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Research Article

Single-Arm Feasibility Trial to Assess the Technical/Medical Performance and Safety of Locally Applied Frequency Therapy in Patients with Knee Osteoarthritis (OA)

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Abstract

Background: The "e.CHI FrequencyChip" device is based on the idea that each molecule and structure has a unique radiation spectrum of frequencies and vice versa electromagnetic waves have an influence on them. The device is designed to be attached to the skin at the affected area. Specific frequencies influence the natural magnetic field of the tissue and therefore activates cell regeneration and brings disturbed processes back into order. This mechanism's effectiveness is currently being investigated in the context of knee osteoarthritis, a prevalent condition.

Objectives: The study was designed to evaluate the performance and safety of the "e.CHI FrequencyChip" device in the treatment of patients with osteoarthritis of the knee.

Methods: In a prospective, single-arm, multicentre interventional therapeutic trial with a calculated sample size of 24 patients with confirmed osteoarthritis of the knee, an "e.CHI FrequencyChip" device for magnetic field frequency therapy was applied to the skin at the affected area for 24 hours a day for 3 months.

Outcomes were measured using the Patient's Assessment (average pain, maximum pain, pain at rest) on the Numeric Rating Scale (NRS) (0-10), KOOS (Knee Injury and Osteoarthritis Outcome Score), PDI (Pain Disability Index) and questionnaire (Western Ontario and McMaster Universities Osteoarthritis Index) at baseline, week 6 and week 12.

Results: The results from all measurements and time points are statistically significant and consistently demonstrate a trend of improvement from week 6 to week 12.

Conclusion: The "e.CHI FrequencyChip" device utilised for magnetic field frequency therapy has been demonstrated to be both safe and effective in the treatment of knee osteoarthritis.

Keywords: Knee Osteoarthritis; Knee Pain; Local Magnetic Field Frequency Therapy; Novel Treatment

Introduction

Background

Osteoarthritis of the knee is a prevalent disease in adults, with a prevalence ranging from 27 to 90% across different studies. In the 'Study on the Health of Adults in Germany' (DEGS1), a survey and investigation study by the RKI [1], 20.2% of all respondents between the ages of 18 and 79 stated that they had medically diagnosed osteoarthritis (women 22.3%, men 18.1%) (www.rki.de/geda). This finding underscores the significant socio-medical implications of osteoarthritis. In the 50-54 age group, 15-16% exhibited radiological signs of knee osteoarthritis; in the 70-74 age group, the figure increased to 36-40% [2].

By the age of 80, the prevalence of radiographic Osteoarthritis (OA) rises to 33% in men and 53% in women. However, the prevalence of clinical symptoms of radiographically proven knee osteoarthritis is lower, and is estimated to be between 10% and 15% [3].

Rationale

The functioning of living organisms is equally dependent on bio-chemical and biophysical regulatory processes. Recent technological advancements, particularly in the domains of metrology and computing, have facilitated a more profound comprehension of the impact of physical (particularly electromagnetic) impulses on biological systems. A substantial body of research has demonstrated the impact of electromagnetic (EM) fields at the cellular, immunological and organological levels [4].

Furthermore, it has been demonstrated that organic substances generate different EM fields, with correspondingly different frequency spectra and frequency patterns. Conversely, EM fields exhibiting specific frequency patterns can exert varied effects on organic systems. The employment of a specially developed storage medium, designated as the 'e.CHI FrequencyChip', facilitates the continuous emission of these frequencies to neighbouring structures through simple application to the skin. The memory chip is composed of quartz mixtures

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loaded with specific frequencies and formulated for medical applications, and silicone, with magnetic particles affixed to the surface. The positive effect of the 'e.CHI FrequencyChip' has already been demonstrated in vitro on neutrophils. A statistically significant ($p<0.05$) increase in cell number, cell size, cell metabolism and the production of superoxide anion radicals was observed [5].

The therapeutic potential of high energy EM fields in osteoarthritis patients is adequately documented in the literature and supported by a recent systematic review [6].

Nevertheless, the efficacy of a user-friendly method employing an adhesive 'e.CHI FrequencyChip' storage medium in reducing pain and enhancing general health remains to be demonstrated.

