Long term study of implant supported fixed prostheses in the edentulous mandible
A comparison between early versus delayed loading

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Abstract

**Purpose:** To evaluate the clinical outcome and patient satisfaction in patients treated with implant supported fixed mandibular prostheses (ISFMP) according to early and delayed loading implant protocols.

**Materials and methods:** Inclusion criteria comprised all consecutive patient treated between 1999 and 2004. A total of 111 patients had received ISFMP during the period, of which 84 (40 men, 44 women) participated in the study (mean age 68 years, range 47-90). 44 of the patients were treated with early and 40 with delayed loading. The registrations included a clinical examination, radiographs, data collected from patient records and a questionnaire. **Results:** A total number of 84 prostheses were performed on 380 implants. The mean observation time was 3.5 years (range 1-6 years). Prosthesis and implant survival rate was 93.2% and 96.5% for early loading and 97.5% and 96.7% for delayed loading. The mean radiographic bone loss during the first year was 0.5 mm for the early and 0.1 mm for the delayed loading group. More patients experienced complications in the early loading group (32%) compared to the delayed loading (25%). Generally, patients treated according to the early loading concept were more satisfied.

**Conclusion:** The hypothesis that the concept of early loading has the same predictability as delayed loading was to great extent supported.

**Keywords:** Dental implants; complications; early loading; delayed loading; prostheses and implants; retrospective studies.
Introduction

Titanium implants for prosthetic rehabilitation of edentulous and partially edentulous jaws have been one of the most significant breakthroughs in dentistry over the past 30 years. With survival rates for individual implants of up to 99% over 10-15 years in the mandible, the treatment appears to be highly predictable in large patient groups (Adell et al. 1990, Henry et al. 1995, Carlsson et al. 2000, Ekelund et al. 2003). The excellent biocompatibility of titanium is largely explained by its good corrosion resistance, which has been ascribed to the chemical stability of titanium dioxide in biologic environments (Ivanoff et al. 2003).

Functional ankylosis, referred to as osseointegration, is a term and concept originally coined and developed by Per-Ingvar Brånemark. Although it was clear that osseointegration implied a direct contact between implant and bone tissue, the more precise definition of the term remained unclear. Today osseointegration is defined as “bone-to-implant contact at the light microscopic level” (Cochran et al. 2004).

In 1965 Per-Ingvar Brånemark initiated his experimental implant trial and twelve years later Brånemark et al. published their 10-year clinical experiences of oral implants. It was the first long-term follow-up study on oral implants, providing the scientific foundation of modern dental implantology. The predictability of implant integration according to
Brånemark and collaborators was obtained by adherence to a strict surgical and prosthodontic protocol (Szmukler-Moncler et al. 2000). The most important requirements were: 1) use of a biocompatible material, i.e. titanium; 2) use of a 2-stage surgical procedure; 3) use of a stress-free healing period of 3-6 months before loading; 4) use of an atraumatic surgery involving low-speed drilling; 5) use of a mucobuccal incision and avoid a crestal one; 6) use of sterile conditions as “in a fully equipped surgical unit”; 7) use of titanium ancillary; 8) avoid radiographs before the end of the healing period and; 9) use of acrylic occlusal contact surfaces (Brånemark et al. 1977).

The implant rehabilitation path of Brånemark during 1965-1975 was divided into three different periods, named the initial period, the development period and the routine period. Different delayed loading periods were used. Having noted that “insufficient healing time was greatly increasing the risk of immediate or late implant mobility”, it was increased. In line with their 10-year clinical experience, they stressed that osseointegration requires a long healing period of at least 3 months in the mandible and at least 5-6 months in the maxilla. The reason for such a long delayed loading was to minimize the risk of infection and the risk for excessive early loading and to prevent apical down growth of mucosal epithelium leading to fibrous tissue encapsulation instead of direct bone apposition. By this submerged technique, the healing takes place separated from the oral microbiological
environment and the implant is unloaded during this period (Adell et al 1990, Ericsson et al. 1997). Another argument for the extended healing time was that the necrotic bone at the implant bed border is not capable of load bearing and must be first replaced by new bone (Brånemark et al. 1969).

Parallel developments with bone-anchored implants were well underway in Switzerland by André Schroeder and collaborators, which finally resulted in the ITI-implants (Straumann, Waldenburg, Switzerland). There were clear differences in the implant concept used by Schroeder et al. compared to that of Brånemark et al. They used a one-piece hollow cylindrical implant with various designs and a roughened implant surface. The implant was placed with a one-stage surgery technique, thus leaving the implant exposed to the oral environment during the healing period (Buser et al. 1997, Mericske-Stern et al. 2001). In spite of the different implant systems under development in Europe and the promising results published, implant treatment was not seen as a viable treatment alternative in other parts of the world. This was a result of previous reports of implant treatments often with a detrimental effect for the patient. Professor George Zarb, by initiating the Toronto study 1979, was in principle responsible for spreading the message about osseointegration throughout the North American Continent (Albrektsson and Wennerberg 2005).

