The clinical and radiographic outcome of innovative protocols in implant dentistry.

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GENERAL INTRODUCTION AND OBJECTIVES
General introduction and objectives

Osseointegration is the direct structural and functional connection between living bone and the surface of a load-bearing artificial implant, typically made of titanium. The discovery in the early sixties by Brånemark and his team, that bone was formed in close contact to a Titanium screw, has led to the development of dental implants to be used as a functional intra-osseous anchorage for a variety of dental prostheses in fully or partially edentulous patients. Oral rehabilitation using implant-supported prostheses has been well documented in the dental literature since then. Today, this therapy is widely used in the dental clinic and there is a growing demand from clinicians and patients to optimise the treatment protocols. The evolution since the discovery of osseointegration has led to changes in implant-design, surface configuration, surgical techniques, restorative modalities and improvements in diagnostic techniques and pre-surgical planning tools. The latter have simplified functional and aesthetic treatment with dental implants. There is a consensus that scientific evidence is needed prior to introducing changed implant hardware, components or treatment protocols for daily clinical usage.

There is a growing interest in shortening the healing period after implant installation. The original Brånemark-protocol proposed an extended healing time of 5 to 9 months prior to loading. It was postulated that the surgical site should be left undisturbed to allow the implant to osseointegrate within the surrounding bone. Today it is stated that the early or immediate loading has similar survival rates as the delayed loading protocol when certain clinical criteria are taken into account. Moreover, immediate restoration is advocated to optimise soft tissue healing and aesthetic outcome. Although immediate restoration or loading on implants is a predictable treatment when it comes to survival of the implants, more research is needed to evaluate the marginal bone and mucosal stability around the implants.

Minimizing the surgical flap during implant installation can have advantages for hard and soft tissue healing as well as patient comfort. In a flapless procedure a dental implant is installed through the mucosal tissues without reflecting a flap. This is predominantly of interest for the patient because a flapless procedure reduces post-operative sequellae such as swelling, pain and bleeding. Retrospective studies indicate that implant survival rates obtained with flapless surgery are predictable with an appropriate technique and patient selection. Nevertheless, consequences of flapless surgery on implant position related to the bone anatomy have never been investigated.
When dealing with implant rehabilitation, the use of radiographs is necessary to evaluate the surgical site pre-operatively. A variety of imaging techniques are available for this purpose. Periapical radiographs or panoramic radiographs provide relevant information for standard implant cases. For more complex cases an accurate image of the surgical field in 3 dimensions can be obtained through computerized tomography (CT). When using designed scanning templates, it is possible to visualize both soft and hard tissues on the CT-images for advanced treatment planning. These data can be converted to use with software for three-dimensional modelling and simulation of implant surgery. Computer simulated implant positioning may result in predictable implant placement. Implant location and inclination can be planned according to restorative goals and anatomic limitations. Stereolithographic surgical guides transfer this planning to the surgical field. Before allowing this protocol to be used on an extensive scale, it seems necessary to investigate in a standardised way the implant survival, implant success, peri-implant parameters, patient opinion and aesthetical outcome.

The findings of Brånemark and his team have led to the development of a commercially available turned titanium implant. Enhanced implant surfaces were developed since then to improve predictability with implant treatment. Those are predominantly based on increased surface roughness consequently leading to surface enlargement and increasing bone-to-implant contact area.

New implant designs or components are developed to enhance marginal bone preservation, soft tissue stability or to facilitate surgical or prosthodontic procedures. Moreover, new product developments have also a tremendous commercial impact for the implant companies dictating the clinician and sometimes science seems overrun by commerce. To the benefit of the patient, long-term clinical trials should be carried out before launching a new product on the market. But what happens if an implant company forgets the scientific timeframe to quench its commercial thirst?
Objectives

The overall objective of this thesis is to scrutinise whether recently introduced surgical and restorative protocols are beneficial for the patient and offer a successful treatment outcome.

Hence, the aims of the present thesis are:

1. To describe the changes in implant treatment protocol over the last decades.
2. To evaluate the clinical and radiographic outcome of immediate loading of turned surface and rough surface implants placed in the completely and partially edentulous patient.
3. To evaluate the clinical and radiographic outcome of immediate non-functional loading of rough surface implants placed in single unit edentulous areas of the maxilla.
4. To evaluate in-vitro the position and inclination of implants placed with a free-handed flapless approach.
5. To evaluate the clinical and radiographic outcome of implants placed with a guided flapless approach and immediately restored with a provisional bridge.
6. To evaluate the clinical and radiographic outcome of implants with a novel design.
List of papers

Part of this thesis is published or in preparation as.


Paper V  The impact of implants design on preservation of marginal bone around dental implants. Van de Velde TLA, Collaert B, Sennerby L, De Bruyn H. Clinical Implant Dentistry and Related Research, Accepted for publication.

Paper VI  The immediate provisionalization with a definitive ceramic abutment and an acrylic crown of implants in the aesthetic zone. Van de Velde TLA, De Bruyn H. to be submitted.


Paper VIII  The clinical and radiographic outcome of implants placed with a guided flapless approach and immediately loaded in the posterior maxilla. A randomized clinical trial with a split-mouth design. Van de Velde TLA, De Bruyn H. to be submitted.

GLOSSARY
Glossary

Specific terms commonly used are defined in this glossary for an easy understanding of the content of this thesis.

**Osseointegration** is the direct structural and functional connection between living bone and the surface of a load-bearing artificial implant, typically made of titanium.

Throughout this thesis **implant success** is defined according to the criteria proposed by the European Academy of Periodontology\(^1\). An implant was considered a “**failure**” when it showed individually checked mobility, persistent infection, pain or was removed during the studied interval for any other reason. According to the criteria, all individual implants, exhibiting less than 1.5 mm bone remodelling during the first year of loading and thereafter less than 0.2 mm annually, were considered a “**success**”. Implants, not failing but showing more bone loss are referred to as “**survivals**”.

**One-stage surgery** is an implant procedure to install one or more implants, mounted with healing abutments that act as a healing scaffold for the mucosal tissues that are sutured around the healing abutments for a non-submerged healing.

**Two-stage surgery** is an implant procedure to install one or more implants mounted with cover screws that protect the implant-abutment connection. The mucosal tissues are sutured over the cover screws for a submerged healing of the implants.

**Flapless implant surgery** is an implant procedure to install one or more implants with a minimal invasive approach. The implants are installed without opening a mucosal flap to reduce postoperative swelling and complications.

**Guided implant surgery** is an implant procedure to install one or more implants according to a preoperative plan realised on computer simulation software. The implant procedure is guided by directing the drilling and/or installation of the implants through stereolithographic surgical templates or tactile navigation.

A **stereolithographic (surgical) template** is a surgical guide processed by a computer-assisted design and computer-assisted manufacturing (CAD-CAM) procedure. Stereolithography creates a three-dimensional model by laser-polymerizing acrylic resin layer by layer. The surgical template contains metal guide tubes that accurately direct the drills or implants according to the preoperative designed plan.
**Delayed loading** is an implant procedure with a time frame between implant insertion and prosthesis connection of more than 3 weeks after implant insertion to allow for healing of the peri-implant tissues.

**Early loading** is an implant treatment procedure with a time frame between implant insertion and prosthesis connection of less than 2 months after implant insertion.

**Immediate loading** is a procedure where implants are restored and functionally loaded within 72 hours after implant insertion.

**Surface roughness** of an implant refers to the surface modification to improve predictability with implant treatment based on increased surface roughness consequently leading to surface enlargement and increasing bone-to-implant contact area. Commercial titanium implants are available with a **minimally rough** (Sa< 1 µm), **moderately rough** (1 µm < Sa < 2 µm) or **rough** surface (2 µm < Sa). Implants without a roughened surface are referred to as **turned surface** implants. Roughness can be increased by ablative procedures (acid etching, sandblasting, electrochemical oxidizing) or additive procedures (hydroxyapatite coating, titanium plasma spray coating)

(Sa= arithmetic average height deviation) ADVIES ANN TEKST DOORZOEKEN NR TIUNITE SLA ASTRA...

An **abutment** is an implant component, which is attached to the implant body and functions as the connection between the implant and the prosthesis. An abutment is predominantly screwed on the implant and attaches to the prosthesis in a screw-retained, cement-retained or friction retained manner.

A **prosthesis** is a device to replace and mimic one or more missing teeth and/or oral tissues to restore both oral function and aesthetics. A prosthesis is either removable or fixed and can be tooth-supported, implant supported or a combination of the two. A prosthesis to replace one missing tooth is commonly called a crown, a fixed prosthesis to replace more teeth is called a bridge or fixed partial denture and a removable prosthesis a removable partial or complete denture.
THE CHANGES IN IMPLANT TREATMENT PROTOCOLS OVER THE LAST DECADES

Part of this chapter has been published as:

Van de Velde, T.L.A. & De Bruyn, H.
Evolution from delayed to early loading on Brånemark implants. Clinical implications and case reports.

Van de Velde, T.L.A. & De Bruyn, H.
Immediate loading in the completely edentulous jaw: technical procedures and case reports.
1. THE CHANGES IN IMPLANT TREATMENT PROTOCOLS OVER THE LAST DECADES

1.1 The original surgical two-stage implant protocol

Clinical protocols for placing dental implants were originally developed by Brånemark and co-workers. These investigators carried out an extensive number of studies to improve the success rates of osseointegration with dental implants. During the early stages of their research, one aspect that was thoroughly investigated was loading protocols. It was concluded that shorter healing times or premature loading resulted in non-integration of the implants.

The original Brånemark protocol advocated implant installation in two stages.\(^2\) It was dogmatically believed that after fixture installation the implant had to be covered by mucosa to avoid epithelial down-growth between bone and implants and to minimize the risk for premature loading. In order to allow bone to integrate with the titanium-oxide layer covering the implant surface, it was postulated that an implant needed an extended healing time of 3 months in the mandible and 6 months in the maxilla.\(^3\) Premature loading was thought to compromise the bone remodelling around the recently installed implant resulting in a fibrous encapsulation. Often, the patients were not allowed to wear removable dentures during the first weeks after surgery, to minimize the risk for overloading which could jeopardise osseointegration. In the second-stage surgery the implants were exposed and healing abutments were connected. The prosthodontic procedure was started after another 6-8 weeks healing of the mucosal tissues. In clinical practice this meant a total treatment period of at least 5-6 months in the mandible and 8-9 months in the maxilla. These guidelines, however, were empirically based on clinical experience rather than on knowledge of biological principles. Many clinicians used these healing times in studies and, as such, 3 months in the mandible and 6 months in the maxilla became established as the conventional healing period.

1.2 From two-stage to one-stage surgery

During the last decade there has been a tendency in simplification of the surgical and restorative procedure. Shortening the time frame between implant installation and functional loading has been an important evolution in clinical practice, hence, lowering the barrier for the patient to go for an implant procedure. The first step has been to modify the surgical protocol from a two-stage to a one-stage procedure. After one-stage surgery the implants are perforating the mucosal flaps and mounted with healing abutments that act as a healing scaffold for the mucosal tissues. Several investigators have proposed this non-submerged healing, yet with a mainly stress-free waiting time of 3 months. For this purpose investigators developed an implant specifically to be used for non-submerged healing.\(^4\) After installation the flaps are sutured around the polished neck portion of the implant avoiding the need for a
second stage surgery. Their findings suggested that with one-stage surgery very high success rates could also be obtained.\textsuperscript{5, 6} Henry & Rosenberg\textsuperscript{7} have described the successful use of one-stage surgery in the mandible, yet with a 3 months waiting time before loading, in a group of completely edentulous patients. Ericsson and co-workers\textsuperscript{8} have demonstrated in a split-mouth study on 11 participants that turned surface Brånemark implants installed in a one-stage procedure, albeit functionally unloaded during 3 months, performed identically as implants installed in two stages. Implant survival and bone-to-implant adaptation were comparable in both treatment modalities, both initially and up to 5 years of loading.\textsuperscript{9} This was confirmed for mandibular implants installed for overdenture therapy in the anterior interforamina area\textsuperscript{10} or in the premolar-molar areas of partially edentulous mandibles.\textsuperscript{11, 12} A large-scale follow-up study was conducted at the Center Periodontology Implantology Brussels from 1994 – 2000.\textsuperscript{13} The one-stage approach was retrospectively compared to the two-stage classical approach in completely and partially edentulous mandibular arches. Some patients had some remaining teeth that were extracted during implant installation as shown in case report 1.1, this procedure is called immediate implant placement.

Based on the previously described protocol,\textsuperscript{12} patients treated in the two-stage group were heavy smokers, bruxists, patients with a small interarch distance and patients who wanted to wear their denture day and night. The patients treated in the one-stage group were advised to refrain from denture wearing as much as possible during the 3 months healing period. This was not a problem for the partially edentulous patients, since most of the implants were installed in the premolar-molar areas where the esthetical consequences of having no teeth are less important than in the anterior region. Table 1.1 shows the results of this study.

Table 1.1: Five years survival of turned surface Brånemark implants installed in the mandible in a one- or two-stage surgical procedure for rehabilitation of a complete (CJ) or partial (PJ) fixed implant anchored bridge. Patient number is given between brackets ( ).

<table>
<thead>
<tr>
<th></th>
<th>Implants installed</th>
<th>Implants lost</th>
<th>Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>CJ one-stage</td>
<td>557 (114)</td>
<td>19 (11)</td>
<td>96.8%</td>
</tr>
<tr>
<td>CJ two-stage</td>
<td>211 (42)</td>
<td>5 (4)</td>
<td>97.7%</td>
</tr>
<tr>
<td>PJ one-stage</td>
<td>287 (122)</td>
<td>27 (22)</td>
<td>90.6%</td>
</tr>
<tr>
<td>PJ two-stage</td>
<td>150 (68)</td>
<td>17 (10)</td>
<td>88.6%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1205 (346)</td>
<td>68 (47)</td>
<td>94.3%</td>
</tr>
</tbody>
</table>
Case report 1.1: one-stage surgery and immediate implant placement

A 50-year old female patient had a removable prosthesis in the mandible to restore function in the posterior zone. The prosthesis provoked continuous pain due to pressure on the mental foramen, which was situated on top of the alveolar crest. The ill-fitting denture and the young age of the patient at the time of teeth extractions caused this extreme bone resorption. The alveolar height was insufficient to place implants posterior to the mental foramen and a new removable prosthesis was contra-indicated because of the superficial located mental foramen (figure 1.1a-1.1b). It was decided to remove the anterior teeth, although in good periodontal condition, and to install 4 standard Brånemark implants of 15 mm (figure 1.1c). Extraction of the remaining teeth and installation of the implants were done simultaneously. The alveolar process was lowered and the harvested bone was collected to fill up the space between the implants and the alveolar bone. No bone substitutes or membranes were used (figure 1.1d). The flaps were meticulously sutured around the healing abutments (figure 1.1e). The patient was instructed not to wear her lower dentures and to leave out the upper prosthesis during the night to avoid pressure and non-functional load on the abutments. After 3 months, a fixed 12-unit bridge was mounted on the implants (figure 1.1f). Occlusion was provided on the anterior teeth as well as on the posterior cantilever to spread the occlusal forces equally to all implants. Comparison of the radiographs after 1 year and after 5 years shows stable bone-height, perfectly filled extraction sockets and a good clinical integration of the implants (figure 1.1g-1.1h).

In total 346 referred patients were treated with 1205 turned surface Brånemark implants of various length, design and width. All implants are at least 4 years in function and the total survival rate is 94%, which is in agreement with other clinical studies. There was no statistically significant difference between one- or two-stage approach both for anterior and posterior regions. Marginal bone levels were comparable between the two techniques as seen in table 2 and in line with the bone remodelling data described previously. A steady state in bone remodelling was established after one year of loading with no further statistically significant differences up to 3 and 5 years (table 1.2).
Case report 1.1: one-stage surgery

Patient with lower anterior teeth, which functioned as support for a removable partial denture. Severe atrophy of the posterior mandible.

Four Brånemark fixtures immediately installed in the extraction sockets.

Bone chips harvested from the alveolar crest were used to fill the gap between implants and alveolar bone.

The flaps were meticulously sutured around the healing abutments.

After three months, a fixed 12-unit bridge was mounted on the implants. This cantilever bridge consists of 12 acrylic teeth that are chemically and mechanically bonded on a gold-Palladium suprastructure. Bone remodelling after extraction caused recession around the abutments.

Radiographic image of the implants which are osseointegrated in the alveolar bone. The alveolae are filled with bone after one year in function.

Radiographic image after five years in function: bone height remains stable around the implants.
In a Cochrane review evaluating whether a one-stage implant procedure is as effective as a two-stage procedure it was concluded that the two procedures did not show clinical significant differences. A one-stage procedure might be beneficial as it reduces the number of surgical interventions and the waiting time before providing the final restoration. However, in some clinical situations, for instance when barriers for guided bone regeneration are used in conjunction implants or when primary stability is not achieved, the two-stage approach might be the option of first choice.

It can be concluded from the presented literature and the clinical data that the classical two-stage surgical approach for standard implant installation has similar success rates as the one-stage approach without jeopardising the clinical outcome. In the afore mentioned studies, however, a 3 to 4 months healing period was respected during which the implants were functionally loaded, with no direct occlusion or articulation on the antagonistic teeth. During this healing period, temporary removable prostheses are often used to restore function and aesthetics. This approach can sometimes lead to complications or even implant failures, especially attributed to overloading of single standing short (<10 mm long) fixtures. Primary stability and lack of micro-movements during the healing phase are considered to be two of the main prerequisites for successful osseointegration of dental implants. Hence, rigid provisional connection of the implants might, in those cases, be an option to reduce the risk for premature overloading. Case report 1.2 shows a failure of a short implant because of overloading.

**Table 1.2:** Average bone remodelling around turned surface Brånemark implants installed in the mandible in a one- or two-stage procedure. Complete bridges on 4-6 implants (CJ) and partial bridges (PJ) on 1-4 implants in premolar-premolar area were evaluated. Comparative measurements on 10 consecutively treated patients up to 5 years in function.

<table>
<thead>
<tr>
<th></th>
<th>0-1 year</th>
<th>0-3 years</th>
<th>0-5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CJ one-stage</strong></td>
<td>0,23 mm</td>
<td>0,35 mm</td>
<td>0,35 mm</td>
</tr>
<tr>
<td><strong>CJ two-stage</strong></td>
<td>0,35 mm</td>
<td>0,60 mm</td>
<td>0,83 mm</td>
</tr>
<tr>
<td><strong>PJ one-stage</strong></td>
<td>0,15 mm</td>
<td>0,26 mm</td>
<td>0,42 mm</td>
</tr>
<tr>
<td><strong>PJ two-stage</strong></td>
<td>0,02 mm</td>
<td>0,20 mm</td>
<td>0,39 mm</td>
</tr>
</tbody>
</table>
1.3 From one-stage to early loading

One of the fundamental factors for successful osseointegration is the stability of the implant during the healing phase such that any motion at the bone-to-implant interface is below a critical threshold.\textsuperscript{19} If the micro-motion at the bone-to-implant interface is kept below 150 microns, implants seem to integrate with a predictable outcome.\textsuperscript{20} Hence, the crucial factor is not the timing of loading but the capability to minimize movements of the implants during the healing phase. One of the main problems after one-stage surgery is the risk of a provisional removable prosthesis applying overload on the newly installed implants. Investigators have proposed to change the delayed loading protocols and started to rigidly splint implants shortly after implant installation. Early loading means that the implants are installed with a one-stage approach and functionally loaded within 2 months.\textsuperscript{21} There is sufficient evidence for good clinical results with early loading on turned surface Brånemark implants installed in the anterior mandible. Randow and co-workers\textsuperscript{22} have treated 16 completely edentulous mandibles using a one-stage procedure and early loading within 3 weeks with a fixed rigid prosthetic reconstruction on 5-6 implants. In comparison with a control group of 11 patients treated with the conventional two-stage procedure and loading after 4 months, they reported similar results regarding implant success and marginal bone levels after 18-36 months. No further complications occurred over a 5 years period of loading and bone resorption was found to be within the same range in both procedures.\textsuperscript{16} Tawse-Smith\textsuperscript{23} compared two early loaded with two conventionally loaded implants supporting an overdenture in the edentulous mandible. There were no statistically significant differences for prosthesis failures, implant failures and marginal bone levels between the different loading groups. Malo and co-workers\textsuperscript{24} have recently shown 96% of implant survival in a study whereby partial bridgework in the aesthetical zone of both maxilla and mandible was functionally loaded with a provisional prosthesis shortly after implant surgery. The prostheses were free of occlusion and articulation for 5 months and then replaced by the final restoration. They reported a small number of complications, however, not differing in character from those normally encountered with conventional implant treatment.

In a study of De Bruyn and Collaert\textsuperscript{25} a total of 184 turned surface titanium implants (Nobel Biocare Gothenburg Sweden) of various length (7-18mm), width (3.75-5.0 mm) or screw design (standard, MK II, MK III, MK IV) were inserted in completely edentulous mandibles. The diameter 3.75 mm implant was the first choice implant but in 15% of the sites wider 4 or 5 mm implants were needed to obtain optimal initial stability. An insertion torque value of 40 Ncm was considered a prerequisite for early loading. Implants were positioned predominantly between the mental foraminae and only 9 implants (5 patients) were positioned posterior to the mental foramen.
Case report 1.2: radiological changes in a full case with one-stage surgery and delayed loading during five years of follow-up

Figure 1.2a: Six months after surgery (June 1996) the short implant showed pronounced bone loss but without clinical signs of infection. Because the patient refused to have the implant removed, it was connected to a provisional bridge, but kept out of functional loading. The black arrow indicates the implant-abutment interface and the red arrow indicates the abutment-prosthesis interface.

Figure 1.2b: Ten months later (May 1997) the bone-to-implant adaptation remained stable and a final bridge was made with occlusal loading. Black arrows indicate the marginal bone level evaluated on the radiograph.

Figure 1.2c: Eight months after functional loading (January 1998) further bone loss was seen.

Figure 1.2d: Another 10 months (October 1998) later the implant completely exfoliated and was removed.
Abutments of various types were connected immediately after implant installation and an impression was taken either immediately or within 1 week at the time of suture removal. The prosthodontic treatment was done by the referring dentists and finished on average 18 days after surgery. The majority of the prostheses were of the typical Brånemark bridge design with 1.5-2 cm long cantilevers posterior to the most distally located implants. Opposing dentures, when present, were renewed or remounted. Implant stability was checked clinically after removal of the reconstruction after 12 and 24 months of loading. The prostheses were not removed routinely after this initial period. Periapical radiographs were taken with long-cone technique immediately after prosthesis connection and further yearly to assess bone to implant contact. Thirteen out of 184 (7.1%) implants failed within 3 months of loading in 5 out of 36 patients: 1 out of 153 implants (0.7%) failed in healed bone, and 12 out of 31 failed in fresh extraction sites. This consequently meant a loss of 3 out of 36 prostheses, all in the extraction group. The average marginal bone level measured initially and after 1, 2, and 3 years was 0.8 mm (SD = 0.5), 1.0 mm (SD = 0.4), 1.1 mm (SD = 0.3), and 1.4 mm (SD = 0.5), respectively. This reflects a normal bone remodelling during function, a normal biological phenomenon related to healing of the peri-implant tissues after piercing the gingival tissues.

It was concluded that early loading of a fixed jaw anchored restoration on 4-6 turned surface Brånemark implants in completely edentulous mandibular bone is a predictable treatment option in healed bone. This is in accordance with other studies using the same approach and the same implants and comparable with the classical two-stage delayed treatment protocol. Immediate installation of turned surface implants after extraction and early loading yields more failures and seems to be unpredictable.

1.4 From early to immediate loading

Immediate loading has been introduced as an innovative technique in the early 90’s. In many cases, patients are not satisfied with a transition period of wearing a temporary removable prosthesis after implant surgery. Therefore, there was a growing interest in shortening the time frame between implant installation and functional loading of the prosthesis. It has now been acknowledged that early and immediate loading can provide similar results as the classical one- or two-stage delayed loading protocols if certain criteria are fulfilled.

1.4.1 Success rate of immediate loading

Schnitman and co-workers have published 10 years results of 28 one-stage immediately loaded implants and reported 4 out of 28 failures compared to no failures with a two-stage surgery and loading after a healing period of 3 to 4 months. However, the lost implants were
only 10 mm long and supported extensive restorations. They concluded that more research was needed to obtain a good long-term prognosis for implants distal to the anterior region of the mandible. Several other prospective studies reported survival rates of 91.4-100% for immediately loaded implants when rigidly connected to restore completely edentulous mandibles (table 1.3). 7, 28-38

Table 1.3: Prospective studies on immediate loading in the completely edentulous mandible.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Implant surface</th>
<th>Number of patients/implants</th>
<th>Follow-up period (years)</th>
<th>Implant survival rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Henry &amp; Rosenberg (1994)</td>
<td>Turned titanium, Brånemark implants</td>
<td>5/20</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td>Chow et al. (2000)</td>
<td>Turned titanium, Brånemark implants</td>
<td>27/123</td>
<td>2.5</td>
<td>98.3</td>
</tr>
<tr>
<td>Colomina (2001)</td>
<td>?</td>
<td>13/61</td>
<td>1.5</td>
<td>96.7</td>
</tr>
<tr>
<td>Hatano et al. (2003)</td>
<td>Turned titanium, Brånemark implants</td>
<td>43/129</td>
<td>0.25-4</td>
<td>97.6</td>
</tr>
<tr>
<td>Nikellis et al. (2004)</td>
<td>Sand-blasted, acid-etched, Southern implants</td>
<td>10/51</td>
<td>1-2</td>
<td>100</td>
</tr>
<tr>
<td>Testori et al. (2004)</td>
<td>Acid-etched, 3i</td>
<td>62/325</td>
<td>1.5</td>
<td>99.4</td>
</tr>
<tr>
<td>Degidi &amp; Piatelli (2005)</td>
<td>Grit blasted, acid etched, IMZ</td>
<td>6/43</td>
<td>7</td>
<td>100</td>
</tr>
<tr>
<td>Glauser et al. (2005)</td>
<td>Oxidized, Ti-Unite, Brånemark implants</td>
<td>1/5</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>Ibanez et al. (2005)</td>
<td>Double acid-etched, Osseotite, 3i</td>
<td>7/126</td>
<td>1-6</td>
<td>100</td>
</tr>
<tr>
<td>Becktor et al. (2007)</td>
<td>Turned titanium, Brånemark implants</td>
<td>38/198</td>
<td>3</td>
<td>91.4</td>
</tr>
<tr>
<td>Van de Velde et al. (2007)</td>
<td>Turned titanium/ oxidized, Ti-Unite, Brånemark implants</td>
<td>18/91</td>
<td>2-3</td>
<td>96.7</td>
</tr>
<tr>
<td>De Bruyn et al. (2008)</td>
<td>Grit blasted, acid etched, TiOblast, Astra</td>
<td>25/125</td>
<td>3</td>
<td>100</td>
</tr>
</tbody>
</table>

? data not specified

Fewer reports are available evaluating the success of immediately loaded implants in the completely edentulous maxilla. However, some prospective studies reported lower survival rates ranging from 83.3% to 100% (table 1.4). 31, 35, 39-43
Table 1.4: Prospective studies on immediate loading in the completely edentulous maxilla.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Implant surface and name</th>
<th>Number of patients/implants</th>
<th>Follow-up period (years)</th>
<th>Implant survival rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grunder (2001)</td>
<td>Double acid-etched, Osseotite, 3i</td>
<td>5/48</td>
<td>1-2</td>
<td>100</td>
</tr>
<tr>
<td>Jaffin et al. (2004)</td>
<td>Sand-blasted, large grid, acid-etched, Straumann</td>
<td>34/236</td>
<td>1</td>
<td>92,3</td>
</tr>
<tr>
<td>Nikellis et al. (2004)</td>
<td>Sand-blasted, acid-etched, Southern implants</td>
<td>14/85</td>
<td>1-2</td>
<td>100</td>
</tr>
<tr>
<td>van Steenberghe et al. (2004)</td>
<td>Oxidized, Ti-Unite, Brånemark implants</td>
<td>8/?</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Ibanez et al. (2005)</td>
<td>Double acid-etched, Osseotite, 3i</td>
<td>7/217</td>
<td>1-6</td>
<td>100</td>
</tr>
<tr>
<td>Degidi &amp; Piatelli (2005)</td>
<td>Grit blasted, acid etched, IMZ</td>
<td>1/12</td>
<td>7</td>
<td>83,3</td>
</tr>
<tr>
<td>Ostman et al. (2005)</td>
<td>Oxidized, Ti-Unite, Brånemark implants</td>
<td>20/123</td>
<td>1-3</td>
<td>99,6</td>
</tr>
<tr>
<td>Bergkvist et al. (2008)</td>
<td>Sand-blasted, large grid, acid-etched, Straumann</td>
<td>28/168</td>
<td>2,5</td>
<td>98,2</td>
</tr>
<tr>
<td>Tealdo et al. (2008)</td>
<td>?</td>
<td>21/111</td>
<td>1-2</td>
<td>92,8</td>
</tr>
</tbody>
</table>

? data not specified

Studies on immediate loading of implants in multi-unit situations in the partially edentulous mandible\textsuperscript{31, 33, 34, 44-46} or maxilla\textsuperscript{31, 33, 44-47} are summarised in table 1.5. Implant survival rates ranged from 88,5 to 100% in the maxilla and from 91,3 to 100% in the mandible. Degidi & Piatelli\textsuperscript{46} compared immediate functional loading with immediate non-functional loading in the partially edentulous mandible. They concluded that the survival rates dropped from 100% to 92,3% when the implants were loaded immediately after installation. This illustrates the importance of reducing micro-movements at the bone-to-implant interface during healing of newly installed implants. When the occlusal load is too high on the provisional restoration (even when splinted to each other) the healing is disturbed resulting in a non-integration of the implant(s).
### Table 1.5: Prospective studies on immediate loading in multi-unit situations of the partially edentulous patient.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Jaw</th>
<th>Implant surface and name</th>
<th>Number of patient(s)/implants</th>
<th>Follow-up period (years)</th>
<th>Implant survival rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vanden Bogaerde et al. (2003)</td>
<td>Mandible</td>
<td>Turned titanium, Brånemark implants</td>
<td>19/56</td>
<td>1.5</td>
<td>96.4</td>
</tr>
<tr>
<td>Vanden Bogaerde et al. (2003)</td>
<td>Maxilla</td>
<td>Turned titanium, Brånemark implants</td>
<td>14/45</td>
<td>1.5</td>
<td>95.6</td>
</tr>
<tr>
<td>Nikellis et al. (2004)</td>
<td>Mandible</td>
<td>Sand-blasted, acid-etched, Southern implants</td>
<td>14/37</td>
<td>1-2</td>
<td>100</td>
</tr>
<tr>
<td>Glauser et al. (2005)</td>
<td>Mandible</td>
<td>Oxidized, Ti-Unite, Brånemark implants</td>
<td>20/51</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>Glauser et al. (2005)</td>
<td>Maxilla</td>
<td>Oxidized, Ti-Unite, Brånemark implants</td>
<td>10/26</td>
<td>4</td>
<td>88.5</td>
</tr>
<tr>
<td>Calandriello &amp; Tomatis (2005)</td>
<td>Maxilla</td>
<td>Turned titanium, Brånemark implants</td>
<td>11/26</td>
<td>1</td>
<td>100</td>
</tr>
</tbody>
</table>

* data not specified
Most studies concerning immediate loading of single tooth implants applied a fixed provisional restoration out of occlusion and placed immediately after surgery. Implant survival rates of 96.4% to 100% are reported (table 1.6). However, little is known about the long-term outcome in aesthetically demanding cases. The currently available papers report implant survival or success rates but not the aesthetical outcome of a single-tooth implant, which is determined by a stable and harmonious soft and hard tissue reconstruction. The influence of immediate provisionalization with different implant components or dental materials on the stability of the peri-implant tissues is still unclear. A study of Proussaefs & Lozada described the mucosal dimensions around hydroxyapatite-coated implants placed in premolar sites and immediately loaded with a screw retained provisional acrylic resin crown. They revealed that the distance from the implant shoulder to the gingival crevice remains stable up to 36 months (2.8, 2.4, 2.4 and 3.1 mm at 3, 6, 12 and 36 months after surgery). However, nothing is mentioned about the appearance of the single-tooth restoration in harmony with the neighbouring natural teeth.

