

REVIEW ARTICLE

Early and Immediate Loading Protocols for Overdentures in Completely Edentulous Maxillas: A Comprehensive Review of Clinical Trials

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ABSTRACT

A comprehensive review was conducted to answer the question 'Does the immediate loading of dental implants with an overdenture in the maxilla provide predictable clinical and psychological outcomes?' Detailed search strategies were used to identify pertinent articles in English that were published between 1975 and August 2013 and indexed in PubMed, MEDLINE, Embase, The Cochrane Central Register of Controlled Trials, and a personal library; in addition, relevant journals were manually searched. Only randomized controlled clinical trials (RCTs), controlled clinical trials (CCTs), and prospective studies with a follow-up period of at least one year, all involving 10 or more adult participants, were considered. Six prospective studies reporting on outcomes of up to 2 years were included, five of which employed a bar-retained overdenture, and one of which used a ball attachment as a retention mechanism. Short term reports demonstrate that immediate/early loading of dental implants with a maxillary overdenture is a predictable treatment approach and results in favorable implant/prosthesis survival, soft tissue health, and patient satisfaction outcomes. However, for a definitive conclusion, well-designed long-term trials are required to establish a consensus on treatment planning, longevity, long-term complications and maintenance, cost-effectiveness, and patients-mediated outcomes.

Keywords: Implant, Immediate loading, Early loading, Maxilla, Overdenture, Review.

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INTRODUCTION

The original implant loading protocol recommended by Branemark et al was based on maintaining maximum primary stability and avoiding any loading factors that might challenge the osseointegration process.¹ Often, the second-stage surgery would not occur until at least 3 to 4 months after the implant placement surgery. However, as a result of advances in implant systems and in clinicians' understanding of the nature of the osseointegration process, the original treatment protocol has been questioned. Single-stage surgery and early and immediate loading protocols have been explored since the early 1990s.^{2,3} The number of clinical trials reporting high success rates for dental implants that were loaded earlier than the originally recommended load-free period continues to increase.⁴⁻¹¹

Despite 20 years passing since the introduction of immediate/early loading protocols, there is no consensus on the definition of 'immediate' and 'early protocols. Consequently, throughout the dental literature, the same terminology may be used to describe different loading times.¹²⁻¹⁶ However, immediate implant loading often refers to the occlusal loading of an implant-supported or retained prosthesis within 48 hours of implant placement surgery. Early loading is described as the occlusal loading of implants between 2 days and 3 months after implant placement surgery.¹⁶

The rationale for the immediate and early loading protocols is to shorten the time frame for both surgery and prosthesis insertion. They should therefore translate into the faster achievement of masticatory functional occlusion and improved aesthetics without affecting the high success rates that have been reported for endosseous dental implants. However, for immediate loading protocols to be deemed successful, consideration should be given to several key factors pertaining to the surgical and prosthodontic aspects. These factors include primary implant stability and control of micromotion, implant geometry and surface topography, surgical technique, bone quality and quantity, prosthesis design, and occlusal forces.

The objective of this literature review was to present sound clinical evidence about the use of an immediately loaded implant-supported overdenture in the edentulous maxilla, to scientifically appraise the reported clinical and psychosocial outcomes. The methodology, results, conclusions, and drawbacks are analyzed, and recommendations for future studies are provided.

MATERIALS AND METHODS

Search Strategy for Identification of Studies

Comprehensive search strategies were developed for each database. These were based on the search strategy developed for PubMed but modified for each database. Articles published in English peer reviewed journals between 1975 and August 2013 were searched. The databases included PubMed, MEDLINE, Embase, and The Cochrane Central Register of Controlled Trials.

The search strategy combined controlled MeSH with free text terms based on the following: Dental Implants, (dental implantation) or Dental Implants, Dental Prosthesis, implant supported dental prosthesis, overdenture, (dental or oral), maxilla, maxillary, immediate loading, early loading, [(Dental Implants) or ((dental implantation) or (Dental Implants))] or Dental Prosthesis] or (implant supported dental prosthesis) or (dental or oral), [(Dental Implants) or (dental implantation) or (Dental Implants) or Dental Prosthesis) or implant supported dental prosthesis] or (dental or oral) and (overdenture) and (maxilla) and immediate loading.

