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ORIGINAL ARTICLE

Immediate versus conventional loading of palatal implants in humans: a first report of a multicenter RCT

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Abstract This study aims to analyze the clinical performance of two loading concepts on second-generation palatal implants (Orthosystem, Straumann, Basel, Switzerland) in a prospective multicenter randomized controlled clinical trial. At the time of this interim analysis, 41 patients have been randomized on a 1:1 basis to one of two treatment

Britta A. Jung and Martin Kunkel contributed equally to this work.

Trial registration Current Controlled Trials ISRCTN97142521.

Authors' contributions BJ and MK designed the study and served as the main contact persons for the sponsor and secondary study centers. BJ was in charge of the organization and will be responsible for the documentation of the study, which includes data collection, ethics committee approvals (all study centers), and orthodontic treatment (primary study center); BJ wrote the present manuscript. MK and MM are responsible for surgical implant insertion (primary study center). MK will be responsible for histomorphometric analyses. HW has a national and international reputation in skeletal anchorage. His entire experiences and consolidated knowledge concerning skeletal anchorage will be rendered accessible to the investigators (BJ, MK, HW, WH, PD, TG, GL) for the current research proposal. Werner Hopfenmüller (WH) performed the sample size calculation. All authors have read and approved the final manuscript.

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groups. Group 1 underwent conventional loading of palatal implants after a healing period of 12 weeks (gold standard) while group 2 underwent immediate implant loading within 1 week after implant insertion. We report initial results at 6 months after functional loading. The primary outcome parameter was implant success (no implant mobility, no implant loss). The implants in both groups were initially stable at the time of insertion, and all were eligible for randomization. Twenty-two patients (group 1) were subjected to conventional implant loading after 12 weeks while 19 patients (group 2) received immediate functional loading within the first week after insertion. Direct (e.g. distal jet appliances) as well as indirect forms of anchorage (conventional or modified transpalatal arch) were used. The magnitude of orthodontic forces ranged between 1 and 4 N for the immediate loading group and between 1 and 5 N for the conventional loading group. One implant in group 1 was lost during the healing phase. One dropout was registered in group 2. Thirty-nine implants were functionally loaded for over 6 months now. These preliminary data provide first evidence of the fact that immediate loading of palatal implants yields equivalent success rates as conventional loading to 4 N after 6 months.

Keywords Immediate loading of palatal implants · Skeletal anchorage · Multicenter RCT

Introduction

In the last few decades, palatal implants have evolved as the new gold standard in positional stable anchorage. An overwhelming body of clinical [1–4] and experimental data has confirmed [5] that palatal implants subjected to a conventional loading concept after a healing period of 12 weeks are fully resistant to orthodontic forces, regardless of the diversity of anchorage forms and indications.

Although long-term results are still a source of controversy, the concepts of early and immediate loading concepts have been empirically established in conventional dental implantology [6–9]. According to the Cochrane Review Group [10], early loading is defined as implant loading between 1 week and 2 months after surgical insertion, whereas immediate loading is performed within 1 week after surgical insertion. By and large, success rates of 88.5% to 100% have been reported for dental implants [11].

Although the criteria [12, 13] generally used to allocate implants to an early or immediate loading concept are typically not fulfilled in palatal implants, the success rates derived from empirical case series have shown no substantial differences between the different loading concepts for palatal implants. However, these data have not been confirmed at the level of a randomized controlled trial.

At this time, we set out to initiate a multicenter RCT to clarify whether the concept of immediate loading can be transferred to short orthodontic anchorage implants. Apart from clinical success rates, limitations that may arise from immediate loading in the presence of different indications for skeletal orthodontic anchorage were addressed.

Therefore, the aim of the present RCT was to investigate the equivalence of immediate and conventional loading in second-generation palatal implants (Orthosystem, Straumann, Basel, Switzerland). In this communication, we report preliminary results in 41 patients after 6 months of functional orthodontic loading.

Methods/design

Study design and patients

The study was designed as a prospective, randomized controlled multicenter clinical trial. Patients were treated at four university centers: Mainz, Dresden, Greifswald, and Aachen (Germany). Local statutory board approval was obtained from the ethics committees of the provincial medical society of Rheinland-Pfalz, Mecklenburg-Vorpommern, and the institutional review boards of the University of Dresden and Aachen.