We can conclude that prospective studies in the current literature using several different techniques for immediate loading of dental implants have demonstrated high survival and success rates (for a review: 26, 59-62). Unfortunately in some studies, bone or mucosal level data are sometimes lacking or reported inconsistently. In a Cochrane review evaluating the clinical outcome of dental implants loaded at different times after implant insertion, the authors conclude that it is possible to load implants immediately after insertion in selected patients. This means that implants, loaded immediately after surgery, are successful if certain surgical, prosthodontic and psychological criteria are fulfilled.
<table>
<thead>
<tr>
<th>Authors</th>
<th>jaw</th>
<th>Implant surface and name</th>
<th>Number of patients/implants</th>
<th>Follow-up period (years)</th>
<th>Implant survival rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wörle (1998)</td>
<td>Maxilla</td>
<td>Acid-etched titanium plasma-sprayed or HA-coated, Replace implants</td>
<td>14/14</td>
<td>1-3</td>
<td>100</td>
</tr>
<tr>
<td>Ericsson et al. (2000)</td>
<td>Mandible</td>
<td>Turned titanium, Brånemark implants</td>
<td>3/3</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Ericsson et al. (2000)</td>
<td>Maxilla</td>
<td>Turned titanium, Brånemark implants</td>
<td>11/11</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Hui et al. (2001)</td>
<td>Maxilla</td>
<td>Turned titanium, Brånemark implants</td>
<td>24/24</td>
<td>0-1</td>
<td>100</td>
</tr>
<tr>
<td>Proussaefs et al. (2002)</td>
<td>Maxilla</td>
<td>HA-coated, Replace implants</td>
<td>10/10</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Andersen et al. (2002)</td>
<td>Maxilla</td>
<td>Titanium plasma-sprayed, Straumann implants</td>
<td>8/8</td>
<td>5</td>
<td>100</td>
</tr>
<tr>
<td>Cannizzaro &amp; Leone (2003)</td>
<td>Mandible</td>
<td>Microtextured, Spline Twist MTX</td>
<td>2/2</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td>Cannizzaro &amp; Leone (2003)</td>
<td>Maxilla</td>
<td>Microtextured, Spline Twist MTX</td>
<td>3/3</td>
<td>2</td>
<td>100</td>
</tr>
<tr>
<td>Kan et al. (2003)</td>
<td>Maxilla</td>
<td>HA-coated, Replace implants</td>
<td>35/35</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Lorenzoni et al. (2003)</td>
<td>Mand/ max</td>
<td>Grit blasted, acid etched, Frialitt-2</td>
<td>12/12</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Cornelini et al. (2004)</td>
<td>Mand/ max</td>
<td>Sand-blasted, large grid, acid-etched, Straumann</td>
<td>30/30</td>
<td>1</td>
<td>96,7</td>
</tr>
<tr>
<td>Nikellis et al. (2004)</td>
<td>Mand/ max</td>
<td>Sand-blasted, acid-etched, Southern implants</td>
<td>2/2</td>
<td>1-2</td>
<td>100</td>
</tr>
<tr>
<td>Glauser et al. (2005)</td>
<td>Mandible</td>
<td>Oxidized, Ti-Unite, Brånemark implants</td>
<td>?/8</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>Glauser et al. (2005)</td>
<td>Maxilla</td>
<td>Oxidized, Ti-Unite, Brånemark implants</td>
<td>12/12</td>
<td>4</td>
<td>100</td>
</tr>
</tbody>
</table>

? data not specified
1.4.2 Techniques for immediate loading

Besides less discomfort for the patient, a shortening of treatment time and a reduction in chair time and post-operative care, immediate loading has a remarkably positive psychological impact.\textsuperscript{63} It is possible to obtain a predictable outcome with the immediate loading of dental implants, although not all clinicians may achieve optimal results. A high degree of primary implant stability (high value of insertion torque) seems to be one of the prerequisites for a successful immediate/early loading procedure.\textsuperscript{26} Modifications in implant design, the use of longer implants and altered surgical techniques can contribute to a better implant primary stability. For this purpose it is advised to adapt the surgical preparation (under-preparing) of the implant bed according to the bone quality. However, care should be taken to avoid over-compression as this could result in additional bone resorption and even loss of integration. Changes in implant surface predominantly based on increased surface roughness and consequently leading to surface enlargement, increases the healing response at the bone-to-implant interface. This reduces the healing time before an implant becomes integrated and thus the risk for premature overloading.

It is important to install the prosthesis as soon as possible after surgery because it reduces post-operative pain and overcomes with overnight swelling which jeopardizes easy positioning of the implant bridge. The main problem in providing immediate loading is the time needed to process the prosthesis in the dental laboratory. Several authors have reported practical ways to cope with this problem. The Novum\textsuperscript{\textregistered} procedure (Nobel Biocare, Gothenburg, Sweden) introduced precision-fit surgical and prosthetic templates to guide 3 wide body implants loaded the same day with a hybrid prefabricated prosthesis.\textsuperscript{64, 65} The one-year results reported an overall implant survival of 98\%\textsuperscript{66} but after 3 years this dropped to 91\%.\textsuperscript{41} The main disadvantage of this technique is that the alveolar crest has to be adapted to fit with the standard templates, often by surgically reducing bone height. Comparable implant failure of 9\% and prosthetic failure of 15\% were reported when 3 turned surface Brånemark implants were loaded with a fixed bridge within 1 week after surgery.\textsuperscript{67} Consequently, the clinical outcome of these minimal concepts based on 3 supporting implants is significantly lower than results obtained with conventionally loaded bridges supported on 4-6 implants probably because of implant overloading. Another clinical method to provide immediate loading is based on the pick-up technique\textsuperscript{68, 69} described elsewhere as the Hong Kong Bridge protocol.\textsuperscript{28} In a denture conversion technique, temporary abutments are placed and a prefabricated prosthesis is adjusted to fit around the abutments by means of autopolymerizing cold-curing resin.\textsuperscript{70, 71} Several implant companies have recently introduced prosthetic technical parts to allow an easy and quick chair-side denture conversion for immediate loading procedures.\textsuperscript{72} Although some implant components appear promising to solve some practical issues, little is known about their long-term prognosis or influence on peri-implant tissues.
1.5 Flapless surgery: freehanded versus guided implant surgery

There is a growing interest to install implants with a minimally invasive approach without exposing the bone by flap manipulation. Fortin and co-workers\(^73\) demonstrated minimal post-operative complications with flapless surgery and patients reported less pain and needed less pain-killers than those conventionally treated. Moreover, the patients heal with minor or no swelling.\(^74\)

A retrospective study of Rocci and co-workers\(^75\) evaluated implants placed in the maxilla using flapless surgery. These implants were placed in predetermined positions and loaded with prefabricated provisional restorations. A cumulative success percentage of 91% was reported after 3 years of function. Failures occurred in smokers, implants placed in soft bone and single tooth replacements. Since flapless surgery is generally “blind” surgery, care must be taken to place the implants in a correct position. Little is known about implants placed with a freehanded flapless approach and their positioning within the alveolar bone. Campelo and Camara\(^76\) reported on the critical surgical procedure and the negative effect of perforations of the buccal or lingual cortical plates. Their cumulative success rates of 74.1% for implants placed in 1990 and 100% for implants placed in 2000 are indicative of the learning curve typically to start using a new technique.

Intra-operative navigation or stereolithographic templates can offer an extra dimension to the “blind” flapless surgical procedure; this is generally referred to as (computer) guided implant surgery. Anatomic limitations and bone quantity can now be precisely evaluated using 3D radiographic techniques (e.g., computed tomography (CT) technology). Implant-placement-simulation software allows to virtually plan the ideal implant position preoperatively. By means of stereolithographic rapid prototyping, surgical templates are constructed that transfer the pre-operative implant planning to the patient in pre-determined positions with high accuracy.\(^77\)\(^-\)\(^79\) A study of Sarment and co-workers\(^80\) reported a higher accuracy obtained with guided implant surgery compared to conventional surgery. The accuracy of guided surgery is generally measured based on the virtual fusion of the preoperative planning and a postoperative CT. Several investigators reported about the accuracy of guided surgery using stereolithographic templates (Table 1.7).\(^80\)\(^-\)\(^84\)

With a meticulous planning, it is possible to prefabricate a provisional prosthesis, which requires only minimal adjustments after guided implant installation.
Table 1.7: Accuracy of implant guided surgery using stereolithographic templates. These templates can either be bone supported or tooth/mucosa supported for flapless surgery.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Support</th>
<th>deviation implant shoulder (mm)</th>
<th>deviation implant apex (mm)</th>
<th>Implant type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Van Steenberghe et al. (2003)</td>
<td>bone</td>
<td>0.1- 4.67</td>
<td>0.12- 6.74</td>
<td>zygoma</td>
</tr>
<tr>
<td>Sarment et al. (2003)</td>
<td>bone</td>
<td>0.9</td>
<td>1.0</td>
<td>dental</td>
</tr>
<tr>
<td>Vrielinck et al.(2003)</td>
<td>bone</td>
<td>2.8</td>
<td>4.5</td>
<td>zygoma</td>
</tr>
<tr>
<td>Vrielinck et al.(2003)</td>
<td>bone</td>
<td>1.51</td>
<td>3.07</td>
<td>dental</td>
</tr>
<tr>
<td>Vrielinck et al.(2003)</td>
<td>bone</td>
<td>3.57</td>
<td>7.77</td>
<td>pterygoid</td>
</tr>
<tr>
<td>Di Giacomo et al. (2005)</td>
<td>bone</td>
<td>1.45</td>
<td>2.99</td>
<td>dental</td>
</tr>
<tr>
<td>Van Assche et al. (2007)</td>
<td>Tooth/mucosa</td>
<td>1.1</td>
<td>1.2</td>
<td>dental</td>
</tr>
</tbody>
</table>

At present, several commercial systems are available to allow flapless implant surgery and immediate loading by means of a drill template. However, the outcome of such procedures has shown varying results in implant (83-100%) and prosthetic survival rate (70-100%)(table 1.8). This is mainly caused by the deviations between the preoperative and postoperative implant location. The prefabricated prosthesis is adapted from the preoperative plan but not 100% accurately transferred to the surgical field. Hence, more research seems warranted to refine this promising surgical and prosthodontic procedure.

Table 1.8: Implant survival rates (%), prosthetic survival rates (%) and complications encountered during guided flapless surgery by means of a drill template followed by immediate loading.

<table>
<thead>
<tr>
<th>Study</th>
<th>Implant survival rate</th>
<th>Prosthetic survival rate</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balshi et al. 2008</td>
<td>97.60%</td>
<td>100%</td>
<td>1.2% misfit</td>
</tr>
<tr>
<td>Komiyama et al. 2008</td>
<td>89 % (maxilla: 92%-mandible: 83%)</td>
<td>83.8% (maxilla: 90%-mandible: 70%)</td>
<td>42% surgical &amp; technical</td>
</tr>
<tr>
<td>Yong et al. 2008</td>
<td>89.80%</td>
<td>79.60%</td>
<td>Surgical &amp; technical</td>
</tr>
<tr>
<td>van Steenberghe et al. 2005</td>
<td>100% (maxilla)</td>
<td>100% (maxilla)</td>
<td>Surgical &amp; technical</td>
</tr>
<tr>
<td>Rocci et al. 2003</td>
<td>91% (maxilla)</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
</tbody>
</table>
Chapter II

IMMEDIATE LOADING IN COMPLETELY AND PARTIALLY EDENTULOUS JAWS

Part of this chapter has been published/submitted as:

Van de Velde, T.L.A., Collaert, B., De Bruyn, H.
Immediate loading in the completely edentulous mandible: technical procedure and clinical results up to 3 years of functional loading.

De Bruyn, H., Van de Velde, T.L.A., Collaert, B.
Immediate functional loading of TiOblast dental implants in full-arch edentulous mandibles: a 3-year prospective study.

Van de Velde, T.L.A., Collaert, B., De Bruyn, H.
Effect of implant surface or microthread design on preservation of peri-implant bone in the mandible.
Clinical Implant Dentistry and Related Research, Accepted
2.1 Immediate loading in the completely edentulous mandible

2.1.1 Introduction and objectives

Over the last decades the average age of the population increased. This evolution has led to changes in dental care and altered treatment options for the elderly. Many edentulous patients suffer from severe atrophy of the maxilla and/or the mandible due to a long period of ongoing bone resorption associated with denture wearing. The resorption rate of the mandibular bone is approximately 4 times higher than the bone of the maxilla. Therefore, most problems in denture wearers occur predominantly in the lower jaw of which instability and lack of retention of the prosthesis are the major complaints. Hence, implant therapy has originally been developed to relieve edentulism in the mandible.

The use of dental implants in overdenture treatment has proven to be of great benefit. Long-term studies report on very high survival rates and patient’s satisfaction. The McGill consensus statement suggests that for the restoration of the edentulous mandible, a two-implant retained overdenture should be the first choice treatment. Many patients, however, require more denture stability or prefer the comfort of a fixed implant supported bridge. The original Brånemark-protocol, advocated a healing time of 5 to 9 months prior to loading in order to achieve sufficient osseointegration. Today there is evidence that early and immediately loaded implants in the mandible can have similar survival rates as delayed loaded implants.

Two studies will be described in this section reporting the clinical and radiographic outcome of immediately loaded turned and rough surface Brånemark implants (study 1) and moderately rough surface Astra Tech implants (study 2) placed in the completely edentulous mandible.

2.1.2 Immediate loading in the completely edentulous mandible: clinical and technical procedures

2.1.2.1 Planning procedure

Panoramic radiographs were used for patient’s inclusion and the referring dentists were asked to provide a model based planning with a wax set-up of the mandibular teeth in central occlusion with the antagonists. Patients with a complete removable maxillary denture received a new denture when considered necessary for functional and/or aesthetical purposes. Based on this tooth set-up, a surgical guide to be used during implant installation was made by the dental technician (case 2a). This guide was used for correct implant positioning, as impression tray and for simultaneous occlusal bite registration (case 2b). The surgical guide therefore
contained thin buccal flanges of denture teeth (Vitapan 3D-master, Vita Zahnfabrik Bad Säckingen, Germany) and provided enough space for the drilling procedure (case 2c) and the impression copings (case 2d). It can be positioned in the exact jaw-relationship as determined by the dentist after checking the occlusion and the aesthetical appearance. In order to provide extra stability during the surgical procedure, care was taken to include an extended additional alveolar support on the retromolar area including also an easy repositioning into central occlusion. The intention was also to use the provisional teeth of the guide plate into the provisional bridge.

2.1.2.2 Clinical procedure
Surgical treatment was performed under local anaesthesia and none of the patients received a sedative or antibiotic prophylaxis prior to surgery. A crestal incision was made to raise a full thickness muco-periosteal flap. Implants (4-6) were installed according to the manufacturer’s guidelines and located intentionally in the anterior mandible between the mental foraminae. An attempt was made to install the longest fixture possible. The appropriate impression copings were connected to the abutments or fixtures and the gingival tissues were sutured around these copings in order to avoid impression material abundantly in contact with the alveolar bone (case 2e). A polyether impression (Impregum Penta Soft, 3M ESPE AG, Seefeld, Germany) was taken with the surgical guide after closing the gap with wax and registration of the bite according to the planned position (case 2f-g). Implant or abutment analogues were connected to the impression copings and repositioned in the impression tray (case 2h). Healing abutments were connected on the fixtures or abutments after the impression was taken to avoid collapse of the gingival tissues and in order to close the flap and stop the bleeding. Patients received a post-surgical analgetic (Ibuprofen 400 mg or paracetamol 500 mg) and were supplied with an ice-pack to reduce post-surgical swelling.

2.1.2.3 Laboratory procedure
A 10-unit provisional bridge was manufactured in the dental laboratory. A glassfiber-polymethylmethacrylate mesh (Sticktech, Sticktech Ltd Oy, Turku Finland) was placed lingually to the cylinders for reinforcement of the autopolymerisation resin (Biodent® K + B Plus, Dentsply USA) that was poured between the remaining acrylic teeth and the lingual flange of the surgical guide plate. After heat pressuring during one hour, the dimension of the prosthesis was adjusted. The occlusal contacts were evenly distributed on all teeth including the teeth on the cantilevers, which were maximal one tooth long to minimize the risk for fractures.
Case report 3: Immediate loading in the edentulous mandible

3a: Pre-surgical planning: The guide plate is positioned in centric occlusion with the complete upper removable denture.

3b: The surgical guide contains the teeth-position, space for the impression material and can be positioned in the exact occlusion. There is sufficient palatal support to keep the guide in place during surgery and impression. An extension distal of the first molar is fabricated to verify the occlusion during surgery. The resin teeth are incorporated in the provisional prosthesis after surgery.

3c: Brånemark implants are installed according to the manufacturer’s guidelines. The surgical guide assists to install the implants in a position for enhanced loading support.

3d: The impression copings are installed verifying there is no interference with the impression tray.

3e: The mucoperiosteal flap is sutured around the impression copings in order to avoid impression material abundantly in contact with the alveolar bone.

3f: Impression paste is applied around the impression copings and in the tray, leaving the dorsal saddle ends free to avoid increase of the vertical dimension.

3g: The impression and the bite-registration are completed in one single procedure.

3h: Implant analogues are connected to the impression copings by the surgeon and sent to the lab to create a working model.

3i: Occlusal view of the temporary fixed provisional prosthesis delivered the same day as surgery.

3j: Frontal view of the temporary fixed provisional prosthesis in centric occlusion with the complete upper removable denture.

3k: Composition of apical radiographs 1 year after loading showing a porcelain-fused-to-metal bilateral extension-bridge on 5 implants.
2.1.2.4 Placement of the provisional bridge
Within 6 hours after finalizing the surgery, the provisional bridges were installed and torqued according to the manufacturer’s guidelines (case 2i). Minor adjustments were needed in order to achieve maximal occlusal contacts and bilaterally balanced group function in articulation was aimed for (case 2i).

2.1.2.5 Postoperative care
The patients were instructed to brush the provisional bridge from the day of surgery with a very soft toothbrush (Special care, Tepe, Malmö, Sweden) and given the advice to rinse with chlorhexidine 0.12% (PerioAid, Dentaid Spain). No special dietary advice was given. The patients were given ibuprofen 400mg or Paracetamol 500 mg after surgery, to be taken at their own discretion. After 1 week the sutures were removed. For this purpose and for wound inspection and disinfection, the bridges were removed and retightened with the recommended torque values. Oral hygiene was reinstructed with the soft manual toothbrush and additionally with appropriate sized interdental brushes (Tepe, Malmö, Sweden). Patients were recalled at 1, 2 and 3 months for clinical inspection and when necessary oral hygiene reinstruction was given. After 3 months the bridges were unscrewed and the implants were individually checked for clinical mobility, pain or infection.

2.1.2.6 Placement of the final bridge and recall
Abutments were retightened to prescribed torque values before replacing the bridge and the patient was then referred to the general dentist for final prosthodontic reconstruction. The provisional and final prosthesis were fabricated by several dentists but with the same dental laboratory according to a standard protocol. After finalizing the prosthodontic work, the patients were seen by the surgeons to double-check occlusion and articulation, to torque the bridge-screws as recommended and to reinforce oral hygiene measures. Patients were furthermore included in an individual recall program for regular professional maintenance at a 6 to 12 months interval. Supragingival scaling was performed and when necessary the prosthetic construction was unscrewed for this purpose. Oral hygiene reinstruction was given whenever considered necessary.
2.1.3 Immediate loading in the completely edentulous mandible: materials and methods

2.1.3.1 Materials and methods of study 1: Brånemark implants

Patients

From March 2001 to October 2003, 18 patients were consecutively treated. They were referred by 15 clinicians to the Center of Periodontology and Implantology Brussels for implant treatment in the edentulous mandible to allow a fixed cross-arch restoration. The patients were required to be healthy and to have adequate bone for the placement of 4 to 6 implants (Brånemark, Nobel Biocare, Göteborg Sweden) of 13-15 mm length predominantly in the interforamina region of the mandible. The opposing teeth were complete or partially removable dentures or natural teeth. Heavy smokers (> 10 cig./ day) were not excluded since previous studies have not been able to find substantial evidence on smoking as a risk for implant loss in the mandible. One Down Syndrome patient was allowed into the study because his general condition allowed normal dental treatment under local anesthesia and there were no other medical contra-indications present. The patients were informed about the evidence-based positive outcome of early or immediate loading and asked for informed consent. The ethical comite of the Ghent University Hospital gave approval for the clinical inspection and the retrospective radiographic evaluation by an independent examiner (TVdV) not biased, nor related to the given treatment.

Clinical procedure [case report 2]

4 to 6 Brånemark fixtures were installed according to the manufacturer’s guidelines (Nobel Biocare Gothenburg Sweden) with the procedure as described before. To achieve maximal bone-to-implant contact and maximal initial stability the insertion torque value was set at 40 Ncm. In 9 patients multiunit abutments were installed and torqued according to the manufacturer’s guidelines at 20 Ncm. In the other 9 patients the implant bridge was installed on fixture level. It was decided to insert the bridge on multi-unit abutments or on fixture level depending on the hygienic and esthetical demands.

2.1.3.2 Materials and methods of study 2: TiOblast implants

Patients

In total 25 patients were consecutively treated after referral for implant treatment in the completely edentulous mandible. The patients were required to be healthy and to have adequate bone for the placement of 4 to 6 implants of predominantly 13-15 mm length in the interforamina region. The opposing teeth were complete or partial removable dentures or natural teeth. Heavy smokers (> 10 cig./ day) were not excluded since previous studies have...
not been able to find substantial evidence on smoking as a risk for implant loss in the mandible. Patients underwent periodontal treatment whenever considered necessary on the remaining teeth. Although immediate placement and loading of TiOblast surface implants is today no longer considered a contra-indication, previously published results suggest that turned surface implants are jeopardised when placed and immediately loaded in conjunction with tooth extraction. In case periodontally involved teeth or functionally useless teeth were to be extracted, it was therefore decided that at least 6 weeks waiting time was respected, mainly to allow for soft tissue healing.

Clinical procedure
5 TiOblast implants were installed according to the manufacturer’s guidelines (Astra Tech Dental, Mölndal, Sweden) with the procedure as described before. Diameter 4 mm was considered the standard when bone mass was available and fixtures of 13 or 15 mm were considered as first choice to achieve maximal implant stability. Implant installation was prosthetic driven by the guiding denture. Care was taken to have the implant flush with the alveolar crest mesially and distally but no attempts were made to have the implant completely surrounded with bone at the buccal site because this would often have resulted in deeper placement. To achieve good initial stability the insertion torque value was set at 30 Ncm for the diameter 3.5 mm and 40 Ncm for the diameter 4.0 mm implants. To overcome the eventual problems of decreased implant stability due to unfavourable bone quality, the surgeons had the option to alter the surgical drilling procedure. Uni-abutments were inserted immediately after implant placement and torqued according to the manufacturer’s guidelines at 20 Ncm. Abutment heights were chosen according to the mucosal thickness. The aim was to have no visible titanium after healing. Consequently short (0 mm and 1.5 mm) abutments were chosen when the mucosa was thin.

2.1.3.3 Materials and methods: clinical and radiographic evaluation
An implant was considered a failure according to the criteria proposed by the European Academy of Periodontology when it showed individually checked mobility, persistent infection, pain or was removed during the studied interval for any other reason. Digital apical radiographs were taken with long-cone technique immediately after surgery and 3-6, 12, 24 and 36 months. In order to achieve readable images X-ray positioning devices were used to have the X-ray beam perpendicular to the imaging plate. Marginal bone level was measured on all radiographs by one operator (TVdV). The examiner was calibrated during an initial session with the surgeons for consequent interpretation of the radiographs. The measuring calliper available in the imaging program Visiquick (the Netherlands) was used to examine each individual implant under a magnification ranging between 5 and 10. The implant-abutment or implant-cylinder borderline was used as a baseline reference point from where on bone loss
was calculated to the most apical part of the bone level at the mesial and distal site of the implant. The mean value of both measurements was used as the implant bone value. If the marginal bone level was unclear on a radiograph, it was discarded from the analysis. This explains some missing data. According to the criteria accepted by the European Federation of Periodontology all individual implants exhibiting less than 1.5 mm bone remodelling during the first year of loading and thereafter less than 0.2 mm annual bone loss, were considered a success.¹

2.1.3.4 Materials and methods: statistical analysis
Statistical analysis was done by means of SPSS for Windows (version 12.0.) Descriptive statistics (mean – range – standard deviation) was based on all measured implants. Furthermore, for each patient, the mean bone loss value from all available implants was calculated for statistical analysis of bone remodelling over time by means of Wilcoxon signed ranks test. Absolute numbers were reported according to Albrektson & Zarb in a four-field table as proportion of individual implants with success (Ss), survival (Sl), unaccounted for (U) or failure (F) at the 1,2 or 3 years interval.²⁹
2.1.4 Immediate loading in the completely edentulous mandible: results

2.1.4.1 Results of study 1: Brånemark implants

A total of 91 implants (Brånemark, Nobel Biocare Göteborg Sweden) was inserted (78 turned surface, 13 TiUnite™) in 18 patients (8 males and 10 females) with a mean age of 55 years (range 39-77 years) according to the manufacturer’s guidelines. Patients were between 39 and 77 years old. Table 2.1 shows the distribution of implant length and location. 88 Implants were of diameter 3,75 (MK III) and 3 were diameter 4 (MK IV).

Table 2.1: Distribution of implants installed related to implant length (mm) and implant location (tooth number).

<table>
<thead>
<tr>
<th>Implant Length (mm)</th>
<th>Position</th>
<th>46</th>
<th>44</th>
<th>43</th>
<th>42-41</th>
<th>31-32</th>
<th>33</th>
<th>34</th>
<th>36</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11,5</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td></td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td></td>
<td>12</td>
<td>6</td>
<td>18</td>
<td>15</td>
<td>5</td>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>2</td>
<td>16</td>
<td>8</td>
<td>23</td>
<td>18</td>
<td>7</td>
<td>16</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>91</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All patients received their 10-unit provisional bridge on the same day as the surgery and this was functioning at least three months. It was kept at the approval of the referring dentist when to start the final prosthodontic work. One patient was provided with the final 12-unit titanium implant bridge (Procera, Nobel Biocare, Gothenburg Sweden) already 10 days after surgery for personal reasons. On average, however, the provisional bridge was in place for 144 days (range 10-332 days). No biological or major technical complications such as fractures of the provisional bridge were seen at the regular recall visits. Nine bridges were installed on multi-unit abutments from 1-3 mm length depending on the soft tissue thickness and 9 were constructed on fixture level. All original structures were functional but abrasion and acrylic discolorations were regular features.

