On the role of number of fixtures, surgical technique and timing of loading

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Abstract

Aims: The aims of this thesis were to analyze reduced number of implants supporting full arch fixed mandibular prostheses and fixed partial dentures (FPDs), non-submerged healing and early loading in the edentulous mandible. A further aim was to evaluate fit of Computer Numerical Controlled (CNC) milled I-Bridge® frameworks.

Material & Methods: *Paper I.* One hundred and nineteen patients rehabilitated with full arch mandibular prostheses supported by four implants were evaluated after a mean follow-up of 4.4 years. *Paper II.* A total of 178 patients provided with FPDs supported by two (n=92) or three implants (n=122) of whom 123 were evaluated after a mean follow-up of 9.4 years. *Paper III.* Early and delayed loading of full arch mandibular prostheses were evaluated in 109 patients, 54 with delayed loading and 55 with early loading, with a mean follow-up of 3.6 years. *Paper IV*. Submerged and non-submerged implant placement for supporting fixed prostheses in the edentulous mandible were evaluated after five years in 29 patients. *Paper V.* The precision of fit of CNC-milled I-Bridge® frameworks was evaluated using two different implant systems.

Results: *Paper I.* The five-year cumulative survival rate (CSR) for implants was 99.1% and for prostheses 100%. Mean bone loss from baseline to five-year follow-up was 0.5 mm. No indication could be found that the number of supporting implants influenced the prosthetic complications. *Paper II.* The five-year implant and prosthesis CSR was 97.7% for two-implant supported FPDs and 97.3% for three-implant supported FPDs. Mean bone loss at five years was 0.4 mm. Significantly more prosthetic and abutment screw loosening were seen in two-implant supported FPDs. *Paper III.* Five-year CSR for implants was 94.4% and 92.5% for prostheses in early loading, and 97.9% and 98.0% in the delayed loading group. More prostheses needed adjustment or replacement in the early group, but patients treated with early loading were more pleased with the treatment procedure. *Paper IV*. Five-year CSR survival rate was 99.4%. Three implants fractured in one patient. Mean bone loss at five years was 0.7 mm in submerged implants and 0.5 mm in non-submerged implants. *Paper V.* All frameworks demonstrated clinically acceptable fit with mean distortion values within 23 μm (x-axis), 26 μm (y), 4 μm (z- axis) and 34 μm (3-D) for all frameworks. Control frameworks displayed greater levels of distortion than frameworks produced in a strict test situation.

Conclusion: A reduction of the number of supporting implants to four implants in full arch mandibular prostheses and two implants in three unit FPDs in partial edentulous jaws resulted in the same clinical outcome as when more implants are used. Non-submerged implant placement in the edentulous mandible was as predictable as submerged, but early loading of implant-supported mandibular prostheses incurred more prosthetic complications. Computer numerical controlled milled frameworks presented levels of precision of fit within limits considered to be clinically acceptable and superior to earlier published results on cast frameworks.

Key words: Computer numerical controlled, dental implants, fixed prostheses, non-submerged

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List of Papers

I **Eliasson A, Palmqvist S, Svenson B, Sondell K.** Five-year results with fixed complete arch mandibular prostheses supported by 4 implants. Int J Oral Maxillofac Implants 2000; 15:505-510.

II **Eliasson A, Eriksson T, Johansson A, Wennerberg A.** Fixed partial prostheses supported by two or three implants: A retrospective study up to 18 years. Int J Oral Maxillofac Implants 2006; 21:567-574.

III **Eliasson A, Blomqvist F, Johansson A, Wennerberg A.** A retrospective analysis of early and delayed loading of full-arch mandibular prostheses using three different implant systems: Clinical results up to 5 years of loading. Clin Implant Dent Rel Res. In Press.

IV **Eliasson A, Narby B, Ekstrand K, Hirsch J, Johansson A, Wennerberg A.** A 5-year prospective clinical study of treatments with implant-supported fixed prostheses in the edentulous mandible using the Paragon System Implants placed according to a submerged and non-submerged surgical protocol. Submitted for publication.

V **Eliasson A, Wennerberg A, Johansson A, Örtorp A, Jemt T.** The precision of fit of milled titanium implant frameworks (I-Bridge®) in the edentulous jaw. Submitted for publication.

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Introduction

Background

Residual ridge resorption in patients wearing complete dentures is a problem that affects retention and stability of the denture. In order to improve support for prostheses and restore masticatory function, dental implants have been a topic for research for more than 60 years. During the 1980´s and 1990´s studies were conducted with alveolar ridge augmentation procedures using hydroxylapatite and positive reports were published stating that 90% of the grafted ridges displayed negligible radiographic resorption and prosthesis function was improved.[1,2]

The early metal dental implants were fabricated from various alloys or titanium and were principally of two types; subperiostal or endostal implants.[3-6] A third type of implant was the mandibular staple bone plate, a device used to restore the atrophic mandible.[7-10]

The development of Brånemark system® implants started in the 1960´s when Per-Ingvar Brånemark and co-workers initiated experiments with screw shaped dental implants fabricated from commercially pure (c.p.) titanium with a turned surface. In 1969 the group published results from animal studies concluding that in the dog threaded titanium fixtures could successfully be placed and loaded with axial and lateral forces for several years in both jaws.[11]

New dental implants were also developed by others during the 1970's. André Schroeder and the international team for implantology (ITI) research institute in Bern developed a dental implant system from c.p. titanium with a rough titanium plasma sprayed surface fabricated in various shapes; the implants were used to rehabilitate edentulous patients by means of overdentures supported by a Dolder bar.[12-15] In Germany, Willi Schulte developed a root formed implant system (Frialit) from the ceramic Al_2O_3; with incrementally increased diameters intended for replacing single teeth.[16] The material in the implant was changed to c.p. titanium in 1990 and the name was subsequently changed to Frialit 2.

In 1977 the Brånemark group published their ten-year experience of 1618 dental implants placed in 128 upper and 107 lower jaws, laying the scientific foundation of modern dental implantology and introducing the concept of osseointegration. [17] Further reports by Adell and colleagues promoted the wider acceptance of the Brånemark system® implants.[18] The first international team to learn Brånemark's principles of osseointegration was a group led by George Zarb in Toronto who commenced the Toronto replica study in 1979, now one of the

most important data banks on dental implants. A few years later Zarb initiated the Toronto conference (1982), where osseointegration was first presented and recognised as a reliable treatment possibility for edentulous patients. The proceedings of the Toronto conference were issued as a separate volume of reprints, edited by George Zarb, from the Journal of Prosthetic Dentistry.[19] Another milestone in the dissemination and acceptance of the use of dental implants to support prostheses in edentulous patients was the book "Tissue integrated prostheses: osseointegration in clinical dentistry" edited by Brånemark PI, Zarb GA and Albrektsson T.[20]

During the 1980´s and 1990´s many new implant systems were introduced on the market with sparse scientific documentation. [13] In a review in 1991 Albrektsson and co-workers reported a lack of scientific support by adequate clinical reports of minimally 5-years of follow-up for many of the currently used implant systems and only one implant system presented 15 years' follow-up in 1991.[21] In a recent review Albrektsson & Wennerberg reported that more implants now had sufficient five-year data documenting good results and that the standard of clinical reporting had improved over the years. Yet in 2004 only one of the frequently used moderately rough surfaces, was documented for survival over 10 years of follow-up.[22,23]

The development of the clinical procedures was divided into three periods by the Brånemark group; the "initial period" from July 1965 to March 1968, the "development period" April 1968 to June 1971 and the "routine period" starting in July 1971.[17,18] The three-year survival rates of implants reported by Adell and colleagues (1981) were 53% in the maxilla and 74% in the mandible in the development group, compared with 82% and 91% respectively for the first routine group.[18] The conclusions from the clinical trials resulted in a list of six prerequisites claimed to be the most important for predictable implant integration. These prerequisites have varied with authors and publications, Table 1.[11,24,25] Rehabilitation with implant-supported prostheses according to the Brånemark protocol during the 1980´s and early 1990´s resulted in many of the reports of successful rehabilitation of partially and totally edentulous jaws.[26-38]

Table 1. Prerequisites for osseointegration according to the Brånemark protocol as proposed by different authors.

Brånemark & colleagues -69	Albreksson & colleagues -81	Szmukler-Moncler & colleagues 2000
1) Inert, mechanically and chemically clean implant. 2) Implant size small enough to allow complete embedding in bone. 3) Atraumatic preparation of the bed of the implant. 4) Primary closure of the fixture site from the oral cavity until the barrier function of the tissue has been recovered after the operation. This biological barrier is formed by approximation of hard and soft tissue to the implant. 5) Loading of the implant via a prosthesis result in remodeling of the jawbone. 6) Gingivitis with formation of inflammatory granulation tissue should not be allowed to develop or to persist.	1) Implant material, i.e. titanium 2) Implant design 3) Implant finish 4) Status of the bone 5) Surgical technique 6) Implant loading conditions	1) Use of a biocompatible material, i.e. titanium 2) Use of a 2-stage procedure 3) Use of a stress-free healing period of 3–6 months before loading 4) Atraumatic surgery involving low-speed drilling 5) Use a mucobuccal incision and avoid a crestal one 6) Use of sterile conditions as ‘‘in a fully equipped operating theatre’’ 7) Use of titanium ancillary 8) Avoid radiographs before the end of the healing period 9) Use of acrylic occlusal contact surfaces

Fixed prostheses

The titanium implants developed by professor Brånemark were used for supporting fixed prostheses in mainly edentulous patients receiving full arch fixed prostheses. During the development of the implant treatment procedures only totally edentulous jaws were treated, starting with edentulous mandibles but soon also edentulous maxillas. In the development group ending in 1968 half of the treated jaws were edentulous maxillas.[17] Since the presentation of the successful use of implants supporting fixed prostheses in the 1970´s and 1980´s for edentulous maxillae and mandibles, it has become a standard procedure for decades.[26] Numerous reports on the successful use of Brånemark system® implants in the edentulous mandible with ten years' follow-up or more have been published.[26,35,39-43] Engfors and colleagues published a study on old patients, aged 79 years or more at implant placement, rehabilitated with fixed prostheses and achieving five-year cumulative implant survival rates of 93% in the maxilla and 99.5% in the mandible, the same survival rates as found in the

younger control group.[44] According to published review articles the five-year implant and prosthesis survival/success rates have increased since the early studies and are now 96% - 100% in the mandible. [45-47]

Few patients were treated with implant-supported fixed partial dentures (FPDs) in the early 1980´s but partially edentulous patients were increasingly rehabilitated with implant-supported prostheses during the 1980´s, which have since then become a routine procedure over the years.[48-52] Van Steenberghe reported in 1989 on a multicenter study on FPDs in 38 patients with 133 implants; the follow-up was fairly short (0.5 to 3.5 years) but the success rate reached 87% in the maxilla and 92% in the mandible. Fixed prostheses supported by teeth and implants were also introduced in the mid 1980´s when the remaining teeth were too few or unevenly distributed.[53-56] The use of combined implant and teeth supported prostheses has increased but few RCTs have been conducted. In systematic reviews of prosthesis and implant survival rate for FDPs supported by only implants and FDPs supported by implants and teeth, survival rates were lower for implants and prostheses supported by both teeth and implants than for prostheses supported by implants only.[57,58] The five-year implant and prosthesis survival rates were 95.4% and 95% respectively for implant-supported FPDs, and 90.1% and 94.1% for tooth-implant supported FPDs.[57,58]

The use of implants for single tooth replacement was introduced in the mid 1980´s, as described by Jemt and Ohrnel.[59,60] Three-year results were presented by Jemt and colleagues in 1990.[61] Today single teeth replacement by implants is advocated by some as the first option since it avoids preparation of sound neighboring teeth. Lindh and colleagues and Creugers and co-workers conducted meta-analyses on single implants reporting implant and crown survival rates of 97% to 97.5% for implants and 83% of crowns free of complications after four years.[62,63] Increasing interest in single tooth replacement has led to numerous reports on implant placement and bone augmentation techniques. Yet implant treatment in the esthetic zone is challenging, especially when more than one tooth is missing; thus submerged placement has been recommended in a consensus report by Belser and colleagues.[48,64]

Retrievability

When placing full-arch prostheses supported by implants, retrievability may be important since complications with implants and prostheses are commonly reported in both the totally edentulous and partially edentulous jaw.[51,65-74] The most frequently reported problems with fixed full-arch prostheses are fracture of acrylic resin matrix and acrylic resin teeth, followed

by abutment and prosthetic screw loosening and screw fractures. Fractures of frameworks and extensive wear of acrylic teeth have also been reported.[75-79]

With the increasing use of Brånemark system® implants in the rehabilitation of partially edentulous patients retrievability remained important and prostheses were mostly screw retained. In studies on FPDs the most frequently reported technical complications are chipping of the veneering porcelain and prosthetic or abutment screw loosening or fracture.[73,80-82] Studies on implant rehabilitation often concentrate on implant and bone loss; prosthetic complications are more seldom described.[45] According to meta-analyses performed by Lang and colleagues and Pjetursson and co-workers biological and technical complications are registered in 38.7% of the FPDs within five-years.[57,83]

Meta-analysis articles and review articles on RCTs present 5-year survival rates for implants in the range of 95% - 97.5% and for FPDs 83% - 95%, and 92.8% and 86.7% respectively after ten years, with no major differences between implant systems.[45,57,83,84]

The influence of prosthetic and implant therapy on patient satisfaction and quality of life is a field of research still in development and there is often a lack of information concerning this aspect of implant-supported prostheses. In studies concerning these aspects cost is the least used outcome according to Strassburger and colleagues.[85]

Numerous studies on implant treatments followed the guidelines presented by the Brånemark group, implant placement submerged, a healing period of three months in the mandible and six months in the maxilla, the placement of five or six implants in totally edentulous mandibles and maxillas and three or more implants in the partially edentulous situation, and fabrication of prostheses framework from gold alloy.

Several possible ways exist to reduce the cost of implant treatment with fixed prostheses. The number of implants used in totally and partially edentulous jaws may be reduced by one or two thus reducing cost for implant components as well as the time consumed for implant placement, and the prosthetic procedure will be facilitated. A change in surgical procedure, by using non-submerged healing, would shorten treatment time, and surgical interventions would be reduced reducing the cost of implant placement. If prostheses are immediate or early loaded the use of temporary prostheses after implant placement may be omitted, treatment time would be further reduced resulting in earlier oral rehabilitation and possibly reduced cost. The original treatment concept used frameworks cast in gold alloy, which inevitable results in a considerable cost for the framework. If non precious metals or alloys

could be used the material cost would be significantly reduced and prostheses would become more affordable. The casting procedure of frameworks for implant-supported prostheses is difficult and sectioning and soldering often have to be performed; if industrial methods of framework fabrication could be used the manual labour content would be reduced as well as the cost.

The number of implants needed in different situations

Totally edentulous jaws

The number of implants needed in rehabilitation of totally edentulous jaws with fixed implant-supported prostheses has not been investigated in many studies. From the available literature few studies discuss the use of a reduced number of implants supporting a fixed prosthesis in the mandible. More studies have been performed on overdentures using a reduced number of implants; two instead of four implants for supporting overdentures in the mandible. The current literature shows no differences in bone loss and implant survival rates for implants supporting overdentures in the mandible whether there are two or four implants supporting the prosthesis and implant survival rate is generally within 96% to 99%.[86-91]

The use of fewer than the traditionally prescribed six implants for supporting fixed prostheses in the edentulous mandible and maxilla has been addressed by Brånemark and co-workers, who in 1995 presented no significant difference in survival of prostheses and implants supported by four or six implants over a ten-year period.[39] Thirteen mandibles and fourteen maxillas with prostheses supported by four implants were included. Today, many specialist centres in Sweden use five implants in the edentulous mandible as a routine.[92] With the use of only four implants cost will be reduced further and the prosthetic treatment and cleansing of the prosthesis may be enhanced.

Studies on load transfer and stress distribution by implant-supported prostheses show that when a cantilever prosthesis is loaded most of the load and stress are concentrated on the distal implant and only small stresses were seen at the implant third from the loaded cantilever.[93-95]

Short-term studies on conventional and early loading of only four implants with fixed prostheses have presented encouraging results. Becker and colleagues reported 20 patients, receiving four to six Brånemark system® implants each and loaded within five days, showing a two year cumulative survival rate of 96.5% for implants and 100% for the prostheses.[96]

Slightly less favourable results were described by Kronström and co-workers and Engqvist and colleagues.[97,98] Survival rates of 100% for early/immediate loading of four implants have been reported by Collaert and De Bruyn in 11 patients, Klee de Vasconcellos and co-workers in 15 patients and Capelli and colleagues in 24.[99-101] Reducing the number of implants in the maxilla has been investigated by Maló and colleagues, who reported implant and prosthesis survival rates after one-year of 97.5% and 100% respectively on four immediately loaded implants in the edentulous maxilla.[102]

Studies of fixed prostheses supported by as few as three implants in the edentulous mandible, have reported implant survival rates of 90.5% to 97% after one-year, indicating that even as few as three implants may be sufficient for supporting a fixed full arch prosthesis in the mandible. However, if one implant is lost, the prosthesis must be adjusted or replaced with additional implant placements.[103-108]

During the 1980´s and early 1990´s many reports of implant-supported fixed prostheses in the edentulous mandible followed the original Brånemark protocol with only minor changes in placement procedures. The reported five- and ten-year survival rates for implants and prostheses are in the range of 96% to 100%. The use of less than five implants in the rehabilitation of the edentulous mandible was rarely reported. However studies of stress distribution in the prostheses and at individual implants indicated that the number of implants placed between the distal implants on the right and left side may be of minor importance in stress reduction on the distal abutments. Thus evaluating fixed prostheses in the mandible supported by only four standard implants could provide information as to whether the number of implants can be reduced to four to further reduce cost and facilitate implant placement and prosthesis fabrication without harming the implant and prosthetic survival rate.

