A one year follow up examining bone level preservation utilising platform switching implants

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Abstract

Objective The aim of this research is to observe and evaluate the clinical application of the Esthetic Line [EL] implant system (C-Tech, Bologna, Italy). The EL implant has a surface topography created by sandblasting and acid etching (SLA) and a Morse locking conical connection.

Methods 35 patients with one or more missing teeth were selected and a total of 60 EL implants were placed using either a one stage (non-submerged) placement protocol or a two stage (submerged) protocol. Where applicable, second stage surgery was undertaken 2 ~ 4 months post implantation. Subsequent to this the EL implants were permanently restored over a period of 2 ~ 4 weeks. Clinical examination and imaging analysis were undertaken to evaluate clinical success.

Results All 60 implants osseointegrated successfully, and at the one year follow up there was a 100% retention rate and no adverse reactions in the host. Mesial and distal bone heights were recorded on the day of surgery as well as at the fitting of the permanent restoration and after the implants had been functionally loaded for 12 months. Mesial bone heights were (0. 35 ± 0. 49) mm, (0. 18 ± 0. 44) mm and (0. 25 ± 0. 36) mm respectively. Distal bone heights were (0. 20 ± 0. 42) mm, (0. 08 ± 0. 45) mm and (0. 15 ± 0. 38) mm. In the first year of implant functional load, the total absorption of the mesial bone was (- 0. 11 ± 0. 38) mm and the distance was (- 0. 07 ± 0. 31) mm; There was no significant difference in blood indexes between the preoperative and postoperative three months ($P < 0. 05$).

Conclusion The design of the EL implant incorporating a combination of a parallel walled section with an apical taper, a beveled shoulder, platform switching, a Morse locking conical connection combined with an SLA treated surface and a sophisticated double threaded morphological design all contribute to successful treatment.

Key words Italy; C - Tech Esthetic Line [EL] implant; implant design; surface treatment; Morse-locking.

In recent years, the evolution of implant techniques combined with developments in implant design and restorative techniques has resulted in greater acceptance of implant treatment by the majority of patients. The Stomatology department of our hospital has adopted the Esthetic Line [EL] implant system (C-Tech, Bologna, Italy) for use in our clinic. A study into the clinical results of 60 EL implants placed in 35 patients was undertaken.

1 Materials and Methods

1.1 General information: From April 2015 to May 2016, 35 patients with missing teeth were treated with the EL system. They included 21 males and 14 females, aged 18-67 years, with a median age of 45.6 years old. 19 patients were treated with single implant and16 with two or more implants. All

implants were restored with single crown on each implant. Patient selection ensured that all patients were healthy enough to undergo alveolar surgery and that in each case the mouth opening, occlusal relationship, the size of gap between missing teeth, oral mucosal tissue and bone tissue in the implant area were all evaluated in determining suitability for treatment.

1.2 Equipment and instruments: Esthetic Line dental implants, surgical and prosthetic kit, titanium abutments and peek temporary abutments (C-Tech, Bologna, Italy); Proline-XC dental digital panoramic X-ray machine (Planmeca, Helsinki, Finland); Surgic XT implant machine; 20:1 deceleration hand piece (NSK, Tokyo, Japan).

1. 3 Method process

1.3.1 Preoperative preparation: Routine blood analysis was performed before each procedure. The remaining teeth, occlusal relationship and jaw distance were examined, and panoramic X-rays were taken. The measurement of bone mass and availability (keeping away from nerve tissue where relevant) in each implant site was determined by relevant software.

1.3.2 Implant placement: All procedures followed the same operating room surgical protocol and were conducted with the patient under full anesthesia. Incision and flap design varied from patient to patient allowing for granulation and connective tissue to be removed as appropriate as well as exposing the crest of the alveolar ridge. If necessary, a burr as used to prepare the site prior to using the appropriate osteotomy drills. These drills include a fixed-point locator drill, 2.1 mm diameter pilot drill to prepare each osteotomy and main drills to sequentially widen the osteotomy as required. Drill speeds of 600-1200 rpm were employed. The implantation torque was less than 50 N/cm.

