CLINICAL TRIALS AND TREATMENT OUTCOMES OF EDENTULOUS PATIENTS TREATED WITH IMPLANT-SUPPORTED PROSTHESES

by

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy
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Since their introduction, the use of endosseous implant for replacements of missing teeth has increased dramatically. To date, however, there is no evidence-based answer to the important clinical question: What implant-supported prosthesis designs provide the best outcomes? Cochrane systematic reviews have been used to critically assess scientific literature, to answer a wide array of questions. This approach was used to focus on implant-related treatment outcomes, including patient-based outcomes. Data showed that in most cases clinical and patient-mediated outcomes did not differ significantly from one another regardless of the prosthesis used. However, long-term prognosis of implant-supported overdentures using magnet attachments may produce inferior outcomes when compared to other attachments.

In this dissertation it was shown that long-term results following immediate loading of endosseous implants with overdentures were successful based on biological and clinical parameters, cost to patient, and patient-based outcomes. Moreover, it was noted that well-designed clinical trials evaluating efficacy of immediate loading with fixed prostheses are uncommon. Furthermore, a parallel randomized controlled clinical trial focusing on this issue was carried out. In this trial, the author investigated the effects of immediate and delayed loading of implants with mandibular fixed prostheses. The implant-related outcomes
underscore that even when implants are loaded during the healing period (i.e. immediate loading), successful osseointegration can be achieved and maintained. Patients’ satisfaction and oral health-related quality of life indicated that the two loading schemes addressed patient’s need equally.
Acknowledgments:

I am truly grateful to my dear parents and siblings, who despite the distance, manage to convey incredible love and support, who have always believed in me and made many sacrifices in order that I may realize my goals.

I would like to express my appreciation and gratitude to the members of my research advisory committee: Professors Asbjorn Jokstad, Howard Tenenbaum, and Audrey Laporte for their continuous support and guidance.

Deepest gratitude is also due to the following persons who have made the completion of this dissertation possible:

Mrs. Janet deWinter for assisting with patients recruitment and willingness to help out in all capacities.

Mr. Charles Victor for his patience with the statistical analysis of this project.

Mrs. Wanda Wagner and Mr. Walter Maahre for their help with the laboratory work.

Mrs. Janice Rizo and Dr. Reena Garcha for assisting in patients’ recalls.

Lastly, I owe so much to my wonderful husband and best friend Esam. His encouragement, sense of humor, and love has made this journey so much more enjoyable and fulfilling. I love you and our two angels Najd and Shadin more than words can describe.

To my parents I dedicate this dissertation.
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Preface

This dissertation was prepared in the “Publishable Style”. In chapter one, the literature review, objectives and hypotheses are presented. Chapter two contains a Cochrane Systematic Review aimed directly at examining the hypotheses set out in Chapter one. Chapters three and four present independent studies aimed at investigating the rest of the hypotheses stated in Chapter one. Chapter five discusses the work and offers conclusions in the context of the objectives, hypotheses and our current knowledge. The clinical study in Chapter four has been included in the dissertation as submitted for publication, with permission by the exclusive copyright holder Quintessence Publishing Co., Inc., Carol Stream, Illinois, except for minor editing modifications not included in the original publications. The prospective study in Chapter four is co-authored by Dr. Nikolai Attard (second author), Dr. Lesley David (third author) and myself (first author). The Cochrane Systematic Review is co-authored by Professor Asbjorn Jokstad, Dr. Kirk Preston and myself. Otherwise I am the sole author of the thesis. Other collaborations or technical help have been recognized in the acknowledgments.

PUBLICATIONS FROM THE THESIS:


PUBLISHABLE CHAPTERS TO BE SUBMITTED FROM THE THESIS:


4. Al-Fadda S.A., Jokstad A. A Randomized Controlled Clinical Trial of Edentulous Patients Treated with Immediately Loaded Implant-Supported Mandibular Fixed Prostheses. Part II: Patient-Mediated Outcomes.

Chapter 1

Literature Review and Statement of the Problem
Introduction

Demographic changes:

The Americas continue to experience three major demographic shifts: population growth, urbanization, and aging. Like most industrialized countries, life expectancy in Canada is increasing while birth rates have remained relatively stable. This has led to a shift in the demography in Canada such that the population of seniors has increased in proportion to other age groups (Figure 1.1). This phenomenon is not restricted to Canada in that the proportion of older people around the world is outstripping other age groups (Petersen & Yamamoto, 2005). In recent decades, the elderly Canadian population (i.e. those aged 65 and older) has grown to a total of 4.3 million in 2006 (13% of Canada’s population). By 2056, the percentage of those aged 65 and above is expected to reach 27%. As would be expected on the basis of these findings, the proportion of children and young people fell considerably. On July 1, 2006, the group aged 19 and younger represented 24% of the population, versus 37% in 1946. This trend is expected to continue for the next 50 years (Statistics Canada-overview, 2007).

In 2001, the majority of seniors lived in private households (93%) and only 7% lived in collective dwellings, primarily health care institutions such as nursing homes and hospitals.
Figure 1.1: Canadian population projections, 65 years and older:

Note: Medium growth scenario.
Source: Statistics Canada, Catalogue no. 91-520-XIE.
**Changes in financial status:**

The financial status of Canadian seniors has improved significantly over the last 25 years (Figure 1.2). The median after-tax annual income of elderly married couples based on ‘2005 dollars’, rose from $29,000 in 1980 to $38,900 in 2005; an increase of 34%. Across the provinces, the median after-tax income ranged from $28,700 in Newfoundland and Labrador to $44,100 in Ontario. The incomes of seniors not living with family members rose by even higher percentages in this period. Greater access to the Canada and Quebec pension plans has done much to improve the financial status of seniors, as has the expanded coverage of private employer-sponsored pension plans.

In addition, today’s seniors are now eligible to collect benefits from the Canada and Quebec pension plans and it has been surmised that this has helped lower the percentage of seniors in low income. In 2005, the percentage of seniors living in poverty was lower in Canada than in most industrialized countries (Statistics Canada-overview, 2007).
Figure 1.2: Median income of Canadian seniors, by family type and gender:

Chart 28.2  Median income of seniors, by family type and sex

Source: Statistics Canada, CANSIM table 202-0805.
Educational status:

Senior Canadians have achieved higher levels of education as compared to previous generations, with over half (53%) having received an education higher than primary-school education, with one fifth having attended university or college (Figure 1.3) (Meskin, Dillenberg, Heft, Katz, & Martens, 1990). This trend is expected to continue.

**Figure 1.3: Education attainment of Canadian adults aged 55 and older:**

The higher educational status is striking among Canadians aged 55 to 64. The proportion of men in this age group with less than a high school education fell from 53% in 1990 to 24% in 2006, while the proportion of those with a university degree jumped from 10% to 22%. Importantly, there has been an increase in the percentage of women in this age group with university education. Over this same period, this factor tripled from 5% to 17%.
Accordingly, it might be extrapolated that as successive waves of ‘baby boomers’ enter their sixties, the proportion of seniors that have had a postsecondary education will continue to grow, and the overall level of education in this demographic will rise.
**Demographics and oral health status:**

Edentulism is declining according to data presented in various longitudinal and cross-sectional studies. Analysis carried out in Australia, has indicated that the prevalence of edentulism between 1988 and 2005 has dropped by 50% from a previous level of 14.4% in the past seventeen years (Crocombe & Slade, 2007). As shown in a random sample survey carried out in Switzerland, it has been shown that during the 10-year period under study, edentulism decreased from 5.7% to 3.1% with at least a twofold reduction in edentulism in every age group. In the 55-65 year age group, edentulism decreased from 12.6% to 5.5% , and in the 65-74 year age group from 26.8% to 13.8% (Zitzmann NU, Hagmann E, & Weiger R, 2007; Zitzmann et al., 2008). In the United States, there was an approximate decline in edentulism for the entire population of 10% for each successive 10-year cohort (Marcus, Drury, Brown, & Zion, 1996). Similar findings were reported for a Swedish population (Hugoson & Koch, 2008).

Tomorrow’s elderly (45 to 64 years) have experienced improved oral health compared to previous generations while the percentage of edentulous adults has declined over the past 20 years. With these ideas in mind, one must also take into account several factors before concluding that the need and demand for prosthodontic treatment will decrease over the next two decades as the baby boom generation matures. Given demographic trends pointing towards a continuing and rapid increase in the size and median age of the older population it could be speculated that there should be a decrease in the incidence and prevalence of edentulism, on a percentage basis, for the entire population. However this speculation will be more than offset by the growth in the absolute numbers of
those aged 55 years and older who will be edentulous (Douglass, Shih, & Ostry, 2002). Hence, an overall increase in the need for prosthodontic treatment of edentulism can still be expected for the foreseeable future.

Recognizing this likely need for prosthodontic treatment of edentulism it is important to understand the changing economic status of the aging population. If economic trends slow, the size of certain socioeconomic groups (those just above, at or below the poverty level) might grow disproportionately, which could lead to steeper rise in the prevalence of edentulism as alluded to above. Indeed, another factor that could affect the prevalence and incidence of edentulism in the population is that currently, institutionalized elderly persons and homebound populations are underrepresented in national epidemiologic data. This population will certainly increase. These groups tend to have a greater prevalence of edentulism than the general population (Douglass et al., 2002). It has been shown that retention of natural teeth in older patients translates into an increase in the need and demand for dental care. Furthermore, the greater the number of teeth in older adults, the greater the amount and severity of periodontal disease, and the higher the number of restored teeth (Joshi, Douglass, Feldman, Mitchell, & Jette, 1996).

Increased tooth retention, would still lead to increasing needs for tooth replacement, which is being done with increasing frequency using endosseous implants (Worthington, 1988; Zitzmann et al., 2008). These factors coupled with a predictable increase in the need for prosthodontic replacement of lost teeth shows there will be further growth in the use of dental implants. Consequently, dentists will place more endosseous implants and maintain and repair older implant systems and implant-supported prostheses. Hence, within but not
necessarily limited to the context of quality of life, it is critically important to assess and understand what implant approaches (ranging from the surgical to the restorative phases) are the most reliable and cost-effective.
The advent of immediate loading

The high success rate and consequently the widespread use of dental implants for prosthetic rehabilitation has led to revision of numerous aspects of the original treatment protocols (Branemark et al., 1977; Brånemark, Zarb, & Albrektsson, 1985). In particular, the dogma that implants, once inserted, must not be loaded or otherwise put into function immediately thus necessitating two-staged surgery. Often the second-stage of surgery would not occur until at least 3-4 months after the initial surgery. This approach has been questioned as implant treatment has advanced and has led to modification of surgical implant placement towards single stage surgery and immediate loading of implants. This concept and approach is in direct opposition to the standard concept of delayed loading and two-staged surgical treatment (Balshi & Wolfinger, 1997; Schnitman, Wohrle, & Rubenstein, 1990).

Immediate implant loading as an implant-based surgical technique in which the “implant supported restoration is placed into occlusal loading within at least 48 hours after implant placement” was defined recently following the International Congress of Oral Implantologists (ICOI) meeting in 2006 (Wang et al., 2006). Yet despite researchers’ efforts, definitive criteria to define the different loading protocols are lacking. However, some treatment protocols have been described as follows (Misch, Wang, Misch, Sharawy, Lemons, & Judy, 2004a):

- **Immediate occlusal loading:**
  Immediate occlusal loading within 2 weeks of implant insertion;

- **Early occlusal loading:**
Occlusal load to an implant between 2 weeks and 3 months after implant placement;

- **Non-functional immediate restoration:**
  An implant prosthesis in a partially edentulous patient delivered within 2 weeks of implant insertion with no direct occlusal load;

- **Non-functional early restoration:**
  An implant prosthesis delivered to a partially edentulous patient delivered between 2 weeks and 3 months after implant insertion; and

- **Delayed occlusal loading:**
  Occlusal loading of an implant restoration more than 3 months after implant insertion.

Slightly different definitions in terms of temporal aspects of dental implant loading include (Cooper, Rahman, Moriarty, Chaffee, & Sacco, 2002):

- **Immediate loading:**
  Implant placement with primary stability and prosthetic loading with a provisional prosthetic tooth at the same clinical visit.

- **Early loading:**
  Implants placed with primary stability and loaded with a provisional prosthesis at a subsequent clinical visit prior to attaining osseointegration. Early loading should not perturb initial healing (blot clot formation, cellular infiltration, epithelialization) and should follow the onset of osteogenesis since bone formation is enhanced by mechanical stimulation. Therefore, early loading should occur only after approximately 3 weeks of healing.

- **Conventional loading:**
Implant placement (typically achieving primary stability) and healing for 3 to 6 months in a submerged or non-submerged mucosal orientation. This time frame reflects the requirement for osteogenesis and woven bone remodeling to load-bearing lamellar bone and acknowledges the original recommendations of Brånemark (Branemark et al., 1977).

More recently it has been suggested that ‘topographically enhanced’ implants can be loaded within a period of 6 to 8 weeks following surgery (Roccuzzo, Bunino, Prioglio, & Bianchi, 2001)

**Advantages of immediate loading:**

Given that two-stage implant procedures have produced highly successful outcomes, why then is there such interest in the concept and implementation of immediate loading surgical approaches? It might be speculated that the ultimate goal of the immediate loading protocol is to reduce the number of surgeries, which would clearly lead to decrease in morbidity and would shorten the timeframe for both surgery and prostheses insertion. The latter should therefore translate into faster achievement of masticatory functional occlusion and improved aesthetics *without* affecting the high success rates that have been reported for endosseous dental implants. As laudable as these concepts are, in order for immediate loading protocols to be deemed successful, consideration should be given to several key factors pertaining to the surgical and prosthodontic aspects of single stage surgery/immediate loading protocols. Theses will be discussed below.
Factors influencing the outcome of immediately loaded implants:

1- Primary implant stability:

Control of micromotion at the bone–implant interface has been considered to be one of the most significant biological requirements for healing of a load-bearing endosseous implant (Chiapasco, 2004; Degidi & Piattelli, 2005; Gapski, Wang, Mascarenhas, & Lang, 2003; Romanos, 2004). However, this does not mean that micromotion must be prevented and in fact it has been demonstrated that well-controlled micro-motion enhances bone formation at the bone-implant interface of one implant (Vandamme et al., 2007). This notion is also supported at least in part with histometric investigations, that showed that micromotion of less than 30 µm at the implant–bone interface did not interfere with osteogenesis at the implant–bone interface (Kawahara, Kawahara, Hayakawa, Tamai, Kuremoto, & Matsuda, 2003). However, there is a critical threshold of micromotion, above which fibrous encapsulation prevails over osteogenesis and osseointegration of an endosseous implant. It was shown that micromotion should be less than 100 µm in order to achieve functional bone-to-implant contact (Brunski, 1993). Micromotion of the body of the implant of over 150 µm has been shown to disturb normal bone healing around implants, thus leading to fibrous encapsulation of the implant (Szmukler-Moncler, Salama, Reingewirtz, & Dubruille, 1998).

To control and reduce excessive micromotion that could lead to implant failure it has been suggested that ‘adequate’ insertion torque is required to achieve primary stability, particularly in immediately loaded implants. Recent clinical trials have shown that when immediately loaded implants are placed so that a primary stability (insertion torque) of 30-60 Ncm is achieved, the success rate is in excess of 95% (Calandriello, Tomatis, & Rangert,
2003; Drago & Lazzara, 2006; Horiuchi, Uchida, Yamamoto, & Sugimura, 2000; Ottoni, Oliveira, Mansini, & Cabral, 2005; Vanden Bogaerde et al., 2004). However, the additional torque used to secure or evaluate fixation of an implant in bone may actually result in pressure necrosis and/or increase the strain magnitude at the interface and therefore increase the amount of damage and remodeling. These factors could interfere with osseointegration and hence the strength of the bone implant interface (Misch, Wang, Misch, Sharawy, Lemons, & Judy, 2004a). Hence, this particular aspect of immediate implant placement is not only very important but, there is always a risk of generating too much immediate stability that could then lead to implant failure. Hence, routine use of immediate loading might not be as predictably successful as it should be. This provides one rationale for systematic assessment of success rates using an immediate loading protocol.
2-Implant geometry and surface topography:

Another factor that could affect success rates for immediately loaded implants relates to the interactions between the implant surfaces and the surrounding bone. This of course mirrors the original problems faced using two-stage surgical procedures when implant dentistry was in its infancy. Osseointegration depends on biomechanical bonding – the anchorage of an implant to bone through ingrowth into small irregularities of the implant surface. Rough implant surfaces, to a greater extent than smooth surfaces, demonstrate a higher attachment of bone cells and accelerate implant integration (Buser, Weber, Bragger, & Balsiger, 1991; Thomas et al., 1985; Thomas, Kay, Cook, & Jarcho, 1987). Furthermore, significantly higher bone-to-metal contact was observed for implants blasted with 25-micron particles compared to those blasted with 250-micron particles. (Wennerberg A, 1996). Anchorage of an implant to bone relies on growth of new bone into micrometer-sized surface irregularities of the endosseous component of the implant. This takes time. At the histological level, events of endosseous wound healing (hematoma, clot resolution, osteogenic cell migration) precede the osteoblast interlocking into the surface irregularities of the implant during the first weeks following implant placement(Akimoto et al., 1999; Berglundh, Abrahamsson, Lang, & Lindhe, 2003; Slaets, Carmeli, Nært, & Duyck, 2006; Vandamme et al., 2007; Wang et al., 2006). During that time, the implant is dependent on ‘macro’ design features for retention. An example of this is the screw design, which contributes to initial and late mechanical implant stability and has a greater ability to transfer compressive forces than cylindrical designs (Lefkove & Beals, 1990; Randow, Ericsson, Nilner, Petersson, & Glantz, 1999). This minimizes micromotion of the implant. In addition to improving primary stability, a screw-shaped implant increases the surface area available for micro-stabilization and bone ingrowth compared to an implant of a cylindrical form.
Another dimension that is critically important to successful osseointegration is the implant length and diameter. Insofar as immediately loaded implants are concerned, these aspects have yet to be determined (Gapski et al., 2003; Nkenke & Fenner, 2006). In general it has been suggested that the longer the dental implant the better the success rate. In relation to this it has been shown that there is an approximate failure rate of 50% for implants that are less than 10 mm in length when implants were loaded immediately with fixed prostheses in the mandible (Schnitman, Wohrle, Rubenstein, DaSilva, & Wang, 1997). Similar findings have been reported in other studies showing that longer implants had higher survival rates than shorter implants (Arvidson, Bystedt, Frykholm, von Konow, & Lothigius, 1992; Ganeles, Rosenberg, Holt, & Reichman, 2001; Randow et al., 1999). Moreover, because the immediately restored implant loads the interface before the establishment of cellular or osseous micro-connections, it is believed that implant length is one of the most critical factors, particularly when the implants are placed into softer bone types. Interestingly, the effects of increased implant length are not necessarily seen at the interface between crestal bone and the implant. Instead, implant length provides for ongoing stability while the implant-bone interface remodels somewhat deeper down the implant surface at various and ever-changing locations. Hence the longer the surface, the more stable the implant will be as various areas of the implant-bone interface remodel in what seems to be a somewhat asynchronous manner. Additional implant length may also permit it to engage the opposing cortical plate, which also may increase initial implant stability. This is important since cortical bone has a lower remodeling rate than trabecular bone meaning it can stabilize

(Buser et al., 1997; Frandsen, Christoffersen, & Madsen, 1984; Steigenga, al-Shammari, Nociti, Misch, & Wang, 2003).
the implant more effectively during initial healing and remodeling (Misch, Wang, Misch, Sharawy, Lemons, & Judy, 2004b).
3- Surgical technique:

To perform immediate implant loading surgery, it is advisable to follow the same basic surgical guidelines used to place implants for two-stage protocols. For example, the clinician should pay special attention to minimizing heat generated during drilling. This has to be less than 47°C at less than 1 minute to avoid overheating the bone surface thereby leading to the death of nearby osteoblasts and their progenitors. However, although the temperature of 47°C has been reported to be the critical temperature at which irreversible damage occurs to surrounding bone, others have reported bone cell death at temperatures as low as 40°C (A. Eriksson, Albrektsson, Grane, & McQueen, 1982; A. R. Eriksson & Albrektsson, 1983). Aggressive, inadequately irrigated osteotomy preparation can therefore produce a bone interface that, by virtue of the attendant necrosis, is not suitable for the placement of implant fixtures, especially those that are going to be loaded immediately. This can be minimized by using proper irrigation, sharp drills, and controlled surgical technique consisting of progressive vertical preparation of the receptor area (Haider, Watzek, & Plenk, 1993; Matthews & Hirsch, 1972; Sharawy, Misch, Weller, & Tehemar, 2002).

The zone of non-vital bone formed after surgical trauma has been observed to be progressively remodeled and substituted by vital, functional bone after 6 months, with peaks of activity in the very early stages after implant placement (Roberts, 1984; Roberts, 1984). Some authors have proposed that immediate loading can be useful to stimulate the early formation of lamellar bone around the implant body. This is in line with the concept of regional acceleratory phenomenon (RAP) described by Frost (Frost, 1983). Hence, it can be speculated that this RAP, along with the stimulation of peri-implant bone via immediate loading, might lead to enhanced bone turnover around implants that could lead to the
development of more organized lamellar bone to support the implant (Avila, Galindo, Rios, & Wang, 2007).

One method for decreasing the risk of immediate occlusal overload is to maximize vital bone contact with the implant interface by decreasing surgical trauma during implant placement. As discussed, thermal injury constitutes an important aspect of surgical trauma. It is also important to understand that mechanical trauma that may cause micro-fracture of bone during implant placement. Mechanical trauma can lead to osteonecrosis and possible fibrous and granulation tissue encapsulation around the implant instead of osseointegration.
4- Bone quality and quantity:

The modulus of density and elasticity of bone is an indicator of its quality and quantity. The less dense the bone, the lower the modulus and the less amount of bone–implant contact (Misch, 1990; Misch, Qu, & Bidez, 1999). These factors are critically important in relation to the success or failure of osseointegration of two stage, and presumably even more so as regards single stage implants.

Several clinical trials have reported an increase in implant failure in areas with compromised bone quality (Balshi & Wolfinger, 1997; Glauser et al., 2001; Grunder, 2001; Jaffin & Berman, 1991; Schnitman et al., 1997; Tarnow, Emtiaz, & Classi, 1997; Weng et al., 2003). A recent multivariate analysis involving data from four multicenter studies estimated variances and standard errors (SEs) of risks of implant failure in relation to combinations of bone quality and quantity by using a Jackknife method in conjunction with life table analysis of all inserted implants. The research database consisted of 486 patients and 1,737 implants. Both statistical analyses showed that patients with poor bone quality and resorbed jaws had a significantly higher risk of implant failure (Herrmann, Kultje, Holm, & Lekholm, 2007). One dimension of the problem evidently related to low moduli of density and elasticity, which translate clinically into less density and increased softness of the bone. Type 4 bone quality (Bränemark et al., 1985a) has been shown to have significantly lower resonance frequency values compared to bone types 2 and 3 (O'Sullivan, Sennerby, Jagger, & Meredith, 2004).

Based on the above, there is a general agreement among clinicians that the mandibular interforaminal area contains the best quality bone and therefore is a site where
one can expect more predictable outcomes when placing endosseous implants (Babbush, 1986; Chiapasco, Gatti, Rossi, Haefliger, & Markwalder, 1997; Randow et al., 1999). It is important to emphasize, however, that although cortical bone has a high density and elasticity modulus, it is not necessary the ideal bone bed for implant placement. This is because it has a relatively reduced blood supply as compared to cancellous bone and blood supply is important to healing of implants. Adequate blood supply may be a critical factor when single stage implant treatment is being performed.

Basically if factors affect healing in the two-stage implant treatment, they are likely more important considerations in single stage immediate loading treatments. The importance of respecting biological and mechanical parameters that facilitate osseointegration must be considered more carefully when doing single stage implants. This emerging area of implant dentistry requires intensive study before it can be accepted as a standard of care.
5- Prosthesis design and occlusal forces:

Cross arch splinting of the implant is the prosthetic approach recommended when loading dental implants immediately. Many reports have shown that it enhances primary stability, decreases micromotion and distributes occlusal forces evenly (Balshi & Wolfinger, 1997; Branemark et al., 1999; Ganeles et al., 2001; Horiuchi et al., 2000; Jaffin, Kumar, & Berman, 2000; Randow et al., 1999; Salama, Rose, Salama, & Betts, 1995; Schnitman et al., 1997; Spiekermann, Jansen, & Richter, 1995; Tarnow et al., 1997).

Maximum occlusal contact and minimizing lateral interference is the recommended occlusal design for immediate loaded implant. It is believed that this type of occlusion ensures equal distribution of occlusal forces among the loaded implants. The majority of studies showed that occlusal disorders (e.g severe bruxism and clenching) are contraindications for immediate loading. It has been shown that around 75% of implant failures occurred in patients with parafunctional habits (Avila et al., 2007; Balshi & Wolfinger, 1997; Colomina, 2001; Jaffin, Kumar, & Berman, 2004). Consequently, patients with parafunctional habits, if not excluded, should, at least, be informed about risks associated with implant failure when immediate loading is considered.

The evidence supporting the use of cantilevers in the design of implant-supported fixed prostheses when dental implants are being immediately or early loaded is inconclusive. Some researchers did not recommend using cantilevers in immediate load situations since they are believed to increase the amount of load to the most distal fixture by 2-fold (Brunski, 1993; Brånemark et al., 1985a; Tarnow et al., 1997). Alternatively, results of recent clinical trials indicated that incorporating cantilevers in the design of immediately loaded implant-
supported fixed prosthesis has no detrimental effect on ultimate clinical outcomes (Aalam, Nowzari, & Krivitsky, 2005; Colomina, 2001; Engquist et al., 2004; Randow et al., 1999). Basically current scientific evidence, support that careful occlusal analysis and planning including distribution of occlusal support, assessment of the amount of bite force generated by opposing dentition and the presence or absence of parafunctional habits are key factors to consider when an immediate loading regimen is considered.
**Economic outcomes:**

The effectiveness of different designs of implant-supported prostheses as well as associated treatment modalities, prostheses retention and stability, improvement in speech, function and quality of life have been demonstrated clearly in numerous clinical trials (M. Cune, van Kampen, van der Bilt, & Bosman, 2005; Engfors, Ortorp, & Jemt, 2004; M. E. Geertman, Slagter, van 't Hof, van Waas, & Kalk, 1999; K. Gotfredsen & Holm, 2000; P. S. Wright, Glantz, Randow, & Watson, 2002). However, in spite of the phenomenal growth in the economic evaluation of health care programs in the last two decades, the literature evaluating dental care programs is increasing at a slower pace (Glendor, Jonsson, Halling, & Lindqvist, 2001; Morgan, Crowley, & Wright, 1998).

Most studies compared direct and indirect costs associated with implant-supported overdentures to that of conventional removable complete dentures (Jonsson & Karlsson, 1990; MacEntee & Walton, 1998; van der Wijk, Bouma, van Waas, van Oort, & Rutten, 1998; Visser, Meijer, Raghoebber, & Vissink, 2006). Conclusions that arose from them are dated and perhaps of less relevant than when first published. This is related in part to an increasing number of edentulous patients seeking treatment involving dental implants. Mandibular implant-supported overdenture has been recommended as the minimum standard of care for edentulous patients (Feine J.S., 2003; J. S. Feine et al., 2002).

When critically appraising the available literature on economic analysis in implant dentistry, several shortcomings and drawbacks in the design of available studies are evident. A recent randomized controlled clinical trial with a relatively long-term follow-up (8-year) evaluated one hundred and ten patients who received three types of implant-supported
overdentures (bar on 4 implants, bar on 2 implants, and ball attachment on 2 implants). The main outcomes were focused on after care with emphasis on cost (Stoker, Wismeijer, & van Waas, 2007). It was observed that the initial costs account for the majority of the total cost (75%) of the treatment and was significantly higher in the group with a bar on 4 implants. That said, the group with ball attachments on 2 implants needed a significantly higher number of prosthodontist-patient aftercare visits. Given these findings, the authors concluded that an overdenture with a bar on 2 implants might be most efficient over the longer term. The major strength of this study is that it calculated the “real” cost of aftercare in contrast to extrapolating it with data over a period of one year or less, or by using questionnaires completed by a panel of experts as was done by others (Heydecke, Penrod, Takanashi, Lund, Feine, & Thomason, 2005). Conversely, aftercare was scored in rather general terms, an occurrence that is shared by numerous studies (H. J. Meijer, Raghoebär, Van't Hof, & Visser, 2004; I. E. Naert, Hooghe, Quirynen, & van Steenberghe, 1997; Telleman, Meijer, & Raghoebär, 2006). Therefore it is not clear what constitutes acceptable procedures for aftercare (i.e. regular cleaning might be considered as ‘aftercare’ but this would be expected to be more or less consistent across patient groups. This means that technique-driven aftercare is not reported in detail, which consequently limits the predictability of problems requiring ‘aftercare’ that patients may encounter.

Another limitation of most of the available studies on this topic is the lack of long-term data related to cost. This is important because although treatment with dental implants is more expensive in the short-term, it is likely that parts of these additional short-term costs will lead to savings in the future (van der Wijk et al., 1998). However, the only way to
confirm or reject this hypothesis is to conduct well-designed, long-term clinical trials focused specifically on these questions.

The current guidelines in health economics state that an economic evaluation should include the cost of resources employed in the provision of health care as well as the cost of the time spent by patients during treatment. Only two studies have carried out a comprehensive cost analysis of implant treatments including “time cost” to patients (Attard, Laporte, Locker, & Zarb, 2006; Takanashi, Penrod, Lund, & Feine, 2004b). Economic evaluation of different designs of implant-supported fixed prostheses is clearly needed.
Literature review of clinical studies on immediate loading

I. Immediate/early loading of dental implants in the edentulous mandible with fixed prosthesis:

In light of the potential risks outlined above, it is understandable that the earliest trials focused on the use of immediately loaded implants were undertaken with caution. Some investigations were done so that in addition to the placement of implants that were going to be loaded immediately, submerged implants were placed to act as a backup in case of failure of the immediately/early loaded ones so as to reduce the potential for post-surgical morbidity (Balshi & Wolfinger, 1997; Schnitman et al., 1990; Schnitman et al., 1997). Clearly this caution was not misplaced since the survival rate ranged between 80-85%, which although at face value appears to be high and therefore quite acceptable, represented a figure that was significantly lower than that which has been reported for implants and implant-supported prostheses placed using the more conventional loading techniques. Nonetheless, the authors managed to shed light on some of the critical factors associated with the survival of immediately loaded implants. For example, initial findings suggested that good primary stability as well as good bone quality appeared to be the two most critical factors insofar as implant success was concerned for immediately loaded implants. The zone of the mandible between the mental foramina emerged as the best site in relation to the site that most predictably had the best bone quality in terms of density as well as the presence of thick cortical plates. Therefore, the initial focus of immediate and early loading approaches was in this area of the mandible, chiefly with implants placed between the two mental
foramina. This area is also the same one shown to produce the most reliable outcomes for the more conventional two-stage protocols.

The more recent short and medium-term studies have reported invariably higher success rates (90% to 100%) for immediately loaded implants when combined with fixed prostheses (Table 1.1)(Aalam et al., 2005; De Bruyn, Van de Velde, & Collaert, 2008; Froberg, Lindh, & Ericsson, 2006). This high success rate was attributed to several factors, such as ensuring balanced occlusion and equal distribution of forces between the loaded implants especially when incorporating cantilevers in the prosthesis designs(Aalam et al., 2005; Branemark et al., 1999; Collaert & De Bruyn, 2002; Engquist et al., 2002; Engquist et al., 2004; Ericsson, Randow, Nilner, & Peterson, 2000). As mentioned earlier some authors have excluded heavy bruxers in an effort to control the amount of force exerted on the loaded implants (Chow et al., 2001; Engquist et al., 2002; Engquist et al., 2004; Testori, Del Fabbro, Szmukler-Moncler, Francetti, & Weinstein, 2003; Testori et al., 2004).

As discussed previously, in order to reduce surgical morbidity as well as costs of implants (associated both with treatment and post-treatment) there has been increasing interest in the provision of single-stage implants. An additional cost-saving measure would be to reduce the number of implants for the support of implant-supported prostheses. Indeed, this too has now become an important area of study with several studies focused on the determination of how many fixtures are necessary to provide successful support of their overlying prostheses (Arvidson et al., 2008; Branemark et al., 1999; Collaert & De Bruyn, 2002; De Bruyn et al., 2008; Salama et al., 1995; Salama et al., 1995; Schnitman et al., 1990).
A technique for loading three 5-mm implants using a definitive hybrid mandibular prosthesis on the same day as implant-placement surgery has been described (Branemark et al., 1999). The authors concluded that 3 wide platform implants were sufficient to support the hybrid mandibular prosthesis. However, this high success rate could not be achieved by other researchers, and the survival of individual fixtures was found to be lower when immediate loading of three implants was done (De Bruyn et al., 2001; Engstrand et al., 2003). Moreover, with only three implants to support a fixed restoration, failure of one implant automatically leads to a total prosthetic failure, and re-operation becomes necessary. This concept was supported by results from in vivo studies, that demonstrated that the difference in axial force between three or four supporting implants is not statistically significant (Duyck et al., 2000). However, the bending moments became significantly higher when the number of supporting implants was reduced. These increased bending moments may explain the increased number of failures reported in some of the above-mentioned studies.

Immediate loading of four implants has been shown to be an effective treatment modality. Notably, implants with a diameter of 3.75 or 4 mm were used and preferred over the 5mm diameter implant. This has proven to provide numerous advantages. The smaller diameter avoids excessive obligatory osteoplasty, which generally allows for engagement of the coronal cortical plate of bone and therefore good primary stability. In addition, the use of four implants allows the continued use of the prosthesis in the event of single implant failure (Arvidson et al., 2008; Collaert & De Bruyn, 2002; Klee de Vasconcellos, Bottino, Saad, & Faloppa, 2006; Kronstrom et al., 2003).
The results of these studies clearly indicate that while reducing the number of loaded implants from six to three is unfavorable; four implants may not have a negative effect on the long-term prognosis of implants or prostheses.

