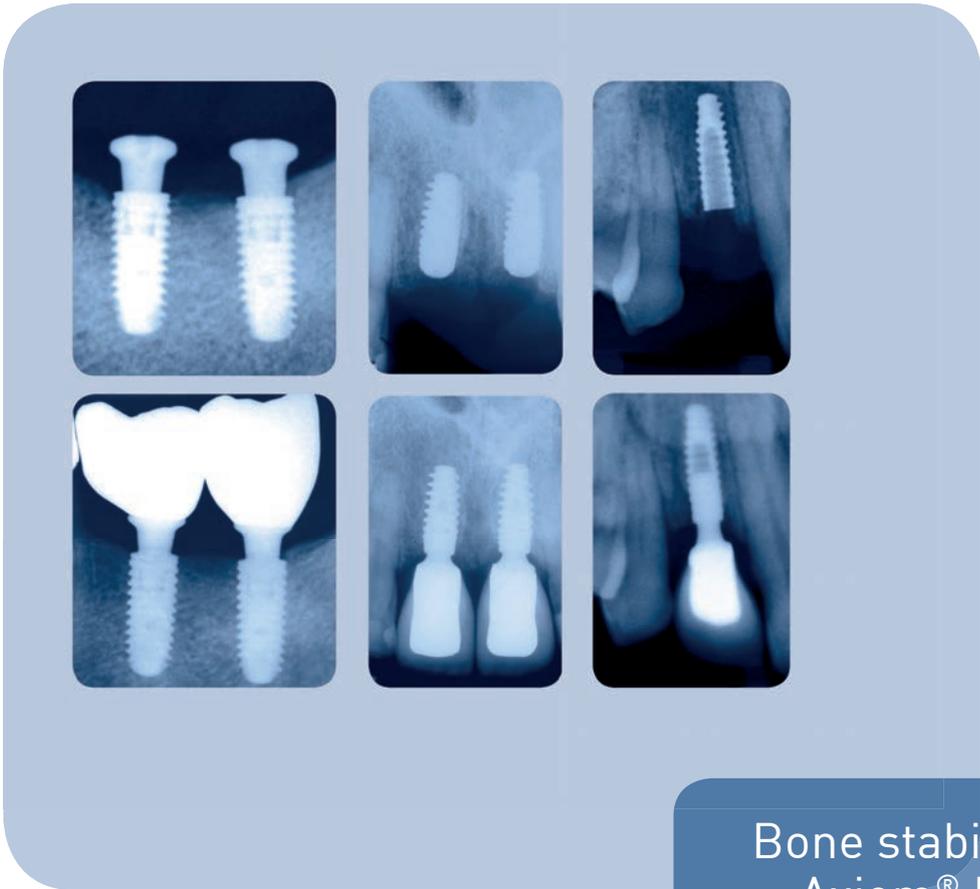


AXIOM[®] CONCEPT RADIOGRAPHIC EVALUATION AT 1-YEAR FOLLOW-UP



Bone stability around
Axiom[®] Implants

INTRODUCTION

Since Branemark's osseointegration principles¹ were developed, crestal bone level alterations around implants are considered a reliable criterion to evaluate the successful outcome of a dental implant.

According to Albrektsson *et al.*², X-rays of implants with an external hex design should show no peri-implant radiolucency, and the annual vertical bone loss should be less than 0.2 mm after the first year of function. However, this study does not take into account the amount of crestal bone lost during the first year. In 1981, Adell³ published a study in which he stated that more than 50% of the bone loss occurring over a 12-month period actually takes place within 3 months of loading. Two years later,⁴ he further stated that the greatest loss occurs during the first 12 months following abutment placement.

In 2007, Misch *et al.* published a consensus paper⁵ in which they defined implant quality of health criteria for rating implant success, survival, and failure. The James-Misch scale was modified to four categories: success, satisfactory survival, compromised survival, and failure. An implant is considered a clinical success when radiographic peri-implant bone loss is less than 2 mm from initial surgery.

