LITERATURE REVIEW

Comparative study of splinted and unsplinted implant-retained maxillary overdentures without palatal coverage: A literature review

Estudo comparativo de sobredentaduras implantorretidas esplintadas e não-esplintadas sem cobertura palatal: Uma revisão de literatura

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ABSTRACT

The palatal coverage is considered as an auxiliary element in the distribution of tensile strains on implant maxillary total prosthesis (implant overdentures) bases, either implant-supported or retained. However, complaints in some patients due to palate and phonetic impairment are constant. The palatal coverage removal would allow the improvement of these issues as well as pharyngeal control, salivary flow and hygiene. Thus, this literature review proposed to analyze the survival rates of dental implants retaining an implant maxillary overdenture without palatal coverage in edentulous maxilla. The review was conducted in Medline database, via PubMed between 2000 to 2016 period, and limited to English language publications. The search strategy took the following key-words, referencing title and / or abstract: dental implants; maxilla; maxillary; overdenture; and palatal coverage. According the data, the rehabilitation of the maxillary edentulous with four implant-supported overdentures with bar attachments and implant-retained with ball attachments has shown great survival rates of dental implants, but there are a few studies reporting the survival rate of implant overdentures. It was concluded that the prosthetic rehabilitation of total maxillary edentulous patients is viable through palateless implant overdentures when a minimum of four to six implants were used with careful planning and execution.

KEYWORDS

Dental Implants; Maxilla; Overdenture; Palatal coverage.

RESUMO

A cobertura palatal é considerada como um elemento auxiliar na distribuição das tensões nas bases das próteses totais maxilares associadas a implantes (sobredentaduras), tanto implantossuportadas ou implantorretidas. Entretanto, as queixas de alguns pacientes devido ao comprometimento do paladar e fonética são constantes. A remoção da cobertura palatal viabilizaria a melhora destas questões, bem como do controle faríngeo, fluxo salivar e da higiene. Deste modo, esta revisão sistemática de literatura buscou analisar as taxas de sobrevivência dos implantes dentários que retêm uma sobredentadura implantossuportada ou implantorretida na maxila edêntula. A revisão foi conduzida na base de dados Medline, via PubMed, entre o período de 2000 a 2016, e limitada às publicações na língua inglesa. A estratégia de busca assumiu as seguintes palavras-chaves, referenciando título e / ou resumo: implantes dentários; maxila; maxilar; sobredentadura; e cobertura palatal. De acordo com os resultados, a reabilitação dos edêntulos maxilares com sobredentaduras implantossuportadas com quatro implantes e retenções à barra e implantorretidas com retenções esféricas têm mostrado excelentes taxas de sobrevivência de implantes dentários, mas existem poucos estudos reportando a taxa de sobrevivência das sobredentaduras associadas a implantes. Foi concluído que a reabilitação protética de pacientes edêntulos totais de maxila é viável através de sobredentaduras associadas a implantes sem cobertura do palato quando um mínimo de quatro a seis implantes forem usados com cuidadoso planejamento e execução.

PALAVRAS-CHAVE

Implantes dentários; Maxila; Sobredentadura; Cobertura palatal.
INTRODUCTION

Many patients suffer from total edentulism and need treatment with prosthesis supported exclusively by fibromucosa, characterizing a conventional total prosthesis. Wide partial bone reabsorption occurs over the years in this type of prosthesis in some patients, becoming the support compromised that result in poor retention and stability of conventional total prosthesis. It generates a great impact on quality of life and well-being [1].

The advent of osseointegrated dental implants overcame those issues by allowing the recovery of the basic requirements of a satisfactory prosthesis. Studies have shown that total edentulous arches rehabilitated with removable implant-supported prostheses (implant overdentures - IOD) provided greater patient satisfaction, improved masticatory efficiency and bite strength [2,3]. In addition, reduced bone reabsorption and prosthesis mobility, increasing the Oral Health–Related Quality of Life – OHRQoL) [4,5].

