Final Report Regarding the Success Rate of BEGOSemados Implants Installed in a Single-Stage Surgical Procedure and a minimum of 60 months Clinical Follow-up Study

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SUMMARY

Between October 2000 and December 2003, 166 patients received 1 or more BEGOSemados implants, positioned during a single-stage surgery procedure. 649 (86%) of 756 implants have been installed using the single-stage procedure. Following a 3 to 6 month healing period, 638 (98%) of the 649 implants could support the final prosthesis. Every patient will be followed and evaluated yearly for a period of 5 years. In December 2008, only 8 patients having a total of 34 implants have missed a periodic follow-up visit. Consequently, 615 implants have been evaluated during follow-up visits. The average period for implant placement was 87 months (ranging from 60 to 98 months), and the average period for loading the implants with the final prosthesis was 73 months (ranging from 56 to 94 months).

INTRODUCTION

Since the work of Dr. Branemark[1] in the 60's, the traditional two-stage surgical approach has considerably evolved. Many studies[2] have shown that implants with a good primary stability could be placed in a single-stage surgical procedure with an equivalent rate of success. It is the implant's primary stability that enables its osseointegration, while resisting to forces from the masticatory muscles as well as micro movements they generate. Every implant system designed for the two-stage technique can be used as a single-stage surgical procedure with the healing abutment being placed at time of surgery. Some systems do offer implants designed for a single-stage surgical procedure (Straumann, Zimmer, Serf, Branemark). For patients, the single-stage surgical approach[3] reduces costs and time, as well as discomfort. In addition, the implant treatment is psychologically more acceptable when only one surgery is performed.

The following article will discuss the results achieved by the authors with the BEGOSemados implants placed using a single-stage surgical procedure in 166 patients, over a minimal period of 60 months.

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MATERIALS AND METHODS

Every patient had to undergo a clinical and radiographic[4] examination and had to fill-in a Medical Questionnaire to determine whether they were apt to undergo an implant surgery. Each patient signed a Consent Form after having been informed of the risks related to their individual case. Those patients and/or procedures representing a higher risk of implant loss were not excluded from this study. In every case, the benefits and risks associated with the implant procedure were discussed at length to assist each patient in their decision making process. For example, at the time of selecting patients, smokers were informed of the higher risk of implant loss. It was recommended to such patients to stop smoking after the surgical procedure, but many asked for and were treated without stopping smoking. Patients suffering from diabetes but in good health were recommended to meticulously control their glycaemia during the healing period. Each recipient site was evaluated to make sure that there was adequate bone height available for placement of a 8.5mm by 3.75mm implant requiring a 5mm wide bone crest. Patients with not enough bone height and width had to undergo an autogenous bone graft or one made of autogenous and allogenic components prior to the implant procedure. When an autogenous bone graft was performed, a minimum 3 months healing period was required before the implant procedure, while a minimum of 6 months was required in the case of a bone graft composed from autogenous and allogenic components. Once the implant was positioned, it was determined acceptable to have part of the implant collar not fully inserted in the bone at the top of the crest if the said crest was less than 5mm wide or if the bone rose alongside an adjacent tooth. The uninserted part had to have a maximum height of 2mm by 180 degrees. An autogenous bone graft had to be performed simultaneously with the implant procedure if the dehiscence was any larger, and that part had to be submerged.

The implants used for this study were between 8.5mm to 13mm in length, and between 3.75 and 5.5mm in width. Each recipient site received an implant of maximum length and diameter in function of the bone available at the time of surgery and the size of the tooth to be replaced. Table 1 indicates the size of the implants used in this study and Table 2 indicates the ideal diameter of the implant as recommended by BEGOSemados in function of the tooth to be replaced. You will note that 16 implants having a diameter of 3.25mm were placed in patients in cases where the bone height and size was over evaluated at the preoperative evaluation and it was judged preferable, at time of surgery, to use a smaller implant rather than performing a graft bone.