Two out of 5 installed TiUnite™ fixtures were lost within 3 months in the Down Syndrome patient but the provisional bridge remained functional on 3 implants until the patient was successfully re-operated. Because the patient has been institutionalised after 1 year, he was not longer attending our clinic for recall. His dentist, who takes care of the regular check-up for practical reasons, has reported that after 32 months and 25 months the respective initial and replaced implants are still functional and this was proven on a panoramic radiograph. However, since
only a panoramic radiograph was available, the patient was not longer included in the
detailed analysis of clinical outcome or bone remodelling. Another implant in a second patient
was lost after 11 months due to a non-detected fracture in the metal framework of the final
bridge, resulting in overloading of the cantilever part. The bridge was adjusted with a shortened
cantilever and the patient was successfully reoperated. However, only the 4 original fixtures are
included in the bone-loss calculation. Since no additional losses occurred during the average
45 months (range 26-57) of follow-up, the total failure rate is 3/91 (3.3%). All but 1 patient have
passed the 3-years follow-up. Unfortunately from 6 of the 18 patients radiographs were not
available at some time points or could not be analyzed properly. 1 patient did not reach the 3
year follow-up period yet; the Down syndrome patient was institutionalised and could not be
radiographically examined; 1 patient did not attend the 3-year recall although the implants
were reported to be functional at the next recall visit; 1 patient withdraw from recall; 2 patients
were checked at 3 years but unfortunately no 1 year radiographs could be traced back in the
files. These 6 patients had to be excluded from the statistical evaluation since this is based on
paired evaluation at all time points.

Table 2.2: Average bone to implant levels measured in mm for 12 patients at baseline, 1 and 3
years of functional loading. Statistical analysis is done by means of Wilcoxon signed ranks test.

<table>
<thead>
<tr>
<th>Time</th>
<th>Mean</th>
<th>St. Deviation</th>
<th>Range</th>
<th>Median</th>
<th>Wilcoxon signed ranks test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0,1</td>
<td>0,2</td>
<td>0,0-0,7</td>
<td>0</td>
<td>P &lt; 0,002</td>
</tr>
<tr>
<td>1 year</td>
<td>1,8</td>
<td>0,2</td>
<td>1,6-2,2</td>
<td>1,6</td>
<td></td>
</tr>
<tr>
<td>3 years</td>
<td>1,8</td>
<td>0,4</td>
<td>1,4-2,6</td>
<td>1,6</td>
<td></td>
</tr>
</tbody>
</table>

From 12 of the 18 patients the mean bone values were compared between initial and 1 and 3
years respectively (Table 2.2). Taking these 12 patients into account for proper statistical
analysis of changes of marginal bone level over time, one can clearly see a shift from bone
adaptation towards the first implant tread within one year of loading but limited minor changes
occurred after this period. Crestal bone loss occurred during the first year of loading (1,7 mm ±
0,2 from baseline to 1-year; p < 0,02). After 3 years no further significant bone loss occurred.
When the success criteria of Albrektson & Isidor1 are applied 56% and 51% of all examined
implants were successful after 1 or 3 years. This is presented in a four-field table according to
Albrektsson & Zarb99 in tables 2.3 and 2.4. This proportion of successful implants is rather
disappointing. Bone loss was not statistically different between cylinder to fixture and abutment
to fixture group. The technical failure rate of the final prosthesis is 1/18, since 1 final bridge had
to be modified after a new implant was installed in 1 patient. The total complication rate of the
final bridge-work is therefore 5.5%.
Table 2.3 & 2.4: Life-table analysis according to Albrektson & Zarb\textsuperscript{99} after 1 and 3 years.

<table>
<thead>
<tr>
<th></th>
<th>SS 52 (57,1%)</th>
<th>U 2 (2,2%)</th>
<th>SI 34 (37,4%)</th>
<th>F 3 (3,3%)</th>
</tr>
</thead>
</table>
| Success (SS) = remodelling ≤ 1.5 mm after 1 year and ≤ 1.5 mm after 3 years
Failure (F)= removed implants
Unaccounted for (U)= implants lost from recall
Survival (SI)= implants in function but with missing bone evaluation or bone value above the success threshold.

2.1.4.2 Results of study 2: TiOblast implants

In total 125 implants were installed; 111 of 15 mm length and 14 of 13 mm length. Implant diameter was 4 mm in 114 implants and 3.5 mm in 11 implants. Of the 25 treated patients, 15 were women and 10 men and the mean age was 58 years (range 35-76); 6 patients were smokers.
Bone quantity and quality is given in table 2.5.\textsuperscript{100} All implants were machinally and manually installed with the applicable insertion torque of at least 35 Ncm.

Table 2.5: Bone quantity and quality on patient level according to Lekholm and Zarb.\textsuperscript{100}

<table>
<thead>
<tr>
<th>Bone quantity</th>
<th>Bone quality</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>4</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>5</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

After 1, 2 and 3 years of loading respectively 125, 120 and 105 implants were checked and all found clinically stable without signs of infection. The clinical survival rate is 100% at all intervals. Based on marginal bone levels, the individual implant success was after 1, 2 and 3 years respectively 78\%, 82\% and 79\%.
Figure 2.1: Case representing the radiographs of one patient with the worst marginal bone levels after 3 years of loading

Figure 2.2: Case representing the radiographs of one patient with the least marginal bone levels after 3 years of loading

The radiographs of the worse and best case regarding bone loss after 3 years of loading are shown in figure 2.1 and 2.2 indicative of the wide inter- and intra patient’s range.

Table 2.6: Marginal bone levels measured in mm from the implant-abutment interface for 21 patients with all evaluation intervals available up to 3 years. Changes with respect to previous interval are measured with Wilcoxon Signed Ranks Test and p < 0.05 is statistically significant and indicated with an asterix.

<table>
<thead>
<tr>
<th>Time</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>St. deviation</th>
<th>P-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>0,00</td>
<td>0,64</td>
<td>0,25</td>
<td>0,21</td>
<td></td>
</tr>
<tr>
<td>3 months</td>
<td>0,04</td>
<td>2,5</td>
<td>0,93</td>
<td>0,71</td>
<td>0,001 *</td>
</tr>
<tr>
<td>12 months</td>
<td>0,08</td>
<td>2,7</td>
<td>1,18</td>
<td>0,79</td>
<td>0,025 *</td>
</tr>
<tr>
<td>24 months</td>
<td>0,08</td>
<td>2,87</td>
<td>1,29</td>
<td>0,93</td>
<td>0,114</td>
</tr>
<tr>
<td>36 months</td>
<td>0,12</td>
<td>3,2</td>
<td>1,46</td>
<td>0,99</td>
<td>0,078</td>
</tr>
</tbody>
</table>

Marginal bone levels were available from 21 patients with a corresponding 105 implants for all evaluation intervals. The descriptive statistics of those 21 patients are reported in table 2.6.
Changes with respect to the previous interval are measured with Wilcoxon Signed Ranks Test and P < 0.05 is statistically significant. Figure 2.3 shows the corresponding box-plot of the 21 patients’ mean bone values up to 3 years.

Figure 2.3: Boxplot expressing radiographic marginal bone level measured in mm for 21 patients with all values available after 3 years.

The mean bone loss value is shown in table 2.7. Statistically significant bone loss on patient level was only detected between baseline and 3 months or between 3 months and 12 months after which a steady state situation was eminent.

Table 2.7: Mean bone loss, SD, range and number of patients in the respective intervals.

<table>
<thead>
<tr>
<th>Interval</th>
<th>Mean</th>
<th>St. deviation</th>
<th>Range</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>0,6</td>
<td>0,68</td>
<td>0,04-1,90</td>
<td>23</td>
</tr>
<tr>
<td>12 months</td>
<td>0,84</td>
<td>0,82</td>
<td>0,08-2,10</td>
<td>25</td>
</tr>
<tr>
<td>24 months</td>
<td>0,84</td>
<td>0,92</td>
<td>0,08-2,20</td>
<td>23</td>
</tr>
<tr>
<td>36 months</td>
<td>1,2</td>
<td>1,03</td>
<td>0,12-2,60</td>
<td>21</td>
</tr>
</tbody>
</table>

Based on individual implants, the mean bone loss between the 3-months and 1-year interval was 0,16 ± 0,89 (range -3.8 to 2.7) and only 3.5% of the implants showed bone loss above 1 mm. When the success criteria of Albrektson & Isidor1 are applied 78,4% and 66,4% of all
examined implants were successful after 1 or 3 years. This is presented in a four-field table according to Albrektsson & Zarb in tables 2.8 and 2.9.

**Table 2.8 & 2.9: Life-table analysis according to Albrektson & Zarb after 1 and 3 years.**

<table>
<thead>
<tr>
<th></th>
<th>SS</th>
<th>U</th>
<th>SI</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>SS</td>
<td>98 (78,4%)</td>
<td>0 (0%)</td>
<td>27 (21,6%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>SI</td>
<td>22 (17,6%)</td>
<td>20 (16,0%)</td>
<td>34 (37,4%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Success (SS) = remodelling ≤ 1.5 mm after 1 year and ≤ 1.9 mm after 3 years.
Failure (F) = removed implants
Unaccounted for (U) = implants lost from recall
Survival (Sl) = implants in function but with missing bone evaluation or bone value above the success threshold

Normally the drilling protocol prescribes that for implants of diameter 4 mm the implant bed is over the total length prepared with drills of 3,7mm or 3,85 mm wide and the most coronal part is prepared with a twist drill to diameter 4 mm. As can bee seen from table 2.10, this drilling sequence was significantly altered in 12% of the implants.

**Table 2.10: Final drill diameter (mm) used to obtain perfect initial stability with implants of diameter 3.5 or 4.0 mm.**

<table>
<thead>
<tr>
<th>Final drill diameter</th>
<th>Implant diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2,5 mm</td>
</tr>
<tr>
<td>4,0 mm</td>
<td>5</td>
</tr>
<tr>
<td>3,5 mm</td>
<td>0</td>
</tr>
</tbody>
</table>

This under-preparing of the implant bed allowed us to increase initial implant stability and obtain good prognosis even in 3 of the 25 patients with unfavourable bone quality 3 and 4 (table 2.5). On the other hand, 20/125 implants needed further manual torquing into position because the implant got stuck into the drilled socket before reaching the final position. This additional friction induces a higher risk for over-compression and overheating of the bone and may jeopardize healing and impede with osseointegration. Statistical analysis, however, showed that this additional bone compression procedure did not lead to more crestal bone loss.
2.1.5 Immediate loading in the completely edentulous mandible: discussion

2.1.5.1 Discussion of study 1: Brånemark implants

The aim of the present study was to describe a clinical and technical procedure to achieve immediate loading of predominantly turned surface dental implants with a complete mandibular fixed bridge. On a total of 91 implants, 3 failed to integrate. The total failure rate of 3.3% is comparable or better than other clinical studies summarized in Table 2. It is seen that the success rate of the same clinical protocol for immediate loading on 3 implants is remarkably lower (91.0%). In the latter study the bone remodelling did not reach a steady state after one year but continued up to 3 years of loading.

An early implant failure can be caused by several factors such as trauma to the implant bed, bacterial infection acquired during implant installation, overloading or technical failures. A possible reason for the 2 failures in the Down Syndrome patient could be overloading. Since it is difficult to communicate with the patient, one cannot rely that post-operative instructions in general are followed up appropriately, although the patient’s caretaker was informed properly. In the light of the finding that implant-born masticatory function has different neuromuscular coordination than a natural occlusion, it cannot be excluded that clenching habits, tongue pressure and changes in proprioception jeopardized implant integration in the Down Syndrome patient. One implant was lost in another patient after 11 months due to a technical complication. A non-detected fracture in the metal framework, resulting in an increased bending moment of the cantilever part, was responsible for this failure. This, however, did not lead to loss of the final prosthesis, which was resoldered and easily modified with a new set-up of acrylic teeth after the new implant was installed. Sixteen of the final prostheses had a bilateral extension part (Table 2.3) of up to 2 cm and were free of any technical failures. This cantilever design enables better occlusal stability and bilaterally balanced articulation with the maxillary removable denture.

Overall, the implant survival of 96.7% and the final prosthetic outcome of 94.5% demonstrate that the described immediate loading protocol on turned surface implants has an excellent prognosis. It should be noted, however, that the bone of the interforamina region is predominantly dense in nature allowing ideal initial stability and favourable implant length. This might explain why we never experienced problems with spinning implants when unscrewing the provisional bridge at the time of suture removal. Therefore results of immediately restored overdentures on splinted and non-splinted implants are comparable with the survival rates of fixed bridges in the mandible. It is not clear whether implants placed in softer bone can bear the same amounts of load. There are indications that splinting of implants and a modification of implant design and surface roughness are promoting good
results in soft bone. Glauser and co-workers\textsuperscript{34} installed slightly tapered implants with a modified rough surface (TiUnite\textsuperscript{TM}, Nobel Biocare) and demonstrated that this approach was successful in regions of soft quality bone. Roccuzzo and Wilson\textsuperscript{114} increased initial bone-to-implant contact by limiting drilling and condensing the bone with osteotomes. They concluded that implants could be early loaded in regions of soft quality bone when primary stability is improved.

Bone level alterations occurred during the initial healing period as measured between implant installation and the first year of functional loading, which is consistent with data from other studies evaluating one-stage early loaded implants.\textsuperscript{22, 25, 50, 112} This mean marginal bone loss on patient level during the first year of loading was within the acceptable threshold of 1,5 mm as stipulated in the Proceedings of the 1st European workshop on Periodontology.\textsuperscript{1} However on individual implant level only 57,1% of the implants are successful (table 2.3). Bone loss during the first year is thought to be the result of establishing a biological width of mucosal tissues around the implant neck.\textsuperscript{115} After 1 year a steady state condition in bone to implant contact was found. This explains why no biological peri-implant complications such as hypertrophy, pocket-formation or spontaneous bleeding were reported during the 6 to 12 months recall visits.

A disadvantage of taking an impression immediately after surgery is the time needed to process the provisional prosthesis. To avoid this, techniques are described to fit an existing or prefabricated prosthesis around the abutments with the use of autopolymerizing cold-curing resin.\textsuperscript{28, 68-71} The use of cold-curing polymers immediately after surgery enhances the risk for monomer leakage, which could cause allergic problems to some patients. This can be minimized by full curing of the acrylic prosthesis under pressure under laboratory conditions. This treatment concept provides a reinforced provisional bridge within a limited amount of time. The loss of some additional time needed to install the provisional prosthesis at the late afternoon of the implant surgery does not seem to be a major problem for patients or clinicians. Both patients and referring dentists benefit of the temporization of the final prosthetic work. The final bridge is installed after bone remodelling due to implant surgery has occurred. Adjustments in prosthetic design can be made before finalizing the definitive bridge. It is the opinion of the authors that the limited additional technical cost of 1000 € for the provisional bridge and planning denture contributes to a better and more time-saving prosthetic rehabilitation, a better understanding of the patients needs and a more safe method for immediate loading procedures.
2.1.5.2 Discussion of study 2: TiOblast implants

The results of this prospective 3-years follow-up study indicate that immediate loading is a feasible restorative option for cross-arch bridges in the mandible. None of the fixtures failed and based on the criteria\(^1\) nearly more than 66.4% can be considered a success with less than 1.5 or 1.9 mm of total bone loss after 1 and 3 years. This corresponds to a mean additional yearly bone loss of 0.2 mm. From 4 patients there are no data available after 3 years although one of these patients showed up at a later stage with functional and successful implants. The latter one was not included in the bone evaluation data. The 100% survival rate is slightly better than the 98.5% reported after 3 years in a group of 53 subjects with 308 TiOblast fixtures installed in a classical 2-stage delayed protocol.\(^{116}\) The clinical outcome is comparable with early loading on TiOblast implants described previously to have a 100% survival of all the inserted implants after 2 years.\(^{117}\) Other implant systems used in the same indication have shown comparable clinical results, albeit with shorter evaluation periods. An 18 months clinical survival rate of 99.4% and 100% was reported for 3i Osseotite implants\(^{32}\) and an-oxidized TiUnite implants\(^{118}\) and similar survivals were reported for ITI\(^{111}\) and Southern implants.\(^{31}\) The TiOblast implants used in this study yield a moderately rough implant surface and seemingly lead to an improvement of clinical prognosis compared with the 96.7% survival obtained with predominantly turned Brånemark implants using the same selection criteria and treatment protocol and performed by the same surgeons.\(^{37}\)

The present study examined bone loss from the day of surgery. Table 2.7 shows that more than 75% of the first year’s bone loss occurs during the first 3 months. This explains why the bone loss measured in the present study is slightly higher than values reported with early loading\(^{117}\) or classical delayed loading in 2-stage surgery\(^{116}\) using the same implant system in the completely edentulous mandible.

Table 2.11. Marginal bone level compared between a group of delayed\(^{116}\), early\(^{117}\) or immediately loaded (present study) TiOblast implants.

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>DELAYED mean (mm)</th>
<th>DELAYED max (mm)</th>
<th>EARLY mean (mm)</th>
<th>EARLY max (mm)</th>
<th>IMMEDIATE mean (mm)</th>
<th>IMMEDIATE max (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>0,09</td>
<td>1,42</td>
<td>0,6</td>
<td>2,2</td>
<td>1,2</td>
<td>2,7</td>
</tr>
<tr>
<td>24</td>
<td>-</td>
<td>-</td>
<td>0,7</td>
<td>2,2</td>
<td>1,3</td>
<td>2,9</td>
</tr>
<tr>
<td>36</td>
<td>0,2</td>
<td>1,73</td>
<td>-</td>
<td>-</td>
<td>1,5</td>
<td>3,2</td>
</tr>
</tbody>
</table>

Table 2.11 summarizes the reported marginal bone levels values for these studies after 1, 2 and 3 years. More bone loss is apparent in the immediately treated implant group compared to the early loaded group, the latter having more bone loss than the delayed loading implants. Several possible explanations for these differences can be discussed. Firstly, the very initial bone
remodelling, starting immediately after surgery has not been taken into account when baseline radiographs were taken after prosthetic loading some weeks or months after surgery. This common way of designing implant studies in the past is believed to underestimate the real bone loss. Secondly, in the early and delayed loading studies the implants are intentionally installed deeper according to the manufacturer’s protocol of the nineties because the implant is completely buried underneath the closed mucoperiosteal flap. This deeper placement creates intentionally more space for biological width formation and longer dimensions of the epithelial and connective tissues. In this study it was observed that marginal bone levels were closer to the reference point for countersunk implants compared to implants installed supracrestally. The bone loss created intentionally by drilling the countersunk implants subcrestally is not taken into account since the biological bone loss is measured from the reference, which is the abutment-implant border. In the present study, implants were on average 0.3 mm coronal to the bony crest (table 2.6). Thirdly, implant installation was prosthetic driven by the guiding denture and not necessarily in the best anatomical position. Consequently fenestration s and dehiscences were accepted since guided bone regeneration techniques were excluded by the protocol. Since intra-oral radiographs only disclose information of the mesial and distal bone level, it is not unlikely that buccal or lingual bone changes may also have affected interproximal bone remodelling. Finally, it has been suggested that bone loss is a consequence of a biological phenomenon necessary to obtain a successful peri-implant mucosal integration. In the early loading study an inverse relation was found between abutment height and bone loss, an aspect also confirmed in the present study. Statistical analysis of the mean bone loss after 3 months and the mean abutment height (measured with the patient as a unit) revealed a negative correlation (Spearman’s correlation coefficient -0.566) at a statistically significant level (P = 0.005). A scatter diagram of the mean abutment height versus mean bone loss clarifies this relation in figure 2.4.
Figure 2.4: Scatter diagram of mean bone loss (mm) at 3 months versus mean abutment height (mm) calculated on patient level.

The majority (70%) of the abutments were 0.0 or 1.5 mm long (table 2.12). This reflects the thin mucosal thickness and can explain why some more bone loss is needed to establish biological width formation.¹²⁰

Table 2.12: number of abutments with their respective height used in the study

<table>
<thead>
<tr>
<th>Abutment height (mm)</th>
<th>Number installed</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>52</td>
</tr>
<tr>
<td>1.5</td>
<td>35</td>
</tr>
<tr>
<td>3</td>
<td>31</td>
</tr>
<tr>
<td>4.5</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>

The calculated mean bone loss of 0.8 mm around TiOblast implants after 1 year (table 2.7) is, however, far superior to the 1.7 mm obtained with turned Brånemark implants³⁷ but comparable to the 0.8 - 0.9 mm obtained with other moderately rough implants.³², ¹¹⁸ The changes observed in coronal bone are within the criteria of success accepted by the European Federation for Periodontology¹ and statistically reaching a steady state situation after 1 year.
Immediate and functional loading of multiple splinted implants is a challenging treatment option for the edentulous jaw. Primary stability, a term coined to express sufficient bone to implant contact in order to avoid relative micro-movement between implant and healing bone, is one of the determinants of successful osseointegration when using both a classical two-stage approach with delayed loading or a one-stage approach with immediate loading. This stability depends mainly on biomechanical factors, which are determined by implant design, surgical technique and bone properties. The latter are in clinically oriented scientific papers described by bone quantity or quality. Bone quantity was sufficient in the present study and long implants could be installed which is an important decisive factor for immediate loading procedures. Bone quality was deemed perfect or good in the majority of the patients. In three patients poor bone quality (type 3 and 4) was encountered. It has been suggested that tapered implants are necessary to induce an improved initial stability in soft bone. The Astra Tech implant, however, has a cylindrical screw design and yet we encountered no difference in clinical and radiological outcome in soft bone. We believe that the drilling modification has improved the final stability by osseocompression and this also explains why sometimes the implant blocked into the implant bed before reaching the final position. This is an aspect that can occur even in the hands of experienced surgeons because it is difficult to predict bone quality clinically during the drilling procedure. Since all implant sites were coronally widened to 3.5 or 4 mm, to match with the chosen implant diameter, the over-compression was not applied onto the crestal cortical bone. This is important to avoid overheating of dense bone and explains why the crestal bone remodelling was uneventful. It is therefore in our believes that the immediate loading procedure should be looked upon as a high risk scenario requiring experienced surgeons. To our opinion, the issue of bone quality is overstressed in the past and probably not a determining issue anymore in patient selection criteria because the surgeon can obtain good initial stability by adapting the drilling to the given bone condition. Also, the determination of bone quality based on pre-surgical radiological planning is difficult. Moreover, in the anterior mandible thick cortical bone often creates a falls impression of good bone quality while the implant becomes finally seated in more spongious bone.

Although, it seems wise to keep the option open to go to a two-stage procedure, whenever considered safer during the surgical procedure, this clinical choice is often irrelevant because the patient has mentally been prepared for a fast procedure giving immediate comfort. Changing this promise in the course of the treatment procedure would have a tremendous psychological impact but also causes practical problems. Often, the patient’s complete denture was converted to a guiding denture the day before surgery, meaning that the denture as such is destroyed and non-functional anymore. All patients referred for the immediate loading procedure were treated consecutively and the option of a two-stage surgical procedure was never explored.
Last but not least, long-term success of immediate loading procedures depends on maintenance of peri-implant health and controlling of occlusion and articulation. This implies a strict maintenance protocol and regular check-up, at least once a year. Patients were included in a recall program and the majority of the patients were compliant. Whenever possible, depending on the opposing dentition being a removable denture or fixed natural teeth, the cross-arch implant supported restoration was given a fully balanced occlusion and articulation with an equal spread of the load to all implants including cantilever teeth.\textsuperscript{124}

2.1.6 Immediate loading in the completely edentulous mandible: conclusion

The results of those prospective clinical investigations suggest that the clinical protocol allows a practically, easy, time saving and safe method for immediate loading of implants in the complete arch mandible. Turned surface Brånemark implants have similar early success rates as implants placed with a conventional delayed loading protocol in the mandible and the bone-remodelling pattern is indicative of a steady state situation established within 1 year of loading. Immediate loading in the mandible on 5 moderately rough Astra Tech TiOblast fixtures provides 100% clinical survival of both implants and prostheses and with overall steady state bone conditions within 12 months of loading.
2.2 Effect of implant design on peri-implant bone preservation in the mandible

2.2.1 Introduction

Turned surface implants have been used on a large scale since the research initiated by the Brånemark group in Gothenburg. The original protocol for mandibular implant treatment advocated a period of subcrestal burial of the fixtures and recommended a waiting time of at least 3 months before functional loading. Today, this has been altered substantially and is not longer considered as the only procedure of first choice. One-stage surgery is feasible and yields a good long-term prognosis with implant survival rates of 96-100% irrespective of the implant system used. To improve predictability with immediate loading, enhanced implant surfaces were developed, predominantly based on increased surface roughness consequently leading to surface enlargement and increasing bone-to-implant contact area. Recent studies demonstrated higher success rate with rough surface Ti-Unite compared to turned Brånemark implants in completely and partially edentulous mandibles with comparable bone loss data.

The Astra Tech fixtures are since 1992 made of pure titanium grade 4 and blasted with titanium dioxide particles making the surface moderately rough (TiOblast Astra Tech AB, Mölndal Sweden). The texture of the TiOblast surface is highly uniform and has demonstrated increased bone-to-implant contact, higher regeneration of bone at defect sites and increased stability as measured with resonance frequency compared to turned titanium surfaces. Long-term follow-up revealed a 10-year survival rate of 96.9% and mean bone loss after 7 years of 1.27 mm. In completely edentulous jaw anchored restorations the implants yielded 100% survival in early loading or immediate loading conditions. Since 7 years the Astra Tech implants were provided with a microthreaded implant neck as a modification of the normal design, albeit on the same TiOblast surface. This design is suggested to enhance marginal bone preservation.

This report discusses about the effect of the implant design, on bone preservation in immediately loaded implants supporting a full arch fixed bridge in the mandible. The study compares 3 implant types used by the same surgeons and with the same immediate loading protocol: 1) Turned Brånemark (Ma); 2) TiOblast conventional non-microthread (Ti) and 3) TiOblast Microthread (Mi). Since both Astra Tech fixtures have the same surface configuration the impact of fixture design on clinical survival and radiographic marginal bone level is investigated. The study protocol has been scrutinised and accepted by the ethics committee of the University Hospital Ghent.
2.2.2 Materials and methods

Selection of groups

This comparative study was based on the two studies described previously \(^{37, 38}\) (section 2.1) including 18 patients treated with Brånemark implants and 25 treated on Astra Tech implants of both designs (TiOblast and Microthread) and all immediately loaded with a provisional full-bridge in the lower jaw. However, since 1 Down-Syndrome patient with turned Brånemark implants was a failure case and needed retreatment he could not be included in the statistics. Three other patients had received 13 rough TiUnite™ surface Brånemark implants in conjunction with 3 turned implants and they were discarded because this did not fall within the scope of the paper. In total 14 patients treated with 70 Ma were included. 15 patients received 75 Ti implants and 10 received 50 Mi implants.

2.2.3 Results

In the original material the survival rate was 97% for Ma (18 subjects; 91 implants) and 100% for Ti (15 subjects; 75 implants) and Mi (10 subjects; 50 implants).\(^ {37, 38}\) The total number of subjects to be evaluated from both studies comprised 43, 25 females and 18 males. The mean age was 58 years (SD 9.7) ranging from 35-77. One Down-Syndrome patient in the Ma group was a failure case and 3 other patients were treated with TiUnite™ surface implants and they did not fit in the scope of the paper. Consequently those 4 subjects were omitted from the bone loss analysis.

The mean one year marginal bone loss for the whole group of 39 selected subjects was 1.03 mm ± 0.87 with a range from -0.77 and 2.50. A Kruskal-Wallis statistical test revealed that the 3 treatments groups were not statistically comparable as far as bone loss was concerned. Table 2.13 summarizes the mean marginal bone loss after 1 year for the 3 groups. Wilcoxon ranks sum test revealed that bone loss was more pronounced in Ma than in Ti (P=0.023) or Mi (P=0.046), the latter two being equal (P= 0.698).
Table 2.13: Bone loss (in mm) after 1 year of loading for the 3 experimental groups on patient and implant level.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>Range</th>
<th>N</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ma patients</td>
<td>1.52</td>
<td>0.66</td>
<td>0.17 - 2.50</td>
<td>14</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Ti patients</td>
<td>0.79</td>
<td>0.79</td>
<td>-0.30 - 2.05</td>
<td>15</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Mi patients</td>
<td>0.70</td>
<td>1.01</td>
<td>-0.77 - 2.34</td>
<td>10</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Ma implants</td>
<td>1.52</td>
<td>0.64</td>
<td>0.17 - 2.50</td>
<td>70</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Ti implants</td>
<td>0.80</td>
<td>0.98</td>
<td>-0.90 - 3.80</td>
<td>75</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Mi implants</td>
<td>0.81</td>
<td>1.11</td>
<td>-0.90 - 3.90</td>
<td>50</td>
<td>0.76</td>
</tr>
</tbody>
</table>

Figure 2.5 shows bone loss after 1 year expressed in a boxplot for the 3 examined groups and with the patient as a unit.

