

## An 8-year clinical evaluation of 76 patients with non-submerged dental implants

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في هذه الدراسة السريرية تم متابعة الزرعات السنوية المكشوفة والموضوعة بالفك السفلي الفاقدة لجميع الأسنان (الادرد الكامل). ٧٦ مريض زرع لهم ما مجموعه ٢٤٤ زرعة سنوية بالفك السفلي لثرت عليها الأطقم السفلية المثبتة بواسطة هذه الزرعات، خمسة فقط من هؤلاء المرضى استعدوا من الدراسة وذلك لأسباب أخرى لا تتعلق بفشل الزرعات. تم متابعة ٢٢٧ زرعة سنوية على مدى ٨ سنوات متواصلة وذلك لبيان مدى نجاح هذه الزرعات ولقد تبين من تحليل الجداول للمرضى الذين تم فحصهم بأن نسبة النجاح التراكمي قد بلغت ٩٩,٠% على مدى فترة المتابعة. دلت الدراسة بأن هذه الزرعات المكشوفة والتي تحمل مثبتات على شكل قضيب أو وصلات إحكام كروية الشكل الأطقم المتحركة في مكانها هي إحدى طرق العلاج التي يمكن استخدامها كطريقة ناجحة في تعويض الأسنان المفقودة عند مرضى الادرد الكامل وذلك مقارنة بالأطقم العادية المستخدمة والتي تحمل الكثير من المتاعب للمرضى المسنين.

The aim of this clinical study was to quantitatively assess the cumulative success and survival rates of the use of non-submerged ITI® dental implants in fully edentulous mandibles. A total of 76 patients received 244 fixtures in the mandible to retain overdentures. Of the 76 patients treated, five patients dropped-out for reasons other than implant failure. Eight-year cumulative success and survival rates were evaluated for 227 fixtures utilizing the life table analysis. Life table analysis for the investigated patients with a total of 227 implant fixtures revealed a cumulative survival and success rates of 90.9% at 8-years. The results indicated that the non-submerged osseointegrated dental implants with bar and ball attachments retaining overdentures could be successful treatment modality for edentulous patients with long-standing conventional complete denture problems.

### Introduction

The loss of alveolar bone as part of the ageing process affects both jaws. Several factors, such as genetic background, hormonal and metabolic disturbances and the loss of the natural teeth, may contribute to the degree of bone loss.<sup>1</sup> Atrophic changes in edentulous jaws mass create a clinical challenge due to reduced retention, stability and load bearing capacity of complete dentures. This may lead to a low level dental function.<sup>2</sup>

Patients with complete dentures sometimes complain of looseness of their mandibular dentures.<sup>3</sup> These are usually treated by conventional means that may include surgical techniques such as vestibuloplasty and ridge augmentation in an attempt to improve the quality of the denture bearing area. However, it is generally accepted that these forms of treatment may not be efficient in providing functional improvements.<sup>4</sup> These modalities have largely been superseded by the use of osseointegrated implant techniques. The introduction of osseointegrated dental implants has resulted in marked improvements in dental function, substantiated by many studies that evaluated bite force, chewing efficiency, speech and psychological status in patients treated with implant-fixed prosthesis and implant-retained overdentures.<sup>5-8</sup>

Reports on osseointegrated dental implants were based on retrospective clinical studies on completely edentulous patients treated with the Brånemark system. Implants survival rate of 86% in the mandible and 78% in the maxilla after 15 years of function was reported.<sup>9</sup> Prospective clinical studies with different follow-up periods reported favourable results with the use of the Brånemark implant system in totally edentulous<sup>10</sup> and partially edentulous individuals.<sup>11</sup> Previous studies<sup>12-14</sup> found that the success and survival rates of implant-retained overdentures were in the range of 91% to 97.7% in the mandible, when non sub-merged (that is one-step surgery and transmucosal from the onset) and submerged (that is two-step surgery, where another surgery is needed to connect the superstructure in the oral cavity) dental implant systems were employed.