The results presented by Schroeder et al. indicated that maybe not all of the prerequisites proposed by Brånemark et al. were necessary. In Brånemarks...
10-year study, conclusions were drawn from particularly demanding clinical conditions and there were no clear correlation between healing time and implant failure. The necessity of waiting to load an implant was not scientifically but rather clinically based. It was impossible to provide “detailed statistical analysis of separate parameters”. Today, however, high levels of predictability in implant therapy have been demonstrated. This has encouraged re-evaluation of several aspects of the traditional Brånemark implant protocol (Szmukler-Moncler et al. 2000, Chiapasco 2004).

The first re-evaluated requirement was the need for a 2-stage procedure. As indicated earlier, the work from Schroeder et al. 1981, showed that non-submerged implants according to the 1-stage technique, still osseointegrated as predictable as implants installed using the traditional submerged procedure (Bernard et al. 1995, Collaert et al.1998, Abrahamsson et al. 1999, Attard et al. 2005). In 1997 Buser et al. reported in an 8-year life table analysis of a prospective multicenter study a cumulative survival rate of 96.7% for non-submerged implants. Implants installed with a one-stage surgery are probably exposed to a higher amount of load by the denture, from tongue pressure and food flow than implants installed according to 2-step surgical procedure (Becker et al. 2003). In spite of this, several animal studies indicate that one-stage surgery and moderate micromotion per se does not lead to the expected fibrous interposition layer (Ericsson et al. 1996, Abrahamsson et al. 1999, Abrahamsson et al. 2004). The threshold for
tolerated micromotion is set at various levels by different researchers. Today, there seem to be a tolerable threshold for micromotions somewhere between 50 and 150 µm (Szmukler-Moncler et al. 1998).

Over the past 20 years, the original protocol has been re-evaluated and significantly modified, due to development of implant design, implant dimensions, surgical technique and biomechanical features of the prosthesis (Duyck et al. 2006). At a consensus conference in Spain 2002, the definition of immediately, early, delayed loading and recommended clinical procedures regarding loading protocols for rough-surfaced titanium implants were established. Immediate loading was defined as when ”The prosthesis is attached to the implants the same day the implants are placed”. Early loading was defined as when “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 was defined as when “The prosthesis is attached at a second procedure after a conventional healing period of 3 to 6 months” (Aparicio et al. 2003).

Immediate and early loading protocols were first described for the edentulous mandible in the anterior area and are today a commonly used technique. This region is often very predictable regarding bone quality. The bone is often typically extremely dense and large amounts of primary bone contact occur at implant installation. Thus, the implant is instantaneous mechanically retained in large amounts of cortical bone, both at the
implant’s apical and crestal portion, giving the implant immediate stability (Schnitman et al. 1997). The use of such protocols has obvious advantages for the patient, for instance, treatment time and the number of surgical interventions is reduced. Many researchers, including Brånemark, have demonstrated comparable results for integration of implants placed under immediate and early functional load (Brånemark et al. 1999, Friberg et al. 1999, Randow et al. 1999, Ericsson et al. 2000, Collaert and De Bruyn 2002, Engstrand et al. 2003, Friberg et al. 2005). Schnitman and coworkers published the first longitudinal trial in 1990. Prior to that Lederman had reported on early loading of implant retained overdentures. Although the success rates were lower than for the two-stage approach, it remained above 90% (van Steenberghe et al. 2004).

The number of implants needed to support the supraconstruction has been evaluated. Brånmark and co-workers found equal implant and prosthesis survival rates when four instead of six implants were used (Brånemark et al. 1995). This has been confirmed by other studies (Eliasson et al. 2000, Engqvist et al. 2002, 2005). In 1999 Brånemark et al. presented a new implant system dedicated for immediate-loading, Brånemark Novum, with survival rates of 98% after 6-36 months. The system is based on three implants splinted together with prefabricated bars. This concept was the first implant protocol to create a final prosthesis in 1-day in the edentulous mandible. In two later studies on the same system the comparable
cumulative survival rate was 91% to 99% after a mean follow-up time of one respectively 2.5 years (Henry et al. 2003, Engstrand et al. 2003). With the use of prefabricated components the method is limited to patients with specific jawbone morphology. De Bruyn and coworkers used three standard (RP) Brånemark implants to support early loaded full arch fixed prostheses in 20 patients and reported 10% implant losses and that loss of one implant led to a complete prosthetic failure in 15% of the patients within the first year. Together with results from other studies this has led to the recommendation that at least four implants should be placed in an edentulous mandible to support a fixed prosthesis (De Bruyn et al. 2001, Eliasson et al 2000, Wolfinger et al. 2003, Attard and Zarb 2005). In addition, another new technique has been developed on immediate function in the edentulous maxilla using a specially designed surgical guide made from computer images (Malo et al. 2005). Obviously though, no unanimous protocol exists regarding bone density, number of implants, or type of prosthesis to be used in immediate loading cases (Gapski et al. 2003). Even though most results concerning early and immediate loading protocols in the interforamina area are convincing, all implants will not require identical healing periods. A careful patient selection is necessary. Individuals suffering from metabolic and systemic diseases such as osteoporosis, hyperparathyroidism and diabetes, might not be good candidates for early or immediately loading. The situation is similar for
smokers, patients who have undergone radiation therapy, bruxism, previously bone grafted jaws and patients with severe maxillo-mandibular skeletal discrepancy (Gapski et al. 2003). To determine whether a 1-stage or a 2-stage approach should be used, which type of supraconstruction to choose, healing time requested, and to detect failing implants, a Resonance Frequency Analysis (RAF) could be useful. RAF quantifies the lateral movements of an implant under controlled force (Sennerby and Meridith 2002, Raghoebbar et al. 2003).