Figure 2.5: Boxplot representing bone loss (mm) at the 1 year interval for the TiOblast (n=15), Microthread (n=10) and Turned implants (n=14). The mean patient bone loss is the unit of analysis.
Figure 2.6-2.7: Cumulative percentage of individual patients (left) \(n=39\) and implants (right) \(n=195\) and corresponding marginal bone loss expressed in mm after 1 year of loading for TiOblast, Microthread and Turned implants. The 1.5 mm reference line is indicative of implant success based on the criteria of Albrektsson and Isidor.\(^1\)

Figure 2.6 and 2.7 represent the cumulative percent of subjects or implants in relation with their corresponding mean bone loss. Thirty percent of the Ma patients/implants represented with less than 1.5 mm bone loss compared to 80% of the patients/implants treated with either Ti or Mi.

### 2.2.4 Discussion

With an implant survival rate of 97-100%, this study confirms the predictable outcome described with immediate loading in full arch mandibles with other implant systems.\(^{31, 62, 111, 134-136}\) The survival of 97% with the immediately loaded turned implants corresponds to findings of investigators\(^ {125}\) who used the same implant but with a TiUnite\(^{TM}\) surface in early loading conditions. The use of TiUnite\(^{TM}\) surface implants yielded a 100% survival after 1 year of loading. On the other hand the same authors described a 97.5% survival rate when turned implants were installed. The failure of 3 implants in the original turned implant group in the present study may also have been affected by the inclusion of a risk patient who lost 2 out of his 5 implants.

Down syndrome patients are known risk patients for periodontal breakdown with rapid horizontal bone loss and alterations in immunological response\(^ {137}\) and excessive tooth wear maybe induced by bruxism.\(^ {138}\) This could have attributed to the implant failures in this patient.
Although one could argue that this risk patient should not have been included in the study in the first place, the study protocol was based on consecutive inclusion and hence the patient was included. Excluding these patients gives a survival rate of 98.8% in the turned implant group, which is clinically comparable with the 100% of the TiOblast surface group. The effect of implant design, and with a different surface (turned- TiOblast) did seem to influence the survival rate of implants installed and immediately loaded in this study.

A drawback of some clinical reports is the lacking of marginal bone loss data and the absence of strict success criteria. Albrektsson and Isidor suggested that mean bone loss on patient level during the first year should not exceed 1.5 mm in order to consider an implant successful and 0.2 mm annually thereafter. Table 2.13 indicates that this is the case for the 3 groups compared in the present report. The previous reports revealed that initial marginal bone loss reflecting establishment of a peri-implant biological attachment reached a steady state condition after 1 year and remained stable up to 3 years. Since additional bone loss after 1 year was not statistically significant, it was decided to compare marginal bone loss around the 3 implant types at the one-year time-point.

Figure 2.5, expressing a box-plot of bone loss on patient level, clarifies the difference between Ma and Ti/Mi implants. Even more striking is the finding that mean patient values from table 2.11 match the success criteria, yet only 30% of the Ma subjects have acceptable mean bone loss values compared to 80% in both Astra Tech implants. This difference can be attributed to the implant design with the Ma implants promoting more bone loss compared to the Ti/Mi implants. This rather low success rate for the Ma implants can be attributed to the criteria to distinguish success from survival. These criteria were originally described based on data obtained with two-stage surgery and delayed loading protocols and measuring marginal bone levels at a later stage of implant healing (abutment connection) when initial bone remodelling has already taken place. One could say that for immediate loading protocols, these applied criteria for success are stricter because initial bone resorption is not overlooked.

The effect of the Micro-thread design but with the same TiOblast texture does not seem to enhance bone preservation in the mandible. The claim made by the company based on previous research in-vitro or predominantly in the maxilla cannot be sustained within the limitations of this investigation. Given the specific condition of the edentulous mandible with corticalized bone and rather thin mucosal tissues these conclusions may not be generalised. Several studies show an inverse relation between abutment height, reflecting the thickness of mucosal tissues, and bone loss. In cases of thin mucosal tissues more bone loss can be expected to establish biological width formation. In other indications such as the maxilla where we can expect thicker mucosal tissues there might be a benefit of the Microthread design in preserving bone. Collaert & De Bruyn have indeed described that the Microthread design preserved marginal bone in the maxilla after 1 year of loading.
A mean radiographic bone loss of 0.7-0.8 mm for both implant designs after 1 year of functional loading appears to be very encouraging. With the 1.5 mm bone loss taken as threshold for success, more than 80% of the subjects/implants were treated successfully. Åstrand and co-workers\textsuperscript{139} used TiOblast fixtures in a conventional 2-stage protocol. They found a mean radiographic bone loss of 1.06 mm in the edentulous mandible after 1 year of functional loading.

The clinical protocol scrutinised in this report, provides the patients with a provisional full resin bridge of 10 teeth with only a minor extension distal to the last fixtures. After a 3 months provisionalization period, the final bridge was made. The benefit of replacing the short-arch bridge after the transient initial period with a final construction is adaptation to the improved function and soft tissue stabilisation. Cantilever extensions of up to 2 cm in the mandible are possible, which is for technical reasons difficult to achieve with a provisional reconstruction.

\textbf{2.2.5 Conclusion}

The results show that immediate functional rehabilitation of the completely edentulous mandible is possible with turned as well as rough texture implants with a different design. Crestal bone loss was, however, preserved when the Astra implant design is used. Microthreads at the coronal part of the implants have no significant effect on bone preservation in the edentulous mandible.
2.3 Immediate loading in the partially edentulous maxilla

2.3.1 Introduction

Immediate loading of oral implants has been defined as a procedure where the superstructure is attached to the newly installed implants within 72 hours after implant installation.\(^{61}\) Clinical recommendations for a successful immediate loading procedure are to use screw-type rough surface implants that are installed with a high initial stability and splinted to each other to develop a bone-to-implant contact similar with that of implants that are loaded conventionally. A rigid connection between the implants seems to be a prerequisite when functional load is applied on newly installed implants. A study of Bergkvist and co-workers\(^ {140}\) showed that splinting of implants resulted in a 9 times lower stress level in the surrounding bone compared to uncoupled implants. This is not possible in single tooth restorations. Studies are lacking to show if implants for single tooth restorations can be immediately functionally loaded with comparable results as conventional loaded implants. Most studies concerning immediate loading of single tooth implants applied a non-functional loaded provisional restoration.

The posterior maxilla is a challenging implant recipient site because of its predominantly poorer quality of bone as well as anatomical limitations. Mean bone density values, measured in Hounsfield Units on computerized tomography of implant recipient sites in the posterior maxilla are much lower compared to the anterior maxilla or the mandible.\(^ {141}\) Hence, if we want to investigate whether immediate loading has a similar clinical outcome as delayed loading, the maxilla is the most critical area. In a review article, Jokstad and co-workers\(^ {135}\) evaluated the effect of time-to-loading on the implant treatment outcome. They reported that the average outcome was in favour of delayed loading but there seems not to be indications that immediate or early loading cannot be a safe procedure if certain conditions are respected. Implant survival rates of 88.5-100% for the immediate loading of implants in the partially edentulous maxilla are described in other studies.\(^ {31, 33, 34, 44-47, 142, 143}\) These figures seem to be somewhat lower than the immediate loading in the completely edentulous mandible. Consensus papers today accept that the immediate loading of the completely edentulous mandible is less critical than the maxilla.\(^ {61, 144, 145}\) On the other hand, immediate loading procedures in the posterior mandible are often not a real clinical issue. Patients, missing some premolars or molars, can accept easily a transition period between implant installation and loading because the posterior mandible is less aesthetically demanding. As such, one-stage surgery with delayed loading after 6 or more weeks is a more commonly performed procedure because the healing abutments can be kept unloaded. This protocol yields a similar treatment outcome as a delayed loading procedure for the mandible\(^ {12}\) as well as the maxilla.\(^ {146}\) In the partially edentulous patient, missing teeth in the maxillary premolar-molar area, aesthetical
demands often require provisionalization with temporary removable dentures. This however increases the risk for implant loss due to overloading when the denture is directly in contact with the healing abutments that are not connected to each other. Therefore, one-stage surgery is often followed by a period of load-free healing whereby the removable denture cannot be worn. This is a period of aesthetical burden for the patient.

The aim of this section is to describe the results of a study whether implants placed in the posterior maxilla and immediately loaded have similar treatment outcomes as implants placed with a conventional protocol. The data used in this section are part of a clinical trial that is described in detail in chapter 5. A summary of the materials and methods and the results of this study that are relevant for the aim of this section are reported here below.

### 2.3.2 Materials & Methods

Fourteen patients were consecutively treated for implant treatment in the partially edentulous maxilla. The patients had to be edentulous in the posterior region of the maxilla (premolar-molar) in both sides of the jaw to be included in this study.

A virtual planning was made to install with a guided surgery protocol implants according to its most ideal anatomical and prosthetic position. This planning resulted in the production of a set of drill templates to accurately guide the implant drills during surgery. Patients received in one side of the maxilla 2 or 3 Straumann TE implants (Straumann, Basel, Switzerland) placed with a flapless approach and immediately loaded with a provisional prosthesis (test) and in the contra-lateral side implants placed with a conventional protocol (control). A prefabricated provisional bridge was relined and attached on the test implants immediately after surgery. The control implants were loaded 6 weeks after implant installation.

Six months after surgery the patients were sent to the referring dentist for the restoration with a definitive bridge on both sides of the maxilla. Design and retention modality were left at the discretion of the referring dentist.

Clinical and radiographic evaluation of peri-implant tissues was performed at time of implant surgery, after 1 week, 6 weeks, 3, 6, 12 and 18 months.
2.3.3 Results

Fourteen patients were included in the study (10 females and 4 males). Patients were between 39 and 75 years old (mean: 55.7 years). One female patient was excluded from the study at time of implant surgery because bone regeneration was necessary during implant placement. Another male patient died during the course of the study (3 months) for reasons not related to this study and his data are discarded for long-term statistical analysis.

A total of 70 Straumann TE implants (Straumann AG, Basel, Switzerland) were inserted according to the protocol (36 flapless and immediately loaded (test), 34 conventional (control)) in 13 patients (4 males and 9 females). All patients received a 2- or 3-unit provisional bridge on the test implants the same day as the surgery and at week 6 on the control implants. Twelve patients received the final implant supported prosthesis 6 months after implant placement. The technical failure rate of the final prosthesis is 0/24.

One implant was lost in the test group. The patient presented at the clinic with a fracture of the provisional bridge mesially of the most posterior implant. Overloading of the non-splinted implant resulted in disintegration of the distal implant. Since no additional losses occurred during the 18 months of follow-up, the total cumulative failure rate is 1/36 (2.7%) for the test group and 0/34 (0%) for the control group.

All patients but 1 (one patient died at 3 months) have passed the 18-months follow-up. This patient had to be excluded from the statistical evaluation since this is based on paired evaluation at all time points. The mean bone level for respectively test and control sides was 1.95 mm ± 0.70 (n=12) and 1.93 mm ± 0.42 (n=12) after 18 months, which was not statistically significant different. At baseline the marginal bone level was significantly different compared to the other evaluation periods (p < 0.05). From 12 of the 13 patients the mean bone loss was compared between baseline and 6 weeks, 3, 6, 12 and 18 months respectively. Crestal bone loss occurred during the first 3 months (1.05 mm ± 0.33 from baseline to 3 months for the test group; 0.93 mm ± 0.56 for the control group). After 3 months no further significant bone loss occurred. There are no statistically significant differences for bone loss between the test and the control group at all intervals.

Taking these 12 patients into account for proper statistical analysis of changes of marginal bone level over time, one can see a clearly shift from bone adaptation within the first 3 months but limited minor changes occurred after this period. A box plot is represented in figure 2.8 of the bone loss at different time intervals for the test and control implants.
When the success criteria of Albrektson & Isidor\(^1\) are applied, 72.2% and 82.4% of all examined implants were successful after 1 year for respectively the test and the control group. This is presented in a four-field table according to Albrektsson & Zarb\(^9\) (Tables 2.12 & 2.13).

Table 2.12 & 2.13: Life-table analysis according to Albrektson & Zarb\(^9\) for the test (n=36) and control group (n=34).

<table>
<thead>
<tr>
<th></th>
<th>Test (n=36)</th>
<th>Control (n=34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SS</td>
<td>26 (72.2 %)</td>
<td>U 3 (8.3 %)</td>
</tr>
<tr>
<td>SI</td>
<td>6 (16.7 %)</td>
<td>F 1 (2.8 %)</td>
</tr>
</tbody>
</table>

Success (SS) = remodelling ≤ 1.5 mm after 1 year.
Failure (F)= removed implants
Unaccounted for (U)= implants lost from recall
Survival (SI)= implants in function but with missing bone evaluation or bone value above the success threshold.

Figure 2.9 represents the cumulative percent of the available implants with bone loss values in relation with their corresponding mean bone loss. More than 80% of the test implants (n=33) represented with less than 1.5 mm bone loss compared to 88% of the control implants.
2.3.4 Discussion

The results of this study indicate that implants placed with a guided flapless protocol in the posterior maxilla can be immediately loaded with comparable results to a conventional protocol (flap surgery and delayed loading). The immediate loading of implants in the maxilla with predominantly soft bone has not been extensively investigated. Implant survival rates of 88.5-100% for the immediate loading of implants in the partially edentulous maxilla are described in other studies. The excellent cumulative survival rates of 97.3% for the immediately loaded implants in the present study are indicative of the good prognosis with this protocol.

Other studies recommend using tapered implants, underpreparing implant sites where soft bone is present and splinting the implants with a provisional construction. The tapered implants used in this study were splinted, but underpreparing was not performed with this guided surgery protocol. One implant was lost after a fracture of the provisional bridge and it is our believe that this technical complication caused undesired overloading of unsplinted single-standing implant. In an in-vitro study of Bergkvist and co-workers the authors suggest that splinting of implants results in a 9 times lower stress level in the surrounding bone compared to uncoupled implants. Hence, in this study, loading on the remaining part of the prosthesis
attached on the most posterior implant could have resulted in high lateral forces and disintegration of the implant. The implant was mobile at time of evaluation albeit without causing discomfort or without signs of infection.

The marginal bone levels of the implants in the test and control group were not statistically significant at all time intervals. Flapless surgery and immediate loading did not alter bone level changes compared to a conventional protocol. This is in accordance with other studies evaluating the effect of flapless surgery or immediate loading on marginal bone levels around implants placed in the maxilla. The mean marginal bone level from the reference point at implant placement (baseline) was 0.95 mm ± 0.60 for the test implants and 1.16 mm ± 0.39 for the control implants. After 3 months the mean marginal bone level reached a steady state (1.98 mm ± 0.43 and 2.08 mm ± 0.46 for test and control implants respectively). This steady state was also seen in the immediate loading studies in completely edentulous mandibles with Brånemark and Astra implants described previously. The Brånemark implants lost 1.7 mm ± 0.2 and the Astra implants lost 0.84 mm ± 0.82 during the first year. The annual bone change after the steady state situation was on average a gain of 0.03 mm for test implants and 0.15 mm for control implants. A study of Malo and co-workers reported a mean bone loss of 1.9 mm during the first year of implants placed with a flapless and immediate loading protocol. This bone loss is higher than the 1.10 mm ± 0.39 mm bone loss after 1 year in this present study.

2.3.5 Conclusion

Implants in the posterior maxilla can be immediately loaded with a provisional prosthesis and have a comparable clinical and radiographic outcome than implants installed with delayed loading. Compared to other studies the results of this present study are indicative of an excellent prognosis with the used protocol.
Chapter III

THE CLINICAL AND RADIOGRAPHIC OUTCOME OF SINGLE IMPLANTS IMMEDIATELY RESTORED WITH A DEFINITIVE CERAMIC ABUTMENT AND ACRYLIC PROVISIONAL CROWN
3. THE CLINICAL AND RADIOGRAPHIC OUTCOME OF SINGLE IMPLANTS IMMEDIATELY RESTORED WITH A DEFINITIVE CERAMIC ABUTMENT AND ACRYLIC PROVISIONAL CROWN

3.1 Introduction

Implantology today tries to mimicry the aesthetic appearance of the natural dentition. There has been little evidence that immediate provisionalization might help obtaining a better aesthetic result in the short term.\cite{153,154}

The aesthetic appearance of a single tooth implant depends on the harmony of the implant restoration with both soft and hard peri-implant tissues.\cite{155} The formation and dimensions of the peri-implant soft tissue depends predominantly on the underlying marginal bone configuration. It has been shown in several studies that the marginal bone levels around single tooth implants reaches a steady state after initial bone resorption.\cite{133,156,157} The soft tissue around dental implants functions as a barrier to protect the underlying bone and has an apico-coronally dimension of 3-4 mm (biologic width). Unlike to natural teeth, the connective tissue component of this soft tissue seal is poorly connected to the implant/abutment because it lacks inserting fibres into the surface of the implant.\cite{158} It seems interesting to investigate possible methods for minimizing the marginal bone resorption that occurs after the insertion of dental implants and to establish an adhesion of the soft tissue to the surface of an implant/abutment.

Marginal bone loss around two-piece implants is related to an inflammatory cell infiltrate around the implant-abutment connection (microgap), which is infiltrated by microorganisms.\cite{159}

The location of this microgap related to the bone will dictate the amount of bone loss in a vertical and horizontal dimension.\cite{161,162} Reinstallation of healing abutments, impression copings and abutments disturb the peri-implant conditions at the level of this implant-abutment interface and induces additional bone loss and an apical migration of the peri-implant connective tissue.\cite{163} Micromovements of abutments on the implant induces significantly more bone loss compared to laser welded implant-abutment connections.\cite{164} Moreover, the material and surface characteristics of components, which are attached to the implant and facing the soft tissues at the transmucosal level have an effect on the inflammatory cell infiltrate around an implant. Abrahamsson and co-workers\cite{165} showed in a histologic study in dogs that abutments made of titanium or Al₂O₃ ceramic allowed the formation of a mucosal attachment. At sites where abutments made of gold alloy or dental Feldspathic porcelain were used, no proper attachment formed at the abutment level, but the soft tissue margin receded and bone resorption occurred. Degidi and co-workers\cite{166} observed significantly lower
inflammatory levels in tissues surrounding zirconium oxide healing caps compared to tissues surrounding titanium healing caps.

Furthermore a moderate rough surface or fine threads in the cervical region of the implant seems to reduce crestal bone loss as well.\textsuperscript{133, 167, 168} One could say that the crestal bone loss around a two-piece implant is a complex interaction of different parameters but seems to be positively influenced by a stable connection between the implant and an abutment with soft tissue friendly characteristics.

The aim of this study is to describe and analyze the outcome of Straumann dental implants (Straumann AG, Basel, Switzerland) installed with a definitive ceramic abutment and provisionalized with an acrylic crown immediately after implant surgery.

### 3.2 Materials and Methods

#### 3.2.1 Patients

Patients with a single unit edentulous space in the aesthetic zone were selected for inclusion in the study and treated from July 2006 to February 2007. All patients were required to be generally and periodontally healthy. They needed to have adequate bone for the placement of a Straumann Standard Plus (SP) or Tapered Effect (TE) implant of 10-12mm length and a width of 3.3-4.1mm with a sandblasted and acid-etched surface (SLA) (Straumann AG, Basel, Switzerland). The opposing teeth were natural teeth or fixed partial dentures (FPD's). Smoking of less than 10 cigarettes was not an exclusion criterion. The patients were informed about the evidence-based positive outcome of immediate loading and asked for informed consent. The ethical comitee of the Ghent University Hospital gave approval for the clinical study.

#### 3.2.2 Planning procedure

Panoramic radiographs were used for patient inclusion. If appropriate computerized tomograms (CT) were obtained to evaluate the implant recipient site. Routine dental examination was performed to evaluate dental and periodontal health.

Alginate impressions were made for planning of the implant site and processing of the definitive abutment. An implant analogue was installed in the plaster model by the implant surgeon (TVdV). The aim was to create an ideal prosthetic implant location in the working model relative to the available anatomical information. The model was sent to the dental technician and was scanned for the fabrication of a Computer Aided Restoration (CARES, Straumann AG, Basel, Switzerland) ceramic abutment.
3.2.3 Clinical procedure
Patients were asked to rinse with a chlorhexidine solution preoperatively (Perio-Aid®. Dentaid, Barcelona, Spain). Surgical treatment was performed under local anaesthesia and none of the patients received a sedative prior to surgery. For all implant-sites a crestal incision was made to expose the bone but this was kept minimal to obtain a superior aesthetic outcome. Implants were installed according to the manufacturer’s guidelines. If needed the recipient sites were underprepared to achieve maximal initial stability and to obtain an insertion torque value of 40 Ncm. The implants were mounted with a Synocta abutment (Straumann AG, Basel, Switzerland) torqued at 35 Ncm and the individual CARES ceramic abutment (insertion torque: 15 Ncm) during surgery. Minimal grinding of the ceramic abutment was done with a high-speed diamond drill under excessive water-cooling to correct for deviations between planned analogue and obtained implant positioning. This was done outside the mouth to avoid contamination of ceramic particles in the surgical site. The screw access holes were filled with a cotton pellet and a temporary filling. A temporary acrylic crown was made by the prosthodontist (JbH) and cemented with provisional cement. After 6 months, a definitive crown was made by the same prosthodontist. If necessary, due to minor recessions, the prosthodontist was allowed to slightly correct the finishing margins to a level of 1.5mm submucosally without disconnecting the abutment. A polyether impression (Impregum Penta Soft, 3M ESPE AG, Seefeld, Germany) was made after exposing the abutment finishing line with a retraction cord. Clinical pictures of the procedure are given in case report 3.1 and 3.2.

3.2.4 Postoperative care
The patients were instructed to brush the provisional crown from the day of surgery with a very soft toothbrush (Special care®, Tepe, Malmö, Sweden) and given the advice to rinse with chlorhexidine 0.12%. No special dietary advice was given. The patients were given ibuprofen 600mg or Paracetamol 500 mg after surgery, to be taken at their own discretion. After 1 week the sutures were removed. Oral hygiene was re instructed with the soft manual toothbrush and additionally with appropriate sized interdental brushes (Tepe®, Malmö, Sweden). Patients were recalled at 6 weeks, 3 months and 6 months for clinical inspection and when necessary oral hygiene re instruction was given.
Case report 3.1: immediate provisionalization with a definitive ceramic abutment

Intra-oral photograph of an edentulous single unit area before surgery (3a). A CARES was made pre-operatively based on an installed implant analogue in a working cast by the implant surgeon (3b). During implant surgery the flap was reflected as minimal as possible to obtain a superior aesthetic outcome (3c).

A synocta abutment was installed immediately after surgery with an insertion torque of 35 Ncm (3d). The CARES ceramic abutment was screwed on the Synocta with torque of 15 Ncm (3e-f).

Intra-oral photographs immediately after surgery with the provisional acrylic crown (3g), after 3 months (3h) and with the definitive crown after 6 months (3i).

Radiographs immediately after surgery (3j), after 3 (3k) and 6 months (3l).
Case report 3.2: immediate provisionalization with a definitive ceramic abutment - complication

Intra-oral photograph of an edentulous single unit area before surgery (3m). During implant surgery the flap was reflected as minimal as possible to obtain a superior aesthetic outcome (3n). A ceramic CARES abutment was installed on the implant (3o).

Intra-oral photographs immediately after surgery (3p), after 1 week ((3q) and 3 months (3r). At the 3 months visit the patient presented with a fistula originating from the implant-abutment interface (3r).

Internal contamination of the components was visible (3s). Abutments were unscrewed (3t), irrigated with a chlorhexidine solution and reinstalled (3u).

Intra-oral photograph of the definitive restoration at 6 months (3v).

Radiographs immediately after surgery (3w), after 3 (3x) and 6 months (3y).
3.2.5 Clinical and radiographic evaluation

Technical or prosthetic complications were recorded at every visit. Routine clinical evaluation of implant stability and peri-implant health was performed after 1 week, 3 and 6 months. An implant was considered a failure according to the criteria proposed by the European Academy of Periodontology when it showed individually checked mobility, persistent infection, pain or was removed during the studied interval for any other reason. Periapical radiographs were taken with long-cone technique immediately after surgery (baseline) and 3 and 6 months. In order to achieve readable images X-ray positioning devices were used to have the X-ray beam perpendicular to the imaging plate. Marginal bone level was measured on all radiographs by an independent operator (CR) not involved with the actual treatment using the software Image J 1.38x (National Institutes of Health, USA). The examiner was calibrated during an initial session with the surgeon for consequent interpretation of the radiographs. The scale of each radiograph was calibrated according to the known distances between implant threads. The measuring calliper, available in the program, was used to examine each individual implant under a magnification ranging between 5 and 10. The implant-abutment (test group) or implant-cylinder borderline (control group) was used as a baseline reference point from where on marginal bone level was calculated to the most apical part of the bone level at the mesial and distal site of the implant (figure 3.1). The mean value of both measurements was used as the implant bone value. According to the criteria of Albrektson & Isidor all individual implants exhibiting less than 1.5 mm bone remodelling during the first year of loading and thereafter less than 0.2 mm annual bone loss, were considered a success.

3.2.6 Control group

Ten implants neighbouring a natural tooth treated by the same periodontist (TVdV) with the same implant system were used as a control group. Implant surgery and follow-up was performed with a similar protocol but left unloaded for at least 6 weeks with a healing abutment. After 6 weeks a temporary titanium cylinder was installed and added with acrylic to form a provisional crown. Definitive crowns were installed after 6 months.

3.2.7 Statistical analysis

Statistical analysis was done by means of SPSS for Windows (version 15.0.) Descriptive statistics was based on all measured implants. Furthermore, for each patient, the mean bone loss value was calculated for statistical analysis of bone remodelling over time by means of Wilcoxon signed rank tests. Absolute numbers were reported according to Albrektson & Zarb in a four-field table as proportion of individual implants with success (Ss), survival (S1), unaccounted for (U) or failure (F) at the 6 months interval.
3.3 Results

Ten patients with one implant each were included in both the test group (5 females and 5 males) (mean age: 42.7 years; range: 25-64 years) and the control group (7 females and 3 males (mean age: 49.4 years; range: 35-62 years). A total of 20 Straumann SP (n=6) or TE (n=14) implants were inserted according to the manufacturer’s guidelines. Nineteen implants were of diameter 4.1mm and one implant was 3.3mm, implant length was 12mm (n=14) or 10mm (n=6).

All implants integrated successfully resulting in a survival rate of 100% for both groups. Marginal bone levels and bone loss are presented in table 3.1 and figure 3.1. There was no statistically significant difference between test and control groups.

Table 3.1: Marginal bone level (mm) and additional bone loss (mm) compared to the previous interval for test and control implants.

<table>
<thead>
<tr>
<th>Interval</th>
<th>Marginal bone level (mm)</th>
<th>Marginal bone loss (mm)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. deviation</td>
</tr>
<tr>
<td></td>
<td>Test</td>
<td>Control</td>
</tr>
<tr>
<td>Baseline</td>
<td>0.71</td>
<td>1.02</td>
</tr>
<tr>
<td>3 months</td>
<td>1.22</td>
<td>1.74</td>
</tr>
<tr>
<td>6 months</td>
<td>1.57</td>
<td>2.13</td>
</tr>
</tbody>
</table>

Figure 3.1: Marginal bone levels at baseline, 3 and 6 months for test and control implants. The black arrow represents the reference point from where bone levels are calculated.
When the success criteria of Albrektsson & Isidor\textsuperscript{1} are applied, 100\% and 90\% of all implants were successful after 6 months for the test and the control group respectively (table 3.2 & 3.3).

Table 3.2 & 3.3: Life-table analysis according to Albrektson & Zarb\textsuperscript{99} for the test (n=10) and control group (n=10).

<table>
<thead>
<tr>
<th>SS</th>
<th>U</th>
<th>SI</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Success (SS)= remodelling ≤ 1.5 mm after 6 months.
Failure (F)= removed implants
Unaccounted for (U)= implants lost from recall
Survival (SI)= implants in function but with missing bone evaluation or bone value above the success threshold.

Minor prosthetic complications were frequently reported in the test group but absent in the control group. Loosening of the abutment screw was the most common complication (4/10). The second patient treated lost a final restoration because of screw loosening. In one patient, a provisional acrylic crown lost retention and was fractured. One patient presented with a fistula originating from the implant-abutment interface at the 3-month recall visit. The temporary filling material that sealed the screw access hole had dissolved and internal contamination of the abutment was visible. The components were detached from the implant and internally irrigated with a chlorhexidine solution. After one week the fistula had disappeared completely and no other signs of inflammation could be observed around the implant after healing.

Since a loosening of the abutment screw was observed in 4/10 cases in the test group and these abutments were reinstalled, it was decided to stop the treatment protocol for the test implants. Prior to definitive restoration, all remaining abutments were unscrewed for safety purposes. It was considered non-ethical to leave the abutments without proper retightening. The implants were internally irrigated and abutments were reinstalled according to the applicable insertion torques.
3.4 Discussion

The 100% survival and success obtained in this study indicates that Straumann implants can be immediately non-functionally loaded with a definitive ceramic abutment and acrylic provisional crown. The clinical and radiographic outcome of those implants is comparable to the outcome of implants that are restored after a healing period of 6 weeks with a screw-retained acrylic crown. Immediate provisionalization with a definitive abutment has several clinical benefits compared to a conventional protocol. The idea to install a definitive abutment immediately after implant insertion seems interesting. Reconnection of components on implants seems to cause additional bone loss and an apical migration of the peri-implant connective tissue\textsuperscript{163}. A zirconium abutment seems to have excellent technical,\textsuperscript{169-171} aesthetical\textsuperscript{172} and biological characteristics\textsuperscript{166, 173} with good clinical results.