The purpose of the present study was to evaluate the cumulative success rate, longevity and maintenance of 227 consecutively inserted International Team for Oral Implantology (ITI)® implant fixtures over a period of 8 years using the life table analysis.

### Materials and Methods

A total of 76 patients with long standing mandibular denture problems were treated with ITI fixtures in the anterior mandible to retain an overdenture.

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### Presenting Complaints

Seventy-six patients, 18 males and 58 females of an average age of 58 years at the time of implant placement were included in this study. All patients had been referred by their dental practitioners or by other hospital departments to the Department of Prosthodontics at Glasgow Dental Hospital, UK for consideration of implant treatment. They presented with a variety of chronic problems associated with instability of conventional mandibular dentures. Most of the patients had difficulties with eating. Some patients reported speech problems and many felt socially handicapped because of poor denture function. Dental history of the patients revealed that they had been edentulous in the mandible for 3 to 15 years prior to implant treatment, during which they had been provided with at least 3 sets of dentures for both upper and lower dental arches. A total of 244 fixtures were installed with different forms and lengths, and most of the fixtures were 10 mm (ITI)<sup>®</sup> hollow cylinders.

### Clinical Assessment

The clinical assessments for patients were carried out between 1 and 8 years after completion of implant treatment. All the patients were reviewed and assessed by the same clinician (author) over a period of 5 months. Of the 76 patients treated, 5 abandoned the treatment for reasons other than implant failure. Of the latter, 2 patients had died; 2 patients could not attend because of chronic health problems and in 1 patient, four healthy mandibular implants had been removed for psychological reasons (Table 1). There was no indication that there had been clinical problems during the earlier follow-up of any of these 5 patients.

The remaining 71 patients (55 females and 16 males) with a total of 227 fixtures were assessed. The mandibular implant-retained overdentures were anchored to ball attachments in 18 patients and 53 overdentures were anchored to bar attachments (Table 2). Seven out of the 227 implant fixtures had failed and 2 implant fixtures were not used in the final prostheses from the start because of buccal positioning, although they were fully osseointegrated.

The implant fixtures were examined for successful osseointegration according to the following predefined criteria of success.<sup>15</sup>

1. Absence of persistent subjective complaints, such as pain

2. Absence of recurrent peri-implant infection with suppuration
3. Absence of mobility
4. Absence of continuous radiographic radiolucency around the fixture

**Table 1.** Fixtures per patients, total number of fixtures, deceased and dropped-out patients, fixture failures and sleepers

Fixture number per patient	Number of patients	Total no. of fixtures	Deceased (Patients)	Dropped out (Patients)	Failure (Fixtures)	Sleeper (Fixtures)
2	25	50	1	0		
3	10	30	1	0	7	2
4	41	164	0	3		
Total	76	244	+2 #5	+3 #12		2

\* Remaining subjects \*\* Remaining fixtures # Total of lost fixtures (17) + Total of dropped-out patients (5).

**Table 2.** Number of fixtures which retained the attachments, number and types of attachments

Ball attachment	Two fixtures	Four fixtures	Total
	12	6	18
	Two fixtures short bar / distal extension cantilever	Three/ Four fixtures long bar	Total
	3/2	15/33	53

Clinical examination was carried out to evaluate the mobility of each fixture by application of manual pressure on different sides of each abutment using a dental mirror handle. Each implant was percussed with a dental mirror handle. For the overdenture retained by bar attachment, the bar was dismantled and each fixture was examined separately. A sharp high-pitched metallic sound with no discomfort to the patients was considered as an indicator of clinical osseointegration. If percussion gave a dull sound pitch, clinical examination was supported by the use of the annually taken radiographs and the present radiographs taken at the time of clinical assessment. None of the examined fixtures showed any sign of mobility when tested. All patients seen in this study had been seen within the Department of Prosthodontics as part of ongoing maintenance and care. Radiographs (orthopantomograph and periapical) were taken for each patient during this follow-up and it was considered as a routine assessment due to the limitation of using a standardized technique to measure and assess the marginal bone loss.

