

1 *Type of the Paper: Review*

2 **Radiological Outcomes of Bone-Level and Tissue-Level** 3 **Dental Implants: Systematic Review**

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17 **Abstract: Purpose:** to assess any differences on marginal bone loss between bone-level or tissue-
18 level dental implants through a systematic review of literature until September 2019.: **Materials and**
19 **methods:** MEDLINE, Embase and other database were searched by two independent authors. The
20 search was limited to articles in English. **Results:** The search provided 1028 records and, after
21 removing the duplicates through titles and abstracts screening, 45 full-text articles were assessed for
22 eligibility. For qualitative analysis 20 articles were included, 17 articles of them for quantitative
23 analysis. A total of 1161 patients (mean age 54,4 years) and 2933 implants were observed, 1427
24 (Tissue-level) and 1506 (Bone-level). The survival rate and the success rate were more than 90%,
25 except for 2 studies with a success rate of 88% and 86.2%. No studies reported any differences
26 between groups in term of success and survival rates. Three studies showed that BL-implants had
27 statistically less marginal bone loss ($P < 0.05$). Only one study reported statistically less marginal
28 bone loss in TL-implants ($P < 0.05$). In the most part of the studies, differences between implant types
29 in marginal bone loss were not statistically significant. **Conclusion:** Despite to the peri-implant
30 tissue around transmucosal implants has been reported to be inflammation-free because of the
31 absence of bacterial infiltration in the micro-gap between the fixture and abutment, no clinical and
32 radiological differences were highlighted between groups from the included studies after a variable
33 period of follow-up ranged between 1 to 5 years.

34 **Keywords:** tissue-level; bone-level; dental implants; transmucosal; marginal bone loss; systematic
35 review

36 1. INTRODUCTION

37 Dental implants are the gold standard treatment to restore single edentulous space and partially
38 or completely edentulous jaws due to their long-term success rate, the positive impact on patients'
39 quality of life and the simplified modern surgical procedures with low morbidity.^{1,2}

40 To reach the increasing patients' needs for aesthetic results, low cost and fastest result, several
41 factors must be taken into account before choosing the implant type and the protocol with the goal
42 of a long survival and success rates of the implant-prosthetic rehabilitation.

43 Among these factors, the clinician's experience, the loading time, the type or surgery, the
44 insertion torque, the oral hygiene maintenance protocols, the implant neck configuration and the

45 implant-abutment connection, may influence the preservation of healthy peri-implant hard and soft
46 tissues.^{3,4}

47 The most used and objective clinical and radiological parameters to evaluate the stability of the
48 peri-implant soft and hard tissue, so that the success of the rehabilitations, are respectively bleeding
49 score, gingival index and marginal bone loss (Δ MBL).

50 Dental implants, after the healing period of 2-5 months, are anchored to the bone because of
51 osseointegration. Traditionally, implants are two-pieces, so they are connected to the prosthetic
52 rehabilitation through a transmucosal component, called abutment.

53 The early bone loss is observed after the connection of the abutment and when the prosthesis is
54 loaded on the implant. It is well known that there are a lots of factors to explain marginal bone
55 resorption around dental implants such as: the occlusal trauma, biologic width establishment,
56 gingival biotype, insertion torque of the implants, prosthesis loading timing, thickness of the
57 remaining bone, type of surgery, primary stability, lack of bone to implant contact (BIC), bacterial
58 colonization of the implant-abutment junction (IAJ), the macro and micro characteristic of abutment
59 and the coronal portion of the fixture (shoulder/neck of the implant) and the position of the implant.⁵

60 To avoid some of these disadvantages, Schroeder and co-workers (1981) introduced a “one-
61 piece” implants to remove the contamination of the implant-abutment junction (IAJ) and to reduce
62 the micromovements in the connection.⁶

63 Nevertheless, one-piece implants have a difficult first surgery due to vertical dimension and due
64 to the orientation of the remaining bone and the final prosthetic rehabilitation. One-piece implants
65 must be inserted according the final prosthesis position, not only considering hard and soft tissue
66 availability. Moreover, if there are biomechanical complications, it is not possible to remove the
67 abutment, instead all the implant must be removed.

68 In modern literature, the term “one-piece implant” has modified its meaning. The new
69 conception of “one-piece implants” regards both endosseous and transmucosal components, but the
70 link with the abutment still remains, located at increased distance from the bone, at tissue level.⁷

71 To compare one-piece and two-pieces implants several clinical studies and some systematic
72 review were performed in the last years.

73 Iglhaut and co-workers (2014) stated that the microgrooved surface could be associated with a
74 longer connective tissue attachment and less bone resorption around implants.⁸

75 Even though, considering the literature data, doubts still remain about the question: “What is
76 the difference between one piece (bone-level) and two-piece (transmucosal) dental implants at single
77 or multiple edentulous sites in terms of clinical and radiological outcomes during a long follow-up
78 period?”

79 Focusing on the literature until September 2019, the aim of the present systematic review was to
80 identify whether there are relationships between different implants’ position (tissue level or bone
81 level) and radiographic marginal bone loss in single or multiple rehabilitation, after at least 1-year of
82 function.

83 2. MATERIAL AND METHODS

84 The present review has been conducted in accordance with the guidelines for Systematic
85 Reviews and Meta-Analyses (PRISMA).⁹

86 Before starting the systematic review, a protocol has been developed and registered at
87 PROSPERO with number: CRD42020157607.

88 This question follows the PICO guidelines. The population (Population) was systemically
89 healthy patients who (Intervention) received at least one implant and those implants that had been
90 in place for at least one year. The Comparison in this type of studies was between two treatment
91 groups according the level of implants: bone level and tissue level implants. The Outcome was the
92 marginal bone loss.

93 The focused question was: are there any differences in terms of marginal bone loss in single or
94 multiple rehabilitation between bone level implant and transmucosal implant?

