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OTOLOGY

Importance of adhesiolysis in revision surgery for vibrant soundbridge device failures at the short incus process

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Abstract The objectives of the study were to report a vibrant soundbridge (VSB) implant revision surgical method involving adhesiolysis at the short incus process under local anesthesia and demonstrate successful hearing performance after surgery. Three cases of VSB surgery, performed in 2016, were enrolled. All cases had diagnoses of device failure. This 'seven-incision line' exposed the floating mass transducer directly, after which the three steps (adhesiolysis, curettage, and hydrocortisone injection) were performed. Upon fitting the VSB, sound fields were evaluated immediately and at 3 months after the revision. During the revisions of surgery, all patients achieved immediate hearing gains and noticed differences in the outer devices with different amplifications. Satisfactory improvements in hearing thresholds and speech recognition abilities were confirmed by improvements of 20–30 dB in hearing loss 3 months after revision surgery. The VSB implant revision surgical method involving adhesiolysis is safe and efficient for patients who experience a VSB device failure. This method will reduce the requirement for surgery under general anesthesia, reduce the overall period of clinical therapy and, therefore, minimize patients' medical costs.

Level of Evidence 4

Keywords Vibrant soundbridge · Revision · Short incus process · Adhesiolysis

Introduction

The vibrant soundbridge (VSB; Vibrant MED-EL, Innsbruck, Austria), a semi-implantable middle ear device created in 1997, provides a treatment option for patients with mild-to-severe sensorineural hearing loss who are unable to wear or are dissatisfied with conventional hearing aids [1]. Multiple published reports describe the applications of VSB with a focus on both the surgical and audiological outcomes [2, 3]. In addition to the benefits, however, these reports presented long-term data on device complications related to medical or technical problems, including the need for diagnostic magnetic resonance imaging and device failure. Sterkers et al. [4] reported that during a short-term follow-up of 17 months, 5 device failures (4%) occurred. In addition, Mosnier et al. [2] reported results collected from 77 patients with a VSB during an average follow-up of 6 years. Five patients (6%) required revision surgery, mainly because of problems with coupling of the floating mass transducer (FMT) onto the incus, magnet issues, and fibrous tissue in the middle ear. Rameh et al. [5] reported a revision rate of 9% because of implant dysfunction. As the frequency of VSB surgery continues to increase, the incidence of VSB revision for several reasons is also expected to increase.

Recently, attachment of the FMT to the short incus process, a procedure comparable to stimulation when the FMT is attached to the long incus process [6], was introduced. A comparison of FMT attachment to the short and long incus processes revealed similar stapes footplate and

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round window membrane velocity responses with both procedures. However, no reports have described complications, especially VSB revision, associated with the new techniques used to fix the FMT to the short incus process.

The current study aimed to introduce adhesiolysis around the FMT during revision surgery under local anesthesia for a non-functioning VSB at the short incus process and to demonstrate the successful immediate hearing gains achieved immediately after the revision. This is the first report and guideline for this VSB revision method at the short incus process.

Methods

Subjects

Three patients who underwent initial VSB surgery at the short incus process in 2016 were subjected to revision surgery following complaints of no improvements in hearing with the VSB. The patients ranged in age from 50 to 65 years old. All had 'no hearing gain with the device' after several rounds of VSB fitting over a 3-month period [7]. Pure tone audiometry (PTA), sound field of the device, and transocular X-ray view were evaluated before the revision operation. The PTA and sound field results with VSB are shown in Fig. 1. The patients achieved no subjective hearing gains and no gains on the sound field hearing test. Transocular X-ray revealed that the FMTs were well positioned in the middle ear cavity and that their locations had not changed compared to the postoperative images after initial VSB surgery. Upon receiving written consent from the patients, we decided to perform VSB revision surgeries under local anesthesia to address hearing performance immediately after the adhesiolysis around the VSB.