Patients were asked simple chairside questions regarding oral functions such as ability to eat and

chew hard food and whether they considered their prosthesis a part of their body or as foreign objects. Difficulties in maintaining good hygiene of prostheses with respect to attachment systems, prosthetic complications, soft tissue reaction and patient's complaints were also assessed.

### Statistical Analysis

Statistical analysis was performed with the use of life-table analysis.<sup>16</sup>

This analysis calculated the internal success rate for each time interval and the cumulative success rate for the entire 8-year period. All fixtures exhibiting suppurative peri-implant infection, pain, continuous radiographic radiolucency and clinical mobility at the final assessment were included in the group of failures.

### Results

A total of 244 ITI® implant fixtures were placed in edentulous mandibles in the interforaminal region in 76 patients. Five patients dropped-out for the reasons mentioned earlier.

Life table analysis for 71 patients with a total of 227 implant fixtures revealed a cumulative success rate of 90.9% over 8 years follow-up period and the over all success rate was in the range of 90.9% to 96.9% (Table 3).

**Table 3.** Number of fixtures, follow-up period, number of failures and the cumulative success rate (CSR)

No. of fixtures	Follow-up period (yrs)	No. of failures	No. of sleepers	% Success rate	C.S.R %
22	7-8			90.9	90.9
35	6-7	2		94.3	93.0
40	5-6	2		95	93.8
28	4-5	2		100	95.2
43	3-4	0	2	100	96.4
39	2-3	0		97.4	96.6
20	1-2	1		100	96.9
227	-	0			

A total of 7 hollow screw implant fixtures were lost, in six different patients and they were considered as an early failure. Two patients each lost a fixture during the osseointegration period in

the first year, these fixtures never having been loaded. Another 2 fixtures were lost in the second year. There was one further early failure during the healing phase due to lack of osseointegration.

One patient lost 2 implants after 5 years in function and this was counted as a late failure. In this patient, peri-implant infection with increased probing depth (approximately 8 mm), bleeding on probing and suppuration was apparent and peri-apical radiographs showed signs of vertical and horizontal bone resorption, where only the apical 1/3 of the fixtures were engaged by an intact bone. After microbiological investigation, the patient was treated with systemic oral antibiotics (Penicillin V 4x250 mg/daily and Metronidazol 3x250/daily) for 10 days and local irrigation of the peri-implant pocket with 0.5% chlorhexidine-digluconate gel. Thereafter, the patient was monitored for 5 months, but due to the recurrence of the infection, which became a source of discomfort to the patient, the 2 fixtures were taken out. Subsequently, this patient's overdenture was modified for anchorage to the 2 remaining implants by bar attachments.

All the patients with bar attachment reported difficulties in cleaning and maintaining good hygiene to the implant fixtures compared to patients wearing overdentures retained with ball attachment. Soft tissue hyperplasia ranged from slight to mild was found in 4 patients with stud attachments. Likewise, in 25 cases wearing overdentures retained with bar attachments, soft tissue hyperplasia ranged from slight to severe conditions. In 5 patients, at least 2 gingivectomies were carried out. Loose clips were reported in 3 patients and fractured clips in 4 patients. Overdenture renewal was carried out in 7 patients due to loss of the clips, golden matrices and fractured or worn acrylic teeth. The chief complaint from 30 patients was food trapping underneath the lower denture and this was greater in patients wearing an overdenture retrained with a bar attachment. All the patients were satisfied with both ball and bar attachments compared to their original conventional dentures with respect to oral functions.

