Construction of a clinical implant performance scale for implant systems with overdentures with the Delphi method

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Statement of problem. The success of an implant system is often judged on the survival rate of the separate implants. This does not give a complete view of the "real" success of a system. To make that possible the total clinical performance, surgical and prosthetic, has to be considered.

Purpose. This study aimed to set up a clinical performance scale for different implant systems retaining mandibular overdentures.

Material and Methods. All data regarding surgical and prosthetic complications incurred and treatment procedures needed after implant placement were collected from a group of 90 patients who were treated either with two root form implants connected with a bar and supporting a mandibular overdenture or with a transmandibular implant system that supported an overdenture. All items were scored into five categories on the scale, defined as the "clinical implant performance" scale. The Delphi method was applied to categorize each item. A panel of experts assessed the items.

Results. After three rounds there was complete consensus between the experts for 65% of the items for the root form implant systems, and for 87% of the items at least five out of six experts gave the same score. For 55% of the items for the transmandibular implants systems there was complete consensus, and for 85% of the items at least five out of six experts scored in the same way.

Conclusions. The Delphi method provides a useful scale for evaluating the clinical performance of implant systems retaining mandibular overdentures. The presented scale makes it possible to compare the overall performance of different implant systems for overdentures. (J Prosthet Dent 1997;77:503-9.)

CLINICAL IMPLICATIONS

Comparison of different implant systems for overdentures is impossible when the clinical and prosthetic complications are not translated in comparable scores. With the Delphi method such a translation was made and presented.

Medical science is making progress in the implementation of quantitative methods to evaluate different treatment strategies, which is necessary because there always are many ways to solve a clinical problem. Such a clinical situation in dentistry is the treatment of edentulous patients with implant-retained mandibular overdentures. Many systems or methods have become available during the last 20 years.¹ Different root form implants are used; in some situations two are used, and

in others three or four are used. These implants are inserted between the mental foramina and are provided with bar, magnet, or ball attachments to give retention and stability for an overdenture. Transmandibular implants are also used; they consist of a plate under the mandible with posts that penetrate the mandible on which a triple bar is made. These different implant systems are mostly evaluated separately and are assessed only on the criteria of survival of the separate implants. Such an approach does not give a realistic evaluation of the success of a system used in a clinical situation, and comparison between different systems is impossible. That comparison can only be done by conducting a randomized clinical trial with different implant systems and taking the clinical performance of an "all-in-all" system into consideration.

To assess the overall clinical performance of implant systems for overdentures, an inventory must be made of the surgical and prosthetic complications that occurred and the treatment procedures that were necessary after implant insertion and overdenture fabrication. A scale

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Table 1. The categories in the clinical implant scale (the CIP scale)

	Category
No complication or need for treatment.	0
Minor complications that do not need intervention or are easily treated.	1
Complication or treatment procedure with reasonable chance of recovery or stabilization of the situation.	2
Serious complication or treatment procedure that may lead to failure of the implant system.	3
Complete failure of the implant system.	4

has to be constructed to bring all the items into one overall judgment. To do this each complication that can occur and each treatment procedure that can be necessary after placement must receive a category score that expresses the severity of the items viewed from the overall performance of the implant system. After a certain period of time each patient with a specific implant system receives a score on this scale, the "clinical implant performance" scale (CIP scale). Giving patients a score enables comparison of different implant systems and treatment strategies in a proper way. Such scores must be based on the judgments of a panel of experts.² The Delphi method pioneered by Dalkey³ uses a panel of experts, which makes it possible to arrive prudently at such a judgment.⁴⁻⁶ The method is used in health conferences on coronary heart diseases⁷ and osteoporosis.⁸ In dentistry it has been used in diagnostic radiology⁹ and in dental care for mentally ill elderly people.¹⁰

The objective of this study was to establish a CIP scale for root form and transmandibular implant-retained mandibular overdentures by use of the Delphi method.

