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Efficacy Confirmatory Study of Foods Containing *Garcinia indica* Extract on Liver Function: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study

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Abstract

Objectives: A randomized, double-blind, placebo-controlled, parallel-group study was conducted to evaluate the impact of foods containing *Garcinia indica* extract on liver function in healthy participants. **Methods:** Eighty healthy participants (alanine aminotransferase (ALT) ≤ 50 U/L, aspartate aminotransferase (AST) ≤ 50 U/L, gamma-glutamyl transferase (γ-GTP) ≤ 100 U/L, and body mass index < 30) were enrolled and randomly divided into two groups: the active group, who consumed food containing *G. indica* extract (18.0 mg/day of garcinol) for 12 weeks, and the placebo group, who consumed food without *G. indica* extract for the same duration. The primary outcome—the serum ALT and AST levels—was evaluated along with secondary outcomes, including γ-GTP and a Likert scale questionnaire on stool form. **Results:** There was a statistically significant difference in the ALT and AST levels ($P < 0.05$) between the active group and the placebo group. No adverse events attributable to the test foods were observed during the study period. Furthermore, the initial values of ALT and AST levels of the active group subjects in this study were slightly higher than the national average values reported in the 2019 National Health and Nutrition Survey published by the Ministry of Health, Labour and Welfare in Japan. **Conclusions:** Overall, these findings indicate that foods containing *G. indica* extract contributed to a slight reduction in ALT and AST levels, which, although within the normal range, were marginally elevated in healthy participants.

Keywords

Garcinia indica Extract, Garcinol, Liver Function, Liver Enzyme

1. Introduction

The liver is the largest organ in the human body and plays a vital role in maintaining biological functions such as glucose metabolism, fat metabolism, protein synthesis, and detoxification. The most common liver disease worldwide is MASLD (Metabolic Dysfunction-Associated Steatotic Liver Disease), an alternative name for NAFLD (Non-Alcoholic Fatty Liver Disease) [1]. Its prevalence has been increasing annually [2] [3]. In Japan, it has been reported that approximately 30% of adults are affected by MASLD [4]. Additionally, MASLD has been suggested to be correlated with ALT levels among liver function markers, and its association with metabolic syndrome-related conditions such as obesity and hypertension is well known [5] [6]. As MASLD progresses, it may lead to cirrhosis or liver cancer [7], and it is estimated that approximately 2 million people die annually from these liver diseases [8]. Therefore, maintaining liver health on a daily basis is considered important for maintaining and promoting overall health.

Furthermore, the "Standard Health Checkup and Health Guidance Program (2024 Edition)" issued by Japan's Ministry of Health, Labour and Welfare includes liver function tests as one of the basic examination items for specific health screenings. These tests use alanine aminotransferase (ALT), aspartate aminotransferase (AST), and gamma-glutamyl transferase (γ-GTP) [9]. The threshold values recommending a visit to a medical institution are set at 51 U/L or higher for both ALT and AST, and 101 U/L or higher for γ-GTP. Therefore, it is considered important to reduce these liver function enzyme levels and maintain them within the normal range.

Garcinia indica is a plant belonging to the Clusiaceae family and has a long history of use in Ayurveda, India's traditional medicine system [10]. In India, the fruit is still widely used as a sour spice in many dishes for its various health benefits [10], and the peel is used to make juice that is drunk in summer [11]. *Garcinia indica* extract is standardized to contain garcinol as its characteristic component, and anti-obesity effects have been reported in humans [12]. Additionally, continuous garcinol intake has been reported to reduce blood levels of liver function enzymes (ALT, AST) in animals [13], and exploratory studies have reported that continuous *Garcinia indica* extract intake reduces blood levels of liver function enzymes (ALT, AST) [14].

In this study, we developed a new tablet-form food product with *Garcinia indica* extract as the main ingredient. Focusing on the reported liver function enzyme (ALT, AST) value-improving effect of *Garcinia indica* extract in exploratory studies, we conducted a randomized, double-blind, placebo-controlled, parallel-group comparative trial targeting healthy adult men and women to verify whether the newly developed food containing *Garcinia indica* extract lowers liver function enzyme (ALT, AST) levels, which are indicators of liver function. We also evaluated levels of γ-GTP, another liver function enzyme, and conducted an exploratory assessment of stool form related to the reported intestinal microbiota-improving effects of garcinol in mice [15].

