Long-Term Follow-Up of CeraOne™ Single-Implant Restorations: An 18-Year Follow-Up Study Based on a Prospective Patient Cohort

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ABSTRACT

Background: Knowledge on long-term clinical performance of more than 5 years on the single-implant CeraOne™ (Nobel Biocare AB, Gothenburg, Sweden) concept is limited.

Purpose: The aim of this study is to report the long-term clinical performance of the first CeraOne single-implant restorations, installed 17 to 19 years ago.

Materials and Methods: The group comprised 57 patients provided with 65 CeraOne single-tooth restorations. Sixty-two all-ceramic and three metal-ceramic crowns were cemented between 1989 and 1991. Patients were followed up clinically and with intraoral radiographs at placement, after 1, 5, and between 17 and 19 years after placement.

Results: Data were available for altogether 48 patients, followed up on an average time of 18 years. Excluding deceased patients ($n = 2$) and failed implant patients ($n = 2$), only five patients were lost to follow-up (8.8%). Two implants failed, resulting in an 18-year implant cumulative success rate (CSR) of 96.8%, and altogether eight original single-crown restorations were replaced (CSR 83.8%). The most common reason for crown replacement was infra-position of the implant crown ($n = 3$). Many of the remaining original crowns showed various signs of implant crown infraposition at the termination of the study. In general, the soft tissue at the restorations was assessed to be healthy and comparable with the gingiva at the adjacent natural teeth. Bone levels were on an average stable with only few patients exhibiting bone loss of more than 2 mm during 18 years in function.

Conclusion: This long-term follow-up study of single-implant restorations shows encouraging results with few implant failures and minimal bone loss over an 18-year period. Original single-crown restorations were replaced more frequently, because of, for example, implant crown infraposition and veneer fractures. The CeraOne concept proved to be a highly predictable and safe prosthodontic treatment.

KEY WORDS: bone loss, ceramic crowns, complications, dental implants, follow-up, infraposition, single-tooth

INTRODUCTION

Earlier, noninvasive techniques such as removable partial dentures and adhesive fixed partial dentures have been the alternatives to the more invasive approach of using conventional three-unit fixed partial prostheses. However, for the last two decades, single-implant treatments have increasingly been used to permanently replace single missing teeth as well.

The first implant-supported single-tooth restoration according to osseointegration principles was placed in 1983.[1] This first treated patient started a period of about 6 years, when different components and

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techniques were tested to establish a protocol for using implants in this situation (development period). Accordingly, the need for improved aesthetics was at that time solved by designing special abutments where the crown margins could be placed below the margin of the mucosa in a controlled manner.[1]The clinical protocol for these early restorations was based on a two-stage surgical procedure, involving placement of healing abutments at the second stage of surgery. Final impressions were then made at implant level, and single crowns were cemented to the selected single abutment cylinders.[1–3] The patients treated during this development period have been followed up both for short-term[3–6] as well as long-term periods,[7–9] indicating good clinical results. However, a more strict protocol was introduced during the late 1980s, using pre-machined abutment cylinders (CeraOne™ abutments, Nobel Biocare AB, Gothenburg, Sweden) that were permanently placed at second stage surgery. Impressions and final cementations of the crowns were performed directly onto these abutments.[10,11] The protocol of using abutments that were not removed after second stage surgery as well as using pre-machined components for impressions and standard gold-alloy or ceramic cylinders for fabrication of the crowns were considered important.[10] Prospective follow-up studies have shown that this CeraOne protocol provided good clinical results during early- and medium-term follow-up situations for the original group,[10,11] and also for other groups and implant systems.[12–16] However, long-term clinical follow-up studies of more than 5 years on this CeraOne technique are rare.

The aim of this study was to report the long-term clinical performance of a consecutive group of patients treated with CeraOne single-implant restorations 17 to 19 years ago.

MATERIALS AND METHODS

The present publication is a clinical follow-up study based on patients originally included in a 5-year prospective follow-up study comprising the first patients provided with CeraOne single-tooth restorations.[10,11] The patients were treated between 1989 and 1991 and are now followed up after 17 to 19 years.