Surgical technique

During VSB revision, the surgical field was sufficient to expose a 2 cm-wide postauricular groove from the skin to the hairline, without any further haircut. Xylocaine (1% with 1:100,000 epinephrine) was injected subcutaneously into the postauricular sulcus between the mastoid fascia and ear cartilage to avoid injury to the VSB electrode. After identifying the previous periosteal flap (Palva flap), flap incision was initiated with a blade at the mastoid tip and continued along the external auditory canal (Fig. 2a; Suppl movie 1). Coagulation was performed only with a bipolar electrosurgical instrument. The incision finally terminated at the temporal line to expose the antrum. This 'seven-incision line' was the best way to expose the FMT while avoiding electrode injury. 'Adhesiolysis' is the term for the surgical lysis of (intra-abdominal) adhesions, usually by laparoscopy. We used the adhesiolysis in removing the adhesion around the FMT. Adhesions to the electrode were removed via dissection with cold, sharp scissors along with bipolar backup to ensure the least risk of reformation [7]. Three steps were performed for adhesions around the FMT in the antrum. First, microsurgical instruments (picks and microforceps) were used for adhesiolysis from the lateral sides and inferior side, and finally to the upper side (Fig. 2b). Adhesiolysis on the upper side of FMT requires caution because the area where the adhesion interfered with the vibration of the FMT was located between the fossa incudis and upper side of the FMT. Second, minimal curettages (Fig. 2c) were needed around the FMT, especially on the fossa incudis (upper side of FMT), to ensure that the FMT did not touch bone. During this step, the achievement of subjective hearing gains should be monitored by attaching different external audio processors with individually adjusted and full gains and comparing the status relative to performance without the external device. Under the surgical drape, the audiologist changed the audio processors and checked hearing gains using several simple tests (ling 6, simple word lists, and simple sentences). Finally,

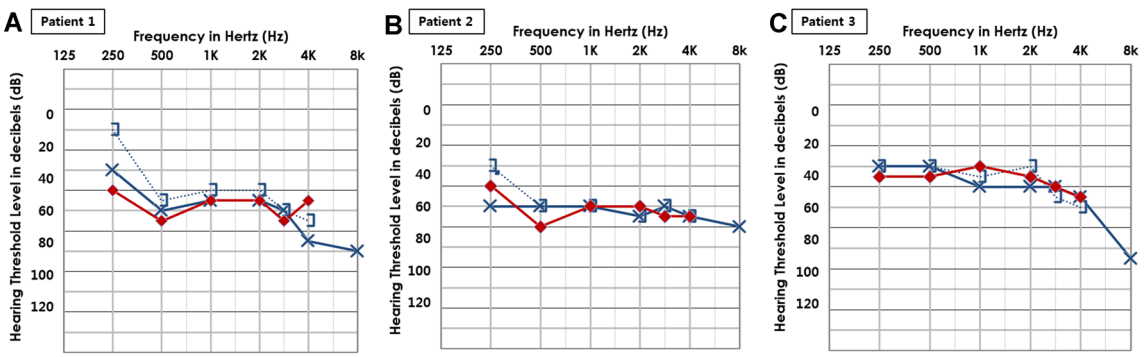

Fig. 1 Pure-tone audiometer results of all cases before the first vibrant soundbridge (VSB) surgery (*blue lines*). Postoperative thresholds with VSB activation in the sound field are also shown (*red lines*)

