Clinical Trial Results Report

Clinical Study to Test the Effectiveness of Magnetic Field Stimulation to Stimulate and Strengthen Pelvic Floor Muscles to Treat Urinary Incontinence

(IRB No. 2022-0399-011)

ver.1.0 / 2023.06.13

Clinical Trials Devices	Medical Magnetic Field Generators / CMSLIM MAX
Principal Investigator	, Severance Christian Hospital, Yonsei University , Korea
Implementing Organization	Yonsei University Wonju Severance Christian Hospital (20, Ilsan-ro, Wonju-si, Gangwon-do)
Sponsor	Ocean Medical Devices㈜ (147, Donghwa-gongdan-ro, Munmak-eup, Wonju-si, Gangwon-do)
Trial period	IRB Approval Date (11/08/2022)~ 2023.07.31
Protocols	Version 1.0 (2023.06.13)

Results report overview

<table>
<tr><td>Plan number</td><td colspan="5">Protocol Version 1.0</td></tr>
<tr><td>Clinical trial task name</td><td colspan="5">Clinical Study to Test the Effectiveness of Magnetic Field Stimulation to Stimulate and Strengthen Pelvic Floor Muscles to Treat Urinary Incontinence</td></tr>
<tr><td>Categorize trials</td><td colspan="5">Investigator-initiated trials (IIT) ■ Sponsor-initiated trials (SIT)</td></tr>
<tr><td>How trials work</td><td colspan="5">■Prospective studies☐ Retrospective studies ☐PMS</td></tr>
<tr><td rowspan="3">Clinical trial devices</td><td colspan="2">Item taxonomy number (class)</td><td colspan="2">Item name</td><td>Model Name</td></tr>
<tr><td colspan="2">A85020.01(2)</td><td colspan="2">Medical electromagnetic generators</td><td>CMSLIM MAX</td></tr>
<tr><td colspan="2">Purpose</td><td colspan="3">Relieves muscle pain and inhibits urination, including urinary incontinence</td></tr>
<tr><td rowspan="5">Researchers</td><td></td><td>First Name</td><td>Department name</td><td colspan="2">Phone number/Email</td></tr>
<tr><td>Principal Investigator</td><td>Hyunchul Jung</td><td>Urology</td><td colspan="2">010-7376-5063
Chc7174@yonsei.ac.kr</td></tr>
<tr><td>Principal Investigator</td><td>Tae Wook Kang</td><td>Urology</td><td colspan="2">010-8589-5238
twkang@gmail.com</td></tr>
<tr><td>Coordinators</td><td>Eunhye Lee</td><td>Urology</td><td colspan="2"></td></tr>
<tr><td>Coordinators</td><td>Soonhee Han</td><td>Urology</td><td colspan="2"></td></tr>
<tr><td>Sponsor basics</td><td colspan="3">Company Name: Ocean Medical Devices(주)</td><td colspan="2">CEO: Jungseob Yoon</td></tr>
<tr><td>Clinical trial objectives</td><td colspan="5">Academic ☐Domestic ☐International</td></tr>
<tr><td rowspan="2">Food and Drug Administration approval status and indication range</td><td colspan="5">☐Not applicable ■Domestic license☐ No domestic license
International license (☐USA ☐Europe ☐Japan ■Other (Brazil))</td></tr>
<tr><td colspan="5">In-license research ☐Out-of-license research☐ N/A</td></tr>
<tr><td>Whether the plan has been approved by the Food and Drug Administration</td><td colspan="5">☐Approval required (Approval date:) No authorization required</td></tr>
<tr><td rowspan="4">Clinical trial taxonomy</td><td>Bioethics law</td><td colspan="4">Human Subjects Research☐ Human Derivatives ResearchTherapyTesting
☐Human Derivatives Bank ☐Germ ☐Stem☐ N/A</td></tr>
<tr><td>Research subjects</td><td colspan="4">Pharmaceuticals ☐Drugs ☐Biologics ■Medical devicesdiagnosticsupplements ☐Medical
Medical practice/procedure/treatment/diagnosis ☐Other</td></tr>
<tr><td>Study Classification</td><td colspan="4">☐Clinical trials■ Patient-controlled studies ☐Observational, surveys, and interview studies
☐Case seriesand analysis study ☐Registry studyrecord use study ☐Case report ☐Cohort study
☐Epidemiologic survey ☐Other</td></tr>
<tr><td>Research phase (Medicine)</td><td colspan="4">☐Phase 1 ☐Phase 234 ☐PMS☐ bioequivalence ☐Other</td></tr>
</table>

