

# Insertion Torque of Mini Dental Implants and their Failure Risk after Immediate Loading

Torque de Inserción de Mini Implantes Dentales y su Riesgo de Fracaso cuando son Cargados Inmediatamente

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**ABSTRACT:** A minimum insertion torque has been suggested for immediate function of regular diameter implants. Even when there is a growing tendency to use Mini Dental Implants (MDIs) for immediate function of dentures, there is no clinical data concerning MDIs insertion torque, nor its influence on implant failure. The aim of this prospective study was to assess the insertion torque of immediate loaded MDIs in edentulous patients and its association with risk failure. Ninety MDIs were placed in the anterior mandible of 45 edentulous patients, two per patient. The insertion torque was recorded with an electronic device and failures were documented during two years follow-up. All implants were immediately loaded with overdentures, using ball (44/90) or bar (46/90) attachments. A Kaplan–Meier survival probability estimator and a fitted multiple Cox regression model were performed to establish the influence of insertion torque and other clinical parameters on implant risk failure. The average insertion torque of 90 MDIs was  $12.5 \pm 7.8$  Ncm. A cumulative survival rate of 94.2% (5/90) was found by means of the Kaplan-Meier estimation. The Cox proportional-hazards regression model showed no association between insertion torque and MDIs failure. MDIs have much lower insertion torque than average conventional implants. The insertion torque of MDIs immediately loaded with mandibular dentures, seems not to be a risk factor associated to failure, at two years follow-up.

**KEY WORDS:** mini dental implant, insertion torque, denture, overlay, mini implant failure, jaw, edentulous.

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## INTRODUCTION

Mini dental implants (MDIs) have been reported as an alternative treatment for patients with totally edentulous mandibles (Christensen, 2006; Bulard & Vance, 2005; Shatkin *et al.*, 2007; Siddiqui *et al.*, 2006). Advantages of this procedure include implant placement in horizontally narrow sites, minimally invasive surgery and the possibility to load the implants immediately (Cho *et al.*, 2007; Velasco Ortega *et al.*, 2004; LaBarre *et al.*, 2008; Preoteasa *et al.* 2010). MDIs are one-piece implant designed to be loaded immediately after insertion (Griffitts *et al.*, 2005).

Implant primary stability has been considered to be one of the key factors for immediate loading

(Esposito *et al.*, 2007) and several studies have validated the insertion torque for conventional implants as an objective measure of primary stability (Albrektsson *et al.*, 1981; Cehreli *et al.*, 2009). A minimum insertion torque of 32 to 35 Ncm has been suggested as the requirement for immediate implant function or loading (Uribe *et al.*, 2005; Horiuchi *et al.*, 2000; Misch *et al.*, 2004); however, there is no data in the literature regarding the minimal insertion torque required for MDIs, nor the influence of primary stability on the prognosis of this treatment.

The surface area of an MDI is about 1/4 of a standard diameter implant (Flanagan & Mascolo,

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2010), resulting in less mechanical anchor. This was evaluated in recent *in vitro* tests in which torque values for MDIs were far below the minimal standards required for the immediate loading of conventional implants (Dilek *et al.*, 2008).

The purpose of this study was to assess the insertion torque values of MDIs and their associations with implant failure after immediate loading.

## MATERIAL AND METHOD

**Patients and treatment.** This study is a part of a two-year, single-center, randomized clinical trial (Jofre *et al.*, 2010a, 2010b) that evaluated the clinical and biomechanical behavior of overdentures using two retention systems. All participants received oral and written information about the trial prior to signing a written informed consent to participate. The study protocol was approved by the Ethics Committee of the University of Concepcion and the Chilean "National Commission on Scientific and Technological Research".

Totally edentulous patients suffering persistent retention problems with their overdentures were recruited at a public health center in Concepcion, Chile. The trial included male and female edentulous patients between 45 and 90 years old with no medical condition contraindicating implant surgery and no TMD (Temporomandibular Disorder). Patients with an uncontrolled systemic disease (e.g. hypertension, diabetes), those with diagnosis of severe osteoporosis and/or taking biphosphonates, patients with mental disorders, and those receiving radiotherapy in the 18 months before the trial were excluded.