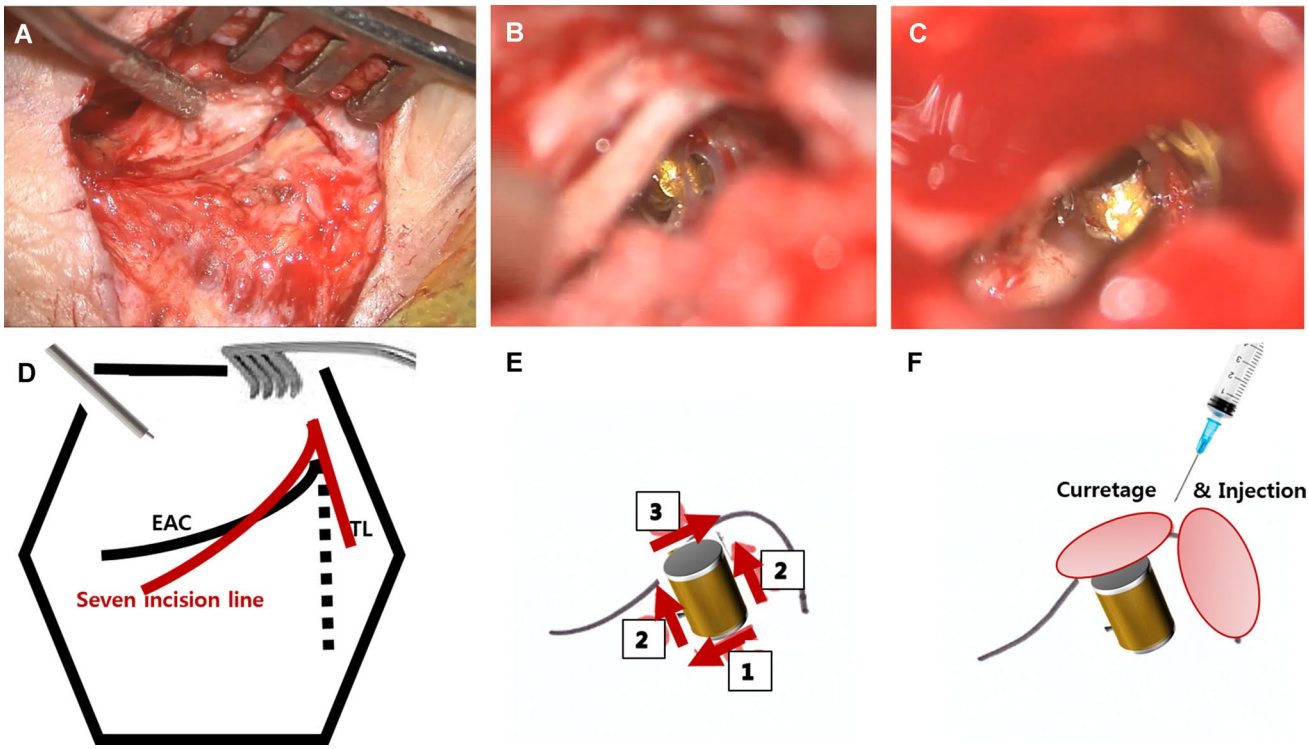

Fig. 2 **a**, **d** View of the seven-incision line (*red line*) on the previous periosteal flap to avoid the injuries to the vibrant soundbridge (VSB) electrodes. The incision on the flap, made with a blade, began at the mastoid tip and continued along the external auditory canal (EAC), finally terminating at the temporal line (TL) to exposure the antrum. **b**, **e** Adhesiolysis was performed from the inferior side and lateral sides and finally to the *upper side*. **c**, **f** Minimal curettage was needed around the floating mass transducer (FMT), especially on the fossa incudis (**a**, *upper side* of FMT) and around the dula plate (**b**, *lateral side* of FMT). Finally, hydrocortisone was injected around the FMT to prevent adhesion reformation

after confirming that patients achieved hearing gains, hydrocortisone was spread around the FMT to prevent adhesion reformation. The skin flap was then closed sequentially.

Audiologic evaluation

PTA was performed according to the standard procedures with standard equipment. Air conduction thresholds were obtained at 0.25, 0.5, 1, 2, 4, and 8 kHz, and bone conduction thresholds were obtained at 0.5, 1, 2, and 4 kHz. Functional gains, or the differences between unaided and aided sound field thresholds, were determined using warble tones from 250 to 8 kHz at a modulation frequency of 5%. The sound field setup was calibrated according to Morgan et al. [8]. Functional gains were calculated at the implant ear, with the contralateral ear occluded.

When fitting the Amadé audio processor of the VSB, each patient's threshold and dynamic range (uncomfortable level, UCL) were defined using the Vibrogram. DSL I/O was applied as the fitting formula in the fitting method. The acclimatization level setting reflected the audiologist's experience with amplification from conventional hearing systems. The input/output (gain) curve display could be drawn using Connexx software (Piscataway, NJ, USA).

Results

All three subjects underwent immediate check-ups performed by an audiologist after the adhesiolysis, but before skin closure over the surgical field. A Vibrogram test was performed for all subjects, and the results indicated good coupling between the FMT and stapes. External audio processors with individually adjusted and full gains were attached in regular sequence. All patients achieved unexpected, immediate hearing gains and sensed differences when the outer devices were used with different amplifications. Two patients were more satisfied with the full gains than the adjusted gains used before the revision surgery, whereas one patient complained the hauling of self-voice despite a greater hearing gain. No complications, including hearing loss, peripheral facial paralysis, tinnitus, and vertigo, were observed immediately after the revision. During a 3-month follow-up, no events such as FMT dislocation,

coil extrusion, facial palsy, headache, or skin dehiscence were observed.