Partially edentulous jaws

Fixed partial dentures supported by implants have been used for 40 years; Brånemark and co-workers placed the first fixed partial dentures in 1968.[109] The numbers of implants used per prosthesis are not reported in many studies, but the mean number of implants is often less than three.[33,82,110,111] The use of more than two implants is in accordance with the recommendations by Rangert and co-workers; who proposed that implants should if possible be placed in a tripod configuration in order to withstand non-axial forces better.[112] Different opinions exist and Buser & von Arx stated that in situations with three occlusal units missing and sufficient bone anatomy the standard solution should be two implants supporting a three-unit FPD, in

order to reduce cost.[48] The use of only two ITI® implants supporting a three-unit FPD finds some support in a finite element study by Iplikçioğlu and Akça, who found that two 10 mm long ITI® 4.1 mm diameter implants supporting a three-unit FPD, had a similar stress distribution to three 3.75 mm diameter implants.[113] On the other hand both Rangert and co-workers and Buser & von Arx suggested that cantilevers should not be used in order to avoid unfavourable bending movements and, if used, the cantilevers should preferably be placed medially.[48,112] Still, cantilevers have been used for various reasons; one being insufficient bone volume for additional implants. Reports on cantilever FPDs have been published by Wennström and colleagues and Romero and colleagues with an implant survival rate of 97% in both studies and prosthesis survival rates of 92.3% and 98% respectively and no significant increase in bone loss in a short perspective.[110,114,115] These reports are supported by the reviews from Lang and colleagues and Pjetursson and co-workers, who reported no significant differences in five-year survival rates for cantilever FPDs or conventional FPDs; with survival rates of 92.5% and 93.8% respectively.[57,58]

Numerous studies on implant-supported FPDs include some prostheses supported by only two implants: some of them reporting higher complication rates for two-implant supported prostheses. The increased complication rates mostly concern screw loosening but implant fractures have been reported.[31,33,37,72-74,81,116,117]

The reported incidence of failed/lost short implants differs between implant systems with more implant losses reported for short Brånemark system® implants with a turned surface, than for ITI® implants. [116,118-122] In their review article das Neves and colleagues reported a mean implant loss of 9.7% for 7 mm Brånemark system® implants.[123] Conversely Maló and colleagues reported 100% survival for short implants with the TiUnite™ surface.[122] Buser and Arx stated that the use of short implants is not contraindicated but one implant per FPD unit should be placed when short implants (6 or 8 mm) are used.[48]

During the late 1980´s and 1990´s an increasing number of studies were published on implant-supported FPDs presenting five-year implant survival rates of 95% to 97.5% and 83% to 95% for prostheses. The ten-year survival rates were 92.8% and 86.7% respectively without dividing results between prostheses supported by two or more implants. Studies of implant and prosthesis outcome reported more technical complications with FPDs supported by only two implants than for those supported by three or more implants. Thus there is some scientific evidence supporting the use of two-implant supported FPDs. In the clinical situation anatomic structures sometimes reduce the available bone volume for implant placement; the

choice is then either to perform bone augmentation procedures or to rely on a reduced number of implants placed. If bone augmentation procedures can be omitted without jeopardising the treatment outcome, surgical interventions and treatment time can be reduced as well as patient morbidity: with less surgical interventions and the use of only two implants cost can be reduced. Thus long-term follow-up studies of FPDs supported by two or three implants reporting implant and prosthesis complications and failure rates may provide support for the further use of two-implant supported FPDs.

Development of surgical techniques

Two major differences were seen between the implant systems developed by Brånemark and Schroeder. Firstly, the Brånemark system® implants were finished with a turned surface and the ITI® system with a rough titanium plasma sprayed surface. Secondly, the Brånemark system® implants were two-pieced while the ITI® was a one-piece implant. Whether theses differences made the implants more or less suitable for different surgical procedures have been investigated in animal and clinical studies over the years. As a result, implant placement procedures for two-piece implants have changed since the above prerequisites were stated. The position of the incision (mucobuccal or crestal) has also been tested in Randomized Controlled Clinical Trials (RCTs). Coulthard and co-workers stated in their review in 2003 that few RTCs of the different techniques were available; but no differences in implant failures, marginal bone levels, morbidity or patient satisfaction were reported whether a mucobuccal or crestal incision was used.[124] Leaving the implants buried under the oral mucosa during the healing phase was one of the prerequisites to be challenged, since it was not used in the studies conducted by Schroeder and the ITI institute, who nevertheless achieved successful osseointegration with ITI® implants. Reports of successful use of non-submerged ITI® implants were increasingly published during the 1980´s and early 1990´s.[125-130]

Animal studies on one- and two-stage placement of dental implants

The different surgical protocols used by Brånemark and Schroeder were first tested in animal models prior to placing implants in humans. Since then an increasing number of studies on tissue response to implants has been conducted in animals.[131-140] Weber and co-workers and Fiorellini and colleagues undertook split mouth studies in Beagle dogs comparing the two surgical techniques and reported different bone loss during the healing phases; but at the end

of the 18 week study no significant differences in bone levels were registered between one- and two-stage implant placement.[134,139]

Histological evaluations of the soft tissue response to the two surgical techniques also present diverging results. Weber and colleagues reported significantly greater apical extension of the periimplant epithelium and significantly lower attachment level to submerged implants with second-stage transmucosal abutments than in non-submerged, one-stage implants.[134] Others, on the other hand, described similar appearances at submerged and non-submerged implants.[135,136,141] Abrahamsson and colleagues placed three different commercially available implant systems (Brånemark system®, Astra Tech® dental implant system and ITI® dental implant system) in beagle dogs according to the recommendations of the respective manufacturer; histometric analysis of the mucosal barrier at the titanium surface after one-stage or two-stage installations identified similar dimensions and compositions at the three implant systems studied.[141] However the mucosal barrier formed at implants and abutments may be compromised by repeated manipulation of the abutments. One shifting of abutments after second-stage surgery did not affect the dimension and quality but repeated disruption of the mucosal barrier resulted in a more "apically" positioned zone of connective tissue and additional marginal bone resorption.[142,143]

Animal studies on loading of implants

Animal studies on the early bone-to-implant contact (BIC) against different titanium surfaces clearly showed that a moderately rough surface promotes bone healing in loaded and unloaded situations.[144-148] Piatelli and colleagues studied bone reactions to loaded and unloaded implants in monkeys and found that implants loaded after 30 days presented thicker lamellar and cortical bone at the neck of loaded implants.[149] Further studies in monkeys on immediate loading presented 100% implant survival and more BIC at loaded implants than unloaded controls.[150-152]

Tests of loading of osseointegrated implants have been performed using both static and dynamic loads. In studies by Gotfredsen and colleagues, static loading of implants in the dog did not cause any significant changes in bone loss compared to unloaded implants but displayed signs of a structural adaptation.[146,153,154] Berglundh and colleagues used a dog model to demonstrate increased BIC in loaded implants but no difference in bone level between loaded implants and controls; diverging results were presented by Duyck and colleagues who noted no adverse effects to static load but a crater like bone defect lateral to

implants subjected to excessive dynamic load.[148,155] Isidor presented similar results from a monkey study when excessive lateral loading was applied to the implants, reporting implant mobility after 4.5 months for two of the eight test implants and additional three implant losses after 15.5 months.[156]

Clinical studies on one- and two-stage placement of dental implants

Implant studies on the ITI® implant system have consistently used non-submerged placement in partially and totally edentulous patients with good results, and submerged healing has only been advocated in sites with esthetic priority. [48,125,127,157] Since the mid 1990´s an increasing number of studies of non-submerged placement of two-piece implants have reported success figures comparable to the traditional submerged implant placement procedure.[92,158-165] Diverging results were reported by Røynesdahl and colleagues and Fenlon and co-workers who reported increased implant losses when turned implants were placed non-submerged in the anterior mandible.[166,167] A slightly less successful use of non-submerged Brånemark system implants in the edentulous mandible was also reported by Becktor and colleagues in a prospective multicenter study on one- and two-stage implant placement in 77 patients, with survival figures of 91.4% for one-stage surgery and 97.6% for two-stage implant placement.[168] Petersson and colleagues undertook a five-year study with three different treatment concepts; submerged, non-submerged implant placement with conventional loading and non-submerged implant placement with early loading.[169] After prosthesis connection bone loss was significantly lower in the early functional loading group compared to the one- and two-step surgical technique groups, but after 18 months and after 5 years no differences remained.[169] In a recent review by Esposito and colleagues three RTC trials of submerged and non-submerged implant placement were identified; two of them with a total of 45 patients were included in the analysis. From these trials, on a patient, rather than per implant basis, there were no statistically significant differences.[170] The authors' conclusion was; "The number of patients included in the trials was too small to draw reliable conclusions but it appears that the two procedures did not show clinically significant differences. If these preliminary results will be confirmed by more robust trials, a one-stage procedure might be preferable since it avoids one minor surgical intervention and shortens the waiting time to provide the final restoration". Non-submerged implant placement reduces the time consumed by implant placement procedures, thus reducing the cost of surgery. Prosthetic treatment may also be facilitated by the presence of healed periimplant tissue at impression making, which

may decrease the need for later adjustments of the prostheses to optimize prosthesis adaptation to the soft tissue. Cecchinato and colleagues published two-year results of a multicenter randomised controlled trial on submerged and non-submerged placement of Astra tech® implants in the posterior part of the dentition, reporting 2.1% early implant losses with no differences between the groups and bone loss less than 0.1 mm in the non-submerged group and 0.2 mm in the submerged group.[165] Moberg and colleagues compared treatment of mandibular edentulism with submerged and non-submerged implants presenting cumulative success rates of 97.9% and 96.8% for the two techniques.[171]

In spite of numerous published studies on implant rehabilitation with the different surgical techniques, some studies report lower survival figures for implants with turned surfaces placed non-submerged; the reason for this is not elucidated. Few RCTs have been published confirming that the implant placement technique (submerged or not-submerged) does not effect implant survival rate and bone loss between the two techniques. A split mouth RCT may add further scientific evidence for the use of non-submerged implant placement in the anterior part of the edentulous mandible.

Loading of implants

There are different opinions on when a dental implant is loaded; some consider the implant as loaded when placed submerged buried by the mucosa but subjected to loading through the mucosa by chewing food with or without removable prostheses. Others consider the implant as loaded when it penetrates the oral mucosa and becomes visible in the oral cavity, regardless of whether it is a cover screw or healing abutment that is visible. Theoretically different types of load can now be applied to the implant, such as pressure from tongue and cheek, food pressing on top of the implant or a removable prosthesis leaning on or gripping the implant component. Other investigators suggest that the implant is loaded when a temporary prosthesis or implant component is placed onto the implant and protrudes into the oral cavity but not in occlusion with the opposing dentition. Finally, some authors consider the implant as loaded when a temporary or final implant restoration is in direct contact with the opposing dentition, which may be a more objective measurement according to Cochran.[172]
Non-submerged implant placement simplifies rehabilitation of edentulous patients by reducing the surgical interventions. With the acceptance that two-stage surgery was not a pre-

requisite for implant osseointegration, focus was turned on the time of healing before loading. If implants can be loaded early or immediately a considerable reduction in treatment time can be achieved and the use of removable temporary prostheses during the healing phase can be omitted. In order to have a universal understanding of the meaning of immediate, early and delayed loading, this issue has been addressed at different consensus conferences and thereafter reported by groups of authors presenting diverse lists of definitions, Table 2.[173-175]

Table 2. Consensus statements concerning loading protocols.

Aparicio et al. 2003	Cochran et al. 2004	Misch et al. 2004
Immediate loading: The prosthesis is attached to the implants the same day the implants are placed. Early loading: The prosthesis is attached at a second procedure, earlier than the conventional healing period of 3 to 6 months; time of loading should be stated in days/weeks. Delayed loading: The prosthesis is attached at a second procedure after a conventional healing period of 3 to 6 months.	Immediate restoration: A restoration inserted within 48 hours of implant placement but not in occlusion with opposing dentition Immediate loading: A restoration placed in occlusion with opposing dentition within 48 hours of implant placement Early loading: A restoration in contact with the opposing dentition and placed at least 48 hours after implant placement but not later than 3 months afterward. Conventional loading: The prosthesis is attached at a second procedure after a healing period of 3 to 6 months. Delayed loading: The prosthesis is attached in a second procedure that takes place sometimes later than the conventional healing period of 3 to 6 months.	Immediate occlusal loading: Immediate occlusal loading within 2 weeks of implant insertion. Early occlusal loading: Occlusal load to an implant prosthesis between 2 weeks and 3 months after implant placement. The actual time may use the number of weeks in parentheses (ie, early (5 weeks) occlusal loading). Non functional immediate restoration: An implant prosthesis in a patient who is partially edentulous delivered within 2 weeks of implant insertion with no direct occlusal load. Non functional early restoration: An implant restoration delivered to a patient who is partially edentulous between 2 weeks and 3 months after implant insertion. Delayed or staged occlusal loading: Occlusal loading to an implant restoration more than 3 months after implant insertion. Two-stage delayed occlusal loading The soft tissue covers the implant after placement. A second stage surgery after 3 months exposes the implant to the oral environment. One-stage delayed occlusal loading The implant is positioned slightly above the soft tissue during the initial implant placement. The implant is restored into occlusal load after more than 3 months.

Development of loading protocols

The loading protocol used during the first decade after the Toronto conference was in most cases, in accordance with the recommendations by Brånemark, with three months of submerged healing in the mandible and the six months healing in the maxilla.[17] Some support for this was gained by results on bone healing at dental implants presented by Roberts, who suggested that endosseous implants could be provisionally loaded at about 18 weeks, but full maturation of the implant interface required approximately one year.[176]

The increasing use of different dental implants during the 1980´s and 1990´s resulted in observations that implants could be loaded earlier than the proposed three or six months in the mandible or maxilla. Szmuckler-Moncler and colleagues reviewed the literature concerning timing of loading and reported diverging results; from early animal studies presenting fibrous encapsulation of implants subjected to early loading to later studies presenting osseointegration in implants immediately loaded.[177] The conclusion made was that the absence of loading *per se* was not critical for osseointegration but rather the absence of excessive micromovements at the bone-implant interface. Micromovements of 50 micron (μm) were tolerated, and micromovements up to 150 μm may be tolerated. The tolerated thresholds varies according to surface and/or implant design and may be as high as 150 μm; thus a long stress-free healing period may not be mandatory to achieve osseointegration for splinted screw shaped implants.[177] The amount of loading that result in these levels of micromotions depends on several factors; such as the masticatory forces, bruxism, bone quality and quantity, implant length, length of cantilever, implant shape and surface, surgical skill and placement technique. In order to avoid heavy loading of individual implants it has been advocated that the implants should be rigidly connected, either with a bar construction supporting an overdenture or a fixed prosthesis.

Implant-supported overdentures

Implant-supported overdentures are a treatment option which significantly improves prosthesis function at a lower cost than fixed implant-supported prostheses. In a survey of the use of mandibular implant overdentures in ten countries the frequency of implant overdentures ranged from 7% in Japan to 81% in the Netherlands.[178] Treatment cost was reported as the main reason for choosing overdentures instead of fixed prostheses.

The successful use of implant-supported overdentures has been reported in several clinical studies with ten to twelve years' follow-up presenting implant survival rates of 90% to 97.2%,

with no difference in treatment outcome for splinted or unsplinted implants. [91,179,180] The first to describe immediate loading of implants was Ledermann, who in 1979 reported on implants loaded with an overdenture supported by a bar construction.[181] In a multicenter study comprising 226 patients, Chiapasco and colleagues reported on the use of immediate loading of implant-supported mandibular overdentures, presenting 96.9% survival of the implants and 98.5% on the prostheses. Since then many reports have been published on immediate and early loading of implant-supported overdentures in the edentulous mandible, presenting survival rates from 96.1% to 100% in studies with a follow-up time ranging from one to five years.[182-187] In 2000, Szmukler-Moncler and colleagues stated that "It is shown that successful premature loading protocols require a careful and strict patient selection aimed to achieve the best primary stability".[25] In 2004 Chiapasco and Cochran and colleagues in review articles on early and immediate loading of implants in completely edentulous patients, reported implant survival rates ranging from 96% to 100% for immediate loaded overdentures and Cochran and colleagues stated that "immediate loading of four implants in the interforaminal area with rigid bar fixation and cross arch stabilisation is a predictable and well documented procedure".[174,188] Scientific evidence for early loading was less substantial, in the reviews by Chiapasco and Cochran and co-workers only six publications with a total of 85 patients were identified and included.[174,188] In 2006, Del Fabbro and colleagues published a review including 14 studies on immediate loading of overdentures, reporting implant survival rate of 95.1% for the immediate loaded implants of which 96.5% had a rough surface.[189] During 2007 three review articles were published on the subject different times of loading, concluding that it is possible to successfully load dental implants immediately though not all clinicians may achieve optimal results, careful case selection, meticulous surgery and proper design of prostheses are essential for optimal outcomes.[190-192]

Fixed full arch prostheses

Immediate loading

The first reports on immediately loaded fixed interim implant-supported prostheses was published in 1990 by Schnitman and colleagues reporting on the outcome of seven patients provided with a fixed temporary prosthesis supported by three implants during the healing phase of the additional three or four submerged implants.[193] In a ten-year follow-up study of ten cases survival rate for immediate loaded implants was 84.7% and 100% for the delayed loaded implants.[194] Different solutions have been utilised with the introduction of immediate

loading using fixed interim prostheses such as converted complete dentures, new acrylic prostheses or acrylic resin prostheses with a metal inner casting. [182,195-200] In a review Morton and colleagues suggested that the influence of cantilevers should be reduced by using an appropriate number of implants and by optimizing distribution.[201] The number of patients, implants placed in each patient and the number of immediately loaded implants varies between studies. The study populations in some of the early studies are small, ten to fifteen patients in each study, with a reported survival rate of 80% to 98.3% after one to two years.[195-197] Ibañez and colleagues reported on immediate loading of both maxillas and mandibles, presenting a 99.4% success rate after a follow-up of 6 to 72 months; the same survival rate was reported by Testori and colleagues in edentulous mandibles.[198,200]

The first attempt to decrease the cost of rehabilitation of the edentulous mandible with a fixed prosthesis was made by professor Brånemark with the introduction of the Brånemark Novum® concept (Nobel Biocare AB), consisting of a prefabricated titanium framework supported by three wide body implants. Implant placement was performed using a surgical template and the prosthesis was delivered on the same day or the day after. The results achieved with this technique showed that three implants are sufficient to support full-arch prosthesis in the edentulous mandible.[103] One-year results for the concept have been reported by Engstrand and co-workers and Henry and colleagues in 94 and 51 patients respectively, with implant survival rates of 95% and 91% respectively.[105,202] Hatano and colleagues developed a technique for prosthesis fabrication for immediate loading using three standard Brånemark system® implants with a customised metal framework fitted with acrylic resin teeth and delivered the same day.[106] An implant survival rate of 97.6% was reported on 43 patients after 3 to 49 months.

In a review by Cochran including 16 studies with a total of 387 patients the reported implant survival rate ranged from 80% to 100% with a mean of 95%; the conclusion was that "immediate loading of implants in the edentulous mandible is a predictable and well documented procedure provided that a relatively large number of implants are placed".[174] Two years later a review by Del Fabbro and colleagues included 25 studies with a total of 593 mandibles; the mean number of implants supporting the prostheses was 4.54 and an implant survival rate of 97.2% was reported.[189] Of the included studies, 179 mandibles were treated with three Brånemark implants supporting full-arch prostheses.