PRINCIPLES OF THE DELPHI METHOD

The Delphi method can be characterized as a technique that structures a "group communication process" so the individuals of the group effectively deal with a complex problem. To accomplish this structured communication, assessment of the views of each member of the group and feedback of the individual contributors is necessary, and this assessment also provides the opportunity for individuals to revise views and allows a degree of anonymity for the individual responses.¹¹ The cardinal features in drawing out the group opinion are anonymity, iteration, and feedback. Anonymity means that no member of the group knows what any other member's category score is to a particular item. In this way verbally gifted experts cannot impose their own view, and the chance on socialization of the answers is ruled out. On the other hand, it does not necessarily require that the identities of the other members are hidden; it may in fact be advantageous or motivating if one knows the

names of the other participants. The items are presented in two or more iterations; the items are the same in each round, but it is possible that new items are raised based on earlier responses. Feedback, closely allied to iteration, refers to the inclusion of additional information at each iteration in the form of statistics on the earlier responses of the panel of experts as a whole.

In this study the method was applied to clinical and prosthetic complications and treatment procedures with respect to implant systems that were used to retain mandibular overdentures. The acquired answers were the category scores of the CIP score and were thus a measure of the degree of the clinical success of the implant system. The assumption was that the "true" degree of success associated with the clinical and prosthetic complications and treatment procedures was to some extent "within" the panel of experts, and by properly drawing out a group consensus, we obtained a well-considered category score for each complication or treatment procedure.

The most common form of the Delphi method is performed as follows. A monitor team designs the scale with descriptions of different categories, in this case the categories of the CIP scale. The team selects items on the basis of the experiences during patient treatment from the literature or retrospective studies. The list of these items is sent in the form of a questionnaire to the panel of invited experts, who give their first score for each item. This questionnaire is returned to the monitor team, which samples the scores of the experts, summarizes the results, and adds the answers score anonymously to the items in the questionnaire. In the next rounds the experts reevaluate their original scores based on their examination of the responses of the experts in the previous round. When experts strongly disagree, they are asked for an explanation. The monitor team may directly react for explanations and solve misunderstandings or may pass the explanation to the other experts. This procedure is repeated in the next round. The procedure ends when the opinions are to their nearest approach or when the divergence in the answers does not change any more.

MATERIAL AND METHODS

Three implant systems used to retain mandibular overdentures in edentulous patients with severe mandibular bone loss were used for sampling the items of the scale. Data were collected on the basis of case histories of 90 patients from a multicenter clinical trial carried out at the Universities of Nijmegen and Groningen and comprised surgical, prosthetic, periimplant, and radiographic information.¹²⁻¹⁴ The first two implants were the two-stage IMZ-system (Van Stroter, Nieuwegein, The Netherlands) with a cylindric root form and the Bränemark system (Nobel Biocare, Göteborg, Sweden) with a screw-type root form.^{15,16} Two implants were in-

Table II. Items of the CIP scale and the diversity of the items given by six experts in each Delphi round for the *root form* implant systems*

Items to be judged	Diversity first round	Diversity second round	Diversity third round
01 Broken abutment	4 : 2	6 : 0	
02 Hyperplastic mucosa around implant	3 : 3	4 : 2	5 : 1
04 Not fitting superstructure	3 : 3	3 : 3	6 : 0
07 Broken superstructure	4 : 1	5 : 1	
08 Incorrect occlusion and articulation	6 : 0		
09 Loss of complete implant system	6 : 0		
10 Loosening of one or more screws of the superstructure	6 : 0		
11 Relining necessary for upper or lower denture	6 : 0		
12 Minor disturbance mental nerve	4 : 2	4 : 2	4 : 2
13 Severe disturbance mental nerve	4 : 2	4 : 2	4 : 2
14 Replacement implant after fracture	3 : 2 : 1	6 : 0	
15 Removal of one implant	3 : 3	4 : 2	4 : 2
16 Removal of two implants	5 : 1	6 : 0	
18 X-ray score=0 and probing depth 3-5.5 mm	5 : 0	6 : 0	
19 X-ray score=0 and probing depth >5.5 mm	5 : 0	6 : 0	
20 X-ray score=1 and probing depth 0-3 mm	3 : 1 : 1	5 : 1	
21 X-ray score=1 and probing depth 3-5.5 mm	4 : 1	5 : 1	
22 X-ray score=1 and probing depth >5.5 mm	5 : 0	6 : 0	
23 X-ray score=2 and probing depth 0-3 mm	6 : 0		
24 X-ray score=2 and probing depth 3-5.5 mm	6 : 0		
25 X-ray score=2 and probing depth >5.5 mm	4 : 2	6 : 0	
26 X-ray score=3 and probing depth 3-5.5 mm	5 : 1	6 : 0	
27 X-ray score=3 and probing depth >5.5 mm	4 : 2	5 : 1	

