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Research Article

Parathyroid Hormone Enhances Primary Stability of Dental Implants and Radiographic Analysis: Randomized, Split-Mouth Clinical Trial

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Abstract

Background: Dental implants are a highly effective treatment in modern dentistry and are employed when enough high-quality bones are available to give optimal support and long-term success in restoring function. No material meets all the criteria to be considered the ideal graft. Parathyroid hormone, specifically PTH1-34, offers a promising and efficient approach to enhancing bone regeneration. ***Objective***: To evaluate the effect of PTH with bone graft on socket preservation in radiographical assessment and primary stability of the implant. ***Methods***: This study included 16 patients with 32 sockets; 16 received xenograft only, and 16 received xenograft with PTH after tooth extraction. The bone height and width of the socket were measured after extraction and before placing the implant using cone beam computed tomography (CBCT). The implant stability was measured using Osstell® (ISQ) and was recorded immediately. ***Results***: After a 4-month follow-up period, the reduction of buccal bone height (BBH), labial bone height (LBH), and horizontal bone width (HBW) between the group of bone grafts only, and the bone graft with PTH group was statistically non-significant. Additionally, highly significant primary stability in the PTH group. ***Conclusions***: The use of xenograft and PTH (1–34) can enhance the primary stability of the implant and recovery of cortical and cancellous bone surrounding dental implants.

Keywords: CBCT imaging, Parathyroid hormone, Socket preservation, Tooth extraction.

هرمون الغدة الجار درقية يعزز الاستقرار الأولي لزراعة الأسنان والتحليل الشعاعي: تجربة سريرية عشوائية منقسمة الفم

الخلاصة

الخلفية: تعتبر زراعة الأسنان علاجا فعالا للغاية في طب الأسنان الحديث ويتم استخدامها عند توفر عظام عالية الجودة كافية لتقديم الدعم الأمثل والنجاح على المدى الطويل في استعادة الوظيفة. لا توجد مادة تفي بجميع المعايير ليتم اعتبارها الأختيارالمثالي. يقدم هرمون الغدة الجار درقية، وتحديدا PTH1-34، نهجا واعدا وفعالا لتعزيز تجديد العظام. **الهدف**: تقييم تأثير PTH مع ترقيع العظام على الحفاظ على التجويف في التقييم الشعاعي والاستقرار الأولي للزرع. **الأساليب**: تضمنت هذه الدراسة 16 مريضا مع 32 تجويف ؛ تلقى 16 طعما زينا فقط ، و 16 تلقوا الطعم الغريب مع PTH بعد قلع الأسنان. تم قياس ارتفاع عظم التجويف وعرضه بعد القلع وقبل وضع الغرسة باستخدام التصوير المقطعي المحوسب بالحزمة المخروطية (CBCT). تم قياس ثبات الغرسة باستخدام Osstell® (ISQ) وتم تسجيله على الفور. **النتائج**: بعد فترة متابعة مدتها 4 أشهر ، كان انخفاض ارتفاع عظم الخد (BBH) وارتفاع عظم الشفرين (LBH) وعرض العظام الأفقي (HBW) بين مجموعة ترقيع العظام والطعم العظمي مع مجموعات PTH غير معتد به إحصائيا. بالإضافة إلى ذلك، حصل استقرار أولي مهم للغاية في مجموعة PTH. **الاستنتاجات**: يمكن أن يؤدي استخدام xenograft و PTH (1-34) إلى تعزيز استعادة العظام القشرية والاسفنجية المحيطة بزراعة الأسنان.

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INTRODUCTION

Tooth extraction is recommended when a tooth is beyond repair or cannot be maintained for an extended period in terms of appearance or functionality [1]. Tooth extractions lead to physiological resorption that decreases the height and width of the alveolar ridge [2]. Alveolar bone loss can occur after a tooth extraction, with most of the bone loss happening within the first three months of the healing process [3]. There are two scenarios when this might present difficulties. Firstly, it can create cosmetic problems when making fixed prostheses. Secondly, it can pose a risk to the placement of dental implants and necessitate the use of guided bone regeneration (GBR) [4]. Before implant placement, it is essential to do a thorough clinical and radiographic assessment of the adjacent bone [5]. Dental implant-supported prostheses are considered a very effective approach for oral rehabilitation due to their excellent cosmetic outcomes, low failure rates, and superior ability to chew food. After implant therapy, achieving optimal functional and cosmetic prosthetic restoration necessitates adequate alveolar bone volume in both the vertical and horizontal dimensions [6]. To address this issue, a detailed surgical approach has been developed to maintain the alveolar ridge in the

