On various protocols for direct loading of implant-supported fixed prostheses

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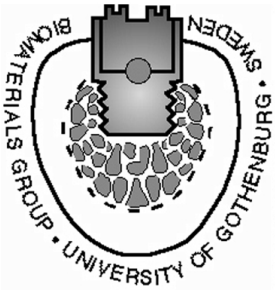

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ABSTRACT

Backgrund: Prosthetic rehabilitation of the edentulous patient with implant-supported bridges is today a routine and predictable treatment modality. The original protocol prescribed a healing period of 3 to 6 months prior to loading which means that the total treatment time can be extensive and that the patients often need to wear removable provisional prostheses during healing and treatment. The use of immediate implant loading protocols would significantly reduce treatment time.

Aims: The aim of this thesis was to clinically and radiographically evaluate different protocols for immediate loading of dental implants with regard to implant survival and marginal bone resorption.

Material & Methods: *Paper I.* The use of provisional implants (PIs) for support of a fixed temporary bridge during the healing of permanent implants was evaluated in 45 patients with either partially (19 patients) or totally (26 patients) edentulous maxillae. The patients were followed from implant surgery to abutment connection of the permanent implants. *Paper II.* The primary implant stability of 905 implants in 267 consecutive patients treated with implant-supported fixed prostheses was assessed using resonance frequency analysis (RFA) measurements (implants stability quations, ISQ) at implant placement surgery. The results were correlated with parameters related to the patient, implant site and the implant components. *Paper III.* A total of 96 patients were evaluated for immediate loading of implant-supported bridges in the posterior mandible (insertion torque > 30 Ncm, ISQ > 60). 77 patients (85%) met with the criteria and a total of 257 implants were placed, 77 with a turned and minimally rough surface and 180 with an oxidized and moderately rough surface. A total of 111 FPDs were made. The bridges were supported by one implant and tooth or were freestanding constructions supported by 2, 3 or 4 implants. The patients were followed for at least one year with clinical and radiographic examinations. *Paper IV.* Twenty (20) patients treated with immediately loaded implant-supported bridges in the edentulous maxilla participated in the study group. Inclusion criteria for immediate loading were a minimum insertion torque of 30 Ncm and an implant stability value of 60 ISQ for the two posterior fixtures and a total sum of 200 (mean ISQ 50) for the four anterior fixtures was required. A group of 20 patients previously treated with implant-supported bridges in the maxilla by the same team following a two-stage protocol was used as a reference group. The patients were followed for one year with clinical and radiographic examinations. *Paper V.* A total of 115 one-piece implants (OPIs) with a moderately rough surface all the way up through the mocosa, were placed in 48 patients for immediate loading of single crowns and partial bridges in the mandible and the maxilla. A group of 97 patients previously treated by the same team under identical conditions with 380 two-piece implants (TPIs) for immediate loading was used as a control group. The patients were followed for one year with clinical and radiographic examinations.

Results: *Paper I.* Seven (3.6%) PIs failed owing to infection or pain during the observation period and were removed. Seventeen (9%) of 192 provisional implants showed mobility at the second-stage surgery, although they had served as support for the provisional bridge without clinical symptoms during the follow-up time. Five (2.2%) of the 230 permanent implants placed did not integrate and were subsequently removed at the second-stage surgery. *Paper II.* The mean primary stability for the 905 implants was 67.4 ISQ (SD 8.6) where 582 (64.3 %) showed an ISQ value of 65 or higher and 761 (84.1%) implants an ISQ value of 60 or higher. Male patients showed higher ISQ values than females, mandibular implants were more stable than maxillary ones. Implants placed in posterior regions were more stable than in anterior sites, wide platform implants were more stable than regular/narrow platform ones. There was a correlation between bone quality and primary stability, with lower ISQ values with softer bone. A lower stability was seen with increased implant length. *Paper III.* A total of four (1.6 %) of the 257 implants placed did not integrate and were subsequently removed. The overall cumulative survival rate was 98.4 % after 1 year follow-up, 96.1% and 99.4 % for turned and oxidized implants, respectively. The average bone loss was 0.7 (S.D. 0.8) mm after one year of follow-up. *Paper IV.* One (0.8%) of 123 immediately loaded implants placed did not integrate. In the control group, no implants were lost. The overall cumulative survival rates after 1 year were 99.2% for the study group and 100% for the reference group. The mean change of marginal bone level was 0.78 mm (SD 0.90 mm) for immediately loaded implants and 0.91 mm (SD 1.04 mm) for reference group implants. The differences were not significantly different. *Paper V.* Six OPIs (5.2%) were removed during the follow-up period because of extensive bone resorption and subsequent soft tissue problems. After 1 year, the mean marginal bone loss was 2.1mm (SD 1.3) for OPIs and 0.8mm (SD 1) for TPIs. 20% of OPIs showed more than 3mm of bone loss compared with 0.6% for TPIs. When compensating for vertical placement depth, OPIs still showed a lower marginal bone level and thus more exposed threads than TPIs. Depending on the criteria used, the success rate for OPIs was 46.1% or 72.2% compared with 85% or 91.6% for TPIs.

Conclusion: It is concluded that immediate loading of two-piece dental implants results in good clinical outcomes if high primary stability is achieved and a rigid splinting with well controlled occlusion is applied. Provisional implants can be used as support of a provisional bridge during submerged healing of permanent two-piece implants. Moreover, it is concluded that one-piece implants show more bone resorption and higher failure rates than two-piece implants after one year in function.

Keywords: dental implants, immediate loading, clinical studies, radiography, implant stability, resonance frequency analysis.

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List of papers

I. ***Östman PO, Hellman M, Nilson H, Ericsson I.*** Provisional implants: a clinical prospective study in 45 patients, from implant placement to delivery of the final bridge. Clin Implant Dent Relat Res. 2004;6(3):142-9.

II. ***Östman PO, Hellman M, Wendelhag I, Sennerby L.*** Resonance frequency analysis measurements of implants at placement surgery. Int J Prosthodont. 2006 Jan-Feb;19(1):77-83.

III. ***Östman PO, Hellman PO, Sennerby L.*** Immediate Occlusal Loading of Implants in the Partially Edentate Mandible: A Prospective 1-year Radiographic and 4-Year Clinical Study. Int J Oral Maxillofac Implants. *In press*

IV. ***Östman PO, Hellman M, Sennerby L.*** Direct implant loading in the edentulous maxilla using a bone density-adapted surgical protocol and primary implant stability criteria for inclusion. Clin Implant Dent Relat Res. 2005;7 Suppl 1:S60-9.

V. ***Östman P-O, Hellman M, Albrektsson T, Sennerby L.*** Direct loading of Nobel Directs and Nobel Perfects one-piece implants: a 1-year prospective clinical and radiographic study. Clin Oral Impl Res 2007;18: 409–418.

Appendix:

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Introduction

Prosthetic rehabilitation of the edentulous patient with implant supported bridges has been developed to a viable and predictable treatment option during the last 40 years. The fact that long-term studies have reported high clinical success rates with the original protocols[1] has given clinicians and researcher's confidence to further develop and refine the osseointegration technique and, consequently, implants are used in more challenging situations and on wider indications [2]. For instance, we have gone from rehabilitation of the total edentulous mandible with implants in the intra-foramina region to single implants in grafted areas in the posterior part of the maxillae. A similar trend is seen for timing of implant loading. A submerged healing period of 3 to 6 months was originally considered a prerequisite for achieving osseointegration of titanium implants[1]. However, during the last 10 to 15 years this traditional protocol has been questioned and challenged and numerous clinical studies have reported on the outcome of early and immediate loading in various clinical situations.[3,4] There has also been a change of focus of the treatment from originally being a strict functional rehabilitation to being a treatment modality with great attention on esthetics[5].

Another consequence of the widespread use of the osseointegration technique is the rapid launching of new implant designs and treatment concepts. Although some of the new implant systems are supported by clinical documentation, the majority are not. In some sense it is therefore the task of clinicians and researchers to critically scrutinize new implant and treatment concepts. Dentists should rely on proper scientific studies rather than on partly unsupported claims by implant manufacturers. One example of insufficient information is the Nobel Direct implant (Nobel Biocare, Gothenburg, Sweden), which with little or no documentation prior to its introduction was claimed to reduce marginal bone loss and improve the aesthetic outcome due to "soft tissue integration". However, recent studies showed the Nobel Direct implant system results in higher failure rates and more bone loss compared with conventional implants.[6-8] Having said this, it should be remembered that manufacturers have been instrumental in developing implant surfaces and designs, which have increased the predictability of implant therapy in challenging situations, such as the use of immediate-loading implants.

WHY IMMEDIATE LOADING?

Immediate reduction of handicap - Edentulous, thereby orally handicapped patients seek treatment to restore function and aesthetic appearance. Traditionally, this rehabilitation has involved the use of removable full or partial dentures. ,

Patients are, however, not always satisfied with this treatment due to a sense of insecurity, reduced chewing capacity and taste. Frequently they show less self-esteem. In a controlled study, Blomberg et al[9] examined 26 patients before and 3 months postoperatively and then 2 years after the insertion of an implant-supported bridge. The majority of them stated that there had been a significant improvement in their lives, that they had regained confidence in themselves, and that, in contrast to a conventional denture, they accept the fixed bridge as part of their body. Implant treatment according to the traditional protocols may take a long time, specially if extended healing is required before implant surgery. This means long periods with no teeth or with removable dentures with the disadvantages discussed above. The use of immediate/early loading protocols have obvious advantages as the patients can be rehabilitated with fixed teeth for immediate function and esthetics i.e. an immediate reduction of their oral handicap.

Biological response - Experimental studies and histology of clinically retrieved implants have shown a similar and sometimes better bone- implant contact (BIC) for immediately loaded implants[10-18] compared to delayed cases. Piattelli et al[13], compared histologically non-submerged unloaded with early-loaded titanium screw implants in monkeys. They found, a tight contact of new bone to the implant surfaces in all samples examined. Moreover, around the implant necks of the early-loaded screws was a pattern of lamellar, cortical bone, thicker than in unloaded implants. In a pilot study[11], the bone reactions to early loaded titanium plasma-sprayed implants were analyzed in a monkey model. Twenty implants were immediately loaded and 4 implants functioned as controls. The result showed a BIC of 67.2% of the maxillary implant surface (10 implants), and 80.7% BIC of mandibular implant surfaces (10 implants). No differences were found in the percentage of bone-implant contact in the control implants. However, the loaded implants showed a more compact appearance compared to the controls. Testori et al[15], in a case found a higher BIC for immediately loaded Osseotite (Biomet 3i) implant (64.2%) compared to submerged implants (38.9 %). Rocci et al[17], retrieved 9 oxidized titanium implants after 5 to 9 months in function. Two implants had been loaded the same day, whereas seven implants were loaded after 2 months of healing. Morphometric measurements in the two immediately loaded implants showed a mean BIC value of 92.9%. The corresponding values for the six early loaded implants were 81.4%. Although the limited number of samples in the above referred papers, a tendency to higher BIC values can be seen in immediately loaded compared to non loaded implants. Frost[18] postulated that both too modest and too excessive loading could result in negative tissue reactions.

Fischer and Stenberg[20] showed a statistically verified difference in marginal bone resorption between immediately loaded SLA (Straumann, Basel, Switzerland) implants compared to a delayed loading control group.

The influence of the peri-implants soft tissue morphology on immediate loaded implants in total edentulous maxillas was analyzed by Gallucci et al[19]. They found, after immediate provisionalization an increase in width for both central implants and interproximal implant sections. One other finding was that the most coronal part of the papilla like mucosa at interproximal sites would be nearest to the original mucosal level before treatment.

Although more histological, radiographical and soft tissue studies comparing immediate loaded vs delayed loading are needed, the findings from the literature indicate favorable tissue response to immediately loaded implants.

TERMINOLOGY

The terminology used when discussing immediate loading is often confusing although attempts have been made to agree upon definitions.[21,22] The following definitions are proposed by the present author:

Definition of Timing of Implant Load

Immediate/ direct loading: The provisional/definitive prosthetic construction is attached to the implant within 24 hours after the implant is placed.

Early loading/Early functional loading: The provisional/definitive prosthetic construction is attached to the implant within days/weeks after the implant is placed.

Delayed loading: The provisional/definitive prosthetic construction is attached at a second procedure after a conventional healing period of 3 to 6 months.

Definition of Surgical protocol

One stage: The implant heals without protection of the oral mucosa and is accessible through the mucosa during healing time.

Two stage: The implant heals under the soft tissue and is after a healing period accessed through a second stage surgery.

Definition of Prosthetic load of Implant

Occlusal loading: The crown/bridge is in contact with the opposing dentition in centric occlusion.

Non occlusal loading: The crown/ bridge is *not* in contact in centric occlusion with opposing dentition in natural jaw positions.

Definition of success criteria

Success grade I – Criteria for success include absence of implant mobility and absence of pain and neuropathy. One mm of bone loss from the lower corner of the implant head is acceptable during the first year and less than 0.2 mm annually thereafter.

Success grade II – Criteria for success include absence of implant mobility and absence of pain and neuropathy. Two mm of bone loss from the lower corner of the implant head is acceptable during the first year and less than 0.2 mm annually thereafter.

Survival – An implant still in the bone that does not meet with or has not been tested for success criteria.

Unaccounted for – An implant in a patient who dropped out of the study for any reason.

Failure – An implant removed for any reason.

Definition of stability

Primary stability – The stability obtained immediately after implant placement. Can be measured with insertion torque and resonance frequency analysis.

Secondary stability - The stability gained after the implant healed 3-6 months.

TOTALLY EDENTULOUS MANDIBLE

In the original Brånemark protocol a stress-free submerged healing time of 3 to 6 months was required for osseointegration.[23-29] The rationale for this long undisturbed healing time was that premature loading may lead to fibrous tissue encapsulation instead of osseointegration.[30,31] However, clinical and experimental evidence has shown that implants osseointegrate even though they are left exposed to the oral cavity during healing.[32-37]

Early loading

During the last decade scientific reports on early loading have been published with acceptable outcome.[38-42] Engquist et al[43] included 108 patients with edentulous mandibles. Each patient was treated with full fixed prostheses attached to 4 Brånemark System implants. Patients were consecutively treated and were distributed in four groups: group A (one-stage surgery), group B (control group with two-stage surgery), group C (one-piece implants), and group D (early loading). In group D 26 patients received in total 104 implants. Time before loading was 10 days to 3 weeks before a permanent fixed prosthesis were attached. Seven of the 104 (6.7%) implants failed between insertion and 3 years of loading. In the control group 3 of 120 (2.5%) implants failed. No significant difference was seen between the two groups. The bone loss in group D was significantly less than that in the control group (group B) whereas there were no differences in marginal bone change between the other groups.

Friberg et al[44] included 152 individuals with 750 turned Brånemark System implants of various designs placed in edentulous mandibles by means of one-stage surgery. The prosthetic procedure was commenced at a mean of 13 days after the surgical intervention. A total of 18 implants in 12 patients in the study group was found to be mobile up to and including the first annual check-up, equivalent to a 1-year implant cumulative survival rate (CSR) of 97.5%. The corresponding CSR for the control group was 99.7%. No significant difference was seen on the patient level ($p > .05$). The mean marginal bone resorption during the first year of function was 0.4 mm in both groups.

Immediate loading

Ledermann[45] showed as early as 1979 that immediately loaded TPS (Straumann, Basel, Switzerland) screw implants could support overdentures in the mandible with predictable outcome. The first report on immediately loaded Brånemark implants with fixed prostheses were presented by Schnitman et al[46] 1990. Five or six Brånemark implants were placed between and two additional fixtures were placed distally to the foramina. Three of the installed implants in strategic positions were connected to a provisional prosthesis, converted from the patient's denture. The remaining fixtures were allowed to heal in the conventional manner. They concluded that this method was successfully applied in seven patients who were reconstructed with mandibular fixed-detachable bridges without ever wearing a removable prosthesis. The overall, long-term implant therapy was not adversely affected by this technique. In a follow up study by the same author[47] Brånemark implants were placed in 10 patients. Twenty-eight implants were immediately loaded with a screw-retained fixed provisional prosthesis. Of the 28 immediately loaded implants 4 (14.3%) failed while the remaining implants with conventional healing time showed 100% survival. Statistical analysis between the two groups showed significantly higher failure rate for the immediate loaded group. They concluded that although mandibular implants can be successfully placed into immediate function in the short term to support fixed provisional prostheses, long-term prognosis is guarded for those implants placed into immediate function distal to the incisor region.

Tarnow and colleges[48] treated 10 consecutive patients with immediately loaded implants. A minimum of 10 implants were placed in each patient's arch. A minimum of five implants were submerged initially and allowed to heal without loading. The remaining implants were immediately loaded. Two implants that had been immediately loaded and one submerged implants failed They concluded, that immediate loading of multiple implants rigidly splinted in a completely edentulous arch can be a viable treatment modality. Other studies[49-50] with the same design, a mixture of submerged and non-submerged implants in the same patient has reported similar results.

Other concepts for immediate loading of totally edentulous mandibles include reducing the number of implants. The minimum number of implants reported in the literature, supporting fixed bridge in the totally edentulous mandible, is 3 screws.[51-58] De Bruyn and colleges[56] included 20 patients in a prospective study. Nineteen patients received five implants in the mandible, of which three were functionally loaded with the one-stage technique. The loaded implants were inserted in a tripodal position, one implant in the symphysis and two located anterior to the mental foramen in the bicuspid area. Two additional implants were inserted for safety reasons but were not loaded. Immediately after surgery, the im-

plants were loaded with a rebuild denture. The patients received a 10- to 12-unit prosthetic reconstruction between 4-5 weeks after surgery. Six of 60 functionally loaded implants (10%) and 3 of 20 prostheses (15%) failed within the first year. They concluded that the results of treatment using three implants supporting a fixed mandibular arch reconstruction were less favorable than the outcome that can be expected with a standard four- to six-implant with one-stage surgery.

At present 4 to 6 implants in a completely edentulous mandible seems to be sufficient to retain a fixed prosthesis with good long-time results. Chow et al[59] rehabilitated 14 patients with 4 implants each. The implants were placed in the inter-foramina area in totally edentulous mandible. The implants were loaded within 24 h with a screw-retained temporary prosthesis. After one year follow-up the survival rate was 100%. Testori et al[60] treated 15 patients who received in total 103 Osseotite implants. The first two patients received both immediately loaded and submerged implants, while the remaining patients had all implants immediately loaded. Temporary prostheses was delivered between 4-36 hours. One failure (out of the 92 immediately loaded implants) occurred after 3 weeks of function. This implant was lost because of infection. A cumulative success rate of 98.9% was achieved for up to 48 months of follow-up, while the prosthetic cumulative success rate for the same period was 100%. No difference in marginal bone loss for the immediately loaded implants could be observed compared with the generally accepted conventional limits for standard delayed loading protocols.

In a prospective multicenter study by the same authors[61] 325 Osseotite implants were placed in 62 patients (4 centers). The temporary prosthesis was delivered 4 h from surgery. Two implants failed to integrate within 2 months. A cumulative implant success rate of 99.4% was achieved for a period of 12-60, mean 28.6 months. Crestal bone loss around the immediately loaded implants was similar to that reported for standard delayed loading protocols. It was concluded that the rehabilitation of the edentulous mandible by an immediate loaded protocol supported by five to six Osseotite implants represents a viable alternative treatment to traditional delayed loading protocols. Another study[62] reports the clinical experience and outcome of rehabilitation of 16 patients with completely edentulous mandibles, immediately loaded with cross-arch screw-retained hybrid prostheses. Ninety Brånemark System Mk III implants were analyzed. Three implants failed to meet the criteria of success, bringing the cumulative success rate to 96.6%, with a 100% prosthetic success rate at 3 years. Seventy-seven (85.5%) of the dental implants were placed in high-density bone. At 3 years post loading, the average bone loss was -1.2+/-0.1 mm. Table 1 presents a summary of articles on immediately loaded total edentulous mandible fixed prosthesis.

Table 1. *Published articles on immediate loading in the total edentulous mandible, fixed prostheses.*

Authors	Type of study	No. of patients	No. of loaded implants	Years of follow-up	No. of lost implants	***Implant CSR %***
Schnitman et al.[47]	Prospective	10	28	10	4	***85.7***
Tarnow et al.[48]	Prospective	6	36	1-5	2	***97.4***
Brånemark et al.[51]	Prospective	50	150	6 months-3years	3	***98***
Balshi & Wolfinger[49]	Prospective	10	40	1	8	***80***
De Bruyn et al.[56]	Prospective	20	60	1	6	***90***
Chow et al.[59]	Prospective	14	56	1	0	***100***
Testori et al.[60]	Prospective	15	103	4	1	***98.9***
Testori et al.[61]	Prospective/ multicenter	62	325	1-5	2	***99.4***
Wolfingeret al.[50]	Prospective	24	144	3-5	5	***97***
Engstrand et al.[52]	Prospective	95	295	1-5	18	***93.3***
Henry et al.[53]	Prospectiev	51	153	1	14	***91***
Aalam et al.[62]	Prospective	16	90	3	3	***96.6***
Total		***373***	***1480***			

Conclusion immediately loaded implants in totally edentulous mandible

When evaluating immediate loading protocols in the edentulous mandible, survival/success rates should be compared with those of the traditional two-stage approach. For instance an implant survival rate of 99% was reported after 15 years by Lindquist et al.[63] The use of three implants for immediate loading resulted in survival rates ranging from 90% to 98%. Re-operation is obviously required if an implant is lost which is a drawback. On the other hand a smaller number of implants reduces the costs of the treatment.

Four or more implants are sufficient number of implants supporting a fixed prosthesis with high predictable outcome 95-100%. Immediate loading in the totally edentulous mandible is a predictable and well documented treatment if a sufficient number of implants are used. However, patient selection must be considered if predictable high success rates are to be achieved. It may be argued that the slightly lower survival rate compared with the two-stage approach is acceptable when considering immediate handicap reduction, one surgery and fewer visits to the dental office.