Reports on immediate loading in the edentulous maxilla have increased in the last few years; in a review in 2004 of immediate loading of edentulous maxillas with fixed prostheses only five studies with a total of 30 patients were included.[188] Two years later, Nkenke and Fenner

their review of immediate loading included nine studies with a total of 164 patients treated with immediately loaded implants in the maxilla, with survival rates ranged from 83.3% to 100%.[46] Del Fabbro and colleagues in the same year included 16 studies of immediate loading of edentulous maxillas, presenting mean implant survival of 98.2%, with significantly lower success rates for implants with turned surfaces.[189] Bergkvist and colleagues and Östman and co-workers reported similar one-year implant survival rates.[203,204]

Early loading

Henry and Rosenberg in 1994 reported on single-stage surgery and early loading of four Brånemark system® implants with a fixed prosthesis in the edentulous mandible in five patients.[205] Eriksson and colleagues in 2000 presented five-year results of early loading of implants in the anterior mandible with a fixed prosthesis, reporting 100% survival for implants in both test (16 patients) and control groups (11 patients).[206] In a review by Chiapasco in 2004 only six studies were included with a total of 51 patients and 274 implants. Survival of implants ranged from 90.5% to 100% with a mean of 97.3%.[188] Since then reports on larger patient populations have been published; Engquist and colleagues reported on 26 patients provided with 104 Brånemark system® implants with a turned surface supporting fixed prostheses in the mandible. The reported three-year implant survival rate was 93.3%.[97] In 2005, Friberg and colleagues reported on 152 patients provided with 750 Brånemark system® implants with a turned surface and prostheses loaded with a mean of 42 days after implant placement, presenting a one-year implant survival rate of 97.5%.[207] In 2008, Friberg and Jemt reported on 90 patients provided with 450 Brånemark system® implants with a TiUnite™ surface reporting a one-year survival rate of 100%.[208]

Few publications report prosthetic complications and maintenance procedures during the first years in function or modification of the prosthesis to accommodate the soft tissue. Reports on early loading in the maxilla were also sparse in 2004; Chiapasco found only four studies with a total of 26 patients supporting the use of early loading of implants in the edentulous maxilla with a fixed prostheses; presenting 89% to 100% survival rate after one to five years.[188] Since then more studies have been published supporting early loading in the maxilla; Nordin and co-workers reported on 53 consecutively treated patients of whom 20 were treated with fixed prostheses in the edentulous maxilla; only 0.9% of the implants were lost.[209] Fisher and Stenberg reported a prospective controlled study with a 100% success rate in the 16 tests and 8 control cases after three years of loading.[210] Nordin and colleagues reported early loading of

maxillary implants in fresh extraction sockets in 19 patients; after two to three years the survival rate was 98%.[211]

The use of immediate and early loading has proven to be effective in short follow-up studies when a strict surgical and loading protocol has been utilized. From a biological point of view immediate loading of splinted implants may be a safer procedure than early loading, in which the implants are left unsplinted and subjected to uncontrolled loading from a temporary removable prosthesis until delivery of the final prosthesis. Furthermore, a fixed intermediate restoration can preferably be fabricated with a reduced cantilever; thus reducing the risk of overloading the implants during the healing phase. On the other hand, using a temporary prosthesis during the healing phase leads to fabrication of two prostheses; one interim and one definitive prosthesis three to six months later; inevitable increasing the cost. Conversely, by starting fabrication of the final prosthesis at or shortly after implant placement the final prosthesis can be delivered within two to six weeks; thus reducing treatment time and maybe treatment cost. Whether this can be performed with results comparable to conventional loading concerning biological and technical complications is under researched; and many have not investigated the cost of treatment. Further studies comparing results achieved with early loading and delayed loading may provide additional information as to whether this is cost effective or not.

Impression and model fabrication for implant-supported prostheses

Rehabilitation with implant-supported prostheses requires many different steps before placement of the prostheses. Distortion in the final prosthesis can be due to some of the following; inaccuracy of the interface relationship between implant components, distortion introduced by the impression material and/or technique, fabrication of the model and choice of stone plaster used for fabrication, waxing and casting techniques. Different impression materials and techniques have been tested during the years, with no material producing an exact copy of the positioning of the implants/abutments but polyether and addition silicone produce similar results with little distortion if handled properly.[212,213] Today polyether, polyvinyl siloxane or plaster impression material are the most used.

Impressions can be made with impression copings for either indirect or direct technique. Direct technique implies that the transfer coping is removed from the abutment/implant with the impression on removal. The technique can be used with a closed tray and transfer copings

of "snap on" type (as for the ITI® system) or with an open tray and screw retained impression copings. When the direct technique is applied, the transfer copings should be properly seated in the impression after removal and appropriate analogs can then be attached to the copings without disturbing the positioning of the transfer copings.

The indirect technique uses screw retained transfer copings with a closed tray; when the impression is removed from the mouth the transfer copings are still fastened to the abutments. The transfer copings then have to be removed and provided with appropriated abutment analogs prior to repositioning in the impression. There is inconsistency in the results reported for the two techniques; first Carr and independently Naconecy and co-workers reported the direct technique and open tray to be more precise; Humphries reported less distortion with the indirect technique. [214-216]

Diverging results have also been reported as to whether the impression coping should be splinted with acrylic resin or not before impression making with polyether or polyvinyl siloxane. Some report splinting with auto polymerizing resin in combination with polyether impression material to be more precise.[217-220] Conversely, others reported the non-splinting impression technique to be more precise.[221-223] Two studies by Vigolo and colleagues evaluated different impression techniques; reporting that all impression techniques resulted in a model with larger lateral distances between the distal implants than the master model: the increase in lateral distance was from 18 µm to 46 µm in the first and 34 µm to 78 µm in the second study.[217,218]

Studies on the accuracy of different Brånemark system® components during the 1990´s by Wichmann, Ma and colleagues and Rubenstein & Ma reported horizontal tolerances between pairs of components such as; impression copings/abutments, impression copings/replica, gold cylinder/replica and gold cylinder/abutment ranging from 22 to 149 µm.[224-226] Wichmann reported that the cumulative distortion from impression taking to the metal framework on the model could be as much as 239 µm for standard abutments and 515 µm for the Estheticone® abutment.[224]

Fabrication of prosthetic frameworks

Frameworks for full arch prostheses can be designed for metal acrylic prostheses, metal ceramic prostheses or all ceramic. The most commonly used in Scandinavia are metal acrylic prostheses, with occlusion in acrylic resin teeth, the same as used for complete dentures. The teeth are cured to the metallic framework by acrylic resin.

Frameworks cast in gold alloys, veneered with acrylic resin/acrylic resin teeth, were introduced by the Brånemark group and became the routine prostheses fabrication technique for many years. [26,227,228] Due to the high cost of precious alloys, other materials such as cobalt-chromium alloys, silver palladium alloys, titanium and acrylic resins reinforced by carbon fibers have been used to reduce the cost.[17,75,229-233]

Casting of implant-supported prostheses is performed by the lost wax technique described by Zarb and Jansson.[227] With the introduction of casting machines for titanium a bioinert framework could be fabricated with reduced metal cost. Despite the current stage of development of available casting methods, problems frequently remain irrespective of the metal used. Casting of frameworks inevitably results in distortions; additional problems usually related with titanium are porosities, castability, and surface contamination.[234-236] As a consequence different solutions have been tried to improve fit of cast frameworks, such as sectioning and soldering, laser welding horizontally or vertically, bonding gold cylinders to cast frameworks and cementation on conical abutments.[232,237-239] One technique to improve fit with horizontal laser welding is the CrescoTi® Precision™ method (Astra Tech AB), where distortion in cast titanium frameworks is corrected with horizontal sectioning and laser welding.[232] In the mid 1980´s the Procera® (Nobel Biocare AB) framework was introduced; a framework fabricated from premachined titanium parts assembled through a vertical laser welding procedure.[240,241] Fit of Procera® frameworks assembled by vertical or horizontal laser welding was evaluated and the accuracy of fit achieved was comparable to or better than cast frameworks.[231,242] However theses frameworks suffered more fractures of veneer and framework during follow-up than cast gold frameworks in full arch prostheses: the same pattern was seen in patients provided with implant-supported FPDs.[43,243]

The fourth generation of Procera® frameworks described by Jemt and co-workers in 1999 is a framework milled from one piece of grade 2 titanium.[244] The fabrication technique requires an acrylic pattern to be made and a laser scanner provides the information on framework design to the machine. Information on the implant position in the model is retrieved by a coordinate measuring machine.[244] The framework is then milled under cooling from a solid block of grade 2 titanium; thus distortion due to thermal changes is avoided in the fabrication process. This was the first technique to produce a framework fabricated from a homogenous material free of soldered or welded joints, with fit superior to cast frameworks.[245-247] In a five-year follow-up study, Computer numeric controlled (CNC)-milled frameworks have performed better than the first two generations of Procera® frameworks and comparably to cast gold frameworks.[248]

Fit of prosthesis and impact of misfit

The technique of using osseointegrated implants as support for fixed prostheses introduced higher demands on the precision of fit of the frameworks than for conventional tooth supported prostheses due to the ancylotic character of the implant abutment. Misfit of the prosthesis will introduce tension in the framework, bone-implant interfaces and increase the risk of complications.[224,249-251] When the fit is poor, forces are wasted on clamping the parts together and the effective use of preload is decreased.[252]

Impact of misfit has been discussed but mostly as an explanation for technical complications, in the absence of radiographic signs of adverse biological responses.[251] Jemt and Book performed a study on the fit of prostheses in clinical use for one to four years, reporting that distortions were registered in the frameworks but no statistical correlations between change of marginal bone levels and different parameters of prosthesis misfit were observed, concluding that a certain biological tolerance for misfit may be present.[253] This is supported by animal studies of prostheses fabricated with vertical distortion of 500 or 1000 µm with no harmful influences on the osseointegration or bone remodeling at implants.[250,254] Static loading of implants in animal models has not resulted in implant or bone loss, but mere adaptation to the load.[146,153,154] On the other hand, diverging opinions exist as to whether excessive dynamic load is detrimental for the osseointegration.[148,156] With the above mentioned possible ways of introducing distortion in implant-supported prosthetic frameworks, passive fit is probably not achieved in any prosthesis. In spite of that, numerous studies report excellent long-term survivals for implants and prostheses in totally and partially edentulous jaws with cast frameworks. Recently clinical trends to reduce cost further and enhance esthetics have resulted in fabrication of prostheses on the implant level. This may set higher demands on the accuracy of prosthesis fit with the increased tightening torque used at the implant level, in order to avoid high preloads in the bone-implant interface. Short-term follow-up studies on prostheses fabricated on the implant level have reported survival rates for implants and prostheses comparable with prostheses fabricated on the abutment level.[255,256]

Evaluation techniques of fit of prosthetic frameworks

There are many possible ways of introducing misfit from the impression making to framework fabrication, not to mention the play in the different prefabricated components used for information transfer from patient to prostheses. The best way to evaluate precision of the fabrication technique may be to evaluate fit of frameworks on the master model. To ensure

evaluation of the final prosthesis fit, measurements should preferably be performed after veneering. On the other hand, Örtorp and colleagues evaluated fit of Procera® CNC-milled frameworks before and after veneering with acrylic and low fusing porcelain, registering no increase in distortion for either of the veneering procedures.

There are at least three possible ways to evaluate fit of frameworks. [235,257,258]

1. Evaluation of fit by external observations using a digital micrometer and micrometer microscope or high magnification 35 mm transparencies and representative scanning electron microscopy.

2. Evaluation of fit by using impressions of the connection gap between framework and abutment or implant. A light-bodied polyvinyl siloxane impression material is syringed onto the abutment prior to prosthesis placement and tightening of the framework with a torque wrench or applying finger pressure. After seating a medium bodied polyvinyl siloxane impression material is syringed one side at a time of the light-bodied impression creating a sandwich construction. The sandwich impression is then sectioned and placed under a travelling microscope.

3. Computer aided evaluation systems, Jemt and colleagues have described four different systems; two based on stylus contact techniques, one using a laser as its reader source, and one system is photogrammetric.[258] All are capable of providing data as three-dimensional x, y, and z axis coordinate values that can be transformed into linear and angular data characterizing the bearing surfaces of abutments or abutment replicas and their mating components in the prosthesis framework. The data is used to compute center points for framework cylinders and abutment/implant replicas in the model. With computer-aided system, various techniques can be employed; the least squares method or an alternative method here called “zero-method”. The least squares method as described by Bülow positions the framework in the best possible position compared to the model, reducing the overall distortion by optimizing the positioning in a similar way to when the prosthesis is placed in the patient. The Zero method, when used on a model comprising five implants, utilises a specially designed software program to orientate the framework coordinates on the model by placing the centre point of framework cylinder one at the origin of the corresponding master replica cylinder for all three coordinates (x, y, z), cylinder five is placed at the origin of the corresponding master replica cylinder in the y and z plane and for cylinder three the centre point is placed in the z-axis. With this orientation framework distortions were described in relation to the centre points of the cylinders two and four for all x-, y- and z-axes but only for the y-and z-axes on cylinder three and z-axis on cylinder five.

Drawbacks with the different evaluation techniques

Technique one (evaluation by digital micrometer); If rounded or damaged outer corners of frameworks or abutment/implant replicas are present, misfit may be recorded in spite of good fit on the inner corner of the mating surfaces. However there are measuring techniques that can detect this.[259]

Technique two (cast impression under load): either finger pressure or tightening of the framework prosthetic screws with a torque wrench is required or gaps may be larger than they really are. The consequent risk is that the applied axial forces reduce the actual gap by deformation of the framework.

Technique three, with the computer aided interpretation of the misfit either by the use of the least squares or zero method; negative values are used when distortion is calculated in all axes. This is naturally not possible for vertical distortion since impingement of the physical components will have prevented negative levels of vertical distortion. Thus vertical distortions are underestimated.

Cost for treatment

From the patient's perspective a reduction in treatment time and cost is desirable for oral rehabilitation with implant-supported prostheses.[92,104,106,108] If treatment can be simplified by reducing surgical interventions, treatment time and use of less expensive framework materials, implant-supported fixed prostheses might become affordable for less affluent patients. There are at least two economical considerations to be made before initiating implant treatment; the initial cost of the treatment and the cost of maintenance. Oral rehabilitation with implant-supported prostheses often requires that the patient need follow-up visits at a dental hygienist once or twice a year, and a special supportive periodontal therapy is essential for patients experiencing tooth loses due to periodontitis.[260] The reported incidence of peri-implantitis differs between studies; Berglundh and colleague found that the incidence of peri-implantitis was not reported in many of the studies: for those studies reporting peri-implantitis the range was from 0% to 16.2% for all implant system and treatment indications.[45] Roos-Jansåker and co-workers reported that 16% of the patients and 6.6% of the implants had peri-implantitis.[261]

The expected lifetime of conventional fixed prostheses has been investigated in several meta-analyses, reporting 25% to 31% of fixed prostheses to be lost after 15 years.[262,263] Long term follow-up studies on implant-supported prostheses in the edentulous mandible indicate that

complications such as veneer and acrylic fracture do occur, but continuous prosthesis stability can be maintained in almost 100% for ten to twenty years.[26,35,39-41,43,45,57,58,73]

Few studies have addressed the cost of treatment with implant-supported prostheses. Engqvist and co-workers compared submerged and non-submerged implant placement and two loading protocols using four implants to reduce cost.[92] They measured the time needed for implant placement with the different implants and placement procedures. On the other hand no evaluation was performed on the cost of prosthetic treatment even though titanium frameworks were chosen for cost reasons.[92] Moberg and colleagues compared two implant systems and in submerged and non-submerged implant placement reporting shorter time for implant placement with a non-submerged procedure, this was also reported by Engquist et al.[97,171] Attard and co-workers presented the patient-based outcomes and associated clinical costs of an immediate loading protocol for mandibular overdentures in edentulous patients, reporting that the immediate protocol was associated with higher maintenance costs, with resultant higher total costs.[264] More prosthetic adjustments were also reported by Friberg and colleagues in early loading due to implant losses.[207] Palmqvist and colleagues compared treatment and fabrication times and material costs for fixed prostheses and overdentures supported by three implants, reporting less clinical time and more laboratory hours for fixed prostheses but concluding that a fixed prostheses could be provided at about the same cost as bar retained overdentures.[108] Others proposed the use of less expensive implant systems with simplified prosthesis fabrication techniques.[265,266] The use of less expensive materials and industrial techniques for fabrication of frameworks has increased during the last decades, starting with laser welded titanium components, cast titanium and non noble alloys. The introduction of the Procera® Implant Bridge a CNC-milled framework machined from one piece of grade 2 titanium, reduced costs for material and improved fit.[244,246,247] However the cost of fabricating these frameworks still exceeds the costs of casting frameworks in titanium and non-precious alloys.

Thus, cost may be reduced by; reducing the number of implants, changing implant placement procedures and/or loading protocols, and by avoiding expensive implant components or alloys in the frameworks.

Background to the present thesis

Four implants placed in the interforaminal area in the mandible, conventionally or immediate loaded can be used for supporting fixed prostheses in the mandible; short follow-up studies show comparable results to studies using more implants. Long and medium term results are sparse but what results there are do indicate no significant differences compared to prostheses supported by more implants.

FPDs with cantilevers achieve five-year survival rates in the range of 93% to 100% for implants and 90% to 100% for prostheses, which is comparable to those of FPDs without cantilevers. The reported use of only two implants supporting FPDs with or without cantilevers is sparse and scientific evidence for the use of only two implants supporting FPDs is less substantial.

Few RTC studies have been performed comparing submerged and non-submerged implant placement: animal studies present similar histological bone and soft tissue reaction towards implants placed submerged or non-submerged. Studies using one- or two-stage placement indicate that there may not be any difference in treatment outcome due to surgical technique.

Scientific evidence for successful immediate loading of implants with fixed prostheses is more substantial than early loading of implants in the mandible with full arch prostheses. Animal studies demonstrate increased bone apposition on implants subjected to immediate loading. Both treatment concepts have presented one-year survival rates for implants of 93% to 100% when strict surgical protocols are used.

Computer numerical controlled milled frameworks fabricated from pure titanium achieve superior fit to cast frameworks and excellent short-term results, with a substantial decrease in cost for framework material.

Design of the thesis

The thesis comprises two parts, part one is based on clinical studies of implant-supported prostheses and part two is based on an assessment of precision of fit of CNC-milled titanium frameworks.

Part one. Clinical follow-up studies on implant-supported prostheses with reduced number of implants, loading and surgical concepts.

Part one comprises four clinical studies (I to IV) of fixed prostheses; Study I and II evaluating reduced numbers of implants supporting fixed prostheses. Study I evaluated the five-year survival of prostheses and implants when four implants have been used for a fixed prosthesis in the edentulous mandible. Study II evaluated fixed partial dentures (FPDs) retained on two or three implants in the maxilla and mandible after a mean of nine years.

Study III evaluated implant and prosthesis survival rates of fixed implant-supported prostheses in the mandible according to two loading protocols, early or delayed loading with up to five-year results.

Study IV prospectively compares the five-year results of implants placed according to one-stage or two-stage surgery for rehabilitation of edentulous mandibles with a fixed implant-supported prosthesis.

Part two. In vitro study on precision of fit of CNC-milled frameworks.