Primary stability of individual implants is enhanced when cross-arch implant splinting is performed, as with full arch fixed prosthesis. Gold alloy has been used since the early 1970s for fabricating frameworks for fixed prostheses. To improve precision, pre-machined gold-alloy cylinders were introduced to be incorporated in the cast framework. Besides the conventional techniques for cast frameworks, other methods to manufacture prostheses have been tested through the years. One such technique was to use laser-welded titanium frameworks. However, the early laser-welded titanium frames showed higher incidence of fractures as compared to conventional cast gold alloy frameworks (Örtorp and Jemt 1999). The technique with laser-welded titanium frames was further developed into the single-piece milled titanium implant bridge. This new implant technology is part of the Procera product line (Procera Implant Bridge, PIB, Nobel Biocare), and is available through a growing network of dental laboratories.
It is demonstrated that the fit of a framework made with the Procera system is significantly better than that of a framework cast in gold-alloy (Jemt et al. 1999, Parel 2003, Takahashi and Gunne 2003, Örtorp and Jemt 2004).

Another solution to get a tension free framework is the Cresco Ti Precision method (Cresco Ti systems, Astra Tech, Gothenburg, Sweden), where a framework is cast in titanium or CoCr and then passive fit to the master model is achieved by a horizontal “cutting” and assembling of the framework by laser welding (Helldén et al. 2005).

Advanced jaw resorption and poor bone quality have been linked to high rates of implant failure. An index often referred to, when classifying bone resorption and quality, is the one by Lekholm and Zarb (1985). To improve the clinical success rate and to reduce healing time in favor of functional healing, focus is set on shape and surface characteristics of the implants.

The length of the implant is important in order to increase the surface area. A 50% failure rate is reported for immediate loading for implant lengths $\leq 10$ mm (Gapski et al. 2003). Several studies, focused on surface-enlarged implants, have indicated a larger amount of early bone to implant contact of titanium implants with a roughened surface compared with implants with a polished or turned surface (Ivanoff et al. 2003, Wennerberg 2003, Abrahamsson et al. 2004). Screw shaped implants and increased surface roughness enhance mechanical interlocking between the macromolecules of the implant surface and the bone, resulting in increased resistance to
compression, tension and shear stress (Jungner et al. 2005). If the oxide layer of the implant is enhanced it will have influence on surface morphology, chemical composition, crystal structure and surface topography affecting the osteoconductivity of the implant via improved blood clot retention (Cooper et al. 2002). Ivanoff et al. (2003) showed surface enlargement of 37% for oxidized implants, versus 15% for turned implants and significantly more bone was found to be in contact with the oxidized surface. Previously most implants were either minimally rough, such as the turned screw or very rough, such as the plasma-sprayed implant. Today the most commonly used implant is moderately roughened, surface roughness of 1-2µm (Albrektsson and Wennerberg 2005). It can not entirely be supported that a rough surface is always necessary to improve the implant success outcomes, since long-term studies have shown excellent results with machined implants in edentulous patients with favorable bone quantity and quality (Carlsson et al. 2000, Ekelund et al. 2003). With rougher implant surfaces combined with poor oral hygiene, a higher incidence of periimplant lesions might be expected, causing more complications, higher bone loss and loss of implants in the long-term prospective (Ekelund et al. 2003, Attard and Zarb 2004). More rapid integration has also been attempted by stimulating the surrounding tissues with growth-promoting substances such as bone grafts and growth factors (Cochran et al. 2004).
The most reliable variable in evaluating the outcome of implants is probably the change in marginal bone level and the most commonly used parameters are radiographic examinations and implant mobility tests. Many studies, in which changes of the marginal bone level at implants have been evaluated, have been published and different amounts of bone loss have been described. According to Albrektsson et al. (1986), a successful implant should not lose more than 1.0 mm of bone during the first year of function, followed by a mean maximal 0.2 mm loss of bone per year during the subsequent years and that “steady state” in marginal bone resorption means that the change for each individual implant should thus not exceed 0.4 mm between the 1-year and 3-year examination. Progressive loss of marginal bone is a pathological sign, which can lead to implant failure. Surgical trauma together with anatomical conditions are believed to be the most important etiological factors for early implant losses, while bone volume, bone quality and overload together with chronic infection seem to be responsible for late implant losses (Esposito et al. 1998). Factors like smoking and poor oral hygiene are highly associated to periimplant bone loss (Lindquist et al. 1996). The majority of studies show no difference in bone resorption, when different loading concepts are compared. Attard and Zarb (2005) reviewed the literature over immediate and early loading protocols and concluded that the marginal bone loss measured, irrespective of prosthesis design, was of the same magnitude as presented for the
conventional loading approach. The same findings were reported on implants placed in extraction sites (Schnitman et al. 1997, Randow et al. 1999, Ericsson et al. 2000, De Bruyn et al. 2001, Petersson et al. 2001, Engquist et al. 2005) but divergent results have been shown (Friberg et al. 2005). Still the indications for immediate and early loading have to be sufficiently specified because the main factors involved are not completely understood (Colomina 2001). Despite an increasing number of publications on immediate and early loading reporting high survival rates for the loaded implants, much controversy still exists over the reliability of the reported data, because the publications frequently demonstrate insufficient methodological quality. So far, the best documented implant system is the Brånemark system (Åstrand et al. 1996), which is based on the submerged technique, but documentation of other systems is increasing. More well designed RCTs are needed to understand how predictable immediate and early loading are before this approach can be widely used (Esposito et al. 2005).

