系统综述

种植体颈部微螺纹设计对种植体周围边缘骨吸收的影响：系统性回顾与荟萃分析

牛文芝 王鹏来 朱绍跃 刘宗响 汲 平

摘 要

目的：系统评价种植体有无颈部微螺纹设计对种植体边缘骨吸收（MBL）量的影响。**方法**：计算机检索 PubMed，Cochrane Central Register of Controlled Trials，EMBASE，Web of Sciences，and AMED（Ovid） databases 数据库辅以手工检索及文献追溯，收集 2015 年 8 月 19 日前所有公开发表的研究有无颈部微螺纹设计对种植体 MBL 影响的随机对照试验（RCT），由 2 位评价者根据纳入与排除标准独立筛选文献，对纳入文献进行描述、质量评价和 Meta 分析。**结果**：共 5 篇文献 339 颗种植体纳入定性分析，其中 3 篇文献纳入 Meta 分析。4 篇文献显示微螺纹设计可以显著减少 MBL，1 篇文献未发现显著性差异。3 篇纳入 Meta 分析的文献异质性在可接受的范围内（I2=0.49）。Meta 分析结果显示颈部微螺纹设计种植体边缘骨吸收量显著低于无微螺纹设计的种植体（P=0.030；MD：−0.09；CI：−0.18 to−0.01）。**结论**：现有的有限数据表明，种植体颈部微螺纹设计相对于无微螺纹设计可以减少种植体边缘骨吸收。研究结果尚有待于高质量大样本的随机对照试验予以证实。

关键词 种植体；边缘骨吸收；颈部微螺纹

临床研究显示种植体的长期存留率为 96%[1,2]。种植体的失败影响因素很多，包括卫生条件、牙槽骨骨质和骨量，种植体系统选择等[3,4]。种植体的宏观和微观设计是影响种植体初始稳定性和应力分布的重要因素[5]。目前临床上应用的种植体有 100 多个品牌[6–8]。临床研究表明种植体颈部采用粗糙微螺纹设计可以显著减少种植体长期负荷后的边缘骨吸收（Marginal bone loss，MBL）[9–15]。有限元分析显示微螺纹种植体模型在种植体周围的皮质骨区域内有更高的压应力和更小的剪切力，因而减小了种植体边缘骨吸收的量[16–19]。动物研究显示微螺纹种植体的种植体边缘骨结合率更高，骨结合更好[20,21]。然而，也有一些学者持不同意见：如果口腔卫生条件良好，微螺纹和普通螺纹设计的种植体

作者单位 天津市河西区九龙路 84 号 300204

负荷后边缘骨吸收无显著性差异[22-25]。这篇 Meta 分析的目的就是研究颈部微螺纹设计对减少种植体 MBL 是否有效。

1　材料和方法

本文在 PRISMA 指南指导下进行系统性回顾与 Meta 分析，并在 PROSPERO 平台进行了注册（CRD 42015023971）[26,27]。分析的 PICO（patient，intervention，comparator，outcome：患者、干预措施、比较、结果）问题是：对于接受种植治疗的患者，种植体颈部微螺纹设计能否改变种植体周边缘骨吸收的量？

1.1　检索方法

2 名研究员（牛文芝、王鹏来）分别独立对 PubMed，Cochrane Central Register of Controlled Trials（CENTRAL），EMBASE，Web of Sciences，AMED（Ovid）数据库进行检索，无语言限制。应用 Mesh 主题词为‘Dental implant’，‘Dental implantation’，自由词为‘dental implant*’，‘oral implant*’，‘tooth implant*’，‘teeth implant*’，‘osseointegrated AND implant*’ and ‘microthread*’。主题和自由词组合检索 2015 年 8 月 19 日前所有发表的文献。为每个数据库制定检索式，以 Pubmed 为例，检索式见表 1。同时手工检索以下杂志：*Clinical Implant Dentistry and Related Research*，*Clinical Oral Implants Research*，*European Journal of Oral Implantology*，*Implant Dentistry*，*International Journal of Oral and Maxillofacial Surgery*，*Journal of Cranio Maxillofacial Surgery*，*Journal of Dental Research*，*Journal of Oral Implantology*，*and Journal of Periodontolog*。

