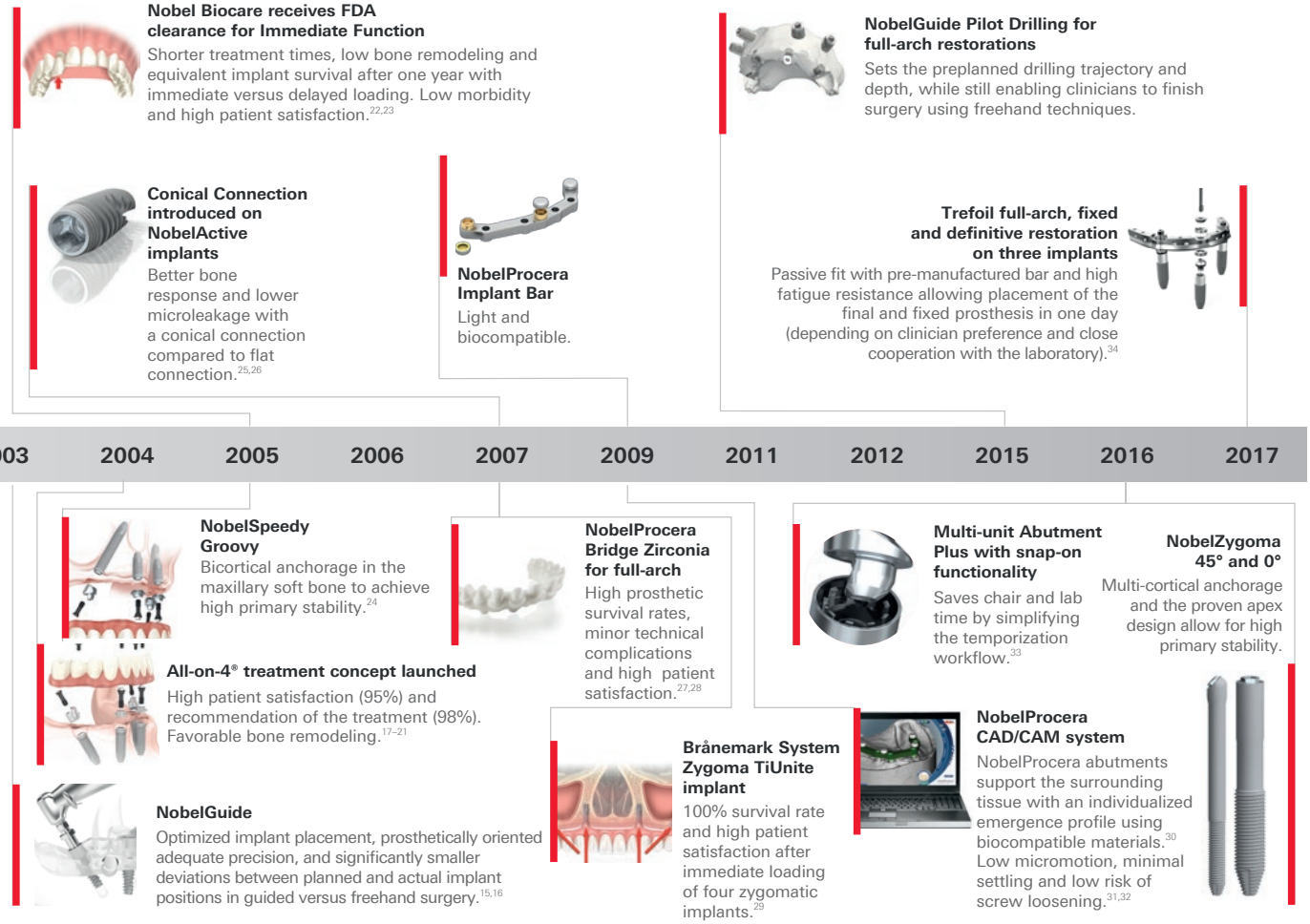
A Arithmetic mean (implant level) of all reported and calculated (cumulative) survival rates.
B Arithmetic mean of all reported and calculated mean follow-up times.
C Arithmetic mean (patient level) of all reported and calculated (cumulative) survival rates.

Meaningful innovation in edentulism

At Nobel Biocare, we're dedicated to helping treat more edentulous patients better. This philosophy is built on many years of continuous innovation stemming from Prof. Per-Ingvar Brånemark's groundbreaking work on osseointegration and first implant surgery in 1965. His first patient, Gösta Larsson, died in 2006 with his implants still intact and his teeth still functioning. Since then we've assisted our customers in the successful treatment of millions of edentulous patients and patients with failing dentition.

Nobel Biocare quality

Designed and tested as a total system, all Nobel Biocare components are optimized for mechanical performance and to meet the requirements of the clinical indication. Independent peer review studies confirm the quality of Nobel Biocare system designs through outstanding mechanical,[31,32] biological[25] and long term clinical performance.[35]



Nobel Biocare receives FDA clearance for Immediate Function
Shorter treatment times, low bone remodeling and equivalent implant survival after one year with immediate versus delayed loading. Low morbidity and high patient satisfaction.[22,23]

Conical Connection introduced on NobelActive implants
Better bone response and lower microleakage with a conical connection compared to flat connection.[25,26]

NobelProcera Implant Bar
Light and biocompatible.

NobelGuide Pilot Drilling for full-arch restorations
Sets the preplanned drilling trajectory and depth, while still enabling clinicians to finish surgery using freehand techniques.

Trefoil full-arch, fixed and definitive restoration on three implants
Passive fit with pre-manufactured bar and high fatigue resistance allowing placement of the final and fixed prosthesis in one day (depending on clinician preference and close cooperation with the laboratory).[34]

NobelSpeedy Groovy
Bicortical anchorage in the maxillary soft bone to achieve high primary stability.[24]

All-on-4® treatment concept launched
High patient satisfaction (95%) and recommendation of the treatment (98%). Favorable bone remodeling.[17–21]

NobelGuide
Optimized implant placement, prosthetically oriented adequate precision, and significantly smaller deviations between planned and actual implant positions in guided versus freehand surgery.[15,16]

NobelProcera Bridge Zirconia for full-arch
High prosthetic survival rates, minor technical complications and high patient satisfaction.[27,28]

Brånemark System Zygoma TiUnite implant
100% survival rate and high patient satisfaction after immediate loading of four zygomatic implants.[29]

Multi-unit Abutment Plus with snap-on functionality
Saves chair and lab time by simplifying the temporization workflow.[33]

NobelZygoma 45° and 0°
Multi-cortical anchorage and the proven apex design allow for high primary stability.

NobelProcera CAD/CAM system
NobelProcera abutments support the surrounding tissue with an individualized emergence profile using biocompatible materials.[30] Low micromotion, minimal settling and low risk of screw loosening.[31,32]

Trefoil™: the next full-arch revolution

Trefoil definitive and fixed solution for the mandible

For some edentulous patients, a fixed-removable implant-supported restoration is a viable, but not optimal, solution. In these cases, a fixed implant-supported prosthesis may be a better solution. Compared to fixed-removable solutions, fixed solutions offer improved function with a higher bite force, better retention and stability, avoidance of some disadvantages of removable solutions, including specific mucosal problems and the wear of components.[36] One new treatment approach, designed to offer the possibility of same-day (depending on clinician preference and close cooperation with the laboratory) rehabilitation of the edentulous mandible or a failing dentition in the lower jaw, is the revolutionary new Trefoil system.

The Trefoil system features a groundbreaking innovation—a pre-manufactured, passively fitting titanium bar with a novel fixation mechanism—which makes a fixed, full-arch restoration on three implants possible on the day of surgery (depending on clinician preference and close cooperation with the laboratory).

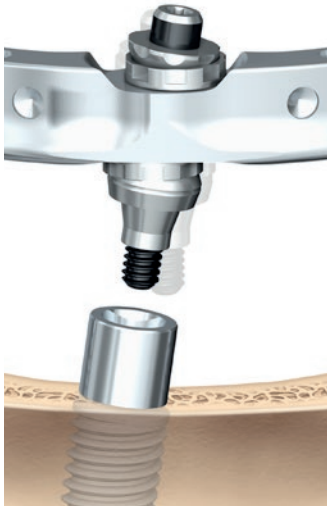
Among patients who have previously received similar restorations supported by three implants, implant survival rates of 96.7–100 % have been reported in several studies with various loading protocols and mean follow-up periods of up to 5 years.[37–44]

The pre-manufactured bar, anatomically designed for the natural arch of the mandible, contains adaptive joints that adjust to compensate for horizontal, vertical and angular deviations from the ideal implant position. The bar, together with a simplified clinical workflow, minimized componentry, and a standardized drill guide, is expected to result in significant savings in time and cost. As a result, clinicians may be able to offer an affordable restorative solution to more patients with an edentulous mandible or a failing dentition in the lower jaw.

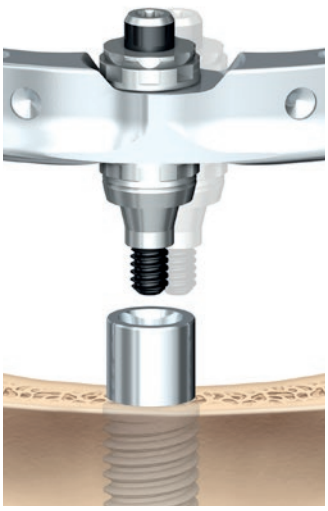
The Trefoil system offers the first pre-manufactured precision bar with a passive fit

The implants are designed with a machined collar for implant placement at tissue level, allowing easy access to the implant and leaving the soft tissue undisturbed throughout the entire workflow.

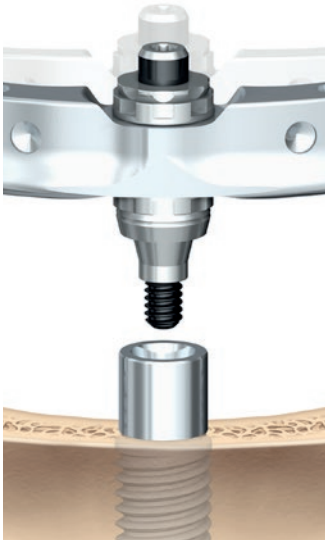
The ingenious fixation mechanism



Angular deviation



Horizontal deviation



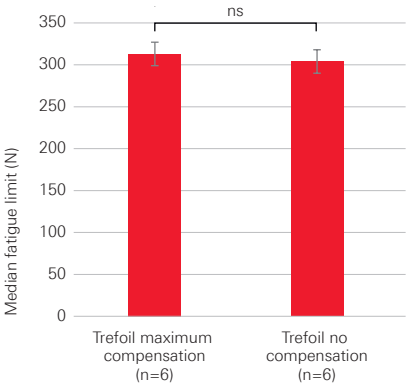
Vertical deviation

The maximum independent range of passive fit provided by the adaptive joint is: angular deviation ±4.0°, horizontal deviation ±0.4 mm and vertical deviation ±0.5 mm.

Each mechanism has five self-adjusting joints that help correct the position of the pre-manufactured bar, enabling the passive fit of the definitive prosthesis. The unique compensation mechanism supports resistance to mechanical fatigue within the full compensation range.[34]

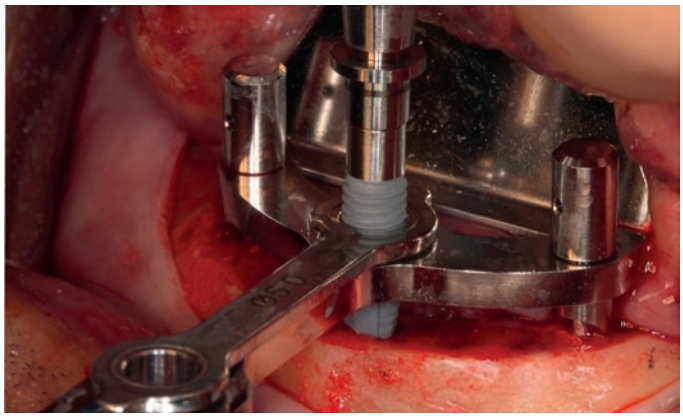
A prospective, multicenter clinical study across four continents is currently under way (ClinicalTrials.gov: NCT02940353; October 20, 2016). First results are expected to be published in October 2017.[45] At the request of participating clinicians seeking to better address the unmet clinical needs of their patients, this study was expanded from 90 patients to include a total of 110 patients.

The Trefoil system maintains its strength when pushed to the limit

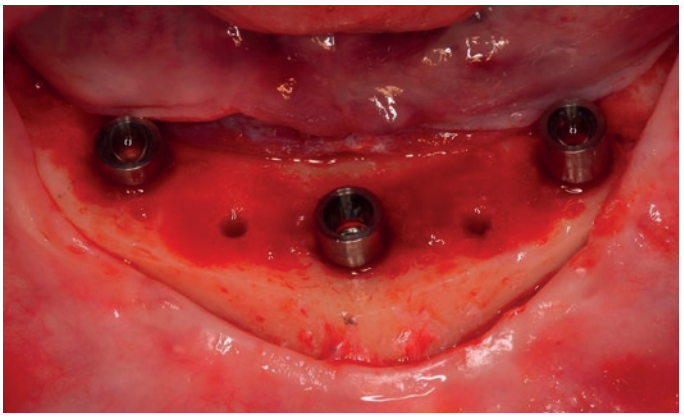


The test system showed no significant difference in fatigue resistance under no compensation versus maximum compensation conditions. Mean ± standard deviation; * $p \leq 0.05$; ns, not significant; two-sided two-sample t-test.[34]

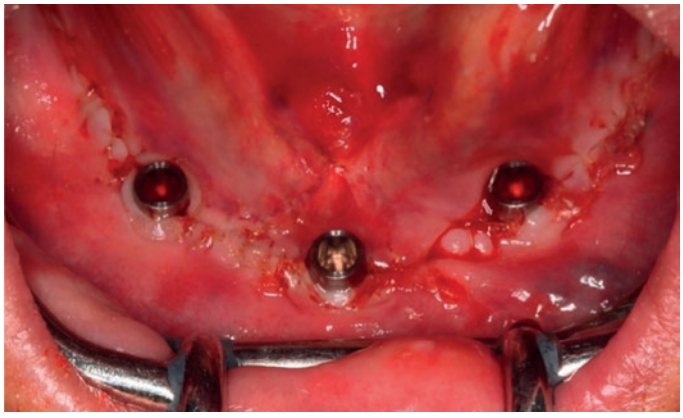
Clinical case – Trefoil treatment in a fully edentulous 82-year-old male



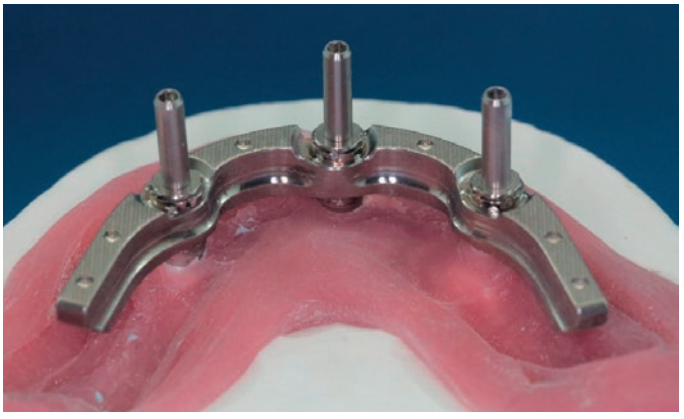
Insertion of three implants into the mandible using the Trefoil surgical guide.



Exposed mandible following implant insertion showing the three implants positioned between the mental foramen.

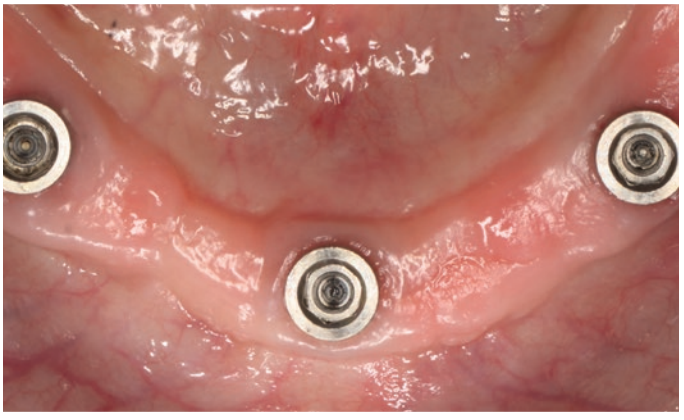


Soft tissue immediately following flap closure and suturing.



