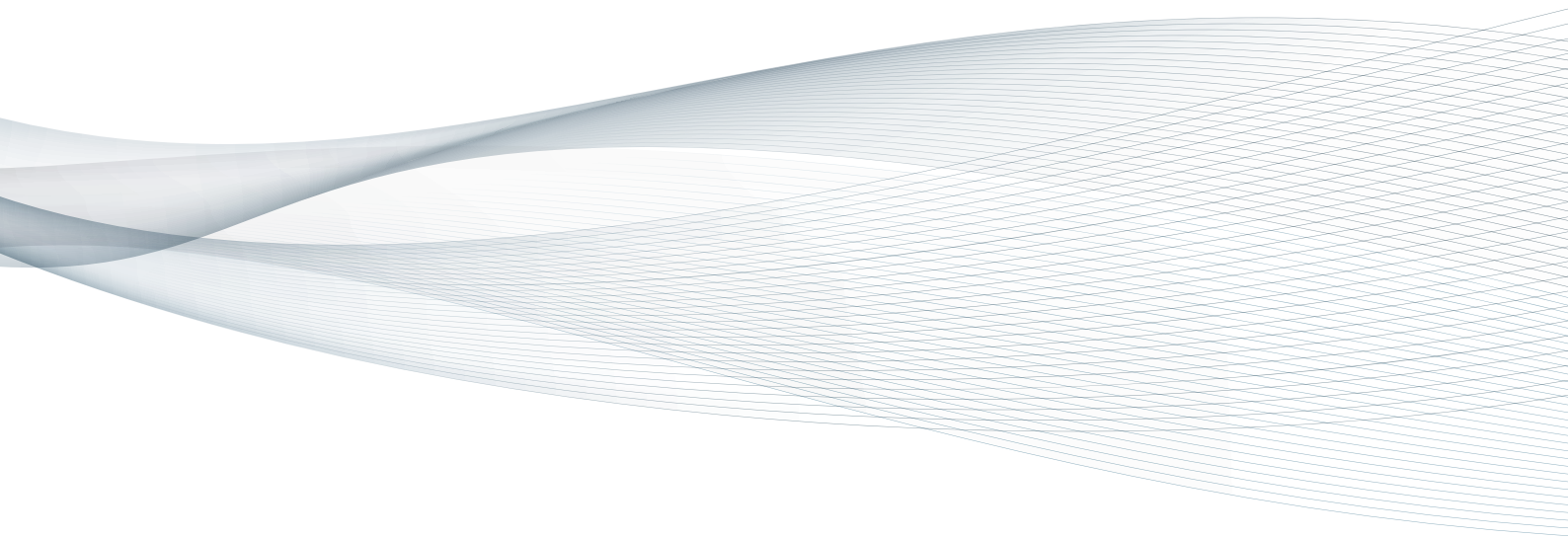


Recommended reading for TiUnite[®]

Fifteen key publications supporting the safety and efficacy of TiUnite



Comprehensive literature search identifies key TiUnite publications.

Introduction

Following an extensive Medline search of peer-reviewed journals, Nobel Biocare has identified a number of reports/publications that are key to supporting the safety and efficacy of TiUnite.

Approximately 10,500 abstracts were screened. Additionally, internal data from ongoing studies (e.g., submitted manuscripts, manuscripts in writing) were included in the review.

Terminology

BOP: Bleeding on probing

CSR: Cumulative survival rate

ISQ: Initial stability quotient

MBL: Marginal bone loss

NS: Not statistically significant

PD: Probing depth

PES: Pink esthetic score

RCT: Randomized controlled trial

VAS: Visual analog scale

Results

Seventy (70) publications/manuscripts met the **minimum** inclusion criteria: ten patients, one-year follow-up period, x-ray assessment of marginal bone levels and TiUnite implants.

Together, these publications document:

- Number of patients 2897
- Number of implants 6997 (607 with textured necks and grooves on threads)

Of the 70 publications/manuscripts, 15 publications (selected by the quality of the study design and a rating system used by the University of Oxford, Centre for Evidence-based Medicine*) best demonstrate the safety and efficacy of TiUnite.

