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ORIGINAL ARTICLE

A 5-year retrospective case series evaluating Brånemark Integration BioHelix™ dental implants placed in a private practice by a specialist

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Abstract

Objective. To evaluate, in a case series, survival rate and complications of Brånemark Integration BioHelix™ dental implants, placed according to conventional procedures in patients treated consecutively in a Swedish specialist private practice after 5 years. ***Materials and methods.*** Eighty-three consecutively-treated patients received 89 final fixed prostheses supported by 310 implants placed according to 'conventional' procedure, i.e. no implants shorter than 10 mm, no immediate post-extraction implants and no bone-grafting procedures. In 70 patients, implants were left to heal submerged, whereas 13 patients were treated according to the one-stage protocol. All implants were incorporated in a prosthetic restoration. Probing was only performed when clinical signs of inflammation were present and this was then evaluated further with intra-oral radiographic examination. Outcome measures were implant survival and prosthetic complications. ***Results.*** Five years after implant placement, two fixtures were removed because of loosening. One fixture was lost after 12 months in the lower jaw in one patient and one fixture was lost in the upper jaw in another patient after 3 years, both inserted using the two-stage technique. No other prosthetic complications occurred, giving a 99.3% cumulative survival rate. ***Conclusions.*** Brånemark Integration BioHelix™ dental implants placed according to one- or two-stage procedures in patients in a private practice produced excellent 5-year results. Randomized clinical trials with suitable controls are suggested to confirm these results.

Key Words: *Dental implantation, implant survival rate, observational study, private practice*

Introduction

It is generally believed that the properties of the implant surface, topographical and chemical alike, play an important role in the properties of the tissue–titanium interface. Differently shaped and surface-modified dental implants have been evaluated for decades, but it is still not known which surface properties influence the clinical performance and success and to which degree. To date, the traditional machined/turned surface Brånemark dental implants are the best-documented osseointegrated dental implants in terms of both numbers and longevity [1]. High success rates have been reported for both partially and fully edentulous patients [1,2], but a Cochrane systematic review suggested that Brånemark implants characterized by a relatively smooth surface (machined/turned) showed a tendency towards increased early failure rates when compared with implants with rougher surfaces, whereas, in the medium-term (3–5 years), Brånemark implants were significantly less affected by peri-implantitis, defined as the progressive loss of peri-implant bone in the presence of infection signs, than implants with rougher surfaces [3].

A laser micro-machining process was developed to create roughness in the inner part of the thread. The aim of this retrospective case series was to study survival rate and complications of Brånemark Integration BioHelix™ dental implants placed according to a conventional standard procedure in consecutively-treated patients at a Swedish specialist private practice after 5 years. This study follows the STROBE Statement (www.strobe-statement.org) for observational studies.

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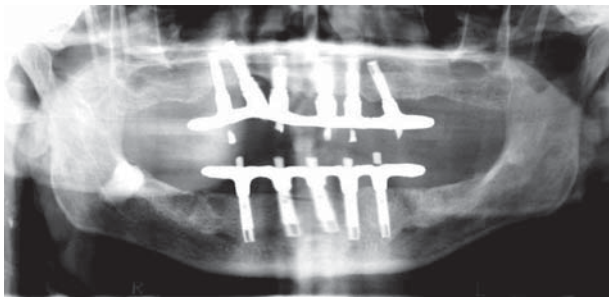

Figure 1. Panoramic radiograph after 1 year of function, showing five implants loaded after 10 days in the mandible. The six maxillary implants were placed more than 10 years before and are conventional Brånemark System™ implants.

Materials and methods

Study design, inclusion/exclusion criteria and outcome measurements

This study is a 5-year retrospective observational case series comprising consecutively-treated patients. No ethical or institutional review board approval was sought, but all patients signed a written informed consent. In the 1-year published report, detailed information on implant design, study population and short-term results was presented [4]. Implant placements were performed at a Swedish specialist private dental practice between 2006–2007. All procedures and assessments were performed by a single experienced clinician. In all, 83 patients, 47 males (56.6%) and 36 females (43.4%), were consecutively treated [4]. Panoramic radiographs and, when needed, CT scans were used for radiographic examination prior to implant placement.