Wax-up for the construction of the acrylic prosthesis around the framework.

Wax-up for the construction of the acrylic prosthesis around the framework.



Excellent soft tissue health at 12-month review.

Images courtesy of Prof. Glen Liddelow and Michael Standish CDT, Australia.

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Scientific evidence

Offering a host of benefits over conventional dentures, implant-retained overdentures are widely accepted by edentulous patients.[1] The recent trend for retaining such overdentures with fewer implants – and loading the implants immediately after insertion – has been strongly supported by implants with a TiUnite surface.

Implant-retained overdentures with TiUnite-surface implants in fully edentulous patients have been documented in 16 studies with over 500 patients followed for up to 10 years.

Key findings

- Mean implant survival rate of 92.6 %[A] in 8 studies with restorations supported by 2 or more ball attachments with a follow-up of 1–10 years (see table on page 21)
- Very high mean implant survival rate of 99.1 %[A] in 5 studies with bar overdentures with a follow-up of 1–6.2 years (see table on page 21)
- High implant primary stability enables immediate-to-early loading.[2–4] Support and retention of the removable prosthesis by TiUnite surface implants is efficacious in both the maxilla[5] and the mandible.[6]
- Limited biological and technical complications.[7,8]
- Components such as implants are rarely affected by prosthetic complications, which are mostly related to the suprastructure.[8]

How many implants are enough?

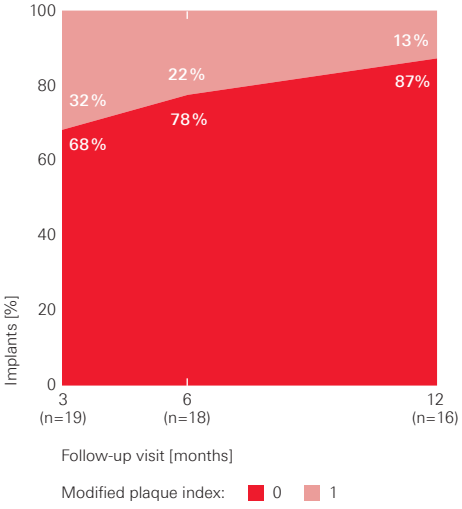
The use of two mandibular implants, either splinted with a bar[9] or connected to single-unit, retentive components, is a frequently applied concept for restoration of the edentulous mandible.[3] Expert consensus and evidence from systematic reviews supports the use of two-implant overdentures in the mandible[10–12] as a 'minimum standard' implant-supported restoration.[12] When it comes to the maxilla, there is an increased rate of implant loss when fewer than four implants with a non-splinted anchorage are used.[10] In a recent systematic review of 54 studies, Kern and coworkers concluded that four implants were needed in the maxilla to yield satisfying results with both fixed restorations and removable overdentures.[1]

Two-implant supported restorations in the mandible

In studies where pairs of TiUnite-surface implants have been used to retain implant overdentures using ball attachments, high mean implant survival rates have been observed (see table on page 21). Those reporting both implant and prosthesis survival show weighted mean survival rates of 97.4% and 97.6% respectively at 1-year follow-up.[3, 13, 14]

Prosthetic solutions utilizing overdentures retained by two ball attachments on TiUnite-surface implants have been shown to facilitate high levels of oral hygiene.[3] This, in turn, has been credited with minimal plaque formation, favorable peri-implant conditions and stable marginal bone levels after initial remodeling.[3] Complications are commonly limited to screw loosening, a need to replace the attachment matrices, cracks in the acrylic base, or loosening of the abutment on the implant.[13]

High levels of oral hygiene with two ball-retained overdentures

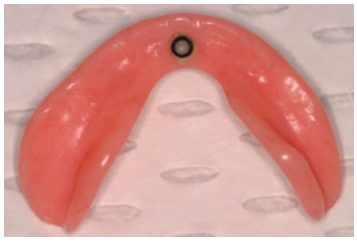


Negligible plaque accumulation was observed throughout the 1-year follow-up period, quantified by no significant change in Mombelli modified plaque index.[15] All implants had no detectable plaque (0) or minimal plaque (1) recognized only by running a probe across the smooth marginal surface of the implant. n = number of implants.[3]

The use of a single implant in the mandibular midline has also been investigated, albeit with limited clinical success. In one study, Liddelow and Henry observed high rates of patient satisfaction, with significant increases in comfort and function, over a 3-year observation period.[16] However, unexpectedly low implant survival rates have been observed in another study where only a single implant has been used to support a mandibular overdenture.[17]

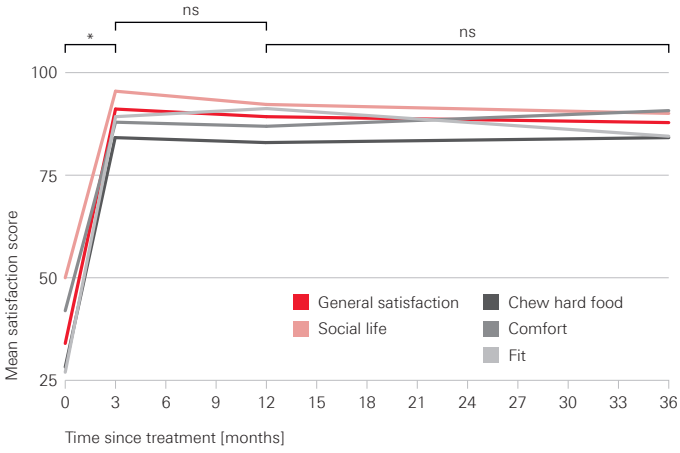
A Weighted by number of initially placed implants

Single TiUnite-surface implants performed better than single machined implants when immediately loaded with a mandibular overdenture



A denture with a retentive element.

Images courtesy of Prof. Glen Liddelow, Australia.

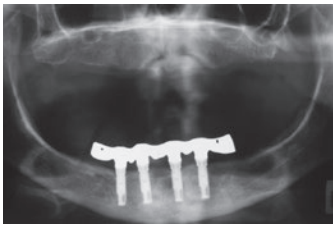


Patients reported a significant immediate improvement in satisfaction (assessed at three months) which was sustained, as well as significant functional improvements in chewing, comfort and fit following treatment. * $p \leq 0.05$; ns, not significant; one-way ANOVA.[6]

The splinted approach and CAD/CAM implant bars

Bar retention is an alternative to a fixed, full-arch prosthesis in patients with severe resorption to avoid bone augmentation. By splinting implants in a tripod arrangement, three implants have been used to support mandibular dentures with no implant failures at two years and enabling favorable peri-implant parameters.[18] With four TiUnite-surface implants supporting a mandibular overdenture bar, favorable results for marginal bone-level change and peri-implant soft tissue parameters (modified plaque index 67 %, bleeding on probing 17 %, probing pocket depth 2.56 mm ± 0.28 mm) have been observed.[19]

Restoring the edentulous mandible with a bar overdenture on four implants



Example of an edentulous mandible restored with four axially placed implants supporting gold alloy bar. The design of the bar is conducive to oral hygiene measures ensuring healthy peri-implant conditions.[19]

Computer-aided design/computer-aided manufacturing (CAD/CAM) technology with use of modern implants show good outcomes in an ongoing prospective study involving 73 patients treated with 292 NobelReplace Conical Connection implants and NobelProcera CAD/CAM bars.[20] After one year, the cumulative survival rate of the implants was 98.8 % while 100 % of all restorations survived.

Pozzi et al restored 18 consecutive patients with class IV-VI resorption (Cawood and Howell) with an anatomically designed CAD/CAM titanium bar and a removable overdenture, all supported by 4 NobelReplace CC implants. Maxillae and mandibles were restored, both with 100 % implant and prosthetic survival rates at one year.[21] As a solution for both jaws, patients reported great satisfaction and significantly improved oral-health-related quality of life.[21] Pozzi et al. also showed outstanding hard tissue response with CAD/CAM titanium bars, limited to -0.29 mm ± 0.16 mm at one year.[21]

Immediate loading: successful with implant-retained overdenture solutions

Two independent clinical studies with TiUnite-surface implants followed for five years[22] and seven years[4] demonstrated that immediate loading is predictable whether using bar or ball attachments. Either option led to continued patient satisfaction and no difference in marginal bone-level change as compared to delayed loading.

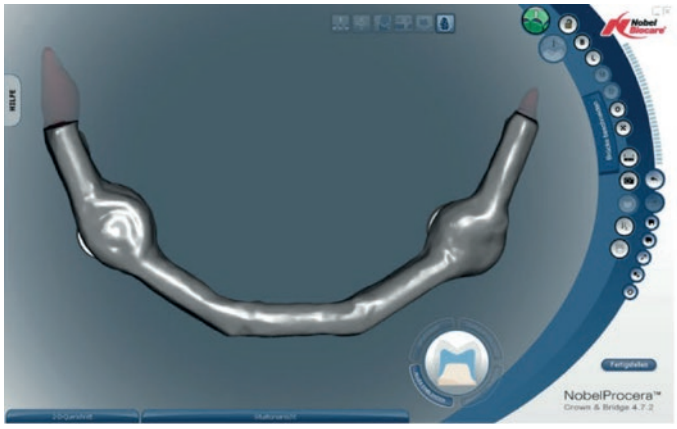
The advantage of CAD/CAM titanium bars

In a retrospective analysis of 213 edentulous patients who received 276 titanium CAD/CAM NobelProcera and 112 conventionally fabricated soldered gold bars, NobelProcera showed fewer complications overall.[8] Gold bars typically fractured distal of the gold abutment at the solder joints, indicating that the fabrication method of the bar influences clinical complication rates. With respect to biological complications, patients experienced a significantly lower rate of mucosal hyperplasia with CAD/CAM implant bars versus gold bars (8 % versus 65 %, respectively).[7]

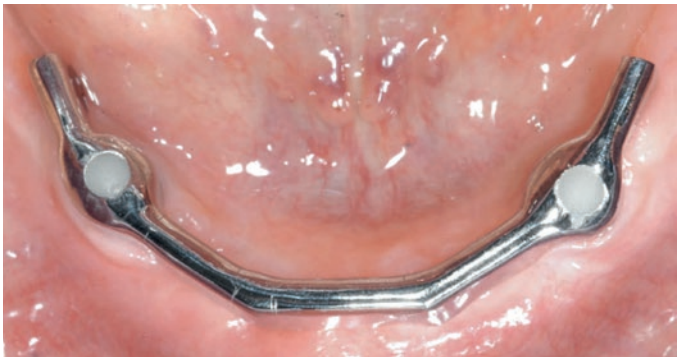
Moreover, the high precision of CAD/CAM implant-supported bars and their individualized design leads to excellent clinical performance.[8,21]

Bar-retained overdentures

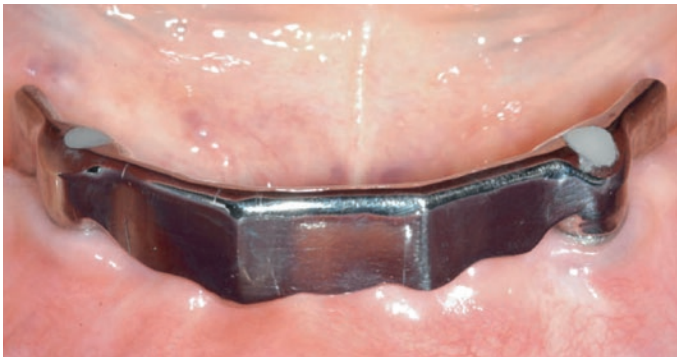
The images below and right show the restorative workflow for a mandibular bar-retained complete denture using CAD/CAM fabrication. Virtual planning allows for adequate dimensions of the bar even when cantilever sections are included.[8]



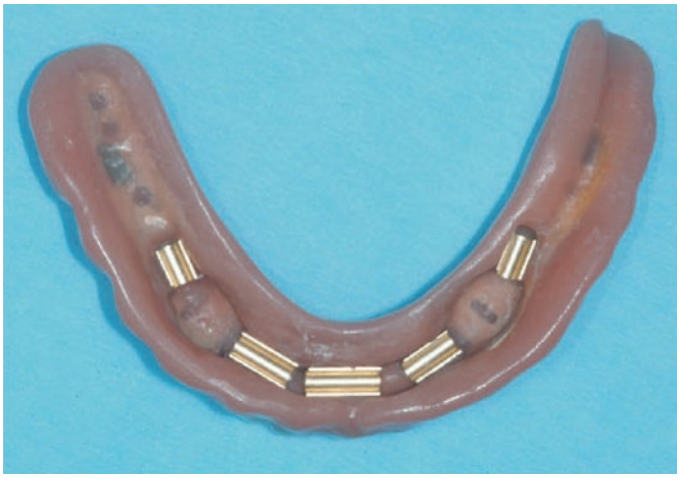
Computer-assisted designing of the CAD/CAM bar.



Occlusal view of a CAD/CAM titanium bar in situ. Access holes were covered with acrylic composite material.

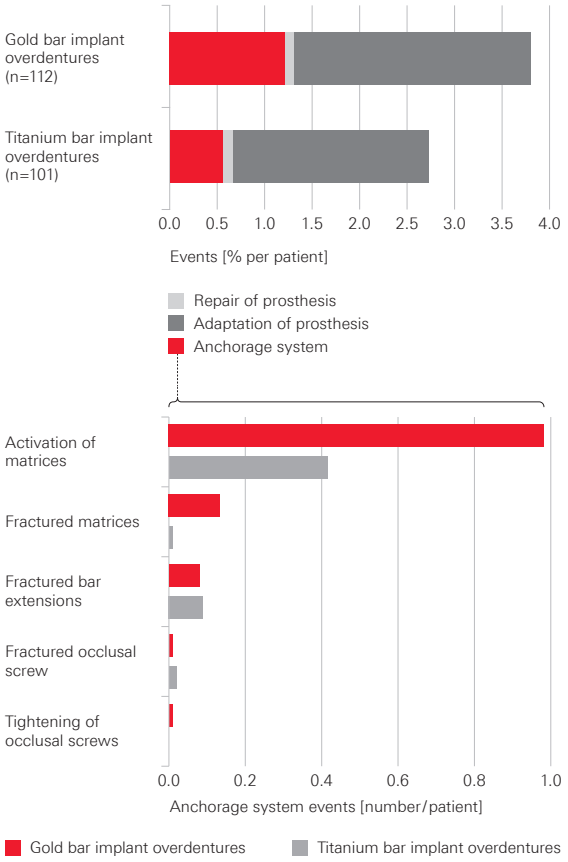


Frontal view of a CAD/CAM titanium bar with an individualized vertical height.



Internal view of a bar-retained implant overdenture with the prefabricated female retainers.

Fewer complications with Nobel Biocare CAD/CAM titanium bars compared with traditional soldered gold bars



Percentage of prosthetic complications observed in bar-retained mandibular complete dentures during a 3- to 4-year observation period. The use of NobelProcera titanium bars versus gold bars resulted in significantly lower fracture rates for bar extensions and matrices.[8]

Overview of studies

The following overview includes clinical studies on fixed-removable restorative solutions supported by TiUnite-surface implants. The studies are grouped by the type of retention – ball attachment, titanium or gold bar, and Locator® attachment.

Only peer-reviewed publications are listed. Meeting abstracts, reviews, single case reports, technique descriptions and animal and in-vitro tests are excluded. The total number of TiUnite-surface implants and patients included in this overview is over 1,500 and 550 respectively, with mean implant and prosthetic survival rates of 95.5 % and 92.9 %, respectively.[A]

For more information on these studies visit PubMed at pubmed.gov.