95 The rationale is that the position of implant-abutment connection could influence the healing
 96 process of the peri-implant tissues even after 1 or more years of follow-up, because of inflammation
 97 and bacterial infiltration in the micro-gap.^{10,11}

98 2.1. Search strategy

99 The search was carried out independent by two authors and on four databases (MEDLINE,
 100 Embase, Inspec, and Cochrane Central Register of Controlled Trials) using synonyms as [(dental
 101 Implant OR abutment) AND (shoulder design OR implant abutment interface OR transmucosal OR
 102 bone-level OR scalloped implant OR sloped implant OR flat implant OR one-piece or two-pieces)].

103 The search was limited to articles in English. No restrictions on follow-up period were applied
 104 when searching the first electronic databases to be as inclusive as possible. These databases were
 105 searched until September 2019.

106 The exclusion criteria were applied after the electronic search. The bibliographies of all identified
 107 clinical included studies and relevant review articles were checked in order to identify other eligible
 108 articles related to the topic.

109 A complementary manual search which included a complete revision up to September 2019 was
 110 made of the following journals: Journal of Clinical Periodontology, Journal of Periodontal Research,
 111 Journal of Oral Science & Rehabilitation and Journal of Dental Research.

112 2.2. Study selection and eligibility criteria

113 Randomized clinical trials (RCTs), case-control studies, comparative studies and clinical trials
 114 comparing the clinical and/or radiological outcomes of different dental implant shoulder/neck
 115 position related to the crestal bone have been searched. The publications with the following inclusion
 116 criteria were selected:

117 Comparison of different neck/shoulder position (One-piece vs two-pieces or tissue-level or
 118 transmucosal vs bone-level) of dental implants with at least 1-year follow-up after loading;

- 119 ▪ Patients aged between 18 to 70 years old;
- 120 ▪ Patients without severe systemic (e.g. recent cardiovascular event or tumoral pathology)
 121 or psychiatric disease;
- 122 ▪ Clinical and radiological parameters measured were at least respectively bleeding on
 123 probing (BoP), and marginal bone loss (Δ MBL);
- 124 ▪ Only studies published in English.

125 The gingival recession was evaluated as a secondary outcome of interest in order to compare the
 126 possible association of one type of electric toothbrush with gingival recession prevalence.

127 Reviews, letters, animal model and vitro studies were excluded. Other exclusion criteria were:

- 128 ▪ Studies included orthodontics patients;
- 129 ▪ Studies included patients with disabilities;
- 130 ▪ Studies included patients who are taking bisphosphonates;
- 131 ▪ Studies comparing 2 or more different types of implant-abutment connections (e.g.,
 132 Switching platform) not focusing on position related to the bone;
- 133 ▪ Studies comparing 2 or more different types of implant surgical technique with similar
 134 implant (e.g. one step surgery or two step) not focusing on position related to the bone;
- 135 ▪ Studies comparing 2 or more different types of implant or abutment micro design;
- 136 ▪ Studies comparing 2 or more different types of micro design of the implant neck or of
 137 the abutment;
- 138 ▪ Final timepoint after less than 1 year after loading;
- 139 ▪ Studies evaluating mini-implants (in literature defined as implant $<8,5$ mm);¹²
- 140 ▪ Studies investigating implant prostheses directly screwed into the implant head;
- 141 ▪ Studies analysing implants and abutments used to retain removable prosthesis;
- 142 ▪ Studies published before 1990.
- 143 ▪ Studies with results published more than once were included only one time;

144 2.3. Screening and Study selection

145 Records identified through database searching were upload on End-Note (ISI Researchsoft 2001,
146 Berkeley, CA <http://www.endnote.com>) to exclude the duplicates.

147 Then, titles and abstracts of all remaining articles were independently scanned by two reviewers
148 following inclusion and exclusion criteria. Disagreements between authors were resolved after
149 discussion by the intervention of a third author.

150 For studies appearing to meet the inclusion criteria, or for which there were insufficient
151 information in the title and abstract to assess a clear decision, the full-text was obtained. The screening
152 of full-text articles was performed by two reviewers independently to establish whether or not the
153 studies met the inclusion and exclusion criteria. Disagreements were resolved by discussion of two
154 authors. When resolution was not possible, a third reviewer was consulted.

155 Full-text rejected at this, or subsequent stages, were recorded in the table of excluded studies
156 explaining reasons for exclusion.

157 All full-text articles meeting the inclusion criteria and assessed for eligibility were evaluated
158 again by 3 authors to assess the quality of the methodology of each article and to perform data
159 extraction.

160 2.4. Quality assessment (risk of bias of included RCTs)

161 A quality assessment of the included studies was performed according to the Cochrane
162 Handbook for Systematic Reviews of Interventions (version 5.1.0; updated March 2011 by Higgins
163 and Green, 2011)

164 According to handbook guideline five main quality criteria were evaluated:

165 Random sequence generation,

166 allocation concealment,

167 1. blinding of participants, personnel and outcomes assessors,

168 2. Incomplete outcome data

169 3. Selective outcome reporting

170 Depending on the descriptions given for each main article of included studies, these criteria were
171 rated as: low, unclear or high risk of bias.

172 2.5. Quantitative analysis

173 Mean marginal bone changes values were extracted from each study by one author and
174 compared weighting parameters according to the number of implants for each study. The data were
175 analysed using the T-test with a $p < 0.05$.

176 3. Results

177 The purpose of this review was to summarize the available evidences reported in literature of
178 the included studies comparing the bone level changes between one-piece (TL) and two-piece (BL)
179 dental implants.