Two factors are most influential in reducing bone loss:

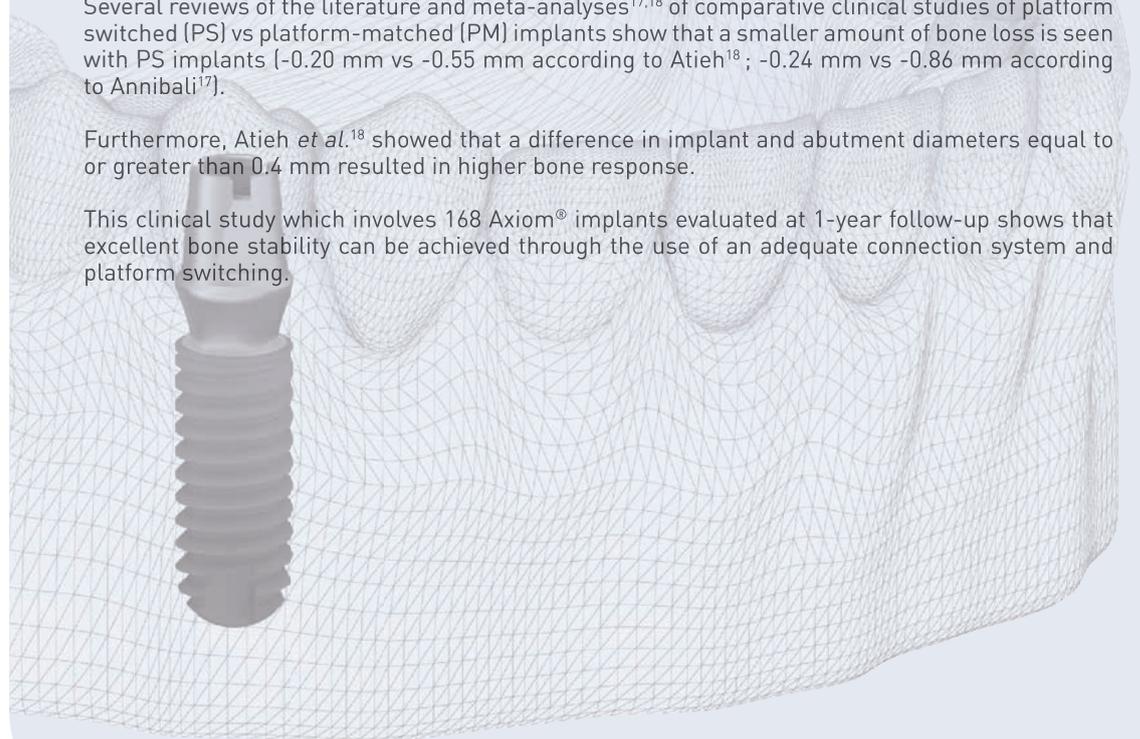
1. Tight implant-abutment junction to avoid bacterial colonization which results in soft tissue⁶ inflammation. It has been demonstrated⁷ that systems which feature a conical connection like the Axiom[®] implant system exhibit the lowest rate of microgaps (absence of microvements at the implant-abutment interface under loading conditions) as compared to systems with a flat-to-flat connection. The very low rate of bacterial leakage in implant systems with a conical connection is well documented in the literature^{8,9}.

2. Platform switching - This concept was introduced in the literature by Lazzara *et al.*¹⁰ and Gardner¹¹. As a matter of fact, platform switching seems to be an effective way to reduce the bone loss resulting from microgaps, and also to improve the predictability of long-term treatment outcome by allowing preservation of peri-implant hard and soft tissue.^{12,13,14,15,16}

Several reviews of the literature and meta-analyses^{17,18} of comparative clinical studies of platform switched (PS) vs platform-matched (PM) implants show that a smaller amount of bone loss is seen with PS implants (-0.20 mm vs -0.55 mm according to Atieh¹⁸; -0.24 mm vs -0.86 mm according to Annibali¹⁷).

