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A retrospective case series evaluating Brånemark BioHelix implants placed in a specialist private practice following 'conventional' procedures. One-year results after placement

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Purpose: To evaluate, in a retrospective case series, survival rates and complications of Brånemark dental implants placed according to 'conventional' procedures in patients consecutively treated in a Swedish specialist private practice.

Materials and methods: Eighty-three consecutively treated patients received 89 final fixed prostheses (31 mandibular and 58 maxillary) supported by 310 (101 mandibular and 209 maxillary) implants placed according to 'conventional' procedures, that is, no implants shorter than 10 mm, no immediate post-extractive implants and no bone grafting procedures. In 70 patients, implants were left to heal submerged, whereas 13 patients were treated according to a one-stage procedure. All restorations (40 screw-retained cross-arch bridges, 32 screw-retained partial bridges and 17 cemented single crowns) were delivered about 2 (mandible) to 3 or 4 (maxilla) months after implant placement. Outcome measures were prosthesis success, implant survival and complications.

Results: One year after implant placement, no patients had dropped-out. No prostheses or implants had failed and no biological or biomechanical complications had occurred.

Conclusions: Brånemark BioHelix dental implants placed according to 'conventional' procedures in 'selected' patients provided excellent short-term results. Randomised clinical trials with suitable controls are needed to confirm these preliminary results.

Introduction

Brånemark dental implants are the best-documented osseointegrated dental implants, both in terms of numbers and longevity[1]. High success rates have been reported for both partially and fully edentulous patients[1]. However, a Cochrane systematic review suggested that Brånemark implants, characterised by a relatively smooth surface (machined or turned) showed a tendency to increased early failure rates when compared with implants having rougher surfaces. However, in the medium-term (3 to 5 years), Brånemark implants were significantly less affected by peri-implantitis (defined as progressive loss of peri-implant bone in the presence of signs of infection) compared with implants with rougher surfaces such as titanium plasma-sprayed (TPS)[2]. Therefore, a possible improvement of the 'classic'