	Categorization (Medical Devices)	For product authorization (☐safety, efficacy target ☐addindication ☐performance ☐academic Feasibility/Pilot Study ☐Other	
	Research organizations	■Single organization☐ Domestic multiagency☐ International multiagency	
Trial duration	2022-11-08~ 2023-07-31		
Clinical trial subject information	**Number of subjects**	All: 57 people.	Test group: 28 patients. Control group: 29 people.
	☐Healthy individuals ■Patients ■Vulnerable research subjects (☐ as applicable below)		
	☐People who lack capacity (including people with disabilitieswomen ☐Children/minors ☐Children 15 years of age or older ☐Children under 6 years of age ☐Over~ Under 15 years of age ☐Newborns, institutionalized persons Employee (researcher, student, employee, etc.) of an institution, researcher, sponsoretc ☐Senior citizen (80 years of age or older ☐Other		
	plan describes how to protect vulnerable populations.		■Yes☐ No ☐Not
	plan describes measures to protect the privacy of human subjects.		■Yes☐ No ☐Not
	plan describes how confidentiality of research data will be maintained.		■Yes☐ No ☐Not

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1. Overview

Client Name/Company Name	Ocean Medical Devices㈜
Investigational Device Name	CMSLIM MAX
Item name	Medical electromagnetic generators
Study title	A clinical study to determine the efficacy of pelvic floor muscle stimulation and strengthening by magnetic field stimulation for the treatment of urinary incontinence.
Clinical trial sites	Wonju Severance Christian Hospital
Principal Investigator	Wonju Severance Christian Hospital Department of Urology Prof. Hyun Chul Jung
Trial duration	First Audience Date: 2022-12-13 Last Eligible End Date: 2023-06-23
Clinical trial categorization	Sponsor-initiated clinical studies (SIT)
Conditions (indications)	Urination disorders, such as urinary incontinence
Clinical trial objectives	Validating the effectiveness of magnetic field stimulation to treat urinary incontinence
Number of subjects	62 participants (28 experimental, 29 control, 5 dropouts)
Selection criteria	1) 30 years old with a history of urinary incontinence~ 80 years old 2) For women, have had a natural childbirth 3) For men, more than 4 months after a prostatectomy 4) Only for those who voluntarily signed a consent form

Exclusion Criteria	1) People who have not voluntarily agreed to participate in a clinical trial 2) Received physical therapy involving pelvic floor muscle strengthening, including electrical stimulation, in a clinical setting within 30 days prior to this study. 3) You are currently participating in a study that may affect the results of the study, or you have a Have participated in a drug study or received treatment within the past 30 days 4) People with implanted medication pumps, neurostimulators, , , hearing aids, etc. 5) Anyone who wears a metal prosthesis on their body and does not remove it before each treatment. 6) Those with bleeding, circulatory disorders (such as thrombotic atherosclerosis), acute inflammation of joints and bones, and soft tissue deposits 7) Pregnant or planning to become pregnant during the study 8) People with uncontrolled high blood pressure, high fever, or malignancy 9) Suspected of having a fever or serious infectious diseases and illnesses that can suppress fever 10) People with skin sensitivity abnormalities in the pelvis, buttocks, and lower extremities 11) Recovering from a burn or burn injury 12) Have allergies, skin conditions, or other medical conditions 13) Patients with symptomatic UTIs 14) Medications that may affect bladder function, such as diuretics, bronchodilators, etc.	
	who take 15) Otherwise, in the opinion of the investigator, not suitable for participation in this study. If you determine that	
Evaluation Variables	Validation	1) Change in incontinence symptom score questionnaire from pre- to post-treatment 2) Change in incontinence volume before and after treatment 3) Change in peak urethral closure pressure pre- and post-treatment
	Safety Evaluatio	1) Adverse events 2) Vital signs

	n	
Statistical methods	For the efficacy evaluation variables, incontinence questionnaire symptom score and 1-hour pad test, and maximum urethral closure pressure at pre-treatment, 4 weeks, and 8 weeks, t-test was performed to test the change from pre-treatment to post-treatment, with a significance level of 5%, and the general characteristics of the study subjects are presented as mean±standard deviation, median [minimum, maximum] for continuous data, and frequency (%) for categorical data. To test the difference in distribution between two groups, Independent t-test is used for continuous variables if the normal distribution can be satisfied, Wilcoxon rank sum test is used if the normal distribution is not satisfied, and Chi-square test is used for categorical variables. Perform a chi-square test or Fisher's exact test.	
Summary of results	Validation	1. **Incontinence symptom score (International Consultation on Incontinence modular Questionnaire (ICIQ))** The improvement in the incontinence symptom score after treatment showed a symptom improvement in the experimental group compared to the control group (2.64±4.19 vs 1.42±3.03 p Value = 0.229), but it was not statistically significant, but the degree of improvement in the symptom improvement score in the experimental group was maintained more consistently than in the control group. However, there was no statistical significance in the change in scores between the experimental and control groups in severe subjects with symptom scores of 6 or more (2.88±4.37 vs 1.90±2.90 p Value = 0.106). **2. 1-hour pad test - measures the amount of incontinence** The experimental group was measured to have more incontinence than the control group, but the number of leakage subjects was too small to statistically significant. **3. Maximal urethral closure pressure (MUCP)** Pre- and post-treatment urethral closure pressure readings were 55.18 versus 60.14 in the control group and the experimental group decreased from 65.29 to 57.81, which is a significant decrease from the