2. Materials and Methods

2.1. Study Participants and Setting

The participants were recruited as paid volunteers, and the investigator enrolled Japanese men and women who met the following inclusion criteria and did not violate the exclusion criteria. The subjects were given a full explanation of the details of the study prior to its start, and their written consent was obtained. The inclusion criteria were: 1) Healthy males and females aged 20 to 64 years old; 2) Subjects whose AST and ALT are up to 50 U/L, and γ-GTP are up to 100 U/L in the screening test; 3) Subjects whose BMI are less than 30; 4) Subjects who are judged not suffering from a disease by the investigator; 5) Subjects who can make self-judgment and are voluntarily giving written informed consent. The exclusion criteria were: 1) Subjects who regularly use medications; 2) Subjects who contract or are under treatment for serious diseases (e.g., liver disease, cardiovascular disease, respiratory disease, endocrine disease and/or metabolic disease); 3) Subjects who have a history and/or a surgical history of digestive disease affecting digestion and absorption; 4) Subjects who have a history of and/or contract drug addiction and/or alcoholism; 5) Subjects who have excessive alcohol intake more than approximately 60 g/day of pure alcohol equivalent or habit of drinking not less than 5 days a week; 6) Subjects who can't stop using supplements and/or functional foods (including Food for Specified Health Uses or Foods with Function Claims) during test periods; 7) Subjects who can't stop drinking from 2 days before each measurement; 8) Subjects who have declared allergic reaction to ingredients of test foods; 9) Subjects who are shiftworker and/or midnight-shift worker; 10) Subjects with extremely irregular dietary habits; 11) Subjects who plan to travel abroad, including overseas travel, during test periods; 12) Subjects who have been pregnant or have a plan to become pregnant, or breast feed during the study period; 13) Subjects who have donated over 200 mL of blood and/or blood components within the last 4 weeks prior to the current study or over 400 mL of blood and/or blood components within the last three months prior to the current study; 14) Subjects who are planning to participate and/or had participated in other clinical studies within the last one month prior to the current study; 15) Subjects who are judged as unsuitable for the current study by the investigator for other reasons.

This study was reviewed and approved by the "Ethical Committee of Kobuna Orthopedics Clinic" (Chairman: Toshio Kawada, approval date: 4 April 2024), in accordance with the "Declaration of Helsinki October 2013 WMA Fortaleza General Assembly (Brazil) Amendments" and "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" (enacted on 23 March 2021, partially amended on 27 March 2023), and was conducted under the supervision of physicians. This study was conducted at the Nihonbashi Cardiology Clinic. The research protocol for this study is registered in the clinical trial registration system operated by the University Hospital Medical Information Network Research Center, with registration ID UMIN000054362 (trial registration name: A Study on the Effect of Food Containing Plant Extract on Liver Function—A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study).

2.2. Research Methods

This study was conducted as a 13-week randomized, double-blind, placebo-controlled, parallel-group comparative trial (allocation ratio: 1:1) consisting of a pre-observation period (1 week) and an intake period (12 weeks), with no methodological changes after the start of the study. Using random numbers generated by a computer, the subjects were assigned to the two groups using a block randomization method (block size 4) with gender, age, ALT, AST, and γ-GTP as adjustment factors. The two groups were then assigned to the active group and the placebo group by a trial food assignment officer who was not directly involved in the study. Furthermore, the test food assignment officer created and sealed a table (key code) recording the assignment results, and kept it sealed until the analysis subjects were determined, thereby ensuring blindness to parties other than the test food assignment officer. The target sample size for this study was set at 40 participants per group (total of 80 participants) based on a previous exploratory study reporting an improvement in ALT levels due to the liver-function-improving effects of continuous intake of *Garcinia indica* [14].

Additionally, during the study period, participants were instructed to avoid using supplements or health foods, maintain the same lifestyle as before the study began, avoid excessive alcohol consumption, and refrain from participating in other trials. Furthermore, participants were instructed to avoid alcohol consumption for two days prior to all tests, to consume dinner by 9 PM on the day before all tests, to avoid strenuous exercise from the day before all tests until the end of the tests, and to avoid consuming anything other than water and refrain from smoking on the day of all tests. Participants were permitted to use medications only with the approval of the principal investigator or co-investigator, except in emergencies.