Manual Searching

The following journals were identified and searched manually:

Clinical Implant Dentistry and Related Research, International Journal of Prosthodontics, British Journal of Oral and Maxillofacial Surgery, Implant Dentistry, International Journal of Oral and Maxillofacial Implants, International Journal of Oral and Maxillofacial Surgery, International Journal of Periodontics and Restorative Dentistry, Journal of the American Dental Association, Journal of Biomedical Materials Research, Journal of Clinical Periodontology, Journal of Dental Research, Journal of Oral Implantology, Journal of Oral and Maxillofacial Surgery, Journal of Periodontology.

Journal of Prosthetic Dentistry, Clinical Oral Implants Research, and Journal of Prosthodontics. The bibliographies of all of the included papers and relevant review articles were checked for studies published outside the manually searched journals. A personal library was also searched.

Criteria for Studies to be considered for this Review

Designs of Studies

Prospective studies, RCTs and CCTs that reported outcomes of immediate or early loaded endosseous implants with a complete maxillary overdenture. The minimum post-insertion follow-up was 1 year.

Type of Participant

Completely edentulous adult patients.

Type of Intervention

Implant-supported maxillary overdenture.

The main inclusion and exclusion criteria for this review are listed in Table 1.

Types of Outcome Measures

Assessment of function and treatment failure.¹⁷ The key determinants reflected both the patients' and the dentists' concerns and included the following domains: success/survival and psychological impact.

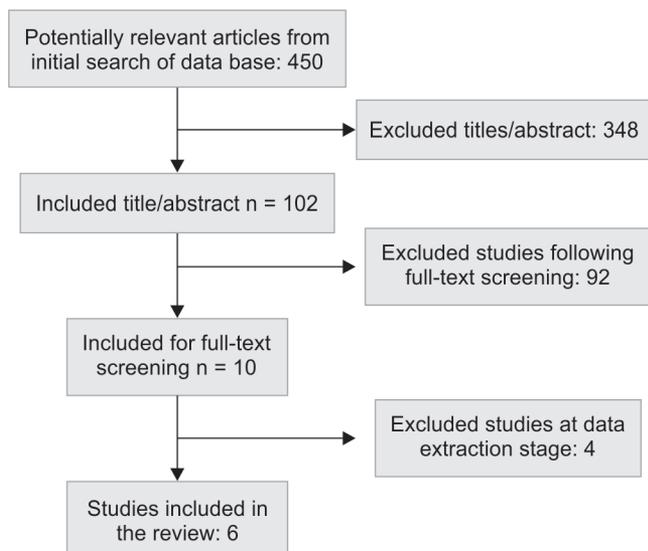
For each study included, the following outcomes were recorded when available:

- a. Psychological impact:
 - Patients' satisfaction with the treatment, aesthetics, function, and changes in the quality of life, and the patients' preference regarding treatment.
- b. Cumulative success/survival of implants and/or prostheses.
- c. Biological complications:
 1. Marginal bone loss.
 2. Incidence and severity of neurological disturbances and pain.
- d. Mechanical complications:
 1. Type and frequency of adjustments/maintenance.
 2. Incidence of prosthesis failure.

Table 1: Studies' inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Randomized controlled trials and prospective studies	1. Does not report outcomes for edentulous arches separately
2. Completely edentulous maxilla	2. Outcome data poorly controlled for confounding variables
3. Implant-supported overdenture on one or more dental implants	3. Less than 10 patients
4. Number of participants ≥ 10	
5. Number of subjects and implants per subject stated	
6. Follow-up period of ≥ 1 year	

Flow Chart 1: Search strategy of relevant articles



Data Collection and Analysis

The titles and abstracts of all the reports identified were scanned. For studies that met the inclusion criteria, or where the title/abstract presented insufficient data to make a clear-cut decision, the full-text article was obtained. All studies included underwent validity assessment and data extraction. The studies rejected at the full-text stage and the reasons for their exclusion were recorded.

Quality Assessment of included Studies

At the data extraction stage, the methodological quality of the included trials was evaluated. Five main quality criteria were assessed, i.e., the randomization process; the allocation concealment method; the blinding of the clinician/investigator, patient, and outcome assessor; the clarity of reporting on participant drop out and withdrawals; and the definition of the inclusion/exclusion criteria.