Patients

In total, 57 patients were included; 25 females (42%). The mean age at implant placement was 31.9 years (SD 10.66); age ranging from 15 to 57 years. Only one patient was below the age of 18 years. Mean age at termination of the study was 50.0 years (SD 10.59). A majority of the patients (56%) were treated with implants because of tooth loss as a result of trauma. Fifty-four patients (94.7%) were healthy and without any medication at inclusion. Information on use of tobacco was available in 27 patients (47%) of whom 19 patients (70%) reported no use at the inclusion. Information on smoking habits was collected for all patients at the termination of the study when nine patients (18%) reported use of tobacco.

Implants and Abutments

Information on time from tooth extraction (deciduous/permanent) to implant placement was available for 44 patients, showing a mean healing time of 25.6 months (SD 35.99), with a range from 0 to 132 months before implant placement. Another eight implants, placed in four patients, were placed because of partial anodontia, without any prior tooth extraction.

A total of 65 implants (Nobel Biocare AB) were placed during a period from 1988 to 1990. Sixty-two implants were inserted in the maxilla and three in the mandible, a majority of the implants were 15 mm or longer.[10,11] Fifty patients had one implant, six patients had two implants, and one patient had three implants inserted each, respectively. The implants were placed according to a standard two-stage surgical procedure in one clinic (Table 1).[2,17] Fifty-four (83%) implants were standard turned Brånemark System implants (Nobel Biocare AB), and 11 (17%) were Brånemark implants with conical head.[10,11]

After a mean healing period of 6.9 months (SD 2.12), CeraOne abutments were connected at second stage surgery and tightened to the implants at 32 Ncm with a special torque driver (Nobel Biocare AB) and thereafter not removed.[10,11] The abutments were available in different heights from 1 mm to 5 mm.

Crown Restorations

Sixty-two all-ceramic crowns (95%) with prefabricated sintered aluminium-oxide ceramic caps (Nobel Biocare AB) and three porcelain fused to metal crowns (5%) were cemented with zinc phosphate cement (De Trey Zink cement, De Trey Division, Dentsply Ltd, Konstanz, Germany) onto the CeraOne abutments during a period from 1989 to 1991.[10,11] Occlusion was adjusted to

TABLE 1 Life Table of Single Implants and Original Single-Crown Restorations

	Implant and Original Single-Crown Life Table							
	Single Implants				Original Single Crowns			
Follow-Up Period	Implants	Withdrawn	Fail	CSR	Crown	Withdrawn	Fail	CSR
Implant surgery*	65			100				
Crown plac.	65			100	65			100
Plac.-1st year	64		1	98.5	61		4	93.8
1st–5th year	62	2		98.5	57	2	2	90.65
5th–18th year	53	8	1	96.8	45	8	4	83.8
Total†	53	10	2	96.8	45	10	10	83.8

*Fifty-seven patients.
†Forty-eight patients (one patient/implant not clinically reexamined).

prevent the implant supported crown from primary contact in any position.[10,11] Mean time period between second stage surgery and placement of the crown restoration was 4.4 weeks (SD 1.90). In the maxilla, 51 crowns replaced missing central ($n = 32$) and lateral incisors ($n = 19$), 10 replaced premolars, and 1 replaced a canine tooth. In the mandible, three premolars were replaced.[10,11]

Clinical Examination and Follow-Up

According to the protocol of the original prospective study, follow-up examinations were scheduled after 2 weeks, and then after 1, 3, and 6 months, followed by annual examinations every year during the first 5 years in function.[10,11] Following the termination of the prospective part of the study (after 5 years), no regular protocol for follow-up has been performed. However, after an average of 18.4 years (SD 0.90 years, range 17–19 years), all earlier included patients were recalled for a clinical and radiographic examination, as performed at the termination of the earlier study after 5 years.[10,11]

The present final clinical examination was performed by two dentists, one of them also involved in the prospective part of the study (B.A.). In brief, the examination included tooth/implant mobility, an assessment of the gingival and peri-implant mucosal health. Pocket depths >4 mm, and "bleeding on probing" (BoP) was recorded at implants and adjacent teeth.[10,11] Furthermore, the position of the implant crown-abutment margin in the peri-implant sulcus was measured as "below," "at," or "above" the mucosal margin.[10,11] Signs of occlusal interferences and facets in occlusion were noted. Occlusal contacts between the implant crowns and the opposing teeth were recorded using 0.8 mm occlusal strip. Also, all complications reported by the patient or observed by the dentists were recorded. Data were retrieved from patients' files, including all problems encountered during the entire follow-up period.