180 The combined search in 4 databases provided 1028 records (Table 1).

181 **Table 1:** Flow chart diagram (2009) of search strategy adapted from PRISMA

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Identification

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Screening

Eligibility

Included

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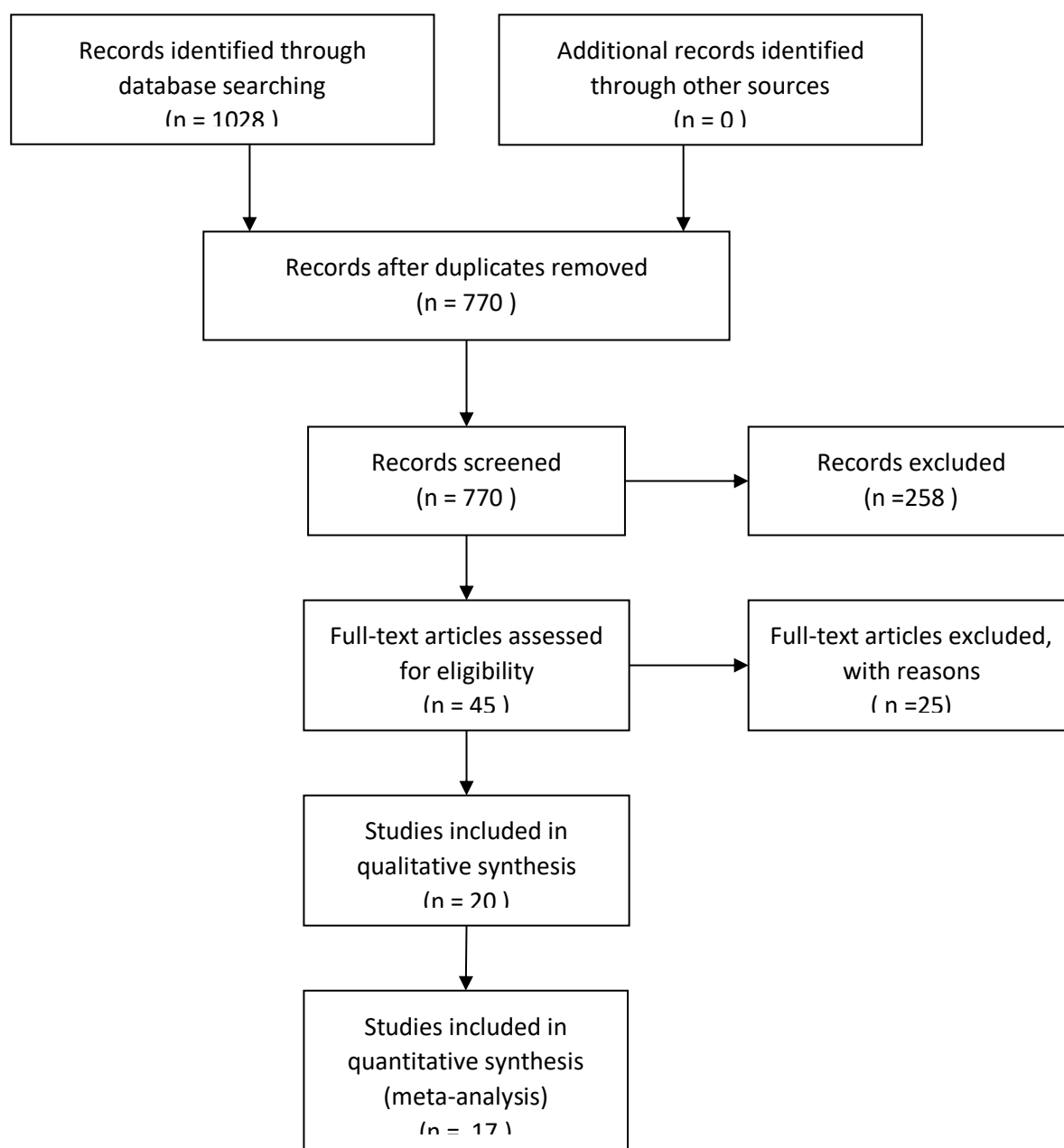
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After removing the duplicates using the software End-Note (ISI Researchsoft 2001) and the screening of title and abstract according to the relevance of the topic 45 articles remained. Following inclusion and exclusion criteria, the full-text of these article was obtained. In table 2 28 excluded articles were reported with reasons, 3 of them (coloured in grey) were excluded only from quantitative analysis, but not qualitative.

Table 2: Excluded articles after full-text screening; the articles marked in grey rows were included for qualitative analysis, but not quantitative one.

Nr.	References	Exclusion motivation
1	Becktor JP et all. Clin Implant Dent Relat Res. 2007 Dec	Excluded for the quantitative analysis:

		Excluded for the quantitative analysis: The parameter “marginal bone level” was not clearly reported
2	Bratu EA et al. Clin Oral Implants Res. 2009 Aug	Implants have same shoulder design; the comparison is on microthreads on the surface
3	De Siqueira RAC et al. Clin Oral Implants Res. 2017 Oct	The topic is similar but the comparison is between equi-crestal and sub-crestal implants.
4	Chappuis V et al. Clin Oral Implants Res. 2016 Sep	Excluded for the quantitative analysis: Excluded because it reports median, not mean value of MBL
5	Chien HH et al. J Oral Implantol. 2014 Oct	It is focused on abutment design
6	<u>Cosyn J et al. J Periodontol. 2007 Sep</u>	Implants have same shoulder design, the comparison is on microthreads on the surface
7	Ebler S et al. Clin Oral Implants Res. 2016 Sep	The implants compared were 2 different type of bone level
8	Esposito M et al. Eur J Oral Implantol. 2016	The implants compared have the same position related to the bone
9	<u>Hof M et al. Clin Implant Dent Relat Res. 2014 Oct</u>	<u>It is focused on insertion torque and on the micro-design of the neck</u>
10	<u>Herrero-Climent M et al. Int J Oral Maxillofac Implants 2014 Nov-Dec</u>	<u>Implants of both groups were placed maintaining the same shoulder-crest level.</u>
11	Judgar R et al. Biomed Res Int. 2014 Jun	The parameter “marginal bone level” and was not reported. It was a histometrical analyses.
12	Khorsand A et al. Implant Dent 2016 Feb	Implants position of both groups are similar, and the marginal bone loss is not measured
13	<u>Khraisat A et al. Int J Oral Maxillofac Implants 2013 Mar-Apr</u>	It is focused on implant-abutment connection
14	<u>Kim JJ et al. Clin Oral Implants Res 2010 Apr</u>	It does not follow all inclusion criteria, even if the comparison is focused on macro-design of the implant neck

