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The effect of maximum bite force on marginal bone loss of mini-implants supporting a mandibular overdenture: a randomized controlled trial

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Key words: marginal bone loss, maximum bite force, mini-implants, overdentures

Abstract

Objectives: To evaluate the effect of maximum bite force (mBF) on marginal bone loss (MBL) around mini-implants in edentulous patients wearing mandibular overdentures with two retention systems: ball and bar.

Material and methods: Forty-five totally edentulous patients were selected from a public health center. All of them received two mini-implants (1.8 × 15 mm; Sendax®) in the anterior mandible using a minimally invasive technique. A single randomization was performed to allocate the patients in two groups. Group I ($n=22$) received two single ball-type mini-implants and Group II ($n=23$) received two mini-implants splinted with a prefabricated bar. The mBF was recorded using a press-sensitive sheet Dental Prescale® (Fuji) and MBL using standardized radiographs of each mini-implant at the baseline and 5, 7, 10, and 15 months after surgery; the values were compared between groups.

Results: Two members of Group I failed to complete the study, decreasing the number of participants to 20. There was no relationship between the mBF and the MBL of the mini-implants (Spearman's ρ $r_s=0.147$; $P=0.378$). At the 15-month follow-up, the average mBF for Group I (ball) was 247.53 ± 132.91 N and that of Group II (bar) only 203.23 ± 76.85 N (Mann–Whitney test; $P=0.586$). The MBL values were also higher for Group I (1.40 ± 1.02 mm) than Group II (0.84 ± 0.66 mm) during the entire 15-month follow-up period (Mann–Whitney test; $P=0.077$).

Conclusions: No relationship was found between mBF and MBL for patients wearing overdentures retained on mini-implants using bar or ball attachment systems.

Patients treated with implant overdentures have shown higher levels of satisfaction than patients wearing conventional dentures (Cune et al. 1994; Meijer et al. 2001; Stellingsma et al. 2003). Overwhelming evidence indicates that a two-implant overdenture should become the first choice for standard treatment of edentulous mandibles (Adell et al. 1981; Van Steenberghe et al. 1987; Feine et al. 2002).

The use of mini-implants has been suggested in order to reduce trauma for elderly patients when the use of standard-sized implants (>3 mm in diameter) would require bone reshaping or grafting (Flanagan 2006; Siddiqui et al. 2006; Christensen 2008). Advantages of this procedure include implant placement in narrow sites, minimally invasive surgery, and immediate loading of the implants (Velasco Ortega E 2004; Christensen 2006; Cho et al. 2007; LaBarre et al. 2008). Clinical reports have showed that mini-implant success rates for retaining mandibular dentures are good (Froum et al. 1998; Bulard 2001; Bulard & Vance 2005; Griffitts et al. 2005; Shatkin et al. 2007). However, randomized clinical trials supporting (or even rejecting) the long-term use of small diameter (1.8 mm) implants is lacking in the literature (Christensen 2006).

Date:
Accepted 2 August 2009

To cite this article:
Jofré J, Hamada T, Nishimura M, Klattenhoff C. The effect of maximum bite force on marginal bone loss of mini-implants supporting a mandibular overdenture: a randomized controlled trial.
Clin. Oral Impl. Res. **21**, 2010; 243–249.
doi: 10.1111/j.1600-0501.2009.01834.x

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Prospective studies have shown the positive effect of conventional implant therapy on maximum bite force (mBF) (Feine et al. 1994; Fontijn-Tekamp; et al. 1998; Tang et al. 1999; Bakke et al. 2002; van Kampen et al. 2002). However, bones carrying mechanical loads adapt their strength to the load applied by bone modeling/remodeling. The response to increased mechanical stress beyond a certain threshold produces fatigue micro-damage resulting in bone resorption (Isidor 2006). Mathematical finite element analyses of narrow implants have shown high levels of risk due to stress on the bone, suggesting that they cannot be used as definitive, under masticatory loads (Petrie & Williams 2005).

An implant can be considered to be definitive if the bone around it remains stable after receiving a physiological load. With conventional implants, the average bone loss in the first year is 1.0 mm. These arguments have not been evaluated for small-diameter (mini) implants (<3 mm).