The technical and biological complication rate for the test implants was very high. Although this was resolved in all cases, it created unnecessary burden to patient and clinician. The abutment screws became loose in 4 out of 10 cases, one acrylic provisional crown was fractured and in one patient a fistula was observed. Because the aim of the study was to investigate the influence of the immediate installation of a definitive abutment (without removing it) the study protocol was aborted and all remaining 5 out of 10 abutments were unscrewed and retightened prior to definitive restoration. This affected the peri-implant tissues in a way similar to a delayed loading procedure since reinstallation of the components is necessary. Since then, all cases were treated according to a normal clinical protocol for single tooth restoration.

One patient presented with a fistula originating from the implant-abutment connection. The temporary sealing of the screw access hole was dissolved and the internal components were contaminated. A fistula was formed following the path of least resistance through the buccal peri-implant soft tissues without pocket formation. One could speculate that the zirconium abutment established some kind of soft tissue connection above the level of the implant-abutment interface\textsuperscript{165}, which was strong enough to withstand the pressure of the inflammation exudate.

These findings could suggest that the immediate connection of a zirconium abutment could have favourable results on peri-implant parameters. A prerequisite for investigating such a procedure, however, is to accomplish a strong and stable implant-abutment connection, which could not be attained in this study.
3.5 Conclusions

The results of this study indicate that single implants can be successfully loaded non-functionally immediately after surgery. Although the use of a final abutment should have potential benefits from a biological point-of-view, possibly enhancing the aesthetic outcome, the disappointing results of the present study did not allow proper follow-up of such a protocol. The demanding technical procedure with the frequent complications suggest that this tested approach with Straumann SP or TE implants and a CARES abutments can not be recommended for clinical usage.
Chapter IV

A MODEL STUDY ON FLAPLESS IMPLANT PLACEMENT BY CLINICIANS WITH A DIFFERENT EXPERIENCE LEVEL IN IMPLANT SURGERY.

Part of this chapter has been published as:

Van de Velde, T.L.A., Glor, F., De Bruyn, H.  
A model study on flapless implant placement by clinicians with a different experience level in implant surgery.  
Clinical Oral Implants Research 2008; 19(1); p. 66-72.
4. A MODEL STUDY ON FLAPLESS IMPLANT PLACEMENT BY CLINICIANS WITH A DIFFERENT EXPERIENCE LEVEL IN IMPLANT SURGERY.

4.1 Introduction

Oral implantology tends to evolve into a less time-consuming, a more aesthetic and a less invasive way to restore a lost dentition. In this context, some implant companies advocate that flapless implant surgery is easy to perform and beneficial for aesthetics and patient morbidity. A variety of tools are available to improve the outcome of flapless surgery. The use of radiographic images is necessary to evaluate the surgical site underneath the soft tissues. Computerized tomographic (CT) images provide an accurate image of the surgical field in 3 dimensions.\textsuperscript{174, 175} When using radio-opaque material, it is possible to visualize both soft and hard tissue dimensions on the CT-images in relation to the template. This pre-surgical CT-image is often used for implant selection but not for precise implant positioning. With conventional surgery the radiological information obtained on the CT-image is not exactly transferred to the intra-operative situation. In most cases the surgeon decides in situ on the chosen implant position once the flap is raised, the bone exposed and with the template as a direction indicator. As a consequence, in most cases an extended flap is needed to visualise the bone sufficiently in order to avoid perforations of critical anatomical structures. Minimizing the surgical flap can have advantages for soft tissue healing and patient comfort.\textsuperscript{73} If one wants to do flapless surgical procedures, an exact transfer of the anatomical information obtained via the CT images to the intra-oral situation during surgery is necessary. Several authors have advocated the use of drill guides\textsuperscript{81, 83} or intra-operative navigation systems\textsuperscript{176} to link the virtual preoperative treatment plan based on the CT-images to the situation encountered during surgery.

Although retrospective studies indicate that implant survival rates obtained with flapless surgery are predictable with an appropriate technique and patient selection\textsuperscript{75} the results seem highly influenced by the practitioner’s learning curve.\textsuperscript{76} Little is known of exact implant position when freehanded flapless surgery is performed since re-entry studies objectively analyzing the position of the implant in the bone are lacking. The aesthetical and phonetical outcome is often not reported in clinical implant survival studies. This outcome is highly influenced by correct implant positioning and bone support especially on the buccal side. Several studies reported a period of 3 months to 3 years after implant surgery for speech and articulation adaptation.\textsuperscript{177-179} These studies did not report whether implant positioning in the bone and in relation to the prosthetic suprastructure influenced the alterations in speech and articulation. Yet, in a study of Jacobs and co-workers\textsuperscript{180} it is stated that speech is influenced by tongue
position and thus the palatal shaping of the prosthesis and the teeth. Frontal diastema do not play such a big role. On the other hand, bad hearing is detrimental as the failing hearing feedback may prevent speech adaptation.

The aim of the present in-vitro model study was to analyze deviations in position and inclination of a flapless implant procedure without drill guide compared to the ideally planned position and to examine whether the outcome is affected by experience level.

4.2 Materials and Methods

4.2.1 Model planning
In total 12 models were constructed with different degrees of radio-opacity of teeth, bone and soft tissue. All models (mixture of Exaktoform® (Bredent, Germany) with 10 weight % Barium sulphate powder) were identical and had missing teeth at positions 16, 14, 12, 22, 24 and 26 (Frasaco GmbH, Tettnang, Germany) and a silicone lining (Omnidouble, Omnident GmbH, Rodgau Nieder-Roden, Germany) mimicking the soft tissues. All sites had a sufficient amount of bone (figure 4.1) to receive a Straumann implant (Straumann AG, Basel, Switzerland) but at premolar sites an artificial bone defect was created to make the implant location critical in width (figure 4.2).

![Figure 4.1-4.2: Cross-sectional computerized tomographic scan image of the model at tooth location 14 (figure 4.1) and 16 (figure 4.2).](image)

The experimental model was scanned (Volume Zoom, Siemens, Erlangen, Germany). The CT data were imported in SimPlant™ PRO 9.2 (Materialise NV, Leuven, Belgium). Because of the different degrees of radio-opacity used in the model, the software was able to delineate the bone, the soft tissue and teeth easily (figure 4.3 and figure 4.4).
Case report 4: flapless implant surgery

Patient with fractured left central (21) incisor in the maxilla. After careful removal of the root the decision was made to immediately proceed with the implant placement in the remaining alveolar socket.

A flapless implant procedure was performed to install a Straumann TE SLA (4.1 x 12 mm) (Straumann AG, Basel, Switzerland) implant in an ideal 3 dimensional position (4c). A palatal engagement of the implant in the alveolar socket avoids a buccal bone perforation during surgery and future buccal bone resorption during healing (4d).

The gap between the implant and the alveolar socket was filled with demineralised bovine bone mineral (Bio-Oss®, Geistlich, Wolhusen, Switzerland) to obtain a decrease of resorption of the buccal bone (4e). A minimal flap elevation allowed adding more Bio-Oss and a resorbable collagen membrane (Bio-Gide®, Geistlich, Wolhusen, Switzerland) buccally to ensure an aesthetic outcome (4f).

After 3 months of submerged healing a provisional crown was installed immediately after second stage surgery to allow the peri-implant mucosal tissues to heal in the desired dimensions. Figure 4h shows the definitive cemented crown on a ceramic abutment. Note the minimal recession of buccal mucosa that occurred compared to the pre-operative situation, typical for immediate implant procedures in the aestetical zone.
Virtual implant location was performed on 6 tooth positions (Figure 4.5). Within this software it is possible to virtually install an implant in its most ideal position taking the bony morphology, the soft tissues and the prosthetic outcome into account. All implants were planned according to the criteria described by Buser and co-workers.$^{181}$ This treatment plan was considered as the ideal implant location (reference).

Figure 4.3- 4.4: Computer image of the model. Red represents soft tissue, purple represents the teeth. Because the phantom contains different degrees of radio-opacity, the soft tissues can easily be separated from the bone (yellow) in the software.

Figure 4.5: The treatment plan was based on the CT scan data of the model imported in Simplant® PRO 9.2 (Materialise NV, Leuven, Belgium)


4.2.2 Study participants

Eighteen clinicians with a different level of experience in oral implantology working at the University Dental School participated in this study; 6 were trained periodontists regularly performing implant surgery, 6 were general dentists and 6 were last term dental students, all inexperienced in implant surgery. Prior to the test run all participants were informed about the goals of the model study during a seminar. They received a brief review on the implant procedure and were instructed in flapless surgery and the specific sequence of drilling. All candidates were provided with a set of surgical drills (round burr Ø 2.2 mm; pilot drill Ø 2.2 mm; pilot drill Ø 2.8 mm; twist drill Ø 3.5 mm; twist drill Ø 4.2 mm) provided by Straumann (Straumann AG, Basel, Switzerland), a periodontal probe to investigate the thickness of the artificial soft tissue by means of bone sounding, a panoramic overview of the model, an axial section and a cross-sectional CT-image of each edentulous zone.

All 18 participants were asked to prepare 4 recipient sites with a flapless approach on 4 specific locations on one or two identical models. They were allowed to pre-test the model and the drilling procedure. The models were placed on a flat surface and could be freely rotated in order to inspect and drill the sites. Each participant was given 4 predetermined locations and drilled at least one incisor and one premolar for a 4.1 mm Straumann implant and one molar for a wide 4.8 mm implant. In total, the 18 participants drilled 24 incisors, 24 premolars and 24 molars. It was decided not to install implants in the drill sites in order to avoid artefacts on the CT-scan taken after the experimental drilling.

A CT scan was taken from every drilled model. The drill holes were segmented manually in Mimics 9.0 (Materialise NV, Leuven, Belgium) and reconstructed in 3D. Cylinders of the same size as the body of the implants were constructed in Magics 9.9 (Materialise NV, Leuven, Belgium) and virtually installed in the prepared drill holes. A detailed description of the registration algorithm is given in the Mimics manual (Mimics 9.0 Reference Guide). This registration algorithm allowed for the cylinders to be positioned at the place where the implant would have been if the implants had been inserted exactly in the drilled location. The drilled cast together with the registered cylinders was exported as an “.stl-file” and registered on the original CT scan containing the treatment plan.

As a result of this procedure, the coordinates of every drill hole were known in the coordinate system of the original CT scan. Since the treatment plan was done in that coordinate system, the coordinates of the planned implants and drill holes can be compared with each other. Figure 4.6 shows the planned implant and the test implant in the same coordinate system.

The distance between the two centres of the implants (figure 4.6) mimics the global deviation. It can be decomposed in a part along the axis of the planned implant (the depth deviation) and a part perpendicular to it (the horizontal deviation). The angle deviation is the 3D angle made by the centrelines of the planned and test implant.
Statistical analysis was performed with SPSS for Windows (version 12.0). Descriptive statistics for all parameters was based on all implants and separately for incisor, premolar and molar sites. Student t-tests were used to examine statistical differences between test groups. Chi-square tests were used to evaluate different perforations per implant site.

![Diagram of planned implant and test implant seen in the same coordinate system.](image)

**Figure 4.6:** Planned implant and test implant seen in the same coordinate system.

### 4.3 Results

The evaluated parameters for the specialists versus general dentists and students are summarized in table 4.1 for all implants, tables 4.2-4.4 for implants placed respectively in incisor, premolar and molar regions.

Table 4.1: Mean deviation (global deviation, angle deviation, depth and horizontal deviation) from the ideal, expressed in mm and standard deviations (St. dev.) of different variables for all implant sites divided by experience group (n= 72). (*) indicates a statistically significant difference between parameters.

<table>
<thead>
<tr>
<th></th>
<th>specialists</th>
<th>general dentists</th>
<th>students</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. dev.</td>
<td>Mean</td>
</tr>
<tr>
<td>Global deviation (mm)</td>
<td>2.97</td>
<td>1.2</td>
<td>2.44 (*)</td>
</tr>
<tr>
<td>Angle deviation (°)</td>
<td>7.33</td>
<td>3.77</td>
<td>9.76 (*)</td>
</tr>
<tr>
<td>Depth deviation (mm)</td>
<td>2.88</td>
<td>1.27</td>
<td>2.28</td>
</tr>
<tr>
<td>Horizontal deviation (mm)</td>
<td>0.68 (*)</td>
<td>0.35</td>
<td>0.83</td>
</tr>
</tbody>
</table>
Table 4.2: Mean deviation (global deviation, angle deviation, depth and horizontal deviation) from the ideal, expressed in mm and standard deviations (St. dev.) of different variables for implants in incisor sites divided by experience group (n= 24). (*) and (**) indicates a statistically significant difference between parameters.

<table>
<thead>
<tr>
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<th>general dentists</th>
<th>students</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. dev.</td>
<td>Mean</td>
</tr>
<tr>
<td>Global deviation (mm)</td>
<td>3,67 (*)</td>
<td>0,66</td>
<td>2,65 (***)</td>
</tr>
<tr>
<td>Angle deviation (°)</td>
<td>7,75</td>
<td>4,55</td>
<td>11,56 (*)</td>
</tr>
<tr>
<td>Depth deviation (mm)</td>
<td>3,63 (*)</td>
<td>0,70</td>
<td>2,54 (***)</td>
</tr>
<tr>
<td>Horizontal deviation (mm)</td>
<td>0,71</td>
<td>0,34</td>
<td>0,88</td>
</tr>
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</table>

Table 4.3: Mean deviation (global deviation, angle deviation, depth and horizontal deviation) from the ideal, expressed in mm and standard deviations (St. dev.) of different variables for implants in premolar regions divided by experience group (n= 24).

<table>
<thead>
<tr>
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<th>students</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. dev.</td>
<td>Mean</td>
</tr>
<tr>
<td>Global deviation (mm)</td>
<td>3,36</td>
<td>1,14</td>
<td>2,59</td>
</tr>
<tr>
<td>Angle deviation (°)</td>
<td>7,27</td>
<td>2,75</td>
<td>9,11</td>
</tr>
<tr>
<td>Depth deviation (mm)</td>
<td>3,21</td>
<td>1,79</td>
<td>2,53</td>
</tr>
<tr>
<td>Horizontal deviation (mm)</td>
<td>0,86</td>
<td>0,56</td>
<td>0,62</td>
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</table>

Table 4.4: Mean deviation (global deviation, angle deviation, depth and horizontal deviation) from the ideal, expressed in mm and standard deviations (St. dev.) of different variables for implants in molar regions divided by experience group (n= 24). (*) indicates a statistically significant difference between parameters.

<table>
<thead>
<tr>
<th></th>
<th>specialists</th>
<th>general dentists</th>
<th>students</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. dev.</td>
<td>Mean</td>
</tr>
<tr>
<td>Global deviation (mm)</td>
<td>2,12</td>
<td>0,90</td>
<td>2,03</td>
</tr>
<tr>
<td>Angle deviation (°)</td>
<td>6,94</td>
<td>3,58</td>
<td>8,88</td>
</tr>
<tr>
<td>Depth deviation (mm)</td>
<td>2,00</td>
<td>1,02</td>
<td>1,66</td>
</tr>
<tr>
<td>Horizontal deviation (mm)</td>
<td>0,58 (*)</td>
<td>0,27</td>
<td>1,06 (*)</td>
</tr>
</tbody>
</table>

When all implants were measured there were no statistically significant differences between the experience groups (Table 4.1) for all parameters except for global deviations between dentist and students (P < 0.05), angle deviations between dentists and students (P < 0.01) and horizontal deviations between specialists and students (P < 0.05).
In incisor sites (table 4.2), specialists and students deviated significantly more in global deviation and depth than dentists ($P < 0.01$). Angle deviations of students were significantly less than those of dentists ($P < 0.05$). There were no statistical differences in premolar implants (table 4.3) for all groups.

Statistically significant differences are seen for horizontal deviation between specialists and dentists in molar-implants (table 4.4).

As a consequence of the malpositioning, perforations were seen in 59.7% (43/72) of the implant locations when the artificial mucosa was removed from the model (figure 4.7).

![Figure 4.7: Photograph of a model with the artificial mucosa removed showing an extended palatal dehiscence in a premolar region.](image)

These were located in 13/24 (54.1%) sites of the specialist group, 14/24 (58.3%) of the general dentist group and 16/24 (6.7%) of the student group (table 4.5). Perforations were seen in 13/24 incisor sites, 19/24 premolar sites and 11/24 molar sites (table 4.6).

<table>
<thead>
<tr>
<th></th>
<th>specialists</th>
<th>general dentists</th>
<th>students</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>palatal</td>
<td>11/24 (*)</td>
<td>13/24 (*)</td>
<td>11/24 (*)</td>
<td>35/72 (*)</td>
</tr>
<tr>
<td>buccal</td>
<td>2/24 (*)</td>
<td>1/24 (*)</td>
<td>5/24 (*)</td>
<td>8/72 (*)</td>
</tr>
<tr>
<td>total</td>
<td>13/24</td>
<td>14/24</td>
<td>16/24</td>
<td>43/72</td>
</tr>
</tbody>
</table>

Table 4.5: number of perforations divided by experience group. (*) Indicates a statistically significant difference between palatal and buccal perforations ($P < 0.05$).

<table>
<thead>
<tr>
<th></th>
<th>Buccal dehiscence</th>
<th>Buccal fenestration</th>
<th>Palatal dehiscence</th>
<th>Palatal fenestration</th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td>incisors</td>
<td>0</td>
<td>1</td>
<td>12</td>
<td>0</td>
<td>13/24</td>
</tr>
<tr>
<td>premolars</td>
<td>7</td>
<td>0</td>
<td>12</td>
<td>0</td>
<td>19/24</td>
</tr>
<tr>
<td>molars</td>
<td>0</td>
<td>0</td>
<td>11</td>
<td>0</td>
<td>11/24</td>
</tr>
</tbody>
</table>

Table 4.6: number of perforations divided by region and defect anatomy.
There were no statistically significant differences between experience groups. Perforations were evenly distributed in incisor, premolar and molar sites (Chi-square test $P > 0.05$) but palatal dehiscences were statistically more frequent (Chi-square test $P < 0.01$).

4.4 Discussion

The results of this in vitro study suggest that flapless implant placement without the use of any surgical guidance is a non-accurate procedure. The variations in implant positioning deviated from the ideal implant position irrespective of surgical experience. Flapless implant placement is a popular topic in implant dentistry. This concept was introduced in the late '70's but rarely investigated in the scientific literature. With the evolution in radiological imaging and introduction of new techniques it became a more predictable procedure. One should be aware, however, of the possible complications related to a blind surgical procedure whereby implants are installed without raising a flap and without exposing the alveolar crest.

A study of Becker and co-workers describes the benefits of a flapless implant procedure being reduced surgical time, minimal changes in crestal bone levels, probing depth, and inflammation; perceived minimized bleeding and lessened postoperative discomfort. Campelo and Camara evaluated retrospectively 770 implants placed with a flapless approach over a period of 10 years. The cumulative success rate for implants placed using a flapless 1-stage surgical technique after a 10-year period varied from 74.1% for implants placed in 1990 to 100% in the year 2000. Considering this learning curve and the results of this in vitro study, one should be aware of risking to deviate implants by performing a blind procedure. The benefits related to flapless surgery could easily turn into an aesthetical disaster when perforating the implant bed by performing a freehanded flapless surgery. Until now, we cannot recommend freehanded flapless implant surgery as a treatment of first choice.

As a consequence of malpositioning, perforations were seen in nearly 60% of the implants. In a clinical setting, absence of a bony support for gingival tissues can lead to aesthetical problems, phonetical problems or even loss of implant stability and jeopardise the clinical outcome in the long run. This does not necessarily leads to higher failure rates but could have an impact on patient’s appreciation of the implant treatment.

We would like to point out that all implant sites were drilled and no implants were placed in the models. This was done for reasons of radiographic analysis. It should be noted that perforations could even become worse when installing an implant in its prepared site since there is a 0.6 mm difference in diameter between the final drill and the intended implant. After evaluation of the perforations implants were inserted in every site to evaluate this phenomenon. It was seen that perforations increased in size by pushing the borders of the resin outwards (figure 4.8).
This could mean that complications could be underestimated in this study. Since the elasticity of the model resin does not match the elasticity of human bone and the model-bone was not protected by a firm periosteum, this should be evaluated in a clinical setting.

There were no significant differences in deviations (global, angle, depth and horizontal deviation) between specialists and general dentists when all implants are measured (table 4.1). Students differed significantly with general dentists for global and angle deviation and with specialists for horizontal deviation. However, no conclusive tendencies were seen when measuring all implant locations. Statistical differences showed up especially in incisor sites. Specialists and students deviated significantly more in “global deviation” and depth of implants compared to the general dentists (table 4.2). One explanation could be that specialists and students tried to overcome aesthetic problems by placing the implants a little deeper. There was also a tendency to shift the implant position to the palatal side. Twelve out of 13 perforations in incisors were palatal dehiscences, 35/43 perforations were located at the palatal side for all implant sites (table 4.5). It is clear that those perforations were caused to avoid the buccal plate to minimize the risk for aesthetical complications. However, a palatally located implant could compromise the desired emergence profile increasing the risk for a ridge-lap restoration (toilet-seat design), a disharmonious scalloping of the gingival margins or phonetical problems.

An artificial defect was created at premolar sites in order to create an implant site with critical bucco-palatal dimensions. There were no statistical significant differences in deviations between experience groups (table 4.2) but 79% of these sites showed perforations compared to 54% for incisors or 45% for molar regions. As a consequence of the limited amount of bone,
Premolar sites showed equal amounts of perforations both in palatal and buccal directions. The latter were not detected in incisors and molars. At molar sites there were no statistical significant differences between experience groups, except for a smaller horizontal deviation of specialists compared to general dentists (table 4.4). This is mainly because there was a safe sufficient width of the crest in bucco-palatal direction. It seems from this finding that implant placement in molar sites is the easiest and most safe at least from a location and angulation point of view. Clinically however, the bone condition and anatomical structures on molar areas are more likely to require an experienced surgeon.

It is our believe that the benefits of flapless implant surgery do count in specific cases, but care should be taken not to risk malpositioning by freehanded blind surgery. With today’s technology it is now possible to visualise the configuration of the bony volume without opening the mucosal tissues. Computerized tomographic (CT) images provide an accurate image of the surgical field in 3 dimensions. When using designed scanning templates, it is possible to visualize both soft and hard tissues on the CT-images. These data can be converted to use with software for three-dimensional modelling and simulation of implant surgery. Computer simulated implant positioning may provide benefits in predictable implant placement. Implant location and inclination can be planned according to restorative goals and anatomic limitations. Computer designed surgical guides or navigation systems accurately transfer the planning to the surgical field. An in-vitro study of Kramer and co-workers showed that the precision of navigated surgery was better than a freehanded surgery for repeated implant placements to restore a maxillary single tooth. The variation in inclination, depth and angle deviation was less when a tactile navigation system was used compared to a freehanded surgery.

### 4.5 Conclusion

This in-vitro model study shows that the three-dimensional location of implants installed with a freehanded flapless approach differs significantly from the ideal. Although neighbouring teeth were present and maximal radiographic information was available, practitioners with a different level in oral implantology failed to install implants within acceptable deviations to the ideal plan. As a consequence of malpositioning, a shocking 59.7% of perforations were noted. Within the limitations of this study, it seems necessary to point out that these deviations would in a clinical situation lead to complications such as loss of implant stability, aesthetical and phonetical consequences. The level of experience in implant surgery did not influence the evaluated parameters. This points out that more precise measurements of soft tissue in situ or additional use of guiding systems are recommended when installing implants with a flapless protocol.
Chapter V

THE CLINICAL AND RADIOGRAPHIC OUTCOME OF IMPLANTS PLACED WITH A GUIDED FLAPLESS APPROACH AND IMMEDIATELY RESTORED WITH A PROVISIONAL BRIDGE
5. THE CLINICAL AND RADIOGRAPHIC OUTCOME OF IMPLANTS PLACED IN THE POSTERIOR MAXILLA WITH A GUIDED FLAPLESS APPROACH AND IMMEDIATELY RESTORED WITH A PROVISIONAL BRIDGE. A RANDOMISED CLINICAL TRIAL

5.1 Introduction

The success of oral implant treatment depends on the synergy between patient factors, treatment planning, surgical factors, prosthodontic and technical aspects of the restoration/rehabilitation. New concepts in implant dentistry concentrate on the improvement of one or more of these variables. Guided implant surgery using implant simulation software can contribute to a better treatment planning and a more accurate implant placement. Implant simulation software is based on DICOM (Digital Imaging and Communication in Medicine) data obtained by computerized tomography (CT) or magnetic resonance imaging (MRI) and provides a pre-operative view of the anatomical structures of the patient related to a scanning template representing the future prosthetics. Hereby, it becomes possible to virtually plan the ideal implant position according to anatomical and prosthetic information. The planned implant position should then be transferred to the patient with a high level of accuracy. This transfer can be obtained with drill guides processed by stereolithographic rapid prototyping.

Guided implant surgery can especially be useful in cases with a critical bone volume or anatomy where a unique implant positioning is mandatory or in cases where implants are placed with a minimal surgical exposure of bone or a flapless approach. Minimizing the surgical flap can have advantages for soft tissue healing and patient comfort. However, flapless implant surgery has certain drawbacks as shown by Van de Velde and co-workers who described in an in-vitro experiment that perforations frequently occur when performing freehanded flapless surgery (chapter IV). Hence, guiding the implant placement can resolve the problems related to blind surgery and avoid possible perforations due to malpositioning. It is still unclear, however, if predictable results can be obtained with the systems commercially available today.

In a review article, Jokstad and co-workers evaluate the effect of time-to-loading on the implant treatment outcome. They report that the average outcome was in favour of delayed loading, although there seems not to be any arguments that immediate or early loading cannot be a safe procedure. Implant survival rates of 88,5-100% for the immediate loading of implants in the partially edentulous maxilla are described in other studies. These figures seem to be somewhat lower than the immediate loading in the completely edentulous mandible. Consensus papers accept that the immediate loading of the completely edentulous mandible is the most common indication for safe usage of immediate loading.
The aim of the present study was to analyze the clinical and radiographic outcome of implants placed with a guided flapless approach followed by immediately loading with a provisional bridge in the posterior maxilla. The outcome of the experimental protocol was compared with a conventional protocol with one-stage surgery and delayed loading as a control. A randomised controlled clinical trial with a split-mouth design was used with a follow-up period of at least 18 months. The ethical committee of the Ghent University Hospital gave approval for the clinical prospective study.

5.2 Materials & Methods

5.2.1 Patients
From September 2005 to July 2006, 14 patients were consecutively treated. They were referred to the University Hospital Ghent, Department of Periodontology and Oral Implantology for implant treatment in the partially edentulous maxilla. The patients had to be edentulous in the posterior region of the maxilla (premolar-molar) in both sides of the jaw to be included in this study. The patients were required to be healthy and to have adequate bone for the placement of 2 to 3 Straumann Tapered Effect (TE) implants of 8-12 mm length and a width of 4.1 mm with a sandblasted and acid-etched surface (SLA) (Straumann AG, Basel, Switzerland). The opposing teeth were fixed partial dentures or natural teeth. Heavy smokers (> 10 cigarettes/ day) were excluded from this study. All patients were required to be periodontally healthy. If teeth needed to be extracted at an implant site, a healing period of at least 4 months prior to implant placement was scheduled. In cases of insufficient amount of bone volume bone grafts or sinuslifts were planned with a minimum healing time of 6 months prior to implant installation. The patients were informed about the evidence-based, positive outcome of implant treatment and the experimental approach of flapless surgery and immediate loading. All patients gave their informed and written consent.

5.2.2 Pre-surgical planning procedure
Before surgery all patients underwent clinical and radiographic examinations. Oral hygiene was improved until reasonable plaque and bleeding scores (<20%), indicative of periodontal health, were obtained. Impressions were taken and bite registrations were done in order to provide an ideal prosthetic set-up of the teeth to be restored (case 5a). This tooth set-up was duplicated in a radiographic scan prosthesis (case 5b). The latter consisted of a mixture of 85 % acrylic resin and 15 % radio-opaque Barium sulphate powder to visualize the tooth set-up and the soft tissues (radiolucent area between radiographic prosthesis and bone) (case 5d & 5e) on the CT images. All patients were scanned using a Volume Zoom CT device (Siemens, Erlangen,
Computed tomography (CT) data (DICOM) were imported in Simplant 9.0 (Materialise NV, Leuven, Belgium) and rendered for planning. On both sites of the maxilla 2 or 3 Straumann SLA TE implants were planned according to the most ideal anatomical and prosthetic positions. All surgical plannings were made by the same surgeon (TVdV). The data were electronically sent to process a set of surgical drill templates using stereolithographic rapid prototyping (case 5f). For every specific diameter of implant drills required by the manufacturer respectively 2.2 mm, 2.8 mm and 3.5 mm, a different template was constructed. The internal diameter of the guide tubes were 0.2 mm wider than the corresponding drill. One template was used to process a pre-surgical provisional bridge. Implant analogues were installed in a working model transferring the position and inclination via the guide tubes in the template (case 5g). The tooth set-up was duplicated in acrylic (case 5h), prepared to fit around the temporary cylinders mounted on the implant analogues with an extra space of 1-2 mm (case 5i). This space was created to polymerize with cold-curing acrylic immediately after surgery to compensate for the inaccuracies inherent to this technique.