TOTALLY EDENTULOUS MAXILLAE

Less long-term data on immediate loading in the totally edentulous maxilla is available as compared to the mandible and most papers are case reports.[48, 64-67]

Early loading

Fischer & Stenberg[68] studied early loading of 24 patients with completely edentulous maxillae, randomized into a test group of 16 and a control group of 8 patients. All patients received 5 or 6 solid screw-type titanium implants with sandblasted, large-grit, acid-etched (SLA) surfaces. In total, 142 implants were placed and 139 implants were loaded with full-arch prostheses. The follow up time was 3 years. The cumulative implant success rate 3 years after loading was 100%. The 3-year radiographic evaluation showed less marginal bone resorption in the test group compared to the control. No significant differences between the test and control groups were noted for any other outcome measure. They concluded that that the early loading protocol is a viable alternative to the standard protocol in the rehabilitation of a completely edentulous maxilla with a complete implant-supported fixed prosthesis. In another study presented by Olson and colleagues[69] 10 patients were followed for 1 year with clinical and radiographic examinations, loaded with a fixed full-arch bridge in the maxilla 1 to 9 days after implant placement. The patients received in total 61 oxidized titanium implants. Nine patients had six implants and one patient had eight implants supporting the bridge. The provisional bridge was replaced with a permanent bridge after 2 to 7 months of loading. The results showed that 4 implants failed (6.6%). All 4 implants were lost in one patient after 10 weeks of loading owing to an infection. The other implants were clinically stable with a mean marginal bone loss of 1.3 mm after 1 year of loading.

Immediate loading

Bergkvist et al[70] evaluated the survival rate of immediately loaded SLA implants in the edentulous maxilla after 8 months of loading. Twenty-eight patients were treated and a total of 168 implants were placed. A fixed provisional prosthesis was placed within 24 hours after surgery. After a mean healing time of 15 weeks, the patient received a definitive, screw-retained, implant-supported fixed prosthesis. Three implants failed during the healing period (1.8%). The mean marginal bone resorption was 1.6 mm during the 8-months follow-up. The authors discussed the importance of splinting the implants immediately after placement.

In another study[71], 41 consecutive patients were treated. Of these 41 patients, 26 maxillary cases were loaded within 48 hours, by using resin provisional prostheses, metal-reinforced provisional prostheses, or definitive prostheses (metal -acrylic or metal-ceramic). All implants had double acid-etched surface, Osseotite, and were followed for 12 to 74 months. Follow-up consisted of clinical as well as radiographic examination. The success rate was 100% after 12 to 74 months. The average radiographic bone level change was 0.56 mm at 12 and 0.94 mm at 72 months. The author concluded that a high success rate can be achieved when double acid-etched implants were immediately loaded with fixed full-arch restorations in the maxilla.

Degidi and colleges[72] followed 43 patients with a total of 388 implants (mean 9 implants per case) immediately loaded with cross-arch acrylic provisional restorations performed directly after surgery. At the 5-year follow-up, the survival rate was 98%. All failures occurred within 6 months from loading. They concluded that immediate functional loading is a reliable surgical-prosthetic procedure in edentulous maxillae.

Balshi et al[73] included 55 patients in a clinical investigation of immediate functional loading of Brånemark System implants in edentulous maxillas. A total of 552 implants were placed in immediate extraction or healed sites. A mean number of 10 implants were placed per patient. Five hundred twenty-two of the 552 implants were immediately loaded with screw-retained all-acrylic fixed prostheses at the time of surgery. The 30 submerged implants were uncovered after 4-6 months of healing, and a definitive metal-reinforced prosthesis was delivered to each patient. The immediately loaded implant cumulative survival rate was 99.0% for these patients. The prosthesis survival rate was 100%.

Table 2 presents a summary of articles on immediately loaded fixed prostheses in totally edentulous maxillae.

Table 2. *Published articles on immediate loading, totally edentulous maxillae, fixed prostheses.*

Author	Type of study	No Patients	No implants loaded	Follow-up years	Lost implants	*Survival rate %*
Tarnow et al[48]	prosp/cr*	4	14	1 - 4	0	***100***
Horiuchi et al[64]	Prosp/cr*	5	44	1 - 2	2	***96,5***
Grunder[65]	Retro/cr*	5	48	1 - 5	6	***87,5***
Bergkvist et al[70]	prosp	28	168	8 months	3	***98,2***
Degidi et al[72]	Prosp	43	388	5	8	***98***
Balshi et al[73]	prosp	55	522	1	5	***99***
Total		***140***	***1184***	-	-	

*cr=case reports

Conclusion immediately loaded implants in totally edentulous maxillae

Only few studies evaluating immediate loading protocols in the edentulous maxillae are available in the literature. Most papers report treatments using a high number of implants, more than 6, to support the prosthesis. Few studies on early and immediate loading with 6 to 8 implants were found. The survival rate presented ranged from 87,5% to 100% after an observation time on 1-5 years which is comparable with the 5-year survival rates reported for two-stage protocols.

Only one paper presenting 5 year data was found[72]. No change in survival rate could be seen in this study after initial failures that occurred during the first 6 months. The data indicate that if good primary implant stability is achieved in combination with medium/dense bone quality, a predictable outcome of immediately loaded full arch maxillae could be expected.

More short/long-term data are needed before immediate loading could be recommended as a standard procedure in the maxilla.

PARTIALLY EDENTULOUS MAXILLA/MANDIBLE

Early/immediate loading is theoretically more challenging in the partial maxilla/mandible compared to totally edentulous jaws. In partial cases the implants are fewer and often placed on a straight line and therefore exposed to lateral forces, whilst implants in the totally edentulous situation can be placed in an arch form to efficiently counteract bending. Moreover, in the posterior region of the oral cavity the bone is usually softer and bite forces are higher[74] compared to in the anterior part. However, histological studies have shown favorable results from immediate implant loading also in the posterior mandible. For instance, Rocci et al[17] retrieved nine oxidized Brånemark implants; two implants had been loaded the same day, whereas seven implants were loaded after 2 months of healing. A gross histological examination showed an undisturbed healing of soft and bone tissues with no apparent differences between responses to immediately and early loaded implants. Lamellar bone surrounded the implants, and remodelling was evident and more marked near the implant surface. The morphometric measurements showed high BIC values ranging from 84 to 92%.

Early loading

Testori and colleges[75] reported on 475 Osseotite implants in a longitudinal, prospective, multicenter study on early loading. All implants were placed in the posterior region of 175 patients and restored within 2 months. Six of 475 implants were classified as early failures, whereas 3 implants were classified as late ones, giving a cumulative survival rate on 97.7% after 3 years follow-up. Cochran et al[76] presented a longitudinal, prospective, multicenter study on 383 SLA implants placed in the posterior jaws of 307 patients. Healing time ranged from 42-63 days for implants in class 1-3 bone to 105 days in class 4 bone. At abutment placement 3 implants were mobile and removed. In addition 3 implants were not rotationally stable and 6 were associated with pain. These 9 implants were allowed to heal and became eventually stable. The survival rate after 1 year follow-up was 99.1%. Roccuzzo and Wilson[77] published a report on 36 ITI implants placed in the posterior maxillae. Twenty-nine non-smoking patients were treated with a surgical protocol aiming to enhance primary stability. Abutments were placed after 43 days and the implants were loaded with a temporary bridge in infra-occlusion. After additional 6 weeks definitive prosthesis were made. One implant failed, giving a survival rate of 97.2% after one year of loading. Another study presented by Roccuzzo and coworkers[78] reported on a prospective split mouth study comparing early loading of 68 SLA implants loaded after 6 weeks compared with 68 TPS implants loaded at 12 weeks. Four of the 68 SLA implants were non-rotationally stable at 6 weeks abutment placement and were allowed to heal for additional 6 weeks. After 1 year

follow-up 100% survival rate was noticed for both groups. No significant difference could be observed between the two groups concerning clinical and radiographic parameters.

Luongo and colleges[79] presented a multicenter one-year follow up study of an immediate/early loading protocol in the posterior maxilla and mandible. Eighty-two SLA implants in 40 patients were loaded between 0 and 11 days after implant placement. For inclusion in the study 2 implants were to support either 2 splinted crowns or a 3 unit bridge. The torque values were between 15 and 45 Ncm. Four sites were evaluated as bone quality 4. One implant failed during the first year. The overall survival rate of the implants at 1 year was 98.8%. The mean bone loss at 1 year was 0.52 +/- 0.98 mm. They concluded that early and immediate loading of 2 implants in the posterior maxilla and mandible may be suitable in selected patients. After one year follow-up, the results were similar to those achieved with a delayed procedure.

Vanden Bogaerde et al[80] included 31 consecutive patients in a multicenter study. A total of 111 implants were inserted in 37 edentulous areas. Of these, 69 implants were inserted in 22 partial ridges in maxillas, and 42 implants were placed in 22 partial edentulous posterior mandibles . Bruxism and uncontrolled periodontal disease were exclusion criteria. Temporary prostheses were generally placed within 9 days but not after 16 days from implant placement. Of the 111 implants placed, 1 failed, giving an overall survival rate of 99.1% after 18 months. The failed implant was located in the posterior maxilla. The prosthesis survival was 100%. The radiographs were readable for 81% of the implants at baseline, 84% at placement of the final prosthesis, and 88% at 1 year after placement of the final prostheses. The marginal bone resorption from readable x-rays was 0.8 mm. The authors concluded that a clinical protocol, aiming at high primary stability, and the use of oxidized titanium implants for early functional loading in the maxilla and the posterior mandible resulted in a high implant survival rate and a favorable marginal bone level.

Salvi et al[81] reported on a prospective controlled clinical trial that evaluated the effect of early loading of ITI implants, based on clinical and radiographic parameters. 27 consecutively admitted patients presenting bilateral edentulous posterior mandibular areas were included. Sixty-seven implants were installed bilaterally in molar and premolar areas according to a one-stage surgical protocol. One week (test) and 5 weeks (control) after implant placement, abutments were connected using a torque of 35 Ncm. No provisional restoration was fabricated. Two weeks (test) and 6 weeks (control) after implant placement, porcelain-fused-to-metal single-tooth crowns were cemented. After 1 year, implant survival was 100%. Two test and one control implant rotated at the time of abutment connection and were left unloaded for 12 additional weeks. At the 1-year examination, no

significant differences were found between the test and control sites with respect to pocket probing depths, mean clinical attachment levels, mean percentages of sites bleeding on probing, mean widths of keratinized mucosa, mean PerioTest values or mean crestal bone loss measurements. They concluded that early loading (2 weeks) did not appear to jeopardize the osseointegration healing process in the posterior mandible.

Immediate loading

Rocci et al[82] immediately loaded partial fixed bridges in the posterior mandible. Forty-four patients were randomized for test and control therapy. In the test group, 22 patients received 66 Brånemark System TiUnite surface implants supporting 24 fixed partial bridges, all of which were connected on the day of implant insertion. In the control group, 22 patients received 55 Brånemark System turned-surface implants supporting 22 fixed partial bridges, which also were connected on the day of implant insertion. All constructions were two- to four-unit bridges. Three TiUnite and eight tuned-surface implants failed during the first 7 weeks of loading. The cumulative success rate was 95.5% for TiUnite surface implants after 1 year of prosthetic load in the posterior mandible. The corresponding cumulative success rate for tuned-surface implants was 85.5%. The marginal bone resorption after 1 year of loading showed no difference between the two groups. They concluded that a moderately rough surface such as TiUnite gave a 10% decrease in failure compared to turned implants.

Drago and Lazzara[83] reported on 93 Osseotite implants that were restored with fixed provisional crowns out of occlusion immediately after implant placement. 38 partially edentulous patients were included in the study. All implants were immediately restored with prefabricated abutments and cement-retained provisional crowns without centric or eccentric occlusal contacts. The implants were restored with definitive restorations approximately 8 to 12 weeks after placement. All patients included in the study were followed-up for at least 18 months after implant placement. Seventy-seven of the 93 implants satisfied the inclusion criteria. Seventy-five implants became osseointegrated. The overall survival rate was 97.4%. Radiographic bone loss 18 months after implant placement (the mean of both interproximal surfaces) was 0.76 mm. Machtei et al[84] followed 20 patients treated with implant therapy in the partial mandible. The patients were systemically healthy but previously treated for chronic periodontitis. Five of the 49 (10%) implants failed. They concluded that immediate loading protocols are a predictable therapy in periodontally susceptible patients, but careful consideration should be given to implants placed in the molar region.

Schincaglia and co-workers[85] studied 10 patients with bilateral partial edentualism in the posterior mandible. A split mouth design was conducted to compare

implants with either turned or titanium oxide surfaces. Forty-two implants, 20 test and 22 controls, were placed and loaded within 24 hours. The overall implant survival rate was 95%. No implant was lost in the test group and 2 failed in the control. No significant difference was seen between the test and control group although there was a tendency to less bone resorption in the test group. They concluded that immediate loading of implants in the posterior mandible may be a treatment option if implants are inserted with a torque exceeding 20 Ncm and show an ISQ value above 60 Ncm. Cornelini et al[86] treated 20 patients with a total of 40 implants in the posterior mandible. Two implants supporting an immediately loaded 3-unite bridge were evaluated. After a follow up time of 1 year one implant had failed giving a survival rate of 97.5%. Table 3 presents a summary of articles on fixed prostheses in immediately loaded partially edentulous maxilla/mandible.

Table 3*.Published articles on early/immediate loading partially edentulous maxillae/mandible fixed prostheses.*

Author	Type of study	Immediate/ early loading	No Patients	No implants loaded	Follow-up years	Lost implants	***Survival rate %***
Testori et al [75]	prosp	Early (2 month)	175	405	3 y	9	***97.7%***
Cochran et al[76]	prosp	Early (3 weeks)	307	383	1 y	3	***99.1%***
Roccuzzo et al[77]	prosp	Early (6 weeks)	29	36	1y	1	***97.2%***
Roccuzzo et al[78]	prosp	Early (6 weeks)	32	68	1y	0	***100%***
Luongo et al[79]	prosp	Early	40	82	1y	1	***98.8%***
Vanden Bogaerde et al[80]	prosp	Early	31	111	1y	1	***99.1%***
Rocci et al[82]	prosp	Immediate	22	55	1y	3	***95.5%***
Schincaglia et al [85]	Prosp	Immediate	10	42	1y	2	***95%***
Cornelini et al [86]	Prosp	Immediate	20	40	1y	1	***97.5%***
Machtei et al [84]	prosp	Immediate	20	49	1y	5	***90%***
Total, immediate			***72***	***186***	-	-	

Conclusion immediately loaded implants in partially edentulous maxilla/ mandible

The longest follow-up of early loading protocols was 3 years and of immediate loading 1 year. The overall implant survival rate based on available papers ranged from 90%-97.5% which for some studies is less good than the 5 year survival rates obtained for two-stage procedures, i.e. 94 to 96%. More short/long-term data are needed before immediate loading could be recommended as a standard procedure in the posterior maxillae/mandible.

EARLY/IMMEDIATELY LOADING OF SINGLE-TOOTH RESTORATION MAXILLA/MANDIBLE

Single tooth loss is probably the most common indication for implant treatment.[86] From an oral handicap point of view, the loss of a single tooth may be a traumatic experience for many patients and early/immediate loading is therefore an attractive treatment option. On the other hand, single teeth replacements using implants in the aesthetic zone is one of the most challenging situations a clinician faces, also when applying a two-stage protocol. Careful judgments of soft and hard tissue volumes and implant placement must be made. In cases of severe resorption, hard and soft tissue augmentation procedures may be needed. In a retrospective study made by Vermylen et al[87] patient opinion and professionally assessed quality of single-tooth restorations were analysed. The quality of 43 single implant crowns was evaluated according to the modified guidelines for assessment of quality and professional performance used for evaluation of design, fit, occlusion/articulation and aesthetics. Patients were very positive with regard to aesthetics, phonetics, eating comfort and overall satisfaction. Nevertheless, 6 of 40 patients would not undergo the same treatment again, yet all of them would recommend it to others.

Early loading

In a study by Andersen et al[88], immediate loading of single-teeth TPS implants in the maxilla were evaluated. Temporary acrylic resin restorations, fabricated from impressions taken immediately after implant placement, were connected one week later. With the strict definition of an immediately loaded protocol (within 24 hours) this study would be classified as early loaded implants. Eight implants were early loaded after placement in eight different patients, and were followed for five years. The temporary restorations were adjusted in order to avoid any direct occlusive contacts. After six months, the provisional crowns were replaced by definitive ceramic crowns. No implants were lost, and the mean marginal bone level for the eight implants *increased* by 0.53 mm from placement to the final examination. Only minor complications were noted, and overall patient satisfaction was high.

Immediate loading

Ericsson and colleagues[89] performed a prospective clinical and radiographical study on single teeth replacements with temporary crowns retained to implants according to a immediate loading protocol and compared that to the original 2-stage concept. The immediate loading group comprised 14 patients (= 14 implants) and the 2-stage control group comprised 8 patients (= 8 implants), all with single tooth losses anterior to the molars. The patients had to be non-smokers and have sufficient bone to hold a 13 mm implant of regular (3.75 mm) platform. Moreover the jaw relationship had to allow for bilateral occlusal stability and the patients had to be judged as non-bruxers. In the immediate loaded group a temporary crown was connected to the implant within 24 h following fixture installation. Six months later this crown was replaced with a permanent one. In the 2 stage group the surgical and prosthetic treatment followed the standard protocol. Out of the 14 fixtures in the immediately loaded group two implants were lost up to 5 months in function. All remaining 12 implants were stable. No fixture losses were recorded in the traditional 2-stage protocol group and all implants were stable at the follow-ups. The analyses of radiographs from both groups showed a mean change of bone support about 0.1 mm at the12-months follow-up.

In another prospective clinical study presented by Hui and co-workers[90] 24 patients were followed. Single-tooth implant replacement was done according to an immediate provisional protocol. Thirteen of the 24 patients had immediate implant placement after tooth extraction. All implants were placed in the esthetic zone. The surgical protocol was aimed at enhancing primary implant stability with a minimal insertion torque of at least 40 Ncm. Within the follow-up period of between 1 month and 15 months, all fixtures in the 24 patients were stable. Crestal bone loss greater than one thread was not detected. The esthetic result was considered satisfactory by all patients.

Calandriello at al[91] reported on a prospective multicenter study including 44 patients and a total of 50 Brånemark System TiUnite Wide-Platform implants. All implants had passed the 6-months follow-up; 24 had been followed up for 1 year. All implants were provided with provisional crowns in centric occlusion at the time of surgery. No implant was lost. Marginal bone levels were found in accordance with normal biologic width requirements. Resonance frequency analysis showed high and consistent implant stability.

Rocci and co-workers[92] evaluated 97 Brånemark System Mk IV implants placed flap-less and immediate loaded. Of these implants 27 were single units. In total 9 implants in 8 patients failed during the first 8 weeks of loading. Five of 8 patients lost single-teeth implants, of which two had been inserted in fresh extraction sites. Three patients lost four implants in partial restorations. The survival rate for im-

plants in a partial reconstructions was 94% and for single restorations 81% after 3 years of prosthetic load, the difference being significant (p = .04). The marginal bone resorption was, on an average 1.0 mm during the first year of loading, 0.4 mm during the second year, and 0.1 mm during the third year.

Lorenzoni et al[93] evaluated clinical outcomes of immediately loaded FRIALIT-2 Synchro implants 12 months after placement in the maxillary incisal region. The implants were inserted with an increasing torque up to 45 Ncm. All implants were immediately restored with unsplinted acrylic resin provisional crowns and the patients provided with occlusal splints. No implant failed up to 12 months after insertion, resulting in a 100% survival rate. The mean coronal bone level changes at 6 and 12 months were 0.45 and 0.75 mm. The bone resorption after 6 and 12 months was according to the authors even less than evaluated for implants placed in a standard two-stage procedure.

Digidi and co-workers[94] evaluated 111 single implants that had been immediately non-functionally loaded. All implants were placed with a minimum insertion torque of 25 Ncm. During the 5 years follow-up time, the survival rate was 95.5%. They found a significant difference regarding healed vs. post extraction implant sites (100% and 92.5%) and type of bone (Q1 vs Q4 yielded 100% and 95.5%)

Table 4 presents a summary of articles on immediately loaded single restorations in maxilla/ mandible.

Table 4. *Published articles on early/immediate loading, single restorations maxillae/mandible*

Author	Type of study	No Patients	No implants loaded	Follow-up years	Lost implants	***Survival rate %*** ***%***
Andersen et al[188]	Retro/e*	8	8	5	0	***100 %***
Ericsson et al[89]	Prosp	14	14	1	2	***86%***
Hui[90]	Prosp	24	24	1-15 month	0	***100%***
Calandriello et al[91]	Prosp	44	50	6-12 month	0	***100%***
Rocci et al [92]	Retro	27	27	3	5	***81%***
Lorenzoni et al [93]	Retro	12	12	1	0	***100%***
Digidi et al [94]	Retro	111	111	5	5	***95.5%***
Total		***240***	***246***	-	-	

e early loading within 2 weeks*

Conclusion immediately loaded single implants

The longest follow-up time of early loading and of immediate loading protocols are 5 year. The overall implant survival rate based on available papers ranged from 81%-100% More long-term data are needed before immediate loading could be recommended as a standard procedure for single restorations in maxillae/mandible.

General conclusions

It can be concluded from the literature review that more short and long-term data are needed to evaluate benefits and risks of immediate loading. Up to today only totally edentulous mandibles can be regarded as well documented concerning immediate loading. With good primary stability totally edentulous maxillas show good short/medium long term results, although more data is needed before it can be regarded a safe treatment. Excellent short term data have been presented in all other locations. More studies on patient benefit are needed. Besides shorter treatment time for the doctor/patient, are there other psychological factors from the patient perspective that need to be considered?