Objectives

The aim of this study is to perform a statistical evaluation of the technical/medical performance and safety of the "e.CHI FrequencyChip" device for magnetic field frequency therapy in patients with osteoarthritis of the knee.

Patients and Methods

Trial design

This therapeutic, investigator-initiated trial was designed as a prospective, single-armed, open-label, multi-center, interventional clinical study without a statistical interim analysis and with a calculated sample size of 24 patients. An "e.CHI FrequencyChip" device for magnetic field frequency therapy was applied to the skin in the area of pain for 24 hours a day for 3 months.

After the study start no important changes to methods were introduced. However, when checking the data for consistency before statistical analysis, we found that some exclusion criteria were met. Despite the exclusion criterion "BMI>35 (obesity grade II)", 3 patients with a higher BMI were included (35.4, 38.6 and 38.8 (kg/m2)). In addition, we exceeded the exclusion criterion of "disease duration of more than 5 years" in 11 patients, in some cases more than 20 years, resulting in a high mean value as shown in Table 2a. Another exclusion criterion was "average pain intensity within the last 3 days of at least 5 out of 10 points on the 11-point NRS". Also for this variable, when checking the data by frequency table, we found that 9 patients reported a lower value at baseline (1 point: 1 patient; 2 points: 2 patients; 3 points: 4 patients; 4 points: 2 patients). All patients reported that they avoided any activities provoking pain during exercises and afterwards at rest. Therefore, their pain levels were reported low, although suffering for a long time and being limited.

As these protocol violations increase variability and tend to worsen rather than improve study results, we decided to include these patients in the analysis and make the violation transparent.

Participants

The study was conducted from December 2023 to December 2024 as a multi-center study at three different sites in Austria: Vienna, Brunn am Gerbirge and Innsbruck. All eligible male and female patients aged 18-80 years with a confirmed diagnosis of osteoarthritis of the knee who presented themselves at the study centre were offered participation in the study. Only patients with Kellgren-Lawrence (KL) grade II-III osteoarthritis of the knee confirmed by imaging (knee radiographs) not older than 3 months were included. Further inclusion and exclusion criteria are given in table 1.

Inclusion Criteria
• confirmed diagnosis: osteoarthritis of the knee
• diagnosis confirmed with imaging procedures (X-ray knee) not older than 3 months
• grade II to III Kellgren-Lawrence score
• average pain intensity within the last 3 days of at least 5 out of 10 points on the 11-point NRS
• duration of illness ≥ 6 weeks
• age 18 to 80 years
• sufficient communication skills
• the patient must be able to recognize the nature, significance and scope of the clinical trial and to align his/her will accordingly
Exclusion Criteria
• BMI>35 (obesity grade II)
• duration of illness longer than 5 years
• indication for a knee joint endoprosthesis
• for women: Pregnancy
• participation in another intervention study within the last 30 days before the start of therapy
• current pension applications
• pacemaker
• previous magnetic field frequency therapy using the "e.CHI FrequencyChip" on the affected knee in the last year
• any kind of injection into the affected knee joint within the last 12 weeks before the start of therapy (e.g. with cortisone, hyaluronic acid, etc.)
• taking systemic pain medication within the last 24 hours before the start of therapy
• taking systemic cortisone preparations within the last 12 weeks before the start of therapy
• taking opiates within the last 6 months before the start of therapy
• any operations including arthroscopy on the knee joint to be treated in the last 3 months
• any history of fractures close to the knee joint to be treated
• any history of systemic or inflammatory joint disease (e.g. rheumatoid or autoimmune arthritis or Reiter's disease)
• gout
• pain syndromes of other origins (lumboischialgia, hip joint pain, etc.)
• spinal cord syndromes (e.g. radiculitis)
• nerve compression syndromes of the lower extremities
• organic brain psychosyndom
• alcoholism
• addiction to painkillers, drugs or opiates
• local infections
• peripheral neuropathy
• renal disease requiring dialysis
• known diabetes mellitus
• arterial or venous occlusive disease of the lower extremities
• lymphoedema in the area of the affected joints
• other medical reasons as decided by the study physician.