*Note that the chosen categories cannot be read from the Table.

serted in the interforaminal part of the mandible with the patient under local anesthesia. The implants were connected with a bar on which an overdenture with clip attachment was manufactured. The third system, the transmandibular implant (W. Lorenz, Jacksonville, Fla.) developed and described by Bosker and Van Dijk,¹⁷ was placed through a submental approach with the patient under general anesthesia. It consisted of a baseplate fixed to the caudal border of the mandible. Four posts were screwed through the mandible, and a superstructure was manufactured with a triple bar construction with cantilever extensions. A part of this prospective study was to register all surgical and prosthetic complications incurred and treatment procedures needed after implant placement. A list of all the items registered during the first and second year was used.

A five-point ordinal scale that varied from category 0 (no complications) to category 4 (complete failure of the implant system) was selected by the monitor team. The monitor team consisted of two dentists and a statistician (Table I). All conceivable clinical and prosthetic complications that occurred and treatment procedures that were necessary during the first- and second-year evaluation in the previously mentioned group of patients were collected as items for the scale.

Items collected are presented in Tables II and III. "Disturbances of the mental nerve" were assessed by asking the patient to close his or her eyes. The dentist

then touched the skin of the lip and the chin with a paintbrush and asked the patient his or her feeling (normal or paresthesia or anesthesia); the category "minor" meant a paresthesia or anesthesia in an area of less than 4 cm², which the patient had to some extent but was not disturbing. "Severe" meant a paresthesia or anesthesia of more than 4 cm² that disturbed the patient daily. "Hyperplasia" was scored when correction of a hyperplasia around an implant post was necessary because of pain, bleeding, and pseudopockets. For the periimplant complications items were based on a combination of both an evaluation of the amount of bone loss around the implants and the probing depths around the implants or implant posts. Probing depths were assessed by two observers at the buccal, lingual, mesial, and distal sides of the implants or posts with a Merit B periodontal probe (Hu-Friedy), and the highest of the mean values of both observers recorded were used. Orthopantomographic radiographs were used for the evaluation of the bone loss. The amount of bone loss found when the bone heights on the radiographs were compared directly after implantation with the bone heights on the radiographs made at a later time was discriminated in four x-ray scores (0 to 3). Score 0 represented no bone loss, 1 represented bone loss less than one third the length of the implant or post, 2 represented bone loss one third to one half the length of the implant or post, and x-ray score 3 represented bone loss more than one half the length of the

Table III. Items of the CIP scale and diversity of the items given by six experts in each Delphi round for the transmandibular implant system*