Radiographic Examination and Follow-Up

Radiographs were taken by using a paralleling technique.[10,11] The radiographs from crown placement (baseline) and after 1 and 5 years as well as at the final examination, on an average 18.4 years after crown placement, were analyzed. Bone levels were measured in relation to the threads of the implants to the closest 0.3 mm on the mesial and distal side of the implant and calculated in relation to the fixture/abutment junction (FAJ). A mean value between the mesial and distal side was used for each implant. Thereafter, bone loss between two different observations for each individual implants was calculated. Gaps between abutments and crown restorations and/or between abutments and implant heads were measured with a magnification loop (×7). Gaps were noted as "present" when wider than 0.2 mm.

Vertical distance between FAJ of the single implant in relation to the cement-enamel junction (CEJ) of the adjacent tooth (Figure 1) on the mesial side was measured at the baseline and at the final examination according to Jemt.[9]

Radiographs were assessed by one observer who was not earlier involved with the treatment of the patients. A second assessment on 20 randomly selected implants was performed by the same observer 2 months later. Intraindividual mean differences of measurements between the implants at placement, first year, and at the

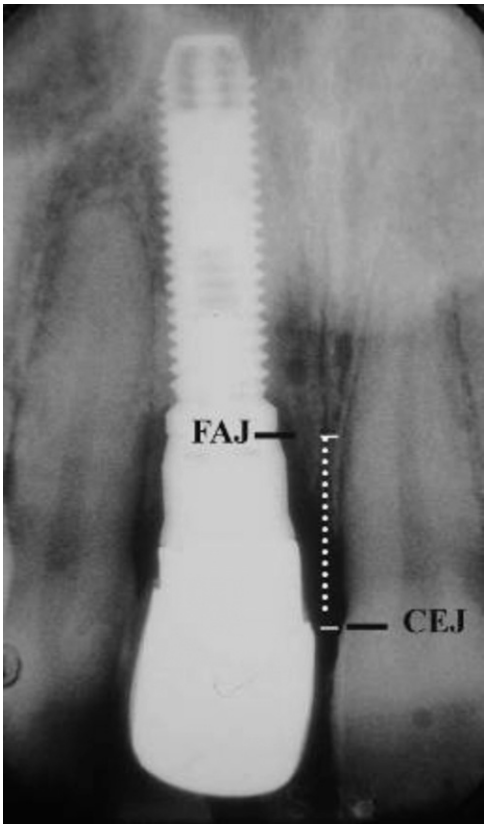

Figure 1 The vertical distance was measured (in mm) between fixture-abutment junction (FAJ) and cement-enamel junction (CEJ) at the adjacent mesial tooth.

termination of the study were calculated to 0.0 mm (SD 0.09), −0.1 mm (SD 0.28), and 0.0 mm (SD 0.21), respectively. Corresponding interindividual mean difference between two different observers was 0.2 mm (SD 0.60), 0.1 mm (SD 0.42), and 0.1 mm (SD 0.34), respectively.

Success Criteria

Loose or fractured implants were recorded as failures. Success rates for implants still in function without any signs of pain or discomfort were calculated. Also, criteria for implant success according to Albrektsson and Isidor[18] were used to identify implant performance. These success criteria allowed for less than 1.5 mm bone loss during the first year in function and thereafter less than 0.2 mm of bone loss annually. Survival rates were calculated for the original crown restorations still in function at the final examination. Crowns that had been replaced were recorded as failures, but the implants were still followed up and recorded as successful if still in function supporting a new crown restoration.

Statistics

Descriptive statistics and conventional life table analysis with regard to cumulative success rates (CSR) for implants and original crown restorations were used in the present study. *t*-Test for paired observations was used to test differences between different registration periods. Tests were performed at patient level only, and significance was set to 5%.

RESULTS

Patients Lost to Follow-Up

Altogether 47 patients, provided with 52 crown restorations were available for examination at the termination of the study. However, it was possible to retrieve the file and radiographs for one more patient that failed to attend the final clinical examination. It was then possible to confirm that the original crown was still in function. This patient has not been included in the results of clinical examinations but has been included in the life table and radiographic results. Accordingly, the life table covers 53 implants (81.5%), placed in 48 patients (84.2%), at the termination of the study (see Table 1).