**Prosthetic procedure.** All dentures were made with anatomical teeth (Marche Ltda., Santiago, Chile). A prosthodontist re-established the vertical dimension of all participants. Furthermore, the extension and prosthetic fit was improved at the maxillary and mandibular prostheses relining with a low-exothermic acrylic resin (Tokuyama, J. Morita Corp., Tokyo, Japan). Dynamic occlusion was checked by using articulating paper to confirm a balanced bilateral occlusal scheme.

**Surgical phase.** In all patients panoramic X-rays (Auto III ECM Asahi, Roegten ind CO: Ltda. Japan) were taken and software for cephalometrics (Radiocef 2.0 – Radiomemory, Belo Horizonte, MG, Brazil) were used

to evaluate the bone height available in the mandible. Mini implants of 15 mm length were necessary for the entire sample.

Each patient received a prophylactic antibiotic (amoxicillin) one hour prior to (2 g) and six hours after surgery (500 mg), plus a non-steroidal anti-inflammatory Ibuprofen 600 mg one hour prior to and 400 mg orally every 8 hours for 2 days after surgery (Friberg, 1999; Naert *et al.*, 1998). A total of 90 MDIs (1.8 x 15 mm) (Sendax® MDI, IMTEC, Ardmore, OK USA) sandblasted and acid-etched surfaces were inserted in the anterior mandibular zone of selected participants (two per patient) using a drilling device that allowed measuring cutting resistance (Osseocare®, DEC 600, Nobel Biocare AB, Göteborg, Sweden).

Following instructions of the manufacturer, only one drill of 1.1 mm diameter was used for routine bone preparation. The perforation depth was always 7 mm, near half of the implant length. Implants of 1.8 mm diameter were then totally inserted using their self-tapping properties. To control an accurate insertion of the implant into the jaw bone by performing a flapless procedure, a standard surgical guide was used (US patent N° 7682151 B2). The standard guide also allowed the use of a prefabricated bar, which was applied in twenty-three patients (46 of 90 implants). The rest of the patients were treated using ball attachment (44 out of 90 implants).

After insertion, all implants were immediately loaded fitting the patient's denture and fixing a clip or o'ring attachment by using acrylic resin (Alike; GC America, Alsip, IL).

The dynamic occlusion was evaluated by using articulating paper and a balanced bilateral occlusal scheme with stable dental contacts was confirmed. The patients were instructed in appropriate oral hygiene techniques and post-operative care.

**Assessment.** The primary outcome was to assess the MDIs insertion torque values and their associations with risk of implant failure.

The secondary outcome was the association between the risk of implant failure with other clinical factors (e.g keratinized tissue, index plaque, attachment system and bone loss).

The following clinical measures were recorded:

**Insertion torque.** The average insertion torque from three zones (crestal, middle, and apical) was obtained automatically by means of an electronic device (Osseocare®, DEC 600, Nobel Biocare AB, Göteborg, Sweden) (Friberg).

For the statistical analysis, only the apical zone was used, as final insertion torque.

**Implant failure.** The criterion of Naert and Chiapasco (Naert *et al.*; Chiapasco & Gatti, 2003) was used to assess MDI failures. This criterion is based on the classical Albrektsson and Zarb criterion (Albrektsson *et al.*, 1986) but adapted for implant overdentures.

Implant failure was defined as removal of the implant due to any of the following signs and symptoms during the evaluation:

- 1) The implant showed signs or symptoms, such as pain or infection.
- 2) Peri-implant radiolucency evaluated on panoramic radiographs.
- 3) The individual implant showed signs of mobility at clinical assessment, which normally led to implant removal.

### Clinical Parameters

**Bone loss at 2 years follow-up.** Standardized retroalveolar radiographs of each mini-implant were taken using a long-cone technique with a device that allowed a reproducible unidirectional focus (Jofre *et al.*, 2010a, 2010b).

**Keratinized tissue.** The width of the keratinized gingiva was measured by means of a periodontal probe, painting the gingiva and alveolar mucosa with Schiller iodine solution (5% iodine and 10% potassium iodide). The keratinized tissue remains unstained because this tissue is glycogen-free (Maurer *et al.*, 2000).