To conclude, it is worthwhile to investigate the possibility of reducing the number of implants to decrease surgical morbidity and cost. However, this should not lead to increased complications and technical problems over time.
**Table 1.1: Studies on immediately/early loaded implants with mandibular fixed prostheses:**

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Design</th>
<th>Implant</th>
<th>Participants (Implants)</th>
<th>Implants Length</th>
<th>Site</th>
<th>Bone Quality</th>
<th>Interval to loading</th>
<th>Follow-up</th>
<th>Implant Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aalam, 2005</td>
<td>Pros.</td>
<td>Branemark&lt;sup&gt;1&lt;/sup&gt;</td>
<td>16 (90)</td>
<td>10-18 mm</td>
<td>Zone 1 &amp; 2</td>
<td>Type 1 &amp; 2</td>
<td>Same day of surgery. Final prosthesis: 3 months post-surgery</td>
<td>3-year</td>
<td>96.6%</td>
</tr>
<tr>
<td>Arvidson, 2008</td>
<td>Pros.</td>
<td>Straumann&lt;sup&gt;5&lt;/sup&gt;</td>
<td>62 (250)</td>
<td>10,12 mm</td>
<td>Zone 1</td>
<td>Type 1-4</td>
<td>Mean 6.6 days post surgery.</td>
<td>3-year</td>
<td>98.55% (survival)</td>
</tr>
<tr>
<td>Balshi, 1997,  (Wolfinger, 2003)</td>
<td>Pros</td>
<td>Branemark</td>
<td>Group A: 10 (4/pt; 40IL, 90 DL) Group B: 24 (144; average 6/pt)</td>
<td>≥ 7 mm</td>
<td>Zone 1 &amp; 2</td>
<td>Type 2-4</td>
<td>Group A: Same day of surgery. Final prosthesis: 6 weeks post second-stage surgery with additional 6-11 implants. Group B: Same day of surgery.</td>
<td>5-year</td>
<td>Group A: 80% (IL) 96% (DL) Group B: 97% (survival)</td>
</tr>
<tr>
<td>Branemark, 1999</td>
<td>Pros.</td>
<td>Branemark Novum&lt;sup&gt;1&lt;/sup&gt;</td>
<td>50 (150,3/pt)</td>
<td>13 mm</td>
<td>Zone 1 &amp; 2</td>
<td>1-3 (majority type 2)</td>
<td>Same day of surgery (final prosthesis)</td>
<td>1-3 years</td>
<td>98% (survival)</td>
</tr>
</tbody>
</table>

RCT= Randomized Clinical Trial, CCT= Controlled Clinical Trial, Pros.=Prospective, Retro.= Retrospective, NI=Not Indicated., IL: Immediate Load, DL: Delayed Load, Zone 1= interferaminal area, Zone 2=distal to mental foramina.

<sup>1</sup>Nobel Biocare, Gothenburg, Sweden,  
<sup>2</sup>AstraTech, Molndal, Sweden,  
<sup>3</sup>Implant Innovations Inc, West Palm Beach, Florida,  
<sup>4</sup>Biohorizons, Maestro Dental Implants, Birmingham, AL, USA,  
<sup>5</sup>Straumann, Waldenburg, Switzerland,  
<sup>6</sup>Friadent, Irvine, CA, USA,  
<sup>7</sup>Connect AR, Conexao, Sao Paulo, Brazil.
Table 1.1: Studies on immediately/early loaded implants with mandibular fixed prostheses:

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</thead>
<tbody>
<tr>
<td>De Bryun, 2001</td>
<td>Pros.</td>
<td>Branemark¹</td>
<td>19 (98; 60 IL, 19 submerged, 19 one-stage unloaded)</td>
<td>13-15mm</td>
<td>Zone 1</td>
<td>Type 1-3 (majority type 1)</td>
<td>Same day (denture relined). Final prosthesis: average 31 days post-surgery.</td>
<td>Up to 3 years</td>
<td>90.5% (survival)</td>
</tr>
<tr>
<td>De Bryun, 2008</td>
<td>Pros.</td>
<td>AstraTech²</td>
<td>25(125)</td>
<td>11-17 mm</td>
<td>Zone 1</td>
<td>Type 1-4 (majority type 1)</td>
<td>Same day of surgery. Final prosthesis: 3-4 months post-surgery.</td>
<td>36 months</td>
<td>100% (survival)</td>
</tr>
<tr>
<td>Chow, 2001</td>
<td>Pros.</td>
<td>Branemark</td>
<td>27(123)</td>
<td>13-18mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Same day of surgery. Final prosthesis: 8 weeks post-surgery.</td>
<td>3-30 months (15 pts &gt;1yr)</td>
<td>98.3% (survival)</td>
</tr>
<tr>
<td>Collaert, 2002</td>
<td>Pros.</td>
<td>AstraTech</td>
<td>25(108; 4/pt n=11 patients, 5/pt n=14 patients)</td>
<td>9-17mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Final prosthesis: 5-32 days post-surgery.</td>
<td>7-24 months</td>
<td>100% (survival)</td>
</tr>
<tr>
<td>Collaert, 1998</td>
<td>Pros.</td>
<td>Branemark</td>
<td>Group A: 33 (170) Group B: 17(70)</td>
<td>7-15mm</td>
<td>Zone 1 &amp; 2</td>
<td>Failure in poor bone quality</td>
<td>Group A: within 4 months post-implant placement surgery Group B: ≥ 6 months post-surgery</td>
<td>6-30 months</td>
<td>Group A: 97.6% Group B: 92.9%</td>
</tr>
</tbody>
</table>

RCT = Randomized Clinical Trial, CCT = Controlled Clinical Trial, Pros. = Prospective, Retro. = Retrospective, NI = Not Indicated., IL: Immediate Load, DL: Delayed Load, Zone 1 = interforaminal area, Zone 2 = distal to mental foramina, Eden = edentulous, Par = Partially edentulous.
¹ Nobel Biocare, Gothenburg, Sweden, ² AstraTech, Molndal, Sweden, ³ Implant Innovations Inc, West Palm Beach, Florida, ⁴ Biohorizons, Maestro Dental Implants, Birmingham, AL, USA, ⁵ Straumann, Waldenburg, Switzerland, ⁶ Friadent, Irvine, CA, USA, ⁷ Connect AR, Conexao, Sao Paulo, Brazil.
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</tr>
</thead>
<tbody>
<tr>
<td>Cooper, 2002</td>
<td>Pros.</td>
<td>AstraTech$^2$</td>
<td>10 (54; 48 IL)</td>
<td>11.13 mm</td>
<td>Zone 1</td>
<td>“Sufficient bone density”</td>
<td>Same day of surgery.</td>
<td>6-18 months</td>
<td>100%</td>
</tr>
<tr>
<td>De Smet, 2007</td>
<td>Pros.</td>
<td>Group A: Branemark$^1$ Group B: Branemark Group C: Branemark Novum.</td>
<td>Group A: 10 (2/pt) Group B: 10 (2/pt) Group C: 10 (3/pt)</td>
<td>11.6-15 mm</td>
<td>Zone 1</td>
<td>Type 1-4 (majority type 2&amp;3)</td>
<td>Group A: 1 week post-surgery-Ball overdenture. Group B: 4 months post surgery-Ball overdenture Group C: Same day of surgery.</td>
<td>1-2 years</td>
<td>Group A&amp;B: 90% Group C: 86.7% (survival)</td>
</tr>
<tr>
<td>de Vasconcellos, 2006</td>
<td>Pros.</td>
<td>Connect AR$^7$</td>
<td>15(60)</td>
<td>13-15 mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Same day of surgery.</td>
<td>Mean 19 months</td>
<td>100% (success)</td>
</tr>
<tr>
<td>Engquistt, 2002, 2004</td>
<td>CCT</td>
<td>Branemark</td>
<td>Group A: 30(120) Group B: 30 (120) Group C: 22 (88) Group D: 26 (104)</td>
<td>10-21mm</td>
<td>Zone 1</td>
<td>Type 1-4 (majority type 2 &amp; 3)</td>
<td>Group A: 3-months post-surgery (one-stage surgery, 2-piece implant). Group B: 3-months post-surgery (two-stage surgery, 2-piece implant). Group C: 3-months post-surgery (one-stage surgery, 1-piece implant). Group D: within 3 weeks postsurgery, no loading during the first 10 days (one stage surgery, 2-piece implant).</td>
<td>1-year</td>
<td>Group A: 93.3% (survival) Group B: 97.5% (survival) Group C: 93.2% (survival) Group D: 93.3% (survival)</td>
</tr>
<tr>
<td>Engstrand, 2003</td>
<td>Pros.</td>
<td>Branemark Novum</td>
<td>95</td>
<td>11.5-13.5mm</td>
<td>Zone 1</td>
<td>Type 1-3 (majority type 2)</td>
<td>Same day to 40 days postsurgery.</td>
<td>1 to 5 years</td>
<td>93.3% (survival)</td>
</tr>
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<th>Follow-up</th>
<th>Implant Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ericsson, 2000</td>
<td>CCT</td>
<td>Branemark¹</td>
<td>Group A: 16 (88, 5-6/patient)</td>
<td>At least 10mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Group A: no denture for the first 10 days Final prosthesis: 20 days post-surgery. Group B: 4 months post-surgery.</td>
<td>18 months – 5 years</td>
<td>100%</td>
</tr>
<tr>
<td>Froberg, 2006</td>
<td>RCT-Split Mouth</td>
<td>Branemark</td>
<td>15 (45 turned-surface, 44 TiUnite)</td>
<td>13-18 mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Same day of surgery Permanent prosthesis: 10 days post-surgery.</td>
<td>18 months</td>
<td>100%</td>
</tr>
<tr>
<td>Ganeles, 2001</td>
<td>Pros.</td>
<td>Straumann³, AstraTech, Friadent⁶</td>
<td>27(161)</td>
<td>NI</td>
<td>Zone 1 &amp; 2</td>
<td>NI</td>
<td>Same day to 3 days post-surgery</td>
<td>Mean of 25 months</td>
<td>99.4 %</td>
</tr>
<tr>
<td>Hatano, 2001</td>
<td>Pros.</td>
<td>Branemark</td>
<td>35(105)</td>
<td>13-21mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Same day of surgery</td>
<td>3-year</td>
<td>97.7% (survival)</td>
</tr>
<tr>
<td>Henry, 2003</td>
<td>Pros.</td>
<td>Branemark Novum¹</td>
<td>51</td>
<td>11.5mm</td>
<td>Zone 1</td>
<td>Type 1-4 (majority type 2&amp;3)</td>
<td>Same day to 2 days post-surgery</td>
<td>1-year</td>
<td>90.7% (survival)</td>
</tr>
<tr>
<td>Komiyama, 2008</td>
<td>Pros.</td>
<td>Branemark (Nobel Guide)²</td>
<td>29 (176; 52 in the mandible, 124 in the maxilla)</td>
<td>7-15 mm</td>
<td>Zone 1 &amp; 2</td>
<td>NI</td>
<td>Same day of surgery.</td>
<td>Up to 44 months</td>
<td>83% (survival)</td>
</tr>
</tbody>
</table>

RCT= Randomized Clinical Trial, CCT= Controlled Clinical Trial, Pros.=Prospective, Retro.= Retrospective, NI=Not Indicated., IL: Immediate Load, DL: Delayed Load, Zone 1= interforaminal area, Zone 2=distal to mental foramina.

¹ Nobel Biocare, Gothenburg, Sweden, ² AstraTech, Molndal, Sweden, ³ Implant Innovations Inc, West Palm Beach, Florida, ⁴ Biohorizons, Maestro Dental Implants, Birmingham, AL, USA, ⁵ Straumann, Waldenburg, Switzerland, ⁶ Friadent, Irvine, CA, USA, ⁷ Connect AR, Conexao, Sao Paulo, Brazil.
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<th>Follow-up</th>
<th>Implant Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kronstrom, 2003</td>
<td>Pros.</td>
<td>Branemark¹</td>
<td>17 (68; 4/pt)</td>
<td>13-21mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Same day: Existing denture relined with resilient denture lining material. Final prosthesis: 2-11 weeks post-surgery</td>
<td>1-year</td>
<td>93% (survival)</td>
</tr>
<tr>
<td>Malo, 2003</td>
<td>Retro.</td>
<td>Branemark</td>
<td>Group A: 20 (80)</td>
<td>10-18 mm</td>
<td>Zone 1 (Rescue implants: Zone 1 &amp; 2)</td>
<td>NI</td>
<td>Group A: Same day of surgery. Group B: Same day of surgery. Final prosthesis: 4-6 months post-surgery, incorporating the rescue implants.</td>
<td>2-year</td>
<td>Group A: 96.7% (survival) Group B: 98.2% (survival)</td>
</tr>
<tr>
<td>Misch, 2003</td>
<td>Pros.</td>
<td>Biohorizons⁴</td>
<td>19 (136)</td>
<td>9,12mm</td>
<td>Zone 1.2</td>
<td>Type 1-3 (majority type 3)</td>
<td>Transitional fixed prosthesis same day or 10-14 days post-surgery. Final prosthesis: 4-7 months post-surgery.</td>
<td>1-5 years (average 2.6 years)</td>
<td>100% (survival)</td>
</tr>
<tr>
<td>Raghoebar, 2003</td>
<td>Pros.</td>
<td>Branemark</td>
<td>10 (5/patient)</td>
<td>10-18mm</td>
<td>Zone 1</td>
<td>Type 1-4</td>
<td>Group A: no denture for the first 10 days Final prosthesis: 20 days post-surgery. Group B: 4 months post-surgery.</td>
<td>3-year</td>
<td>93% (survival)</td>
</tr>
<tr>
<td>Randow, 1999</td>
<td>CCT</td>
<td>Branemark</td>
<td>Group A: 16 (88)</td>
<td>At least 10mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Group A: no denture for the first 10 days Final prosthesis: 20 days post-surgery. Group B: 4 months post-surgery.</td>
<td>18 months</td>
<td>100%</td>
</tr>
</tbody>
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</tr>
</thead>
<tbody>
<tr>
<td>Schnitman, 1990, 1997</td>
<td>Pros.</td>
<td>Branemark¹</td>
<td>10 (63:28 IL, 35 DL)</td>
<td>7-15 mm</td>
<td>Zone 1, 2</td>
<td>NI</td>
<td>Same day of surgery.</td>
<td>10-Year</td>
<td>84.7% (survival)</td>
</tr>
<tr>
<td>Testori, 2003</td>
<td>Pros.</td>
<td>Osseotite²</td>
<td>15 (103)</td>
<td>7-18 mm</td>
<td>Zone 1, 2</td>
<td>“Normal bone quality”</td>
<td>Same day of surgery.</td>
<td>Up to 48 months</td>
<td>98.9%</td>
</tr>
<tr>
<td>Testori, 2004</td>
<td>Pros.</td>
<td>Osseotite</td>
<td>62 (325)</td>
<td>10-18 mm</td>
<td>Zone 1, 2</td>
<td>Type 1-4</td>
<td>Same day of surgery. Final prosthesis: 6 months post-surgery.</td>
<td>1-5 years (mean 2.38 years)</td>
<td>99.4% (success)</td>
</tr>
<tr>
<td>Tortamano, 2006</td>
<td>Pros.</td>
<td>Straumann¹</td>
<td>9 (36)</td>
<td>10 mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Within 48 hours post-surgery.</td>
<td>2-year</td>
<td>100%</td>
</tr>
<tr>
<td>Van de Velde, 2007</td>
<td>Pros.</td>
<td>Branemark</td>
<td>18 (90; 5/pt)</td>
<td>10-18 mm</td>
<td>Zone 1</td>
<td>NI</td>
<td>Same day of surgery. Final prosthesis: average 144 days post-surgery.</td>
<td>2.45 year</td>
<td>96.7%</td>
</tr>
<tr>
<td>Van Steenberghe, 2004</td>
<td>Pros.</td>
<td>Branemark¹ Novum</td>
<td>50 (150)</td>
<td>11.5, 13.5 mm</td>
<td>Zone 1</td>
<td>Type 1-3</td>
<td>2-10 days post-surgery.</td>
<td>1-year</td>
<td>92.7% (survival)</td>
</tr>
</tbody>
</table>

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II. Immediate loading of dental implants in the edentulous mandible with overdenture:

The protocol of early clinical trials on immediate loading of dental implants with a mandibular overdenture was to place four implants and then splint them to one another using a bar (Babbush, Kent, & Misiek, 1986; Chiapasco, Gatti, Rossi, Haefliger, & Markwalder, 1997; Chiapasco, Abati, Romeo, & Vogel, 2001; Chiapasco & Gatti, 2003; Degidi & Piattelli, 2005; Gatti, Haefliger, & Chiapasco, 2000; Gatti & Chiapasco, 2002; Mau et al., 2003; Romeo, Chiapasco, Lazza, Casentini, Ghisolfi, Iorio, & Vogel, 2002; Rungcharassaeng, Lozada, Kan, Kim, Campagni, & Munoz, 2002; Vassos, 1997). Several common factors were identified in these reports including the fact that the number of implants placed, their distribution, and the type of rigid connection used appear to be critical. The choice of four implants to support an overdenture was based on the idea that four implants offer sufficient stability and significantly reduce movement that may compromise osseointegration (Chiapasco, Gatti, Rossi, Haefliger, & Markwalder, 1997; Gatti et al., 2000).

The U-shaped gold bar was preferred in many of the earlier studies. This preference was based on the notion that with this kind of bar, it is possible to minimize rotational movements and to transfer loads to the implants mostly in a vertical direction. This is believed to reduce the risk of macromovements, with a subsequent lower risk of compromising osseointegration. Other designs, such as Akermann bars with a round profile or Dolder bars with an oval profile in a straight (not U-shaped) arrangement, are thought to allow rotation of the denture and extra-axial loads to implants. Therefore, the risk of osseointegration failure could be higher (Chiapasco, Gatti, Rossi, Haefliger, & Markwalder, 1997; Gatti et al., 2000; Romeo, Chiapasco, Lazza, Casentini, Ghisolfi, Iorio, & Vogel,
2002). However, other researchers have reported similarly high success rates (98.6%) when a straight ovoid bar was used in an immediate load clinical scenario (Attard, David, & Zarb, 2005).

With the promising results of immediate loading with overdentures reported by earlier studies, a general shift in the literature from four to two implants is seen. Moreover, the use of ball attachments in an attempt to reduce the initial treatment cost is increasing. This may be because researchers now believe that implants’ primary stability can be obtained by other factors independent of splinting (De Smet, Duyck, Vander Sloten, Jacobs, & Naert, 2007; Marzola, Scotti, Fazi, & Schincaglia, 2007; Ormianer, Garg, & Palti, 2006; Wittwer, Adeyemo, Wagner, & Enislidis, 2007). Macro retention offered by implant threads can reduce the risk of implant movement in the case of immediate loading and enhances primary stability. The screw design of implants with the self tapping insertion mode was found to minimize surgical time and to create more intimate contact with bone during placement. This increases the percentage of bone attachment to the implant after healing, thus providing primary stability (A. S. Assad, Hassan, Shawky, & Badawy, 2007). Moreover, good bone quality (type 2 or 3 according to Lekholm and Zarb), bicortical initial stabilization, and control of the occlusal forces all are factors that are now believed to optimize outcomes of the immediately-loaded implant. Whenever these conditions are not met or where there is doubt concerning primary stability of placed implants, the standard 2-stage technique is recommended.

The nature of the opposing occlusion was not accurately accounted for in all trials, which would seem to be a major weakness in the study design. In general, the majority of
patients were completely edentulous in the maxilla and restored with a conventional complete denture (Bernard, Belser, Martinet, & Borgis, 1995; Chiapasco, Gatti, Rossi, Haefliger, & Markwalder, 1997; Chiapasco, Abati, Romeo, & Vogel, 2001; Cooper et al., 1999; A. G. Payne, Tawse-Smith, Kumara, & Thomson, 2001; Roynesdal, Amundrud, & Hannaes, 2001; Tawse-Smith, Perio, Payne, Kumara, & Thomson, 2001). Considering that bite forces generated by conventional complete dentures are generally lower than those exerted by natural dentitions or implant-supported prostheses, it is worthwhile focusing on this parameter, and investigating the possibility of the existence of a correlation between the status of opposing dentition and outcomes of the immediate loading protocol.
Table 1.2: Studies on immediately loaded implants with mandibular overdentures:

<table>
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<tr>
<th>Author</th>
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<th>Implant</th>
<th>Participants (Implants)</th>
<th>Implants Length</th>
<th>Interval to loading</th>
<th>Overdenture Attachment</th>
<th>Follow-up Time</th>
<th>Implant Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Babbush, 1986</td>
<td>Retro.</td>
<td>TPS(^{5})</td>
<td>129(4/pt)</td>
<td>≥10 mm</td>
<td>Denture relined on bar 2-3 days post-surgery. Matrix added 2-3 weeks post- surgery.</td>
<td>Bar</td>
<td>Up to 5.5 years</td>
<td>96.1% (survival)</td>
</tr>
<tr>
<td>Chiapasco, 1997</td>
<td>Retro.</td>
<td>ITI(^{5}), TPS, NLS(^{9}), HA-Ti(^{8})</td>
<td>226 (904;4/pt)</td>
<td>10-20mm</td>
<td>1 day post-surgery</td>
<td>Bar</td>
<td>Mean 6.4 years</td>
<td>96.9%</td>
</tr>
<tr>
<td>Chiapasco, 2003</td>
<td>Pros-Case Series</td>
<td>HA-Ti, ITI, Branemark, Frialoc(^{9})</td>
<td>82 (328; 4/pt)</td>
<td>10-20mm</td>
<td>1 day post-surgery.</td>
<td>Bar</td>
<td>Mean 62 months</td>
<td>96.1%(survival)</td>
</tr>
</tbody>
</table>

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\(^{1}\)Nobel Biocare, Gothenburg, Sweden, \(^{2}\)AstraTech, Molndal, Sweden, \(^{3}\)Implant Innovations Inc, West Palm Beach, Florida, \(^{4}\)Biohorizons, Maestro Dental Implants, Birmingham, AL, USA, \(^{5}\)Straumann, Waldenburg, Switzerland, \(^{6}\)Friadent, Irvine, CA, USA, \(^{7}\)Connect AR, Conexao, Sao Paulo, Brazil, \(^{8}\)Mathys Dental Implants; Bettlach; Switzerland, \(^{9}\)Friadent; Mannheim; Germany, \(^{10}\)Core-Vent Corporation, Las Vegas, NV, \(^{11}\)Semados, Bego, Bremen, Germany.
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<tbody>
<tr>
<td>Degidi, 2005</td>
<td>Pros.</td>
<td>IMZ⁹, Frialit-2⁹</td>
<td>Group A: 4</td>
<td>NI</td>
<td>Within 24-hour post-surgery.</td>
<td>Group A: Bar.</td>
<td>7-year</td>
<td>100 % (edentulous mandible)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Group B: 11</td>
<td></td>
<td></td>
<td>Group B: provisional prosthesis of 3 to 12 elements. Group C: metal-ceramic bridge.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Group C: 1</td>
<td></td>
<td></td>
<td>Group C: Same day of surgery.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>NI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degidi, 2007</td>
<td>Retro.</td>
<td>Frialoc³, XIVE TG</td>
<td>50(200;4/pt)</td>
<td>10-18mm</td>
<td>Same day of surgery.</td>
<td>Bar</td>
<td>Mean 43 months</td>
<td>100% (survival)</td>
</tr>
<tr>
<td>Engelke 2005</td>
<td>Pros.</td>
<td>Semados¹¹</td>
<td>20</td>
<td>13-18mm</td>
<td>Same day of surgery.</td>
<td>Ball</td>
<td>Mean 10 months</td>
<td>100% (survival)</td>
</tr>
<tr>
<td>Gatti, 2000</td>
<td>Pros.</td>
<td>ITI⁵</td>
<td>21(84; 4/pt)</td>
<td>10-14mm</td>
<td>1 day post-surgery.</td>
<td>Bar</td>
<td>Mean 37 months</td>
<td>96% (survival)</td>
</tr>
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<tr>
<td>Gatti, 2002</td>
<td>RCT</td>
<td>Branemark, Conical Transmucosal Implants ¹</td>
<td>Group A: 5 (4/pt) Group B: 5 (4/pt)</td>
<td>11.5-18mm</td>
<td>Within 24-hour post-surgery for both groups.</td>
<td>Bar</td>
<td>2-year</td>
<td>100%</td>
</tr>
<tr>
<td>Lorenzoni, 2003</td>
<td>Pros.</td>
<td>Frialit-2 ⁹</td>
<td>7 (14 IL, 28 DL)</td>
<td>10-15mm</td>
<td>2-4 days post-surgery. Final prosthesis: 6-month post-surgery incorporating the DL implants.</td>
<td>Bar</td>
<td>6 months</td>
<td>100%</td>
</tr>
<tr>
<td>Marzola, 2007</td>
<td>Pros-Case Series</td>
<td>MK III TiUnite²</td>
<td>17 (2/pt)</td>
<td>8.5-15mm</td>
<td>Same day of surgery.</td>
<td>Ball</td>
<td>1-year</td>
<td>100% (survival)</td>
</tr>
<tr>
<td>Ormianer, 2006</td>
<td>Pros-Case Series</td>
<td>Zimmer dental</td>
<td>10 (28; 3/pt but only 2 implants were IL)</td>
<td>13mm</td>
<td>Same day of surgery.</td>
<td>Ball</td>
<td>12-30 months</td>
<td>96.4%</td>
</tr>
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<th>Follow-up Time</th>
<th>Implant Success Rate</th>
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<tbody>
<tr>
<td>Romeo, 2002</td>
<td>RCT</td>
<td>ITI³</td>
<td>Group A: 10 (4/pt)</td>
<td>≥10 mm</td>
<td>Group A: 2 days post-surgery. Group B: 3-4 months post-surgery.</td>
<td>Bar</td>
<td>2-year</td>
<td>Group A: 100% Group B: 97.5%</td>
</tr>
<tr>
<td>Roynesdal, 2001</td>
<td>Pros.</td>
<td>ITI</td>
<td>Group A: 11 (2/pt)</td>
<td>10-16 mm</td>
<td>Group A: within 3 weeks post-surgery. Group B: 3 months post-surgery.</td>
<td>Ball</td>
<td>2-year</td>
<td>100% (survival)</td>
</tr>
<tr>
<td>Vassos, 1997</td>
<td>Retro.</td>
<td>Sterioss</td>
<td>58 (240; 4/pt)</td>
<td>8-18 mm</td>
<td>1-5 days (average 2.8 days post-surgery).</td>
<td>Bar</td>
<td>Average 22.9 months</td>
<td>99.2% (survival)</td>
</tr>
<tr>
<td>Wittwer, 2007</td>
<td>Pros.</td>
<td>Ankylos⁹</td>
<td>22 (88; 4/pt)</td>
<td>11-17 mm</td>
<td>Same day of surgery.</td>
<td>Caps</td>
<td>2-year</td>
<td>97.7% (survival)</td>
</tr>
</tbody>
</table>

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Conclusions, objectives and hypotheses

1. The efficacy of immediate loading for rehabilitation of the completely edentulous mandible has been demonstrated in recent studies. However, a recent systematic review (Jokstad & Carr, 2007) on the effect of time-to-loading of dental implants on outcomes has concluded that the general impression of the available literature was that (1) the methodological rigor of the trials was not strong (2) the reported treatment outcomes were mostly surrogate and less patient-centered, and (3) the follow-up times were short. It has been recommended that additional outcomes ought to be evaluated in future immediate loading studies. These would include: physiologic impact (chewing, phonetics, maintenance of supporting tissues), psychologic impact (patient satisfaction, aesthetics, and quality of life), cost and effort (initial and recurring) (Cochran, Morton, & Weber, 2004). Moreover, few randomized studies on immediate implant loading can be found in the literature.

We therefore have decided to study the efficacy of osseointegrated dental implants in the area of removable and fixed prosthesis applications. These two studies attempt to merge the demonstrated merits of the overdenture and fixed prosthesis techniques with the merits of immediate loading of implants in the anterior zone of the mandible.
I) The objectives of the randomized controlled clinical trial of edentulous patients treated with immediately loaded implant-supported mandibular fixed prostheses are:

1. To determine whether four dental implants can be loaded immediately thereby providing successful implant-supported fixed prostheses.
2. To elucidate the efficacy of the recently developed TiUnite dental implant (NobelBiocare®, Gotenberg, Sweden).
3. To evaluate implant survival, clinical function and long-term prognosis of implant-supported fixed prostheses.
4. To determine the level of patient satisfaction with treatment for patients treated with the immediate loading protocol as compared to patients treated using the conventional one.
5. To measure the quality of life profile, and determine whether there are differences between the patients treated with the immediate loading versus those treated using the conventional protocol.

The Null hypotheses of the randomized controlled clinical trial of edentulous patients treated with immediately loaded implant-supported mandibular fixed prostheses are:

1. The TiUnite dental implant is not efficacious for immediate loading of fixed prosthesis in the mandible.
2. There is no increase in the failure rates of prostheses and immediately loaded implants in comparison to implants placed with a delayed loading protocol.
3. No improvement in the patient denture satisfaction scores will be observed in edentulous patients treated with an immediate loading protocol versus patients treated with the conventional loading protocol.
4. No improvement in the patient oral-related quality of life outcomes will be observed in edentulous patients treated with an immediate loading protocol versus patients treated with the conventional loading protocol.

II) The **objectives** of the five-year clinical results of immediately loaded dental implants using mandibular overdentures are:

1. Establish if two dental implants can be immediately loaded successfully with overdenture prosthesis.
2. Investigate the efficacy of the TiUnite dental implant to determine whether its success rate is equivalent to those reported for commonly used implants.
3. Evaluate the implant survival, clinical function and long-term prognosis of the overdenture in the mandible.
4. Establish a patient satisfaction and quality of life profile for the patients treated with the immediate loading protocol.
5. Conduct an economic evaluation of an immediate loading protocol with mandibular overdentures.
The **Null hypotheses** of the five-year clinical results of immediately loaded dental implants using mandibular overdentures are:

1. There is no difference between immediately loaded TiUnite implants and Branemark implants (NobelBiocare®, Gotenberg, Sweden) that were loaded according to the conventional protocol.
2. There are no differences in the prosthodontic treatment outcomes with immediate or conventional loading protocols.
3. There are no improvements in denture satisfaction and oral health related quality of life outcomes with the immediate loading protocol.
4. In the edentulous patient treated with overdentures, immediate loading protocol with overdentures is not a more expensive approach when compared to the conventional loading protocol.
2. Over the past thirty years, clinicians have been restoring aesthetics and function in edentulous patients using various implant-supported prostheses. The choice of prosthesis design has significant economic implications but it is not known whether there are actually specific clinical implications, particularly with regard to success of treatment as well as patient satisfaction with treatment. Hence it is critically important to learn whether or not there are meaningful differences in outcomes based on the type of implant-supported prosthesis used.

III) The **objective** of the Cochrane systematic review titled: Intervention for replacing missing teeth in completely edentulous patients: Effect of type of prosthesis on treatment outcomes is:

To determine the effect of the type of implant-supported prosthesis used for the replacement for totally absent dentition on the long term success, morbidity, function and patient-mediated concerns.

The **Null hypotheses** of the Cochrane systematic review titled: intervention for replacing missing teeth: Effect of type of prosthesis on treatment outcomes are:

a) There is no difference in outcomes between the different types of removable prostheses supported by root formed implants.

b) There is no difference in outcomes between the different types of fixed prostheses supported by root formed implants.

c) There is no difference in outcomes between the different types of removable and fixed prostheses supported by root formed implant.
Chapter 2

Intervention for Replacing Missing Teeth in Completely Edentulous Patients: Effect of Prosthesis Type on Treatment Outcomes: A Cochrane Systematic Review
Abstract:

Background:
Over the past thirty years, clinicians have been restoring aesthetics and function in edentulous patients using implant-supported prostheses of different design. The choice of prosthesis design has significant economic implications but it is not known whether there are specific clinical implications, particularly with regard to success of treatment as well as patient satisfaction. Hence it is critically important to determine whether there are meaningful differences in outcomes, based on the type of implant-supported prosthesis used.

Objective:
To determine the effect of the type of implant-supported prosthesis used for the replacement for totally absent dentition on the long term success, morbidity, function and patient-mediated concerns.

Search methods:
The Cochrane Central Register of Controlled Trials, Medline and Embase were searched. Hand searching included several dental journals and references from several textbooks on Prosthodontics.

Selection criteria:
All Randomized Clinical Trials (RCT's) and Controlled Clinical Trials (CCT's) reporting outcomes of removable and fixed implant-supported prostheses in edentulous jaws.

Data collection and analysis:
Screening of eligible studies, assessment of the methodological quality of the trials and data extraction were conducted independently and in duplicate. The statistical guidelines outlined in the Cochrane Handbook were followed.
**Results:**

Of the thirty five eligible trials identified, thirty four studies were randomized controlled trials, and only one study was a controlled clinical trial. Based on the available evidence, there were no significant differences in treatment outcomes when comparing either the different types of implant-supported fixed prostheses, or the different types of implant-supported removable prostheses. Moreover, very limited evidence suggests that there is no difference in outcomes between implant-supported fixed prostheses and bar overdentures.

**Authors' conclusions:**

The available scientific evidence suggests that the type of prosthesis design used has little or no effect on clinical and patient-related outcomes. Therefore, clinicians' clinical decisions should be case specific, and should aim at providing their patients with the type of prosthesis that ensures optimum outcomes and is the most cost-effective.

**Synopsis:**

Multiple implant-retained prostheses designs are available to rehabilitate the edentulous mouth. However, evidence-based guidelines are needed to determine whether the design of the prostheses used has any significant impact on clinical and patient-based outcomes.