Furthermore, Atieh *et al.*¹⁸ showed that a difference in implant and abutment diameters equal to or greater than 0.4 mm resulted in higher bone response.

This clinical study which involves 168 Axiom[®] implants evaluated at 1-year follow-up shows that excellent bone stability can be achieved through the use of an adequate connection system and platform switching.



► MATERIALS AND METHODS

INVESTIGATIONAL CENTERS AND PATIENTS

This follow-up study was conducted in 10 investigational centers, some of which were already involved in other follow-up studies. All practitioners were Axiom® implant system users.

In total 84 patients have been involved in this study, 168 Axiom® implants were placed and followed during 1 year.

STUDY DESIGN

Each patient was evaluated at different stages:

1. At subcrestal implant placement in a one-stage or two-stage surgery (according to surgeon preferences);
2. At sutures removal (if necessary), 2 weeks after surgery;
3. At loading, that is, 2-3 months post-surgery;
4. At placement of the final prosthesis;
5. At 6-month and 1-year follow-ups.

► RATING OF IMPLANT SUCCESS

In order to evaluate the suitability of the surgical and prosthetic phases, practitioners were requested to fill in a questionnaire at each of the above mentioned stages.

Rating of implant success was performed after the first year of function, according to the criteria defined by Misch⁵:

1. No pain or tenderness upon function
2. 0 mobility
3. <2 mm radiographic bone loss from initial surgery
4. No exudates history.

Implant failure⁵ was defined by any of the following:

1. Pain on function
2. Mobility
3. Radiographic bone loss > 1/2 length of implant
4. Uncontrolled exudates
5. Implant no longer in mouth.

Changes in crestal bone level were measured by an independent dental surgeon using the Scion Image software. This software allows to compute pixel values and scale images. To achieve the highest accuracy, the software was calibrated using the implant length (the longest known distance reference on X-ray).

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axiom[®] REG CLINICAL FOLLOW-UP



▶ PATIENTS

Seventeen patients recruited from 5 centers received a total of 18 implants (4.0 mm x 10.0 mm) which were placed in the posterior tooth region. All restored teeth were premolars or molars (Fig. 1). There were only single-tooth replacements and all of them were performed in one stage surgery.

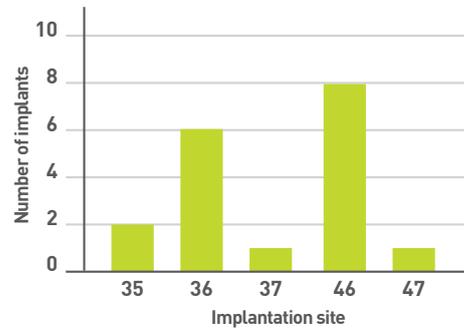


Fig. 1 - Restored teeth

▶ RESULTS (Table 1)

In 16 out of 18 implants, the X-rays taken at implantation and at 12-month follow-up showed no bone loss. Increase in bone density was found in 2 implants and bone loss was only 0.5 mm, which was considered a success according to the criteria defined in the literature.⁵ No device-related adverse events have been reported.

Investigational centers	5
Patients	17
Implants followed for 1 year	18
Bone gain	2
Bone loss <2 mm	2
Bone loss >2 mm	0
Implants no longer in mouth	0
SUCCESS RATE	100 %

Table 1: Results of the clinical follow-up of Axiom[®] REG implants

► **CLINICAL CASE** *courtesy of Dr. Carlos Francischone Jr, Brazil*



Fig 2: Initial status



Fig 3: Implant placement



Fig 4: Immediate postoperative X-ray



Fig 5: X-ray taken at 12 months postop with the crown in situ

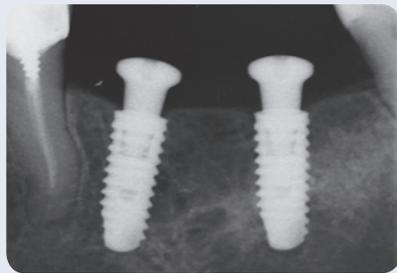


Fig 6: 12 months later. Implant is stable and esthetic result is optimal

► **ADDITIONAL RADIOGRAPHS**

X-rays of 3 cases followed for one year. No change in bone level.