		The experimental group showed a greater change than the control group.
	Safety assesmen t	Only 1 subject had fever, but the final examination was unrelated to the study and all subjects with medical devices applied. No vital sign abnormalities or adverse events occurred in the study.
Conclusion - Reflections	In the study on the efficacy of pelvic floor muscle stimulation and strengthening by magnetic field stimulation for incontinence, the experimental group showed a tendency to improve and maintain incontinence symptom scores after treatment compared to the control group, but there was no statistical significance. This finding suggests that a study with a larger number of patients is needed, and furthermore, it is necessary to determine the effectiveness of the treatment according to the patient's symptoms. A detailed study design is required.	

2. List of acronyms and definitions of terms

1) Clinical Trial/Study

   Clinical trials are the testing or study of medical devices in humans to prove their safety and effectiveness.

2) Protocol

   A document that describes the purpose, population, study methodology, statistical considerations, and organizations involved in the study to provide background or rationale for the study.

3) Case Report Form (CRF)

   A printed or electronic document that records the information required by the protocol for each individual patient and is intended to be delivered to the sponsor.

4) Clinical Trial/Study Report ("Results Report")

   A document that synthesizes and describes the results from a clinical trial in clinical and statistical terms.

5) Testers

   Test and control devices used in a clinical trial.

6) Subject/Trial Subject ('Patient')

   A person who is participating in a clinical trial either as an investigational medical device subject or as part of a control group.

7) Vulnerable Subjects in Vulnerable Environment

   Patients whose expectations of benefits associated with participation in the clinical trial or concerns about the disadvantages they may receive from those higher up in the organizational hierarchy if they refuse to participate are likely to influence their decision to voluntarily participate (students of medical schools, oriental medicine schools, pharmacy schools, dental schools, nursing schools, employees of medical institutions, research institutes, etc,), terminally ill persons,「 persons housed in collective facilities in accordance with Article 22 of the Enforcement Rules of the Medical Device Act」, unemployed persons, indigent persons, patients in emergency situations, racial minorities, vagrants, homeless persons, refugees, minors, and patients who are unable to give free and voluntary consent.

8) Principal Investigator

   The person at a site who is responsible for the conduct of a clinical trial.

9) Sponsor ("Sponsor")

   An individual, company, site, or organization that is responsible for planning, managing, and financing a clinical trial.

10) Adverse Event (AE)

Any unintended condition, symptom, or disease that occurs in a patient during a clinical trial, including but not limited to a symptom, sign, or abnormality in laboratory test results, that is not necessarily causally related to the investigational medical device.

11) Adverse Device Effect (ADE)

Any harmful, unintended reaction caused by an investigational medical device for which the causal relationship to the investigational medical device cannot be denied.

12) Serious Adverse Events - Adverse Medical Device Events (Serious AE-ADE)

An adverse event or medical device event caused by a medical device used in a clinical trial that meets any of the following criteria

(1) Death or danger to life has occurred

(2) If you need to be hospitalized or have an extended hospital stay

(3) Resulted in permanent or significant disability and reduced functionality

(4) The fetus has a malformation or abnormality

13) Institutional Review Board ("IRB")

A standing committee established independently within an institution to protect the rights, safety, and welfare of human subjects participating in clinical trials by reviewing and continually verifying the protocol or amendments to the protocol, the methods used to obtain written informed consent from subjects, and the information provided.

3. Ethics

3.1. Institutional Review Board (IRB)

The protocol of this clinical study was initially approved by the IRB of Severance Christian Hospital, Yonsei University Wonju, Korea on September 21, 2022, and any changes to the protocol before and during the study were reported to the IRB for approval, as shown in Table 1.