5.2.3 Implant surgery
Randomisation assigned which side of the maxilla was treated as test side (flapless surgery and immediate loading) or control side (one-stage surgery and delayed loading) just before surgery.

Patients were asked to rinse with a chlorhexidine solution (Perio-Aid, Dentaid, Spain) before surgery. Local anaesthetics were given bilaterally. The first surgical drill template was fitted and at the test sides implant sites were prepared by drilling through the template (case 5q). After the final drill corresponding to the manufacturer’s guidelines, remnants of soft tissues were removed around the osteotomy sites and 2 or 3 implants were installed through the mucosal tissues (case 5r). Consequently at control sides a mucoperiosteal flap was raised to expose the bone and 2 or 3 implants were installed using the same drill protocol without using the drill template. Healing abutments were mounted at control implants and the flap was sutured to allow non-submerged healing (case 5j).

5.2.4 Prosthodontic procedure
Temporary cylinders were mounted on the test implants and the prepared provisional bridge was indexed to these cylinders with cold-curing acrylic resin (case 5s). After setting of the acrylic the bridge was finalized outside the mouth, polished and installed on the implants with a torque of 15Ncm (case 5t). Screw access holes were filled with a cotton pellet and a temporary filling (Ciprospad, Dentsply, St. Quentin en Yveslines, France). Occlusion was checked and adjusted to allow only contact in centric occlusal contact but not during excursion movements.
Case report 5: guided flapless implant surgery and immediate loading - planning

The CT data were imported in Simplant 9.0 (Materialise NV, Leuven, Belgium) and an ideal planning was virtually made according to anatomical and prosthetical information. The data were electronically sent to Materialise NV to process a set of surgical drill templates using stereolithographic rapid prototyping. For every diameter of drills (2.2 mm; 2.8 mm; 3.5 mm) a different template was constructed with guide tubes internally measuring 0.2 mm more than the corresponding drill.

An ideal prosthetic set-up was made of the edentulous areas to be treated (figure 5a). This was duplicated in a scanning prosthesis (figure 5b). With this prosthesis the patients were sent to the CT scan (figure 5c).

One template (figure 5f) was used to process a provisional bridge. Implant analogues were installed in a working model transferring the position and inclination via the guide tubes in the template (figure 5g). Temporary titanium cylinders were mounted on the implant analogues. The tooth set-up was then duplicated in acrylic resin (figure 5h) and prepared to fit around the temporary cylinders with an extra space of 2 mm (figure 5i). This space was created to polymerize with cold-curing resin immediately after surgery to compensate for the inaccuracies inherent to this technique.
This same protocol was followed for control implants (delayed loading) after 6 weeks of healing. Six months after surgery the patients were sent to the referring dentist for the final restoration with definitive bridges on both sides of the maxilla (case 5n-5v). Design and retention modality, either screw-retained or cemented, were left at the discretion of the referring dentist.

5.2.5 Post-operative care

The patients were given ibuprofen 600 mg or Paracetamol 500 mg after surgery, to be taken at their own discretion. The patients were instructed to brush the provisional bridge or the healing abutments from the day of surgery with a very soft toothbrush (Special care, Tepe, Malmö, Sweden) and advised to rinse with chlorhexidine 0.12% (PerioAid, Dentaid, Barcelona, Spain). Patients were asked not to chew hard food with the provisional bridge during the first 6 weeks. After 1 week the sutures were removed from the control sides. Oral hygiene was reinstalled with the soft manual toothbrush and additionally with appropriate sized interdental brushes (Tepe, Malmö, Sweden). Patients were recalled at 6 weeks, 3, 6, 12 and 18 months for clinical inspection, radiographic analysis and oral hygiene reinstruction.

5.2.6 Clinical and radiographic examination

Clinical evaluation of peri-implant tissues was performed at time of implant surgery, and after 1 week, 6 weeks, 3, 6, 12 and 18 months. Height of the attached mucosa on the buccal side of every implant was measured with a periodontal probe and recorded. Peri-apical radiographs were taken with the long-cone technique immediately after surgery, and after 6 weeks, 3, 6, 12, and 18 months. In order to achieve readable images X-ray positioning devices were used to have the X-ray beam perpendicular to the imaging plate. Marginal bone level was measured on all radiographs by an independent clinician not involved during the treatment using the software ImageJ 1.38x (National Institutes of Health, USA). The examiner was calibrated during an initial session with the surgeon for consequent interpretation of the radiographs.

The scale of each radiograph was calibrated according to the known distance of 0.8 mm between implant threads. The measuring tool available in the program was used to examine each individual implant under a magnification ranging between 5 and 10.
Case report 5: guided flapless implant surgery and immediate loading

Intra-oral photographs during implant surgery. A drill template was fabricated for guided surgery (figure 5q). Implants were installed flapless using this template in test sides (figure 5r) and conventional implant surgery with installation of healing abutment was performed in control sides (figure 5p).

A provisional bridge was made immediately after surgery on the test implants and after 6 weeks on the control implants. Intra-oral photographs of a provisional bridge before relining of temporary cylinders (figure 5s), after installation immediately after surgery (figure 5t), before (figure 5u) and after installation of the definitive prosthesis (figure 5v).

Intra-oral photographs of patient before surgery, immediately after surgery and after 6 weeks. Implants are installed with a flapless and immediate loading procedure at the test side and conventional surgery with loading after 6 weeks at the control side.

Clinical and radiographic condition after 18 months. Intra-oral photograph and radiographs of the patient with the definitive prostheses (implant supported crowns) in both sides of the posterior maxilla.
Figure 5.1: Straumann TE implant with a known distance of 0.8 mm between threads and 1.8 mm height of the turned neck section. The reference point from where marginal bone levels were measured on the radiographs is located at the shoulder of the implant.

The implant shoulder was used as a baseline reference point from where the marginal bone level was calculated to the most apical part of the bone visually contacting the implant at the mesial and distal site (figure 5.1). The mean value of both measurements was used as the implant bone value. An implant was considered a failure according to the criteria proposed by the European Academy of Periodontology when it showed individually checked mobility, persistent infection, pain or was removed during the studied interval for any other reason. According to the criteria, all individual implants exhibiting less than 1.5 mm bone remodelling during the first year of loading and thereafter less than 0.2 mm annually, were considered a success.

Patients were asked to fill out a questionnaire using a Visual Analogue Scale (VAS) measuring their opinion about the procedure, discomfort, pain, function, aesthetics, self-confidence and overall treatment satisfaction.

5.2.7 Statistical analysis
Statistical analysis was done by means of SPSS for Windows (version 16.0.) Descriptive statistics was based on all measured parameters. For statistical computation the patient was considered as the unit. For each patient the mean bone level, bone loss, height of the attached mucosa and VAS scores were calculated for statistical analysis by means of Wilcoxon signed ranks test. Additional statistical analysis was done on implant level to evaluate implant success depending
on bone loss and absolute numbers were reported according to Albrektson & Zarb in a four-field table as the proportion of individual implants with success (Ss), survival (Sl), unaccounted for (U) or failure (F) at the 1, 2 or 3 years interval.

5.3 Results

Fourteen patients were included in the study (10 females and 4 males). Patients were between 39 and 75 years old (mean = 55.7 years). One female patient had to be excluded according to the study protocol at time of implant surgery because bone regeneration was necessary during implant placement. Another male patient died unexpectedly during the course of the study (3 months) for reasons not related to the study. Because long-term follow-up was lacking his data were discarded for statistical analysis. In total 12 patients continued for the 18-month follow-up. Six patients received bone augmentation procedures at least 6 months prior to implant surgery. A list of the included patients with descriptive parameters (prior bone augmentation-implant number-complications-final prosthodontic design) is summarized in table 5.1.

Table 5.1: List of included patients with descriptive parameters: prior bone augmentation procedures (GBR= guided bone regeneration; SL= sinus lift; LA= lateral ridge augmentation with autologeous bone)- number of implants-design of final prosthesis-complications. The two excluded patients are highlighted in grey.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Augmentation procedure</th>
<th>Number of implants test-control</th>
<th>Prosthetic design</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>BG</td>
<td></td>
<td>2</td>
<td>Screw ret./ cemented</td>
<td></td>
</tr>
<tr>
<td>BH</td>
<td></td>
<td>3</td>
<td>Screw retained</td>
<td></td>
</tr>
<tr>
<td>BI</td>
<td></td>
<td>3</td>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>BM</td>
<td></td>
<td>3</td>
<td>Screw retained</td>
<td></td>
</tr>
<tr>
<td>CF</td>
<td>SL+ LA</td>
<td>3</td>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>CG</td>
<td>GBR</td>
<td>3</td>
<td>Cemented</td>
<td>GBR failure (excluded)</td>
</tr>
<tr>
<td>DMR</td>
<td></td>
<td>3</td>
<td>-</td>
<td>Patient died after 3 months</td>
</tr>
<tr>
<td>JS</td>
<td>SL+ LA</td>
<td>2</td>
<td>Cemented</td>
<td>Fracture provisional 1 test implant lost (3 m.)</td>
</tr>
<tr>
<td>MJP</td>
<td></td>
<td>3</td>
<td>Cemented</td>
<td>Fracture of provisional bridge</td>
</tr>
<tr>
<td>MM</td>
<td></td>
<td>2</td>
<td>Cemented</td>
<td>Fracture of provisional bridge</td>
</tr>
<tr>
<td>MR</td>
<td></td>
<td>3</td>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>MV</td>
<td>SL+ LA</td>
<td>3</td>
<td>Cemented</td>
<td>Fracture of provisional bridge</td>
</tr>
<tr>
<td>VHG</td>
<td>SL+ LA</td>
<td>3</td>
<td>Cemented</td>
<td></td>
</tr>
<tr>
<td>VK</td>
<td>SL+ LA</td>
<td>3</td>
<td>Cemented</td>
<td>Fracture of provisional bridge</td>
</tr>
<tr>
<td></td>
<td></td>
<td>39</td>
<td>36</td>
<td></td>
</tr>
</tbody>
</table>
A total of 70 Straumann SLA TE implants (Straumann AG, Basel, Switzerland) were inserted according to the protocol (36 flapless and immediately loaded (test), 34 conventional (control)) in 13 patients (4 males and 9 females). Table 5.2 shows the distribution of implant diameter and length according to treatment modality.

Table 5.2: Distribution of installed implants according to treatment modality in 13 patients. Excluded implants in one patient lost to follow-up are given between brackets.

<table>
<thead>
<tr>
<th>Implant type</th>
<th>Test group</th>
<th>Control group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>TE 4.1 mm x 12 mm</td>
<td>25 (1)</td>
<td>13</td>
<td>38 (1)</td>
</tr>
<tr>
<td>TE 4.1 mm x 10 mm</td>
<td>8 (1)</td>
<td>20 (2)</td>
<td>28 (3)</td>
</tr>
<tr>
<td>TE 4.1 mm x 8 mm</td>
<td>2 (1)</td>
<td>0</td>
<td>2 (1)</td>
</tr>
<tr>
<td>TE 4.8 mm x 12 mm</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>36 (3)</strong></td>
<td><strong>34 (2)</strong></td>
<td><strong>70 (5)</strong></td>
</tr>
</tbody>
</table>

All 13 patients received a 2- or 3-unit provisional bridge on the test implants the same day as the surgery and at week 6 on the control implants. Fractures of the provisional bridge were seen in 3 cases on the test implants. All fractures could be repaired and prostheses were immediately re-installed. All provisional bridges remained functional but abrasion and acrylic discolorations were regular features. Twelve patients received the final implant supported prosthesis 6 months after implant placement. The technical failure rate of the final prosthesis is 0/24.

One implant was lost in the test group. He presented at the clinic with a fracture of the provisional bridge mesially of the most posterior implant. Overloading of the non-splinted implant resulted in disintegration of the distal implant. The patient did not experience any pain or infection but the implant was mobile and was removed according to the protocol.

Since no additional losses occurred during the 18 months of follow-up, the total cumulative failure rate is 1/36 (2.7%) for the test group and 0/34 (0%) for the control group.

Twelve patients have reached the 18-months follow-up. Table 5.3 shows the marginal bone levels in mm from the reference point at the different evaluation periods for 12 patients. There were no statistically significant differences between the test and control implants but at baseline the marginal bone level was significantly lower compared to the other evaluation periods (P < 0.05). The mean bone level for test and control implants was 1.95 mm ± 0.70 and 1.93 mm ± 0.42 after 18 months respectively.
Table 5.3: Mean marginal bone level measured in mm from the reference point, for 12 patients at baseline, 6 weeks, 3, 6 and 18 months. Statistical analysis is done by means of Wilcoxon signed ranks test. P-values present statistical significant differences at α=0.05 level with the next time period.

<table>
<thead>
<tr>
<th>Time</th>
<th>Marginal bone level (mm)</th>
<th>Wilcoxon signed ranks test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. Deviation</td>
</tr>
<tr>
<td></td>
<td>Test</td>
<td>control</td>
</tr>
<tr>
<td>Baseline</td>
<td>0.95</td>
<td>1.16</td>
</tr>
<tr>
<td>6 weeks</td>
<td>1.60</td>
<td>1.84</td>
</tr>
<tr>
<td>3 months</td>
<td>1.98</td>
<td>2.08</td>
</tr>
<tr>
<td>6 months</td>
<td>2.02</td>
<td>2.15</td>
</tr>
<tr>
<td>12 months</td>
<td>2.05</td>
<td>2.04</td>
</tr>
<tr>
<td>18 months</td>
<td>1.95</td>
<td>1.93</td>
</tr>
</tbody>
</table>

From 12 of the 13 patients the mean bone loss was compared between baseline and 6 weeks, 3, 6, 12 and 18 months respectively (table 5.4). Taking these 12 patients into account for proper statistical analysis of changes of marginal bone level over time, a clear shift as a result of bone adaptation within the first 3 months is apparent but limited and statistically unsignificant changes occurred after this period.

Table 5.4: Bone loss in mm at different time intervals (bone level at given time minus bone level at baseline) on patient level (n=12). P-values represent the statistically significant difference between time intervals.

<table>
<thead>
<tr>
<th>Time interval</th>
<th>Marginal bone loss (mm)</th>
<th>Wilcoxon signed ranks test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. deviation</td>
</tr>
<tr>
<td></td>
<td>Test</td>
<td>control</td>
</tr>
<tr>
<td>0-6 weeks</td>
<td>0.65</td>
<td>0.68</td>
</tr>
<tr>
<td>0-3 months</td>
<td>1.03</td>
<td>0.92</td>
</tr>
<tr>
<td>0-6 months</td>
<td>1.07</td>
<td>0.99</td>
</tr>
<tr>
<td>0-12 months</td>
<td>1.10</td>
<td>0.88</td>
</tr>
<tr>
<td>0-18 months</td>
<td>1.00</td>
<td>0.77</td>
</tr>
</tbody>
</table>

Crestal bone loss occurred during the first 3 months (1.05 mm ± 0.33 from baseline to 3 months for the test group; 0.93 mm ± 0.56 for the control group). A statistically significant difference was
found between the bone loss at 0-6 weeks and 0-3 months. After 3 months no further significant bone loss occurred. There are no statistically significant differences for bone loss between the test and the control group.

Based on the success criteria 72.2% (table 5.5) and 82.4% (table 5.6) of all examined implants were successful after 1 year for the test and the control group respectively.

Table 5.5 & 5.6: Life-table analysis according to Albrektson & Zarb 99 for the test (n=36) and control group (n=34).

<table>
<thead>
<tr>
<th>Time</th>
<th>SS</th>
<th>U</th>
<th>SI</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>26 (72.2 %)</td>
<td>3 (8.3 %)</td>
<td>6 (16.7 %)</td>
<td>1 (2.8 %)</td>
</tr>
<tr>
<td>1 week</td>
<td>28 (82.4 %)</td>
<td>2 (5.9 %)</td>
<td>4 (11.8 %)</td>
<td>0 (0 %)</td>
</tr>
</tbody>
</table>

Success = remodelling ≤ 1.5 mm after 1 year.
Failure = removed implants
Unaccounted for = implants lost from recall
Survival = implants in function but with missing bone evaluation or bone value above the success threshold.

The mean height of the attached mucosa at the buccal side of the test and control sides on patient level at different time periods is summarized in table 5.7 and figure 5.2.

Table 5.7: Height of the attached mucosa at the buccal side of test and control implants on patient level (n=12). P-values represent a statistically significant difference between test and control sides. The arrow represents a statistically significant difference between time intervals.

<table>
<thead>
<tr>
<th>Time</th>
<th>Mean</th>
<th>St. deviation</th>
<th>Range</th>
<th>Wilcoxon signed ranks test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>test</td>
<td>control</td>
<td>test</td>
<td>control</td>
</tr>
<tr>
<td>Baseline</td>
<td>2.94</td>
<td>3.85</td>
<td>1.63</td>
<td>0.90</td>
</tr>
<tr>
<td>1 week</td>
<td>3.26</td>
<td>6.01 (*)</td>
<td>1.57</td>
<td>1.10</td>
</tr>
<tr>
<td>6 weeks</td>
<td>2.65</td>
<td>3.39</td>
<td>1.39</td>
<td>1.08</td>
</tr>
<tr>
<td>3 months</td>
<td>2.92</td>
<td>3.67</td>
<td>1.38</td>
<td>1.03</td>
</tr>
<tr>
<td>6 months</td>
<td>3.15</td>
<td>3.99</td>
<td>1.72</td>
<td>1.34</td>
</tr>
<tr>
<td>12 months</td>
<td>2.90</td>
<td>4.10</td>
<td>1.73</td>
<td>1.24</td>
</tr>
<tr>
<td>18 months</td>
<td>3.14</td>
<td>4.08</td>
<td>1.89</td>
<td>1.54</td>
</tr>
</tbody>
</table>
A statistically significant difference was found between the test and the control group at week 1 and week 6. Additionally, there was a significant change in height of the attached mucosa at control implants between post-operative and 1 week and between 1 week and 6 weeks (*).

One week after surgery, statistically significant differences were found between the test side and the control side for opinion about speech, function, aesthetics and self-confidence (table 5.9). Those differences disappeared when evaluating the implants on the control side after loading with a provisional restoration (6 weeks). VAS scores for speech, function, aesthetics and self-confidence improved after 1 week for test sides and after 6 weeks for control sides. There was no statistically significant difference between test and control sides for pain/comfort scores and overall treatment satisfaction scores at any time point (table 5.10).
Table 5.8: VAS scores for speech, function, aesthetics and confidence at different evaluation periods. Statistically significant differences at P < 0.05 between test and control sides (n=12) are marked with (*).

<table>
<thead>
<tr>
<th>Time</th>
<th>VAS speech test</th>
<th>VAS function test</th>
<th>VAS aesthetics test</th>
<th>VAS confidence test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>control</td>
<td>control</td>
<td>control</td>
<td>control</td>
</tr>
<tr>
<td>Pre-operative</td>
<td>6,71</td>
<td>6,71</td>
<td>5,41</td>
<td>5,41</td>
</tr>
<tr>
<td>1 week</td>
<td>8,45 (*)</td>
<td>6,94</td>
<td>6,19 (*)</td>
<td>4,23</td>
</tr>
<tr>
<td>6 weeks</td>
<td>7,63</td>
<td>7,75</td>
<td>7,12</td>
<td>6,72</td>
</tr>
<tr>
<td>3 months</td>
<td>8,53</td>
<td>8,87</td>
<td>7,74</td>
<td>7,66</td>
</tr>
<tr>
<td>6 months</td>
<td>8,99</td>
<td>8,95</td>
<td>9,04</td>
<td>8,97</td>
</tr>
</tbody>
</table>

Table 5.10: VAS scores for overall treatment satisfaction and pain/comfort at different evaluation periods. There were no statistically significant differences between test and control sides (n=12).

<table>
<thead>
<tr>
<th>Time</th>
<th>VAS treatment satisfaction test</th>
<th>VAS treatment satisfaction control</th>
<th>VAS pain/ comfort test</th>
<th>VAS pain/ comfort control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>control</td>
<td>control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>-</td>
<td>-</td>
<td>6,95</td>
<td>6,86</td>
</tr>
<tr>
<td>1 week</td>
<td>8,26</td>
<td>6,66</td>
<td>7,62</td>
<td>6,45</td>
</tr>
<tr>
<td>6 weeks</td>
<td>8,21</td>
<td>8,09</td>
<td>7,72</td>
<td>7,51</td>
</tr>
<tr>
<td>3 months</td>
<td>7,61</td>
<td>8,07</td>
<td>7,81</td>
<td>8,08</td>
</tr>
<tr>
<td>6 months</td>
<td>9,09</td>
<td>8,99</td>
<td>8,79</td>
<td>8,80</td>
</tr>
</tbody>
</table>
5.4 Discussion

The results of this study indicate that implants placed with a guided flapless protocol in the posterior maxilla can be immediately loaded with comparable results to a conventional protocol (one-stage surgery and delayed loading). The immediate loading of implants in the maxilla with predominantly soft bone has not been extensively investigated. Other studies recommend using tapered implants, underpreparing implant sites where soft bone is present and splinting the implants with a provisional construction.142, 143, 147, 148 The tapered implants used in this study were splinted, but underpreparing was not performed with this guided surgery protocol. One implant was lost after a fracture of the provisional bridge and it is our believe that this technical complication caused undesired overloading of unsplinted single-standing implant. In an in-vitro study of Bergkvist and co-workers140 the authors suggest that splinting of implants results in a 9 times lower stress level in the surrounding bone compared to uncoupled implants. Hence, in this study, loading on the remaining part of the prosthesis attached on the most posterior implant could have resulted in high lateral forces and disintegration of the implant. The implant was mobile at time of evaluation albeit without causing discomfort or without signs of infection.

The accuracy of guided implant surgery is determined by the sum of possible errors occurring during all steps the procedure from implant planning over implant installation to prosthetic reconstruction. They result in deviations between the virtual implant planning and post-operative implant location. Maximum deviations at the apical level of implants should be taken into consideration when critical anatomical structures are in the proximity of the planned implants. Clinical factors such as artefacts on the CT scan, length of the planned implants, stabilization of the guiding template during surgery and location of the implant compared to template support should be taken care of and influence decision-making during implant planning. It is the experience of the clinician that dictates the limitations to what extent a guided surgery treatment planning is possible. Deviations at the shoulder of the implants are important when a prosthesis is finalized before surgery. A recent cadaver study of Van Assche and co-workers84 reports deviations of on average 1.1 mm (range 0.3 – 2.3 mm) at the shoulder of the implant and on average 1.2 mm (range 0.3 – 2.4 mm) at the tip of the implant. Inaccuracies at the level of the implant-shoulder result in a misfit of the prosthesis and complicate the long-term outcome of the newly installed implants. A recent study of Komiyama and co-workers86 report on the high occurrence of surgical and technical complications. Misfit of the abutment-bridge appeared in 5/29 cases. Hence, it is in our believes that with the current available techniques and reported inaccuracies91 it is not possible to prefabricate a prosthesis, completely ready to install on implants based on the guided treatment planning. It is therefore recommended to take an impression or reline a provisional prosthesis immediately after surgery when following an immediate loading protocol. However, the
The technique used in this study has the advantage that the clinician can do the prosthodontic work chair-side and with lower technical costs.

The high occurrence of fractures of the provisional bridges in the test group (3/13) is a warning sign of the difficulty when relining a pre-fabricated provisional prosthesis immediately after surgery. The design of the Straumann TE implant with its flared neck complicates the adaptation of the temporary cylinders when the implants are placed with flapless procedure. The transmucosal part of the implant is wider than the punch through the soft tissues resulting in a narrow adaptation of the soft tissues around the implant neck. This can result in a possible misfit of the implant with the temporary cylinder (figure 5.3). When the temporary bridge is relined in the mouth and then installed after finishing outside the mouth, a possible misfit can result in internal tension and possible fractures within the provisional. Another explanation for high fracture rate could be a lack of retention of the cold-curing acrylic with the sandblasted titanium temporary cylinder, eventually contaminated by blood from the surgical procedure. This is sustained by the finding that no fractures of the provisional bridges were seen in the control side, made in the same way. The implants were installed with healing abutments for 6 weeks, resulting in a better adaptation of the soft tissues around the implant neck and no contamination with blood during the adaptation with resin. For this purpose, implant designs with a platform switched implant-abutment connection might have an easier handling in such flapless and immediate loading procedures.

Figure 5.3: Radiographs of the test side of a patient at baseline, after 3 and 12 months. The temporary cylinder was not completely seated on the most distal implant immediately after surgery. The bridge needed to be adapted to resolve this misfit (->) at the implant-abutment interface.

The marginal bone levels of the implants in the test and control group were not statistically significant. Flapless surgery and immediate loading did not alter bone level changes compared to a conventional protocol. This is in accordance with other studies evaluating the effect of flapless surgery\textsuperscript{149} or immediate loading\textsuperscript{150, 151} on marginal bone level around implants placed in the maxilla. The mean marginal bone level from the reference point at implant placement (baseline) was 0.95 mm ± 0.60 for the test implants and 1.16 mm ± 0.39 for the control implants. After 3 months the mean marginal bone level reached a steady state (1.98 mm ± 0.43 and 2.08 mm ± 0.46 for test and control implants respectively). This in accordance with other studies
evaluating the radiographic outcome of Straumann dental implants.\textsuperscript{192-194} Some of the implants showed minor bone gain, although statistically (and clinically) insignificant. This can be attributed to the stimulating capacity of the implants on surrounding crestal bone during load. This has been shown in other studies.\textsuperscript{3, 195} Another possible explanation is the method of analyzing the marginal bone levels on radiographs.

After 18 months the mean marginal bone level was 1.95 mm $\pm$ 0.70 and 1.93 $\pm$ 0.42. This distance corresponds approximately to the turned neck section of the Straumann TE implant, which measures 1.8 mm (figure 5.1). Those results are indicative for the bone loss that occurs when installing implants with the microgap close to the bone as shown in a study of Alomrani and co-workers.\textsuperscript{167} They installed implants with the implant-abutment microgap at different levels related to the crest of the bone in canine mandibles. The average bone loss was greater in implants placed with the microgap more apical to the alveolar crest. However the level of the marginal bone was located closer to the reference point (microgap) for deeper installed implants. It seems that bacterial contamination of the microgap results in an inflammatory cell response that could be associated with cells responsible for bone resorption.\textsuperscript{159, 160} This explains why the implants in our study, which were placed with the microgap (reference point) on average 0.95 mm for test implants and 1.16 mm for control implants above the crest of the bone, lost respectively 1.03 mm and 0.92 mm of bone during the first 3 months. For the long-term clinical success of implants it seems advantageous to have a stable marginal bone level (as a result of minimal bone loss) very close to the implant-abutment interface. A deep submucosal implant-abutment interface is easier to handle for obtaining an aesthetic result because the emergence profile can be modified with mucosa-friendly materials according to the established soft tissue level. For this implant design it seems required to install the implants somehow deeper to obtain a submucosal implant-abutment interface. It seems interesting if the microgap and hence the inflammatory cell infiltrate could be transferred away from the bone without compromising the aesthetic result as might happen when the titanium implant shoulder is located superficially related to the soft tissue level. This can be seen with other implant designs where the connection between implant and abutment is positioned inwardly and away from the outer edges of the implant platform (platform switching) with promising results.\textsuperscript{196-198}

One of the main advantages of flapless implant surgery is very well reflected by the changes in soft tissue height on the buccal side of the implants. A statistically significant gain in height was seen 1 week after surgery at conventional surgery sites, caused by the post-operative swelling occurring after flap surgery. Implants placed with a flapless approach did not cause such a swelling. This results in less post-operative pain and less need for painkillers as shown by Fortin and co-workers.\textsuperscript{73} A trend was seen that flapless implants have less attached mucosa compared to the control implants, although this was only statistically significant at week 1 and 6. This was caused by punching or drilling through the mucosal tissues during implant installation
because the guide sleeves of the drilling template determine the punch location. A disadvantage of flapless guided surgery is that the discrimination between keratinised and non-keratinised mucosa cannot be visualized on the implant planning software. In cases with limited amounts of attached mucosa at implants sites it is recommended to make small crestal- or palatal-orientated incisions pushing the tissues to the buccal side to avoid losing keratinised mucosa more often caused by punching with the flapless procedure.

The overall patient’s opinion about the two different procedures indicative of treatment satisfaction, was very high and improved after installing the final prosthesis, although this was not statistically significant. Scores for opinion about speech, function, aesthetics, self-confidence and overall appreciation of the healing abutments/provisional prosthesis were, however, significantly better at test sides compared to control sides the first weeks post-operatively. This difference is attributed to the immediate loading procedure since the differences disappeared once the control sides were provided with a provisional prosthesis as well. There was no significant difference between the two procedures in overall treatment satisfaction. This may reflect a lower treatment need for immediate implant restoration in the posterior maxilla. The patients did benefit in speech, function, aesthetics, self-confidence and appreciation of how the provisional felt with the immediate loaded implants but overall they were equally satisfied with the conventional treatment since they were aware that the provisional prosthesis would also be loaded after 6 weeks. This does not necessarily apply when implants needs to be installed in the anterior maxilla regarded more often as "the aesthetical zone".