Reference	Mean follow-up time [years][B]	Study type	Indication	Implant type[C]	No. of implants	No. of patients	Implant survival rate [%]	Prosthesis survival rate [%]
Ball attachments								
Ma et al., 2015[5] **Payne et al., 2004[23]**	10	Prospective	Maxilla, fully edentulous	Brånemark System TiUnite	60	20	91.7[D]	NR
Turkyilmaz et al., 2006[24] **Turkyilmaz et al., 2006[25]** **Turkyilmaz et al., 2012[4]**	7	Prospective	Mandible, fully edentulous	Brånemark System Mk III TiUnite	52	26	100	NR
Lal et al., 2013[26]	3	Retrospective	Maxilla and mandible, fully edentulous	Brånemark System Mk III	273	36	83.5	100
Kronstrom et al., 2014[17] **Kronstrom et al., 2010[2]**	3	Prospective	Mandible, fully edentulous	Brånemark System TiUnite	55	36	81.8	100[D]
Liddelow et al., 2010[6] **Liddelow et al., 2007[16]**	3	Prospective	Mandible, fully edentulous	Brånemark System Mk III TiUnite	25	25	100	87.0[D]
Katsoulis et al., 2011[7]	2.5	Retrospective	Maxilla, fully edentulous	Replace Select Tapered	193	41	100[D]	NR
Turkyilmaz et al., 2006[27] **Turkyilmaz et al., 2006[28]** **Turkyilmaz et al., 2007[29]**	2	Prospective	Mandible, fully edentulous	Brånemark System Mk III TiUnite	40	20	100	NR
Marzola et al., 2007[13]	1	Prospective	Mandible, fully edentulous	Brånemark System Mk III	34	17	100	100
Botos et al., 2011[14]	1	Prospective	Mandible, fully edentulous	Replace Select	30	15	96.7[D]	93.3[D]
Liao et al., 2010[3]	1	Prospective	Mandible, fully edentulous	Replace Select TC	20	10	94	100[D]
Titanium or gold bars								
Katsoulis et al., 2015[8]	6.2	Retrospective	Maxilla and mandible, fully edentulous	Replace Select Tapered	477	213	99[D]	89.7[D]
Alfadda et al., 2009[22] **Attard et al., 2005[30]**	5	Retrospective	Maxilla and mandible, fully edentulous	TiUnite (brand not specified)	70	35	98.4	NR
Watzak et al., 2006[19]	2.8	Retrospective	Mandible, fully edentulous	Brånemark System Mk III TiUnite	60	16	98.4	NR
Stephan et al., 2007[31]	1	Prospective	Mandible, fully edentulous	Brånemark System Mk III	78	26	100	NR
Pozzi et al., 2016[21]	1.4	Prospective	Mandible, fully edentulous	NobelReplace CC	72	18	100	100
Locator® attachment								
Emami et al., 2015[32]	0.3	Prospective	Mandible, fully edentulous	Brånemark System Mk III TiUnite	72	24	NR	NR

Source: Nobel Biocare data on file (TiUnite Rep 134625, last search December 15, 2016), updated with Nobel Biocare database and PubMed search results for publications in 2016-2017.

A Arithmetic means weighted by number of initially placed implants (implant survival rate) or number of patients treated (prosthetic survival rate)

B Where the mean follow-up time was not available the reported follow-up time was used

C Minimum 10 implants; Non-TiUnite implants are not reported in this table

D The percentage of surviving implants/prostheses was calculated

NR Not reported

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Scientific evidence

The All-on-4® treatment concept is a cost-efficient, graftless solution that uses just four implants to provide patients with a provisional fixed full-arch prosthesis on the day of surgery. With the first treatment performed by Dr. Paulo Maló in 1998, this efficient and effective concept has since demonstrated high survival rates and stable marginal bone levels. TiUnite-surface implants, which exhibit fast osseointegration and usually foster a healthy peri-implant soft tissue, are particularly suitable for use with this solution.[1]

The All-on-4® treatment concept retained with TiUnite-surface implants has been documented in 37 clinical studies with over 10,500 implants placed in more than 2,600 patients.

Key findings

- Proven long-term solution – up to 7.5 years mean follow-up in the mandible and 7.0 years mean follow-up in the maxilla for the All-on-4® treatment concept retained using TiUnite-surface implants[2] (see table on page 35).
- Excellent mean implant survival of 98 %[A] in 37 studies with a follow-up of 1–7.5 years (see table on page 35).
- High mean prosthesis survival of 98.3 %[B] in 33 studies with a follow-up of 1–7.5 years (see table on page 35).
- Optimized use of existing bone and maximized anterior–posterior spread of the implants.[3–6]
- Substantially reduced time and cost in comparison to alternative full-arch rehabilitation reported in a study in the USA.[7]
- High patient satisfaction, with phonetic, masticatory and esthetic outcomes at one year being rated excellent or very good by up to 78 %, 91 % and 83 % of patients, respectively.[8, 9]

Introduction to the All-on-4® treatment concept

In 1998, Dr. Paulo Maló and coworkers first performed a type of restoration that later became known as the All-on-4® treatment concept. The All-on-4® treatment concept involves immediate loading of four implants in the edentulous jaw, using two axial implants in the anterior and two tilted implants in the posterior, with a fixed, full-arch prosthesis.[3] The use of tilted posterior implants in the All-on-4® treatment concept is beneficial in several respects. Tilted implants make maximum use of the existing bone, placing posterior fixed teeth with minimum cantilever in a region where bone height would not be sufficient for implant placement. The use of tilted implants is key for this rehabilitation concept and allows: the implant length to be enlarged; the avoidance of critical anatomical structures such as nerves or the sinus; and, the implant support to be moved posteriorly. The latter allows for a favorable inter-implant distance, and minimal cantilevers. In the maxilla, the implant is able to follow a dense bone structure (anterior wall of maxillary sinus) and reach high-density bone in the anterior maxilla, thereby enhancing primary stability.[4]

Moreover, using finite element analysis, it is possible to conclude that there is a biomechanical advantage in using splinted tilted distal implants rather than axial implants supporting distal cantilever units when comparing the coronal stress.[10]

Depending on the degree of resorption, the posterior implant head will emerge at different positions at the bone crest, normally between the first premolar (high resorption) and the first molar (moderate resorption).[11] Tilted implants, therefore allow the mandibular canal and maxillary sinus to be avoided and also reduce the need for graft procedures.[3–5]

As a result, Dr. Maló's one-stage procedure substantially reduced the time and cost needed to deliver a four-implant-supported fixed restoration versus conventional full-arch rehabilitation.[7] The All-on-4® treatment concept has since come into widespread use and has been documented in a significant body of literature.

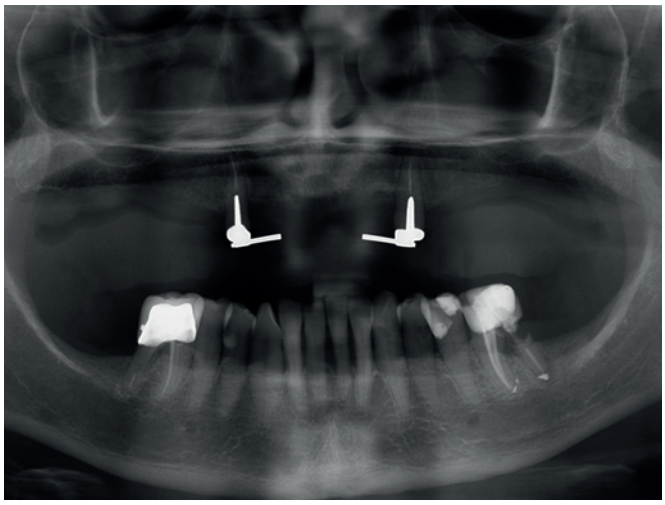
Use of the All-on-4® treatment concept in rehabilitation of a complete edentulous maxilla

In the rehabilitation shown here, the axially placed implants emerge slightly palatal to the central maxillary incisors while the tilted posterior implants emerge in the region of the first molar. It should be noted that no posterior cantilever is present through the illustrated approach.[12]

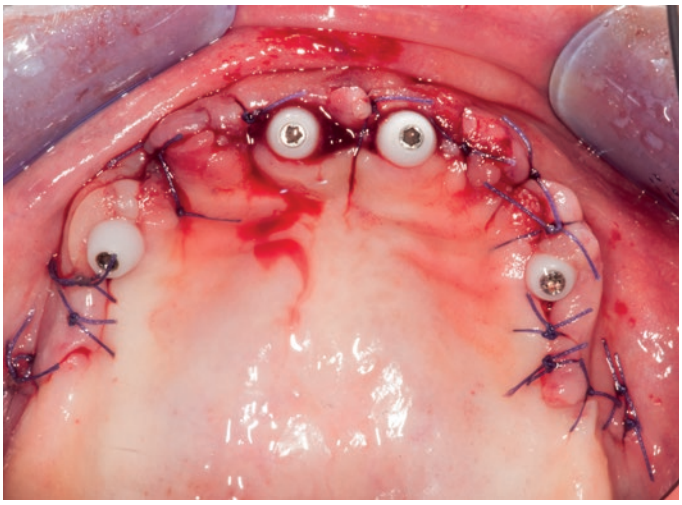
The All-on-4® treatment concept is suitable not only in healed edentulous ridges, but has also shown effectiveness in compromised situations where fenestrations and dehiscence are present, as well as in fresh extraction sockets.[13–15]

A Weighted by number of initially placed implants
B Weighted by number of patients treated

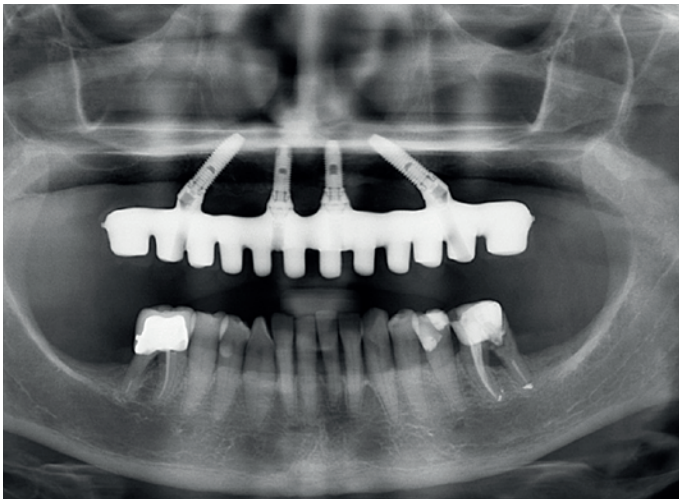
Minimally invasive extraction of both canines to facilitate maxillary full-arch restoration using the All-on-4® treatment concept



Orthopantomograph showing residual maxillary canines supporting a removable complete prostheses.



Healing caps are placed over the abutments to prevent the collapse of the gingiva after the suture.



Orthopantomograph with the final rehabilitation at three-year recall.

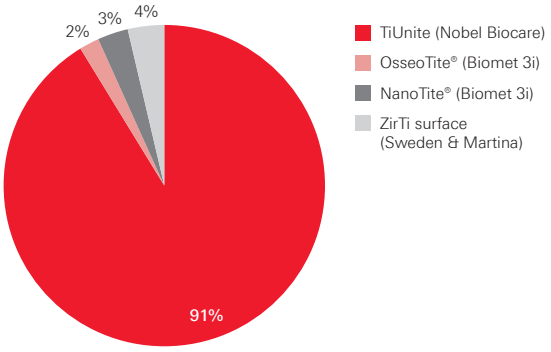
Images courtesy of Dr. Enrico Agliardi, Italy.

TiUnite-surface implants – the implants of choice for the All-on-4® treatment concept

In 2014, using a systematic review methodology, Patzelt and coworkers investigated the long-term success of the All-on-4® treatment concept.[16] From a total of 487 screened publications, 13 papers met their inclusion criteria for quality and completeness of reporting. These 13 studies reported outcomes with 4,804 implants placed in 1,201 jaws, according to the All-on-4® treatment concept.

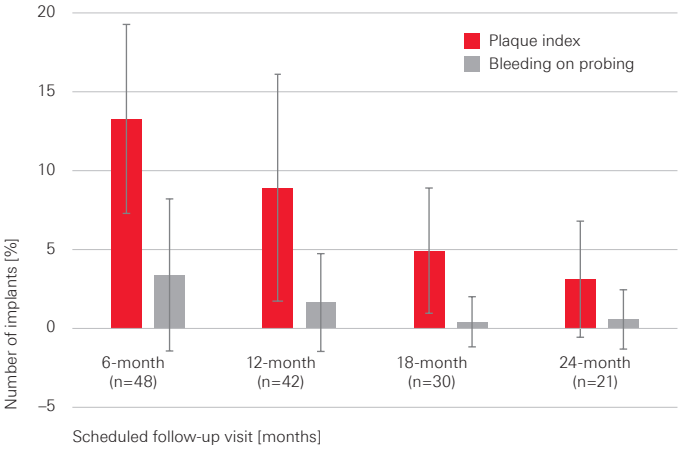
Over 91 % of the implants documented in the systematic review by Patzelt and coworkers were manufactured by Nobel Biocare and had a TiUnite surface.[16] Their meta-analysis of the published results determined the 36-month implant survival rate to be 99.0 % and the prosthetic survival to be 99.9 %.[16] These excellent results led the authors to advocate the All-on-4® treatment concept as an important strategy to "minimize treatment costs and patient morbidity while providing the most-satisfying patient-centered treatment outcomes according to the state of the art of the dental practice".[16] In a more recent systematic review by Soto-Peñaloza, a high survival rate was also reported (99.8 % at longer than 24 months). As well, as few biological complications (e.g. peri-implantitis) after a mean follow-up of two years.[17]

TiUnite-surface implants shown to be the predominant surface in the All-on-4® treatment concept



A systematic review of clinical studies describing the All-on-4® treatment concept shows that Nobel Biocare implants with the TiUnite surface are predominantly used for this type of full-arch dental restoration.[16]

Oral hygiene and peri-implant health indicators improve steadily over time after rehabilitation with the All-on-4® treatment concept



62 patients treated with the All-on-4® treatment concept showed marked improvement in plaque index and concurrently bleeding on probing over a 2-year follow-up period.
n = number of patients. Mean ± standard deviation.[1]

Bone response

Several studies have evaluated marginal bone remodeling around TiUnite-surface implants placed according to the All-on-4® treatment concept (see table on page 35).

Where changes in marginal bone levels were reported both at one year post-implantation and at a later time follow up time, a pattern emerges of bone levels that are generally maintained in a steady state after the first year following implantation.[18] The consensus statement following the 2007 Conference of the International Congress of Oral Implantologists, which took place in Pisa, Italy, defined <2 mm of radiographic bone loss from initial surgery as a marker of clinical success.[19] By this measure, the mean marginal bone changes observed in studies of TiUnite-surface implants placed according to the All-on-4® treatment concept comfortably fall within this range.

Another set of success criteria, those published by Zarb and Albrektsson,[20] permit 0.2 mm mean vertical bone loss annually following the first year of function. Of the studies published to date on TiUnite-surface implants placed according to the All-on-4® treatment concept, two studies report longitudinal data on marginal bone levels.[21,22] Both studies report mean rates of annual bone losses within this range with up to 7 years of follow up.

Only one study reported ongoing marginal bone loss with the All-on-4® treatment concept.[23] In this 20-patient study, the mean bone loss between the 1-year and 3-year assessments was reported to be –0.48 mm (SD 0.66; range -1.2 to -3.6), albeit with 100 % implant survival. The authors suggested that overloading and surgical aspects might warrant further investigation as possible explanations for the observed bone level changes and also highlighted that there was no control group to determine the effect of the surgical procedures used.[23]

Several aspects may contribute to marginal bone loss, including clinician and patient factors, as well as implant characteristics (macro-morphology and prosthetic connection) and prosthetic aspects (materials and fit). The balance of evidence on TiUnite-surface implants, placed according to the All-on-4® treatment concept, points towards very good long-term clinical results with maintained bone levels.[24]

Clinical outcomes for tilted and axial implants

Several studies have included comparisons of clinical outcomes between tilted and axial TiUnite-surface implants placed according to the All-on-4® treatment concept (see table below).

Most of these studies show no clinically relevant differences in marginal bone loss or rates of implant survival between tilted and axial implants.