Table 1. IRB change approval milestones, including protocols

IRB approval date	Major changes
Nov. 8, 2022	• Initial authorization - Protocol ver.1.0 - Casebook ver.1.0 - Human Subjects Statement and Consent Form ver.1.0
Nov. 8, 2022	• Fix case note errors - Casebook ver.1.1 • Add a research coordinator

2023-03-14	• Posting a study recruitment announcement - For study recruitment banners - Research Participant Recruitment Announcement for homepage
2023-04-04	• Posting a study recruitment announcement
IRB approval date	**Major changes**
	- For study recruitment banners
2023-04-25	• Adverse Events (Acute Pyelonephritis) - Not relevant to this study - Termination of adverse events and discontinuation of this subject from the study
2024-06-13	• Change the study period - Before the change: ~ 2023.06.30 - After the change: ~ July 31, 2023
July 4, 2023	• Exit reporting

3.2. Ethical considerations for clinical trials

This clinical trial was conducted in accordance with ethical standards based on the Declaration of Helsinki.

3.3. Patient information and consent

Prior to the screening to select subjects for this study, all volunteers were fully about the study and voluntarily signed the consent form.

4. Investigators and clinical trial support organizations

4.1. Clinical trial site and address

1) Organization Name: Wonju Severance Christian Hospital
2) Address: 20, Ilsan-ro, Wonju-si, Gangwon-do, Korea

4.2. Principal Investigator/Person in Charge

1) Principal Investigator: Hyun-Cheol Jung, Professor, Department of Urology
2) Principal Investigator: Tae-Wook Kang, Clinical Associate Professor, Department of Urology
3) : Eunhye Lee, Department of , and Han, Research Nurse

5. Clinical trial purpose and background

5.1. Purpose

Medical electromagnetic generator (CMSLIM MAX) is a medical device that treats urinary incontinence by electrically stimulating muscles, nerve tissues, etc. by inducing (generating) an electric current through a high-frequency magnetic field, and this study was conducted to confirm the effectiveness of the CMSLIM MAX for its intended use.

was conducted to confirm the effectiveness of the CMSLIM MAX for its intended use.

5.2. Backgrounds

Urinary incontinence is the involuntary leakage of urine, which is rarely fatal, but it causes hygiene problems and is a major factor in reducing the patient's quality of life. In the early stages, it only interferes with daily life, but as the symptoms become more severe, it can make it impossible to socialize, psychologically withdraw from social activities, become part of the geriatric syndrome, especially in older people, and increase the risk of developing urinary tract infections and depression. In severe cases, it can lead to depression.

Incontinence can be categorized into three main types, and a 2005 study found that 48.8% of those surveyed with urinary incontinence were classified as having stress incontinence, 7.7% as urge incontinence, and 41.6% as mixed incontinence.

- Stress Urinary Incontinence (SUI): Incontinence that occurs when abdominal pressure rises with physical exertion, coughing, or sneezing.
- Urge Urinary Incontinence (UUI): Urinary incontinence that occurs after a sudden feeling of needing to urinate.
- Maxed Urinary Incontinence (MUI): Urinary incontinence characterized by a mixture of stress and urgency incontinence.

Urinary incontinence is a condition with many different diagnoses and treatments, depending on the cause, and can occur at any age, not just in women or the elderly. It is especially common in women and the elderly after middle age, with a prevalence of about twice as high in women as in men. In women, it is more common in the elderly, with prevalence of about twice as high in women as in men. In women, it often follows pregnancy and childbirth, and in men, often follows prostate surgery.

There are surgical and non-surgical for urinary incontinence (Kegel exercises, electrical stimulation therapy, biofeedback therapy, magnetic field therapy). Unlike Europe, where non-surgical therapies are widely used, surgical treatment has been favored in Korea, but recently there has been a trend toward non-surgical treatment except for severe cases. Several studies have shown that urinary incontinence can be prevented and treated through self-management with non-surgical therapies such as continuous pelvic floor exercises.

Instead of Kegel exercises, vaginal device insertion, electrical stimulation therapy, and biofeedback therapy, which are non-surgical therapies with limited efficacy and persistence, or vaginal device insertion, which patients report discomfort and resistance to, this study aims to test the efficacy of magnetic field incontinence therapy, a non-invasive treatment for urinary incontinence that has been shown to be more comfortable and adherent to patients, and can target deep neural tissue without the side effects and energy attenuation of electrical stimulation therapy.

6. Clinical trial planning

6.1. Skills in clinical trial design and planning

This study was designed as a randomized, patient-controlled, experimental study to test the efficacy of a non-invasive treatment for urinary incontinence, the magnetic urinary incontinence device, by comparing changes in urinary incontinence symptom scores and peak urethral closure pressure in patients with urinary incontinence.

Single-blinded subjects to differentiate between the timing of device application in the experimental and control groups.

The device was applied twice a week for a 4-week period, 8 sessions total, 30 minutes per session, and subjects were blinded to the content of the study, with a final follow-up visit scheduled for 2 months after the first study visit, following a 4-week device application period.

