

# SINUS IMPLANTS STABILIZATION IN MISCH IV CLASS BY MEANS OF S.I.S. DEVICE: A CLINICAL STUDY

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## SUMMARY

### *Sinus implants stabilization in Misch IV Class by means of S.I.S. device: A Clinical Study*

**Aims.** In Misch Class IV dental implants are not normally placed at the same time as the sinus lift procedure. For this type of situation the use of several devices to immediately stabilise implants lacking in primary stability is proposed. Among these, the titanium S.I.S. plate results as being the most straightforward. This study proposes the evaluation of the effectiveness and stability of the results of this method in the short term on a greater number of patients, monitoring bones levels and implant stability.

**Method.** 14 patients were selected, 9 males and 5 females, aged between 43 and 75 years of age.

Overall, 42 implants were placed in the upper posterior edentulous zones with Misch Class IV atrophy including first and second premolars and first molars, opposite fixed teeth, and were stabilised using the S.I.S. plate.

**Results.** Radiographic controls and ISQ measurements with AFR at 1, 6 and 12 months after loading testify to the stability of the bone levels which concur with success criteria found in literature. The technique described seems to be able to ensure success in cases of Misch Class IV with contemporaneous placement of the osseo-integrated implants.

**Conclusion.** This clinical study, even if carried out on a small number of patients (14) and implants (42) represents the largest case history published. The technique described seems to ensure the success of cases of Misch Class IV with contemporaneous placement of osseo-integrated implants. The technique is straightforward and reproducible and does not cause further trauma. The S.I.S. allows for the stabilisation of the dental implants and the residual crest when there is a lack of primary stability. In Misch Class IV this means a considerable reduction in treatment times.

**Key words:** S.I.S., primary stability, sinus lift, implant stabilisation.

## RIASSUNTO

### *Stabilizzazione implantare intrasinusale nelle IV Classi di Misch per mezzo di dispositivo S.I.S.: studio clinico*

**Obiettivi.** Nelle IV classi di Misch non è di norma possibile inserire impianti dentali contestualmente alla procedura di rialzo di seno. Per queste situazioni è stato proposto l'uso di diversi presidi per stabilizzare immediatamente impianti privi di stabilità primaria. Tra questi risulta di uso più semplice la placca in titanio S.I.S. Questo studio si propone di valutare l'efficacia e la stabilità del risultato nel breve termine di questa metodica su un maggiore numero di pazienti monitorando livelli ossei e stabilità implantare.

**Metodi.** Sono stati selezionati 14 pazienti, 9 maschi e 5 femmine, di età compresa tra 43 e 75 anni.

Sono stati inseriti complessivamente 42 impianti nelle zone edentule postero superiori con atrofia di IV Classe di Misch che includessero primo e secondo premolare e primo molare, opposti a dentatura fissa, solidarizzandoli tramite placca S.I.S.

**Risultati.** Controlli radiografici e misurazione di ISQ con AFR ad 1,6 e 12 mesi dal carico testimoniano stabilità dei livelli ossei in linea con i criteri di successo della letteratura. La tecnica descritta sembra poter assicurare il successo nei casi di IV Classe di Misch con inserimento contestuale di impianti osseo integrati.

**Conclusioni.** Questo studio clinico pur su un piccolo numero di pazienti (14) e di impianti (42) rappresenta la maggiore casistica pubblicata. La tecnica descritta sembra poter assicurare il successo nei casi di IV Classe di Misch con inserimento contestuale di impianti osseo integrati. La tecnica appare semplice e riproducibile senza essere causa di ulteriore traumatismo. La placca S.I.S. consente di stabilizzare tra loro e alla cresta residua gli impianti dentali inseriti in assenza di stabilità primaria. Nelle classi IV di Misch ciò comporta un notevole accorciamento dell'iter terapeutico.

**Parole chiave:** S.I.S., stabilità primaria, rialzo di seno, stabilizzazione implantare.

## Introduction

In the rehabilitation of the upper lateral sector, a bone crest, insufficient for the placement of implants, is frequent. This deficit is attributable to the combined effect of post extractive bone resorption and maxillary sinus expanding. Examining the different clinical situations which may occur in these cases, Misch has identified four classes:

### CLASS I

More than 12mm of bone availability. In these cases is possible to introduce fixtures of correct dimensions according to the usual techniques.

### CLASS II

Bone availability between 12 and 8 mm. In these cases short fixtures can be placed but is advisable to begin sinus lifting using non invasive techniques in order to introduce longer fixtures.