The reviewers found some evidence to suggest better performance of certain designs over others. However, the heterogeneity of the studies examined precluded further analysis of the data and therefore definite conclusions could not be made. That said, this review also underscores the need for further research, with particular attention being paid to trials comparing fixed and removable implant-supported prostheses.
**Background:**

The introduction of dental implants to the scientific community has been one of the major breakthroughs in dentistry. Implant-retained prostheses provide successful long-term outcomes, particularly when used to rehabilitate the edentulous mandible (A. Assad, Mohamed, & Badawy, 2004; Chan, Johnston, Howell, & Cawood, 1995; Davis & Packer, 1999; I. Naert, Alsaadi, van Steenberghe, & Quirynen, 2004). The degree of stability, chewing efficiency, and ultimately patient satisfaction achievable with such prostheses exceeds that obtained with conventional denture treatment.

Various prosthesis designs utilizing dental implants can be used successfully as an effective modality for restoring aesthetics and function in edentulous patients. The choice of the optimal prosthesis design has a direct impact on the patient in terms of cost, time and surgical morbidity (Stoker, Wismeijer, & van Waas, 2007; Watson, Payne, Purton, & Murray Thomson, 2002). Numerous studies on this subject have been published. However, to date, it seems that there are no consensuses or evidence-based guidelines to assist clinicians in making informed clinical decisions with regards to the type of implant-supported prostheses. This can be attributed to several factors, one being variability in design and quality of the studies. The existence of such heterogeneity precludes direct comparison between studies. Moreover, to date, only one systematic review has been published on this subject (Bryant, MacDonald-Jankowski, & Kim, 2007). However, beside RCTs, the authors have included consecutively treated arches in prospective or retrospective cohort studies. Including studies other than randomized trials in a review might increase the risk that the result of the review will be influenced by publication bias. Moreover, some treatment
outcomes were not investigated as indicated by the review authors (e.g. occlusal, function, satisfaction, economic analysis).

Therefore, this Systematic Review was conducted to identify the best scientific evidence available in the literature on clinical and patient-mediated outcomes as a function of different prosthesis design.

The null hypotheses are:

1. There is no difference in outcomes between the different types of fixed prostheses supported by root formed implants.
2. There is no difference in outcomes between the different types of removable and fixed prostheses supported by root formed implants.
3. There is no difference in outcomes between the different types of removable prostheses supported by root formed implants.

**Objective:**

To determine the effect of the type of implant-supported prosthesis used for the replacement for totally absent dentition on the long term success, morbidity, function and patient-mediated concerns.
Methodology:

Criteria for considering studies for this review:

Types of studies:

We aimed to identify all RCTs and CCTs which reported outcomes of removable and/or fixed prostheses supported by dental implants in edentulous jaws with a post-insertion follow-up of at least one year.

Types of participants:

Adult patients who were having osseointegrated root-formed dental implants.

Types of interventions:

Complete removable and/or fixed prostheses supported by root-formed implants.

Types of outcome measures:

Measures of improvement of function and aesthetics, with an emphasis on subjective assessment of function and treatment failure (Carr, 1998). The key determinants will reflect both patient and dentist mediated concerns and include the following domains:

1) Psychological impact,
2) Longevity/survival,
3) Physiologic impact, and

The following outcomes were recorded when available:
a) Psychological impact

1. patient satisfaction with treatment,
2. patient satisfaction with aesthetics,
3. patient satisfaction with function,
4. reported changes in social activity,
5. quality of life changes or health changes,
6. patient preference for prosthesis,

b) Longevity/survival

1. cumulative survival of prosthesis and implant,
2. cumulative success of prosthesis and implant

c) Biological complications: incidence and/or severity

1. surgical and post surgical complications,
2. neurological disturbances,
3. adverse changes (e.g. bone loss)

d) Mechanical complications: incidence and/or severity

1. adjustments/maintenance,
2. time to first adjustment,
3. prosthesis failure

e) Biopsychosocial complications:

1. Pain

f) Physiologic impact

1. prosthesis retention/mobility,
2. operator evaluation of function

g) Economic impact: direct, maintenance or indirect costs

1. service utilization or resource use with or without link to outcomes,
2. clinician contact, including number of office and/or maintenance visits,
3. prosthesis/internal fixation device costs,
4. need for additional diagnostic investigations
Main inclusion criteria:

1. Completely edentulous maxilla or mandible
2. Study duration of at least one year
3. Implant supported prostheses on one or more dental implants
4. Controlled or randomized clinical trial

Main exclusion criteria:

1. Does not report outcomes for edentulous arches separately
2. Not a controlled clinical trial
3. Outcome data poorly controlled for confounding variables
4. Less than 5 patients

Search methods for identification of studies:

Search strategy for identification of studies:

Oral Health Group methods were used.

For the identification of studies included or considered for this review, detailed search strategies were developed for each database searched. These were based on the search strategy developed for MEDLINE (OVID) but revised appropriately for each database. The search strategy used a combination of controlled vocabulary and free text terms based on the following:

1. exp Dental Implants/
2. exp Dental Implantation/ or dental implantation
3. exp Dental Prosthesis, Implant-Supported/
4. ((osseointegrated adj implant$) and (dental or oral))
5. dental implant$
6. (implant$ adj5 dent$)
7. (((overdenture$ or crown$ or bridge$ or prosthesis or restoration$) adj5 (Dental or oral)) and implant$)
8. "implant supported dental prosthesis"
9. ("blade implant$" and (dental or oral))
10. ((endosseous adj5 implant$) and (dental or oral))
11. ((dental or oral) adj5 implant$)
12. OR/1-11
The above search was run with phases 1 and 2 of the Cochrane Sensitive Search Strategy for Randomized Controlled Trials (RCTs) as published in Appendix 5b.2 of the Cochrane Handbook for Systematic Reviews of Interventions 4.2.5 (updated May 2005) and amended by the Cochrane Oral Health Group as follows:

1. RANDOMIZED CONTROLLED TRIAL.pt.
2. CONTROLLED CLINICAL TRIAL.pt.
3. RANDOMIZED CONTROLLED TRIALS.sh.
4. RANDOM ALLOCATION.sh.
5. DOUBLE BLIND METHOD.sh.
6. SINGLE BLIND METHOD.sh.
7. CROSS-OVER STUDIES.sh.
8. MULTICENTER STUDIES.sh.
9. ("multicentre stud$" or "multicentre trial$" or "multicenter stud$") or ("multi-centre stud$") or ("multi-center trial$").ti,ab.
10. MULTICENTER STUDY.pt.
11. Latin square.ti,ab.
12. (crossover or cross-over).ti,ab.
13. (split adj (mouth or plot)).ti,ab.
14. or/1-13
15. (ANIMALS not HUMAN).sh.
16. 14 not 15
17. CLINICAL TRIAL.pt.
18. exp CLINICAL TRIALS/
20. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
21. PLACEBOS.sh.
22. placebo$.ti,ab.
23. random$.ti,ab.
24. RESEARCH DESIGN.sh.
25. or/17-24
26. 25 not 15
27. 26 not 9
28. 16 or 27

Searched databases:
The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2006, Issue 4).

Language:
The search was restricted to English language only.
Hand-searching:

Details of the journals being hand searched by the Cochrane Oral Health Group's ongoing program are given on the website: http://www.ohg.cochrane.org.


The bibliographies of all identified studies and relevant review articles were checked for studies outside the hand-searched journals. Personal references were also searched. The initial Medline, Embase, Central and hand search searches identified 562. The final list contained 81 articles of which 46 were excluded and 35 were included.

Data collection and analysis:

Study selection:

The titles and abstracts (when available) of all reports identified through the electronic searches were scanned independently by two review authors (SA, KP). For studies
appearing to meet the inclusion criteria, or for which there were insufficient data in the title and abstract to make a clear decision, the full report was obtained. Full reports were assessed independently by two review authors (SA, KP) using an extraction form developed especially for this process (Appendix I) to establish whether the studies met the inclusion criteria or not. Disagreements were resolved by discussion. Where resolution was not possible, a third review author was consulted (AJ). All included studies underwent validity assessment and data extraction. Studies rejected at this or subsequent stages and reasons for exclusion were recorded.

Quality assessment:

The quality assessment of the included trials was undertaken independently and in duplicate by two review authors (SA, KP) as part of the data extraction process. Five main quality criteria for study methodology were examined.

(1) Study design and conduct:

- Clinician/investigator blinded:
  
  (A) Yes
  
  (B) No
  
  (c) Not clear
• Patient blinded:

(A) Yes

(B) No

(c) Not clear

• Outcome assessor blinded:

(A) Yes

(B) No

(c) Not clear

(2) Randomization method:

(A) Clearly adequate (centralized and third party contact)

(B) Unclear

(C) Clearly inadequate (Transparent before assignment, unsealed envelopes)

(D) Not described

(3) Allocation concealment method:

(A) Adequate-centralized randomization, sealed opaque envelopes

(B) Unclear-envelopes

(C) Inadequate-transparent before assignment, unsealed envelopes

(D) Not used/not described
(4) Completeness of follow up (is there a clear explanation for withdrawals and drop outs in each treatment group?) :

(A) Yes. In the case that clear explanations for drop outs were given, a further subjective evaluation of the risk of bias assessing the reasons for the drop out would be made.

(B) No

(5) Intention to treat analysis

(A) Yes

(B) No

Studies were grouped into the following categories:

(A) Low risk of bias (plausible bias unlikely to seriously alter the results) if all criteria were met.

(B) moderate risk of bias (plausible bias that raises some doubt about the results) if one or more criteria were partly met (when attempts were made to conceal the allocation of patients, to blind the assessors or to give an explanation for withdrawals, but these attempts were not judge to be ideal).

(C) High risk of bias (plausible bias that seriously weakens confidence in the results) if one or more criteria were not met.

Further quality assessment was carried out to assess sample size calculations, definition of exclusion/inclusion criteria, and comparability of control and test groups at entry. The quality assessment criteria were pilot tested by two authors (SA, KP) using several articles.
Data extraction:

Data were extracted independently by two review authors (SA, KP) using a specially designed data extraction form. The data extraction form was piloted and modified as required before use. Any disagreements were discussed and a third review author (AJ) consulted when necessary.

- For each trial the following data were recorded:
- Year of publication, country of origin and source of study funding.
- Details of the participants including demographic characteristics, source of recruitment and criteria for inclusion.
- Details of the type of intervention
- Details of the outcomes reported, including method of assessment, and time intervals.
- Details of whether exclusion and inclusion criteria were clearly defined.
- Details of whether the groups were comparable at entry for important prognostic factors.

Data synthesis

For dichotomous outcomes, the estimate of effect of an intervention was expressed as risk ratios (RR) together with 95% confidence intervals (CIs). For continuous outcomes mean differences and standard deviations were used to summarize the data for each group using mean differences and 95% CIs.

Metanalysis was to be carried out only if there were studies of similar comparisons reporting the same outcome measures. Risk ratios were to be combined for dichotomous data, and mean differences for continuous data, using random-effects models.
The significance of any discrepancies in the estimates of the treatment effects from the different trials was to be assessed by means of Cochran's test for heterogeneity, which is an extension of McNemar's Chi-square test for changes in frequencies or proportions to more than two dependent samples. Specifically, it describes the percentage total variation across studies that is due to heterogeneity rather than chance. Clinical heterogeneity was assessed by examining the types of participants and interventions for all outcomes in each study.
**Results:**

**Description of studies:**

**Characteristics of the methods and participants:**

Of the eighty-one eligible trials, thirty-five studies were included (Table 2.1). Twenty-eight studies were randomized controlled trials (RCT's) and had a parallel group study design, while six studies were randomized controlled trials (RCT's) that had a cross-over study design. One study (P. Wright, Glantz, Randow, & Watson, 2002) was a controlled clinical trial (CCT) with a parallel group study design. All trials included adults only. The earliest included paper was published in 1994 (Burns, Unger, Elswick, & Giglio, 1994) and the most recent paper was published in 2007 (Stoker, Wismeijer, & van Waas, 2007). Only thirteen of the eligible studies reported data for 5 years, while one trial (I. Naert, Gizani, Vuysteke, & van Steenberghe, 1998) reported on the same study population at different time points and on different outcomes (I. Naert, Gizani, Vuysteke, & van Steenberghe, 1999; I. Naert, Alsaadi, & Quirynen, 2004; I. Naert, Alsaadi, van Steenberghe et al., 2004), another trial reported on the same study population on different outcomes (Stoker, Wismeijer, & van Waas, 2007; Timmerman et al., 2004), leaving only eight trials reporting data for five or more years (Bergendal & Enquist, 1998; Davis & Packer, 1999; k. Gotfredsen & Holm, 2000; Jemt et al., 2002; Kwakman, Voorsmit, Freihofer, Van Waas, & Geertman, 1998; Murphy, Absi, Gregory, & Williams, 2002; I. Naert et al., 1998; Timmerman et al., 2004) (See Table 2.1 for reports on the same study population).
**Characteristics of the interventions:**

Patients in all included studies were edentulous. The primary intervention for twenty-nine of the studies was a mandibular implant-supported overdenture, using balls, bars, or magnets as the retentive mechanism, while three studies (Jemt et al., 1998; Jemt et al., 2002; Ortorp & Jemt, 2004) used maxillary fixed prostheses supported by either titanium or cast-gold superstructures. One trial compared two types of alloys for a mandibular fixed prosthesis superstructure (Murphy et al., 2002), and two trials compared mandibular implant-supported fixed prosthesis to overdenture (Palmqvist, Owall, & Scholl, 2004; P. Wright et al., 2002). Two trials (Jemt et al., 1998; Jemt et al., 2002) were actually one trial reporting on the same study population at different time points reporting on similar outcomes, except for the reporting alveolar bone loss and adjustment and maintenance complications in the 5-year study (Jemt et al., 2002). All patients who received a mandibular implant-supported prosthesis as their intervention also received a complete upper denture. Nineteen studies used a mandibular overdenture supported by 2 implants, while eleven studies compared implant-supported mandibular overdentures on 2 implants versus similar overdentures supported by 3 or more implants. All mandibular implants in all the studies were inserted under local anesthesia in the mandibular interforaminal region. Most studies used a two-stage delayed loading protocol; however some studies used a one-stage surgical protocol (Stoker, Wismeijer, & van Waas, 2007; Timmerman et al., 2004; Wismeijer, van Waas, Vermeern, Mulder, & Kalk, 1997; Wismeijer, van Waas, Mulder, Vermeern, & Kalk, 1999).
Characteristics of outcome measures:

The main or primary outcomes (psychological impact, longevity/survival, biological complications, physiological impact, and economic impact) were recorded (when reported) for all studies.

Study duration:

- Less than one to more than two years (Palmqvist et al., 2004).

- One year (A. Assad et al., 2004; Batenburg, Raghoebars, van, Heijdenrijck, & Geert, 1998; Burns et al., 1994; Burns, Unger, Elswick, & Beck, 1995; M. Geertman, Ranwaas, van't Hof, & Kalk, 1996; M. Geertman, Slagter, van'thof, van Waas, & Kalk, 1999; Watson, Payne, Purton, & Murray Thomson, 2002).


- Five years (Davis & Packer, 1999; k. Gotfredsen & Holm, 2000; Jemt et al., 2002; Kwakman et al., 1998; Murphy et al., 2002; I. Naert et al., 1998; I. Naert et al., 1999; Ortorp & Jemt, 2004; P. Wright et al., 2002).

- Eight years (Stoker, Wismeijer, & van Waas, 2007; Timmerman et al., 2004).

Risk of bias in included studies:

The agreed quality of the included trials is summarized in table 2.2. For each of the five domains we assessed whether it was at a low, high or unclear risk of bias. Assigning. A judgement of ‘Yes’ indicates low risk of bias, ‘No’ indicates high risk of bias, and ‘Unclear’ indicates unclear or unknown risk of bias.

1) Blinding:

For obvious reasons it was not possible to blind the clinician/investigator or the patients to the interventions. In general it was also not possible to blind the outcome assessors to the interventions including mandibular overdenture prostheses since in all cases the type of prostheses was recognizable. In studies involving maxillary fixed prostheses, it was possible to have the assessor of outcomes blinded; however, in the four studies (Jemt et al., 1998; Jemt et al., 2002; Murphy et al., 2002; Ortorp & Jemt, 2004) comparing these different fixed prostheses the assessor measuring the outcomes was not blinded.

2) Allocation concealment method:

The method of allocation concealment was considered "Adequate" (Code A) in eight studies (M. Geertman, Ranwaas et al., 1996; M. Geertman et al., 1999; Jemt et al., 1998; Jemt et al., 2002; MacEntee MI. Walton JN. Glick,N., 2005; Timmerman et al., 2004; Wismeijer, van Waas, Vermeern et al., 1997; Wismeijer et al., 1999), "Unclear" (Code B) in 21 studies (Batenburg, Raghoebar et al., 1998; Bergendal & Enquist, 1998; Burns et al., 1994; Burns et al., 1995; M. Cune, van Kampen, van der Bilt, & Bosmen, 2005; Davis & Packer, 1999;
Kwakman et al., 1996; Kwakman et al., 1998; I. Naert, Quirynen, Hooghe, & van Steenberghe, 1994; I. Naert et al., 1997; I. Naert et al., 1998; I. Naert et al., 1999; I. Naert, Alsaadi, & Quirynen, 2004; I. Naert, Alsaadi, van Steenberghe et al., 2004; Ortorp & Jemt, 2004; Stoker, Wismeijer, & van Waas, 2007; van der Bilt, van Kampen, & Cune, 2006; van Kampen, van der Bilt, Cune, & Bosman, 2002; van Kampen, van der Bilt, Cune, Fontijn-Tekamp, & Bosman, 2004; Walton, 2003; Watson, Payne, Purton, & Murray Thomson, 2002; P. Wright et al., 2002). The method of allocation concealment was considered "Inadequate" (Code C) in one study (k. Gotfredsen & Holm, 2000) and "Not used/not described" (Code D) in four studies (A. Assad et al., 2004; Murphy et al., 2002; Palmqvist et al., 2004; A. G. T. Payne & Solomons, 2000).

3) Sample size:

A priori power calculation was undertaken and confirmed by calculation in five studies (M. Cune, van Kampen, van der Bilt, & Bosmen, 2005; MacEntee MI. Walton JN. Glick,N., 2005; Timmerman et al., 2004; van der Bilt et al., 2006; Walton, 2003), and was undertaken but not confirmed by calculation in five studies (Stoker, Wismeijer, & van Waas, 2007; van Kampen et al., 2002; van Kampen et al., 2004; Wismeijer, van Waas, Vermeern et al., 1997; Wismeijer et al., 1999). However, in 25 of the studies, a priori power calculations were not mentioned.
4) **Withdrawals:**

The reporting of withdrawals was adequate for all trials except one study (Stoker, Wismeijer, & van Waas, 2007) which did specify that there were withdrawals. There were no reasons cited for the withdrawals.

5) **Inclusion/exclusion criteria:**

Detailed description of inclusion/exclusion criteria were given in 32 studies. In three studies (M. Geertman, Ranwaas et al., 1996; M. Geertman et al., 1999; Palmqvist et al., 2004) only the inclusion criteria was stated, and in one study (A. G. T. Payne & Solomons, 2000) neither the inclusion nor exclusion criteria was stated.

6) **Effects of interventions:**

The initial Medline, Embase, central and hand search searches identified 562 papers. The final list contained 81 articles from which 46 were excluded and 35 included.

The following list summarizes reasons for exclusion of 46 trials:
Failure to compare different types of superstructures:


Similar superstructures vs. different loading protocols:

(Chiapasco, Abati, Romeo, & Vogel, 2001; K. Fischer & Stenberg, 2004; k. Fischer & Stenberg, 2006; A. Payne, Tawse-Smith, Duncan, & Kumara, 2002).

Total follow-up time less than one year:


Different number of implants supporting different types of superstructures:
(Makkonen et al., 1997).

Only provisional superstructures were used:
(Krennmair et al., 2005).

Similar superstructures used with multiple types of implants:
(Per et al., 1999).

Need for grafting at time of implant placement:
(Stellingsma, Bouma, Stegenga, Meijer, & Raghoebear, 2003).

Difficult to compare data between groups:
(Visser et al., 2002).

Outcomes not reported based on the type of superstructure:
(Wismeijer, van Waas, Vermeeren, & Kalk, 1997)
Null hypothesis I: There is no difference in outcomes between the different types of fixed prostheses supported by root formed implants:

(1) Outcomes comparing longevity/survival:

Cumulative survival of prosthesis and implants

Prosthesis success/survival:

Jemt 1998, 2002 (Jemt et al., 1998; Jemt et al., 2002): A parallel group design study reported on cumulative survival and success rates (CSRs) of implant-supported fixed prostheses made with either laser-welded titanium frameworks or conventional cast-gold alloy frameworks in completely edentulous maxilla. Twenty eight patients were included in the first group and thirty in the second one. Two and 5-year reports found no statistically significant difference between the two groups.

Ortorp, 2004 (Ortorp & Jemt, 2004): A parallel group design study reported on cumulative survival rates (CSRs) of prostheses made with Computer Numeric Control (CNC)-Milled titanium frameworks (23 prostheses in the maxilla, 44 in the mandible) and conventional cast gold alloy frameworks (31 prostheses in the maxilla and 31 in the mandible). No significant difference was found between the two groups during the first 5 years of follow-up.

Implant survival:

Ortorp, 2004 (Ortorp & Jemt, 2004): A parallel group design study reported on cumulative survival rates (CSRs) of implants in two groups of completely edentulous patients. Patients in the first group received prostheses made with CNC-Milled titanium frameworks (23 prostheses in the maxilla, 44 in the mandible). The second group had prostheses made with
conventional cast gold alloy frameworks (31 prostheses in the maxilla and 31 in the mandible). There were no significant differences between the two groups in the lower jaw at 5 years. More loaded implants, however, were lost in the maxilla in the Computer Numeric Control-Milled titanium frameworks.

Implant success:
Murphy, 2002 (Murphy et al., 2002): A parallel group design study compared mandibular fixed prostheses made with two different types of framework alloys: Chicago IV gold alloy and Palliang M silver-palladium alloy in 26 edentulous patients (13 patients in each group). Clinical performance of both materials was similar over 5 years.

(2) Outcomes comparing biological complications:

Adverse changes (alveolar bone loss):
Jemt 1998, 2002 (Jemt et al., 1998; Jemt et al., 2002): A parallel group design study compared implant-supported fixed prostheses made with either laser-welded titanium framework or conventional cast-gold alloy framework in completely edentulous maxilla. Twenty eight patients were included in the first group and 30 patients in the second. Intraoral periapical radiographs were taken at the time of insertion and at the annual checkups. No significant differences in bone response could be observed between the two groups during the first five years.

Murphy, 2002 (Murphy et al., 2002): A parallel group design study compared mandibular fixed prostheses made with two different types of framework alloys: Chicago IV gold alloy
and Palliang M silver-palladium alloy in 26 edentulous patients (13 patients in each group). Two Orthopantomogram films of each patients were compared, the first taken immediately after placement of the prosthesis and the second 5 years later. No significant differences in bone response were detected when comparing the two groups over the first five years.

Ortorp, 2004 (Ortorp & Jemt, 2004): Alveolar bone loss around dental implants in two groups of completely edentulous patients was assessed in a parallel group study design. The first group (test) received prostheses made with CNC-Milled titanium frameworks (23 prostheses in the maxilla, 44 in the mandible). The second group (control) had prostheses made using conventional cast gold alloy frameworks (31 prostheses in the maxilla and 31 in the mandible). Intraoral periapical radiographs were taken at the time of prosthesis insertion and at the first and fifth annual checkups. Bone loss was measured to the closest 0.3mm in relation to the implant reference point (placed 0.8 mm below the implant/abutment junction) on the mesial and distal sides of the implant. No significant differences in bone response were observed between the two groups for five years.

(3) Outcomes comparing mechanical complications: incidence and/or severity:

Adjustment/maintenance:

Jemt 1998, 2002 (Jemt et al., 1998; Jemt et al., 2002): A parallel group design study recorded prosthetic and surgical aftercare of implant-supported fixed prostheses made with either laser-welded titanium framework or conventional cast gold alloy framework in completely edentulous maxilla. Twenty eight patients were included in the first group and 30
patients in the second one. Complications were categorized as fractures of implants or hardware, fracture of resin material or teeth, mobile/unstable prosthesis, loose gold screws, and adverse soft tissue reaction. No scale to indicate severity was used and no statistical analysis was done. A tendency toward more soft tissue problems was reported in the cast framework group as compared to the titanium group after 5 years.

Ortorp, 2004 (Ortorp & Jemt, 2004): A parallel group design study reported on frequency of complications in two groups of completely edentulous patients. The first group (test) received prosthesis made with CNC-Milled titanium frameworks (23 prostheses in the maxilla, 44 in the mandible). The second group (control) had prostheses made with conventional cast gold alloy frameworks (31 prostheses in the maxilla and 31 in the mandible). During the first five years, there was a statistically significantly greater number of resin veneer fractures in the upper jaw in the control group. No statistically significant difference was reported for problems in the mandible.

**Null hypothesis II: There is no difference in outcomes between the different types of removable and fixed prostheses supported by root formed implants:**

1) Outcomes comparing biological complications:

*Adverse changes (alveolar bone loss):*

Wright, 2002 (P. Wright et al., 2002): A parallel group design study investigated the change over time in the area of the posterior mandibular residual ridge in patients wearing either mandibular overdentures with bar attachments, or mandibular fixed cantilever prostheses stabilized on five or six implants. Twenty one patients were included in the overdenture group, and twenty three in the fixed prosthesis one. Bone measurements were made by
digitizing tracings of panoramic radiographs that were taken shortly after implant insertion and up to seven years later. In an attempt to avoid the problems of magnifications and distortion, the residual ridge was measured in bilateral posterior areas, by one operator using a method of proportional measurement. The mean interval between radiographs was 5.2 and 2.9 years for overdentures and fixed prostheses respectively. The type of prosthesis correlated significantly with change in posterior bone. Mandibular fixed cantilever prostheses demonstrated bone apposition in the posterior mandibular residual ridge while overdentures showed bone resorption in the same area.

(2) Outcomes comparing economic impact, direct, maintenance or indirect costs:

Service utilization or resource use with or without link to outcomes:

Palmqvist, 2004 (Palmqvist et al., 2004): A parallel group design study compared clinical and laboratory working hours, and laboratory costs including materials in patients wearing either mandibular overdentures with bar attachments, or mandibular fixed prostheses using a CNC-milled frameworks. Both types of prostheses were supported by 3 implants. Six patients were included in the overdenture group, and eleven in the fixed prosthesis one. The time needed to complete the prosthetic treatment, including post-insertion corrections, was recorded for each patient. The time used for laboratory procedures was recorded for each patient, together with material costs. The mean number of clinical working hours was higher in the overdenture group compared to the fixed prosthesis group. Conversely, more laboratory working hours were used in the fixed prosthesis group. The mean sum of money billed by the laboratory, based on working hours and material costs, was about 25% higher in the fixed prosthesis group. Follow-up time was not clearly specified (“ranged from less
than a year to more than 2 years post-implant loading”). The technician working time involved in the milling procedure of the CNC-milled frameworks was not accounted for.

**Null hypothesis III: There is no difference in outcomes between the different types of removable prostheses supported by root formed implants:**

(1) Outcomes comparing psychological impact:

1. *Patient satisfaction with treatment:*

Burns, 1994 (Burns et al., 1994): A cross-over design study comparing 2 implant-supported mandibular overdentures on either magnet or O-ring attachments in seventeen patients. A questionnaire was administered before implant placement, 1 week after attachment placement and just before alternate attachment placement or completion of the study. The 8-question patient satisfaction questionnaire scores ranged from 0 (very dissatisfied) to 16 (totally satisfied). There were no significant differences with respect to patient satisfaction with treatment when comparing the two groups.

Naert 1997, 1999, 2004 (I. Naert et al., 1997; I. Naert et al., 1999; I. Naert, Alsaadi, & Quirynen, 2004): A 10-year parallel group design study compared three different attachment systems (bars, magnets, and balls) used to retain mandibular overdentures. Two sets of questionnaires were used to assess patient satisfaction with treatment. The first one was administered at the 12, 60 and 120-month follow-up visits. The scale ranges from 1 (very bad) to 9 (excellent). Other questions had to be answered with a “yes/no” response, and some questions required more descriptive answers. The second questionnaire was based on a visual analogue scale (VAS) at one time point (year 10). There were no significant
differences between the three groups insofar as responses to the questionnaires were concerned.

Kwakman, 1996 (Kwakman et al., 1996): A parallel group design study compared mandibular overdentures supported by either 4 transmandibular implants (TMI) with a triple bar and cantilever extensions, or 2 intermobile cylinder implants (IMZ) connected by a Dolder bar. Thirty patients were included in the first group and twenty nine in the second one. A five-point rating scale questionnaire ranging from highly satisfied to highly dissatisfied, was used to measure patient satisfaction. The mean follow-up period was 3 years. Most patients in both groups were satisfied or highly satisfied. No means were reported but there were no notable differences between the two treatment groups.

Timmerman, 2004 (Timmerman et al., 2004): This parallel group design study compared mandibular overdentures supported by either 2 implants with ball attachment, 2 implants with single bar, or 4 implants with triple bar. Thirty six patients were included in the first group and thirty seven in each of the two other groups. A 46-item questionnaire focusing on various aspects of denture satisfaction and social functioning (including speech, aesthetics, retention, comfort, general satisfaction, and mastication) was administered. After 8 years, there was no difference in participant satisfaction in any of the parameters.

Cune, 2005 (M. Cune, van Kampen, van der Bilt, & Bosmen, 2005): A cross-over design study evaluated 18 edentulous patients with mandibular overdentures. These dentures were fitted with one of three attachment types (magnet, bar-clip, and ball-socket). Data were gathered prior to implant treatment (existing denture), just prior to second stage surgery
(new denture without attachments, after 3 months of function), and after 3 months of function with each of the attachment types. Patient satisfaction was measured with the aid of a four-point scale list ranging from 0 (no complaint) to 3 (severe complaint). In addition, VASs were used to measure patients' overall appreciation with their dentures. Results showed that patients favored the bar-clip and ball-socket attachments.

MacEntee, 2005 (MacEntee MI. Walton JN. Glick, N., 2005): A parallel group design study compared 2 implant-supported mandibular overdentures, with or without a reinforcing frameworks, connected to implants by either a bar-clip or a ball-spring matrix and matrix. One hundred subjects were enrolled at baseline. However, 2 patients died, 5 withdrew, 6 were lost to follow-up, and 19 subjects had less than 3 years in the trial since receiving new dentures. Therefore data were reported on 68 patients (34 in each group). Patients' satisfaction was assessed with conventional dentures prior to the study and then with new overdentures at 1 month, 1 year and 2 years using VAS. There were no significant differences in patient satisfaction whether they received one or the other attachment system over the 2-year follow-up period.

2. Patient satisfaction with aesthetics:

Naert 1999, 2004 (I. Naert et al., 1999; I. Naert, Alsaadi, & Quirynen, 2004): A 10-year parallel group design study compared three different attachment systems (bars, magnets, and balls) used to retain mandibular overdentures. A self-administered questionnaire was administered at the 12, 60 and 120 months follow-up visits. The scale ranges from 1 (very bad) to 9 (excellent). Other questions had to be answered with a "yes/no" response, and some
questions required more descriptive answers. There were no significant differences between the three study groups.

3. Patient satisfaction with chewing:

Naert 1997, 1999, 2004 (I. Naert et al., 1997; I. Naert et al., 1999; I. Naert, Alsaadi, & Quirynen, 2004): A 10-year parallel group study compared three different attachment systems (bars, magnets, and balls) used to retain mandibular overdentures. Two sets of questionnaires were used to assess patient satisfaction with chewing. The first questionnaire was administered at the 12, 60 and 120 month follow-up visits. The scale ranged from 1(very bad) to 9 (excellent). Other questions had to be answered with a "yes/no" response, and some questions required more descriptive answers. The second questionnaire was based on a visual analogue scale (VAS) but at only one time point, that being year 10. There was significantly reduced comfort with chewing in the magnet group as compared to the ball and bar groups.

Geertman 1996,1999 (M. Geertman, Ranwaas et al., 1996; M. Geertman et al., 1999): A parallel group design study compared mandibular overdentures supported by either 4 transmandibular implants (TMI) with a triple bar and cantilever extensions, and 2 intermobile cylinder implants(IMZ) connected by a Dolder bar. Thirty one patients were included in the first group and thirty three in the second one. Chewing ability was assessed by questions about eight different types of food. A three-point rating scale (0 = good, 2 = bad) was administered one year after insertion of the new overdentures. There were no significant differences between the two groups.
Wismeijer, 1997 (Wismeijer, van Waas, Vermeern et al., 1997): A parallel group design study compared three different treatment strategies: a mandibular overdenture supported by 2 implants with ball attachments (2IBA), two implants with an interconnecting bar (2ISB), or four interconnected implants (4ITB). Thirty six patients were included in the first group (2IBA) and thirty seven in the other two groups. A self-administered questionnaire focused on patients’ satisfaction with their prostheses based on several factors including satisfaction with speech, aesthetics, retention and mastication. It was administered before the allocation of treatment and sixteen months after the insertion of the new dentures. Each item was scored on a four or a five-point scale. There was no difference in the participants' satisfaction based on all factors studied.

4. Patient satisfaction with speech:

Naert 1997, 1999, 2004 (I. Naert et al., 1997; I. Naert et al., 1999; I. Naert, Alsaadi, & Quirynen, 2004): A 10-year parallel group design study compared three different attachment systems (bars, magnets, and balls) used to retain mandibular overdentures. Two sets of questionnaires were used to assess patient satisfaction with factors related to speech. The scale ranged from 1(very bad) to 9(excellent). The first questionnaire was administered at the 12, 60 and 120-month follow-up visits. Other questions required a "yes/no" response, and some questions required descriptive answers. The second questionnaire was based on a visual analogue scale (VAS) at one time point, that being year 10. There did not appear to be a significant impact of prosthesis design on speech capacity when comparing the three study groups.
5. *Change in social activity:*

Wismeijer, 1997 (Wismeijer, van Waas, Vermeern et al., 1997): A parallel group design study compared three different treatment strategies: a mandibular overdenture supported by 2 implants with ball attachments (2IBA), two implants with interconnecting bar (2ISB), or four interconnected implants (4ITB). Thirty six patients were included in the first group (2IBA) and thirty seven in each of the two other groups. A self-administered questionnaire consisting of seven questions on a five-point scale was used to assess changes in social activities, and was administered before the allocation of treatment and sixteen months after insertion of the new dentures. Based on reported mean scores, there were no significant differences in social activity amongst the three treatment groups. However, no standard deviations or confidence intervals were reported.