Together, these publications document:

- Number of patients 640
- Number of implants 1328 implants
- Time range 1- to 5-year follow-up periods
- Type of Implants Brånemark System 825
Replace System 63
Newer types with textured necks 440 (all published in 2009/2010)
- CSR 1 year: 91.7–100%
2 year: 100%
3 year: 98.4–100%
5 year: 97.1–98.2%
- MBL 1 year: 0.3 to 1.2 mm
2 year: 0.4 to 0.5 mm
3 year: 0.89 to 1.05 mm
5 year: 0.75 to 1.54 mm

* Phillips B, Ball C, Sackett D, Badenoch D, Straus S, Haynes B, Dawes M (1998, updated 2009, Howick J). Levels of Evidence (online). Available: <http://www.cebm.net/?o=1025> (accessed 1 July 2010).

TiUnite implants versus machined surfaced implants.

1—Attard NJ, David LA, Zarb GA. Immediate loading of implants with mandibular overdentures one-year clinical results of a prospective study. *Int J Prosthodont* 2005; 18(6) 463-470.

Study design

Prospective: two groups of edentulous patients received bar-retained overdentures in healed mandibles (flap, counter-sunk). The first group consisted of 35 patients who received 70 immediately loaded (10 days following surgery, as defined in this paper) Brånemark System TiUnite implants. The second group was a historical cohort comprised of 42 patients who received 111 conventionally loaded Brånemark System machined implants. One-year follow-up period. Paper focuses on prosthetic maintenance.

Results

- TiUnite CSR 98.6%, MBL 0.4 mm
- Machined CSR 98.2%, MBL 1.1 mm
- MBL difference was statistically significant

Rationale for recommendation

The paper reports that cumulative survival rates (CSR) of immediately loaded implants (TiUnite) are comparable to conventionally loaded implants (machined). Furthermore, immediately loaded TiUnite implants demonstrated less bone loss than conventionally loaded machined implants. Informed consent/ethical vote obtained. Inclusion criteria given. Success criteria given. Prospective. Consecutive inclusion.

Key message(s)

Immediately loaded TiUnite implants showed less bone loss than conventionally loaded machined implants.

2—Friberg B and Jemt T. Clinical experience of TiUnite implants a 5-year cross sectional, retrospective follow-up study. *Clin Implant Dent Relat Res* 2010; 12 suppl 1: 95-103 (e-pub).

Study design

Retrospective: five-year, cross-sectional follow-up study on 110 machined and 280 Brånemark System TiUnite implants. TiUnite implants placed in critical sites (total 111 patients).

Results

- TiUnite CSR 98.2, MBL ca 0.75 mm
- Machined CSR 99.1, MBL 0.6 mm
- No statistical significant differences between groups

Rationale for recommendation

Analysis performed by independent radiologists using large groups and long follow-up periods. TiUnite used in demanding situations.

Key message(s)

Cumulative survival rates for the two implant surfaces are favorable at 5 years. Marginal bone loss is low and similar for both implant surfaces. TiUnite implants demonstrate predictable outcomes, especially in critical clinical indications.

3—Liddel G and Henry P. The immediately loaded single implant-retained mandibular overdenture a 36-month prospective study. *Int J Prosthodont* 2010; 23(1)13-21.

Study design

Prospective, RCT: 27 Brånemark System MkIII TiUnite were compared to 8 machined implants. Immediately loaded overdentures in the mandible supported by only one implant (35 patients). Three-year follow-up period.

Results

- TiUnite CSR 100%, MBL 0.89 mm
- Machined CSR 62.5%, MBL 2.2 mm
- Machined group discontinued due to high failure rate

Rationale for recommendation

RCT. Informed consent/ethical vote obtained. Inclusion/exclusion criteria given. Success/survival criteria given. Prospective. Intention to treat given. Confirms previously reported findings (Glauser 2001) for TiUnite and machined implant ISQ-values. VAS satisfaction performed.