32 of the 60 implants had good initial stability, implant torque > 35 N/cm. Appropriate healing abutments were used with a suitable gingival height in non-submerged approach. The other 28 implants were submerged in a two-stage protocol with the gingiva sutured tightly over the implant after the procedure. Post operatively, patients were given oral hygiene instructions including use of mouthwash. A cold compress was applied over each site for 24 hours and oral antibiotics were taken for 3-5 days. Sutures were removed after 7-10 days. Patients with discomfort could also be followed up.

1.3.3 Restoration: 2-4 months after implantation, open tray transfer copings were used to take impressions and allow the permanent restoration to be fabricated and fitted. Those patients undergoing a two-stage procedure had second stage surgery to uncover the implant and fit healing abutments to allow gingival formation. Impression taking was subsequently performed after 2-4 weeks.

1.3.4 Outcome evaluation: To verify and evaluate the safety, applicability and effectiveness of Esthetic Line implants in clinical application, a 1 year follow up in line with Albrektsson et al. published oral implant evaluation criteria [1] was undertaken to ascertain the clinical outcome. The success rate, sample size, complications, morbidity and 1-year survival rate of implants in different implant areas were observed. The marginal bone height of implants on the day after implantation, the day after permanent restoration and the year after functional loading was measured by X-ray, and the bone absorption at the implant margin was observed and compared. The changes of blood indices before and 3 months after implantation were also observed.

1.3.5 Measurement and calculation methods: Using the standard projection method, bone height and implant length at collar margin of implant were measured directly in panoramic image. Implant bone margin height = (implant real length / implant measurement length) * implant bone margin measurement height [2]; alveolar bone resorption = （implant length measured by X-ray- the distance between the contact point of the implant and the bottom of the implant）/the actual length of the implant [3].

1.4 Statistical methods: SPSS 16.0 statistical software was used, measurement data were expressed by x+s, t test was used for comparison between groups, and X^2 test was used for counting data, with $P < 0.05$ as the statistical difference.

2 Results

A total of 60 implants were implanted in 35 patients, including 15 anterior teeth、18 premolars and 27 molars. There were 37 implants in the maxilla and 23 implants in mandible. The implant number, incidence of complications, number of dropouts and one-year retention rate of implants in different regions are shown in Table 1.

Table 1 Number of implants, complications, morbidity, number of dropouts and one-year retention rate of implants in different regions

implant area	Number of implants	Complication	Morbidity (%)	Number of dropouts	One-year retention rate (%)
maxillary					
Anterior area	9	0	0.00	0	100.00
Molar area	28	2	7.14	0	100.00
Mandible					
Anterior area	6	0	0.00	0	100.00
Molar area	17	1	15.88	0	100.00

No complications such as infection, numbness of lower lip, rupture of maxillary sinus mucosa perforation and nasal bleeding occurred in the 35 patients.

No loosening or failing of 60 implants was observed in follow-up observation of the implants. X-ray examination showed no shadow around the implants. Those patients whose implants were placed in a single stage non-submerged approach had their implants restored two to four months post implantation. With one exception, those patients who underwent a two stage procedure had their implants restored 2 to 4 weeks after second stage surgery. The one exception was for a case where a maxillary sinus elevation and bone graft was undertaken, with the subsequent second stage restoration performed 9 months post operatively. All implants were successfully loaded and after clinical observation, implant restoration achieved good clinical results with a success rate of 100%.

After 12 months of functional loading, none of the 35 patients lost their implants, and the 1-year retention rate was 100%. One patient had obvious food impaction accompanied by gingivitis, one patient had chewing discomfort accompanied by mild gingival hyperplasia, one patient had mild periodontitis and other complications; two patients had porcelain-fused-to-metal (PFM) collapsed porcelain, (this was corrected by remaking the crowns). The complication rate was 8.6% and the total effective rate was 91.4%. The complication rate of implant prosthesis was 5.0% and the total effective rate was 95.0%.