The Following Data were recorded for Each Trial

Author(s), study design, year of publication, source of funding, source of recruitment of the participants and criteria for inclusion/exclusion, details of the type of treatment intervention, follow-up period, number of participants and implants, number of implants per subject, type of implant system used, implant length, timing of loading, overdenture attachment type, implant and prosthesis success rate, implant and prosthesis survival rate, peri-implant marginal bone loss, patient satisfaction, opposing dentition, use of bone graft at the implant site, occlusal scheme, soft tissue condition and related complications, and special post-operative instructions.

RESULTS

The initial search yielded 450 potentially relevant articles. The application of additional inclusion criteria resulted in 102 eligible articles. Of these articles, 10 were selected for extensive full-text analysis. Four articles were excluded, and 6 were included (Flow Chart 1).¹⁸⁻²³ All of the included studies were prospective clinical trials and included adults only. The earliest paper included was published in 2003,²¹ and the most recent was published in 2012.¹⁹ One study reported data for 2 years,¹⁸ whereas the rest had a follow-up period of one year. Two studies presented results for immediately loaded implants (4 to 48 hours post implant placement surgery),^{22,23} and four studies reported on early loaded implants (2 to 12 weeks post implant placement surgery).¹⁸⁻²¹ All but one study²⁰ employed a bar as an attachment system. The overdentures were supported by at least three and not more than eight implants (Table 2).

DISCUSSION

Early loading with maxillary overdenture:

1. Outcomes comparing success/survival:
 - a. *Implant success/survival rates*: The implant success rates ranged between 81 and 100%.^{18,20,21,23} A momentous finding of the current review is that the overall implant success and/or survival outcomes have improved significantly since the first published study in this field. This improvement can be attributed to the recent development of implant surface topography and to clinicians' better understanding of the nature of the osseointegration mechanism and possible compromising factors. Another significant finding is the general trend in the timing of implant failure. Most failures occurred within the first two months of implant loading. This time period is critical because it is when most of the peri-implant bone healing and remodeling occurs. The control of micromotion at the bone-implant interface is considered one of the most significant biological requirements for the healing of a load-bearing endosseous implant.^{24,25} However, control does not mean that micromotion must be prevented. In fact, it has been demonstrated that well-controlled micro-motion enhances bone formation at the bone-implant interface of an implant.^{26,27} Nonetheless, there is a critical threshold of micromotion, above which fibrous encapsulation prevails over the osteogenesis and osseointegration of an endosseous implant. It is believed that micromotion should be less than

Table 2: Studies on immediate or early loaded implants with overdenture in the maxilla

Author, Year	Study design	Observation period	Number of participants	Number of implants	Implants/ patients	Implant type	Implant length	Time of loading	Attachment type	Success rate
Slot et al, 2012	Pros.	1 year	50	300	6	- Ant gp: OsseoSpeed Astra Tech. - Post. gp: SLA Straumann	- Ant. gp: ≥ 11 mm - Post. gp: 12 mm	- Ant gp: 3 mts. - Post. gp: 2 wks.	Bar	- Ant. gp: 98% (b) - Post. gp: 99.3% (b)
Payne et al, 2004	Pros.	1 year	39	117	3	- Gp1: Branemark Nobel Biocare - Gp2: Southern Implants	10-15 mm	12 wks.	Ball	81% (a) 84.61% (b)
Raghoobar et al, 2003	Pros.	1 year	10	68	6 or 8	Osseotite 3i	11.5-15	2 mts	Bar	95.6% (a)
Cannizzaro et al, 2007	Pros.	1 year	12	48	4	Tapered Swiss Plus Zimmer Spline	≥ 10 mm	4-8 hrs	Bar	97.9% (a)
Van Assche et al, 2012	Pros.	2 years	12	72	6	SLActive, Standard Plus, Straumann	6-14 mm	6 wks	Bar	- Short impls: 97.9% - Long impls: 100%
Pieri et al, 2009	Pros.	1 year	22	103	4 or 5	PrimaConnex	10-15	48 hrs	Bar	95.2% (a) 97.1% (b)

(a): Success rate, (b): Survival rate, Impl: Implants. Ant: Anterior; Posterior

100 μm to achieve functional bone-to-implant contact. Micromotion of the body of the implant of over 150 μm has been demonstrated to disturb normal bone healing around implants, leading to the fibrous encapsulation of the implant.²⁸