The literature is very assertive and has reported relevant results obtained with rehabilitation of the total mandible edentulous with implant overdenture prosthesis. There are several studies associated with the mandible, but when it comes to the maxilla the numbers are much lower and the results less satisfactory. The maxillary IOD was associated with a great loss of implants and complications [6–8]. Factors such as poor bone quality and quantity and divergent implants turn the treatment difficult and become a challenge [9]. However, the careful evaluation and a good diagnosis are the most important topics for the management of total maxillary edentulous patients and the professionals should be aware of their responsibilities in helping patients in the choice of adequate therapy [10].

The possibility of removal the palatal coverage of the implant-supported or implant-retained and muco-supported overdenture would allow valuable benefits to edentulous patients in the maxilla, such as increased palate, better pharyngeal reflex control and ease of hygiene, salivary flow rate and improved phonetics [11–13]. It has been discussed the removal of the palatal coverage of maxillary IOD, its advantages and disadvantages. In older studies, the support of the maxillary IOD with minimum number of six implants to remove the palate from the prosthesis was suggested with relative success [14,15]. At the same time, other studies have indicated the removal of the palatal coverage with only four installed implants when connected to a long bar to improve the retention and stability of the prosthesis, as well as increase hygiene and pharyngeal reflex control [12,16].

A pilot study evaluated the contribution of the palate overdentures supported by four remaining teeth or four implants distributed in the maxilla of four patients in a similar way through miniature strain gauges and force transducers and concluded that the palate provided limited support to the base of prostheses IODs [17].

Despite those facts, the palatal coverage of a maxillary IOD was considered advantageous because it better distributed the functional loads on implants and peri-implant tissues. The increase of mucosal and palatal support should be considered in cases where it is needed to improve loads distribution, noticing that the quantity of implants in the maxilla can diversify, as long as had ensured that an IOD had enough implant support to disposal the palatal coverage [18].

Divergent guidelines regarding treatment with maxillary IOD without palatal coverage were suggested. This literature review aimed to verify the results presented in the current literature on implant overdentures prostheses without palatal coverage in a purpose to evaluate the edentulous maxillary rehabilitation with a palateless implant maxillary overdenture through the implants survival rates.
MATERIAL AND METHODS

Search Strategy and Design of the study

This literature review followed a scientific question: Is the implant overdenture prostheses without palatal coverage a safe treatment for edentulous maxilla? An electronic research was made through Medline data, via PubMed (National Library of Medicine and National Institute of Health, USA), between the period of 2000 to 2016, limited to English papers. Key words referencing title and/or abstract used in the research were: dental implants; maxilla; maxillary; overdenture; e palatal coverage.

The obtained articles were subjected to inclusion and exclusion criteria. Were included in this review randomized controlled-clinical trials (RCT), nonrandomized controlled studies, prospective and retrospective studies. Were accepted studies with minimum 12-months follow-up. Full text analysis was performed by two reviewers independently and in case of disagreement, a consensus was reached by discussion, if necessary in consultation with a third reviewer.

Exclusion criteria:
1. Other prostheses, but implant overdenture
2. Partial implant overdentures
3. Telescopic crowns
4. Immediate loaded dental implants
5. Provisional dental implants
6. Zygomatic, short, zirconia or mini implants
7. Children’s treatments
8. Systemic diseases (Parkinson, Cleidocranial dysplasia, Ectodermal dysplasia)
9. Combination syndrome patients
10. Severe maxilla atrophy
11. Patients with palatal cleft (bucconasal communication)

Inclusion criteria:
1. Total removal of palatal overdenture coverage
2. Splinted and/or unsplinted implant approach
3. Overdenture supported by at least four implants

Outcome measures:
The following outcome measures were assessed:
- Anchorage design
- Implant survival rates
- Number of implants lost

RESULTS

The electronic research conducted through Medline, concluded in September 2016, identified a total of 588 articles, which had their titles analyzed, and then 119 were selected for the abstracts analysis. Using the exclusion and inclusion criteria, 32 articles were maintained for full-text reviews. Of these, 20 were excluded for reasons of technical content, such as insufficient data, remaining 12 that composed the present literature review.