### CLASS III

Bone availability between 8 and 5 mm. In these cases is necessary to obtain a greater lift of the sinus floor. The most commonly used technique is the one with lateral approach described by Misch and Tatum (2, 3) followed by insertion of fixtures at the same time.

### CLASS IV

Less than 5 mm of bone availability. In these cases a sinus floor lift is foreseen but with fixture insertion postponed until after graft integration. In the latter case, the impossibility of obtaining sufficient primary stability to gain osseo-integration requires the postponement of fixture insertion. Primary stability and healing in absence of micro-movements are pre-requisites for osseo-integration (4, 5, 6). Without these conditions a fibrous connection will occur instead of osseo-integration (7, 8, 9). In order to reduce treatment length and the number of surgical stages, some authors have proposed stabilising the fixtures together to eliminate their mobility. In 1993 Cranin and Russel (10) successfully used a Leibinger splint for stabilising stability-free fixtures introduced after sinus lifting, obtaining clinical suc-

cess. In 2000, Sontheimer (11) and Vollmer in 2002 (12) proposed, for the same aim, the use of mini-plates for osteosynthesis. In 2000 Patyk et al. (13) developed an extra sinusal stabiliser plate made of a re-absorbable material (polylactate). In 2002, Engelke(14) stabilised single fixtures lacking primary stability with osteosynthesis plates welded to a screwed abutment obtaining osseous regeneration and osseo-integration in domestic pigs. In 2004, Lindorf and Müller-Herzog proposed (15) the ASIS technique by using a block of cortical bone from the mandibular ramus as an extra sinusal fixture stabiliser in association with a sinus lift. In 1999, Lang (16) created a titanium plate, better described below, specifically destined to stabilize dental implants for the same purpose. Positive results with the device invented by Lang were obtained by Kaps in 1999 (17) and, in Italy, by Morlino in 2000 (18) and Grandi in 2008 (19).

## Aims

In Misch Class IV it is not usually possible to place fixtures at the same time as carrying out the sinus lift procedure. For these situations, the use of several devices to immediately stabilise implants lacking in primary stability have been proposed. Among these, the most simple to use is the titanium S.I.S. plate. The S.I.S. plate allows for the solidification of the implants together and the residual crest in absence of primary stability. In Misch Class IV, this means considerably reducing treatment times. So far, the literature available concerning this type of technique is limited and made up mostly of case reports. This study proposes the evaluation of the effectiveness and stability of the results for this method in the short term on a greater number of patients while monitoring the peri-implant bone levels and implant stability.

## Patient selection

In order to follow the research protocol, the patients also had to satisfy the following conditions:  
- they must come under class ASA I and II (Guide-

lines for pre-anesthesia evaluation. The American Society of Anesthesia)

- they must not present contra-indications on insertion of the dental implant
- they must not be smokers
- they must present at least upper partial edentulia including the first premolar, second premolar and first molar
- they must present fixed teeth opposite the edentulous area to be rehabilitated
- they must have atrophy of Misch class IV (bone availability, measured on Deta-Scan sections, inferior to 5 mm in at least two out of three sites) (Fig. 1). 14 patients were selected of which 9 were male and 5 female, ageing between 43 and 75 years of age. Overall, 42 implants were placed in the edentulous regions being examined.

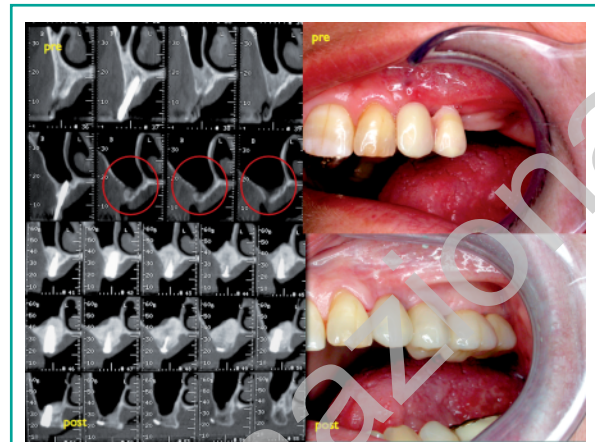
## Materials and methods

The aim is to allow, in the case of Misch Class IV, for the insertion of implants at the same time as the sinus lift. The implants are stabilised, while completely lacking in primary stability, through the use of the stabilising S.I.S. plate (Sinus Implantat Stabilisator, Mondeal Medical Systems GmbH, Germany – Tuttlingen, distributed in Italy by GEASS Srl, Pozzuolo del Friuli – Italy) created by Lang (16). This device is a titanium plate, 0.6 mm in thickness with larger holes for the fixing of the cover screws onto the implant, alternated with smaller holes for fixing the device to the bone crest using osteosynthesis screws and dedicated tools (Syntesis, GEASS Srl, Pozzuolo del Friuli – Italy) (Fig. 2).