Table 1: Inclusion and Exclusion criteria.

Interventions

An "e CHI FrequencyChip" device for frequency therapy was applied to the skin in the area of pain for 24 hours. The intentionally induced hormetic disturbances of the electromagnetic field of humans is created through specific and individually imprinted frequencies on the chip. By this an interference between the human body and the e CHI is possible. Its main effects take place on the skin side where the chip is placed (Figure 1).

Figure 1: An "e.CHI FrequencyChip" device glued to the lateral knee joint.

Outcomes

All outcomes were measured at baseline, month 1 and month 3.

Main outcomes were measured using the Patient's Assessment of Arthritis Pain in the last week (average pain, maximum pain, pain at rest) on the Numeric Rating Scale (NRS) (0–10) [7].

Next outcomes were measured using the Knee Injury and Osteoarthritis Outcome Score (KOOS). The KOOS was developed by Roos and colleagues to assess patients' opinions about their knee and related problems [8,9]. The KOOS consists of 42 questions divided into five subscales: Pain (9 questions), Symptoms (7 questions), Activities of Daily Living (ADL) (17 questions), Sport/Recreational Function (5 questions), Knee-related Quality of Life (4 questions). For the KOOS, all scores are read: low values = high symptoms; high values = low symptoms.

Other outcomes were measured using the Pain Disability Index (PDI) [10]. The PDI measures the subjective level of impairment caused by pain in everyday life. It is based on a multidimensional concept of pain-related disability and the WHO (1980) distinction between the consequences of disease and injury. Seven areas of life are covered: (1) family/domestic responsibilities, (2) leisure, (3) social activities, (4) work, (5) sex life, (6) self-care and (7) essential activities.

On an 11-point rating scale, anchored verbally at 0 = 'no impairment' and 10 = 'total impairment', the patient rates the typical level of impairment.

As primary outcome we chose Patient's Assessment of Arthritis Pain in the last week (average pain) by Numeric Rating Scale (NRS) (0–10) [7]: Statistical analysis of intra-individual differences between baseline and month 3 values.

Secondary evaluation criteria are all other evaluation measurements of Patient's Assessment of Arthritis Pain, KOOS sub-domains and scales of the Pain Disability Index (PDI) at each time point listed above. Safety was assessed based on the adverse event form.

Sample Size

Sample size calculation was based on the primary outcome.

For the primary outcome, a two-sided test problem was established: H0: $\mu=0$ versus H1: $\mu \neq 0$, where μ denotes the mean of the intraindividual difference in values between baseline and month 3.

Therapeutic effectiveness was considered clinically relevant with a mean in the primary endpoint of at least $\Delta/\sigma=0.6$. The test was performed at a two-sided global significance level of $\alpha = 0.05$.

A minimum sample size of 24 evaluable patients is required to demonstrate a significant therapeutic effect in the primary statistical analysis using the paired t-test with 80% power.

A drop-out rate of 10% was assumed. As a result, a total of 28 patients were included in the study.

Statistical methods

Statistical analyses were performed using descriptive techniques (i.e. frequency tables, means, standard deviations, effect sizes) and inferential analyses using appropriate significance tests and confidence intervals.

Missing values in the KOOS questionnaire were imputed according to the KOOS guidelines. Probabilities for continuous data were calculated using a two-tailed Wilcoxon signed-rank test. All tests were performed with a global significance level of $\alpha=0.05$ and the null hypothesis that the mean effect is 0.

The statistical analysis of the primary and secondary endpoints was performed according to the principle of the Full Analysis Set (FAS). This population includes all trial participants who have at least one measure of the effectiveness of the primary outcome after treatment. Results were interpreted on a confirmatory basis. Safety was assessed exploratively. Statistical analysis was performed using SPSS version 25.0.