1.2　纳入标准和排除标准

比较种植体颈部有无微螺纹设计对种植体周边缘骨吸收影响的 RCT 纳入研究。排除标准主要是：病例报告、综述、动物研究、有限元分析、体外研究、混杂有微螺纹外的其他因素，研究的观察时间少于 1 年。2 名研究者（牛文芝、朱绍跃）分别阅读题目和摘要来确定文献是否纳入研究，必要时阅读全文。如遇分歧，由第三人（汲平）与研究者一起讨论解决。

1.3　质量评价

2 个研究者（牛文芝、王鹏来）应用 Cochrane 偏倚风险评估量表（Cochrane Collaboration tool for assessing risk of bias）[28] 分别进行质量评价，评价包括 7 个维度：随机序列的产生、分配隐藏、实施者和参与者双盲、结局评估中的盲法、不全结局数据、选择性报告、其他偏倚。如遇分歧通过讨论来确定。

1.4　数据提取和统计分析

2 个研究者（牛文芝、王鹏来）单独进行数据提取，包括以下内容：出版年限、参与者特征、随访时间、种植体品牌、种植体表面特点（粗糙还是光滑、颈部是否有微螺纹）、种植体失败数据、边缘骨吸收数据。如果数据不清楚则与作者联系。MBL 变化的量采用均值差及其 95%CI 作为效应分析统计量。应用 Cochrane 协作网提供的统计学软件 Review Manager v5.3 进行统计分析。

2　结果

2.1　检索结果

初检筛出相关文献 174 篇（计算机检索得到 138 篇，手工检索 36 篇），去重后得到文献 94 篇。根据纳入和排除标准，通过阅读文题、摘要，排除文献 57 篇。剩下的 37 篇通过阅读全文，排除文献

表 1　PubMed 检索策略

PubMed search strategy
Search ((((((((((((dental implant[MeSH Terms]) OR dental implantation[MeSH Terms]) OR dental prosthesis, implant supported[MeSH Terms]) OR dental implant*[Text Word]) OR oral implant*[Text Word]) OR ((tooth implant*[Text Word]) OR teeth implant*[Text Word])) OR (((osseointegrated AND implant*) AND (dental OR oral)))) OR ((dent*[Text Word]) AND implant*[Text Word])) OR endosseous implant*[Text Word]) OR ((overdenture*[Text Word]) AND implant*[Text Word])) OR (((((crown*[Text Word]) OR bridge*[Text Word]) OR prosthesis[Text Word]) OR prostheses[Text Word]) OR restoration[Text Word]) AND implant*[Text Word]))) AND microthread*[Text Word]

32 篇（没有对照组[29−46]、混杂有其他因素[14,23,47,48]、数据不完整[13]），最终 5 篇文献纳入系统性分析，其中 3 篇纳入 Meta 分析 (具体纳入流程见图 1)。这 5 篇的详细数据见表 2。所有研究对象都是成年人（23 岁～ 78 岁）。每篇文献均研究了 2 组种植体的 MBL，这两组种植体品牌、外形、表面处理、种植体基台连接方式均相同，只有颈部设计不同。共有 339 颗种植体纳入研究，随访周期是 1 ～ 5 年。随访期内无种植体脱落。一共有 4 篇文献[10,15,16,24]认为颈部微螺纹设计可以显著降低功能负荷后种植体周围 MBL 的量，1 篇文献[12]认为 1 年功能负荷后微螺纹颈部种植体周围 MBL 的量和普通螺纹颈部无显著性差异。研究又可分为 2 个亚组：S1 组包括 2 篇文献[12,15]，比较粗糙微螺纹颈部和光滑颈部；S2 包括 3 篇文献[10,16,24]比较粗糙的微螺纹颈部和粗糙的无微螺纹颈部。S1 组的 2 篇研究 MBL 的基线不同无法进行 Meta 分析。每篇文献的偏倚评估显示在图 2 中。

2.2 Meta 分析结果

3 篇文献[10,16,24]共 57 颗种植体纳入了 Meta 分析，异质性检测显示在可接受的范围内 (I^2=0.49)。结果显示有显著性差异，平均差是 −0.09（95%CI =−0.18 to −0.01）

