CLINICAL ORAL IMPLANTS RESEARCH

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Clinical and radiographic evaluation of implants placed by means of inferior alveolar nerve lateralization: a 5-year follow-up study

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Abstract

Objective: To evaluate clinical and radiological responses of implants placed in combination with inferior alveolar nerve lateralization, analyzing survival and success rates over 5 years functional loading.

Materials and methods: This prospective, longitudinal, single-center study recruited 40 patients with mandibular atrophy in the posterior sectors, who underwent lateralization of the inferior alveolar nerve. Three months after surgery and implant placement, the implants were loaded by means of screw-retained implant-supported partial prostheses or fixed complete prostheses. Clinical and radiographic examinations were performed immediately after implant placement and at 12, 24, 36, 48 and 60-month follow-up visits.

Results: The 40 patients received a total of 129 implants (Phibo TSA™, Phibo Dental Solutions, Sentmenat, Barcelona, Spain). Two implants were lost in the first month after surgery, generating an implant cumulative survival rate (CSR) of 98.44%. The success rate after 5 years of loading was 98.44%. No intra-operative or postoperative soft tissue or prosthetic complications occurred during the 5-year follow-up.

Conclusions: Inferior alveolar nerve lateralization performed to allow placement of (Phibo TSA™) implants in patients with mandibular atrophy obtained predictable clinical and radiological results over five years of functional loading.

Dental loss is accompanied by bone resorption of the alveolar crest. In this context, rehabilitation of the posterior region by dental implants is obstructed by the presence of the inferior alveolar nerve, accompanied by insufficient bone height and width for implant placement (Peñarrocha-Oltra et al. 2014). For some years, this limitation has been resolved by applying various techniques such as intra- or extra-oral bone grafts (placed as on-lays or inlays), distraction osteogenesis, short implants or mobilization of the inferior alveolar nerve.

The first case of nerve mobilization simultaneous to implant placement was described in the 1980s, and since then, various techniques have been investigated including lateralization, which is one of the most important (Lorean et al. 2013). In spite of possible complications, the lateralization technique offers attractive advantages compared with other procedures, including minimal surgical time, economic cost and the possibility of using longer implants, which will allow bicortical anchorage, better primary stability, as well as a biomechanically favorable crown-to-root relation (Barbu et al. 2014).

Although there is some controversy surrounding the technique in terms of implant success rates and the complications that can occur, recent studies have obtained success rates close to other techniques that would appear to vouch for the efficacy of simultaneous lateralization and implant placement (Fernandez-Diaz & Naval-Gías 2013; Khojasteh et al. 2015). But to date, the scientific literature includes few studies with long follow-up periods.

For this reason, the aim of this study was to analyze the clinical and radiological

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responses of implants placed simultaneously to inferior alveolar nerve lateralization, evaluating implant survival and success rates over five years of functional loading.

Material and methods

Study design and patient sample

This prospective, longitudinal and single-center study followed guidelines established by the Declaration of Helsinki (version 2008) for research involving humans and was approved by the Clinical Research Ethics Committee at the San Carlos Hospital (Madrid, Spain). A total of 45 patients were selected to take part in the study attending the Buccofacial and Implant Dentistry Service at Virgen de la Paloma Hospital (Madrid, Spain) for rehabilitation by implants of atrophic mandibular posterior regions. All patients met the following predetermined inclusion criteria:

1. Male and female ASA 1 and ASA 2 patients who, having received information about the study design, aims and possible risks involved, gave their informed consent to take part in writing.
2. Smokers were admitted providing consumption did not exceed 10 cigarettes per day, and providing they were periodontally stable.
3. Patients with an edentulous mandibular posterior region that showed a distance between bone crest and the top of the alveolar nerve duct of less than 5 mm.
4. Patients who attended all clinical check-up and radiological appointments scheduled during the 5-year follow-up.

Of the 45 study candidates, five were excluded: two refused surgery and three failed to attend the programed check-up appointments (Fig. 1).

The implants placed were cylindrical and had the acid-etched Avantblast™ surface (Phibo TSA™, Phibo Dental Solutions).

The total patient sample comprised 24 women and 16 men with a mean age of 57.1 years, who underwent 48 lateralizations to receive 129 implants.

Pre- and postsurgical measures

All patients underwent diagnostic exploration by means of panoramic radiographs and helical scans which provided information for planning surgery.