Aims

The aims of the present thesis are:

To evaluate the use of provisional implants (PIs) to provide patients with a fixed provisional bridge during submerged healing of permanent implants **(paper 1).**

To evaluate primary implant stability using RFA measurements and to correlate obtained RFA values with patient-, surgery- and implant-related factors. (**paper 2)**

To evaluate the clinical outcome and stability of immediately loaded turned and oxidized titanium implants in the partially edentate mandible when using a modified surgical protocol and inclusion criteria based on primary implant stability measurements. (**paper 3)**

To evaluate the clinical outcome and stability of immediately loaded oxidized titanium implants in the edentulous maxilla when using a modified surgical protocol and inclusion criteria based on primary implant stability measurements. **(paper 4)**

To evaluate clinically and radiographically the novel oxidized implants Nobel Direct and Nobel Perfect one-piece when used for immediate loading. Specific aims were to analyze if this implant minimizes marginal bone loss, if vertical placement can be varied and if the esthetic result is optimized as claimed by the manufacturer. (**paper 5)**

Material and methods

Preliminary inclusion criteria paper I-V

The pre-surgical evaluation included clinical and radiographic examinations. The patients were thoroughly informed about the procedure and agreed to participate in the studies.

Primary inclusion criteria

Need for rehabilitation with implant-supported prostheses.

Presence of residual bone sufficient to house adequate number of implants.

Implant site free from infection.

Exclusion criteria

General contraindications for oral surgery.

Age less than 18 years.

Ethical considerations Paper I-V

In paper I-IV no application for ethical approval was done. The studies was done as quality assurance at the clinic according to The National Board of Health and Welfare SOSFS 2005:12 (M).

According to The National Board of Health and Welfare SOSFS 2005:12 (M) health profession should, to ensure the quality in our daily work establish a system for quality and patient safety. On a regular basis we should follow-up on the procedures we conduct, document and report success and failures. By continuous quality insurance we have the ability to prevent care related damages. In the ”Audit bill” which was passed in Sweden in 1997,(Socialstyrelsen 1996-00-116, Stockholm, 1996) it was required that ”right things will be done the right way” to acquire productivity and efficiency in the organization. The material in the present thesis has been collected throughout the daily work at Team Holmgatan Privet Dental Clinic, Sweden. One may consider paper I-IV as well as paper V as representative of one form of SOSFS 2005:12.

Ethical considerations Paper V

The study was approved by the ethical committee Uppsala University, Uppsala, Sweden.

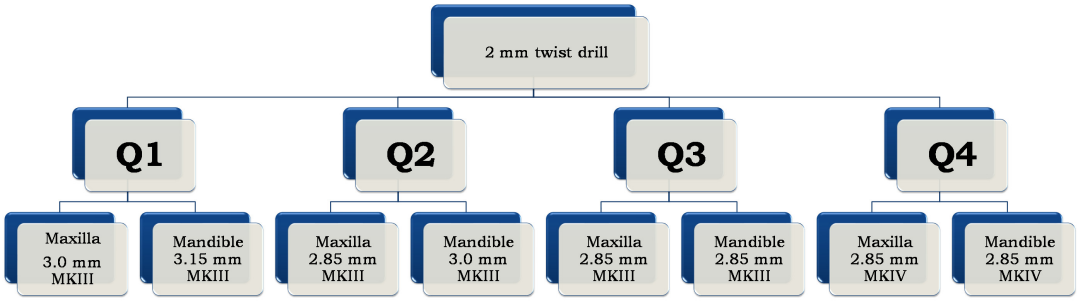
Surgery paper I-V

All patients were informed that the final decision on whether to load immediately was taken during surgery according to the following criteria: (1) a minimum insertion torque of 30 Ncm before final seating of the implant as measured with an Osseocare™ drill unit (Nobel Biocare AB) and (2) an implant stability quotient (ISQ) value above 60 measured (paper III) with an Osstell™ instrument (Integration Diagnostics AB, Göteborg, Sweden). In paper IV an ISQ value above 60 for the two posterior fixtures and a total sum of 200 (mean ISQ 50) for the four anterior fixtures as measured with an Osstell™ instrument.

Prophylactic antibiotic and sedative cover was provided by administration of 3 g of amoxicillin (Amimox®, Tika Läkemedel AB, Lund, Sweden) and diazepam (Stesolid®, Alpharma, Stockholm, Sweden) (0.3 mg/kg body weight) orally 1 hour prior to surgery. Infiltration anesthesia with lidocaine (Xylocaine®-Adrenaline, AstraZeneca, Södertälje, Sweden) was used. The edentulous crest was exposed through a midcrestal incision. After reflection of the flap, the optimal implant position was decided on both aesthetic and biomechanical considerations. In paper IV, a small fenestration was opened into the sinus to identify the anterior border of the sinus wall enabling tilting of the most posterior implants distally and therby placement in the most posterior position, reducing the need for cantilevers.

Bone quality and quantity were determined according to Lekholm and Zarb's criteria[95]. Implants were placed in undersized sites to enhance primary stability. The final drill size was determined as follows: In bone determined as quality 2 to 3, the final drill was 2.85 mm. In type 4 bone, a final drill of 2.85 mm and a Mk IV fixture or a Replace Select® Tapered implant with reduced drilling depth of the final burr (Nobel Biocare AB) were preferred, Fig. 1. Countersinking was limited to a shallow angle to engage as much of the crestal bone as possible. Abutments, if used, and impression copings were mounted prior to wound closure. The wound was closed with resorbable Vicryl 4.0 sutures.

Figure 1. *The different final drill size and fixture depending on bone quality.*



PATIENTS, IMPLANTS AND PROSTHETICS

Paper I

Twenty female and 25 male patients were included in the study. The 45 patients were treated either for partially (19 patients) or totally (26 patients) edentulous maxillas.

In edentulous maxillas five to seven Brånemark System implants were placed; in partially edentulous situations two to four implants were placed. The fixtures had either turned or TiUnite™ surfaces. The majority of the permanent implants that were placed was 13 mm or longer and of regular platform (RP) type (Tables 5 and 6). After placement of the permanent implants, provisional implants (PI) (Nobel Biocare AB) were placed between the permanent implants (Fig. 2a). In brief, the PI is a one-piece implant with a bendable neck to which a provisional bridge can be cemented (Fig. 2b). The diameter is 2.8 mm; the threaded part is 14 mm long and is supplied with a turned titanium alloy surface. The site is prepared with a 1.5 mm twist drill, and the self-tapping PI is placed. In the present study as many PIs as possible were placed at a distance of 2 to 3 mm to the permanent implants (Fig. 2 c). A special effort was made to find dense bone. In types I and II bone the full length of the twist drill was used whereas in bone of quality levels 3 to 4, only a 5- to 7-mm-deep entrance was prepared (Fig. 2d). The PIs were then inserted to full depth. Before adaptation and suturing of the flaps, the angulation of the PIs was checked, and necessary adjustments were performed by bending (Fig. 2e). The total number of permanent implants placed was 230; the corresponding figure for the PIs was 192. The most common quality found was Q3 bone (n=26 (58%)) followed by Q4 (n=12 (27%)) and Q2 (n=7 (15%)). The minimal number of permanent implants placed was 2, and the maximum number was 7. The corresponding figures for PIs were 2 and 8.

Prosthetic Procedures - After the surgical session and after suturing, copings were placed on the PIs (Fig. 2f), and a quick-setting high-viscosity polyvinyl siloxane (Dimension™ Penta™ H Quick, 3M ESPE, St. Paul, MN, USA) impression was taken of the upper jaw, with the copings embedded in the impression (fig. 2g). Bite registration (with any suitable material) was performed, and a traditional impression of the opposing jaw was taken. The provisional FPD was most commonly fabricated with an indirect technique, that is, the existing removable denture was rebuilt in such a way that it could be cemented to the PIs (Fig. 2h-i) or to the tooth

or teeth included as abutments in the provisionally fixed bridge (Fig. 2j-n). No cantilever units exceeding 5 mm were accepted. The first choice of cement was a temporary one (eg, ImProveTM, Nobel Biocare AB)

Table 5. *Surface of the Permanent implants.*

Implants, Surface and diameter	**NP**	**RP**	**WP**	***Total***
Mk III, turned	8	31	1	*40*
Mk IV, turned	–	22	–	*22*
Mk III, TiUnite	*19*	*147*	*2*	*168*

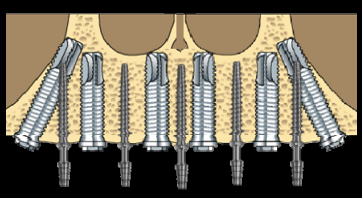
NP = narrow platform; RP = regular platform; WP = wide platform

Table 6. *Length and Platform of Permanent implants.*

Length (mm)	**NP**	**RP**	**WP**	**Total**
10	2	3	—	5
11,5	—	2	2	4
13	8	22	1	31
15	17	112	—	129
18	—	61	—	61
Total	27	200	3	230

Second-Stage Surgery - Six months after initial implant placement, mucoperiosteal flaps were raised to enable proper abutment connection according to the original protocol. At the same session, all or some of the PIs were removed by rotating them anticlockwise with the insertion tool mounted on the torque device (Fig. 2o). In situations when not all PIs were removed, the remaining ones served as abutments for the provisional FPD during the fabrication of the permanent FPD. At the latest, all remaining PIs were removed when it was time to connect the permanent FPD to the permanent implants.

Paper I, Fig. 2a-o



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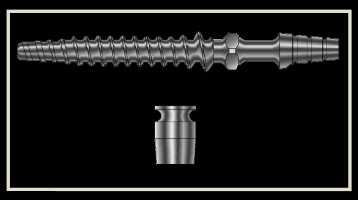

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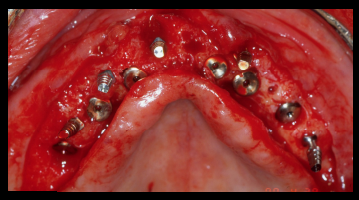

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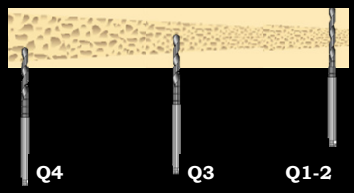

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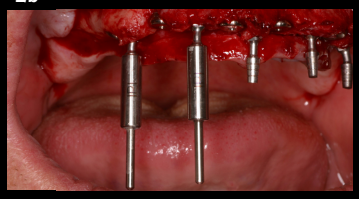

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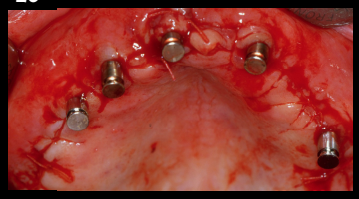

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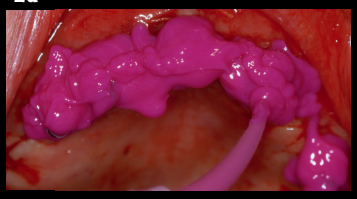

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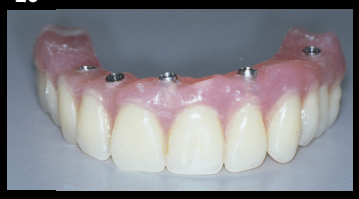

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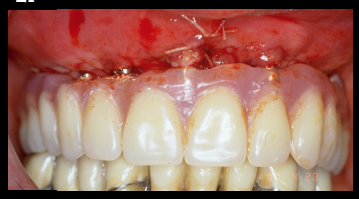

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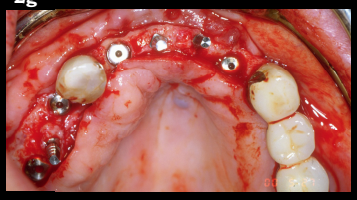

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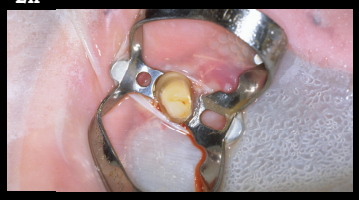

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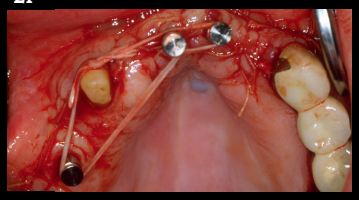

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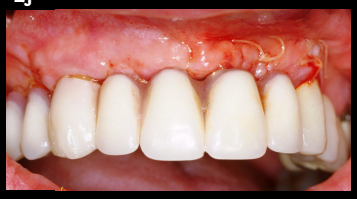

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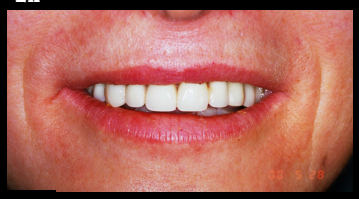

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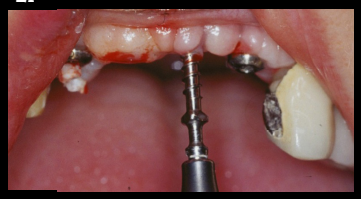


2o

2a/ Following placement of the permanent implants, provisional implants are placed between them. 2b/The Immediate Provisional Implant is a one-piece implant with a bendable neck. 2c/ Clinical photograph taken after installation of permanent and provisional implants. The space between the different implants should be 2 to 3 mm. 2d/In types I and II bone the full length of the twist drill was used whereas in bone of quality levels 3 to 4, only a 5-to 7-mm-deep entrance was prepared. 2e/Before adaptation and suturing of the flaps, the angulations of the PIs are adjusted by bending. 2f/ Impression copings mounted on the temporary implants. 2g/ Provisional implant coping used as impression copings embedded in the impression. The same copings are used as retention elements in the final provisional implant bridge. 2h/A view of a removable denture rebuilt by the dental laboratory in such a way that it can be cemented to the provisional implants. The copings are embedded in the acrylic as retention elements. 2i/A rebuilt removable denture fitted in a patient. The provisional implant bridge has an extension from 15 to 25 and is supported by five provisional implants. 2j-n/A partial denture rebuilt to a provisional implant bridge. 2m-n/Tooth 13 is integrated in the construction. Extension is from 13 to 25; support is by three provisional implants. 2o/The provisional implants were removed by rotating them anticlockwise with the insertion tool mounted on the torque device.

Paper II

RFA measurements in 267 consecutive patients (141 female, 126 male, mean age 65.2 years) treated with implant-supported fixed prostheses at one clinic were used for statistical analyses.

All implants (n = 905) were from one manufacturer (Nobel Biocare AB). In total, 479 implants were placed in mandibles and 426 in maxillae. The implants had either a turned (n = 120) or an oxidized (TiUnite™, n = 785) surface and were parallel walled (MKIII, n = 734) or slightly tapered (MKIV, n = 171). Implant lengths varied from 7 to 18 mm (Table 7) and diameters of 3.3 (Narrow Platform, NP), 3.75 (Regular Platform, RP, MKIII), 4.0 (Regular Platform, RP, MKIV), and 5.0 (Wide Platform, WP) mm were utilized (Table 8).

Table 7. *Implant design and lengths*

Implant Length (mm)	MK III TiUnite	MK III* Turned	MK IV¨ TiUnite	MK IV Turned	***Total***
7	9	4	-	-	***13***
8.5	29	-	-	2	***31***
10	67	12	-	7	***86***
11.5	45	2	5	2	***54***
13	92	16	10	10	***128***
15	253	34	42	13	***342***
18	158	13	75	5	***251***
Total	***653***	***81***	***132***	***39***	***905***

**Including standard implants*

Table 8*. Implant platforms*

Implant platform	*Number*
NP (3.3 mm)	*46*
RP (3.75 and 4 mm)	*808*
WP (5 mm)	*51*
Total	***905***

Implants were placed according to the modified surgical protocol described above. In this paper NP/WP implants were included. Therefore, depending on bone density, final drill diameters of 2.7 or 2.85 mm were used for NP implants, 2.85 or 3

mm for RP implants and 3.85 or 4.3 for WP implants. The implant heads were generally not totally submerged into the bone. NP implants were used in narrow ridges. WP implants were used in order to provide a wider platform for molar teeth.

Statistics

The influence of each separate parameter on implant stability was analyzed by Pearson's correlation (quantitative variables) or Student's t-test (binary variables). Furthermore, a stepwise multiple regression was performed to identify independent determinants of implant stability. However, when including a patient more than once in the regression analysis no bias of the beta coefficient is introduced the dependency will imply an underestimation of the variances of the coefficients. Therefore, the p values for the relationships and the p values and confidence intervals for differences were adjusted to the individual level by multiplying the variances with n_{impl}/n_{pat} (n_{impl} denotes number of implants and n_{pat} the number of patients). By using the adjusted variances a conservative method was chosen. P values (two-sided) <0.05 were considered as statistically significant.

Paper III

A total of 94 patients were evaluated, 91 of which included according to the primary inclusion criteria. Fourteen patients did not meet with one or more of the secondary inclusion criteria and they therefore underwent a two-stage procedure. Seventy-seven (77) patients (85%) (39 female, 38 male, age range 33-82 years) were finally included (Table 9).

Table 9. *Age and gender distribution among study patients*

Age	**Male**	**Female**	***Total***
35-49	1	2	***3***
50-59	10	12	***22***
60-69	17	8	***25***
70-79	9	15	***24***
80-	1	2	***3***
Total	***38***	***39***	***77***

A total of 257 Brånemark implants), 77 turned and 180 oxidized (TiUnite™), were placed (Tables 10,11 and 12).

A total of 111 FPDs were made (Table 13). Forty-six patients had one restoration, 30 patients had two restorations and one patient had three restorations. The bridges were supported by one implant and teeth or free-standing constructions supported by 2,3 or 4 implants (Table 14).

Table 10. *Length and type of implants. Failures within brackets.*

Implant Length	Turned				TiUnite		***Total***
	Standard	MK II	MK III	MK IV	MK III	MK IV	
7 mm	-	-	4	-	6		***10***
8.5 mm	-	-	4(2*)	-	19		***23 (2)***
10 mm	3	-	11	4	42		***57***
11.5 mm	-	2	7	2	13(1*)	3	***27(1)***
13 mm	-	2	12	6	37	5	***62***
15 mm	-	2	6	-	15	2	***25***
18 mm	-	-	11(1*)	1	25	13	***50 (1)***
Total	***3***	***6***	***55***	***13***	***157***	***23***	***257***

Table 11. *Number of implants placed relative to bone quality and quantity. Failures within brackets.*

Bone Quantity	**Bone Quality**				**Total No. of Implants**
	1	**2**	**3**	**4**	
A	-	1	-	-	**1**
B	-	25	56	14	**95**
C	-	73(3)	55(1)	18	**146 (4)**
D	-	8	3	4	**15**
E	-	-	-	-	**-**
Total	**-**	***107***	***114***	***36***	***257***

Table 12. *Implants in relation to tooth position*

Tooth position	**47**	**46**	**45**	**44**	**43**	**42**	**41**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**Total**
No of placed implants	25	42	25	19	4	2	3	3	5	2	24	28	45	30	257

Table 13. *Materials used for permanent bridges.*

Materials	***Number of bridges***
Procera implant bridge/porcelain	***91***
Procera implant bridge/composite	***5***
Gold/porcelain	***9***
Carbon fibre/composite	***2***
All-Ceram/Procera abutment	***2***
Titanium/ porcelain	***2***
Total	***111***

Table 14. *Number of implants per prosthetic construction.*

No. of Implants	**Cases**		
	Female	**Male**	**Total**
1 (tooth connected)	1	8	9
2	26	35	61
3	24	14	38
4	2	1	3
Total	**53**	**58**	**111**

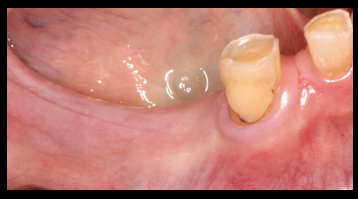
Prosthetic procedures

Immediately following surgery, a quick-setting high-viscosity polyvinyl siloxane impression (Dimension™ Penta™ H Quick) was made using an open tray. An impression was made of the opposing jaw and an occlusal record was performed. Healing caps were placed on the abutments.

Screw-retained provisional fixed partial dentures (PFPD) with cantilevers less than 5 mm were fabricated at a dental laboratory and were delivered within 24 hours. Careful adjustments of occlusion and articulation were performed to minimize lateral forces, e.g. light centric occlusion contacts and no contacts in lateral movement.

One to 3 months after implant placement a new impression was made to obtain a master cast on which the long term fixed partial denture was fabricated. For surgical and prosthetic treatment, see Fig. 3a-l.

