

# Evaluation of INNO™ dental Implants placed with high insertion torques (Up to 135 Ncm)

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## ABSTRACT

*Purpose:* This study evaluated on the clinical outcome of 42 implants placed with an insertion torque equal or greater than 70 Ncm and evaluated bone levels around these implants.

*Methods:* This prospective study included 48 patients treated with 66 implants of 4.5 mm (INNO® implant Cowellmedi, Pusan, Korea). Maximum insertion torque (MIT) was recorded with an electronic torque measuring device (Tohnichi® STC200CN, Hitachi, Tokyo, Japan). Nine implants (control group) presented MIT between 30 and 50 Ncm (mean = 37.1 Ncm) and 42 implants (experimental group) MIT greater than 70 Ncm (mean = 110.6 Ncm, range: 70.8–176 Ncm). Marginal bone levels were recorded at the time of loading and 1 year later for the two groups.

*Results:* After 2–3 months of submerged healing, all implants were clinically stable. Mean marginal bone resorption was 1.03 mm (SD = 0.44) for the control group (low torque) and 0.72 mm (SD = 0.56) for the experimental group (high torque) at time of loading, and 1.09 (SD = 0.62) and 1.24 mm (SD = 0.75), respectively, after 1 year. There were no significant differences between the two groups for bone stability and implant success rate.

*Conclusions:* The use of high insertion torques (up to 135 Ncm) did not prevent osseointegration. Marginal bone levels in the control and experimental groups were similar both at the time of loading and 1 year later.

*Key Words:* crestal bone, implant, insertion torque

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## INTRODUCTION

The goal of achieving primary stability at the time of implant placement is to limit excessive micromotion at the bone-implant interface, which could fracture regenerating bone and prevent osseointegration.<sup>1–3</sup> A critical threshold of deleterious implant micromotion during bone remodeling has been postulated to occur somewhere between 50–150  $\mu\text{m}$ .<sup>1</sup> Implant micromovements below this

range are presumed to be innocuous to bone remodeling;<sup>1</sup> however, and may even account for the denser osseous interface observed around implants immediately loaded as compared with delayed loading.<sup>4,5</sup> Factors that affect primary implant stability include bone quality, the percentage of initial bone-implant interface, implant geometry, surface micromorphology, and method of osteotomy preparation.<sup>6–13</sup>

The use of a slightly narrower final drill with a tapered implant design has been often associated with elevated insertion torque<sup>3,8,12,14,15</sup> and localized bone compression.<sup>16</sup> Both of these factors may help to increase primary implant stability. A histologic study in rabbits found that bone condensation improved the peri-implant bone formation during the first 8 weeks after implantation.<sup>17</sup> If localized stress is too great, however, it could reportedly lead to ischemia and localized bone necrosis at the implant-bone interface.<sup>3,12,18,19</sup>

A possible correlation between primary stability and implant insertion torque has been often suggested in the dental literature.<sup>3,8,10,12,14,20–25</sup> Several studies<sup>24,25</sup> have used average insertion torque as an indicator of primary stability in conjunction with under-dimensioned implant bed preparation. Several researchers<sup>11,26,27</sup> compared insertion torque values during implant placement with resonance frequency values of implant stability after placement, and found no statistical correlation between the two. One study,<sup>28</sup> however, reported a statistically significant correlation between the implant cutting torque during crestal bone penetration in the maxillary jaw and resonance frequency values of implant stability after placement. Other researchers<sup>12,20</sup> compared insertion torque and resonance frequency values of tapered and straight implant designs and found that both values increased for the tapered implants.<sup>12,20</sup> At present, the measurement of insertion torque values to quantify primary implant stability has been widely reported, and some researchers<sup>3,14,21,29–32</sup> have also attempted to identify a minimum insertion torque value that would indicate adequate stability for immediate loading. Although no firm clinical consensus has yet been reached, minimum insertion torque values for immediate loading reported in the dental literature have ranged from 32–50 Ncm.<sup>3,14,21,29–32</sup> They advocated that, even if the amount of micromovement supported by the implants cannot be recorded, the implants primary anchorage with such an insertion torque is sufficient for retaining micromovement within limits.<sup>14,30</sup> Ottoni et al.,<sup>31</sup> in a study on immediate loading of single-tooth implants, concluded that immediate loading should only be proposed when insertion torque was higher than 32 Ncm. Neugebauer et al.<sup>32</sup> reached a similar conclusion, that is, implants placed with an average insertion torque higher than 35 Ncm were associated with success.