Items to be judged	Diversity first round	Diversity second round	Diversity third round
02 Hyperplastic mucosa around implant	3 : 3	3 : 3	5 : 1
03 One mobile post	4 : 2	4 : 2	4 : 2
04 Not fitting superstructure	3 : 3	4 : 2	6 : 0
05 Two mobile posts	4 : 2	3 : 3	5 : 1
06 Broken cantilever of the superstructure	4 : 2	6 : 0	
07 Broken superstructure	4 : 1	6 : 0	
08 Incorrect occlusion and articulation	6 : 0		
09 Loss of complete implant system	6 : 0		
10 Loosening of one or more screws of the superstructure	6 : 0		
11 Relining necessary for upper or lower denture	6 : 0		
12 Minor disturbance mental nerve	4 : 2	4 : 2	4 : 2
13 Severe disturbance mental nerve	4 : 2	4 : 2	4 : 2
14 Replacement of one or more posts after fracture	3 : 2 : 1	4 : 2	5 : 1
15 Removal of one post	5 : 1	5 : 1	
16 Removal of two posts	3 : 3	5 : 1	
17 Removal of three posts	5 : 1	6 : 0	
18 X-ray score=0 and probing depth 3-5.5 mm	5 : 0	6 : 0	
19 X-ray score=0 and probing depth >5.5 mm	5 : 0	6 : 0	
20 X-ray score=1 and probing depth 0-3 mm	3 : 1 : 1	6 : 0	
21 X-ray score=1 and probing depth 3-5.5 mm	4 : 1	5 : 1	
22 X-ray score=1 and probing depth >5.5 mm	5 : 0	6 : 0	
23 X-ray score=2 and probing depth 0-3 mm	6 : 0		
24 X-ray score=2 and probing depth 3-5.5 mm	6 : 0		
25 X-ray score=2 and probing depth >5.5 mm	4 : 2	5 : 1	
26 X-ray score=3 and probing depth 3-5.5 mm	5 : 1	6 : 0	
27 X-ray score=3 and probing depth >5.5 mm	4 : 2	5 : 1	
28 Loosening of one or more caudal screws of the posts		4 : 2	4 : 2

*See note Table II.

implant or post. Every combination of "bone loss" and "probing depth" was divided into three categories (<3 mm, 3 to 5.5 mm, >5.5 mm) and was presented as an item on the CIP scale.

APPLICATION OF THE DELPHI METHOD TO THE CIP SCALE

The Delphi procedure is performed in three phases. In phase one a list of clinical and prosthetic complications and necessary treatment procedures observed in the 90 previously mentioned case histories of patients was made by the monitor team. It was presented to a panel of six experts consisting of two oral surgeons and four prosthodontists. Three of the experts were from the University of Nijmegen, and three were from the University of Groningen. All the experts had wide experience in either the surgical or prosthetic treatment procedures of patients receiving implants. In the first round they were sent a query sheet with items on it and were asked to assign each complication or treatment procedure in a category of the CIP scale without consultation with others. In phase two the assignments were tabulated in a list. When consensus with respect to an item was achieved, the procedure ended. When different

scores occurred, the experts were given the diversity in the answer score of the first round and were asked to rate the item again in a second round, again without consultation with others. If an expert disagreed with the score of most of the other experts in this round, he or she was asked for an explanation. In phase three the experts were consulted by telephone about the differences that still existed after the second round. The procedure was ended after three rounds or earlier when five out of six experts had the same opinion.

RESULTS

Tables II and III present the list of collected clinical and prosthetic complications and treatment procedures in the root form and transmandibular implant systems separately and the diversity of the given category scores in every round of the Delphi procedure assigned to each item by the six experts. After the first round one new complication was proposed by one expert with respect to the transmandibular systems: the item "loosening of one or more caudal screws of the posts." One expert did not assign scores to items 18 to 22 in the first round because of problems with the interpretation of these items. In the second round a definition of these items was added to the