Based on a sample size calculation (WH; 0.8 power to detect a significant difference at the two-sided 5% level with an assumed loss to follow-up of 5%), the total study population will consist of 124 patients. The complete study protocol has been published recently [14].

Exclusion criteria were the following: cleft-lip and palate, syndrome-associated craniofacial anomalies, reduced immune defense, diseases requiring continuous steroid treatment, radiotherapy, or chemotherapy, bone metabolism disease, drug or alcohol abuse, and pregnancy.

The primary outcome variable was the clinical success of the implant (no implant mobility, no implant loss) 6 months after functional loading. The following parameters were analyzed as secondary endpoints: wound healing, peri-implant soft tissue reactions, and local mechanical complications secondary to the orthodontic appliances.

This interim analysis (Fig. 1) comprised 41 patients (35 female and 6 male patients) aged 12 to 65 years. Orthodontic treatment required stationary anchorage in all patients.

Pre-study calibration

Prior to the onset of surgical treatment, the surgeons involved in the study met to standardize the operative approach. All surgical steps were demonstrated via life surgery (MK) and repeated by *ex vivo* model surgery. The

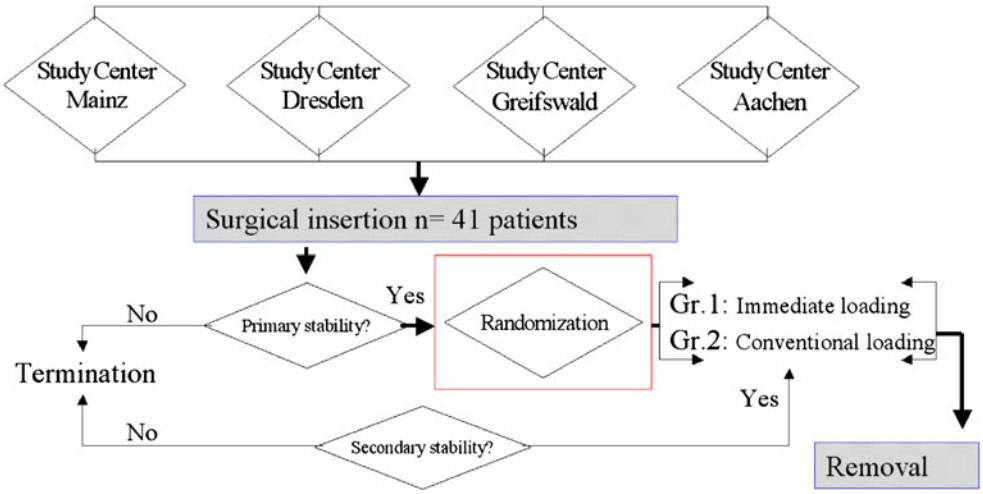

Fig. 1 The flow chart shows the course of the multicenter randomized controlled trial (RCT) from patient recruitment to conclusion of the study. Exclusion criteria were the following: **a** no primary intra-operative stability, **b** the implants could not be loaded because of the absence of secondary stability

orthodontists involved in the trial were informed about, and consented to, the individual orthodontic steps.

Palatal implant

Commercially available palatal implants of the second generation (Palatal implant, Straumann, Basel, Switzerland; diameter: 4.1×4.2 mm) with a sandblasted and acid-etched surface were used. In accordance with the manufacturer`s instructions, the implants were inserted in the paramedian or median region of the anterior palate. Following administration of oral antibiotics (20 mg/kg of a second-generation cephalosporin, 1 h prior to surgery), local anesthesia was given at the palatal foramina and the incisory canal. By means of a small mucosal punch, the palatine mucosa was removed at the insertion site. Using a round bur, a slight bony groove was created in or close to the midline. The implant site was then prepared in an ascending sequence of spiral drills to a diameter of 3.5 mm. All drilling procedures were performed under copious irrigation with sterile physiological saline. Then the self-cutting implant was inserted using the appropriate ratchet and was sealed with the healing cap.

Randomization

After clinical confirmation of primary stability, the implants were randomized in a 1:1 ratio at an independent external institute of biometry (Coordination Center for Clinical Trials (KKS) Mainz, Germany), using a computerized random numbers generator. According to the randomization fax, the implants were either subjected to loading after a healing period of 12 weeks (group 1, gold standard) or within 1 week (group 2). The allocation of treatment remained unchanged after randomization. All patients complied with the allocated protocol.