6. *Patient preference for prosthesis:*

Cune, 2005 (M. Cune, van Kampen, van der Bilt, & Bosmen, 2005): A cross-over design study evaluated 18 edentulous patients with mandibular overdentures. These dentures were fitted with one of three attachment types (magnet, bar-clip, and ball-socket). The attachment type was changed randomly after 3 and 6 months. At the end of the study, and after having tried all attachment types, subjects were asked which one they preferred. Patients preferred bar-clip and ball-socket attachments to magnet attachments.
(2) Outcomes comparing longevity/survival:

1. **Cumulative survival of prosthesis and implants:**

**Prosthesis success:**

Walton, 2003 (Walton, 2003): A parallel group design study compared 2 implant-supported mandibular overdentures with either bar and a metal clip or ball attachments. Fifty patients were included in each of the study groups. A six-field outcome protocol was used to assess prosthesis success and included the following factors; successful, surviving, unknown (lost to follow-up), dead, re-treatment (repair), re-treatment (replace). After two years, there was a statistically significant advantage the bar attachment in comparison to the ball attachments.

**Prosthesis survival:**

Gotfredsen, 2000 (Gotfredsen & Holm, 2000): A parallel group design study compared two implant-supported mandibular overdentures retained either by bar or ball attachments. Eleven patients were included in the first group and fifteen in the second one. No implants were lost from baseline to the 5-year registration, and 100% of prostheses survived regardless of the attachment used.

**Implant survival:**

Bergendal, 1998 (Bergendal & Enquist, 1998): A parallel group design study compared implant-supported overdentures placed in both jaws on either a round, 2-mm alveolar clasp bar or a ball attachment with rubber ring retention. In the maxilla, four overdentures were placed on 2-implant supported bars, four on 3-implant supported bars, six on 2-implant supported balls, and two on 3-implant supported balls. In the mandible, fifteen dentures were
placed on 2-implant supported bars, three on 3-implant supported bars, thirteen on 2-implant supported balls, and one on 3-implant supported balls. After a mean observation period of 62 months it was shown that there were no significant differences in implant survival between the different groups.

Batenburg, 1998 (Batenburg, Raghoebbar et al., 1998): To determine whether the number of supporting endosseous implants would have an impact on survival of the prosthesis, a parallel group design study compared mandibular bar overdentures supported by either 2 or 4 implants over a one year period. Thirty patients were included in each group. One implant was lost in the first group during the healing period prior to second-stage surgery. Implant survival rates between the two groups were similar.

Implant success:
Naert 1998, 1999 (I. Naert et al., 1998; I. Naert et al., 1999): A 5-year parallel group design study compared three different attachment systems (bars, magnets, and balls) used to retain mandibular overdentures. Twelve patients were included in each group. After loading there were no implant failures in any of the groups during the five-year observation period.
(3) Outcomes comparing biological complications: Incidence and/or severity:

1. Pain:
Wismeijer, 1997 (Wismeijer, van Waas, Vermeern et al., 1997): A parallel group design study compared three different treatment strategies: a mandibular overdenture supported by 2 implants with ball attachments (2IBA), two implants with interconnecting bar (2ISB), or four interconnected implants (4ITB). Thirty six patients were included in the first group (2IBA) and thirty seven in each of the two other groups. A self-administered questionnaire was given before the allocation of treatment, and again sixteen months after insertion of the new dentures. As part of the questionnaire, patients were asked "Do you feel pain under your lower denture?" Based on reported mean scores, there was no significant difference between the three treatment strategies with respect to pain under the mandibular denture. No standard deviations were reported.

2. Neurological disturbances:
Batenburg, 1998 (Batenburg, Raghoebbar et al., 1998): A parallel group design study compared mandibular bar overdentures supported by either 2 or 4 implants over a period of one year. Thirty patients were included in each group. Sensory changes of the skin were examined by touching the lip and chin regions of the patient with a cotton pellet in predefined areas. None of the patients showed any signs of sensory change in the lip or chin area.

Kwakman, 1998 (Kwakman et al., 1998): A parallel group design study compared mandibular overdentures supported by either 4 transmandibular implants (TMI) with a triple
bar and cantilever extensions, and 2 intermobile cylinder implants(IMZ) connected by a Dolder bar. Thirty patients were included in the first group and twenty nine in the second one. The Clinical Implant Performance scale (CIP-scale) was used to report complications that occurred during the 5-year evaluation period. This included disturbances of the mental nerve. Only one patient (TMI group) reported minor disturbances of the mental nerve during the five-year follow-up period.

3. Adverse changes (alveolar bone loss):

Davis, 1999 (Davis & Packer, 1999): A parallel group design study compared 2 implant-supported mandibular overdentures on either ball or magnet attachments. Thirteen patients were included in the first group and twelve in the second one. Bone levels were monitored annually with intraoral radiographs using the long-cone paralleling technique for 5 years. Based on the mean values presented, the magnet overdenture group exhibited statistically significant greater marginal bone loss.

Wismeijer, 1999 (Wismeijer et al., 1999): A parallel group design study compared three different treatment strategies: a mandibular overdenture supported by 2 implants with ball attachments (2IBA), two implants with interconnecting bar (2ISB), or four interconnected implants (4ITB). Thirty six patients were included in the first group (2IBA) and thirty seven in each of the two other groups. Orthopantomographic radiographs were used to evaluate the amount of marginal bone loss. The differences in bone height measured on the radiographs obtained directly after surgery and those obtained 19 months later were classified on a 5-point scale ranging from M0 (less than 25% of the length of the implant and M4 (the implant
Bone resorption was compared between laterally positioned implants across the three groups. Radiographic analyses showed no significant differences in average bone loss in the three treatment groups.

Naert 1994, 1997, 1998, 2004 (I. Naert et al., 1994; I. Naert et al., 1997; I. Naert et al., 1998; I. Naert, Alsaadi, van Steenberghe et al., 2004): A 10-year parallel group design study compared three different attachment systems (bars, magnets, and balls) used to retain mandibular overdentures. Standardized radiographs made with a parallel long-cone technique were used to assess marginal bone loss. Radiographic follow-up of bone level changes was performed at baseline, 1, 5 and 10 years after loading of the prostheses. There were no significant differences in bone levels between any of the groups when measured 10 years after loading.

Kwakman, 1998 (Kwakman et al., 1998): A parallel group design study compared mandibular overdentures supported by either 4 transmandibular implants (TMI) with a triple bar and cantilever extensions, and 2 intermobile cylinder implants (IMZ) connected by a Dolder bar. Thirty patients were included in the first group and twenty nine in the second one. Orthopantomographic radiographs were used to assess the amount of bone loss. The radiographs were scored on a four-point scale (0-3), where 0 represents no bone loss and 3 represents bone loss of more than half the length of the implant. There was no evidence for radiographically measured bone loss in twenty four TMI patients and nineteen IMZ patients after the five-year follow up period.
Gotfredsen 2000 (k. Gotfredsen & Holm, 2000): A parallel group design study compared 2 implant-supported mandibular overdentures on either bar or ball attachments. Eleven patients were included in the first group and fifteen in the second. Standardized intraoral radiographs using a specially designed film-holding device were taken periodically. After 5 years, the average loss of bone in the two groups was $0.2 \pm 0.6\text{mm}$ and $0.1 \pm 0.8\text{mm}$ respectively, which was not a significant difference.

Bergendal, 1998 (Bergendal & Enquist, 1998): A parallel group design study compared implant-supported overdentures placed in both jaws on either a round 2-mm alveolar clasp bar or ball attachment with rubber ring retention. In the maxilla, four dentures were placed on 2-implant supported bar, four on 3-implant supported bar, six on 2-implant supported ball, and two on 3-implant supported ball. In the mandible, fifteen dentures were placed on 2-implant supported bar, three on 3-implant supported bar, thirteen on 2-implant supported ball, and one on 3-implant supported ball. Standardized radiographs were taken using the long-cone technique at baseline and then annually thereafter to assess bone loss. Resorption was somewhat higher in the maxilla for both attachment systems and showed great variation between groups.

Batenburg, 1998 (Batenburg, Raghoebet al., 1998): A parallel group design study compared mandibular bar overdentures supported by either 2 or 4 implants over a period of one year. Thirty patients were included in each group. Intraoral radiographs were made using the long cone technique with an aiming device. No significant loss in bone height was found in either of the two study groups after 12 months of loading and there were also no statistically significant differences between either group.
(4) Outcomes comparing mechanical complications: incidence and severity:

Adjustment/maintenance:

Bergendal, 1998 (Bergendal & Enquist, 1998): A parallel group design study compared implant-supported overdentures placed in both jaws on either a round 2-mm alveolar clasp bar or ball attachment with rubber ring retention. In the maxilla, four dentures were placed on a 2-implant supported bar, four on a 3-implant supported bar, six on a 2-implant supported ball, and two on a 3-implant supported ball. In the mandible, fifteen dentures were placed on 2-implant supported bar, three on 3-implant supported bar, thirteen on 2-implant supported ball, and one on 3-implant supported ball. The type and number of technical procedures performed during the follow-up period were recorded at regular intervals for a mean observation period of 62 months. Raw data were reported in a table comparing both treatment groups, and statistical analysis was completed. Denture repair was over-represented in bar overdenture patients.

Gotfredsen, 2000 (k. Gotfredsen & Holm, 2000): A parallel group design study compared 2 implant-supported mandibular overdentures on either bar or ball attachments. Eleven patients were included in the first group and fifteen in the second. The incidence of complications/repairs over a follow-up period of 5 years was reported. During the first year, significantly more complications/repairs were registered in the bar group. In the following years, no significant differences between the two groups were registered.

Kwakman 1996,1998 (Kwakman et al., 1996; Kwakman et al., 1998): A parallel group study design compared mandibular overdentures supported by either 4 transmandibular implants
(TMI) with a triple bar and cantilever extensions, and 2 intermobile cylinder implants (IMZ) connected by a Dolder bar. Thirty patients were included in the first group and twenty nine in the second. Clinical Implant Performance scale (CIP-scale) was used in order to assess severity of complications. A score of 0 indicated no complications. A score of 3 was given in the case of a serious complication that could lead to failure of the implant system. In the IMZ group, over the five year follow-up, significantly fewer problems and complications were found as compared to the TMI group.

Stoker, 2007 (Stoker, Wismeijer, & van Waas, 2007): A parallel group design study compared three types of mandibular overdentures: bar overdenture on 2 implants, bar overdenture on 4 implants and ball overdenture on 2 implants. Thirty six patients were included in the first group and thirty seven in the other two groups. Aftercare, defined as all care and maintenance provided during the evaluation period, was recorded. Care given up to 3 months after the insertion of the overdenture was recorded as part of the initial treatment, and not as aftercare. Eight-year follow-up data showed that there was a statistically significant increased demand for aftercare in the 2-implant ball attachment overdenture group.

MacEntee, 2005 (MacEntee MI. Walton JN. Glick,N., 2005): A parallel group study design compared 2 implant-supported mandibular overdentures, with or without reinforcing frameworks, connected to implants by either a bar-clip or a ball-spring matrix and matrix. One hundred subjects were enrolled at baseline. However, 2 patients died, 5 withdrew, 6 were lost to follow-up, and 19 subjects had less than 3 years in the trial since receiving new dentures. Therefore data were available for only 68 patients (34 in each group). The
maintenance required for each prosthesis was recorded either as an adjustment (modification that did not add new material or replace missing or broken component) or repair (addition or replacement of material or teeth). Significantly fewer repairs were required in the bar attachment group as recorded over the 3-year follow-up period.

Walton, 2003 (Walton, 2003): A parallel group study design compared 2 implant-supported mandibular overdentures with either bar and a metal clip or ball attachments. Fifty patients were included in each of the study groups. Maintenance and complications were reported using six-field outcome protocols including: (successful, surviving, unknown (lost to follow-up), dead, re-treatment (repair), re-treatment (replace). Ball attachment overdentures were significantly more likely to require re-treatment (repair) during the first 2 years of the follow-up period.

Davis, 1999 (Davis & Packer, 1999): A parallel group study design compared 2 implant-supported mandibular overdentures on either ball or magnet attachments. Thirteen patients were included in the first group and twelve in the second one. The findings showed that 56 episodes of maintenance were required for prostheses supported with the ball attachment, while those supported with the magnet attachment mechanism required only 29 episodes. This difference was statistically significant. However there was no significant difference in the actual number of maintenance visits required for both groups.

overdentures. Mechanical complications of the abutment and attachment components were recorded at 4, 6, 24, 36, 48, 60, and 120 months after abutment connection. A higher need for adjustment and maintenance in the magnet group was reported after a 10-year follow-up period. The frequency of maintenance and adjustments was similar in both the bar and ball groups.

(5) Outcomes comparing mechanical physiologic impact:

1. Prosthesis retention/mobility:

Burns, 1995 (Burns et al., 1995): A cross-over design study comparing mandibular magnet overdentures on 2 implants versus O-ring attachments in seventeen patients. Data on denture retention and stability were recorded independently and concurrently by three prosthodontists at 1-week and 6-months after placement of each attachment system. O-ring attachment had statistically significantly greater retention. There were no significant differences in denture stability between the two attachment systems stability.

Naert 1997, 2004 (I. Naert et al., 1997; I. Naert, Alsaadi, & Quirynen, 2004): A 10-year parallel group design study compared three different attachment systems (bars, magnets, and balls) used to retain mandibular overdentures. Prosthesis retention was recorded by means of a dynamometer (Correx) with a maximum capacity of 2,000 grams at 6, 12, 60, and 120 months after abutment connection. Retention with ball attachment increased over time, yet decreased for the bar and magnet attachments groups. Wide retention ranges were reported for each group. The claims of statistical significance were not supported by calculations in
the text. Prosthesis stability was significantly lower in the magnet group compared to the ball and bar groups.

2. Patients' evaluation of retention:

Wismeijer, 1997 (Wismeijer, van Waas, Vermeern et al., 1997): A parallel group design study compared three different treatment strategies: a mandibular overdenture supported by 2 implants with ball attachments (2IBA), two implants with interconnecting bar (2ISB), or four interconnected implants (4ITB). Thirty six patients were included in the first group (2IBA) and thirty seven in each of the other two groups. Patients were presented with a self-administered questionnaire on denture satisfaction before treatment allocation (baseline) and sixteen months after insertion of the new denture. The questionnaire consisted of items referring to the mandibular and maxillary dentures specifically, as well as general items such as speech, aesthetics, retention and mastication. Each item was scored on a four or a five-point scale. There were no statistically significant differences between the three treatment groups in respect to patients' satisfaction with retention.

3. Operator evaluation of chewing:

Geertman, 1999 (M. Geertman et al., 1999): A parallel group design study compared mandibular overdentures supported by either 4 transmandibular implants (TMI) with a triple bar and cantilever extensions, and 2 intermobile cylinder implants(IMZ) connected by a Dolder bar. Thirty one patients were included in the first group and thirty three in the second one. Masticatory performance was determined using the comminution of a standardized artificial test food one year after the insertion of the new prosthesis. No significant difference between the two implant-supported overdentures was reported.
van der Bilt, 2006 (van der Bilt et al., 2006): A cross-over design study compared 2 implant-supported mandibular overdentures with three different suprastructural modalities: a magnet, a ball, and a bar-clip attachments in eighteen patients. Aspects of oral function were quantified by measuring the electromyographic activity of the jaw muscles and jaw movement during chewing. The subjects were measured at five points during the 14-month treatment period: with the old denture (just prior to first-stage surgery), 3 months after using the new conventional complete denture (just prior to second-stage surgery), and at the end of the three periods of 3 months, during which the three different attachment types were incorporated into the new denture. No significant differences in cycle duration, movement trajectory, and muscle activity were noted when comparing muscle activity and jaw motion in the three test groups.

van Kampen, 2002, 2004 (van Kampen et al., 2002; van Kampen et al., 2004): A cross-over design study comparing mandibular overdentures with three different suprastructural modalities: a magnet, a ball, and a bar-clip attachments in eighteen patients. Vertical interocclusal bite forces were measured bilaterally with a bite-force transducer 14 months post-insertion of the new overdenture. Maximum bite force generated with ball attachments was statistically significantly higher than that generated with the magnet construction. However, the difference was not large enough to be considered clinically significant. Slightly better masticatory performance with ball and bar-clip was demonstrated as compared to magnet attachments.
(6) Outcomes comparing economic impact, direct, maintenance or indirect costs:

Service utilization or resource use with or without link to outcomes:

Watson, 2002 (Watson, Payne, Purton, & Murray Thomson, 2002): A parallel group design study compared 3 different types of implant systems supporting mandibular ball overdentures. Seventy-two patients were randomly allocated into three groups. Professional time analysis was performed for prosthodontic maintenance in the first year. No significant difference between the three groups was found.

Stoker, 2007 (Stoker, Wismeijer, & van Waas, 2007): A parallel group design study compared three types of mandibular overdentures: bar overdenture on 2 implants, bar overdenture on 4 implants and ball overdenture on 2 implants. Thirty six patients were included in the first group and thirty seven in each of the other two groups. Long-term costs as related to the type of mandibular overdenture were analyzed. After 8 years, there were no significant differences in mean total direct costs of aftercare when comparing both groups.
**Discussion:**

The answer to the clinical question of whether there is any difference in outcomes between different types of implant-supported prostheses will assist clinicians in making sound clinical decisions, potentially reducing surgical morbidity, treatment time and cost. Further understanding of these issues may lead to the elucidation of whether or not any one type of treatment is superior. If one approach to placement of implant-supported prostheses proved more effective, this could represent a gold standard against which other treatments could be compared.

Regardless of the types of implant-supported fixed prostheses used, it was not possible to find any statistically significant differences in a wide array of outcomes including prosthesis survival/success, marginal bone loss or adjustment and maintenance.

Only two studies compared implant-supported fixed prostheses to bar overdenture. More bone apposition in the posterior residual ridge in the fixed prosthesis group was reported. However, in that study, bone level changes were assessed using panoramic radiographs, which is not the recommended method for optimum monitoring changes in bone levels around dental implants and so the reliability of the bone-related data is questionable.

Studies that compared different types of removable prostheses showed no difference in the overall patient mediated and long-term direct costs outcomes. There is weak evidence suggesting that the clinical performance of mandibular implant-supported overdentures retained by magnet attachments appears to be slightly inferior to that of bar and ball
attachment overdentures with respect to denture retention, stability, chewing ability, need for adjustment and maintenance, overall patient satisfaction and preference, and amount of marginal bone loss. Notably, this inferior performance was observed in only two clinical trials (Burns et al., 1995; I. Naert et al., 1997; I. Naert, Alsaadi, & Quirynen, 2004). This underscores that it is premature to draw a conclusion regarding the clinical performance of this type of overdenture attachment.

This systematic review was limited to RCTs and CCTs since it is established that those two study designs provide the highest level of scientific evidence. It should be recognized, however, that RCTs have their own limitations and may not be the optimum study design for measuring the effectiveness of a given outcome. One must question how typical the patients are who are enrolled in the studies. In the majority of the papers included in this review, the subjects were relatively healthy individuals who were motivated to volunteer for the study, and were willing to attend appointments regularly. Most practicing dentists would recognize this as an "ideal" situation that is not common in private practice. A reasonable alternative would be the inclusion of studies other than RCTs and CCTs such as long-term follow-up cohort studies.
**Quality of the evidence:**

Although a total of thirty five trials were included, only one 5-year follow-up trial had a number of 60 participants or more in each group and was judged to be of high quality. Most of the studies had a small sample size and did not mention whether or not a priori sample size was calculated to ensure detection of potential true difference between the different groups.

Differences between studies in terms of methodological factors, such as use of blinding and concealment of allocation, or the way the outcomes are defined and measured, may be expected to lead to differences in the observed intervention effects. The allocation concealment of eight studies was judged to be adequate. In the remaining studies the concealment was either improperly conducted or not reported.

Most studies did not report standard deviations, odds ratios or confidence intervals. All of these differences constitute significant heterogeneity, which limits the potential for further statistical analysis and makes comparison across studies difficult.

**Potential biases in the review process:**

A thorough and double search of the data base, hand search of a wide range of dental journals and personal library was performed and the preset, detailed inclusion and exclusion criteria translate into a low probability of excluding eligible studies.
The assumption that negative unpublished studies may exist is possible. This factor is outside the control of the review authors.

**Agreements and disagreements with other studies or reviews:**

This systematic review is in agreement with the finding of others. Bryant et al (Bryant, MacDonald-Jankowski, & Kim, 2007) conducted a systematic review to answer the question “Does the type of implant prosthesis affect outcomes for the completely edentulous arch?” Beside RCTs, the review included consecutively treated arches in prospective or retrospective cohort studies with follow-up periods of at least 5 years. Although some outcomes were not investigated (e.g. occlusal, function, satisfaction, economic analysis) as mentioned above, the authors of this thorough systematic review concluded that currently there can not yet be an equivocal consensus on the optimal type of prosthesis to rehabilitate the edentulous arch.

**Authors' conclusions:**

**Implications for practice:**

There is no strong evidence to suggest the superiority of one type of prosthesis. However, this does not mean that this possible difference does not exist. It simply means that available scientific evidence is not sufficient to prove or disapprove this assumption. Consequently, in light of the findings of this systematic review, the clinical decision on the type of implant-supported prosthesis should be case specific focusing on providing the patient with optimal clinical and psychosocial outcomes.
Implications for research:

In order to disclose if there is any difference in outcomes between different types of implant-supported prostheses, well-designed, long-term RCTs and CCTs are needed. It is recommended that such trials include:

- A sufficient number of patients (with sufficient power) to disclose a true difference, if any.
- Proper group allocation concealment.
- Reproducible, statistically analyzable measurement techniques.
- Independent outcome assessors, when blinding is not possible to minimize detection bias.
- A sufficient duration (5 years or more).
- Treatment groups other than those needing mandibular implant-supported overdentures.
- Adherence to the reporting guidelines of the Consolidated Standards of Reporting Trial (CONSORT) (Moher, Schulz, Altman, & Consort, 2001).

Contributions of authors:

- Appraising quality of papers. SA, AJ, KP
- Abstracting data from papers. SA, KP
- Data management of the review. SA, KP
- Entering data on Revman. SA, KP
- Analysis of data. SA, KP
- Interpretation of data. SA, AJ, KP
- Providing a methodological perspective. SA, AJ, KP
- Providing a clinical perspective. SA, KP
- Writing the review. SA, KP
### Characteristics of studies:

#### Table 2.1: Characteristics of included studies

**Assad 2004:**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, Press-fit implants (Dyna), parallel group, 18 months trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Group A: 5 pts</td>
</tr>
<tr>
<td></td>
<td>Group B: 5 pts</td>
</tr>
<tr>
<td>Interventions</td>
<td>Group A: MD magnet OD on 2 implants</td>
</tr>
<tr>
<td></td>
<td>Group B: MD bar OD on 2 implants</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Alveolar bone height (highly significant difference on the distal side of the implants; more bone height in the bar group)</td>
</tr>
</tbody>
</table>

**Risk of bias table**

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>D - Not used</td>
</tr>
</tbody>
</table>

**Batenburg 1998:**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, IMZ® implants, parallel group, 1-year trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Group A: 30 pts</td>
</tr>
<tr>
<td></td>
<td>Group B: 30 pts</td>
</tr>
<tr>
<td>Interventions</td>
<td>Group A: MD round bar OD on 2 implants</td>
</tr>
<tr>
<td></td>
<td>Group B: MD round bar on 4 implants</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Implant survival (no significant difference between groups)</td>
</tr>
<tr>
<td></td>
<td>Neurological disturbances (no neurological disturbances found in either group)</td>
</tr>
<tr>
<td></td>
<td>Alveolar bone loss (larger but not significant increase of bone loss in the patients of 2 IMZ implants group)</td>
</tr>
</tbody>
</table>

**Risk of bias table**

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>
### Bergendal 1998:

<table>
<thead>
<tr>
<th><strong>Methods</strong></th>
<th>RCT, Branemark implants (Nobel Biocare®-NB), parallel group, (mean observation time 62 months)</th>
</tr>
</thead>
</table>
| **Participants** | Group A: 28 pts  
Group B: 22 pts |
| **Interventions** | Group A: MD round bar OD on 2 implants  
Group B: MD ball OD on 2 implants |
| **Outcomes** | Adjustment / maintenance (denture repair was over represented in the bar group)  
Implant survival (In patients with implant loss there was an equal distribution of bar and ball systems)  
Alveolar bone loss (maxillary final resorption was somewhat higher than the mandible for both attachments) |
| **Notes** | Implant survival is reported per jaw and not per prosthesis type |

**Risk of bias table**

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

### Burns 1994, 1995:

<table>
<thead>
<tr>
<th><strong>Methods</strong></th>
<th>RCT, Integral implants (Calcitek®), cross-over, 1-year trial (6 months for each attachment system)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants</strong></td>
<td>17 pts</td>
</tr>
</tbody>
</table>
| **Interventions** | Group A: MD magnet OD on 2 implants  
Group B: MD ball (O-ring) OD on 2 implants |
| **Outcomes** | Patients satisfaction (no significant difference)  
Denture stability (no significant difference)  
Denture retention (O-ring attachment had statistically significantly greater retention) |

**Risk of bias table**

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>
Cune 2005; van Kampen 2004; van der Bilt 2006:

**Methods**
RCT, Frialit-2 implants (Friadent®), cross-over, 14 months trial

**Participants**
18 pts

**Interventions**
MD OD supported by:
magnet (3-month), bar-clip (3-month), ball attachment (3-month).
Each patient used each attachment system for 3 months.

**Outcomes**
Mandibular denture complaint (no significant difference between the three attachment types)
General complaint (bar and ball attachments score best, magnets did not noticeably improve patient satisfaction)
Patients satisfaction with aesthetics (no marked subjective difference between the 3 types of attachments)
Patients preference of prosthesis (mostly favoured the bar clip and ball attachments)
Masseter and temporalis muscles activity;
Activity during maximum clenching (no significant difference between the three types of attachments)
Cycle duration (no significant difference between the three types of attachments)
Movement trajectory (no significant difference between the three types of attachments)
Bite force (significantly higher with bar and ball than that generated with the magnet construction)
Muscles activity using EMG (masseter and temporalis) (no significant difference)
Operator evaluation of masticatory performance (less effective masticatory performance obtained with magnet)
Operator evaluation of chewing cycle (small difference noted between the three groups)

**Notes**
- Bite force measured with bite force transducer

**Risk of bias table**

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>
**Davis, 1999**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, Astra Tech® implants, parallel group, 5-year trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Group A: 13 pts</td>
</tr>
<tr>
<td></td>
<td>Group B: 12 pts</td>
</tr>
<tr>
<td>Interventions</td>
<td>Group A: MD ball OD on 2 implants</td>
</tr>
<tr>
<td></td>
<td>Group B: MD magnet OD on 2 implants</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Alveolar bone loss (significant difference between groups; bone loss in magnet group &gt; ball attachments group)</td>
</tr>
<tr>
<td></td>
<td>Maintenance (significant difference between groups; more maintenance required in the ball attachment group)</td>
</tr>
<tr>
<td></td>
<td>Number of office visits (no significant difference between groups)</td>
</tr>
</tbody>
</table>

**Risk of bias table**

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

**Gotfredsen 2000:**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, Astra Tech implants, parallel group, 5-year trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Group A: 11 pts</td>
</tr>
<tr>
<td></td>
<td>Group B: 15 pts</td>
</tr>
<tr>
<td>Interventions</td>
<td>Group A: MD round bar OD on 2 implants</td>
</tr>
<tr>
<td></td>
<td>Group B: MD ball OD on 2 implants</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Prosthesis survival (100% in both groups)</td>
</tr>
<tr>
<td></td>
<td>Alveolar bone loss (no significant difference)</td>
</tr>
<tr>
<td></td>
<td>Adjustment/maintenance (significantly more complications/repairs in the bar group in the first year. In the following years, no significant differences were registered)</td>
</tr>
<tr>
<td>Notes</td>
<td>-One implant was lost before the baseline registration (at abutments connection stage) and was not accounted for</td>
</tr>
</tbody>
</table>

**Risk of bias table**

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>No</td>
<td>C - Inadequate</td>
</tr>
</tbody>
</table>

**Jemt 1998, 2002:**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, Branemark implants (NB), parallel group, 2-year trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Group A: 28 pts</td>
</tr>
<tr>
<td></td>
<td>Group B: 30 pts</td>
</tr>
</tbody>
</table>
| Interventions          | Group A: MX laser-welded titanium fixed prosthesis  
                          Group B: MX cast-gold alloy fixed prosthesis |
|------------------------|--------------------------------------------------------------------------------------------------|
| Outcomes               | Implant survival (no significant difference between groups)  
                          Prosthesis survival (no significant difference between groups)  
                          Alveolar bone loss (no significant difference)  
                          Adjustment/ maintenance (no statistical analysis performed) |
| Notes                  | Adjustment/ maintenance (no statistical analysis performed)  
                          Complications: no scale used. categorized as fracture of implants, gold screw...etc  
                          Alveolar bone loss (no mean bone loss was recorded for all sites) |

**Risk of bias table**

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>A - Adequate</td>
</tr>
</tbody>
</table>

**Kwakman 1996, 1998; Geertman 1996, 1999:**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, TMI/IMZ implants, parallel group, 3-year trial</th>
</tr>
</thead>
</table>
| Participants              | Group A: 29 pts  
                          Group B: 29 pts |
| Interventions             | Group A: MD bar OD on 2 IMZ implants  
                          Group B: MD bar OD on 4 TMI implants |
| Outcomes                  | Neurological disturbances ( only one incidence of minor disturbance of mental nerve)  
                          Alveolar bone loss (CIP-scale)  
                          Adjustment/ maintenance(CIP-scale) single bar tends to favour multiple bars  
                          patient satisfaction( no significant difference)  
                          patient satisfaction with chewing ( no significant difference)  
                          Patient chewing experience and chewing ability ( no significant difference)  
                          Operator evaluation of masticatory performance ( no significant difference)  
                          patient satisfaction (no means reported. Most patients in both groups were satisfied or highly satisfied)  
                          Alveolar bone loss ( no radiographic bone loss could be ascertained in 24 TMI patients and 19 IMZ patients |
Adjustment/ maintenance (complication rate in TMI group was higher than that in the IMZ group)

Notes
- Bone loss was assessed using panoramic radiographs
- No SD reported.
- CIP-scale: reflects various complications with the systems
- TMI were early loaded (next day)
- IMZ implants were loaded 3 months post implant placement surgery

Risk of bias table

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

MacEntee 2005; Walton 2003:

Methods
- RCT, Branemark implants (NB), parallel group, 2-3 years trial

Participants
- Group A: 50 pts (data reported on 34 pts)
- Group B: 50 pts (data reported on 34 pts)

Interventions
- Group A: MD bar OD on 2 implants
- Group B: MD ball-spring OD on 2 implants

Outcomes
- Patient satisfaction (no significant difference between groups)
- Adjustment/ maintenance (no significant difference between groups)
- Repairs (bar attachment group had significantly fewer repairs than ball group).
- Cumulative success of the prosthesis (bar design was statistically significant more "successful")
- Adjustment/ maintenance (ball attachment dentures were significantly more likely to require repair)

Notes
- Six-field outcome scale used; successful, surviving, unknown (lost to follow up), dead, re-treatment (repair), re-treatment (replace)

Risk of bias table

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>A - Adequate</td>
</tr>
</tbody>
</table>
Murphy, 2002

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, Astra Tech implants, parallel group, 5-years</th>
</tr>
</thead>
</table>
| Participants     | Group A: 13 pts  
Group B: 13 pts |
| Interventions    | Group A: MD Chicago IV alloy fixed prosthesis  
Group B: MD Palliag M silver palladium alloy fixed prosthesis |
| Outcomes         | Implant success ("clinical performance of both prostheses was similar")  
Alveolar bone loss (no significant difference) |

Risk of bias table

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>D - Not used</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, Branemark implants (NB), parallel group, 5-year trial</th>
</tr>
</thead>
</table>
| Participants             | Group A: 12 pts  
Group B: 12 pts  
Group C:12 pts |
| Interventions            | Group A: MD bar OD on 2 implants  
Group B: MD magnet OD on 2 implants  
Group C: MD ball OD on 2 implants |
| Outcomes                 | Patient satisfaction with treatment (no significant difference)  
Patient satisfaction with aesthetics (no significant difference)  
Patient satisfaction with chewing (chewing comfort was less with magnet group)  
Patient satisfaction with speech (no significant difference)  
Adjustment /maintenance (more need for adjustment and maintenance in the magnet group. Bar and ball group reported similar frequency of maintenance and adjustment needed)  
Prosthesis retention/mobility( ball attachment showed the greatest vertical retention force)  
Cumulative success of implants (100% success with all groups-5years report) |
| Notes                    | Alveolar bone loss(no significant difference)  
Adjustment /maintenance: values are total number of complications divided by number of patients. |
Risk of bias table

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

Ortorp, 2004

Methods
RCT, Branemark implants (NB), parallel group, 5-year trial

Participants
Group A: 65 pts
Group B: 61 pts

Interventions
Group A: Mx/ MD Computer Numeric Control-milled Titanium fixed prosthesis (CNC)
Group B: MX/ MD cast gold fixed prosthesis

Outcomes
Cumulative implant survival (significantly greater loss of loaded implants in the upper jaw in the CNC group. No difference found between groups in the lower jaw)
Cumulative survival of prosthesis (no significant difference)
Adjustment/maintenance (significantly more resin veneers fractures in the upper jaw in group B. No significant difference found in the mandible.
Alveolar bone loss (no significant difference)

Risk of bias table

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

Palmqvist, 2004

Methods
RCT, Branemark implants (NB), parallel group, 6 months to 2-year trial

Participants
Group A: 11 pts
Group B: 6 pts

Interventions
Group A: MD fixed prosthesis on 3 implants
Group B: MD bar OD on 3 implants

Outcomes
- Clinical hours used by prosthodontist (mean number was higher in the overdenture group)
- Hours used by dental technician (mean number was higher in the fixed prosthesis group)
- Sum billed by dental laboratory (about 25% higher in the fixed prostheses group)

Notes
- Concluded: in total, the two treatments are about equal in the mean overall number of hours
### Payne, 2000

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>D - Not described</td>
</tr>
</tbody>
</table>

#### Methods
- RCT, Branemark implants (NB), parallel group, 3-year trial

#### Participants
- Group A: 18 pts
- Group B: 20 pts
- Group C: 21 pts

#### Interventions
- Group A: MD ball OD on 2 implants
- Group B: MD bar OD on 2 implants
- Group C: MD bar OD on 3-4 implants

#### Outcomes
- Adjustment/maintenance ("comparison between splinted designs with round bars revealed no statistically significant difference with either retentive clip activation or fracture").