Case 1:



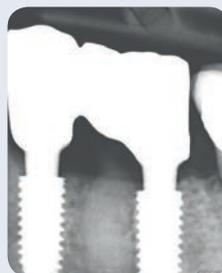
Case 2:



Case 3:



Post-surgery



1-year follow-up

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axiom[®] PX CLINICAL FOLLOW-UP



► PATIENTS

Fifty-eight patients recruited from 4 centers received a total of 127 implants: 49% of the implants supported single-tooth restorations, 34% supported complete dentures, and 17% supported bridges (Fig. 7).

In 71 cases, the implants were placed in fresh sockets immediately after tooth extraction.

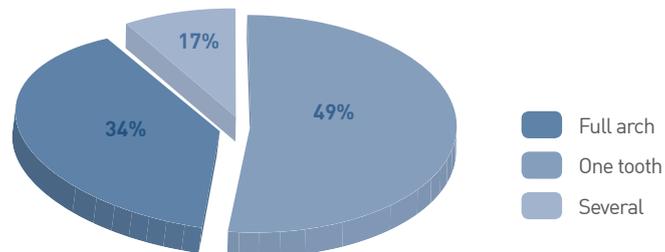


Fig 7: Percentage distribution of restorations

► RESULTS (Table 2)

All the implants but 4 were rated successful. These 4 implants were very challenging cases:

- One implant was lost in a female patient who said that she had placed excessive load on her tooth. The implant was replaced successfully.
- In one patient treated with a 10 unit bridge supported by 5 implants placed in fresh sockets immediately after tooth extraction, one implant had 2 mm of marginal bone loss.
- In one patient treated with a 4 unit bridge supported by 2 implants, one implant had 2 mm of marginal bone loss.
- In a full upper arch restoration with immediate loading, one implant had 3 mm of marginal bone loss.

In the last 3 cases, bone loss did not adversely affect the stability of the restoration.

In 7 implants, bone loss was less than 2 mm.

Investigational centers	4
Patients	58
Implants followed for 1 year	127
Bone gain	1
Bone loss <2 mm	7
Bone loss >2 mm	3
Implants no longer in mouth	1
SUCCESS RATE	96,8 %

Table 2: Results of the clinical follow-up of Axiom[®] PX implants

MULTICENTER CLINICAL STUDIES AT 1-YEAR FOLLOW-UP

► **CLINICAL CASE** *courtesy of Dr. Carlos Francischone Jr, Brazil*



Fig 8: Horizontal fracture of tooth number 11



Fig 9: Atraumatic extraction



Fig 10: Implant placement



Fig 11: Immediate loading



Fig 12,13 and 14: 12 months later. Esthetic result is optimal

► **ADDITIONAL RADIOGRAPHS**

X-rays of 3 cases followed for one year. No change in bone level.

	<u>Case 1:</u>	<u>Case 2:</u>	<u>Case 3:</u>
Post-surgery			
1-year follow-up			

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axiom[®] 2.8 CLINICAL FOLLOW-UP

► PATIENTS

Eleven patients with restricted mesial-distal space recruited from 4 centers received a total of 23 Axiom[®] 2.8 implants. In 50% of the patients, edentulism resulted from periodontal problems, in 25% from agenesis, and in the remaining patients, from trauma and cysts. Six implants were placed in fresh sockets immediately after tooth extraction. All the surgeries were performed in one stage. Restored teeth were mostly mandibular central incisors (Fig. 15).

