

## Invasive electrical stimulation in the treatment of avascular osteonecrosis of the femoral head — mid-term results

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**The study aimed to evaluate the outcomes of osteonecrosis of the femoral head (ONFH) in adults after surgical treatment including invasive electromagnetic osteostimulation (E-Stim). Further, the influence of disease stage and several comorbidities on the joint preservation rate should be examined.**

**Sixty patients (66 hip joints) with ONFH were included in this retrospective cross-sectional analysis (mean follow-up: 58 months, 19-110 months). Potential ONFH risk factors and comorbidities (ONFH stage, age, sex, alcohol, smoking, cortisone medication, chemotherapy) were recorded. The influence of specific parameters on the joint preservation rates was evaluated by a multivariate logistic regression analysis. Finally, patients with preserved hip joints underwent an assessment of their last available X-rays.**

**The joint preservation rate depended on the initial ONFH Steinberg stage (I+II: 82.8%, III: 70.8%,  $\geq$  IVa: 38.5%). Initially collapsed ONFH ( $p \leq 0.001$ ) and cortisone therapy ( $p = 0.004$ ) significantly decreased the joint preservation rates. In case of progressed ONFH, the presence of  $\geq 2$  risk factors resulted in higher THA conversion rates (stage III: OR 18.8; stage  $\geq$  IVa: OR 12). In 94% of the available X-rays, the ONFH stage improved or did not progress. No complications could be attributed to the E-Stim device or procedure.**

**The present surgical protocol including minimally invasive E-Stim revealed high joint preservation rates for non-collapsed ONFH after mid-term postoperative follow-up. Especially in progressed ONFH, the-risk profile seems to be crucial and hence, for joint preserving surgery, careful patient selection is recommended.**

**Keywords:** hip joint, electrical stimulation, minimally invasive treatment, avascular necrosis, femoral head.

### INTRODUCTION

Atraumatic avascular osteonecrosis of the adult femoral head (ONFH) is a locally destructive disease and a common reason for total hip arthroplasty (THA), even in young patients<sup>1,2</sup>. To avoid ONFH progression and eventual collapse of the femoral head, core decompression (CD) is considered to be the gold standard for all precollaptic stages<sup>1,3,4</sup>. In case of progressed ONFH, CD is augmented with bone-marrow injection, autologous bone grafting (ABG), or femoral osteotomy<sup>3,5-10</sup>.

Furthermore, based on the findings of the piezo-electrical properties of bone, invasive and non-invasive electromagnetic osteostimulation (E-Stim) was established for the treatment of pseudarthroses and ONFH in the last decades<sup>11-19</sup>. In contrast to external non-invasive E-Stim, invasive E-Stim provides electrical stimulation directly to the bone independently of the surrounding tissue<sup>13,17,18</sup>. However, a significant amount

of implanted foreign material is usually involved. Aiming for a safe and less invasive application, a bipolar induction system was implemented using a single bone screw for postoperative E-Stim by inductive coupling with the Magnetodyn<sup>®</sup> system<sup>7,13,19,20</sup>. With view to early results of this procedure a single retrospective clinical study (including 56 hips) reported that 86% of hips were preserved after 33 months (mean) in non-collapsed ONFH<sup>7</sup>.

Our present retrospective study investigated the mid-term outcomes after minimally invasive surgical ONFH treatment including invasive E-Stim with the Magnetodyn<sup>®</sup> system. The main objective was to evaluate therapy success based on the joint preservation rate as well as the radiological outcomes of patients with preserved hips. Furthermore, the influence of ONFH disease stage, patient comorbidities, and basic risk profile on the success of therapy were investigated. Finally, potential complications associated with E-Stim were analysed.

## MATERIALS AND METHODS

All patients consecutively treated for ONFH using invasive E-Stim at one university hospital between 2004 and 2012 qualified for this retrospective descriptive cross-sectional study. An approval of the local ethics committee (Number: A-2013-0004) and informed consent of the patients were obtained.