The parameters that were considered were loosening of implants;

- Any implant which had to be removed due to infection, loosening or fracture was considered a failure. Implants were individually assessed for stability—only at the time of abutment connection;
- Any clinical signs of biological complications, such as mucosal inflammation, including redness, swelling or bleeding or granulation of the tissue; and

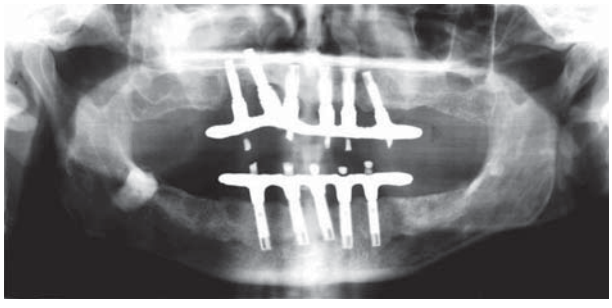

Figure 2. The same patient as in Figure 1. Panoramic radiograph after 5 years of function.

- Any clinical signs of prosthetic complications that required removal of the bridge/crown temporarily or permanently.

All follow-up assessments were made by the same clinician with clinical and radiographic examinations using panoramic radiographs scheduled after 6–12 months depending on one- or two-stage protocols, during years 2 and 3 and, finally, 5 years post-operatively. Probing was only performed in the presence of mucosal inflammation and was further checked with intra-oral radiographs when indicated. To evaluate survival rates, Albrektsson's criteria for implant success and survival were used [5].

Cylindrical, screw-shaped BioHelix™ dental implants (Brånemark Integration AB, Göteborg, Sweden) were used. The implants were 3.75 mm in diameter and the implant lengths were 10, 13, 15 and 18 mm.

The surgical and post-operative procedures have been described previously [4]. Implants were left to osseointegrate either submerged or with transmucosal healing abutments for ~ 2 months in mandibles and 3–4 months in maxillae. Only in one fully edentulous patient were five implants placed in the mandible loaded after 10 days, panoramic radiographs after 1 year (Figure 1) and 5 years (Figure 2) of function. Implants were not connected with natural teeth and no over-dentures were delivered. Single implants were restored with cemented titanium-ceramic or gold-ceramic crowns, whereas partial and full titanium-ceramic or gold-ceramic were screw-retained. Cantilevers a maximum of 12 mm in length were allowed in cross-arch bridges (Figures 1 and 2). Patients received professional oral hygiene at the time of prosthesis insertion, 14 days later, and continuous maintenance every 6 months or according to their individual needs. Any inflammatory signs and/or occlusal trauma were evaluated and, when needed, they were further checked with probing and intra-oral radiographic examination.

Statistical evaluation

Descriptive measurements were used to present the research material. The cumulative survival rate was calculated using the principles of Kaplan-Meier [6].

Results

A total of 310 implants were inserted, 101 (32.6%) were placed in the mandible and 209 (67.4%) in the maxilla. The different lengths and numbers of implants are summarized (Table I). In 70 patients (84.3%), the two-stage technique was used and, in 13 patients (15.7%), the one-stage technique with abutment connection at the same time as implant installation was used.

Table I. Length of the implants.

Implant length	*n* (%)
10 mm	13 (4.2%)
13 mm	16 (5.2%)
15 mm	227 (73.2%)
18 mm	54 (17.4%)
Total	310 (100%)

All patients received their prosthetic constructions. In all, 89 fixed constructions were connected (31 in the mandible and 58 in the maxilla) (Table II): 40 (45%) screw-retained cross-arch bridges, 32 screw-retained partial bridges (36%) and 17 (19%) cemented single crowns.

Five years after implant placement, all but two patients were examined and all the other 81 patients had a functioning prosthetic construction at their last examination. One patient rehabilitated with six fixtures in the upper jaw died after 1 year and one patient rehabilitated with two fixtures in the lower jaw died after 3 years, without any clinical complications related to the treatment being reported.