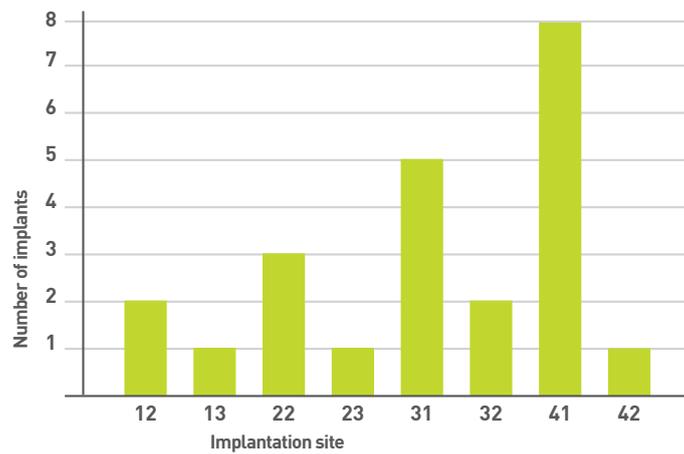


Fig 15: Restored teeth

► RESULTS (Table 3)

1 out of the 11 patients had 1 mm bone loss, which is considered a success according to the criteria defined in the literature.⁵ In the other 10 patients, no bone loss was noted. Increase in bone density even occurred in 2 patients. No adverse events have been reported.

Investigational centers	4
Patients	11
Implants followed for 1 year	23
Bone gain	2
Bone loss <2 mm	1
Bone loss >2 mm	0
Implants no longer in mouth	0
SUCCESS RATE	100 %

Table 3: Results of the clinical follow-up of Axiom[®] 2.8 implants

MULTICENTER CLINICAL STUDIES AT 1-YEAR FOLLOW-UP

► **CLINICAL CASE** *courtesy of Dr. Carlos Francischone Jr, Brazil*

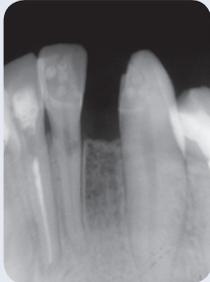


Fig 16: Preoperative X-ray



Fig 17: Restricted mesial-distal space



Fig 18: Implant placement



Fig 19: Postoperative X-ray



Fig 20: Healing plug in place



Fig 21: Abutment impaction



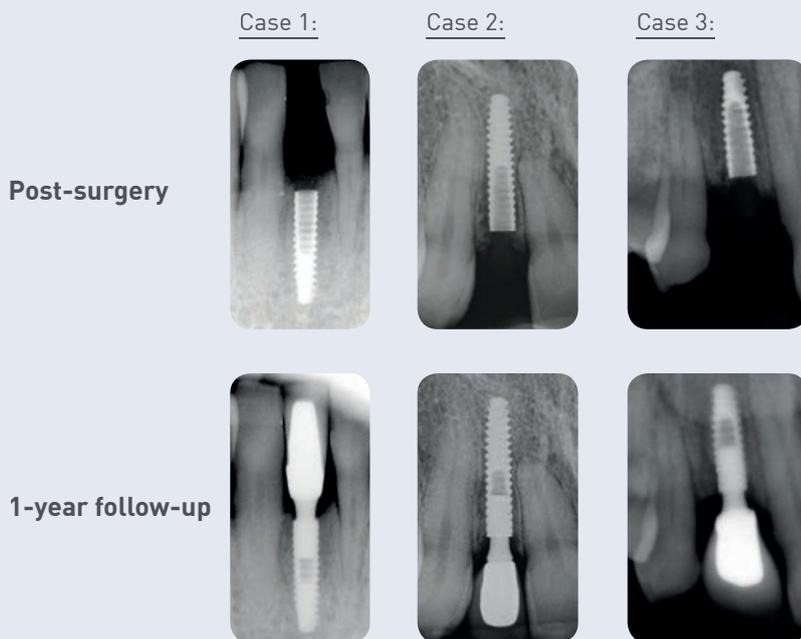
Fig 22: X-ray taken at 1-year postop



Fig 23 : Facial smile of patient at 1-year postop

► **ADDITIONAL RADIOGRAPHS**

X-rays of 3 cases followed for one year. No change in bone level.