Table 1 Size of implants used in phases 1 and 2

Implant Table								
	Total	1- phase	%	Upper	Lower	Two- phase	Upper	Lower
3,25 L10	4	3	0,4	1	2	1	1	-
3,25 L13	12	5	0,7	-	5	7	7	-
3,75 L8,5	25	16	2,1	-	16	9	3	6
3,75 L10	77	71	9,4	8	63	6	6	-
3,75 L11,5	91	83	11,0	23	60	8	7	1
3,75 L13	299	268	35,5	91	177	31	26	5
4,5 L8,5	19	16	2,1	-	16	3	3	-
4,5 L10	79	62	8,2	13	49	17	13	4
4,5 L13	128	107	14,2	50	57	21	17	4
5,5 L8,5	1	-	0	-	-	1	1	-
5,5 L10	13	12	1,6	7	5	1	1	-
5,5 L13	8	6	0,8	1	5	2	1	1
Total :	756	649	86	194	455	107	86	21

Table 2 **Size of Implants as Recommended by BEGOSemados for Each Implant Site**

	Implant Size							
Maxilla	3.25	(-)	(X)	(-)	(-)	(-)	(-)	(-)
	3.75	(+)	++	(+)	+	+	(X)	(X)
	4.5	++	(+)	+	++	+	+	+
	5.5	(+)	(-)	+	+	+	+	++
Tooth		1	2	3	4	5	6	7
Mandible	3.25	(+)	(+)	(-)	(-)	(-)	(-)	(-)
	3.75	++	+	+	+	+	(+)	(+)
	4.5	+	+	++	++	++	+	+
	5.5	(-)	(-)	(-)	(-)	(-)	++	++

Legend

(-) = Not Suitable	+ = Suitable
(X) = Can be used in connexion with other implants or teeth	++ = Recommended
(+) = Suitable, can be used together with other implants	

The BEGOSemados implant has been designed as a two-stage surgical procedure implant. It is made of pure grade IV Titanium, has a cylindrical shape and a internal hexagon of 2.5mm. The implant's surface is micro-textured to increase osseointegration. Over 1mm of the collar is polished and it is a self-tapping screw type endosseous implant. It comes in the following diameters: 3.25, 3.75, 4.5 and 5.5 mm, and in lengths of 7, 8.5, 10, 11.5, 13, 15 and 18 mm.

There were no restrictions regarding types of edentulism that was to be treated. Partially edentulous patients had to accept the treatment recommended by the restorative dentist. Fully edentulous patients could choose between a Dolder-bar supported removable prosthesis loaded on the implants, or a fixed prosthesis (Montreal bar type or crown and bridge type). The choice was based on the bone resorption at the implant site, the patient's expectations as well as financial considerations. Table 3 indicates the number of implants placed according to the type of prosthesis designed and created.

Table 3 Number of Implants Placed According to the Type of Restoration

Type of Restoration		Implants		
	Qty	Total Implants	Upper	Lower
One single crown (1 implant)	58	58	31	27
2 splinted crowns (2 implants)	55	110	34	76
3 splinted crowns (3 implants)	39	117	90	27
4 splinted crowns (4 implants)	1	4	4	-
6 splinted crowns (6 implants)	1	6	6	-
One 3-Unit Bridge, Upper (2 implants)	2	4	4	-
One 4-Unit Bridge, Upper (3 implants)	3	9	9	-
One 6-Unit Bridge, Upper (4 implants)	5	20	20	-
One 6-Unit Bridge, Upper (5 implants)	2	10	10	-
One 7-Unit Bridge, Upper (4 implants)	1	4	4	-
One 7-Unit Bridge, Upper (5 implants)	1	5	5	-
One 7-Unit Bridge, Upper (6 implants)	2	12	12	-
One 8-Unit Bridge, Upper (4 implants)	1	4	4	-
One 10-Unit Bridge, Upper (6 implants)	2	12	12	-
One 3-Unit Bridge, Lower (2 implants)	7	14	-	14
One 4-Unit Bridge, Lower (3 implants)	1	3	-	3
One 6-Unit Bridge, Lower (2 implants)	2	4	-	4
One 6-Unit Bridge, Lower (3 implants)	1	3	-	3
Dolder Bar, Upper + c/ (5 implants)	1	5	5	-
Dolder Bar, Upper + c/ (6 implants)	1	6	6	-
Dolder Bar, Upper + c/ (7 implants)	2	14	14	-
Fixed Bar, Upper (7 implants)	1	7	7	-
Dolder Bar, Lower + /c (4 implants)	39	156	-	156
Dolder Bar, Lower + /c (2 implants)	4	8	-	8
Dolder Bar, Lower + /c (5 implants)	14	70	-	70
Fixed Bar, Lower (5 implants)	15	75	-	75
Fixed Bar, Lower (6 implants)	2	12	-	12
1 Special Case Addition of 1 Lower Implant on Existing Case	1	1	-	1
3 Implants Lost and not Replaced	3	3	3	-
Total :		756	280	476