A total of two fixtures in two different patients were lost. Both fixtures were part of fractured full-bridge constructions. One bridge fractured due to failure in the casting procedure and the other bridge fractured because of an under-sized bridge skeleton. In both patients, the lost fixture was positioned adjacent to the fracture lines of the prosthetic constructions. One fixture was 18 mm long and was lost after 1 year in the region of 43. The patient was a man and a light smoker. The second fixture (in the region of 23) was 15 mm long and part of a bridge which fractured after 2.5 years. The patient was a man and a heavy smoker. Both patients received a new bridge, supported by the remaining implants, replacing the fractured one. Apart from these two treatments, none of the other patients required any prosthetic correction of their constructions, according to the patient files. The cumulative survival rate is 99.3% for both jaws, 99.5% for the maxilla and 99.0% for the mandible (Table III). All inserted implants that did not fail or were unaccounted for were referred to as survivals. Clinical examinations indicating signs of peri-implantitis, requiring further evaluation with pocket depth registrations, were not performed for any of the patients in the cohort group. Six patients had poor oral hygiene and visited the dental hygienist for treatment more frequently than the rest of the patients.

Table II. Type of prosthetic construction and location.

	Mandible (%)	Maxilla (%)	Total (%)
Single crowns	2	15	17 (19%)
Partial bridges	15	17	32 (36%)
Cross-arch bridges	14	26	40 (45%)
Total	31	59	89 (100%)

In none of the treated patients was severe bone loss around the implants noted from abutment connection to permanent prosthesis and from abutment connection to the 5-year follow-up.

Discussion

This is the first clinical, long-term (5-year), follow-up study of a new concept for an implant surface modification combining a partly machined surface with a partly laser-modified surface on screw-shaped dental titanium implants. This specific concept has been studied under experimental conditions and the surface modification/the combination/the concept has shown improved osseointegration and increased primary stability for both pure titanium and alloyed titanium after 8 weeks and 6 months in rabbit bone [7–9]. Laser modification of entire implant surfaces has been studied by other groups and similar results have been presented, i.e. advantageous for the strength of the bone–implant interface evaluated with biomechanical tests [10–13].

The main finding in this study is that, 5 years after placement, Brånemark Integration BioHelix™ dental implants, inserted by an experienced surgeon according to conventional procedures, in selected patients, produce excellent results.

Some limitations of the study are the retrospective design, the lack of suitable controls and the lack of an objective evaluation of implant success (implant stability and intra-oral radiographs). However, the patients have now been followed with clinical and

Table III. Life table.

Time period	Inserted/ followed	Failure (lost)	Withdrawn (dead)	CSR
Both jaws				
Insertion–1 year	310	1	6	99.7%
1–3 years	303	1	2	99.3%
3–5 years	300	0	0	99.3%
5 years	300			
Maxilla				
Insertion–1 year	209	0	6	100%
1–3 years	203	1	0	99.5%
3–5 years	202	0	0	99.5%
5 years	202			
Mandible				
Insertion–1 year	101	1	0	99.0%
1–3 years	100	0	2	99.0%
3–5 years	98	0	0	99.0%
5 years	98			

panoramic radiographic examination 5 years post-operatively, which improves the value of the results. Despite the fact that uncontrolled studies are not the ideal study design to evaluate the efficacy of an intervention [14], they are still able to provide some information about whether or not a certain implant design or surface modification functions. The results of longer-term (20 years), uncontrolled, retrospective [2] and prospective [15] studies of the Brånemark implant system reveal a low degree of implant failure and a low frequency of progressive bone loss. The results of shorter (5 years) uncontrolled, retrospective studies [16,17] and controlled, prospective studies [18,19] show similar results, with favourable survival and success rates and with low and similar values for marginal bone loss when comparing different surface modifications. However, in compromised situations, such as irradiated bone, the machined/turned surface shows higher failure rates compared with a rougher surface, although the difference was not significant [20]. Randomized clinical trials (RCTs) are the gold standard to evaluate the efficacy of medical interventions [21] and, so far, no RCT evaluating this implant surface modification has been published. In actual fact, to our knowledge, this is the first long-term clinical report on Brånemark Integration BioHelix™ dental implants.