Postoperative measures consisted of antibiotic administration for 7 days (875 mg Amoxicillin and 125 mg Clavulanic acid every 12 h), anti-inflammatories for three days (400 mg Ibuprofen every 12 h) and 0.12% chlorhexidine digluconate mouthwash (Perio-Aid, Dentaid, Barcelona, Spain) for 15 days.

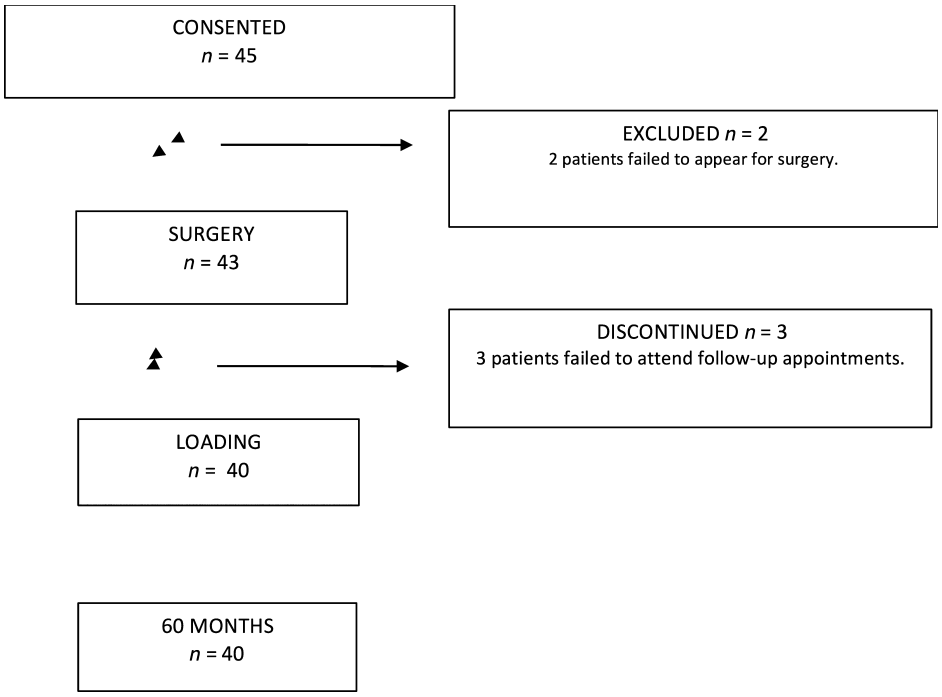

Fig. 1. Flowchart shows the number of subjects enrolled in the study who completed the 5-year follow-up.

Surgical procedure

All surgery was performed by a single experienced surgeon, under general anesthesia. A triangular crestal incision was made reaching to the retromolar space, with vertical release. A mucoperiosteal flap was raised, and subperiosteal dissection of the mental foramen was carefully performed. To free the inferior alveolar nerve from the supporting bone, circumference osteotomy was performed 3 mm behind the mental foramen, using the Piezotome™ (Satelec, Merignac, France), following the line of the nerve canal.

Remaining spongy bone was carefully eliminated with a surgical scoop until the inferior alveolar neurovascular bundle was exposed and then tractioned using a vessel loop. When the nerve had been lateralized to a safe position, the implant sites were prepared according to the preplanned implant diameters and lengths following the usual procedure (Table 1).

After inserting the implants, the primary stability of each was checked with a resonance frequency analyzer (RFA) (Osstell ISQ, Göteborg, Sweden). Afterward, bovine bone grafts were placed (Bioss™, Geistlich Pharma AG, Wolhusen, Switzerland) covered by a resorbable collagen membrane (Bio-Guide™, Geistlich Pharma AG, Wolhusen, Switzerland) over the surgical window defects. After this, the flaps were repositioned and sutured with 000 monofilament silk (Laboratorio Aragó SA, Barcelona, Spain).

Sutures were removed 10–12 days after surgery, and implants were loaded three months after insertion, placing implant-supported screw-retained metal-ceramic partial prostheses (35 patients/114 implants) or fixed complete prostheses (5 patients/15 implants).

Clinical and radiographic follow-up

A follow-up protocol was arranged for each patient, whereby a single clinician performed all check-ups (JC) with the following schedule: after the first month and thereafter at 3, 12, 24, 36, 48 and 60 months after surgery, evaluating the following parameters:

Implant survival and success

Implant success rate was determined applying the clinical–radiological criteria proposed by Zarb & Albrektsson (1998) and calculating the implant cumulative survival rate (CSR).