The aim of this study is to evaluate clinically whether the level of maximal bite force (mBF) affects marginal bone loss (MBL) around immediately loaded mini-implants retaining overdentures.

Fig. 1. Attachment systems: ball (left) and bar (right).

Materials and methods

Forty-five edentulous patients were selected at a public health center in Concepcion, Chile. All participants received oral and written information about the trial before signing a written informed consent to participate. The study protocol was approved by a local ethical review board to ensure the protection of the participants.

Patient population

Participants were recruited from December 2004 to July 2005. The trial included edentulous patients suffering persistent retention problems with their overdentures but with no general health disorders, no temporomandibular disorder, and class I of Angle; patients with a systemic disease that could compromise implant surgery were excluded. All dentures were made with anatomical teeth (Marche Ltd., Santiago, Chile) by the same operator and laboratory. A specialist in prosthodontics standardized the entire sample, re-establishing the vertical dimension before participant allocation. Moreover, this specialist improved the extension and prosthetic fit of the maxillary and mandibular prosthetic device using a low exothermic acrylic (J. Tokuyama, Morita, Japan), given a stable support area and a balanced bilateral occlusion with multiple occlusal contacts points.

A single randomization was performed to allocate the participants into one of two groups. Group I (ball) consisted of 22 patients who received overdentures retained by two single-standing ball-type mini-implants in the anterior mandible. Group II (bar) consisted of 23 patients who received overdentures retained by two square-headed mini-implants splinted to a cemented bar. Each mini-implant was 1.8 × 15 mm. Neither the surgeon nor the prosthodontist participated in the assignment of patients to the groups.

The baseline participant characteristics (e.g., gender, age, morbid conditions) were recorded in order to assure comparability between the groups.

Surgical phase

Each patient received a prophylactic antibiotic (amoxicillin) 1 h before (2 g) and 6 h after surgery (500 mg), plus a non-steroidal anti-inflammatory 1 h before and 24 h after surgery (Andersen et al. 2002; Lorenzoni et al. 2003). A total of 90 mini-implants (1.8 × 15 mm) (Sendax® MDI, IMTEC, Corporation, Oklahoma, USA) with treated surfaces were inserted, two per patient, in the anterior mandibular zone using an electronic OsseoCare DEC600 motor (Nobel Biocare, Göteborg, Sweden). In all cases, a flapless surgical protocol was performed by an experienced oral surgeon.

In Group I (ball), 44 single-standing ball-type mini-implants were inserted in zones 4.3 and 3.3; the implants were separated by 19–22 mm. In Group II (bar), 46 square-headed mini-implants were set in parallel at a standardized distance of 11 mm in the center of the bone tissue (Fig. 1). The insertion of implants in Group II (bar) required the use of a 3D surgical guide as standard protocol; this was not required for Group I (ball). In Group II (bar), a 2-mm diameter pre-fabricated round bar was cemented over the implants. After insertion, all implants were immediately loaded with mandibular overdentures.

Assessment

We assessed primarily the correlation between mBF and MBL for the entire sample. Between and within-group comparisons of the average mBF and MBL for different study periods were considered as secondary outcomes.

mBF

The mBF was recorded using a thin (98 μm), press-sensitive sheet Dental Prescale (Fuji Photo Film Co., Ltd. Tokyo, Japan) (Hidaka et al. 1999) at the baseline (pre-surgical) and at 5, 7, 10, and 15 months. The patients were instructed to bite twice before using the Dental Prescale sheet (50 HR type R). The patients were seated with their heads in a vertical position and instructed to bite the Dental Prescale sheet with the maximal bite force once, holding the position for 3 s. After 3 min, this protocol was repeated. The Prescale was then scanned and analyzed (in MPa) using a computer occluzer FPD703 (GC Corporation, Tokyo, Japan) (Suzuki et al. 1997). We took the average of these two consecutive bites to be the mBF.

MBL

The prospective evaluation of MBL (expressed in mm) was performed by taking standardized retroalveolar radiographs of each mini-implant immediately after surgery. A long-cone technique was performed with a device that allowed a reproducible unidirectional focus.