Highest recorded peak insertion torque values generally range from 50 to approximately 70 Ncm.<sup>3,12,33,34</sup> Some researchers<sup>35,36</sup> have used an electric surgical unit (OsseoCare, NobelBiocare AB, Göteborg, Sweden) as a torque measuring device, but were technically limited in measuring insertion torque values beyond 50 Ncm, especially for implants that had to be manually placed.<sup>35,36</sup> An outlier study by Rabel et al.,<sup>27</sup> however, compared the primary stability of two dental implants systems and recorded mean insertion torque values of 28.8 and 25.9 Ncm, respectively, but a very high peak insertion torque value of 135 Ncm for both systems. These values were recorded by an electric surgical unit (Frios Unit E, Friadent GmbH, Mannheim, Germany) and were evaluated after data transmission to a computer.<sup>27</sup> No further explanation was given concerning these peak values obtained with a surgical unit that normally stops when the 70 Ncm limit is reached.<sup>27</sup> The clinical observation period lasted for 12 months and nine (1.5%) of the 602 study implants failed after placement.<sup>27</sup>

The aim of this study was to report on the clinical outcome of 42 implants placed with an insertion torque equal or greater than 70 Ncm and evaluate bone levels around these implants.

## MATERIALS AND METHODS

This was a non-randomized, non-blinded, prospective clinical study. Candidates were partially edentulous patients who presented in a private dental practice with one or more missing teeth in the maxillary and/or mandibular jaw. All patients were subjected to a preliminary evaluation that included careful review of their medical and dental histories, detailed clinical examination, and evaluation of oral hygiene. Radiographic evaluations were also conducted utilizing panoramic radiographs and computed tomography scans, and included assessment of bone quality and quantity according to the Lekholm & Zarb<sup>37</sup> index.

Patients were included in the study according to the following criteria: (1) completely edentulous in the mandible or having hopeless remaining teeth requiring extraction; (2) rehabilitation with endosseous dental implants considered the ideal treatment of choice; (3) informed consent signed; and (4) physically and mentally

able to tolerate conventional surgical and restorative procedures. The exclusion criteria were the following: (1) active infection in the sites selected for implant placement; (2) systemic diseases, such as diabetes without control; (3) pregnancy; and (4) severe bruxism



**Figure 1** INNO™ implant which has the upper straight and lower tapered portions.

INNO® implant (Cowellmedi, Pusan, Korea) were used in this study at Seoul implant center, Seoul, Korea. These implant's surface was sandblasted and acid etched (Figure 1). In order to standardize implant geometry, only 4.5 mm diameter implants were considered for torque measurement. On these tapered implants, the widest thread measured 4.7 mm (most cervical) and the narrowest was 3.8 mm (more apical).

Each patient was instructed in the use of chlorhexidine digluconate for the chemical control of plaque, which commenced 1 day after the implant surgery and continued for 10 days postoperative. Antibiotic prophylaxis involved daily administration of 2 g of amoxicillin and clavulanic acid, beginning 2 hours before surgery and for 6 days thereafter. On the day of surgery, the patient was anesthetized by local infiltration with lidocaine. A midcrestal incision was performed, followed by elevation of a mucoperiosteal flap that was kept small to preserve the periosteal vascular supply. The osteotomy was prepared and the implant was placed according to the manufacturer's protocol. During implant placement, insertion torque was manually recorded with an electronic digital torque measuring device (Tohnichi STC200CN, Hitachi, Tokyo, Japan), which was able to measure insertion torque within a range of 30–200 Ncm, with 3% precision. Torque levels below 30 Ncm could not be measured by this instrument. After placement, a cover screw was attached to the implant and the soft tissues were sutured around it with 4-0 vicryl sutures (Ethicon, Inc.,

Somerville, NJ, USA). The implant was allowed a submerged healing period of 3 months in the mandible or 6 months in the maxilla.