Results

Participant flow (Figure 2)

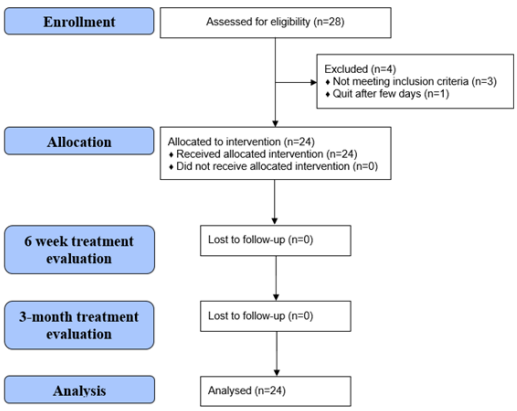

Figure 2: CONSORT Flow Diagram showing enrollment, allocation, timepoints of treatment evaluation and participants included in statistical analysis.

Recruitment

From December 2023 to September 2024, 28 patients were assessed for eligibility. Of these, 3 patients did not meet the inclusion or exclusion criteria and 1 patient refused to participate in the study. As a result, 24 patients were assigned to treatment and enrolled in the study. All of these patients completed the full course of treatment.

Baseline data

Baseline data for demographics, and pre-existing conditions are showed in tables 2a and 2b.

Evaluation characteristics		Measurements
	n	mean ± SD (95% CI of mean)
Height (cm)	24	177.6 ± 10.58 (173.2 to 182.1)
Body weight (kg)	24	91.50 ± 21.08 (82.6 to 100.4)
BMI (kg/m2)	24	28.73 ± 4.7 (26.74 to 30.72)
Age (years)	24	52.50 ± 11.17 (47.79 to 57.22)
Duration of disease (years)	24	10.50 ± 10.05 (6.26 to 14.74)

Table 2a: Demographic characteristics, and pre-existing conditions (mean ± SD).

n: total number of cases; CI: confidence interval; SD: standard deviation

Description of population	n (%)
Total	24 (100)
Gender	
Female	8 (33.33)
Male	16 (66.67)
Knee joint	
Left	15 (62.50)
Right	9 (37.50)
BMI (kg/m2) (Classified groups)	
Normal	6 (25.00)
Overweight	10 (41.67)
Obese Class I & II	8 (33.33)
Smoking status	
No	12 (50.00)
Yes	4 (16.67)
Ex	7 (29.17)
Missing	1 (4.17)
Disease trigger	
Professional activities	2 (8.33)
Sports activities	15 (62.50)
Unknown	7 (29.17)
Pain assessment: Average at baseline (Classified)	
0 -3	7 (29.17)
4 -6	8 (33.33)
7 -10	9 (37.50)

Table 2b: Demographic characteristics, and pre-existing conditions (frequencies).

n: total number of cases

All outcome measurements at baseline, week 6 and week 12 including differences from baseline are shown in tables 3a & 3b.

Primary Outcome

Change in Patient's Assessment of Arthritis Pain in the last week (average pain) by Numeric Rating Scale (NRS) from baseline to 6 and 12 weeks: A statistical analysis of the NRS (average pain) demonstrates a mean improvement of 2.13 points after 6 weeks. This provides an effect size of 1.12 (p=0.0001). Subsequent to 12 weeks, the improvement increases to 3.08 points, thereby enhancing the effect size to 1.40 (p=0.0001) (Table 3a).

Secondary Outcome

Change in Patient's Assessment of Arthritis Pain in the last week (maximum pain) and (pain at rest) by Numeric Rating Scale (NRS): A comparison of the average pain results with the maximum pain results also shows a similar confirmation of the improvement at week 6 with an effect size of 1.17 (p=0.0001) and again a larger improvement at week 12 with an effect size of 1.51 (p=0.0001) (Table 2a).

The findings pertaining to the pain at rest variable are comparatively inferior to those of the other two variables. However, it should be noted that these results are statistically significant, too. The effect size is 0.7 (p=0.0038) after six weeks and 1.19 (p=0.0002) after 12 weeks. A similar trend of increasing improvement from week 6 to week 12 is also evident in this data (Table 3a).