Criteria of implant stability and success

Primary stability was assessed intraoperatively by the surgeon and additionally by resonance frequency analysis. At the time of this interim analysis (6 months after functional loading), a palatal implant was rated "successful" (a) prior to preparation of the cast when there was no clinically detectable implant mobility and (b) during orthodontic treatment directly and indirectly when there was no clinically detectable implant mobility and when there was no undesired movement of orthodontic suprastructures.

An event of implant mobility was rated as failure because a clinically mobile palatal implant provides no absolute stationary anchorage per definition.

Suprastructure and force systems

Implants of patients in group 1 (conventional loading protocol, control group) were cast after about 10 weeks with alginate, when the implant was confirmed to be clinically stable. These implants were then subjected to functional loading after 12 weeks. Implants in patients of group 2 (immediate loading protocol) were cast immediately and functional loaded within the first week after insertion. All impressions in both groups were taken without direct pressure on the implants.

Depending on the type of malocclusion, a customized palatal suprastructure was prepared on the work model for both groups. Force magnitudes were measured chairside during insertion of the devices by the use of a spring balance (Correx, Haag Streit, Switzerland).

Statistical evaluation

Absolute and relative frequencies are given for the success rates for the palatal implants used in the study.

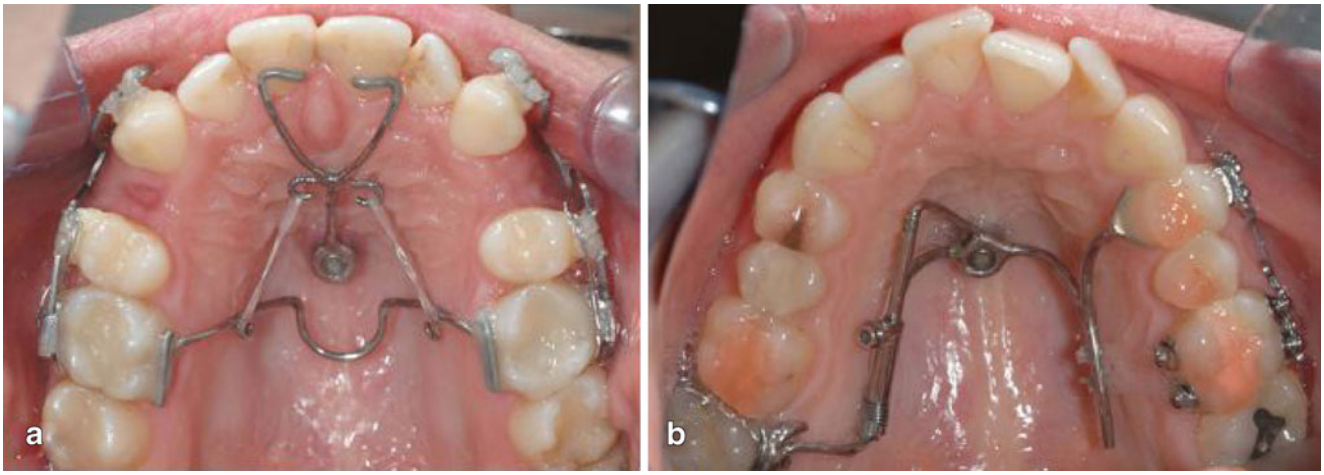

Fig. 2 Clinical situation shows direct implant anchorage **a** for symmetrical mesialization of posterior teeth and **b** for unilateral distalization using a distal jet appliance and indirect implant anchorage for unilateral intrusion