2.3. Consumption of Study Foods

During the consumption period, study subjects were given one packet (two tablets) of the study food (active food for the active group and placebo food for the placebo group) once a day with water or lukewarm water. The active food consisted of *Garcinia indica* extract (Sabinsa Japan Corporation, Tokyo), maltitol, cellulose, cocoa powder, calcium stearate, and silicon dioxide, and was tableted. The control food was formulated to be indistinguishable from the test food in appearance, with the *Garcinia indica* extract replaced with caramel color and the maltitol content adjusted. Both the test food and control food were designed for a daily intake of 250 mg × 2 tablets. The study food was packaged in plain aluminum bags containing two tablets each and distributed to the study subjects to ensure blinding for both the subjects and the intervention implementers.

The caloric and nutritional values per daily intake of the study food are shown in Table 1. The *Garcinia indica*-derived garcinol content in the active food was 18.0 mg per daily intake.

Table 1. Analysis value of nutrient composition for test food.

	Placebo (2 tablets)	Active (2 tablets)
Energy (kcal)[a]	1.0	1.0
Protein (g)[b]	0.0	0.0
Fat (g)	0.0	0.0
Carbohydrate (g)	0.2	0.2
Salt equivalent (g)	0.000	0.000

[a]Calorie conversion factor: protein, 4; fat, 9; carbohydrate, 4. [b]Nitrogen-to-protein conversion factor: 6.25.

2.4. Evaluation Items

The primary evaluation items were ALT and AST, and the secondary evaluation items were γ-GTP and a Likert scale questionnaire regarding stool form. ALT, AST, and γ-GTP were evaluated four times: before intake, 4 weeks after intake, 8 weeks after intake, and 12 weeks after intake. Stool form was evaluated twice, excluding 4 weeks and 8 weeks after intake, using a 7-point Likert scale (1-hard stool, 2-firm stool, 3-slightly firm stool, 4-normal stool, 5-slightly soft stool, 6-muddy stool, 7-watery stool) for the stool sample closest to each test date. No changes in outcomes were observed after the start of the study.

Study participants were provided with a food diary and a participant diary, and were instructed to record the following items daily from one week prior to the start of consumption through the consumption period: 1) research food intake status, 2) presence or absence of changes in physical condition, 3) presence or absence of changes in living conditions, 4) presence or absence of menstruation (women only), 5) bedtime, 6) use of medications (prescription drugs, newly designated over-the-counter drugs, newly classified over-the-counter drugs), and 7) meal content (including beverages).

2.5. Statistical Analysis

The analysis population was defined as the per-protocol set (PPS). Repeated measures analysis of variance was performed for ALT, AST, and γ-GTP to confirm the interaction between groups and time points. In addition, group comparisons were performed using independent t-tests for each test for the measured values and changes from before intake. For the Likert scale questionnaire regarding stool form, group comparisons were performed using the Mann-Whitney U test. All tests were two-sided with a significance level of 5%. Statistical analysis was performed using IBM SPSS Statistics 28. Participant background data were presented as mean ± standard deviation, and other data were presented as mean ± standard error. No additional analyses were performed.

3. Results

3.1. Study Participants

A total of 80 participants (52 men and 28 women) were enrolled in this study. There were no dropouts after randomization, and the study was initiated with 80 participants, with 40 participants in each group receiving the assigned intervention. During the study period, one participant (female) in the active group was excluded due to meeting the discontinuation criteria, resulting in a total of 79 participants completing the study. Additionally, after the study ended, seven participants were found to meet the exclusion criteria, resulting in 72 participants (47 males and 25 females; four in the placebo group and three in the active group) being included in the analysis. Note that the analysis was conducted according to the original allocation for each group.

The period from recruitment of study participants to completion of follow-up was from May 2024 to September 2024, and the study was concluded upon completion of follow-up for all cases. Table 2 shows the background of the study participants included in the analysis, and Figure 1 shows a flowchart illustrating the process from enrollment to analysis.