Key message(s)

Over a 3-year observation period, immediately loaded single implant-retained mandibular overdentures, using TiUnite implants provided a beneficial treatment outcome. TiUnite implants showed significantly higher survival rates compared to machined implants: CSR 100% after 3 years.

4—Rocci A, Martignoni M, Gottlow J. Immediate loading of Brånemark System TiUnite and machined-surface implants in the posterior mandible a randomized open-ended clinical trial. *Clin Implant Dent Relat Res* 2003; 5 suppl 1 57-63.

Study design

Prospective, RCT: In the test group, 22 patients received 66 Brånemark System MkIII/IV TiUnite implants (placed using a flapless protocol) in the mandible supporting 24 immediately loaded, fixed partial bridges. In the control group, 22 patients received 55 Brånemark System machined implants supporting 22 immediately loaded, fixed partial bridges in immediate loading. One-year follow-up period.

Results

- TiUnite CSR 95.5%, MBL 0.9 mm
- Machined CSR 85.5%, MBL 1.0 mm

TiUnite implants versus machined surfaced implants cont.

Rationale for recommendation

RCT. Favorable results on TiUnite. Inclusion/exclusion criteria given. Success/failure criteria given. X-ray assessment performed by independent radiologist. Low percentage of bone loss more than 2 mm (5%). RCT. Performed according to declaration of Helsinki. Supports flapless protocols. No drop outs.

Key message(s)

TiUnite implants showed higher survival rates compared to machined implants after one year.

5—Watzak G, Zechner W, Busenlechner D, Arnhart C, Gruber R, Watzek G. Radiological and clinical follow-up of machined- and anodized-surface implants after mean functional loading for 33 months. Clin Oral Implants Res 2006; 17(6) 651-657.

Study design

Retrospective: 50 patients, each treated with four screw-type implants, were included (bar-retained overdenture, healed sites, 2-stage surgical protocol, delayed loading). 31 patients (62%) with a total number of 124 implants (64 Brånemark System MkIII machined and 60 Brånemark System MkIII TiUnite) were available for the 33-month follow-up period.

Results

- TiUnite CSR 98.4%. MBL 1.17 mm
- Machined CSR 100%, MBL 1.42 mm
- TiUnite implants showed significantly less marginal bone loss than machined surface implants
- Both favorable soft tissue values (NS)

Rationale for recommendation

Positive results for TiUnite after 33 months (study shows less peri-implant bone loss for TiUnite implants compared to the machined implants). Consecutive inclusion. Inclusion/exclusion criteria given. Cohort controlled. Groups are very similar in indication (edentulous mandible). Low percentage of bone loss over 2 mm (however, no exact data given). Surgery performed according to manufacturer's recommendations.

Key message(s)

Significantly less peri-implant bone loss was seen around TiUnite implant surfaces. The beneficial effect occurred especially at distal implants and in smokers. CSR 98.4% after 33 months.

TiUnite implants in immediate loading protocols.

6—Glaser R, Zembic A, Ruhstaller P, Windisch S. Five-year results of implants with an oxidized surface placed predominantly in soft quality bone and subjected to immediate occlusal loading. J Prosthet Dent 2007; 97(6 Suppl) 59-68.

Study design

Prospective: 102 Brånemark System MkIV TiUnite in 38 patients placed in various regions of the jaws (soft bone, extraction/ healed sites, bone augmentation/bone grafting) and immediately loaded with 20 single-tooth restorations, 30 fixed partial dentures, and 1 complete fixed lower jaw restoration. ISQ measurements recorded and all patients followed for five years.

Results

– CSR 97.1%, MBL 1.54 mm (stable after first year), BOP 25%

Rationale for recommendation

Prospective. Five-year results of implants placed in demanding indications. Authors concluded that the 5-year outcome of the study is similar to that documented for conventional delayed loading. Informed consent/ethical vote obtained. Consecutively enrolled. Inclusion/exclusion criteria given. Independent x-ray reading. Soft tissue data available. Success criteria given. Implants with bone loss more than 2 mm during the first year, show an average bone gain in later years.