利用漏斗图来评价纳入文献的发表偏倚，漏斗图没有显示明显的不对称性，意味着发表偏倚不明显。然而，因为纳入的研究较少，这种评价发表偏倚的方法效能可能不确定。

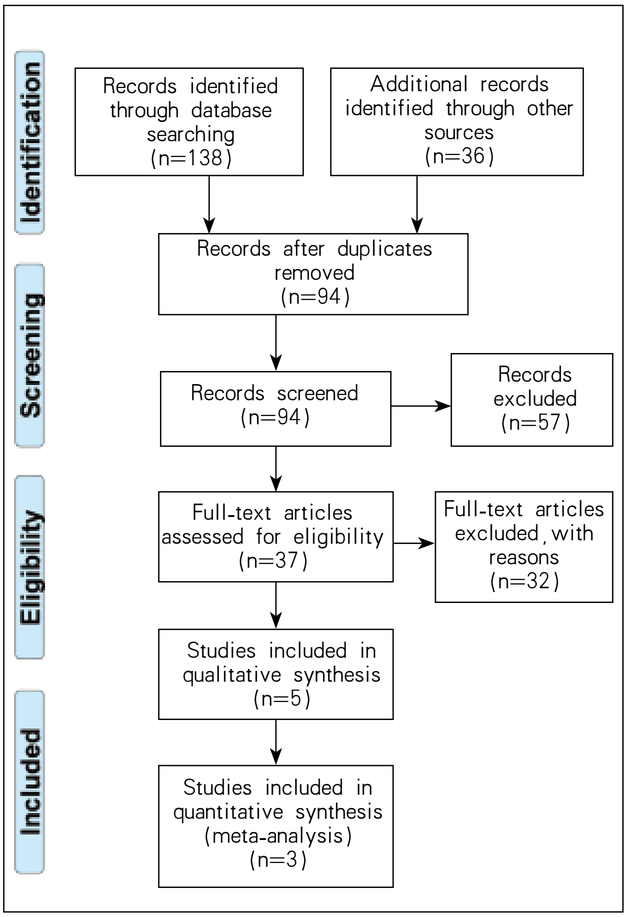

图 1 Literature search flow

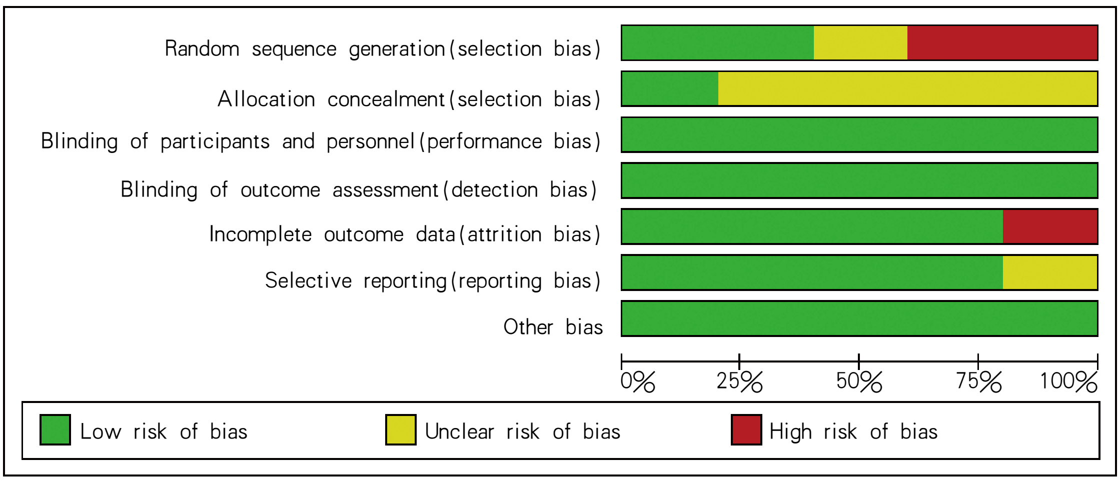

图 2 Risk of bias graph: review authors judgements about each risk of bias item presented as percentages across included studies.

表2 纳入研究的具体情况

研究	年度	患者(n)and性别	患者年龄(均值)	种植体数目(n)	失败的种植体(n)	随访周期(年)	1年功能负荷后种植体边缘骨吸收的量(mean ± SD)(mm)	种植体品牌	种植体表面特点
Bratu et al[12]	2009	46 (NR)[a]	23–65(NR)	92 (C46, E46)	0/92	1	1.47±0.4(C) 0.69±0.25(E)	MIS–Implants Inc	C polished neck E rough microthreaded
Kang et al[24]	2012	20(12M,8F)	23–65(52.6)	40 (C20, E 20)	0/40	1	0.15±0.14(C) 0.13±0.14(E)	Megagen	C rough macrothreaded E rough microthreaded
Lee et al[10]	2007	17(9M, 8F)	31–76(53.3)	34 (C17, E17)	0/34	3	0.28±0.19(C) 0.14±0.11(E)	Astra Tech TiOblast Implant	C rough E rough microthreaded
Song et al[16]	2009	20(11M, 9F)	37–78(57.3)	40 (C20, E 20)	0/40	1	0.30±0.22(C) 0.16±0.19(E)	Dentium	C rough without microthread at the top 0.5mm of the neck E rough with microthread at the top
Nickenig et al[15]	2013	34(NM)	25.2–55.5 (45.2)	133 (C63, E70)	0/133	5	0.8 (0～2.4)(C)[b] 0.4 (0～2.1)(E)	Replace, Nobel	C polished neck E rough microthreaded