The aim of this study was to retrospectively compare treatment of consecutive patients with mandibular edentulism by the concept of early loading and the classic two-stage surgical technique by means of biological and prosthodontic variables and patient satisfaction. The hypothesis is that there are no differences between the two methods concerning treatment outcome.
Material and method

All consecutive patients treated with full arch fixed implant supported prostheses in the mandible during the period March 1999 to December 2004 at the Department of Prosthetic Dentistry, Postgraduate Dental Education Centre, Örebro, Sweden were invited to participate in the study. The treatment period was chosen in order to include all patients treated with early loading as well as delayed loading of implant supported fixed mandibular prostheses (ISFMP) and to make it possible to have at least a one year follow up of the prostheses.

There were a total of 111 patients treated with ISFMP and of these, 84 patients (40 men and 44 women) accepted to participate in the study. Both men and women had a mean age of 68 years (rang 47-90 years) at the follow-up. 44 patients were treated with a one-stage surgical procedure and early loading (loading within the first 3 weeks) and 40 patients were treated with a two-stage protocol and delayed loading after 3-4 months of submerged healing (Table 1).

The study included a questionnaire, data collection from dental records and a clinical examination, including radiographs. All patients were enrolled in the clinic’s routine follow-up system with yearly check-ups of the prosthesis and periimplant tissues. The majority of the patients also had regular visits to the dental hygienist at least once a year.
Table 1. Number, sex and age of patients according to loading protocol at the follow-up.

<table>
<thead>
<tr>
<th>Age</th>
<th>Men Early loading</th>
<th>Men Delayed loading</th>
<th>Women Early loading</th>
<th>Women Delayed loading</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>40-49</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>50-59</td>
<td>1</td>
<td>2</td>
<td>7</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>60-69</td>
<td>12</td>
<td>9</td>
<td>7</td>
<td>9</td>
<td>37</td>
</tr>
<tr>
<td>70-79</td>
<td>5</td>
<td>7</td>
<td>5</td>
<td>6</td>
<td>23</td>
</tr>
<tr>
<td>80-89</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>90-99</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>20</td>
<td>24</td>
<td>20</td>
<td>84</td>
</tr>
</tbody>
</table>

Radiographs were taken after delivery of the prosthesis (baseline), and at the 1-year and 5-year check-ups, additional radiographs were taken of all study patients having passed the 3-year check-up and not having reached the 5-year follow-up. Before the initiation of the study, an ethical approval was obtained by the Regional Human Review Board, and all patients were informed and gave their signed consent.

Surgical procedures

The patients treated with one-stage procedure and early loading had implants installed and abutments or healing abutments mounted at the surgical department. The soft tissue was closely adapted to the abutments according to the surgical procedures described by Randow et al. (1999).
Antibiotics, non-steroidal analgesics were prescribed for a 7-day period. A daily rinse with a 0.2% chlorhexidine (Corsodyl®) mouthwash was prescribed for one week. In the one-stage group, three different brands of implants were used; Brånemark implants (Nobel Biocare, Gothenburg, Sweden) (n=156), Astra Tech implants (Astra Tech AB, Mölndahl, Sweden) (n=14) and ITI Monotype implants (Institute Straumann AG, Waldenburg, Switzerland) (n=24). The Brånemark implants were of two different kinds, the conical implant with a turned surface and a smooth neck of 3.5 mm and the standard implant with or without a multi-unit abutment. The Brånemark implants had two different surface treatments, the traditional turned surface and the new TiUnite surface. The Astra Tech implants had a titanium-blasted surface (TiO-blast) and the ITI Monotype implants had a sandblasted and acid-etched (SLA) surface.

Patients treated with a two-stage surgery and delayed loading had implants installed according to the standard protocol with cover screws and submerged healing. Sutures were removed after 10-14 days of healing. The antibiotic regime was the same as described above and after 3-4 months of submerged healing, the second stage surgery was performed and healing or permanent abutments were mounted.