Tilted versus axial implants followed for at least 1 year

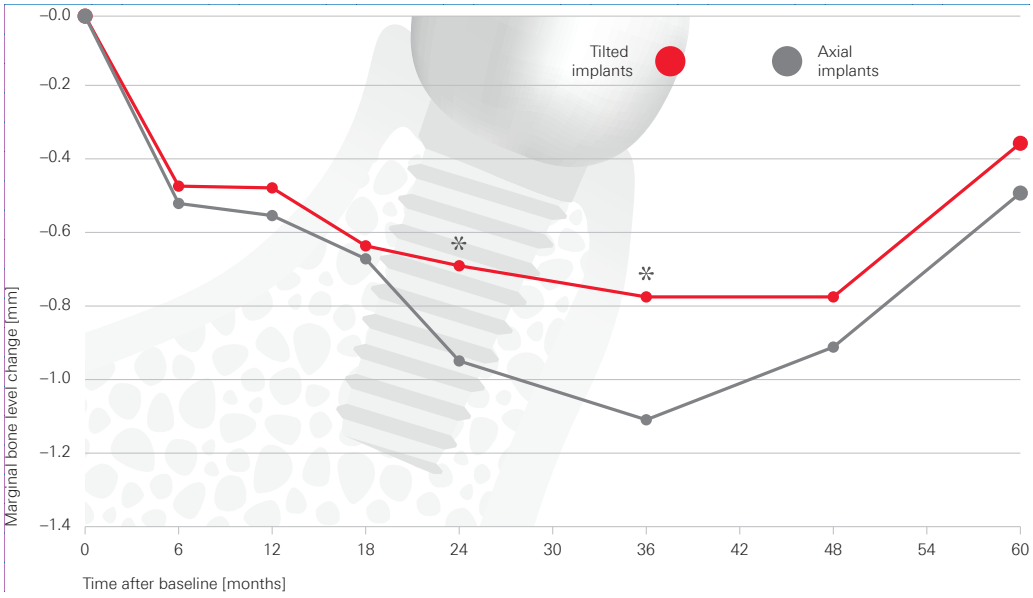
Study	Mean follow-up [years][A]	No. of implants/ patients	Tilted or axial	Implant type[B]	Mean bone level change [mm]	Implant survival rate [%]
Maló et al., 2016[25]	5	532/111	Axial	NobelSpeedy	NR	NR
			Tilted	NobelSpeedy	NR	NR
Pozzi et al., 2012[26]	3	52/27	Axial	Nobel Speedy Replace, Nobel Speedy Groovy	–0.5	NR
			Tilted	Nobel Speedy Replace, Nobel Speedy Groovy	–0.6	NR
Drago, 2016[27]	2	766/129	Axial	NobelActive	NR	95.6
			Tilted	NobelActive	NR	99.5
Weinstein et al., 2012[8]	1	72/18	Axial	Brånemark System Mk IV, NobelSpeedy Groovy	–0.6	100
			Tilted	Brånemark System Mk IV, NobelSpeedy Groovy	–0.7	100
Galindo et al., 2012[28]	1	732/43	Axial	NobelSpeedy Groovy, NobelActive	≤ –1	99.7[C]
			Tilted	NobelSpeedy Groovy, NobelActive	≤ –1	100[C]
Agliardi et al., 2010[9]	1	96/24	Axial	Brånemark System Mk IV, NobelSpeedy Groovy	–0.9	100
			Tilted	Brånemark System Mk IV, NobelSpeedy Groovy	–0.8	100
Francetti et al., 2008[1]	1	248/62	Axial	NobelSpeedy Groovy	–0.7	100
			Tilted	NobelSpeedy Groovy	–0.7	100

Between study comparisons are not valid due to differences in baseline reporting. Source: Nobel Biocare data on file (TiUnite Rep 134625, last search December 15, 2016).
A Where the mean follow-up time was not available the reported follow-up time was used (minimum one-year follow-up)
B Minimum 10 implants; Non-TiUnite implants are not reported in this table
C The percentage of surviving implants/prostheses was calculated
NR Not reported

For example, medium-term follow-up of TiUnite-surface implants in a prospective analysis including 62 patients followed for a mean of 22.4 months,[1] or a retrospective analysis including 69 patients followed for a mean of 33.7 months, showed no difference between bone remodeling at axial versus tilted implants.[29] Indeed, in a systematic review, which included evaluation of marginal bone around axial versus tilted implants after 1–3 years of function, no significant differences were observed in crestal bone level changes.[16]

Rates of failure for tilted implants versus axial implants are also comparably low. In the 16 studies that investigated both implant survival and bone remodeling, representing more than 4,500 TiUnite-surface implants in nearly 1,000 patients, the weighted mean survival rates for axial and tilted implants were 98.2 % and 98.9 %, respectively. The two implant orientations also showed no influence on marginal bone response (weighted mean bone remodeling of –1.02 mm for the axial and –1.07 mm for the tilted implants).

Favorable bone remodeling for both tilted and axial implants



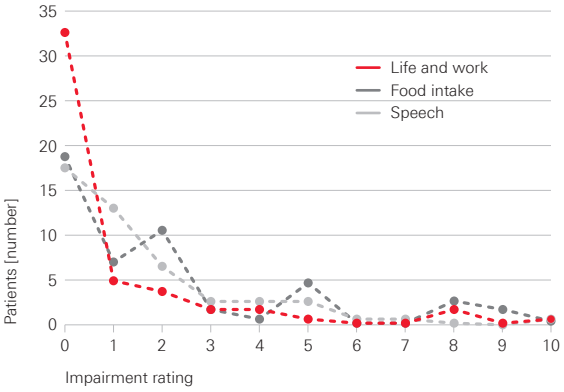
Implants immediately loaded with radiographic baseline set at time of insertion. Therefore, all bone remodeling was reported. Results for the mandible are shown, which are similar to the results for the maxilla. * Statistically significant difference for tilted versus axial ($p \leq 0.05$).[30]

High patient satisfaction

Edentulous patients who receive restorations according to the All-on-4® treatment concept exhibit high levels of satisfaction with their functional and esthetic outcomes. In two studies, which evaluated patient satisfaction with phonetics, mastication and esthetics after one year, these factors were rated excellent or very good by up to 78 %, 91 % and 83 % of patients, respectively.[8,9]

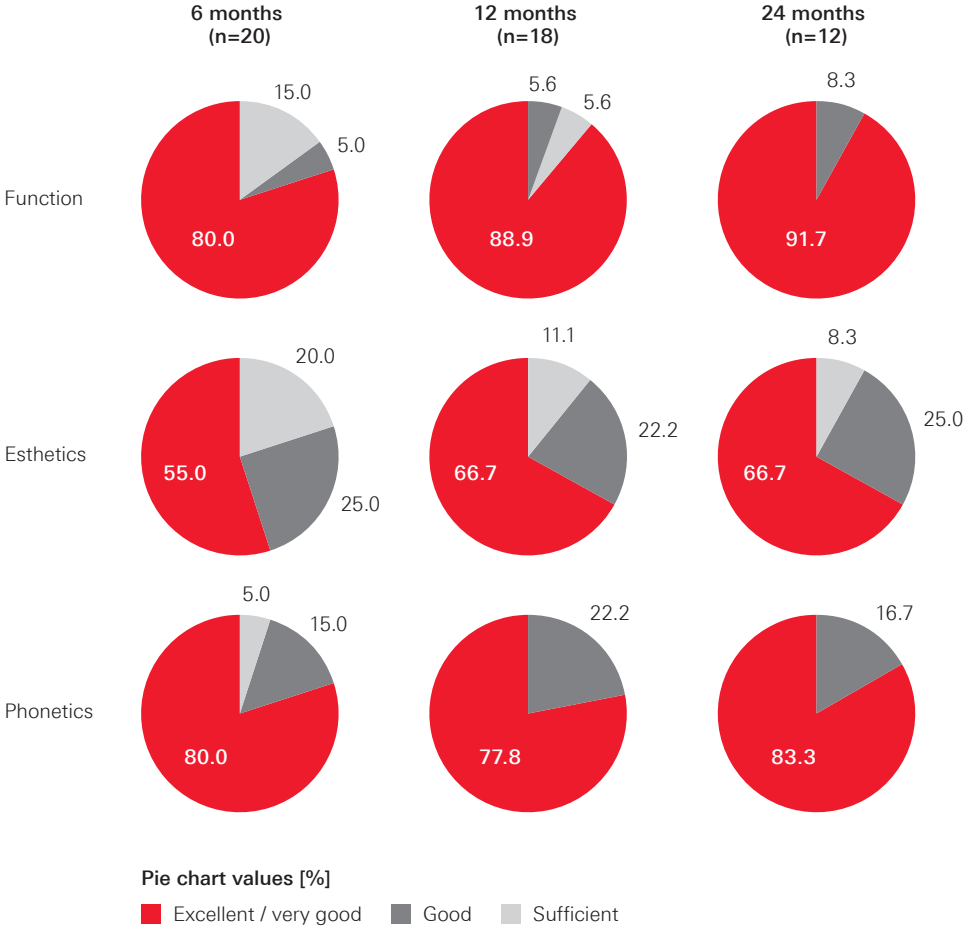
In a separate study of 50 patients transitioned from a failing dentition to a restoration with the All-on-4® treatment concept in either the maxilla or in the mandible, the majority were back to normal life one week after surgery, while food intake and speech posed a minor problem in about half of the patients.[15] In another study, the improvement in oral health-related quality of life was significant two months after surgery.[31]

Low functional impairment one week after restoration according to the All-on-4® treatment concept



One week after immediate transition from a failing dentition to a fixed implant-supported full-arch restoration according to the All-on-4® treatment concept, the majority of patients did not feel any impairment in daily life and work. Food intake and speech required a longer adaptation period.[15]

Continued high patient satisfaction with the All-on-4® treatment concept

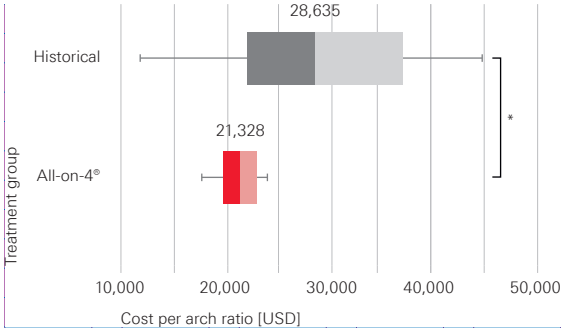


Patient satisfaction in response to the All-on-4® treatment concept, as reported in a prospective study of 20 patients with extreme mandibular atrophy rehabilitated with TiUnite-surface implants.[8]

Low and predictable treatment costs

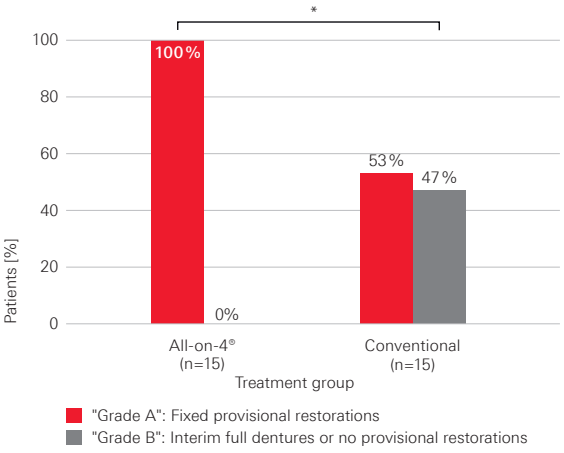
Analyzing data from 30 patients who received restorations according to the All-on-4® treatment concept, Babbush and coworkers[7] compared the associated costs of treatment with those from historical concepts that used varying numbers of implants. They found that the All-on-4® treatment concept was associated with lower costs – most likely due to fewer surgeries per patient. In addition, while it is difficult to compare the quality of provisional dental restorations between treatment concepts, the study claimed a clear trend towards higher quality in those provided with the All-on-4® treatment concept.

Costs for the All-on-4® treatment concept in comparison to historical prosthetic restorations of edentulous patients



Comparison of cost-per-arch ratio for the All-on-4® treatment concept with that of a variety of historical treatment options in the USA. Both the median cost as well as the variation of the treatment cost were lower with the All-on-4® treatment concept. * $p \leq 0.05$.[7]

Provisional dental restorations used in conventional restorations and the All-on-4® treatment concept



All patients treated according to the All-on-4® treatment concept were temporarily restored with fixed restorations. By contrast, 47% of patients in the conventional treatment group either had no provisional restoration or a removable prosthetic appliance. n = number of patients. * $p \leq 0.05$; Mann-Whitney ranked test.[7]

The All-on-4® treatment concept or a fixed dental prosthesis anchored on six implants?

The 2014 Foundation for Oral Rehabilitation (FOR) Consensus Conference on the treatment of edentulous patients concluded from the available literature that "In the maxilla, the placement of two frontal axial implants and two distal tilted implants leads to high survival rates. The placement of supplementary implants, just to avoid revision surgery should a failure occur, does not seem reasonable anymore".[32]

The debate over whether four or six implants are the optimal number on which to anchor a fixed dental prosthesis in edentulous patients has long been a topic for discussion. Long-term implant and prosthesis survival rates between four-implant versus six-implant solutions are similar. In a randomized clinical trial, comparing edentulous maxilla patients rehabilitated with the All-on-4® treatment concept or "All-on-6" implants, no differences in implant survival, bone remodeling or biological and technical complications were found.[21]

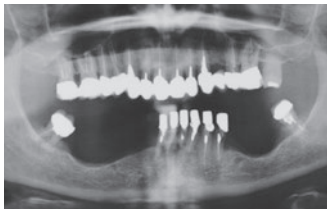
In a prospective study of 40 patients followed up for 5 years there were no statistically significant differences for any of the tested parameters, including implant and prosthesis survival, bone remodeling, technical and biological complications, or soft tissue parameters.[21] Similarly, in a retrospective analysis of 30 patients, 1-year implant and prosthetic survival were high and comparable in both treatment groups.[33] However, these findings should be interpreted with caution due to the limited number of patients included.

While non-significant, some authors have reported a tendency towards lower implant survival rates in the maxilla compared to the mandible with the All-on-4® treatment concept.[5, 34–36] In a retrospective review of 285 maxillary rehabilitations (1,140 implants) that used a tilted-distal, four-implant approach, Parel and Phillips investigated the risk factors associated with implant failure.[5] For 85 % of the 41 implants that failed, poor bone density was identified as a primary or secondary contributor to implant loss.

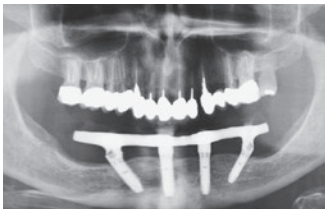
Whether a patient has adequate bone quantity is an important consideration in the rehabilitation of edentulous jaws using implants in immediate function.[37] While their patient numbers and implant failure rates were relatively small, Parel and Phillips initiated a profiling approach to later treatment planning, in which 59 patients considered at significant risk for implant failure were reevaluated for an alternative restorative solution.[5] Among these patients, the application of an alternative protocol, such as immediate loading of a prosthesis supported by more than four implants, decreased the rate of primary implant failures to zero. In another study of 16 patients, Maló and coworkers observed that implants of 20–25 mm length were beneficial in cases of reduced bone quality.[37] Such longer implants may benefit from increased stability, due to a greater implant–bone interface.[37]

Immediate rehabilitation of the edentulous jaws with full fixed prostheses supported by four implants: interim results of a single cohort prospective study

Agliardi E, Panigatti S, Clericò M, Villa C, Maló P
Clin Oral Implants Res 2010;21(5):459–65


Pre-operative panoramic radiograph


Post-surgical panoramic radiograph


Panoramic radiograph with final prosthesis


Final CAD/CAM Procera

Summary of the study

In this cohort prospective study, clinical and radiographic outcomes of immediately loaded full-arch fixed prostheses supported by a combination of axially and tilted positioned implants were investigated.