**Plaque index.** The bacterial plaque was evaluated according to the modified Plaque Index of Mombelli (Mombelli *et al.*, 1987). Tartar was removed using a plastic curette when necessary (Rutar *et al.*, 2001). The highest value recorded from four sites around each implant (mesiobuccal, mesiolingual, distobuccal, and distolingual) was considered for the statistical analysis. Plaque Index (PI) was dichotomized considering from 0 to 2 as “low level” and 3 as “high level”.

**Prosthetic attachment system.** Two attachment systems were used in this study: 1) ball system was used in 22 patients, 44 single-standing ball-type MDIs 2) bar system was used in 43 patients, 46 square-headed MDIs splinted with a 2 mm diameter pre-fabricated round bar.

**Statistical analysis.** Data was analyzed using SPSS version 15.0 (SPSS Inc. Chicago, IL, USA). All mini implants were pooled for statistical analysis. Descriptive statistics (mean and standard deviation) of the insertion torque were calculated at the level of the implant (insertion torque value was calculated for each mini implant).

Using R Statistical Software Version: 2.15.0, a Kaplan–Meier estimator was used to obtain the survival rate of MDIs survival at two-year period. The Cox proportional hazards regression model was performed to establish the influence of insertion torque and other clinical parameters of implant risk failure. P values less than 0.05 were considered statistically significant.

## RESULTS

Demographic and morbidities data of the sample are shown in Table I. The average insertion torque of 90 MDIs was  $12.5 \pm 7.8$  N/cm (Min: 3.0 – Max: 23.7) and is shown in Figure 1.

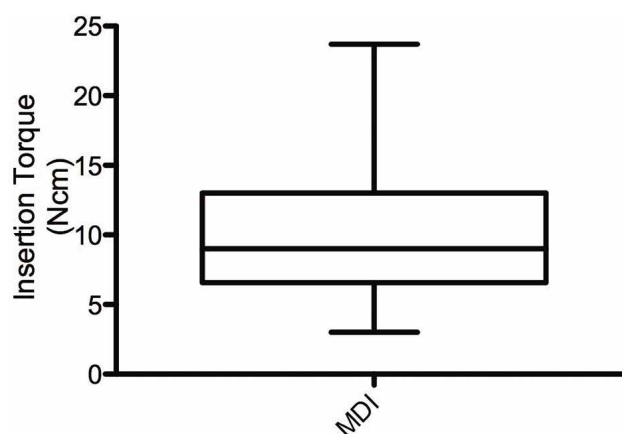


Fig. 1. Insertion Torque distribution in MDIs samples (n=90).

Insertion torque distribution of failing MDIs compared with the successful ones, are shown in Figure 2.

After two years of follow-up, five MDIs failed in 4 patients (5/90 MDIs). Kaplan and Meier analysis revealed a survival rate of 94.2% (Fig. 3).

association between the studied parameters and the probability of implant failure. Table III, shows the 95% confidence interval for the hazard ratio and p-values.

The recorded clinical parameters of the failed implants are described in Table II. The multivariate Cox regression model was fitted for analysis of potential

The results showed no association between studied clinical variables, including insertion torque and risk of implant failure.

Table I. Baseline patient characteristics.

	Group-ball	Group-bar	Difference between groups
Sex (F/M)	13/9	14/9	>0.999*
Age (years)	69 ± 8.7	73 ± 9.6	0.106*
Morbid conditions			
<i>Diabetes</i>	2/22	3/23	> 0.999*
<i>Osteoporosis</i>	1/22	0/23	0.489*
<i>Smoking</i>	1/22	1/23	> 0.999*

\*= difference not statistically significant (Fisher's exact test P>0.05).

Table II. Clinical parameters at the time of MDI failure.