In this study there was no statistically significant difference for pain or comfort scores between the test and control sides. This is contradictory to the study of Fortin and co-workers who report less experienced pain when implants were installed with a flapless procedure. However the split-mouth design used in the present study might not be apt to differentiate pain experience. Either a patient has pain or not to a certain level and it is difficult to distinguish or locate the pain to a certain region in the mouth. Furthermore patients were allowed to take painkillers. Moreover, the flapless installed implants were immediately loaded resulting in a different perception with a new fixed prosthesis in function. The study of Fortin and co-workers compared a group of patients with flapless surgery to a group with conventional surgery, which is probably a more accurate way to investigate post-operative discomfort.
5.5 Conclusion

Implants installed with a guided flapless protocol and immediately loaded with a provisional prosthesis have a comparable clinical and radiographic outcome than implants installed with a conventional procedure and delayed loading. The high survival and success rates are indicative of an excellent prognosis obtained with the Straumann TE implants in the posterior maxilla, either with immediate or delayed loading.

A flapless procedure results in less swelling of mucosal tissues during the healing phase compared to conventional surgery. From a patient’s point of view a flapless procedure and immediate loading of implants in the posterior maxilla did not significantly altered the perception on treatment satisfaction.
THE CLINICAL AND RADIOGRAPHIC OUTCOME OF A NOVEL IMPLANT DESIGN: THE NOBEL DIRECT® IMPLANT

Part of this chapter has been published as:

Two-year outcome with Nobel Direct® implants. A retrospective radiographic and microbiological study in 10 patients.

6. THE CLINICAL AND RADIOGRAPHIC OUTCOME OF A NOVEL IMPLANT DESIGN: THE NOBEL DIRECT® IMPLANT.

6.1 Introduction

Oral implantology has shifted from a basic scientific background in the early 1970’s to a well-established clinical procedure in today’s daily dental practise. Dental implant treatment is now considered simple and unfussy provided the practitioner does not disregard certain guidelines to support an evidence-based treatment. Some implant systems and treatment protocols have sufficient long-term scientific evidence to sustain their usage for successful treatment of partial and complete edentulism.5, 14, 15, 139, 199-204

From the clinician’s perspective there is a consensus that long-term scientific evidence is needed before changing an aspect of the oral implant equipment.205 However research and clinical trials runs behind clinical reality and sometimes implants are already outdated at the time of publication. As a consequence what is published seems often “old-school” for clinicians visiting industry-sponsored meetings. More and more, the dental implant industry is dictating today’s practise and science seems overrun by commerce. Nowadays, the evolution of implant-design together with patient’s demands is pushing the boundaries of the oral biology. Implant companies claim treatment concepts dominating the implant environment and advice surgical and prosthetic protocols without sustained evidence. What happens if an implant company forgets the scientific timeframe to quench its commercial thirst?

The Nobel Direct® implant was commercially launched in 2004. This one-piece implant was designed to minimize marginal bone resorption as there is no submucosal microgap.206 Furthermore, the rough Ti-Unite™ surface, which is left towards the mucosa, would form a “soft tissue integration” for an optimized aesthetic outcome. This soft tissue integration was a new concept without any scientific and clinical evidence. The company advised and sustained by their brochure to install the implant with a flapless approach and immediately prepare the supramucosal part with carbide burs for immediate function (Nobel Biocare, 2003). The first papers report inconclusive success rates from 46,1% to 97,9% and are published in the peer-reviewed literature starting from 2005. 207-212

The aim of this present study was to evaluate the clinical and radiographic outcome and failure rate of Nobel Direct® implants and relate those findings to the current knowledge of successful dental implants.
6.2 Material and methods

The present study was conducted in accordance with the principles of the Declaration of Helsinki (1975). Informed consent was obtained from all subjects prior to clinical examination. The Ethical Committee of the Ghent University Hospital approved the study protocol.

6.2.1 Subjects

In total 10 subjects were consecutively treated by a periodontal surgeon (ET) with 18 years of experience. They were treated after referral for implant treatment in the partially edentulous mandible or maxilla in spring 2005. At the time of surgery a pre-surgical assessment involved clinical and radiographic examination. The subjects were required to be healthy and to have adequate bone for the placement of at least 1 implant in the edentulous space. The opposing teeth were natural teeth or complete or partial removable dentures. Heavy smokers (> 10 cig./day) were not excluded. The subjects underwent periodontal treatment whenever considered necessary on the remaining teeth. Exclusion criteria were general contra-indications for oral implant surgery and inadequate bone volume or infection at the implant recipient site. Previous tooth extractions at the implant recipient site were performed at least 3 months prior to implant insertion.

6.2.2 Clinical procedure

Surgical treatment was performed under local anaesthesia. The flap design was kept as minimally invasive as possible. When indicated a flapless procedure was performed with a soft-tissue punch (n= 4). For the flap cases, a crestal incision was made to raise a full thickness muco-periosteal flap (n= 8). At least 1 Nobel Direct® implant was installed in every edentulous space according to the manufacturer's guidelines. Implant installation was prosthetic driven by a surgical guide. Implants were intentionally installed with the implant threads completely covered by bone. To achieve perfect initial stability the insertion torque value was set at 30 Ncm for the diameter 3.5 mm and 40 Ncm for the diameter 4.3 mm and 5 mm implants. Periapical radiographs were taken immediately after surgery (baseline). Subjects received a post-surgical analgesic (Ibuprofen 600 mg or Paracetamol 500 mg), and were supplied with an ice-pack to reduce post-surgical swelling.

6.2.3 Postoperative care

The subjects were given the advice to rinse with Chlorhexidine 0.12% (PerioAid, Dentaid, Barcelona, Spain) and to perform standard oral hygiene measures. No special dietary advice was given. The subjects were advised to take ibuprofen 600 mg or Paracetamol 500 mg painkillers at their own discretion. Amoxicilline antibiotics were administered 2g daily for 4 days.
After 10 days the sutures were removed. Oral hygiene was re instructed with a soft manual toothbrush.

6.2.4 Prosthodontics
Implants were left unloaded during the early healing phase. The supramucosal part of the implant was not prepared until subjects were recalled 3-6 months after surgery for radiographic evaluation and evaluation of clinical mobility, pain or infection. The subjects were then referred to the general dentist for implant prosthetics and regular professional maintenance. Preparation of the abutment portion of the implant was done with purpose-made drills (Nobel Biocare AB, Gothenburg, Sweden) on a high-speed hand-piece. A circumferential margin was prepared in order to create a prosthetic pillar. Excessive water-cooling was used during drilling to protect the implant from overheating. The type of the implant restoration was left at the discretion of the general dentist. Subjects with a history of periodontal disease were regularly followed-up by the periodontist.

6.2.5 Research examination
Subjects were recalled after 2 years. Digital peri-apical radiographs were taken with a commercially available filmholder. Measurements were done by an independent clinician not involved during the treatment using the software ImageJ 1.38x (National Institutes of Health, USA). The examiner was calibrated during an initial session with the surgeon for consequent interpretation of the radiographs. The lower corner of the coronal cylinder of the Nobel Direct implant was used as a reference point from where on marginal bone level was calculated at the mesial and distal site. Each radiograph was calibrated using the known implant length to correct for magnifications. True bone resorption was calculated comparing the marginal bone level on the post-operative radiograph with the follow-up radiographs. The mean of mesial and distal measurements was taken as the individual implant value and used to calculate mean bone loss on patient level and those were used for statistical analysis of bone loss over time by means of the paired Wilcoxon signed ranks test. The criteria used to discriminate surviving from successful implants allowed a maximal bone loss of 1.5 mm during the first year and furthermore < 0.2 mm yearly and were done on implant level.

6.2.6 Microbiological sampling and processing
Bacterial samples were taken after two years of function. The bacterial samples were collected at the implant site with five sterile endodontic paper points. The paper points remained in situ for 10 seconds. The five samples from each implant were placed in a dry Eppendorf vial. Samples were shipped to the Oral Microbiology laboratory at the University of Berne, Switzerland and immediately processed by the checkerboard DNA-DNA hybridization method.
as described elsewhere.\textsuperscript{213-215} A total of 74 bacterial strains were analyzed. The checkerboard DNA-DNA panel had been developed by using known species provided by the Forsyth Institute (Boston, Mass, USA) or had been purchased from the ATCC collection of species (LGC Promochem Sarl, Molsheim Cedex, France). In order to receive a fully detailed account of the identified bacteria, the digitized information was analyzed by a software program (ImageQuant, Amersham Pharmacia, Piscataway, NJ, USA) allowing comparison of signals against standard-lanes of known bacterial amounts (105 cells) in the appropriate checkerboard slot. Signals were converted to absolute counts by comparison with these standards and studied as the proportion of sites defined as having $\geq 1.0 \times 10^4$ and $\geq 1.0 \times 10^5$ bacterial cells. Cross-reactivity is routinely tested in the microbiology laboratory between known pure bacterial standards with results consistent with those reported elsewhere by others.\textsuperscript{214}

6.2.7 Chemical analyses
Surface chemical analyses were performed on 3 unused implants delivered in unbroken containers with different LOT numbers. Two regions per implant were investigated using the PHI 5500 instrument (Physical Electronics Industries, Al Ka monochromatic radiation).

6.2.8 Retrieved sample preparation
Because of ongoing bone resorption and continuous infection one implant needed to be removed after 21 months to preserve remaining peri-implant tissues. The subject consented to have the trephined implant histologically examined. The specimen was immersed in fixative and processed according to the so-called Exakt technique (Exakt Apparatebau, Norderstedt, Germany) initially described by Donath and Breuner.\textsuperscript{216} This preparation results in undecalcified cut and ground sections of 10 μm. The sections were stained by Toluidine-blue mixed with Pyronin G. The light microscopic investigation involved qualitative and quantitative analyses of tissue surrounding the implant. The latter was done with a computerized image analysis tool and involved bone-to-implant contact and bone area inside the threads.

6.2.9 Statistical methods.
Statistical analysis was performed with SPSS for Windows (version 12.0). Descriptive statistics were used for the clinical and microbiological data and to report the histological findings. The radiographic bone level data were used as the primary outcome measure of implant success. The paired Wilcoxon signed rank test was used for assessment of radiographic bone loss declaring a significant difference at the $P < 0.05$. 
6.3 Results

Implants were on average 23.4 months (SD 2.7 months; range 19-27) in function. A total of 12 implants was installed; 1 of 16 mm length, 3 of 13 mm length and 8 of 10 mm length. Implant diameter was 5 mm in 1 implant, 4.3 mm in 6 implants and 3.5 mm in 5 implants. Of the 10 treated subjects, 4 were women and 6 were men with a mean age of 54.7 years (SD 5.4 years; range 46-64 years). Only one subject was a smoker. The implant in this subject belonged to the successful implants.

All implants were installed with a maximum of 40 Ncm insertion torque. A summary of subject selection, implant type, surgical procedure and true bone loss is summarized in table 6.1.

Table 6.1: Summary of subject selection, implant type, surgical procedure and bone loss.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (years)</th>
<th>Implant position</th>
<th>Implant type</th>
<th>Flapless</th>
<th>bone loss (mm) 0-6 months</th>
<th>bone loss (mm) 0-2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.L.</td>
<td>51</td>
<td>46</td>
<td>RP 4.3 x 13</td>
<td>No</td>
<td>0.67 1.9 1.30</td>
<td>1.67 1.85 1.76</td>
</tr>
<tr>
<td>B.L.</td>
<td>53</td>
<td>36</td>
<td>RP 4.3 x 13</td>
<td>No</td>
<td>2.73 3.45 3.09</td>
<td>2.73 3.45 3.09</td>
</tr>
<tr>
<td>D.J.</td>
<td>53</td>
<td>46</td>
<td>RP 4.3 x 10</td>
<td>No</td>
<td>1.25 1.5 1.38</td>
<td>1.62 1.89 1.76</td>
</tr>
<tr>
<td>D.J.</td>
<td>53</td>
<td>36</td>
<td>RP 4.3 x 10</td>
<td>No</td>
<td>4.83 4.17 4.50</td>
<td>failure failure failure</td>
</tr>
<tr>
<td>L.J.</td>
<td>56</td>
<td>47</td>
<td>WP 5 x 10</td>
<td>No</td>
<td>-               -</td>
<td>1.4 1.20</td>
</tr>
<tr>
<td>P.H.</td>
<td>50</td>
<td>33</td>
<td>NP 3.5 x 13</td>
<td>No</td>
<td>2.64 0.05 1.35</td>
<td>3.81 2.4 2.96</td>
</tr>
<tr>
<td>P.J.</td>
<td>64</td>
<td>15</td>
<td>RP 4.3 x 10</td>
<td>Yes</td>
<td>-               -</td>
<td>1.85 2.71 2.28</td>
</tr>
<tr>
<td>P.L.</td>
<td>46</td>
<td>14</td>
<td>NP 3.5 x 16</td>
<td>Yes</td>
<td>1.1 2.35 1.73</td>
<td>2.06 2.82 2.44</td>
</tr>
<tr>
<td>S.T.</td>
<td>57</td>
<td>26</td>
<td>NP 3.5 x 10</td>
<td>Yes</td>
<td>0.4 0.65 0.53</td>
<td>0.45 0.84 0.65</td>
</tr>
<tr>
<td>S.G.</td>
<td>54</td>
<td>14</td>
<td>NP 3.5 x 10</td>
<td>No</td>
<td>4.9 3.86 4.38</td>
<td>failure failure failure</td>
</tr>
<tr>
<td>VW.J.</td>
<td>62</td>
<td>34</td>
<td>RP 4.3 x 10</td>
<td>No</td>
<td>0.87 1.28 1.08</td>
<td>1.6 1.34 1.47</td>
</tr>
<tr>
<td>DS.G.</td>
<td>54</td>
<td>24</td>
<td>NP 3.5 x 13</td>
<td>Yes</td>
<td>3.18 2.01 2.60</td>
<td>2.7 2.44 2.57</td>
</tr>
</tbody>
</table>

After 6 months and 2 years of loading respectively, 12 and 9 implants were checked and all were found to be clinically stable and without clinical signs of inflammation. Between the two intervals, however, 3 implants had to be removed because of ongoing bone resorption and infection. The clinical survival rate was 100% at the 6-months follow-up and 75% at the 2-years follow-up. Based on marginal bone levels the individual implant success was after 6 months and 2 years 42% and 25% respectively. A 4-field distribution of one-piece implants according to the success criteria of Albrektsson & Isidor\textsuperscript{21} is shown in table 6.2 and 6.3.

Table 6.2 & 6.3: Four-field table representing the proportion of one-piece implants (n= 12) at 6 months and 2 years (n=12) according to Albrektson & Zarb\textsuperscript{99}.

<table>
<thead>
<tr>
<th>SS</th>
<th>U</th>
<th>2</th>
<th>SS</th>
<th>U</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>SI</td>
<td>5</td>
<td>F</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SI</td>
<td>6</td>
<td>F</td>
<td>3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Success = remodelling ≤ 1.5 mm after 1 year and ≤ 1.7 mm after 2 years.
Failure = removed implants
Unaccounted for = implants lost from recall
Survival = implants in function but with missing bone evaluation or bone value above the success threshold.
As an example of the variability in bone loss, radiographs of 3 implants with 2 years of loading are shown in figure 6.1. Mean marginal bone levels at patient level are shown in table 6.4 and illustrated at implant level in figure 6.2. Readings were available from 7 subjects for all evaluation intervals (table 6.5). Statistically significant bone loss was detected after 6 months and 2 years.

Table 6.4. Mean bone level, SD, range and number of subjects in the respective intervals.

<table>
<thead>
<tr>
<th>Time</th>
<th>Marginal bone level (mm)</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. deviation</td>
</tr>
<tr>
<td>Baseline</td>
<td>0,74</td>
<td>0,57</td>
</tr>
<tr>
<td>6 months</td>
<td>1,43</td>
<td>1,65</td>
</tr>
<tr>
<td>24 months</td>
<td>1,11</td>
<td>1,02</td>
</tr>
</tbody>
</table>

Table 6.5: Marginal bone level measured in mm from the implant reference point for 7 subjects with all evaluation intervals available up to 2 years. Changes with respect to previous interval are measured with Wilcoxon Signed Rank Test and P < 0.05 is statistically significant and indicated with an asterix.

<table>
<thead>
<tr>
<th>Time</th>
<th>Marginal bone level (mm)</th>
<th>Bone loss (mm)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>St. deviation</td>
<td>range</td>
</tr>
<tr>
<td>Baseline</td>
<td>0,71</td>
<td>0,59</td>
<td>-1,67 - 0,00</td>
</tr>
<tr>
<td>6 months</td>
<td>0,71</td>
<td>0,96</td>
<td>-1,14 - 1,63</td>
</tr>
<tr>
<td>24 months</td>
<td>1,23</td>
<td>1,14</td>
<td>-1,02 - 1,76</td>
</tr>
</tbody>
</table>
Figure 6.1: Three radiographs of 3 patients with implants 2 years in function. Note the variability of bone loss around the implants.

Figure 6.2: Marginal bone level according to the reference point for all implants. The lower corner of the coronal cylinder of the Nobel Direct implant was used as a reference point from where on marginal bone level was calculated at the mesial and distal site. Lines marked with "***" represent the imaginary bone loss that occurred for 3/12 implant failures.

Bacterial samples
The distribution of bacteria present > 1x10^5 cells are presented for implant samples (table 6.6). A total of 45/76 species assessed were present in one or more samples from implant sites. The highest prevalence rates were found for Fusobacterium spp., L.buccalis, P.melaninogenica, and V.parvula and all present in all implant samples. In addition, A.actinomycetemcomitans (Y4), S.aureus, P.aeruginosa, P.intermedia, T.forsythia, T.denticola, and T.socransky were commonly also present.

Chemical analyses
Irrespective of analyzed region, similar findings were obtained. Moreover, all 3 implants revealed similar contaminations with some minor differences between different implants. Besides the signals from Ti, O and C peaks of P, F, S, N and Ca could be observed. The results from the chemical analyses on 2 different implants are shown in figure 6.3.
Table 6.6: The distribution of bacteria present > 1x10^5 cells for implant samples.

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Implant (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aggregatibacter actinomycetemcomitans (Y4)</td>
<td>75.0%</td>
</tr>
<tr>
<td>Aggregatibacter actinomycetemcomitans (b)</td>
<td>12.5%</td>
</tr>
<tr>
<td>Actinomyces israelii</td>
<td>12.5%</td>
</tr>
<tr>
<td>Actinomyces naeslundii</td>
<td>12.5%</td>
</tr>
<tr>
<td>Actinomyces odontolyticus</td>
<td>12.5%</td>
</tr>
<tr>
<td>Bacteroides ureolyticus</td>
<td>37.5%</td>
</tr>
<tr>
<td>Campylobacter rectus</td>
<td>50.0%</td>
</tr>
<tr>
<td>Campylobacter gracilis</td>
<td>37.5%</td>
</tr>
<tr>
<td>Campylobacter showae</td>
<td>12.5%</td>
</tr>
<tr>
<td>Capnocytophaga gingivalis</td>
<td>25.0%</td>
</tr>
<tr>
<td>Capnocytophaga ochracea</td>
<td>37.5%</td>
</tr>
<tr>
<td>Capnocytophaga sputigena</td>
<td>50.0%</td>
</tr>
<tr>
<td>Eikenella corrodens</td>
<td>12.5%</td>
</tr>
<tr>
<td>Eubacterium saburreum</td>
<td>12.5%</td>
</tr>
<tr>
<td>Fusobacterium nucleatum ss.nucleatum</td>
<td>100.0%</td>
</tr>
<tr>
<td>Fusobacterium periodonticum</td>
<td>100.0%</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>12.5%</td>
</tr>
<tr>
<td>Lactobacillus acidophilus</td>
<td>37.5%</td>
</tr>
<tr>
<td>Lactobacillus cispatus</td>
<td>62.5%</td>
</tr>
<tr>
<td>Lactobacillus iners</td>
<td>12.5%</td>
</tr>
<tr>
<td>Leptotrichia buccalis</td>
<td>100.0%</td>
</tr>
<tr>
<td>Mobiluncus curtisi</td>
<td>12.5%</td>
</tr>
<tr>
<td>Neisseria mucosa</td>
<td>62.5%</td>
</tr>
<tr>
<td>Peptostreptococcus micros</td>
<td>37.5%</td>
</tr>
<tr>
<td>Prevotella bivia</td>
<td>37.5%</td>
</tr>
<tr>
<td>Prevotella disiens</td>
<td>12.5%</td>
</tr>
<tr>
<td>Prevotella intermedia</td>
<td>62.5%</td>
</tr>
<tr>
<td>Prevotella nigrescens</td>
<td>37.5%</td>
</tr>
<tr>
<td>Porphyromonas gingivalis</td>
<td>37.5%</td>
</tr>
<tr>
<td>Proteus mirabilis</td>
<td>12.5%</td>
</tr>
<tr>
<td>Prevotella melaninogenica</td>
<td>100.0%</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>25.0%</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>50.0%</td>
</tr>
<tr>
<td>Streptococcus anginosus</td>
<td>12.5%</td>
</tr>
<tr>
<td>Streptococcus constellatus</td>
<td>12.5%</td>
</tr>
<tr>
<td>Streptococcus gordonii</td>
<td>50.0%</td>
</tr>
<tr>
<td>Streptococcus intermedius</td>
<td>12.5%</td>
</tr>
<tr>
<td>Streptococcus mitis</td>
<td>12.5%</td>
</tr>
<tr>
<td>Streptococcus mutans</td>
<td>12.5%</td>
</tr>
<tr>
<td>Streptococcus oralis</td>
<td>25.0%</td>
</tr>
<tr>
<td>Streptococcus sanguinis</td>
<td>12.5%</td>
</tr>
<tr>
<td>Tannerella forsythia</td>
<td>62.5%</td>
</tr>
<tr>
<td>Treponema denticola</td>
<td>50.0%</td>
</tr>
<tr>
<td>Treponema socransky</td>
<td>50.0%</td>
</tr>
<tr>
<td>Veillonella parvula</td>
<td>100%</td>
</tr>
</tbody>
</table>
Figure 6.3: Results of the chemical analysis of 2 Nobel Direct implants with a different LOT number. Note the differences in peaks for Ca2s/ Ca2p and F1s between the 2 implants.

Retrieved sample

The survey picture of the cut and ground section demonstrated the bone tissue to be located in the lower part of the implant. About 50% of the entire implants was lacking tissue in the upper region (figure 6.4A). The distance from the implant neck to the first bony contact level
was about 4 mm. The mean bone to implant contact based on all available threads was 19% and the bone area inside the threads was 46%.

Along some of the bone free upper region of the implant surface, blue stained areas / rims could be observed. No other signs of soft tissue or inflammatory cells could be observed in this area, i.e. the implant surface was possibly covered by bio-film.

The uppermost bone tissue surface (cranial part) seemed to have been under resorption (clear reversal lines) however, new-formed woven bone type tissue were located on the old pre-resorbed surface. Focusing on the tissue outside the implant, i.e. in the thread regions, in higher magnification, Haversian canals with clearly visible cement lines were located close to the implant surface (figure 6.4B) and several regions with compact mature-like bone tissue in “direct contact” to the implant surface could be seen. With the aid of polarizing filters mostly lamellar bone (with various directions of the lamella) could be observed inside the threads (figure 6.4C). Moreover, some immature woven bone was also noted. Remodelling cavities were observed both inside the bone and close to the implant, revealing both active bone forming- and bone resorption sites. Regions with entrapped “bone-dust particles” were seen being encapsulated in the bone. Osteocytes with empty- and / or pycnotic nuclei, i.e. devitalised osteocytes were observed in close relation the implant in some places. The innermost interfacial tissue had a darker stained rim in close apposition to the implant coat. If this “ceramic like” tissue rim is due to the implant surface treatment we cannot judge. In even higher magnification the presence of an irregular implant-surface-coat (appearing brownish) could be observed and at some parts non-mineralized, osteoid like tissue (lacking vital cells) was observed in close relation to the coat (figure 6.4D). Soft tissue regions were also observed in close relation to the implant surface. In these regions macrophages and PMNG’s were noted as well as some cells with possibly oxide particles internalized.
Figure 6.4:
Figure A: Survey picture of the 10 um thin undecalcified cut and ground section stained in Toluidine blue mixed with pyronin G. Arrow pointing at possibly bio-film remnants. Bar = 1000 um.
Figure B: Higher magnification of Figure A revealing mostly mature, lamellar bone (LB) and some areas with immature, woven bone tissue (WB). Cement lines are clearly visible (small short arrows) in the lamellar bone. In some regions close to the implant surface the presence of non-mineralized, osteoid like tissue (lacking vital cells) could be observed. These regions could possibly be “disturbed bone mineralization areas” (longer arrow). Bar = 100 um.
Figure C: Similar figure as in B, however, prepared with the aid of polarizing filter as well as a lambda filter. The directions of especially the lamellar bone (LB) are clearly visible. Bar = 100 um.
Figure D: A dark-stained, a-cellular rim revealing “ceramic like tissue” (black arrows) could be observed outside the irregular brownish-coat (white arrows). The white space between the tissue and the coat may be due to fixative artefacts, i.e. shrinkage of the tissue. Bar = 10 um.
Note pycnotic like osteocytes to the left. Bar = 10 um.
6.4 Discussion

Implant success criteria have been described to scientifically evaluate a treatment outcome. It is highly important that new implant designs are carefully evaluated preferably in multi-centre prospective randomized clinical trials in comparison to a well-established successful implant system. The clinical reality is, however, often more demanding than objective scientific criteria. From the patient’s point of view, aesthetics, comfort and treatment satisfaction need to be considered as the patient’s treatment outcome can only be successful or unsuccessful. In order to be clinically used, an implant system should be thoroughly investigated during a reasonably long period of time. If a significant change in implant configuration is proposed, the advantages of the new design have to be scientifically proven by means of randomised controlled clinical trials.

The literature concerning the Nobel Direct® implant system lacks clear evidence of good clinical results. Hahn reported a cumulative survival rate (CSR) of 97.9% after 3 years. The proportion of subjects, however, which reached the 2- and 3-year follow-up was only 16/30 and 4/30 respectively. Cumulative survival rates are a statistical way of boosting scientific figures since they do not take into account the dropouts or the subjects who have not passed a certain time-period. According to the study by Hahn, the CSR after 3 years was 97.9%, but only 75% of the implants could be considered a success according to Albrektsson & Isidor. Furthermore lack of baseline radiographic information makes it impossible to assess the study outcome based on clearly defined radiographic criteria.

Finne and co-workers evaluated 152 Nobel Direct® and Nobel Perfect® one-piece implants. They reported radiographic bone level measurements at baseline, 6 months, 1 year and 2 years, reporting mean values of 0.33 mm, -0.77 mm, -0.98 mm and 0.17 mm respectively. Although they started with 152 implants they only had radiographs of 141, 138, 123 and 26 implants at respectively implant placement, 6 months, 1 year and 2 years. After 1 year of function 21 implants (18%) showed bone levels of > 2.0 mm under the reference point. A retrospective study of Siepenkothen and co-workers reported a mean bone loss during the first year of 0.91 mm (+- 1.27 mm). The studies of Finne and Siepenkothen have similar results compared with studies evaluating radiographic bone levels around 2-piece implants.

However, the authors of both studies failed to relate the radiographic bone measurements to their implant success criteria. Finne and co-workers modified the success-criteria as proposed by Albrektsson and co-workers ignoring the radiographic bone level and Siepenkothen did not mention success rates at all.

Östman and co-workers evaluated Nobel Direct implants according to success criteria somewhat less strict than those proposed by Albrektson and co-workers. They accepted more bone loss dividing the studied implants in grade 1 (< 2 mm bone resorption at 1-year follow-up) and grade 2-success (< 3 mm bone resorption at 1-year follow-up). When applying
those less strict criteria, implant success grade 1 was 46.1% for Nobel Direct® implants compared to 85.5% for a 2-piece implant control group. The corresponding success rates when applying the grade 2 criteria were 72.2% and 91.6% for 1-piece implants compared to 2-piece implants.

The Nobel Direct® one-piece implant system was believed to preserve peri-implant soft tissue and marginal bone levels. When using a two-piece implant system, abutments need to be changed during the treatment period before the delivery of the final prosthesis. This leads to disruption of the soft tissue seal and additional bone resorption. The implant-abutment connection of clearance fit implant systems seems to be unstable under loading conditions.

In this in-vitro study the author showed micro-motion of the implant-abutment interface when load was put on the abutment. This could theoretically in a clinical situation lead to the formation of a wider zone of inflammatory cell tissue around the micro-gap resulting in more peri-implant bone loss. A one-piece implant system combines the intra-osseous threaded implant body, the transmucosal abutment, and the pillar for crown cementation in a single piece. The abutment portion of the implant can be prepared, which makes it possible to create an individualized preparation borderline that follows the anatomy of the soft tissue margin, without violating the soft tissue seal. The Nobel Direct® one-piece implant system was in this philosophy believed to have better soft and hard tissue responses compared to a two-piece implant system. However, this could not be shown in clinical reports as discussed above. Moreover, the success rates are inconclusive and when critically analyzed worryingly low indicating that the Nobel Direct® implants perform worse than conventional implants.