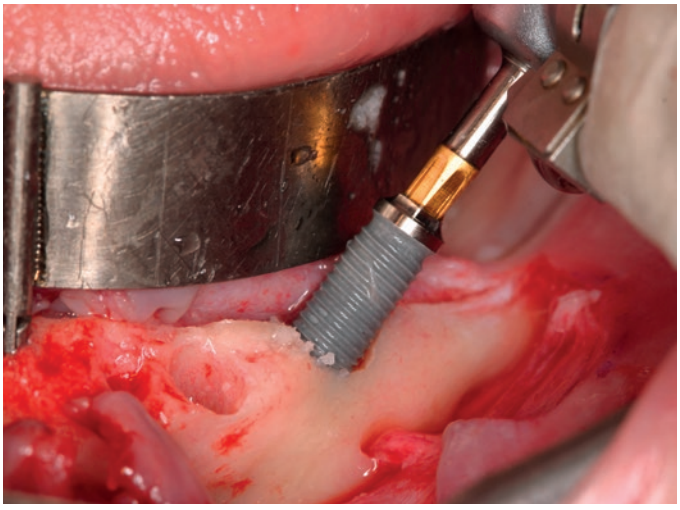
Edentulous patients received a full-arch fixed prosthesis supported by two distal tilted implants and two anterior axially placed implants (Brånemark System Mk IV or NobelSpeedy Groovy). Provisional functional acrylic prostheses were delivered the same day as surgery and all cases were finalized 4–6 months later. Follow-up visits were scheduled at 6 and 12 months, and annually thereafter, for up to 5 years. At follow-up, plaque and bleeding score assessments and radiographic evaluations were performed.

From 173 cases, 154 patients met inclusion criteria and were included in the analysis. Four axially placed implants failed in the maxilla and one tilted implant failed in the mandible; all within 6 months of loading. No further implant failures were observed. Implant survival rates at 1 year were 98.36 % and 99.73 % for the maxilla and the mandible, respectively, and these rates were sustained for up to 5 years. Marginal bone loss at 1 year averaged 0.9 mm ± 0.7 mm in the maxilla (204 implants) and 1.2 mm ± 0.9 mm in the mandible (292 implants). No differences in the degree of marginal bone loss were observed between axial and tilted implants. Plaque and bleeding scores progressively improved from 6–12 months. Fracture of the acrylic prosthesis occurred in 14 % of cases.

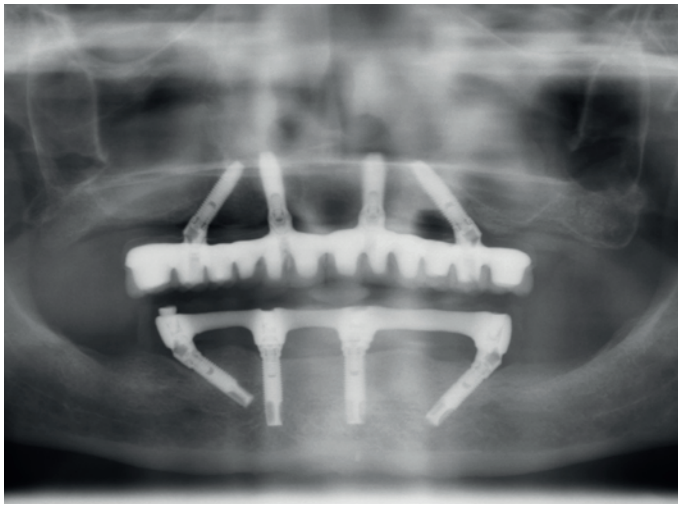
These observations from a relatively large population suggest that immediately loaded full-arch fixed prostheses, when supported by a combination of axially and non-axially positioned implants, are a viable treatment option for the immediate rehabilitation of both jaws.

A longitudinal study of the survival of All-on-4 implants in the mandible with up to 10 years of follow-up

Maló P, de Araújo Nobre M, Lopes A, Moss SM, Molina GJ
J Am Dent Assoc 2011;142(3):310–20



Intraoral photograph of a patient's posterior implant placement with a 30° inclination



Orthopantomographic scan of the same patient who was rehabilitated using the All-on-4® treatment concept

Summary of the study

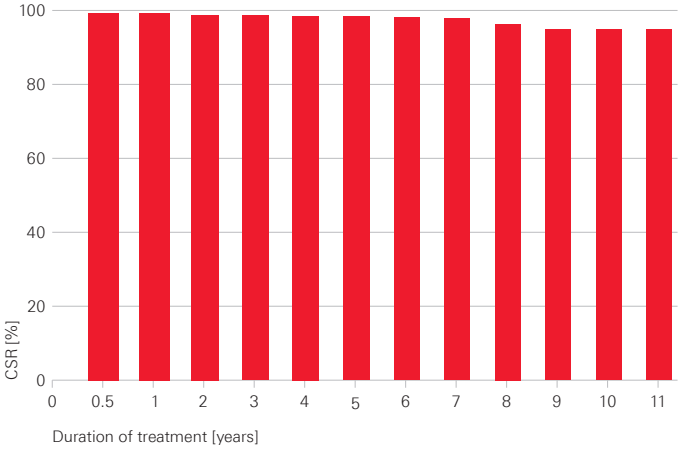
In this retrospective, longitudinal study, long-term clinical outcomes in patients with an edentulous mandible rehabilitated using the All-on-4® treatment concept to support a fixed prosthesis, were investigated.

This study included 245 patients with an edentulous mandible, or a mandible with hopeless teeth in need of fixed-implant restorations. Patients received a total of 980 implants, all placed according to the All-on-4® treatment concept and immediately loaded to support fixed full-arch mandibular prostheses.

In 13/245 patients, a total of 21 implants failed. Cumulative survival rates at 5 years for the overall population were 94.8% at the patient level and 98.1% at the implant level. With up to 10 years of follow-up, cumulative survival rates were 93.8% at patient level and 94.8% at implant level. Survival rates of prostheses were 99.2% with up to 10 years of follow-up.

The observations show that rehabilitation of the edentulous mandible using the All-on-4® treatment concept is viable in the long term, with high rates of prosthesis survival.

Cumulative survival rate (CSR) at implant level

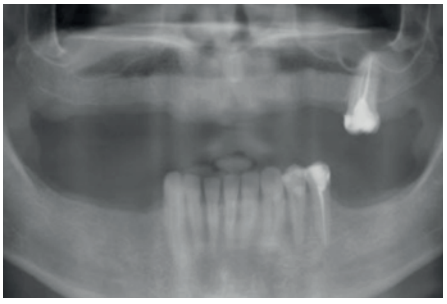


Implant-related cumulative success rates for mandibular implants.

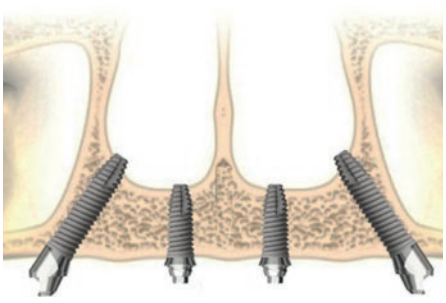
Preliminary report on the outcome of tilted implants with longer lengths (20–25 mm) in low-density bone: one-year follow-up of a prospective cohort study

Maló P, de Araújo Nobre M, Lopes A, Rodrigues R
Clin Implant Dent Relat Res 2015;17(Suppl 1):e134–42

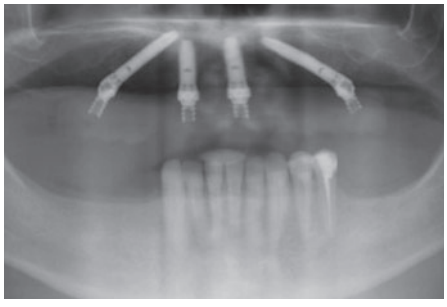
Intraoral photograph of a initial situation. Maxilla is planned for rehabilitation with the All-on-4® treatment concept using long NobelSpeedy implants (20–25mm length)



Orthopantomography of initial situation. Maxilla is planned for rehabilitation with the All-on-4® treatment concept using long NobelSpeedy implants



Establishing a bicortical anchorage at implant insertion using the maxillary and nasal corticals



Orthopantomography of a complete edentulous maxillary rehabilitation using long NobelSpeedy implants (implants on positions 16 and 26)

Intraoral photograph (occlusal view) of a complete edentulous maxillary rehabilitation using long NobelSpeedy implants after 1 year of follow-up

Intraoral photograph of a complete edentulous maxillary rehabilitation using long NobelSpeedy implants after 1 year of follow-up

Summary of the study

This prospective cohort study investigated short-term outcomes in patients with edentulous jaws and low-density bone, undergoing partial or complete rehabilitation through use of tilted implants of 20–25 mm length, in immediate function with bicortical anchorage.

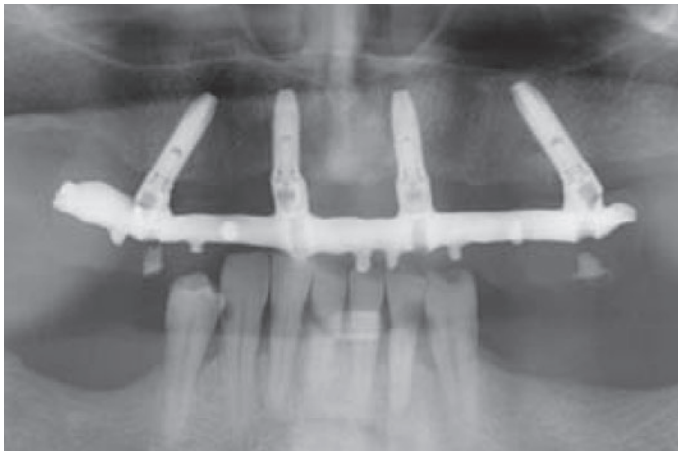
A total of 25 long NobelSpeedy Groovy implants (20–25 mm of length) in immediate function and metal-ceramic implant-supported fixed prosthesis with a titanium NobelProcera framework were used. Sixteen patients were included in the study and followed for an average of 14 months (range 6–26 months). Outcome measures were implant survival, marginal bone remodeling, biological and mechanical complications assessed at 10 days, 2, 4 and 6 months, 1-year post-treatment, and thereafter every 6 months.

Two patients (n = 4 study implants plus 2 non-study anterior implants) supporting two edentulous rehabilitations were lost to follow-up after 6 and 11 months. No implants failed, resulting in a cumulative implant survival rate of 100 %. The average marginal bone remodeling after 6 months and 1 year was 0.50 mm ± 0.34 mm and 0.86 mm ± 0.46 mm, respectively. One mechanical complication (abutment loosening) was observed in one patient, 1 month after surgery.

While long-term, prospective evaluation is needed, short-term outcomes from the prosthetic rehabilitation of patients with low-density bone using NobelSpeedy Groovy implants (20–25 mm of length) in immediate function show high rates of implant survival and low rates of marginal bone remodeling and complications.

Five-year results of a randomized controlled trial comparing patients rehabilitated with immediately loaded maxillary cross-arch fixed dental prosthesis supported by four or six implants placed using guided surgery

Tallarico M, Meloni SM, Canullo L, Caneva M, Polizzi G
Clin Implant Dent Relat Res 2016;18(5):965–72



Orthopantomograph at 5-year follow-up of a cross-arch rehabilitation in All-on-4® treatment concept

Orthopantomograph at 6-year follow-up of a cross-arch rehabilitation using six implants

Image courtesy of Dr. Marco Tallarico, Italy.

Summary of the study

In this prospective, randomized, controlled trial, 5-year clinical and radiological outcomes in patients rehabilitated with the All-on-4® treatment concept or with six implants placed using guided surgery and immediate function were compared.

Forty edentulous patients received a total of 200 NobelSpeedy Groovy implants, which were placed using NobelGuide and immediately loaded. Outcome measures were survival rates of implants and prostheses, rates of complications, peri implant marginal bone loss, and soft tissue parameters.

All patients were evaluable at 5 years. During follow-up, 1/80 implants (1.25 %) in the All-on-4® treatment concept group failed and 6/120 implants (5 %) in the six-implant cohort failed. Implant failure rates between cohorts were not significantly different (p = 0.246). No prosthetic failures occurred. Both groups experienced some technical and biologic complications (e.g. veneering material fracture, screw loosening); differences in rates between groups were not significant. No significant differences between groups were observed in marginal bone loss from baseline to 5 year follow-up. For soft tissue parameters, there were no differences between groups (p > 0.05).

	All-on-4® treatment concept	Prosthesis supported by 6 implants	p value
Number of patients	20	20	
Number of implants	80	120	
Implant failures	1 (1.25%)	6 (5.0%)	0.246
Final prosthesis failures	0	0	NA
Marginal bone loss (mm)	−1.71 ± 0.42	−1.51 ± 0.36	0.12
Complications (technical and biological)	8	5	0.501

Failure, complications and mean marginal bone remodeling comparison between the All-on-4® treatment concept versus restorations supported by 6 implants. NA, not available.

While longer, randomized, controlled studies are warranted, this trial demonstrates that the All-on-4® treatment concept and six implant-supported restorations are viable and predictable approaches for the rehabilitation of the complete edentulous maxilla.

Overview of studies

The following overview includes clinical studies on the All-on-4® treatment concept with TiUnite-surface implants. The studies are grouped by follow-up time.

Only peer-reviewed publications are listed. Meeting abstracts, reviews, single case reports, technique descriptions and animal and in-vitro tests are excluded. The total number of TiUnite-surface implants and patients included in this overview is more than 10,500, and 2,600 respectively, with mean survival implant and prosthetic survival rates of 98 % and 98.3 %, respectively.[A]

For more information on these studies visit PubMed at pubmed.gov.

Reference	Mean follow up time [years][B]	Study type	Indication	Implant type[C]	No. of implants	No. of patients	Implant survival rate [%]	Prosthesis survival rate [%]
Follow-up time ≥ 5 years								
Maló et al., 2011[2]	7.5	Retrospective	Mandible	NobelSpeedy	50	20	92	95 [D]
Lopes et al., 2017[38]	7	Retrospective	Maxilla and mandible	NobelSpeedy	532	111	94.5	97.8
Tallarico et al., 2016[21]	5.3	Prospective	Maxilla	NobelSpeedy Groovy	80	20	98.8[D]	100
Maló et al., 2015[39]	5	Retrospective	Maxilla and mandible	NobelSpeedy Groovy	440	110	95.5	100
Maló et al., 2016[25]	5	Retrospective	Maxilla and mandible	Brånemark System Mk III, Mk IV	189	46	97.3	NR
Jensen et al., 2016[6]	5	Retrospective	Maxilla	NobelActive	158	39	94.9[D]	100[D]
Ayna et al., 2015[40]	5	Prospective	Mandible	NobelSpeedy Groovy	116	27	100[D]	100
Lopes et al., 2015[41] Maló et al., 2007[34]	5	Prospective	Maxilla and mandible	NobelSpeedy Groovy	92	23	96.6	100
Li et al., 2017[42]	5	Prospective	Maxilla and mandible	Brånemark Mk III, NobelSpeedy Groovy, NobelActive	80	17	98.8	100
Follow-up time 2–4 years								
Maló et al., 2012[43]	4	Retrospective	Maxilla	Brånemark System Mk III TiUnite, Brånemark System Mk IV TiUnite, NobelSpeedy Groovy	968	242	98	100
Sannino et al., 2016[44]	3.6	Retrospective	Maxilla and mandible	Nobel Speedy Replace, NobelActive	340	85	98.2	100
Babbush et al., 2014[7]	3.4	Retrospective	Maxilla and mandible	NobelActive	60	15	98.3	100
Tallarico et al., 2016[22]	3.3	Retrospective	Maxilla and mandible	NobelSpeedy Groovy, Brånemark System Mk III Groovy, NobelReplace Tapered Groovy (CC and select)	224	56	99.6	100
Tallarico et al., 2016[45]	3	Prospective	Maxilla and mandible	NobelSpeedy Groovy	120	30	99.2	100
Maló et al., 2013[46]	3	Retrospective	Maxilla	NobelSpeedy Replace, NobelSpeedy Shorty	280	70	98.2[D]	100
Maló et al., 2015[37]	3	Retrospective	Maxilla	NobelSpeedy Shorty, NobelSpeedy Groovy	172	43	95.5[D]	97.7
Browaeys et al., 2015[23]	3	Prospective	Maxilla and mandible	Brånemark System Mk III Groovy TiUnite, NobelSpeedy Groovy	80	20	100	100
Di et al., 2013[29]	2.8	Prospective	Maxilla and mandible	Brånemark System Mk III, NobelSpeedy Groovy	344	69	96.2	96.5

A Arithmetic means weighted by number of initially placed implants (implant survival rate) or number of patients treated (prosthetic survival rate)