Table IV. The final category scores of the CIP scale based on the Delphi method

Items to be judged	Transmandibular implant system	Root form implant system
01 Broken abutment	*	1
02 Hyperplastic mucosa around implant	1	1
03 One mobile post	3	*
04 Not fitting superstructure	2	2
05 Two mobile posts	3	*
06 Broken cantilever of the superstructure	1	*
07 Broken superstructure	2	2
08 Incorrect occlusion and articulation	1	1
09 Loss of complete implant system	4	4
10 Loosening of one or more screws of the superstructure	2	1
11 Relining necessary for upper or lower denture	1	1
12 Minor disturbance mental nerve	1	1
13 Severe disturbance mental nerve	2	2
14 Replacement of one or more posts after fracture	2	4
15 Removal of one post/implant	3	4
16 Removal of two posts/implants	4	4
17 Removal of three posts	4	*
18 X-ray score=0 and probing depth 3-5.5 mm	0	0
19 X-ray score=0 and probing depth >5.5 mm	1	1
20 X-ray score=1 and probing depth 0-3 mm	1	1
21 X-ray score=1 and probing depth 3-5.5 mm	1	1
22 X-ray score=1 and probing depth >5.5 mm	2	2
23 X-ray score=2 and probing depth 0-3 mm	2	2
24 X-ray score=2 and probing depth 3-5.5 mm	2	2
25 X-ray score=2 and probing depth >5.5 mm	3	3
26 X-ray score=3 and probing depth 3-5.5 mm	3	3
27 X-ray score =3 and probing depth >5.5 mm	3	3
28 Loosening of one or more caudal screws of the posts	2	*

*Not applicable for the corresponding implant system.

questionnaire. In the third round only items with differences in scores of 4:2 or 3:3 were presented again to experts by telephone. This procedure was needed for four items of the root form implant systems and for eight items of the transmandibular implant system.

For some items a divergence occurred in the scores between the oral surgeons and the prosthodontists. The "correction hyperplastic mucosa around implant," for instance, was a simple surgical complication in the view of the oral surgeons (category 1), but the prosthodontists had the opinion that a correction means a failure in management of the patient's oral hygiene maintenance and that it is not a minor but a more serious complication (category 2). Disturbances of the mental nerve are a result of the surgery caused by the insertion of the implants or posts close to the mental nerve. Some experts considered this a complication of the implant (category 2); others considered it an unpleasant result of the surgery with no consequence for the success of the implant system (category 1). Discrimination between "minor" and "severe" did not improve consensus. Concerning item 15, "removing of one post of the transmandibular implant system," there is theoretically a failure of the implant, but the sys-

tem and the overdenture are still in function, so a category of 3 was given.

After three rounds complete agreement was achieved with respect to the root form implant systems in 65% of the items; in 22% one of the six experts had a different opinion, and in 13% two or more experts had a different opinion on an item. With respect to the transmandibular implant system the experts completely agreed in 55% of the items; in 30% one expert had a different opinion, and in 15% two or more experts had a different opinion. Table IV presents the final CIP scores for each item.

DISCUSSION

The CIP scale has been developed to compare different implant systems and includes the complications that occurred and the treatment procedures necessary in the aftercare period. Most studies have reported on survival rates of separate implants,¹⁸⁻²¹ which does not provide information about the clinical performance of a treatment procedure with implants in general. The evaluation based on the success criteria described by Smith and Zarb²¹ is much more specified but still has an absolute character of "yes" or "no" with respect to success

or failure. Albrektsson and Zarb²² have suggested that every implant should be evaluated as part of a four-grade scale representing "success," "survival," "unaccounted for," and "failure." In this study a scale was constructed that included not only the success criteria of a separate implant but also a scale that gave a score to the total surgical and prosthetic treatment procedure; thus it included all kinds of complications or treatment procedures that occurred or were necessary. This scale makes it possible to compare the treatment strategies in edentulous patients with different implant systems.

The Delphi procedure went by uneventfully. Tables II and III reveal that there was a substantial increase in consensus from the first to the third round. For many items there was not even a divergence in the views of the experts in the first round. After the third round a high congruency regarding almost all items was found. There was complete agreement with respect to the root form implant systems in 65% of the items; in 87% at least five out of six experts gave the same score. With respect to the transmandibular implant system the experts completely agreed in 55% of the items; in 85% at least five out of six experts scored in the same way.