Evaluation characteristics		Measurements		Difference to Baseline		
	n	mean ± SD (95% CI of mean)	n	mean ± SD (95% CI of mean)	Effect Size*	p-value**
Pain assessment: Average						
Baseline	24	5.54 ± 2.48 (4.49 to 6.59)				
Week 6	24	3.42 ± 2.30 (2.45 to 4.39)	24	-2.13 ± 1.90 (-2.93 to -1.33)	-1.12	0.0001
Week 12	24	2.46 ± 1.91 (1.65 to 3.27)	24	-3.08 ± 2.21 (-4.01 to -2.15)	-1.40	0.0001
Pain assessment: Maximum						
Baseline	24	6.96 ± 2.14 (6.06 to 7.86)				
Week 6	24	4.50 ± 2.54 (3.43 to 5.57)	24	-2.46 ± 2.11 (-3.35 to -1.57)	-1.17	0.0001
Week 12	24	3.54 ± 2.17 (2.63 to 4.46)	24	-3.42 ± 2.26 (-4.37 to -2.46)	-1.51	<0.0001
Pain assessment: Pain at rest						
Baseline	24	3.75 ± 2.15 (2.84 to 4.66)				
Week 6	24	2.29 ± 2.12 (1.40 to 3.19)	24	-1.46 ± 2.08 (-2.34 to -0.58)	-0.70	0.0038
Week 12	24	1.46 ± 1.79 (0.70 to 2.22)	24	-2.29 ± 1.92 (-3.10 to -1.48)	-1.19	0.0002

Table 3a: Pain assessment: All outcome measurements at baseline, week 6 and week 12 including differences from baseline.

* Cohen's d: Cohen's measure of sample effect size within group

**probability value of Wilcoxon signed-rank test (2-sided)

n: total number of cases; CI: confidence interval; SD: standard deviation

Knee Injury and Osteoarthritis Outcome Score (KOOS): The results from all KOOS subdomains and time points are statistically significant and consistently demonstrate a trend of improvement from week 6 to week 12, with an enhancement of between at least 9.92 points and 16.26 points after 6 weeks and between 19.09 and 27.86 points after 12 weeks. The subdomain Quality of Life demonstrated the most substantial improvement, while the subdomain Sport/Recreation exhibited the least improvement, with an effect size of 0.45 (p=0.0146). A statistical analysis of the KOOS Pain Sum score revealed a mean improvement by 13.96 after 6 weeks, resulting in an effect size of 0.83 (p=0.0012). Subsequent to 12 weeks, the improvement increases by 22.78 points, thereby enhancing the effect size to 1.18 (p=0.0001) (Table 3b).

Evaluation characteristics		Measurements		Difference to Baseline		
	n	mean ± SD (95% CI of mean)	n	mean ± SD (95% CI of mean)	Effect Size*	p-value**
KOOS Pain Sum score						
Baseline	24	53.17 ± 18.87 (45.20 to 61.14)				
Week 6	24	67.17 ± 17.09 (59.95 to 74.38)	24	13.96 ± 16.79 (6.87 to 21.05)	0.83	0.0012
Week 12	23	76.22 ± 19.89 (67.62 to 84.82)	23	22.78 ± 19.27 (14.45 to 31.12)	1.18	0.0001
KOOS Symptoms Sum score						
Baseline	24	53.54 ± 19.12 (45.47 to 61.61)				
Week 6	24	63.63 ± 20.64 (54.91 to 72.34)	24	9.92 ± 19.61 (1.64 to 18.20)	0.51	0.0248
Week 12	23	73.17 ± 21.05 (64.07 to 82.28)	23	19.09 ± 20.51 (10.22 to 27.96)	0.93	0.0024
KOOS ADL Sum score						
Baseline	24	63.08 ± 17.51 (55.69 to 70.48)				
Week 6	24	78.17 ± 12.87 (72.73 to 83.60)	24	15.04 ± 13.93 (9.16 to 20.92)	1.08	0.0001
Week 12	23	84.17 ± 15.79 (77.35 to 91.00)	23	20.70 ± 17.23 (13.25 to 28.15)	1.20	0.0001
KOOS Sport/Recreation Sum score						
Baseline	24	39.83 ± 24.85 (29.34 to 50.33)				
Week 6	23	52.44 ± 20.89 (43.40 to 61.47)	23	11.48 ± 25.37 (0.51 to 22.45)	0.45	0.0146
Week 12	22	62.09 ± 23.06 (51.87 to 72.32)	22	20.46 ± 21.43 (10.95 to 29.96)	0.95	0.0013
KOOS Quality of Life Sum score						
Baseline	24	36.42 ± 20.20 (27.89 to 44.95)				
Week 6	23	51.74 ± 22.02 (42.22 to 61.26)	23	16.26 ± 12.07 (11.04 to 21.48)	1.35	0.0001
Week 12	22	64.32 ± 24.40 (53.50 to 75.14)	22	27.86 ± 15.88 (20.82 to 34.91)	1.75	0.0001