Thus, were obtained three randomized controlled clinical trials (RCT), one prospective clinical case study (PS), nine retrospective studies (RS). The characteristics of the selected studies are described in Table I and only palateless IOD design was considered in each topic.
Table I - Selected studies presentation

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Study design</th>
<th>Follow-up (mo)</th>
<th>No. of patients</th>
<th>Implant system</th>
<th>Implants per patient</th>
<th>Anchorage design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuquerque Jr et al.</td>
<td>2000</td>
<td>RCT</td>
<td>21</td>
<td>13</td>
<td>Brånemark</td>
<td>4</td>
<td>Bar</td>
</tr>
<tr>
<td>Kiener et al.</td>
<td>2001</td>
<td>RS</td>
<td>38</td>
<td>41</td>
<td>Straumann</td>
<td>4–6</td>
<td>Bar and Ball</td>
</tr>
<tr>
<td>Närhi et al.</td>
<td>2001</td>
<td>RS</td>
<td>72</td>
<td>7</td>
<td>Brånemark; IMZ</td>
<td>6</td>
<td>Bar</td>
</tr>
<tr>
<td>Cavallaro &amp; Tarnow</td>
<td>2007</td>
<td>PS</td>
<td>48</td>
<td>5</td>
<td></td>
<td>#</td>
<td>4–6</td>
</tr>
<tr>
<td>Krennmaier et al.</td>
<td>2008</td>
<td>RS</td>
<td>412</td>
<td>34</td>
<td>Camlog; Frialit</td>
<td>4–8</td>
<td>Bar</td>
</tr>
<tr>
<td>Sanna et al.</td>
<td>2009</td>
<td>RS</td>
<td>258</td>
<td>44</td>
<td>Brånemark</td>
<td>2–6</td>
<td>Bar</td>
</tr>
<tr>
<td>Visser et al.</td>
<td>2009</td>
<td>RS</td>
<td>120</td>
<td>39</td>
<td>Brånemark</td>
<td>6</td>
<td>Bar</td>
</tr>
<tr>
<td>Slot et al.</td>
<td>2013</td>
<td>RCT</td>
<td>12</td>
<td>49</td>
<td>Astra</td>
<td>4–6</td>
<td>Bar</td>
</tr>
<tr>
<td>Slot et al.</td>
<td>2014</td>
<td>RCT</td>
<td>12</td>
<td>66</td>
<td>Straumann</td>
<td>5–6</td>
<td>Bar</td>
</tr>
<tr>
<td>Kuoppala &amp; Raustia</td>
<td>2015</td>
<td>RS</td>
<td>79.7</td>
<td>6</td>
<td>Straumann; IMZ; XiVe; Astra</td>
<td>4–5</td>
<td>Bar and Ball</td>
</tr>
<tr>
<td>Strong</td>
<td>2015</td>
<td>RS</td>
<td>107</td>
<td>15</td>
<td>#</td>
<td>4–6</td>
<td>Ball</td>
</tr>
<tr>
<td>Wang et al.</td>
<td>2016</td>
<td>RS</td>
<td>46</td>
<td>26</td>
<td>Straumann</td>
<td>4</td>
<td>Ball</td>
</tr>
</tbody>
</table>

Legend: RCT- Randomized Controlled clinical Trial; RS- Retrospective study; PS- Prospective study.

Splinting of the implants

The classification of the implant overdentures anchorage design was defined based on the support offered by the prosthesis. Due to the heterogeneity of the studies, the anchorage designs were generically classified into two groups: bar and ball type – implants splinted to the bar or isolated and not splinted, respectively.

This criterion was based on a prosthetic classification [19], in which the removable prostheses were classified in PR4 and PR5. PR4 removable prostheses are fully supported by splinted implants to a bar or superstructure, while PR5 removable prostheses bring together the retention of the implants and the mucosal support offered by the residual ridge.

In general, were four to six dental implants supporting an IOD without palatal coverage. Some studies presented a variable number of dental implants rating to four to six implants per patient [20–26] and others employed a fixed number like four [27,28] or six dental implants [29,30]. The same variation occurred to anchorage design. The follow-up period ranged from twelve [23,24] to two hundred fifty eight months [31] in splinted design and forty eight [21] to one hundred seven months [26] in unsplinted design.

Seven studies used splinted bar implants and three of them were RCTs; three used unsplinted implants; and only two did a mixed approach with splinted and unsplinted implants to support an IOD without palatal coverage of different implant systems, those two articles its shown in both sections (splinted and unsplinted design) of table 2 presenting the data in each design.