Paper III, Fig. 3a-o



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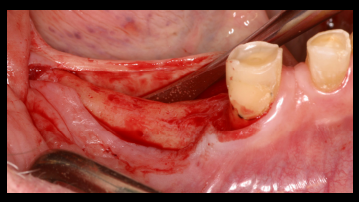

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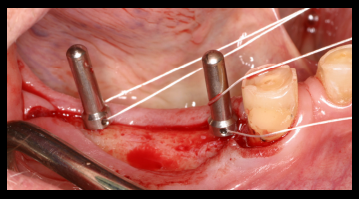

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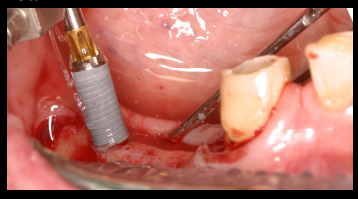

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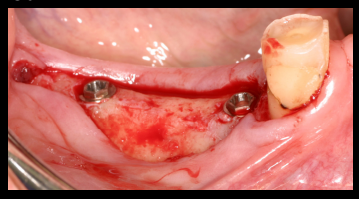

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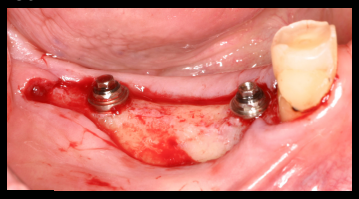

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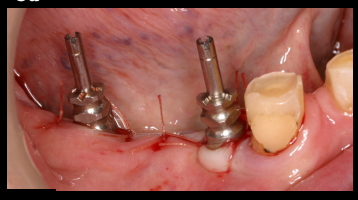

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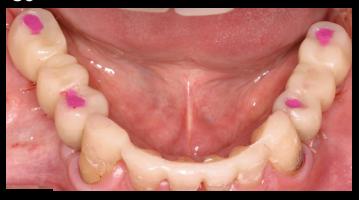

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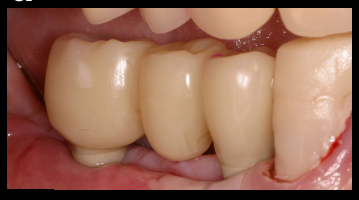

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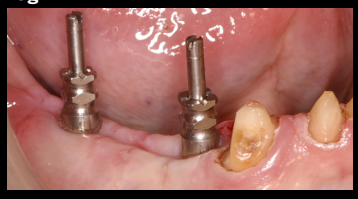

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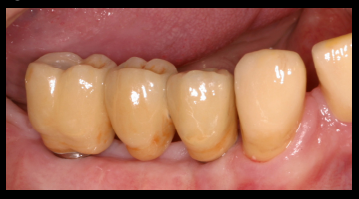

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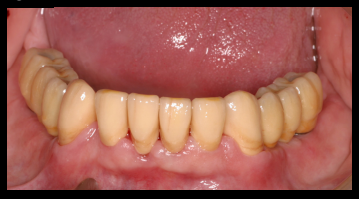

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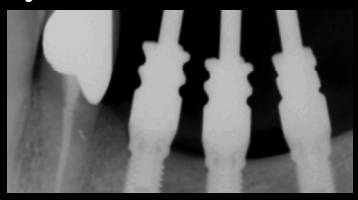

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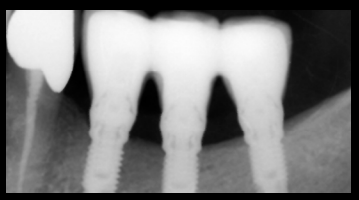

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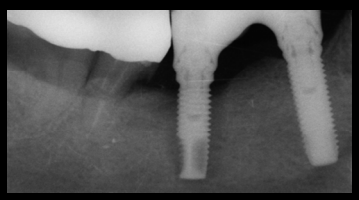


3o

3a/ A patient missing premolar and molars bilaterally . 3b/A mid crestal .incision was made and flap was raised 3c/ Care was taken to place the fixture in optimal direction from both esthetic and biomechanical view. 3d-f/Implants and abutments were placed. 3g/ Before suturing impression copings were mounted. 3h/Screw-retained provisional fixed partial dentures (PFPD) with cantilevers less than 5 mm were fabricated at a dental laboratory and were delivered within 24 hours. Careful adjustments of occlusion and articulation were performed to minimize lateral forces, e.g. light centric occlusion contacts and no contacts in lateral movement. 3i-l/One to 3 month after implant placement a new impression was made to obtain a master cast on which the long term fixed partial denture was fabricated. 3m/The marginal bone level was evaluated in digital periapical radiographs taken after surgery (baseline) and 3n/after one year in function .

3o/One implant showing a peri-implant radiolucency.

Paper IV

Twenty patients (10 female and 10 male; mean age 73 years, range 58–87 years) planned for treatment with implant-supported bridges in the edentulous maxilla participated in the study group. All patients were healthy. Two patients were smokers.

In cases with remaining teeth, extraction was undertaken after patients were included on the basis of insertion torque and RFA measurements of implants placed in healed sites. Abutments (MUA, Nobel Biocare AB) and sterile impression copings were connected to the implants. Both straight and angulated abutments were used depending on implant angulation's (Fig. 4a-j).

All 20 patients met the final inclusion criteria. One hundred twenty-three oxidized titanium implants (TiUnite™) of various designs (Mk III, Mk IV, Replace Select Tapered) in various bone qualities were implanted (Table 15,16).

Table 15. *Type and length of implants in the test group.*

Type of fixture	Length	Placed	***Failed***
Brånemark MkIV TiUnite	13 mm	1	-
	15 mm	25	-
	18 mm	22	-
	10 mm	2	-
	11,5 mm	3	-
Brånemark MkIII TiUnite	13 mm	4	-
	15 mm	21	-
	18 mm	12	-
Replace Select Tapered	13 mm	6	-
	16 mm	27	*1*
Total		***123***	***1***

Table 16. *Bone quality and quantity in test and reference groups. Failure within bracket.*

	Direct – test group					**Two-stage – control group**				
	1	**2**	**3**	**4**	**Total**	**1**	**2**	**3**	**4**	**Total**
A	-	-	-	-	-	-	-	-	-	**-**
B	-	-	36 (1)	12	48	-	6	30	36	**72**
C	-	6	26	24	56	-	-	27	-	**27**
D	-	13	-	6	19	-	12	9	-	**21**
Total	-	**19**	**62**	**42**	**123**	**-**	**18**	**66**	**36**	**120**

Prosthetic Procedures

Immediately following the surgical session, a quicksetting, high-viscosity polyvinyl siloxane (Dimension™ Penta™ H Quick) impression was taken of the upper jaw using an open tray. Bite registration was performed (Fig. 4k), and an impression of the opposing jaw was taken. Healing caps were placed on the abutments. Provisional bridges with no cantilevers exceeding 5 mm were fabricated at a dental laboratory. The bridges were delivered within 12 hours. Fig. 4 l. Careful adjustment of occlusion and articulation were performed to minimize lateral forces. Three months after fixture installation, a new impression was taken for the manufacture of a permanent bridge (Fig. 4m-n). All but one were Procera® Implant Bridges (Nobel Biocare AB) with acrylic or porcelain teeth (Table 17 and Fig. 4o). Distal cantilevers were allowed. The occlusion was adjusted to minimize loading of the distal cantilevers.

Table 17. *Type of bridges used as final construction in the test group*

Type of construction	***Number***
Carbonfibre /Acrylic	*1*
Procera Implant Bridge/Acrylic	*8*
Procera Implant Bridge/Porcelain	*11*
Total	***20***

Reference Group

A group of 20 patients (8 female and 12 male; mean age 64 years, range 50–80 years) previously treated with implant-supported bridges in the maxilla by the same team following a two-stage protocol were used as the reference group. The subjects represented consecutive treatments immediately prior to the treatment of the test group. One hundred twenty implants (Nobel Biocare AB), 11 Mk IV implants with turned surfaces and 109 Mk III with oxidized surfaces (TiUnite), had been placed in the reference group (Table 18). A healing period of 6 months had been used between implant placement and abutment connection. All patients received a fixed bridge (Table 19) within 4 to 6 weeks after abutment connection surgery.

Table 18. *Type and length of implants in the reference group.*

Type of fixture	Length	Placed	Failed
	13 mm	1	-
Brånemark MkIV machined	15 mm	7	-
	18 mm	3	-
	10 mm	2	-
	11,5 mm	2	-
Brånemark MkIII TiUnite	13 mm	13	-
	15 mm	62	-
	18 mm	30	-
Total		***120***	-

Table 19. *Type of prosthetic construction in the reference group.*

Type of construction	Number
Carbonfibre /Acrylic	*0*
Procera Implant Bridge/Acrylic	*4*
Procera Implant Bridge/Porcelain	*16*
Total	***20***

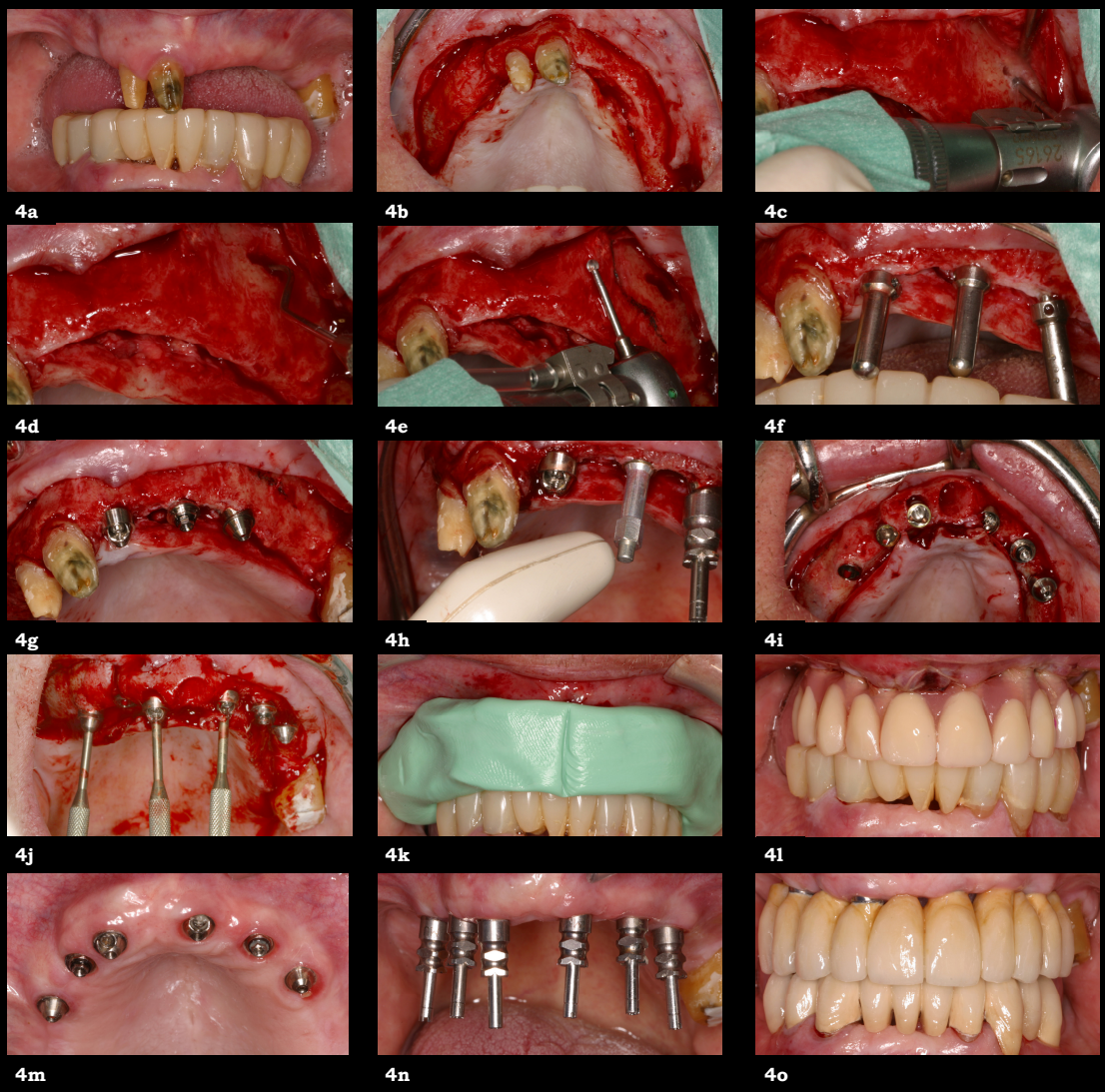
Survival Criteria and Withdrawn Patients

An implant was regarded as failed if it was removed for any reason. All stable implants without symptoms of pain or infection were regarded as survivors. No patients dropped out during the study; all attended the scheduled follow-up examinations.

Statistics

The Mann-Whitney U test was used to verify possible differences between the groups. A difference was considered if $p < .05$.

PAPER IV, Fig. 4a-o



4a/ Clinical view prior to surgical treatment. This patient had undergone extractions 6 months earlier. Three teeth were saved and used as abutments for a provisional bridge. 4b/A mid crestal .incision was made and flap was raised 4c-e/ A fenestration is made into the sinus to identify the position of the anterior sinus wall. 4f-h/Inclination and position of the sites were carefully checked with direction indicators before final preparation and placement of fixtures.4i/An implant in the socket after extraction of the right lateral incisor. In this cases, measurements (cutting resistance and ISQ) are made on placed implants before extraction of the remaining teeth. If the inclusion criteria are not met, a two-stage procedure will be carried out and the teeth will be used for the provisional bridge during implant healing. 4j/Angulated abutments mounted and directed for optimal angulations before flap closure. One to 3 month after implant placement a new impression was made to obtain a master cast on which the long term fixed partial denture was fabricated. 4k/Bite registration with a putty index. 4l/A temporary bridge is delivered 6 to 12 hours after surgery. No cantilevers exceeding 5 mm are accepted. Occlusion and articulation are carefully checked to minimize lateral forces and overload. 4m-n/3 months of soft tissue healing. The soft tissue has matured and an impression is taken. 4o/ Final Procera Implant Bridge.

Paper V

A total of 48 patients (28 females, 20 males, mean age 67.8 years) from consecutive referrals for rehabilitation with implant-supported prostheses in the mandible and/or the maxilla participated in the study. The treatments were performed by one surgeon and one restorative dentist in one centre. Infected extraction sites healed for 3 months in the maxillae and 6 months in the mandible before implant installation, respectively. Patients who met the inclusion criteria were invited to participate in the study and were thoroughly informed about the procedure.

A total of 115 OPIs were used. Seventy-seven were Nobel Direct implants and 38 were Nobel Perfects OPIs with diameters from 3 to 5 mm and lengths from 10 to 16 mm (Fig. 5a and b; Table 20). Nobel Perfect implants have a scalloped contour between the smooth and rough-surfaced part of the integrated abutment cylinder and the supra-mucosal part while Nobel Direct implants have a horizontal contour. They otherwise have identical designs.

Table 20. *Nobel Direct™ and Nobel Perfect™ one-piece implants (OPIs) used in the test group. Failures within brackets.*

		One-piece implants	
Implant	Length	Maxilla	Mandible
NobelDirect, NP	10 mm	0	2
	13 mm	0	6 (1)
	16 mm	3	3 (1)
NobelDirect, RP	10 mm	0	16
	13 mm	2	6
	16 mm	12	11
NobelDirect, WP	10 mm	0	4
	13 mm	0	2
	16 mm	1	2
NobelDirect 3.0	15 mm	3	4
Total NobelDirect (n=77)		**21**	**56**
NobelPerfect One-piece, NP	10 mm	0	2
	13 mm	0	0
	16 mm	0	5
NobelPerfect One-piece , RP	10 mm	0	9
	13 mm	1	4
	16 mm	4	2
NobelPerfect One-piece, WP	10 mm	0	6 (4)
	13 mm	0	1
	16 mm	4	0
Total Nobel Perfect one piece (n=38)		**9**	**29**
Total, test group		***30***	**85 (6)**

Surgery

Implant placement was made using a flapless procedure (n=23) or by raising mucoperiosteal flaps (n=92). One-hundred and one implants were placed in healed sites and 14 in extraction sockets. For flap-less placement in healed sites (n=10), a 2 mm twist drill and a slide-over guide sleeve were used to evaluate and determine the position of the osteotomy. A tissue punch guide was placed and a motor-driven circular tissue punch was used to remove the soft tissue. In flapped cases, an incision was made on the top of the crest. In mandibular cases of sufficient bone width, a muco-periosteal flap was raised only at the lingual aspect to enable visibility and avoid perforation into the floor of the mouth. Relieving incisions were made in the mandible to enable identification of the mental foramen. The continuing preparation for both flapless and flapped sites followed the drill steps (preparation protocol) for Replace Select Tapered implants (Nobel Biocare AB, Gothenburg, Sweden). The vertical position was determined by the goal of placing each implant with some rough surface just visible above the highest point of the mucosa, usually at approximal aspects (Fig. 5c-i). However, in flapped cases where it was possible to control implant threads in relation to marginal bone, the first priority was to place all implant threads in bone, which, in some cases, resulted in a deeper final positioning of the implant. The implants were inserted by motor and exceeded an insertion torque of 30 Ncm. If the final insertion torque was above 50Ncm, as determined by the manual torque wrench, the implant was backed out and inserted again with a torque of 30–50 Ncm in order to avoid overtightening. No bone augmentation was performed when implants were placed in a fresh extraction socket or in healed sites. Bone quality and quantity are presented in table 21.

Table 21. *Bone quality and quantity of the implant sites in the OPI group according to Lekholm & Zarb. Failures within brackets.*

Nobel Direct™ and Nobel Perfect™ one-piece implants					
Bone Quantity	**Bone Quality**				**Total No. of Implants**
	1	**2**	**3**	**4**	
A		1	5		**6**
B		9(1)	20	2	**31**
C		30(3)	24	2	**56**
D		10(2)	10	2	**22**
E					
Total		**50**	**59**	**6**	**115**

Prosthetics

The prosthetic treatment was carried out immediately after surgery. No preparation of the implants was made at this point, except in situations when the implant height interfered with occlusion. In such cases, preparation was made using drills

manufactured for the purpose (Nobel Biocare AB) with protection of the wound by a rubber dam (Fig. 5j). Care was taken not to overheat the fixture by using generous irrigation with a lower temperature fluid than normally used on vital teeth. In single-tooth cases (23 implants), a prefabricated translucent strip crown (Frasaco, Tettnang, Germany) was filled with a composite (Ceram-x, Dentsply, York, PA,USA). Care was taken to present the material from entering the pocket by using a rubber dam and not overfilling the strip crown. No bonding was used to prevent contamination of the TiUnitet surface. After light curing, the composite crown was adjusted outside the mouth and then cemented with temporary cement using a rubberdam (except in one case). Single crowns were not in occlusion and were free from approximal contacts. In partially dentate cases (82 implants), a quick-setting high-viscosity polyvinyl siloxane impression (Dimensiont Pentat H Quick,) was taken after application of a rubber dam (except in one case with two implants). Bite registration was performed and an impression of the opposing jaw was taken. The provisional bridges were fabricated in a dental laboratory using Triad composite (Raintree Essix Inc., Los Angeles, CA,USA) without cantilevers. The constructions were cemented with temporary cement using a rubber dam (except in the one case with two implants) and ground into light centric occlusion (Fig. 5k-l). Careful adjustment of occlusion and articulation were performed to minimize lateral forces. All 48 patients received a provisional construction within 6 h. One to three months after fixture installation, depending on soft tissue healing, the fixtures were prepared with a chamfer using purpose-made drills as described above (Fig. 2m). Impression cores were placed superficially in the pocket to ensure proper impression of the preparation border according to the manual. An impression was then taken with the same technique as that described for the temporary solution. The final prosthetic crowns and bridges were fabricated from All-zirconium with Rondo porcelain (Nobel Biocare). The constructions were cemented with Ketac cem (3M ESPE) (Fig. 2n). Minimal amounts of cement were used for temporary and final constructions in all cases and applied to the crowns with a brush. Radiographs were used to ensure that no excess cement remained beneath the crown margins (Fig. 5o and p).

Reference patient group

A group of 97 patients (48 men, 49 female, mean age 62.3 years) treated by the same team under identical conditions with 380 two-piece implants (TPIs) (MKIII, MKIV and Replace Select Tapered; Nobel Biocare AB) with either turned (n=77) or oxidized (n=303) surfaces were used as a control (Table 22 and Table 23). Twenty patients had been treated with 123 implants for immediate loading in the totally edentulous maxilla (paper IV), and 77 patients had been treated with 257 implants for immediate loading in the partially edentulous mandible and followed for at least 1 year (paper III).