► CONCLUSION

Overall, from the 168 implants followed for one year, only 3 exhibited bone loss equal to or greater than 2 mm (Table 4). Within the limitation of this clinical follow-up, bone levels found confirm that Axiom® implants have an excellent success rate at one year: **97.6 %**.

	axiom [®] REG	axiom [®] PX	axiom [®] 2.8	Total
Investigational centers	5	4	4	10
Patients	17	58	11	84
Implants followed for 1 year	18	127	23	168
Bone gain	2	1	2	4
Bone loss <2 mm	2	7	1	10
Bone loss >2 mm	0	3	0	3
Implants no longer in mouth	0	1	0	1
SUCCESS RATE	100 %	96,9 %	100 %	97,6 %

Table 4: Results of the clinical follow-up of Axiom® implants

Moreover, mean bone loss in the whole series was -0.09 mm, much lower than the 2 mm loss which is considered by Misch⁵ as a criterion of success, and lower than the results published in the literature [-0.20 mm according to Atieh,¹⁸ and -0.24 mm according to Annibaldi¹⁷ for platform-switched implants] (Fig 24).

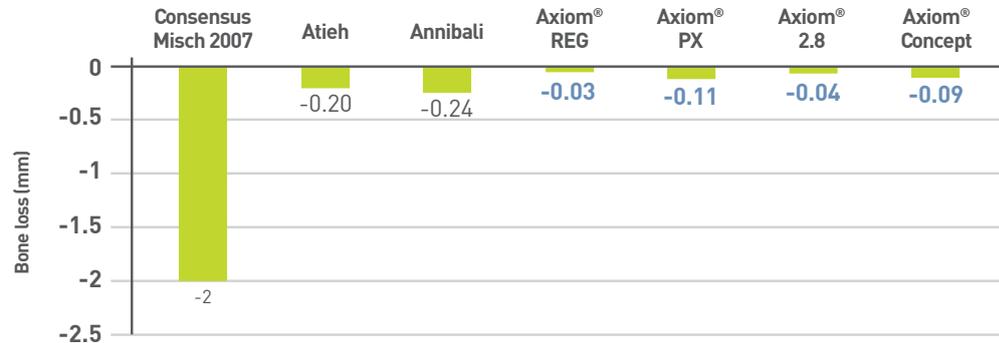


Fig 24: Mean bone loss observed during the Axiom® clinical follow-up study

Figures 25 and 26 show an increase in bone density and bone apposition induced by platform switching. This can be attributed to the excellent biocompatibility of the implant surface and the stable connection system. As far as this study goes, both have been found to promote long-term stability of Axiom® implants.

X-rays of an Axiom® REG implant from the study group:



Fig 25: Postoperative X-ray

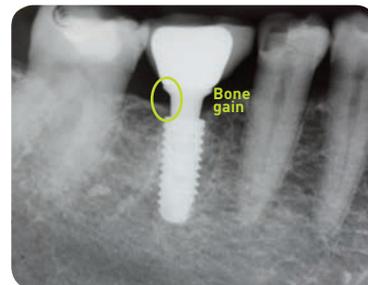


Fig 26: 1-year follow-up

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Acknowledgements to all contributors to this study: Dr André Adan (Créteil, France), Dr Franck Azam (Aix les Bains, France), Dr Francis Bailly (Vienne, France), Dr Michel Bergoin (Challes les Eaux, France), Dr Charles Durif (Chambéry, France), Dr Pierre Esseyric (Chamonix, France), Dr Carlos Francischone Jr (Sao Paulo, Brazil), Dr Christian Legros (Limoges, France), Dr Bertrand Rousselet (Ambérieu en Bugey, France), Dr Jacques Vermeulen (Flumet, France).

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