extraction socket, hence minimizing bone resorption. Different graft materials have been utilized, such as autografts, xenografts, and alloplastic materials [7]. Applying a barrier membrane across them may disrupt the bone resorption process and reduce the loss of the alveolar ridge. Systemic anabolic agents might stimulate alveolar bone repair. Teriparatide, the first 34 amino acids of the parathyroid hormone, is a Food and Drug Administration (FDA)-approved osteoporosis anabolic. Teriparatide increases bone mineral density and reduces fracture risk in osteoporosis patients, according to many clinical studies [8]. Due to a lack of studies that use parathyroid hormone PTH in humans, which has been proven to enhance bone quality, and directly injecting it into the study animals. While these results can show the stability or integration of dental implants, improvements in RFA (resonance frequency analysis) or Osstell ISQ might give a clearer picture of how PTH affects implant integration. Kuroshima *et al.* showed that intermittent PTH treatment greatly improved bone regeneration in tooth extraction sockets in rats that did not receive grafts [9]. Regardless of the kind of graft materials used, intermittent parathyroid hormone (PTH) treatment resulted in a considerable increase in bone fill in the extraction sockets of grafted teeth. Multiple investigations have demonstrated that PTH (1-34) has dual effects; it promotes bone growth when given intermittently and produces catabolic effects when supplied continuously [10]. Administering PTH subcutaneously and intermittently at a dose of 80 µg/kg every day enhanced the regeneration of alveolar bone in the tooth extraction socket. Intermittent and systemic parathyroid hormone (PTH) treatment decreased alveolar bone loss in hyperglycemic rats [11]. Thus, PTH therapy can be considered a promising approach to enhance the quantity of newly formed calcified bone and improve the mechanical integrity of the bone [12]. This study presents a new approach for keeping the area where a tooth was removed stable and improving the support for dental implants. It uses PTH (1–34) and a type of bone graft from another species to immediately fill the empty socket. This method aims to boost bone growth and maintain the socket after tooth removal and implant insertion. By maintaining the height and width of the alveolar bone, the main result was socket preservation. A secondary outcome was optimizing the primary stability of the implant. Observed individuals who appear to have aged prematurely due to tooth loss and a lack of lip and facial support; maintaining bone levels as patients age is a continuous challenge in the field of dentistry. After teeth removal, there is a significant decrease in bone height and width, which presents a challenge for maintaining aesthetic appearance and ensuring stability during restoration procedures; it is crucial to preserve bone mass before it undergoes resorption. The alveolar ridge enhancement uses different techniques to optimize implant installation and primary stability. This study aims to evaluate the influence of PTH with bone graft on socket preservation in radiographical assessment and primary stability of the implants.

METHODS

Study design and setting

This clinical study was blinded, randomized, and a split-mouth design conducted between September 2022 and September 2023. The target population included patients seeking implant therapy diagnosed with two or more non-adjacent, non-restorable teeth.

Inclusion criteria

Adult patients with hopeless teeth should have their teeth extracted (due to severe decay, endodontic issues, fractured roots, or prosthetic reasons), and their implant placement should be postponed. The patients had no localized or systemic illnesses that could have impaired their healing ability after surgery.

Exclusion criteria

Uncooperative patients, smokers, received chemotherapy or radiation therapy to the head and neck area, diabetes, osteoporosis, auto immune disease as well as those who have used bisphosphonate medication.