Observation and measurement of X-rays revealed good implant bone integration. Table 2 shows marginal bone heights at different stages post implantation. One year after implantation, the neck bone resorption was (-0.11±0.38) mm in mesial and (-0.07±0.31) mm in distal. The results showed

that the height of marginal bone increased one year after implant loading. The diameter and length

Table 2 Number of marginal bone heights of implants at different implant stages (mm, x + s)

Implant stage	implant number	mesial marginal bone heights	distal marginal bone heights
On day after implantation	60	0.35±0.49	0.20±0.42
The day of permanent restoration	60	0.18±0.44	0.08±0.45
12 months after functional loading	60	0.25±0.36	0.15±0.38

of the Esthetic Line implants are shown in Table 3.

Table 3 Diameter and length distribution of C - TECH implants (Number)

Implant diameter (mm)	7mm	9mm	11mm	13mm
3.0			4	
3.8			6	3
4.3		9	19	1
5.1	6	10	2	

The routine blood examination (blood routine, liver function, kidney function, blood coagulation routine, etc.) of 35 patients before and within 3 months after operation showed that the values were within the normal range, and there was no significant difference ($P > 0.05$).

3 Discussion

Dental implants and related technologies provide an excellent choice for replacing lost dentition. More than 30 years of continuous development has ensured dental implantolgy is an indispensable part of clinical treatment. Advances in aesthetics and surgical techniques coupled with chewing function comparable with natural teeth has resulted in implant-based treatments becoming more and more extensive.

The design of the Esthetic Line implant is parallel walled in combination with an apical taper. The thread macro-architecture ensures an appropriate tapping performance as well as preserving bone. This implant design not only squeezes the cancellous bone properly, but also increases the contact area between the implant and bone because the threads are double threaded - thread in thread and groove and groove. This results in reduced shear force, more beneficial to bone bonding. Some scholars have shown that cylindrical implants have the smallest implant torque and removal torque, while tapered implants have the largest implant torque, hybrid implants have higher removal torque and the best initial stability [5 - 6]. The design of the thread edge is between the "V" shape and the rectangle shape. It has a certain self-tapping ability, at the same time, it also has a moderate bone extrusion. The implant basically does not need tapping, is conducive to self-tapping which ensures any stress is well dispersed. The neck of the implant is parallel walled with thin and shallow

threads, which can reduce bone compression, prevent bone absorption, increase contact area and increase bone bonding. Limited prospective studies have shown that the bone resorption of threadless cylindrical implants is higher than that of threaded implants [7]. In the platform switching concept, the smaller the shoulder angle and the wider the width, the better the stress distribution in the cortical bone around the neck of the implant, and the smaller the peak stress [8]. The upper part of the EL implant with a large bevelled shoulder and rough platform is conducive to early osseointegration. Above the shoulder, bone tissue can be embedded on both sides of the shoulder of the implant, which provides a good bone base for soft tissue attachment. The results which Guo Zhishun [9] and other studies showed that the increase of shoulder width of platform switching implants would be beneficial to maintain the surrounding hard and soft tissues. The large apical taper of the implant, round flat bottom and modified "V" thread edge has both a cutting function and a protective function. The study observed that most of the 60 implants were successfully implanted 0.5-1.0 mm sub-crestally. No entry or lateral penetration occurs, and good initial stability is achieved. Although the implant has a certain degree of self-tapping, in cases with type I and II category bone the osteotomy should be prepared with matching hard bone drills prior to implantation to reduce the pressure of bone around the implant [10].

The results showed that among 60 implants, 11 mm in length was the most used, accounting for 51.7%; 9 mm in length, accounting for 31.6%; 4.3 mm in diameter, accounting for 48.3%; 5.1 mm in diameter, accounting for 30%. The results showed that the implants with diameter of 4.3 mm and length of 11 mm were the most used. They could be used in both molar and premolar areas, but also in anterior areas with abundant bone mass. When the vertical bone mass is insufficient, the widest diameter implant should be chosen as far as possible. When the buccal-lingual bone mass is insufficient and the vertical safe distance is large[11], the longest implant should be chosen as far as possible[12].Such an option is to ensure sufficient contact area between the implant and bone tissue in order to achieve primary stability and improve the success rate of the procedure[13].