It was therefore decided by the authors to retrospectively evaluate the treatment outcome of a series of Nobel Direct® implants placed in a private practise setting. The results of this study clearly show that the failure rate and the proportion of unsuccessful Nobel Direct® implants are higher compared to validated implant systems. According to the success criteria of Albrektsson & Isidor the individual implant success was after 6 months and 2 years respectively 42% and 25%. This means that after 2 years only 1 of 4 subjects had acceptable bone levels when radiographically evaluated. Sennerby and co-workers indicated that flapless implant placement and immediate loading might be a possible reason for a higher failure rate of Nobel Direct® implants. It can be assumed that a non-guided flapless surgical technique affects the correct positioning of implants within the alveolar bone resulting in perforations and exposure of the trenched part of an implant. This was showed in an in-vitro study evaluating the possible complications encountered with non-guided flapless implant surgery. The positioning of implants placed with a flapless approach deviated significantly from the ideal position resulting in perforations in 59.7% of the investigated implant sites.

There are few studies that have assayed on microbiological distributions in implant health and disease by checkerboard DNA- hybridization over longer time periods. A recent study by
Renvert and co-workers demonstrated that at healthy implant sites S. aureus was found at 8% of sites, P. gingivalis at 8% and A. actinomycetemcomitans (Y4) at 3%. In the present study these bacteria were found at 50%, 75% and 38% respectively. The implants investigated in the study by Renvert and co-workers were all Brånemark implants with a turned surface and placed before the year 2000. The present study suggested that the rough surface not covered by bone could act as a microbial niche for select bacterial colonisation of significant pathogens. The histological analysis of the retrieved implant in this study showed some bone to implant contact on the lower part of the implant. The upper part of the implant surface was covered by biofilm and lacking bone. This means that the infection and bone loss around the upper half of the implant did not affect the osseointegration below at time of explantation. Some pycnotic cells and an atypical ceramic-like tissue in close relation to the surface of the implant could be seen. No conclusions can be drawn however based on this individual sample.

6.5 Conclusion

Radiographic evidence showed a very low success rate for the Nobel Direct® implants in this study. High counts and prevalence of significant pathogens were found at surviving implants. Although extensive bone loss had occurred in the coronal part, the apical portion of the implant showed some bone to implant integration. Hence, the authors suggest that before allowing a new implant on the market this should be thoroughly investigated in a standardised way by independent researchers. This Nobel Direct implant did not meet the criteria for success and should therefore be omitted from usage in patients.
GENERAL DISCUSSION
General discussion referenties in discussie nog nakijken!

Voorstel om de eerste 2 paragrafen te verwijderen uit de “discussie” en te verplaatsen naar de samenvatting?

The use of oral implants for the treatment of partially or completely edentulous patients has become an evidence-based treatment modality in every day’s practise. Implant rehabilitation varies from a single tooth restoration with the highest aesthetic demands to the restoration of oral function in severely resorbed jaws whereby stability and retention for a conventional removable prosthesis is lacking. It is clear that different indications may require implants or components with different features leading to more appropriate results for the specific solution required.

Turned titanium implants became commercially available in the late 70’s shortly after the revelation of research findings regarding the osseointegration of oral implants. Scientific evidence guided changes in implant-design, surface configuration, surgical techniques, restorative modalities and improvements in diagnostic techniques and pre-surgical planning tools. Nowadays, the demands of patients and clinicians to optimise treatment outcomes leads a booming evolution that has become so fast that research often lags the introduction of a new implant, component or technique.

The overall objective of this thesis was to scrutinise whether recently introduced surgical and restorative protocols are beneficial for the patient and offer a successful treatment outcome. Advantages, disadvantages and arguments to perform certain treatments are described throughout the different chapters of the thesis. The procedures are investigated with regards to the clinical and radiographic outcome including technical and biological complications. Healthy soft tissue and crestal bone stability are considered necessary for the long-term success of implant-borne restorations. An implant was considered a failure according to the criteria proposed by the European Academy of Periodontology when it showed individually checked mobility, persistent infection, pain or was removed during the studied interval for any other reason. All individual implants exhibiting 1,5 mm or less bone remodelling during the first year of loading and thereafter less than 0,2 mm annual bone loss, were considered a success.

Chapter one (paper I & II) describes the changes in treatment protocols over the last decades. The introduction of the original protocol advocated a submucosal healing and waiting period of 3-6 months after implant insertion before prosthetic reconstruction. One-stage implant procedures have been proven to yield equivalent results as two-stage procedures and have the advantage that a second surgical procedure, to uncover the inserted implants, can be avoided.

When an oral implant is inserted in the bone, it takes a healing time to allow newly formed bone to grow in intimate contact with the implant surface. The implant becomes
osseointegrated and can withstand functional load once it gained enough stability. The speed of this process is depending on several factors but has improved significantly since the introduction of (moderately) rough surface implants.\textsuperscript{202, 225, 226} The time frame before load can be applied on implants has shifted from the classical delayed loading (several months)\textsuperscript{3}, early loading (within 2 months),\textsuperscript{22, 25, 112, 227} or even immediate loading (within 72 hours).\textsuperscript{31, 37, 38, 59, 61, 62, 69, 228} Several techniques are described to perform immediate loading of dental implants and focus on a facilitated procedure for both the clinical procedure and the patient centred treatment outcome. Special implant components, impression techniques or prosthesis designs have been introduced to be advantageous during the immediate loading procedure.

Recently, advanced techniques using CT-data and implant planning software are introduced to accurately guide implants during surgery according to a preoperatively planned position.\textsuperscript{78, 79, 83} Using this guided surgery it is possible to install implants in predetermined positions without the need of reflecting a flap. This seems to be especially beneficial for the patient since post-operative discomfort is reduced.\textsuperscript{73} The expanding evolution in protocols, techniques or materials has had a remarkable positive impact on treatment outcome. However, sometimes scientific data is lacking and more research is needed to further explore some of those promising innovations.

**Chapter two** (paper III- IV- V) focuses on immediate loading in the completely and partially edentulous patient. Two clinical trials are discussed, investigating turned (paper III) and rough surface implants (paper IV) in the completely edentulous mandible with the same immediate loading protocol. A specific guide was used for correct implant positioning, as impression tray and simultaneous bite registration during implant surgery. The clinical and radiographic outcome of the two studies show that implants can be successfully loaded immediately after surgery with survival rates comparable to conventional loading protocols in the edentulous mandible. A survival rate of 96.7% was obtained with the turned titanium Brånemark implants and 100% with the moderately rough surface TiOblast and Microthread Astra implants after 3 years of loading. The designs of the investigated implants are compared to each other to analyse the influence of implant design on the clinical success rates and radiographic bone loss (paper V). The mean bone loss for Brånemark implants was 1.52 mm, 0.79 mm for TiOblast and 0.70 mm for Microthread implants. There was a significant difference between the Brånemark and TiOblast/Microthread Astra implants but not within both Astra implants types. The immediate loading of implants placed in the posterior maxilla of partially edentulous patients is described in another section. The posterior maxilla is chosen because the alveolar bone in this region is predominantly of poor quality\textsuperscript{141} and considered more critical from a surgical point of view as well as from loading aspects. Implant survival rates of 88.5-100% for the immediate loading of implants in the partially edentulous maxilla are described in other studies.\textsuperscript{31, 33, 34, 47, 142, 143} These figures seem to be somewhat lower than the immediate loading in
the completely edentulous mandible. Consensus papers accept that the immediate loading of the completely edentulous mandible is the most common indication for immediate loading.\textsuperscript{61, 144, 145} The very high survival (97.3\%) and success rates (72.2\%) in our study show that implants can be immediately loaded in this region using splinted screw-retained provisional bridges with similar results compared to the completely edentulous mandible.

We can conclude that immediate loading protocols have similar clinical results when certain criteria are fulfilled. The prerequisite for immediate loading seems to be an implant inserted in healed bone with enough initial stability and splinted with other implants to withstand micro-movements that would prevent the integration of the implant. The attached prosthesis should have a controlled occlusion/articulation to avoid overload on the implants. If one of those parameters cannot be achieved a delayed loading protocol should be conducted not to risk the outcome of the treatment.

It seems interesting to further investigate the influence of different implant designs and components on the peri-implant tissues. Furthermore new criteria should be developed to define implant success for immediate loading procedures. The criteria used in our investigations distinguish surviving implants from successful implants depending on healthy peri-implant tissues and the amount marginal bone loss.\textsuperscript{1} However, those criteria were originally described based on data obtained with two-stage surgery and are stricter for immediate loading procedures because the initial bone remodelling is added. Furthermore, an effort should be made to include patient-centred variables (e.g., patient satisfaction, phonetic, functional or aesthetic improvement) when creating new treatment success criteria.

Chapter three describes the non-functional loading of single tooth implants \textsuperscript{[paper VI].} Single tooth implant restorations are mainly aesthetically driven instead of functionally because patients are often not concerned about a missing tooth in the non-visible zone of the mouth. Hence, it is of great benefit for the patient to reduce the treatment time and restore a single tooth implant as soon possible with a high aesthetical outcome. The immediate non-functional loading of single tooth implants is an established procedure.\textsuperscript{24, 52-54, 151, 155, 229-231} Installing and removing components on implants disturbs the submucosal tissues around the implant-abutment interface and causes additional bone loss and consequently an apical migration of soft tissues.\textsuperscript{163} Hence, it seems interesting to install a definitive abutment immediately or early after surgery. A protocol to provisionalize single tooth implants immediately after surgery with a definitive ceramic abutment was analyzed. A prefabricated ceramic abutment and acrylic provisional crown was installed on ten implants for single tooth restorations in the aesthetic zone. The clinical and radiographic outcome showed promising results with a 100\% success rate and a mean marginal bone loss of 1.11 mm observed after 6 months. However, there was a high complication rate (6/10 complications) with the components used in this clinical trial. The most frequent reported complication was loosening of the abutment screw. A stable and
strong implant-abutment connection could not be attained in this study. This suggests a refinement of the technical aspects of the implant components to be used in such a protocol and might be an interesting aspect for future research.

Less invasive surgery has been the focus of many developments in the medical field. It has the main advantage that the post-operative discomfort is substantially reduced. One of the biggest drawbacks is that the visibility on the surgical field is impaired and therefore complicates the outcome of certain procedures. The installation of oral implants without reflecting a flap is sometimes advocated to be very easy to perform because the surgical procedures are simplified. This is often taught to inexperienced dentists in order to convince them to start installing implants in their patients. Little is known, however, about the positioning within the alveolar bone and the complication rate of implants installed with this flapless surgical protocol. An in-vitro study, analyzing the positioning and complications encountered during freehanded flapless surgery is described in chapter four (paper V). The results indicate that blind surgery negatively influences the positioning of implants and that perforations of the surrounding bone occur in a higher frequency (59.7%), even in the hands of experienced surgeons. For all implants sites, 81.4% of the perforations were located to the palatal side. It is clear that those perforations were caused to avoid the buccal plate to minimize the risk for aesthetic complications. However, a palatally located implant could compromise the desired emergence profile increasing the risk for a ridge-lap restoration (toilet-seat design), a disharmonious scalloping of the gingival margins or phonetical problems. Hence, the use of more precise measurements of soft tissue in situ or the additional use of guiding systems are recommended when installing implants with a flapless protocol.

This guidance can be accurately obtained during surgery when using specially designed drill templates fabricated by stereolithographic rapid prototyping. A protocol for guided flapless surgery and immediate loading in the partially edentulous maxilla is described in chapter five (paper VII). An extensive preoperative planning with implant simulation software was conducted to prefabricate a provisional bridge for easy chair-side relining immediately after surgery. A randomized clinical trial with a split-mouth design was used to compare this protocol to a conventional surgical protocol with delayed loading. The findings of this study are indicative of the very high survival (test: 97.2%- control: 100%) and success rates (test: 72.2%-control: 82.4%) that can be obtained with both clinical protocols with similar results. The mean marginal bone loss at 18 months was 1.00mm and 0.77mm for test and control implants respectively. This in accordance with other studies evaluating the radiographic outcome of Straumann dental implants. The advantages of guided flapless surgery on soft tissue healing and the minor post-operative swelling are clearly confirmed by this study. A significant increase in height of the mucosa was seen around the control implants (flap surgery) compared to the flapless installed implants. Although guided flapless implant surgery has
several advantages, there are some limitations as well. The accuracy of guided implant placement is an area that needs improvement to obtain better results.\textsuperscript{191} This should be the focus of future research. Another limitation is the inability to perform surgical procedures (such as bone augmentation or reduction, soft tissue grafting, periodontal plastic surgery) to improve the aesthetic treatment outcome when doing flapless surgery. It is the experience of the clinician that should determine whether guided flapless implant surgery is indicated for a given case and therefore not indicated for all cases.

Evolution in implant dentistry is limited and stops with complications or a negative patient centred outcome. Biology cannot be pushed and certain guidelines cannot be discarded. The commercial industry has gained a lot of impact on the dental society. Nowadays, certain implant companies claim treatment concepts and advice surgical and prosthetic protocols without sustained evidence. The consequence of implant companies forgetting the scientific timeframe to quench their commercial thirst is described in chapter six. The clinical and radiographic outcome of a novel implant design is described (paper IX). Because of inconsequent reports with inconclusive results in the literature,\textsuperscript{207-210} this implant design was investigated in 10 patients. A failure rate of 25\% and a mean bone loss of 1,94 mm after 2 years around those implants suggest that this implant does not meet the criteria for success and should therefore be omitted from usage in patients. We would strongly suggest that before allowing a new implant on the market this should be thoroughly investigated in a standardized way by independent researchers.

Overview on proposed topics for future research

- Influence of implant design or modification on peri-implant tissue preservation
- Development of a strong and stable implant-abutment interface with tissue-friendly characteristics
- Increase the accuracy of implant guided surgery
- Development of patient-centred success criteria according to established treatment protocols
- The continuous effort of the academic world to investigate innovative protocols before commercial interest and clinical use.
Success (Ss) = remodelling ≤ 1.5 mm after 1 year, and ≤ 0.2 mm annually thereafter. Failure (F) = removed implants
Unaccounted for (U) = implants lost from recall
Survival (Sl) = implants in function but with missing bone evaluation or bone value above the success threshold.

An overview of the different life-table analyses is given in table 1. It is not the aim, however, to compare the numbers of the studies with each other because different protocols in different edentulous regions are applied.

The difference in bone loss patterns after installation of the respective implants is the result of the applied surgical protocol and mainly the implant design. There is a trend that implants seem to show a higher initial bone loss when the implant-abutment interface is located closer to the bone. For this reason it is more appropriate to mention both marginal bone levels as well as bone loss for the radiographic outcome of a certain implant. The clinical relevance of this initial bone remodelling is low when the marginal bone level reaches a steady state over a long-term period and did not lead to biological complications. A successful patient centred outcome relies more on the clinical and aesthetic outcome and the patient’s appraisal of his treatment.
Clinical guidelines

1) **Immediate loading** of implants can be performed if the surgical or prosthodontic technique does not compromise the process of osseointegration:
   - The implant bed is free of ongoing infection
   - Bone-to-implant contact is maximized
     - Avoid extraction sockets
     - Avoid short implants
   - Implants are primary stable
     - Screw design implants
     - Under-preparation of the implant bed
   - Implants are used with enhanced bone healing properties (moderately rough surface)
   - Implants are splinted within a fixed restoration
   - Occlusal forces on the provisional construction are
     - evenly distributed
     - kept minimal
     - in an axial direction to the implant axis

2) **Freehanded flapless implant surgery** cannot be recommended

3) **Guided implant surgery** is still under development and not 100% accurate
   - Optimize the preoperative radiological information
     - Scanning prosthesis
     - Avoid artefacts on CT
   - Deviations at the shoulder of the implants require adaptation of the immediate loading construction (impression-relining)
   - Deviations at the apex of the implants require a minimum distance < 2 mm of critical anatomical structures for selected cases
   - Flapless procedures have limited indications
     - No possibility for hard or soft tissue resective surgical procedures
     - No possibility for hard or soft tissue augmentation procedures
     - Avoid punching in cases with a limited amount of attached mucosa

4) Do not use **innovative** dental implants or components that are not scientifically documented
We can conclude that innovative protocols in implants dentistry can provide certain benefits and can therefore contribute to a better patient centred outcome compared to the conventional protocols. However, every treatment protocol has limitations and is not applicable for all indications. It is the clinical and radiographic outcome that determines if a protocol shows acceptable long-term results in a given situation. Hence, it should be essential that changes in implant hardware or protocols are scrutinised before clinical use in patients. It is the task of the academic world to lead this research in order to create an objective and evidence-based treatment. However, one should not forget the impact of the clinician’s experience when treating patients with a certain protocol. Changing habits, working with new materials or introducing other protocols goes always hand in hand with a learning curve. It is mandatory that a clinician involved in implant dentistry should be aware of his own expertise and limitations. It is again the academic world that should focus on teaching and sharing its knowledge and experience, for the benefit of our patients.
**Summary**

Turned titanium implants became commercially available in the late 70’s shortly after the revelation of research findings regarding the osseointegration of oral implants. It was discovered that implants could form a direct connection with living bone that is preserved during functional load on an attached prosthesis. This was the start of modern oral implantology. Since then, patients are treated for various indications, requiring implants or components with different features leading to more appropriate results for the specific wanted outcome.

Originally it was advocated that implants had to be covered by mucosal tissues after installation to allow a submerged healing period of 3 months in the mandible and 6 months in the maxilla. After integration, the implants were uncovered before starting the prosthodontic procedures in a second-stage surgery. This protocol was empirically based on clinical findings rather than on scientific evidence. Today innovative treatment protocols are introduced that show better results compared to the two-stage surgical protocol with delayed loading. The development of new implant-designs, surface configuration, surgical techniques, restorative modalities and improvements in diagnostic techniques and pre-surgical planning tools can offer several benefits for the patient.

The overall objective of this thesis was to scrutinise whether recently introduced surgical and restorative protocols are beneficial for the patient and offer a successful treatment outcome. The procedures are investigated with regards to the clinical and radiographic outcome including technical and biological complications.

The first chapter gives an overview on the changes in implant treatment protocols during the last decades. The focus of many investigations is to reduce the total duration of implant treatment. The loading of dental implants with a prosthesis immediately after surgery is now an established procedure showing good results. Several techniques are described to practically carry out an immediate loading procedure. With the use of surgical templates it is possible to install implants in predetermined positions. This is especially useful for flapless surgery, which is beneficial for patients since postoperative discomfort is reduced.

Chapter two describes the immediate loading of implants in the completely and partially edentulous patient. One of the major indications for immediate loading is the edentulous mandible. Two clinical trials are discussed, investigating implants with a different design (Brånemark- Astra Ti-Oblast/Microthread) with the same immediate loading protocol in the completely edentulous mandible. The clinical and radiological outcome of the two studies show that implants can be successfully loaded immediately after surgery in the edentulous mandible with predictable long-term results. When comparing the three different designs the Astra implants showed less marginal bone loss.
The immediate loading of implants placed in the posterior maxilla of partially edentulous patients is described in a next section. The very good results of this study show that implants can be immediately loaded in this region with a predictable outcome.

It was concluded that immediate loading protocols have similar clinical results when certain criteria are fulfilled, an implant inserted in healthy bone splinted by a prosthesis with a controlled occlusion/articulation to avoid overload on the implants.

Chapter three describes the non-functional loading of single tooth Straumann implants. Because those implants cannot be splinted the restorations are put out of occlusion. Single tooth implant restorations are mainly aesthetically driven. Hence, it is of great benefit for the patient to reduce the treatment time and restore a single tooth implant as soon possible with a high aesthetical outcome. Installing and removing components on implants disturbs the submucosal tissues around the implant-abutment interface and causes additional bone loss and consequently an apical migration of soft tissues. Hence, it seems interesting to install a definitive abutment immediately or early after surgery. A protocol to provisionalize single tooth implants immediately after surgery with a definitive ceramic abutment was analyzed. The clinical and radiographic outcome show that implants can be restored according to this protocol, however a high complication rate with the components used in this clinical trial was reported. The most frequent reported complication was loosening of the abutment screw. This suggests a refinement of the technical aspects of the implant components to be used in such a protocol and might be an interesting aspect for future research.

Minimal invasive surgery has gained a lot of attention in the medical field. Implants can be installed without reflecting a mucosal flap to reduce the post-operative discomfort. Patients experience less pain and show less swelling after flapless implant surgery. Little is known, however, about the positioning within the alveolar bone and the complication rate of implants installed with a flapless surgical protocol. An in-vitro study, analyzing the positioning and complications encountered during freehanded flapless surgery is described in chapter four. Implants were installed in a model by clinicians with a different level of experience in implant surgery. There were significant deviations in positioning and perforations of the surrounding bone occurred in a high frequency (60%), even in the hands of experienced surgeons. Hence, the use of more precise measurements of soft tissue in situ or the additional use of guiding systems are recommended when installing implants with a flapless protocol.

A protocol for guided implant surgery and immediate loading was compared to the conventional protocol in chapter five. Implants were placed in one side of the posterior maxilla using guided surgery and immediately loaded and on the other side conventionally with delayed loading. The clinical and radiographic outcome of this study show that guided surgery can be predictable with comparable results as a conventional procedure. It was observed that the mucosal tissues around flapless implants showed less post-operative swelling. The
immediate loading for this indication instantly improved the patients’ opinion about function, aesthetics, speech and self-confidence.

Evolution in implant dentistry is limited. Nowadays, certain implant companies claim new concepts without sustained scientific evidence. This can have negative consequences for the patients if unexpected complications occur. The outcome of a novel implant design with no scientific data at time of commercial launch is described in chapter six. A high failure rate and extensive bone loss around those implants suggest that this implant does not meet the criteria for success and should therefore be omitted from usage in patients. The commercial industry gained a lot of impact on today’s concepts in implant dentistry. Innovations should be carefully investigated for their long-term outcome before spreading a new product on the market. It is the task of the academic world to lead this research. Moreover, clinicians should be well educated to have sufficient knowledge before including new treatment protocols in their daily practise. It is again the academic world that should focus on teaching and sharing its knowledge and experience, for the benefit of our patients.

**Nederlandse samenvatting**

In de jaren ’70 werd ontdekt dat titanium schroeven kunnen integreren en in direct contact met kaakbot blijven na functionele belasting door middel van een prothese. Dit was de oorsprong van de hedendaagse orale implantologie. Titanium implantaten met een glad oppervlak werden daarop gecommercialiseerd voor gebruik als verankering van een prothese. Sindsdien worden patiënten behandeld met schroefvormige implantaten voor uiteenlopende indicaties. Het spreekt voor zich dat deze uiteenlopende indicaties implantaatcomponenten met verschillende eigenschappen vergen om het gewenste eindresultaat te bekomen.

Oorspronkelijk werd aanbevolen implantaten na plaatsing volledig te bedekken door tandvlees en ze nadien gedurende 3 maanden in de onderkaak en 6 maanden in de bovenkaak te laten ingroeien. Na de genezingsperiode werden in een tweede ingreep de implantaten vrijgelegd alvorens de prothetische fase op te starten. Dit behandelingsprotocol was echter meer gebaseerd op empirische bevindingen dan op wetenschappelijke evidentie. Thans worden allerlei behandelingsprotocollen voorgesteld die betere resultaten geven dan de originele twee-fase-chirurgie en uitgestelde belasting. De ontwikkeling in implantaatdesign en/of -oppervlakte, chirurgische technieken, restauratieve mogelijkheden, geavanceerde diagnostische middelen en planningshulpmiddelen heeft er toe geleid dat deze nieuwe protocollen een aantal voordelen kunnen bieden voor de patiënt.

Het doel van deze thesis was om een aantal van deze nieuwe chirurgische en prothetische protocollen te evalueren. De klinische en radiografische parameters moeten op lange termijn een succesvolle behandeling kunnen garanderen, alvorens in de dagelijkse praktijk te worden aangewend.
In het eerste hoofdstuk wordt een overzicht gegeven van de veranderingen in behandelingsprotocollen gedurende de laatste decennia. Veel onderzoekers focussen zich op het korter maken van de totale behandelingsduur. Zo kunnen tegenwoordig implantaten worden geplaatst en onmiddellijk worden voorzien van een prothetische constructie met voorspelbare resultaten. Er worden verschillende technieken beschreven om deze onmiddellijke belasting uit te voeren. Gidsplaten laten toe om tijdens de ingreep implantaten te plaatsen op vooraf bepaalde posities. Deze gidsplaten kunnen ook worden gebruikt voor een ingreep waarbij het tandvlees niet meer moet worden open gemaakt. Dit geeft voor de patiënt het grote voordeel dat de postoperatieve ongemakken heel beperkt blijven.

In het tweede hoofdstuk wordt de onmiddellijke belasting van implantaten in de volledig en partiële edentate patiënt geëvalueerd. De volledig edentate onderkaak wordt beschouwd als de belangrijkste indicatie voor het toepassen van onmiddellijke belasting. Er worden twee onderzoeken beschreven waarbij implantaten met een verschillend design (Brânemark-Astra Ti-Oblast/Microthread) onmiddellijk belast worden met een voorlopige constructie. De klinische en radiografische bevindingen geven aan dat deze implantaten onmiddellijk kunnen worden belast met voorspelbare resultaten op lange termijn. De drie implantaatdesigns worden in een volgend onderdeel vergeleken met elkaar. Er werd een verschil vastgesteld in botverlies in het voordeel van de Astra-implantaten.

In het laatste onderdeel van hoofdstuk twee worden de resultaten voorgesteld van een onderzoek naar de onmiddellijke belasting van implantaten in de posterieure bovenkaak. De uitstekende resultaten van dit onderzoek tonen aan dat ook in de posterieure bovenkaak onmiddellijke belasting mogelijk is. De onmiddellijke belasting heeft voorspelbare resultaten als aan een aantal voorwaarden wordt voldaan: het verblokkken van implantaten die in gezond kaakbot worden geplaatst en die gelijkmatig worden belast door een prothese.

Minimaal invasieve ingrepen worden tegenwoordig in alle takken van de geneeskunde aangewend, alsook in de orale implantologie. Implantaten die doorheen de mucosa worden geplaatst (“flapless”) geven minder postoperatieve ongemakken voor de patiënt. Het tandvlees moet niet worden open gemaakt tijdens de ingreep en de nalast en zwelling blijven beperkt. Er is echter weinig geweten over de positie van implantaten in het kaakbot die op deze “blinde” manier worden geplaatst. In een vierde hoofdstuk wordt een in-vitro onderzoek voorgesteld waarbij op een model implantaten “flapless” worden geïmplanteerd door personen met verschillende ervaring in de orale implantologie. Nadien werd de positie van deze implantaten in het kaakbot geëvalueerd. Er werden significante deviaties gezien ten opzichte van de ideale positie en perforaties van het kaakbot traden op in 60% van de implantaten. In een klinische situatie zou dit ernstige complicaties kunnen veroorzaken. De conclusie is dat wanneer we implantaten “flapless” willen plaatsen, we een uitgebreide planning moeten maken en de positie van de implantaten accuraat kunnen leiden om meer voorspelbare resultaten te bekomen. Dit is mogelijk met geleide chirurgie, waarbij gebruik wordt gemaakt van gidsplaten tijdens de implantatiesleeprocedure.

In een vijfde hoofdstuk wordt dergelijk protocol vergeleken met een klassieke procedure. Er werden bij patiënten in de posterieure bovenkaak aan de ene zijde implantaten geplaatst volgens de klassieke manier en uitgestelde belasting en aan de contralaterale zijde met geleide chirurgie en onmiddellijke belasting. De klinische en radiografische resultaten tonen aan dat dit protocol zeer voorspelbaar is en vergelijkbaar met een klassieke procedure. Er werd ook vastgesteld dat de zwelling, die zich normaal manifesteert na een ingreep niet optrad rondom de implantaten die “flapless” werden geplaatst. De onmiddellijke belasting van de implantaten gaf, volgens de patiënten, ook een onmiddellijke verbetering op het vlak van spraak, functie, esthetiek en zelfvertrouwen.

De evolutie van vernieuwingen in de orale implantologie is echter gelimiteerd. Sommige systemen of behandelingenprotocollen komen op de markt zonder gedegen onderzoek. Nadien blijkt dat er complicaties optreden die blijvend nadelig kunnen zijn voor de patiënt. Dit wordt aangehaald in een laatste hoofdstuk. Daarin worden de resultaten van een nieuw implantatiedesign geëvalueerd. De grote aantal mislukkingen en de uitgebreide botverliesen tonen aan dat dit implantatsysteem niet kan worden aangeraden. Negatief is ook het feit dat dit systeem op de markt kwam voor het bekendmaken van de eerste onderzoeksresultaten. De invloed en de druk van de industrie wordt steeds groter. Nieuwe ontwikkelingen die niet degelijk worden onderzocht op een onafhankelijke manier kunnen leiden tot catastrofale gevolgen. De academische wereld heeft als taak deze onderzoeken te leiden en de cliniërs een goede opleiding te geven, zodat deze de indicaties en beperkingen van een nieuwe behandeling kunnen inschatten. Alleen op deze manier kunnen we zeker zijn dat behandelingen worden uitgevoerd die succesvol zijn op de lange termijn.
REFERENCES