Table 3b. KOOS: All outcome measurements at baseline, week 6 and week 12 including differences from baseline.

* Cohen's d: Cohen's measure of sample effect size within groups

**probability value of Wilcoxon signed-rank test (2-sided)

n: total number of cases; CI: confidence interval; SD: standard deviation

Exploratory Outcome

Treatment evaluation: The overall response to the therapy was positive, with more than 75% of patients rating it as excellent or good after six weeks. After a period of 12 weeks, the proportion of patients who rated the therapy as excellent increased from 54.17% to 66.66%.

Conversely, at both time points, 8.66% of patients rated the therapy as poor or no response. The exact results are presented in figure 3.

In table 4 the most specified standard care procedures and their experiences are listed. The reduction in load was met with a favorable response. The implementation of physiotherapeutic measures was found to be average. For all other procedures (not listed in table 4) either no experience was reported or the improvement tended to be manageable.

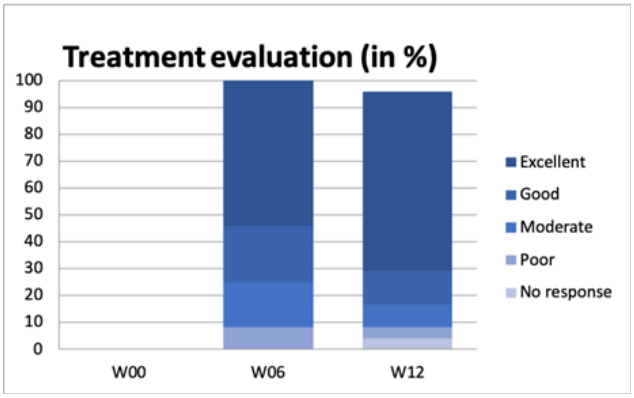

Figure 3: Treatment evaluation (in %) of "e.CHI FrequencyChip" at week 6 and week12.

Therapy evaluation	Load reduction	NSAR	Cooling	Physio-therapy
	n (%)	n (%)	n (%)	n (%)
Total	24 (100)	24 (100)	24 (100)	24 (100)
Excellent	0 (0,00)	0 (0,00)	0 (0,00)	1 (4.17)
Good	9 (37.50)	5 (20.83)	2 (8.33)	3 (12.50)
Moderate	4 (16.67)	4 (16.67)	7 (29.17)	3 (12.50)

Poor	1 (4.17)	0 (0,00)	4 (16.67)	3 (12.50)
No response	0 (0,00)	1 (4.17)	2 (8.33)	0 (0,00)
Unknown	10 (41.67)	14 (58.33)	9 (37.50)	14 (58.33)

Table 4: Assessment of selected previous treatment experience: Load reduction, NSAR, cooling and physiotherapy.

Exploratory Outcome

Sports activities: The proportion of sporting activity at 6 weeks was similar to baseline, but by week 12, the proportion of 'current participation in sport, but not in the sport of choice' and 'current participation in the sport of choice, but not at pre-injury levels' improved from 62.50% to 87.5%. The exact results are presented in table 5.

	Baseline	Week 6	Week 12
Sports activities	**n (%)**	**n (%)**	**n (%)**
Total	**-**	**24 (100)**	**24 (100)**
No sport before injury	1 (4.17)	1 (4.17)	0 (0.00)
No current sport due to injury	7 (29.17)	7 (29.17)	2 (8.33)
Current participation in sport, but not in the desired sport	8 (33.33)	6 (25.00)	11 (45.83)
Current participation in desired sport, but not at pre-injury level	7 (29.17)	9 (37.50)	10 (41.67)
Current participation in desired sport at pre-injury level	1 (4.17)	0 (0.00)	0 (0.00)
Missing	0 (0.00)	1 (4.17)	1 (4.17)

Table 5: Sports activities at week 6 and week 12.