### Patients and X-ray follow-up

Between January 2004 and December 2012, 72 patients (79 hip joints) with ONFH underwent joint-preserving surgery at our hospital including postoperative E-Stim therapy (Figure 1). All patients were contacted by phone in a period of 3 months starting 18

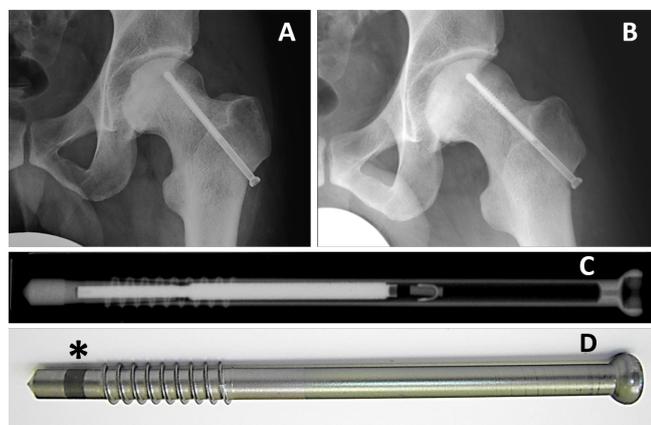


Fig. 1. — X-ray of the left hip in a.p. direction (A) and axial view (B) with implanted inductive screw. X-ray (C) and native view (D) of the inductive screw system: the 2 titanium electrodes are separated by a polymer isolator (\*).

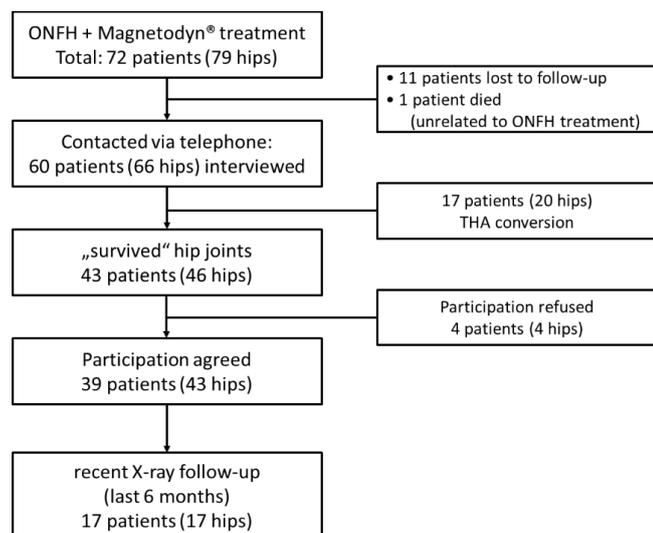


Fig. 2. — Flowchart of the ONFH patients treated with postoperative E Stim. Recruitment process for the provided data and statistical evaluation.

months after inclusion of the last patient. All patient who could be reached (60 patients, 66 hip joints) were eligible for the study (Figure 2). Of them, all agreed to answer whether their treated hip joint already required THA. Conversion to THA as well as reported pending THA were rated as “conversion to THA”. Seventeen patients confirmed, that an X-ray of the treated hip was performed within the last 6 months. All X-rays were collected in digital form for assessment. Any comorbidities requiring current medication as well as specific ONFH risk factors were collected from the patient records including our standardized examination and medical history sheets. Harmful alcohol consumption (daily consumption or >280 g per week), present nicotine consumption, ongoing cortisone use (independent of dosage) and a history of chemotherapy were rated as major risk factors.

### ONFH staging and surgical protocol

ONFH staging was performed according to Steinberg et al.<sup>21</sup>. The typical indication for joint-preserving surgery including invasive E-Stim therapy using Magnetodyn® was pre-collapse and early post-collapse ONFH without manifest osteoarthritis. The treatment protocol was adopted from Ellenrieder et al.<sup>7</sup>. A hip arthroscopy was performed in case of clinically or radiologically (MRI) suspected intra-articular pathologies (Table I) using standard techniques and portals<sup>22</sup>. In cases with critical joint alterations in the MRI the final decision regarding a joint-preserving therapy was supported by arthroscopy. ONFH treatment commenced by fluoroscopy-guided positioning of a 3.2-mm drill wire in the centre of the necrotic zone via a small lateral subtrochanteric approach. Up to 3 drillings were performed depending on the volume of the ONFH. Subsequently, using a cannulated drill (8.0 mm), the central working canal was established for curettage of the necrotic bone and ABG if indicated (Table I). Cancellous bone was taken from the intertrochanteric femoral region or the iliac crest using OATS® instruments (Arthrex, Inc., Naples, FL, USA). Finally, the tip of the inductive screw was positioned centrally in the necrosis (Figure 1). Postoperatively, we recommended partial weight-bearing (10 kg) for 6 weeks (small volume necrosis) or 12 weeks (large volume necrosis: stage IIc, IIIc, and ≥ IVa). Hence, in case of bilateral preservable ONFH we performed a sequential treatment starting with the higher stage ONFH joint. After 3 months, the screw was removed via stab incision in an outpatient procedure. To simplify the data analysis, ONFH stages were clustered as “early”, “critical” and “late” (Table II).