15	<u>Kütan E et al. Implant Dent Relat Res. 2015 Oct</u>	The implants compared have were both bone level, crestal and subcrestal implants
16	Marconcini S et al. Clin Implant Dent Relat Res. 2018 Jun	The macro-design of the implants is similar so that it does not follow the inclusion criteria
17	Moberg LE et al. Clin Oral Implants Res. 2001 Oct	Excluded for the quantitative analysis: The parameter "marginal bone level" was not clearly reported
18	Nóvoa L et al. Int J Periodontics Restorative Dent. 2017 Sep/Oct	It is focused on the macro-design of the abutment
19	Ormianer Z et al. Int J Prosthodont. 2015 Nov/Dec	It is the topic of the present review but it is a case series
20	Pellicer-Chover H et al. Med Oral Patol Oral Cir Bucal. 2016 Jan	The implants compared have were both bone level, crestal and subcrestal implants
<u>21</u>	<u>Peñarrocha-Diago MA et al. Clin Oral Implants Res. 2013 Nov</u>	It is focused on the micro-design of the implant neck
<u>22</u>	<u>Pozzi A et al. Clin Implant Dent Relat Res. 2014 Feb</u>	All the implants were placed at different level of bone crest
23	<u>Pozzi A, et al. J Oral Implantol. 2014 Spring</u>	It is focused on the connection
24	<u>Sanz-Martin I et al. J Clin Periodontol. 2017 Aug</u>	It is a study on animal model (Dog)
25	<u>Shin YK et al. Int J Oral Maxillofac Implants. 2006 Sep-Oct</u>	It is focused on microthreads and micro-design
26	<u>Tan WC et al. Clin Oral Implants Res. 2011 Jan</u>	The implant position of the two implants are similar so that it does not follow inclusion criteria
27	Weinländer M et al. Clin Oral Implants Res. 2011 Jul	It is focused on the macro-design of the abutment
28	Wittneben JG et al. J Dent Res. 2017 Feb	It is focused on the macro-design of the abutment

218 At the end of the study selection, a last revision was performed again by two authors and 17
219 articles were included for the final quantitative analysis (20 considering also qualitative analysis as
220 reported in table 3). Possible disagreement was solved through the involvement of the third review
221 with expertise in implantology and oral surgery.

Table 3: All studies included for the qualitative analysis

Studies Qualitative analysis	Study design	Patients sample	Number of implants (BL/TL)	Mean age range of the sample	Type of 6implants BL; TL	Type of prosthetic restoration	Success rate BL/TL	Survival rate BL/TL	Follow-up
1 Astrand P. 2004	prospective randomized comparative multicenter study	28	73/77	61.7 ± SD range: 36-76	BL: Branemark TL:ITI	Fixed Partial Bridges	/	100%	12 months; 36 months;
2 Bassi M 2016	prospective clinical study	133	66/67	60±11 Range: 29-75	BL: I-Fiz EVO conical; TL: Shiner EVO Conical;	52 Single Crown/3 Overdenture/70 Bridges	88 %	100%	60 months;
3 Becktor 2007	prospective multicenter study	80	206/198	TL: 63,5±9.1 range:47-89 BL: 65.5±9.4 range:44-84	Branemark system Nobel Biocare AB	Fixed Prosthetic dentures		97.6%/91.4%	6 months; 12 months; 36 months;
4 Bömicke W 2017	randomized controlled trial study	38	19/19	TL: 54.37±14.62 BL: 51.51±13.96	Nobel Biocare AB	Single Zirconia Crown	/	100%/94.7%	12 months; 36 months;
5 Cecchinato D 2004	multicenter randomized controlled clinical trial	84	171/153	51.6	Astra Tech	Fixed Prosthetic dentures	/	>98%	12 months; 24 months;
6 Cecchinato D 2008	multicenter randomized controlled clinical trial	84	171/153	51.6	Astra Tech	Fixed Prosthetic Dentures	/	>98%	24 months; 60 months;
7 Chappuis V 2016	comparative study	61	20/41	TL: 38.8 range: 24-72 BL: 41.7 range: 24-60	Straumann	Single Crown	/	/	60 months;
8 Duda M 2016	non randomized retrospective study	33	29/24	TL: 42.5 BL: 53.6	Q implants Triron Titanium GmbH		/	100%/91.7%	6, 12, 36 months; 60 months;
9 Eliasson A 2010	prospective clinical study	29	84/84	65	DBA Paragon	Full arch ISFP	86.2%	99.4%	12 months; 60 months;