The results of the present investigation are really very positive; a 99.3% cumulative survival rate for the implants, with no consequences for the overall rehabilitation and with no obvious clinical signs of peri-implantitis. The two patients who each lost an implant had the prosthetic constructions re-made. One 18 mm long implant failed after the 1-year follow-up. The implant was placed in position 43 in bone of medium density, supporting four other 18 mm long implants, a fixed cross-arch bridge. The other implant failed after 2.5 years in a patient who was a heavy smoker, also in the canine area but in the upper jaw. This implant was part of a fixed cross-arch bridge. The reasons for the impressive survival rate in the present study are difficult to explain in relation to the higher failure rates of conventionally-loaded Brånemark implants, particularly in edentulous maxillae observed until a full decade ago [1]. Our knowledge of dental implant treatment has increased as a result of experience over the years and it is, therefore, difficult to make comparisons with historical controls. Factors that may contribute to the high survival rate could be the long-term clinical experience of the surgeon in selecting and treating patients, the modified surface and the skill of the dental technician. However, it could also be that the modified surface of the Brånemark Integration BioHelix™ dental implants was able to enhance the bone–surface interface and reduce the early failure rates, confirming experimental observations. These implants were placed by a very experienced surgeon who carefully selected patients undergoing implant rehabilitation. The surgeon limited the situations which could place an implant at a higher risk of failure. In fact, no immediate post-extractive implants were placed [22], no bone-grafting procedures were implemented [23] and no implant was immediately loaded, with the exception of one patient who had five implants loaded at an early stage after 10 days in the mandible [24]. On the other hand, the majority of the implants were placed in the maxilla (209 vs 101). The placement of dental implants in the maxilla has been reported to have less favourable results [1]. This study design is unable to explain whether such superior results are attributable to the modified implant properties, to the experience of the surgeon and the dental technician or to the careful control of oral hygiene. In order to evaluate whether the modified surface has improved implant success and survival rates, a multi-centre RCT using original machined Brånemark implants as controls would be needed.

This study suggests that Brånemark Integration BioHelix™ dental implants are very successful, as few negative events, such as failures and complications, occurred during the 5-year follow-up period. The results of the present study are likely to be applicable to comparable populations of patients, if a similar treatment approach is taken by experienced clinicians using BioHelix™ implants.

Conclusions

Brånemark Integration BioHelix™ dental implants placed in the mandible and the maxilla according to standard one- and two-stage procedures in patients produce excellent short-term results, 100% [4], and long-term results, 99.3%.

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References

[1] Esposito M, Hirsch J M, Lekholm U, Thomsen P. Biological factors contributing to failures of osseointegrated oral implants. (I). Success criteria and epidemiology. Eur J Oral Sci 1998;106:527–51.

[2] Pikner SS, Grondahl K, Jemt T, Friberg B. Marginal bone loss at implants: a retrospective, long-term follow-up of turned Branemark System implants. Clin Implant Dent Relat Res 2009;11:11–23.

[3] Esposito M, Murray-Curtis L, Grusovin M, Coulthard P, Worthington H. Interventions for replacing missing teeth:

different types of dental implants. Cochrane Database of Systematic Reviews. Chichester, UK: John Wiley & Sons, Ltd; 2007.
[4] Thomsson M, Esposito M. A retrospective case series evaluating Brånemark BioHelix implants placed in a specialist private practice following "conventional" procedures. One-year results after placement. Eur J Oral Implantol 2008;1:229–34.
[5] Roos J, Sennerby L, Lekholm U, Jemt T, Gröndahl K, Albrektsson T. A qualitative and quantitative method for evaluating implant success: a 5-year retrospective analysis of the Brånemark implant. Int J Oral Maxillofac Implants 1997; 12:504–14.
[6] Kaplan E, Meier P. Non-parametric estimation from incomplete observation. J Am Stat Assoc 1958;53:457–81.
[7] Palmquist A. On a novel technique for preparation and analysis of the implant surface and its interface to bone. Sahlgrenska Academy. Göteborg: University of Gothenburg; 2008.
[8] Palmquist A, Emanuelsson L, Brånemark R, Thomsen P. Biomechanical, histological and ultrastructural analyses of laser micro- and nano-structured titanium implant after 6 months in rabbit. J Biomed Mater Res B Appl Biomater 2011;97:289–98.
[9] Brånemark R, Emanuelsson L, Palmquist A, Thomsen P. Bone response to laser-induced micro- and nano-size titanium surface features. Nanomedicine 2011;7:220–7.
[10] Cho S, Jung S. A removal torque of the laser-treated titanium implants in rabbit tibia. Biomaterials 2003;24:4859–63.
[11] Hallgren C, Reimers H, Chakarov D, Gold J, Wennerberg A. An *in vivo* study of bone response to implants topographically modified by laser micromachining. Biomaterials 2003;24: 701–10.
[12] Faeda R, Tavares H, Sartori R, Guastaldi A, Marcantonio EJ. Evaluation of titanium implants with surface modification by laser beam. Biomechanical study in rabbit tibias. Braz Oral Res 2009;23:137–43.
[13] Oliveira N, Guastaldi F, Perrotti V, Hochuli-Vieira E, Guastaldi A, Piattelli A, et al. Biomedical Ti-Mo Alloys with surface machined and modified by laser beam: biomechanical, histological, and histometric analysis in rabbits. Clin Implant Dent Relat Res 2011; doi: 10.1111/j.1708-8208. 2011.00354.x. [Epub ahead of print].
[14] Esposito M, Worthington H, Coulthard P. In search of truth: the role of systematic reviews and meta-analyses for assessing the effectiveness of rehabilitation with oral implants. Clin Implant Dent Relat Res 2001;3:6278.
[15] Ekelund JA, Lindquist LW, Carlsson GE, Jemt T. Implant treatment in the edentulous mandible: a prospective study on Branemark system implants over more than 20 years. Int J Prosthodont 2003;16:602–8.
[16] Friberg B, Jemt T. Clinical experience of TiUnite implants: a 5-year cross-sectional, retrospective follow-up study. Clin Implant Dent Relat Res 2010;12:e95–103.
[17] Balshe AA, Assad DA, Eckert SE, Koka S, Weaver AL. A retrospective study of the survival of smooth- and rough-surface dental implants. Int J Oral Maxillofac Implants 2009; 24:1113–18.
[18] Gotfredsen K, Karlsson U. A prospective 5-year study of fixed partial prostheses supported by implants with machined and TiO2-blasted surface. J Prosthodont 2001;10:2–7.
[19] Astrand P, Engquist B, Dahlgren S, Grondahl K, Engquist E, Feldmann H. Astra Tech and Branemark system implants: a 5-year prospective study of marginal bone reactions. Clin Oral Implants Res 2004;15:413–20.
[20] Buddula A, Assad DA, Salinas TJ, Garces YI, Volz JE, Weaver AL. Survival of turned and roughened dental implants in irradiated head and neck cancer patients: a retrospective analysis. J Prosthet Dent 2011;106:290–6.
[21] Esposito M, Grusovin MG, Coulthard P, Thomsen P, Worthington HV. A 5-year follow-up comparative analysis of the efficacy of various osseointegrated dental implant systems: a systematic review of randomized controlled clinical trials. Int J Oral Maxillofac Implants 2005;20: 557–68.
[22] Esposito M, Koukoulopoulu A, Coulthard P, Worthington H. Interventions for replacing missing teeth: dental implants in fresh extraction sockets (immediate, immediate-delayed and delayed implants). Cochrane Database of Systematic Reviews. Chichester, UK: John Wiley & Sons, Ltd; 2006.
[23] Esposito M, Grusovin M, Talati M, Coulthard P, Oliver R, Worthington H. Interventions for replacing missing teeth: antibiotics at dental implant placement to prevent complications. Cochrane Database of Systematic Reviews. Chichester, UK: John Wiley & Sons, Ltd; 2008.
[24] Esposito M, Grusovin M, Willings M, Coulthard P, Worthington H. Interventions for replacing missing teeth: different times for loading dental implants. Cochrane Database of Systematic Reviews. Chichester, UK: John Wiley & Sons, Ltd; 2007.