**Table I.** — Stage-dependent joint-preserving surgical ONFH treatment protocol

ONFH stage <sup>21</sup>	Treatment protocol
I	CD by small-diameter drilling. E-Stim treatment optional.
II	CD by small diameter drilling, curettage, and ABG from the proximal femur (small lesion size: stage IIa, IIb) or additionally from the iliac crest (large size lesion IIc). Arthroscopy optional. E-Stim treatment.
III	Analogous to stage II. Additional ABG impaction close to the subchondral zone (fluoroscopy controlled). E-Stim treatment.
≥ IVa	Contraindications for joint preserving therapy have to be excluded (e.g., significant chondral damage). Analogous to stage II. Additional ABG impaction and reposition of the femoral head impression. E-Stim treatment optional.
ONFH: osteonecrosis of the femoral head; CD: core decompression; E-Stim: electromagnetic osteostimulation; ABG: autologous cancellous bone grafting.	

**Table II.** — Steinberg stage distribution of the osteonecrosis of the femoral head (ONFH) at the time of surgery

Steinberg stage	Disease stage	n (hips)	Follow-up min-max	Hip survival month (mean ± SD)*	THA (n)	Preserved hips (rate)†
I/II	Early	29	6.7-109.8	49.3 ± 23.3	5	82.8%
III	Critical	24	9.3-105.4	49.0 ± 26.7	7	70.8%
≥ IVa	Late	13	2.3-65.9	23.8 ± 21.6	8	38.5%
<b>Total</b>		66	2.3-109.8	44.2 ± 27.2	20	69.7%
*Stage-specific hip joint preservation time (survival) in months (mean ± SD; min-max follow-up time). Number/percentage of hips converted to THA inclusive of pending THA. †Percentage of preserved hip joints at the time point of data analysis with a mean follow-up of 57.7 months (min-max: 18.7-109.8 months). ONFH, osteonecrosis of the femoral head; SD, standard deviation; THA, total hip arthroplasty.						

*Bipolar induction screw and Magnetodyn® osteostimulation*

The inductive screw system was developed by Neue Magnetodyn GmbH, Munich, Germany (BISS) and temporarily distributed by Stryker, Duisburg, Germany (ASNIS-III-s-series screw). E-Stim treatment was started on the fifth postoperative day as a home therapy (45 min, 3 times per day for 3 months). The Magnetodyn® non-invasive external coil system (Neue Magnetodyn GmbH, Munich, Germany) is positioned around the hip generating a sinusoidal oscillating magnetic field (magnetic induction 5 mT; frequency 12-20 Hz) which induces an electrical potential of up to 700 mV around the tip of the screw<sup>13,20</sup>.

*Statistics*

In order to evaluate the influence of the factors (sex, age, BMI, pre-existing conditions, alcohol/ nicotine abuse, cortisone, Steinberg stage) on the outcome of therapy, bivariate analyses of the individual factors were performed and the odds ratio (OR) was calculated. The significance test was carried out using the  $\chi$ -square test. The overall model shows a  $\chi^2$  value of 31.531, which was highly significant with a p-value of 0.001. Nagelkerke’s R<sup>2</sup> is 0.537, thus the quality of the model and the respective statistical explanatory power are given. In addition, the influencing factors were subjected to a multivariate logistic regression

analysis in order to analyse the interdependency of the individual variables as an entire model and thus to be able to recognize or exclude confounding variables. For the evaluation of the stage-related survival time of the hip joint, an event-time analysis was also performed using the Kaplan-Meier method in order to consider the different follow-up periods of the individual hip joints. For the stages of necrosis, the homogeneity of the follow-up periods was tested by Levene tests and T-test. The distribution of hip joint maintenance times between the groups (stages) was compared using the logrank test. Statistical significance was assessed by the p-value, with  $p \leq 0.05$  representing the significance level. Data were stored on MS Excel (Microsoft Corporation, Redmond, WA, USA) and analysed using the statistical package SPSS 21.0 (SPSS, Chicago, IL, USA).