Implants Survival

The implant survival rate was defined as the percentage of implants that were initially installed in the patients and remained present during the follow-up of the study. Implants lost of each study during the osseointegration phase were not considered in the analysis. In total, 1626 implants were osseointegrated in 345 patient's maxillaries, excluding implants failures that occurred at healing phase, a total failure of 79 maxillary implants associated to the IODs without the palatal coverage was obtained. The general variation noted was 86.1% [30] to 100%.
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Comparative study of splinted and unsplinted implant-retained maxillary overdentures without palatal coverage [21–25] on the survival rate of maxillary dental implants. The maxillary implants survival rate in implant-supported overdentures (PR4) by four dental implants ranged from 96.7% [27] to 100% [21–25] and implant-retained and mucosupported (PR5) by four implants ranged from 95.5% [20] to 100% [21,25,26].

The implant and IOD survival rate and the maxillary overdentures anchorage design used in each article is shown in table II. The number of implants placed to support IOD without palatal coverage in the studies and the number of implants lost were identified. Those articles that addressed a variation in the implants number installed in the IOD support, only five identified specifically the number of implant which failed [23,24,29,31] and one did not differentiated the number of implants lost [20].

Table II - Comparison according to anchorage design

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Total no. of initial implants in palateless IOD design*</th>
<th>No. of implants lost*</th>
<th>Implants survival rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPLINTED DESIGN (PR4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>de Albuquerque Jr. et al.</td>
<td>2000</td>
<td>60 (4 Implants)</td>
<td>2 (4 Implants)</td>
<td>96.7% (4 Implants)</td>
</tr>
<tr>
<td>Kiener et al.</td>
<td>2001</td>
<td>126 (4-6 Implants)</td>
<td>10**</td>
<td>95.5%**</td>
</tr>
<tr>
<td>Närhi et al.</td>
<td>2001</td>
<td>45 (6 implants)</td>
<td>1 (6 Implants)</td>
<td>97.7% (6 Implants)</td>
</tr>
<tr>
<td>Krennmaier et al.</td>
<td>2008</td>
<td>64 (4 Implants)</td>
<td>115 (6 Implants)</td>
<td>100% (4-6 Implants)</td>
</tr>
<tr>
<td>Visser et al.</td>
<td>2009</td>
<td>252 (6 Implants)</td>
<td>35 (6 Implants)</td>
<td>86.1% (6 Implants)</td>
</tr>
<tr>
<td>Sanna et al.</td>
<td>2009</td>
<td>138 (4-6 Implants)</td>
<td>0 (4-6 Implants)</td>
<td>100% (4-6 Implants)</td>
</tr>
<tr>
<td>Slot et al.</td>
<td>2013</td>
<td>100 (4 Implants)</td>
<td>0 (4 Implants)</td>
<td>100% (4 Implants)</td>
</tr>
<tr>
<td>Slot et al.</td>
<td>2014</td>
<td>132 (4 Implants)</td>
<td>0 (4 Implants)</td>
<td>100% (4 Implants)</td>
</tr>
<tr>
<td>Kuoppala &amp; Raustia</td>
<td>2015</td>
<td>4 (4 Implants)</td>
<td>6 (6 Implants)</td>
<td>100% (4-5 Implants)</td>
</tr>
</tbody>
</table>

| UNSPLINTED DESIGN (PR5)   |           |                                                        |                       |                         |
| Kleiner et al.            | 2001      | 25 (4-6 implants)                                     | 10**                  | 95.5%**                 |
| Cavallaro & Tarnow        | 2007      | 25 (4-6 implants)                                     | 0                     | 100%                    |
| Strong                    | 2015      | 48 (4 implants)                                       | 5 (5 implants)        | 100%                    |
| Wang et al.               | 2016      | 104 (4 implants)                                      | 5                     | 95.2%                   |
| Kuoppala & Raustia        | 2015      | 12 (4 implants)                                       | 5 (5 implants)        | 100% (4-5 implants)     |

* Does not include early implant failures.
** Study did not differentiate no. of implants per patient and/or design anchorage
DISCUSSION

This review sought to analyze the maxillary dental implants survival and IOD without palatal coverage in total edentulous patients as well as the decision to anchor with splinted or unsplinted implants. All the studies included in this study dealt with a total removal palatal coverage overdentures design.

