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study

Morbidity following transcrestal and lateral sinus-floor elevation: A randomised trial

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RELEVANT BACKGROUND

Maxillary sinus-floor elevation with a lateral (lSFE) or transcrestal (tSFE) approach are augmentation techniques that have been used to achieve a vertical increase in alveolar-ridge dimension in the edentulous posterior maxilla. Reported survival rates for implants placed in augmented sites using both approaches are high.

With both surgical techniques, a varying degree of intra- and postoperative morbidity has been reported in the literature. Signs include swelling, bruising, and nasal discharge/bleeding. Although some studies have reported differences in morbidity between the two approaches, they either lack a randomised design or compare different clinical scenarios (e.g. different residual-bone heights (RBH), one- or two-stage procedures, or a different number of implants placed per patient). Without high-quality comparative data on intra- and postoperative morbidity of lSFE and tSFE, it is difficult to extrapolate potential differences in outcomes and complication risks when applied in similar clinical scenarios.

AIMS

The aim of this randomised clinical trial (RCT) was to compare postoperative morbidity following tSFE or lSFE with concomitant implant placement in sites with a limited RBH (3-6mm).

MATERIALS AND METHODS

- A single-blind randomised controlled trial (RCT) with a parallel design was carried out in two centres in Italy.
- Healthy non-smoking patients requiring implant placement in the posterior maxilla, with RBH of 3 to 6mm and residual bone width allowing placement of implants ≥3.5mm wide.
- tSFE: the transcrestal technique was used in combination with a collagen matrix plug (Mucograft Seal) and deproteinised bovine bone mineral (DBBM; Bio-Oss) as grafting material.
- lSFE: lateral access to the maxillary sinus was created with rotating diamond burrs and/or piezoelectric instruments, and the window was either completely abraded, removed, or introflected into the sinus. Grafting was performed with DBBM and the window was covered with a resorbable collagen membrane (Bio-Gide).
- Implants (SPI Inicell Element) were placed immediately following grafting with a submerged or transmucosal healing protocol. They were loaded between weeks 24 and 32.
- Patients in the lSFE group received an intra-muscular injection of 8mg of dexamethasone in the masseter lateral to the surgical site.
- In both groups, antibiotics were administered one hour before the surgical procedure and for up to six days after surgery. Anti-inflammatory drugs were prescribed to be used when needed post-surgery.
- Outcome measures were: (i) postoperative complications (such as early implant failure) and (ii) patient-reported outcomes, including pain level, level of discomfort, limitations in daily functions, postoperative signs and symptoms, and willingness to undergo the same type of surgery. Pain level was recorded using a 100 mm visual analogue scale (VAS).
- VAS pain was considered the primary outcome. The patient was the statistical unit, and non-parametric statistical methods were used.

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results

- Twenty-nine patients were included in the tSFE group and 28 in the lSFE group.
- **Surgical aspects:** Statistically significant differences were found between the two groups. lSFE required a higher dose of anaesthetic, releasing incisions were performed more frequently, more graft material was inserted into the sinus, and the duration of the procedure was longer. There was no statistically significant difference in implant length between the two groups.
- **Postsurgical complications:** Two implants in the tSFE group were lost before loading, and one patient in the lSFE group had an orbital and periorbital sub-cutaneous emphysema. There were no statistically significant differences in the incidence of membrane perforation (two cases in the tSFE group versus five in the lSFE group), and all cases could be treated, with implant placement proceeding as planned.
- **Patient-reported outcomes:**
  - Both groups reported low VAS pain levels (<15mm). Pain level and consumption of analgesics were significantly higher in the tSFE group at Day 0. However, only the lSFE group reported high or very high discomfort at Day 2, and analgesic consumption was higher in the lSFE group at Day 3.
  - The tSFE group had lower postoperative morbidity (incidence of swelling, bruising, and nasal discharge/bleeding), and a more tolerable postoperative course (limitation in swallowing, continuing with daily activities, eating, speaking, opening the mouth, and continuing school/work activities).
  - There were no differences in the willingness to undergo the procedure again if needed.

LIMITATIONS

- Allocation was concealed only to the end of the screening appointment, which may imply risk for bias.
- There is no information on possible differences in treatment allocation between the centres.
- Seven different surgeons performed the procedures. In addition, there were differences in the lSFE techniques and instruments used. These variations could have had an impact on postoperative morbidity.
- A dexamethasone intramuscular injection was administered immediately after surgery in the lSFE group. As dexamethasone has been shown to reduce postoperative pain, this could have affected the main outcome of this study.
- The method to record limitations in daily functions has not previously been validated.
- The study may be underpowered for some of the reported outcome variables.

CONCLUSIONS

In edentulous maxillary posterior sites with RBH of 3 to 6mm in healthy, non-smoker patients, lSFE was associated with lower pain on the day of surgery, while tSFE showed lower postoperative morbidity according to the measured parameters and a more tolerable postoperative course.

IMPACT

In regard to postoperative morbidity, tSFE may be an alternative to lSFE in the presence of limited RBH. Even though pain was higher on the day of surgery, the postoperative course seems to be more rapid and eventless. However, comparative data on the long-term outcomes of both treatment approaches are needed to evaluate whether one may be superior to the other.

LINK TO ORIGINAL JCP ARTICLE:

https://www.onlinelibrary.wiley.com/doi/10.1111/jcpe.12985

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