The remaining nine patients (12 implants) were lost to follow-up and withdrawn (see Table 1) because they had either moved from the area ($n = 3$), were deceased ($n = 2$), were not compliant ($n = 2$), or had implant failures ($n = 2$).

Implants and Crown Restorations

In total, two implants failed during the follow-up period (18 years implant CSR 96.8%; see Table 1). One patient lost one implant during the first year in function, and the other patient lost one of two implants as a result of implant fracture after 9 years in function. The second implant in this patient was withdrawn from the study after placement of a tooth-supported fixed prosthesis covering both implant sites.

Altogether 10 original single crowns failed during the follow-up period (18 years original crown CSR 83.8%; see Table 1). Two crowns failed as a result of implant failures ($n = 2$). Another three original crowns were replaced because of infraposition in relation to adjacent teeth ($n = 3$), two because of porcelain fractures ($n = 2$), one because of a too-wide cement margin ($n = 1$), one because of poorly seated abutment onto the implant head ($n = 1$) and one because of a fistula ($n = 1$), respectively. The three implant crowns in

infraposition were replaced after 15 to 16 years in function, all placed in female patients.

Information on crown margins in relation to the mucosa was available for 42 original crowns at baseline (crown placement). Thirty-one of these original crowns (73.8%) were still in function at termination. At baseline, altogether 39 of the crowns were judged to be placed "below," and the remaining three crowns "at" the buccal mucosal margin. At the termination of the study, two of the original crowns (6.5%) showed a change of the placement of buccal margin, both presenting a mucosal "recession" from "below" to "above," and from "below" to "at," respectively.

Presence of plaque and BoP showed basically a healthy clinical situation, comparable for implants and adjacent teeth. Probing depths at implants ranged from 0 mm to 9 mm, and pocket depths at teeth range from 0 mm to 8 mm. Out of 212 implant sites, 124 (58.5%) were not accessible for probing due to crown design, compared with at adjacent teeth at which all sites were able to be probed. Fifty-six implant sites (26.4%) were deeper than 4 mm as compared with seven sites at the teeth (1.7%). The prevalence of BoP at implants was 4.2% (nine implants), and all of these nine implant sites presented a probing depth deeper than 5 mm.

Maintenance

Problems resulting in replacement of the original crowns are accounted for above. Beyond those problems, maintenance regarding the other crowns was basically observed regarding problems with small porcelain fractures ($n = 3$), loosened abutment screws ($n = 2$), gaps between the abutments and the crown restorations and/or between abutments and fixtures, and remnants of cement ($n = 2$) in the mucosal pocket. Fistulas at the implant were observed at three crown restorations at the termination of the study (5.7%).

No problems related to the implant treatment could be observed at the adjacent teeth.

Radiographic Observations

At baseline, vertical distance between the implant head (FAJ) and the CEJ of the adjacent teeth ranged from 2.0 to 11.0 mm, with a mean distance of 6.4 mm (SD 2.13). Distribution of implants with regard to distance FAJ–CEJ is presented in Table 2. The distance (FAJ–CEJ) increased on an average 0.3 mm (SD 0.37) from baseline to termination ($n = 47$) of the study ($p > .05$).

Signs of gaps between the abutments and the crown restorations and/or between abutments and fixtures (≥0.2 mm) could be observed at five implant restorations at the termination of the study.

Mean marginal bone levels in relation to FAJ for all implants were 0.5 mm (SD 0.73), 1.0 mm (SD 1.15), 1.0 mm (SD 0.89), and 0.9 mm (SD 0.74) at baseline, first, fifth, and at termination of the study, respectively. For the conical implants ($n = 11$), the corresponding mean bone levels were 0.6 mm (SD 0.88), 0.8 mm (SD 0.58), 0.9 mm (SD 0.20), and 0.7 mm (SD 0.60), respectively. Bone levels for standard implants are presented more in detail in Table 3. No differences could be observed between mean bone levels of standard and conical implants ($p > .05$).