Key message(s)

CSR 97.1% and stable marginal bone levels over time with TiUnite implants (even bone gain seen in sub-groups). Five-year follow-up data indicate that an immediate loading protocol using a slightly tapered implant design with an oxidized, textured surface is a successful treatment alternative in regions exhibiting soft bone quality.

7—Marzola R, Scotti R, Fazi G, Schincaglia GP. Immediate loading of two implants supporting a ball attachment-retained mandibular overdenture a prospective clinical study. Clin Implant Dent Relat Res 2007; 9(3) 136-143.

Study design

Prospective: 17 edentulous patients received two implants (34 Brånemark System MkIII TiUnite) inserted into the mandible after a minimal flap reflection. Immediate prosthesis connection (overdenture, ball-retained). One-year follow-up period.

Results

– CSR 100%, MBL 0.7 mm

Rationale for recommendation

Clinical outcome supports the safety and efficacy of TiUnite. Prospective. Informed consent/ethical vote obtained. Inclusion/exclusion criteria given. Success/failure criteria given. No drop out. Homogenous indication.

Key message(s)

The immediate loading of two TiUnite implants by means of a ball attachment-retained mandibular complete denture may be a predictable treatment option. This clinical approach offered increased stability and comfort, with high implant success rate (CSR 100%).

TiUnite implants in immediate versus delayed loading protocols.

8—Güncü MB, Aslan Y, Tumer C, Güncü GN, Uysal S. In-patient comparison of immediate and conventional loaded implants in mandibular molar sites within 12 months. Clin Oral Implants Res 2008; 19(4) 335-341.

Study design

Prospective, RCT: split-mouth study with 12 patients, each received 2 Brånemark System MkIII TiUnite implants in mandibular molar sites (single-tooth, flapped procedure). One implant was immediately functionally loaded, while the other was conventionally loaded. ISQ measurements, radiographic MBL assessment, peri-implant evaluation during the 1-year follow-up period.

Results

- Immediate CSR 91.7% (1 failure), MBL 0.45 mm
- Delayed loading CSR 100%, MBL 0.68 mm
- PD ca 2 mm
- Excellent soft tissue health
- No statistical significant differences between groups

Rationale for recommendation

RCT. Split mouth study design. One-year results with reported excellent peri-implant health. Favorable radiographic results. Informed consent/ethical vote obtained. Inclusion/exclusion criteria given. Success (survival) criteria given.

Key message(s)

Implant stability, marginal bone levels and peri-implant health are comparable for single-tooth implants, using immediate functional loading and conventional loading approaches.

9—Schincaglia GP, Marzola R, Giovanni GF, Chiara CS, Scotti R. Replacement of mandibular molars with single-unit restorations supported by wide-body implants immediate versus delayed loading. A randomized controlled study. Int J Oral Maxillofac Implants 2008; 23(3) 474-480.

Study design

Prospective, RCT: 30 patients requiring single mandibular molar replacement were treated. Each patient received one Brånemark System MkIII TiUnite WP (no grafting, flap, healed sites, no pre-tapping). Fifteen subjects were assigned to delayed loading protocol and 15 to immediate loading protocol according to a randomization table. One-year follow-up period.

Results

- Immediate CSR 93.3%, MBL 0.7 mm
- Delayed CSR 100%, MBL 1.2 mm
- Statistical significant differences with respect to MBL

Rationale for recommendation

RCT with patients consecutively included. Reports positive results on immediate loading compared to delayed loading. Prospective. Informed consent/ethical vote obtained. Good randomization. Exclusion/inclusion criteria given. Success/failure criteria given. No drop outs. X-ray examination blinded. Similar indications (single crown in mandibular molar). No bone augmentation. Please note: low CSR due to small groups.