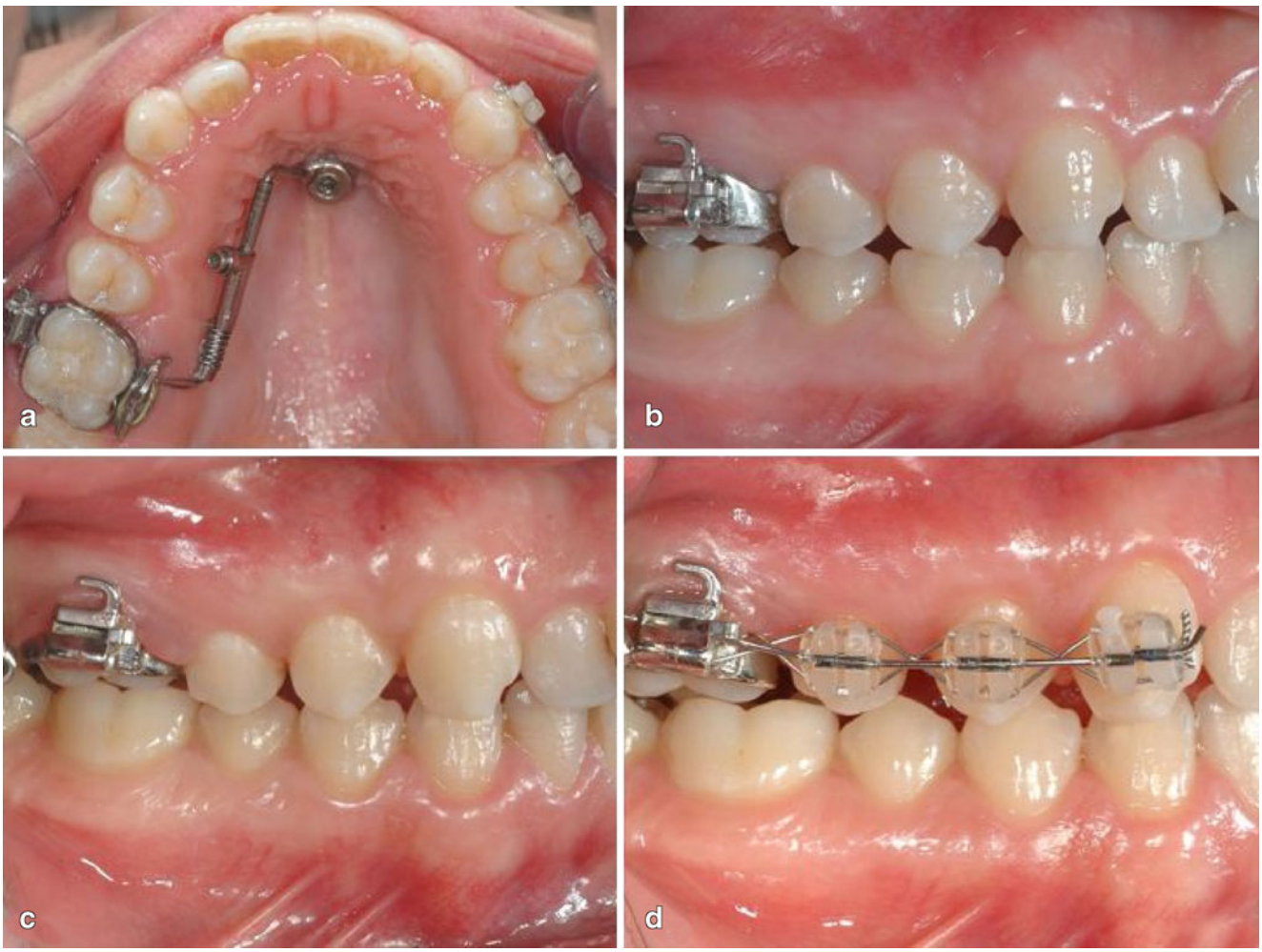

Fig. 3 Clinical situation shows direct implant (immediate-loaded implant) anchorage for unilateral distalization using a unilateral implant supported distal jet appliance before (**a**), during (**b**, **c**), and after (**d**) distalization of tooth 16

Table 1 Distribution of patients with regard to type of malocclusion, form of implant anchorage and orthodontic treatment of treated according to protocol 1 (n = 22)