The patients were treated with two different brands of implants; Brånemark implants (n=132) and Astra Tech implants (n=41), the Brånemark implants were standard implants either with the turned surface or the TiUnite surface
and the Astra Tech implants with TiO-blast surface, the same as those used in the early loading group (Table 2).

Table 2. Distribution of implants according to sex, loading protocol, surface treatment and manufacturing company.

<table>
<thead>
<tr>
<th>Implant Type</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantaion Type</td>
<td>Early loading</td>
<td>Delayed loading</td>
<td>Early loading</td>
</tr>
<tr>
<td>Nobel* Standard machined</td>
<td>4</td>
<td>41</td>
<td>0</td>
</tr>
<tr>
<td>Standard TiUnite</td>
<td>15</td>
<td>28</td>
<td>26</td>
</tr>
<tr>
<td>Conical machined</td>
<td>61</td>
<td>0</td>
<td>54</td>
</tr>
<tr>
<td>Astra TiO-blast</td>
<td>9</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>Straumann ITI monotype SLA</td>
<td>4</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>93</td>
<td>93</td>
<td>105</td>
</tr>
</tbody>
</table>

* All Nobel implants were Brånemark implants, regular platform except 3 that were Nobel Biocare Novum® 4.5 mm

Prosthetic procedures

Patients in the early loading group were directly after the surgery admitted to the Department of Prosthodontics where impression was made using a polyether impression material (Impregum NF®, ESPE, Germany). Bite registration and try in of the wax set up was performed in the next few days, and in some cases the metal framework was tried in as to check the fit before delivering of the prosthesis. In most cases, the prostheses were delivered within 2 weeks. All but two prostheses were fabricated with a metal framework, either in milled titanium (Procera Implant Bridge, Nobel
Biocare) or cast in a high precious gold alloy (KAR Sjödings® C3 gold, Stockholm, Sweden), with acrylic teeth (SR Vivodent®, Ivoclar Vivadent AG, Schaan, Lichtenstein). The sutures were in most cases removed at the delivery of the prosthesis. The patients were instructed to be careful and avoid tough food during the first month after delivery.

Patients treated with delayed loading had their temporary removable prostheses adjusted with soft relining material after one week and then relined every sixth week until the delivery of the final prosthesis. One week after second stage surgery the definite abutments were mounted and the abutment screws were torqued according to the manufacturer’s instructions. Impression copings were adapted and impression was made according to the procedure mentioned previously. The fabrication of the prosthesis included the same try in procedures as for the early loading group except for an extra visit to check the fit of the framework before delivering of the prosthesis.

Most frameworks in the delayed loading group were made in gold (Table 3).

Registered variables

The follow-up included a self-administered questionnaire, a clinical examination, and a review of the patients’ records and radiographs of the implants from baseline, 1, 3, or 5-year check-ups. The questionnaire comprised issues concerning general health such as, number of drugs used daily, self-esteem of general health, smoking habits, TMD symptoms, discomfort associated with the manufacturing and use of the implant
prosthesis in addition to general satisfaction regarding speech, hygienic and esthetics.

Table 3. Framework material according to sex and treatment group.

<table>
<thead>
<tr>
<th>Framework</th>
<th>Early loading Men</th>
<th>Delayed loading Men</th>
<th>Early loading Women</th>
<th>Delayed loading Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milled titanium</td>
<td>15</td>
<td>1</td>
<td>16</td>
<td>3</td>
<td>35</td>
</tr>
<tr>
<td>Cast titanium</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Cast gold</td>
<td>5</td>
<td>17</td>
<td>8</td>
<td>17</td>
<td>47</td>
</tr>
<tr>
<td>Metal/ceramic gold</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>20</td>
<td>24</td>
<td>20</td>
<td>84</td>
</tr>
</tbody>
</table>

The clinical examination included registrations of the peri-implant mucosa with respect to keratinized or non-keratinized attachment, gingival inflammation and presence of calculus. A silicon impression (Provil®, Heraeus Kulzer GmbH & Co. KG, Hanau, Germany) was taken under the prosthesis in order to establish the distance between the soft tissue and the prosthesis. The thickness of the impression was measured in sex regions, regions 45, 43, 41, 31, 33, 35, using a caliper with a 0.1 mm scale. The stability of the construction was checked without removing the prosthesis. Prosthetic complications such as loosening or fractures of retention and abutment screws, acrylic defects, fractures of acrylic resin teeth, loosening of screw access-hole fillings and fractures of frameworks were noted. The
number and type of implants used were registered and the length of the cantilever from the most distal implant to the distal end of the prosthesis was measured to the nearest mm. Occlusal tooth wear was registered as minor (<0.5 mm), moderate (0.5-1.0 mm) or major (>1.0mm). Type of opposing dentition, as well as jaw relation in the horizontal, vertical and transversal plane was registered. Detailed information about treatment outcome, number of planned, unplanned appointments, time required to complete the rehabilitation and all complications during the follow-up period was retrieved from the patients’ records. Bone level at all implants was estimated from conventional analogue intraoral radiographs, except in a few cases where it was made from digitalized images due to a change from analogue to digital radiographs at the Radiographic Department in the late 2005. The distance from the implant-abutment junction to the most apical marginal bone level in contact with the implant surface was measured by one of the Senior Consultants at the Prosthetic Department. A Peak scale loupe with a magnifying factor of ×7 and a scale graded in 0.1 mm steps was used and the measurements were made at the mesial and distal surface of the implant. The highest value obtained was used as the registered value for each implant. The fit of the framework was evaluated both clinically and from the radiographs.
Search strategy