Key message(s)

Immediate loading of wide platform TiUnite implants supporting single restorations in mandibular molar sites seems to be a suitable clinical option. Moreover, the radiographic bone level change observed after 12 months of loading was significantly less for immediately loaded implants compared to delayed loaded implants.

TiUnite implants in early versus late loading protocols.

10—Turkyilmaz I, Sennerby L, Tumer C, Yenigul M, Avci M. Stability and marginal bone level measurements of unsplinted implants used for mandibular overdentures a 1-year randomized prospective clinical study comparing early and conventional loading protocols. Clin Oral Implants Res 2006;17(5) 501-505.

Study design

Prospective, RCT: Outcomes of implant-supported mandibular overdentures using 2 different loading protocols were evaluated. Two groups of 10 edentulous patients each were selected for the study. Each patient received 2 Brånemark System MkIII TiUnite implants placed in the mandibular canine sites (flap, healed sites, total 40 implants) and loaded early (1 week) or delayed (3 months). ISQ measurements recorded and all patients followed for one year.

Results

- Early loading CSR 100%, MBL 0.3 mm
- Delayed loading CSR 100%, MBL 0.3 mm

Rationale for recommendation

RCT. Well designed, randomized prospective study. Shows very good CSR. Informed consent/ethical vote obtained. Inclusion/exclusion criteria given. Surgery according to manufacturer's recommendation. Success criteria given. Homogenous indication (mandible overdenture).

Key message(s)

Implant stability and marginal bone conditions are comparable for two unsplinted TiUnite implants supporting an overdenture, using early and delayed (after 3 months) loading approaches. MBL 0.3 mm

11—Turkyilmaz I and Tumer C. Early versus late loading of unsplinted TiUnite surface implants supporting mandibular overdentures a 2-year report from a prospective study. J Oral Rehabil 2007; 34(10) 773-780.

Study design

Prospective, RCT: 20 edentulous patients received 40 Brånemark System MkIII TiUnite in the canine areas of the mandibles of all patients using the one-stage approach for ball retained overdenture (flap, healed sites). Overdentures were delivered to 10 patients in the test group 1 week after surgery, while 10 patients in the control group received overdentures 3 months after surgery. ISQ measurement recorded and all patients followed for two years.

Results

- Early loading CSR 100% MBL 0.4 mm
- Delayed loading CSR 100% MBL 0.5 mm
- No statistical significant differences between groups

Rationale for recommendation

RCT. Excellent results, prospective study. Informed consent/ethical vote obtained. Inclusion/exclusion criteria given. Homogenous indication (mandibular overdenture). Analysis of prosthetics included. Standardized radiographs. Success criteria indirectly given.

Key message(s)

Brånemark System TiUnite implants, supporting mandibular overdentures, perform equally as well in a one-week early loading approach, as in a delayed loading approach. CSR 100% at the 2-year follow-up period.

12—Turkyilmaz I, Tözüm TF, Tumer C, Ozbek EN. A 2-year clinical report of patients treated with two loading protocols for mandibular overdentures early versus conventional loading. J Periodontol 2006; 77(12) 1998-2004.

Study design

Prospective: 26 edentulous patients received two unsplinted Brånemark System TiUnite implants to support mandibular overdentures. Implants placed using flapped, one-stage, no grafting protocols in healed sites. In the test group, overdentures were connected one week after surgery. In the control group, overdentures were connected 3 months after surgery. ISQ, peri-implant parameters were recorded throughout the 2-year follow-up period.

Results

- Early CSR 100%, MBL 0.4 mm
- Delayed CSR 100%, MBL 0.5 mm
- Excellent soft tissue
- No statistical significant differences between groups

Rationale for recommendation

Favorable results on TiUnite and early loading. Good study design. Informed consent/ethical vote obtained. Inclusion/exclusion criteria given. Soft tissue parameter assessed. Similar indication for all patients.

Key message(s)

Peri-implant soft tissue health, marginal bone resorption, and implant stability are comparable for Brånemark System MkIII TiUnite implants supporting a mandibular overdenture, using both an early and delayed loading approach. Excellent soft tissue. CSR 100% at the 2-year follow-up period.