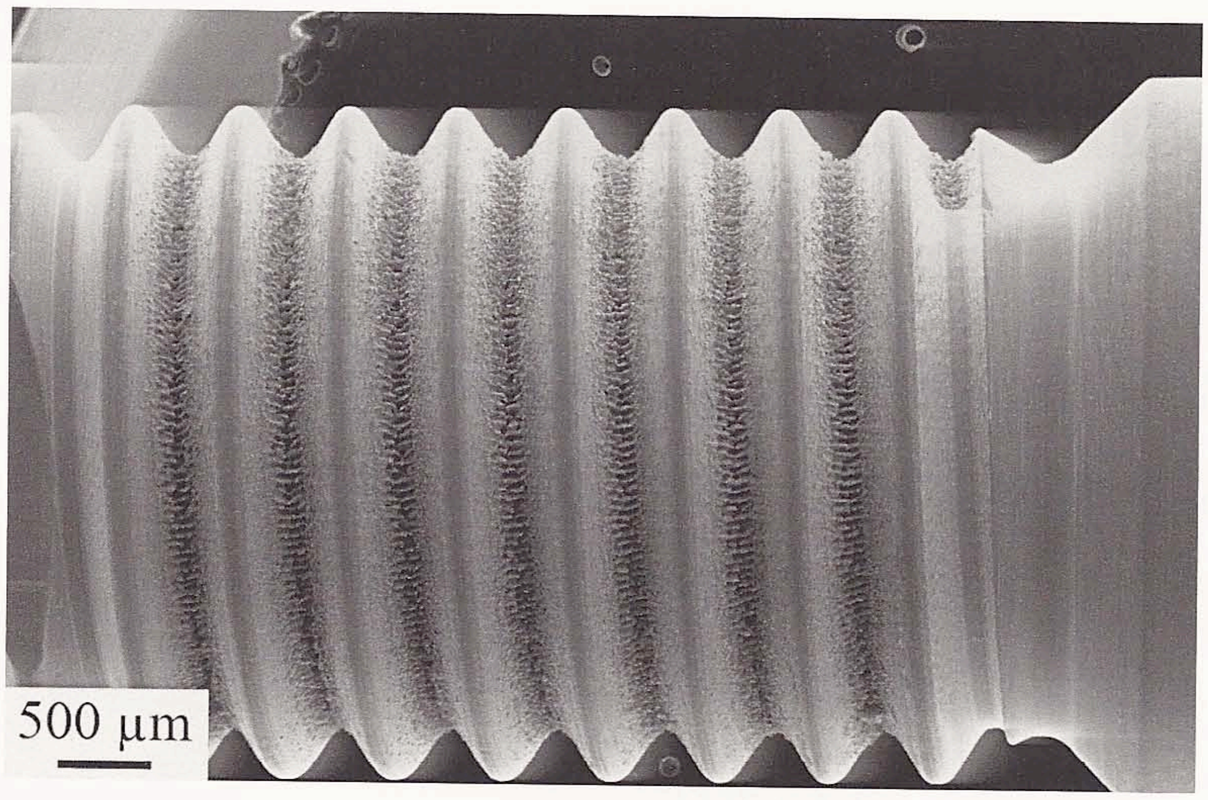

Fig 1 Scanning electron microscope micrograph of the implant at 18X magnification. The bottom portion of the threads is modified by laser processing, whereas the parts of the flanks and the tops are as machined.

Fig 2 Scanning electron microscope micrograph at 1000X magnification showing the resolidified material from the laser processing.

Fig 3 Higher magnification (10,000X magnification) of the laser modified surface, showing the nano-topography.

Brånemark implant was to modify the machined surface in order to have a surface that provides an improved and earlier osseointegration, without jeopardising the good long-term prognosis.

A laser micromachining process has been developed to create roughness in only the inner part of the thread (Figs 1 to 3). The inner part of the thread is believed to be more suitable for bone

formation than the outer part[3]. The laser technique has several advantages, it is precise, adds no chemicals and can be used in routine manufacturing. Only the middle portion of the implant was laser-treated (Fig 1) and not the coronal or the apical portions. The idea behind this design is that the upper portion of the implant, which might have a higher risk for peri-implantitis, is characterised by a relatively smooth surface to minimise the potential retention of microorganisms, whereas the rest of the implant has a rougher surface in the inner part of the threads (valleys) to maximise bone-to-implant contact.

A recent animal study[4,5] in ten rabbits evaluated the biomechanical properties and the ultrastructure of the bone response to the laser-modified Ti_6Al_4V implant compared with turned (machined) controls after 8 weeks. The biomechanical testing demonstrated a 270% increase in torque values for the laser-treated implants. Interestingly, at the laser-modified surface, the fracture occurred in the mineralised bone rather than at the interface, as in the machined implants.

The aim of this retrospective case series was to evaluate survival rates and complications of Brånemark BioHelix dental implants placed according to 'conventional' procedures in consecutively treated patients in a Swedish specialist private practice. This study is reported following the STROBE Statement for observational studies[6].

Materials and methods

Study design, inclusion/exclusion criteria and outcome measures

This investigation was designed as a retrospective observational cases series including consecutively treated patients. All patients signed a written informed consent form. Follow-up was 1 year after implant placement for all patients. Interventions were delivered at a Swedish specialist private dental practice between 2006 and 2007. All procedures and assessments were performed by a single experienced operator (MT). Inclusion criteria were patients had to be 18 years or older, require rehabilitation with dental implants, with sufficient bone volume to accommodate implants with a 3.75 mm diameter and at least 10 mm long without the need for bone augmentation procedures. No immediate post-extractive implants were used. Exclusion criteria were:

- oral lichen planus lesions, irradiation in the head and neck region or chemotherapy during the previous 5 years
- severe skeletal arch discrepancies
- patients showing dubious co-operation
- unrealistic aesthetic expectations
- emotional instability and psychiatric problems
- substance abusers
- patients affected by HIV, autoimmune diseases, metabolic diseases affecting bone
- uncontrolled diabetes
- serious coagulation problems
- pregnant and lactating women
- infections at the implant sites.