A Medline search was conducted (Pub Med at [www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov)). The following search terms, alone or in combination, were used: “Early loading”, “Immediate loading”, “Brånemark”, “Oxidized surfaces”, “Implant frameworks”, “follow-up study”. Authors, explicit and related articles were used. The titles and abstracts were screened for possible relevance for this study and subsequently ordered in full text.

Statistical analysis

All data was analyzed in Statistical Package for Social Science (SPSS) version 14 (SPSS Inc. Headquarters, Chicago, Illinois, USA). Only descriptive statistics were used to analyze the clinical variables and findings from patient records and the self-administrated questionnaire.
Results

Demographics

84 of the original 111 patients were examined, 17 had died, 3 had moved out of the county and another 7 patients did not want to participate in the study due to poor health or lack of interest. The 84 patients had received a total of 380 implants (Table 4). There was a mean follow-up of 3.4 years (range 1-6 years, SD 1.37) in the early loading group and 3.7 years (range 1-6 years, SD 1.72) in the delayed loading group.

Most of the prostheses were made with either a framework cast in gold alloy or a milled titanium framework, see table 3. All restorations except one were fabricated with acrylic resin teeth. The mean number of installed implants was 4.5 for both groups, ranging from 3-6 in the early loading group and 4-6 in the delayed loading group and the mean length of the cantilever was 14 mm (range 0-20 in the early loading group and 0-22 in the delayed loading group). The mean number of acrylic resin teeth was 11.5 in both groups (range 10-13).

Most patients had a neutral jaw relation, only a few patients (n=4) presented minor class II and class III relation. However patients with cross bite were more often found in the early loading group (9 patients compared to 3 patients). 42% of the patients had a complete removable denture in the maxilla. Fixed implant supported prostheses in the opposing jaw were more common in the delayed loading group, 35% verses 18%. A natural dentition
or fixed partial dentures were registered in 22% of the patients in the
delayed loading group versus 36% in the early loading group.

Table 4. Number of and lengths of implants according to treatment group.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Type</th>
<th>Length</th>
<th>Early loading</th>
<th>Delayed loading</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nobel Biocare</td>
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<td>17</td>
<td>3</td>
<td>9</td>
<td>12</td>
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<tr>
<td>Strauman ITI</td>
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<td>10</td>
<td>7</td>
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<td>Total</td>
<td></td>
<td>198</td>
<td>182</td>
<td>380</td>
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</table>
The amount of tooth wear was comparable in the two groups and the tooth wear was proportional to the time in service. In a few patients the tooth wear was so extensive that the acrylic resin teeth were replaced within the first five years.

*Implant failure*

There was no difference in the number of implant losses between the two groups i.e. 3.3% in the delayed loading group and 3.5% in the early loading group. The pattern of implant-losses differed between the groups. In the early loading group, implants were lost after loading and in the delayed loading group implants were predominantly lost before loading. In the early loading group seven implants were lost, two patients lost one implant each and one patient lost five implants. In the delayed loading group two patients lost two implants and one patient lost one implant prior to loading and one patient lost one implant after five years (Astra Tech). All implants lost were Brånemark implants except the one lost after five years. The patient who lost all five implants was re-operated according to submerged and delayed healing.

The implants lost in the early loading group were placed by the same surgeon who had performed more than half of the implant placements in the early loading group and one third of the implants placed in the delayed loading group. Inexperienced surgeons, who accounted for 13 of the patients
in the delayed loading group and none of the patients in the early loading group, placed all implants lost prior to loading in the delayed loading group.

**Bone loss**

The bone loss pattern differed between the different implants used. Bone loss was often registered to the first thread of the Brânemark conical implants and to the rough surface of the ITI implants. The bone loss at Brânemark standard implant was usually seen down to the neck of the implant and the Astra TiO-blast implant, in most cases, presented only minor bone loss. In the early loading group most implants were one-piece implants with a smooth neck. They were often countersunk into the bone at implant placement. Bone loss was in general small, but was higher during the first year in the early loading group (mean of 0.5 mm) compared to the delayed loading group (mean 0.1 mm). The bone loss after the first year was small in both groups with a mean of 0.2 mm between the 1-year follow up and the 5-year follow up. There were few implants showing a bone loss exceeding 0.6 mm from the 1-year to the 5-year follow-up.