10	Engquist B 2002 It is not clear the number of the coort, n=106 or 113?	Controlled prospective study	82	113/80	TL: 65	BL: 64	Branemark system Noble Biocare AB	Fixed Prosthetic bridges	/	97.5%/93.2%	12 months;
11	Engquist B 2005	Controlled prospective study	108	110/106	64.9		Branemark system Nobel Biocare AB	Fixed Prosthetic bridges with cantilever	/	100%/100%	12 months; 36 months;
12	Ericsson I 1994	Longitudinal study	11	33/30	61 range: 42-72		Branemark system	Fixed Prosthetic Bridges	/	/	12 months; 18 months;
13	Gamper FA 2017	randomized controlled clinical trial study	60	86/65	TL: 47.5±15 BL: 55.8±14		BL: Branemark system Nobel Biocare AB TL: Straumann	Removable Prosthetic prostheses/ screw retained prostheses/cemented prostheses	/	98.9%/96.6%	60 months;
14	Gulati M 2015	prospective randomized comparative study	19	10/10	TL:28.22±3.27 BL:27.20±2.78 Range:23-33		Adin Dental Implant System	Screw-Retained Porcelain Fused to Metal Prosthesis	/	/	3 and 6 months;
15	Hadzik J 2017	clinical study	13	16/16	TL: 46.3 BL:45.9 Range:20-63		BL: Osseospeed TX, Astra tech TL: RN SLActive®, Straumann	Cemented Crowns	/	100%	6 months;
16	Heijdenrijk K. 2006	prospective randomized study	60	38/38	58±11		unknown	Overdenture with clip attachment	/	/	12, 24,36, 48 and 60 months;
17	Lago L 2018	randomized clinical trial	100	102/100	50.5 range:25-70		Straumann	Single Crowns		96.1% / 98%	12 and 60 months;
18	Moberg 2001	Randomized prospective study	40	103/106	BL: 62.6±7.0 Range: 44.2-75.2 TL: 64.0±6.8 Range: 40.2-77.2		BL: Branemark system Nobel Biocare AB TL: ITI system	Screw Prosthetic Bridges	97.9%/96.8%	/	6 months; 12 months; 36 months;
19	Paolantoni G 2016	randomized controlled clinical trial study	65	29/45	53±4		Thommen Medical AG	Single Crowns		100 %	60 months;
20	Sanz-Martin I 2016	prospective randomized controlled clinical study	33	18/15	unknown		BL: Branemark system Nobel Biocare AB TL: Strumann	group 2 piece: SCs-4FDPs group 1 piece: SCs-4FDPs	/	/	12 months;
Total			1161	2933							3-60 months;

224 3.1. *Qualitative analysis*

225 The data collected from each study of were resumed in a table 3.¹³⁻³²

226 In 3 studies the implants were positioned in the maxilla (Astrand 2004, Gamper 2017 and
227 Paolantoni 2016) in 9 studies the implant rehabilitation involved the mandible (Boemike 2017,
228 Cavalcanti 2017, Eliasson 2010, Engquist 2002, Engquist 2004, Ericson 2004, Gulati 2013, Hadzick
229 2017, Heidenrick 2006) while in the other studies the patients received the implants in both jaws.

230 In one study (Paolantoni 2016) the implants were inserted in the anterior region of the maxilla,
231 in 1 study (Cavalcanti 2017) the implants were positioned in the anterior region of the mandible,
232 whereas in 3 studies (Boemike 2017, Culati 2013, Hadzick 2017) the implant treatment was performed
233 in the posterior region of the mandible. In the majority of the studies, the patients were treated with
234 the dental implants in both anterior and posterior region of maxillae.

235 The totality of the studies analysed two types of implant systems: bone level implants and tissue
236 level implants in different groups with different surgery and prosthetic protocols by different clinics
237 and clinicians.

238 The parameter "Marginal Bone Level" was evaluated by the radiographic examination (intraoral
239 radiography) in order to compare the changes in the bone level at the baseline and in the different
240 time of follow up.

241 The timing of each follow-up varied considerably through the studies, from a first evaluation at
242 a minimum of 3 months (Gulati 2013) to a maximum of 5 years (Bassi 2016, Cecchinato 2018, Eliasson
243 2010, Engquist 2002, Gamper 2017, Heijdenrik 2006, Paolantoni 2016, Lago 2018), even if the overall
244 follow up that ranged from 1 years to 3 years in the majority of the studies.

245 The study included 1161 patients (mean age 54,4 years), who needed implants rehabilitation for
246 mandibular and maxilla edentulism by fixed and removable prosthetic prostheses (Gamper 2017).

247 In total, 2933 implants were placed, 1427 according to the non-submerged protocols and 1506
248 according to the traditional submerged procedure. In both groups (submerged versus transmucosal
249 group), the most used implants brands were the Branemark implants system Nobel Biocare AB, the
250 ITI systems, the Astra Tech system and the Straumann systems with exception for some studies as
251 noticed in Table 3.

252 For both implant systems, the fabrication of fixed prostheses has provided for single crowns and
253 bridges in most cases. Some authors did not specify the prosthetic protocol and no information was
254 given about the design of the framework except for Bomike 2017, Gamper 2017, Gulati 2015, Hadzik
255 2017, Heijdenrik 2006, Moberg 2001.

256 In the present review, the only parameter used was marginal bone loss changes in the
257 quantitative analysis because of the too wide variability of each studies in other clinical
258 outcomes. The studies analysed bleeding score did not report any statically significant differences
259 between groups.

260 The survival rate and success rate if reported were more than 90%, except for 2 studies (Bassi
261 2016, Eliasson 2010) that had a success rate of 88% and 86.2% respectively. No studies reported any
262 differences between groups in term of success and survival rates.

263 Three studies (Bömicke W 2017, Duda M 2016, Lado L 2018) showed that BL-implants had
264 statistically less marginal bone loss compared with TL-implants ($P < 0.05$). Only one study (Gamper
265 FA 2017) reported statistically greater peri-implant bone maintenance over time in TL-implants ($P <$
266 0.05).

267 In the most part of the studies, differences between implant types in marginal bone loss were
268 not statistically neither clinically significant.