Activation was performed 1 week post-operation because of the untouched FMT-incus joint. During programming, the Vibrogram test result was inputted as a fundamental parameter to create a fitting map. The patients' fitting maps are presented in Fig. 3 as the level of output (Fig. 3a–c) and gains in specific frequency (Fig. 3d–f). After activating the processor, the hearing levels (0.5, 1, 2, 3, 4 and 8 kHz) were tested in the sound field; the speech discrimination test (MCL most comfortable loudness level and PB max maximum score of phonetically balanced with monosyllabic words HL in MCL) was tested 3 months after adhesiolysis. Test results confirmed the obvious improvements in both the hearing threshold (Fig. 4) and speech recognition ability (Table 1). The auditory results from the long-term follow-up will be reported later.

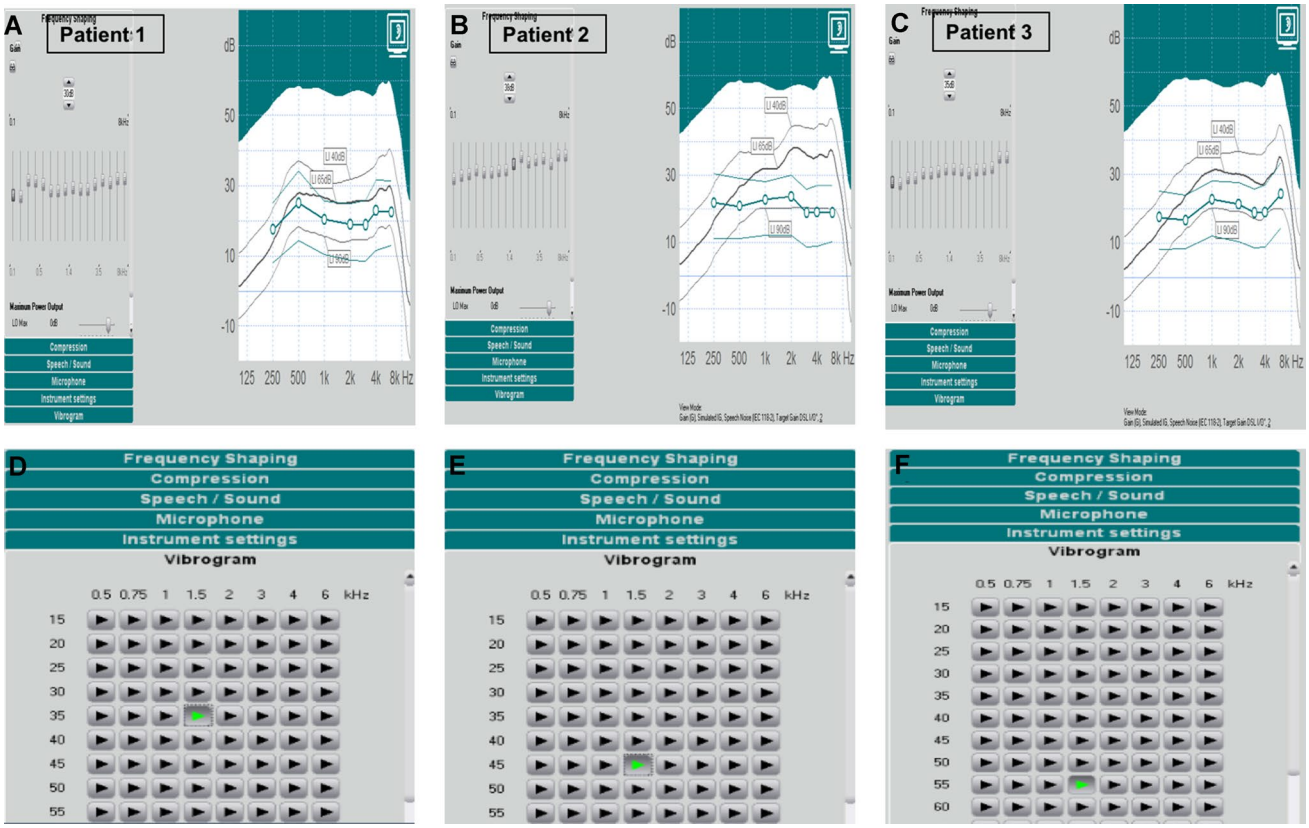

Fig. 3 Patient fitting maps, showing the levels of output (**a**–**c**, *green lines with dots* indicate target gains ranging from the minimal threshold level of 40 dB to an uncomfortable threshold level of 90 dB). *Panels* **d**–**f** show specific frequency gains in each patient

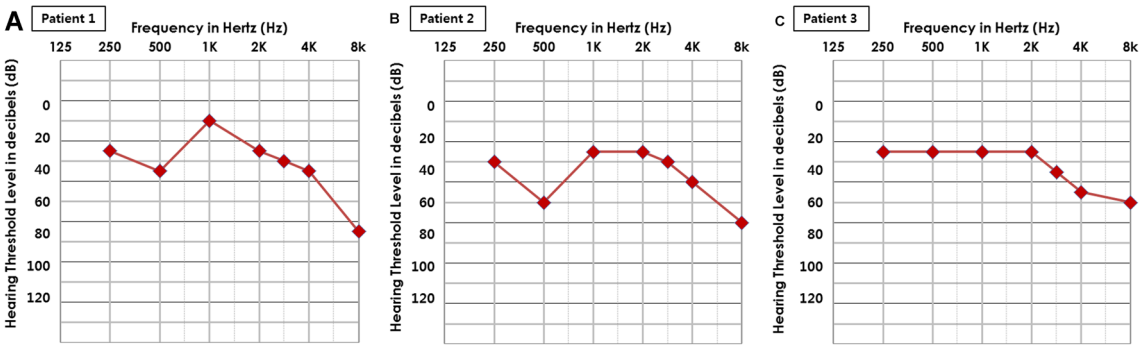

Fig. 4 Postoperative thresholds in sound fields 3 months after adhesiolysis of the vibrant soundbridge in three patients

Table 1 Subjects' characteristics and hearing results

Subject	Sex	Age (years)	Operation side	Position of FMT	Average threshold (pre-op) (dB HL)	Average threshold (post-op) (dB HL)	Speech audiometry (pre-op)		Speech audiometry (post-op)	
							MCL (dB)	PB max (%)	MCL (dB)	PB max (%)
Patient 1	Male	78	Left	Short process, incus	55.8	25	90	64	62	60
Patient 2	Female	51	Left	Short process, incus	61.7	30	94	48	60	80
Patient 3	Female	71	Left	Short process, incus	44.2	25.8	84	72	62	70

FMT floating mass transducer, *pre-op* preoperative, *post-op* postoperative, *HL* hearing level, *MCL* most comfortable loudness level, *PB max* maximum score of phonetically balanced with monosyllabic words HL in MCL