Periodontal clinical parameters

Probing depth (PD) was evaluated in millimeters on both mesial and distal aspects of each implant, together with bleeding on probing (BoP) around the implants registered as YES or NO at four points per implant using a periodontal probe (PCP-UNC 15, Hu-Friedy, Chicago, IL, USA).

Table 1. **Implant lengths and diameters for the 129 implants placed in the study**

Implants	3.75 mm	4.75 mm
10 mm	14	14
11.5 mm	30	35
13 mm	22	14
Total	66	63

Radiographic examination

Radiographic examination was performed using panoramic and periapical radiographs with parallelism technique. A bite block was made for each patient to ensure parallelism and adequate standardization for future comparison. Each radiograph was labeled individually with the patient's identification number, date and implant length and diameter. The following parameters were evaluated using periapical radiographs: (i) marginal bone height over time and (ii) bone-to-implant contact (with the aim of detecting any loss of osseointegration). Marginal bone height was determined on both mesial and distal implant surfaces by measuring the distance between a reference point (the implant shoulder) and the marginal bone-to-implant contact level using a (7×) magnifying lens. Method error (method used for assessing the radiographic marginal bone height) was as described by Wennström et al. (2005).

Implant stability

Implant stability was assessed by measuring the frequency of implant oscillation inside the bone (Meredith et al. 1996, 1997; Tealdo et al. 2015). Stability values were expressed as implant stability quotient (ISQ) units, which range from 1 (low stability) to 100 (high stability). Values < 45 ISQ units indicate implant failure, whereas an ISQ value of around 60–70 ISQ indicates success (Sennerby & Roos 1998; Aparicio et al. 2006). There is a specific transducer for each type of implant designed, so that the values obtained do not depend on the type of transducer used (Sennerby & Meredith 2008). Assessments were made at the time of implant insertion, and after 5 years of functional loading on right (RFA right), central (RFA central) and left (RFA left) implants.

Complications

Any complications deriving from the technique were registered. These potentially included intra-operative complications such as hemorrhage, insufficient implant stability or mandibular fracture, and postoperative complications such as soft tissue disorders, infection, mandibular fracture or prosthetic fracture. During the postoperative follow-up, the appearance of any sensation disorders and their evolution were monitored by means of two-point discrimination one month after surgery and thereafter at three, six, nine and twelve months, applying criteria described by Nishioka, whereby discrimination of less than 14 mm was considered as normal sensitivity, 14–20 mm was regarded as reduced sensitivity (hypoesthesia) and over 20 mm as absence of sensitivity (Nishioka et al. 1987).

Statistical analysis

Statistical analysis was performed using SPSS 22.0 software (SPSS Inc., Chicago, IL, USA). Firstly, descriptive analysis of quantitative and qualitative variables generated mean values, standard deviations, ranges and frequencies. The Kolmogorov–Smirnov test was applied to determine if quantitative variables presented normal distribution. Afterward, Student's t-test was used for comparing mean quantitative variables (bone loss, periodontal pocket depth and ISQ) contrasted using the Levene test. ANOVA was applied for comparing multiple mean values. The chi-squared test and Fisher's exact test were applied to determine the influence of the BoP variable. Lastly, a correlation test was used to determine whether there was any relation between the parameters evaluated. Statistical significance was established as $P < 0.05$ for all tests.

Results

Of the 48 lateralizations performed, 6 were bilateral, with 58.33% of the unilateral lateralizations performed on the right side. A total of 129 implants were placed, two of which were lost, producing a CSR of 98.44% over the five-year follow-up. The two lost implants belonged to male patients and were removed within a month of placement as a result of infection. In this way, the implant failure rate per year was 1.6% in the first year and 0.0 in the remaining four years. The success rate over 5 years was 98.44%. No intra-operative complications were registered. As for postoperative complications, while no soft tissue disorders, or mandibular or prosthetic fractures occurred during five years of functional loading, sensation disorders (hypoesthesia) were identified by two-point discrimination during the first nine months, although these did not persist beyond the twelve-month check-up (Table 2).

Periodontal clinical parameters

Mean probe depth (PD) was 2.66 mm in women and 3.19 mm in men (mean: 2.92 mm) after the first year and 3.41 and 3.70 mm after five years, respectively (mean: 3.53 mm).

Statistically significant differences in PD were wound between men and women during the first four years of functional loading (Table 3). Implant length influenced PD in the first and third years of loading ($P = 0.030$ and $P = 0.017$, respectively). But, no significant relations between PD and implant diameter or patient age were identified ($P \geq 0.05$).