269 3.2. *Quality assessment*

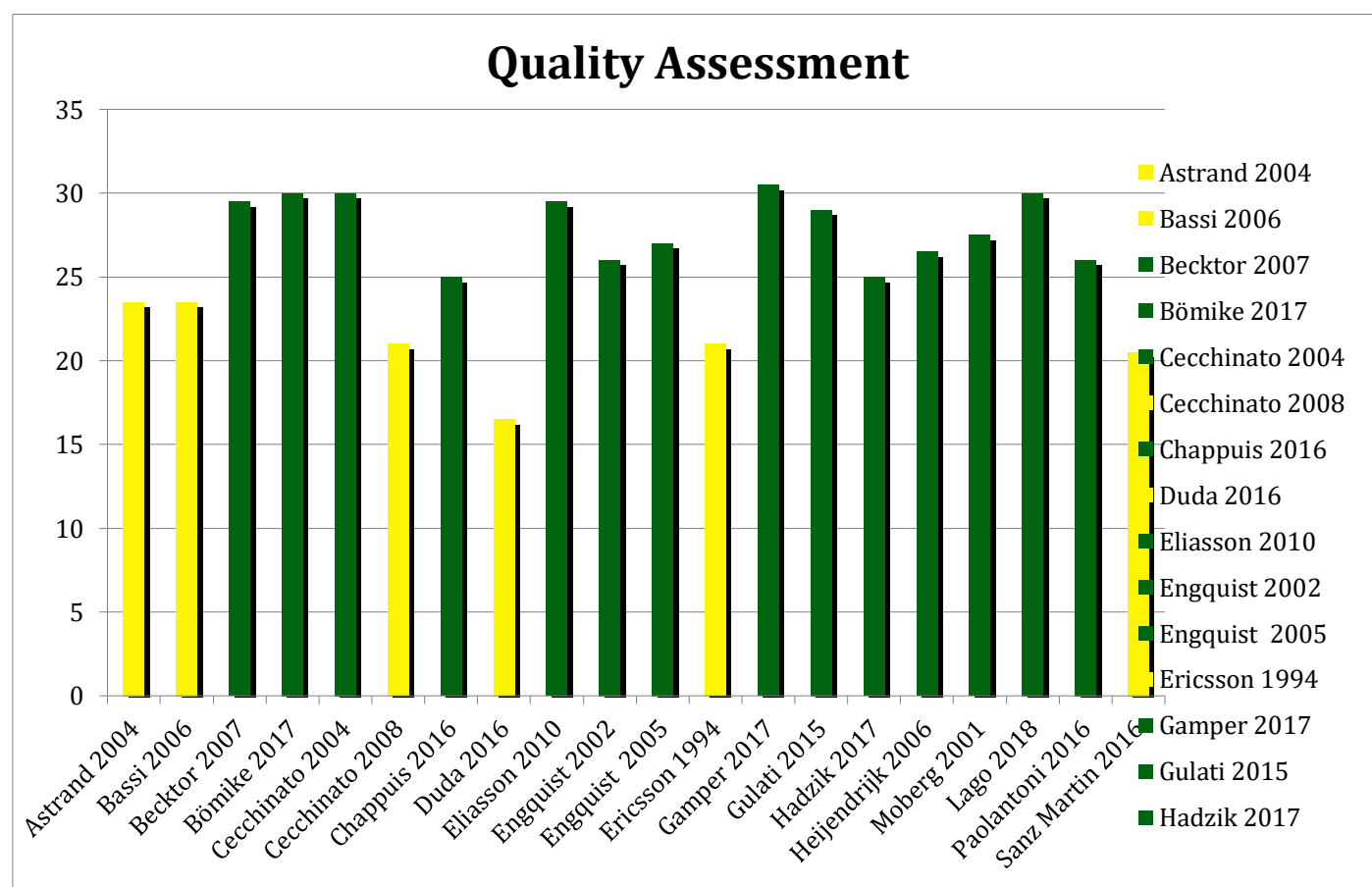
270 The methodological quality was assessed using the "Downs and Black Scale" and the "New
271 Castle Ottawa Scale Cohort Studies" as suggested by the Chocrane Handbook.³³

272 The quality scores was graded as high for the studies with a score ≥ 24 , medium for the studies
273 with a score between 12 and 24 and low for the studies with a score ≤ 12 .^{34,35}

274 Two reviewers investigated the internal validity of the eligible studies and according to the
275 quality assessment tool and reported the results in table 4: fourteen studies showed high quality
276 (Bomike 2017, Becktor 2007, Chappuis 2016, Cecchinato 2004, Eliasson 2010, Engquist 2002, Engquist
277 2005, Gamper 2017, Gulati 2005, Hadzik 2017, Heidenrik 2010, Lago 2018, Moberg 2001, Paolantoni
278 2016) meanwhile the other studies showed a moderate quality (Astrand 2004, Bassi 2006, Cecchinato
279 2008, Duda 2016, Ericson 1994, Sanz-Martin 2016).

280

Table 4. Quality assessment of the studies.



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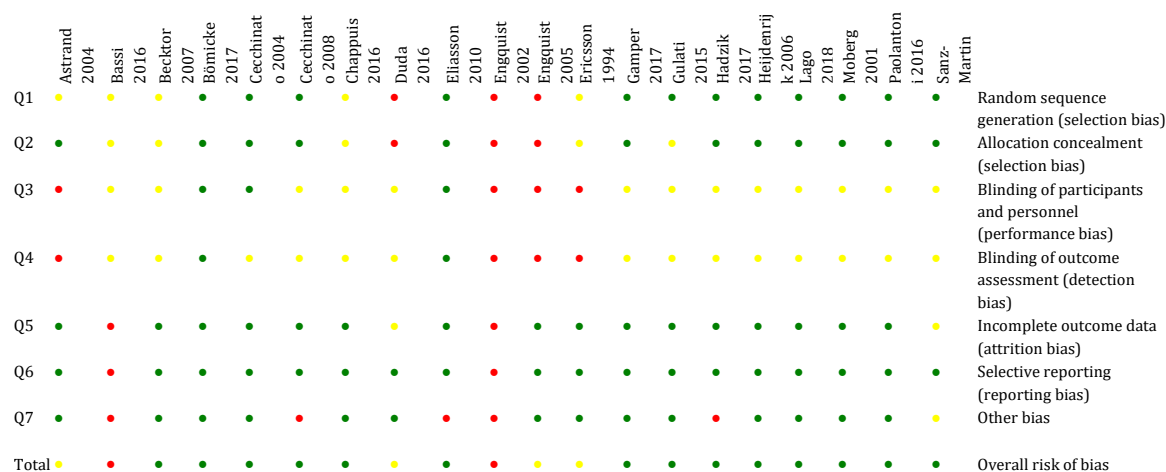
282 Two authors investigated on the factors which could systematically affect the observations and
283 the conclusions of the studies.³⁶

284 The two independent and calibrated authors assessed each single study, according to the
285 Cochrane collaboration' tool (2018).