Reference	Mean follow up time [years][B]	Study type	Indication	Implant type[C]	No. of implants	No. of patients	Implant survival rate [%]	Prosthesis survival rate [%]
Agliardi et al., 2010[9]	2.7	Prospective	Mandible	Brånemark System Mk IV, NobelSpeedy Groovy	96	24	100	100
Weinstein et al., 2012[8]	2.5	Prospective	Mandible	Brånemark System Mk IV TiUnite, NobelSpeedy Groovy	80	20	100	100
Agliardi et al., 2010[35]	2.2	Prospective	Maxilla and mandible	Brånemark System Mk IV, NobelSpeedy Groovy	692	173	99.3[D]	84.4
Maló et al., 2012[13]	2.2	Prospective	Maxilla and mandible	NobelSpeedy, Brånemark System Mk III, Brånemark System Mk IV	227	142	96.9[E]	100
De Vico et al., 2011[47]	2.1	Prospective	Maxilla and mandible	NobelActive	140	35	100	100
Babbush et al., 2011[36]	2	Retrospective	Maxilla and mandible	NobelActive	708	165	99.6	100
Mozzati et al., 2013[14]	2	Retrospective	Mandible	NobelSpeedy Groovy, Brånemark System Mk III	200	50	100	100
Drago et al., 2016[48] Drago et al., 2016[27]	2	Retrospective	Maxilla and mandible	NobelActive	766	129	99.5	99.5[D]
Follow-up time < 2 years								
Francetti et al., 2008[1]	1.9	Prospective	Mandible	Brånemark System Mk IV, NobelSpeedy Groovy	248	62	100	100
Parel et al., 2011[5]	1.6	Retrospective	Maxilla and mandible	TiUnite	1140	285	96.5	NR
Antoun et al., 2012[49]	1.5	Retrospective	Maxilla and mandible	Brånemark System TiUnite	78	31	97.4	NR
Babbush et al., 2016[50]	1.3	Prospective	Maxilla and mandible	NobelActive	856	169	99.8	100
Maló et al., 2015[12]	1.2	Prospective	Maxilla and mandible, posterior	NobelSpeedy Groovy	25	16	100	100
Galindo et al., 2012[28]	1	Retrospective	Mandible	Brånemark System, NobelSpeedy Groovy NobelActive	732	183	99.9	98.9
Babbush et al., 2013[51]	1	Retrospective	Maxilla and mandible	NobelActive	219	48	99.1	100
Maló et al., 2005[4]	1	Retrospective	Maxilla	Brånemark System Mk III, Brånemark System Mk IV	128	32	97.6	100
Pomares et al., 2010[33]	1	Retrospective	Maxilla and mandible	NobelSpeedy Groovy, Brånemark System Mk III Groovy	111	NR	98.2[E]	100[E]
Compagnoni et al., 2014[31]	1	Prospective	Mandible	NobelSpeedy	64	16	90.6[E]	NR
Landazuri-Del et al., 2013[52]	1	Prospective	Mandible	NobelSpeedy Replace	64	16	90	93.8

Source: Nobel Biocare data on file (TiUnite Rep 134625, last search December 15, 2016), updated with Nobel Biocare database and PubMed search results for publications in 2016-2017.
B Where the mean follow-up time was not available the reported follow-up time was used (minimum one-year follow-up)
C Minimum 10 implants. Non-TiUnite implants are not reported in this table
D The percentage of surviving implants/prostheses was calculated
E Tilted
NR Not reported

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Scientific evidence

Nobel Biocare zygomatic implants provide a graftless solution with immediate-loading protocol for patients with severe maxillary bone resorption. Used in dental clinics for over 25 years, these solutions do not only avoid complex bone-grafting procedures, but show remarkable long-term survival rates and high patient satisfaction.

Key findings

Zygomatic implants represent a reliable graftless treatment option for successful rehabilitation of patients with severe maxillary bone resorption.[1–10]

- Zygomatic implants have demonstrated remarkable long-term survival: one study showed a cumulative 10-year survival of 95.12 % with machined implants.[11]
- In a study of 352 patients who received a total of 747 Nobel Biocare zygomatic TiUnite-surface implants, the cumulative implant survival at 7 years was 98.2 %.[4]
- Zygomatic implants can be used successfully with immediate function protocols.[1–9]
- Performance of conventional implants used in combination with zygomatic implants is not compromised.[1, 4–8]
- Reduced patient morbidity and shorter treatment periods are reported with zygomatic implants versus bone grafting and implant placement.[2, 12, 13]
- Low rates of complications; sinusitis is reported in a low percentage of patients, but is usually manageable without further consequences.[14]

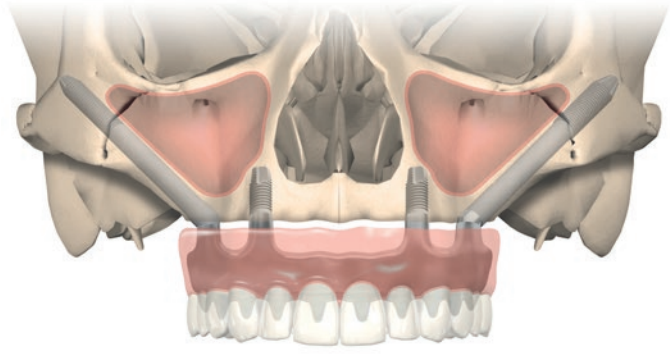
Treating patients with severely compromised bone

Traditional treatment approaches require extensive bone grafting and pose a substantial burden on patients. Techniques such as the LeFort I osteotomy in conjunction with interpositional bone grafts have been shown to positively affect esthetics and function of dental restorations.[15] There is a clear need for less-invasive procedures, especially for patients who cannot undergo bone grafting.[16]

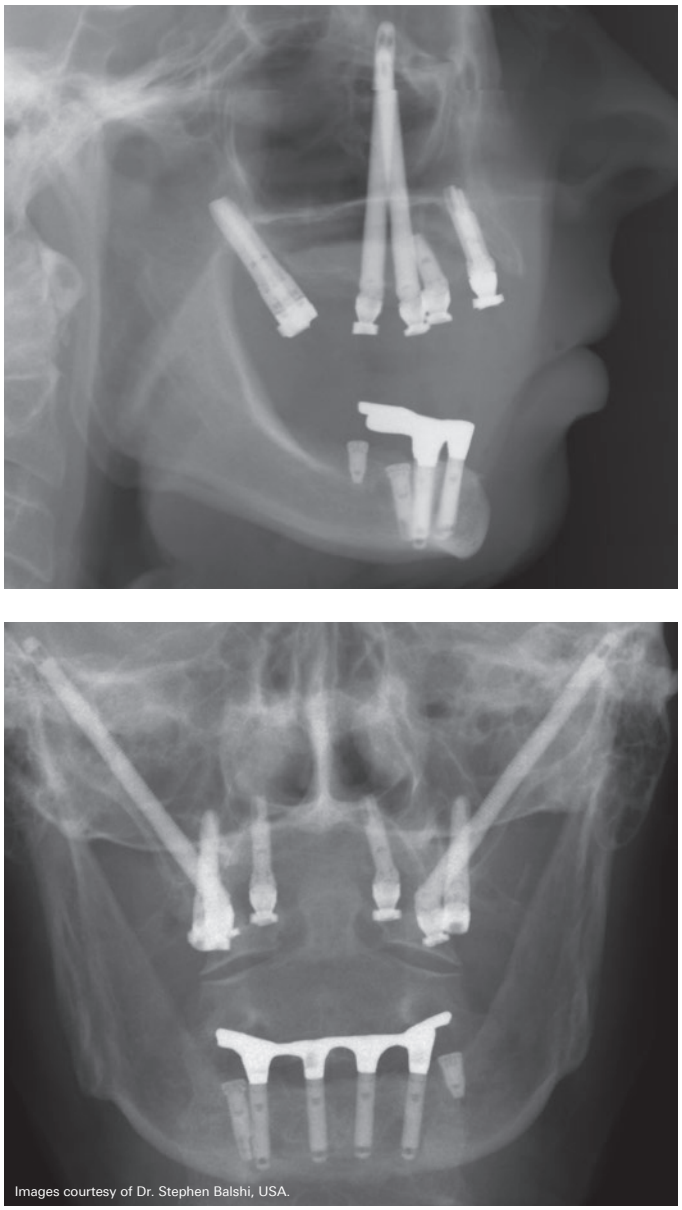
Graftless solutions

Zygomatic implants represent a reliable alternative to bone grafts for the rehabilitation of edentulous patients with pronounced maxillary bone resorption who have insufficient bone volume for placing conventional implants posterior to the canines.[1–10, 14, 16–19]

Classically, zygomatic implants are inserted into the maxillary alveolar process and the zygomatic bone, passing through the maxillary sinus. The upper end of these implants is inserted into a zygomatic area with wider and thicker trabecular bone. This technique was initially reported by Brånemark and coworkers[20] and is known as the intra-sinus or intra-maxillary technique. More recently, it was recognized that parts of the implant body may be situated in the maxillary sinus wall or even outside, depending on the patient's anatomical situation.[21] Some researchers even propose fully extra-sinus or extra-maxillary techniques.[22, 23] This technique was developed to obtain a crestal emergence of the implant and to minimize potential sinus complications, which seem to be the main complications—albeit at a low rate—associated with zygomatic implants.[1, 6] It is therefore recommended that any pathologic condition of the maxillary sinus is treated before a zygomatic implant is placed.[2]



Restoring a patient with a severely resorbed maxilla



Images courtesy of Dr. Stephen Balshi, USA.

The anterior maxilla, zygomatic and pterygomaxillary region are used for anchoring implants.

Improved surgical and prosthetic flexibility

In July 2007, Nobel Biocare CE marked zygoma implants with the TiUnite surface. More recently, Nobel Biocare has developed NobelZygoma implants, with a new, improved design that covers a range of lengths, diameters, and a choice between a straight (0°) or angulated 45° neck. These implants feature a tapered tip for ease of use at insertion and to facilitate primary stability (Immediate Function). In addition, the implant body is partially unthreaded at the coronal part, which interfaces with the soft tissue and is not necessarily engaged in bone. A retrospective study to assess clinical outcomes of 33 NobelZygoma 45° implants in 13 patients who were followed for a mean of 7.8 months, reported that all zygomatic implants achieved a primary stability sufficient for immediate loading and a 100 % survival rate at follow-up.[9]

Clinical performance of zygomatic implants

Nobel Biocare zygomatic implants have demonstrated remarkable long-term survival: one study showed a cumulative 10-year survival of 95.12 % with machined implants.[11] In studies of TiUnite-surface zygomatic implants, reported rates of survival are within the range of 98–100 % with up to 7 years of follow up.[1–5, 7, 8, 10, 14, 17–19]

The advantages of zygomatic implants compared with other strategies, particularly bone grafting, have been outlined in different publications.[1, 2, 10, 11, 14, 16, 23, 24] Such advantages include greater predictability, lower associated morbidity, and a greater acceptance by patients. Improvements to patient satisfaction have also been reported after maxillary restoration with zygomatic implants.[16]

Several studies have reported successful outcomes with immediately loaded zygomatic implants.[1–8, 18] Furthermore, studies have also shown that the performance of conventional implants in combination with zygomatic implants is not compromised.[1, 4–8]

Using the extra-maxillary technique to rehabilitate 352 edentulous patients with 747 zygomatic TiUnite-surface implants and 795 conventional implants, the estimated survival rates of these implant types at seven years were similar at 98.2 % and 96.7 %, respectively.[4] Mechanical and biological complications were also recorded during the seven years of follow-up. Sinus infection and peri-implant pathology were observed in 80 patients (22.7 %) and resolved via nonsurgical therapy in the majority of cases. There were no reports of soft tissue inflammation, fistula formation, or pain. Mechanical complications occurred in 156 patients (44 %), with one-third of these occurring in patients diagnosed with bruxism before the rehabilitation.

Davo et al (2013) assessed 42 patients who received 81 zygomatic and 140 conventional implants for full- and partial-arch rehabilitation (n = 37 and 5, respectively) over 5 years.[7] Zygomatic implants achieved a 98.5 % survival rate (1 failure). With only one case of sinusitis observed, the rate of complications was very low. In another 5-year study conducted by Davo et al.,[3] 17 patients with severe atrophy in the maxillae, who were rehabilitated using four immediately loaded zygomatic implants, exhibited no prosthetic or zygomatic failures. Although 7 patients experienced complications, all of these were resolved without clinical consequences. Furthermore, a high degree of oral health-related quality of life (mean Oral Health Impact Profile (OHIP)-14 score = 3.8) in line with that expected in a general population, indicated that patients were highly satisfied with the treatment.

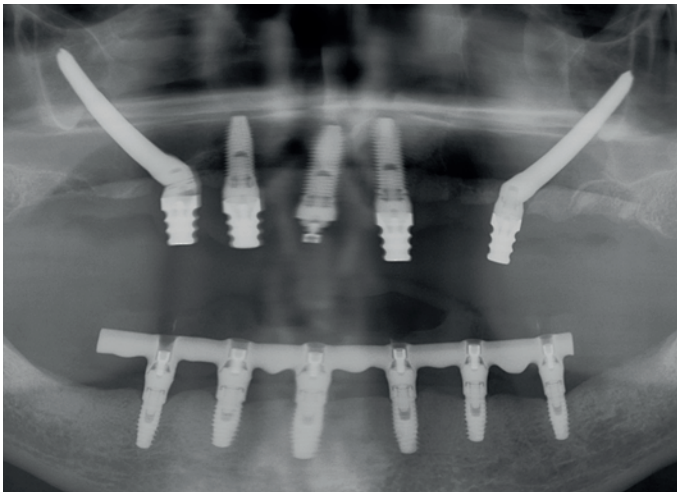
Mozzati et al.[1] reported 100 % survival rates for 14 zygomatic and 34 conventional implants placed in 7 patients according to an immediate loading protocol. At a 24-month follow-up, the authors reported no clinical problems. The implants remained stable, there were no symptoms of sinusitis, and the peri-implant tissues remained free of inflammation, suppuration and pain.

Short-term soft tissue outcomes were investigated in a prospective study of 40 patients with edentulous atrophic maxillae rehabilitated using a hybrid Nobel Biocare All-on-4® treatment concept (four immediate function implants in a combination of conventional and extra maxillary zygomatic implants).[5] No significant differences between peri-implant conditions (pocket probing depth, modified plaque index, modified bleeding index, clinical mobility and suppuration) at zygomatic and conventional implants were observed.

Despite some complications, excellent results are broadly reported using the extra maxillary technique.[4–6, 14, 25] However, placement of zygomatic implants is complex and requires special training and experience.

Excellent esthetic outcome using Nobel Biocare NobelZygoma 45° implants to support a maxillary fixed prosthesis in a patient with severe bone atrophy

Intra-oral view of maxilla, showing severe atrophy.



Panoramic x-ray showing use of NobelZygoma 45° implants in the posterior and NobelSpeedy Groovy implants in the anterior regions.

Occlusal view after healing, with zygomatic fixtures emerging at the level of the residual crest.

Excellent esthetic outcome following loading of the final maxillary fixed prosthesis.

Images courtesy of Dr. Enrico Agliardi, Italy.

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Scientific evidence

Nobel Biocare implant-supported CAD/CAM bridges offer high prosthetic versatility that enable clinicians to meet their patients' restorative needs. Use of CAD/CAM technology introduces materials of high strength and biocompatibility combined with precision engineering. This leads to fewer biological and technical complications, improved esthetics, and a longer prosthetic survival.

Nobel Biocare computer-aided design and computer-aided manufacturing (CAD/CAM) full-arch implant bridges supported with TiUnite-surface implants have been documented in 33 studies with 1,862 patients followed for up to 7.5 years. The performance (prosthetic survival) of full-arch NobelProcera titanium and zirconia implant bridges supported by TiUnite-surface implants has been reported in 29 and 7 studies, respectively.