**RESULTS**

At the time of surgery, the mean age of the 60 patients (40 men, 20 women) was 44.1 years (28.4-62.5 years), and the mean body mass index was 26.6 kg/m<sup>2</sup> (14.9-44.3 kg/m<sup>2</sup>).

*Hip joint survival depending on ONFH stage*

Overall hip joint survival was 69.7% but depended on the initial ONFH stage (Table II, Figure 3). Regarding ONFH stages Steinberg I-III, 77.4% of the hip joints

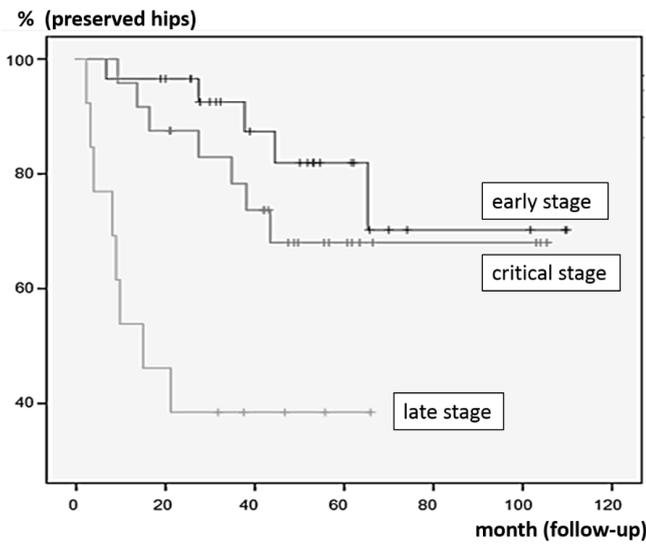


Fig. 3. — Kaplan-Meier curves of the 3 subgroups: Early-stage (Steinberg I, II), Critical-stage (Steinberg III), and Late-stage (Steinberg ≥ IVa). The curves show the percentage of hip joints without conversion to THA depending on the time (in months) after surgery. The vertical lines indicate the follow-up period for hips without THA conversion (censored). THA, total hip arthroplasty.

could be preserved. In patients treated for collapsed ONFH (late stage, Steinberg ≥ VIa) the conversion rate to THA was significantly higher ( $p \leq 0.001$ ) than in early-stage patients (Steinberg I, II). ONFH initially staged as “critical” (Steinberg III) resulted in a higher conversion rate to THA compared to early-stage ONFH (OR 4.8) (Table II). In our collective 6 patients underwent double-sided sequential ONFH treatment (2 patients: both hips preserved, 1 patient: 1 hip preserved, 3 patients: both hips converted to THA). No complications associated with induction screw insertion, postoperative E-stim, or later screw removal were observed.

*Influence of risk factors and comorbidities on hip joint preservation*

Current nicotine and harmful alcohol consumption increased the OR for THA conversion; however, only cortisone use significantly increased the THA conversion rate (Table III). In 47 of 66 hip joints, at least 1 comorbidity requiring medication was present;

this increased the conversion rate to THA (OR 2.8). Age and sex did not affect the conversion rate to THA. With view to treatment outcome of critical and late stage ONFH, we identified patients with a high risk-profile ( $\geq 2$  factors out of cortisone therapy, alcohol consumption, smoking and chemotherapy). Such a high-risk profile was associated with a higher risk for THA conversion (stage III: OR 18.8; stage ≥ IVa: OR 12).

*Radiological evaluation*

Of 39 eligible patients, 17 patients (44%) had recent radiographs representing a mean follow-up of 28.8 months (6.0-71.0 months) after surgery. Overall, in 94%, an improvement (12 hips) or at least no progression (4 hips) of the ONFH stage was recorded. Only 1 case (5.9%) showed a radiological ONFH progression from stage IVc to V at 57 months postoperatively.