286 As shown in Table 5, papers were divided according risk of bias in 3 categories: low risk,
287 moderate risk and high risk.

288

Table 5. Risk bias word.



289

290 The tool items were scored as 1 if the item was considered fully fulfilled, as 0 if the item was
 291 clearly not fulfilled and as 0.5 if the item was unclearly or only partially fulfilled.

292 Studies with a score ≤ 2.3 were considered with high risk of bias, with a score between 2,4 and
 293 4,6 of moderate risk instead with a score $\geq 4,7$ were considered with low risk of bias.

294 The majority of the studies showed a low risk of bias, whereas 6 studies had a moderate risk of
 295 bias: (Astrand 2004, Bassi 2016, Duda 2016, Engquist 2002 and 2005, Ericsson 1994).

296 3.4. Quantitative analysis

297 Seventeen studies were selected for the quantitative analysis and the marginal bone loss
 298 comparison. The radiographic outcome refers to a total of 980 patients and 2260 implants: 1178
 299 implants in BL-groups and 1082 implants in TL-groups.

300 Three studies reported marginal bone changes at 6 months, twelve studies at 1 year, five studies
 301 at 3 year and seven studies at 5 year, only few studies reported the values at 3 months (Gulati 2015),
 302 at 18 months (Ericson 1994) and finally at 2 year (Cecchinato 2004, Heijdenrijk 2006).

303 Duda 2016 had the following follow-up: 6 months, 12 months, 24 months, 36 months and 60
 304 months reporting better performances of BL-implants in the first timing except for 60-months with
 305 there is in no radiological values for TL-implants.

306 The distribution of the mean bone level changes was presented in Table 6. The mean values of
 307 marginal bone loss (changes) were weighted considering the number of implants of each study, so
 308 that differences between 2 intervention groups were calculated with a significance <0.05 .

309 **Table 6.** The mean values of marginal bone loss (changes) in relation to the number of implants of
 310 each study with corresponding P-values.

Mean value marginal bone changes#	Bone Level implant	Tissue Level	Significance ($p<0.05$)
3 months	0.19	0.28	/ (Only Gulati 2013)
6 months	0.33	0.42	0.0169* (3 studies)
N=115	n=65	n=50	
12 months	0.25	0.18	0.0000* (12 studies)
N=1850	n=971	n=879	
18 months	0.05	0.04	/ (Only Ericsson 1994)
24 months	0.18	0.24	0.1907 (2 studies)
36 months	0.45	0.48	0.5031 (5 studies)
48 months	1.4	1.6	/ (Only Heijdenrijk 2006)
60 months	0.29	0.38	0.0050* (7 studies)

N=1069

n=576

n=493

#The mean values of marginal bone loss (changes) are weighted considering the number of implants of each study.

*The T-test reported significance with $p < 0.05$

311

312 At 3 and 4 months the marginal bone loss was less in BL-groups, but the differences were not
313 significant, plus only one study had such a short follow-up (Gulati 2015).

314 At 6 months the marginal bone loss was calculated in a total of 115 implants and it was lower in
315 BL-groups than TL-groups, with a significance < 0.05 . This statistically significant difference was
316 inverted at 12 months (less in TL than BL) with a sample of 1850 implants ($p < 0.01$). The follow-up 12
317 months is the most representative of all included studies. The bone loss reported was again less in TL
318 at 18 months, less in BL at 24 months and 36 months, but these 3 time-point were not statistically
319 significant.

320 After 60 months of follow-up the mean marginal bone loss was less in BL-group then in TL-
321 group with a sample of 1069 implants ($p < 0.01$).

322 4. Discussion

323 This review gave clinicians an overall view of the topic to improve the knowledge of the
324 marginal bone level changes after several years of follow up, thus showing if different implant
325 systems (bone level vs tissue level) could affect bone resorption.

326 Two recent systematic reviews and meta-analyses conducted by Sanz-Martín and colleagues
327 (2018) analysed all randomised controlled trials (RCTs) until 2016 that investigated macroscopic
328 design, surface topography, and the manipulation of the abutment. The authors reported no
329 significant differences between these implants on peri-implant parameters. Only the abutment
330 material had a significant impact on BoP values and Δ MBL.^{37,38}

331 While Sanz-Martín and colleagues focused on the topic on abutment, other reviews studied the
332 shoulder of the fixture. Starch-Jensen, Christensen, and Lorenzen (2017) reported significantly more
333 peri-implant marginal bone loss and higher BoP score in implants with a scalloped implant-abutment
334 connection and not in the flat implant-abutment connection, despite their initial hypothesis.³⁹ But
335 their review included only three studies.

336 Also, Tallarico and colleagues (2018), in another systematic review on the topic that also
337 analysed studies until 2016 (7 RCTs and 5 comparative studies), highlighted no significant evidence
338 that the implant shoulder position/orientation and design offered improvements in clinical and
339 radiological outcomes. Nevertheless, they also included one-piece implants and they admitted that
340 these results were limited due to the quality of available studies.⁴⁰

341 In the present analysis, three studies (Astrand 2004; Chappuis 2016; Sanz-Martin 2016) reported
342 slightly better values in marginal bone loss in BL-groups than TL but with no significance. No
343 significant differences were found also in three studies (Bassi 2016; Cecchinato 2004, 2008) in which
344 the marginal bone loss was slightly less in TL than in BL; while three studies (Bömicke 2017; Duda
345 2016; Lago 2018) reported statistically significant bone loss lower for BL than TL and only one study
346 (Gamper 2017) highlighted better radiological outcomes in TL. The other 10 studies did not highlight
347 any statistical differences.