#### Notes
- Frequency of complications reported. No statistical analysis.
- Treatment group C could have been divided into 2 groups. Group I: 2 clips and group II: 3 clips.

### Stoker 2007; Timmerman 2004; Wismeijer 1997, 1999:

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>D - Not used</td>
</tr>
</tbody>
</table>

#### Methods
- RCT, ITI implants, (Straumann®), parallel group, 8-year trial

#### Participants
- Group1: 36 pts
- Group2: 37 pts
- Group 3: 37 pts

#### Interventions
- Group A: MD bar OD on 2 implants
- Group B: MD bar OD on 4 implants
- Group C: MD ball OD on 2 implants

#### Outcomes
- Treatment time (no significant difference between groups)
- Direct treatment cost (no significant difference between groups)
- Maintenance (increase demand for aftercare in group C for simple re-adjustment).
- Patient satisfaction with treatment (no significant difference in
general satisfaction)

Alveolar bone loss (no significant difference between groups in bone loss for all implants placed in lateral positions)

Patient satisfaction with retention (no significant difference)
Patient satisfaction with chewing (no significant difference)
Changes in social function (no significant difference)
Patient reported pain (no significant difference)

Notes
- Patient satisfaction with treatment: no overall mean for each group.
- Bone loss assessed using panoramic radiographs

Risk of bias table

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

Watson, 2002

Methods
RCT, Steri-Oss implants (NB)/ITI/Southern, parallel group, 1-year trial

Participants
Group A: 24 pts
Group B: 24 pts
Group C: 24 pts

Interventions
Group A: MD bar OD on 2 Steri-oss implants (NB)
Group B: MD bar OD on 2 ITI implants (Strauman)
Group C: MD bar OD on 2 southern implants

Outcomes
Clinician time required for prosthodontic maintenance of the mandibular denture (no significant difference)
Time for all maintenance events for the mandibular denture alone or with the opposing maxillary overdenture (no significant difference)

Risk of bias table

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>
Wright, 2002

<table>
<thead>
<tr>
<th>Methods</th>
<th>CCT, Branemark implants (NB), parallel group, up to 7-year trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Group A: 21 pts</td>
</tr>
<tr>
<td></td>
<td>Group B: 23 pts</td>
</tr>
<tr>
<td>Interventions</td>
<td>Group A: MD bar OD on 2 implants</td>
</tr>
<tr>
<td></td>
<td>Group B: MD fixed prosthesis on 5-6 implants</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Alveolar bone loss (significant difference between the two groups; low rates of posterior residual ridge resorption in the overdenture group, and bone apposition in the same area in the fixed prosthesis group.</td>
</tr>
<tr>
<td>Notes</td>
<td>Bone level changes assessed using panoramic radiographs.</td>
</tr>
</tbody>
</table>

Risk of bias table

<table>
<thead>
<tr>
<th>Item</th>
<th>Judgment</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Unclear</td>
<td>B - Unclear</td>
</tr>
</tbody>
</table>

MD: Mandibular, MX: Maxillary, OD: Overdenture, Pts: Patients
Table 2.2: Methodological assessment of included studies:

<table>
<thead>
<tr>
<th>Study</th>
<th>Blinding</th>
<th>Allocation conceal.</th>
<th>Sample size</th>
<th>Withdrawals</th>
<th>Incl/excl criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assad, 2004</td>
<td>none</td>
<td>none</td>
<td>not mentioned</td>
<td>All accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Batenburg, 1998</td>
<td>none</td>
<td>unclear</td>
<td>not mentioned</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Bergendal, 1998</td>
<td>none</td>
<td>unclear</td>
<td>not mentioned</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Burns, 1995</td>
<td>none</td>
<td>unclear</td>
<td>not mentioned</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Burns, 1994</td>
<td>none</td>
<td>unclear</td>
<td>not mentioned</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Cune, 2005</td>
<td>none</td>
<td>unclear</td>
<td>yes, confirmed</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Davis, 1999</td>
<td>none</td>
<td>unclear</td>
<td>not mentioned</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Geertman, 1999</td>
<td>none</td>
<td>adequate</td>
<td>not mentioned</td>
<td>all accounted for</td>
<td>no (inclusion only)</td>
</tr>
<tr>
<td>Geertman, 1996</td>
<td>none</td>
<td>adequate</td>
<td>not mentioned</td>
<td>all accounted for</td>
<td>no (inclusion only)</td>
</tr>
<tr>
<td>Gottfredsen, 2000</td>
<td>none</td>
<td>inadequate</td>
<td>not mentioned</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Jemt, 1998</td>
<td>none</td>
<td>adequate</td>
<td>not mentioned</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Jemt, 2002</td>
<td>none</td>
<td>adequate</td>
<td>not mentioned</td>
<td>all accounted for</td>
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<tr>
<td>Kwakman, 1998</td>
<td>none</td>
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<td>not mentioned</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
<td>Kwakman, 1996</td>
<td>none</td>
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<td>not mentioned</td>
<td>all accounted for</td>
<td>yes</td>
</tr>
<tr>
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<tr>
<td>Naert, 1997</td>
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Table 2.2 (cont’d): Methodological assessment of included studies:

<table>
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<tr>
<th>Study</th>
<th>Blinding</th>
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<th>Withdrawals</th>
<th>Incl/excl criteria</th>
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<td>Wismeijer, 1999</td>
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Chapter 3

A Randomized Controlled Clinical Trial of Edentulous Patients

Treated with Immediately Loaded Implant-Supported

Mandibular Fixed Prostheses
Introduction:

A recent study focused on immediate loading of implants was completed in the author’s clinical research unit. The data showed that immediate loading of two dental implants with overdentures in the edentulous mandible is an effective modality of treatment and has a high success rate (Attard NJ, 2004). The present investigation was developed in order to determine whether the previously reported findings might be expanded to include immediate loading for fixed prostheses. In this investigation, we looked at the feasibility of loading four dental implants immediately with a fixed prosthesis in the anterior zone of the edentulous mandible.

The following objectives are addressed in this chapter:

1. To determine whether four endosseous dental implants can be loaded immediately following surgical placement and still provide a reliable foundation for successful implant-supported fixed prostheses.

2. To determine the efficacy of the recently developed TiUnite dental implant.

3. To evaluate implant survival, clinical function and long-term prognosis of implant-supported fixed prostheses.

4. To assess the level of patient satisfaction with the immediate loading protocol as compared to the conventional (delayed loading) option.

5. To determine whether there are differences in the oral-related quality of life between the patients treated with immediate loading versus those treated using delayed loading.
The Null hypotheses of this study are:

1. The TiUnite dental implant is not efficacious for immediate loading of fixed prosthesis in the mandible.

2. There are differences in the prosthodontic treatment outcomes with immediate and conventional protocols.

3. No improvement in the patient denture satisfaction scores will be observed in edentulous patients treated with an immediate loading protocol versus patients treated with the conventional loading protocol.

4. No improvement in the patient oral-related quality of life outcomes will be observed in edentulous patients treated with an immediate loading protocol versus patients treated with the conventional loading protocol.
**Materials and Methods:**

**Sample Size Calculation:**

The sample size was calculated by comparing means and standard deviations (SDs) of bone loss around implants that were loaded immediately or implants that were loaded after osseointegration has been achieved (i.e. delayed loading). Mean peri-implant bone loss for immediately loaded implants was based on a previous study that presented bone loss data based on sixty implant measurement sites from 12 patients.(De Bruyn et al., 2001). The mean value for peri-implant bone loss during the first year was 0.9 mm (SD 1.1mm). Subsequently, these data were compared to bone loss results for the mandible from another study. The mean bone loss during the first year of loading was 0.09 mm (SD 0.55mm) (Engquist et al., 2004).

The sample size was calculated by relying on data reported previously by De Bruyn et al. and Engquist et al. using the following formula:

\[ \delta = [\mu + \nu] \cdot \left[ \delta_1^2 + \delta_2^2 \right] / [\eta_1 - \eta_2]^2, \]

The value, \( \mu \), is one-sided percentage point of the normal distribution corresponding to the proposed power of the study.

The power \( \nu \) is the percentage point of the normal distribution corresponding to the (two-sided) significance level \( p<0.05 \).

\([\delta_1 + \delta_2]\) is the sum of the SDs.

\([\eta_1 - \eta_2]\) is the difference between means for the samples.
Therefore, when \( p=0.05 \) and the power of the study is set at 80%, \( \mu =0.85 \) and \( \nu=1.96 \) and \( \delta \) is the SD for each sample and \( [\eta_1-\eta_2] \) is the difference between the means, the sample size calculation would look like this: Sample size= \( [0.85+1.96]^2 * [1.1^2+0.55^2] / [0.9-0.09]^2 \)

Based on this calculation it was estimated that a minimum of 18 patients was required per group. Thus, the proposed number of 20 patients per group was chosen to allow for dropouts during follow-up.

The Human Ethics Board of the University of Toronto approved the treatment protocol described for a clinical *Parallel Randomized Controlled Trial* in June, 2006 (protocol reference number: 16903) (Appendix 4).

**Study design and recruitment of patients:**

This clinical study was a parallel randomized controlled trial. The two study arms consisted of the experimental arm, where patients underwent the immediate loading protocol and the control arm where patients were treated using the standard delayed loading protocol. The subjects were recruited from new patients seeking treatment at the Implant Prosthodontic Unit (IPU), Faculty of Dentistry, University of Toronto.

**Informed consent:**

During the initial consultation, patients were informed about the treatment protocol at the Faculty of Dentistry. The patients were advised about the treatment timeframe, costs involved and the success rate for the proposed treatment.
The main investigator discussed both treatment protocols (immediate and conventional) in detail to each potential subject. The patients were also provided with a detailed information package explaining each protocol and the number of visits needed. They were encouraged to read and understand the information package. When they agreed to participate in the study, they were asked to sign consent form. The latter was signed by the patient and countersigned by a witness before the patient was entered in the study. Moreover, it was explained that any patient may withdraw from the study at any time without penalty and would be offered an alternative treatment related to their dental condition.

**Randomization of patients into the two study arms:**

Patients who agreed to participate in the study were assigned randomly to one of two study arms:

A randomization list was generated by an independent statistician. The patients were randomized into one of two treatment arms. The full randomization list was held in the statistician’s office for future reference.

After the principal investigator identified eligible patients and obtained a signed, witnessed, consent document, the statistician allocated a randomization number from the list and inserted it into the blank field indicated in the patients’ randomization list. Then a sealed numbered randomization envelope was returned to the principal investigator. The envelope was opened only when the implant-placement surgery had been completed in order to eliminate any possible operator bias during surgery. Following opening of the randomization
envelope and the allocation of the patient to either of the study arms, the investigator signed and dated the envelope.

The randomization list was compared with the treatment document by the independent statistician to ensure that they matched and that the randomization process was executed as planned.
Pre-operative protocol for both study arms:

Prior to implant surgery, each patient and each proposed prosthetic site was assessed by a prosthodontist using an appropriate combination of medical questionnaires as well as both clinical and radiographic examination.

The criteria used for patient selection are listed below and can be categorized into inclusion criteria, systemic, local, and secondary exclusion criteria. They were similar to those used for selection of patients in past studies (Aalam et al., 2005; Attard & Zarb, 2004; Zarb & Schmitt, 1996).

Inclusion criteria:

1. The patient is at least 18 years of age or older.
2. The patient is edentulous in the mandible and subjectively desires an implant-supported screw retained fixed prosthesis.
3. The teeth at the implant site have been extracted or lost at least three months prior to the date of implants placement.
4. No Guided Bone Regeneration (GBR) or Guided Tissue Regeneration (GTR) procedures had been performed at the implant sites.
5. The bone quality and quantity allow placement of four TiUnite dental implants (NobelBiocare®, Gothenburg, Sweden), of at least 3.75mm in diameter and 10mm in length between the two mental foramina without the use of concurrent bone augmentation techniques.
6. The patient committed to participating in the three-year follow-up examinations of this study.

If one or more of the inclusion criteria was answered with “NO”, the patient was considered not eligible.

_Systemic exclusion criteria_: 

1. Presence of a medical condition requiring prolonged use of steroids.

2. Presence of a history of leukocyte dysfunction and deficiencies.


4. Presence of a history of neoplastic disease requiring the use of radiation or chemotherapy.

5. Presence of a history of renal failure.


8. Presence of a physical handicap that would interfere with the ability to perform adequate oral hygiene.

9. The use any investigational drug or device within the 30 day period immediately prior to implant surgery.


11. Heavy smokers (>20 cigarettes per day) or cigar equivalents or chewing tobacco equivalents.
12. Presence of conditions or circumstances, which in the opinion of the investigator, would prevent completion of study participation or interfere with the analysis of study results (e.g. history of non-compliance, or unreliability).

13. Advanced age and/or compromised general health such that the long surgical and prosthodontic appointments required for the standard implant-supported fixed prosthesis protocol is too demanding.

14. Presence of psychiatric contraindications (Blomberg & Lindquist, 1983). These include psychotic syndromes, severe character disorders and neurotic syndromes. Patients who might demand unrealistic outcomes were also excluded from participation in this investigation.

*Local exclusion criteria:*

1. Presence of a local inflammation, including untreated periodontitis.

2. Presence of a history of local irradiation therapy.

3. Presence of osseous lesion.

4. Presence of any unhealed extraction sites (less than 3 months post-extraction of teeth in intended sites).

5. Presence of persistent intraoral infection.

6. Inadequate oral hygiene or lack of motivation for adequate home care.
Secondary exclusion criteria (at implant placement surgery):

1. Lack of sufficient bone for the procedure.

2. Inability to place implants according to protocol requirements.

Radiographic examination:

The radiographic examinations involved the use of one or more periapical, occlusal, panoramic, lateral cephalometric, and/or tomographic radiography views. The panoramic radiographs normally involve Kodak T-Mat G/RA panoramic PAN/TMG/RAJ, 5 x 12 inch radiographic film (Eastman Kodak, Rochester, NY, USA) used in combination with an extraoral panoramic x-ray machine (Siemens Orthopantomograph 10) typically set at 75 kVp and 6mA for 15 seconds. The lateral cephalometric radiographs normally involved Kodak T-Mat TMG/RA-1, 8 x 10 inch radiographic film (Eastman Kodak, Rochester, NY, USA) used in combination with an extraoral x-ray machine (General Electric Canada DXD-350 II) typically set at 74 kVp and 100L mA for 0.25 seconds. Following this clinical and radiographic assessment, the patients were informed if they were suitable candidates for the study.

Prosthesis Preparation:

Prosthesis preparation followed one of two routes:

The current maxillary and mandibular dentures were assessed clinically. If it was determined that they were adequate, then they were utilized as an interim restoration following implant placement surgery. In most cases this involved only minor adjustments. The clinician and patient alike decided on the adequacy of the prostheses by judging the following factors: satisfactory esthetics, absence/presence of pain and adequate function. In essence, these are requisites of a physiologic occlusion.

If during the examination the prostheses were found to be inadequate and could not be optimized, a new prostheses were fabricated to provide a physiologic occlusion.

Surgical protocol (applied to both study arms):

The surgical protocol is a standardized one that has already been established and validated. The surgery was carried out under local anesthetic and antibiotic coverage. A crestal incision in the mandible was done extending about 1 cm beyond the mental foramina. The mucoperiosteum was then elevated and the bone was prepared gently to prepare host sites for the implants. Four TiUnite dental implants (NobelBiocare®, Gotenberg, Sweden) were placed between the mental foramina.
Immediately following surgery, the initial stability of the implants was assessed by hand testing using a torque wrench. If any implant lacked primary stability (torque value ≥ 35 Ncm), the delayed loading protocol was used to ensure that adequate time was provided for bone growth around the unstable implant(s). Intention to Treat (ITT) and Per-Protocol Analyses were carried out in order to provide results with both clinical scenarios (i.e. if patients were treated in the group they were randomized to, or if they had to be transferred to the control group due to the lack of initial stability).

For patients whose implants demonstrated good initial stability, allocation to either arm of the study was determined using the randomization envelope that corresponded to the patient as described above.

If the patient was assigned to the experimental arm, permanent multi-unit abutments (NobelBiocare®, Gothenburg, Sweden) were installed on the four implants and torqued to 20 Ncm with a standardized manual torque wrench, and the soft tissues were then sutured. The location of the implants was indicated on the mandibular denture using Fit Checker (GC America®, Alsip, IL, USA). Then four multi-unit temporary copings (NobelBiocare®, Gothenberg, Sweden) were installed on the implants, and the surgical site was protected using rubber dam. If necessary, the temporary copings were modified to allow occlusion with the maxillary teeth or denture, and then they were picked up using the mandibular denture as a tray in cold-cured acrylic resin (ProBase, Ivoclar Vivadent Inc., Mississauga, Ontario, Canada). In order to minimize the amount of exothermic heat generated during the curing process, a minimum amount of acrylic resin was used, and intraoral water coolant was
circulated constantly. The mandibular denture was then sent to the lab where it was modified into an interim implant-supported fixed prosthesis. This was inserted the same day as implant-placement surgery. The occlusion was evaluated and refined when necessary. Patients were given post-operative instructions. The fabrication of the permanent implant-supported prosthesis was initiated two weeks after surgery following previously established protocols (Brånemark et al., 1985a).

Patients who were assigned to the control group had healing abutments (NobelBiocare®, Gotenberg, Sweden) placed on the four implants and the soft tissues were then sutured. The mandibular denture was hollowed out and relined with a soft tissue reline material (COE-SOFT™, GC America®, Alsip, IL, USA). The soft tissue reline material was adjusted so that it was not resting on the healing abutments in order to prevent loading of the implants. The permanent implant-supported fixed prosthesis fabrication process was initiated three to four months post-surgery as described previously (Brånemark et al., 1985a).

Patients were assessed regularly and in a blinded fashion by a calibrated independent investigator at 2, 6 and 12 months following completion of treatment.

Data collection:

1. Patient demographics:

These included age, gender, marital status, educational level, income, occupation, health and medications, smoking history, reason for tooth loss, oral hygiene at recall visits, the number of dentures used in the past, as well as the period of time the subject had been edentulous prior to implant-placement surgery.
2. **Implant related outcomes:**

Implant length and platform, bone quality and quantity as per the Lekholm and Zarb classification were recorded (Brånemark et al., 1985a). During follow-up visits, osseointegration was evaluated by torquing the implants with a standardized torque wrench set at 20Ncm. If an implant was shown to be mobile or painful while torquing, it was considered a failure and removed. Standardized radiographs were taken at the final prosthesis insertion day (baseline) and during the 1-year follow-up visit.

3. **Patient satisfaction and quality of life outcomes:**

Patient-based outcomes were collected using a self-reported Denture Satisfaction Scale (P. F. Allen, McMillan, & Walshaw, 2001)(Appendix 2) and the short form version of the Oral Health Impact Profile questionnaire (OHIP-20)(F. Allen & Locker, 2002)(Appendix 3). The denture satisfaction scale consists of a Likert response format that ranges from 1 to 5 (“totally satisfied” to “not at all satisfied,” respectively. The variables assessed included general satisfaction, retention, comfort, stability, speech, appearance, and occlusion for both maxillary and mandibular dentures. The questionnaire was administered at the pre-operative visit (baseline) prior to obtaining informed consent for the study and during the 1-year recall visit.

The short form version of the OHIP-20 consists of twenty items, which were designed specifically for edentulous patients. As with the Denture Satisfaction Scale, responses are based on a Likert scale format. The patient could answer: never =1, rarely =2, occasionally =3, often =4, very often =5 and all of the time =6 (Minimum score 20 - Highest Score 120).
The questionnaire was administered at the pre-operative visit (baseline) and then at 2, 6 and 12 months following the insertion of the permanent mandibular implant-supported fixed prosthesis. In both questionnaires (i.e. Denture Satisfaction Scale and OHIP-20), higher scores signified greater levels of patient dissatisfaction or compromised quality of life.

The scores from the Denture Satisfaction Scale were first analyzed globally and then divided into questions related to the individual prosthesis and those related to functional status. The OHIP scores were first analyzed globally and were also divided into function-related questions as well as questions related to psychosocial issues. Sub-scale scores were created by summing the responses to the respective questions (Attard, Laporte, Locker, & Zarb, 2006).

Radiographic imaging and bone measurements

Standardized long-cone intra-oral periapical radiographs were used to assess peri-implants bone levels. These radiographs were taken on two different occasions; at the insertion of the permanent mandibular implant-supported fixed prosthesis stage (baseline), and during the 12-month recall visit.

A special holder described by Cox and Pharoah (Cox & Pharoah, 1986) and modified by Chaytor et al. (Chaytor, Zarb, Schmitt, & Lewis, 1991) was attached to the multi-unit abutment and used to standardize the measurements. The device also allowed for accurate positioning of the central ray of the x-ray beam so that it would be perpendicular to the implant and the film.
As the study progressed, it was found that removal of fixed prostheses during the maintenance visits for the purpose of radiographic assessment of one or more implants was both time-consuming and uncomfortable for the patient. Therefore, to take further radiographs, without having to remove the mandibular implant-supported fixed prosthesis, an alternative but equally well-established and validated technique for taking standardized radiographs with slight modification was used (M. S. Cune, van Rossen, de Putter, & Wils, 1996; van Kampen, Cune, van der Bilt, & Bosman, 2005). A modified film holder (Dentsply RINN-XCP®, Elgin, IL, USA) was used and individualized by means of a heavy body impression compound (Cltofax® mix, Coltene, Whaledent®, USA). Maxillary and mandibular prostheses were left in situ whilst taking the radiograph. Kodak Ultraspeed double-packed radiographic film (Eastman Kodak, Rochester, NY, USA) was used with an intra-oral x-ray machine equipped with a long cone (GX-770, GENDEX, Des Plaines, IL, USA) set at 70 kVp and 10mA for 0.28 seconds. All films were developed in an automatic processor (Siemens Dent-X9000) with accurate time and temperature controls and fresh chemical solutions.

Management of radiographs:

Photographs of the individual radiographs were taken with a digital camera (Nikon coolpix 995, Melville, NY, U.S.A) mounted on a copy stand for stability at 8” distance from the radiograph. The illuminated area was masked off, leaving only the area for the size of a periapical radiograph uncovered, allowing for accurate light meter reading for each individual density.
The resultant images were then processed, stored, and measured using public domain software (ImageJ, U.S. National Institute of Health) on a DELL Inspiron 640m computer using the technique described and validated by previous investigators (Avivi-Arber L, 1994; Wyatt C, 1996).

**Crestal bone measurements:**

The measurement of bone level was performed by the main investigator in a blinded fashion (i.e. blinded as to patient name and the chronology of the radiographic series by random presentation of the implant images). Prior to the initiation of radiographic assessment, an intra-class correlation study was done to calibrate the main investigator and to assess the degree of agreement between the investigator and an experienced investigator in the Department of Prosthodontics. The measurements were repeated on two separate occasions and a mean was calculated between the two measurements for each site. The mean measurement was then utilized for statistical analysis of changes in crestal bone level.

The vertical distance in millimeters from the apical edge of the implant collar to the most apical initial point of contact observed between the implant and the bone was measured at the mesial and distal sites with the measurement tool function of the ImageJ software. The effects of any misalignment of the film plane relative to the implant long axis on apparent crestal bone position were accounted for by using the known thread pitch of the implant to calibrate the measurements for each implant.
**Statistical Analysis:**

Demographic and clinical characteristics were summarized with frequencies and proportions for categorical data (e.g. sex, marital status, profession), and means and standard deviations for continuous data (e.g. age, number of years edentulous). To assess differences between treatment arms, patients assigned to the control arm were compared to those assigned to the immediate arm. Chi-square tests of association were used to evaluate differences between the treatment arms with respect to sex and medical health status. Due to small numbers of patients within some cross-tabulated cells, Fisher’s exact test was used to identify significant associations between treatment and income, marital status, education level, profession, smoking history, reasons for tooth loss, and number of dentures. Students’ T-tests were used to determine significant differences between treatment arms with respect to continuous variables: age, duration of edentulism in the maxilla and mandible for all patients, number of years smoke-free, and number of years smoked for former and current smokers respectively.

Implant success rate was calculated across all implants, and Fisher’s exact tests were used to examine differences between treatment arms.

To assess the primary outcome, whether the immediate loading protocol was significantly equivalent to or better than the conventional loading protocol with respect to bone loss, tests of non-inferiority were used. These tests are more appropriate than a traditional test for differences when attempting to demonstrate that a new therapy option is at least equivalent to the current standard of care. For these tests a margin of equivalence was
set at 1 mm of bone loss (i.e. the immediate loading protocol would be considered statistically equivalent or better than the control condition if a bone loss of 1 mm or less was found). Average bone loss estimates for use in the tests of non-inferiority were calculated by averaging across all implants. Variance estimates for bone loss were calculated adjusting for within-patient correlation using Taylor linearization, to prevent artificially small variance estimates.

To assess the association between denture satisfaction, and OHIP scores between treatment groups at 2-, 6-, and 12-month follow-up, mixed models were utilized. Mixed models are a powerful class of models that account for the correlated repeated measurements of the outcome, yet do not make as many strict assumptions as repeated-measures ANOVA. F-tests from these models were used to determine statistical significance.

Finally, to identify variables that explained the change in post-operative OHIP scores at 1-year post operation, multivariate linear regression was performed. The independent variables were age, gender, profession, years edentulous in the mandible, bone quantity, bone quality, and baseline and 1-year denture satisfaction scores.

Apart from the initial demographic analyses, all analyses comparing the two treatment arms were conducted in two different ways. First, the tests were conducted using the ITT analysis. Two patients randomized to the immediate load arm were treated following the conventional loading protocol due to the reasons mentioned in the results section. In the ITT analysis, these patients were analyzed according to the treatment arm they were randomized to. Secondly, PPA was performed in which the two patients randomized to the
immediate loading arm but receiving the conventional loading treatment were analyzed as though they had been randomized to the control arm.

All analyses were conducted using SAS 9.1.3 (Cary, North Carolina). Statistical significance was determined when p was < 0.05.
**Results:**

**Patient demographics:**

A total of 42 patients were enrolled in the study. The process of participants’ enrollment, allocation of interventions, withdrawals, and timing of outcome measures is shown in the Consolidated Standards of Reporting Trials (CONSORT) flow diagram recommended for use when reporting randomized controlled clinical trials (Figure 3.1).

The mean (± SD) age of the patients was 61.5 ± 10.35 years. Twenty three (57.5%) of the participants were female, and 17 (42.5%) were male. Demographic data of the patients in both study arms are shown in Table 3.1 and Figures 3.2 and 3.3. Patient characteristics between the two treatment arms did not differ significantly suggesting successful randomization (Table 3.1).
Figure 3.1: CONSORT flow diagram of participants, withdrawals, and timing of outcome measures:

Assessed for eligibility: n = 45

Not meeting inclusion criteria (n= 3)

Randomized (n = 42)

Received standard intervention as allocated (n = 22)
Did not receive standard intervention as allocated (n= 0)
Reasons (N/A)

Received experimental intervention as allocated (n=16)
Did not receive experimental intervention as allocated (n= 4)
Reasons:
1. lack of primary implant stability at placement [≥ 35 Ncm]; (n = 2)
2. inability to place 4 implants between the mental foramina: (n = 1)
3. inability to load implants on the same day of surgery : ( n = 1)

Discontinued intervention: (n = 0)
Lost to follow-up: (n = 1 after 6-month of follow-up). (Reason: unable to locate).

Analyzed: (n = 22)
Excluded from analysis: (n = 0)

Discontinued intervention: (n = 1)
Lost to follow-up: (n = 1 after 6-month of follow-up). (Reason: unable to locate).

Analyzed: (n = 18)
Excluded from analysis: (n = 2)
The status of opposing dentition was also recorded. The majority of patients had a conventional complete denture in the maxilla (32 patients), 7 had a removable partial denture, and 2 had implant-supported fixed prostheses.

**Table 3.1: Demographics of patients in both study arms:**

<table>
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<tr>
<th>Arms</th>
<th>Overall (N=40)</th>
<th>Control (N=22)</th>
<th>Immediate (N=18)</th>
<th>p-value for differences between groups</th>
</tr>
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<td>Gender: N (%)</td>
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<td></td>
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<td>0.289*</td>
</tr>
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<td>Female</td>
<td>23 (57.5)</td>
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<td>12 (66.7)</td>
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</tr>
<tr>
<td>Male</td>
<td>17 (42.5)</td>
<td>11 (50.0)</td>
<td>6 (33.3)</td>
<td></td>
</tr>
<tr>
<td>Age: Mean (SD) / Median</td>
<td>61.5 (10.35) / 62</td>
<td>61.18 (9.56) / 61.50</td>
<td>61.89 (11.51) / 64.00</td>
<td>0.836</td>
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<td>Profession</td>
<td></td>
<td></td>
<td></td>
<td>0.743**</td>
</tr>
<tr>
<td>Professional</td>
<td>4 (10.0 %)</td>
<td>2 (9.1 %)</td>
<td>2 (11.1 %)</td>
<td></td>
</tr>
<tr>
<td>Non-professional</td>
<td>14 (35.0 %)</td>
<td>8 (36.4 %)</td>
<td>6 (33.3 %)</td>
<td></td>
</tr>
<tr>
<td>Housewife</td>
<td>4 (10.0 %)</td>
<td>1 (4.6 %)</td>
<td>3 (16.7 %)</td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>18 (45.0 %)</td>
<td>11 (50.0 %)</td>
<td>7 (38.9 %)</td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
<td></td>
<td>0.130**</td>
</tr>
<tr>
<td>&lt; 20,000</td>
<td>25 (62.5 %)</td>
<td>11 (50.0 %)</td>
<td>14 (77.8 %)</td>
<td></td>
</tr>
<tr>
<td>20,000 – 39,999</td>
<td>13 (32.5 %)</td>
<td>9 (40.9 %)</td>
<td>4 (22.2 %)</td>
<td></td>
</tr>
<tr>
<td>40,000 – 59,999</td>
<td>2 (5.0 %)</td>
<td>2 (9.1 %)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
<td>0.348**</td>
</tr>
<tr>
<td>Single</td>
<td>5 (12.5 %)</td>
<td>3 (13.6 %)</td>
<td>2 (11.1 %)</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>26 (65.0 %)</td>
<td>14 (63.6 %)</td>
<td>12 (66.7 %)</td>
<td></td>
</tr>
<tr>
<td>Divorced</td>
<td>6 (15.0 %)</td>
<td>2 (9.1 %)</td>
<td>4 (22.2 %)</td>
<td></td>
</tr>
<tr>
<td>Widow</td>
<td>3 (7.5 %)</td>
<td>3 (13.6 %)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>College</td>
<td></td>
<td></td>
<td></td>
<td>0.663**</td>
</tr>
<tr>
<td>Completed</td>
<td>6 (15.0 %)</td>
<td>3 (13.6 %)</td>
<td>3 (16.7 %)</td>
<td></td>
</tr>
<tr>
<td>Not completed</td>
<td>33 (82.5 %)</td>
<td>19 (86.4 %)</td>
<td>14 (77.8 %)</td>
<td></td>
</tr>
<tr>
<td>University</td>
<td>1 (2.5 %)</td>
<td>0</td>
<td>1 (5.6 %)</td>
<td></td>
</tr>
</tbody>
</table>

* Chi-square test for association.
** Fisher’s Exact test, | Students T-test.
Table 3.1 (cont’d): Demographics of patients in both study arms:

<table>
<thead>
<tr>
<th>Reason for extraction</th>
<th>Overall</th>
<th>Control (N=22)</th>
<th>Immediate (N=18)</th>
<th>p-value for differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periodontal disease</td>
<td>9 (22.5 %)</td>
<td>5 (22.7 %)</td>
<td>4 (22.2 %)</td>
<td>0.532**</td>
</tr>
<tr>
<td>Caries</td>
<td>25 (62.5 %)</td>
<td>15 (68.2 %)</td>
<td>10 (55.6 %)</td>
<td></td>
</tr>
<tr>
<td>Trauma</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Neglect</td>
<td>6 (15.0 %)</td>
<td>2 (9.1 %)</td>
<td>4 (22.2 %)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of Lower Dentures</th>
<th>Overall</th>
<th>Control (N=22)</th>
<th>Immediate (N=18)</th>
<th>p-value for differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>33 (82.5 %)</td>
<td>19 (86.4 %)</td>
<td>14 (77.8 %)</td>
<td>0.623**</td>
</tr>
<tr>
<td>2</td>
<td>5 (12.5 %)</td>
<td>2 (9.1 %)</td>
<td>3 (16.7 %)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 (2.5 %)</td>
<td>1 (4.6 %)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>1 (2.5 %)</td>
<td>0</td>
<td>1 (5.6 %)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years Edentulous (mandible): mean (SD) / median</th>
<th>Overall</th>
<th>Control (N=22)</th>
<th>Immediate (N=18)</th>
<th>p-value for differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Years Edentulous (mandible): mean (SD) / median</td>
<td>7.99 (11.63) / 1.00</td>
<td>6.43 (11.43) / 1.00</td>
<td>9.64 (12.05) / 2.50</td>
<td>0.396</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years Edentulous (maxilla): mean (SD) / median</th>
<th>Overall</th>
<th>Control (N=22)</th>
<th>Immediate (N=18)</th>
<th>p-value for differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Years Edentulous (maxilla): mean (SD) / median</td>
<td>12.61 (12.45) / 9.00</td>
<td>13.58 (13.95) / 8.00</td>
<td>11.53 (10.85) / 10.00</td>
<td>0.624</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medical Consideration</th>
<th>Overall</th>
<th>Control (N=22)</th>
<th>Immediate (N=18)</th>
<th>p-value for differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>18 (45 %)</td>
<td>11 (50 %)</td>
<td>7 (33.3 %)</td>
<td></td>
</tr>
<tr>
<td>Non-healthy</td>
<td>22 (55 %)</td>
<td>11 (50 %)</td>
<td>11 (66.7 %)</td>
<td></td>
</tr>
</tbody>
</table>

* Chi-square test for association
** Fisher’s Exact test used due to small cell sizes, | Students T-test
Table 3.1 (cont’d): Demographics of patients in both study arms:

<table>
<thead>
<tr>
<th></th>
<th>Overall (N=22)</th>
<th>Control (N=18)</th>
<th>Immediate (N=18)</th>
<th>p-value for differences between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>8 (20 %)</td>
<td>7 (31.8 %)</td>
<td>1 (5.6 %)</td>
<td>0.077**</td>
</tr>
<tr>
<td>Former smoker</td>
<td>16 (40 %)</td>
<td>9 (40.9 %)</td>
<td>7 (38.9 %)</td>
<td></td>
</tr>
<tr>
<td>Non-smoker</td>
<td>16 (40 %)</td>
<td>6 (27.3 %)</td>
<td>10 (55.6 %)</td>
<td></td>
</tr>
<tr>
<td>Packs per day smoked</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>smoked (among smokers)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 1</td>
<td>5(62.5 %)</td>
<td>5 (71.43 %)</td>
<td>0</td>
<td>0.209**</td>
</tr>
<tr>
<td>1</td>
<td>3 (37.5 %)</td>
<td>2 (28.57 %)</td>
<td>1 (100 %)</td>
<td></td>
</tr>
<tr>
<td>Years smoked (current +</td>
<td>29.39 (11.49) /</td>
<td>32.23 (11.93) /</td>
<td>25.70 (10.30) /</td>
<td>0.174</td>
</tr>
<tr>
<td>former smokers)</td>
<td>30.00</td>
<td>35.00</td>
<td>25.00</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years since quit (former</td>
<td>15.43 (14.33) /</td>
<td>10.92 (12.68) /</td>
<td>18.44 (15.28) /</td>
<td>0.320</td>
</tr>
<tr>
<td>smokers): mean (SD) / median</td>
<td>10.00</td>
<td>8.50</td>
<td>10.00</td>
<td></td>
</tr>
</tbody>
</table>

* Chi-square test for association
** Fisher’s Exact test used due to small cell sizes
| Students T-test
The majority of patients reported earning less than $CAD 20,000/year to up to $CAD 40,000/year, and were non-professional or retired (Figure 3.2). The main reason reported for tooth loss was dental caries (62.5 %) followed by periodontal disease (22.5 %). None of the patients had lost their teeth due to trauma. No difference was found in the timing of seeking dental implant treatment when comparing younger (≤ 50 years old) to older patients.