Part two comprises one experimental study assessing precision of fit of a new CNC-milled framework for fixed implant-supported prostheses.

Aims of the present thesis

The research goals of this investigation of implant-supported prostheses and CNC-milled frameworks was to:

1. To investigate whether the standard implant treatment protocol for the edentulous mandible using five to six implants can be reduced to four with the same clinical outcome, considering complications and survival of prosthesis and survival and bone loss of the supporting implants.

2. Compare the outcome of implant-supported FPDs on two or three implants after a mean of nine years by means of complications and survival of prosthesis and survival and bone loss of the supporting implants.

3. Evaluate the early results of full-arch implant-supported fixed prostheses in the mandible using two loading protocols, early and delayed loading, in terms of survival of implants and prostheses, cost of treatment and bone loss of the supporting implants.

4. Investigate clinically and radiographically the five-year performance of implants placed by non-submerged or submerged in the edentulous mandible supporting fixed prostheses.

5. Assess the precision of fit of I-Bridge® CNC-milled frameworks for full-arch mandibular prostheses using two implant systems and to compare precision of fit of study frameworks and blinded controls.

Materials and Methods

In this section a brief description of the materials and methods used in the different papers is presented; for more detailed descriptions the readers are referred to the respective papers.

Part one. Clinical follow-up studies of implant-supported prostheses exploring reduced number of implants, loading concepts and surgical concepts.

In total four clinical studies were undertaken; three studies of implant-supported prostheses in the edentulous mandible with reduced number of implants, two with early and delayed loading protocols and one study of surgical protocols. The fourth study investigated implant-supported prostheses in partially edentulous jaws supported by two or three implants. All patients were treated at two specialist clinics. Patients in studies I, II and III were treated at the Department of Prosthetic Dentistry, Postgraduate Dental Education Center, Örebro, Sweden. Patient in study IV were treated at Department of Prosthetic Dentistry, Public Dental Health Service, Uppsala, Sweden. Implant placement was performed by specialists or residents in Oral and Maxillofacial surgery (study I, II and IV) and specialists or residents in Oral and Maxillofacial surgery or Periodontists (study III). All prosthetic treatment was performed by specialists or residents in Prosthetic dentistry. In study I and II all implants, abutments, impression copings and replicas were Brånemark system® (Nobel Biocare AB, Göteborg, Sweden). In study III three implant systems were used; Brånemark system®, Astra Tech® implants (Astra Tech AB Dental Implant System, Mölndahl, Sweden) and ITI® MonoType SLA implants (ITI® Dental Implant System®, Institute Straumann AG, Waldenburg, Switzerland). In study IV Paragon dental implants (DBA Paragon Company, Encino, CA, USA) were used. Impressions were made in accordance with the instructions from the manufacturers of the two impression materials used; plaster (Dr Kühns Abdrucksgips, Ernst Hirnischs GmbH, Goslar, Germany) and polyether (Impregum™, ESPE, Seefeld, Germany). Individually fabricated acrylic resin trays, and plaster were used in study I and polyether was used in partly and totally edentulous patients in study II, III and IV. Frameworks were fabricated in gold alloy (C3 gold, KAR Sjödings®, Stockholm, Sweden), cobalt chromium alloy, laser welded titanium Procera®, CNC-milled titanium Procera® and cast titanium. In study II metal-ceramic prostheses were fabricated using gold alloy (M3 gold, KAR Sjödings®, Stockholm, Sweden).

Clinical study I

In total, 119 patients (71 women and 48 men) with edentulous mandibles were treated according to the concept "fixed prostheses in the edentulous mandible supported by four implants" during the years 1985 to 1996. The mean age of the patients at implant placement was 59 years for men (range 26 to 83) and 58 for women (range 28 to 74).

All patients were provided with four Brånemark system® turned surface implants between the mental foramina according to a two-stage surgery as described by Adell and colleagues.[267] The concept called for implant lengths to be at least 10 mm long, however due to anatomical restriction a total of six 7 mm long implants were used. Most of the implants placed were 15 mm (n=196) or 18 mm (n=125) long, for further details see paper I.

One hundred and three of the prostheses had frameworks cast in gold alloy, fifteen were laser-welded titanium frameworks and one framework was cast in a cobalt chromium alloy. Artificial resin teeth (Biodent®, Dentsply, DeTray GmbH, Konstanz, Germany) were used for all but one of the prostheses, the exception was a titanium framework fitted with low fused porcelain veneer. All patients received full arch prostheses from the first molar region on one side to the first molar region on the other side with a distal cantilever of 10 to 22 millimetres. In the maxilla 65 patients received a complete removable denture, 33 patients an implant-supported fixed prosthesis.

Follow-up

The patients were followed-up annually using the routine protocol at the department where clinical assessment was made, including occlusion, stability of the prostheses, fracture of resin teeth and periimplant soft tissue conditions. Radiographic examinations immediately after insertion of the prosthesis (year 0) and at one-year, five-year and ten-year were included. The fixed prostheses were checked for clinical stability but were not detached to mechanically test the osseointegration of the separate implants. Therefore, the results of the implants are given as survival rates (not as success rates) according to Albrektsson & Zarb.[13]

Clinical study II

Between 1985 and 1998 a total of 178 patients were consecutively treated with implant-supported fixed partial dentures, supported by two or three implants. The patients had a mean age of 53 years for men (range 20 to 76) and 57 for women (range 20 to 82) at implant

placement. One hundred and twenty-three of these patients with a total of 146 prostheses participated in a clinical follow-up (77 women and 46 men). They had received a total of 375 implants; most were 10 mm (n=115) 13 mm (n=84) or 15 mm (n=118) long. Only 13 implants were shorter than 10 mm and of these five were wide body implants (Ø 5.0 mm).

Brånemark system® implants with a turned surface were used in all patients, placed by a two-stage procedure as in study I. Prosthetic treatment was performed with freestanding screw-retained fixed FPDs supported either by two or three implants. Fifty-six percent of the prostheses supported by two implants had cantilevers compared to 32 percent of the prostheses supported by three implants. One hundred and twenty-eight of the prostheses were fabricated in metal-ceramic, fifteen in cast gold alloy with resin veneer and three were fabricated in titanium veneered with porcelain.

Follow-up

The protocol called for a follow-up of at least five years. The patients were monitored through annual check-ups in accordance with the routine protocol at the department. These included radiographic examinations following insertion of the prosthesis (baseline) and at one-year, five-years and ten-years. During the follow-up complications of a biological and/or mechanical nature were registered such as: loss of osseointegration, fistulae, peri-implantitis, fracture of the veneering material, loose retaining or abutment screws, fracture of retaining or abutment screws and fracture of framework / implant. The prostheses were checked for clinical stability but were not detached to mechanically test the osseointegration of the separate implants. Therefore, the results of the implants are given as survival rates. Patient satisfaction was assessed through a self-administered questionnaire at the time of the clinical examination, comprising questions concerning function and aesthetics and experience of implant treatment.

Clinical study III

Between March 1999 and December 2004, 109 patients with edentulous mandibles were treated with fixed implant-supported prostheses; 55 with early loading and 54 with delayed loading. Of these, 83 patients (39 men and 44 women) participated in the clinical follow-up study. Patients having received irradiation to the head and neck, with diabetes, signs of bruxism or heavy smokers (>20 cigarettes/day) were normally allocated to the delayed

loading group; however there was one patient with diabetes in the early loading group. No random allocation was performed and the choice of treatment method (early or delayed loading) was made by the Prosthodontist and Oral and Maxillofacial surgeon/Periodontist.

Early loading group

Fifty-five patients (32 women) with a mean age of 67.6 years (range 49 to 89) at implant placement were treated with a one-stage surgical procedure and early loading with the intention to place the prosthesis within the first two weeks.

Surgical procedures

Implant placement followed the guidelines described by Buser and colleagues.[268] Experienced surgeons placed all but five implants, which were placed in one patient by a less experienced surgeon. A total of 248 implants were placed and patients were provided with four to six implants each (mean 4.5). Three different implant systems were used; Brånemark system® implants, Astra Tech® implants with a TiOblast® surface and ITI® MonoType® SLA implants. The Brånemark system® implants were of two different types; the conical fixture with a turned surface and a 3.5 mm conical neck (fixture conical, Nobel Biocare AB) and the Mk III fixture. The Mk III implants had two different surfaces; the traditional turned surface and the oxidized (TiUnite™, Nobel Biocare AB) surface. Most implants placed were 13 mm (n=47) or 15 mm long (n=100).

Impression copings, abutments or healing abutments were connected at the same occasion and tightened in accordance with the manufacturer's instructions without counter torque. Thirty-nine of the patients had impression copings mounted by surgeons before the treatment at the prosthetic department. Great care was taken in adjusting the mucoperiosteal flaps closely to the impression copings or abutments. Antibiotics and non-steroidal analgesics were prescribed for a seven-day period, as was a daily rinse with a 0.2% clorhexidine (Corsodyl®, GlaxoSmithKline, Brentford, England) mouthwash. Sutures were removed after 10-14 days at which time most of the prostheses were placed.

Prosthetic procedures

Impressions were made using individual acrylic trays or stock trays, impression copings for open trays and polyether impression material (Impregum™), an occlusion record was made with silicon putty (Provil®, Heraeus Kulzer GmbH & Co. KG, Hanau, Germany) or wax (Tenaxvax, SS White group, Gloucester, England) on healing abutments. The tooth arrangement was tried within the next few days, and in some cases a try-in of the framework

was performed separately prior to prosthesis delivery. Forty-four of the prostheses were delivered within two weeks; mean time for prosthesis placement was 2.1 weeks (SD 1.3) Thirty-four of the prostheses were fabricated with CNC-milled titanium frameworks (Procera®) and twenty-one were cast in a high-noble alloy. Acrylic teeth (SR Vivodent®, Ivoclar Vivadent AG, Schaan, Lichtenstein) were used for all prostheses. In 48 cases the prostheses were fabricated with two-unit bilateral cantilevers. Occlusal adjustments were performed to ensure even distribution of occlusal forces and no contacts on the cantilevers during excursive movements. A soft diet was recommended during the first four to six weeks after prosthesis placement.

Delayed loading group

Fifty-four patients (24 women) with a mean age of 65.5 years (range 45 to 88) at implant placement were treated according to the traditional two-stage surgery with three months submerged healing. Prostheses were placed seven to ten weeks after second-stage surgery.

Surgical procedures

Implant placement followed the guidelines described by Adell and colleagues.[267] Experienced surgeons performed most implant placements but inexperienced surgeons treated 13 patients. A total of 242 implants were placed and patients received four to six implants each (mean of 4.5). Patients were treated with two different implant systems; Brånemark system® Mk III implants (n=42 patients 187 implants) with either the turned surface or the TiUnite™ surface and Astra Tech® TiOblast™ implants (n=12 patients 55 implants). Most implants placed were 13 mm (n=41) or 15 mm long (n=139). Sutures were removed 10-14 days after implant placement. The patients received the same antibiotic regime as the early loading group. Three to four months of submerged healing was allowed before abutments or healing abutments were mounted at second-stage surgery. One week after second-stage surgery sutures were removed.

Prosthetic procedures

Patients treated according to delayed loading had their temporary removable prostheses adjusted with soft relining material (CoeSoft™, GC America Inc, Alpsip, IL 60803, USA or Viscogel®, Dentsply, DeTrey GmbH, Konstanz, Germany) 7-10 days after implant placement and again every sixth week until delivery of the final prosthesis. Definitive abutments or healing abutments were placed at second-stage surgery. For those patients receiving healing abutments at second-stage surgery, definitive abutments were placed one to three weeks later

and tightened in accordance with the manufacturer's instructions. Impressions were made using individual acrylic resin trays or stock trays, impression copings for open trays and Impregum™. Fabrication of the prosthesis involved the same procedures as for the early loading group excepting an additional visit to check the fit of the framework before delivery of the prosthesis. Thirty-nine of the prostheses were delivered within 28 weeks, with a mean of 24 weeks (SD 8.0) after implant placement. Forty-seven of the frameworks in the delayed loading group were cast in high-noble alloy, four were CNC-milled frameworks and one prosthesis had a cast titanium framework: all were fabricated with acrylic resin teeth as used for the early loading group. Two prostheses were fabricated in metal-ceramic using a high noble alloy and porcelain fused to metal. Forty-eight of the prostheses were provided with two-unit bilateral cantilevers.

Follow-up

The patients were followed-up annually in accordance with the routine protocol at the department. These included radiographic examinations following insertion of the prosthesis (year 0) and at one-year and five-years. During the follow-up complications of a biological and/or mechanical nature were registered, such as loss of osseointegration, fistulae, peri-implantitis, fractures of the veneering material, loose retaining or abutment screws, fracture of retaining or abutment screws and fracture of framework/implant. The prostheses were checked for clinical stability but were not detached to mechanically test the osseointegration of the separate implants. Therefore, the results of the implants are given as survival rates. Patient satisfaction was assessed through a questionnaire at the time of the clinical examination, comprising questions about the function, aesthetics and experience of implant treatment.

Clinical study IV

The study population consists of all consecutive edentulous mandible referrals to a specialist clinic for treatment with full arch fixed implant-supported prosthesis (ISP) from June 1998 to December 1999, who accepted participation in the study. The aim was to have a study population of 30 patients, but at the end of the recruiting period 29 patients (16 men and 13 women) met the inclusion criteria, they had a mean age of 65 years (range 49 to 84) at implant placement. The only exclusion criterion was poor general health, in order to avoid dropouts.

Surgical procedures

Two well-trained oral surgeons with long experience of implant surgery performed all implant placements. All surgery was performed under local anaesthesia according to the standard protocols for the respective technique.[267,268] The patients were randomly assigned to receive a two-stage procedure with submerged healing in one side of the mandible, and with one-stage surgery and non-submerged healing on the opposite side. The patients received six or four implants each, placed with a non-submerged procedure on one side and a submerged procedure on the other side. Short healing abutments were connected (length 0.75 mm or 2.0 mm) on the non-submerged implants. If the anatomical structures did not allow placement of six implants, then only four implants were used. A total of 168 implants were placed in the 29 patients, who received six (n=26) or four implants each (n=3). All implants were Paragon screw shaped implants with a titanium plasma sprayed surface treatment (TPS) and 3.75-mm diameter. One hour prior to surgery, the patients received premedication, one single-dose of 3 g amoxicillin (Imacillin, AstraZeneca, Södertälje, Sweden) and oral sedation with diazepam 0,2 mg/kg (Stesolid® Alpharma, Stockholm, Sweden). During the primary healing period chemical plaque control was recommended through rinsing with a 0.1% chlorhexidine solution twice daily for one week. Most implants placed were 16 mm (n=131); four implants were 10 mm and the remainder were 13 mm long (n=33). The sutures were removed after 7-10 days. Second-stage surgery was performed under local anaesthesia three to four months later and healing abutments were connected on the submerged side.

Prosthetic procedures

Prosthetic treatment was performed by three well-trained prosthodontic specialists. One to two weeks after implant placement the complete dentures were fitted after being adjusted and relined with CoeSoft™. The relining material was checked monthly and replaced when necessary during the healing period. Due to adaptation problems two patients did not wear a temporary prosthesis during the healing period. Seven to ten days after second stage surgery the prosthetic treatment was started for all but four patients. Definitive abutments were mounted in accordance with the manufacturers instruction and impressions were taken using custom made trays and polyether impression material. The prosthetic treatment followed the routine protocol at the specialist clinic and prostheses were delivered within seven weeks of second-stage surgery for 25 patients.

All patients received a full-arch implant-supported fixed prosthesis fabricated in gold alloy with SR-Vivodent® acrylic teeth by a local dental laboratory. All but two of the prostheses

were provided with 12 acrylic teeth; both exceptions were provided with 10 teeth. The dentition in the maxilla were in most cases implant-supported fixed prostheses (n=14) or natural teeth/fixed partial dentures (n=8).

Follow-up

The patients were followed-up in accordance with the study protocol with 6, 12, 18 and 24 month checkups and thereafter annually. These included radiographic examinations following insertion of the prosthesis (baseline) and at one-year, three-years and five-years. During the follow-up complications of a biological and/or mechanical nature were registered, such as loss of osseointegration, fistulae, peri-implantitis, fracture of acrylic resin and/or, loose retaining or abutment screws, fracture of retaining or abutment screws and fracture of framework / implant. The prostheses were checked for clinical stability and each year were detached to mechanically test the osseointegration of each implant. The results are reported as success and survival rates for implants and prostheses.

A specialist in prosthodontics, not responsible for any of the treatments performed and blinded to the implant placement procedures, performed the final examination and radiographic evaluation. Patient satisfaction was assessed through an interview at the time of the five-year clinical examination, comprising questions about function and aesthetics, ease of cleaning the prosthesis and experience of implant treatment.

Clinical and Radiographic examinations and registrations

During fabrication all frameworks were tested for clinically acceptable fit through visual inspection and a screw resistance test. The screw resistance tests in studies I, II and III, judged up to one quarter of a turn of the bridge screw as acceptable fit; a slightly stricter criterion than originally proposed by Jemt.[231] After prosthesis placement patients were referred to a dental hygienist for instruction in hygiene regimes and were scheduled for annual recalls. They were encouraged to contact the clinic if problems should arise with their prostheses.

Radiographic examinations were performed with routine intraoral radiographs using the parallel technique or scanograms obtained with the Scanora X-ray unit (Scanora®, Soredex, Orion, Helsinki, Finland) (detailed narrow-beam DNB radiographs) as described by Svenson.[269] In studies I, III and IV intraoral radiographs were used when possible and scanograms were used in patients with more pronounced bone resorption. In study II routine intraoral radiographs were used for all patients. In the radiographs fit of prostheses and abutments was checked and the bone level relative to the implants was registered. A specialist

in oral radiology performed the analysis of all radiographs in study I. In studies II, III and IV recordings of bone level was assessed by a specialist in oral radiology at the time of radiographic examination, and a senior consultant at the prosthetic department performed a new analysis of all radiographs. The implant/abutment or implant/prosthesis junction was used as the reference point. Bone level and bone loss were evaluated by comparing radiographs taken at baseline and at the one-, five- and ten-year follow-up visits. At the time of radiographic evaluation the threads of the implants were used as a measuring scale and registration of marginal bone loss was related to the nearest individual thread on the mesial and distal surface of each implant. With a known distance between the threads for Brånemark system® implants (0.6 mm), the bone loss in millimeters could be estimated (Palmqvist 1996). At reanalysis, bone level was assessed to the closes 0.3 mm in relation to the reference point using a Peak scale loupe with a magnification of ×7 and a scale graded in 0.1 mm steps in studies II, III and IV. The mean of the bone level registered on the mesial and distal sides of the implants was used in the statistical analysis.