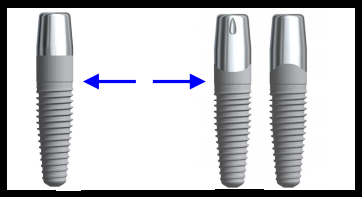
Table 22 *Two-piece implants used in the reference group. Failures within brackets.*

		Two-piece implants	
Implant	**Length**	**Maxilla**	**Mandible**
MkII, turned	11,5 mm		2
	13 mm		2
	15 mm		2
MkIII, turned	7 mm		4
	8,5 mm		4 (2)
	10 mm		11
	11,5 mm		7
	13 mm		12
	15 mm		6
	18 mm		11 (1)
MkIV, turned	10 mm		4
	11,5 mm		2
	13 mm		6
	18 mm		1
Standard, turned	10 mm		3
Total, control turned (n=77)			77 (3)
MkIV, TiUnite	11,5 mm		3
	13 mm	1	5
	15 mm	25	2
	18 mm	22	13
MKIII, TiUnite	7 mm		6
	8,5 mm		19
	10 mm	2	42
	11,5 mm	3	13 (1)
	13 mm	4	37
	15 mm	21	15
	18 mm	12	25
Replace Select Tapered	13 mm	6	
	16 mm	27 (1)	
Total, control TiUnite (n=303)		123 (1)	180 (1)
Total, control (n=380)		**123 (1)**	**257 (4)**

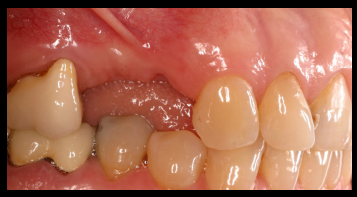
Table 23 *Bone quality and quantity of the implant sites in the two-piece implant group according to Lekholm & Zarb. Failures within brackets.*

	Two-piece implants				
Bone Quantity	**Bone Quality**				**Total No. of Implants***
	1	**2**	**3**	**4**	
A	-	1	-	-	**1**
B	-	25	92 (1)	26	**143 (1)**
C	-	79(3)	81(1)	42	**202(4)**
D	-	21	3	10	**34**
E	-	-	-	-	**-**
Total	**-**	**126**	**176**	**78**	**380**

PAPER V, Fig. 5 a-p



5a 5b



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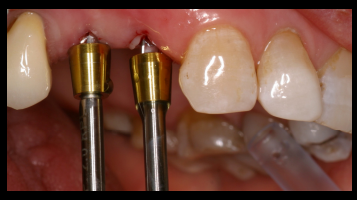

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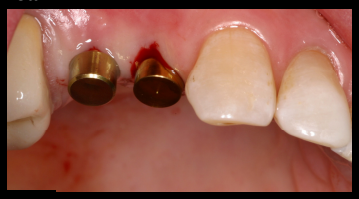

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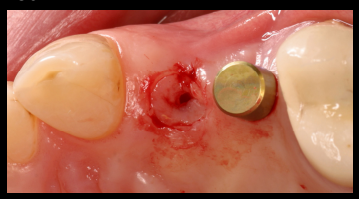

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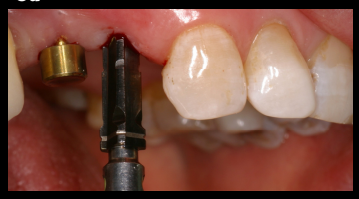

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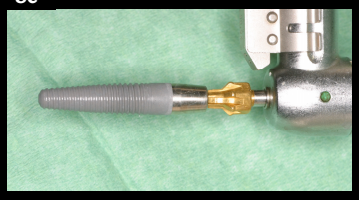

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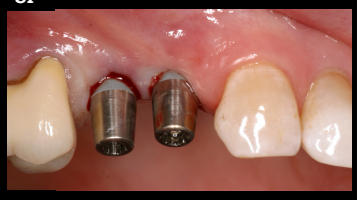

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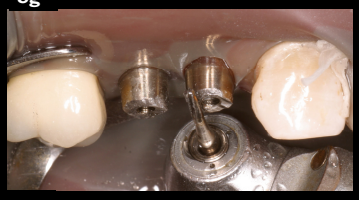

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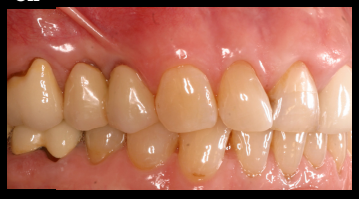

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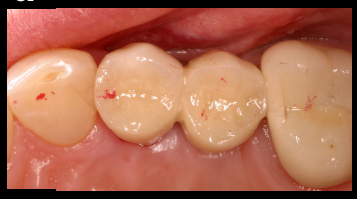

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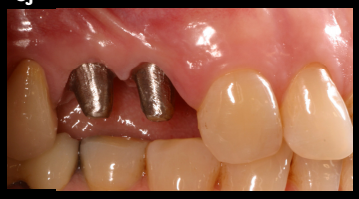

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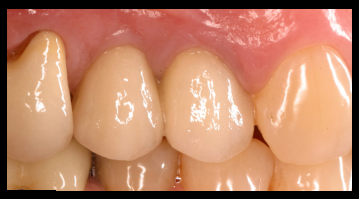

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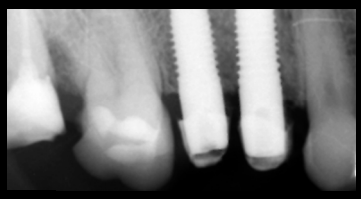

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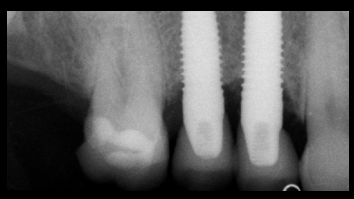


5p

5a/ Schematics of the Nobel Direct™ and 5b/ Nobel Perfect™ one-piece implants tested in the study. Arrow indicates the reference point. 5c-i/ Clinical photographs illustrating the Nobel Direct™ technique. The implants were placed with some rough surface visible above the highest point of the mucosa, usually at approximal aspects. 5j/ A rubber-dam was used to protect the wound during height reduction of the implants. 5k-l/ Showing the temporary crowns in place. 5m/ The fixtures were prepared with a chamfer using purpose-made drills after 3 months of healing. 5n/ Clinical appearance after cementation of the final construction. 3. Radiographs of the case shown in figure 2. 5o/ Baseline radiograph after cementation of the provisionals to ensure that no excess cement remained beneath the crown margins. 5p/ 12 months later. Note the ongoing marginal bone loss which is more extensive at the implant in the 1st premolar region.

Statistics (paper V)

In paper V descriptive statistics were used and the data were presented as mean values with standard deviations. A frequency distribution was made of marginal bone measurements and divided into quartiles. The 'best' 25% and 'worst' 25% of implants from the OPI and TPI groups were compared. A life table was used to calculate implant survival rates. The Spearman's correlation test was used to evaluate the possible relation between implant insertion depth and marginal bone resorption.

Post-operative measures (paper I-V)

During 10 days after implant installation the patients were given 2 g/day of V-penicillin (Kåvepenin, AstraZeneca, Södertälje, Sweden), mouth rinsing with chlorhexidine 0.1% 2 times a day and recommendation to eat soft food.

Clinical follow-up (paper I,III-V)

All patients participating in the studies agreed to be enrolled in a strict and individually designed maintenance care program focusing on the following: (1) oral hygiene, (2) stability of provisional/permanent bridge, (3) soft tissue condition and (4) function of the therapy (patient satisfaction, aesthetic outcome, occlusion/ articulation). Clinical follow-up was carried out at 3, 6, 12 months and yearly thereafter. In paper III and IV implant stability was registered by RFA after 6 months when the FPDs were removed. Besides planned check-ups, hygiene controls were carried out individually.

Marginal bone resorption (paper III-V)

The marginal bone level was evaluated in digital periapical radiographs taken after surgery (baseline), 6 months and after one year in function. Care was taken to reproduce the radiograph at the different time points. The distance from the implant/abutment junction to the marginal bone level was measured at mesial and distal aspects of each implant by an independent radiologist. Bone loss was presented as mean values of distal and mesial measurements for each implant and time point. In paper V each radiograph was calibrated using the known width of the coronal cylinders of the implants. The lower corner of the coronal cylinder was used as a reference point for measurements (Fig.5a and b). For TPIs, the marginal bone level was measured from the implant–abutment junction. Measurements were used to calculate (i) the true bone resorption, i.e. the distance from the initial bone level to the bone level at follow-up examinations, and (ii) the marginal

bone level in relation to the lower corner of the coronal cylinder of OPIs and in relation to the lower corner of the head of the TPIs at placement and after 1 year.

RFA measurements (paper II-IV)

RFA measurements were performed immediately following implant placement using an Osstell™ instrument. The transducer was attached to the implant perpendicularly to the alveolar crest with a screwdriver using about 10 Ncm torque. Care was taken to make sure that no tissue was trapped between the implant head and the transducer. The measurement was momentarily shown as a frequency/amplitude plot and an ISQ value. If the plot showed one clear peak the measurement was accepted and the ISQ value noted. If the plot indicated an erroneous measurement, the transducer was removed and the implant site cleaned and a new measurement was made. Different transducers were used for the different platforms.

Success rating (paper III &V)

Implant success was evaluated using a Four-Field table according to Albrektsson & Zarb[96] using the following categories:

Success – An implant meeting with success criteria. Criteria for success according to Albrektsson & Zarb[96] include absence of implant mobility and absence of pain and neuropathy. Originally, one mm of bone loss from the lower corner of the implant head was acceptable during the first year and less than 0.2 mm annually thereafter. Slightly less strict criteria were used in the present study since implants were individually tested for mobility only after 6 months and not later. Moreover, more bone loss was accepted since measurements were made from the implant platform which for MKII and MKIII implants is situated 0.8 mm above the reference point used in previous studies; Success grade 1 was defined as an implant with no clinical and radiographic signs of pathology showing less than 2 mm of bone resorption at one year of follow up. Success grade 2 was defined as an implant with no clinical and radiographic signs of pathology showing less than 3 mm of bone resorption at one year of follow up.

Survival – An implant still in the bone that does not meet with or has not been tested for success criteria.

Unaccounted for – An implant in a patient who dropped out of the study for any reason.

Failure – An implant removed for any reason.

Results

Paper I

Five (2.2%) of the 230 permanent implants placed did not integrate and were subsequently removed at the second-stage surgery. Seven of 192 (3.6%) PIs failed owing to infection or pain during the observation period and were removed. Seventeen (9%) of 192 PIs placed showed mobility at the second-stage surgery, although they had served as support for the provisional bridge without clinical symptoms. All the mobile PIs had been placed in bone of qualities 3 and 4. All PIs could be removed before delivery of permanent prostheses. Forty-four of 45 patients had stable provisionally fixed bridges at the time of the second-stage surgery. In one patient the provisionally fixed bridge was removed after 10 weeks because of pain and mobility. In this case the permanent implants were loaded with a fixed temporary bridge during the remaining 3-months period until fabrication of the permanent bridge. One provisional fixed bridge was fractured during the observation interval; it was mended and functioned well throughout the observation period.

Paper II

The mean primary stability for all implants was 67.4 ISQ (SD 8.6). Of all 905 implants, 582 (64.3 %) showed an ISQ value of 65 or higher and 761 (84.1%) implants an ISQ of 60 or higher.

The results from the statistical analyses are presented in Tables 24 and 25. Univariate analyses with the implant or patient as unit revealed significant differences when comparing different parameters:

- Male patients showed higher ISQ values than females, 68.5 (SD 8.4) vs. 66.5 (SD 8.8, $p < 0.04$).
- Mandibular implants with ISQ 71.4 (SD 7.5) were more stable than maxillary ones with ISQ 63.0 (SD 7.6, $p < 0.001$, Fig. 6).
- Implants placed in posterior regions were more stable than in anterior sites, 68.7 (SD 8.5) vs. 65.2 (SD 7.7, $p < 0.001$, Fig.6)
- Wide platform implants showed a mean ISQ of 73.1 (SD 9.8) and were more stable than regular/narrow platform ones which had a mean ISQ of 67.1 (SD 8.4, $p < 0.007$, Fig. 7).

There was a correlation between bone quality and primary stability, with lower ISQ values with softer bone (r = -0.24, $p < 0.001$, Fig. 8).

A lower stability was seen with increased implant length (r = -0.15, $p < 0.001$, Fig. 9).

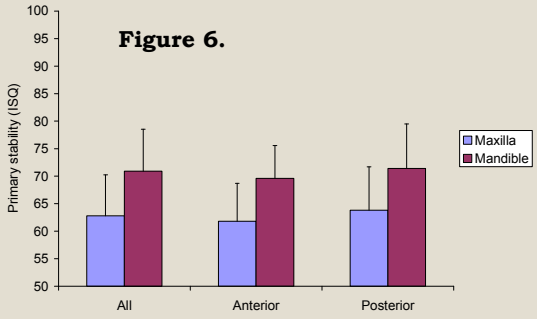
A stepwise multiple regression analysis using the implant as unit showed that jaw type, platform, bone quality, position (anterior vs. posterior) and gender determined the degree of primary stability ($R^2 = 0.27$). Based on the patient as unit, jaw type and gender were independent determinants of primary stability. There was no difference in the distribution of different bone qualities in the groups of male and female patients (Table 24).

Table 24. *Univariate analysis of primary implant stability (ISQ).*

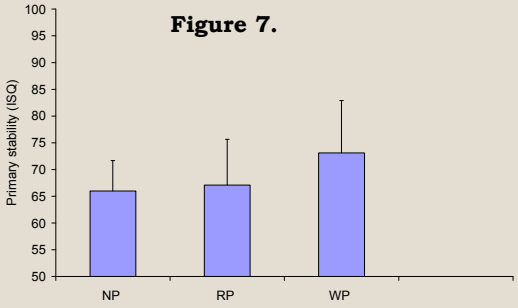
				Implant based (n=905)				Individual based (n=267)	
				Difference		Correlation			
Variable	n	Mean	(SD)	95% CI	P value	r	p value	95% CI	p value
Age	905					-0.03	>0.30		>0.30
Gender									
female	486	66.5	(8.8)	0.9 – 3.1	<0.001			1.3 – 5.3	0.04
male	419	68.5	(8.4)						
Jaw type									
maxilla	426	63.0	(7.6)	-9.4 – -7.4	<0.001			-10.2 – -6.6	<0.001
mandible	479	71.4	(7.5)						
Ant-post									
anterior	338	65.2	(7.7)	-4.7 – -2.4	<0.001			-5.7 – -1.5	<0.001
posterior	567	68.7	(8.9)						
Bone quality	905					-0.24	<0.001		<0.001
Bone quantity	905					-0.05	0.12		0.25
Platform									
NP-RP	854	67.1	(8.4)	-8.5 – -3.7	<0.001			-10.5 – -1.6	0.007
WP	51	73.1	(9.8)						
Implant type									
Mk III	734	67.8	(8.7)	0.4 – 3.3	0.01			-0.8 – 4.5	0.16
Mk IV	171	65.9	(8.2)						
Implant length	905					-0.15	<0.001		<0.001

Table 25. *Stepwise multivariate regression analysis of primary implant stability (ISQ).*

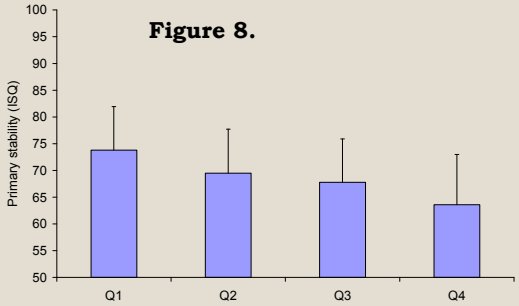
	Implant based (n = 905)			Individual based (n = 267)	
	Coefficient	**(SE)**	***p* value**	**(SE)**	***p* value**
Jaw type (maxilla, mandible)	7.4	(0.5)	<0.001	(0.9)	<0.001
Gender	-1.9	(0.5)	<0.001	(0.9)	0.04
Bone quality	-1.2	(0.4)	0.002	(0.7)	0.10
Anterior - posterior	1.3	(0.5)	0.016	(1.0)	0.19
Platform (NP-RP, WP)	2.6	(1.1)	0.017	(2.0)	0.20



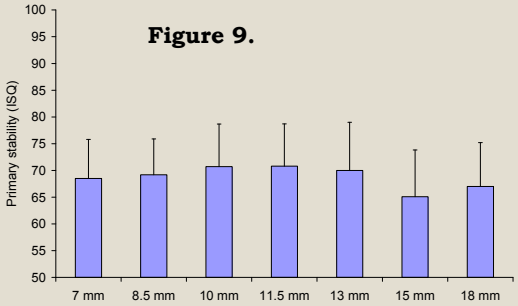
Mean values of primary stability in the mandible and in the maxilla for all implants and for anterior and posterior regions. Mandibular implants were statistically more stable than maxillary ones (Table 24).



Primary stability with implant diameter. (NP = narrow platform, 3.3 mm, RP = regular platform 3.75 mm, WP = wide platform, 5.0 mm) WP implants were statistically more stable than NP and RP implants (Table 24).



Primary stability with bone quality according to the index proposed by Lekholm and Zarb[95]. There was a statistically significant decrease of stability with softer bone (table 24).



Primary stability with implant length. There was a statistically significant decrease of stability with implant length (table 24).

Clinical observations

Few complications were observed during the follow-up. One patient showed anesthesia of the inferior alveolar nerve for three months. Three provisional FPDs showed mobility due to loosening of the prosthetic screw. Two patients with 3 implants each were withdrawn from the study after the first annual check-up. One of the patients had died and one had moved from the region.

Implant survival

Four (1.6 %) of the 257 implants placed did not integrate and were subsequently removed. The overall cumulative survival rate was 98.4 % after one year and 96.1% and 99.4 % for turned and oxidized implants, respectively (Table 26).

Implant failures

One patient lost two implants and two patient's one implant each. One implant showed no radiographic signs of de-integration but was found rotationally mobile when taking an impression for the permanent bridge after two months. Three implants showed a peri-implant radiolucency, all after placement of the final FPD (Fig. 3o) after 4 (one implant) and 13 months (2 implants). Three of the failed implants had a turned surface and one had an oxidized surface (Table 27).

***Table 26**. Life table showing cumulative survival rate.*

Time period	All implants				Turned implants				TiUnite implants			
	Implants	Out	WD	CSR%	Implants	Out	WD	CSR%	Implants	Out	WD	CSR%
Loading-1Year	257	2	3*	99,2	77	1	3	98,7	180	1	0	99,4
1-2 Years	252	2	0	98,4	73	2	0	96,1	179	0	0	99,4
2-3 Years	150	0	3**	98,4	71	0	0	96,1	179	0	3	99,4
3-4 Years	147	0	0	98,4	71	0	0	96,1	176	0	0	99,4
>=4 Years	125	-	-	-	59	-	-	-	66	-	-	-

* One patient (3 fixtures) died before year 1 ** One patient (3 fixtures) moved away before 3 years follow-up.

***Table 27.** Characteristics of lost implants*

Position	Implant type	Time (months)	Bone Quality	Bone Quantity	Smoking	Probable Cause
46*	Mk III turned 3.75/8.5	13	2	C	No	Bruxism
47*	Mk III turned 3.75/8.5	13	2	C	No	Bruxism
45	MK III turned 3.75/18	7	2	B	No	Bruxism
44	Mk III TiUnite 3.75/11.5	4	3	C	No	Overtightening

* Same patient

Resonance Frequency Analysis (RFA)

RFA showed a mean ISQ value of 72.2 (S.D 7.5) at placement and ISQ 72.5 (S.D. 5.7) after 6 months of loading (Table 28). There were no significant differences between turned and oxidized implants. The initial RFA values for the failed implants were 71, 66, 65 and 82, respectively.

Table 28. *ISQ measurements at implant surgery and 6 month follow-up.*

Time of measurement	All implants			TiUnite			Turned		
	No.	Mean	SD	No.	Mean	SD	No.	Mean	SD
Implant surgery	214	72.2	7.5	182	71.8	7.3	32	74.6	8.5
6 months	238	72.5	5.7	184	72.7	5.8	54	71.8	5.5

Marginal bone resorption

Marginal bone measurements could be performed in 228 of the 257 implants placed. The marginal bone level was situated 0.4 (S.D. 0.5) mm below the implant-abutment junction at baseline and 1.1 (S.D. 0.7) mm after one year of loading. The average bone loss was 0.7 (S.D. 0.8) mm after one year of follow-up (Table 29). Turned implants showed an average bone loss of 0.5 (SD 0.8) mm and oxidized 0.7 (SD 0.8) mm.

Eleven (4,9%) implants showed more than 2 mm and 2 of these (0.9 %) more than 3 mm of bone loss after one year. The corresponding figures were 0 % and 1,5 % for turned and 5,6 % and 0.6% for oxidized implants.

Table 29*. Marginal bone level at baseline and one year follow-up.*

	Marginal bone level at fixture placement		Marginal bone level at follow-up visit, 1 y		Marginal bone resorption between placement – 1 y	
Number	227		228		225	
Mean value	0,41		1,11		0,71	
Standard deviation	0,54		0,73		0,78	
<0					23	10%
0	116	51%	25	11%	27	12%
0,1 - 1,0	72	32%	84	37%	104	46%
1,1 - 2,0	37	16%	102	49%	60	27%
2,1 - 3,0	2	1%	14	6%	9	4%
>3,0			3	1%	2	0.9 %
Total	227		228		225	

Success rating

Based on available radiographs and examined implants, the Success Grade 1 was found to be 81% and Success Grade 2 was 85% (Table 30).

Table 30. *Four-field distribution of implants according to Success Grade 1 and 2 criteria.*

Success grade 1	Unaccounted for
81,0%	12,5 %
Survival	Failure
4,9%	1,6 %

Success grade 2	Unaccounted for
85,0%	12,5 %
Survival	Failure
0,9%	1,6 %

Paper IV

Clinical Observations

Few complications were observed during the follow-up. Two patients in the direct loading group experienced fracture of the provisional bridge, one owing to bruxism and one owing to trauma. The bridges were repaired and could be used until replacement with a permanent bridge. A third patient in the test group showed extensive gingivitis and candidiasis, which was treated with antimycotics and oral hygiene measures.

Implant Survival

One (0.8%) of the 123 implants placed did not integrate and was subsequently removed. In the control group, no implants were lost. The overall cumulative survival rates after 1 year were 99.2% for the study group and 100% for the reference group. No further implant failures were experienced beyond the first annual examination (Table 31).

Table 31. *Life table for survival rates of immediately loaded and two-stage implants.*

	Direct loading			Two-stage		
Time period	Implants	Failed	CSR %	Implants	Failed	CSR %
Placement>>1 year	123	1	99.6	120	0	100
1 year>>2 years	123	0	99.6	114	0	100
2>>3 years	83	0	99.6	72	0	100
>3years	36	0	-	36	-	-

Marginal Bone Resorption

For immediately loaded implants, the marginal bone level was situated 0.54 mm (SD 0.85 mm) below and 1.30 mm (SD 1.06 mm) below the reference point at baseline after 1 year of loading. The corresponding figures for the reference group implants were 0.59 mm (SD 0.82mm) and 1.46 mm (SD 1.07 mm) at baseline and after 1 year, respectively. The mean change of marginal bone level was 0.78 mm (SD 0.90 mm) for immediately loaded implants and 0.91 mm (SD 1.04 mm) for reference group implants (Table 32). The differences were not significantly different.

Table 32*. Results from measurements of marginal bone levels at immediately loaded and two-stage implants.*

	Immediate loading			Two-stage		
	Mesial	Distal	(m+d)2	Mesial	Distal	(m+d)2
Number	114	115	115	108	111	111
Mean value, mm	0,73	0,84	0,78	0,95	0,86	0,91
Standard deviation	1,01	1,01	0,90	1,14	1,21	1,04

Resonance Frequency Analysis

RFA showed a mean value of 62.9 ISQ (SD 4.9) at placement. Measurements at the 6-months follow-up showed a mean value of 64.5 ISQ (SD 4.8). For the control group, the mean values were 61.3 (SD 8.8) at placement and 62.6 (SD 7.0) at the 6 -months follow-up (Table 33). There were no significant differences between time points or groups.