MBL was measured as the distance from the initial point of the implant thread to the

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first bone-to-implant contact with a digital caliper (ABS Digimatic Caliper, Mitutoyo Corporation, Kawasaki, Japan). An experienced radiologist took these measurements twice at two proximal implant sites (mesial and distal) over a 2-week interval, averaging the values (Heydenrijk et al. 2002).

According to Weber et al. (1992), the first radiography should be taken immediately after surgery and is used to establish a baseline in terms of contact between bone tissue and the mini-implant. Differences between this baseline and successive measurements (taken 5, 7, 10, and 15 months later) were determined as the number of threads between the baseline and the new bone contact location observed in the control X-rays (Fig. 2). MBL corresponded to the average of the mesial and distal measurements for each follow-up period.

All patients received post-operative implant care instructions. In order to minimize abandonment in the follow-up, all patients were transported free of charge to and from their houses and the university clinic for each programmed exam.

Statistical analysis

Data were analyzed using SPSS version 15.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics (mean and standard deviation) of the mBF and MBL were calculated per patient; values were based on two mini-implants per case. Basal patient's characteristics were compared using Fisher's exact test (categorical variables) and Mann–Whitney test (continuous variables), a statistically significant difference was considered if $P \leq 0.05$. We then calculated Spearman's ρ correlation coefficient, which allowed us to correlate mBF with MBL. A regression line was used to examine the relationship between mBF and MBL. For between-group comparisons, the non-parametric Mann-Whitney test was used. Differences were considered to be statistically significant if $P \leq 0.05$. Within-group comparisons of mBF and MBL were carried out using multiple measuring by Wilcoxon's rank tests, applying a Bonferroni's correction which considered the adjusted significance level of 0.005.

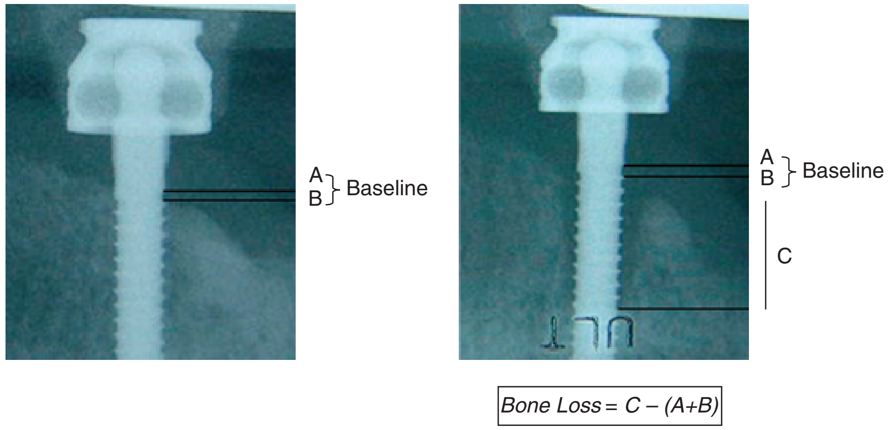

Fig. 2. Left: radiography taken immediately after surgery showing the reference point (A) and the first bone-implant contact (B). Right: radiography 15 months after loading, showing bone loss, which is calculated as the distance between the reference point (A) and the bone-implant contact (C) minus the baseline data (A + B).

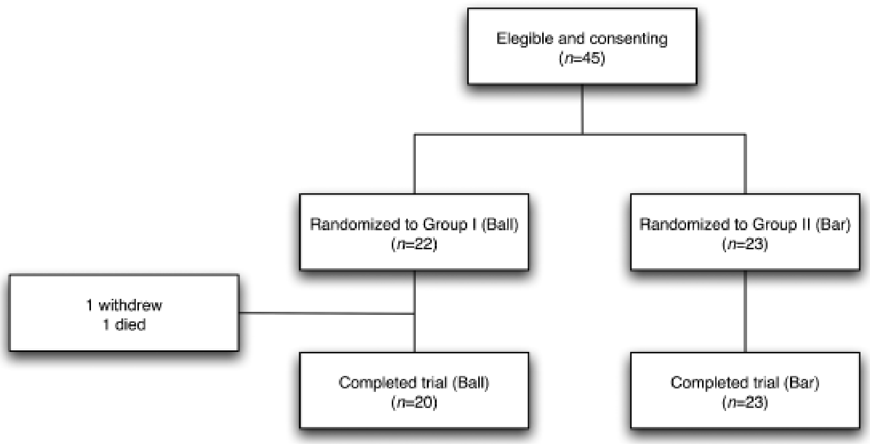

Fig. 3. Flow of participants.