The advantage of the Delphi method is that the assessment of the category score of an item is arrived at by independent judgment of experts. However, it does not solve the problem that the results are dependent on the quality and the subjectivity of the panel of experts. A different panel may reach other results. That was the reason that no attempts were made to find further consensus when five out of six experts had the same opinion. The last expert confronted with the opinion of the others might have felt forced to change his or her opinion. Another problem is that the criteria with which the experts have to comply are difficult to describe exactly, and their interpretation by the experts differs. Because the scores are, however, used just for comparison of the results in a clinical trial, these drawbacks are less important, because all treatment strategies are assessed in the same way.

Based on the high percentages of agreement it can be concluded that the CIP scale gives a reasonable and satisfactory answer to the clinical problem for assessing implant performance in mandibular overdentures. The scale is applicable for root form and transmandibular implant systems. When the final patient score is obtained by taking the highest score from all items, it makes it possible to compare different systems not just on the basis of failures, as is frequently done in literature, but on all complications that occurred or treatment procedures that were necessary after implant insertion. It differs from the implant success scale presented by Smith and Zarb,²¹ because that scale evaluates implants as separate units, and the CIP scale evaluates the implant system as a whole, as recommended in a previous study.²³ The former study is of interest to answer questions with regard to the success of the individual implants, whereas

the latter study gives more insight in the total, surgical, and prosthetic success of an implant system. In this way comparison of completely different systems in randomized clinical trials is possible.

CONCLUSIONS

Under the conditions of this study the following conclusions were drawn.

1. The study demonstrates the feasibility of the Delphi method in evaluating dental treatment procedures.
2. After three rounds at least five out of six experts gave the same score in 87% of the items for root form implant systems and in 85% for transmandibular systems.
3. With the Delphi method a useful scale for evaluating the clinical performance of implant systems retaining mandibular overdentures is obtained.

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Noteworthy Abstracts of the Current Literature

Bond strength of resilient lining materials to various denture base resins.

Al-Athel MS, Jagger RG, Jerolimov V. *Int J Prosthodont* 1996;9:167-7.

Purpose. This study compared the shear bond strength of three soft lining materials (Coe Super Soft, Coe, Chicago, Ill.; Molloplast-B, Regneri GMBH, Karlsruhe, Germany; Novus, Hygienic, Akron, Ohio) with three different denture base acrylic resins (TS 1195, Cole Polymers, Croydon, U.K.; Trevalon, De Trey, Weybridge, U.K.; Lucitone 199, Dentsply, York, Pa.).

Material and Methods. Three groups ($n = 10$) of consulting of shear specimens bonded to plates of each acrylic resin were prepared for each soft liner. A Lloyd Instruments Materials testing machine was used to test the prepared specimens. The load at which failure occurred was recorded along with the type of failure (cohesive, adhesive, or mixed). A one-way analysis of variance (ANOVA) was used to compare the generated shear bond strengths.

Results. Coe Super Soft lining material failed mostly cohesively, Molloplast-B lining material always failed cohesively, and Novus lining material consistently failed adhesively. Coe Super Soft always exhibited the highest bond strength values and Molloplast-B always exhibited the lowest. ANOVA revealed that the shear bond strength of the materials was significantly different when they were bonded to the same denture base resin. The shear bond strength of the three soft liners was significantly greater when they were processed with Lucitone 199 acrylic resin. Novus lining material, however, exhibited the greatest shear bond strength value when it was processed with TS 1195 acrylic resin. No significant difference in bond strength was noted between Novus processed with TS 1195 and Lucitone 199 acrylic resins. No significant difference was noted between the bond strength of Coe Super Soft lining materials with TS 1195 and Trevalon acrylic resins. There was also no significant difference noted between the shear bond strengths of Molloplast-B lining materials processed with TS 1195 and Trevalon acrylic resins.

Conclusions. (1) The bond strengths of both Coe Super Soft and Molloplast-B lining materials were higher than their shear bond strengths. (2) The specimens fabricated from Coe Super Soft lining materials exhibited the highest shear bond strength. (3) The bond strength of Novus lining materials depended on the denture base material to which it was processed. This bond strength was greatest with TS 1195 acrylic resin. 5 references.—*DI, Dixon*