In subjects with 5 or fewer implants, it was necessary to replace a lost implant to support the maxillary overdenture.^{22,23} Such replacement was not necessary if six or more implants were placed.^{18,19,21} There is as yet no consensus on the minimum required number of immediately loaded implants to support a complete maxillary overdenture. However, the lower cancellous bone density and thinner trabeculae in the maxilla together with the substantially thinner cortex compared to the mandible^{29,30} requires a higher number of loaded implants to compensate for these compromising factors if significantly successful outcomes are to be achieved. This increased number of implants is especially true if the healing process at the bone-implant interface is to be challenged by loading forces.

Three studies reported on the implant survival rate, which ranged between 84.61 and 99.3%.^{19,20,23} The effect of the implants' site on the cumulative survival was also investigated.¹⁹ Recently, slot assessed the treatment outcomes of maxillary overdenture supported by six implants. The implants were placed either in the anterior region (i.e., the anterior area of the maxilla between the first premolars) or in the posterior region, using a different implant system for each group. Although the two groups were not directly compared to each other because different implant systems were used, the one-year survival rates demonstrated high success (anterior group: 98%, posterior group: 99.3%). The authors concluded that the early loading of six implants placed in either the anterior or posterior regions of the maxilla and splinted with a rigid bar is a feasible treatment option. This study is the only one that attempted to compare the success rate of early-loaded implants in the anterior and posterior maxilla. These encouraging results may suggest that the rigid splinting of the early loaded implants to control the amount of micromotion has a more significant role in achieving successful osseointegration than the bone quality per se; however, more clinical trials are required to further investigate this assumption.

Ridge-expansion-with-osteotome-only showed a higher probability of implant survival compared to a combined ridge-split-and-osteotome proce-

dure (95.7 and 83.3%, respectively).²⁰ The authors commented that the study findings suggest that rehabilitating edentulous maxilla using implant-supported overdentures is more likely to be successful if ridge-expansion-with-osteotome-only is performed at an earlier stage, before much atrophy of the maxilla has occurred. This conclusion is in line with what is known about the role of bone quantity in the success of osseointegration.^{2,31-36} Mechanical trauma may cause microfracture of the bone during implant placement, which can lead to osteonecrosis and possible fibrous and granulation tissue encapsulation around the implant instead of osseointegration. Thus, minimizing the surgical manipulation of the bone bed is recommended to reduce mechanical trauma and the consequent implant failure.

Implants placed in extraction sockets showed comparable survival and success rates to implants placed in healed ones (100 and 96.7%, respectively).²³ Hence, it could be speculated that the immediate rigid splinting of four or more implants will provide adequate primary stability for the implants, therefore compensating for the less than ideal site in the form of fresh extraction sockets.

- b. *Prosthesis survival*: Five studies reported on this outcome.^{18,19,21-23} All provided the patients with bar-retained overdentures. None of the maxillary overdentures was replaced as a result of technical complications, which translates into an overall prosthesis survival rate of 100%. This result is in line with the high prosthesis survival rate reported for immediately loaded mandibular overdentures.³⁷⁻³⁹
2. Outcomes comparing biological complications:
 - a. *Adverse changes (alveolar bone loss)*: Another interesting finding of this review is that in spite of the variation among the included clinical trials in terms of the experimental characteristics, the amount of peri-implant marginal bone loss was comparable.¹⁹⁻²¹ It ranged from 0.2 to 0.7 mm, which is less than the acceptable amount of peri-implant bone loss suggested by Albrektsson and Zarb during the first year of implant loading.⁴⁰ Van Assche and coworkers presented results for early loaded SLActive implants splinted using a bar superstructure.¹⁸ The most distal implants in each quadrant were 6 mm in height (S), and the rest of the implants ranged between 10 and 14 mm (L). The one- and two-year marginal bone loss for the long implants was higher than the values reported by other researchers (1.3 and 1.5 mm, respectively).