**Soft tissue complications**

Soft tissue was registered as healthy at most implants irrespective of attached or non-attached periimplant mucosa (Table 5). Soft tissue complications were rare; periimplantitis was registered in three patients, two in the early loading group and one in the delayed loading group. The distance between the ISFMP and the alveolar crest was different in the
posterior and anterior regions indicating that the recession of soft tissue was higher in the anterior region. Median measured distance in the posterior region was 0.8 mm and 1.3 mm in the front region in both groups, with generally more extreme values in the early loading group.

Table 5. Soft tissue conditions of early loaded and delayed loaded Implant Supported Prostheses

<table>
<thead>
<tr>
<th></th>
<th>Delayed loading</th>
<th>Early loading</th>
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<tbody>
<tr>
<td></td>
<td>Attached</td>
<td>Non-attached</td>
</tr>
<tr>
<td>Healthy</td>
<td>63%</td>
<td>27%</td>
</tr>
<tr>
<td>Inflamed</td>
<td>1.5%</td>
<td>6%</td>
</tr>
<tr>
<td>Suppuration</td>
<td>1.5%</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

Remaking and repair/adjustment of prostheses

Framework fracture was registered in one case. It was the cast titanium framework in the delayed loading group, which fractured within a year and was replaced by a new prosthesis. Due to implant losses and misfit of the prosthesis as a result of improper mounting of impression copings and/or insufficient impressions, three prostheses had to be remade in the early loading group (all titanium frameworks). It was also more common with relining of the prostheses in the early loading group due to shrinking of the soft tissue (Table 6).
Table 6. Complications in number of patients (P) and in number of occasions (O).

<table>
<thead>
<tr>
<th>Type of complication</th>
<th>Early loading (n=44)</th>
<th>Delayed loading (n=40)</th>
<th>Total (n=84)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>P</td>
<td>O</td>
<td>P</td>
</tr>
<tr>
<td>No complication</td>
<td>30</td>
<td>0</td>
<td>30</td>
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<tr>
<td>Loose retaining screw</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Fractured retaining screw</td>
<td>1</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Loose abutment screw</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Fractured abutment screw</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lost composite sealing</td>
<td>7</td>
<td>10</td>
<td>5</td>
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<tr>
<td>Lost acrylic resin teeth</td>
<td>5</td>
<td>9</td>
<td>3</td>
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<tr>
<td>Acrylic fracture</td>
<td>4</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Fracture of framework</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Remake of framework</td>
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<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Relining</td>
<td>4</td>
<td>4</td>
<td>0</td>
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<tr>
<td>Periimplantitis</td>
<td>2</td>
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<td>1</td>
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<tr>
<td>Implant loss before loading</td>
<td>0</td>
<td>0</td>
<td>3</td>
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<tr>
<td>Implant loss after loading</td>
<td>3</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Reoperation</td>
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<td>2</td>
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</tr>
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</table>

The most common complication was fracture of the acrylic/acrylic resin teeth and it was seen more often in the early loading group, seven patients...
with 14 occasions in the early loading group and three patients with three occasions in the delayed loading group. No difference was noticed between the various framework materials. Four patients with cast gold alloy frameworks and four patients with milled titanium frameworks experienced loss of acrylic resin teeth and/or fracture of the acrylic. The need for emergency visits, as well as scheduled appointments after completed treatment was more common in the early loading group compared to the delayed loading group. 3.4 planned and 1.5 unplanned visits compared to 2.1 and 0.9 respectively. The mean time from implant installation to placement of the prosthesis was 13.5 days (range 0-49 days) for the early loading group and 24.5 weeks (range 12-42 weeks) for the delayed loading group. The number of scheduled appointments during the manufacturing of the prosthesis was lower for the former group. Loosening and fracture of retaining and abutment screws were seen in five patients, one patient had recurrent problems with a total of 12 fractured retaining screws during the 5 year follow-up.

**Implant/prosthesis failures**

The survival rate was 96.5% for the implants and 93.2% for the prostheses in the early loading group and 96.7% respective 97.5% in the delayed loading group.
Questionnaire

The questionnaire comprised 16 questions and all of the patients participating in the clinical examination responded. The results indicated that patients treated according to the early loading protocol were more satisfied with the process of manufacturing the prosthesis 82% versus 72% in the delayed loading group. Reasons for this, given by the patients in the early loading group, were such as: 1) not having to wear a temporary prosthesis; 2) not having to be subjected to a second surgery; 3) less time associated with the treatment. Most patients in both groups considered the treatment cost appropriate and they were in general satisfied with the esthetic result. There were no differences in self-reported general health, TMD symptoms, number of drugs used, chewing ability, hygienic, and speech problems. Those patients who reported speech problems had in most cases received a new prosthesis in the maxilla at the time of delivery of the ISFMP.
Discussion

From the originally 111 treated patients, only 84 patients were available for follow-up, corresponding to a participation rate of 76%. Seventy-four percent of the patients not attending the follow-up had either died (63%) or moved from the county (11%). Thus, it was generally “natural” reasons for not attending, which suggests that a bias due to the dropout is probably not to any greater extent introduced in the present result.