Key findings

- Very high mean prosthesis survival rate of 99.5 %[A] in 30 studies with a follow up of 1–7.5 years (see table on page 47).
- Only 1–3 % of final restorations were reported to have fractured in six studies with up to 10 years of follow-up.[1–7]
- Low rates of biological complications that resolved with minimal inconvenience.[8–12]
- Over 98 % patient satisfaction with esthetics[11, 13] and 95 % patient satisfaction with function over longer-term follow-up.[2, 8, 11–13]

Advantages of CAD/CAM technology

CAD/CAM fabrication of frameworks for fixed restorations introduces prosthetic versatility that enables various patient needs to be met.[14] In addition, the easy-to-use software, the ability to use materials such as titanium or zirconia, and the more-accurate precision-of-fit versus traditional cast frameworks,[15] facilitates excellent technical outcomes. Several studies have observed a less-than 3 % rate of fractures in final restorations with up to 5 years of follow-up.[2, 16] A recent systematic review of NobelProcera/Procera zirconia implant bridges showed that, after a mean observation period of 3.5 years, all of the 65 zirconia restorations survived with only minor technical complications such as veneer chipping (n=9).[17] Following 18 full-arch restorations in 16 patients for at least 3 years of function, Pozzi and coworkers observed only one minor chip-off fracture of the veneering ceramic, which could be repaired while the restoration remained in the patient's mouth.[11] In another study, Pozzi and coworkers experienced an adhesive chip-off fracture of the veneering ceramic in 3/26 restorations.[12]

High survival of Nobel Biocare CAD/CAM implant bridges in long-term clinical follow-up

Study	Mean follow-up time [years]	Material	Prosthesis survival
Örtorp et al., 2012[5]	10	Titanium	95.6%
Maló et al., 2011[3]	7.5	Titanium	95.0%
Maló et al., 2015[18]	7	Titanium	100%
Polizzi et al., 2015[19]	5.1	Titanium	100%
Jemt et al., 2011[1]	5	Titanium	100%
Maló et al., 2011[20]	5	Titanium + zirconium (crowns only)	98.6%
Pettersson et al., 2015[21]	5	Titanium + zirconium (crowns only)	100%
Pozzi et al., 2015[11]	5	Zirconium	100%
Lopes et al., 2015[22]	5	Titanium + zirconium (crowns only)	100%
Maló et al., 2015[23]	5	Titanium	100%

List includes studies on use of NobelProcera and Procera Implant Bridges supported using TiUnite and/or machined implants in fully or partially edentulous patents, with a mean follow-up time of ≥5 years and reporting restoration survival rates.

Biological and clinical outcomes

While faults with CAD/CAM frameworks may affect the biological healing around their supporting implants, few studies have observed major biological complications with full-arch implant bridges.[8, 10–12] Minor biological complications, which occur infrequently, are typically resolved with minimal inconvenience.[8, 10]

Studies evaluating patient opinions have observed high rates of satisfaction with esthetics and functional outcomes with Nobel Biocare implant-supported CAD/CAM bridges.[13] Two studies, with a total of 212 patients treated for maxillary or mandibular edentulism with the All-on-4® treatment concept and NobelProcera or Procera Implant Bridges, reported no esthetic or functional (phonetic, masticatory, comfort, hygienic) complaints.[2, 8]

A Weighted by number of patients treated

On a visual analog scale (VAS) evaluating patient satisfaction, one study reported an esthetic VAS score of 98.1 % and a functional VAS score of 95.5 % after 3 years of function.[11] In another study by Sannino and coworkers, VAS scores were 98.8 % ± 2.7 % for esthetics, 99.5 % ± 2.2 % for masticatory function and 99.3 % ± 2.5 % for phonetic function.[13]

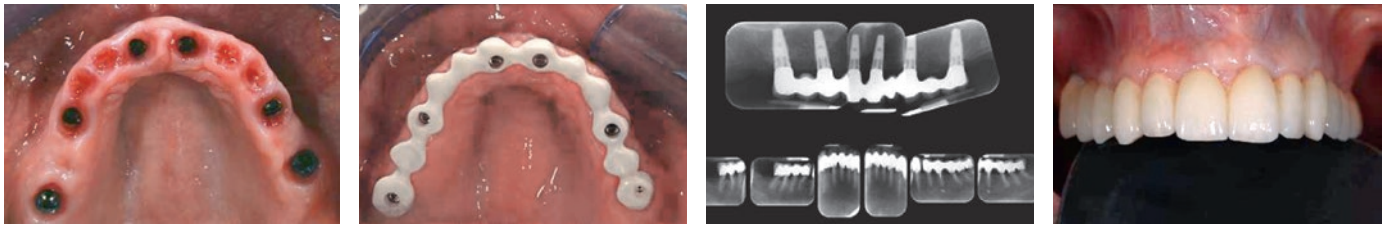
Zirconia or titanium?

While hybrid restorations consisting of metal frameworks, resin teeth and resin soft tissue may represent a cost-effective solution, esthetics and soft-tissue response are improved when ceramic restorative materials are used.[24] Depending on the patient desires, esthetics can be further maximized by using individual ceramic crowns that are cemented onto CAD/CAM frameworks.[11] Pozzi and coworkers, who cemented crowns on zirconia frameworks, demonstrated that this approach may overcome some of the limitations related to the chipping of porcelain fused to zirconia restorations.[11] In addition, the zirconia framework, which is not placed into the oven for baking the porcelain, maintains all the mechanical features of the industrial milling and sintering process.[11]

Full-arch titanium implant bridge with resin teeth

CAD/CAM-fabricated Procera implant bridges in titanium connect to the restorative interface of the supporting implants. The titanium can be directly veneered with resin composite.[25]

Optimized esthetics with zirconia implant bridges



Case with fixed full-arch restoration supported by six implants. A zirconia framework is used and directly veneered.[25]

Overview of studies

The following overview includes clinical studies reporting prosthesis survival outcomes with full-arch NobelProcera Implant Bridges supported by TiUnite-surface implants. The studies are grouped by follow-up time and restoration material (titanium and zirconia).

Only peer-reviewed publications are listed. Meeting abstracts, reviews, single case reports, technique descriptions and animal and in-vitro tests are excluded. The total number of TiUnite-surface implants and patients included in this overview is 8,179 and 1,862 with mean implant and prosthetic survival rates of 98.2 % and 99.5 %, respectively.[A]

For more information on these studies visit PubMed at pubmed.gov.

Reference	Mean follow-up time [years][B]	Study type	Indication	Implant type[C]	No. of implants	No. of patients	Implant survival rate [%]	Restoration material	Prosthesis survival rate [%]
Follow-up time ≥ 5 years									
Maló et al., 2011[3]	7.5	Retro-spective	Mandible, anterior and fully edentulous	NobelSpeedy	50	20	92	Titanium	95.0[D]
Friberg et al., 2015[26] **Friberg et al., 2010**[27] **Friberg et al., 2008**[28]	5	Retro-spective	Mandible, fully edentulous	Brånemark System Mk III TiUnite, Brånemark System Mk IV TiUnite	750	165	98.6[D]	Titanium	98.6[D]
Jemt et al., 2011[1] **Jemt et al., 2011**[16]	5	Retro-spective	Maxilla, fully edentulous	Brånemark System TiUnite	310	63	99.4[D]	Titanium	100
Maló et al., 2015[23]	5	Retro-spective	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy	440	110	95.5	Titanium with ceramic or acrylic crowns	100
Lopes et al., 2015[22] **Maló et al., 2007**[29]	5	Prospec-tive	Maxilla and mandible, fully edentulous	NobelSpeedy	92	23	96.6	Titanium with all-ceramic zirconia crowns	100
Follow-up time 2–5 years									
Maló et al., 2014[30] **Maló et al., 2008**[31] **Maló et al., 2012**[32]	5	Retro-spective	Maxilla, fully edentulous	Brånemark System Zygoma, NobelSpeedy	169	39	98.8	Titanium	100
Agliardi et al., 2014[33]	4.6	Prospec-tive	Maxilla, fully edentulous	Brånemark System Mk IV, NobelSpeedy Groovy	192	32	99.0[D]	Titanium	100
Pozzi et al., 2015[11]	4.1	Prospec-tive	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy, NobelSpeedy Replace, NobelActive	132	16	100	Zirconia, lithium disilicate full-contour crowns bonded to framework	100
Maló et al., 2012[34]	4	Retro-spective	Maxilla, anterior and fully edentulous	Brånemark System Mk III TiUnite, Brånemark System Mk IV TiUnite, NobelSpeedy	968	242	98	Titanium	100
Sannino et al., 2006[13]	3.6	Retro-spective	Mandible	Nobel Speedy Replace, NobelActive	340	85	98.2	Titanium or zirconia	100
Pozzi et al., 2015[12]	3.5	Retro-spective	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy, NobelActive, NobelReplace Tapered Groovy, NobelSpeedy Replace	170	22	100	Zirconia	100
Cavalli et al., 2012[4]	3.2	Retro-spective	Maxilla, fully edentulous	Brånemark System Mk IV, NobelSpeedy Groovy	136	34	100	Titanium	NR

A Arithmetic means weighted by number of initially placed implants (implant survival rate) or number of patients treated (prosthetic survival rate)

Reference	Mean follow-up time [years][B]	Study type	Indication	Implant type[C]	No. of implants	No. of patients	Implant survival rate [%]	Restoration material	Prosthesis survival rate [%]
Marra et al., 2013[35]	3	Prospective	Maxilla and mandible, fully edentulous	Nobel Speedy Groovy, Brånemark Mk III	312	30	97.9	Titanium	NR
Maló et al., 2013[36]	3	Retrospective	Maxilla, fully edentulous	Brånemark System Zygoma, NobelSpeedy	1542	352	98.0[D]	Titanium	99.7
Maló et al., 2013[2]	3	Retrospective	Maxilla, fully edentulous	NobelSpeedy Replace, NobelSpeedy Shorty	280	70	98.2[D]	Titanium	100
Maló et al., 2015[37]	3	Retrospective	Maxilla, fully edentulous	NobelSpeedy Shorty, NobelSpeedy Groovy	172	43	95.5[D]	Titanium	97.7
Gillot et al., 2010[38]	2.6	Retrospective	Maxilla, anterior and fully edentulous	NobelSpeedy, Brånemark System Mk III, Brånemark System Mk IV	211	33	98.1	Titanium	100
Meloni et al., 2013[10]	2.5	Prospective	Maxilla and mandible, fully edentulous	NobelReplace Tapered Groovy	120	20	97.7	Titanium or Zirconia	100
Maló et al., 2012[8]	2.2	Prospective	Maxilla and mandible, fully edentulous	NobelSpeedy, Brånemark System Mk III, Brånemark System Mk IV	227	142	96.9[D]	Titanium	100
De Vico et al., 2011[39]	2.1	Prospective	Maxilla and mandible, fully edentulous	NobelActive	140	35	100	Titanium	100
Meloni et al., 2013[40]	2	Prospective	Maxilla and mandible, fully edentulous	NobelReplace Tapered Groovy (RP, WP)	72	12	100	Titanium or Zirconia	100
Follow-up time 1–2 years									
Meloni et al., 2010[25]	1.5	Retrospective	Maxilla, fully edentulous	NobelReplace Tapered Groovy	90	15	97.8	Titanium or Zirconia	100[D]
Fröberg et al., 2006[41]	1.5	Prospective	Mandible, fullyedentulous	Brånemark System Mk III	44	15	100	Titanium	100[D]
Maló et al., 2015[42]	1.2	Prospective	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy	25	16	100	Titanium with ceramic or acrylic crowns	100
Johansson et al., 2009[43]	1	Prospective	Maxilla, screw, fully edentulous	Brånemark System Mk III	312	52	99.4	Titanium	96.2
Yamada et al., 2015[44]	1	Prospective	Maxilla, anterior and posterior, screw, fully edentulous	NobelActive (NP, RP)	290	50	98.6	Titanium	98.6
Maló et al., 2006[45]	1	Retrospective	Maxilla and mandible, anterior and posterior, screw, fully edentulous	NobelSpeedy	189	46	98.9	Titanium	100
Östman et al., 2005[46]	1	Prospective	Maxilla, fully edentulous	Brånemark System Mk III & Mk IV & Replace Select Tapered	123	20	99.2	Titanium	100
Olsson et al., 2003[47]	1	Prospective	Maxilla, fully edentulous	Brånemark Mk III & Mk IV TiUnite	61	10	93.4	Titanium	100[D]
de Araujo Nobre et al., 2015[48]	1	Prospective	Maxilla, fully edentulous	Brånemark System Extramaxillary Zygoma TiUnite, NobelSpeedy Groovy, NobelSpeedy Shorty	160	40	97.5[D]	Titanium with all ceramic crowns	NR
Meloni et al., 2013[9]	1	Prospective	Maxilla and mandible, fully edentulous	NobelReplace Tapered Groovy	60	10	100	Titanium or Zirconia	100[D]

Source: Nobel Biocare data on file (TiUnite Rep 134625, last search December 15, 2016), updated with Nobel Biocare database and PubMed search results for publications in 2016-2017.
B Where the mean follow-up time was not available the reported follow-up time was used (minimum one-year follow-up)
C Minimum 10 implants. Non-TiUnite implants are not reported in this table
D The percentage of surviving implants/prostheses was calculated
NR Not reported

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Scientific evidence

NobelClinician and NobelGuide offer a complete concept for prosthetic-driven treatment planning and guided implant surgery. Combining 3D imagery of anatomical structures with soft tissue information, NobelClinician software precisely visualizes the patient situation improving both diagnostics and treatment planning. Optimized planning may potentially reduce the need for pre-implantologic augmentative interventions. NobelGuide has been demonstrated in studies to achieve more-accurate implant placement compared with freehand surgery. The NobelGuide portfolio offers both guided pilot drilling and fully guided implant insertion.

Use of NobelClinician and NobelGuide has been evaluated in 34 clinical studies on more than 1,000 edentulous patients treated with more than 8,200 implants.

Key findings

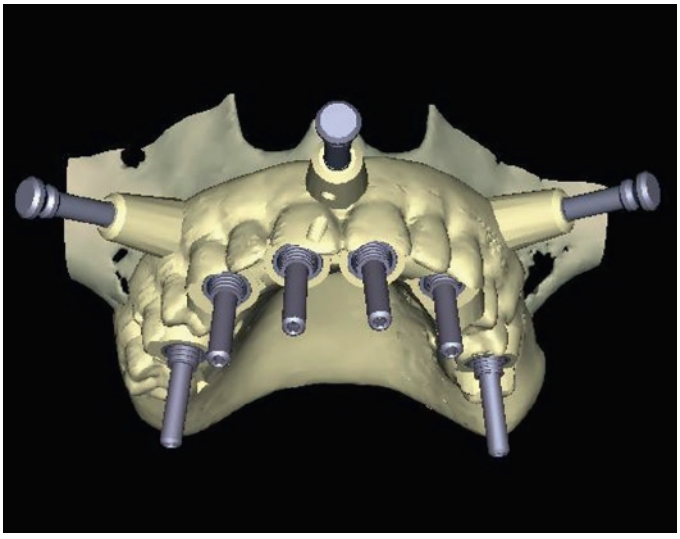
- Mean implant survival rate of 96.9 %[A] in 34 studies with a follow up of 1–7 years (see table on page 55).
- Mean prosthesis survival rate of 98.4 %[B] in 28 studies with a follow up of 1–7 years (see table on page 55).
- Precise planning through virtual visualization of implant positions and accurate assessment of available bone volume facilitating final decision making in implant prosthodontic treatment.[1, 2]
- Increased application of minimally invasive treatment such as flapless surgery and less-frequent bone augmentation procedures.[3–6]
- Accurate implant placement: higher accuracy of implant positions with guided versus freehand surgery.[7–9] High accuracy in edentulous patients was achieved with the use of guide pins.[8]
- NobelGuide facilitates flapless surgery, which results in implants exhibiting higher stability than conventionally inserted implants.[10]
- High patient satisfaction attributed to shorter treatment times and reduced discomfort. All patients in one study stated that intervention was worth the cost and that they would undergo the same procedure again.[11]
- Significantly lower swelling, edema and pain as well as use of analgesics with guided flapless surgery compared with freehand surgery.[4]

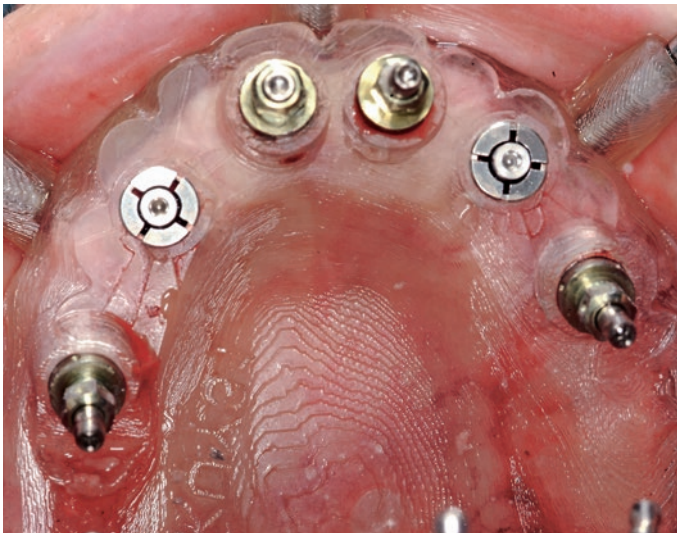
Advantages of digital treatment planning and guided surgery