Following the healing period, clinical osseointegration<sup>38</sup> was manually evaluated via axial percussion, lateral pressure movements, and healing collar removal. The realization of these clinical tests should not produce any discomfort and the clinician should not perceive any movement of the implant. Radiographic evaluation was also performed to determine a lack of peri-implant radiolucency.<sup>38</sup> In this study, implant failure was defined as implant mobility, peri-implant radiolucency, and/or pain or discomfort, altered sensation, or infection attributable to the implants. With the validation of this clinical assessment, the implant is considered clinically stable and ready for loading.

After inserting the implants, the patients received follow-up care at 1 and 2 weeks, at 3, and 6 months, and every 12 months thereafter. Radiographic examinations were performed at every visit. Radiographic changes were calculated with respect to the implant's known length and the marginal bone height with Easydent viewer version 4.5 software (Vatec, Anseong, Korea). (Figure 2)

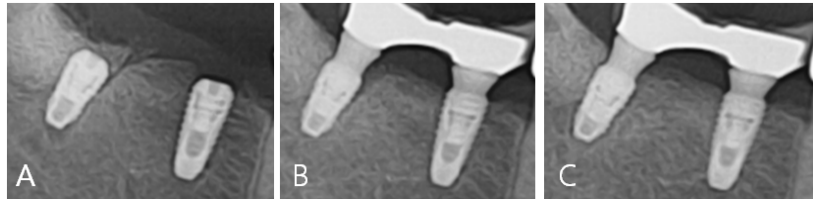
## RESULTS

Because of the shape and size of the torque measuring device and the difficulty of accessing posterior implant sites, data collection was limited to 66 implants placed in 38 patients (Table 2).

For six patients (four women, two men) with an average age of 63 years (range 34–75 years old), nine implants (three implants of 10 mm length, five implants of 13 mm, and one of 16 mm) were placed with maximum insertion torques between 30 and 50 Ncm (control group).

For 32 patients (19 women, 13 men) with an average age of 64 years (range 32–84 years old), 42 implants (eight implants of 10 mm length, 30 implants of 13 mm, and four of 16 mm) were placed with maximum insertion torques equal or greater than 70 Ncm (experimental group).

Fifteen implants with maximum insertion torques ranging from 50 to 70 Ncm were excluded from the study. They



**Figure 2** 3Radiological evaluation A: At the implant placement and immediate loading, B: Final restoration after 3 month healing period, C: at 1 year follow-up visit,

**TABLE 1** Distribution of Patients and Implants

Study Group	Number of Patients		Patient Age Mean (Range)	Number of Implants by Length (mm)		
	Males	Females		10	12	14
	Control	2		4	63 (34–75)	3
Experimental	13	19	64 (32–84)	8	30	4

were placed in 10 patients (six women, four men) with an average age of 59 years (range 32–71 years old).

Mean maximum insertion torque values were 37.1 Ncm (range = 30–50 Ncm) for the control group and 110.6 Ncm (range = 70.8–135 Ncm) for the experimental group. All study implants successfully osseointegrated. Two implants in the experimental group presented gingival complications in the week following placement, but this was quickly resolved with antibiotic therapy and analgesics. All implants were clinically stable after 1 year of loading. Mean marginal bone resorption was 1.03 mm (SD = 0.44) for the control group (low torque) and 0.72 mm (SD = 0.56) for the experimental group (high torque) at time of loading, and 1.09 (SD = 0.62) and 1.24 mm (SD = 0.75), respectively, after 1 year. There was no difference between low and high torque groups (Wilcoxon Rank Sum test,  $p > .05$ ) at any time. Moreover, there was no correlation between insertion torque and marginal bone

resorption when all measurements were grouped (Spearman correlation test,  $p > .05$ ).