**DISCUSSION**

The present study reports high mid-term hip joint survival rates of up to 83% (Steinberg stages I, II) in non-collapsed ONFH using CD, ABG and an inductive screw system for postoperative E-Stim. A presence of initially collapsed ONFH and cortisone therapy significantly decreased the mid-term joint preservation rates. Additionally, a history of ongoing nicotine and harmful alcohol consumption as well as chemotherapy increased the OR for THA conversion, especially in case of progressed ONFH (Steinberg stages ≥ III).

The treatment regimen of the present study included optional hip arthroscopy. E-Stim was not contraindicated in arthroscopically confirmed mild and local partial-thickness cartilage damage due to the favourable effects of low-frequency electromagnetic fields on the metabolism and the proliferation of chondrocytes<sup>16,23</sup>. With the screw system in situ, any MRI is contraindicated due to potential heating and uncontrolled induction effects. Hence, we removed the screw routinely after 3 months.

Re-staged according to Ficat<sup>24</sup>, the conversion rates of the present study were 0% (Ficat I), 24% (Ficat

**Table III.** — Distribution of typical ONFH risk factors in the study group (60 patients, 66 hips)

Risk factor	Patients/hips	Conversion to THA (hips)	OR	p-value
Alcohol	23/25	11 (44.0%)	2.79	0.059
Nicotine	36/41	14 (34.1%)	1.64	0.384
Cortisone	13/15	9 (60.0%)	5.46	0.004

ONFH, osteonecrosis of the femoral head; THA, total hip arthroplasty; OR, odds ratio.

II), and 67% (Ficat III). Marker et al. included 26 publications comprising 1268 hip joints in their meta-analysis on the effects of CD by drilling<sup>3</sup>. Failure of CD monotherapy after 65 months (mean) was found in 15% (Ficat I), 44% (Ficat II), and 67% (Ficat III) of hips when considering study results prior to 1992.<sup>3</sup> Reviewing more recent studies (1992-2007), the failure rates were 20% (Ficat I), 35% (Ficat II), and 66% (Ficat III) after 63 months (mean)<sup>3</sup>. Augmenting CD with ABG reportedly further improves the success rate<sup>10,25</sup>.

Sallam et al. reported 33 hip-preserving surgeries, including inverted femoral bone graft, with clinical failure rates of 0% (Ficat I), 25%/50% (Ficat IIA/IIB), and 22% (Ficat III) after a minimum follow-up of 3 years (3–14 years).<sup>10</sup> In contrast to other studies<sup>1,3,5,7,14,15,19,25-27</sup> the joint preservation rates in the ABG cohort of Sallam et al.<sup>10</sup> were much better for collapsed ONFH (78%) than for pre-collapse-stage ONFH (71%). Israelite et al. performed CD with ABG in 193 patients (276 hips) and reported conversion to THA in 28%, 34%, 23%, and 49% (Steinberg stages I, II, III, and IV, respectively) of the hips after 61 months (24-145 months)<sup>26</sup>. Considering these data, the present study tended to show superior hip joint survival rates, at least for non-collapsed ONFH compared to CD alone and CD + ABG<sup>3,10,26</sup>. Nevertheless, the effects of E-Stim could not be quantified due to the lack of a control group.

However, Steinberg et al. initiated two E-Stim studies: the first including 74 hips receiving invasive direct current stimulation and ABG<sup>14</sup>; the second comprised 20 patients treated with ABG and non-invasive E-stim by capacitive coupling<sup>15</sup>. After 31-44 months (mean), the patients with invasive E-Stim had a lower conversion rate to THA than the patients who underwent nonoperative treatment or CD + ABG<sup>14,15</sup>. This advantageous effect of E-Stim could not be

confirmed by the authors subsequently after 63 months (mean)<sup>5,14,15</sup>. These findings suggest that invasive E-Stim is most effective in the early postoperative period.

However, this is not supported by Windisch et al. who, after 12 months, could not find a significant difference in THA conversion rates and clinical outcomes of 18 ONFH hips treated with CD + ABG compared to 22 hips with additional invasive E-Stim using the Magnetodyn<sup>®</sup> system<sup>19</sup>. Notably, the cohorts of Windisch et al. were relatively small, and their THA conversion rates of 18% (E-Stim group) and 22% (control group) were higher than in our present study (12% at 12 months)<sup>19</sup>. A positive effect of invasive E-Stim on the mid-term outcomes 56 months after ONFH treatment was reported by Fornell et al. in their retrospective study<sup>27</sup>. Comparing conservative treatment (8 hips), CD (30 hips), and CD + invasive E-Stim (17 hips), hip survival was significantly higher with E-stim in Steinberg stages 0-II<sup>27</sup>. Nevertheless, the E-stim system used by Fornell et al. appears to be more invasive and required more components than E-Stim with Magnetodyn<sup>®</sup>. Table IV contains a comprehensive overview of the data from the studies discussed.