The maxillary IODs are considered first-choice treatments for maxillary edentulous patients for effectively reducing most of the complications and prosthetic complaints arising from conventional total dentures [32]. There is a consensus that IODs provide an effective, predictable and reliable treatment if a good planning and a correct indication were made previously [30]. A recent retrospective study evaluated the results of treatments performed with maxillary IODs in a 6.6-year observation period, concluding that a properly performed selection that considers individual biological risk factors of the patients, with careful surgery and customized prosthetic treatment seemed to contribute to the maxillary IOD success results, even in a reduced number of maxillary implants [25].

High implant failure rates were reported in patients who were initially planned to receive fixed implants prostheses, but due to the lost and insufficient number of implants they eventually received maxillary IODs. In contrast, patients who were initially planned for maxillary implant-supported prostheses had low implant failure rates [33].

It was also discussed the number of dental implants recommended to be installed to support or retain a maxillary implant-supported or retained overdenture. The data obtained in this review were varied regarding the number of implants located in the maxilla to support a palateless IOD. In fact, the great majority of the studies showed different numbers of implants for the rehabilitation of maxillary edentulous patients. It has been reported in long terms of results that the installation of six implants in the maxilla would be the best strategy to obtain good dental implants survival rates [30,34]. Therefore, the use of six implants for maxillary IODs was expected to present satisfactory results by performing a favorable distribution of the masticatory loads under the prosthesis, but with a higher cost and, eventually, with a bone grafting requirement.

In general, studies have suggested that the edentulous maxilla should be rehabilitated with four to six implants, which would lead to better results over time. It seems that the minimum favorable number in the literature to support an IOD without palate coverage is four maxillary implants [14,20,35] connected to a long bar to improve retention and stability of the prosthesis, as well to increase hygiene and pharyngeal reflex control [12,16,27].

The use of four splinted implants with bar has been used to support maxillary IODs and was considered a treatment of high implant survival rates [22–25,31], not achieving inferior results when compared to the same anchorage design supported by six maxillary implants. There was an indicative advantage in the use of four implants instead of six to reduce treatment costs [23,24]. Although the maxillary overdentures retained by six implants were said to provided better patient satisfaction, it was considered more costly [36]. Few articles reported the treatment cost, however, all who addressed the topic were unanimous in saying that treatment with IOD retained by unsplinted implants was advantageous in the financial aspect.

The implant-supported prostheses were prioritized in comparison to implant-retained and muco-supported prostheses in the maxilla [8,37] because its offers advantages such as lower rotation of the prosthesis around the fulcrum of the implant compared to a few implants situation and better prosthesis survival in case of implant failure [38,39]. In general, the bar allows greater retention compared to solitary anchorage when in vertical and oblique forces [40].
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The choice of palateless IOD anchorage design by bars has provided good peri-implant tissue health, patient satisfaction, low incidence of prosthetic maintenance [22,24]. It is considered more favorable for the implants survival and prosthesis stability [20] probably for better dissipating the stresses applied on the prostheses. It must be noticed that in a bar design occurs an expressive plaque retentive factor, due to its greater area and complexity of hygiene when compared to unsplinted implants. Another disadvantage would be the minimum space of twelve millimeters, between the mucosa and the occlusal plane, necessary to accommodate the bar and the attachments in patients with short interocclusal distance [19]. Greater mucosal changes such as hyperplasias and inflammatory reactions in prostheses with implants attached to bar were related, but those complications could be avoided with patient hygiene guidelines and proper cleaning [29]. The prostheses supported by unsplinted implants, on the other hand, tended to a greater peri-implant bone loss.

Certainly, one of the factors that complicate the rehabilitation of patients with edentulous maxilla with removable prosthesis retained by unsplinted implants (PR5) is the lack of parallelism. This type of anchorage system requires perfect positioning, in which the implants must be parallel to each other. The non-parallelism between them to the overdenture insertion axis causes significant wear on the attachments and the greater the number of implants involved, the greater the difficulty of alignment between the attachments [40]. Advantages such as the easy maintenance and repair of the prosthesis, either by loss of implant, removal or replacement of components were described.