Table 1. **Baseline patient characteristics**

	Group I (ball)	Group II (bar)	Test for difference between groups
Sex (F/M)	13/9	14/9	> 0.999*
Age (years)	69 ± 8.7	73 ± 9.6	0.106*
Morbid condition			
Diabetes	2/22	3/23	> 0.999*
Osteoporosis	1/22	0/23	0.489*
Smoking	1/22	1/23	> 0.999*

*Not significant.
Categorical variables were compared using Fisher's exact test and continuous variables using Mann–Whitney test. A statistically significant difference is considered if $P \leq 0.05$.

Results

We interviewed a total of 200 edentulous patients with difficulty in retaining conventional mandibular dentures; 75 of these patients were eligible for the study and 45 agreed to participate. These 45 patients were randomized into two groups: 22 in Group I (ball) and 23 in Group II (bar). One patient did not return for the check-up and another died before the end of the study, reducing the number of participants in Group I to 20 (Fig. 3). The baseline characteristics were similar between the two groups ($P > 0.05$) (Table 1).

No relationship was found between the mBF and MBL in either group of patients wearing overdentures retained on

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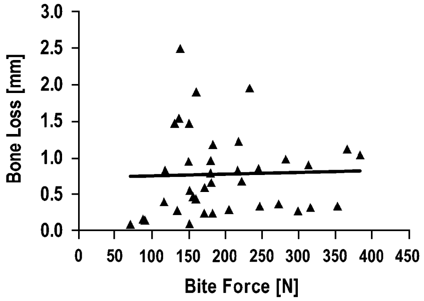

Fig. 4. Bi-dimensional dispersion diagram showing the relationship between mBF and MBL at 15 months. The regression line ($R^2 = 0.001$) showed no relationship between the two variables, and mBF values were not able to predict MBL values.

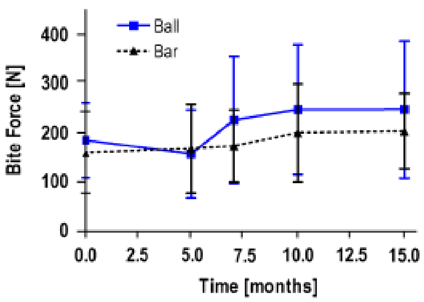

Fig. 5. Average maximal bite force (mBF) during the follow-up period for each study group.

Table 2. **Between-group comparisons using the non-parametric Mann–Whitney test showed no statistical differences between the groups**

Bite force	*n*	Group I (ball) Mean ± SD	*n*	Group II (bar) Mean ± SD	Between groups *P*
At baseline	22	184.7 ± 76.7	20	159.0 ± 82.9	0.151
At 5 months	22	156.6 ± 89.8	19	167.5 ± 90.8	0.695
At 7 months	19	226.1 ± 130.1	19	172.8 ± 73.7	0.274
At 10 months	16	247.4 ± 132.9	18	199.7 ± 100.2	0.317
At 15 months	18	247.5 ± 139.9	17	203.2 ± 76.8	0.586

The intra-group analysis using Wilcoxon-Bonferroni revealed no statistically significant differences between the baseline and 15 months for both Group I (ball) ($P = 0.043$) and Group II (bar) ($P = 0.062$).

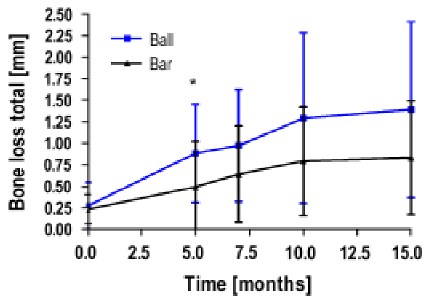

Fig. 6. Average marginal bone loss (MBL) for each group during the follow-up period.

mini-implants (Spearman's ρ $r_s = 0.147$, $P = 0.378$). It is not possible to predict the MBL from the mBF (linear regression $R^2 = 0.001$) (Fig. 4).

