clinical study

BCR-Therapy

Biologische-Zellregulations-Therapie --- Biological-Cellregulation-Therapy
BZR-Therapie BCR-Therapy

Randomized clinical study concerning the benefits for patients of the biological cell regulation therapy after implantation of a full knee endoprosthesis

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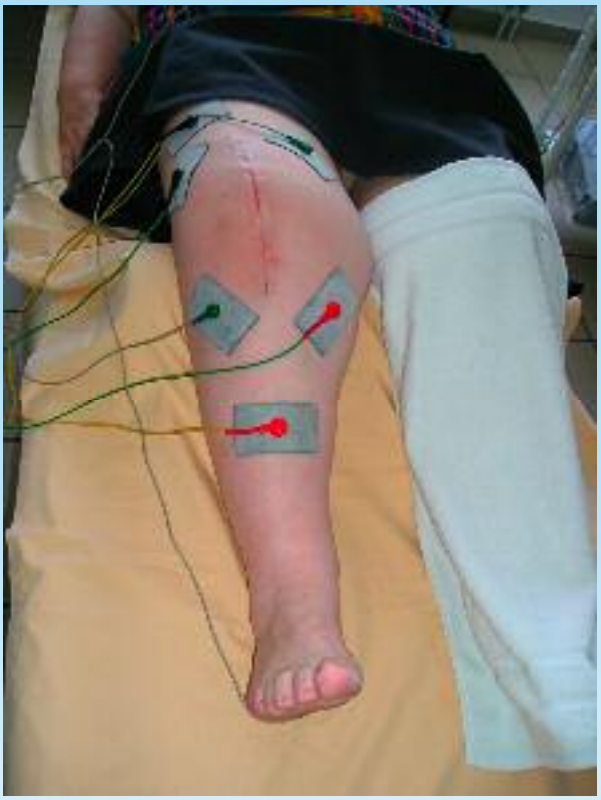
Objective: In the course of a randomized, masked (for the patient) clinical trial, the benefit of the biological cell regulation therapy (BCR) which is administered in addition to a standard therapy in the course of an inpatient post-curative treatment (AHB) shall be measured. With the use of validated questionnaires concerning every day function and illness-related quality of life it shall be examined whether patients who receive additional BCR therapy can achieve an early and/or more profound recovery.

Materials and Methods: The ethics committee of the Medical Faculty of Carl Gustav Carus Technical University Dresden has approved the procedure explained below on Sept. 12, 2007 without any objections.

Study design: After obtaining their written consent to take part in the study 78 patients who were admitted to an inpatient AHB in the Clinic Bavaria Kreischa after an implantation of a full knee endoprosthesis were randomized into an intervention and a control random test group.

During the course of the AHB and in addition to the standard treatment, all participants received either ten applications of either the BCR therapy or a placebo therapy. Two Clinic Master Professional medical units of identical construction were used, whereas one unit did not supply any power (control random test group) so that the therapy was masked for the patient vis-à-vis the placebo therapy. All participants were asked to complete a questionnaire interview concerning the functional and subjective result of the overall treatment before the beginning of the study, after five therapy sessions, once more after 10 therapy sessions as well as after three months.

Measuring instruments: The questionnaire OSWESTRY works with ten standardized questions which require the patient to assess his quality of life with respect to an ailment their in musculoskeletal system whereas the questionnaire works with an index of 0 - 100 %. The questionnaire WOMAC works with 24 standardized questions which concern activities of everyday life and seeks to assess the functional condition of the patient. By using a visual analogue scale (VAS), the subjective pain perception of the patient was documented.

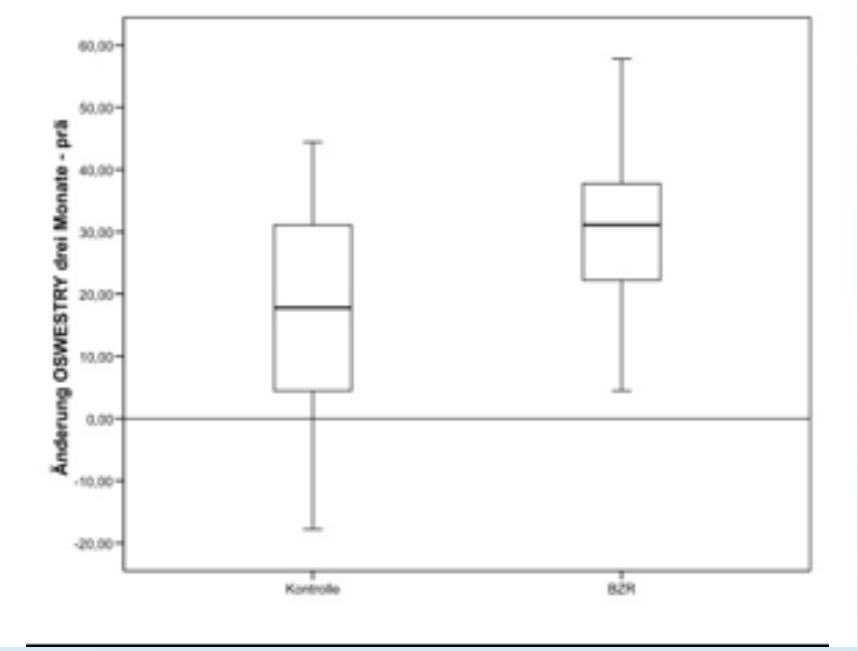


Confimatory Analysis: Primary end point of the study was the three month increase of the OSWESTRY-index; by using a two-sided Wilcoxon-Tests in relation to a 5% level, the random tests at this end point were contrasted to each other.