A prospective study aimed that the reduction of palatal coverage is satisfactory for the patient, regardless of the number of implants installed, even in the installation of only two implants [41]. The IODs retained by unsplinted implants could be a good prosthetic solution provided since if had a minimum number of three to six implants and ten millimeters in length [26]. Although the disclosure of good results related to maxillary implant-retained and muco-supported overdentures design in the selected studies, there were no RCTs studies in unsplinted design such as a few dental implants compared to the splinted one. Therefore, RCTs studies are still necessary for more evidence and data base.

It’s been believed that the planned distribution of maxillary implants provides a more favorable loads distribution to implants and peri-implant tissues, but there are few studies indicating the location of the implants used and the stress generated in maxillary implant-supported or retained ODs without palatal coverage. For some authors, it is evident that the total palatal coverage as well as the anchorage by bar-attachment system has a more favorable pattern of tensions dissipation suffered by implant-supported overdentures, in contrast, other studies have revealed satisfactory results that justify the use of implant-retained ODs by unsplinted without full palate coverage extension.

The close correlation of implants distribution and the measured force on the palate in IODs retained by Locator attachments (unsplinted anchorage) was analyzed by an in vitro study and it’s was suggested that the palate of implant-retained overdentures by four Locators with a distance of sixteen millimeters or more did not contributed significantly to the loads transmission on the underlying hard palate, although eight millimeters produced less stress there was no significant difference between four Locators with distance from sixteen to twenty-four millimeters [42]. The resulting stress at the bone-implant interface of maxillary IODs without palatal coverage could be lessened if the elastic modulus and the thickness of the stress-breaking materials were controlled [43].

Fractures of maxillary IODs are one of the most frequent clinical complications [44]. Therefore, literature has claimed that complete
palatal coverage would be more beneficial since it would reduce the wear of the abutments and minimize the risk of fracture of the prosthesis base [33,45]. This risk of fracture can be decreased using framework reinforcement for the IOD, and it must have a suitable design and thickness to allow sufficient thickness for the acrylic resin [46,47]. The prostheses without palatal coverage suffers from compressive forces and the anterior palate area being the region that suffered the greatest load, and the reinforcement of the prostheses without palatal coverage reduced the risk of fractures and deformations [48].

A recent study attempted to analyze the attachment’s materials and the correlation with stress concentration forces and the results showed that plastic clips provided a great reduction of stress of the denture base when compared to metallic clips, suggesting that this may be a way to solve the potential risk of fractures of the of maxillary IODs bases [49].

Many aspects are needed to be contemplated in the treatment with overdentures without the palatal, such as the retention system employed and especially the material. In view of the fact that they are the first structures to receive the functional loads transmitted to the dentures base and only then are directed to the dental implants and following to the peri-implant bone tissue in sequence. The literature has provided divergent positions about various points, which include the rehabilitation of an edentulous maxilla patient with implant-supported or retained overdenture without palatal coverage.

Within the limits of this review and pondering the available evidence, treatments with satisfactory results were observed, such as the use of at least four maxillary implants by bar and ball anchorage design. But, despite those significant results, there were no randomized controlled-clinical trials that approached the unsplinted design in this literature review, only the splinted design. Other approaches to the topic of removal of palatal coverage are necessary to develop a clinical-prosthetic protocol. Further studies are suggested:

- In vivo prospective studies to evaluate comparatively patients with four maxillary implants with the different types of support of the IODs without palatal coverage; implant-retained and muco-supported prostheses (PR4 and PR5), which preferably control randomly the cases and provide data on the survival rate of maxillary implants and implant overdentures.
- In vitro studies to analyze and compare the stress transmitted to IODs without palatal coverage with different anchorage designs, dental implants and peri-implant tissues.

CONCLUSION

Based on available literature, there is a substantial lack of articles approaching the palate removal of IOD. The support of splinted bar-retained overdentures without palatal by four to six maxillary implants such as unsplinted implant-retained and muco-supported design seems to be sufficient to remove the palate, has shown good survival rates and represents a successful treatment. While unsplinted implant-retained and muco-supported anchorage design turned out to be a lower cost treatment and could be an alternative treatment for public health services or low-income patients. However, more randomized controlled clinical trials on the subject are required for this anchorage design. Thus, further studies of the location of implants, load transmission, and generated stress on IODs without palatal coverage and their components are required.
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