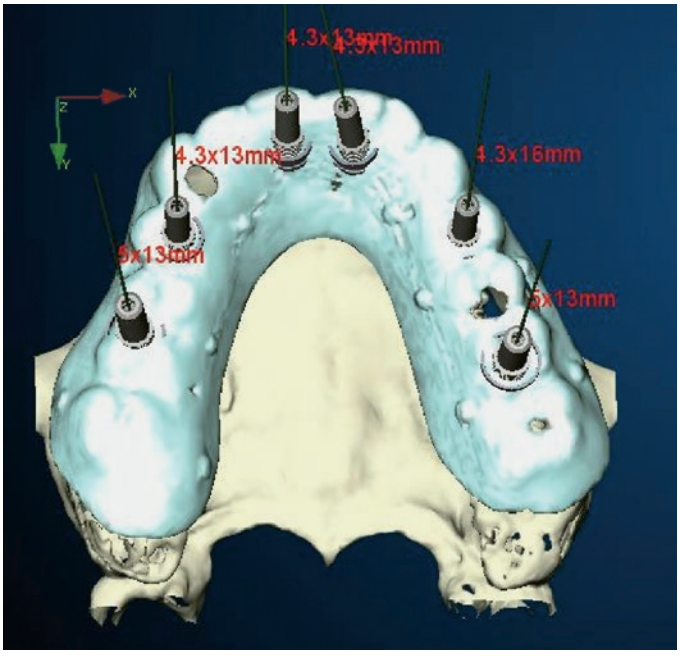
Proper data acquisition during cone beam computed tomography has made virtual planning of implant positions and restorations feasible and enables predictable implant placement.[12, 13] CAD/CAM fabricated surgical guides employing the NobelGuide concept also aid favorable implant positioning in a flapless approach, thereby minimizing patient morbidity, treatment time and cost.[11, 14, 15]

A Weighted by number of initially placed implants
B Weighted by number of patients treated

NobelGuide-driven restoration of the edentulous maxilla







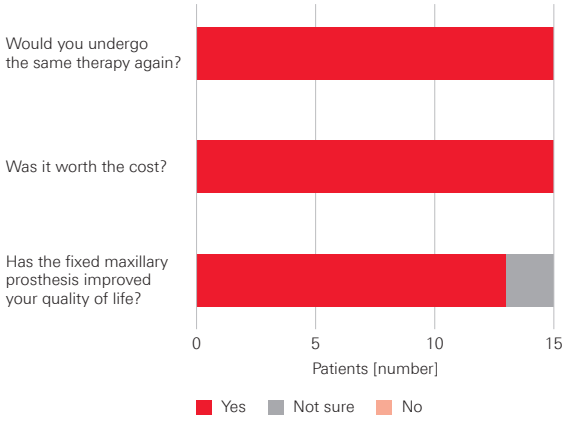
Representative workflow for guided surgery using NobelGuide in edentulous patients: Following data acquisition (double-scan technique), the implant positions and the fixation pins for the drill guide are planned in a 3D-virtual environment, then transferred to the clinical situation. The use of fixation pins is of particular importance in edentulous patients to avoid positional translational changes of the guide.[11]

High patient satisfaction

Digital treatment planning and guided implant insertion according to the NobelGuide concept allows clinicians to avoid open-flap surgery and/or bone augmentation, both of which are associated with increased post-surgical pain or at least discomfort.[3–6, 10] It is therefore no surprise that patients treated with guided surgery express a high level of satisfaction with the procedure and its outcomes.

A retrospective analysis of 15 patients with an edentulous maxilla, treated according to the NobelGuide concept with immediately provisionalized prostheses, showed outstanding levels of patient satisfaction 18 months after surgery.[11] The authors attributed this observation to the short treatment times and low levels of discomfort. All patients considered the treatment worth the cost and would have chosen the same therapy again. Only two patients were unsure if the fixed maxillary prosthesis had improved their quality of life.

All patients considered NobelGuide to be worth the cost and would undergo the procedure again

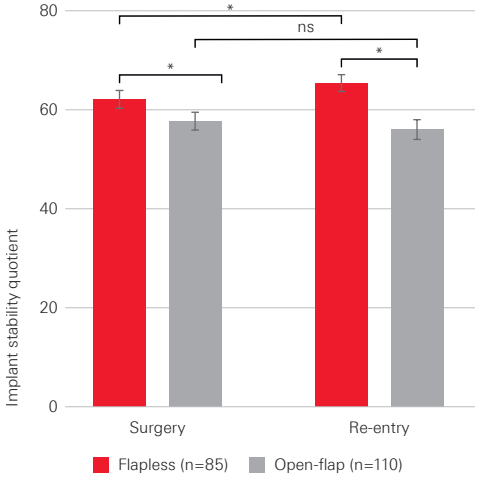


Patients presenting with edentulous maxilla (n = 15) were treated with flapless guided surgery according to the NobelGuide concept and their satisfaction with the treatment polled 18 months later. All patients reported that the shorter time, and minimal surgery and discomfort, associated with NobelGuide was worth the higher cost incurred.[2] In cases of the possible avoidance of augmentation procedures with NobelGuide, the overall costs can be compensated or even reduced.

Flapless implant insertion for higher stability

Guided surgery supports flapless implant insertion, which in turn favors a high degree of implant stability – a finding recently described in a clinical study with 195 implants placed in 40 edentulous maxillae.[10] Specifically, implants inserted in a flapless, guided approach following virtual planning with NobelGuide showed significantly greater stability both at implant insertion and at re-entry compared with implants inserted using a conventional flap approach. The authors point to the undisturbed blood supply as one potential reason underlying this observation. High primary stability of the implants, achievable even in areas of less dense bone, is also attributed to the enhanced pretreatment information and reliable transfer of planned treatment to the patient, which may improve outcomes.[2]

Implants inserted according to the NobelGuide concept in a flapless surgery show higher stability



Stability of implants, expressed as the implant stability quotient, which indicates the degree of stability on a scale between 1 (lowest stability) and 100 (highest stability), was significantly higher at both surgery and 3 months later at re-entry when the placement was carried out using the flapless NobelGuide protocol compared with placement using a conventional surgical template and raising a muco-periostal flap. Mean ± 95% confidence interval; * $p \leq 0.001$; ns, not significant; Mann–Whitney U test.[10]

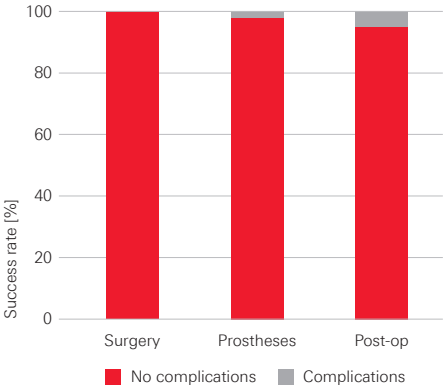
Protocol in edentulous patients

A systematic review and two meta-analyses have reported that guided implant placement has significantly better accuracy compared to freehand surgery.[7, 16, 17] Although guided surgery in edentulous patients generally results in a highly accurate implant placement,[7, 18–20] the reported precision varies and, at least in part, depends on the patient situation. For example, bone augmentations before implant insertion have been identified as a critical factor that might lead to greater implant deviations in guided surgery. This is due to angulations and translations of the surgical template.[9] Using tooth-supported templates in partially edentulous patients is an approach shown to limit deviation in implant placement.[21] Retaining the hopeless teeth until the day of surgery has another benefit of allowing the patient a smooth transition from failing dentition to implant-supported prostheses, without wearing an interim removable denture [22,23]

Despite some implant-position deviations being observed among edentulous patients, the results of virtual planning and guided surgery with NobelGuide are on the whole good and reliable. In a recent five-year prospective study in 66 patients with 356 implants placed using NobelGuide, the authors explicitly stated that deviations in implant position did not lead to any clinically relevant drawbacks, and the cumulative implant survival rate was 98.1 %.[24]

In a single clinical study where deviations exceeded the safety zone recommended by NobelGuide, implants were placed in augmented bone.[9] The authors had abandoned the use of pins in most cases and suggest that the drills may shift away at the transition of original cortical bone to the more spongious augmented bone.[9]

No surgical complications and high success rates with NobelGuide flapless guided surgery in edentulous patients



Of 278 TiUnite NobelActive implants placed in 48 patients with edentulous maxillae using NobelGuide flapless guided surgery, no intraoperative complications occurred. Implants (4–6 per patient) were immediately loaded with provisional prefabricated prostheses, which were replaced 4–7 months later with definitive titanium NobelProcera Implant Bridges. Only minimal postoperative complications were observed: fracture of provisional prosthesis – 1/48 (2.1%), abutment screw loosening – 10/278 (3.6%), mobility of implant – 4/278 (1.4%). These findings validate the reliable and predictable outcome obtained with NobelGuide.[25]

Overview of studies

The following overview includes clinical studies reporting use of NobelClinician and/or NobelGuide with TiUnite-surface implants. The studies are grouped by follow-up time.

Only peer-reviewed publications are listed. Meeting abstracts, reviews, single case reports, technique descriptions and animal and in-vitro tests are excluded. The total number of TiUnite-surface implants and patients included in this overview is more than 8,200, and 1,000, with mean implant and prosthetic survival rates of 96.9 % and 98.4 %, respectively.[A]

For more information on these studies visit PubMed at pubmed.gov.

Reference	Mean follow-up time [years][B]	Study type	Indication	Implant type[C]	No. of implants	No. of patients	Implant survival rate [%]	Prosthesis survival rate [%]
Follow-up time ≥ 5 years								
Balshi et al., 2013[5]	7	Retrospective	Maxilla, fully, edentulous	Brånemark Mk III groovy	898	NR	95.4	NR
Niedermaier et al., 2017[26]	NR	Retrospective, single-arm, single center	Maxilla and mandible, fully edentulous	NobelActive, NobelSpeedy Groovy, NobelSpeedy Replace, NobelReplace CC	1712	NR	98.5[D]	NR
Meloni et al., 2017[24]	5	Prospective	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy, NobelReplace Groovy	356	66	98.1	97.1
Tallarico et al., 2016[27]	5	Prospective	Maxilla, fully edentulous	NobelSpeedy Groovy	200	40	96.5[D]	100
Lopes et al., 2017[28]	5	Retrospective	Maxilla and mandible, fully edentulous	NobelSpeedy	532	111	94.5	97.8
Marra et al., 2017[29]	5	Retrospective	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy, Brånemark System Mk III	312	30	97.9	100[D]
Lopes et al., 2015[30] **Maló et al., 2007**[31]	5	Prospective	Maxilla and mandible, fully edentulous	NobelSpeedy	92	23	96.6	100
Tallarico et al., 2016[32]	4.5	Prospective	Maxilla, fully edentulous	NobelSpeedy Groovy	60	15	98.3	100
Schnitman et al., 2014[2]	4.2	Retrospective	Maxilla and mandible, fully edentulous	Brånemark System Mk III & Mk IV, NobelSpeedy Groovy, NobelActive, Replace Select Straight, Replace Select Taper	80	27	100	NR
Pozzi et al., 2015[33]	4.1	Prospective	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy, NobelSpeedy Replace, NobelActive	132	16	100	100
Follow-up time 2–4 years								
Sannino et al., 2016[34]	3.6	Retrospective	Mandible	Nobel Speedy Replace, NobelActive	340	85	98.2	100
Pozzi et al., 2015[35]	3.5	Retrospective	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy, Nobel Speedy Replace, NobelActive, NobelReplace Tapered Groovy	170	22	100	100
Lal et al., 2013[36]	3	Retrospective	Maxilla and mandible, fully edentulous	Brånemark System Mk III	273	36	83.5	100
Papaspyridakos et al., 2013[37]	3	Retrospective	Maxilla and mandible, fully edentulous	NR	103	14	100	100

A Arithmetic means weighted by number of initially placed implants (implant survival rate) or number of patients treated (prosthetic survival rate)

Reference	Mean follow-up time [years][B]	Study type	Indication	Implant type[C]	No. of implants	No. of patients	Implant survival rate [%]	Prosthesis survival rate [%]
Browaeys et al., 2015[38]	3	Prospective	Maxilla and mandible, fully edentulous	Brånemark System Mk III Groovy TiUnite, NobelSpeedy Groovy	80	20	100	100
Nocini et al., 2013[3]	2.7	Retrospective	Maxilla and mandible, fully edentulous	Brånemark System Mk III TiUnite, Brånemark System Groovy TiUnite, NobelSpeedy Groovy	342	65	96.5	95
Gillot et al., 2010[39]	2.6	Retrospective	Maxilla, fully edentulous	NobelSpeedy, Brånemark System Mk III, Brånemark System Mk IV	211	33	98.1	100
Meloni et al., 2013[40]	2.5	Prospective	Maxilla and mandible, fully edentulous	NobelReplace Tapered Groovy	120	20	97.7	100
Polizzi et al., 2016[41]	2.4	Retrospective	Maxilla, fully edentulous	NobelActive	160	27	99.4	100
Sanna et al., 2007[42]	2.2	Retrospective	Maxilla and mandible, fully edentulous	TiUnite Brånemark System	212	30	91.5	NR
De Vico et al., 2011[43]	2.1	Prospective	Maxilla and mandible, fully edentulous	NobelActive	140	35	100	100
Meloni et al., 2013[15]	2	Prospective	Maxilla and mandible, fully edentulous	NobelReplace Tapered Groovy	72	12	100	100[D]
Follow-up time < 2 years								
Komiyama et al., 2012[13] **Komiyama et al., 2008**[44] **Komiyama et al., 2011**[19] **Pettersson et al., 2012**[45]	1.6	Prospective	Maxilla and mandible, fully edentulous	Brånemark System Mk III	191	29	90[D]	85.3
Meloni et al., 2010[11]	1.5	Retrospective	Maxilla, fully edentulous	NobelReplace Tapered Groovy	90	15	97.8	100[D]
Turkyilmaz et al., 2017[46]	1.5	Prospective	Maxilla & Mandible, fully-edentulous	NobelReplace Straight Groovy, NobelReplace Tapered Groovy	40	7	97.5	100
Pozzi et al., 2016[47]	1.4	Prospective	Maxilla and mandible, fully edentulous	NobelReplace CC	72	18	100	100
Daas et al., 2015[48]	1.3	Prospective	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy	99	14	98	NR
Johansson et al., 2009[49]	1	Prospective	Maxilla, fully edentulous	Brånemark System Mk III	312	52	99.4	96.2
Yamada et al., 2015[25]	1	Prospective	Maxilla, fully edentulous	NobelActive (NP, RP)	290	50	98.6	100
Pomares et al., 2010[50]	1	Retrospective	Maxilla and mandible, fully edentulous	NobelSpeedy Groovy, Brånemark System Mk III Groovy	195	30	97.9[D]	100[D]
van Steenberghe et al., 2005[12]	1	Prospective	Maxilla, fully edentulous	Brånemark System Mk III TiUnite	184	27	100	100
Compagnoni et al., 2014[51]	1	Prospective	Mandible, fully edentulous	NobelSpeedy	64	16	90.6[D]	NR
Landazuri-Del Barrio et al., 2013[52]	1	Prospective	Mandible, fully edentulous	NobelSpeedy Replace	64	16	90	93.8[D]
Meloni et al., 2013[53]	1	Prospective	Maxilla and mandible, edentulous	NobelReplace Tapered Groovy	60	10	100	100[D]

Source: Nobel Biocare data on file (TiUnite Rep 134625, last search December 15, 2016), updated with Nobel Biocare database search results.
B Where the mean follow-up time was not available the reported follow-up time was used (minimum one-year follow-up)
C Minimum 10 implants. Non-TiUnite implants are not reported in this table
D The percentage of surviving implants/prostheses was calculated
NR Not reported

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