A lower BoP index was found among women than men, with statistically significant differences in the second and third years of loading ($P = 0.049$ and $P = 0.031$, respectively). The presence of BoP was not influenced by either age or implant diameter and length ($P \geq 0.05$).

Radiographic examination

Radiographic bone loss measurements were registered at five different time points (t1, t2, t3, t4 and t5). Statistically significant differences in marginal bone loss were found between men and women ($P < 0.05$). Marginal bone loss in relation to gender at all follow-up visits is shown in Table 4. An association between bone loss and implant diameter was also found during the first two years of loading ($P = 0.04$), so that bone loss was more evident around implants of a 3.75 mm diameter; however, no relation was found between bone loss and either patient age or implant length ($P \geq 0.05$).

Implant stability

RFA values were recorded at two time points (t0 and t5). Immediately after implant insertion (t0), the mean RFA value was 64.05 ISQ (range 55–73). The two failed implants presented initial ISQ values of 55 and 60, respectively. After 5 years of functional loading, ISQ values had increased slightly to a mean

Table 2. **Evolution of patient sensitivity alterations**

	1 month	3 months	6 months	9 months	12 months
Anesthesia	0	0	0	0	0
Hypoesthesia	40	34	15	4	0
Normal	0	6	25	36	40
Total	40	40	40	40	40

Table 3. **Changes in probe depth among males and females during the 5-year follow-up**

Gender		Implants	Mean	Standard deviation	Mean standard error	*t*-test (*P* value)
1 Year	Male	53	3.19	0.921	0.127	0.003
	Female	74	2.66	1.024	0.119	
2 Years	Male	53	3.25	0.939	0.129	0.023
	Female	74	2.82	1.077	0.125	
3 Years	Male	53	3.53	1.012	0.139	0.004
	Female	74	3.00	1.073	0.125	
4 Years	Male	53	3.64	0.963	0.132	0.023
	Female	74	3.24	0.962	0.112	
5 Years	Male	53	3.70	0.822	0.113	0.061
	Female	74	3.41	0.890	0.103	

The level of significance was set at $P < 0.05$.

Table 4. **Marginal bone loss in males and females between baseline and 1-,2-, 3-, 4- and 5-year follow-up**

Gender		Implants	Bone loss mean	Standard deviation	Mean standard error	*t*-test (*P* value)
1 Year	Male	53	0.485	0.3549	0.0487	0.031
	Female	74	0.354	0.3206	0.0373	
2 Years	Male	53	0.626	0.4082	0.0561	0.024
	Female	74	0.468	0.3724	0.0433	
3 Years	Male	53	0.851	0.4894	0.0672	0.003
	Female	74	0.609	0.4152	0.0483	
4 Years	Male	53	1.083	0.5154	0.0708	0.001
	Female	74	0.795	0.4887	0.0568	
5 Years	Male	53	1.313	0.5273	0.0724	0.001
	Female	74	1.015	0.5090	0.0592	

The level of significance was set at $P < 0.05$.

Table 5. **Correlation between marginal bone loss and clinical parameters after 1-year and 5-year follow-up**

Correlations				
		Bleeding 1	PD 1	ISQ
Bone loss 1	Pearson's correlation	0.451	0.443	−0.083
	Sig. (bilateral)	0.000	0.000	0.353
	N implants	127	127	127
		Bleeding 5	**PD 5**	**ISQ 5**
Bone loss 5	Pearson's correlation	0.384	0.576	−0.298
	Sig. (bilateral)	0.000	0.000	0.001
	N implants	127	127	127

PD, Probing depth.
The level of significance was set at $P < 0.05$.

of 69.46 (range 60–79), with significant difference between men and women ($P = 0.03$). Neither patient age nor implant diameter and length showed any influence on ISQ values ($P \geq 0.05$).

Table 5 shows correlations between marginal bone loss in the first year and after 5 years of loading, and clinical parameters PD, BoP and ISQ.

Discussion

Rehabilitation of severely atrophic mandibular posterior regions by means of implants presents a clinical challenge due to the anatomical limitations caused by the presence of the inferior alveolar nerve. Mobilization of the nerve is one way of meeting this challenge.