The plate provides predetermined sites for the first premolar, the second premolar and the first molar. It is produced in two sizes to adapt to the different types of implants with different connections and in two shapes, straight and curved so that it can be adapted to the different shapes of edentulous ridges.

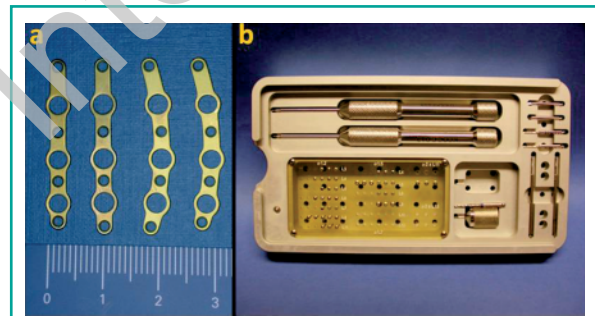
## Clinical protocol

The patients are pharmacologically treated with 2 gr of Amoxicillina and Clavulanic Acid. Anaesthesia



**Figure 1**

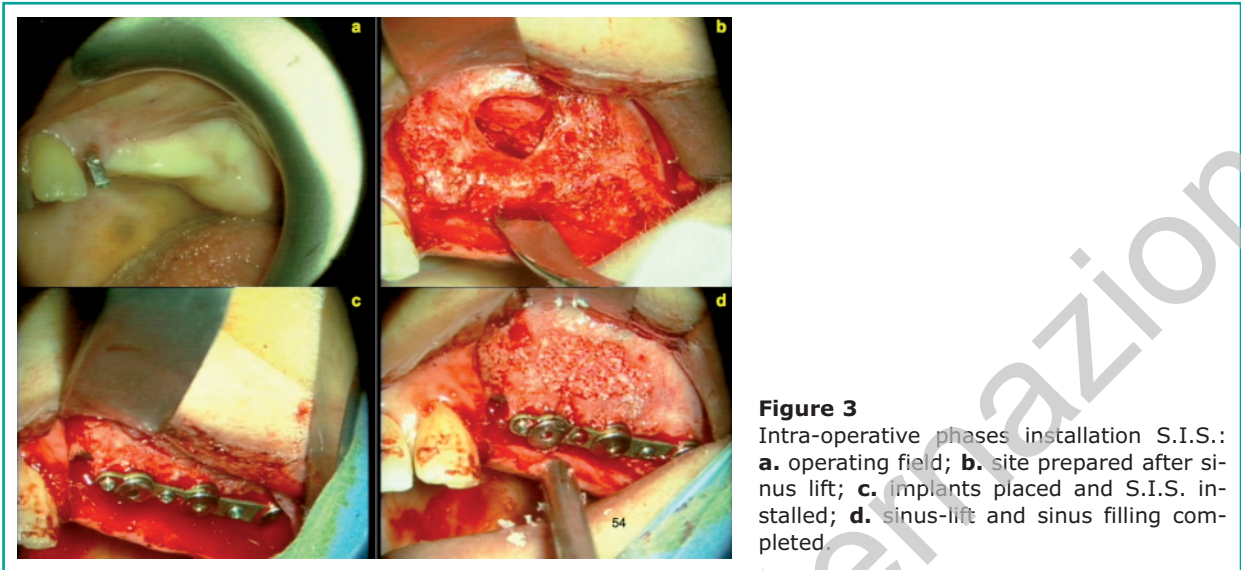
Initial and final images: at the top - CT scans and initial images; at the bottom - CT scans and final images.