348 The results of this review showed that most parts of the articles reported no differences between
349 BL and TL according to bone loss, survival and success rate, or clinical outcomes. This observation is
350 confirmed by the last review of Palacios-Garzón, Velasco-Ortega, and López-López (2019), which
351 reported a similar bone loss for both types of implants.⁴¹

352 Despite the bone level changes being worse in TL-implants than BL-implants at 6-months of
353 follow-up ($p < 0.05$) and 60-months of follow-up ($p < 0.01$), as reported in the results, the time-point the
354 most representative of all quantitative analysis is 12-months because it has the larger sample of
355 implants involving a major number of studies. In fact, 12 studies reported the radiological outcome
356 at 12-months of follow-up, 7 studies at 60-months of follow-up and only 3-studies at 6-months.

357 It could be reasonable to assume that the results at 12-months are more important for the number
358 of implants and studies involved, nevertheless there are too many differences for each time-point.
359 Moreover, Duda 2016 missed the radiological outcome of TL-implants at 60-months so only the
360 comparison on the other time-point were analysed.

361 The results of the present review are limited due to the quality of data, the number of comparable
362 available studies, and the wide variability, all of which could influence the final results.

363 Also, the different surgical protocols (one-stage or two-stages) may influence the bone changes,
364 especially in the first period of healing and the prosthetic final rehabilitation is not standardized in
365 the included articles, plus some studies did not reported specific information about the kind of
366 prosthesis.

367 Moreover, in the majority of the studies included in this review, the implants were inserted in
368 mandible, but the bone quality and healing are different between upper and lower jaws.

369 It has been reported that the peri-implant tissues are more susceptible to inflammation than
370 natural teeth.⁴² Nevertheless, the definitions of survival rate/success/failure used in the literature do
371 not necessarily reflect the patients' chances of success or the function and aesthetics of the treatment
372 because bleeding on probing (BoP), increasing of pocked probing depth (PPD), and other clinical
373 outcomes are surrogates and the true link with the peri-implant tissues is questionable.⁴³

374 It has been reported that the implant type and the surgical protocol (bone level vs tissue Level)
375 is correlated to the soft tissue bleeding response after probing (BoP) because of the presence of a
376 chronic infiltrate at the implant-abutment interface of two-piece implants, attributed to the micro-gap
377 between the implant and the abutment.⁴⁴

378 On the contrary, the peri-implant tissue around transmucosal implants has been reported to be
379 inflammation-free, possibly due to the absence of a micro-gap reporting a lower prevalence of BoP.^{45,46}
380 According to the literature, in fact, there is a higher BoP prevalence detected in two-piece implants
381 than in one-piece implants.⁴⁷

382 These studies, plus the biological rationale for the inflammation, have been pushing clinicians
383 and researchers to assess if there are clinical differences in BoP and marginal bone changes in one-
384 and two-piece dental implants. However, in more recent articles, these clinical and radiological
385 differences between types of implants are not statistically significant reported probably due to the
386 more efficient platform switching, the surface of the neck and the type of abutment material.^{48,49}

387 Moreover, several authors have reported a lack of correlation between clinical outcomes (PPD
388 and BoP) and crestal bone loss around implants.^{50,51}

389 A retrospective study on 4591 implants in 2060 patients with 10-year follow-up reported that,
390 while BoP was very commonly detected on implants (40% of implants in the cohort study), only 3%
391 of these implants had more than 1 mm of marginal bone loss. The study concluded that the minimal
392 bleeding on probing in implants was not correlated with marginal bone loss and therefore probing
393 healthy implants was not recommended.⁵²

394 Even if the BoP level is reported to be more frequent in BL implants compared TL one as a
395 marker of local inflammation in two-pieces implants, the latest systematic review conducted by Paul
396 and Petsch (2017) reported no differences between these types of implants, infact the clinical
397 examination of BoP around dental implants is not completely validated as a clinical outcome to
398 evaluate the bone loss.⁵³

399 In the present review, a statistically less marginal bone loss was reported at one-year follow-up
400 in TL-implants, but after five years of follow-up the BL reported statistically better results. The
401 heterogeneity of the results in the different studies and the oscillation between BL and TL bone loss
402 according to the follow-up are possibly due to other confounding factors such as implant micro
403 surfaces, implant shape, and the implant-abutment connection to prevent bacterial infiltration.^{54,55}

404 Implant dentistry needs more prospective studies with more standardized characteristic
405 considering, the bone quality, the site position, the type of loading in order to analyse the bone loss
406 differences associated to one or two-pieces implants.

407 Nowadays, the focus should be shifted to the morphology and geometry of the implant neck.
 408 This could improve connective and bone stability and guide bone healing, especially in the period
 409 immediately after surgery.⁵⁶

410 5. Conclusions

411 In the present review, no evidence was found of differences in marginal bone loss or implant
 412 survival rate between bone-level and transmucosal dental implants after a period of follow-up
 413 variable from 12 to 60 months. Some patients, especially with chronic disease, may benefit from
 414 transmucosal implants because of the lack of bacterial leakage in the implant-abutment connection,
 415 but no evidence of long-term effect on bone loss is reported. It could be concluded that many other
 416 clinical and surgical variables influence marginal bone level and implant survival. More homogenous
 417 clinical trials with larger samples are needed to support these conclusions and to give more precise
 418 clinical indications.

419 BIC: Bone to Implant Contact

420 BL: Bone-Level (implants)

421 BoP: Bleeding on Probing

422 PPD: Pocked Probing Depth

423 IAJ: Implant-Abutment Junction

424 Δ MBL: Marginal Bone Loss

425 RCTs: Randomized Clinical Trials

426 TL: Tissue-Level (implants)

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