Table 33. *Results from RFA measurements at placement and after 6 months of loading for directly loaded and two- stage implants.*

	Direct loading		Two-stage	
Time period	Fixture insertion	Follow-up 6 m	Fixture insertion	Follow-up 6 m
Average	62.9 (SD 4.9)	64.5 (SD 4.8)	61.3 (SD 8.8)	62.6 (SD 7.0)
Range	51- 77	54 - 76	37 - 98	46 - 79

Paper V

Clinical observations

The initial soft tissue healing around the OPIs was uneventful in most cases. Grey coloring of the marginal mucosa was frequently seen (Fig. 10a–c). With time, many sites showed retraction of soft tissue and papillae and exposure of the TiUnite surface, often in conjunction with radiographic bone loss (Fig. 11a and b). Excess cement could not be identified in patients with exposed crown margins. Few complications were observed for the TPIs and were generally related to fracture of the provisional prostheses, which could be repaired.

10a-c/Clinical examples of gray colouring of the marginal mucosa at one-piece implant sites. a/ Anterior mandible. b/ Left posterior mandible. c/ Right posterior mandible. 11 a-b. Clinical examples of soft tissue retraction and exposure of the oxidized surface at one-piece implant sites .a/ Right posterior mandible. b/ Right posterior mandible.

Implant failure

Six OPIs (5.2%) were removed during the follow-up period because of extensive bone resorption and subsequent soft tissue problems (Table 34) (Fig. 12a–d,13). All failures occurred in the mandible (7.1%) (Table 20). Two implants were lost within 3 months, one after 6 months and three implants were removed during the

second year in function (after 14 months). Two Nobel Direct and four Nobel Perfect OPIs failed (Table 20). Five (1.3%) TPIs failed in the reference group: one in the maxilla and four in the mandible (Table 23). All failures occurred during the first year of loading (after 2, 3, 4 and 11 months) (Table 35). Two of the implants were found to be rotationally mobile when taking an impression for the definitive prosthesis with no radiographic signs of failure. Three implants showed peri-implant radiolucency and were found to be mobile. None of the failures showed crater-like defects. Two oxidized (MKIII and Replace Select Tapered) and three turned implants (MKIII) failed (Table 23).

Table 34. *Life-table of Nobel Direct™ and Nobel Perfect™ one-piece implants.*

Nobel Direct™ and Nobel Perfect™ one-piece implants			
Interval	Implants in interval	Failures	CSR
Placement-6 months	115	3	97.4
6 to 12 months	112	0	97.4
12 to 24	111	3	94.8
> 24 months	111	3	92,2

Table 35. *Life-table of the two-piece implants in the references group.*

Two-piece implants			
Interval	Implants in interval	Failures	CSR
Placement-6 months	380	3	99.2
6 to 12 months	377	2	98.7
12 to 24 months	260	-	98.7
24to 36 months	211	-	98.7
> 36 months	92		

Marginal bone measurements /Marginal bone resorption

Marginal bone resorption at OPIs was seen as thin vertical defects (Fig. 14a and b) crater-like lesions (Fig. 14c–f) or as horizontal bone loss (Fig. 14g and h). The average marginal bone loss was 2.1 mm (SD 1.3) for OPIs based on 104 radiographs of the 115 implants followed (Table 36). The bone loss was similar for mandibular and maxillary implants, i.e., 2.1 mm (SD 1.3). Single tooth implants showed 2.2mm (SD 1.3) and implants in multi-unit constructions showed 2.1 mm (SD 1.3) of bone loss. For TPIs, the bone loss was 0.8 mm (SD 1) based on measurements

in 350 radiographs of the 380 implants (Table 36). For OPIs, 49% showed more than 2mm and 20% more than 3 mm of bone loss after 1 year. For TPIs, 7.7% showed more than 2 mm and 0.6% more than 3 mm of bone loss after 1 year (Table 36, Fig. 15a and b). The marginal bone loss data were divided into quartiles for comparison of the 25% best (Q1) and the 25% worst (Q4) implants. The mean Q1 value was -0.6mm (SD 0.3) (bone loss) for OPIs and 0.4 mm (SD 0.8) (bone gain) for TPIs. The mean Q4 values were -3.9 mm (SD 0.8) and -1.9 mm (SD 0.6) for OPIs and TPIs, respectively (Table 36). There was a significant correlation between vertical placement depth of OPIs and marginal bone loss ($P<0.001$, $r= -0.32$), indicating that the cylindrical part of the implant did not integrate with the bone (Fig. 16).

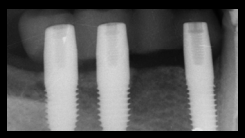


Fig. 12a

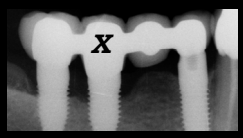


Fig. 12b

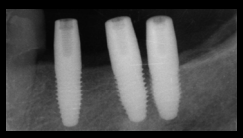


Fig. 12c

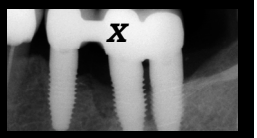


Fig. **12d**

12 a-d/Radiographs showing crater-like marginal bone resorption at one-piece implants leading to soft tissue problems and implant removal. a/ Baseline radiograph of three implants in the posterior mandible b/ 6 months later. The two posterior implants show bone loss and the middle one was removed (X). c/ Baseline radiograph of three implants in the left posterior mandible. d/ 12 months later. The two posterior implants were removed (X)

13/Clinical photograph showing the implants in Fig. 12c and d at surgical removal. Note cratershaped defect and granulation tissue.

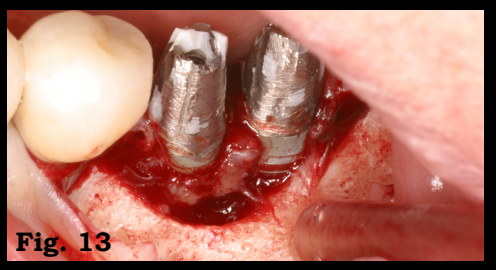


Fig. 13

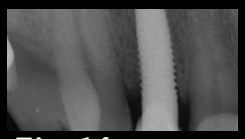


Fig. 14a

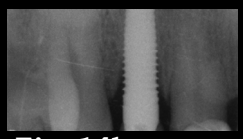


Fig. 14b

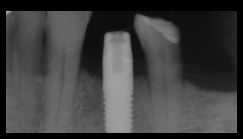


Fig. 14c

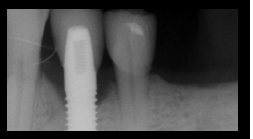


Fig. 14d

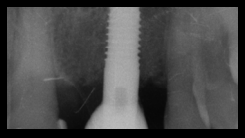


Fig. 14e

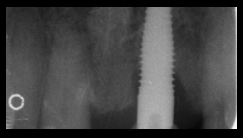


Fig. 14f

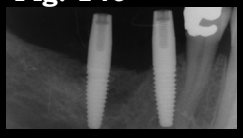


Fig. 14g

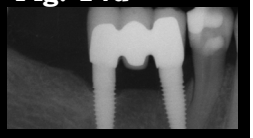


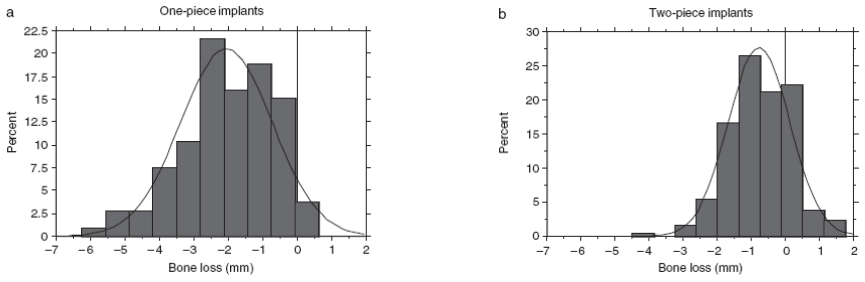
Fig. 14h

14a-d/Series of radiographs demonstrating marginal bone loss. a/ Baseline radiograph of a maxillary single tooth replacement. b/ 12 months later. Note thin vertical defect. c/ Baseline radiograph of a mandibular single tooh replacement. d/ 12 months later. Note crater-like defect. e/ Baseline radiograph of a maxillary single tooth replacement. f/ 12 months later. Note drater-like defect. g/ Baseline radiograph of two posterior mandibular implants. h/ 12 months later. Note horizontal bone loss.

Table 36. *Marginal bone loss at Nobel Direct™ and Nobel Perfect™ one-piece implants and two-piece reference implants.*

	One-piece implants (n=104)	**Two-piece implants (n=350)**
Change, (mm (SD))	-2.1 (1.3)	-0.8 (1.0)
Change Q1 (25% best, mm (SD))	-0.6 (0.3)	0.4 (0.8)
Change Q4 (25% worst, mm (SD))	-3.9 (0.8)	-1.9 (0.6)
> 2 mm (%)	49	7.7
> 3 mm (%)	20	0.6

Fig. 15. *Frequency distribution diagrams of marginal bone loss from baseline to the 1-year follow-up examination for (a) one-piece and (b) two-piece implants.*



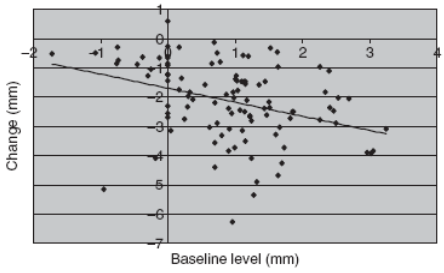


Fig. 16. *A plot showing a statistically significant correlation (p < 0.001) between one-piece implant insertion depth (baseline level) and change of marginal bone loss from placement to the 12 month follow-up.*

Table 37. *Marginal bone level in relation to reference point at Nobel Direct™ and Nobel Perfect™ one-piece implants and two-piece reference implants.*

	One-piece implants (n=104)	**Two-piece implants (n=350)**
Marginal bone level, (mm (SD))	-1.2 (1.3)	-0.2 (0.8)
Bone level Q1 (25% best, mm (SD))	-0.3 (0.5)	0.6 (0.2)
Bone level Q4 (25% worst, mm (SD))	-3.0 (1.0)	-1.5 (0.7)
> 2 mm from ref. point (%)	25	4.6
> 3 mm from ref.point (%)	7.7	1.1

Marginal bone level in relation to the reference point

After 1 year, the marginal bone was on average 1.2 mm (SD 1.3) below the reference point at OPIs and 0.2 mm (SD 0.8) at TPIs (Table 37). For OPIs, 25% showed a marginal bone level more than 2 mm and 7.7% more than 3 mm below the reference point after 1year. For TPIs, 4.6% showed a marginal bone level more than 2 mm and 1.1% more than 3 mm below the reference point after 1 year. Quartile analysis of bone level data showed that for Q1 OPIs, the bone level was –0.3 mm (SD 0.5) (below the reference point) and 0.6 mm for TPIs (SD 0.2) (above the reference point). The Q4 values were -3 (SD 1) for OPIs and -1.5 mm (SD 0.7) for TPIs.

Implant success

When applying the stricter criteria, implant success grade 1 was 46.1% for OPIs and 85.5% for TPIs (Table 38). When applying the more moderate success grade 2 criteria, the corresponding success grades were 72.2% and 91.6% for OPIs and TPIs, respectively (Table 39).

Table 38. *Four-field distribution of one-piece and two-piece implants according to Success Grade 1 criteria.*

Nobel Direct™ and Nobel Perfect™ one-piece implants

Success grade 1	Unaccounted for
46.1%	0 %
Survival	Failure
48.7%	5.2 %

Two-piece turned/oxidised implants

Success grade 1	Unaccounted for
85.5%	0 %
Survival	Failure
13.2%	1.3%

Table 39. *Four-field distribution of one-piece and two-piece implants according to Success Grade 2 criteria.*

Nobel Direct™ and Nobel Perfect™ one-piece implants

Success grade 2	Unaccounted for
72.2%	0%
Survival	Failure
22.6%	5.2%

Two-piece turned/oxidised implants

Success grade 2	Unaccounted for
91.6%	0%
Survival	Failure
7.1%	1.3%

Discussion

An increasing number of publications report clinical outcomes from immediate loading protocols. Recent literature reviews and consensus reports seem to agree that immediate loading is a well documented treatment modality for the totally edentulous mandible but that more research is needed for other indications.[21-22,97] For instance, only a few studies have focused on immediate implant loading in the partially edentate mandibles and fully edentulous maxillaes.[68-73,79,92,99] Moreover, few studies have presented strict protocols for immediate loading. This was one reason for conducting the present thesis.

Methodological reflections

This thesis is based on prospective single-center studies. From a strict scientific point of view, a randomized study design would have been preferred with patients allotted for 1) immediate loading or a two-stage protocol, 2) provisional implants or submerged healing with partial/full removable dentures, 3) standard drill protocol or drill protocol aiming for enhanced stability. The reason for not using randomization was our good experience with immediate implant loading in pilot cases both in the maxilla and mandible. Moreover, the literature on immediate loading mostly indicated similar prosthesis survival rates, although more implants may be lost in some situations.[92,100] From the patient's perspective, it was therefore considered wrong to extend the treatment period unnecessarily. As a compromise, a historical reference group treated by the same team using a two-stage protocol was used for comparison regarding totally edentulous maxillas, especially with regard to marginal bone resorption and implant stability. No similar control group could be obtained regarding resonance frequency analyses and partially edentulous mandibles. Concerning the study on Nobel Direct a group of 97 patients treated by the same team under identical conditions with 380 two-piece implants (MKIII, MKIV and Replace Select Tapered), with either turned (n=77) or oxidized (n= 303) surfaces were used as a control.

Primary implant stability

Insertion torque/modified drilling protocol

The inclusion criterion for immediate loading in this thesis (paper III-V) was an insertion torque that was equal or exceeding 30 Ncm. If the final insertion torque exceeded 50 Ncm modification was made to avoid a to high bone compression. The final drill size was determined as follows: In bone determined as

quality 1 standard protocol was followed, with a 3.0 final twist drill, placing a 3.75 parallel wall implant (MKIII). In quality 2 to 3, the final drill was 2.85 mm and a 3.75 mm implant was placed (MKIII). In type 4 bone, a final drill of 2.85 mm and a Mk IV fixture or a Replace Select® Tapered implant with reduced drilling depth of final burr were referred, e.g. if a 16 mm 4.0 implant was placed full length of the 3.5 burr was used and a 8.5 or 10 mm 4.0 burr for widening the cortical part of the osteotomy. Countersinking was limited to a shallow angle to engage as much of the crestal bone as possible. The modified drilling protocol and primary stability based inclusion criteria may be one of the explanations for the low failure rate in this thesis.

With regard to implant design, it was evident that wide implants were more stable than narrower ones. This may be due to that wider implants engage more of the buccal/lingual cortical bone walls, both due to the width *per se* and to the surface enlargement factor.[101] Previous studies have shown that primary implant stability can be improved by using a tapered implant design.[102-103] In the present study, when including all implants in the analysis and not adjusted to the individual, the tapered MKIV implants were less stable than the parallel walled MKIII implants. This is explained by the fact that tapered implants were only used in compromised, quality 4 bone and that a reduced drill diameter was utilized when placing most of the 3.75 mm MKIII implants. The use of a tapered implant or reduced drill diameter will most likely both create a similarly increased stability due to lateral compression of the bone when placing the implant.[104] Nevertheless, it is likely that if implants had been placed in quality 4 bone without adapting the surgical technique, implant stability had certainly been lower. It can also be speculated that implants with a more pronounced taper than the MKIV design, for instance the Replace Select Tapered or NT fixture (Biomet 3i), may be used to further improve primary stability in quality 4 bone. Although a control group was missing, it can be anticipated that the use of an adapted surgical technique resulted in high primary stability in all jaw bone regions. However, the use of thinner drills and/or tapered implants could not fully overshadow the effect of bone density, as indicated by the correlation between bone quality and stability. Interestingly, lower implant stability was seen for females compared to men, in spite of a similar distribution of all parameters within the male and female groups. The result from the present study indicated a difference in bone density between female and men, which, however, could not be subjectively discriminated using the Lekholm and Zarb index[95] and, therefore, may not be clinically relevant. For instance, according to Sennerby et al[105], no clinical follow-up studies on dental implants have reported differences in implant failure rates in male and female patients.

A decreasing implant stability was seen with decreasing bone quality which is in line with the findings of Friberg et al [106] who demonstrated a correlation be-

tween bone density, as assessed by cutting torque measurements when placing implants, and RFA measurements. This is most likely explained by the presence/ absence of cortical bone, which is 10 to 20 times stiffer than trabecular bone. Differences between mandibular and maxillary implants can also be explained in terms of bone density, since maxillary bone is often softer due to lesser extents of cortical bone. [107-109] In the present study, implant stability was higher in posterior than in anterior regions, which corroborates the findings of Balleri et al.[110] This indicates similar bone morphologies in anterior and posterior sites, in spite of that implant placement generally is regarded as more challenging in posterior regions due to the anticipated more frequent presence of soft bone quality. Our results can also be explained by the fact that all wide implants in the study were placed in posterior regions.

One intriguing finding was that implant stability decreased with increased implant length, a finding which corresponds with Balleri et al.[110] This may have to do with the manufacturing of the implants and of the nature of the RFA technique. In order to minimize friction heat when placing long implants, the diameter is slightly reduced in coronal direction.[111] Friberg et al[106] measured bone density in the marginal, mid and apical parts of implant sites in the maxilla. Subsequent RFA measurements showed a correlation between implant stability and the density of the marginal bone but not other parts of the implant site. The authors concluded that mainly the properties of the marginal bone determined the outcome of the RFA measurements. The lower stability for the long implants may therefore be explained by the reduced diameter in the marginal bone. It is also possible that the longer drilling time for placement of long implants resulted in an over-preparation of the implant site.

Resonance frequency analysis

Comparing immediate/early loading with two-stage procedures, it seems like higher implant failure rates can be expected in partially edentulous jaws and especially in the posterior maxilla. [112] Further analyses of follow-up studies indicate that soft bone and immediate occlusal loading are some of the risk factors[92,112-113] which implies that relative overload is a major cause for implant failure. The RFA technique may therefore be a useful tool to identify implants with a sufficient degree of stability and to monitor the clinical performance of the implants during loading. Glauser et al[114] measured the stability of 81 immediately loaded implants during one year. Nine implants were lost and the RFA measurements showed a statistically lower stability for failing implants after one and two months compared with the implants that remained successful. Their results showed that the risk of failure increased with decreased ISQ value as measured after one month of loading. Sennerby and Meredith[104] observed in 20 patients that a primary stability of around 65 ISQ did not result in any changes of stability with

time and suggested this as a safe level for immediate loading. In the present material, about 65% of all implants showed ISQ values of 65 or above. If considering ISQ 60 as a lower limit, about 85% of all implants could have been considered for immediate loading. However, clinical prospective studies are needed to verify this hypothesis.

Then comparing the two-stage group with the immediately loaded group treated for totally edentulous maxillas, a tendency toward a steeper increase and higher secondary stability were seen for the immediately loaded implants 6 months after implant placement. The results indicate favorable remodeling under the influence of loading. Moreover, the statistically verified difference in marginal bone resorption observed by another research group[20] and the tendency in the present study on totally edentulous maxillas further support the idea of a stimulatory effect of loading. It is well known from orthopedic surgery that physiologic loading is a precondition for sufficient healing of fractures and maintenance of the biomechanical properties of bone. Thus, it seems that six implants in the maxilla with controlled loading of a provisional bridge result in stresses within physiologic limits.

Moderately rough surfaces

When analyzing the provisional implant patients (paper I), the five permanent implants that did not integrate had turned surfaces and had been placed in type 3 and 4 bone. Soft bone will most likely result in a lesser initial implant stability. This has been pointed out as a main reason for implant failure.[115-117] Jaffin and Berman[115] reported a failure rate of 44% for implants placed in type 4 bone. The corresponding figure for implants placed in bone of types 1, 2, and 3 was only 3,6%. The moderately rough surface seems, at least in type 4 bone, to be more beneficial than the turned one.[116-117] This observation is in agreement with previously reported experimental data. Zechner and colleagues[118] compared bone-to-implant contact at three different implant surfaces on “Brånemark bodies” in minipigs. The authors reported a bone-to-implant contact of about 20% at the turned surface. The corresponding figure for the TiUnite surface was 43%.

Of the 257 implants installed in the partial mandile (paper III), 77 had a turned and 180 an oxidized, moderately rough surface. Interestingly, three of the four failures encountered were implants with turned surface, giving a failure rate of 3.9 % for the turned and 0.6% for the oxidized implants, thus indicating a better outcome with the surface modified implants.

Histology has shown a stronger bone response and a more rapid integration of oxidized implants compared to turned ones [118-119] which may explain the differ-

ences in clinical outcome. A similar observation was made by Rocci et al[14] who reported a 10% higher survival rate for oxidized in comparison with turned implants after one year. Moreover, they reported a significantly higher failure rate for turned implants among smokers. In the present study, all failures occurred in non -smokers. Glauser et al [112,120] evaluated turned and oxidized implants for immediate loading in two different studies. The authors experienced a failure rate of 17% for turned and 3% for oxidized implants. By using repeated RFA measurements during the follow-up in both studies, an initial drop of stability during the first 3 to 4 months could be demonstrated followed by an increase. In an analysis of turned implants from the first study it was revealed that failing implants showed a continuous decrease of stability until the clinical manifestation of failure.[114] In a separate study, Glauser et al[116] demonstrated a significantly lower initial decrease of stability for oxidized in comparison with turned implants during functional loading in the posterior maxilla, which indicated a higher resistance to loading forces.