Intervention and outcome measurements

A minimum of two hopeless teeth were removed for each of the 16 patients in the sample, aged 25 to 60; 9 of them were female, and 7 of them were male. A bone graft (bovine-derived) and PTH (1-34) were placed into one of the sockets, and the other sockets were filled with bone graft only. By flipping a coin, the intervention was distributed to these locations randomly. For preoperative assessment of an implant site (using On-demand software), a cone beam 3D system (Kavo OP 3D Pro, Panorex + Cone Beam) with a resolution range from 80 to 400 µm was employed. The settings were set at 90 kV, 6.8 mA, and 10-20 s with an 80-400 µm image voxel size. The end osseous dental implant (Medentika, Heilsheim, Germany) that was utilized (Botiss dental GmbH, Berlin, Germany) was bovine bone-derived (xenograft), and parathyroid hormone (PTH 1-34) used was powder and soluble at 0.40 mg/ml in water.

Surgical procedure

Before the procedure, the patient was under local anesthesia with a 1:1,000,000 dose of lidocaine with epinephrine. The hopeless teeth were carefully removed with elevators and forceps to reduce the risk of buccal bone plate fracture and to use a minimally intrusive method as in Figure 1A. Following appropriate degranulation of the extraction sites, the patient received appropriate instructions before having two teeth extracted for the same patient. A xenograft is placed in one extraction socket and combined with parathyroid hormone in another socket (Figure 1B). The socket was stitched up with 0-3 black silk stitches after putting in a collagen membrane for tissue regeneration (Figure 1C).

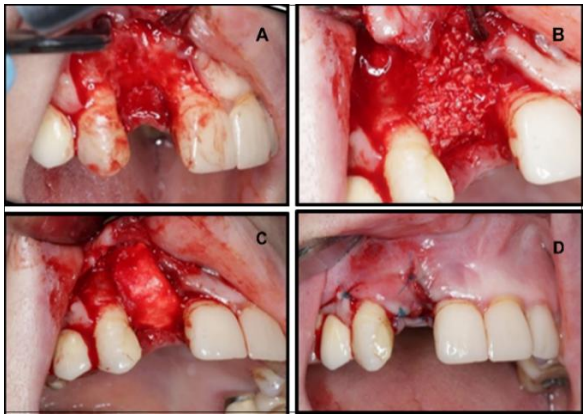

Figure 1: The surgical extraction (A) and placement of the bone graft (B), with or without PTH (C) in the socket and collagen membrane with suturing (D).

Radiographic evaluation after extraction and before implant placement

Using the on-demand software tools at the same reference locations and lines, CBCT measurements were performed at baseline before extraction and four months after grafting material. From the apical reference point, a vertical line was drawn through the line socket center (A). At the most apical point of the extraction socket, which was perpendicular to the vertical line, the line drooped horizontally (B). The ridge's height was measured at the mid-lingual/palatal (LBH) and mid-buccal/labial (BBH) aspects from most coronal areas to an apical reference point of the socket parallel to the vertical reference line. We measured the top part of the alveolar bone crest to determine the horizontal ridge width (HBW). This measurement was taken parallel to a horizontal reference line and was less than 2 mm from the crest. The sockets were measured after four months, and the results were compared to the initial measurements in each group and between two groups. Group I: An extraction socket filled with a resorbable collagen membrane (CM; Jason, Botiss dental GmbH) and mineral from bovine bone (BBM, Botiss dental GmbH, Berlin, Germany). Group II: an extraction socket filled with bovine bone and PTH (1-34) that combined and homogenized with a dose of 2.0 µl PTH 1-34 to 157 mm^3 of Botiss dental GmbH (PTH 1-34) in a dose of 2.0 µl PTH 1-34 to 157 mm^3 of xenograft [14]. Then, utilizing the reference line of the cementoenamel junction of the last tooth that was present (Figure 2 B and C).