The number of subjects was calculated to be 60, taking into account a 10% dropout rate, with enrollment and randomization taking from December 2022 to April 2023, with the goal of completing follow-up and study visits for all subjects in June 2023.

The allocation of subjects was single-blinded, randomized, in which were blinded to the treatment group/control group until the end of the pre- and post-treatment periods, and the randomization was performed by a stratified block randomization method with a block size of 4 and 6. A randomization table was prepared to assign subjects to one of the two groups, and they were sequentially assigned in the order of enrollment according to this randomization table.

Statistical analysis was performed to test the change from pre- to post-treatment for the efficacy evaluation variables, incontinence questionnaire symptom score, 1-hour pad test, and maximum urethral closure pressure at pre-treatment, 4 weeks, and 8 weeks, using t-test with a significance level of 5%, and the general characteristics of the study subjects were presented as mean±standard deviation, median [minimum, maximum] for continuous data, and frequency (percentage) for categorical data. To test the difference in distribution between the two groups, Independent t-test was planned for continuous variables if the normal distribution could be satisfied, Wilcoxon rank sum test if the normal distribution was not satisfied, and Chi-square test or Fisher's exact test for categorical variables.

6.2. Description of clinical trial design, including control group selection

Urinary incontinence is a common problem in older adults, with a prevalence rate of 24.4% according to 2005 statistics, making it a common geriatric condition. Most treatments for incontinence include lifestyle modifications, medications, and in severe cases, surgery. However, as with most geriatric , if treated early enough, many patients can avoid surgical treatment with behavioral and medication therapy. Behavioral treatments for urinary incontinence include fluid intake control, pelvic muscle exercises, and bladder training. In particular, the International Continence Society (ICS) recommends pelvic exercises that involve contracting the pelvic floor muscles for 6-8 seconds, repeated three times for 8-10 repetitions, and the frequency of training should be 3-4 times a week for at least 15-20 weeks. However, the strength and characteristics of each patient"s pelvic floor muscles should be taken into account, and a one-size-fits-all program be avoided, as it can lead to overtraining, muscle fatigue, or, conversely, insufficient training. Short-term studies pelvic floor exercises have shown improvement in 60-80% of patients and require at least 3-6 months of consistent practice to be effective. However, since most elderly patients suffer from cognitive decline and muscle weakness, there has been a growing interest in pelvic muscle exercises using magnetic fields as an alternative. Extracorporeal magnetic field therapy utilizes the principle the same frequency of electric current generated by a magnetic field causes contraction and relaxation of nerve-muscle units in the pelvic muscles, which has the effect of inhibiting bladder activity and inducing reinnervation. It should be done at least twice a week, for 10 to 30 minutes each time, for 6 weeks to be effective. and.

It is recommended that electrostimulation and extracorporeal magnetic field therapy be used in combination with medication rather than alone (Overactive Bladder Guidelines 2011). For patients who do not achieve sufficient pelvic muscle control with biofeedback, electrostimulation or extracorporeal magnetic field therapy may be used. These passive exercises compared to active pelvic floor exercises, in which electrical or magnetic currents are to the pelvic muscles to artificially generate movement. It is a common method to be treated for about 30 minutes once a week for about 4 weeks, 2-3 times a week, and in particular, extracorporeal magnetic field therapy is very comfortable because it is performed while sitting in a chair with full clothes without inserting sensors into the vagina or anus. In a study by Galloway et al, 50 patients with abdominal pressure urinary incontinence were treated with extracorporeal magnetic field for 20 minutes per session, twice a week for 6 weeks and followed up for 3 months, and the average number of pads decreased from 2.5 to 1.3, and the average number of urinary leaks decreased from 3.3 to 1.7, with significant improvement, and the effect was maintained at 6 months (Korean J Fam Med. 2010).

6.3. Selecting subjects

6.3.1. Selection criteria

1) 30 years old with a history of urinary incontinence~ 80 years old
2) For women, have had a natural childbirth
3) For men, more than 4 months after a prostatectomy
4) Only for those who voluntarily signed a consent form

6.3.2. Exclusion Criteria

1) People who have not voluntarily agreed to participate in a clinical trial
2) Received physical therapy involving pelvic floor muscle strengthening, including electrical stimulation, in a clinical setting within 30 days prior to this study.
3) Currently participating in a study that may affect the results of the study or have participated in a drug study or received treatment within the last 30 days
4) People with implanted medication pumps, nerve stimulators, , , , hearing aids, etc.
5) Anyone who wears a metal prosthesis on their body and does not remove it before each treatment.
6) People with bleeding, circulatory disorders (such as thrombotic atherosclerosis), acute inflammation of the joints and bones, and soft tissue deposits
7) Pregnant or planning to become pregnant during the study
8) People with uncontrolled hypertension, high fever, or malignancy
9) Suspected of having a fever or serious infectious diseases and illnesses that can suppress fever
10) People with skin sensitivity abnormalities in the pelvis, buttocks, and lower extremities
11) Recovering from a burn or burn injury
12) Have allergies, skin conditions, or other medical conditions
13) Patients with symptomatic UTIs
14) Take medications that may affect function, such as diuretics, bronchodilators, etc.
15) Otherwise, in the judgment of the investigator, you are not appropriate to participate in this study.