NR, not reported; C, control group; E, experiment group; SD, standard deviation

[a]There were 48 participants in study, however, two participants failed to complete all follow–up meetings, and were thus excluded.

[b] Data show amount of MBL after 6 months functional loading. Study did not reported MBL after 1 year functional loading.

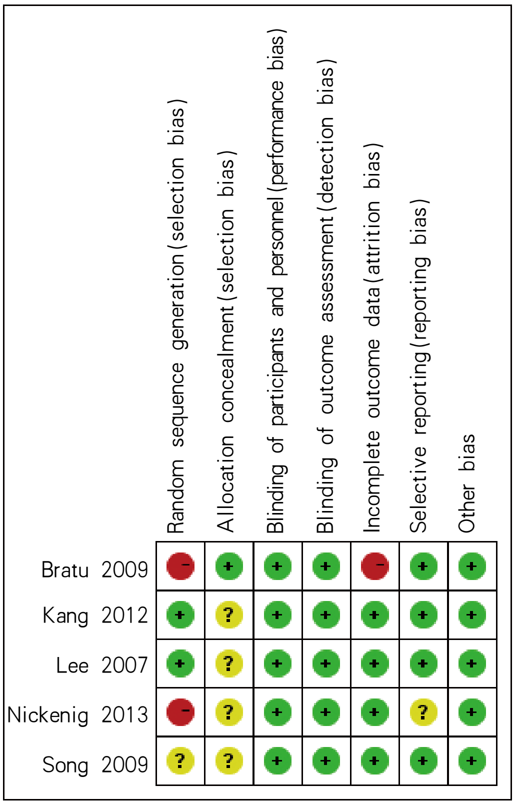

图 3　Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

3　讨论

本次系统性回顾和 Meta 分析的目的是评价不同种植体颈部设计 MBL 的不同。研究发现颈部微螺纹种植体周围 MBL 的量显著低于无微螺纹种植体。所有的纳入文献均为 RCT。异质性是可接受的，应用了随机效应模型来进行 Meta 分析。MBL 对种植体长期存留率和最终美学效果十分重要。种植体成功关键的一点是第一年 MBL 低于 1 ~ 1.5mm，以后每年低于 0.2mm[49]。Hansson[50] 在三维有限元分析的基础上提出修饰有微螺纹的粗糙颈部设计可以减少种植体周围的剪切力从而降低种植体周围边缘骨吸收。之后很多学者在微螺纹方面进行研究认为微螺纹设计对降低 MBL 有利，然而，部分研究混杂有其他因素。比如 Shin[9] 和 Piao[14] 研究比较的种植体品牌和种植体外形宏观设计不同。类似混杂有其他因素的研究本次没有纳入。本文纳入的文章研究的种植体仅有颈部设计不同，因而可以明确反应种植体颈部微螺纹设计的作用。Meta 分析的结果显示有微螺纹设计的粗糙颈部种植体周围边缘骨吸收的量明显小于无微螺纹的 (P=0.03)。然而，这个差别的绝对值较小 (MD：−0.09；CI：−0.18 to−0.01) 在种植体长期临床存留率和失败率未见明