**Figure 2**

S.I.S. plates and Syntesis tool kit: **a.** S.I.S. plates with two sizes and two shapes (straight and curve); **b.** Osteosynthesis tools for fixing-screws insertion.

is obtained by blocking the greater palatine, the inferior-orbital nerve and infiltrating the tuberosity region. Subsequently, a full thickness crestal incision is carried out with mesial and distal releasing incisions and elevation of the mucoperiosteal flap. Then a buccal window is made with multi-blade burs in the initial phase and diamond burs in the final phase in proximity to the Schneider membrane. Subsequently, the buccal window and the sinus membrane are raised with the usual manual instruments, alternating surgical manoeuvres with pauses in order to verify that the membrane is synchronised with the respiratory activity. Once the elevation has been carried out and having verified the integrity of the membrane, proceed with initial filling using heterologous



**Figure 3**  
Intra-operative phases installation S.I.S.:  
**a.** operating field; **b.** site prepared after sinus lift; **c.** implants placed and S.I.S. installed; **d.** sinus-lift and sinus filling completed.

bone (Bio-gen, Bioteck, Arcugnano – Italy) and a clot previously taken from the patient. In the initial phase, insert the first implant into position 4 (Kentron, Geass srl, Italia – Pozzuolo del Friuli). Subsequently, after momentarily fixing and after moulding the S.I.S. plate onto the implant using the cover screw and after aligning it with the crest, a hole corresponding to the implant in position 5 is made. The plate is then removed and the implant is placed into position 5. The S.I.S. plate is re-fixed, this time to the two implants in positions 4 and 5 and repeating the same sequence the implant is situated in position 6. The three fixtures are therefore tightly stabilised together on the S.I.S. plate using cover screws and to the osseous ridge using osteosintesis screws.

Finally, the whole implant-plate system is totally immobile and rigidly connected to the ridge. After having filled the area with bio-material, it should be covered with a collagen membrane (Biocollagen, Bioteck, Arcugnano – Italy) and a suture is performed using single and mattress stitches (supramyd 4-0, Butterfly Italia S. r. l. – Cavenago) (Fig. 3). Eight months on from the initial surgical phase, the second step is carried out. With a slightly palatal incision, partially elevate a flap with a large band of keratinized tissue to be moved in a vestibular direction. The cover screws, the osteosintesi screws and the S.I.S. plate are removed. After the insertion of healing abutments suture with single stitches (supramyd 4-0, But-

terfly Italia S.r.l. – Cavenago) (Fig. 4). Once healed, proceed with prosthetic restoration (Fig. 5).

## Verification systems

The quantification of the clinical data has foreseen: Evaluation of the initial bone width.

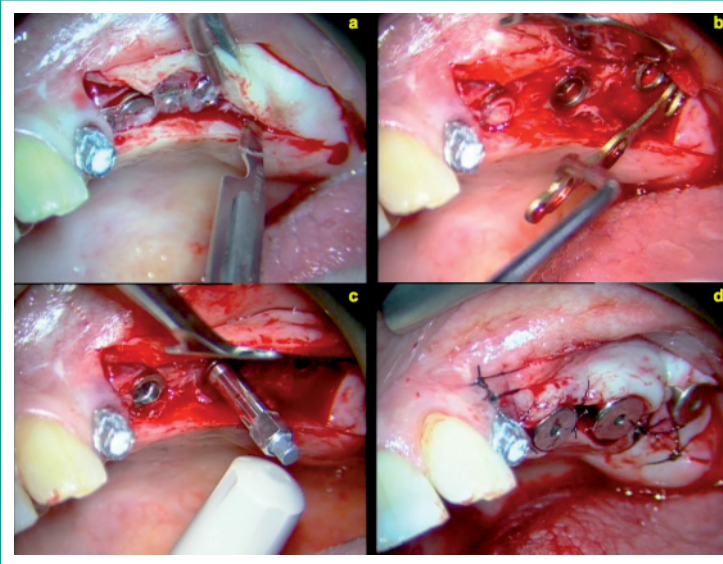
The evaluation of the initial bone width, i.e. the bone available in the implant placement area, was carried out through TC section analyses Dentascan using the Sidexis® (Sirona Dental Systems, Bensheim – Germany) software. The reference scale is the one integrated into the Dentascan images.

- Radiographic evaluation of the peri-implant bone levels at 0, 1, 6 and 12 months.