6.4. Application of Investigational Medical Devices

1) Item name (taxonomy number [class]): Medical electromagnetic generators (A85020.01[2])
2) Model Name: CMSLIM MAX
3) Manufacturer: Ocean Medical㈜
4) Part number: Jane 22-4480
5) Purpose: To relieve muscle pain and control urination, including urinary incontinence.
6) Performance

① Output frequency: 1~ 150 Hz

Magnetic field strength: 0.6~ 2.5 T

③ Magnetic field pulse width: 240 us

④ Output intensity adjustment range: 1~ 100%

⑤ Output time: 5~ 30 minutes

6.5. Efficacy and safety endpoints

1) Validation cycle

Before treatment

Brief efficacy evaluation using questionnaires immediately after the last treatment or within 24 hours

③ Follow-up: At least 3 weeks after the last treatment and~ within 4 weeks (within the project period)

2) Validation methods

Questionnaire: International Consultation on Incontinence modular Questionnaire (ICIQ,

Incontinence Symptom Score)

1-hour pad test [18] - measures the amount of incontinence

(1) Wear a pre-weighed pad without urinating for at least 2 hours before the test.
(2) The subject drinks 500 ml of fluids for 15 minutes and or rests.
(3) ③ The subject performs walking activities, including walking up and down stairs, for 30 minutes.
(4) ④ Depending on the subject's physical condition, sit and stand for 30 minutes, cough, run in place, bend at the waist to pick up objects from the floor, wash hands under running water, etc.
(5) After 1 hour, weigh the pad you were wearing to calculate the weight of urine leaked.

3) Maximal urethral closure pressure (MUCP)

(1) Insert a maximal urethral closure pressure catheter and inject normal saline through it at a rate of 2 ml/sec while retracting the catheter from the bladder at a rate of 1 mm/sec.

6.6. Quality assurance of materials

We did not use a separate system to ensure the quality of clinical trial data, but to ensure the reliability accuracy of the research results, we controlled the timing of the application of the medical devices in the experimental and groups to prevent the sharing of the results between the two groups, and ensured that researchers and research personnel were familiar with the medical device user manuals for proper use and management of the medical devices. The study was conducted through timely deliberations through the institutional IRB, including approval of the protocol, regular reporting, and changes and other reports as needed.

6.7. Statistical Methods and Number of Patients in the Protocol

The aim of this study was to compare the change in subjective symptom scores and the change in maximum urethral closure pressure in patients with urinary incontinence using a non-invasive treatment for urinary incontinence, the magnetic incontinence device. In a study by BUT et al. that was similarly designed to this study, the ratio of the experimental group to the control group was 23 to 16. For this study, an independent t-test was conducted using the results of the above studies, and the alpha value was set to 0.05 power 80%, and the improvement effect of group 1 was 73.9% and group 2 was 31.3% using https://clincalc.com/stats/samplesize.aspx to calculate 27 subjects in each group. The number of subjects required for the study is 54, and the total number of subjects required for the study is 60, assuming a dropout rate of 10% and a serious protocol violation rate of 10%.

Statistical analysis was performed to test the change from pre- to post-treatment for the efficacy evaluation variables, incontinence questionnaire symptom score and 1-hour pad test, and maximum urethral closure pressure at pre-treatment, 4 weeks, and 8 weeks, using t-test, with a significance level of 5%, and the general characteristics of the study subjects were presented as mean±standard deviation, median [minimum, maximum] for continuous data, and frequency (percentage) for categorical data. To test the difference in distribution between the two groups, Independent t-test was planned for continuous variables if the normal distribution could be satisfied, Wilcoxon rank sum test if the normal distribution was not satisfied, and Chi-square test or Fisher's exact test for categorical variables.

6.8. Changes in clinical trial conduct and planned analytical methods

Not applicable

7. Subjects

7.1. Patient engagement status

Final enrollment count	Number of people eliminated	Experimental group (dropouts)	Control (dropout)	Final number of studies completed
62	5	28(3)	29(2)	57

7.2. Protocol violations

violations of the plan were reported during this exam.