The authors suggested that the observed amount of bone loss may be explained by the fact that most of these patients lost their teeth because of severe periodontitis. Heavy smokers and patients with poor oral hygiene experienced excessive localized bone loss. Parafunction (clenching and bruxing), and dehiscences that resulted from further resorption of the anterior jawbone were also possible reasons for the reported increased peri-implant marginal bone loss.¹⁸ It is unlikely that the placement of short implants in the most distal sites resulted in occlusal overload and consequently contributed to the increased amount of peri-implant bone loss. This assumption is further supported by the observation that the bone loss around the short dental implants, which were placed closer to the fulcrum of the mandibular lever and were thus subjected to a higher amount of occlusal load, remained within the acceptable range. However, more studies, perhaps with fewer confounding factors, are needed to reach a sound conclusion.

- b. *Soft tissue*: Two studies used gingival index,⁴¹ bleeding and plaque indices (Mombelli et al, 1987)⁴² to qualify the degree of peri-implant inflammation. The mean indices showed favorable results, in line with the results reported in the literature for the delayed loading protocol.⁴³

The one- and two-year probing depth was associated with healthy soft tissue. It ranged between 3.2 and 4.3 mm.^{18,19,21} The study by Van Assche and colleagues was the only study found to report on the incidence of gingival hyperplasia in early loaded maxillary overdentures.¹⁸ Four out of twelve patients (33%) experienced some form of gingival hyperplasia. A higher frequency was reported with the delayed loading protocol.⁴⁴ Katsoulis et al. recorded the maintenance services performed during the first two years after the insertion of a bar-retained implant-supported maxillary overdenture in 16 patients. Sixty five percent of the patients exhibited hyperplasia of the peri-implant mucosa. Because the available evidence on peri-implant soft tissue condition in the immediately loaded maxillary overdentures is limited, the data were compared to the early loading protocols. Four or five implants were loaded with a maxillary overdenture within 48 hours post-surgery in twenty-two patients.²³ Twelve months post-loading, gingival hyperplasia was observed in only 22.5% of the patients. This frequency is comparable to the early loading protocol.¹⁸

3. Outcomes comparing mechanical complications:
 - a. *Types and frequency of adjustment/maintenance*: The scientific evidence regarding this clinical parameter is lacking. Only one study documented the maintenance requirements of early-loaded implant-supported maxillary overdentures after two years of loading.¹⁸ The reported adjustments were not major. Two patients required gold screw tightening. The adaptation of occlusion and relining were required in another patient. No replacement or activation of clips was needed. A systematic review on the treatment considerations for maxillary implant-overdenture stated that, regardless of the anchorage system, the most frequent complication in maxillary overdentures involved the fracture of the prosthetic components as a result of a change in the retention system.⁴⁵ This problem was not encountered in the study by Van Assche and colleagues. Although the follow-up period was relatively short, the careful planning that included a balanced occlusion and articulation pattern in the centric and eccentric positions, the use of composite resin teeth, and the use of a CoCr-reinforced denture base have all contributed to the low frequency of complications.
4. Outcomes comparing psychological impact:
 - a. *Patient satisfaction with treatment*: Scientific evidence regarding patient satisfaction was presented in two studies.^{19,21} A validated questionnaire that focused on complaints related to the function of the prosthesis and to esthetics was administered before and one year after the fabrication of the maxillary overdenture.⁴⁶ In addition, the patients were asked to express their overall satisfaction on a 10-point rating scale (1 = very bad to 10 = excellent). Overall, the patients were satisfied with their overdentures in terms of functional complaints, facial esthetics, esthetics of the denture, and neutral space. However, the patients who received 6 implants in the anterior region only to support the maxillary overdenture did not note a significant improvement in esthetics. Further, the patients who had all 6 implants placed in the posterior region showed no significant improvement in the accidental lip, cheek, and tongue biting (neutral space) parameters.¹⁹ In both situations, a possible explanation for the resulting compromised esthetics and function is the lack of interarch space required to accommodate the implant hardware, the thickness of the denture base, and the acrylic teeth. This limitation might have restricted the clinician's freedom to set the denture teeth in a more functionally and esthetically desirable position.