Data

Data were retrieved from patient records and at the final examination patients were asked if any biologic or prosthetic complications had been dealt with elsewhere. Data on sex, age at implant placement, general health, smoking, number and length of placed implants, type of prosthesis, length of cantilever, material in framework and veneer, status of opposing jaw, implant- and marginal bone loss, technical and biological complications after prosthesis placement were retrieved from patient records. All data were gathered by the author or one of the other authors involved in that particular study, and were then checked and analyzed by the author of this thesis. Statistical calculations were performed by the author and one of the co-authors of the papers.

The following data were collected.

- Number of patients treated, age, sex, general health, smoking habits at implant placement.
- Status of opposing jaw, changes of status of opposing jaw during follow-up (studies I to IV).
- Bone quality and quantity (study IV) according to Lekholm and Zarb (Lekholm et al 1985).
- Type, length and number of implants placed; implant losses before loading (studies I to IV).
- Type of surgical protocol for individual implants (studies III and IV).
- Use of temporary prostheses and loading protocol (studies III and IV).
- Type of prosthesis, materials in framework and veneer, length of cantilever (studies I to IV).
- Time from implant placement to prosthesis placement, time from second stage surgery to prosthesis placement (studies III and IV).
- Number of follow-up visits and unscheduled visits during follow-up (studies I to IV).
- Status of peri-implant mucosa (studies I to IV).
- Biological and prosthetic complications encountered after implant and prosthesis placement (studies I to IV).
- Implant- and bone loss after prosthesis placement (studies I to IV).

Definition of treatment outcome with fixed implant-supported prostheses and performance of originally placed implants and prostheses during follow-up studies I to IV, Table 3.

Table 3. Definition of treatment outcome in studies I to IV.

OUTCOME	ORIGINAL PROSTHESIS	IMPLANTS
Survival	The original prosthesis was used continuously; adjustments or repair may have been performed on framework and veneers.	The implant was not individually checked for stability, presenting bone loss within the success criteria proposed by Albrektsson and colleagues or exceeding them. The implant presented signs of fatigue or fracture but was still to some degree supporting the prosthesis.
Failure		Bone loss had reached the apical 1/3 of the implant or the implant was not removed but was no longer connected to and used as support for the prosthesis
Lost	The original framework of the prosthesis was replaced by a new framework due to misfit, fracture or implant losses.	The implant was removed.
Withdrawn	The original prosthesis had been replaced by a new prosthesis supported by more implants or replaced due to tooth losses resulting in extended implant treatment.	More implants had been placed as support or the prosthesis was replaced by an extended prosthesis due to further adjacent tooth losses.

Part two. In vitro study on precision of fit of CNC-milled frameworks.

Computer numerical controlled milled I-Bridge® (Biomain AB, Helsingborg, Sweden) frameworks for full arch prostheses were fabricated for two master models of an edentulous mandible provided with 5 implants to perform evaluation of fit, and precision of different steps of fabrication. A further aim was to compare fit between frameworks produced for study purposes only and those fabricated for clinical cases.

Fabrication of master models

Two implant systems were chosen for the study; Brånemark system® and NobelReplace™ implant system, both having a flat to flat mating surface, one with an external hexed-abutment system and one with an internal hexed-abutment system. Duplicates were made of a cast of an edentulous mandible provided with five Brånemark system® regular platform (RP) implants with a distance between the centre points of the two terminal implant replicas (x-axis) of 33.62 mm and the distance from a straight line through these centre points to the centre point

of the central replica (y-axis) of 6.85 mm (Figure 1). Duplication was performed using impression copings for the two implant systems and Impregum™. Implant replicas for the Brånemark system® (31159, Brånemark system®) and NobelReplace™ system (29500, NobelReplace™ system) were mounted and a vinylpolysiloxane gingival reproduction material (Gingifast Rigid, Zhermack S.P.A., Badia Polesine, Italy) was injected to ensure a three mm distance between the stone plaster (Pro-stone 21, Brenntag Nordic AB, Malmö, Sweden) and the replica/framework connection. The two master models (one for each implant system) were used for fabrication of the study frameworks; five additional models were produced, using Brånemark system® replicas, for "clinical controls".

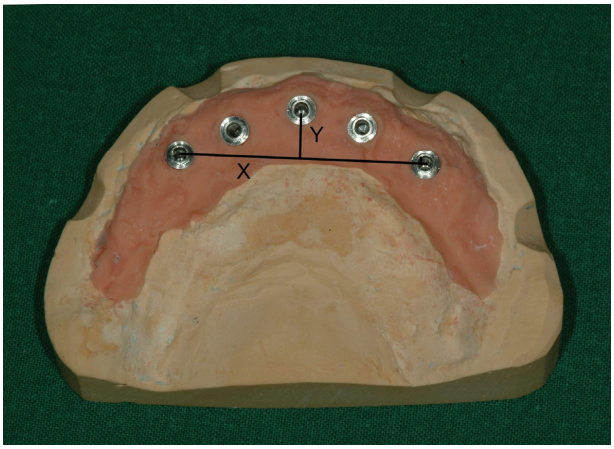

Figure 1. Brånemark system® master model on implant level. Lateral (X; 33.62 mm) and sagittal (Y; 6.85 mm) distances between implants were measured.

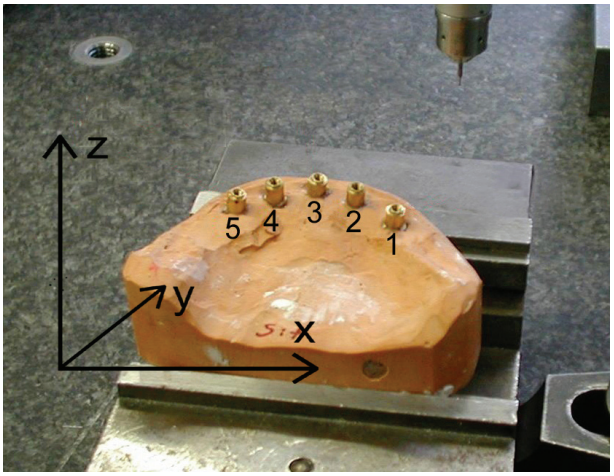

Figure 2. Coordinate system (x-, y- and z-axis) and set up of CMM measuring machine for the measurements. Master model with implant replicas numbered from 1 (right) to 5 (left) mounted in the mould.

Fabrication of resin patterns

Self-curing acrylic resin (GC pattern resin, GC Corporation, Tokyo, Japan) and the titanium cylinders provided in the I-Pac™ (Biomain AB) were used for fabrication of the resin patterns. No abutments were used and the patterns were accordingly designed directly onto the implant replicas for both implant systems. The resin patterns were individually designed with bilateral cantilevers of 14-18 mm. The study protocol called for ten individually numbered resin test patterns to be made for each master model and five additional resin patterns for the Brånemark system® "clinical control" models.

The ten individually numbered resin test patterns and corresponding master models for each implant system were sent to the manufacturer. The five "clinical controls" were also sent, one at a time, from different dentists participating in the study, through different laboraties to be manufactured during a two-month period. The "clinical cases" were not identified by the manufacturer, thereby simulating a routine clinical protocol.

Fabrication of titanium frameworks

High resolution optical scanning was used to gather information on the contours of the 20 individual acrylic resin test patterns and the implant positions in the two master models. In accordance with the study protocol, the master models should bee removed, repositioned and rescanned together with each individual resin test pattern for both implant systems. The data was used to produce ten individual titanium frameworks for each master model. The information from the tenth framework for each implant system was used to produce four additional cloned frameworks, milled from this single scanning procedure. The titanium frameworks were milled from grade 2 titanium in a CNC-milling machine with five degrees of freedom. Specific tools were used for milling the mating surface of each cylinder, in order to optimize surface finish and precision of fit. No manual polishing of the frameworks was performed before the measuring procedures.

The five "clinical control" resin patterns together with the corresponding models were scanned one at a time during a two-month period and frameworks were manufactured in accordance with routine protocols for ordinary production at external laboratories.

Measuring of Master Model and Frameworks

Positions of the centre point of implant replicas in the master models and "clinical cases" and the matching framework fit surfaces were measured with a Coordinate Measuring Machine (CMM, Zeiss Prismo Vast, Carl Zeiss Industrielle Messtechnik GmbH, Oberkochen,

Germany) by an independent laboratory (Mylab AB, Hisings Backa, Sweden). The measuring machine and procedures were described earlier by Örtorp and colleagues.[246] In brief, the two master models were measured and used as the reference for comparison of the ten different and four cloned frameworks for each implant system. For the "clinical controls" each unique model was measured together with its corresponding framework.

Prior to measuring, all master models and frameworks were placed in a mould seated on a stable reinforced concrete table (Figure 2). The CMM had a scanning head equipped with a 0.5 mm diameter stylus that could be positioned in any position within the working space of the CMM. A light force (0.1 N) was applied to the stylus to ensure contact with the surfaces to be measured and to facilitate the measuring process. Data for each cylinder of the frameworks and corresponding implant replicas were condensed to a position of the centre point of the cylinder in 3-D using the x-, y- and z-axis. The nominal linear accuracy of the machine (1 µm in all axes), was confirmed by Örtorp and colleagues.[246]

Analysis of fit

After measurement of all frameworks and master models, data of the centre points of the implants were analysed for fit between each framework and the corresponding master model. Data for the ten individual frameworks for each implant system were used to analyse the reading and milling accuracy. The five cloned frameworks milled from one single scanning procedure were used to analyze the precision of the CNC-milling procedure. The "least squares method" described by Bühler was used to analyze distortion between frameworks and master models. This was performed by superimposing the frameworks to the theoretically best possible fit on the master models in the computer. The computer program calculated the three-dimensional directions of displacement of the centre point of all individual framework cylinders in relation to the centre points of the master model replicas in µm. The values were calculated in real and absolute values (not taking into account the direction of displacement). Further, the distance between the centre points of the frameworks and the master model replicas in 3-D was calculated for each individual cylinder using the formula (3-D = $\sqrt{x^2+y^2+z^2}$).

An alternative technique for measurement of fit was used for comparison, here called the "zero method". With the zero method a specially designed software program placed the centre point of framework cylinder one at the origin of the corresponding master replica cylinder for all three coordinates (x, y, z), cylinder five was placed at the origin of the corresponding

master replica cylinder in the y and z plane and for cylinder three the centre point was placed in the z-axis. With this orientation of the individual centre points the discrepancy in distance between the replicas one and five (arch width) and between the centre point for replica three and a straight line through replicas one and five (arch length) could be calculated for each framework (Figure 1 page 44). As a result of the orientation procedure with the zero method, no distortion of individual centre points will be present in cylinder one, in cylinder five distortion is only possible in the x-axis, in cylinder three distortion can be registered in the x- and y-axis and in cylinders two and four distortion can be registered in all axes.

Statistical analysis

Study I. The Chi-squared test was used for statistical comparison of complications between groups of patients with complete dentures and implant-supported prostheses in the opposing jaw and independent Student's t-test was used to analyze bone level changes for medially and distally placed implants. Statistic significance level was set at $p< 0.05$.

Study II. An Independent-Student's t-test was used to detect differences between type of construction (two- and three-implant supported prostheses) and clinical variables. Paired-Student's t-test was applied to compare intra-group radiographic bone loss at five- and ten-year's follow-up. Statistical significance level was set at $p< 0.05$.

Study III. Student's independent t-test was used to compare bone loss between countersunk and non-countersunk implants, to analyze the bone loss for those implants according to both loading protocols and to compare the distance between prosthesis and soft tissue for the two loading protocols. Conventional descriptive statistics were used for bone level changes. The Mann-Whitney U test was used to analyze differences in the number of scheduled and non-scheduled visits after prosthesis placement and to analyze the self-administrated questionnaire. The Chi-squared test was used to analyze differences in prostheses remade/repaired in the laboratory by loading protocol and a Kruskal-Wallis test was used to analyze complications with respect to the opposing dentition. Statistical significance level was set at $p< 0.05$.

Study IV. A paired Student's t-test was used to evaluate bone level changes at the implants placed submerged and non-submerged and to compare distances between soft tissue and

prosthesis framework at implants placed with one-stage surgery and the contralateral implants placed with two-stage surgery. One-way analysis of variance (ANOVA) was used to evaluate bone-loss at implants with or without attached periimplant mucosa and periimplant mucosa registered as healthy or not. The Chi-squared test was used to evaluate complications such as loosening of retaining screw, abutment screw and implant fractures between groups with or without misfit of the framework. The significance level was set at $p < 0.05$.

Study V. Conventional descriptive statistics were used to present the distortion of frameworks. All measurements were also calculated in absolute figures to present the degree of distortion in all axes without consideration of direction of distortion. The paired Student's t-test was used to compare the two different analysis methods; zero method and least squares method. Non-parametric Mann-Whitney U tests were used for comparisons of fit within and between the groups of frameworks. The Bonferroni-Holms method was used to account for multiple testing. The level of statistical significance was set at $P<0.05$.

Results

The results obtained in the present work are concisely outlined in this section; for detailed descriptions the reader is referred to papers I-V.

Part one. Clinical follow-up studies on implant-supported prostheses evaluating reduced number of implants, loading and surgical concepts.

Patients lost to follow-up

In study I, 21 patients dropped out (17.6%) during the follow-up. Most of the dropouts were due to death or severe illness; Cumulative survival rates were 100% for prostheses and 99.1% for implants after five years, Table 4.

Table 4. Study I, distribution of patients/prostheses examined and lost to follow-up and cumulative survival rate of prostheses and implants.

Period		Number of patients lost to follow-up					Cumulative survival rate	
	No. of patients examined	Deceased	Ill	Moved	Declined to participate	Withdrawn	Prost	Impl
Prosthesis inserted	119						100%	100%
1 year	119						100%	99.6%
2 year	113	2		1	5		100%	99.6%
3 year	105	3			1		100%	99.6%
4 year	77		1				100%	99.6%
5 year	53	1	1				100%	99.1%
6 year	26	2					100%	99.1%
7 year	14	1					100%	99.1%
8 year	9	2					100%	99.1%
9 year	4					1	100%	99.1%
10 year	3						100%	99.1%
11 year	1						100%	99.1%
Total 11 yr	1	11	2	1	6	1	100%	99.1%

One patient was withdrawn after eight years due to additional implant placement after nerve transposition in order to prevent further loosening and/or fractures of prosthetic screws.

In study II, the 178 patients were provided with a total of 213 prostheses. There was a dropout of 55 patients (31%) with a total of 67 prostheses. Of these, 29 prostheses were two-implant

supported and 38 prostheses three-implant supported. Cumulative survival rates after ten-years were 96.5% for prostheses and 97.7% for implants in two-implant supported prostheses and for three-implant supported prostheses the survival rates were 98.3% and 97.0% respectively, Table 5.

Table 5 Study II, distribution of prostheses examined and lost to follow-up during the inclusion period and cumulative survival rate of prostheses and implants.

Period	No. of examined Prostheses		Number of prostheses lost to follow-up								Cumulative survival rate		Cumulative survival rate	
			Deceased		Ill		Moved/ declined		Withdrawn		2 -implant (%)		3-implant (%)	
	2imp	3imp	2imp	3imp	2imp	3imp	2imp	3imp	2imp	3imp	Pro	Impl	Pro	Impl
Placed implants	184	369										99.5		98.4
Prosthesis inserted	92	121									100	99.5	100	98.4
1 year	92	118				1		1			99.0	99.0	98.3	97.6
2 year	88	114	2	2			2	2			99.0	99.0	98.3	97.6
3 year	82	109	2	2			3	2	1	1	99.0	99.0	98.3	97.6
4 year	82	108						1			99.0	99.0	98.3	97.6
5 year	80	105	1	2	1	1					96.5	97.7	98.3	97.3
6 year	71	97	1	1	1	1		4	1	1	96.5	97.7	98.3	97.0
7 year	56	83	2	3			3	1			96.5	97.7	98.3	97.0
8 year	49	69				1					96.5	97.7	98.3	97.0
9 year	40	52		1			1	2			96.5	97.7	98.3	97.0
10 year	32	42									96.5	97.7	98.3	97.0
11 year	23	29		1	2		2	2			96.5	97.7	98.3	97.0
12 year	16	18	2	1		1		1			96.5	97.7	98.3	97.0
13 year	10	12						1			96.5	97.7	98.3	97.0
14 year	6	7						1			96.5	97.7	98.3	97.0
15 year	3	3		1	1						96.5	97.7	98.3	97.0
16 year	1	2									96.5	97.7	98.3	97.0
17 year											96.5	97.7	98.3	97.0
18 year		1									96.5	97.7	98.3	97.0
Total 18 yr	**0**	**1**	**10**	**14**	**5**	**5**	**11**	**18**	**2**	**2**	**96.5**	**97.7**	**98.3**	**97.0**

One implant was lost and replaced before loading in the two-implant supported prostheses and six implants were lost before loading in the three-implant supported prostheses; four new implants were placed before prosthesis provision. Three patients with four prostheses were withdrawn because their existing prostheses were changed to full arch implant-supported prostheses.

In study III, 12 patients dropped out (21.8%) in the early loading group and 14 patients (25.9%) in the delayed loading group with a total of 112 implants. Cumulative survival rates at five years were 92.5% for prostheses and 94.4% for implants (early loading group) and 98.9% and 97.9% (delayed loading group), Table 6.

Table 6. Study III, distribution of patients/prostheses and implants examined and lost to follow-up and cumulative survival rate of prostheses and implants.

Period	Placed / Examined		Deceased		Ill		Moved or declined		Lost		Cumulative survival rate (%)	
	Prosth.	Implants	P	I	P	I	P	I	P	I	Prosth.	Implants
Early loading												
Impl placement		248										
Prosth inserted	55	248									100%	100%
1 year	49	228	1	5			1	4	4	11	92.5%	95.4%
2 year	47	219	1	4			1	5			92.5%	95.4%
3 year	41	187	1	4			1	4			92.5%	95.4%
4 year	33	151	3	12			1	4			92.5%	95.4%
5 year	23	103	1	5	1	5				1	92.5%	94.4%
Total 5 years	**23**	**103**	**7**	**30**	**1**	**5**	**4**	**17**	**4**	**12**	**92.5%**	**94.4%**
Delayed loading												
Impl placement		243							1	5		97.9%
Prosth inserted	54	242									100%	97.9%
1 year	50	230	2	8			1	4			98.0%	97.9%
2 year	41	181	2	10			1	5			98.0%	97.9%
3 year	35	157	3	12							98.0%	97.9%
4 year	29	129	3	12							98.0%	97.9%
5 year	24	106	1	4	1	5					98.0%	97.9%
Total 5 years	**24**	**106**	**11**	**46**	**1**	**5**	**2**	**9**	**1**	**5**	**98.0%**	**97.9%**

Four prostheses in the early loading group were remade; two as a result of implant losses and two as a result of misfit. In the delayed loading group one cast titanium framework fractured at the distal abutment and was replaced by a new framework.

In study IV, five patients dropped out (17.2%) during follow-up. Cumulative survival rates at five years were 100% for prostheses and 99.4% for implants, Table 7.