The lateralization procedure can be carried out by means of two techniques: lateralization or transposition. The difference between the two is that transposition releases the nerve from the supporting bone at the point where it exits the mental foramen, sectioning the mandibular ramus. Even though the transposition technique is more commonly used (Abayev & Juodzbalys 2015), it is subject to a higher risk of sensory disturbance. A recent systematic literature review found a sensory disturbance incidence of 3.4% of patients undergoing lateralization compared with 22.1% of patients treated with transposition (Vetromilla et al. 2014). Another study compared the two techniques evaluating anterior tooth vitality after surgery, concluding that the lateralization technique is more physiological (Khajehahmadi et al. 2013).

Another factor that reduces the risk of sensory damage is the use of piezoelectric osteotomy, as used in the present study (Metzger et al. 2006; Chrcanovic & Custódio 2009).

Monitoring the recovery of sensation in the postoperative period, a wide variety of methods and time frames can be used. The present study evaluated sensory disturbances by means of two-point discrimination, a technique that has been applied in other studies of nerve lateralization (Rosenquist 1994; Kan et al. 1997a,b). Hypoesthesia was identified during the first postoperative months, which desisted gradually so that no permanent sensory disturbances remained by the twelve-month follow-up, a finding that concurs with other research (Hashemi 2010; Fernandez-Diaz & Naval-Gías 2013).

One of the main advantages of the lateralization technique is that it allows the placement of longer implants, which improves the crown-to-root proportion to produce better biomechanics than shorter implants. Using finite element analysis, Vasco et al. (2011) assessed the risk of bone loss comparing 7 with 15 mm implants, concluding that there was a greater risk with short implants. Jayme et al. (2015) also carried out finite element analysis to compare lateralization and transposition, evaluating the impact of increasing the height of the prosthetic crown, obtaining better results for implants placed after lateralization in terms of the risk of bone loss, even though the impact of crown height had similar effects with either technique. However, the present study did not find any relation between marginal bone loss and implant length.

Marginal bone loss can be a key indicator of tissue health around implants. One year after placing prosthetic restorations, some authors have cited marginal bone loss values of between 0.2 and 0.3 mm (Rosenquist 1994; Proussefs, 2005; Khojasteh et al. 2015). The present study obtained slightly higher bone loss values, although within physiological limits, with statistically significant differences between men and women, also observed with 3.75 mm diameter implants during the first 2 years of functional loading. Clearly, marginal bone loss will be closely related to other clinical parameters such as PD and BoP, a fact that the present findings confirm over the 5-year follow-up.

According to other studies, implants placed by means of lateralization show good survival

rates between 88% and 100%, although these percentages derive from heterogeneous evaluation methods and the follow-up periods in these studies were not very long (Morrison et al. 2002; Ferrigno et al. 2005; Chrcanovic & Custódio 2009; Barbu et al. 2014). In the present study, the survival rate was 98.44% after five years and only two implants failed as a result of infection during the first month after surgery. Researchers have proposed a diverse range of factors as possible causes of infection including overheating of the surgical bed during drilling, a dense bone quality with poor vascularization, as well as graft placement simultaneous to nerve mobilization (Karlis et al. 2003; Luna et al. 2008).

Some reports of inferior alveolar nerve lateralization techniques have described profuse intra-operative hemorrhaging that have caused surgery to be suspended (Rosenquist 1994; Kan et al. 1997a,b), a complication that did not occur in the present study. Mandibular fracture is another complication that, although infrequent, has been well described in the literature (Luna et al. 2008; Dos Santos et al. 2013; Losa et al. 2015). Kan et al. (1997a,b) reported a case of spontaneous fracture three weeks after surgery, which the authors believed were caused by the extensive vestibular osteotomy performed to access and visualize the very lingually-positioned neurovascular bundle. Ferrigno et al. (2005) also report a mandibular fracture in a patient who received three implants; the facture required the explantation of the most distal implant while the other two remained intact. The present study did not register any mandibular fractures, or indeed any soft tissue disorders, or prosthetic complications.

Although previous studies have not evaluated ISQ after lateralization of the inferior alveolar nerve, Farzad et al. (2004) showed that it was possible to achieve ISQ values of 50-90 (mean: 70.05) in the mandibular posterior region. The present study obtained ISQ values within the range cited by Farzad et al., with a mean of 64.05 immediately after surgery and 69.46 after five years of functional loading. Another study also suggests that bicortical anchorage, one of the advantages that the lateralization technique offers, in a low-density bone type (Type IV), could provide greater implant stability (Martinez et al. 2001).

Conclusions

Within the limitations of the present study, the use of Phibo TSA™ implants combined with lateralization of the inferior alveolar nerve in patients with mandibular atrophy obtained predictable clinical and radiological outcomes.

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