Overall mean marginal bone loss at the single implants from baseline to the first, fifth year, and termination of study was 0.5 mm (SD 1.14), 0.5 mm (SD

TABLE 2 Number of Implants Arranged into Different Groups, Related to the Distance between the Implant Head (FAJ) and the Cement-Enamel Junction (CEJ) at Placement (baseline). Bone Loss for These Groups is Given for the First 5 Years in Function (0–5 Years) as well as during the Entire Follow-Up Period (0–18 Years), Indicating Similar Levels of Bone Loss Irrespective of Distance (CEJ–FAJ)

Distance CEJ–FAJ (mm)	Bone Loss in mm					
	0 to 5 Years			0 to 18 Years		
	Number	Mean	Standard Deviation	Number	Mean	Standard Deviation
≤4.0	9	0.7	1.14	9	0.6	1.09
>4.0–6.0	16	0.8	1.12	16	0.2	1.21
>6.0–8.0	14	0.7	1.69	15	0.7	1.83
>8.0	8	0.7	1.05	8	0.8	1.75
Total	47			48		

TABLE 3 Mean Marginal Bone Level in Relation to Fixture-Abutment Junction (FAJ) and Distribution of Standard Implants with Regard to Bone Level during Different Periods of Follow-Up. Percentage of Implants Is Given within Brackets. First, Second, Third, and Fourth Threads are Placed 1.9 mm, 2.5 mm, 3.1 mm, and 3.7 mm below FAJ, Respectively

	Follow-Up of Single Implants			
	Placement	1st Year	5th Year	18th Year
Patients	40	39	39	40
Implants	46	45	44	44
	Bone Level in Relation to FAJ in mm			
Mean	0.5	1.0	1.0	0.9
Standard deviation	0.71	1.22	0.95	0.76
Bone Level to FAJ in mm	Number of Implants (%)			
0.0–0.8	0	0	0	0
0.9–1.9	41 (89)	33 (73)	31 (70)	29 (66)
2.0–2.5	3 (7)	7 (16)	6 (14)	10 (23)
2.6–3.1	0	2 (4)	3 (7)	4 (9)
3.2–3.7	2 (4)	1 (2)	2 (5)	1 (2)
>3.7	0	2 (4)	2 (5)	0

1.01), and 0.3 mm (SD 0.92), respectively. Corresponding mean bone loss for the conical implants ($n = 11$) was 0.2 mm (SD 0.88), 0.2 mm (SD 1.02), and 0.2 (SD 1.11), respectively. Bone loss for standard implants is presented more in detail in Table 4.

Mean marginal bone loss in relation to distance between FAJ and CEJ is presented in Table 2, presenting comparable levels of bone loss in relation to different distances of FAJ to CEJ.

DISCUSSION

Since data have indicated that dropout patients may not present the same favorable result as compliant patients followed up for the entire period,[19,20] it is important to recall as many patients as possible. In the present study covering a pioneer group of single-implant patients, data were available for altogether 48 patients, followed up on an average time of 18 years. Excluding deceased ($n = 2$) and failed implant patients ($n = 2$), only five patients were lost to follow-up during this follow-up period because of other reasons (8.8%). This good result is in accordance with results from an earlier long-term follow-up study on another pioneer group, also designed to test a new implant protocol by using a prospective cohort.[21] In other more routine situations, there is a higher risk of less commitment of the patients that together with factors as higher age distributions, multicenter, and retrospective study designs may increase the risk for higher dropout ratio.[19–23]

This study can be considered as a second step of evolution of the single-implant technique, where standardized components and techniques have been used to restore patients with single-implant restorations. Thus, this study can be considered to be the sequel of an earlier 15 years long-term follow-up study on "early development" single-implant crowns.[9] Accordingly, the present study covers the "first" group of patients treated with pre-machined CeraOne single-implant restorations placed about 18 years ago. Further development of the technique has taken place after the CeraOne technique, using custom-made single-abutment components, followed up for 10 years.[24] In accordance with these two earlier studies,[9,24] the present study indicate excellent long-term prognosis for single implants, where only two implants failed (CSR 96.8%) after 18 years of follow-up. One of the two present failures were observed during the first year in function, probably because of poor integration, and the second after 9 years because of fracture. This latter patient showed general severe tooth wear, indicating parafunction.