Figure 3.2: Patient demographic data:
Fifty-five percent of the patients suffered some chronic medical condition and were on medications. Current smokers accounted for 20.0% of the patients. Among smokers, 65.5% smoked 1 pack/day, and the mean years of smoking were 29.39 years (Figure 3.3).

Out of the 168 implants placed, 160 (95.2%) were placed by the same surgeon. One prosthodontist restored 85% of the patients.

Figure 3.3: Patient demographic data (health status, smoking history, number of dentures):
The Lekholm and Zarb classification was used to assess jawbone morphology. Eighty-three percent of the patients had bone quality type 2 or 3 (Figure 3.4). No or minor (< 5mm) reduction of cortical bone was required to place the dental implants.

**Figure 3.4: Bone morphology of anterior mandible (Bone quality: 1, 2, and 3, and bone quantity: A, B, C, and D):**

![Bone Morphology Chart]

**Patient exclusion and dropout:**

In one female patient, the surgeon was not able to place all 4 implants between the mental foramina and in a favorable distribution for an implant-supported fixed prosthesis due to anatomical limitations. Consequently, the patient was excluded from the study and received an implant-supported mandibular overdenture.
As mentioned in the methodology section, each implant placed was tested for initial stability (≥ 35 Ncm) using a torque wrench. One implant in one patient and two in another failed the initial stability test. As a result, it was planned that the patients would be restored following the conventional loading protocol. One of the two patients, however, lost the implant that failed the initial stability test six weeks post-surgery, and was lost to follow-up. Another male patient developed a sudden gag reflex right after implant placement surgery and showed signs of anxiety, and so the prosthodontist was not able to implement the immediate loading protocol i.e. load the implants on the same day of surgery. The patient was reassured and was treated following the conventional loading protocol.

One implant failed in two patients in the immediate load arm and 2 implants failed in one patient in the control arm. Another implant failed in one patient who was treated following the conventional protocol because of the inability to implement the immediate loading protocol as mentioned previously. All implant failures occurred between 6 and 8 weeks post-implant placement surgery. The patients were not excluded from the study, and all lost implants were replaced and loaded with implant-supported fixed prostheses. There were no implant failures following insertion of the permanent fixed prostheses.
Implant outcomes:

Implant success rate:

Overall, 160 implants were placed between the mental foramina; 135 were 3.75 mm-wide implants, 1 was 3.3 mm-wide, and the remaining 24 implants were 4mm in diameter. Implant length ranged between 10 to 15 mm, with the majority being 15mm (75.6 %). No statistically significant difference was found between the two arms in terms of implant diameter distribution (p=0.103) (Figure 3.5).

Figure 3.5: Implant variables (diameter and length):
The implant success rate in the control arm after 1-year of loading exceeded 97%. The corresponding figure for the immediate loading arm was over 95% (Tables 3.2 and 3.3). No statistically significant differences were observed between the two arms for the implant success rates when Per Protocol Analysis (PPA) and Intention To Treat (ITT) analysis were carried out (Tables 3.2 and 3.3).

**Table 3.2: Implant success outcome 1-year post loading - ITT analysis:**

<table>
<thead>
<tr>
<th>Implant Failure</th>
<th>Control</th>
<th>Immediate</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>86 (97.73 %)</td>
<td>69 (95.83 %)</td>
<td>155</td>
</tr>
<tr>
<td>Yes</td>
<td>2 (2.27 %)</td>
<td>3 (4.17 %)</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>88</td>
<td>72</td>
<td>160</td>
</tr>
</tbody>
</table>

Fisher’s Exact test p= 0.6581

**Table 3.3: Implant success outcome 1-year post loading - PPA:**

<table>
<thead>
<tr>
<th>Implant Failure</th>
<th>Control</th>
<th>Immediate</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>93 (96.88 %)</td>
<td>62 (96.88 %)</td>
<td>155</td>
</tr>
<tr>
<td>Yes</td>
<td>3 (3.13 %)</td>
<td>2 (3.13 %)</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>96</td>
<td>64</td>
<td>160</td>
</tr>
</tbody>
</table>

Fisher’s Exact test p= 1.000
Bone loss analysis for the two arms of the study showed that there was statistically significantly more bone loss during the first year of loading in the immediate loading arm as compared to the conventional loading one (Table 3.4) (Figure 3.6).

Table 3.4: Mean peri-implant marginal bone loss 1-year post-loading (mm):

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Immediate</th>
<th>F-value</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sites</td>
<td>Mean Bone Loss</td>
<td>Lower CLΔ</td>
<td>Upper CLΔ</td>
</tr>
<tr>
<td>Overall Bone Loss</td>
<td>148</td>
<td>-0.037</td>
<td>0.104</td>
<td>-0.178</td>
</tr>
<tr>
<td>Distal</td>
<td>72</td>
<td>-0.031</td>
<td>0.156</td>
<td>-0.218</td>
</tr>
<tr>
<td>Mesial</td>
<td>76</td>
<td>-0.042</td>
<td>0.104</td>
<td>-0.188</td>
</tr>
</tbody>
</table>

*Tests are conducted with 95% confidence
*Tests for differences in mean bone loss corrected for clustering effects.
Negative values indicate bone loss, positive values indicate bone gain.
This significant difference was confirmed when both PPA and ITT analyses were carried out (p= 0.021 and p= 0.002 respectively). However, given the fact that the maximum acceptable amount of peri-implant marginal bone loss during the first year of implant loading is 1 mm (Zarb & Albrektsson, 1998), the difference in bone loss between the two study arms is not clinically significant. Moreover, there was no significant interaction between site (distal vs. mesial) and intervention group. That is, the differences in bone loss between the treatment arms was similar for both the mesial and distal sites (PPA: p=0.885, ITT: p=0.761) (Table 3.4) (Figure 3.7).

**Figure 3.6: Mean overall peri-implant marginal bone loss 1-year post-loading:**

![Figure 3.6: Mean overall peri-implant marginal bone loss 1-year post-loading](image)
Using statistical tests of non-inferiority, we evaluated the immediate loading protocol against the delayed loading one. A bone loss difference of 1 mm or less was set *a priori* as the upper bound of statistical non-inferiority. These tests suggest that the bone loss in the immediate loading arm is not statistically similar to the conventional loading arm (Table 3.5).

### Table 3.5: Equivalence of mean peri-implant marginal bone loss 1-year post-loading:

<table>
<thead>
<tr>
<th></th>
<th>Non-Inferiority Bound *</th>
<th>Reject or Not reject Non-inferiority of 1 mm or more**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ITT – Equivalence of</strong></td>
<td>Overall</td>
<td>3.362</td>
</tr>
<tr>
<td><strong>intervention arms</strong></td>
<td>Distal</td>
<td>2.013</td>
</tr>
<tr>
<td></td>
<td>Mesial</td>
<td>1.766</td>
</tr>
<tr>
<td><strong>PPA – Equivalence of</strong></td>
<td>Overall</td>
<td>3.527</td>
</tr>
<tr>
<td><strong>intervention arms</strong></td>
<td>Distal</td>
<td>2.05</td>
</tr>
<tr>
<td></td>
<td>Mesial</td>
<td>1.872</td>
</tr>
</tbody>
</table>

* All Intervals adjusted for clustering effects

** Rejection of Non-inferiority Null hypothesis indicates that the two interventions are statistically equivalent. Non-rejection of null hypothesis indicates that the immediate loading arm is not statistically similar to the conventional loading arm. Tests are conducted with 95% confidence.
To determine predictors of bone loss, multivariate linear regression analyses of the bone loss on patients’ demographic and clinical characteristics were performed. Except of the positive correlation between patient’s age and bone loss in the immediate loading arm (i.e. the older the patient the more the amount of bone loss), there were no significant correlations between bone loss and any of the patients’ demographic variables when each arm was analyzed separately and when data from both arms was pooled together (Tables 3.6, 3.7, 3.8).

Table 3.6: Linear regression for overall mean bone loss (mm/year):

<table>
<thead>
<tr>
<th>Factor</th>
<th>Adjusted</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Beta</td>
<td>SE</td>
<td>Sig.</td>
</tr>
<tr>
<td>Intercept</td>
<td>-0.258</td>
<td>0.790</td>
<td>0.845</td>
</tr>
<tr>
<td>Age</td>
<td>0.008</td>
<td>0.005</td>
<td>0.161</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.137</td>
<td>0.161</td>
<td>0.396</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Former/Current Smokers</td>
<td>0.160</td>
<td>0.137</td>
<td>0.303</td>
</tr>
<tr>
<td>Non-smoker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years edentulous prior to implant surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 - &lt;1year</td>
<td>-0.192</td>
<td>0.152</td>
<td>0.274</td>
</tr>
<tr>
<td>1-10 years</td>
<td>-0.072</td>
<td>0.128</td>
<td>0.659</td>
</tr>
<tr>
<td>&gt;10 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant length</td>
<td>-0.020</td>
<td>0.490</td>
<td>0.695</td>
</tr>
<tr>
<td>Jawbone quality*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>-0.101</td>
<td>0.179</td>
<td>0.573</td>
</tr>
<tr>
<td>2</td>
<td>-0.054</td>
<td>0.116</td>
<td>0.641</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jawbone quantity*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>0.072</td>
<td>0.259</td>
<td>0.948</td>
</tr>
<tr>
<td>B</td>
<td>0.254</td>
<td>0.250</td>
<td>0.573</td>
</tr>
<tr>
<td>C</td>
<td>0.089</td>
<td>0.270</td>
<td>0.459</td>
</tr>
<tr>
<td>D</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SE= Standard Error.* Using Lekholm and Zarb classification.
Table 3.7: Linear regression for mean bone loss in the control arm (mm/year):

<table>
<thead>
<tr>
<th>Overall Bone Loss Year 1</th>
<th>Adjusted</th>
<th>Unadjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Factor</strong></td>
<td><strong>Beta</strong></td>
<td><strong>SE</strong></td>
</tr>
<tr>
<td>Age</td>
<td>0.008</td>
<td>0.008</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.110</td>
<td>0.232</td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Former/Current Smokers</td>
<td>-0.011</td>
<td>0.213</td>
</tr>
<tr>
<td>Non-smoker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years edentulous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>prior to implant surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 - &lt;1year</td>
<td>-0.182</td>
<td>0.202</td>
</tr>
<tr>
<td>1-10 years</td>
<td>0.008</td>
<td>0.188</td>
</tr>
<tr>
<td>&gt;10 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant length</td>
<td>-0.065</td>
<td>0.072</td>
</tr>
<tr>
<td>Jawbone quality*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>-0.055</td>
<td>0.503</td>
</tr>
<tr>
<td>2</td>
<td>0.009</td>
<td>0.598</td>
</tr>
<tr>
<td>3</td>
<td>0.483</td>
<td>0.184</td>
</tr>
<tr>
<td>Jawbone quantity*</td>
<td>A</td>
<td>0.151</td>
</tr>
<tr>
<td>B</td>
<td>0.331</td>
<td>0.184</td>
</tr>
<tr>
<td>C</td>
<td>0.281</td>
<td>0.166</td>
</tr>
<tr>
<td>D</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SE= Standard Error.* Using Lekholm and Zarb classification.
Table 3.8: Linear regression for mean bone loss in the immediate arm (mm/year):

<table>
<thead>
<tr>
<th>Factor</th>
<th>Adjusted</th>
<th>Unadjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Beta</td>
<td>SE</td>
</tr>
<tr>
<td>Age</td>
<td>0.045</td>
<td>0.018</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td></td>
<td>-0.413</td>
<td>0.363</td>
</tr>
<tr>
<td>Smoking history</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Former/Current Smokers</td>
<td>-0.390</td>
<td>0.426</td>
</tr>
<tr>
<td>Non-smoker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years edentulous prior to implant surgery</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td></td>
<td>-0.125</td>
<td>0.417</td>
</tr>
<tr>
<td></td>
<td>-0.998</td>
<td>0.519</td>
</tr>
<tr>
<td>Implant length</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.004</td>
<td>0.088</td>
</tr>
<tr>
<td>Jawbone quality*</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>-0.962</td>
<td>0.422</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jawbone quantity*</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>0.749</td>
<td>0.586</td>
</tr>
<tr>
<td></td>
<td>0.575</td>
<td>0.375</td>
</tr>
<tr>
<td></td>
<td>-0.069</td>
<td>0.503</td>
</tr>
</tbody>
</table>

SE = Standard Error.* Using Lekholm and Zarb classification.
Patient satisfaction:

The degree of patient satisfaction with treatment was measured using the Denture Satisfaction Scale. The questionnaire was administered at baseline and at the 1-year recall visit. The results for both study arms are shown in Table 3.9 and Figure 3.8. A statistically significant difference was found between baseline and 1-year scores in both arms. However, no significant differences were present between treatment arms using either PPA or ITT analyses. This indicates that treatment with implant-supported prostheses improve patients’ satisfaction despite the type of treatment protocol used (Tables 3.10, 3.11).

The maxillary satisfaction scores dropped by 52.4 % from baseline to one year post-insertion of the final prostheses, while the mandibular satisfaction scores dropped by 69.4%, clearly indicating that patients are more satisfied with their mandibular implant-supported fixed prosthesis as compared to the maxillary conventional complete or partial dentures (Table 3.9)(Figure 3.9-a).

Table 3.9: Overall denture satisfaction scale (both study arms):

<table>
<thead>
<tr>
<th>Item</th>
<th>Arm</th>
<th>Baseline</th>
<th>1-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Total</td>
<td>C</td>
<td>47.1</td>
<td>10.7</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>51.0</td>
<td>7.5</td>
</tr>
<tr>
<td>Maxillary Sat</td>
<td>C</td>
<td>18.1</td>
<td>5.3</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>20.3</td>
<td>4.7</td>
</tr>
<tr>
<td>Mandibular Sat</td>
<td>C</td>
<td>21.4</td>
<td>4.9</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>22.6</td>
<td>2.8</td>
</tr>
<tr>
<td>Functional Sat</td>
<td>C</td>
<td>7.6</td>
<td>2.0</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>8.2</td>
<td>1.4</td>
</tr>
</tbody>
</table>

SD = Standard Deviation, LCL = Lowered Confidence Level, UCL = Upper Confidence Level, C=Control, I=Immediate.
Moreover, patients in both arms reported similar satisfaction with function (PPA: $p=0.630$, ITT; $P=0.787$) (Tables 3.10 and 3.11) (Figure3.9-c). The analysis of the effect of interaction between the type of treatment provided and time on the satisfaction scores was not significant, that is the two study arms continued to show similar improvement patterns over time (PPA: $p=0.149$, ITT; $p=0.290$) (Tables 3.10 and 3.11).

**Table 3.10: Association of satisfaction scores on treatment group, time, and the interaction between treatment group and time (ITT):**

<table>
<thead>
<tr>
<th>Satisfaction</th>
<th>ITT p-value</th>
<th>Group effect</th>
<th>Time effect</th>
<th>Group by time interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>F</td>
<td>P</td>
<td>F</td>
<td>P</td>
</tr>
<tr>
<td></td>
<td>0.49</td>
<td>0.489</td>
<td>297.92</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maxillary</td>
<td>0.30</td>
<td>0.587</td>
<td>129.22</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mandibular</td>
<td>0.62</td>
<td>0.434</td>
<td>403.97</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Functional</td>
<td>0.07</td>
<td>0.787</td>
<td>159.90</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

F-test

**Table 3.11: Association of satisfaction scores on treatment group, time, and the interaction between treatment group and time (PPA):**

<table>
<thead>
<tr>
<th>Satisfaction</th>
<th>PPA p-value</th>
<th>Group effect</th>
<th>Time effect</th>
<th>Group by time interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>F</td>
<td>P</td>
<td>F</td>
<td>P</td>
</tr>
<tr>
<td></td>
<td>0.23</td>
<td>0.636</td>
<td>284.43</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Maxillary</td>
<td>0.16</td>
<td>0.689</td>
<td>122.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mandibular</td>
<td>0.12</td>
<td>0.734</td>
<td>391.24</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Functional</td>
<td>0.24</td>
<td>0.630</td>
<td>154.24</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

F-test
Figure 3.8.: Overall denture satisfaction scale (both study arms):

Ctrl= Control arm, IL=Immediate Loading arm, Lowest score=12, highest score=60
Figures 3.9 a, b, and c: Maxillary, mandibular and functional denture satisfaction sub-scales (both study arms):
OHIP scores:

The OHIP scores for both study arms are shown in Table 3.12. No statistically significant differences were found between immediate and conventional loading arms in any of the OHIP subscales (Tables 3.13 and 3.14).

Table 3.12: Overall OHIP scores (both study arms):

<table>
<thead>
<tr>
<th>Item</th>
<th>Arm</th>
<th>Baseline</th>
<th>2-Month</th>
<th>6-Month</th>
<th>1-Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean SD</td>
<td>LCL</td>
<td>UCL</td>
<td>Mean SD</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global</td>
<td>C</td>
<td>83.8 23.1</td>
<td>73.5</td>
<td>94.0</td>
<td>37.0 14.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>87.9 21.1</td>
<td>77.5</td>
<td>98.4</td>
<td>32.4 10.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional</td>
<td>C</td>
<td>49.4 12.0</td>
<td>44.1</td>
<td>54.8</td>
<td>22.1 7.6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>49.7 10.7</td>
<td>44.3</td>
<td>55.0</td>
<td>19.5 6.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychosocial</td>
<td>C</td>
<td>34.4 11.7</td>
<td>29.2</td>
<td>39.5</td>
<td>14.9 7.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>38.3 11.0</td>
<td>32.8</td>
<td>43.8</td>
<td>12.9 5.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lowered Confidence Level, UCL = upper Confidence Level</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A statistically significant improvement in the overall OHIP, functional and psychosocial scores was observed in both arms at different time intervals as compared to the old conventional complete dentures (baseline score) (Figures 3.10,3.11,3.12)(Table 3.12).
Figure 3.10: Global oral health-related OHIP scores (both study arms):

Lowest score= 20, highest score= 120. Ctrl=Control arm, IL= Immediate Load arm
Figure 3.11: Psychosocial-related OHIP scores (both study arms): 

Ctrl=Control arm, IL= Immediate Load arm

Figure 3.12: Functional-related OHIP scores (both study arms): 

Ctrl=Control arm, IL= Immediate Load arm
This significant difference remains when PPA and ITT analyses were carried out and when data was analyzed in sub-scales (Tables 3.13 and 3.14). Notably, the improvement occurred at every stage of treatment (i.e. two, six and twelve months post-insertion of the final prostheses). Furthermore, the mean baseline score in both study arms was significantly higher than all three follow-up intervals (2, 6 and 12 months). The major improvement in the quality of life was observed by two months post-insertion of the permanent mandibular implant-supported fixed prostheses (Table 3.12). There were no statistically significant differences in either arm when looking at scores obtained 2 months post-insertion of the permanent fixed prosthesis as compared to the 1-year recall.

**Table 3.13: Association of OHIP scores on intervention arm, time, and the interaction between intervention arm and time (ITT):**

<table>
<thead>
<tr>
<th>OHIP Score</th>
<th>Group effect</th>
<th>Time effect</th>
<th>Group by time interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>F</td>
<td>P</td>
<td>F</td>
</tr>
<tr>
<td>Total</td>
<td>0.16</td>
<td>0.688</td>
<td>191.09</td>
</tr>
<tr>
<td>Functional</td>
<td>0.58</td>
<td>0.452</td>
<td>212.71</td>
</tr>
<tr>
<td>Psychosocial</td>
<td>0.00</td>
<td>0.996</td>
<td>140.30</td>
</tr>
</tbody>
</table>

F-test
Table 3.14: Association of OHIP scores on intervention arm, time, and the interaction between intervention arm and time (PPA):

<table>
<thead>
<tr>
<th>OHIP Score</th>
<th>Group effect</th>
<th>PPA p-value</th>
<th>Group by time interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>F</td>
<td>P</td>
<td>F</td>
</tr>
<tr>
<td>Total</td>
<td>0.20</td>
<td>0.658</td>
<td>179.78</td>
</tr>
<tr>
<td>Functional</td>
<td>0.53</td>
<td>0.470</td>
<td>202.46</td>
</tr>
<tr>
<td>Psychosocial</td>
<td>0.01</td>
<td>0.916</td>
<td>131.17</td>
</tr>
</tbody>
</table>

F-test
Discussion:

Most studies that have investigated the feasibility of the immediate loading of dental implants with fixed prostheses focused on reporting implant and prosthesis-based outcomes. There was very little emphasis on patient-based outcomes including satisfaction with treatment and improved quality of life. More importantly, most studies had no control groups to which outcomes of the immediate loading treatment could be compared, thus limiting the validity of the conclusions reached. This is the first randomized controlled clinical trial to investigate the efficacy of rehabilitating edentulous patients by means of immediately loaded mandibular implants with fixed prosthesis, and to then compare the treatment and patient-based outcomes against long-established conventional loading protocol.

The success rate of the immediately loaded TiUnite dental implants 1-year post-loading was around 96 %, while the prosthesis survival rate was 100%. This figure was not significantly different from the success rate of the conventionally loaded TiUnite dental implants (97 %) and is comparable to what has been reported in the literature (Aalam et al., 2005; Hatano N, 2001; Malo et al., 2003; Van de Velde et al., 2007). Furthermore, the reduction in the number of immediately loaded mandibular implants from 6 to 4 in the current study did not lower the success rate for the implants. In fact, the success rate reported in this study was comparable to success rates reported in the literature when five or six dental implants were immediately loaded (Balshi & Wolfinger, 1997; Chow J,Hui E,Li D,Liu J, 2001; Henry et al., 2003; G. M. Raghoebar et al., 2003; Van de Velde et al., 2007; Wolfinger et al., 2003). Consequently, our findings show that four TiUnite dental implants can be loaded
immediately with fixed prostheses in the mandible with success. It is important to stress, however, that this high success rate was achievable through careful planning and treatment. Moreover, implant placement was confined to the zone of the anterior mandible, an area that has been shown to provide the most favorable implant outcomes and prognosis (De Bruyn et al., 2008; Froberg et al., 2006; Hatano N, 2001; Tolstunov, 2007). This reduction in the number of implants has a significant impact on shortening treatment time, decreasing potential surgical morbidity and reducing initial and possibly long-term costs for the patient, since this usually means fewer implants and implant hardware to be used and maintained.

Five out of 160 implants placed failed. Four out of those 5 implants were placed in Type 1 bone according to the Lekholm and Zarb classification. These findings correlate with data reported by others (Bass & Triplett, 1991; Moy, Medina, Shetty, & Aghaloo, 2005).

Mean peri-implant bone loss was 0.296 mm for the immediately loaded implants and 0.037 mm for the conventionally loaded ones. Although the difference in bone loss between the two study arms was statistically significant, bone loss of 0.296 mm during the first year of loading is well below 1 mm, the maximum acceptable amount of peri-implant bone loss suggested by Albrektsson and Zarb (Zarb & Albrektsson, 1998). Furthermore, the average bone loss observed in our study is similar to that reported by other researchers (Aalam et al., 2005; Ericsson et al., 2000; Van de Velde et al., 2007; van Steenberghe et al., 2004). In the immediate loading arm, the majority of the final implant-supported fixed prostheses were inserted 3 months following implant placement surgery, while in the control arm the final prostheses were inserted within an average of four and a half months after implant placement. The peri-implant marginal bone level baseline radiographs were taken at
prosthesis insertion. The relatively early intervention and insertion of the final prosthesis in the immediate arm, when bone healing and remodeling process had not yet been completed, might explain the difference in the amount of bone loss identified when comparing the two study arms during the first year of loading.

The precision of the radiographic projection and measurement technique dictates the accuracy of the marginal bone level measurement. Intra-oral imaging using the paralleling technique is recommended since it provides the most accurate crestal bone-to-implant relationship. Beside patient inconvenience when having to remove the mandibular implant-supported fixed prosthesis whenever a standardized intra-oral radiograph of one or more implants is required, in some patients marginal bone resorption of the alveolar crest in the anterior mandible was very severe that using the special holder described by Cox and Pharoah in order to place the film in a position parallel to the implant long axis caused severe patient discomfort. Therefore, an alternative well-established technique for exposing standardized radiographs was used (M. S. Cune et al., 1996; van Kampen et al., 2005). This shift did not affect the accuracy of the measurements since both techniques used the paralleling projection and effects of any slight misalignment of the film relative to the implant long axis on crestal bone position were accounted for by using the known inter-thread distance of the implant to calibrate the measurements for each implant. Furthermore, on very few occasions where considerable film-to-implant misalignment was detected, the particular radiograph was excluded from measurement.

Of note is the use of up to 12 mm cantilevers on the distal extensions bilaterally did not compromise clinical outcomes. Careful organization of the occlusion is the most important
factor to consider when planning cantilevers on immediately loaded dental implants. Group function occlusion was aimed for i.e. in centric relation occlusion; occlusal contacts were evenly distributed on all teeth; including lighter central point contact on the cantilever teeth. The group function occlusal scheme was maintained during lateral excursions as well.

Patient-based concerns should be an integral part of any clinical trial reporting on success of a given treatment modality, but this has not been seen in most of the literature pertaining to immediate versus delayed loading protocols. Of the available studies that focused on patient-based outcomes, the psychometric instruments used had not been validated thus calling into question, their findings (De Bruyn et al., 2001; Henry et al., 2003; Klee de Vasconcellos et al., 2006). Furthermore, some studies only reported short-term satisfaction outcomes. For example Henry et al. (Henry et al., 2003) measured patients’ satisfaction three months post-insertion of the final prosthesis. These results would be more meaningful if patient satisfaction was evaluated again one year post-implant loading especially since more than half of the failed implants (8 out of 14) were lost after the first three months of follow-up. The current study provides a more thorough and complete assessment of patient satisfaction and changes in the quality of life following treatment with either treatment protocol as described above. The parallel study design with concurrent control arm and the longitudinal evaluation of the patient-based outcomes allowed us to formulate an objective and direct comparison between the two treatment protocols. The findings reported here corroborate previous observations reported by others suggesting that while conventional full dentures can improve patient satisfaction, rehabilitating those patients with implant-supported fixed prostheses led to dramatic improvements in their satisfaction and oral health-related quality of life. Moreover, the magnitude of improvement
in satisfaction and quality of life for patients in both treatment arms was similar, indicating that immediate loading protocol has lead to comparable clinical and patient-mediated outcomes.

Although the improvement in patient satisfaction for the maxillary prosthesis was also statistically significant, the percentage of reduction in the satisfaction score was less than the corresponding score for the mandibular prosthesis. This suggests that patients’ overall satisfaction experience with implant-supported fixed prostheses may have resulted in higher outcome expectations for the maxillary conventional complete or partial dentures.

It is noteworthy that the most common concern among patients in both arms of the study was food lodging beneath the mandibular fixed prosthesis. This can be appreciated when comparing the percentage of reduction in OHIP score for each element in the questionnaire. The percentage of score reduction from baseline (conventional complete denture) to two-month post-insertion of the fixed prosthesis was 32% for the question regarding food entrapment under the prosthesis. This percent reduction is considerably lower than the average reduction in all other elements of the OHIP questionnaire (61%). However, the reduction in the score continued and reached 45% at the one year follow-up visit, suggesting that patients rehabilitated with implant-supported fixed prostheses need more frequent oral hygiene instructions in order to be able to carry out proper oral hygiene at home so that entrapped food can be readily removed. This should not only maintain health of oral tissues and prognosis of prosthesis, but will also increase patient satisfaction with treatment.
An improvement in oral health-related quality of life was observed at different time intervals. The most profound improvement was seen when the conventional complete denture was replaced by the implant-supported fixed prosthesis and this improvement was maintained up to the 1-year follow-up.

Due to the nature of their design, randomized controlled clinical trials are generally adequate for measuring the efficacy of a given modality of treatment but not its effectiveness. This is mainly because those types of studies are carried out under “ideal” conditions. The patients included in these studies are usually those who have optimal health and are usually monitored closely over the duration of the study. In our study, however, patients were not excluded based on the presence of medical conditions except of those conditions that are well-established to be considered as absolute contraindications for treatment with dental implants in routine clinical practice (e.g. bleeding disorder). Furthermore, we did not eliminate patients with possible risk factors for implant failure such as smoking habit (≤10 cigarettes/day), and bruxism so this further parallels clinical practice as it were. Therefore, it might be concluded that although this is an idealize randomized controlled clinical trial, the data reported here possess external validity.

In conclusion, the high clinical success rate, patient satisfaction and improvements in quality of life reported in this randomized controlled clinical trial contribute to a growing body of evidence that supports use of immediate loading protocols for dental implants using mandibular implant-supported fixed prostheses. This treatment modality should reduce
treatment time, cost, and surgical morbidity significantly. Nevertheless, longer term follow-up studies are necessary in order to confirm these initial encouraging results.
Chapter 4

Five-Year Clinical Results of Immediately Loaded Dental Implants Using Mandibular Overdentures
Abstract

Purpose: The aim of this report is to present the clinical and patient-based outcomes of an immediate-loading protocol of TiUnite implants with mandibular overdentures in edentulous patients 5 years following initial placement.

Materials and Methods: The study was comprised of two groups of edentulous patients. In the experimental group, thirty-five consecutively-treated patients received 70 TiUnite implants that were loaded immediately as well as 69 Brånemark machined implants as backup treatment. One patient received 1 Brånemark implant. The control group was comprised of patients who were treated previously with conventional two-stage implant procedures, but were all case matched to the intervention group and served as a historical cohort. This group included 42 patients who received 111 Brånemark implants. Both groups of patients were treated with overdentures that were supported with a standardized resilient bar mechanism. Clinical and patient-based outcomes in the immediate group were recorded for the first five years following initial placement of implants and were measured at various stages of treatment using 2 questionnaires: the Denture Satisfaction Scale and the Oral Health Impact Profile (OHIP-20).

Results: Just over 98% of implants were found to be successful in both groups (Fisher’s Exact p=1). A statistically significant improvement in patients’ total, mandibular and functional satisfaction scores was found when comparing baseline data to the data obtained 5-year following loading in the immediate group (p<0.001). There were no significant differences between the 1 and 5-year total, mandibular and functional satisfaction scores, or between baseline and 5-year maxillary denture satisfaction scores. A statistically significant and positive correlation was found between baseline and 1-year maxillary satisfaction scores.
The improvement in the patients’ Quality of Life (QoL) was maintained during the first five years of loading.