Patient initials and gender	Study center	Indication	Orthodontic treatment	Loading concept	Form of implant anchorage	Dropout
FS, female	01	Angle class I	Alignment of impacted and displaced teeth	Conventional	Indirect	No
BJ, female	01	Angle class III, crowding, Ex 15, 24	Mesialization of upper posterior and anterior teeth (bilateral)	Conventional	Direct	No
KE, female	01	Angle class II, Ex 14, midline correction	Retraction of anterior teeth	Conventional	Indirect	No
WA, female	01	Angle class II	Distalization of upper anterior and posterior teeth	Conventional	Direct	No
FB, female	01	Angle class I, missing 26	Mesialization of posterior teeth (unilateral)	Conventional	Indirect	No
SB, female	01	Angle class III	Distalization of upper posterior teeth (bilateral) as part of preoperative treatment	Conventional	Direct	No
KA, female	01	Angle class I	Alignment of impacted and displaced teeth	Conventional	Indirect	No
HD, female	01	Skeletal class III tendency, crowding, Ex 14, 24	Mesialization of upper posterior and anterior teeth (bilateral)	Conventional	Direct	No
HK, female	01	Angle class II, crowding, Ex 15, 26	Retraction of anterior teeth	Conventional	Indirect	No
KS, female	01	Angle class I, spacing	Mesialization of upper posterior and anterior teeth	Failure (healing phase)	–	No
WL, female	03	Angle class II	Distalization of upper posterior teeth (unilateral left)	Conventional	Indirect	No
BS, female	03	Angle class II	Retraction of anterior teeth as part of preoperative treatment	Conventional	Indirect	No
FS, female	03	Angle class II, Ex 14, 24	Retraction of anterior teeth (bilateral)	Conventional	Indirect	No
HS, female	03	Angle class II, increased overjet	Distalization of upper posterior teeth (bilateral)	Conventional	Indirect	No
BA, female	03	Angle class II	Distalization of upper posterior teeth (bilateral)	Conventional	Indirect	No
HW, male	03	Angle class II, open bite, crowding	Distalization of upper posterior teeth (bilateral)	Conventional	Indirect	No
MK, female	03	Angle Class I	Alignment of impacted and displaced teeth 13 and 23	Conventional	Direct	No
HA, female	03	Angle class II	Distalization of upper posterior teeth (bilateral) and distalization 16 and 26	Conventional	Indirect	No
JH, female	04	Angle class I, unilateral crossbite	Correction of posterior crossbite, control of vertical dimension	Conventional	Indirect	No
MT, female	04	Angle class II, Ex 14, 24	Retraction of anterior teeth	Conventional	Indirect	No
KM, female	04	Angle class II	Distalization of upper posterior teeth (unilateral)	Conventional	Direct	No
EU, female	04	Angle class II	Retraction of anterior teeth	Conventional	Indirect	No

Results

Implant success, implant loss, and indication

Forty-one implants (one per patient) were inserted between December 2006 and January 2009. All palatal implants were clinically stable at the time of insertion and were therefore eligible for randomization. No complications were encountered during surgical insertion.

Twenty-two patients (group 1) were randomized to conventional implant loading after 12 weeks while 19 patients (group 2) were randomized to immediate functional loading within the first week after insertion. One implant in group 1 was lost during the healing phase (12th week post-insertion). One dropout was registered in group 2. The reason was non-adherence to the appointment for the postoperative control investigation. Thus, the implant could not be loaded within the first week. This implant was stable at the last clinical visit.

Thirty-nine implants (18 immediate-loaded and 21 conventionally loaded palatal implants) were functionally loaded

Table 2 Distribution of patients with regard to type of malocclusion, form of implant anchorage, and orthodontic treatment of treated according to protocol 2 (n = 19)

Patient initials and gender	Study center	Indication	Orthodontic treatment	Loading concept	Form of implant anchorage	Dropout
WT, female	01	Angle class I	Intrusion of 26	Immediate	Indirect	No
LC, female	01	Angle class III, aplasia 25	Mesialization of upper posterior teeth (unilateral)	Immediate	Indirect	No
SM, female	01	Angle class I, aplasia 12, 22	Mesialization of upper posterior teeth (bilateral)	Immediate	Direct	No
MM, female	01	Angle class II, aplasia 25	Mesialization of upper posterior teeth (unilateral)	Immediate	Indirect	No
HR, male	01	Angle class II	Intrusion and retraction of upper anterior teeth	Immediate	Direct	No
RP, female	01	Angle class I, asymmetric Ex 15	Retraction of anterior teeth, midline correction	Immediate	Indirect	No
KJ, female	01	Angle class I	Extrusion of 26	Immediate	Indirect	No
LT, female	01	Angle class II, open bite	Mesialization and intrusion of posterior teeth (bilateral)	Immediate	Direct	No
KB, female	01	Angle class I	Distalization of upper posterior teeth (unilateral)	Immediate	Direct	No
SK, female	01	Angle class II	Distalization and intrusion of upper posterior teeth	Immediate	Direct and indirect	No
DT, female	01	Angle class II	Distalization of upper posterior teeth (bilateral)	Immediate	–	Yes
RM, male	03	Angle class I	Palatal displaced canine	Immediate	Indirect	No
TC, female	03	Angle class II, asymmetric Ex	Distalization of upper posterior teeth (unilateral) left	Immediate	Indirect	No
KM, female	03	Angle class II	Distalization of upper posterior teeth (bilateral)	Immediate	Indirect	No
TL, female	03	Angle class I, missing 12 and 22	Mesialization of posterior teeth (bilateral), protraction of front teeth (upper jaw)	Immediate	Indirect	No
SF, male	03	Angle class I, crowding	Distalization of upper posterior teeth (bilateral)	Immediate	Indirect	No
MC, male	03	Angle class II, impaction of canine 13, 23	Space opening, distalization, and elongation	Immediate	Indirect	No
RS, male	04	Angle class II, Ex 14, 24	Retraction of anterior teeth	Immediate	Indirect	No
MJ, female	04	Angle class I, Ex 15	Retraction of anterior teeth	Immediate	Indirect	No