Table 7, Study IV, distribution of patients/prostheses examined and lost to follow-up and cumulative survival rate of prostheses and implants.

Period	Placed/Examined		Deceased		Ill		Lost		Cumulative survival rate	
	Prosth (n=29)	Impl (n=168)	Prosth n	Impl n	Prosth (n)	Impl (n)	Prosth (n)	Impl (n)	Prosth (n)	Impl (n)
1 st surgery		168						1	100%	99.4%
Loaded	29	168							100%	99.4%
1 year	27	156	2	12					100%	99.4%
2 year	25	144	1	6	1	6			100%	99.4%
3 year	24	138			1	6			100%	99.4%
4 year	24	138							100%	99.4%
5 year	24	138							100%	99.4%
Total 5 yr	**24**	**138**	**3**	**18**	**2**	**12**		**1**	**100%**	**99.4%**

Three patients died during follow-up and two patients became severely ill and could no longer participate in the study.

Implant loss

Implant losses were infrequent in all studies; in total 14 early implant losses were experienced, and 23 implants were lost after loading, Table 8.

Table 8. Implant losses from implant placement to the end of follow-up

Time of implant loss	Study I	Study II		Study III		Study IV	
		2 implant	3 implant	Early loading	Delayed loading	One stage	Two stage
Early	0	1	6	0	6	0	1
Late	3	3	5	12	0	0	0
Total	**3**	**4**	**11**	**12**	**6**	**0**	**1**

Five of the implant losses before loading were replaced in studies II and III and one in study IV by new implants. Two implant losses after loading in study II in three-implant supported prostheses were not replaced and the prostheses have been followed for more than five years without further complications.

In study III there were no differences in implant loses between prostheses supported by four, five or six implants and all implants lost before loading were in patients treated by inexperienced surgeons. All implants lost in the early loading group were placed by one of the more experienced surgeons. One patient in study II experienced two early implant losses; no more patients lost more than one implant in studies I, II and IV; thus, no clustering of implant losses was seen in these studies. Conversely, two patients in study III lost all implants (four and five respectively) in the early loading group and one patient in the delayed loading group lost two implants before loading. Of the six patients in studies I and III losing one implant each after loading, all of the implant losses were the distal implant on either side.

Bone loss

Bone loss at the implants was calculated from the radiographs taken at the baseline, one-year, five-year and ten-year visits. The mean bone loss was small in all four studies; with no study presenting mean bone loss during the first year exceeding 0.5 mm, Table 9. The range of bone loss during the first year differed in the studies, in studies I and II the range was from -3.6 mm to +0.6 mm, in study III from -6 mm to +1.5 mm and in study IV from -5 mm to + 0.3 mm; the extreme values (≥-3.0 mm) not occurring in more than five implants in any of the studies. More than 60% of the implants in the four studies presented no bone loss from the first year up to the end of the fifth year. The number and percentage of implants with bone loss from baseline to the five-year follow-up is presented in Table 10 by extent. No significant differences in bone loss were seen between implants surrounded by attached or non-attached periimplant mucosa in studies I, II, III. On the other hand, in study IV there was statistically significantly more bone loss at implants surrounded by non-attached periimplant mucosa (mean 1.0 mm) than at implants surrounded by attached periimplant mucosa (mean 0.35 mm). However the number of implants with non-attached periimplant mucosa was few, only 31.

In studies I, III and IV mean bone loss from baseline to five-years was greater at medially placed implants than at distally placed implants. In study I medially placed implants had a mean bone loss of 0.6 mm compared to 0.3 mm at the distally placed implants; the difference being statistically significant. In studies III and IV the difference was smaller with a mean of 0.4 respective 0.5 mm for medially placed implants and 0.3 mm for distally placed implants in both studies (the difference not statistically significant). In study III countersinking of Brånemark system® fixture conical and ITI® Monotype implants resulted in a significant increase of bone loss during the first year, with a mean 0.85 mm for Brånemark system® and

0.92 mm for ITI® Monotype implants. Implants placed without countersinking had a mean bone loss of 0.23 mm for Brånemark system® and 0.21 mm for ITI® Monotype implants.

Table 9. Mean bone loss in mm during the different time intervals in the four studies.

Period	Study I	Study II		Study III		Study IV	
		2 implant	3 implant	Early loading	Delayed loading	One stage	Two stage
0 - 1 year	0.4	0.3	0.2	0.5	0.3	0.2	0.2
1 - 5 year	0.1	0.1	0.1	0.2	0.1	0.2	0.2
0 - 5 year	0.5	0.4	0.2	0.7	0.4	0.4	0.5
5 - 10 year		0.1	0.1				
0 - 10 year		0.5	0.3				

In study I and II all implants were Brånemark system® implants. In study III implants were Brånemark system® implants, Astra Tech® implants and ITI® monotype implants; in study IV all implants were Paragon implants.

Table 10. Number and percentage (%) in brackets of implants presenting bone loss from baseline to the five-year follow-up according to study.

Bone loss	Study I	Study II		Study III		Study IV	
In mm	n = 194	2 implant n = 126	3 implant n = 249	Early loading n =103	Delayed loading n =106	One stage n =66	Two stage n =66
0	112 (57.7)	70 (55.6)	149 (59.8)	40 (38.8)	50 (47.2)	48 (72.7)	38 (57.6)
0 ≤ 0.6	26 (13.4)	29 (23.0)	48 (19.3)	33 (32.0)	29 (27.4)	2 (3.0)	4 (6.0)
0.6 ≤ 1.2	30 (15.5)	16 (12.7)	33 (13.3)	8 (7.8)	18 (17.0)	3 (4.6)	14 (21.2)
1.2 ≤ 1.8	17 (8.8)	8 (6.3)	14 (5.6)	8 (7.8)	4 (3.8)	7 (10.6)	5 (7.6)
1.8 ≤ 2.4	4 (2.1)	1 (0.8)	2 (0.8)	8 (7.8)	1 (0.9)	3 (4.6)	2 (3.0)
2.4 ≤ 3.0	3 (1.5)	2 (1.6)	2 (0.8)	4 (3.9)	1 (0.9)	1 (1.5)	
≥ 3.0	2 (1)		1 (0.4)	2 (1.9)	3 (2.8)	2 (3.0)	3 (4.6)

Most implants displayed bone loss less than 1.2 mm from the first year radiographs to the five-year radiographic examination with less than 6.5% in all studies, Table 11.

Table 11. Number of implants presenting bone loss after the first year up to the five-year examination.

Bone loss	Study I	Study II		Study III			Study IV	
		2 implant	3 implant	BMK	Astra	ITI	One stage	Two stage
< 1.2	185	119	241	141	36	23	57	61
1.2 – 1.8	7	7	7	5		2	3	2
> 1.8	2		1	1		1	3	
Total	**194**	**126**	**249**	**147**	**36**	**26**	**63**	**63**

Surgical complications

Surgical complications were few in the present studies, one patient suffered from paresthesia of the right lower lip in study I, and another patient in the same study had one implant removed due to persistent pain when chewing on the implant-supported prosthesis. Delayed wound healing was seen in a few patients in study III, postponing the prosthetic treatment but not resulting in implant losses or increased bone loss.

Soft tissue complications

Soft tissues were registered as healthy at most implants in all studies irrespective of the implants being surrounded by attached or non-attached periimplant mucosa. In study I, one patient presented hyperplasia at two implants and no signs of periimplantitis were recorded during the follow-up, in study IV one patient with a systemic disease (Polycythemia Vera) had recurrent problems with hyperplasia.

Suppuration at implants/abutments occurred in less than 3% of all patients, in study II, suppuration was observed in 1.5% of the implants in two-implant supported prostheses and in 3.5% of the implants in three-implant supported prostheses. In study III, suppuration was registered in 3% of the implants in the delayed loading group and in 2% of the implants in the early loading group. In study IV suppuration was not discovered in any patient at the final examination.

Peri-implantitis was experienced by three patients in study III with Brånemark system® implants (two patients with TiUnite™ surfaces and one with the turned surface) and in two patients in study IV having Paragon implants.

Soft tissue shrinkage

In studies III and IV distances between soft tissue and prostheses were measured by a silicon impression and a caliper. The distance between the prosthesis and the alveolar crest was less in the posterior region than anteriorly in both studies with means of 1.0 mm and 1.6 mm respectively in study III and 0.7 mm and 1.1 mm in study IV. Generally greater distances between the mucosa on the alveolar crest and the prostheses were registered in the early loading group in study III and on the side with two-stage surgery in study IV. A trend noticed was that increased healing time from the latest surgical intervention to impression making resulted in a better adaptation of the prosthesis to the soft tissue.

Prosthetic complications

Prosthetic complications were prevalent in all four studies; ranging from 23% for the two-implant supported prostheses in study II to 48% for the full arch prostheses in study IV. The most frequent problems with full-arch implant-supported prostheses were fracture and wear of acrylic resin teeth and loose prosthetic or abutment screws. Fractures of frameworks were only seen in seven patients; five patients in study I (two of 15 laser welded titanium frameworks and three of 103 gold alloy frameworks fractured), one patient in study II due to a soldering defect in a four-unit metal-ceramic prosthesis, and in one patient in study III provided with the only cast titanium framework, which fractured within a year.

The dentition in the maxilla had a significant influence on the incidence of fractures of acrylic resin and acrylic resin teeth on the mandibular prostheses. Implant-supported prostheses in both jaws incurred a statistically significant increase in fracture of resin teeth, the number of patients having implant-supported prostheses also in the maxilla ranged from 18% in the early loading group in study III to 48% in study IV. Complications of the prostheses are presented in Table 12.

Table 12. Complications of full-arch prostheses in studies I, III and IV and FDPs in study II.

Type of Complication	Study I (n=119)		Study III (n=109)		Study IV (n=29)		Study II (n=63)	(n=83)
	P	O	P	O	P	O	2 impl	3impl
No complication	87		77		15		48	59
Implant loss before loading			3	3	1	1		
Implant loss after loading	3	3	5	5				
New prosthesis			4	4				
Framework fracture	5	5	1	1				1
Relining			4	4				
New acrylic teeth	2	2	3	3				
Fracture of acrylic resin teeth or porcelain veneer	25	61	9	14	2	3	4	17
Fracture of acrylic	3	4	4	5	1	2		
Fracture abutment screw	1	4	1	1	1	1	2	
Loose abutment screw	3	3	2	2	4	6	7	2
Fracture of retaining screw	1	3	1	4	3	8		
Loose retaining screw	2	2	3	4	6	14	2	3
Loss of access hole filling	2	4	12	15	5	10		

In study IV prostheses were removed every year to check the stability of individual screws and implants, which increased the number of loose screws detected. The reasons for remaking of prostheses in study III were implant losses (n=2) and misfit (n=2).

There was a significant difference in the number of acrylic resin teeth fractures in the three studies on full-arch mandibular fixed prostheses; one reason for this could be that different resin teeth were used in the studies. In study I, Biodent® resin teeth were used and in studies III and IV SR Vivadent® acrylic teeth were used. In study II, fractures of porcelain veneer and loose retaining/abutment screws were the next most common problem. Fractured veneers were experienced in 21 of the fixed partial prostheses (17 of them in the three-implant supported prostheses); most veneer fractures were registered during the first three years. Loose retaining and abutment screws occurred in 19 of the prostheses, 13 of them in two-implant supported prostheses. Screw loosening was in most patients only experienced once and in one third of the prostheses it happened during the first year after prosthesis placement, Table 13. Fractures of frameworks were only experienced by one patient due to inadequate soldering of a metal-ceramic prosthesis; the joint was re-soldering during the second year.

Table 13. Year of retaining and/or abutment screw loosening in FDPs in study II and total follow-up time of the prostheses.

Prosthesis region	No. of supporting implants	Year of follow-up										Total follow-up yrs
		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10yr	
16-14	2	1										7
15-13	2	1										9
12-21	2			1								9
12-11	2				1							10
11-22	2					1						6
25-26	2					1						7
24-26	2	1										7
24-25	2							1				12
23-25	2	1										13
45-43	2		1									8
45-43	2	1								1		12
35-36	2	1										2
34-35	2				1							5
16-12	3					1						12
12-22	3	1										8
23-26	3						1					12
45-43	3							1				12
46-43	3				1	1			1			9
45-43	3				1							5

Patient satisfaction and evaluation of treatment outcome

Information on patient satisfaction and problems experienced were gathered from patient records, the interview (study IV) and a questionnaire (study II and III). The questionnaire comprised 16 questions to which all of the patients participating in the clinical examination responded. In study IV a reduced number of questions was asked at the final examination. All patients in study IV, 95% of the patients in study III and 97% of the patients in study II were satisfied with their chewing ability after receiving implant-supported fixed full arch and partial prostheses (study II). In Study III more patients treated with the early loading protocol were satisfied with the treatment protocol than in the delayed loading group (81% versus 71%). The reasons given for this by the patients in the early loading group were: 1) not having to wear a temporary prosthesis; 2) not having to undergo a second surgery; 3) less time associated with the treatment.

Speech problems were reported in studies I, III and IV during the first year in 10-13% Most of the patients who reported speech problems had received a new complete denture in the maxilla at the time of delivery of the prosthesis.

Food retention problems were reported by 33% in study III and by 44% in study IV.

Cleansing problems were reported by 27% in study III and 22% in study III.

Cost of treatment

With the reduced number of implants used in study I and II in full arch mandibular prostheses, and in the two-implant supported prostheses, treatment cost was reduced. In study III early loaded prostheses needed significantly more adjustments/remakes thus increasing the cost of the treatment. In study IV one-stage implant placement was comparable with two-stage placement, indicating that surgical interventions can be reduced to one in the edentulous mandible.

Part two. In vitro study on precision of fit of CNC-milled frameworks.

Center point distortion

There were significant differences in distortion of frameworks compared to master model and its dependence on arch width (Figure 1; X-axis page 44) between Brånemark system® and NobelReplace™ ($P<0.05$) and between Brånemark system® and "clinical controls" ($P<0.05$), respectively. The arch curvature (Fig1; Y-axis) also differed between the groups of frameworks; Brånemark System® and NobelReplace™ showed a reduced arch curvature and Brånemark System® "clinical controls" an increased arch curvature, the differences in sagittal distortion observed between all three groups being significant ($P<0.05$)(Table 14).

Table 14. Mean difference (SD) in arch width (X) and arch length (Y) for test and control groups of frameworks compared with master models in micron. Number of frameworks/master models (n/n) are given within brackets.

Group of frameworks	Difference in arch width				Difference in arch curvature			
	Mean	(SD)	Min	Max	Mean	(SD)	Min	Max
NobelReplace™								
NobelReplace™ (n=14/1)	27	(28)	-20	65	-4	(24)	-26	51
Brånemark system®								
Brånemark system® (n=14/1)	-5	(7)	-19	8	-23	(5)	-30	-16
Clinical control (n=5/1)	48	(15)	35	71	32	(18)	5	55

The mean individual center point distortion did not differ significantly between individual and cloned frameworks for either of the implant systems used and no significant differences were seen in range of distortion for cloned and individual frameworks when analyzed according to zero method and least square method (Table 15).

The mean distortion in orthogonal directions and in 3-D were small for Brånemark system® and NobelReplace™ frameworks with means less than 12 µm (x), 12 µm (y), 2 µm (z) and 17 µm (3-D) compared to 23 µm, 26 µm, 4 µm and 34 µm respectively for "clinical control" cases when analyzed in accordance with the least square method. The mean distortions were larger in x-, y-axis and 3-D for all groups and smaller in the z-direction for all groups when analyses were made using the zero method, the differences between the methods being statistically significant ($p<0.05$) (Figure 3).

Figure 3. Mean distortion in all axes and 3-D in absolute figures analyzed with zero method (Zero) and least square (LSQ)

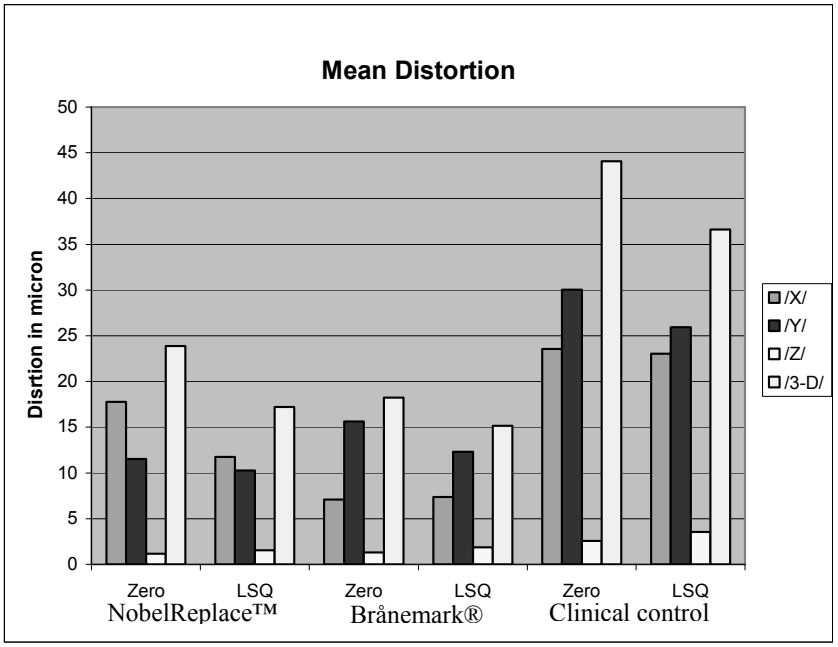

Table 15. Mean individual center point distortion of frameworks in micron (μm) in all axes and 3D for each framework as analyzed with zero method and least square method in absolute figures.