Preliminary screening was done on panoramic orthopantomographs and on CT scans when required.

The following outcome measures were considered.

- Success of the prosthesis: any failed prostheses or a prosthesis that could not be placed was considered a failure.
- Survival of the implants: mobile implants or a stable implant, which had to be removed due to infection were considered as failures. Implants were individually assessed for stability by tightening the abutment screws at abutment connection, but after placement of the final prosthesis individual implant stability was not assessed.
- Any biological or prosthetic intra-operative and post-operative complications.

All follow-up assessments were done by the treating clinician (MT).

Cylindrical Brånemark Integration BioHelix implants (Biohelix™, Göteborg, Sweden) with a laser-treated surface were used. This system is designed for two-stage surgery. The implant diameter used was 3.75 mm and implant lengths were 10, 13, 15 and 18 mm.

Prior to the intervention, patients rinsed with 0.2% chlorhexidine mouthwashes for 1 min and were instructed to continue this two times daily for 2 weeks after the intervention. Prior to implant

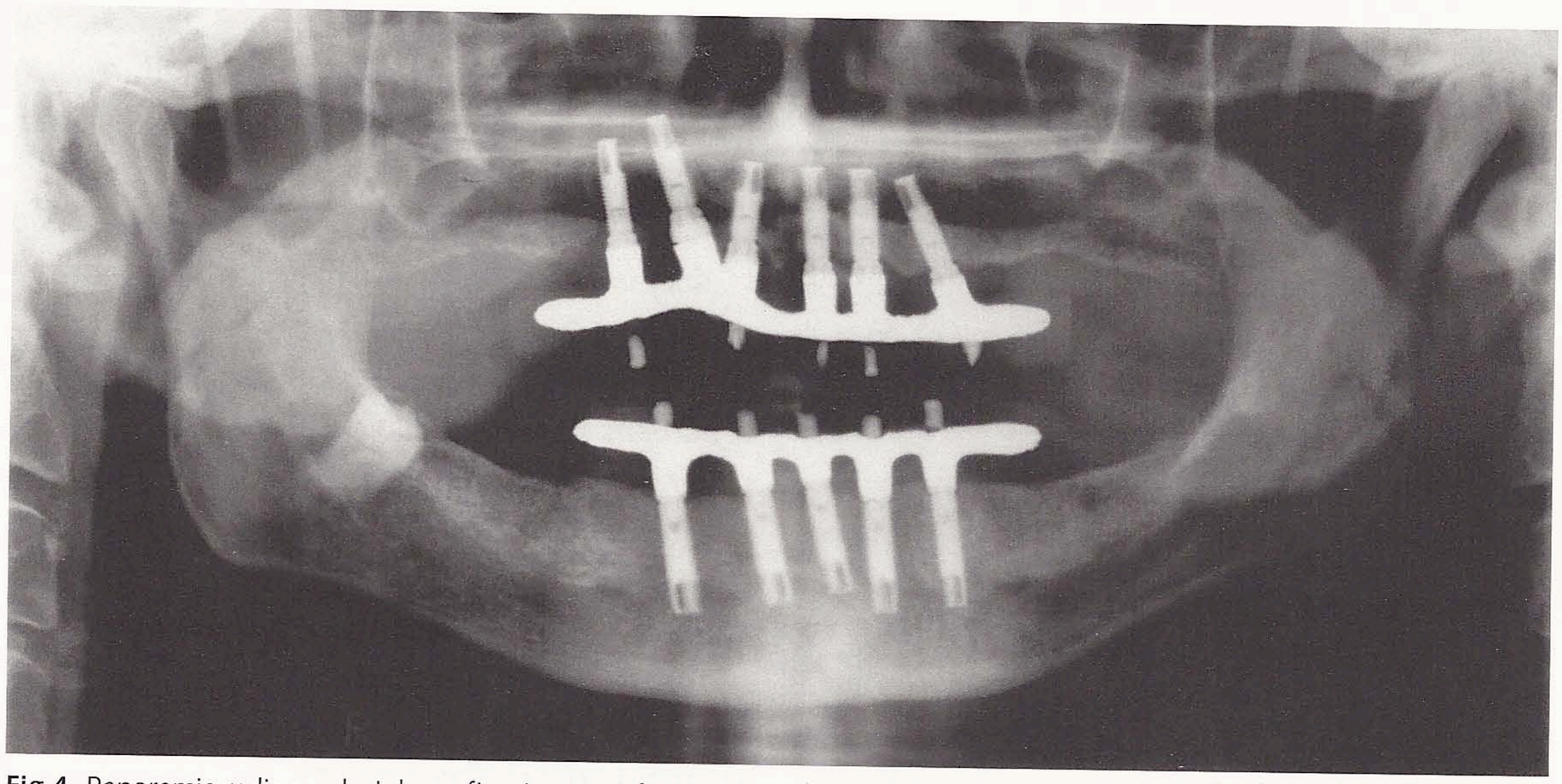

Fig 4 Panoramic radiograph, taken after 1 year in function, showing five mandibular implants early loaded after 10 days. The six maxillary implants were placed more than 10 years before and are conventional Brånemark System™ implants.

placement, 2 g of amoxicillin with clavulanic acid (Augmentin, GlaxoSmithkline, Middlesex, UK) were administered to each patient. The administration continued at 1 g twice a day for 3 days.

The standard drilling sequence suggested by the manufacturer was followed. This began by using a 2 mm guide drill, followed by the 2 mm twist drill and the pilot drill, which starts with a diameter of 2 mm and, in one step, increases the diameter to 3 mm. Depending on the bone quality, final twist drills of 2.85 mm, 3 mm, or 3.15 mm were used. Finally, the countersink was used in hard bone to ease implant insertion. In case of very dense bone, implant sites were tapped with a screw tap. Bicortical engagement of the implants was sought whenever possible. Implants were inserted with a speed of 15 