The main factors determining the biocompatibility and ultimately the success rate of implants are their composition and surface treatment methods. Rough implant surfaces can affect the growth and differentiation of osteoblasts and the formation of extracellular matrix. They also promote the formation of bone, inhibit bone absorption, as well as not only increasing the contact area between the implant and bone, but also improving the mechanical locking force [14 - 16]. The surface of an Esthetic Line implant is treated by a sandblasting and acid etching method (SLA). Research on this surface type shows that two-stage holes of different sizes were formed, such as 20-35 micron and 1.33-6.63 micron. The secondary micropore provides the attachment point for osteoblasts, which is conducive to the growth of osteoblasts [17], thus promoting the formation of osteogenic environment. Relevant clinical evidence shows that SLA surface treatment can shorten the implant-bone bonding time to 6 weeks [18]. A total of 60 Esthetic Line implants were implanted in this study group. All the cases were restored 2 to 4 months post implantation (except for a sinus elevation and grafting case which was restored after 9 months) with satisfactory results. X-ray evaluation showed that the implants had osseointegrated well, with good initial stability and long-term prognosis.

There are two ways to connect the implant with the abutment: in conventional systems, this involves the flat of the abutment connecting to the flat of the implant using a hex (internal or external) to provide for anti-rotation and a securing abutment screw torqued down to hold the abutment in place. This can lead to some bone resorption at the implant abutment junction which is not conducive to the preservation of alveolar ridge height [19]; The other is platform switching technology, which uses an abutment of a smaller diameter than that of the implant, so that the edge of the abutment is within the diameter of the implant neck creating a ‘circumferential horizontal difference in dimension between the implant seating surface and the attached component.’[20], thus reducing the stress concentration around the platform. Platform switching is thought to cause the inflammation cell infiltration zone (aICT) to move inward and limit its scope, reducing the effect on the marginal bone of the collar as well as the vertical absorption of the marginal bone by shifting the biological width horizontally [21 - 22]. The Esthetic Line implant and abutment adopt a

platform switching design, the diameter of the abutment is smaller than the diameter of the implant, forming a narrowing effect of the connecting surface. The abutment is close to the side wall of the implant cavity at the same angle through the 5-degree taper (Morse locking) on the abutment. Anti-rotation and a seal is achieved by tightening the central screw between the abutment and the implant. This close Morse locking connection achieves a “cold weld" effect [23]. The effectiveness of this seal results in a microgap that is smaller than a bacterium, thereby reducing the retention of pathogenic bacteria and therefore the incidence of peri-implant inflammation. In this study, 3 cases of complications of implant prostheses were observed, 2 cases were caused by flaws in the design of the final restorations and 1 case was caused by residual bonding materials.

In this study, 60 implants were successfully loaded for one year. Radiographic evaluation showed that there was no obvious bone absorption at the collar of the implant. The mesial bone absorption at the collar was near to (-0.11 +0.38) mm and distal was (-0.07 +0.31) mm. Most of the bone in the mesial and distal margins of the implant was located level or above the oblique shoulder of the implant. The platform switching design combined with the bevelled shoulder of implant not only avoids bone loss but also facilitates bone growth over the shoulder thereby increasing the long-term success of the restored implant.

4 **Conclusion**

To sum up, the innovative design of the Esthetic Line implant with its sequential thread design, micro-threads to preserve bone at the collar, sophisticated self-cutting and double lead threading preserves bone structure and increases bone to implant contact. This is combined with a SLA surface treatment, a combination of a bevelled shoulder with a platform switching design and a Morse locking conical connection to make it safe and effective in clinical application. The limitation of this study is that the number of cases included is relatively small, only 30 implants of 35 patients were followed up for 12 months. More accurate clinical effect requires more long-term retrospective and prospective clinical observation and research on larger sample size.

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