Discussion

Since its introduction in 1996, the standard surgical approach for VSB positioning involves a subtotal mastoidectomy combined with a posterior tympanotomy at the long incus process.

This surgical approach resulted in good audiological outcomes and stability during long-term use [1, 2, 9–13]. However, subtotal mastoidectomy and posterior tympanotomy could potentially cause facial nerve or chorda tympani injury [6]. Although no reports have discussed facial nerve injury during VSB implantation, the reported incidence of temporary or permanent facial nerve palsy during cochlear implantation with this surgical approach ranges from 0.3 to 2.2% [14]. The dimensions of the FMT necessitate a large opening in the facial recess and exposure of the chorda tympani [15]. Therefore, fixation of the FMT at the short incus process is another surgical issue. Compared with attachment to the long incus process, coupling of the FMT to the short incus process with wide antrostomy yielded similar stapes footplate and RW membrane velocity responses [6]. Polanski et al. [16] also reported that surgical coupling of the FMT to the short process of the incus yielded good clinical and audiological outcomes, especially when the long process and the oval or round window were inaccessible. Since 2015, we have performed 18 cases of VSB at the short incus process. Only four of these cases did not show hearing gain with the device. Because one case involved a mixed hearing loss with conductive postoperative loss, we repositioned the FMT on the round window. In the other three cases, we noticed adhesions around the FMTs, particularly between the bones and the FMTs. In the surgical field, we were able to check patients' immediate responses by attaching an external audio processor after adhesiolysis of the revision. We were convinced that the adhesion around the FMT might be a major cause of poor VSB performance.