**Conclusion:** The results of this longitudinal study suggest that immediate loading of two dental implants by means of bar–retained mandibular overdenture is a predictable treatment option, and leads to substantial improvement in patients’ satisfaction and QoL. Importantly, this mirrors the outcomes found for patients subjected to the more commonly accepted two stage implant procedure.

**Key words:** Dental Implants, Immediate, Implant Success, Patient Satisfaction, Edentulous.
Introduction:

Branemark et al. (Branemark et al., 1977) demonstrated that successful oral rehabilitation could be achieved reliably and reproducibly with the use of titanium tooth root endosseous implants (dental implants). However, success was inextricably linked to the requirement for a 3- to 6- month healing phase following placement of the implants prior to occlusal loading (Adell, Lekholm, Rockler, & Branemark, 1981; Adell, Eriksson, Lekholm, Branemark, & Jemt, 1990; Albrektsson, 1983; Albrektsson, Zarb, Worthington, & Eriksson, 1986; Albrektsson, 1993; Astrand et al., 1996; Branemark et al., 1969; Hobkirk & Watson, 1995). Endosseous implant therapy became more predictable and applicable to a wider spectrum of patients with evolution of new diagnostic modalities, and modifications in dental implant geometry, and surface topography to name a few (Albrektsson, 2008; Sul, 2008; Huang, 2005). The evolution of new and more sophisticated and reproducible surgical approaches such as various bone grafting modalities has also led to improved treatment outcomes as well as broadening the scope of patients to those who might otherwise have been unsuitable for implant treatment in the past. Moreover, the introduction of improved restorative materials and hardware made rehabilitation of edentulous patients with dental implants more predictable (Al-Fadda, Zarb, & Finer, 2007; Jokstad et al., 2003; Ortorp, Jemt, Back, & Jalevik, 2003).

Although the 3- to 6- month period of time required prior to loading of implants has been a mandatory requirement in the past (Brånemark, Zarb, & Albrektsson, 1985b), this is now being challenged so that shorter surgery to implant healing time periods are being advocated (Brånemark, 2001).
Recent studies have compared clinical outcomes following immediate versus conventional delayed protocols and have shown similarly high levels of success whether immediate or delayed loading is carried out (Babbush et al., 1986; Chiapasco, Gatti, Rossi, Haefliger, & Markwalder, 1997; Chiapasco, Abati, Romeo, & Vogel, 2001; Chiapasco & Gatti, 2003; Gatti & Chiapasco, 2002; Lorenzoni et al., 2003; Packer, Watson, & Bryant, 2000; Romeo, Chiapasco, Lazza, Casentini, Ghisolfi, Iorio, & Vogel, 2002; Roynesdal et al., 2001; Rungcharassaeng, Lozada, Kan, Kim, Campagni, & Munoz, 2002; Spiekermann et al., 1995; Vassos, 1997). If this is true, it might be hypothesized that immediate loading of dental implants with overdenture prostheses is more cost-effective and convenient in terms of time management and reduced financial burden for patients. In addition, fewer surgical interventions with early loading/single stage implant procedures are relevant to elderly patients. Despite numerous publications regarding immediate loading, there is actually a dearth of sound scientific data that confirm that single stage procedures are not only less costly (time/money) than two stage procedures, but are equally successful. The literature is generally limited in terms of implant survival or success, two parameters that at first glance might seem identical but which are quite different from one another. Moreover, although there appears to be a large body of information (admittedly observational, non-quantitative, case reports) regarding clinical success for various implant designs and surgical modalities, there is much less information regarding patient-based concerns in relation to treatment outcomes including such factors as quality of life and overall satisfaction (Stricker, Gutwald, Schmelzeisen, & Gellrich, 2004). Our research group has already reported both clinical and patient-based outcomes in patients undergoing single stage implant treatment for immediately loaded mandibular overdenture (Attard et al., 2005; Attard, Laporte, Locker, & Zarb, 2006), but longer term outcomes needed to be studied before concluding that
immediately loaded endosseous implants represent a viable and predictable treatment regimen in comparison to the standard and commonly accepted two stage implant treatment approaches.

Here we report the clinical and patient-based outcomes five years following immediate loading of two dental implants with a bar-retained mandibular overdenture.
**Materials and Methods:**

**Sample size calculation (Attard, 2004):**

The sample size was calculated by comparing the means and SDs of bone loss around implants with immediate and delayed loading protocols. For the immediately loaded implants the mean was calculated as 0.975 mm with a standard deviation of 0.3796 mm {{1971 Bernard, J.P. 1995; }}. This data was compared to bone loss results for the mandible from a multi-center study with the mean bone loss of 0.5 mm and standard deviation of 0.8 mm {{1952 Jemt, T. 1996; }}.

The sample size was calculated with the following formula:

$$\delta^2 = \left[ \mu + \nu \right]^2 \times \left[ \delta_1^2 + \delta_2^2 \right] / \left[ \eta_1 - \eta_2 \right]^2,$$

The value, $\mu$, is one-sided percentage point of the normal distribution corresponding to the proposed power of the study.

The power $\nu$ is the percentage point of the normal distribution corresponding to the (two-sided) significance level $p<0.05$.

$[\delta_1 + \delta_2]$ is the sum of the SDs.

$[\eta_1 - \eta_2]$ is the difference between means for the samples.

Therefore, when $p=0.05$ and the power of the study is set at 80%, $\mu = 0.85$ and $\nu = 1.96$ and $\delta$ is the SD for each sample and $[\eta_1 - \eta_2]$ is the difference between the means, the sample size calculation would look like this: Sample size = $[0.85+1.96]^2 \times [0.38^2+0.8^2] / [0.975-0.5]^2$

Based on this calculation it was estimated that a minimum of 27 patients was required per group. Thus, the proposed number of 30 patients per group was chosen so as to allow for potential dropouts during follow-up period.
The study groups were selected from patients seeking treatment at the Implant Prosthodontic Unit (IPU), University of Toronto as described in the previous report on this population of patients (Attard et al., 2005). The Human Ethics Board of the University of Toronto approved both treatment protocols.

**Conventional loading protocol:**

The conventional loading group (control group) was comprised of 42 patients, treated previously using the ‘conventional’ two stage treatment approach and who therefore served as the historical comparator group or cohort. Of those patients 20.5% were active smokers, and were edentulous for a mean of 13.74 ± 9.77 years. Patients in this group had at least two Brånemark dental implants (NobelBiocare®, Gothenburg, Sweden) placed, followed by a healing period of 4 months. The implants were exposed and implant-supported overdentures were fabricated with a resilient ovoid bar/clip system (Cendres and Métaux). A total of 111 implants were placed in this patient population of which 108 were loaded.

**Immediate loading protocol:**

The experimental group comprised thirty-five patients who were edentulous for a mean of 17.75 ± 17.37 years. Almost forty-four percent of the patients were active smokers (43.5%). First, the patients in this group received new complete conventional dentures and were encouraged to wear them for at least two months prior to implant surgery. This was done in order to identify patients who might have confounding characteristics including denture fabrication-related mal-adaptation behavior. All patients were treated following a
standard protocol described previously (Attard et al., 2005). Briefly, four Nobel Biocare implants (2 Branemark and 2 TiUnite) were placed in the bone. The immediately loaded implants were the 2 TiUnite ones. Right after surgery, the existing dentures were hollowed out and relined with a temporary soft reline (COE-Soft Liner, GC America) that was in direct contact with the healing abutments. An ovoid bar (Cendres Métaux) was fabricated and retrofitted to the overdenture 10 days post-surgery.

For both groups, bilateral balanced occlusion was planned for when implant-supported overdentures were fabricated.

**Recall visits:**

**Data Collection:**

At the 5-year recall visit, various parameters were recorded for patients in the treatment groups. The data collected included but were not limited to patient demographics, general health, smoking history and level of oral hygiene.

The following criteria, as suggested in the Toronto Consensus Conference (Albrektsson & Zarb, 1998) for implant success, included testing for stability by torquing implants up to 20 Ncm, which allowed for detection of both pain and mobility, both criteria for failure of the fixture, and if these were identified, the involved implants were removed.
Patient satisfaction and Quality of Life (QoL) outcomes:

Data on these two parameters were collected for patients treated with the immediate protocol only.

Patients’ satisfaction with their conventional dentures was assessed using the Denture Satisfaction Scale as described previously elsewhere (P. F. Allen, McMillan, & Walshaw, 2001; Attard, Laporte, Locker, & Zarb, 2006). Oral health-related QoL outcomes were measured using the short-form version of the Oral Health Impact Profile questionnaire (OHIP-20) (F. Allen & Locker, 2002). Both questionnaires were administered at the pre-operative visit (baseline) prior to the fabrication of the new mandibular conventional complete denture and prior to obtaining informed consent for the study. Scores are known to correlate directly with higher levels of patient dissatisfaction or compromised QoL. In other words, higher scores indicate less patient satisfaction and compromised QoL. In addition, patients were asked to fill out the OHIP questionnaire following the fabrication of the conventional complete denture and after implant placement surgery and conversion of the complete denture to a bar-retained overdenture. Both questionnaires were again administered one and five years post-surgery.

The scores from the Denture Satisfaction Scale were first analyzed globally and then divided into questions related to the individual prostheses and those related to functional status. The OHIP scores were also analyzed globally and divided into functional and psychosocial-related questions. Subscale scores were created by summing the responses to the respective questions.
**Statistical methods:**

The SAS statistical package was used to carry out the analyses. Fisher’s exact test was used to test for significant differences in implant success (clinical and patient-based) between the two groups. To determine whether satisfaction scores changed significantly over time, a series of repeated measures ANOVAs were performed. To explore the relationship between patients’ demographic characteristics and 1 and 5-year satisfaction scores, a series of univariate (correlations, t-tests, and ANOVAs) and multivariate correlation analyses were performed. A series of ANCOVAs were then performed to assess effects of each demographic factor on the OHIP scores in a multivariate setting. Statistical significance for all tests was set at $p < 0.05$. 
**Results:**

Four patients from the experimental group failed to present for the 5-year recall visit; two had died, and it was not possible to locate the other 2 subjects. As shown in Table 4.1, the percentage of successful implants at five years post-loading was over 98% in both groups, and there were no statistically significant differences between the two groups ($p=1.0$).

**Denture Satisfaction Questionnaire:**

There was a statistically significant improvement in patients’ *total, mandibular* and *functional* satisfaction scores after both one year of treatment and 5 years later (Table 4.2). There were no significant differences at 1 and 5-years in the *total, mandibular* and *functional* satisfaction scores. This indicates that the patients were more satisfied with the new dentures and that this degree of satisfaction was maintained over the first five years of follow-up.

The differences between 5-year and baseline maxillary denture satisfaction scores approached significance (Table 4.2). This lack of significant difference suggests that the patients’ satisfaction with the maxillary conventional complete denture decreases with time. However, there was a significant positive correlation between baseline and 1-year maxillary satisfaction scores ($p=0.0025$, univariate analysis), meaning that the more satisfied the patients with their old maxillary conventional dentures the higher the chance that they will be very satisfied with their new ones. Alternatively, a negative correlation was found between 1-year follow-up satisfaction scores and the duration of edentulism in both arches (mandible: $p=0.04$, maxilla: $p=0.0265$). There was no statistically significant
relationship between the 5-year satisfaction scores and demographic variables when tested using either univariate or multivariate analyses.

**Oral Health-Related QoL Outcomes:**

The mean overall OHIP and functional and psychological subscale scores dropped by 28% following fabrication of the conventional complete denture and then dropped further after implant placement surgery and conversion of the complete denture to a bar-retained overdenture. This relationship remained relatively constant after that point (Figures 4.1, 4.2 and 4.3). This indicates that the improvement in the patients’ quality of life, both globally and for the functional and psychological subscales, was maintained up to five years following loading. No relationship was found between the various 5-year OHIP subscales and patients’ demographic variables.
Discussion:

There is a very large body of evidence which demonstrates that rehabilitation of the edentulous mandible with implant-supported overdentures is a feasible and predictable treatment (Babbush et al., 1986; Bergendal & Engquist, 1998; K. Gotfredsen & Holm, 2000; I. Naert, Alsaadi, & Quirynen, 2004; Spiekermann et al., 1995; Timmerman, Stoker et al., 2004). Besides the established advantages of this treatment modality, it has been postulated that immediate loading protocols provide further advantages, particularly reductions in overall treatment time, as well as decreased morbidity (i.e. second stage surgery).

The data reported here show that there is a virtually identical rate of success for implants inserted using the two-stage approach as compared to implants placed using a single stage surgical procedure followed by immediate loading (i.e. just over 98%). Hence, the longitudinal findings reported here parallel findings reported by others (A. S. Assad et al., 2007; Babbush et al., 1986; Chiapasco, Gatti, Rossi, Haefliger, & Markwalder, 1997; Spiekermann et al., 1995; Vassos, 1997).

Despite mandibular overdentures being supported by only two dental implants, the high success rate is probably related to several factors including planning and execution of the treatment. Implants were all placed within the mandibular interforaminal area. This provides the most favorable bone architecture. In addition, the two dental implants were splinted early on with a passively fitted bar in order to insure that the amount of micro-motion at the bone-implant interface was maintained well below the suggested maximum threshold (Cameron, Pilliar, & MacNab, 1973; Kawahara, Kawahara, Hayakawa, Tamai,
Duyck et al. evaluated the effects of implant displacement on tissue differentiation around immediately loaded cylindrical turned titanium implants in the tibia of ten New Zealand white rabbits using bone chamber methodology (Duyck et al., 2006). Bone-to-implant contact was significantly larger in the unloaded situation compared to implants subjected to 30 µm and 90 µm loading. This led to the conclusion that implant micro-motion has a detrimental effect on bone-to-implant contact, a critically important issue in relation to immediate loading of implants. Another important factor pertains to occlusal loading of implant-supported prostheses such that balanced contacts are produced in both centric and eccentric mandibular positions. This assists in reducing maximum applied stresses at the implant fixture as well as the bone, something that is especially important in a single stage immediate loading situation.

The surface of the TiUnite dental implant is moderately rough (1.0-2.0 µm), a degree of roughness that has been shown to provide the strongest biomechanical bond to the surrounding bone as compared to smooth (<1.0 µm) or even more rough surfaces (> 2.0 µm) (Albrektsson & Wennnerberg, 2004). Furthermore, the novel titanium porous oxide surface of TiUnite implants has been proven to have considerable osteoconductive potential thus promoting a high degree of implant osseointegration even in type IV bone of the posterior maxilla (Huang et al., 2005). Studies carried out in various animal models have reported favorable biomechanical and histomorphometric results comparing the TiUnite surface to other surfaces (Xiropaidis et al., 2005; Zechner et al., 2003). Moreover, the geometry of the TiUnite implants is in the form of a screw. This configuration lends itself to the ability of transmitting an axial tensile or compressive load to the surrounding bone, primarily by compression on the inclined faces of the screw. Consequently, full shear strength of the bone
may develop (Skalak, 1983). All of these favorable characteristics of the TiUnite dental implant may have played a major role in achieving primary stability and high success rates with the immediate loading protocol in the current study.

Satisfaction of patients who received mandibular implant-supported overdentures was sustained up to 5 years as evidenced by low Denture Satisfaction Scale scores. These results are comparable to previous reports (Stricker et al., 2004). Alternatively, 5-year satisfaction scores for maxillary prosthesis were higher than those at one year. Thus, although it is generally considered that maxillary conventional complete dentures are stable and comfortable, the differences reported here show that this is not necessarily the case over the longer term and is consistent with the notion that implant-supported prostheses provide longer term stability and comfort than conventional prostheses. Interestingly, denture satisfaction in the preoperative state of treatment for the maxillary denture is a good predictor of the degree of satisfaction reported at the 1-year postoperative time point as shown by their positive correlation using the univariate analyses. Negative correlation found between the 1-year follow-up satisfaction scores for both arches and duration of edentulism suggests that patients’ adaptation to being edentulous improves with time, and that their treatment expectations tend to be more ‘realistic’ or modest.

The improvement in the QoL following rehabilitation with implant-supported overdentures was sustained at the 5-year follow-up visit. Moreover, the high levels of satisfaction were positively correlated with improved QoL according to the lower OHIP scores. This suggests that positive results on the Denture Satisfaction Questionnaire may indicate an improvement in the QoL. It must be recognized, however, that the Denture
Satisfaction Questionnaire is not a direct measure of QoL but a tool that measures factors that affect QoL.

Some methodological weaknesses can be found in this study. This is not a randomized controlled clinical trial, and the control group was a historical cohort. The rationale for using a historical control group was our team’s previous experience with the patients treated with the conventional protocol. Moreover, it was hard to recruit an adequate number of edentulous patients for the study. We therefore opted for a historical group, since clinical data was collected regularly for patients treated in the clinic (Attard et al., 2005).
Conclusion:

In conclusion, within the limitations of the current clinical trial, the long term clinical and patient-mediated outcomes of immediately loaded dental implants with a bar-retained mandibular overdenture are comparable to the conventional two-stage protocol. Further research is needed to investigate the feasibility of this treatment modality using a variety of prosthetic designs and in the maxilla.
Tables:

Table 4.1: Implant success rates 5 years post-loading:

<table>
<thead>
<tr>
<th>Group</th>
<th>Implants placed (lost)</th>
<th>Implants loaded</th>
<th>Percent Success*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional loading</td>
<td>111(2)</td>
<td>108</td>
<td>98.2%</td>
</tr>
<tr>
<td>Immediate loading</td>
<td>123 (2)</td>
<td>62</td>
<td>98.4%</td>
</tr>
</tbody>
</table>

*Fisher’s exact test; P = 1

Table 4.2: Mean score ± SDs (95% CI) on the Denture Satisfaction Scale

<table>
<thead>
<tr>
<th>Time</th>
<th>Baseline</th>
<th>1-Year</th>
<th>P value*</th>
<th>5-year</th>
<th>P value* (BL vs. 5-year)</th>
<th>P value* (1-year vs. 5-year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Maxilla)</td>
<td>9.5 +/- 5.0 (7.8 , 11.3)</td>
<td>7.1 +/- 2.8 (6.2 , 8.1)</td>
<td>0.0019</td>
<td>7.5 +/- 4.0 (5.8 , 9.1)</td>
<td>0.0619</td>
<td>1.0</td>
</tr>
<tr>
<td>Satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Mandible)</td>
<td>21.0 +/- 2.7 (20.1 , 21.9)</td>
<td>6.6 +/- 2.1 (5.9 , 7.3)</td>
<td>&lt; 0.0001</td>
<td>5.8 +/- 1.9 (5.1 , 6.6)</td>
<td>&lt; 0.0001</td>
<td>0.5671</td>
</tr>
<tr>
<td>Functional</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>satisfaction</td>
<td>5.5 +/- 2.0 (4.8 , 6.2)</td>
<td>2.7 +/- 1.0 (2.3 , 3.0)</td>
<td>&lt; 0.0001</td>
<td>2.8 +/- 1.2 (2.3 , 3.3)</td>
<td>&lt; 0.0001</td>
<td>1.0</td>
</tr>
<tr>
<td>Total</td>
<td>36.1 +/- 8.4 (33.2 , 38.9)</td>
<td>16.4 +/- 4.8 (14.7 , 18.1)</td>
<td>&lt; 0.0001</td>
<td>16.1 +/- 6.5 (13.4 , 18.8)</td>
<td>&lt; 0.0001</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Minimum rating (score) = 12; maximum rating (score) = 60. BL= Baseline. * Bonferroni-adjusted pairwise comparisons.
Figure 4.1: Functional OHIP scores:

**Phases:** 1= Baseline, 2=Conventional Denture Insertion, 3= Implant Insertion, 4= 1-year recall, 5= 5-year recall

**Functional Scores,** repeated measures ANOVA (F=89.00, df=4,128, \( p<0.0001 \))

**Bonferroni-adjusted pairwise comparisons:**

- **a** = Baseline score > Denture Insertion Stage, Implant Insertion Stage, 1 and 5-year recall score (\( P<0.0001 \)).
- **b** = Denture Insertion Stage score > Implant Insertion Stage, 1 and 5-year recall scores (\( P<0.0001 \)).
- **c** = Implant Insertion Stage and 1-year recall scores are not statistically significantly different from each other (\( P = 1 \)).
- **d** = 1 and 5-year recall scores are not statistically significantly different from each other (\( P = 1 \)).
**Figure 4.2: Psychosocial OHIP scores:**

**Phases:** 1= Baseline, 2=Conventional Denture Insertion, 3= Implant Insertion, 4= 1-year recall, 5= 5-year recall

**Psychosocial Scores.** repeated measures ANOVA (F=45.56, df=4,128, \(p<0.0001\))

**Bonferroni-adjusted pairwise comparisons:**

- **a** = Baseline score > Denture Insertion Stage, Implant Insertion Stage, 1 and 5-year recall score (\(P<0.0001\)).
- **b** = Denture Insertion Stage score > Implant Insertion Stage, 1 and 5-year recall scores (\(P<0.0001\)).
- **c** = Implant Insertion Stage and 1-year recall scores are not statistically significantly different from each other (\(P = 1\)).
- **d** = 1 and 5-year recall scores are not statistically significantly different from each other (\(P = 1\)).
**Figure 4.3: Global OHIP scores:**

Phases: 1= Baseline, 2=Conventional Denture Insertion, 3= Implant Insertion, 4= 1-year recall, 5= 5-year recall

Global Scores, repeated measures ANOVA (F=78.54, df=4,128, p<0.0001)

Bonferroni-adjusted pairwise comparisons:

a = Baseline score > Denture Insertion Stage, Implant Insertion Stage, 1 and 5-year recall score (P<0.0001).
b = Denture Insertion Stage score >Implant Insertion Stage, 1 and 5-year recall scores (P<0.0001).
c = Implant Insertion Stage and 1-year recall scores are not statistically significantly different from each other (P = 1).
d = 1 and 5-year recall scores are not statistically significantly different from each other (P = 1).
Economic analysis

The clinical effectiveness of the various implant-supported treatment modalities in terms of success, retention and stability of prosthesis, improvement in speech, function and quality of life have been investigated in numerous clinical trials (M. Cune, van Kampen, van der Bilt, & Bosman, 2005; Engfors et al., 2004; M. E. Geertman et al., 1999; K. Gotfredsen & Holm, 2000; P. S. Wright et al., 2002). However, there is little information about economic burden. This aspect is of particular importance since in most countries the cost of treatment with endosseous dental implants is not covered under public health or private insurance plans. This means that it is usually the patient who bears the cost of treatment through direct out-of-pocket payments. Previously, our group has investigated approaches to the use of endosseous implants with a focus on minimization of cost as well as improvements in cost effectiveness. We have assessed newly emerging approaches in implant therapy including the concept of immediate loading of dental implants with mandibular overdentures. Such prostheses have already been evaluated after one year of loading (Attard, Laporte, Locker, & Zarb, 2006) and the findings showed that the immediate loading protocol was associated with higher maintenance and total costs (Mann Whitney U Test p<0.05) in comparison to the more traditional conventional loading method. However, there were no differences in the time-costs associated between the two protocols. This study builds on that previous research by extending the follow-up period for an additional two years. Of particular interest is whether costs of treatment are front-loaded, that is, whether savings with one treatment modality or another, would manifest several years post-treatment. Higher costs demonstrated after one year might eventually lead to lower costs in the longer
term. To that end, we carried out a 3-year cost minimization analysis for the same group of patients.

**Materials and Methods:**

Analysis was conducted from the patient’s perspective, because in Ontario, Canada, these clinical procedures are not covered by public or private insurance. Moreover, patient-based outcomes probably reflect true success/failure of treatment than most others. In most cases the patient bears the cost of treatment through direct out-of-pocket payment at the point of service, underscoring the merits of such an approach in our economic analysis (Attard, Laporte, Locker, & Zarb, 2006; Drummond MF, Sculpher MJ, Torrance GW et al, 2005). In this regard, willingness to pay is another parameter that reflects the relative importance of a particular service or treatment in any one patient group, and so this patient-based economic analysis should add another dimension to the assessment of various endosseous implant treatment modalities.

**Cost Analyses:**

Treatment costs in 2005 Canadian dollars were calculated standardized to the base year 2002. Following Attard et al. (Attard, Laporte, Locker, & Zarb, 2006) they were composed of:

1. Total costs = (total clinical costs) + (total patient time costs)
2. Total clinical costs = (initial treatment costs) + (maintenance costs)
3. Maintenance costs = (prosthodontic costs for work other than the first implant-supported prosthesis)+ (recall costs)
4. Total patient-time costs = (salary rate/hour) X (clinical time)

The frequency of the recall visits and the fees charged for each clinical procedure reflect the usual care in “real life” scenarios. The cost of initial treatment, remakes and maintenance were collected from the patients’ dental charts. Fees for implant-placement surgery; operating room, hardware, surgeon and prosthodontist fees, were included in the initial treatment costs. The cost of the fabrication of the peri-implant dentures was not included in the initial cost since this is a common treatment in both groups, and from an economic viewpoint we are only interested in the differences between the two study groups. Maintenance costs incurred by the patients included cost of remakes, relines, replacement of hardware, cost for professional services provided by the prosthodontist and/or the surgeon, laboratory costs, and costs for the annual recall visits required by patients.

The clinical time for diverse prosthodontic ‘events’ including initial treatment and management of complications was measured directly for the immediate group. However, for the control group, the time was based on averages obtained by measuring prosthodontic events in a group of edentulous patients that received similar overdenture treatment.

Time spent by patients was valued using the accepted (average) market value of their labor time, consistent with the human capital approach, which is a validated approach used in economic evaluation research (Drummond MF, Sculpher MJ, Torrance GW et al, 2005). To estimate patients’ time cost, average wages in 2002 as further defined by gender, age, and occupation group were obtained from the Census of Canada (Statistic Canada, 1991; Statistic Canada, 2003.; Statistic Canada; Statistics Canada., 1981). Unless stated otherwise in the patient’s chart, retirement age for the patients was considered to be 65 years. The
national average income for Canadians over 65 years of age was obtained from the Income Trends in Canada, Statistics Canada (Statistic Canada., 2003). The income for housewives was proxied by the average salary for housekeepers, in an attempt to value the time they spent in the clinic (time/money equivalent per prosthodontic event).

The costs for every patient were inflated using the Consumer Price Index (CPI), in order to reflect the fact that, over time, the cost of living rises due to inflation. The CPI tracks the cost of a fixed “basket” of commodities purchased by a ‘typical’ consumer during a given year. The average wages from 1985 to 2005 were adjusted by using the “all item CPI” for Canada (base year 2002). Clinical costs (initial intervention, management of complications, and recalls) were inflated using the Health CPI (Statistic Canada., 2002) because the costs of medical supplies and devices tend to increase faster than the general inflation rate.

The average hourly wage was obtained using the following calculation and was based on inflation adjusted salaries that were divided by the following denominator: 365 days – [(52 weeks*2) + National and provincial holidays]* 8 hour day.

**Statistical analysis:**

Cost data were not normally distributed and so non parametric tests were used. Since the data in both groups were positively skewed, the Wilcoxon Rank Sums test was used for the analysis. Repeated Measures ANOVA was used to study the relationship between time and rate of reduction in prosthetic complications. Statistical significance was set at p < 0.05.
Results:

The median initial costs for the immediate loading and conventional groups were $CAN 2595.1 and $CAN 2269.68 respectively. As shown in Figure 4.4, there was wider variation in the initial costs amongst the conventional loading group as compared to the immediate loading group. This variation in initial costs for the conventional group was due to a charge for each individual implant. Alternatively, the group receiving immediately loaded implants, had a fixed treatment cost and the difference occurred because some patients needed extraction of remaining teeth before providing them with an implant-supported overdenture (Table 4.3).

Figure 4.4: Initial costs for patients in Canadian dollars (Median):
Table 4.3: Initial costs for patients in Canadian dollars:

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients (n)</th>
<th>Initial Costs Mean (± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate loading</td>
<td>33</td>
<td>$2621.95 (± 334.93)</td>
</tr>
<tr>
<td>Conventional loading</td>
<td>40</td>
<td>$2613.98 (± 815.74)</td>
</tr>
</tbody>
</table>

p-value 0.024

SD= standard deviation, Wilcoxon Rank Sums Test

In the group that had immediately loaded implants, the patients were only recalled twice during the three years of follow-up. Administrative transitions in the Implant Prosthodontic Unit (IPU) during the follow-up period precluded recalling those patients annually. Conversely, 22 out of the 40 patients who were treated with the conventional loading method were seen for recall visits three times during the 3-year follow-up period. This is due to the fact that most of the patients treated following the conventional loading protocol received treatment between 1985 and 1990, when dental implants were considered relatively new to the field of dentistry. Thus, these patients were monitored very closely and recalled frequently. Since the standard recall protocol for patients rehabilitated with implant-supported prostheses is once every 12-18 months, we assumed that all patients in both groups were seen twice during the follow-up period and that they were charged the same amount for both recall visits. Consequently, the recall costs were considered to be constant for the two groups, while the maintenance costs were related principally to prosthodontic expenditures.
The costs for treatment of complications were significantly higher in the immediate loading group, even three years after treatment ($CAN 446.88 in the immediate loading group as compared to $CAN 241.86 in the conventional loading group) (Figure 4.5). Although there were relatively few complications in patients treated with immediate loading, some costs for treatment of complications were as high as $CAN 1500 while none of the patients in the group treated using the conventional loading protocol had complications requiring expenditures higher than $CAN 400 (Figure 4.5). The mean cost for management of complications over the second and third years of follow-up were $CAN 158.12 (± 260.35) for the patients in the immediate loading group and $CAN 20.88 (± 63.96) for the patients in the conventionally treated group. The difference in costs was statistically significant (p= 0.003) (Table 4.4). However, the corresponding median values were equal to $CAN 0 for both groups indicating that most patients did not experience any complications following the first year of loading.
Figure 4.5: Total complication costs (3-year) for patients in Canadian dollars (Median):

![Box plot showing complication costs for Immediate and Conventional loading groups.]

Table 4.4: Total complication costs for patients in first, second and third years in Canadian dollars:

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients (n)</th>
<th>First year Complications Costs Mean (± SD)</th>
<th>2(^{nd}) and 3(^{rd}) year Complications Costs Mean (± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate loading</td>
<td>33</td>
<td>$341 ± 219.73</td>
<td>$158.12 ± 260.35</td>
</tr>
<tr>
<td>Conventional loading</td>
<td>40</td>
<td>$53.6 ± 102.04</td>
<td>$20.88 ± 63.96</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt; 0.0001</td>
<td>0.003</td>
<td></td>
</tr>
</tbody>
</table>

SD= standard deviation, Wilcoxon Rank Sums Test
We noted that the complication rate declined over time for both groups but that a more rapid reduction in the complication rate was observed for the immediate loading group as compared to the conventional loading group. This difference was statistically significant (Repeated Measures ANOVA, F= 6.76, p = 0.0103).

The median total maintenance costs for patients in the immediate and conventional loading group were $CAN 602.88 and $CAN 156 respectively (Figure 4.6). Since the recall costs in the two groups were the same, the significant difference in the costs associated with management of complications led to statistically significant increase in maintenance costs for patients managed with the immediate loading protocol (p < 0.0001)(Table 4.5).

Figure 4.6: Maintenance costs for patients in Canadian dollars (Median):
Table 4.5: Complication and maintenance costs for patients in Canadian dollars:

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients (n)</th>
<th>Complications costs Mean (±SD)</th>
<th>Maintenance costs Mean (±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate loading</td>
<td>33</td>
<td>$514.63 ± 349.28</td>
<td>$655.04 ± 355.26</td>
</tr>
<tr>
<td>Conventional loading</td>
<td>40</td>
<td>$205.57 ± 100.58</td>
<td>$222.81 ± 112.34</td>
</tr>
</tbody>
</table>

p-value: 0.0061 < 0.0001

SD=standard deviation

It is noteworthy that the difference in the median total patient time costs between the two groups was not statistically significant, even up to three years of follow-up ($CAN 261.63 in the immediate group and $CAN 250.24 in the conventional one) (p= 0.687) (Figure 4.7). Moreover, the salary rate did not play a role in the observed differences found for the time costs, since the average salary rates for the two study groups did not differ significantly. Although in some patients the time costs were as high as $CAN 1500, most of the time costs were less than or equal to $CAN 500 for both groups (Figure 4.7).
Following three years of loading it was found that median total costs for immediate and the conventional loading groups were $CAN 3545.86 and $CAN 3439.29 respectively. The difference was not statistically significant (p = 0.1554) (Figure 4.8, Table 4.6). This indicates that the significant difference in the initial, maintenance and clinical costs were offset by time saved with the immediate protocol and thus the overall time costs.
Figure 4.8: Total costs for patients in Canadian dollars (Median):

Table 4.6: Total clinical, time and total costs for patients in Canadian dollars:

<table>
<thead>
<tr>
<th>Group</th>
<th>Patients (n)</th>
<th>Total Clinical Costs Mean (± SD)</th>
<th>Time Costs Mean (± SD)</th>
<th>Total Costs Mean (±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate loading</td>
<td>33</td>
<td>$3276.99 ± 500.19</td>
<td>$381.71 ± 303.69</td>
<td>$3658.7 ± 614.23</td>
</tr>
<tr>
<td>Conventional loading</td>
<td>40</td>
<td>$2836.79 ± 824.18</td>
<td>$342.42 ± 358.86</td>
<td>$3454.37 ± 657.81</td>
</tr>
<tr>
<td>p-value</td>
<td>0.0019</td>
<td>0.687</td>
<td>0.155</td>
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</table>

SD= standard deviation, Wilcoxon Rank Sums Test
Discussion:

During the first year of loading, twenty-six (74%) of the patients in the immediate loading group required addition of acrylic around the attachment housing to improve the denture seal. In the 1-year report on the same group of patients, Attard et al. (Attard, Laporte, Locker, & Zarb, 2006) assumed that the immediate protocol inadvertently weakened the mandibular prosthesis due to the recurrent tooth and denture fracture, which resulted in remakes of some prostheses. This assumption was confirmed further by our 3-year follow-up results. Six patients in the immediate loading group required fabrication of new mandibular implant-supported overdentures during the second and third years of follow-up. The main reason for this was that the mandibular prostheses were weakened by recurrent fracture. For those in the conventional loading group, however, none required a remake of the mandibular implant-supported overdenture during the first year of loading, and only four patients (9.5%) needed a reline of the mandibular prosthesis. These findings support the assumption that the frequent need for relines and remakes of the mandibular implant-supported overdentures encountered in the immediate loading group is directly related to treatment protocol and not to other factors. Therefore, it seems logical that in order for immediate loading protocols to become more cost-effective, some modification of actual intervention is needed to reduce overall costs of complication. Perhaps more time is needed for soft tissue healing to progress following initial placement of implants even with the immediate loading protocol. This could lead to a reduction in the overall need for denture relines, repairs, and replacement of dislodged bar clips.
Although the costs of complications appear to be significantly greater for patients treated using an immediate loading protocol (as assessed up to three years after loading), total difference in time costs between the two treatment groups was not statistically significant. This indicates that, even after three years of loading, maintenance cost issues were offset by the time gained with the immediate loading protocol.