for more than 6 months now. Direct (force system between the anchorage implant and the teeth that were to remain mobile; e.g. distal jet appliance) as well as indirect forms of anchorage (rigid connection—orthodontic wire—between the anchorage implant and the teeth; e.g. conventional or modified transpalatal arch-based devices) were used (Figs. 2 and 3).

The distribution of direct and indirect forms of anchorage and the principal indications of distalization, mesialization, and setting of impacted teeth were nearly identical in the two loading groups (Tables 1 and 2). The forces ranged between 1 and 5 N for the conventional loading group and between 1 and 4 N for the immediate loading group. No patients have reported pain in connection with orthodontic devices.

Wound healing, peri-implant findings, and local mechanical complications

During the healing phase as well as 6 months after functional loading, all implants showed mild mucositis in the peri-implant region. Neither mucositis nor the hyperplastic reaction in the peri-implant region caused pain or jeopardized the stability of the implant.

In one patient subjected to immediate implant loading, the transpalatal bar fractured after 4 weeks of force application and had to be replaced. However, this did not affect the stability of the implant.

The site of adhesion (e.g. ends of transpalatal arches) to the anchoring tooth had to be renewed at least once in five cases.

Discussion

Preliminary clinical data concerning early and immediate loading protocols of palatal implants have been derived from ongoing clinical trials, with success rates ranging between 90% and 100% [15, 16]. These data referred solely to strict indirect implant loading with orthodontic forces to 4 N. However, in addition to indirect forms of anchorage, other forms such as direct implant anchorage are also used under routine conditions. The yet unanswered questions with respect to different indications concern the applicability of the early/immediate loading concept for various anchorage forms and different magnitudes of orthodontic forces.

A recent retrospective clinical and histological analysis of 76 implants (36 subjected to immediate loading within the first 24 h post-insertion and 40 palatal implants subjected to conventional loading) inserted and loaded in private practice demonstrated the effectiveness of this treatment concept, regardless of the institutional setting [17]. In this case series, we found success rates of 92% for immediate loading implants and of 97% for conventional loaded implants. However, the results of this retrospective analysis will have to be confirmed in a prospective randomized controlled study.

The preliminary data obtained in this RCT for 18 immediate-loaded and 21 conventional loaded palatal implants 6 months after functional loading support the principal equivalence of early loading (within 1 week post-insertion) of palatal implants in spite of a multitude of different devices.

The only implant lost thus far had been allocated to conventional loading but was lost during the healing phase prior to force application.

Up to now, specific parameters related to the type of treatment such as unilateral anchorage forms and the indications or the magnitudes of orthodontic forces did not influence the stability or success of the implants. Thus, we observed no limitations of indications 6 months after functional loading with respect to the principal indications of distalization, mesialization, and alignment of impacted teeth.

Further aspects such as patient's access for oral hygiene and mechanical complications of palatal implants have also been addressed: implants subjected to immediate loading as well as those subjected to conventional loading showed mild mucositis in the immediate peri-implant region. Minimal mucosal reaction has been reported earlier in connection with conventional-loaded palatal implants of the second generation [2]. However, these conditions did not affect the stability of the implants within the time frame of our study.

Conclusions

These preliminary data provide first evidence that immediate loading of palatal implants yields equivalent success rates as conventional loading regardless of treatment indication, force directions, and type of appliance.

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Conflict of interest The authors declare that they have no conflict of interest.

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