- b. *Patient satisfaction with chewing*: The ability to chew nine different types of food was recorded on a 3-point scale (0 = good, 1 = moderate, and 2 = bad).¹⁹ The mean score of chewing ability for soft, tough, and hard food improved significantly from conventional complete dentures to implant-supported overdentures one year later, following the early loading protocol. This improvement is comparable to what has been reported with the conventional loading protocol using overdentures with different retention/support systems.^{47,48} Although these findings are encouraging, it would be interesting to investigate the chewing ability during the first few months of implant loading, when both the hard and soft tissues are healing/remodeling, the implant stability is challenged, and the patient is adjusting to the new denture and retention/support system.

Immediate Loading with Maxillary Overdenture

Only two related studies were eligible for inclusion in this review.^{22,23} In the study by Cannizzaro et al., 12 patients were rehabilitated by means of 4-implant bar-retained overdentures. The implants were loaded four to eight hours post-placement. In another study, 103 implants were inserted in the edentulous maxilla and loaded 48 hours later. Each patient received a bar-retained maxillary overdenture supported by four or five rigidly connected implants.²³ The reported implant survival rate in both studies exceeded 97%. The overall cumulative prosthesis success rate one year post loading was 100%. Soft tissue complications and postoperative pain were very minimal.

The mean peri-implant bone loss between the baseline (implant loading) and the one-year post-loading visit was well below 1 mm, the maximum acceptable amount of periimplant bone loss suggested by Zarb and Albrektsson.⁴⁰ Furthermore, the average bone loss observed is similar to the loss reported by other researchers for the immediate loading protocol in other areas of the mouth and using various types of prostheses.^{40,49-51,52}

Table 3 summarizes the frequency of the prosthetic complications observed during the first year of loading. The most common complication was the frequent need for denture relining. This need is expected, as in the immediate loading protocol, the denture is fitted on swollen soft tissue as a result of the flap design and buccal elevation. Furthermore, the continuous edematous ridge remodeling during the healing process might contribute significantly to the frequent need for a complete relining of the denture.

Patient satisfaction was significantly better than with conventional dentures in five categories (comfort, chewing ability, esthetics, ability to speak, and general satisfaction).²³ However, the patients considered conventional complete dentures easier to clean. This difference was statistically significant. Because the majority of the patients seeking implant-supported complete dentures are elderly with some degree of limited manual dexterity, maintaining a plaque-free environment, especially around the retentive components of the overdenture, presents a daily challenge for this category of patients. Therefore, it is crucial to have a regular hygiene follow-up program to achieve a satisfactory long-term outcome.

All of the studies included were prospective, with well-defined inclusion/exclusion criteria, and had a clear explanation for drop outs and withdrawals in each study group. However, the randomization of patients, blindness of the surgeon/outcome assessor if possible, and intention to treat analysis were not applied in most of the included studies. These clinical trial design parameters are crucial to minimize differences between the subject groups at the outset of the trial. They also aid in controlling any possible intervention or assessment biases.

In conclusion, the available short-term scientific evidence on the immediate and early loading of dental implants with an overdenture is limited. Nonetheless, it demonstrates that, in the short term, this treatment modality is a predictable option in terms of implant/prosthesis survival, soft tissue health, and psychological outcomes. However, the results of this modality in the context of longevity, long-term complications and maintenance, cost-effectiveness, and patient-mediated concerns are yet to be investigated. Additionally, well designed, long-term RCTs and CCTs are required to allow sound conclusions in this subject. It is recommended that such trials include a sufficient number of patients (with sufficient power) to disclose a true difference (if any), appropriate group allocation concealment, reproducible measurement techniques, and independent outcome assessors when blinding is not achievable to minimize the assessment/detection bias. Finally, researchers should try to adhere to the reporting guidelines of the Consolidated Standards of Reporting Trial (CONSORT).⁵³

Table 3: Frequency of prosthetic complications for maxillary overdentures

Complication type	Frequency
Loose abutments	2
Tooth fracture	1
Overdenture fracture	1
Loose gold screw	2
Denture pressing on mucosa	2
Need for reline	1

CONCLUSION

The limited number and heterogeneity of the available studies precluded a decisive conclusion on this topic. Nonetheless, in the short term, it can be concluded that the immediate/early loading of dental implants with a maxillary overdenture is a predictable treatment approach and provides favorable implant/prosthesis survival, soft tissue health, and psychological outcomes. However, well-designed long-term trials are necessary to establish a consensus on longevity, long-term complications and maintenance, cost-effectiveness, and patients' concerns.

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