Implant system and group	Zero method				Least Square Method			
NobelReplace™ Individual	x-axis	y-axis	z-axis	3-D	x-axis	y-axis	z-axis	3-D
Framework 1	35	9	1	37	14	7	2	17
Framework 2	10	3	1	11	7	4	1	8
Framework 3	25	12	2	30	14	10	2	18
Framework 4	10	14	1	18	7	11	1	14
Framework 5	12	6	1	15	11	5	1	13
Framework 6	8	11	1	17	10	9	2	14
Framework 7	18	12	1	24	16	11	1	22
Framework 8	15	8	0	18	9	8	0	14
Framework 9	5	17	1	20	5	14	1	16
Framework 10	31	23	2	44	20	19	3	29
Cloned								
Framework 1	10	4	2	12	10	9	3	15
Framework 2	27	8	1	30	12	10	1	18
Framework 3	24	26	1	42	19	21	1	30
Framework 4	20	6	1	22	10	7	2	13
mean	**18**	**12**	**1**	**24**	**12**	**10**	**2**	**17**
Brånemark system® individual								
Framework 1	6	17	1	19	7	14	2	16
Framework 2	8	11	3	15	8	9	3	13
Framework 3	8	15	1	19	8	12	1	15
Framework 4	7	17	2	20	7	12	2	16
Framework 5	6	16	1	18	7	13	1	15
Framework 6	7	13	2	16	7	10	2	14
Framework 7	9	15	1	21	9	12	2	16
Framework 8	6	17	1	18	6	13	1	15
Framework 9	8	15	1	18	8	12	2	15
Framework 10	6	19	1	20	7	15	2	17
Cloned								
Framework 1	7	17	2	18	7	13	2	16
Framework 2	9	19	1	22	7	15	2	17
Framework 3	6	13	1	15	7	11	2	13
Framework 4	7	14	1	16	7	11	2	14
Mean	**7**	**16**	**1**	**18**	**7**	**12**	**2**	**15**
Clinical control								
Framework 1	19	31	3	44	21	24	5	34
Framework 2	26	39	1	52	28	31	2	43
Framework 3	18	25	1	35	18	20	2	28
Framework 4	29	34	3	53	28	29	3	42
Framework 5	25	21	5	37	20	25	7	36
Mean	**24**	**30**	**3**	**44**	**23**	**26**	**4**	**34**

The four cloned frameworks were milled from the same readings as the tenth of the individual frameworks

The range of distortion differed between "clinical controls" and the study frameworks for the two implant systems when analyzed with both methods. The range of distortion in the x-direction for NobelReplace™ frameworks was significantly greater than that for the Brånemark system® ($p<0.05$). The five "clinical cases" had significantly greater ranges of

distortion in the x- and y-axes and 3-D than frameworks for Brånemark system® and NobelReplace™ system (Table 16).

Table 16. Min, Max and Range of Individual Center Point Distortion of Frameworks (µm) for the Different Groups of Frameworks and Implant Systems.

	Zero method			Least square method		
	Min	Max	Range	Min	Max	Range
NobelReplace™						
Individual frameworks (n=10)						
x-axis	-65	32	97	-37	34	71
y-axis	-37	46	83	-24	22	46
z-axis	-7	6	13	-5	5	10
3-D	0	65	65	3	40	37
Cloned frameworks (n=5)						
x-axis	-65	20	85	-34	31	65
y-axis	-28	51	79	-27	25	52
z-axis	-7	6	13	-4	5	9
3-D	0	65	65	5	40	35
Brånemark system®						
Individual frameworks (n=10)						
x-axis	-13	19	32	-13	12	25
y-axis	-32	0	32	-15	19	34
z-axis	-3	9	12	-5	6	11
3-D	0	34	34	10	21	11
Cloned frameworks (n=5)						
x-axis	-17	8	25	-12	10	22
y-axis	-34	0	32	-14	20	34
z-axis	-3	6	9	-3	4	7
3-D	0	38	38	11	20	9
Brånemark system®						
Clinical control (n=5)						
x-axis	-71	67	138	-48	58	106
y-axis	0	81	81	-54	43	97
z-axis	-14	16	30	-8	12	20
3-D	0	103	103	12	71	59

The first of the cloned frameworks is the tenth of the individual frameworks in the NobelReplace™ and Brånemark system® groups.

As a result of the uniformity of results for individual and cloned frameworks for both implant systems, individual and cloned frameworks were pooled into one group in the further analysis of mean range of distortion using least square method (Table 17). The mean range of distortions in the x-direction were larger for NobelReplace™ compared to Brånemark system® and the mean range of distortion in all axes and 3-D were larger for "clinical controls", (Table 17).

Table 17. Mean range of distortion in all axis and 3-D for frameworks in respective group in micron using least square method.

	Least square method							
	Range X	(SD)	**Range Y**	(SD)	**Range Z**	(SD)	**Range 3-D**	(SD)
Nobel Replace™								
Individual	38	(16)	29	(10)	5	(3)	18	(7)
Cloned	43	(12)	34	(13)	6	(2)	19	(4)
NobelReplace™ Total	**40**	**(14)**	**30**	**(11)**	**5**	**(2)**	**19**	**(6)**
Brånemark system®								
Individual	21	(2)	29	(4)	6	(2)	7	81)
Cloned	20	(1)	29	(4)	5	(1)	5	(1)
Brånemark system® Total	**21**	**(2)**	**29**	**(4)**	**6**	**(2)**	**6**	**(1)**
Clinical control	**86**	**(12)**	**73**	**(10)**	**12**	**(6)**	**44**	**(8)**

Discussion

Discussion of materials and methods

Part one. Clinical follow-up studies; study design and patients lost to follow-up

In order to produce the most reliable data on the outcomes of different treatment protocols Randomized Controlled Trials (RCTs) should be performed. However RCT studies often result in small sample populations if conducted at one clinic, thus reducing the value of the study. In multi centre studies, diverse expertise and experience of the care providers involved may result in differences in outcome between treatment protocols at the included clinics due to treatment bias. Conversely, follow-up studies on patients treated at only one clinic may only give information on the outcome of a certain protocol in the hands of the clinicians there. However, follow-up studies on large patient populations may provide useful information on the outcome of costly and extensive prosthetic rehabilitations.

In the present thesis, studies I, II and III are retrospective studies on patients treated at one specialist clinic evaluating different treatment protocols. In studies I and II results are based on all patients treated according to the inclusion criteria; four implants in the edentulous mandible and two-implant- or three-implant-supported FPDs. In study III all patients with edentulous mandibles rehabilitated with fixed prostheses during the inclusion period were included in the evaluation. With adherence to a strict follow-up regime (offering all patients scheduled recall visits on a yearly basis) most of the patients were seen by a prosthodontist and a dental hygienist every year. At recall visits prosthesis stability, occlusion and periimplant conditions were checked and when necessary occlusal adjustments were performed. All complications were noted in the patient's file. The dental hygienists, having long experience with patients rehabilitated with implant-supported prostheses, registered periimplant health, performed professional cleaning of prostheses and reinstructed patients in cleansing of the prostheses. Radiographic examinations were performed at prosthesis placement and at subsequent one-, five- and ten-year follow-ups.

In study I, no control group was used since practically all patients treated during the actual period received four implants. Few patients received more than four implants, and those that did were; patients having undergone mandibular reconstructions, radiation therapy or showing signs of extensive bruxism. The follow-up times differing from one to eleven years is a drawback; but a fairly large portion of the study population was followed for at least five

years; enabling a separate evaluation of the five-year results. There was a drop out of 21 patients (17.6%), which is quite reasonable considering the age distribution of the patient population. The dropouts were mostly for natural reasons; death or severe illness, which were identified for all patients. All patients treated with fixed implant-supported prostheses on four implants were identified and were included in the reported data as long as the patient was followed. The substantial number of studies reporting five-year follow-up data of implant-supported prostheses in the edentulous mandible supported by five or six implants provide comparable survival data for implant losses, bone loss and prosthetic complications, enabling reasonable comparisons even when the treatment is performed at other centers.

In study II no randomized allocation was made between prostheses supported on two or three implants; prostheses on two implants were either because the available bone volume did not permit the placement of a third implant or when only two teeth were to be replaced. However, the number of prostheses was fairly large and follow-up time was at least five years in both groups. The number of FPDs with cantilevers was more frequent in the two-implant supported prostheses. In both groups most prostheses were distal to the remaining dentition. The dropout in study II was 55 patients (31%); which is comparable with other studies with similar long follow-up.[38,91,261] All dropouts were identified and in most cases the reasons were natural events. Two subgroups could be identified in the dropouts; younger patients (mean age of 51 years at last visit) who had moved out of the county, and older patients (mean age of 72 at last visit) who had either died or declined participation due to severe illness. The dropout patients were to a larger extent treated during the 1980´s; also indicated by a higher proportion of prostheses fabricated in gold acrylic; 32% compared to 10% for those participating in the clinical examination. Dropped out patients did not differ from those clinically examined in respect to implant and bone loss or complications with the prostheses.

In study III no randomized allocation was performed; the choice of early or delayed loading was made jointly by the prosthodontist and maxillofacial surgeon/periodontist. Inexperienced surgeons (having placed less than 50 implants) placed 24% of the implants in the delayed loading group and only 1.8% in the early loading group. Follow-up time was short and only 47 patients were followed for five years. All patients treated with fixed implant-supported prostheses during the inclusion period were identified and were included in the reported data as long as the patient was followed. There was a dropout of 26 patients (23.9%); in most cases for natural reasons (18 died and two had moved out of the county), the cause was identified

for all patients. For comparison of the cost effectiveness of the two treatment methods the short follow-up is probably less important since different numbers of planned and unplanned visits only occurred during the first years. Implant losses in patients subjected to early or delayed loading usually occur during the first years; longer follow-up would probably not influence the results greatly. However, differences in prosthetic complications with the two types of frameworks; CNC-milled and cast gold frameworks, may be evident with a longer follow-up.

Study IV is a prospective RCT performed at another specialist clinic; all patients were enrolled in a follow-up regime with a standard protocol for the implant-supported prostheses and periimplant tissue. Patients also received reinstruction in adequate oral hygiene regimes. All prostheses were removed at the yearly visits (except two cases with damage to the prosthetic screw heads), but at the five-year follow-up visit all prostheses were removed. The use of only 29 patients was because only one clinic was involved in the study and the short inclusion period (18 months) chosen to facilitate follow-up and evaluation of the outcome. Five patients dropped out (17.2%); all for natural reasons (death or severe illness). The use of an implant system with a moderately rough surface was due to the increased marketing of moderately rough surfaces and a decline in the use of implants with a turned surface. A random allocation of implant placement according to the two surgical techniques (submerged and non-submerged placement) was performed and final registration of periimplant conditions and interpretation of radiographs were executed by an observer blinded to the implant placement procedures.

Radiographic examinations and registrations

Intraoral radiographs have proven to be useful in identifying loss of osseointegration in implants even though the identification rate is not 100%. By using several radiographs taken at different years the precision is increased. In a study by Gröndahl and Lekholm only 5% of failing implants were clinically found to be mobile without having been detected radiographically.[270]

In studies I, III and IV intraoral radiographs were used when possible and scanograms were only used in patients with more pronounced bone resorption. In study II routine intraoral radiographs were used for all patients. In studies I to III radiographs were taken at the Department of Oral Radiology in Örebro and in study IV all radiographs were taken at the Department of Oral Radiology in Uppsala. Primary analysis of all radiographs was performed

by specialists in Oral Radiology. A reevaluation was performed by a specialist in oral radiology in study I and by one of the senior Prosthodontists in studies II, III and IV. In studies I and II the bone levels were measured by scores, using the threads of the implants as a built-in measuring scale at primary analysis for Brånemark system® implants. In studies III and IV the distance from the reference point to the first BIC was registered in mm for all implants. At the reexamination in study I the level was estimated to the closest 0.6 mm. At the reexamination in study II, III and IV the level was estimated to the closest 0.3 mm. The reason for not measuring primarily in tenths of a millimeter is the inadequate accuracy of measurements of marginal bone levels in radiographs. It has been shown that a projection change of the vertical angulation by one degree will result in a change of the measured bone level of 0.1mm.[271] It has also been reported that the bone loss must exceed 0.47 mm to be detectable.[272] However, in large patient studies, errors in measured bone height due to projection and other technical changes will probably be self-compensating. Therefore, the mean marginal bone loss in the total patient group was calculated in tenths of a millimeter to permit comparison with other studies. The use of 0.6 mm steps in the reporting on bone loss is due to measurements performed in 0.3 mm or 0.6 mm and earlier reported data using these intervals.

Part two. In vitro study on precision of fit of CNC-milled frameworks.

In study V the study protocol was developed in collaboration with Biomain AB the provider of the CNC-milled I-Bridge® frameworks, and the intention of the study was not blinded for the technician responsible for fabrication of the individual and cloned frameworks. The fabrication procedures were preformed without an external observer verifying that scanning procedures of the two master models were performed in accordance with study protocol. In order to evaluate the precision of the fabrication technique for routine cases five additional models were produced and used for “clinical controls”, blinded for the technician producing the study frameworks. From a statistical viewpoint, the number of blinded control frameworks should have been equal to the other groups but for economical reasons this was not possible.

Measuring technique and analysis of fit

The measuring technique chosen for study V was the use of a Coordinate Measuring Machine (CMM); which has proven precision of measurements in all axes of 1 micron (μm). The technique has been used in other studies and the precision of measurements verified by Örtorp

and colleagues.[246] All measurements were performed by an independent company. Two evaluation methods were available for calculating center point distortion; the least squares method described by Bühler and the zero method, used by Örtorp and colleagues.[246] The methods differ in the calculation process; both methods were used and a statistical test was performed indicating that the zero method reports slightly larger values of distortion in the x-, and y-axes and 3-D and less distortion in the z-axis. The least square technique has been used in studies evaluating fit of frameworks for implant-supported prostheses fabricated with different techniques using a computer aided evaluation technique.[231,244,247] One of the drawbacks with both the zero method and the least square methods is that they can report negative values of z-axis distortion which is not possible from a physical point. Thus the mean distortions in the z-axis calculated in the computer are smaller than the real vertical distortion. However, the results achieved with these techniques enable comparison with other studies performed in a similar way.

Discussion of results

Part one. Clinical follow-up studies.

The first aim was to evaluate the five-year clinical performance on full-arch fixed prosthesis supported by four implants in the edentulous mandible, concerning complications and survival of prosthesis and survival and bone loss of the supporting implants.

Studies I and III

Implant losses

Study I showed an implant cumulative survival rate of 99.1% after five-years in 53 patients, which is very satisfying, being on the same level as the best results from other studies using more implants to support a fixed prosthesis.[26,37,44,75,159] In study III a total of 63 of the included patients were rehabilitated with fixed implant-supported prostheses on four implants, 34 in the delayed loading group and 29 in the early loading group. One patient in the delayed loading group had five implants installed initially but one implant was lost so the prosthesis was fabricated using the remaining four implants as support. In the early loading group one patient experienced four implant losses and received four new implants placed with a submerged healing and loaded after five months. In the delayed loading group no implants

were lost before or after loading and the cumulative survival rate at five years was 100%; the corresponding figure for the early loading group was 96.5%. However, in study III there were few patients who passed the five-year follow-up; sixteen in the delayed loading group and seven in the early loading group. The use of only four implants has been reported by Engquist and colleagues; in early and delayed loading of full arch mandibular prostheses they reported 93.5% survival for early and 97.5% for delayed loading. The differences between groups were small and not statistically significant.[97] The results from study I and III strongly support the findings of Engquist and co-workers and Brånemark and colleagues[39], leading to the conclusion that the number of implants at least 10 mm long could be reduced to four as support for a fixed prosthesis in the mandible. Since few implants in the present studies were shorter than 10 mm the results cannot be extrapolated to support the use of shorter implants. However, Friberg and colleagues, using four to six short implants (7 mm or shorter) placed in the severely atrophic mandible supporting fixed prostheses, reported cumulative survival rates of 95.5% after five years and 92.3% after ten years for the implants; the number of prostheses supported by only four implants was not reported.[118] Some studies report as few as three implants supporting fixed prostheses with good results, but the follow-up times are short and long-term results are lacking.[103-108,202] The Brånemark Novum® treatment protocol used for most of the patients in these studies uses wide body implants whereas the other studies use standard implants; whether this will influence the long term results can not be answered from these studies. With only three implants supporting the prostheses the loss of one implant inevitably requires in additional implant placement and prosthesis repair/replacement. If one implant is lost in a four implant situation the three remaining implants can support the prostheses; but if one of the distal implants is lost the cantilever must be reduced. In study I, two patients lost one distal implant and continued to wear the prostheses, now with a reduce number of teeth, without further complications. One problem with implant placement in the anterior mandible is that the implants sometimes tend to be placed in a reduced arch form due to the short interforaminal distance. In order to increase the curve of the implant placements, some surgeons place the distal implants with a distal inclination to enlarge the supporting area. In studies I and III the posterior implants were sometimes tilted, without any adverse effects observed for the tilted implants. These results are supported by others using tilted implants in edentulous and partially edentulous jaws.[98,101,102,273,274] Krekmanov and colleagues reported an increase in the supporting arch in the mandible of 6.5 mm and 9.3 mm in the maxilla.[273]

Bone loss

In study I mean marginal bone loss after five years was 0.5 mm and in study III it was 0.5 mm with 71% to 77.4% of the implants presenting no bone loss or bone loss up to 0.6 mm from baseline to the five-year follow-up. These results meet well the criteria set by Albrektsson and colleagues and compare well with other studies.[13,35,44,75,97] Six implants in study I and nineteen in study III showed bone loss of more than three threads between baseline and one-year follow-up. Some of these implants might be lost in the future, but steady state might also have been established at the level found after five years. There were only eight (4.1%) implants in study I and nine in study III (4.3%) presenting bone loss exceeding 1.2 mm between one-year and five-year follow-up examinations. In study I bone loss was significantly larger at medially placed implants; 0.6 mm compared to 0.3 mm for distally placed implants. This difference was less pronounced in study III with 0.4 mm and 0.3 mm respectively. Similar results were shown by Lindquist and colleagues who reported a significant correlation between bone loss and smoking / poor oral hygiene, especially for the anteriorly placed implants.[35]

Technical complications

The technical complications in study I were somewhat more than reported from other studies, mainly as a result of a high incidence of resin teeth fractures; however Örtorp and colleagues reported a high incidence of resin tooth fracture for one of the titanium framework designs.[27,30,35,75] Loose abutment and prosthetic screws were registered in three patients. There were five framework fractures; two out of fifteen laser-welded Procera® titanium frameworks fractured. These first generations laser welded Procera® frameworks have been reported to give some problems.[43,69] The three fractured gold alloy frameworks were technically unsatisfactory; being incorrectly dimensioned. Framework fractures were also reported for earlier designs of frameworks by Attard & Zarb.[42] Framework fractures occurred at the cantilever junction at the last gold cylinder; the same as reported by Attard and Zarb and Örtorp and colleagues.[42,43]

The number of resin tooth fractures in the mandibular prostheses was very high in study I. Two possible reasons for this could be identified; the durability of the resin teeth used in these prostheses (Biodent®) and the dentition in the maxilla. The incidence of resin tooth fractures was lower in study III, which may be a result of using different resin teeth (SR-Vivodent®). Then again, in studies I and III the dental conditions in the maxilla had a considerable influence on the number of acrylic resin teeth complications. Patients with an implant-

supported fixed prosthesis also in the maxilla exhibited significantly more resin teeth fractures than those wearing a complete removable denture ($P<0.05$). This was also reported by Davis and colleagues and Carlson & Carlsson, [67,70] although the patient sample analysed by Carlson & Carlsson was too small for further analysis. A simple explanation of the outcome with occluding resin teeth in the different groups is that patients with fixed implant-supported restorations in both jaws applied higher occlusal forces than patients with a complete upper denture. At the same time they did not have the same tactility as those with natural dentition.
The results from the present two studies and other studies on implant-supported mandibular prostheses on four implants showing high implant survival rate and favorable marginal bone levels after five-years indicate that no more than four implants are needed in most edentulous mandibles to support a fixed prosthesis. From an economic point of view, with a reduced number of implants the restoration can be made less expensive for the patient.