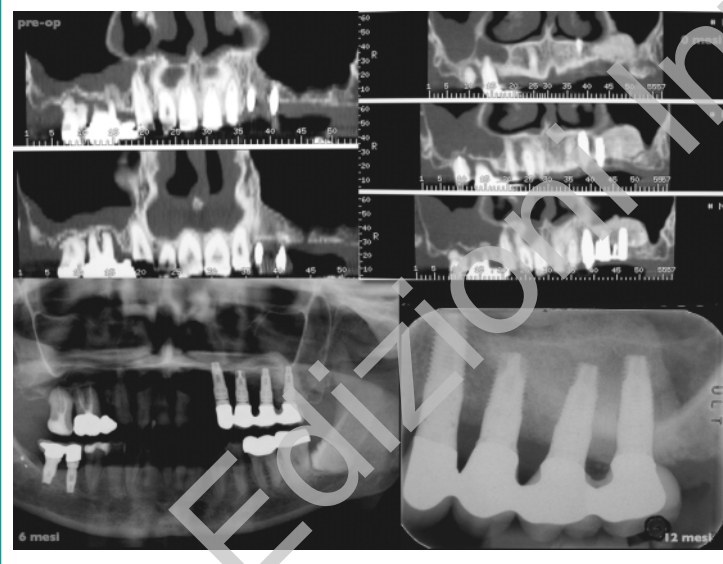
For the evaluation of the peri-implant bone levels, analogical radiographs were used with the standardised parallel technique. The digitalised radiographic images were then subjected to measurement carried out with the Sidexis® software using the known diameter of the implant as the reference scale.

- Evaluation of implant stability.

Implant stability is considered as a reliable indication of clinical osseo-integration (20, 21). Implant stability is measured through AFR (resonance frequency analyses) using Osstell® Mentor (Integration Diagnostics, Göteborg - Swe-



**Figure 4**  
Uncovering and removal S.I.S.: **a.** flap at partial thickness; **b.** removal S.I.S.; **c.** measuring ISQ; **d.** insertion healing abutments and suture.



**Figure 5**  
Check ups: **pre-op** - initial situation; 0 months - control CT after implants and S.I.S. insertion; 6 months - control OPT at definitive prosthesis; 12 months - control X-ray at 12 months from loading

den) equipment on uncovering of the fixtures (ISQ-0), and subsequently at one (ISQ-1), six (ISQ-6) and twelve months from loading (ISQ-12). This equipment supplies a numerical value called ISQ. The ISQ value (implant stability quotient) supplied indicates the level of stability of the implant. According to Nedir et al. (Nedir 2004) (22) ISQ values above or over 49 relate to an elevated level of safety for gaining osseointegration of an implant with delayed loading, while a value of more than or equal to 54 permits the application of an immediate load. In this study, in

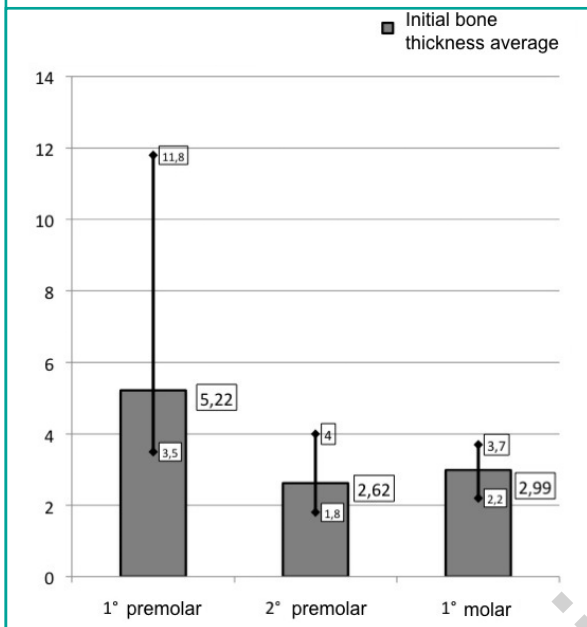
agreement with Cassetta et al. (Cassetta 2004) (23), implants with ISQ above or equal to 57 are judged suitable.

## Results and discussion

The global results have been summarised in table no. 1. Two implants (implant no. 30 in position 14 removed at the 12 month check up, implant no. 35 in position 15 removed at the 6 month check up) were removed because they resulted as mobile.



**Table 2** - Average values of the initial osseous widths in the different sites corresponding to the first premolar, the second premolar and first molar, including the minimum and maximum values.