Implant	Failure Time (Month)	Attachment System	Keratinized Tissue (mm)	Plaque Index	Bone Loss (mm)	Insertion Torque (Ncm)
1	6	Ball	5	2	1.13	7
2	6.5	Ball	4.5	2	1.13	13
3	10	Ball	2	2	2	10.3
4	10	Bar	4	3	1.75	13
5	12	Ball	4	0	1.38	10.3

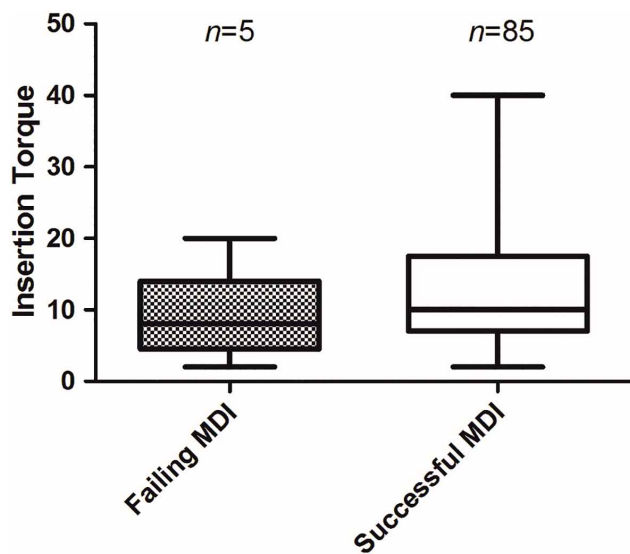


Fig. 2. Boxplot showing the insertion torque value distribution of failing and successful mini implants (MDIs).

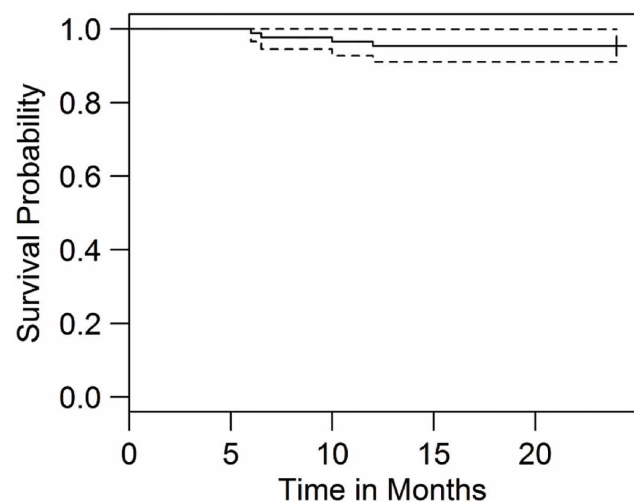


Fig. 3. Kaplan-Meier survival plot for MDIs failures at two years follow-up (95% confidence interval).

Table III. Cox regression analysis of the different variables and the probability of implant failure (n=86).

Clinical Variables	Hazard ratio	CI (95%)		P-Value
		Lower	Upper	
Insertion torque	1.11	0.90	1.37	0.34
Attachment system	13.11	0.50	346.65	0.12
Bone loss	1.00	0.48	2.11	0.98
Keratinized Tissue	0.95	0.60	1.49	0.82
Plaque Index	7.16	0.23	226.19	0.26

## DISCUSSION

Studies of up to 3 years of follow-up have shown that MDIs retaining overdentures might be a successful treatment option for overdentures (Jofre *et al.*, 2010a, 2010b; Scepanovic *et al.*, 2012; Elsyad *et al.*, 2011; Morneburg & Pröschel, 2008; Cho *et al.*).

The MDIs were designed for immediate loading (Zahran *et al.*, 2013; Sendax 1996; Nazarian 2005) despite possible disadvantages due to their narrow diameter (1.8 mm), which results in less implant-bone contact than occurs with the wider diameter implants.

Immediately after insertion, anchorage is achieved purely mechanically, arising from a combination of the bone's displacement and compression; this is defined as primary stability (Florvaag *et al.*, 2010; Elias *et al.*, 2012). Primary stability is determined by the bone-implant stiffness and depends on bone quality, implant geometric design, and surgical technique (Sennerby & Meredith, 2008). In our trial, implant geometry, diameter, length and also surgical technique were standardized.