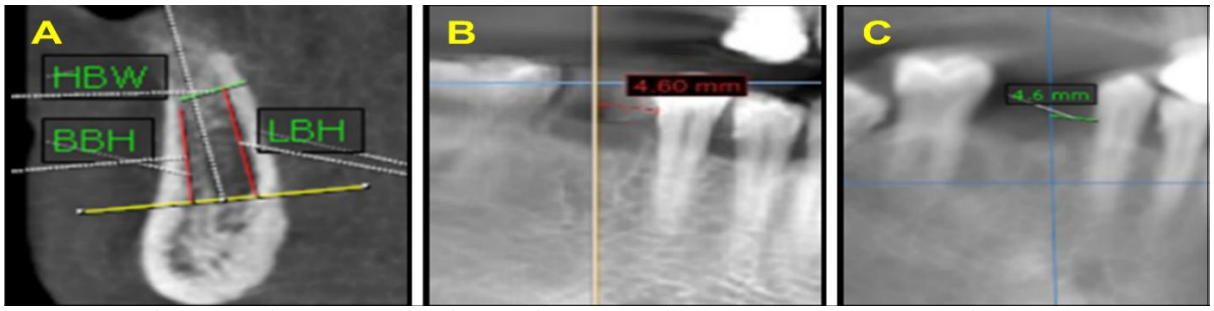

Figure 2: A) the reference line of CBCT measured before and after 4 months of extraction; B) the reference line of the CEJ of adjacent last tooth (before); C) the reference line of the CEJ of adjacent last tooth (after).

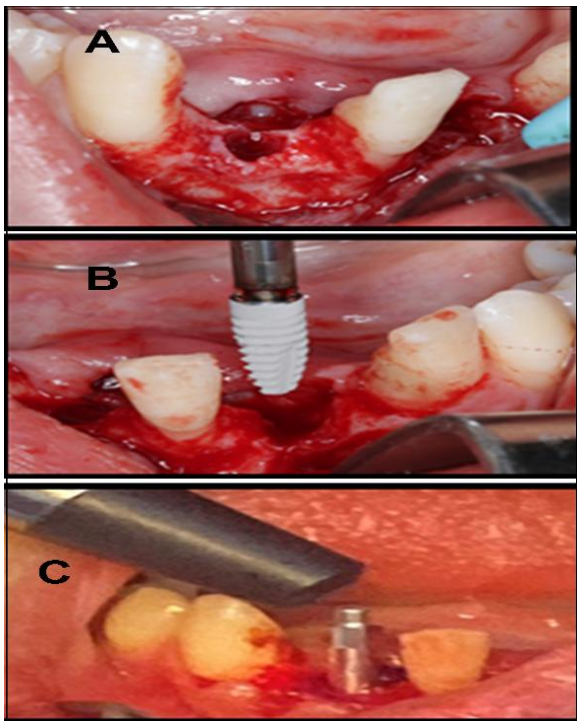

Figure 3: (A) implant site preparation; (B) Implant placement; (C) primary stability measured.

An expert radiologist will perform all measures (baseline and four months post-surgery) under blind supervision. Each CBCT was assigned a code, and patient demographic data was deleted. After implant site preparation and implant placement, the primary stability was measured (Figure 3A, B, and C).

Ethical consideration

The study was conducted in accordance with the ethical principles of Declaration of Helsinki. It was carried out after obtaining the consent of participants before enrollment. The study protocol and the subject information and the consent form were reviewed and approved by a local ethics committee (Reference: 512622, October 2022).

Statistical analysis

The analysis of the data was done with SPSS version 26. The Shapiro-Wilk test was used to determine whether the data was normal. The independent sample *t*-test and the Mann-Whitney U test were used to compare the two groups. Data within groups were

compared using the paired sample *t*-test. At $p< 0.05$, statistical significance was established.

RESULTS

Mean differences in BBH, LBH, and HBW between the PTH group and the non-PTH group were non-significant ($p> 0.05$) (Table 1).

Table 1: Comparison of BBH, LBH and HBW between PTH and non-PTH group

Variable	Treatment	n	Mean±SD (mm)	Range	Mean rank	*p*-value
BBH	No PTH	16	0.55±0.54	0.0-1.9	16.81	0.849
	PTH	16	0.44±0.30	0.1-1.3	16.91	
LBH	No PTH	16	0.46±0.36	0.1-1.4	17.63	0.490
	PTH	16	0.40±0.34	0.0-1.3	15.38	
HBW	No PTH	16	0.75±0.36	0.3-1.5	18.81	0.161
	PTH	16	0.61±0.42	0.2-1.8	14.19	

BBH: buccal bone height; LBH: labial bone height; HBW: horizontal bone width.

The PTH group had significantly higher primary stability than the non-PTH group ($p< 0.05$) as shown in Table 2.

