

# SciComm Bulletin

ZURICH, SWITZERLAND – 2009-08-28

## Can study design affect marginal bone level change?

The goals of this SciComm Bulletin are to summarize the outcome of an internally performed analysis of the preferred study protocols of the three largest implant manufacturers, and illustrate the significance that these protocols have on reported mean marginal bone level change.

Although mean marginal bone level change is only one of several criteria for evaluating dental implant success, it can be substantially influenced by study design, as demonstrated here.

### Clinical study review

Nobel Biocare conducted a thorough website review (Straumann and Astra Tech), and a supplementary MedLine search for Straumann<sup>1</sup>, to retrieve published data with regard to study design and reported mean marginal bone level change.

- The following inclusion criteria formed the basis for the comparison:
  - Minimum 10 patients
  - Minimum 1-year follow-up
  - Radiographically measured mean marginal bone level change
  - Two-piece implants
- From over 200 studies retrieved, 102 studies satisfied the above criteria, and were reviewed in detail:

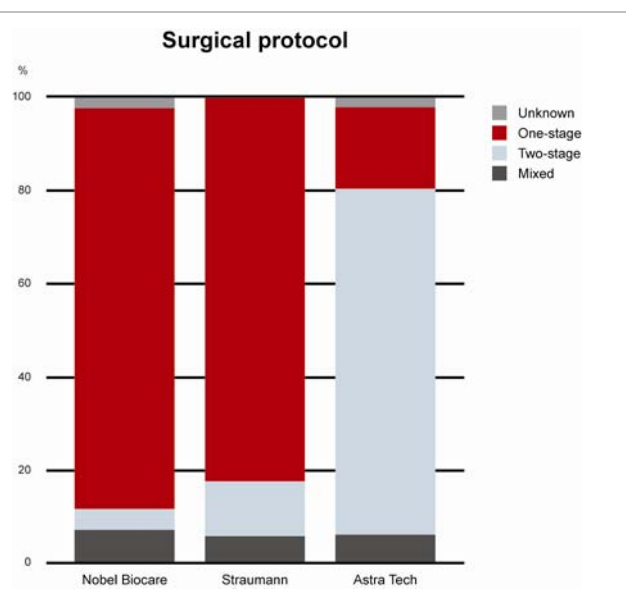
	Nobel Biocare	Straumann	Astra Tech
Number of publications	38	15	49
Number of included patients	1519	665	1875
Number of included implants	4486	1398	5275
Surface(s)	TiUnite	SLA / SLActive	TiOblast / OsseoSpeed

The results of the review have been broken down into three categories: surgical protocol, loading protocol and setting of the radiographic baseline, with observations provided for each presented graph.

### Surgical protocol

#### Observations

- Nobel Biocare and Straumann studies predominantly use a one-stage surgical protocol
- Astra Tech studies predominantly use a two-stage protocol

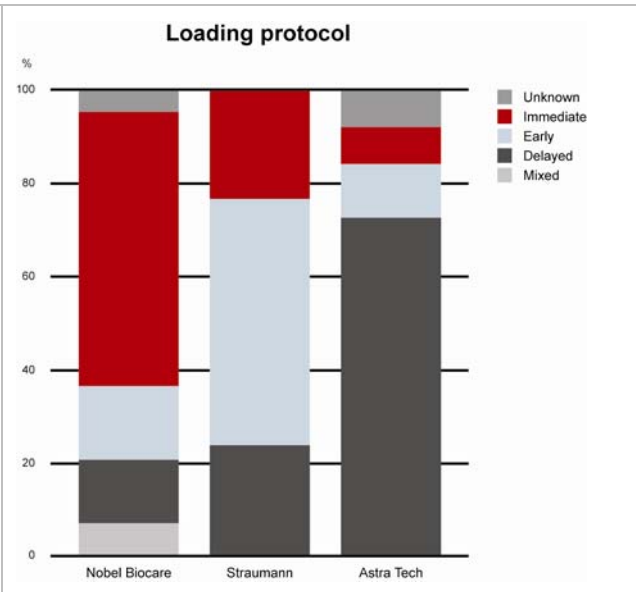


<sup>1</sup> The search string "Straumann dental implants" was used

## Loading protocol

### Observations

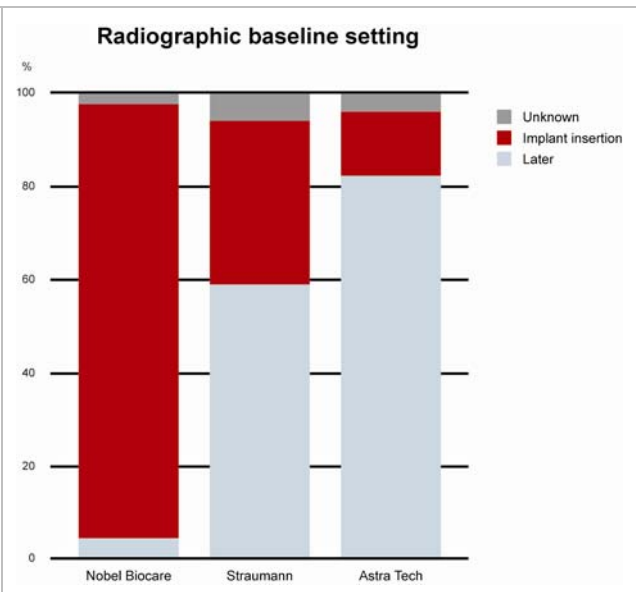
- The disparity in loading protocols<sup>2</sup> is far greater than that of surgical protocol:
  - Nobel Biocare studies primarily use **immediate loading** – no more than 48 hours after implant insertion
  - Straumann studies primarily use **early loading** – more than 48 hours but no later than 3 months after implant insertion
  - Astra Tech studies primarily use **delayed loading** – more than 3 months after implant insertion