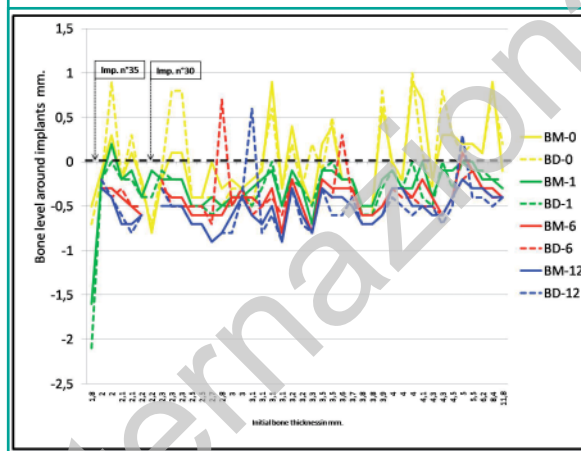


**Table 3** - Variation over time of implant stability in relation to initial osseous width (the failed implants have been highlighted).

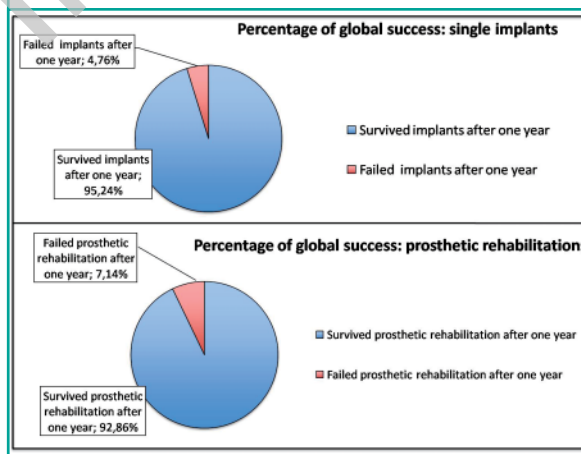


Table no. 2 illustrates initial bone levels. Even in atrophy classifiable as Misch Class IV, in an elevated percentage of cases, the site in zone 4 presented a greater osseous width ensuring good autonomous stability. In the sites in zone 5 and 6 however, there was serious atrophy with average widths respectively of

**Table 4** - Variation over time of the peri-implant bone levels (mesial and distal in relation to the initial osseous width (the failed implants have been highlighted).



**Table 5** - Percentage of global success.



2.62 mm and 2.99 mm. This would normally be insufficient to guarantee good primary stability. Table no. 3 shows the variation over time of the implant stability compared to initial bone width (the failed implants have been highlighted). This shows overall predictable behaviour. After the first month of loading, initial reduction of stability emerges. This reduction ceases to manifest itself and the values average go back up at 6 and 12 months. The highest stability values, in all phases, are reached by the implants with the greatest initial widths. Significant differences between the latter and implants with initial lesser widths cannot however be highlighted.

Table no. 4 allows for the visualisation of the variations of the peri-implant bone levels (mesial and distal) in relation to initial bone width over time (the failed implants have been highlighted). No implant, except the failed ones, have a osseous ridge-implant platform distance which is greater than 1mm after one year. Initial resorption can be seen at 1 and 6 months. Between 6 and 12 months it is possible to see good stability of the bone levels. There are no significant variations to be highlighted in relation to the levels of initial available bone.

The overall percentage of success has been summarised in Table no. 5. After one year, the success rate for the implants was 95,24% (2 implants failed out of 42), while the success rate of prosthetic restoration overall was 92,86% (1 rehabilitation failed out of 14). The difference between the number of failed rehabilitations and the number of failed implants is due to the permanence in the oral cavity of a perfectly functioning rehabilitation in which the implant in zone 15 was removed.

## Conclusions

The technique described seems to be able to ensure success in cases of Misch Class IV with contemporaneous insertion of osseointegrated implants. Compared to similar techniques, it appears to be more straightforward and reproducible, less dependent on the operator (10-14) and with less trauma (15). The technique described permits the immediate stabilisation of dental implants in Misch Class IV. This means considerably reducing treatment time. The results, positive at 12 months after loading, are in line with the success criteria seen in literature, even with the scarcity of literature concerning this topic. This clinical study, even though performed on a small number of patients (14) and implants (42) represents the largest case study published. The technique described seems to be able to ensure success in cases of Misch Class IV with contemporaneous insertion of the osseointegrated implants. The technique appears straightforward and reproducible without causing further trauma. Potential limits are presented by the conformation of the S.I.S. plate: it does not allow for the insertion of the second mo-

lar when lacking primary stability, it is impossible to contemporaneously correct horizontal defects and vertical ridge augmentation. It would be useful to modify the shape of the plate in order to allow the placement of the second molar and permit anchorage of the osteosintesi screws, not only in the centre of the ridge but also in palatal and vestibular positions.

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