Studies have validated the insertion torque of conventional implants as an objective measure of primary stability (Cehreli *et al.*; Albrektsson *et al.*, 1981) and a range of 32 to 50 Ncm has been proposed as the minimum insertion torque necessary for immediate implant loading (Uribe *et al.*; Raghoobar *et al.*, 2003; Lekholm, 2003).

An *in vitro* study of bovine femoral bone (Dilek *et al.*) found a range of insertion torque for mini implants from 5 to 35 Ncm, which is much lower than the minimum required for conventional implants. The study also reported that torque values over 35 Ncm could lead to a fracture of the mini implant body.

In the present study, the insertion torque was measured at the crest, middle and apical of the mini

implant during insertion, as described by Friberg. However, the apical insertion torque (final value obtained) was utilized for this analysis, since this value is commonly used as clinical indicator of primary stability for immediate loading.

The torque values obtained for MDIs in mandibles of edentulous patients ranged from 3 to 23.7 Ncm, similar to the range found by Dilek *et al.* However, implant survival was similar to the reported data for conventional implants (Sohrabi *et al.*, 2012; Cooper, 2012).

Even when the diameter of these implants are narrower with low resistance to the insertion, the implant length, which in this study was 15 mm, gives a final mechanical stiffness that could provide enough stability to receive immediate loading (Dilek *et al.*).

For the first time, this work shows clinical data regarding insertion torque values obtained from MDIs placed in edentulous mandibles. These results suggest that for MDIs, relatively low insertion torque compared to the generally accepted norm would seem to be sufficient to immediate loading of mandibular overdentures.

The ball attachment of MDIs showed 13.1 times more probability to fail than bar system. This trend could be explained by the improvement of biomechanical and clinical behavior, when splinting MDIs, allowing a better load distribution (Jofre *et al.*, 2010b).

Also high plaque index values showed a risk of implant failure 7.16 times higher than implant with low plaque index.

Even when these trends were found, they did not reach the conventional levels of significance. This is probably due to the lower incidence of implant failure.

According to the results, it was concluded that MDIs have much lower insertion torque than average conventional implants. The insertion torque of MDIs, immediately loaded with mandibular dentures, seems not to be a risk factor associated to failure at two years follow-up.

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**RESUMEN:** Un mínimo torque de inserción ha sido sugerido para realizar carga inmediata de implantes de diámetro regular. Aún cuando existe una tendencia creciente a utilizar Mini Implantes Dentales (MID) para la función inmediata de las prótesis totales, no hay datos clínicos relativos a los valores de torque de inserción de estos, ni tampoco de su influencia en el fracaso del implante. El objetivo de este estudio prospectivo fue evaluar el torque de inserción de mini implantes dentales con carga inmediata en pacientes desdentados y su asociación con el riesgo de fracaso. Noventa MIDs fueron colocados en la mandíbula anterior de 45 pacientes desdentados, dos por paciente. El torque de inserción fue obtenido con un dispositivo electrónico y los fracasos fueron documentadas a dos años de seguimiento. Todos los implantes fueron cargados inmediatamente con sobredentaduras, usando un sistema de retención de bola (44/90) o barra (46/90). Se utilizó el estimador de probabilidad de supervivencia de Kaplan-Meier y el modelo riesgos proporcionales de Cox ajustado para establecer la influencia de torque de inserción y otros parámetros clínicos sobre el riesgo de fracaso del implante. El promedio de torque de inserción de 90 MIDs fue  $12,5 \pm 7,8$  Ncm. Los MIDs mostraron a través de la estimación de Kaplan-Meier, una tasa de supervivencia acumulada de 94,2% (5/90). El modelo de riesgos proporcionales de Cox reveló que no existe asociación entre el valor de torque de inserción y el fracaso MIDs. MIDs tienen un valor de torque de inserción mucho más bajo que los implantes convencionales. El torque de inserción de MIDs cargados inmediatamente con prótesis mandibulares, no parece ser un factor de riesgo asociado al fracaso, a dos años de seguimiento.

**PALABRAS CLAVE:** mini implantes dentales, torque de inserción, sobredentadura, fracaso de mini implante, edéntulo mandibular.

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