rpm using a torque of 50 Ncm and, once the motor stopped, manually with a ratchet until seated in the proper position. The neck of the implants was placed flush with the alveolar bone crest, and cover screws or healing abutments were placed. Saline mouthwashes were prescribed after every meal for 2 weeks, together with pain killers. Patients were routinely seen 1 week after surgery, and, if they were wearing provisional prostheses, patients were checked every month.

Implants were left to heal either submerged or with a transmucosal healing abutment for about 2 months in the mandibles and 3 to 4 months in maxillae. In one fully edentulous patient, 5 mandibular implants were loaded after 10 days (Fig 4).

After bone healing, submerged implants were exposed through flap elevation, and impression copies were attached to the implants. Impressions were taken with individual trays using Impregum F (Espe Dental AG, Seefeld, Germany). Implants were not connected to natural dentition. All restorations were fabricated and delivered as definitive prostheses. Single implants were rehabilitated with cemented titanium-ceramic or gold-ceramic crowns, whereas partial and full titanium-ceramic or gold-ceramic bridges were screw-retained. Cantilevers at a maximum of 12 mm long were allowed in cross-arch bridges (Fig 4). No overdentures were delivered. Patients received professional oral hygiene maintenance every 6 months or according to their individual needs.

Results

In total, 83 patients were consecutively treated: 47 males (56.6%) and 36 females (43.4%). Age at implant insertion ranged between 27 and 87 years (mean 67.5 years). Twenty-seven (32.5%) patients suffered from diabetes that was controlled with oral hypoglycaemics or insulin. Sixty-four patients (77.1%) declared themselves to be non-smokers, 18 (21.7%) were light smokers (≤ 10 cigarettes per

day) and one (1.2%) was a heavy smoker (>10 cigarettes per day).

In total, 310 implants were inserted, of these implants 101 (32.6%) were placed in mandibles and 209 (67.4%) in maxillae. The lengths of placed implants are described in Table 1. In 70 patients (84.3%) implants were left healing submerged, whereas in 13 patients (15.7%), implants were left healing with a transmucosal abutment.