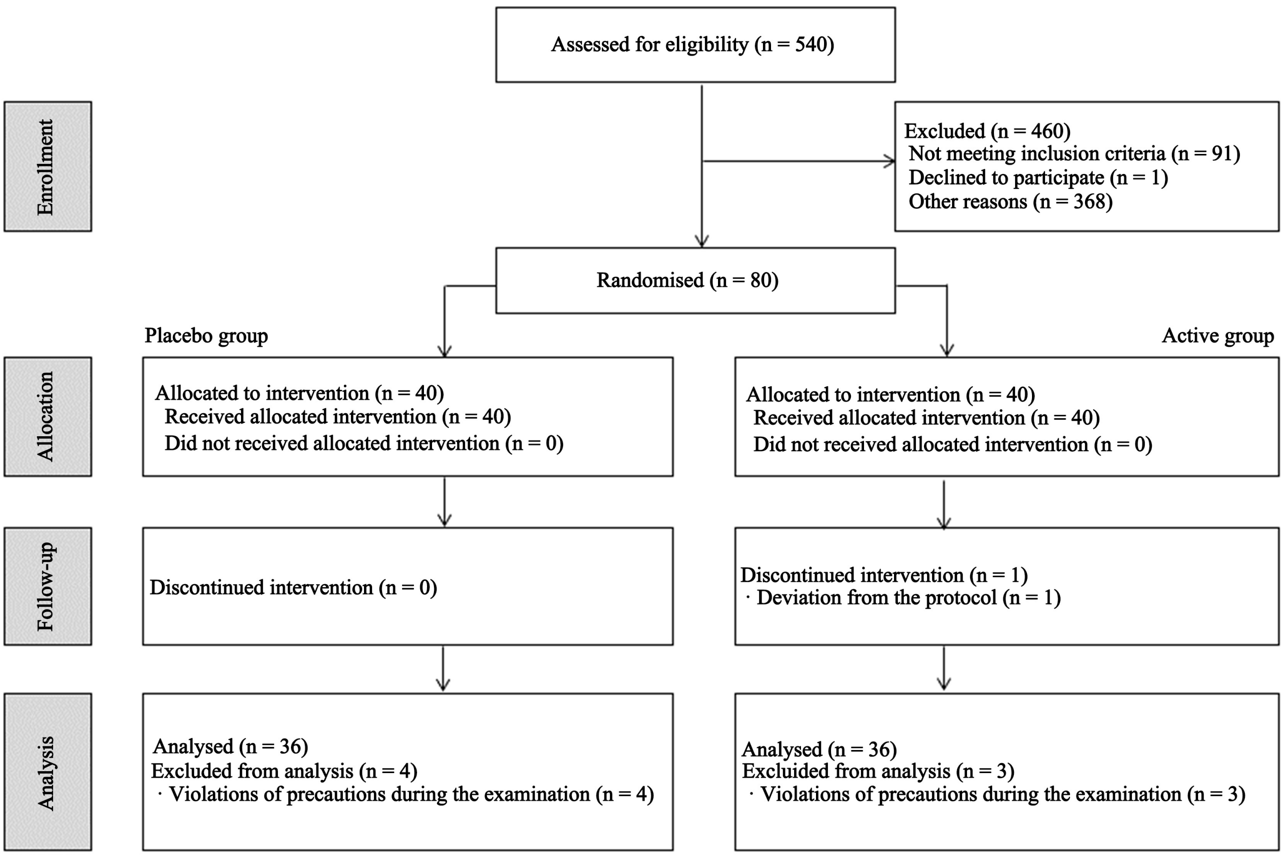

Figure 1. Flow diagram of progress through phases of the randomized, double-blind, placebo-controlled, parallel-group study.

Table 2. Subject characteristics.

	Placebo (n = 36)	Active (n = 36)
Age (years)	48.0 ± 10.0	47.6 ± 9.6
Sex (male/female)	24/12	23/13
Height (cm)	167.0 ± 7.6	167.9 ± 8.1
Weight (kg)	65.8 ± 8.1	65.5 ± 11.0
BMI (kg/m^2)	23.6 ± 2.5	23.1 ± 2.5
ALT (U/L)	27.5 ± 6.8	26.9 ± 6.2
AST (U/L)	24.8 ± 4.6	25.3 ± 5.1
γ-GTP (U/L)	38.0 ± 21.9	36.4 ± 21.7

Values are expressed as means ± SDs. No significant difference was observed.