This is the first study to carry out an economic analysis of immediate and conventional loading of two dental implants with mandibular overdentures. Therefore, a comparison of our results to others is not possible, as we have essentially described a novel paradigm for the assessment of treatment outcomes for patients receiving endosseous implant-supported prosthesis. There was no difference in the total cost of treatment for the two groups of patients up to three years following initial therapy. Hence, it is reasonable to suggest that immediate loading of two dental implants with a bar retained mandibular overdenture is comparable to the conventional protocol. This conclusion is based on biological parameters, patient based outcomes (e.g. patients’ satisfaction with their prostheses), as well as similar improvements in the quality of life outcomes. Thus, it can be stated that the immediate loading protocol is a biologically and economically desirable treatment option.
Chapter 5

Discussion and Conclusions
Discussion:

The successful replacement of missing or irreparably damaged natural teeth by osseointegrated dental implants has been a groundbreaking advance. The availability of this treatment option has broadened the scope of clinical dentistry, creating approaches for restoration of complex cases where functional rehabilitation was previously limited. It is generally agreed that the predictability and long-term success of this modality of treatment have been well documented, irrespective of whether endosseous dental implants are loaded with either removable or fixed prostheses. However as will be outlined below, this perception is not necessarily based on sound scientific evidence. More systematic investigations are still required.

In relation to the above, several core clinical questions remain unanswered. For example, it is not known what type of prosthesis should be placed onto endosseous implants to provide optimum function, aesthetics, reduced surgical morbidity, and optimization of time and cost of treatment. When reviewing the literature, one can appreciate the large variation in materials used, number of implants placed, and other elements of prosthesis fabrication and design.

One major goal of this dissertation was to comprehensively review original articles of outcomes of treatment with endosseous implant-supported prostheses and to systematically evaluate these reports thereby determining the highest level of evidence in the literature to answer a specific clinical question. This presupposes, of course, that systematic reviews can actually deliver this. Many perceived advantages of systematic reviews arise
from corresponding disadvantages of traditional (i.e. narrative) reviews normally plagued by subjectivity. This includes lack of thorough inclusion and exclusion criteria for selection of studies that could potentially lead to selection bias regarding reviewers’ choice of articles. Thereby supporting a preconceived biased viewpoint. Furthermore, most narrative reviews tend to count each study reviewed as equal in a straw poll in reaching a consensus. This does not take into account the wide variability regarding several aspects of research reporting including strengths or weaknesses of study design, absence or presence of statistical analyses, power calculation and a myriad of other factors. Therefore, conclusions reached using narrative reviews could be based on reports that might be flawed, or weakly designed. These leads to conclusions that could be equally flawed and unreliable. As alluded to in introductory chapters, systematic reviews, and in particular the Cochrane type have been designed to overcome problems described for narrative reviews so that conclusions reached are less biased, more meaningful, and reliable.

In the systematic review, the lack of homogeneity amongst even highly selected reports was glaring. Despite the systematic approach used here, the variability in the studies selected precluded further statistical analysis and therefore prevented us from making some definitive conclusions. Nonetheless, this review shed light on current status of research within the realm of implant dentistry. Essentially, it was found that there is inconsistency in reporting outcomes, and a paucity of strong scientific evidence to favor one prosthetic superstructure design. This review showed that there is a great need for well-designed and conducted clinical trials to investigate effectiveness and outcomes related to the entire spectrum of prosthetic protocols currently in use.
Implant-supported fixed prostheses used in completely edentulous patients were the first superstructures used when dental implants were first introduced to the scientific community. To date only three randomized controlled clinical trials have investigated the efficacy of different fixed prosthesis design. Moreover, one of these three studies (Jemt et al., 2002) compared laser-welded frameworks to cast ones. Considering that the fabrication of laser-welded frameworks has been discontinued, the conclusions drawn from the latter study are irrelevant.

The question of whether an implant-supported fixed prosthesis is superior to an overdenture for the rehabilitation of edentulous patients is arguably the most important clinical question to be answered. This is because on most occasions, more implants are placed to support a fixed prosthesis as compared to a removable overdenture (e.g. 5-6 implant for fixed vs. 2-4 implants for the overdenture). It stands to reason that the more implants required, the higher the probability of surgical morbidity. Furthermore it would be expected that for fixed prostheses, longer treatment time, and higher treatment costs would be necessary compared to what might be required for delivery of an implant-supported overdenture. Alternatively, overdentures supported by two implants in the mandible have been shown to cause continuous bone resorption in the posterior parts of the mandible and some signs of increased bone resorption in the maxilla, if the patient is wearing a maxillary complete denture (Gupta, Lechner, & Duckmanton, 1999; Lechner & Mammen, 1996; P. S. Wright et al., 2002). Unfortunately only two studies addressed this question, and definitive conclusions as to which type of implant-supported prosthesis might be more favorable could not be drawn (Palmqvist et al., 2004; P. S. Wright et al., 2002).
The surface of the TiUnite dental implant is moderately rough (1.0-2.0 µm), a degree of roughness that has been shown to provide the strongest biomechanical bond to the surrounding bone as compared to smooth (<1.0 µm) or even more rough surfaces (> 2.0 µm) (Albrektsson & Wennerberg, 2004). Furthermore, the novel titanium porous oxide surface of TiUnite implants has proven to have considerable osteoconductive potential thus promoting a high degree of implant osseointegration even in type IV bone of the posterior maxilla (Huang et al., 2005). Studies carried out in various animal models have reported favorable biomechanical and histomorphometric results comparing the TiUnite surface to other surfaces (Xiropaidis et al., 2005; Zechner et al., 2003). The goal of this study was to explore as comprehensively as possible the long-term clinical outcomes in edentulous patients treated with immediately and conventionally loaded TiUnite implant-supported mandibular overdentures in the context of both patient and clinician-based concerns. In comparing the two treatment modalities, similar rates of success were seen (> 98%). Similarly, a comparable success rate was observed when immediately and conventionally loaded TiUnite dental implants were compared (using mandibular fixed prostheses in the randomized controlled clinical trial). Therefore, excellent treatment outcomes can be expected using any of the treatment methods included in these studies. This is also evidenced by biological outcomes discussed below.

Using the overdenture model, it was found that the amount of 1-year peri-implant marginal bone loss was greater around conventionally loaded implants as compared to those loaded immediately (Attard et al., 2005). Alternatively, more bone loss was measured around immediately loaded implants that were used to support fixed prostheses as compared to bone loss observed about implants used to support conventionally loaded fixed prostheses.
This variation in the results might be explained in two ways. The overdenture study was a prospective study but related to a so-called historical control group. As explained by researchers who initiated this trial, the rationale for using a historical cohort was the group’s previous encouraging experience with patients treated with the conventional protocol. Furthermore, it is difficult to recruit an adequate number of edentulous patients for the study given certain time-constraints. Therefore a historical group was opted for, since clinical data were collected regularly over the years for patients treated in the clinic (Attard & Zarb, 2004; Attard et al., 2005). With respect to this control group, the majority were treated in the 1980’s (the overdenture ‘pioneer group’). Therefore this led to a “learning curve” factor, that included experimentation with bar and the overdentures designs, implant hardware, impression techniques and occlusal schemes. Any or all of these factors might have resulted in an increase in the magnitude of the challenge placed on the implant-bone interface and therefore subsequent greater bone loss, which in this case was higher as noted above. Another possibly confounding factor is the variation in design of the prosthesis supporting mechanism and load distribution between overdentures and fixed prostheses. In the implant-supported overdenture, the occlusal load is distributed as evenly as possible between the dental implants and edentulous ridge, while in the case of a fixed prosthesis the dental implants and the surrounding bone, but not the edentulous ridge bear most of the occlusal load. Therefore, in challenging those implants with an occlusal load while the bone is still going through healing an increase in bone loss as compared to the conventionally loaded implants might be expected.

In addition to purely clinical outcomes, this study focused on patient-based outcomes including satisfaction with treatment, and post-treatment improvements, or lack thereof in
quality of life. This represents the first such report concerning patient-based outcomes following treatment with immediate loading. Patients who received either mandibular implant-supported overdentures or fixed prostheses were significantly more satisfied with treatment outcome as compared to those who were treated with a conventional complete denture. Moreover, this high level of satisfaction was sustained for five years. These results compare favorably with those of others who reported that rehabilitating mandibular edentulous arches with implant-supported prostheses (either fixed or removable) leads to substantial improvements in the perceived patient-based outcomes, as compared to patients treated with conventional complete dentures.

Interestingly, as shown using the Denture Satisfaction Scale, in both clinical trials, the level of patient satisfaction with their maxillary conventional complete dentures increased after the fabrication of a new conventional denture as might be expected. However, this improvement was not as great as that observed in patients who received mandibular implant-supported prostheses (either fixed or overdenture). The 5-year satisfaction scores for the maxillary prostheses in the overdenture study were higher than at one year. Thus, although it is generally considered that maxillary complete dentures are stable and retentive, the differences reported here imply that this is not necessarily the case over the longer term and suggests that, even in the maxilla, implant supported prostheses provide longer term stability and comfort than conventional complete dentures.

The overdenture trial is the first clinical trial in the literature to carry out an economic analysis of immediately and conventionally loaded two dental implants with mandibular overdentures. The 1-year economic analysis showed that, due to higher maintenance costs,
the immediate protocol was not a cheaper alternative when compared to the conventional protocol (Attard, Laporte, Locker, & Zarb, 2006). However, after three years, the economic analysis revealed that there was no significant difference in the total cost of treatment when both groups were compared. This was attributed mainly to the dramatic decrease after the first year of treatment in the rate of complications in the immediate loading group. This led to an overall decrease in the total cost of maintenance of the prostheses. Although these favorable results do not negate the necessity for modifying the immediate loading protocol, they do indicate that the medium term costs for immediate loading of two dental implants with a bar-retained mandibular overdenture are comparable to the conventional protocol. This study also showed that calculating immediate or short-term costs might not reflect the longer-term costs incurred for any given treatment approach. This is because in some treatment modalities, treatment costs may be up front and could lead to the incorrect assumption that such a treatment is more expensive than others, at least over the shorter term. Therefore, long-term review is required before any valid conclusions can be drawn by cost-minimization issues pertaining to treatment.
Conclusions:

Within the limitations of the clinical trials in this dissertation the following conclusions can be stated:

1. The available scientific evidence is inconclusive with regard to the superiority of one of implant-supported prosthesis design. Consequently, in light of the findings of the systematic review, the clinical decision on the type of implant-supported prosthesis should be tailored to each clinical case in order to provide the patient with optimum clinical and psychosocial outcomes.

2. The parallel randomized controlled clinical trial on immediate loading of TiUnite dental implants with a mandibular fixed prosthesis over the 1-year observation period revealed that implant clinical outcomes were comparable to conventional loading.

3. Mandibular fixed prosthesis supported by four implants proved to be as successful as those supported by five or six implants. Therefore, given the advantages of reducing the number of dental implants on shortening treatment time, lowering the treatment costs for patients, and reducing potential of surgical morbidity, implant-supported mandibular fixed prosthesis on four implants should be considered as one of the alternative treatment modalities for rehabilitating edentulous patients.

4. The results of the randomized controlled clinical trial are the first to show that patients who underwent immediate loading of dental implants with mandibular fixed prosthesis protocol had a significant improvement in their satisfaction with treatment and quality of
life. That this improvement was maintained throughout the follow-up period underscores the effectiveness of this approach.

5. The long-term prospective study on immediate loading of TiUnite dental implants with a mandibular overdenture proved that implant outcomes were comparable to conventional loading protocol.

6. The results of the prospective study are the first to provide evidence that over the 3-year observation period, patient-mediated treatment outcomes suggest that immediate loading of dental implants with a mandibular overdenture equally addressed the patient’s concerns from both satisfaction with treatment and oral health-related quality of life perspectives.

7. The 3-year economic analysis of the overdenture study demonstrated that the total cost of treatment with immediate loading of dental implants with mandibular overdenture is similar to the conventional loading protocol. Therefore, it is safe to conclude that the immediate loading protocol is a reliable treatment option in terms of biological, clinical, economic, and patient-mediated outcomes.
Chapter 6

Null Hypotheses
In summary, the null hypotheses stated in the literature review section of this dissertation are addressed below:

**Chapter 2: Intervention for Replacing Missing Teeth: Effect of Type of Prosthesis on Treatment Outcomes-A Cochrane Systematic Review:**

**Null hypothesis: Treatment outcomes do not correlate with the design of implant-supported prostheses**

This null hypothesis was not rejected since there is no strong evidence that demonstrates that one type of prosthesis design is superior. However, it should be stressed that this might only mean that the available scientific evidence is not strong enough to prove or disapprove this. Consequently, the clinical decision of which implant-supported prosthesis to use for a particular patient should be case-specific.

**Chapter 3: A Randomized Controlled Clinical Trial of Edentulous Patients Treated with immediately Loaded Implant-Supported Mandibular Fixed Prostheses:**

**Null hypothesis 1: The TiUnite dental implant is not efficacious for immediate loading of fixed prostheses in the mandible**

The success rate of the immediately loaded TiUnite dental implants 1-year post-loading was observed to be comparable to the conventionally loaded ones. Thus our findings proved that four TiUnite dental implants can be loaded immediately and successfully with implant-supported fixed prostheses in the mandible and therefore this null hypothesis was rejected.

**Null hypothesis 2: There is no increase in the failure rates of prostheses and immediately loaded implants in comparison to implants placed with a delayed loading protocol**
This null hypothesis was not rejected. The prosthesis survival rate 1-year post-loading in the immediate and the control loading arms was the same (100%). No statistically significant difference in implant success rate was observed between the two study arms.

Null hypothesis 3: No improvement in the patient denture satisfaction scores and the oral-related quality of life outcomes will be observed in edentulous patients treated with an immediate loading protocol versus patients treated with the conventional loading protocol.

Rehabilitation of edentulous patients with immediately loaded implant-supported mandibular fixed prostheses resulted in a dramatic improvements in their satisfaction and oral health-related quality of life. Moreover, the magnitude of improvement in both satisfaction and quality of life in the immediate and the conventional loading protocols was comparable. This indicated that the immediate and delayed loading protocols addressed patient-based outcomes equally as well.
Chapter 3: Five-Year Clinical Results of Immediately Loaded Dental Implants Using Mandibular Overdentures:

Null hypothesis 1: There is no difference between immediately loaded TiUnite implants and Branemark implants (NobelBiocare®, Gotenberg, Sweden) that were loaded according to the conventional protocol.

Based on long-term results, this null hypothesis was not rejected. Comparable success rates of implants with both loading protocols were achieved, underscoring the potential usefulness of immediate loading.

Null hypothesis 2: There are no differences in the prosthodontic outcomes with immediate or conventional loading protocols.

Based on the long-term results, this null hypothesis was rejected. Although the rate of complications decreased significantly following the first year of loading, patients in the immediate loading group required more prosthodontic maintenance compared to the conventional loading group.

Null hypothesis 3: There are no improvements in denture satisfaction and oral health related quality of life outcomes with the immediate loading protocol.

This null hypothesis was rejected. A significant improvement in patients’ satisfaction with treatment as well as oral health related quality of life outcomes was observed and maintained throughout the long-term follow-up period.
Null hypothesis 4: In the edentulous patient treated with overdentures, the immediate loading protocol is not more expensive approach when compared to the conventional loading protocol.

Based on the medium-term results, this null hypothesis was not rejected. Although the costs of complications appear to be significantly greater for patients treated using the immediate loading protocol, the total difference in the cost of treatment for the two groups of patients was not statistically significant over the intermediate to longer term. Therefore, these favorable economic outcomes underscore the notion that immediate loading of two dental implants with a bar-retained mandibular overdenture is a reliable treatment option.
Bibliography:


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Statistic Canada. Employment income by occupation. Ottawa: Census of Canada, University of Toronto, data library service. Available at: http://www.chassutoronto.ca/datalib/cc96/dimen96.htm


Statistic Canada. (2002). Consumer price index. Ottawa: Statistics Canada,


Appendices
**Appendix 1:**

**Intervention for Replacing Missing Teeth: Effect of Type of Prosthesis on Treatment Outcomes**

**DATA EXTRACTION FORM**

| Authors:________________________________________ | Country: __________________________ |
| Study References_________________________________ | ____________________________ |

## 1. VERIFICATION/SELECTION OF STUDY ELIGIBILITY

**Randomized controlled trial:**
- Yes
- No
- Unclear

**Study design:**
- Parallel group
- Split mouth
- Cross-over
- Cluster

## Intervention Description

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<th>Different prostheses supported by root formed implants</th>
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</table>

## Outcome

<table>
<thead>
<tr>
<th>Psychological impact</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Patient satisfaction with treatment</td>
<td>Yes  No</td>
</tr>
<tr>
<td>Patient satisfaction with aesthetics</td>
<td>Yes  No</td>
</tr>
<tr>
<td>Patient satisfaction with function (chewing, dietary changes, speech)</td>
<td>Yes  No</td>
</tr>
<tr>
<td>Reported changes of social activity</td>
<td>Yes  No</td>
</tr>
<tr>
<td>Quality of life changes or health changes</td>
<td>Yes  No</td>
</tr>
<tr>
<td>Patient preference for prosthesis</td>
<td>Yes  No</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Longevity/survival</th>
<th>Description</th>
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<tbody>
<tr>
<td>Cumulative survival of prosthesis and implant</td>
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</tr>
<tr>
<td>Cumulative success of prosthesis and implant (with defined success criteria)</td>
<td>Yes  No</td>
</tr>
</tbody>
</table>

## Biological complications: Incidence and/or severity

| Surgical and post-operative complications | Yes  No |
| Pain | Yes  No |
| Neurological disturbances | Yes  No |
| Adverse changes (specify: e.g. alveolar bone loss) | Yes  No |

## Mechanical complications: Incidence and/or severity

| Adjustments/maintenance | Yes  No |
| Time to first adjustment | Yes  No |
| Prosthesis failure | Yes  No |
### Physiologic impact

<p>| | |</p>
<table>
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<tr>
<td>Prosthesis retention/mobility</td>
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<tr>
<td>Operator-evaluation of function: chewing [ ], dietary changes[ ], speech [ ]</td>
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### Economic impact, Direct, maintenance or indirect costs:

<p>| | |</p>
<table>
<thead>
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<th></th>
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</thead>
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<tr>
<td>Service utilization or resource use with or without link to outcomes</td>
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<tr>
<td>Clinician contact, including number of office and/or maintenance visits</td>
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<tr>
<td>Prosthesis/internal fixation device costs</td>
<td>Yes No</td>
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<td>Akm9 additional diagnostic investigations</td>
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IS THE STUDY ELIGIBLE?  Yes  No ________________________________

2. METHODOLOGICAL QUALITIES

Study design and conduct
Clinician/investigator blinded  Yes  No  Unclear
Patient blinded  Yes  No  Unclear
Outcome assessor blinded  Yes  No  Unclear

Randomization method:
A. Clearly adequate: (centralized and third party contact)
B. Unclear
C. Clearly inadequate: (transparent before assignment, e.g. coin toss, sequential randomization) -
D Not described

Allocation concealment method:
A. Adequate - Centralized randomization, sealed opaque envelopes
B. Unclear – Envelopes
C Inadequate - Transparent before assignment, unsealed envelopes
D Not used / not described

Was an a priori power calculation undertaken?
A. Not mentioned
B. Yes, but not confirmed by calculation
C. Yes, confirmed

Intention to treat analysis?  Yes  No

Risk of bias?  Low  Medium  High
3. INTERVENTION

<table>
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<td></td>
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Comments:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

4. PARTICIPANTS

Total Numbers: Eligible subjects ________ Subjects enrolled ___________

Informed Consent/Approved by Institutional Ethics Review Board: Yes No
Exclusion/Inclusion criteria clearly defined: Yes No
Were the groups comparable at entry for important prognostic factors? Yes No Not Stated

BASELINE CHARACTERISTICS (yes/no)

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<td></td>
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<tr>
<td>Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parafunctional signs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Xerostomia signs</td>
<td></td>
<td></td>
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</tbody>
</table>
### NUMBER COMPLETING AND DROPOUTS

<table>
<thead>
<tr>
<th></th>
<th>Treatment 1</th>
<th>Treatment 2</th>
<th>Treatment 3</th>
<th>Treatment 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start number</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss-to-follow-up</td>
<td></td>
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</tr>
<tr>
<td>Reasons</td>
<td></td>
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<tr>
<td>Final Number</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Is there a clear explanation of withdrawals and drop-outs in each treatment group?

*None  Yes  No*
## OUTCOMES - Length of Term

(Short Term: 0-2 y; Intermediate Term: 2-5y; Long Term: >10y)

<table>
<thead>
<tr>
<th>Domains and measures</th>
<th>Maximum Time point</th>
<th>Treatment 1</th>
<th>Treatment 2</th>
<th>Treatment 3</th>
<th>Treatment 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Note[n]</td>
<td>N* mean** (SD)</td>
<td>N* mean** (SD)</td>
<td>N* mean** (SD)</td>
<td>N* mean** (SD)</td>
</tr>
<tr>
<td><strong>Psychological impact</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient satisfaction with treatment</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction with aesthetics</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient satisfaction with function - chewing</td>
<td>[ ], dietary changes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reported changes of social activity</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality of life/health measure: Instrument:</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient preference for prosthesis</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Longevity/survival</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cumulative survival of prosthesis and implant</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cumulative success of prosthesis and implant (with defined success criteria)</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Biological complications</strong></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Surgical and post-operative complications</td>
<td>[ ]</td>
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<td></td>
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<tr>
<td>Pain</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurological disturbances</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse changes (specify: e.g. Alveolar bone loss)</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse biological consequences of prosthesis failure</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mechanical complications</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Adjustments/maintenance</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to first adjustment</td>
<td>[ ]</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Prosthesis failure</td>
<td>[ ]</td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Physiologic impact</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prosthesis retention/mobility</td>
<td>[ ]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Operator-evaluation of function - chewing [ ], dietary changes[ ], speech [ ]

**Economic impact, Direct, maintenance or indirect costs:**

<table>
<thead>
<tr>
<th>Service utilization or resource use</th>
<th>[ ]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Link between resource use and outcomes</td>
<td>[ ]</td>
</tr>
<tr>
<td>Clinician contacts, # office and/or maintenance visits</td>
<td>[ ]</td>
</tr>
<tr>
<td>Prosthesis/internal fixation device (costs)</td>
<td></td>
</tr>
<tr>
<td>Additional diagnostic investigations</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

*Dichotomized categories explanation:

_________________________________________________________________________________________

_________________________________________________________________________________________

_________________________________________________________________________________________

** Scale explanation

_________________________________________________________________________________________

_________________________________________________________________________________________

_________________________________________________________________________________________
Appendix 2:

The Denture Satisfaction Questionnaire

NAME ___________________________ CHART NUMBER ____________________

PLEASE MARK ONE OF THE 5 ANSWERS FOR EACH QUESTION. THANK YOU FOR FILLING IN THE QUESTIONNAIRE!

1. How satisfied are you with your UPPER denture in overall?
   - TOTALLY SATISFIED
   - VERY SATISFIED
   - REASONABLY SATISFIED
   - NOT VERY SATISFIED
   - NOT AT ALL SATISFIED

2. How satisfied are you with your LOWER denture in overall?
   - TOTALLY SATISFIED
   - VERY SATISFIED
   - REASONABLY SATISFIED
   - NOT VERY SATISFIED
   - NOT AT ALL SATISFIED

3. How satisfied are you with the retention of your UPPER denture?
   - TOTALLY SATISFIED
   - VERY SATISFIED
   - REASONABLY SATISFIED
   - NOT VERY SATISFIED
   - NOT AT ALL SATISFIED

4. How satisfied are you with the retention of your LOWER denture?
   - TOTALLY SATISFIED
   - VERY SATISFIED
   - REASONABLY SATISFIED
   - NOT VERY SATISFIED
   - NOT AT ALL SATISFIED

5. How satisfied are you with the stability of your UPPER denture?
   - TOTALLY SATISFIED
   - VERY SATISFIED
   - REASONABLY SATISFIED
   - NOT VERY SATISFIED
   - NOT AT ALL SATISFIED

6. How satisfied are you with the stability of your LOWER denture?
   - TOTALLY SATISFIED
   - VERY SATISFIED
   - REASONABLY SATISFIED
   - NOT VERY SATISFIED
   - NOT AT ALL SATISFIED
7. **How satisfied are you with the comfort of your UPPER denture?**

   - [ ] TOTALLY SATISFIED
   - [ ] VERY SATISFIED
   - [ ] REASONABLY SATISFIED
   - [ ] NOT VERY SATISFIED
   - [ ] NOT AT ALL SATISFIED

8. **How satisfied are you with the comfort of your LOWER denture?**

   - [ ] TOTALLY SATISFIED
   - [ ] VERY SATISFIED
   - [ ] REASONABLY SATISFIED
   - [ ] NOT VERY SATISFIED
   - [ ] NOT AT ALL SATISFIED

9. **How satisfied are you with the chewing efficiency of your dentures?**

   - [ ] TOTALLY SATISFIED
   - [ ] VERY SATISFIED
   - [ ] REASONABLY SATISFIED
   - [ ] NOT VERY SATISFIED
   - [ ] NOT AT ALL SATISFIED

10. **How satisfied are you with the appearance/aesthetics of your UPPER denture?**

    - [ ] TOTALLY SATISFIED
    - [ ] VERY SATISFIED
    - [ ] REASONABLY SATISFIED
    - [ ] NOT VERY SATISFIED
    - [ ] NOT AT ALL SATISFIED

11. **How satisfied are you with the appearance/aesthetics of your LOWER denture?**

    - [ ] TOTALLY SATISFIED
    - [ ] VERY SATISFIED
    - [ ] REASONABLY SATISFIED
    - [ ] NOT VERY SATISFIED
    - [ ] NOT AT ALL SATISFIED

12. **How satisfied are you with the ability to speak with your dentures?**

    - [ ] TOTALLY SATISFIED
    - [ ] VERY SATISFIED
    - [ ] REASONABLY SATISFIED
    - [ ] NOT VERY SATISFIED
    - [ ] NOT AT ALL SATISFIED
Appendix 3:
The Oral Health Impact Profile Questionnaire-20

NAME _________________________ CHART NUMBER _________________________

PLEASE CIRCLE ONE OF THE 6 ANSWERS FOR EACH QUESTION

1. Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?
   NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME

2. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?
   NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME

3. Have you had food catching in your teeth or dentures?
   NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME

4. Have you felt that your dentures have not been fitting properly?
   NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME

5. Have you had painful aching in your mouth?
   NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME
PLEASE CIRCLE ONE OF THE 6 ANSWERS FOR EACH QUESTION

6. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?

NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME

7. Have you had sore spots in your mouth?

NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME

8. Have you had uncomfortable dentures?

NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME

9. Have you been worried by dental problems?

NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME

10. Have you been self conscious because of your teeth, mouth or dentures?

NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME

11. Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?

NEVER  RARELY  OCCASIONALLY  OFTEN  VERY OFTEN  ALL OF THE TIME
PLEASE CIRCLE ONE OF THE 6 ANSWERS FOR EACH QUESTION

12. Have you been unable to eat with your dentures because of problems with them?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>RARELY</th>
<th>OCCASIONALLY</th>
<th>OFTEN</th>
<th>VERY OFTEN</th>
<th>ALL OF THE TIME</th>
</tr>
</thead>
</table>

13. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>RARELY</th>
<th>OCCASIONALLY</th>
<th>OFTEN</th>
<th>VERY OFTEN</th>
<th>ALL OF THE TIME</th>
</tr>
</thead>
</table>

14. Have you been upset because of problems with your teeth, mouth or dentures?

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<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>RARELY</th>
<th>OCCASIONALLY</th>
<th>OFTEN</th>
<th>VERY OFTEN</th>
<th>ALL OF THE TIME</th>
</tr>
</thead>
</table>

15. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>RARELY</th>
<th>OCCASIONALLY</th>
<th>OFTEN</th>
<th>VERY OFTEN</th>
<th>ALL OF THE TIME</th>
</tr>
</thead>
</table>

16. Have you avoided going out because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>RARELY</th>
<th>OCCASIONALLY</th>
<th>OFTEN</th>
<th>VERY OFTEN</th>
<th>ALL OF THE TIME</th>
</tr>
</thead>
</table>

17. Have you been less tolerant of your spouse or family because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th></th>
<th>NEVER</th>
<th>RARELY</th>
<th>OCCASIONALLY</th>
<th>OFTEN</th>
<th>VERY OFTEN</th>
<th>ALL OF THE TIME</th>
</tr>
</thead>
</table>
PLEASE CIRCLE ONE OF THE 6 ANSWERS FOR EACH QUESTION

18. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?
NEVER RARELY OCCASIONALLY OFTEN VERY OFTEN ALL OF THE TIME

19. Have you been unable to enjoy other people’s company as much because of problems with your teeth, mouth or dentures?
NEVER RARELY OCCASIONALLY OFTEN VERY OFTEN ALL OF THE TIME

20. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?
NEVER RARELY OCCASIONALLY OFTEN VERY OFTEN ALL OF THE TIME

THANK YOU FOR FILLING IN THE QUESTIONNAIRE!
Appendix 4:

UNIVERSITY OF TORONTO
Office of the Vice-President, Research and Associate Provost
Ethics Review Office

PROTOCOL REFERENCE #16993  June 15, 2006

Dr. A. Jokstad  Dr. S. Al-Fadda
Prosthodontics  Prosthodontics
Faculty of Dentistry  Faculty of Dentistry
124 Edward Street  124 Edward Street
University of Toronto  University of Toronto
Toronto, ON M5G 1G6  Toronto, ON M5G 1G6

Dear Dr. Jokstad & Dr. Al-Fadda,

Re: Research protocol entitled, “Clinical Trials of Edentulous Patients Treated Immediately Loaded Implant-Supported Mandibular Prostheses” (Response & revisions received June 5, 2006) by Dr. A. Jokstad (supervisor), Dr. S. Al-Fadda (PhD candidate)

ETHICS APPROVAL

Original Approval Date: June 15, 2006
Expiry Date: June 14, 2007

We are writing to advise you that the Health Sciences Research Ethics Board has granted approval to the above-named research study, for a period of one year. Ongoing projects must be renewed prior to the expiry date. Your ethics protocol approval is valid for a period of 1 year. It is the responsibility of the investigator to maintain a valid approval throughout the duration of the research activity, and to report to the Ethics Review Office of its completion. Annual Renewal of Ethics Approval forms and Study Completion Report forms can be found at http://www.research.utoronto.ca/ethics_ch_forms.html

Consequences of expired ethics protocol approvals may include the freezing of funds and/or refusal to review new ethics protocol submissions.

The following documents (revised June 6, 2006) have been approved for use in this study: Revised protocol, Health Questionnaire (App 1), Quality of Life and Denture Satisfaction Questionnaires (App 2), Patient Information Package (App 4), and Recruitment Ad. All documents for research participants are to be printed on U of T Faculty of Dentistry letterhead. Participants should receive a copy of their consent form. We acknowledge receipt of the Health Canada “No Objection Letter”, the Letter of Scientific Merit from the Assoc. Dean of Graduate/Postgraduate Studies of the Faculty of Dentistry, and the Support Agreement between U of T and Novel Biocare AB.

During the course of the research, any significant deviations from the approved protocol (that is, any deviation which would lead to an increase in risk or a decrease in benefit to participants) and/or any unanticipated developments within the research should be brought to the attention of the Ethics Review Unit.

Best wishes for the successful completion of your project.

Yours sincerely,

(Mariana Richardson)

Mariana Richardson
Ethics Review Coordinator

cc: Mr. W. Maurice, Grants Officer, Health Sciences

Simcoe Hall 27 King's College Circle Toronto Ontario M5S 1A1
Telephone 416/978-3165  Fax 416/946-5768  email: ethics.review@utoronto.ca
Appendix 5:

University of Toronto
Faculty of Dentistry

An Investigation of Immediate Loading of Dental Implants with Fixed Prostheses

CONSENT FORM

I acknowledge that the research procedures described on the attached form, and of which I have a copy, have been explained to me and that any questions that I have asked have been answered to my satisfaction.

I have been informed of the alternatives to participation in this study. The possible risks and discomforts have been explained to me. I know that I may ask now, or in the future, any questions I have about the study or the research procedures.

I have been assured that records relating to me will be kept confidential and that no information will be released or printed that would disclose my personal identity without my permission.

I understand that I may withdraw from the study at any time without prejudice and will be offered an alternative treatment related to my dental condition. I further understand that if the study is not completed the level of the dental care will not be affected.

I hereby consent to participate.

Name: ___________________________ Date: ___________________________

Signature: ___________________________
Witness: ___________________________ Date: ___________________________

The person who may be contacted about this research is:
Dr. Sara Al-Fadda

Phone number: (416)979-4900, EXT: 4423, 4618