The patients in the early loading group had on average been edentulous in the mandible a shorter time prior to surgery. In the delayed loading group 23% of the patients had been edentulous for more than 5 years, the corresponding figure for the early loading group was less than 5 %. All surgery in the early loading group was performed by well trained surgeons having placed more than 500 implants each before the study, except in three cases where less skilled surgeons performed the implant placement. In 13 patients in the delayed loading group, more inexperienced surgeons performed surgery. This may partly be the reason why six implants was placed in some patients to support an ISFMP instead of four implants, which is the standard procedure for routine cases. More implants than four are motivated for instance in patients showing signs of extensive clenching habits or in patients with general health problems (having undergone radiation therapy and/or mandibular reconstruction), due to a higher risk of complications. The same observation, regarding the number of implants
used in the early loading group, was made. Some surgeons, in the present study, used five implants in most of the early loading patients. It can be speculated that this reflects the uncertainty in using fewer implants than the original protocol postulates. When a new method is tried, it is safer to use more implants than perhaps are needed.

Patients with a calculated higher risk of implant failures were in most cases treated according to the delayed loading protocol. However, one patient with diabetes was treated according to the early loading protocol and lost all five implants installed.

Prostheses in the early loading group did not differ from prostheses in the delayed loaded group with regards to number of teeth, length of cantilever and number of supporting fixtures. However, there was a difference in the choice of framework, in that respect that most frameworks in the early loading group were made of titanium and cast gold frameworks were dominating in the delayed loading group. There were slightly more biological and technical complications in the early loading group, a similar reflection was made by Friberg et al. (2005). This could partly be ascribed to the difficulties in adapting the impression copings and making a correct impression directly after surgery with the soreness, bleeding and swelling.

The overall prosthetic survival rate for both groups was 95.4% after a mean observation time of 3.5 years. Divided into early and delayed loading groups, the survival rate was 93.2% and 97.5% respectively. The
corresponding implant survival rate was 96.5% and 96.7%, giving an overall total implant survival rate of 96.6%. These results are in accordance with other studies conducted in a similar manner (Ericsson et al. 2000, Ganeles et al. 2001, De Bruyn 2002, Becker et al. 2003, Henry et al. 2003, Kronström et al. 2003, Lorenzoni et al. 2003, Raghoobar et al. 2003, van Steenberghe et al. 2004, Attard and Zarb 2005).

The most commonly used implant in both groups was the Brånemark Standard implant. The other implant systems were only used to a minor degree, why an adequate comparison was not possible. In spite of this, it could be stated that the mean marginal bone loss at the 1, 3 and 5-year radiographic examination in the present study was similar for both types of rehabilitation concept. Concerning soft tissue condition, no notable differences between the groups could be seen. In general, the gingival status was good and soft tissue pathology was seen in only a few cases. This is in accordance with Åstrand et al. (2004). They evaluated in a 5-year prospective study the effect on bone level changes for Astra Tech and Brånemark implants regarding differences in macro-and micro-design. It was found that bone loss between fixture insertion and baseline was higher than between baseline and the 5-year follow up and that a steady state was reached for both systems after the baseline examination. However, due to the complex interactions between surgically induced trauma, stress distribution, microbiota and host response on the marginal bone loss, the
exact role played by various implant design and surface characteristics is

Although submerging seems to reduce initial bone resorption after implant
installation, bone loss after abutment connection is comparable with non-
submerged implants (Moberg et al. 2001). Other studies implicate slight
improvement in marginal periimplant bone loss for immediate loading
protocols and it is speculated that this could be due to the immediate
transmission of functional forces acting as an osteogenic stimulus. Current
bone biologic knowledge suggests that bone formation is enhanced and
bone density is increased by mechanical stimulation within certain limits
(Lino 2001, Cooper et al. 2002). Another explanation could be that the
trauma of the second operation is avoided by preservation of the biologic
width by means of a more superficial placing of implants (Ericsson et al.

Differences between the two groups were observed regarding
implants/abutments penetrating keratinized or non keratinized gingiva,
probably due to the selection of subjects with more remaining crestal bone
qualifying for early loading. Differences in soft tissue appearance though,
could not be substantiated. This observation is supported by Esposito et al.
(1998) who stated that implants penetrating unattached gingiva were not
associated with gingival lesions and accompanied bone loss, but did
increase the risk of entrapment of food debris and foreign particles with its obvious risks.

The technique with early loading has certain advantages, which were reflected in the questionnaire. The patients were more pleased with the shorter treatment time. This is supported in another study where chair-time between conventional and early loading was compared (Jivraj and Chee 2003). The patients also experienced less discomfort during the manufacturing process than the patients treated according to the original protocol did.

This study shows that early loaded implant supported prostheses in the interforamina area is a predictable treatment with a survival rate of 93.2%. It was shown that there were only minor differences between early and delayed loaded prostheses with regard to implant loss and construction survival. The frequency of mechanical complications was however somewhat higher in the early loading group. In spite of this, patients treated according to the early loading concept were more satisfied than those treated according to the original protocol.

In conclusion, the hypothesis that the concept of early loading has the same predictability as the concept of delayed loading with a 2-step surgical approach was to great extent supported.
Acknowledgement

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