TiUnite implants with textured necks and grooves on threads.

13—Kielbassa A, Martinez-de Fuentes R, Goldstein M, Arnhart C, Barlattani A, Jackowski J, Knauf M, Lorenzoni M, Maiorana C, Mericske-Stern R, Rompen E, Sanz M. Randomized controlled trial comparing a variable-thread novel tapered and a standard tapered implant interim 1-year results. J Prosthet Dent 2009; 101(5) 293-305.

Study design

Prospective, multi-center RCT: 177 patients received 325 implants. Patients were randomly allocated to 3 treatment groups: 2 different test implant groups (NobelActive Internal [n=117; internal connection] and NobelActive External [n=82]) and 1 standard treatment group (NobelReplace Tapered Groovy [n=126]). Implants were placed into healed sites, and all but 6 implants were immediately non-occlusally loaded. One-year follow-up period.

Results

- CSR 96.3-97.6, MBL 0.63–0.95 mm
- No statistical significant differences between groups
- 80-95% healthy mucosa

Rationale for recommendation

RCT. Multi-center. Good study design. Inclusion/exclusion given. Informed consent/ethical vote obtained. Comparable indications (healed sites). Newer implant design with textured necks and grooves on threads. Sample size calculation. Big sample. Intention to treat reported.

Key message(s)

The novel implants (NobelActive) showed high survival rates as well as stable bone and soft tissue levels after one year, and can be recommended for clinical use, even under immediate function.

14—Nickenig H, Wichmann M, Schlegel K, Nkenke E, Eitner S. Radiographic evaluation of marginal bone levels adjacent to parallel-screw cylinder machined-neck implants and rough-surfaced micro-threaded implants using digitized panoramic radiographs. Clin Oral Impl Res 2009. 20(1) 550-554.

Study design

Prospective, RCT, split-mouth: 70 NobelReplace Straight Groovy and 63 Replace Select Straight were inserted in the mandible of 34 patients with Kennedy Class I residual dentition (non-smokers, healed sites, two-stage surgical protocol, delayed loading). A 1.9 to 2.1-year follow-up period.

Results

- Textured neck CSR 100%, MBL 0.5 mm
- Machined neck CSR 100%, MBL 1.1 mm
- Statistical significant differences with respect to MBL

Rationale for recommendation

RCT. Well-planned study design. Split mouth. Inclusion/exclusion criteria given. Informed consent obtained. Assessment by blinded examiner. Comparable indications. Surgery according to recommendation of manufacturer.

Key message(s)

NobelReplace Straight implants with textured collars demonstrated more favorable changes in crestal bone levels during healing and under functional loading compared to implants with machined collars.

15—Raghoobar G, Slater J, Hartog L, Meijer H, Vissink A. Comparison of procedures for immediate reconstruction of large osseous defects resulting from removal of a single tooth to prepare for insertion of an endosseous implant after healing. Int J Oral Maxillofac Surg 2009; 38(7) 736-743.

Study design

Prospective: immediate reconstruction of 45 large osseous defects (45 patients) resulting from removal of a single tooth with a 1:2 mixture of bone substitute of bovine origin and autologous tuberosity bone, and three different procedures for soft tissue closing (resorbable bilayer membrane, connective tissue graft, full-thickness palatal mucosa graft; n=15 per group). Implants (45 Replace groovy) were inserted after 3 months (flap). Questionnaire used. One-year follow-up period.

Results

- CSR 100%, MBL 0.54 mm

Rationale for recommendation

RCT. Soft tissue assessed, inclusion/exclusion criteria given. Newer implant design with textured necks and grooves on threads. Critical clinical situations. Questionnaire done.

Key message(s)

All hard-soft tissue procedures resulted in sufficient bone volume for the insertion of implants and a favorable esthetic outcome. TiUnite implants with textured necks showed excellent results in these critical clinical situations.