In both groups, the mBF increased over time. After month 10, a tendency towards stabilization was observed. At the endpoint, the mBF was 247.53 ± 132.91 N for Group I (ball) and 203.23 ± 76.85 N for Group II (bar) ($P = 0.586$) (Fig. 5, Table 2).

No statistically significant differences in mBF were found between the two groups during the follow-up period ($P > 0.05$) (Table 2).

A within-group analysis showed statistically significant differences in mBF between months 5 and 7 ($P = 0.001$) and months 5 and 15 ($P = 0.004$) for Group I (ball), whereas no statistically significant difference was found between the different measurements of mBF over time for Group II (bar) (Wilcoxon–Bonferroni $P > 0.005$).

Overall, bone loss increased over time, although a tendency to stabilize was observed after month 10 (Fig. 6, Table 3).

Bone loss was higher in Group I (ball) than in Group II (bar) for all evaluation periods. At the 15-month evaluation, the average MBL reached 1.40 ± 1.02 mm for Group I (ball) and 0.84 ± 0.66 mm for Group II (bar) ($P = 0.77$). However, during the follow-up period, the between-group differences were not statistically significant ($P > 0.05$) except at 5 months ($P = 0.026$) (Table 3).

The within-group analysis of Group I (ball) showed a statistically significant difference in MBL between the different periods (Wilcoxon–Bonferroni $P < 0.005$), except between 10 and 15 months. For Group II (bar), statistically significant differences occurred in the MBL between different periods (Wilcoxon–Bonferroni $P < 0.005$) except between months 1 and 5, 5 and 7, and 10 and 15.

Discussion

Our results agree with previous reports of conventional implants (Fontijn-Tekamp et al. 1998; van Kampen et al. 2002, 2005); no statistical differences were found in mBF between the two groups of mini-implant retention systems during the 15-month follow-up period.

For both groups, the mBF tended to increase. The drop in mBF at month 5 in Group I (ball) could be explained by the high number of prosthetic complications (e.g., rubber ring exchange) during this time period, which may have caused patients to bite more softly. However, long-term studies with larger samples are required to identify the mini-implants' real effect on the oral function by means of mBF, as reported by Haraldson & Zarb (1988). Such studies would also allow us to confirm whether this trend continues over time.

According to Wolffs' Law, gradual bone loading is associated with superior bone healing (Roberts et al. 1989; Misch 1990). However, reports are conflicting with respect to this issue; immediate and delayed implant load protocols seem to produce similar results in mandibular overdenture treatments (Batenburg et al. 1998a, 1998b; Heydenrijk et al. 2003; van Kampen et al. 2005), suggesting that gradual bone loading is more important in situations of compromised bone quality. In this study, the mini-implants were immediately loaded after surgery and no deleterious effects were observed, like the report by Kawai & Taylor (2007) for conventional implants.

MBL around conventional implants supporting mandibular overdentures has been reported to range from 0.2 to 1.9 mm after the first year (Batenburg et al. 1998a, 1998b; Naert et al. 1998; Gotfredsen & Holm 2000).

The bone loss around the mini-implants used herein was similar to the levels previously reported for conventional implants, and lower than those reported in a similar study by van Kampen (van Kampen et al. 2005). This latter result could be explained by the use of one-piece mini-implants, which avoided the repeated removal of

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***Table 3.* Between-group comparisons of bone loss with the Mann-Whitney test showed a statistical difference between the groups at 5 months**

Bone Loss	*n*	Group I (ball) Mean ± SD	*n*	Group II (bar) Mean ± SD	Between groups *P*
At baseline	19	0.28 ± 0.27	16	0.24 ± 0.17	0.828
At 5 months	15	0.89 ± 0.57	18	0.50 ± 0.53	0.026*
At 7 months	18	0.98 ± 0.65	22	0.65 ± 0.56	0.062
At 10 months	16	1.30 ± 0.99	20	0.80 ± 0.63	0.107
At 15 months	20	1.40 ± 1.02	18	0.84 ± 0.66	0.077

The intra-group analysis using Wilcoxon–Bonferroni evidenced a statistically significant difference between the baseline and 15 months in both Group I (ball) ($P<0.001$) and Group II (bar) ($P<0.001$).
*Statistically significant.

abutment with less marginal bone resorption (Abrahamsson et al. 1997).