### Discussion

Analyses were performed with cumulative success rates using predefined criteria of success.<sup>15</sup> The strict evaluation included all implants as biological failures, when there was suppurative peri-implant infection, clinical

mobility, persistent pain and radiographic radiolucency at the last examination.

A long-term prospective study with an 8-year follow-up period using ITI® dental implant systems reported cumulative success rate of 93.3% of 2359 implant fixtures.<sup>14</sup>

High long-term success rate of individual implants ranging from 86% to 98% have been reported when Brånemark two-stage dental implants were used as a support for prostheses in completely edentulous mandibles.<sup>9</sup> While in short-term studies, an overall success rates of Brånemark dental implants placed in edentulous atrophic mandibles were reported to be 94% and 97%, respectively.<sup>10</sup>

An equally high success rate of 96% in a 6-year-review was reported using the IMZ dental implant was reported.<sup>17</sup> Similar multicentre findings have been reported from in a prospective studies using Brånemark dental implant system to support overdentures.<sup>12,13</sup> Results reported success rates ranging from 94.2% to 97.7% for the mandibular overdentures with 1 to 5 years follow-up period.

Non-submerged, two-part ITI® dental implant system have been assessed as support for single tooth replacement, implant-fixed bridges or implant-retained overdenture in the maxilla and mandible of partially or totally edentulous patients.<sup>18</sup> The follow-up varied from 6 to 36 months. The degree of mandibular ridge atrophy in the edentulous group of patients provided by mandibular implant-retained overdentures was not evaluated. However, the success rate of individual ITI® dental implants was shown to be 92%. The 5-year success rate of (type F or Bonefit) ITI® and Brånemark dental implants placed as support for implant-retained overdentures was reported to be 97% and 91%, respectively.<sup>4,19</sup>

The results of this study on edentulous patients treated with implant-retained mandibular overdentures showed cumulative quantitative success rate of 90.9% over 8-year follow-up period. The small number of failures due to implant mobility during the healing period may be caused by bone necrosis due to overheating of the bone during the preparation of the implant bed. The overall success rates were in the range of 90.9% to 96.9%.

The present study indicated that all the patients were satisfied with both ball and bar attachments compared to their original conventional dentures. All the patients stated that their ability to chew and eat hard food was better with their implant-retained overdentures. These results are in agreement with previously reported findings.<sup>20,21</sup>

All the patients had perceived their implant-retained overdentures as part of themselves and it seemed likely that this perception had resulted from the increased stability of the lower denture provided by the implant fixtures with a resultant improvement in masticatory and social function. This is in agreement with many previously published reports.<sup>22</sup>

In the present study, patients with bar retained-overdentures complained of denture related hygiene problems more than those with ball attachments. Moreover, the vast majority of those patients reported food trapping underneath the lower denture and this was greater in patients wearing an overdenture retrained with a bar attachments. These findings were in agreement with those reported by Donatsky and Hillerup.<sup>23</sup>

In this present clinical study, the criteria used in evaluating implant success did not include the measurements of alveolar bone resorption due to lack of standardized x-ray technique. However, none of the panoramic or the periapical radiographs showed any radiolucencies around the fixtures, and this was substantiated by serial of annual radiographs of the fixture sites of all the patients over the past 8 years and at the time of clinical assessment. Absence of clinical mobility, continuous radiolucency, persistent discomfort, pain, suppuration was the parameter for the definition of success in this study. Therefore, based on the present results, it can be summarized that the non-submerged ITI® dental implants demonstrated success rates above 90.9% for an observation period of time up to 8 years. These present results have confirmed favourable and promising short- and long-term results previously published on ITI® dental implant system.<sup>14,19,24,25</sup>

### Conclusion

This clinical long-term study indicated that the ITI® implant-retained mandibular overdentures with ball and bar attachment systems could be a successful treatment option for patients with long-standing conventional complete denture problems. From the patient point of view, both attachment systems demonstrated an increase in overall satisfaction regarding oral and psychosocial functions.

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