The second aim was to compare the outcome of implant-supported FPDs on two or three implants after a mean of nine years concerning complications and survival of prosthesis and survival and bone loss of the supporting implants.

Study II

Implant losses

In study II a total of 15 implant losses were recorded; seven implants were lost before loading and seven patients suffered a total of eight implant losses after FPD placement. Four of the patients provided with FPDs supported by three implants presented implant losses; one of them experienced two implant losses in the anterior maxilla due to trauma. There were five-year cumulative survival rates of 97.7% (implants) and 96.5% (FPDs) of for two-implant supported FPDs (n=82) and 97.3% (implants) and 98.3% (FPDs) for three-implant supported FPDs (n=107). One implant was lost in one three-implant supported prosthesis in the present study between the five- and ten-year follow-ups; thus the ten-year survival rates for FPDs passing the ten-year follow-up (32 in the two-implant supported prostheses and 42 in the three-implant supported prostheses) were the same as the five-year results for two-implant supported prostheses and 97.0% (implants) respective 98.3% (FPDs) for three-implant supported prostheses. One patient experienced a fractured implant at the six-year follow-up in a two-unit prosthesis replacing two premolars in the mandible. A customised abutment was fabricated as a temporary solution and replacement of the implant was planned but the patient refused further treatment and the patient was lost to follow-up. Romeo and colleagues

reported 97% survival of implants and 98% for prostheses after a mean follow-up of 3.9 years in 49 cantilever FPDs supported on two implants.[114] High survival rates for implants and prostheses in FPDs with cantilevers were also reported by Wennström and colleagues.[110] The high survival rates in study II and in the study by Romeo and colleagues compare well with other studies on implant-supported FPDs regardless of the number of implants supporting the prostheses, and is above the mean CSR figures found in meta-analyses.[32,38,45,49,57,62,80,110] The stable results between the five-year and the ten-year follow-up registrations in study II were supported by Naert and colleagues and Örtorp & Jemt.[49,243]

Bone loss

Bone loss at individual implants was low at both the five- and ten-year follow-ups; with a mean bone loss of 0.4 mm at five years and 0.5 at ten years. The mean bone loss was nearly 0.2 mm larger for two-implant supported prostheses from baseline; this difference remained between the two groups at the five- and ten-year follow-ups. At the ten-year follow-up the mean bone loss in the two-implant supported prostheses was 0.5 mm, which compares well with other long-term follow-ups on FPDs.[49,110,111,116,243] Thus bone loss in FPDs supported by two or three implants is comparable with bone loss in full-arch prostheses and the five- and ten-year figures are well within the criteria proposed by Albrektsson and colleagues.[13]

Technical complications

Technical complications are frequently reported with implant-supported prostheses, both for full-arch prostheses and FPDs. In study II prosthetic and abutment screw loosening and chipping of the veneering porcelain were the most common problems. The incidence of loose prosthetic and abutment screws was greater in the two-implant supported FPDs. This has also been reported by others. [72-74,116,117] However, this is often easily adjusted in the clinic, and in most patients in study II this happened only once. If abutment screw fractures occur; this may cause a problem if the fractured part cannot be removed. However, the reported incidence of this is fairly low and all three abutment screw fractures experienced in study II could be removed and replaced with new screws. Many factors may influence the outcome in FPDs; such as non-axial loading, bruxism, crown to implant ratio and occluding dentition.

In the present study two-implant supported FPDs performed comparably to three-implant supported prostheses in terms of implant losses, bone loss and FPD survival; indicating that two implants may be sufficient for three-unit prostheses with a central or cantilever pontic. This is supported by other studies.[73,114] However, great care should be taken when interpreting

theses results since the number of FPDs included is small and the results can not be extrapolated to be valid in all situations. The scientific evidence for treatment of all patients with three-unit FPDs supported by only two implants without exclusion criteria is still weak.

The third aim was to report on the early results of full-arch implant-supported fixed prosthesis in the mandible using two loading protocols, early and delayed loading, in terms of survival of implants and prostheses, number of unscheduled visits, cost of treatment and bone loss of the supporting implants.

Study III

Implant losses

In study III the cumulative survival rate after five years was 94.4% in the early loading group and 97.9% in the delayed loading group. Theses figures are lower than that demonstrated in study I where the five-year cumulative survival rate was 99.1%. The pattern of implant-losses differed between the groups; four patients in the early loading group lost a total of 12 (5.6%) implants, two patients lost all installed implants (four and five each) within two months. Two patients lost one implant each during the first year and one patient lost one implant after five years; this implant probably lost osseointegration during the first year but the prosthesis was not removed to test the implant and the patient experienced no pain. One experienced surgeon who placed more than one third of all implants was responsible for the placement of all the implants lost during the first year. Both patients who lost all implants were successfully re-operated with two-stage surgery and delayed loading using the same type of implant. In the delayed loading group five (2.1%) implants were lost; two patients lost two implants and one patient lost one implant prior to loading. No implants were lost after loading. Inexperienced surgeons treated all three patients who lost implants. Four of the lost implants were replaced by new implants prior to prosthesis placement.

Engquist and colleagues also reported a somewhat higher incidence of implant losses in early loading of implants in the edentulous mandible; 6.7% compared to 2.5% in the group with two-stage surgery and delayed loading.[97] Conversely, implants placed with a one-stage procedure and subjected to delayed loading displayed no differences in implant losses compared to those subjected to early loading.[97] This might indicate that there is no difference with the implant system used between early and delayed loading protocols, but a difference may exist between submerged and non-submerged placement. Friberg and colleagues reported

a significantly lower CSR in the edentulous mandible of 97.5% for early loaded implants with a turned surface compared to 99.7% for delayed loading.[207] However in a recently published study Friberg and Jemt reported 100% one-year CSR for early loaded implants with a moderately rough surface in the edentulous mandible.[208] There was a difference in time from implant placement to delivery of the prostheses with a mean of 32 days in the later study and 42 days in the previous study.[207,208] Whether the difference in CSR was due to the difference in time of loading or the difference in surface characteristics may be debated. In study III, the mean time from implant placement to prosthesis delivery was 2.1 weeks and Engquist and co-workers reported placement of all but four prostheses within two weeks.[97] Still, implant survival rates were lower in study III and in the study by Engquist and co-workers than with traditional two-stage surgery and delayed loading using the same type of implants with a turned surface. On the other hand, a number of animal studies have reported more BIC with moderately rough surfaces during the first months in loaded and unloaded implants compared to implants with a turned surface.[144-147,150-152] Further, the magnitude of micromovements tolerated differs between implant designs and surfaces according to Smuckler-Monclear and colleagues.[25] Thus differences in early bone response and time for achieving secondary implant stability between implants with a turned surface and implants with a moderately rough surface may be responsible for the increase in early failures when implants with a turned surface are subjected to immediate or early loading.

Bone loss

Bone loss at individual implants was low for both early and immediate loading in the present study, and compares well with other studies.[37,44,75,97,207,208] An increase in bone loss during the first year was registered for implants with a conical neck when these implants were counter sunk at implant placement, placing the turned surface below the bone margin. Nineteen implants in the early loading group demonstrated bone loss exceeding 1.5 mm during the first year compared to seven implants in the delayed loading group. Few implants (six in the early loading group and four in the delayed group) demonstrated bone loss greater than 0.8 mm from the one- to five-year follow-ups. The mean bone loss from one- to five-year follow-up did not differ between early and delayed loading protocols; this is supported by the findings by Engquist and colleagues in a three-year follow-up.[97] No significant difference was demonstrated between different types of implants and mean bone loss was within the criteria suggested by Albrektsson and colleagues.[13]

Technical complications

The technical complications in study III were in most cases related to the acrylic resin teeth and screw access hole fillings. There were no significant differences in this type of complication between the two loading protocols. However, in the early loading group four prostheses required remaking; two due to implant losses and two due to misfit at one of the implants probably caused by improper mounting of the impression copings. Furthermore, four prostheses were removed and the base of the prostheses was fitted with acrylic resin to correct for excessive soft tissue recession leading to patient complaints of food retention between the prosthesis and alveolar crest. Only one patient experienced framework fracture, six patients suffered loose or fractured abutment or prosthetic screws. No fractured screws were experienced by patients with prostheses placed on implant level but screw loosening occurred in two patients. For the 71 patients with prostheses fabricated on the abutment level; fractures of abutment and prosthetic screws were demonstrated in two patients and loose prosthetic and or abutment screw were also recorded in these two patients: two additional patients presented with loose prosthetic screws.

With the early loading concept used in the present study impressions for the final prostheses were taken before soft tissue healing, frameworks were fabricated with a close adaptation to the soft tissue; allowing for soft tissue recession after healing. An attempt was made to register soft tissue adaptation to prosthesis by a silicone impression at the clinical examination one to five years after prostheses placement. No significant differences were registered between prostheses in the early or delayed loading groups, but two prostheses in the early loading group were remade due to misfit and another four prostheses were adjusted before registrations, which might have influenced the results. A similar registration with a silicon impression was used in study IV where small but non-significant differences were registered between the different sides with implants placed submerged or non-submerged. Moberg and colleagues comparing ITI® and Brånemark system® implants in the treatment of mandibular edentulism reported less change in bridge and periimplant mucosa distance in the ITI® group, but four prostheses in this group had to be removed and adjusted to increase the distance between prosthesis and soft tissue.[171] In the study by Moberg and colleagues the time required for implant placement, prostheses fabrication, and adjustments of prostheses was calculated. Although the implant placement procedure was shorter for the ITI® group, total time consumed during the three-year follow-up was shorter for the Brånemark system group but the difference was not significant.[171] In the present study prosthesis remakings/adjustments after connection were significantly higher in the early loading group resulting in a higher total

cost. More prosthetic complications in early loading than delayed loading were also reported by Friberg and colleagues.[207] Attard and colleagues reported a higher cost for immediate loading of overdentures in the mandible compared to conventionally loaded overdentures.[264] With the treatment protocols used in study III treatment cost was higher for early loading; thus no cost reduction was achieved by shortening the time from implant placement to prosthesis delivery, even though patient acceptance of the treatment was higher than for delayed loading.

The fourth aim was to investigate the five-year clinical and radiographic performance of implants placed according to one- and two-stage surgery in the edentulous mandible supporting fixed prostheses.

Study IV

Implant losses

In study IV the cumulative implant and prosthesis survival rate after five years was 99.4%; however three implants in one patient demonstrated fractures of the coronal part of the implant. Implant fractures are rare according to Berglundh and colleagues, who reported a weighted mean of 0.08% implant fractures in studies over five years.[45] For the fractured implants in study IV; customized titanium "abutments" were fabricated and the prostheses could be maintained. Whether these implants should be counted as failures, lost or survivals could be debated. Since they are still osseointegrated and to some extent supporting the prostheses they are calculated as survivals in the results. Ericsson and colleagues used a split mouth study to place 66 implants in 11 patients by one- and two-stage surgery; reporting two early losses in two non-submerged implants, with no further implant losses during the five-year follow-up.[159] Becktor and colleagues' multicenter study placed Brånemark system® implants with a turned surface non-submerged and submerged, reporting implant losses of 8.6% in the non-submerged group and 2.4% in the submerged group.[168] A number of studies have reported five-year cumulative implant survival rates of 97% to 100% for implants with a turned surface placed submerged and loaded after a healing period of at least three months.[26,27,35,37,43,44,171,206] Whether an implant survival rate of less than 97% in the edentulous mandible is acceptable or not may be debated. For patients suffering implant losses and having to undergo removal of non-osseointegrated implants and a new implant placement procedure with a prolonged treatment period as a result the question is easily answered.

Bone loss

The mean bone loss was low, with a mean of 0.4 mm after five years in the non-submerged group and 0.5 mm in the submerged group. Most implants incurred no bone loss but some implants displayed bone loss exceeding the proposed levels for success.[13] Three implants demonstrated bone loss exceeding 1.5 mm during the first year and 18 implants (9 submerged and 9 non-submerged) presented bone losses of more than 0.8 mm from the one-year to the five-year follow-up. The number of implants suffering bone loss greater than 0.8 mm after the first year was comparably higher in study IV than in studies I, II and III. However, only one of the implants presenting bone loss greater than 1.5 mm during the first year presented bone loss more than 0.8 mm from the one- to five-year follow-up. At the five-year follow-up a total of eight implants presented a bone loss from baseline to five-year follow-up of 2 mm or greater. With a mean bone loss for all implants of 0.5 mm or less during the five-year follow-up, mean bone loss was well within the success criteria.[13]

Technical complications

Almost half of the patients demonstrated some complication, with a higher frequency of loose prosthetic and abutment screws than in studies I and III. This may be explained by the fact that in the present study the screws were checked each year and thus a minor movement in the screws was noticed, but in the other studies the screws were not checked if the prosthesis was not mobile. Prosthetic screws in need of retightening have been reported by others without the prostheses being registered as mobile.[171,275] The number of screw access hole fillings coming loose was also higher; probably as a result of fillings being made thinner and easier to remove at the yearly follow-up examinations, and thus failing more frequently. Fractures of acrylic resin and acrylic resin teeth were few and compared favorably with studies I and III and other studies.[27,30,35,75]

In the present study and a number of other studies non-submerged implant placement was as predictable as submerged implant placement in the edentulous mandible.[130,159,161,162,171] Thus one-stage surgery can be used in most patients without increasing the risk of implant failures; however implants with a medium rough surface may be more advantageous than implants with a turned surface.[168,205-208]

Part two. In vitro study on precision of fit of CNC-milled frameworks

The fifth aim was to evaluate the precision of fit of I-Bridge® CNC-milled frameworks for full-arch mandibular prostheses using two implant systems and to compare precision of fit of study frameworks and blinded controls.

Study V

Evaluation of fit

Results from this study indicate that the present new CNC-milled frameworks fabricated for Brånemark system® implants and NobelReplace™ implants displayed precision of fit that compares favorably with cast and CNC-milled frameworks, as shown in other studies.[231,242,244,245,247] All frameworks demonstrated different levels of distortion, with the "clinical controls" demonstrating significantly higher mean and range of distortion in the x- and y-axes and 3-D, compared to the study frameworks. The distortion in the x- and y-axes differed between the groups of frameworks, with frameworks produced for "clinical controls" and NobelReplace™ master model demonstrating an increase in arch width and frameworks for the Brånemark system® master model a reduced arch width. The "clinical control" frameworks also demonstrated an increase in arch curve while the frameworks for Brånemark system® master models presented a decrease in arch curve. Nevertheless, the distortions displayed in all frameworks were within the tolerances built into the I-Bridge®, since all frameworks could easily be seated on the corresponding model without clinically detectable misfit. An increase in arch curve was also reported by Al-Fadda and colleagues for CNC-milled frameworks.[247]

The study protocol called for ten individual and five cloned frameworks to be fabricated; in order to evaluate the precision of fit and the accuracy of the scanning and milling procedures. The results demonstrated no differences in mean and range of distortion between individual and cloned frameworks, suggesting that the optical scanning of the master model was flawless and that all distortions displayed by the different frameworks were caused by the milling procedure. However the higher range of distortion in the "clinical control" frameworks indicates that this may not be the case. Frameworks produced for clinical cases in a routine manufacturing procedure tend to exhibit higher levels of misfit than frameworks produced for study purposes. This is also demonstrated by the differences in levels of distortion for Procera® CNC-milled frameworks reported by Örtorp and colleagues and Al-Fadda and co-workers. While Örtorp and colleagues used a strict study set up, evaluating cloned

frameworks fabricated from one single model and scanning procedure, Al-Fadda and co-workers used a more clinically oriented setup with a blinded procedure and nine different models, reporting considerably larger distortion than Örtorp and colleagus.[246,247]

With a "virtual" approach in analyzing distortion the limitations of the physical implant and framework components are disregarded and vertical discrepancies will be underestimated. Thus the results for vertical distortion should be approached with much caution.

The level of proposed acceptable vertical (z-axis) misfit differs from 30 µm to 150 in the literature, but no consensus has been reached.[231,276] Visual inspection of fit may detect vertical gaps in the range of 50 to 100 µm.[242] Even if the level of distortion in the x- and y-axes were considerably larger than distortion in the z-axis, the vertical discrepancies are probably of more clinical importance in that they will inevitably introduce a preload in the prosthesis-implant-bone complex and reduce the clamping force in the screw joint. With an increasing number of prostheses being fabricated on the implant level a high precision of fit is desirable: the higher tightening torque used on the implant level inevitably increases the preload in the screw joint, but also increases the stress at the implant-bone interface when misfit is present. Since no long-term studies are available on prostheses connected on the implant level, the consequences of this potential risk of higher stress levels due to misfit on the implant-bone interface are unknown. However, short-term static loading of implants in animal models have not negatively influenced the osseointegration and bone remodeling at implants.[146,153-155] Short-term follow-up studies on prostheses fabricated on the implant level have not presented any adverse effect; however long-term data is lacking.[255,256]

A good clinical fit depends on all steps of the framework fabrication; such as precision of fit between implant components, copings and replicas as well as impression technique and fabrication of master cast. Thus frameworks fabricated with a built in tolerance for minor displacement in x- and y-axes are probably a prerequisite for achieving acceptable clinical fit. In the present study the levels of distortions for I-Bridge® frameworks was somewhere between the results of Örtorp and colleagues and Al-Fadda and co-workers, and lower than those reported for cast and laser welded frameworks.[245-247,253] The present data indicate that it is possible to produce CNC-milled frameworks according to the I-Bridge® technique with a higher degree of precision and a considerably lower material cost than cast gold alloy frameworks.

Main observations and conclusions

1. Four implants are sufficient for supporting fixed full-arch prostheses in the mandible, at least in a five-year perspective. The number of technical and biological complications is not affected by reduction of the number of supporting implants.

2. Three-unit FPDs supported by two implants with the pontic placed centrally or as a cantilever may perform equally as well as three-unit FPDs supported by three implants: however a slight increase in the incidence of screw loosening may occur for two-implant supported prostheses.

3. The early loading concept for edentulous mandibles with fixed full-arch prostheses has a better patient acceptance than delayed loading. Strict surgical and prosthetic protocols should be used in order not to jeopardize implant and prosthetic outcome. A high degree of primary implant stability should be observed when early loading is planned. Time of prosthesis placement and implant surface characteristics may influence treatment outcome. Treatment time is shortened but the total cost for treatment may be higher due to an increased number of adjustments after prosthesis placement.

4. Non-submerged implant placement in the edentulous mandible with or without early loading may be as predictable as submerged implant placement if strict surgical protocols are used. A high degree of primary stability should be achieved; otherwise submerged healing should be utilized. Implant surface characteristics and loading from a temporary prosthesis may influence treatment outcome.

5. Frameworks fabricated by CNC-milling present a higher degree of fit than cast frameworks for a lesser material cost. From a biological and technical viewpoint; frameworks milled from one piece of grade 2 titanium without welded joints are advantageous as they are bioinert and can be veneered with either porcelain or acrylic without introducing distortions.

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