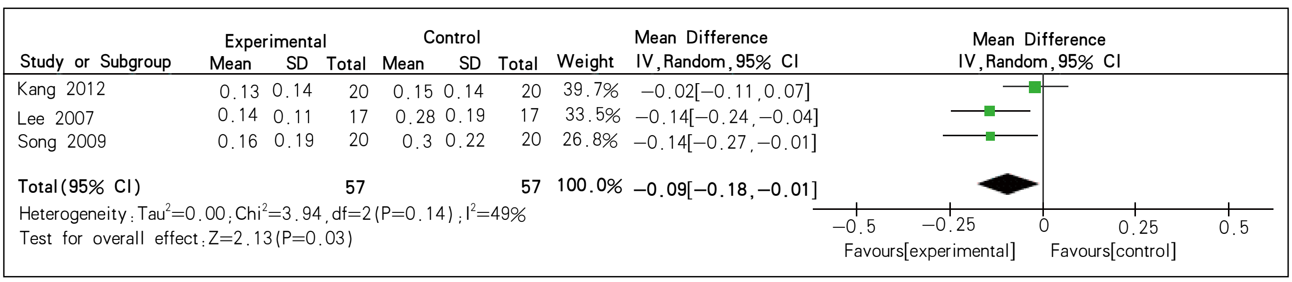

图 4　Forest plot of comparison: marginal bone loss 1 year after functional loading.

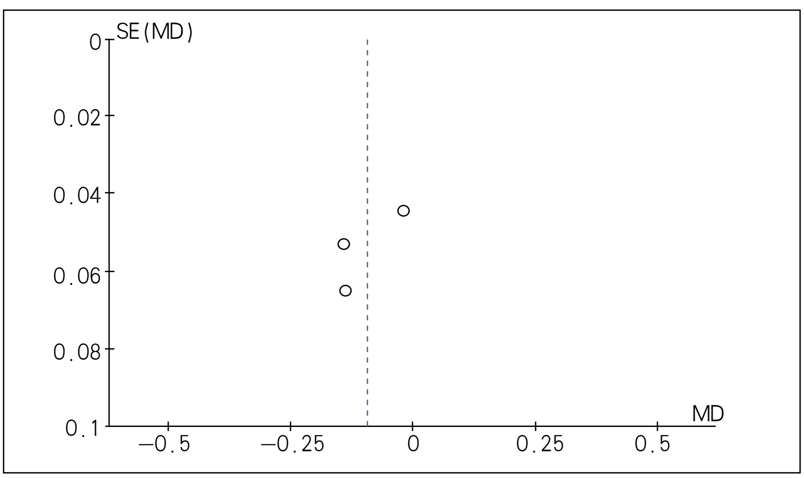

图 5　Funnel plot of comparison: marginal bone loss 1 year after functional loading.

显不同。S1 组中的研究显示粗糙颈部微螺纹种植体比无微螺纹设计的光滑颈部更大，这说明种植体微螺纹和粗糙颈部都可以减少种植体周围边缘骨吸收。Nickenig 等人[15] 比较粗糙微螺纹颈部和光滑颈部发现，微螺纹可以显著降低边缘骨吸收。由于 Nickenig 的文章没有提供精确的数据，本次研究未纳入。

本次研究的局限性有三个方面：第一，随访周期短。有三篇文献的随访周期仅为 1 年[12,16,24]，Lee 等人[10] 的为 3 年，Nickenig 等人[15] 的为 5 年。Lee等人发现第一年的差异比第二三年的更为明显，Nickenig 等人也有此发现。然而，Lee 和 Nickenin 的文献因数据基线不同未纳入 Meta 分析。第二、选择偏倚风险较高。有 2 篇文章[12,15]（40%）在随机序列中评分为高风险。在 1 篇文章中[12]，所有光滑颈部的种植体被植入近中位点，而粗糙微螺纹种植体被植入远中位点。然而，由于近中位点靠近天然牙，被认为骨水平更为稳定[51]。近中位点的光滑颈部种植体周边缘骨吸收的量比远中位点粗糙微螺纹种植体的多，在一定程度上增加了本文结果的可信性。另一篇文献中患者是按照就诊顺序编号的[15]。三、Meta 分析纳入的文章较少。只有 3 篇文献纳入，这是因为 MBL 的影响因素较多，微螺纹设计只是其中一种。很多研究虽然比较了微螺纹，但是混杂有其他因素。只有无混杂因素的 RCT 才能纳入研究，因而这些文章被排除了。由此可见，下一步该问题的研究方向应为加大样本量，延长随访时间，尽量减少混杂因素。

4 结论

4.1 种植体颈部微螺纹设计可以显著减少功能负荷下的种植体周边缘骨吸收。

4.2 粗糙颈部种植体 MBL 的量比光滑颈部种植体的少。

4.3 纳入 RCT 有限，临床证据尚不充分。

4.4 以后需要更多随访周期更长、样本量更大、混杂因素控制较好的 RCT 研究。

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