In the partial mandible study (paper III), RFA showed small changes of stability from placement up to 6 months. Turned implants showed a slightly higher primary stability than oxidized ones. This may be explained by a grinding effect of the rough surface on the bone during placement which resulted in a looser fit compared with the smooth-surfaced turned implants. However, the differences had diminished after 6 months of healing. Implant failure could not be correlated with primary stability.

In paper IV, all of the implants used for immediate loading of totally edentulous maxillas, had a modified surface. The anodic oxidation process used results in growth of the native oxide layer and a porous structure.[121] Animal experiments and histology of clinically retrieved implants have demonstrated rapid establishment of a firm direct bone-implant contact.[17,118-119] It seems that bone integration can occur through so-called contact osteogenesis, implying bone formation directly on the implant surface. Stability measurements have demonstrated higher resistance to torque forces than with turned titanium implants.[122] Moreover, RFA measurements of immediately loaded implants in the posterior maxilla have shown higher stability during functional loading for oxidized implants than for those with a turned surface.[116] It is therefore possible that the surface properties played a role in the clinical outcome of the present study. According to a literature review by Esposito and colleagues[98], a failure rate of about 7.7% may be expected on all indications over a 5-year period, excluding grafting cases, when using turned titanium implants and two-stage protocols. For treatment of the edentulous maxilla with fixed bridges, recent studies have presented 1-year failure rates of 5 to 6%.[123,124] The overall failure rate in the 20 patients of the present study was only 0.4% after 1 year, which may indicate better performance of the surface-modified implants. However, randomized clinical studies comparing turned im-

plants with TiO_2-blasted and titanium plasma–sprayed surfaces revealed no statistically significant differences with regard to survival rate when used in two-stage protocols.[125,126]

The results from the Nobel Direct study clearly showed that the OPI design did not preserve the marginal bone but resulted in more bone resorption than observed for the two-piece reference implants. One feature of this novel implant design is the use of a moderately rough, oxidized, surface also at the part of the implant facing the soft tissues, which, according to the manufacturer, is believed to result in 'soft tissue integration' and better long-term esthetics. A pilot histological study[127]analyzed 12 biopsies of OPIs with either turned, acid-etched or oxidized surfaces against the mucosa and reported less epithelial down growth and a longer connective tissue seal for the rough surfaces after 8 weeks of healing. These preliminary observations seem to support soft tissue integration in the short-term perspective, although meaningful statistics could not be extracted from the small number of specimens. The results are in contrast to the findings from previous in vitro work and the general perception that endothelial cells and fibroblasts are rugophobic and hence prefer smooth surfaces.[128] Although surface roughness may have a positive effect on the submucosal tissue response, any soft tissue retraction and exposure of the rough surface to the oral cavity, as seen in the present study, will facilitate plaque accumulation, which in turn may lead to soft and bony tissue pathology.[129] We are unaware of any published clinical studies on the long-term effects of using rough surfaces in soft tissue. It is possible that contamination of the oxidized surface when making the temporary crown in single cases, during impression taking for provisional bridges and when cementing the constructions, can explain the observed marginal bone loss. However, the wound was protected with a rubber dam during these procedures, and substantial extra care was given to this potential problem with the 3 implants that for illustration purposes were not covered by rubber-dam during cementation.

The presence of oxidized surfaces also at the integrated abutment cylinder of the OP implants allow for variation of vertical placement – according to the manufacturer. According to the instructions for use (Nobel Biocare AB), about 1.5mm of the 3 mm high cylinder should face the soft tissues, meaning that about 1.5 mm should be placed in bone. In the present study, the initial marginal bone level was on average 1.1 mm above the lower corner of the cylinder. Our data showed a correlation between insertion depth and bone loss, indicating that the cylindrical part did not integrate with bone. This is in line with the experiences with the conical Brånemark fixture, which was originally used for single- tooth replacements and in bone-grafting situations. This implant had a 3.5 mm high conical collar that was submerged in bone, and follow-up studies have demonstrated more bone loss for the conical than for the standard Brånemark fixture design.[129-131] A recent follow-up study of 17 Nobel Perfects implants demonstrated a similar loss of about 4

mm of marginal bone, down to the first thread, in spite of an oxidized surface on the collar.[132] However, other implant systems, for instance with a titanium dioxide blasted cylindrical collar in marginal bone, have shown stable bone levels[133] and it is possible that other factors such as implant design, preparation technique and the degree of press fit of the coronal cylinder may have an impact on the marginal bone tissue response. Although, there was a correlation between insertion depth and bone loss for the OPIs of the present study, this alone cannot explain bone loss. Even when compensating for insertion depth, i.e. by calculating the marginal bone level in relation to the lower corner of the collar, the marginal bone level was situated more apical than for TPIs.

Splinting

Immediate loading protocols offer obvious advantages for the patient such as a momentary reduction of oral handicap which is important not the least from a psychological point of view. Another benefit is less post-operative complaints as the wound is not loaded with a removable denture but protected by the temporary bridge during chewing. Moreover, less surgery and chair-time is needed since abutment connection surgery and relining of removable prosthesis are not needed. However, the use of direct loading in clinical routine is resource demanding and logistic problems may be faced. In this study, a surgeon, restorative dentist and a laboratory technician worked as a team. Thereby, the patients could be provided with a temporary bridge within 24 hours.

The focus on immediate loading has promoted the dental profession to develop techniques to provide patients with fixed provisional restorations, made in a laboratory or chair-side. Full arch provisional reconstructions have so far been difficult to make chair-side. Laboratory made provisional constructions have several advantages with regard to finish and aesthetics but are often less cost-effective. It is the experience of the present authors that many patients decline the possibility of immediate loading with a laboratory made temporary bridge because of costs.

In paper I, only 7 of 192 provisional implants were lost during the observation period, but 17 were not stable at the time for second stage surgery. Nevertheless these unstable PIs had obviously contributed to the support of the provisional FPD. Krennmair and colleagues[134] reported a failure rate of 36.2% for maxillary temporary implants. However, in their study the temporary implants were loaded with an overdenture and were not splinted with a fixed bridge. An advantage of using PIs in combination with fixed temporary bridges is that the load meeting the permanent submerged implants will be minimized, thus potentially increasing the success rate of these implants. A side observation made at the second-stage sur-

gery was the excellent condition of the covering mucosa, namely, thin (nonhyperplastic) and with minimal signs of irritation. Whether this condition can be related to the fact that no removable provisional dentures were used is only to be speculated upon. Controlled clinical trials are needed to confirm such a hypothesis. The study clearly demonstrated that PIs can be successfully used to provide patients with a fixed provisional bridge during the healing of permanent implants. Forty-four of 45 FPDs supported by PIs maintained their stability during the healing phase of at least 6 months. Both partially and totally dentate jaws were included. In the partially dentate situations some of the neighboring teeth were sometimes used. The integration of teeth in the provisional FPDs not only increased the number of abutments but also protected the provisional FPD from lateral forces. The failure cases were (1) a partially dentate patient with soft bone (types 3 and 4) who showed signs of bruxism and (2) a totally dentate patient with severe bruxism (she was provided with a nightguard but never used it). Bruxism is most likely one of the contraindications for applying temporary occlusal rehabilitation by means of PIs. Furthermore, the survival rate (97.8%) of the permanent implants in the present study is in line with short term data reported earlier.[135] No clinical signs could be observed, indicating that the implant failures were related to the use of PIs.

One way to simplify the concept of splinting would be to evaluate techniques for chair-side manufacturing of provisional bridges.[136] A way of making a chair-side temporary bridge is explained in appendix I. On a tooth-setup of the area that is candidate for rehabilitation, the template is made. After implant and abutment insertion temporary components (titanium cone and PEEK cap) are mounted. This is done on abutment level. The template is filled with a self setting composite material. After the composite is fully seated, the temporary bridge is trimmed and polished. The construction protects the wound from trauma from day one, thereby making the first days after surgery more pleasant for the patients. It is also possible that the immediate temporary prosthesis may facilitate soft tissue healing leading to better aesthetics. The down side of chair-side temporary bridges is the risk of acrylic or composite contamination of the wound. No adverse reactions towards the bridge, however, were observed in the present study.

The technique described in appendix 1 does not differ from temporalization for natural teeth. In full arch reconstruction, impressions of the opposite jaws in the templates help to orientate the template when the temporary bridge is made in the mouth. This was made by mounting the template on the opposite jaw and then making the patient gently bite together to the correct bit-height. By this procedure, we produced a temporary bridge in the right occlusion. This minimizes time for occlusal adjustments. Canterlivers exceeding 5 mm were not recommended due to risk of fracture. This concept of making temporary constructions could also be made as a laboratory bridge. It still has the advantages of a less time con-

suming and therefore cost-effective way of making temporary solutions for the patient.

The degree of micromotion between implants seems to be of importance for the implant integration process. It has been postulated that the absence of micromotion of the implant is the key factor for osseointegration rather than time of loading.[137-140] Brunski[139] proposed that a 100 µm micromotion is the threshold level for the turned surface. Another study[140] postulated that the tolerated micromotion for roughened implant surfaces is 50 to 150 µm.

In many papers on implant supported dental prostheses it's argued that splinting will reduce the occlusal load transfer to the implants compared to a situation with freestanding implant units. According to Glantz and colleagues[141,142] favorable loading conditions were achieved via rigid implant supported bridge. Therefore it could be argued that good treatment results can be reached provided that a provisional bridge is connected to the implants as soon as possible after fixture placement. In other words, the implants will be rigidly splinted to each other via the temporary bridge, thus decreasing the micromotion at the bone-implant interface, which in turn will facilitate proper osseointegration.

Splinting reduces the lateral forces on implants, if they are three or more in number and placed in a tripod or cross arch situation. [143,144] In such situations, lateral forces are partly compensated by the more favorable axial implant forces. On the other hand, only two implants splinted will not offer this load reduction as these implants will be placed "in-line" with no offset implant to counteract the lateral forces. The principle of cross arch stabilization is well documented clinically[145,146] and also by in vivo load measurements[147].

Bone remodeling

The average marginal bone loss was 0.7 mm during the first year in the partial mandible group. Eleven implants (4,9%) showed more than 2 mm bone loss and two (0.9 %) more than 3 mm after one year of loading. This in line with other researchers experiences when evaluating immediately/early loaded implants. [80,94,120] There were no differences between turned and oxidized implants with regard to average bone loss although more oxidized implants showed more than 2 and 3 mm of bone loss after one year.

The present prospective clinical study (paper V) evaluated the use of 115 OPIs (Nobel Directs and Nobel Perfects) for immediate function in 48 patients. Six of the implants were removed due to extensive bone resorption and subsequent soft tissue problems. Many of the remaining OPIs showed signs of unacceptable

marginal bone loss as 49% showed a loss of more than 2mm and 20% more than 3mm after the first year of function. This was in contrast to the reference group of the TPIs used for immediate loading, where only 7.7% and 0.6% of the implants showed more than 2 and 3mm of bone loss, respectively. Other studies, also using oxidized TPIs for early/immediate- loading protocols, have shown figures similar to our reference group, where 0–4.4% of the implants were reported to have more than 3mm bone resorption during the first 12–18 months.[82,99,148] A multicentre study evaluating 121 oxidized implants used for two-stage procedures showed that about 4% of the implants had more than 3mm of bone loss after 1 year in function.[149] Keeping in mind that the tested OPI concept was designed to minimize marginal bone resorption[150], the results from the present study are alarming. The reasons for the initial bone loss seen at TPIs during the first year have been discussed in the literature and may be related to overload, surgical trauma, periimplantitis, biological width, etc.[151] The Nobel Directs implant was allegedly designed to minimize marginal bone loss based on the theory that contamination of the implant–abutment junction, the microgap and violation of the biological width are the causes for the initial bone loss.[150] Although results from experimental studies in part support such a theory[152], clinical follow-up studies have reported a similar degree of initial bone loss as for non-submerged implants.

Based on the experiences from conventional two-piece Brånemark implants, the bone reactions towards the OPIs were different in many ways. The OPIs often presented with crater-like defects, which are rarely seen around conventional TPIs. Some of the implants also showed atypical juxtaradicular defects. Six implants were removed because of extensive resorption and soft tissue problems, in spite of being clinically stable. The crater-formed defect is generally looked upon as a radiographic sign of peri-implantitis, a condition that is usually seen after many years of loading.[153] Although the present implants were not systematically evaluated with regard to peri-implant infection, deep probing depths, bleeding and pus were experienced around implants with extensive bone loss. The five implants lost in the reference group showed a different pattern as no implant showed crater-like bone resorption. Two implants were found to be rotationally mobile when taking impressions for the permanent bridge after 2 and 3 months without any radiographic signs of failure. Three implants that showed peri-implant radiolucency were found to be mobile and removed.

Success criteria

In paper III, and V a four-Field table according to Albrektsson and Zarb[96,154] was used to evaluate the outcome. With this technique, unaccounted for implants and implants without readable radiographs are not compensated for. No or few drop-out patients are required to get success rates in range of those calculated with life table statistics. In paper III, only one examined implant was found

to not meet with the less strict criteria of 3 mm bone loss. However, the success rate was calculated to 85 % since not all implants had readable radiographs.

The Nobel Direct and Nobel Perfect implants have the same geometry as the Replace Select Tapered implant, but no follow-up studies including radiography have been published that could have been used for comparison. Thus, the marginal bone response to this implant design is unknown. The criteria for success previously presented in the literature are often based on the experiences from the standard Brånemark fixture and two-stage procedures.[96,154,155] This implant design usually shows marginal bone resorption to the first thread during the first year in function while the bone loss is minimal in the subsequent years.[151] Published criteria have stipulated that 1–1.5mm of bone loss is acceptable when measured from the lower corner of the implant head.[96,151] Today, the implant–abutment junction is commonly used as a reference point, which, for the Brånemark implant is situated some 0.8mm above the previous reference point. In the present study, we have therefore accepted up to 2 mm (success grade 1) and 3 mm (success grade 2) of bone loss when evaluating the implants. When applying the criteria, both success grades 1 and 2 were much lower for the OPIs than for the TPIs as presented in four-field tables. The differences would have been even greater if life-table statistics had been used to compensate for implants not evaluated, as proportionally more radiographs of TPI implants could not be evaluated.

Preparation on Nobel Direct

Using a vital microscopic titanium implant chamber model, Eriksson & Albrektsson[156] demonstrated bone tissue damage after heating the chamber to 47° C for 1 min. In situ high-speed preparation of the implant and overheating is another plausible explanation to the problems encountered. However, the majority of implants were not drilled on after placement and many implants showed bone loss already at the time of preparation for the final construction. As no control group with implants allowed to heal before loading was used, the effect of immediate function itself on the clinical outcome could not be evaluated. All provisional single crowns were out of occlusion, while multi-unit constructions were in light centric occlusion. A comparison between the two groups did not reveal any differences in marginal bone loss. However, it could be argued whether the single crowns can be regarded as unloaded as they will be loaded as soon as the patient chews food.

Conclusion

As the overall conclusion of this thesis it can be stated that dental implants can successfully be immediately loaded if high primary stability is achieved and a rigid splinting with well controlled occlusion is applied.

Provisional implants can predictably be used to provide patients with a fixed bridge during healing of permanent implants. No interference with the osseointegration process of the submerged permanent implants owing to the placement of provisional implants can be observed.

High primary stability can be achieved in all jaw regions when using an adapted surgical protocol. However, the use of thinner drills and/or tapered implants cannot fully compensate for the effect of soft bone. Factors related to bone density and implant diameter/length determine the level of primary implant stability. Furthermore, a higher stability is observed in male than in female patients.

Immediate loading of implants with firm primary stability in the partially edentate mandible results in predictable outcome.

When using a modified surgical protocol and inclusion criteria aiming for high primary stability, six to seven oxidized titanium implants can be used for immediate loading of a fixed provisional bridge in the edentulous maxilla. No significant difference can be observed between the immediately loaded and 2-stage implants.

Immediately loaded Nobel Direct and Nobel Perfect one-piece implants show lower success rates and more bone resorption than immediately loaded two -piece implants after 1 year in function. The one-piece implants do not minimize marginal bone resorption, vertical placement can not be varied and the esthetic result is not optimized.

From my point of view, to maintain a high survival rate with immediate loading, some parameters are important. These parameters are **good primary stability; immediate splinting; controlled occlusion/ articulation and moderately rough surfaces** in bone during healing time. The first 3 parameters help avoid micromotion at the bone-implant interface and the last parameter shortens the time for bone-formation around the implant.

If a high primary stability can not be achieved or if any other uncertain parameters concerning the case is present, a two-step approached should be conducted. As a clinician, one should never risk the outcome of the therapy.

PRESENTATION OF A CONCEPT FOR IMMEDIATE LOADING

Together with Dr Mats Hellman the author has developed and evaluated a concept for immediate loading since 1998. Patients have been treated on all indications following a strict protocol aiming at reducing the number of negative biomechanical factors. In essence, a sufficient number of implants had to be placed with firm primary stability for immediate splinting with a fixed bridge in controlled occlusion. In addition, insertion torque and RFA measurements are used to control primary stability. Part of the concept is also the use of moderately rough surface implants which is believed to perform better than turned implants in challenging situations.

Table 40 shows a summary of two-stage vs. immediate loading of in total 1973 fixtures of which 1303 is immediately loaded. The inclusion criteria for this summary were consecutive patients with at least 3 years follow-up (range 3-7 years) and the same concept of enhanced primary stability and splinting within 12 hours. Excluded in this summary are 2 cases of Teeth in an Hour (Nobel Biocare) and 48 cases of Nobel Direct, already reported previously in this thesis. No significant difference was seen between the 2-stages (670 fixtures) and the immediately loaded group (1303 fixtures). A failure rate of 1.0% was seen in the 2-stage group compared to 1.2 % for the immediately loaded group.

Table 40. *Two-stage vs. Immediate loading approach.*

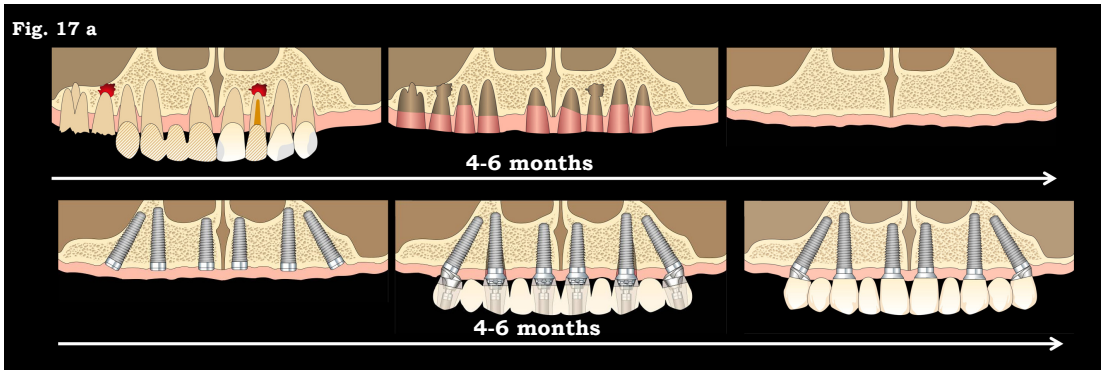
Site specific	Two Stage			Immediate loading			Total		
	No. patients	**No. fixtures**	**No. failed**	**No. patients**	**No. fixtures**	**No. failed**	**No. patients**	**No. fixtures**	**No. failed**
	279 (38%)	670 (34%)	7 (1.0%)	453 (62%)	1303 (66%)	16(1.2%)	732	1973	23
Total mandible	0	0	0	88	388	4 (1%)	88	388	4
Total Maxillae	44	261	4 (1.5%)	56	336	1 (0.3%)	100	597	5
Partial Mandible	22	45	0	149	350	4 (1.1%)	171	395	4
Partial Maxillae	95	246	2(0.8%)	41	110	3 (2.7%)	136	356	5
Single Mandible	39	39	0	55	55	3* (5.4%)	94	94	3
Single Maxillae	79	79	1 (1.3%)	64	64	1 (1.5%)	143	143	2
Total	**279**	**670**	**7**	**453**	**1303**	**16**	**732**	**1973**	**23**

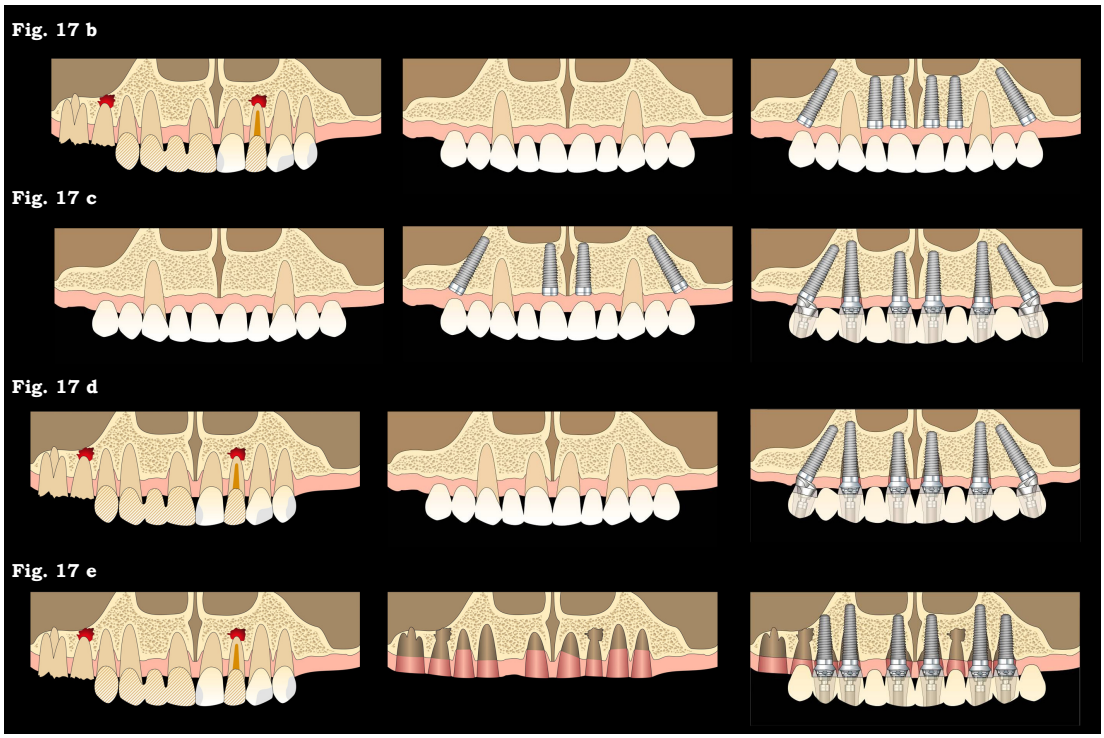
**All first or second molars, without posterior tooth protection.*

Therapy planning

Today, most patients seeking implant treatment are not totally edentulous. If following a traditional protocol, a 4-6 months healing time after tooth extraction would be standard. In addition, a two-stage procedure often requires a healing time of 4-6 months. In other words, a complete implant treatment often takes 8-12 months (Fig. 17a). During that time, the patient is wearing a removable denture or, worst, no dentures. As therapists, we should cause as little dental handicap as possible to our patients. Therefore, the first mission in planning an implant therapy is to evaluate if some teeth can remain during the primary healing phase of bone and mucosa. Fig. 17b-e illustrate different options for oral rehabilitations without using a complete denture during primary healing. Key teeth, such as canines, can often be maintained and used in a temporary bridge construction during the healing phase. By leaving some strategic teeth, the dentist has not only helped the patients but also provided different treatment options. If the patient case is not suitable for immediate loading, a two-step procedure can be performed, without leaving the patient orally handicapped with a removable prosthesis (Fig. 17b). If immediately loading is feasible, the remaining teeth can be extracted during surgery and replaced by implants (Fig. 17c). Figure 17d shows a patient case, where both canines and first incisors are left during primary healing. At time of implant surgery, the posterior maxillary region has healed sufficiently to place implants in a tilted position to allow for adequate space between individual fixtures. The remaining implants are placed in fresh extraction sites or in healed bone adjacent to the extraction socket. In the latter situation, it can be difficult to achieve optimal fixture position. Fig. 17e describes a treatment option with all implants placed in extraction sites. However, such treatment may give rise to a less predictable healing of bone and mucosa.