3.2. Analysis Results

The results of the analysis of liver function enzymes (ALT, AST, and γ-GTP) are presented in Table 3. An interaction was observed for ALT and AST. Upon conducting intergroup comparisons for each test regarding the actual measured values and the changes from before intake, significantly lower values were noted in the active group compared to the placebo group at 12 weeks post-intake for both ALT and AST (ALT $P = 0.036$, AST $P = 0.044$). Additionally, significant reductions were also observed in the changes in ALT and AST values at 12 weeks post-intake in the active group compared to the placebo group (ALT $P = 0.036$, AST $P = 0.010$). No interaction was observed for γ-GTP.

Table 3. Post-intervention changes in each liver function parameter.

Domain	Group		Baseline	4 Weeks	8 Weeks	12 Weeks	*P*-value (interactions between groups and time points)
ALT (U/L)	Placebo (n = 36)	Measured	27.5 ± 1.1	24.7 ± 2.0	22.4 ± 1.0	26.9 ± 1.6	$P = 0.022$
		Changes from baseline		−2.9 ± 2.0	−4.9 ± 1.4	−0.6 ± 1.4	
	Active (n = 36)	Measured	26.9 ± 1.0	22.9 ± 1.5	25.3 ± 2.3	22.4 ± 1.3*	
		Changes from baseline		−4.0 ± 1.2	−1.7 ± 2.0	−4.5 ± 1.1*	
AST (U/L)	Placebo (n = 36)	Measured	24.8 ± 0.8	23.7 ± 1.1	21.8 ± 0.8	23.8 ± 1.3	$P = 0.044$
		Changes from baseline		−1.1 ± 1.2	−2.9 ± 0.9	−1.0 ± 1.1	
	Active (n = 36)	Measured	25.3 ± 0.8	22.8 ± 1.1	21.9 ± 1.1	20.6 ± 0.9*	
		Changes from baseline		−2.5 ± 1.0	−3.4 ± 1.1	−4.7 ± 0.9*	
γ-GTP (U/L)	Placebo (n = 36)	Measured	38.0 ± 3.6	36.4 ± 4.5	37.0 ± 4.0	41.5 ± 4.3	$P = 0.15$
		Changes from baseline		−1.6 ± 2.3	−1.6 ± 2.0	3.5 ± 2.4	
	Active (n = 36)	Measured	36.4 ± 3.6	32.5 ± 3.2	37.6 ± 4.6	35.9 ± 4.0	
		Changes from baseline		−3.9 ± 1.2	1.3 ± 2.2	−0.5 ± 1.7	

Values are expressed as means ± SEs. *Significantly different from the placebo group ($P < 0.05$). After eight weeks of intake, data will be aggregated excluding any missing entries.

The results of the Likert scale questionnaire on stool form are shown in **Table 4**. No significant differences were found in the Likert scale questionnaire regarding stool form.

Table 4. Post-intervention changes in stool form.

Domain	Group		Baseline	12 Weeks
Stool form	Placebo (n = 36)	Measured	4.0 ± 0.2	4.0 ± 0.1
		Changes from baseline		−0.1 ± 0.2
	Active (n = 36)	Measured	3.9 ± 0.2	3.8 ± 0.1
		Changes from baseline		−0.1 ± 0.2

Values are expressed as means ± SEs.

3.3. Adverse Events

No serious adverse events were observed during the study period. All events were deemed by the principal investigator to have no causal relationship with the study food.

4. Discussion

In this study, to investigate the liver function-improving effects of a food containing *Garcinia indica* extract, a randomized, double-blind, placebo-controlled, parallel-group comparative trial was conducted in healthy adult men and women aged 20 to 64 years, who were administered either the active food (containing *Garcinia indica* extract) or the placebo food (without *Garcinia indica* extract) once daily for 12 consecutive weeks. The study participants were healthy adult men and women whose liver function enzyme levels (ALT, AST, and γ-GTP) were confirmed to be below the recommended screening values set by the Ministry of Health, Labour and Welfare [9]. As a result, significant differences were observed in the measured values of ALT and AST after 12 weeks of consumption and in the changes from baseline, with the active group showing lower values compared to the placebo group.

This study targeted healthy adult men and women whose liver function enzyme (ALT, AST, and γ-GTP) values were below the recommended screening threshold. The mean values before intake in the active group were 26.4 U/L for ALT and 25.1 U/L for AST. According to The National Health and Nutrition Survey in Japan, 2019, published by the Ministry of Health, Labour and Welfare, the national average values for adults are 22.2 U/L for ALT and 24.4 U/L for AST [16]. Therefore, the ALT and AST values of the subjects in this study were slightly higher than the national average values.