Table 2: Primary stability in PTH compared to non-PTH group

Treatment	n	Mean±SD	Range	*p*-value
PTH	16	71.00±4.77	65-83	0.004
No PTH	16	65.63±5.08	60-76	

Despite this, there was a considerable decrease in BBH, LBH, and HBW in both groups following treatment ($p< 0.05$), except for HBW, which was a non-significant decrease in the non-PTH group ($p> 0.05$) as shown in Figure 4 and Table 3.

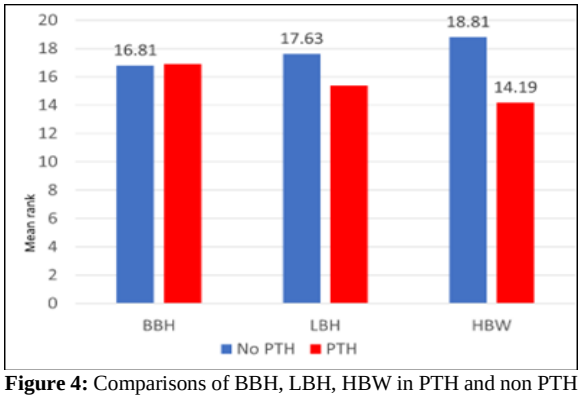

Figure 4: Comparisons of BBH, LBH, HBW in PTH and non PTH group according to the mean difference.

Table 3: Comparisons of BBH, LBH and HBW before and after treatment in PTH and non PTH

Group	Variable	Time	Mean±SD (mm)	*p*-value
No PTH	BBH	Before	11.56±2.33	0.000
		After	11.13±2.21	
	LBH	Before	11.24±2.17	0.000
		After	10.79±2.11	
	HBW	Before	5.86±1.24	0.000
		After	5.11±1.04	
PTH	BBH	Before	11.27±1.76	0.001
		After	10.72±1.56	
	LBH	Before	11.1±1.94	0.000
		After	10.7±1.69	
	HBW	Before	5.91±1.15	0.089
		After	5.49±1.63	

BBH: buccal bone height; LBH: labial bone height; HBW: horizontal bone width.

DISCUSSION

Following a four-month follow-up, there was a notable decrease in alveolar socket height, and this is because bone resorption in the physiological context started as an inflammatory response triggered right after extraction as a natural aspect of bone remodeling. This is consistent with the explanation provided by Horváth *et al*. in their systematic review, which said that vertical and horizontal resorption occurs in the alveolar socket of the extracted tooth as a normal part of bone repair [15]. Bone resorption and soft tissue changes at the extraction site will occur despite all the measures that may be taken to prevent these changes [16]. Radiographically, after the use of PTH with bone graft, there was a considerable limitation in the amount of alveolar socket buccal height loss after a four-month post-extraction period with the mean difference (0.44) than pre-extraction less than that without using PTH with a mean difference of 0.55, also considerable loss of lingual or palatal height loss with a mean difference of 0.40 less than that without PTH (0.46), but there were no significant differences between the groups. It may be attributed to the small sample size shared in this randomized clinical trial, and the samples were distributed randomly in the maxilla and mandible, not determining maxilla or mandible. Although there is a lack of study using PTH in extracted tooth sockets in humans, this study was the first administration of PTH after tooth extraction in humans. It agrees with the study of Emam *et al.*, which used PTH1-34 with xenograft in six domestic pigs to create 3 posterior mandibular defects to simulate tooth extraction sites in humans. CBCT significantly increased the degree of bone mineralization, and local PTH1-34 addition to a xenograft was demonstrated as a great result to improve bone regeneration in the reconstruction of mandibular defects [17]. These findings come in line with Kuroshima *et al*. when intermittent PTH greatly improved bone growth in the grafted sockets that PTH treatment can be very helpful for the success of the ridge preservation procedure in rats whose maxillary first molar teeth were extracted [18]. In addition to Kim *et al*., who clarified that administered. PTH was given for four weeks before tooth extraction for the pre-PTH group and for four weeks following tooth extraction for the post-PTH group in rats, the bone healing in the extraction socket was best in the post-PTH group and helped with the healing of extraction sockets [19]. Another study conducted by Rosha *et al.* suggested that for intermittent PTH 1-34 treatment, the mice were given daily doses of PTH 1–34 or saline for 14 days after femoral allograft reconstruction surgery, which accelerated the healing process as evidenced by new bone formation induced on endosteal and periosteal surfaces and enhanced revitalization of the allogeneic graft [20]. Inconsistent with Xu *et al*., who analyzed the effects of injecting parathyroid hormone (PTH) into the healing of sockets of the rats, although not humans because of a lack of studies that use PTH in human sockets, the results showed that there was no significant difference in the formation of new bone tissue