With respect to the osseo site preparation prior to the placement of the implant and the healing abutment, the restorative dentist had to follow the surgical and prosthetic procedures recommended[5] by BEGOSemados manufacturer saving a few modifications in order to increase the implant's primary stability. The objective was to obtain ideally a torque resistance of at least 20N/cm by modifying the bone drilling according to the bone density at the implant site. For a D1 bone, the tapping of the drill hole was only completed for 50% of the length of the implant to be placed. In a D2 to D4 bone, no tapping was performed. In addition, for a D4 bone, the last recommended drill was not used. Countersink drilling was used only in D1 and D2 bones. Table 4 indicates the number of implants placed according to the bone density at the implant site. The torque resistance was checked with an adjustable torque wrench that is provided in the BEGOSemados' surgical kit and which has a reading guide marked as less than 10 N/cm, more than 10 N/cm, more than 20 N/cm or more than 30 N/cm (refer to Table 5).

Table 4 Number of Implants Placed According to the Bone Density at the Implant Site

Implants VS Bone Density						
	Phase 1			Phase 2		
	Upper	Lower	%	Upper	Lower	%
D1	4	101	13,9 %	-	2	0,3%
D2	131	349	63,5 %	57	19	10,05%
D3	53	5	7,7 %	22	-	2,91%
D4	6	-	0,8 %	7	-	0,92
Total :	194	455	86 %	86	21	14%

Table 5 Torque Resistance Following the Implant's Placement

Upper, Phase 1		Upper, Phase 2	
Torque	Quantity	Torque	Quantity
+30	95	+30	7
+20	58	+20	11
+10	35	+10	6
-10	6	-10	10
0	0	0	52
Total:	194	Total	86
Lower, Phase 1		Lower, Phase 2	
Torque	Quantity	Torque	Quantity
+30	422	+30	9
+20	32	+20	2
+10	1	+10	0
-10	0	-10	0
0	0	0	10
Total :	455	Total :	21
TOTAL :		756	

Following the placement of the implant, the restorative dentist decided whether the implant could be placed in a single-phase surgical procedure or not. An implant showing an evident lack of primary stability or when a bone graft was necessary at the time of the implant's placement had to be submerged and later exposed during a second surgical procedure. Those implants placed in a single-phase surgical procedure received an healing abutment that was as short as possible (3mm), in order to garnish the temporary prosthesis with a soft tissue such as <Truesoft>. For those patients with and edentulous mandible, the healing abutment used was less than 5mm long to retain soft tissue surrounding the posts until new tissue has set on the bone. After a minimum healing phase of 2 months, the 5mm long healing abutments were replaced with 3mm long final posts in the majority of cases. All patients presenting a gingival thickness of over 5mm at the implant site had to undergo a muco gingival surgery at the time of the implant placement to reduce the thickness around the implant to 4mm or less.

Table 6 indicates the length of the healing abutments used and Table 7 indicates the number of implants placed according to the type of temporary prosthesis worn by the patient. No implant or healing abutment was splinted during the surgical phase. The waiting period between the implant placement and the loading of the final prosthesis was a minimum of 3 months for the mandible and a minimum of 6 months for the maxilla. The temporary prosthesis was garnished with a soft tissue immediately after the surgical procedure. Partially edentulous patients or those with fully edentulous mandible were told to wear their prosthesis only if necessary during the first two weeks and eat without their prosthesis. Patients with a fully edentulous maxilla had to wear their prosthesis continuously during the first 48 hours and eat soft food during the first two weeks. Partially edentulous patients who wished to wear their prosthesis while eating, for aesthetic reasons, could do so by chewing using the side without any implants. After the first two weeks, all patients had a soft food diet for at least 2 months (any food that could be cut with a fork). Patients were seen 2 weeks after the surgery to remove sutures and to evaluate the implants. To be considered successful, the implants had to show absence of mobility at touch as well as absence of sensitivity from the patient. Any implant lacking stability or that was sensible to pressure after the healing phase was removed and considered to have failed.