All patients received the planned final prostheses. Eighty-nine final fixed prostheses (31 mandibular and 58 maxillary) were delivered (Table 2): 40 (45%) screw-retained cross-arch bridges, 32 screw-retained partial bridges (36%) and 17 (19%) cemented single crowns.

No patient dropped out up to 1 year after implant placement. No prosthesis or implant failed, and no biological or prosthetic complications occurred.

Discussion

The main finding of this study is that, 1 year after placement, Brånemark BioHelix implants, inserted by an experienced surgeon according to conventional procedures and in selected patients, provided excellent results.

Among the major limitations of this study were the retrospective design, the lack of suitable controls, the lack of an independent assessment of the outcomes, and the lack of an objective evaluation of implant success (implant stability). Despite the fact that retrospective uncontrolled studies are not the ideal study design to evaluate efficacy of an intervention[7], they can still provide some information as to whether or not a certain implant design or surface modification can work, though direct comparisons with other implant systems may provide unreliable results and should be avoided. Randomised clinical trials (RCTs) are the gold standard to evaluate efficacy of medical interventions, and so far no RCT has been published evaluating this implant surface modification. To the best of the authors' knowledge, this is the first clinical report on Brånemark BioHelix implants.

The results of the present investigation are indeed very positive (100% survival rates of the implants with no complications). Indeed, only one 18mm long implant failed after the 1-year follow-up. This was a mandibular implant in position 43 placed in bone of medium-density, supporting, along with the other four 18mm long implants, a cross-arch bridge. The reasons for the impressive survival rate of the present study are difficult to explain in relation to the higher failure rates of conventionally loaded Brånemark implants, particularly in edentulous maxillas, which had not been observed until a decade ago[1]. Of course, additional experience on dental implant treatment has accumulated over the years and, therefore, it is hazardous to make comparisons with historical controls. Any attempted explanation is obviously speculative. However, among the factors that might have contributed to such high success rates, the following are worth mentioning: an improved implant surface and the clinical experience of the surgeon in selecting and treating the patients. It could be that the modified surface of Brånemark BioHelix implants was able to improve bone osseointegration, decreasing early failure rates. The implants were placed by a very experienced surgeon, who carefully selected the patients to undergo implant rehabilitation. The surgeon carefully limited all those situations that may put an implant at a higher risk of

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

Table 1 Length of the implants.

Type of prosthesis	Mandible	Maxilla	Total (%)
Single crowns	2	15	17 (19%)
Partial bridges	15	17	32 (36%)
Cross-arch bridges	14	26	40 (45%)
Total	31	58	89 (100%)

Table 2 Type of prosthesis.

failure. Effective antibiotic prophylaxis prior to implant placement was also provided[8], only a few relatively short 10 and 13 mm implants were used (4.2 and 5.2%, respectively), no immediate post-extractive implant was placed[9], no bone grafting procedures were implemented[10] and no implant was immediately loaded, with the exception of one patient who had 5 mandibular implants early loaded after 10 days[11]. On the other hand, one third of the treated patients were controlled diabetics, the mean patient age was quite advanced (67.5 years) and 45% of the prostheses delivered were cross-arch bridges, with a greater prevalence of maxillary over mandibular bridges (26 versus 14 bridges). This study design cannot explain whether or not such impressive results are attributable to the modified implant surface, to the experience of the surgeon, or to both factors. To evaluate whether or not the modified surface has improved implant success rates, a multi-centre RCT using machined Brånemark implants as controls would be needed.

This study apart, suggesting that Brånemark BioHelix implants appear to very successful is rather uninformative, as no negative events, such as failures and complications, occurred up to 1 year after placement.

The results of the present study are likely to be applicable to comparable populations of patients, if a similar cautious treatment approach is taken by very experienced professionals.

Conclusions

Brånemark BioHelix dental implants placed according to 'conventional' procedures in 'selected' patients provided excellent short-term results. RCTs with suitable controls are needed to confirm these preliminary results and to see whether or not the modified surface determines improved success rates.

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