Ancillary analyses: In the sub-group analysis, the primary outcome measure was stratified according selected demographic characteristics and pre-existing conditions at week 12 to show the within-group effects (Table 6). The table shows a strong centre effect. Men have a slightly higher treatment effect than women (-1.42 compared to -1.34) and non-smokers than smokers (-1.58 compared to -1.50).

High BMI, average pain assessment at baseline, and knee-straining activities at work are associated with significantly higher treatment effects.

The same direction of the signs within the confidence intervals indicates a statistical significance of the effects, despite the partly extremely low number of cases in the respective strata.

Strata of	**n**	**mean (95% CI of mean) ± SD**	**Effect Size***
Overall	24	-3.08 (-4.01 to -2.15) ± 2.21	-1.40
Centre			
Vienna	12	-3.42 (-4.37 to -2.46) ± 1.51	-2.27
Baden	5	-3.80 (-7.96 to 0.36) ± 3.35	-1.14
Innsbruck	7	-2.00 (-4.07 to 0.07) ± 2.24	-0.89
Gender			
Female	8	-3.50 (-5.69 to -1.31) ± 2.62	-1.34
Male	16	-2.88 (-3.96 to -1.79) ± 2.03	-1.42
Knee joint			
Left	15	-3.53 (-4.80 to -2.26) ± 2.29	-1.54
Right	9	-2.33 (-3.82 to -0.85) ± 1.94	-1.20
BMI (kg/m2) (Classified groups)			
Normal	6	-2.50 (-5.45 to 0.45) ± 2.81	-0.89
Overweight	10	-3.00 (-4.69 to -1.31) ± 2.36	-1.27
Obese I & II	8	-3.63 (-4.96 to -2.29) ± 1.60	-2.27
Smoking status			
No	12	-3.33 (-4.67 to -2.00) ± 2.10	-1.58
Yes	4	-2.25 (-4.64 to 0.14) ± 1.50	-1.50
Ex	7	-3.57 (-6.01 to -1.13) ± 2.64	-1.35
Knee-straining activities at the workplace			
None or Mild	16	-2.25 (-3.39 to -1.11) ± 2.14	-1.05
Moderate or Severe	6	-4.50 (-5.79 to -3.22) ± 1.22	-3.67
Pain assessment: Average at baseline (Classified)			
0-3	7	-0.86 (-1.50 to -0.22) ± 0.69	-1.24
4-6	8	-3.25 (-5.29 to -1.21) ± 2.43	-1.33
7-10	9	-4.67 (-5.53 to -3.81) ± 1.12	-4.17

Table 6: Stratification of primary outcome by selected demographic characteristics and pre-existing conditions.

* Cohen's d: Cohen's measure of sample effect size within groups

n: total number of cases; CI: confidence interval; SD: standard deviation

Adverse events: The assessment and documentation of adverse events was a fundamental aspect of the study design. Only one participant reported short term skin problems (redness and itching) because of wearing the device on one place too long. No other Adverse Events (AEs) and no Serious Adverse Events (SAEs) occurred during the entire 12-week intervention period. At each study visit, participants were asked about any adverse events that occurred and the self-report form was checked to see whether any adverse events were documented or not. Patients could withdraw from the study at any time without giving a reason.

Discussion

Interpretation

As far as we know, no clinical study on the application and potential effects of a locally applicable device for frequence therapy has yet been carried out. There is an in-vitro report on the positive effects on neutrophils by P. Dartsch in 2020 [5] approving at least a significant change on cells. Namely an increased cell number by 17.2 ± 3.8% and cell diameter by 9.5 ± 0.2% (mean values ± standard deviations; $p \leq 0.05$). Moreover he reported the basal cell metabolism of the functional neutrophils and the generation of superoxide anion radicals to be increased by 23.0 ± 5.5% and 21.3 ± 6.2%.