8. Validation

8.1. Analyze

A total of 62 patients were enrolled in the study, including 3 in the experimental arm and 2 in the control arm, with 3 patients dropping out due to inadequate screening time and 2 patients dropping out due to time constraints and to attend visits. Only one patient was withdrawn due to symptoms such as fever, but the patient's final examination was unrelated to the study.

8.2. Demographics and other underlying characteristics

There were no statistically significant differences in demographic information and other baseline characteristics between the experimental and control groups.

8.3. Assessing adherence

All analyzed groups completed eight applications of the magnetic incontinence device and a follow-up visit.

8.4. Validation results

1) 1) Incontinence symptom score (International Consultation on Incontinence modular Questionnaire (ICIQ))

   The improvement in incontinence symptom scores after treatment showed a significant improvement in the experimental group compared to the control group (2.64±4.19 vs 1.42±3.03 p Value= 0.229), although it was not statistically significant, and the degree of improvement in symptom scores was maintained in the experimental group compared to the control group. However, there was no statistical significance in the change in scores between the experimental group and the control group in subjects with a symptom score of 6 or more (2.88±4.37 vs 1.90±2.90 p Value = 0.106).

2) 2) 1-hour pad test (measures the amount of incontinence)

   The experimental group was measured to have more incontinence than the control group, but the number of leakage subjects was too small to be statistically significant.

3) 3) maximal urethral closure pressure (MUCP)

   Before and after treatment, urethral closure pressure values decreased from 60.14 to 55.18 in the control group and 65.29 in the experimental group.

   to 57.81, showing a larger change in the experimental group compared to the control group.

9. Safety assessment

9.1. Anomalies

No adverse events occurred in this study.

9.2. Critical adverse events

One serious adverse event occurred in this study, but was determined to be unrelated to the study upon final examination.

9.3. Vital signs, physical exam, other observations related to safety

There were no specific adverse events or abnormalities in the questioning and care of subjects, including vital signs and physical examinations.

9.4. Safety conclusions

Safety was evaluated by vital sign assessments and adverse events during the study in 28 subjects in the treatment group and 29 subjects in the control group. Adverse events occurred during the study, but were not considered to be related to the study, and there was no evidence of clinical harm based on safety evaluations such as physical examinations. Safety evaluations were performed by the investigators who participated in the study.

10. Reflections and conclusions

Urinary incontinence is a common condition among older adults, with a prevalence of 24.4% in 2005. Most treatments for incontinence include lifestyle modifications, medications, and in severe casessurgery. However, most

is a common geriatric condition that, if treated early enough, can be managed with behavioral and medication therapy in most patients, and many patients can avoid surgical treatment. Representative behavioral treatments for urinary incontinence include fluid intake control, pelvic muscle exercises, and bladder training. In particular, the International Continence Society (ICS) recommends pelvic exercises that involve contracting the pelvic muscles for 6-8 seconds for 8-10 repetitions, and the frequency of training is 3-4 times a week for at least 15-20 weeks. However, the strength and characteristics of each patient"s pelvic floor muscles should be taken into account, and a one-size-fits-all program should be avoided, as it can lead to overtraining, muscle fatigue, or vice versa, insufficient training. Short-term studies of pelvic floor exercises have shown symptomatic improvement in 60-80% of patients and require 3-6 months of consistent practice to be effective. However, in the majority of elderly patients, cognitive decline and muscle weakness are also present, so there"s been a growing interest in pelvic floor exercises using magnetic fields as an alternative.

Extracorporeal magnetic field therapy uses principle that an electric current of the same frequency generated by a magnetic field causes contraction/relaxation of the neuromuscular units in the pelvic muscles, which has the effect of inhibiting bladder activity and induces reinnervation the nerves. This should be done at least twice a week, 10-30 minutes per session, for 6 weeks to be effective. It is recommended that electrotherapy and extracorporeal magnetic field therapy be used in combination with medication rather than alone [Overactive Bladder Guidelines, 2011]. Electrostimulation and external magnetic field therapy are recommended in combination with medication rather than alone [Becker, 2011]. These are passive exercises compared to active pelvic floor exercises because they generate electric or magnetic currents in the pelvic muscles. It is a common method of treatment for about 30 minutes a time and is usually performed 2-3 times a week for about 4 weeks, and extracorporeal magnetic field therapy is very comfortable because it is performed while sitting in a chair with full clothes without inserting sensors into the vagina or anus. In a study by Galloway et al, 50 patients with abdominal pressure urinary incontinence were treated with extracorporeal magnetic fields for 20 minutes per session, twice a week for a total of 6 weeks and followed up for 3 months, and the mean number of pads decreased from 2.5 to 1.3, and the mean number of urinary leaks decreased from 3.3 to 1.6, with significant improvement, and the effect was maintained at the 6-month follow-up [Korean J Fam Med. 2010].