## Radiographic baseline setting

### Observations

- Implant insertion is used as radiographic baseline to a greater extent in the TiUnite publications (red bar)
- Straumann and Astra Tech frequently use a later time point as baseline (often the time of prosthetic delivery)

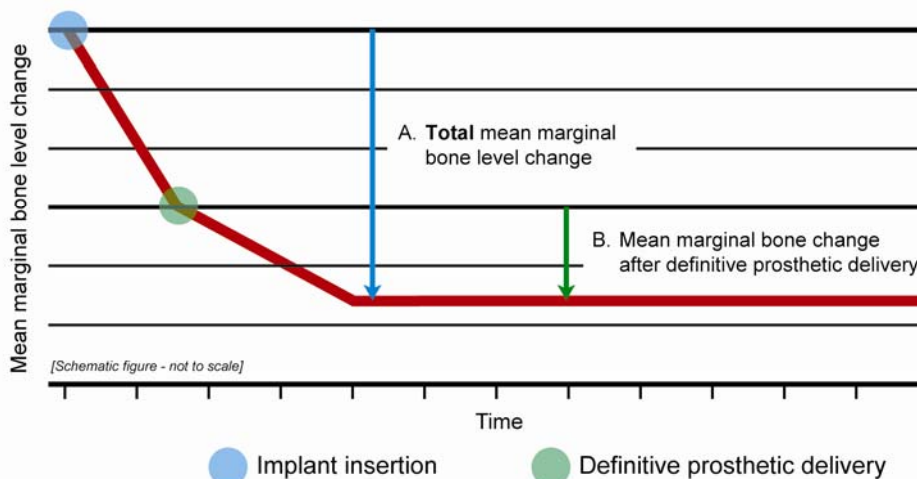


<sup>2</sup> Loading definitions are modifications of a 2004 consensus report (Cochran et al. 2004)

## Discussion

- The clinical study review demonstrates that clinical studies using Nobel Biocare, Straumann and Astra Tech products are conducted using very different protocols:
  - One-stage protocol is applied to a greater extent in the TiUnite and Straumann publications, whereas Astra Tech uses a two-stage protocol more frequently.
  - Immediate loading protocol is applied to a greater extent in the TiUnite publications, whereas Straumann uses an early loading protocol and Astra Tech uses a conventional loading protocol more frequently.
  - Implant insertion was used as radiographic baseline largely in the TiUnite publications, whereas Straumann and Astra Tech used prosthetic delivery as baseline more frequently.
- Nobel Biocare promotes a very demanding protocol (immediate function) with the use of its implants; this protocol maximizes the efficacy of the surgical phase of treatment and benefits the patient with shorter treatment times.
- It has been observed that in the period following implant insertion (up to 6 months), the majority of marginal bone level change occurs (Petersson et al. 2001; Engquist et al. 2004).
- Setting the radiographic baseline at different time points significantly influences the reported mean marginal bone level change (Figure 1):
  - **Only** by including the initial period from implant insertion to definitive prosthetic delivery can **total** marginal bone level change be measured (Figure 1: A).

Figure 1



## Conclusions

- Nobel Biocare runs clinical studies according to a very stringent study protocol.
- The majority of marginal bone level change occurs in the period following implant insertion.
- In more than 90% of the reviewed studies, Nobel Biocare set the radiographic baseline at implant insertion and therefore reported total marginal bone level change (Figure 1: A).
- Straumann and Astra Tech typically set their radiographic baseline some time after implant insertion – most often at the time of definitive prosthetic delivery (Figure 1: B).
- Measuring marginal bone change only after definitive prosthetic delivery omits the critical period of marginal bone level change following implant insertion.
- Due to the differences in study protocols, no direct comparison of mean marginal bone level change is possible.
  - An accurate bone loss comparison would require that the surgical and loading protocol, and setting of the radiographic baseline, be consistent throughout all studies.

### *References*

Cochran DL, Morton D, Weber HP. Consensus statements and recommended clinical procedures regarding loading protocols for endosseous dental implants. *Int J Oral Maxillofac Implants* 2004;19 Suppl:109-13.

Engquist BB, Åstrand P, Anzén B, Dahlgren S, Engquist E, Feldmann H, Karlsson U, Nord PG, Sahlholm S, Svärdröm, P. Simplified methods of implant treatment in the edentulous lower jaw. Part II: early loading. *Clin Impl Dent & Rel Res* 2004; 6(2):90-100.

Petersson A, Rangert B, Randow K, Ericsson I. Marginal bone resorption at different treatment concepts using Brånemark dental implants in anterior mandibles. *Clin Impl Dent & Rel Res* 2001;3(3):142-7.