Figure 17. *Different approaches to maintain teeth during implant treatment. Fig. 1a shows a traditional implant protocol, which requires a 4-6 month healing time after tooth extraction and an additional 4-6 months for submerged healing. Fig. 1b-e illustrate different options for oral rehabilitation without using a complete denture during the primary healing phase.*





Patient selection

Inclusion criteria

- Patients positive to immediate loading
- Elderly and medical compromised patients, were a immediate loading approach gives less stress and ability to minimize manipulation with ongoing medication.

Exclusion criteria

- History of implant failure.
- Head/neck irradiated patients.
- Uncontrolled diabetes mellitus.
- Heavy smokers.
- Deviated bit relations (vertical/ sagital)

Pretreatment

Candidates for immediate loading implant therapy must often receive occlusal and articulation adjustment before or during temporalization in order to avoid unnec-

essary stress to the fixtures. For immediate loading in the totally edentulous maxilla, a fixed situation of minimum 10 teeth in the mandible is considered a rule. A stable occlusion/articulation with minimal lateral forces is a prerequisite for immediate loading.

Clinical assessments during surgery

Bone quality/quantity

Bone quantity and quality of the implant site is the most important parameter in immediate loading protocols. Critical bone features are difficult to evaluate solely by a radiographic analysis. The Lekholm & Zarb[95] index originally served to standardize preoperative planning of an implant case in order to make the outcome of various studies comparable. However, the present author and co-laborators suggests that the precise bone quality can only be determined *per-operatively*. Bony features differ within the edentulous jaw of the same patient, which often necessitates a site-specific analysis.

Quality 4 bone is often been referred to as "poor" bone for implants due to the fact that it is soft, which from a biomechanical view can challenge the efforts to obtain a firm initial stability of an implant. Jaffin & Berman[115] showed high implant failure rate (35%) in type 4 bone. In a study of early outcome of 4,641 Brånemark fixtures, Friberg et al.[135] concluded that most implant losses occurred in fully edentulous maxillae, in which the jaw bone exhibited soft quality and severe resorption. More than 40% of type 4 bone gave rise to implant failures. It should be emphasized that these pioneering works on correlation of bone quality and implant failure were conducted with turned implants and conventional protocols, involving pre-tapping even in type 4 bone quality. From a biological point of view, trabecular bone represents a superior tissue compared to cortical bone. Trabecular bone exhibits a high surface area, which is contiguous with the bone marrow compartment[157], and bone healing is far more rapid compared to the healing pattern present in cortical bone.

Drill protocol, type of fixture, fixture diameter, numbers, and degree of counter sinking

Stability of an implant can be defined as its capacity to withstand loading in axial, lateral and rotational directions. Sennerby and Roos[158] stated in a review article that primary implant stability is determined by bone quality and quantity, implant design and surgical technique. From a clinical perspective, depending on bone quality and quantity dentists need to adapt our drilling protocol and choice of fixture to gain sufficient primary stability.

One of the essentials in succeeding with immediate loading is the therapist ability to judge the implant site. Quality and quantity, thickness of cortex must be determined before final drill and implant are decided. Many scientific reports have reported modified drill protocols depending on bone quality[19,103,106,135,159]. As presented in this thesis[160] analyzes of the primary stability of dental implants placed with a modified drilling protocol were made. It was concluded that high primary stability can be achieved in all jaw regions when using an adapted surgical protocol. However, the use of thinner drills and/or tapered implants can not fully compensate for the effect of soft bone. Slightly tapered or tapered implant designs and surface modifications have decreased implant failure rates dramatically in soft bone. Glauser et al[112] showed that significantly higher torque values were achieved if no pre-tapping were made before placing slightly tapered implants in type 3 bone quality. Friberg et al[103] showed that the slightly tapered implant more frequently required a higher insertion torque and showed a significantly higher primary stability compared to straight parallel walled implant. This difference in stability leveled out over time, and the 2 different implants exhibited similar secondary stability at abutment operation and at the 1-year visit. Our results[165] showed high survival rates (99,2 %) of immediately loaded implants in totally edentulous maxillas when using adapted surgical protocols and slightly tapered (38%)or tapered implants (27%) where the bone was judged to be quality 3 or 4 in (46% and 15% respectively).

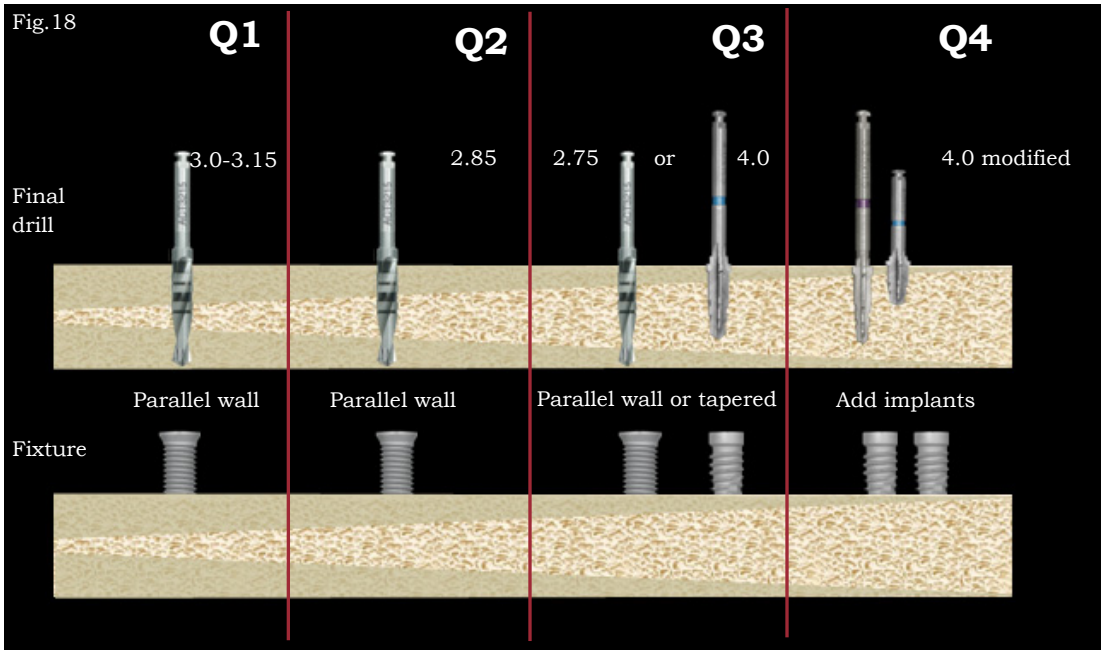
Besides a modified drill protocol and implant design, enhance primary stability can be accomplished by choosing a wider implant diameter. A wider implant will engage the buccal and palatial compacta bone more easily, and enlarge the bone/metal surface contact. The present author and co-laborators[160] found significant higher initial implant stability, measured with Resonance Frequency Analysis, with wider implants compared to narrow/regular implant designs. Friberg et al.[161] suggested to use a drilling protocol with an end-burr of 3.0 mm, and with a short-peg countersink to widen the implant site entrance enough to fit a 5.0 mm implant.

Cortical compacta bone differs both in thickness and density and is almost non-existent in quality 4 bone. Pierrisnard et al.[162] showed that bony stress is concentrated in the cervical area of an implant. It is also assumed that the 1 mm cervical cortical bone layer serves as the major anchoring point for an implant. In case of a thin cortex, countersinking is not recommended at all. Thus, the final burr diameter and counter sinking should not be standardized to fit all clinical situations.

Drill protocols in various bone qualities

The following guidelines are based on the 3.75 mm diameter, straight cylindrical implant design, the tapered implant design with a diameter of 4 mm. The final torque aught to be between 30-50 Ncm. It is recommended to start with a thinner final drill. Two options exist if the bone quality is misjudged and the implants stops at 50 Ncm before being finally seated; 1) Unscrew the implant and choose a wider final drill, or 2) Manually, with a torque wrench, tighten the implant to position, thereafter loosen the fixture by reverse torque and then by a machine at 50 Ncm seat the implant to final depth. Those methods aim at eliminating the risk of over-tightening the implant. In quality 4 bone, full length of 3.5 mm drill is made thereafter widening the preparation in the coronal part with a short 4.0 drill. In extreme soft bona a 2 mm twist drill is used in full length an a coronal widening is made with a 3.5 mm drill, placing a 4.0 mm implant. Figure 18 describes the recommended type of final drill and implant with bone of various density.

Figure 18. *Recommended type of final drill and implant with bone of various density.*



4.0 modified—full drill depth of 3.5 burr and open up the preparation with 8 mm 4.0 drill.

Distribution and number of implants

The biomechanical rules in implant treatment have been known for long. A carefully planed/treated patient has a far better longtime prognosis. To let implants

without unnecessary stress heal is of outmost importance in immediate loading therapy. In quality 4 bone it is recommended to add some implants if available space is present to further reduce stress on the implants. By following the biomechanical roles one can reduce, and thereby, influence the prognosis.

Evaluation of inserted implants

A final torque of 30 Ncm and an ISQ above 60 is recommended to candidate for immediate loading. Side steps from this recommendation can be made if additional implants are inserted or a cross-arch maxillae/mandible is rehabilitated. The most posterior implant should always show a torque of minimum 30 Ncm and an ISQ of 60 or higher. One should not neglect the clinical feeling that comes with time. Even-though the objective numbers collected are positive for loading, experience of implant rehabilitation might lead to a 2-step procedure anyway.

Postoperative care

During 10 days postoperative the patients are recommended to eat soft food, rinse twice a day with chlorhexidine. In addition V-penicillin is recommended for 10 days post operatively to minimize risk of infection.

Prosthetic considerations

Splinting by temporary constructions

Different approaches to provide patients with temporary constructions have been presented. Most of these techniques involve dental technicians, for example to convert existing dentures and making acrylic bridges. The laboratory procedure is well controlled and has several advantages to chair-side manufacturing of temporary constructions such as better finish and esthetics. On the other hand, the laboratory produced temporary constructions need extended logistic, tend to be more expensive and take longer time to produce. The use of chair-side made temporary constructions have the advantages of an immediate reduction of handicap, immediate splinting and cost effectiveness. Moreover, a chair-side made bridge can be manufactured and delivered during remaining anesthesia induced for the surgical placement of the implants. On the down side are the esthetic outcome and a possible risk for contamination of newly operated areas with temporary prosthetic materials.

Fabrication of temporary bridges according to a chair-side concept[163]

This chair-side temporary concept aims to convert a screw-retained temporary prosthesis to a cement-retained temporary prosthesis during the healing period.

The temporary components fit onto screw retained conical abutments (Biomet 3I) (Fig 19a) and consist of 2 parts. A conical titanium alloy part (Fig. 19b) is mounted, with an integrated screw, onto the conical abutment, and a PEEK (Poly etheretherketone) plastic cap, which covers the abutment (Fig. 19c), will become part of the provisional prosthesis. The retention of the PEEK cap to the titanium cone is firm, which will allow the provisional prosthesis to be retained only by a snap.

Fig. 19d-n shows a typical treatment of a partial/total implant treatment. The treatment starts with selective extraction or extraction at time for surgery if possible without any risk for the treatment outcome. (Fig. 19d-e). Extraction of the remaining teeth can occur during implant surgery, if sufficient stability of the fixtures is obtained. Before surgery, an alginate impression of both jaws is made. In full denture patients, impressions are made of the denture. Occlusal record is preformed. At the dental laboratory, stone casts are made and placed in an articulator. In case of missing teeth, a tooth wax-up is made. A translucent vacuum template is fabricated using a 2.5 mm thick thermoformed material. On the template, an impression is obtained of the opposite jaw in order to orient the template in the mouth.

The bony crest is exposed through a mid-crestal surgical incision (fig 19f). After reflecting the surgical flap, the optimal implant position is decided upon based on aesthetic and biomechanical considerations. Insertion torque and Resonance Frequency Analysis measurements are used to check stability of the fixtures and to evaluate the feasibility of employing immediate-loaded implants (fig 19g). Next, the conical abutments are mounted (Fig. 19h), and the temporary titanium cone and PEEK cap are placed onto the conical abutments (Fig. 19i) before closing the surgical flap (Fig. 19j). The translucent template is mounted to verify that the temporary parts fit the template. Self-setting acrylic/composite provisional prosthetic material is then injected into the template. The template is seated with guidance of adjacent teeth and/or the opposite jaw, and allowed to set for 4 minutes (Fig. 19k-l) while the patient is biting together. The temporary prosthesis is removed from the titanium interface and trimmed outside the mouth and remounted (Fig. 19m-n). During the initial healing time, which is approximately 10 days, the temporary prosthesis is fixed with a 1% chlorhexidine gel. Cantilevers cannot exceed 5 mm.

After an additional 3-6 month of healing (fig 20a), the temporary prosthesis is snapped off and impression copings are mounted on the titanium copings (Fig. 20b). A closed tray impression is then made. The translucent template used for fabrication of the temporary prosthesis is used for bite registration. It is produced by filling the template with bite registration material (fig 20 c-d). This procedure provides an exact index that can be mounted on the temporary titanium copings, and can give the dental technician additional information about tooth shape (Fig.

20e). The template can be reused by the dental laboratory to make the framework master for copy milled titanium framework (Fig. 3f-h). The final screw-retained porcelain/titanium construction is then delivered (Fig 20i-j).

Figure 19. *Reconstruction of a edentulous maxilla with a chair-side approach.*

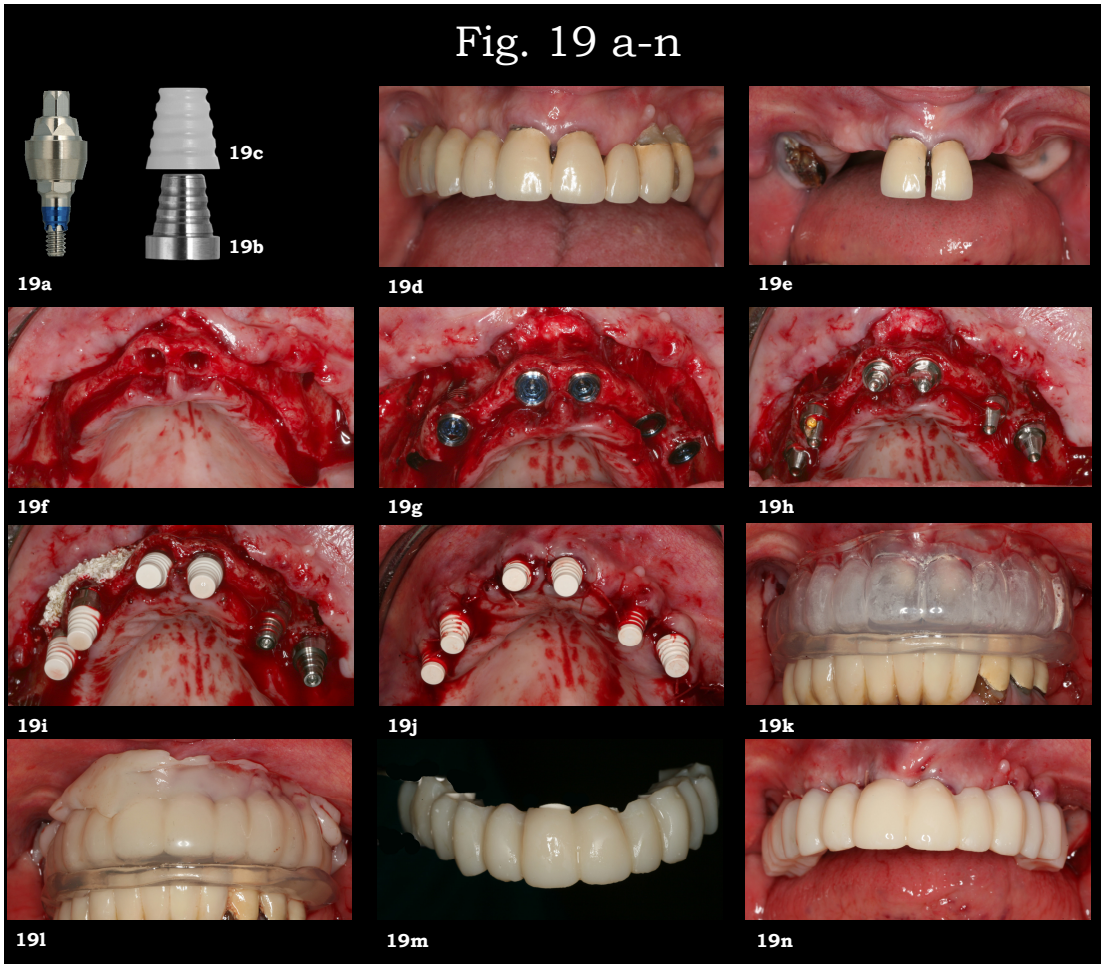


Figure 19a-p shows an implant treatment of a totally edentulous patient. Figure 19a shows the Conical abutment and figure 19 b-c the temporary QuickBridge™ components, a titanium cone and a PEEK snap on cap (Biomet 3i). Figure 19d –e shows the patient before start of surgery, and fig 19f-g extraction and implant installation of Certain Prevail NanoTite. Conical abutments are mounted (fig. 19h). On the conical abutments, the QuickBridge titanium coping and PEEK cap are mounted (fig 19 i-j) before the surgical flap is closed (fig 19j). The translucent template is mounted to verify that the temporary parts fit into the template.(fig 19k) Temporary self-setting composite material is injected into the template. The template is oriented by fitting it on the opposite jaw and the patient gently closing in to centric occlusion and allowed to set for 4 minutes (Fig 19l). The temporary prosthesis is removed from the titanium interface with the PEEK cap integrated in the material, trimmed outside the mouth and remounted (Fig. 19m-n).

Figure 20 *Conversion of chair-side made temporary prosthesis to copy-milled titanium/porcelain definitive prosthesis*

Check-up and maintenance

Check-ups are made 2 weeks postoperatively and then once every month. Oral hygiene, soft tissue healing, stability of provisional bridge and fixture status are evaluated. After adequate soft tissue healing, 1-6 months, depending on site and healing ability, permanent prosthetic rehabilitation are made. The permanent prosthesis is preferably made of a biocompatible material, titanium or zirconium. Occlusion and articulation contacts are carefully adjusted to minimize lateral forces. Oral hygiene instructions are made immediately after delivery of the

final prosthesis. Thereafter checkups are individually made but minimally at 6 and 12 months and thereafter annually.

Conclusion of presented concept for immediate loading

Implants with high initial primary stability seem to function well under the influence of immediate load.[165,164] Bone quality needs to be evaluated before final diameter of preparation is made.[160] If surgical strategies are made to enhance the primary implant stability, immediate loading in softer bone can be made with predicable outcome. A final torque exceeding 30 Ncm and an ISQ value above 60 Ncm seems to be sufficient objective values for immediate loading. No differences could be noticed between immediately loaded implants compared to 2-stage implants that had healed unloaded for 4-6 months.[166] No difference in bone remodeling could be observed between the two groups. Splinting, chair-side or laboratory made is importance to obtain high success rate.

Five points for long-term good results - immediate loading:

1. *Excellent primary stability*
2. *Moderately rough surface*
3. *Immediate splinting*
4. *Controlled occlusion*
5. *Biocompatible prosthetic materials*

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