Group I (ball) averaged close to 1.5 times more MBL than did Group II (bar). After 10 months, Group II (bar) showed a stabilization tendency.

Because of the sample size, we did not find significant statistical differences in bone loss between groups of mini-implants, during the follow-up period, except for month 5. This was the first measurement after implant insertion and the significant difference could be due to the fact that immediate loading during the healing period of a single mini-implant could lead to higher bone loss because the implant has less mechanical anchorage than does a splinted mini-implant structure.

In terms of bone loss, both groups met the criteria for success as detailed by Albrektsson & Sennerby (1990) and Albrektsson et al. (1986), in which annual bone loss should not exceed 1.5–2 mm in the first year and 0.2 mm per year thereafter.

The bone loss pattern in Group II (bar) was similar to the bone resorption evaluated for immediately loaded conventional implants. The percentage of bone loss was highest during the first 6 months, after which the velocity of bone resorption tended to decrease until stabilization (Weber et al. 1992). However, we should note that Group II showed a much lower level of bone loss than the minimum acceptable for conventional implants. In this sense, biomechanical factors such as the superstructure could play an important role for mini-implants.

The type of attachment system provides different degrees of horizontal and vertical resistance against dislodging forces that could lead to different magnitudes of loading transmission to the implant–bone interface. This does not seem to evoke bone resorption around conventional implants (Naert et al. 2004; van Kampen et al. 2005). However, the high levels of stress on the bone showed by single narrow implants (Petrie & Williams 2005) could lead to a mechanical overload, causing bone remodeling (Isidor 2006).

The inter-abutment distance has been reported to play a role in overdenture retention (Michelinakis et al. 2006; Doukas et al. 2008). The relevance of this distance for bone loss has not been evaluated. The inter-implant distance range (19–22 mm), applied in Group I, was considered to be the most adequate distance for denture movement, leading to less stress (Hertel & Kalk 1993), whereby it should not play a determinant role in this group. On the other hand, the inter-implant distance of 11 mm for Group II was considered the best biomechanical option for splinted mini-implants.

Four mini-implants have been recommended as an alternative treatment for edentulous patients. However, no published evidence indicates that this option is better than the use of two mini-implants. Moreover, the benefits and good results of mandibular overdentures supported by two and sometimes three implants proves them sufficient for adequate overdenture support (Mericske-Stern & Geering 1988; Mericske-Stern 1998). There is also evidence that two implants should become the standard option for mandibular overdentures (Adell et al. 1981; Van Steenberghe et al. 1987; Feine et al. 2002). Prospective studies comparing two or four endosseous implants supporting mandibular overdentures have shown no differences in clinical and radiographical outcomes (Batenburg et al. 1998a, 1998b; Visser et al. 2005). Based on this information, we decided to evaluate a protocol that considered the use of two mini-implants in the interforaminal zone.

In this study, patients with a high level of bite force did not present a high level of bone loss around the mini-implants when compared with patients who were unable to bite as hard. However, the effect and the way in which occlusal forces are transmitted to the mini-implants and bone via different attachment systems is unknown. Moreover, mBF is only one of the elements that participate in the oral function. Others, such as mastication, should be evaluated to determine how they contribute to the load transmitted to the bone through the implants (Mericske-Stern 1997).

The results of this study suggest that bone loss resulting from mini-implants is not related to a patient's mBF. One explanation could be that the larger support area of the denture is on the mucosa and not on the implant, especially in the case of Group I (ball). For Group II (bar), biomechanical behavior is improved by splinting the mini-implant, increasing the implant–bone anchorage area and the response to the occlusal load.

Conclusion

In this study, the MBL around mini-implants is not related to the maximal bite force in patients wearing overdentures retained by bar or ball attachment system.

Further studies are required to identify the way in which occlusal forces are transmitted to the mini-implants and bone through different attachment systems, and to determine how they contribute to the load transmitted to the bone.

Acknowledgements: This research was supported by a grant from the National Commission for Scientific and Technological Research of Chile (CONICYT), through the Fund for the Promotion of Scientific and Technological Development (FONDEF Project Di1109). The authors would like to thank Claudia Asenjo, MS, for statistical analysis of the data and manuscript preparation.

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