between the groups that received PTH and those that did not. This lack of response to PTH treatment was attributed to the metabolic characteristics of the hyperglycemic rats [21]. The healing follow-up period in the current study was four months, during which most of the changes in dimensions, both vertical and horizontal, of the alveolar ridge occurred. During this period, the state of the alveolar bone had a big impact on how the results are evaluated, as the first three months of the bone resorption process happened mostly because of the buccal bone plate's resorption, while the dimensional alterations may be seen at least a year following the extraction of a tooth [22]. The current study showed a non-significant reduction in horizontal bone width in the PTH group and no PTH group after 4 months; the mean difference in width is 0.75 mm at baseline and 0.61 mm at implant placement. This may be due to the need for more follow-up time, a larger sample size, and different locations of the extracted teeth, which may have affected the socket's ability to heal. It may also be related to the reference position used to measure the horizontal socket width. Since this region has been observed to experience more extensive dimensional change, the measurements of socket width are frequently obtained at a more coronal position (2 mm) [23]. The study found that after teeth are removed, the alveolar process loses bone, especially in the front part (buccal plate), more than in the back (lingual or palatal) as part of the normal healing process. According to Wange *et al*. and Cardaropoli *et al*., the buccal plate is primarily composed of bundle bone, which is extracted whole and subsequently replaced during the rebuilding process with braided bone. Over time, volumetric changes took place, with the reduction in extent being more noticeable than the height [24,25]. The implant stability quotient (ISQ) values are the most used to assess primary implant stability [26]. The study revealed higher primary stability in the PTH group, with an average of 71.00, in contrast to 65.63 in the non-PTH group. The resonance frequency, obtained from the response signal of the Smart-Peg, was calculated as the ISQ, ranging from 1 to 100. ISQ values of stabilized implants typically range from 57 to 82, indicating the state of the bone. This study's findings may be attributed to the influence of bone quality and quantity at the implant placement site on primary stability. Agree with Oki *et al*. when examining the impact of parathyroid hormone (PTH) on the initial stability of dental implants in a bone-reduced model using 10 female rabbits. The main stability value was found to be significantly higher in the PTH group, with an ISQ value over 70. This indicates a more favorable state of bones and suggests that PTH improved the lower density of cortical and cancellous bone [27]. Disagree with Al-Rawi's study on 13 rabbits that received one threaded Titanium dental implant after extraction of the mandibular right incisor and preparing the socket to receive the implant, and 7 of the animals received a daily dose of Forteo® of (0.25 µg/µl/kg). Even though the primary stability is strongly positive, they were less statistically significant, perhaps due to the small size of the study sample. The xenograft, when loaded with PTH teriparatide, resulted in slowing down the function of osteoclast cells and more bone formation [28]. PTH has been proven to positively affect bone regeneration when administered in an intermittent daily dose. This had led it to be the only FDA–approved therapy in the management of postmenopausal osteoporosis. Teriparatide, or PTH1-34, one of the PTH forms, has been numerously studied in treating several skeletal conditions and proved to enhance bone healing.

Conclusion

Radiographic measurements with CBCT demonstrated that loss of alveolar bone height and width following tooth extraction of sockets filled with PTH (1-34) and bovine-derived bone graft was less than with bovine-derived bone graft alone. The primary stability of the implant in sockets filled with PTH (1-34) and bovine-derived bone graft was significantly better than that of the bovine-derived bone graft alone using the resonance frequency analysis (RFA) device Osstell.

Conflict of interests

No conflict of interest was declared by the authors.

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Data sharing statement

Supplementary data can be shared with the corresponding author upon reasonable request.

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