Therefore, the results of this study suggest that the consumption of foods containing *Garcinia indica* extract may be able to slightly reduce elevated ALT and AST levels within the normal range in healthy individuals.

The function of lowering ALT and AST levels observed in this study is thought to be due to garcinol in *Garcinia indica* extract. Garcinol extracted from *Garcinia indica* has been reported to inhibit the production of tumor necrosis factor (TNF-*α*), an inflammatory cytokine, and reduce ALT and AST levels in rat studies [17], as well as protect liver tissue and reduce ALT and AST levels in mouse studies [13]. Therefore, Garcinol extracted from *Garcinia indica* is thought to suppress ALT and AST levels by inhibiting TNF-*α* production and suppressing inflammation and damage in the liver. The sample size in this study was calculated based on the effect size confirmed in previous exploratory studies, and the study was conducted on a larger scale [14]. In this study, similar to the exploratory study, significant reductions in both ALT and AST were observed, consistent with previously reported results.

From the above, it is considered that garcinol derived from *Garcinia indica* suppresses inflammation and damage in the liver, thereby reducing slightly elevated ALT and AST levels in healthy individuals within the normal range.

As mentioned earlier, while significant differences were observed for ALT and AST, no interaction was observed for *γ*-GTP. ALT and AST are indicators of liver function and are likely the most commonly used in both clinical diagnosis and liver damage research [18]. Unlike ALT and AST, which primarily increase due to hepatocyte damage, *γ*-GTP levels are not specific to hepatocyte damage and have been shown to increase in various conditions [19]. Therefore, it is possible that no effect was observed for *γ*-GTP, which may increase due to complex factors.

Additionally, no significant differences were observed in the Likert scale questionnaire on stool form. In this study, the pre-consumption values of the Likert scale questionnaire on stool form were close to 4, which indicates normal stool consistency, for both the active group and the placebo group. Therefore, it is possible that the Likert scale questionnaire used in this study was unable to detect subtle changes in stool consistency, and thus was unable to appropriately evaluate the improvement in stool consistency resulting from the consumption of foods containing *Garcinia indica* extract.

In this study, the safety of *Garcinia indica* extract was confirmed. No adverse events attributable to the intake of foods containing *Garcinia indica* extract were observed, suggesting that long-term intake of food products containing *Garcinia indica* extract is safe.

However, this study has several limitations. This study targeted individuals with ALT ≤ 50 U/L, AST ≤ 50 U/L, *γ*-GTP ≤ 100 U/L, and a BMI below 30. Therefore, the effects on individuals with ALT ≥ 51 U/L, AST ≥ 51 U/L, *γ*-GTP ≥ 101 U/L, a BMI of 30 or higher, or those with MASLD remain unclear. Future research should study the effects of *Garcinia indica* extract on liver function improvement in a broader range of subjects and confirm these effects. Furthermore, although this study involved the consumption of foods containing *Garcinia indica* extract for 12 weeks, the effects of longer-term consumption remain unknown. Therefore, it is considered a research topic to confirm the effects of longer-term consumption of *Garcinia indica* extract on liver function improvement.

5. Conclusion

Foods containing *Garcinia indica* extract were shown to lower slightly elevated ALT and AST values within the normal range in healthy individuals. Maintaining a healthy liver function daily is considered important for overall health. Therefore, *Garcinia indica* extract may be useful as a food ingredient that helps keep liver function enzymes (AST, ALT) levels within a healthy range.

Authors' Contributions

Conceptualization: T.K. and K.T.; methodology: Y.H. and N.M.; validation: S.M.; formal analysis: N.O. and S.M.; investigation: Y.H.; writing—original draft preparation: S.M. and Y.U.; writing—review and editing: K.F.; visualization: Y.U.; supervision: K.T. and Y.I.; project administration: T.O. and T.K. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethical Committee of Kobuna Orthopedics Clinic (approval date: 4 April 2024; approval number: MK-2404-01).

Informed Consent Statement

Informed consent was obtained from all participants involved in the study.

Data Availability Statement

The data used in this manuscript are not publicly available because of commercial restriction, but are available on reasonable request.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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