TABLE 4 Mean Marginal Bone Loss and Distribution of Single Standard Implants with Regard to Bone Resorption during Different Periods of Follow-Up. Percentage of Implants Is Given within Brackets

	Follow-Up of Single Implants					
	0–1 Year	0–5 Years	1–5 Years	0–18 Years	1–18 Years	5–18 Years
Patients	40	38	38	37	37	37
Implants	45	43	43	41	41	41
Bone Loss in mm						
Mean	0.5	0.5	0.0	0.4	–0.1*	–0.2*
Standard deviation	1.18	1.01	0.91	0.89	1.16	0.82
Bone Loss in mm	**Number of Implants (%)**					
0.0†	25 (56)	22 (51)	33 (77)	22 (54)	28 (68)	33 (80)
0.1–0.6	5 (11)	7 (16)	5 (12)	3 (7)	5 (12)	3 (7)
0.7–1.2	10 (22)	7 (16)	3 (7)	10 (24)	6 (15)	4 (10)
1.3–1.8	3 (7)	4 (9)	1 (2)	5 (12)	1 (2)	0
1.9–2.4	0	0	0	0	0	0
>2.4	2 (4)	3 (7)	1 (2)	1 (2)	1 (2)	1 (2)

*Mean value resulting in average increase of bone.
†Also increase of bone is denoted as no bone loss ("0").

Altogether 10 original single-crown restorations failed (CSR 83.8%) during the follow-up period (see Table 1). Again, this is comparable with earlier long-term follow-up studies where original crown survivals range from 74% to 94% after 10 to 15 years of follow-up.[9,24,25] Comparable survival of conventional single crowns on teeth (78%), and alternative conventional three-unit fixed prostheses on teeth (73.1%) has been reported after 18 and 20 years in function, respectively.[26,27]

The most common reason for crown replacement in the present study was infraposition of the implant crown in relation to adjacent teeth, which compromised the aesthetics of the patients ($n = 3$). All three replaced crowns were in females, changed at a late stage of the study. Also, some remaining original crowns showed various signs of infraposition at the termination of the study. This observation is in accordance with observations in an earlier study,[28] indicating slow craniofacial change, also observed in adult patients.[29–32]

Probing depths at implants and teeth showed a different pattern. Altogether 59% of the implant sites were not possible to probe into, probably because of very firm mucosa and/or the design of the implant crown. Another difference was that 26% of the probed implant sites were deeper than 4 mm as compared with only 2% for the examined sites at the teeth. These differences indicate a different anatomical situation at implants where these have been placed deep into the alveolar crest as also observed during the early "development period."[9] In accordance with earlier reports on long-term experience of single-implant restorations,[9,24] deep probing depth at implants, due to deep placement of the implants, are not necessarily a sign of disease or increased risk of bone loss at the single implants in the long-term perspective (see Table 2).

During the early stage of single-implant development, loosening of abutment screws and fistulas have been reported to cause major problems.[3,5,33] With the introduction of the CeraOne system, gold-alloy abutment screws with flat heads were introduced,[10,11,33] and a protocol was designed to control the torque of the abutment screw.[10,11] This study shows that modifications resulted in favorable outcome with only two (3%) loose abutment screws that could be retightened without requiring replacement of the crowns. These observations indicate an obvious improvement compared with early experience of single-implant components.[9]

The radiographic measurements showed only small variations in mean marginal bone levels and there was no clear indication that bone loss should increase by time (see Table 4). Again, these observations are in

accordance with earlier reports.[9,24] No differences in mean bone levels of standard and conical implants could be observed, and only a few implants exhibited bone loss exceeding three threads of the implant (>1.8 mm). Accordingly, even though original crown restorations may have to be changed in the future, stable bone levels indicate a further good prognosis of the present single implants beyond 20 years of follow-up, in accordance with earlier long-term observations.[9]

CONCLUSION

Long-term follow-up of single-implant restorations show encouraging results with few implant failures and complications (18-year CSR 96.8%). Bone levels are on an average stable with only few patients exhibiting bone loss more than 2 mm during 18 years in function, indicating good long-term prognosis. However, the original single-crown restorations are replaced more frequently (CSR 83.4%), sometimes caused by craniofacial changes and implant crown infrapositions. Also, some of the present remaining original crowns show signs of infrapositions, indicating possible need for replacement in the future.

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