This study also confirmed that symptom scores tended to improve and maintain after treatment in the experimental group compared to the control group. This finding suggests the need for a study with a larger number of patients and a more detailed study design, such as determining the effectiveness of the treatment according to the patient's symptoms.

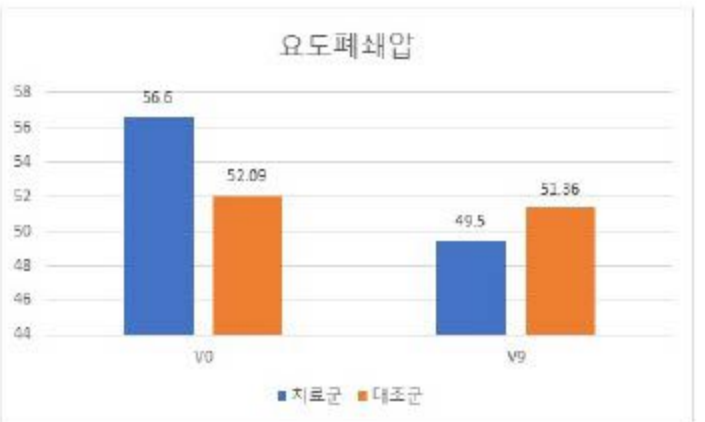
In conclusion, in the study of the effectiveness of pelvic floor muscle stimulation and strengthening by magnetic field stimulation in treating urinary incontinence, a trend of improvement in symptom scores was observed in the experimental group compared to the control group. Further studies with a larger number of patients are needed in the future.

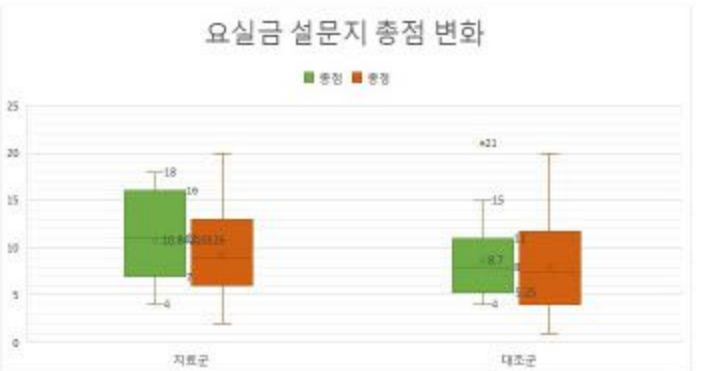
11. Tables, figures, and graphs not included in the text

11.1. Demographic information

Item	Group	N	Average	Standard deviation
Age	Experimental group	28	58.25	11.469
	Control group	29	62.66	10.083
	All	57	60.49	10.917

11.2. Validation materials





Item		Treatment group (21 people)	Control group (22 people)	p-Value
Age		59.9±12.2	63.4±10.1	0.23
Urethral closure pressure		64.2±29.1	59.6±24.7	0.51
Symptom Score	V0	11.3±4.4	8.8±4.3	0.03
	V8	9.24±4.42	7.45±5.13	0.23
	Symptom Score Change	1.09±2.54	0.73±2.81	0.66

11.3. Safety Data Sheet

Not applicable

12. References

1) Van Kerrebroeck P, Abrams P, Chaikin D, Donovan J, Fonda D, Jackson S, et al. *The standardization of terminology in nocturia: report from the standardization subcommittee of the International Continence Society.* BJU Int. J Psychiatry. 2002; 90(Suppl 3):11-5
2) Lee KS, Sung HH, Na, S, Choo MS. *Prevalence of urinary incontinence in Korean women: results of a National Health Interview Survey.* World J Urol. 2008; 26:179-85.
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4) Bo K, Talseth T, Holme I. *Single blind, randomized controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women.* BMJ 1999; 318:487-93
5) Galloway NT, El-Galley RE, Sand PK, Appell, Russell HW, Carlin SJ. *Update on extracorporeal magnetic innervation (EXMI) therapy for stress urinary incontinence.* Urology 2000;56(6 Suppl 1):82-6
6) Jong Bo Choi. *Urinary Incontinence in Women.* Korean J Fam Med. 2010; 31:661-671

13. Appendices

13.1. Clinical trial information: held by the conducting site

13.2. Patient materials list: kept by the site

13.3. Case notes: Retained by the performing organization

13.4. Individual patient data lists: held by the site