Progressed ONFH stages and risk factors such as cortisone use, alcohol and nicotine consumption are known to be associated with ONFH development but also to impair the chances for hip joint preservation after ONFH surgery<sup>1,3,5,14,15,25,28</sup>. Remarkably, within our patient groups with progressed ONFH (Steinberg III and ≥IVa), a high-risk profile (≥2 major factors) was associated with a markedly higher OR for THA. Steinberg et al.<sup>5</sup> also observed a higher THA conversion rate in patients with both steroid and alcohol use than in patients with only one risk factor. Hence, careful patient selection is recommended for joint preserving

**Table IV.** — Comparison of data from the present and previous studies

Author (year)	n (hips)	Therapy	Mean FU (months)	Staging system	Stages (conversion rate to THA)
Israelite (2005) <sup>26</sup>	276	CD, ABG	61	Steinberg	I (28%), II (34%), III (23%), IV (49%)
Fornell (2018) <sup>27</sup>	17	CD, ABG, E-Stim (i)	62	Steinberg	0-II (0%), III (43%)
Steinberg <sup>18</sup>	74	CD, ABG, E-Stim (i)	44	Steinberg	0-III (25%), IV (47%)
Steinberg <sup>15</sup>	20	CD, ABG, E-Stim (ni)	31	Steinberg	I-III (25%)
Present study	66	CD, ABG, E-Stim (i)	57.7	Steinberg	I+II (17.2%), III (29.2%), IV+V (61.5%)
Sallam (2017) <sup>10</sup>	33	CD, ABG	94	Ficat	I (0%), IIA (25%), IIB (50%), III (22%)*
Present study	66	CD, ABG, E-Stim (i)	57.7	Ficat	I (0%), II (24%), III (67%)
Windisch (2014) <sup>19</sup>	22	CD, ABG, E-Stim (i)	12	ARCO	2A (0%), 2B (0%), 2C (29%), 3C (67%)

n: number of hips, FU: follow up, THA: total hip replacement, CD: core decompression, ABG: autologous bone grafting, E-Stim (i): invasive electro-osteostimulation, E-Stim (ni): non-invasive electro-osteostimulation, \*Sallam et al. reported clinical failure rates.

surgery, especially when applied in progressed ONFH (Steinberg  $\geq$ III).

A limitation of our present study is that the X-ray follow-up was available for only a minority of the patients and did not cover the entire follow-up period. Nevertheless, only 5.9% of the patients with preserved hip joints had radiological failure (stage progression). In contrast, Fornell et al. reported up to 86% of hips with radiological failure but a conversion rate to THA of only 57% within their E-Stim cohort<sup>27</sup>. Hence, the missing radiological follow-up in our study does not appear to be of significance for the evaluation of treatment success. Second, we report only mid-term follow-up data; however, this is markedly longer than that of previous E-Stim studies applying Magnetodyn<sup>®7,19</sup>. A third limitation is the absence of a control group which would have halved the study group. Nevertheless, numerous studies which included high ONFH case numbers treated with CD are available and served as a control.

## CONCLUSION

A stage-dependent surgical protocol for ONFH treatment including the insertion of a bipolar induction screw and postoperative stimulation using Magnetodyn<sup>®</sup> revealed high joint preservation rates in non-collapsed ONFH for the mid-term postoperative follow-up compared to literature data for core decompression (CD) monotherapy or combined CD and autologous bone grafting (ABG). The inductive screw system and postoperative E-Stim turned out to be safe and minimally invasive. In the case of progressed ONFH without manifest arthritis, the treatment failure was associated with the presence of multiple risk factors. Especially in patients with progressed ONFH (Steinberg stage  $\geq$ III) a careful patient selection could improve the mid-term joint preservation rates. Further prospective studies are required to investigate the favourable results of the presented treatment protocol including E-Stim in the long-term.

*Declaration of conflicting interests:* the Authors declare that there is no conflict of interest.

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