A quartile analysis was made; control and test implants were grouped and sorted with increasing insertion torques. The first 13 implants with the lowest torque (Q1) (mean 48.2 Ncm, SD 18.4) were compared with the 13 implants showing the highest torque (Q4) (mean 138.3 Ncm, SD 15.9). The mean marginal bone loss at loading was 1.0 mm (SD 0.4) for Q1 and 0.6 mm (SD 0.5) for Q4 implants ( $p < .05$ ). After 1 year of loading, the corresponding figures were 1.3 mm (SD 0.7) and 1.4 mm (SD 1.0) for Q1 and Q4 implants, respectively (NS).

## DISCUSSION

Other studies have attempted to record insertion torque levels with methodologies different from the one used in the present study. To measure insertion and removal torque values, Ueda et al.<sup>19</sup> and Niimi et al.<sup>39</sup> used a different torque gauge (15 BTG-N Tohnichi, Hitachi) from the same manufacturer as the gauge used in this study. Its torque range was lower, which would have precluded its use in measuring the high insertion torque values recorded in the present study. O'Sullivan et al.<sup>12</sup> used a complex mathematic method that combined a modified electronic torque controller (Nobel Biocare AB, Göteborg, Sweden), a digital data acquisition card, and a laptop computer. In this study, a simpler method was used. Calandriello et al.<sup>3</sup> used a torque controller device (ATR, Pistoia, Italy) for both site preparation and torque measurement, but the instrument was only capable of measuring a maximum torque level of 72 Ncm. Nikellis et al.<sup>14</sup> used a simple insertion ratchet with a fixture-mount attached to the implant at 32 Ncm. After implant placement, reverse torque was applied to the fixture-mount screw. If the implant rotated, it was assumed that insertion torque was lower than 32 Ncm. This technique was not meant to provide individual insertion torque measurements as done in this study. Several other researchers<sup>3,11,14,23,36,40</sup> have also reported that they sometimes had to use a manual wrench to finalize implant placement, and therefore had no mean to register the true peak insertion torque.

In this study, a combination of factors could explain why high insertion torques were often observed: the tapered implant design, the slightly wider implant diameter (4.7 mm for the most cervical threads), the absence of bone tapping and a strong internal connection between implant and insertion driver (no torque limitation within the scope of this study).

Excessive tightening creates important compression forces in the surrounding bone. This has been theorized to disturb microcirculation and lead to bone resorption, but the theory has never been scientifically investigated. In this study, all implants successfully osseointegrated. Throughout the course of this study, no clinical signs of bone injury were observed. Furthermore, marginal bone levels were similar to those currently reported (0.9–2 mm) for implants placed via a traditional, twostage surgical protocol.<sup>3,14,20,21,28,29</sup>

Based on the implant treatment outcome of a 15-year follow-up study,<sup>41</sup> Albrektsson et al.<sup>42</sup> included vertical

bone loss as one of the criteria for the assessment of implant success. An upper limit of 1.5 mm was proposed for bone resorption around successfully osseointegrated implants during the first year of loading.<sup>43</sup> In this study, marginal bone resorption for both groups was in that range and did not increase when high insertion torques were applied.

The quartile analysis revealed significantly less marginal bone loss at time of loading between lowest torque implants (1.0 mm) and highest torque implants (0.6 mm). After 1 year, there was no statistical difference. This finding could not be explained.

In the present study, no negative effects of high insertion torque on marginal bone loss could be detected. This may be related to the present implant design, which has a homogenous tapering with no marked steps, edges or other design features. The implant design probably resulted in a continuous lateral compression of the bone during insertion and an even distribution of stresses along the implant surface, which may explain the limited adverse effect at 2–3 months and the lack of adverse effect at 1 year of loading on the surrounding bone.

## CONCLUSIONS

The use of high insertion torque (up to 135 N cm) neither prevented osseointegration nor increased marginal bone resorption around tapered multithreaded dental implants. Further studies on biological reactions of bone under mechanical strain are needed.

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