The adhesions in our cases were mostly observed between the surrounding bones and FMT. Although the FMT is composed of titanium, the biomaterial could trigger a foreign body reaction, leading to adverse reactions such as inflammation and fibrosis. Shortly after implantation, biomaterials are covered with a layer of plasma proteins, especially albumin, fibrinogen, IgG, fibronectin, and von Willebrand factor [17, 18]. These proteins, which are possibly adsorbed via hydrophobic interactions, tend to assume an altered conformation and expose hydrophobic domains that become tightly adherent to hydrophobic biomaterial surfaces [19]. Conformational changes in these adsorbed proteins are thought to be responsible for initiating the above-mentioned adverse reactions [20]. The two points between the fossa incuidis and the FMT and between the dula plate and the FMT were problematic. During the initial surgeries, the FMTs were positioned

to avoid contact with bones; however, we were not able to achieve a sufficient space between the FMT and bone. When adhesions occurred between the bone and FMT, the presence of a narrow gap could increase the severity of the adhesion and thus limit movement of the FMT. All patients achieved hearing gains immediately after adhesiolysis, as demonstrated during surgery, and these improvements of 20–30 dB HL were also observed 3 months later. In the speech discrimination test, the patients achieved high PB max scores (>50%), even under the condition of a lower MCL. Polanski et al. [16] reported a pure tone average of 31 dB during an audiological evaluation with a VSB implant. Another study showed that speech discrimination with VSB improved significantly as compared with unaided conditions, and increased from 63 to 80% in a quiet environment [21].

In our cases of VSB revision with adhesiolysis, the 'seven-incision line' was the most important procedure with regard to avoiding electrode injury. The injections in the local anesthesia would be enough similar in the tympanoplasty via retroauricular approach. The incision along the EAC wall to the temporalis line was extended as far as possible to visualize the adhesions directly around the FMT. In an earlier case of VSB revision, we had attempted to initiate dissection from the body of the VSB and follow the electrode to the FMT. However, this dissection procedure was too lengthy. The patient could not tolerate the long revision time under local anesthesia. After modifying the procedure to include the 'seven-incision line', the surgical time was reduced to within 30 min. None of the patients complained during VSB revision under local anesthesia. This three-step surgical procedure is necessary for adhesiolysis during a VSB revision. Adhesiolysis, minimal bone curettage, and hydrocortisone application must be mastered to ensure a consistent recovery of FMT movement. After these three steps, we got good results with more than 20 dB gains of hearing. Bone curettage was performed to prevent fibrous layer formation between the bone and FMT. The ability of cortisol to prevent adhesion reformation following microsurgical adhesiolysis is well known. Hydrocortisone may also be used intraperitoneally at the conclusion of pelvic microsurgery [22].

In this report, we included three patients from among a small group of 18 cases. We state that the VSB failure rate of 16% is acceptable, and that these cases could be addressed with adhesiolysis. However, the overall VSB hardware failure rate was high (28%), which could be explained by technical failures of early generation implants [23]. Despite the currently low incidence of VSB revision surgery, we must consider the reasons for device failure and perform revision surgeries without hesitation according to this adhesiolysis guideline. If the impedance test of the VSB was good which meant the device was ok and the audiometry after the surgery did not show the air–bone gap which meant ossicles were intact, we should question the adhesion of VSB and decide the revision.

In summary, hearing restoration was achieved following revision surgery involving adhesiolysis around the FMT under local anesthesia in patients who experienced device failure. The seven-incision line and three adhesiolysis steps (adhesiolysis, curettage, and hydrocortisone injection) will facilitate the performance of adhesiolysis revision surgery during a short surgical period under local anesthesia. Moreover, these modifications will reduce the incidence of operation under general anesthesia, reduce the overall period of clinical therapy, and thus minimize patients' medical costs.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

Research involving human participants and/or animals Yes (participants).

Informed consent Yes.

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