The Ponto Bone Anchored Implant System: A Survey of Clinical Outcomes

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Bone anchored hearing systems have been used for over three decades for conductive/mixed hearing loss and profound unilateral sensorineural hearing losses. With the introduction of the Oticon Medical Ponto Bone Anchored Hearing System in 2009 access to novel and innovative solutions through advances in design and technology was made possible to clinicians and patients. In this paper, the findings of the first survey of the Ponto implant and abutment are presented. Ninety-eight patients from three institutions were retrospectively surveyed for implant extrusion, revision surgery and skin complication. There was not a single case of implant extrusion. Nor was there a single case of revision surgery. No adverse skin complications were noted in the vast majority of patients.

Introduction

Bone anchored hearing systems are a well established amplification solution for conductive and mixed hearing loss or sensorineural single-sided deafness. Since its first successful implantation in 1977 by Tjellström, about 75,000 people worldwide have benefited from such a hearing system (Dun et al., 2011).

In spite of its long history of success, only modest advancements were evident in the design and technology of bone anchored hearing systems for much of the three decades they have been around. However, with the advent of Oticon Medical Ponto Bone Anchored Hearing System in 2009, the technology and design landscape of bone anchored hearing systems changed significantly. Innovative and novel advances in the signal processing technology of sound processors were witnessed. These advances included improved performance in terms of sound quality, speech understanding in noise, feedback control and form factors (Olsen et al., 2011; Sockalingam, 2011; Bosman et al., 2011).

The surface and geometry of the implant can influence long term osseointegration. The Brånemark surface, which is applied in the Ponto implant, has been demonstrated in long term studies to achieve safe and effective long term osseointegration (Palmquist et al., 2010). The implant's self-tapping geometry with cutting edges and space for collection of the bone shivers, and tapered front portion facilitates efficient implant insertion by the surgeon. Also, micro grooves situated under the flange are designed to minimize bone resorption along the bone-implant interface (see figure 1).

Figure 1 – Oticon Medical Ponto implant

The design of the Ponto implant-abutment interface allows the skin to be supported by the underlying periosteum all the way up to the abutment (see figure 2). Keeping the skin firmly supported and not having it move against the abutment is pivotal to avoiding skin irritation (Tjellström et al., 2001). Furthermore, the abutment-skin interface is smooth with no grooves for bacteria to collect which could potentially lead to skin inflammation and complications.

With the singular goal of providing the best possible solution, the Ponto Bone Anchored Hearing System is designed to meet the needs of both the clinicians and the patients.

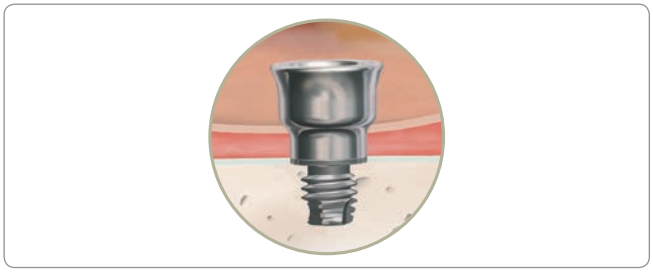

Figure 2 – Oticon Medical Ponto implant and abutment

The Ponto Bone Anchored Implant System Retrospective Survey

In the two years since its introduction, over 3000 implantations of the Ponto Bone Anchored Implant System have been performed by leading otolaryngologists and neurotologists in 18 countries around the world. Data from the very first survey of the Ponto implant and abutment have clearly shown its success in terms of the implant extrusion, revision surgery and skin complication rates.

In the survey, 98 patients (38 males and 60 females) ranging in age from 5 to 79 years (mean age: 51.5 years) from three institutions in the United States – Michigan Ear Institute (MEI), Arizona Hearing and Balance Center (AHBC) and Georgia Health Sciences University (GHSU) – were retrospectively examined.

Summary of Results	
Study centers	AHBC (24), GHSU (11) and MEI (63)
Total number of patients	98
Mean age and range	51.5 years; 5 years to 79 years
Gender	39% males 61% females
Implant loss	0%
Revision surgery	0%
Implant length	3 mm: 2%; 4 mm: 98%
Abutment length	6 mm: 69%; 9 mm: 31%
Surgery type and stages	Linear: 96% Flap and semi elliptical: 4% One stage surgery: 100%
Skin reactions	No adverse skin reactions: 85% Moderate skin reactions: 15% All skin reactions were successfully managed without revision surgery during the follow up period.

There were 63, 24, and 11 patients from MEI, AHBC, and GHSU respectively. All patients had been implanted with the implant and abutment between November 2009 and June 2011.

Descriptive statistics were calculated for age, follow up time, implant length, abutment length, implant extrusion rate, revision surgery rate and skin reaction rate using the SAS (version 9.2) statistical program. Skin reactions were classified as adverse or non-adverse by the surgeon who performed the surgery. The follow up period after surgery, and the type of surgery in terms of stage (one versus two-stage surgery) and technique (e.g. linear incision versus flap) performed were also documented for each patient.

The two major findings of the study were: (1) there was not a single case of implant extrusion, and (2) there was not a single case of revision surgery performed in any of the 98 patients implanted with the Ponto implant and abutment. All patients underwent single stage implantation, with linear incision technique with tissue undermining performed in 95% of them. Ninety-eight percent of patients received the 4 mm implant. The 6 mm abutment was used in 69% of the patients; the remaining 31% of patients used the 9 mm abutment. The mean follow up period was 5.3 months. Furthermore, no adverse skin reactions were documented in 85% of the patients. Skin reactions were either absent or mild in these patients. In the other 15% of the patients the skin reactions were classified as moderate. All skin complications were successfully managed as part of standard clinical care without the need for revision surgery during the follow up period.

The results of the present US study compare favorably with data from a recently published study in the United States by Zeitler et al. (2011). The researchers conducted a retrospective review of 64 adult patients who all underwent single stage bone anchored implantation between 2007 and 2010. They reported both minor and major skin complications in 39% of the patients. There were no cases of osseointegration failure. In the present study, minor and moderate skin complications were documented in 14% and 15% of the patients respectively. As with the Zeitler (2011) survey, there was not a single case of osseointegration failure in the present study.

Conclusion

The success of the Oticon Medical Ponto Bone Anchored Implant System is unequivocal. Out of 98 cases, there was not a single case of osseointegration failure. Nor was there a single case of revision surgery. Eighty-five percent of patients showed no adverse skin reactions. The remaining 15% of the patients who showed moderate skin complications were successfully managed clinically during the follow up period. A multitude of factors contribute to the success of the implant and abutment. Chief among these factors are the design type of surgical technique used, and surgeon/patient related variables. Due to its retrospective nature, the present study does not tell us to what extent each of these variables impact implant success. Only a larger prospective study in which the variables are better controlled can do that.

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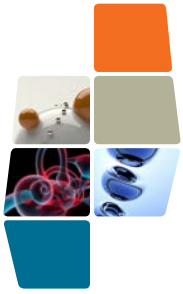

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