Table 6 Length of the Healing Abutments used in Single-Phase

Number of Single-Stage Implants 649	Transmucosal L3-Upper	186	28,66%
	Transmucosal L3-Lower	187	28,81%
	Transmucosal L5-Upper	8	0,01%
	Transmucosal L5-Lower	268	41,29%

Table 7 Implants Placed According to the Provisional Restoration Worn by the Patient

	Phase 1		Phase 2	
	Qty Implants	%	Qty Implants	%
c/c	51	8,44 %	19	3,15 %
c/	62	10,26 %	23	3,81 %
/c	302	50,00 %	1	0,18 %
c/p	50	8,28 %	17	2,81 %
p/p	26	4,30 %	8	1,32 %
p/	30	4,97 %	15	2,48 %
/p	-	-	-	-
Total :	521	86,25 %	83	13,75 %

FOLLOW-UPS :

After the final prosthesis is loaded, each patient is seen after 1, 6, and 12 months thereafter each year there is a visit for a period of 5 years. During each follow-up visit, absence of mobility of the implant and prosthesis is evaluated, as well as the absence of sensitivity of the implants to touch, the patient's comfort, the retention of the prosthesis, the gingivae's peri-implant health (presence of plaque and tartar, colour and mobility of the gingivae, survey at the contour of the implant and gingival recession) as well as any bone loss, with the help of panoramic radiographs, peri-implant survey and gingival recessions at the contour of the implants.

Patients with a screwed-retained prosthesis (Dolder or Montreal bar) undergo a yearly evaluation by which the mobility of each implant is verified after the removing the bar. Implants of patients that have a cement-retained restoration (complete fixed prosthesis at the maxilla or the majority of partial prosthesis) are not evaluated on an individual basis unless some problem is detected during a clinical exam or radiograph; in such a case, the prosthesis was unbounded in order to examine each implant individually.

Of the 8 patients (34 implants) having missed their periodic follow-up visits, only 3 patients (4 implants) never had their periodic follow-up. The 5 others presented themselves for a follow-up visit at least once between 3 and 5 years. Of all the reviewed patients, no implant was lost after the pose on the part prosthetic. The big majority of the implants followed were considered as a s uccess, some being considered satisfactory according to the *Glossary of implant dentistry II* of the l'ICOI

RESULTS

A total of 166 patients received 756 implants. Of this number, 107 implants (14.2%) were installed in a two-stage surgical procedure. Fifteen (2%) of those 107 implants showed a lack of primary stability, while the remaining 92 implants were placed in a two-stage surgical procedure due to a bone graft that had to be performed at the time of the surgery. Of the 107 implants positioned in a two-stage surgical procedure, only one (0.9%) was lost. Of the 649 implants positioned in a Single-stage surgical procedure, 11 (1.7%) were lost. Therefore, there was a total of 12 (1.6%) implants lost out of the 756 placed. From the 11 implants lost during the Single-stage surgical procedure, 8 (4.1%) were lost from the maxilla out of a total of 194 placed, while 3 (0.7%) were lost at the mandible out of a total of 455 positioned. Out of the 107 implants positioned in D1 bones, none were lost. 5 (0.9%) of the 556 ones positioned in D2 bones were lost. Also, 5 (6.3%) of the 80 implants in D3 bones were lost and one (7.7%) of the 13 positioned in D4 bones was lost.

Five (1.0%) implants lost out of 519 implants had a torque resistance of +30 N/cm when positioned. Only 1 (1%) out of 97 implants had a torque resistance of more than 20 N/cm. Five (12.5%) out of 40 implants had a torque resistance of more than 10 N/cm. Out of the 12 implants lost in total, 3 were placed in a sinus bone graft made of autogenous and allogen bones. Table 8 indicates the implants lost in relation to their implant site, the bone density, the size of the implant, the torque resistance at the time of surgery, the length of healing abutments used, the type of interim prosthesis used as well as the use of pre-implant bone grafts.

In the area of the mandibular symphysis, from tooth 35 to 45, only 1 (0.3%) out of 318 implants was lost. All these implants supported a full prosthesis garnished with a soft tissue 2 weeks following surgery. 113 (68.1%) out of 166 patients wore an interim full or partial prosthesis garnished with soft tissue, for a total of 604 (79.9%) out of 756, and 521 (80.3%) out of 649 implants placed in a single-phase surgical procedure. With respect to partially edentulous patients, 3 (4%) out of 75 implants were lost. In the maxilla area, 8 (66.7%) out of 12 implants were lost. Therefore, out of the 280 implants placed in the maxilla area, 8 (2.9%) were lost, 7 (3.6%) out of 194 during the single-stage surgical procedure and 1 (1.2%) out of 86 positioned during a two-stage surgical procedure.

