

Long-term clinical outcomes of percutaneous implants for bone conduction devices:



Prospective five year evaluation of different implant designs and surgical techniques

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Introduction

- Several changes in implant design and surgical technique have been made aiming to decrease complications in BAHIs
- Although implant survival of the 4.5-mm wide implant is high, a difference in survival compared with the 3.75-mm wide implant has not been found in previous investigations
- Tissue preservation showed more favorable results regarding skin sensibility and cosmetic outcomes

But what are the long-term clinical results of this newer implant and surgical technique?

Objective

Evaluation and comparison of the clinical outcomes at 5-years of:

1. 4.5-mm-wide implant, and (previous) 3.75-mm-wide implant
2. Linear incision technique with tissue preservation, and tissue reduction

Methods

- Single follow-up visit of two previously completed clinical studies^{1,2}
- Study A
 - 57 patients; 37 in test and 20 in control
 - Test implanted with 4.5-mm-wide implant
 - Control implanted with 3.75-mm-wide implant
- Study B
 - 50 patients; 25 test, 25 control
 - All patients implanted with 4.5mm implant
 - Test tissue preservation, control tissue reduction
- Outcome measures
 - Implant stability and intrasubject stability over time
 - Implant survival * Soft-tissue status
 - Skin height * Revision surgery
 - Sensitivity around abutment + subjective numbness (study B)

Results

- Study A: 48 patients (84%) completed the 5-year follow-up
- Study B: 39 patients (79%) completed the 5-year follow-up

Clinical outcome

Implant survival (test vs. control)	A: 97.4% vs. 95.0% B: 96% vs. 100%
Adverse soft tissue reaction (test vs. control; Holgers-score)	A: 15.2% vs 23.5% B: 30.0% vs 10.5%
Skin sensibility	96.7% vs 96.3%
ISQ	Shown in figures below

Discussion

- Both implants have excellent survival rates, with higher resonance frequency properties for the 4.5-mm-wide implant
- Between both surgical techniques, no differences in adverse skin reactions or implant survival were observed at 5-years
- Due to the presumptive better stability the 4.5-mm-implant is preferred over the 3.75-mm-wide implant
- Due to shorter surgery time, less invasive character and comparable outcomes, tissue preservation is preferred over tissue reduction

Conclusion

At 5-year follow-up, high implant and abutment survival rates were observed. Adverse skin reactions occurred in a minority of implants and did not significantly differ between groups. It can therefore be concluded that the 4.5-mm-wide implant, as well as the linear incision technique with soft tissue preservation procedure are safe in the long-term.

Fig 1a. Box-and-Whisker plots of ISQ-low and high study A

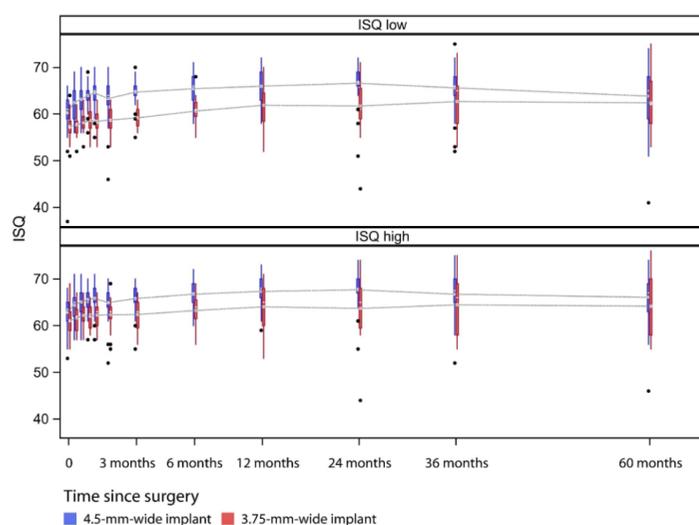
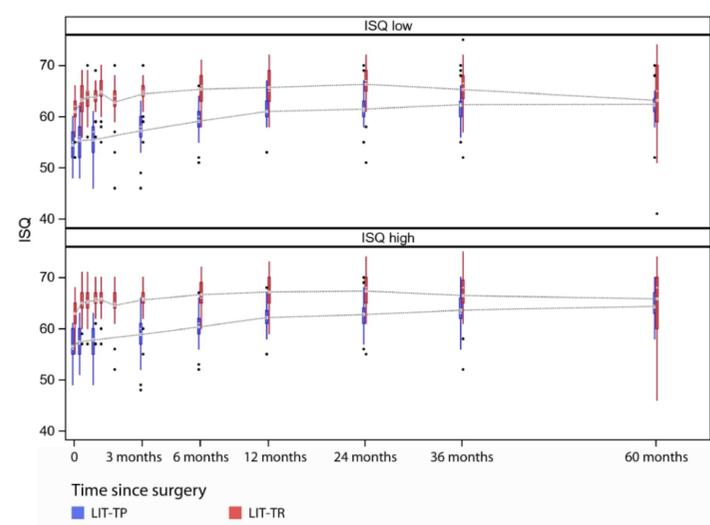


Fig 1b. Box-and-Whisker plots of ISQ-low and high study B



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References

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