The frequence therapy itself is a novel and experimental approach for cell regeneration beside the "traditional" biochemical and pharmagolocial access. Tremendous effort and work had been carried out by S. Kiontke summarized in his book "Physik biologischer Systeme" (Physics in biological systems) [11]. He invented the frequence analysis and frequence therapy computational devices.

Although subjective clinical results reported by patients and user sound impressive, still the underlying mechanism is not fully understood so far.

The basic principle is comparable with EMF therapy (electromagnetic field therapy) where an increasing number of good evidence is

published. L Markovic et al approved the positive effects of EMF on outcomes associated with osteoarthritis in a systematic review of systematic reviews in 2022 [6].

The first author (RS) hypothesizes that in organic systems an electrophysical signal pathway consists, somehow like the mechanism of mechanotransduction. We suggest establishing the term of electro-magnetic transduction. Admitting that a huge amount of more specific research must be done.

Our pilot study shows results that are almost puzzling. However, 8.66% of patients rated the therapy as poor or no response. In contrast more than 75% of patients rating it as excellent or good after six weeks and even 79% after 12 weeks. This leads us to the concept of responders and non-responders without knowing the causes.

Moreover, some bias in the selection of patients can be seen: our participants had symptomatic osteoarthritis over years limiting their activities and being unsatisfied with other conservative treatment options. Obviously looking for other treatment options they heard or read about the E Chi device. On the one hand this included the somehow tough cases reducing the likelihood of good response. On the other hand the high expectations can lead to psychological placebo or self-full-filling effects.

Therefore, we are planning a following study as a randomized control trial comparing lookalike placebo devices with loaded devices.

Limitations

The power of the study is reduced by the small sample size. Despite the small sample size, the multicentre approach made it possible to improve the representativeness of the study results and to present statistically significant effect sizes with all measurement methods and at all time points. Multifactorial analyses were not performed due to the small sample size, but stratification of the primary outcome criterion according to baseline characteristics suggests a strong influence of demographics and pre-existing conditions.

Generalizability

This pilot study was designed to investigate the before/after effect (effectiveness) of frequency therapy using the "e.CHI FrequencyChip". It is therefore only a preliminary study to calculate the sample size for a randomised controlled trial (RCT) on efficacy, which is due to start soon. This is one of the reasons for the detailed tables presented. The good tolerability of the "e.CHI FrequencyChip" demonstrated in our study confirms the experience gained in everyday medical practice and encourages further research into the efficacy of frequency therapy with the "e.CHI FrequencyChip" in larger patient groups.

Conclusion

The outcomes from all measurements and time points have demonstrated statistical significance and have consistently exhibited a trend of improvement from week 6 to week 12. The "e.CHI FrequencyChip" device employed for frequency therapy has been shown to be both safe and effective in the treatment of knee osteoarthritis.

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics Committee of the City of Vienna, Vienna (Reference No. 23-116-0923, 7 November 2023) and conducted in accordance with the tenets of the Declaration of Helsinki to ensure the protection of human subjects. The trial was registered in the German Clinical Trials Register (DRKS00031611) on 11 January 2023. Unique protocol ID: e.CHIGonA1. All patients enrolled in the study were appropriately informed about the study and signed written informed consent.

Consent for publication

Not applicable.

Author's contribution

The authors have approved this version.

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Registration: The trial was registered in the German Clinical Trials Register (DRKS00031611) on 11 January 2023. Unique protocol ID: e.CHIGonA1.

The study was approved by the Leading Ethics Committee of the City of Vienna, Vienna (Reference No. 23-116-0923, 7 November 2023) and by the local Ethics Committee in the Austrian District Lower Austria and Tyrol. It was conducted in accordance with the tenets of the Declaration of Helsinki to ensure the protection of human subjects.

Conflict of interest statement

None of authors have a conflict of interest related to this study.

Availability of data and materials

All materials and data are available in the Sports Surgery Clinic, Baden, Austria.

CONSORT guidelines

The study adheres to CONSORT guidelines and includes a completed CONSORT checklist as an additional file.

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