Table 8 Summary of the Implants Lost

Position	Bone Density	Implant Size	Torqued	Post	Prothesis	Interim Prosthesis	Sinus Graft
11/21	D2	4.5 X 13	- *	-	C/	C/	No
16	D3	4.5 X 10	+10N/cm	L3	C/	C/	No
26	D3	4.5 X 10	+10N/cm	L3	C/	C/	No
26	D4	5.5 X 10	+10N/cm	L3	C/	C/	SA IV **
26	D3	4.5 X 13	+10N/cm	L3	C/	C/	SA IV
13	D3	3.75 X 13	+30N/cm	L3	C/	C/	No
14	D3	3.75 X 13	+10N/cm	L3	C/	C/	SA IV
12	D2	3.75 X 11	+20N/cm	L3	Crown	P/	No
35	D2	3.75 X 10	+30N/cm	L3	Crown	No	No
36	D2	3.75 X 13	+30N/cm	L3	Crown	No	No
44	D2	3.75 X 13	+30N/cm	L5	/C	/C	No
11/21	D2	4.5 X 13	+30N/cm	L3	C/	C/	No

* Implant Placed in 2 phases

** Sinus Filling-up

DISCUSSION

When comparing the results obtained using a single-phase technique with BEGOSemados implants with the results found in existing scientific literature[6], we can say that we have attained an equivalent rate of success, that is 98%. If a good primary stability of the implant is achieved at the moment of loading, which can be easily checked by a torque resistance over 20 N/cm[7] one can immediately place the transgingival abutment during the same stage and get an equivalent rate of success as if it had been submerged. No recommendations other than the usual ones need to be followed by the patient, and the implants do not have to be splinted supra-gingivally with transgingival abutments. In addition, thanks to new PRP (Platelet-Rich Plasma) bone graft techniques, the number of patients treated in a single-stage surgical procedure can be increased since only 15 implants in this study shown a lack of primary stability out of the 107 placed in a two-stage surgical procedure. All other 92 cases 86% which required an autogenous bone graft to compensate for a small dehiscence at the contour of the implant's collar could have been done in a single-stage with the aid of the PRP bone graft technique.

In the area of the anterior symphysis, only one out of 318 implants was lost. All the implants were loaded progressively since the full prosthesis was worn immediately (socially) during the first 2 weeks and subsequently to eat a soft food diet until the last loading process. As other studies have shown, the maxilla area is well suited for immediate loading and BEGOSemados' implant should obtain a rate of success equivalent to that of such studies. As for other areas and for partially edentulous patients, the results obtained lead one to believe that we could at least perform an immediate temporisation sub-occlusaly and obtain a very interesting rate of success.

Full edentulism at the maxilla still represents the highest challenge for the single-stage surgery procedure. The presence of D3 and D4 bones makes it impossible to obtain primary stability that is desirable and in those cases it is still more profitable to proceed with a two-stage surgical procedure. However, techniques of bone compaction with the aid of osteotome as well as the emergence of large threaded implants (Serf, Swiss Plus) are interesting avenues that could enable the restorative dentist to obtain similar results as those in other jaw areas.

CONCLUSION

The rate of success (98%) attained in a private general Implantology practice with BEGOSemados' implants, placed in a single-phase surgical procedure, is comparable to the ones found in existing scientific literature. Therefore, it is advisable to recommend the placement of BEGOSemados' implants in a Single-phase procedure whenever a good primary stability is achieved. Such a primary stability seems sufficient when a torque resistance of more than 20N/cm is attained. The use of an adjustable manual torque wrench as the one provided in BEGOSemados' kit is an adequate instrument of measure. This is the tool the authors have used for this Study and the results are conclusive. For patients, the single-stage surgical approach is most appreciated since it reduces costs and time, as well as discomfort.

Based on the positive results we have obtained, we can conclude that BEGOSemados' implants are ready for clinical testing for immediate loading procedures in fully edentulous mandibles as well as partially edentulous maxillae and mandibles (1-3 teeth). With respect to fully edentulous maxilla, the immediate loading procedure can be risky due to low bone density (D4) found in the maxillary posterior region. The Authors feel they have not acquired enough experience working in D4 bones from this Study, having placed only 13 implants, and that further studies would prove necessary in that regard.

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