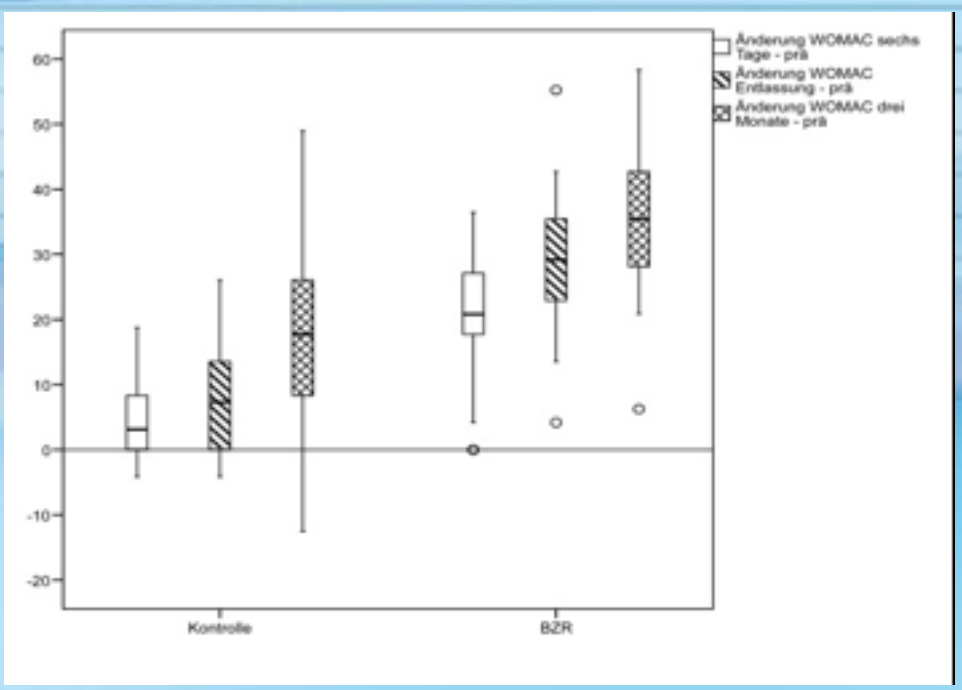
Patient Group: The intervention group (n=37) showed a median age of 60 years at the beginning of the study (41% women), the control group (n=41) showed a median age of 57 years (57% women) with a median body mass-index of 29.4 as opposed to 30.1 kg/sqm. 54% and respectively 39% of the patient reported to have had at least a half-day employment prior to the operation; 5% and, respectively, 15% of the study participants reported to be single.

Results:

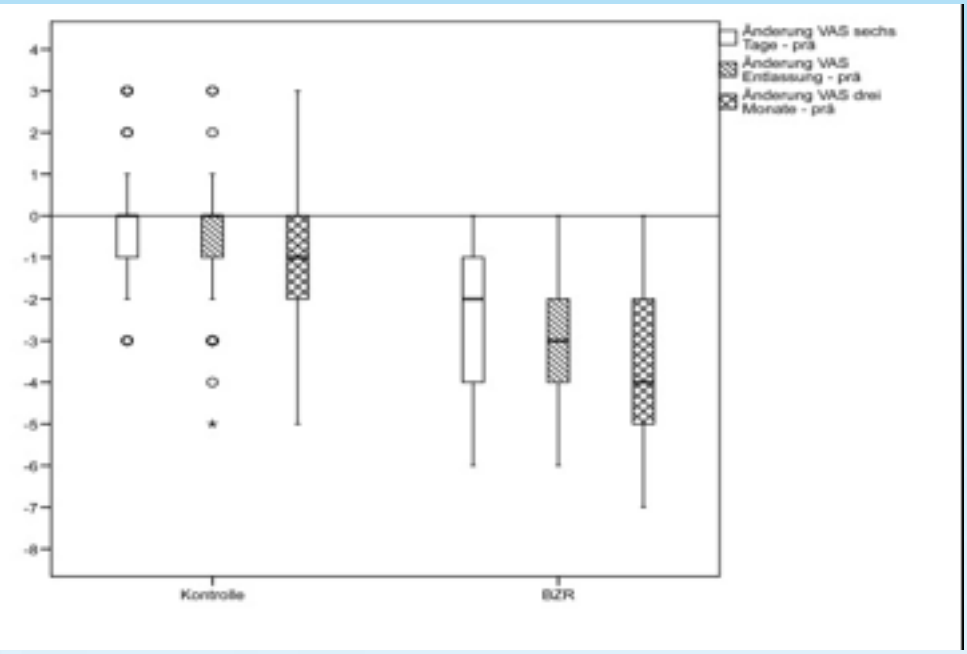
OSWESTRY: With respect to the OSWESTRY index, the intervention random test group (receiving BCR therapy) showed a median three months increase by 31% (interquartile mean 22 to 38 %), thus increasing from a median percentage of 53% at the beginning of the study to a median percentage of 91% three months after AHB; in the control group, there was a median three months' increase of the OSWESTRY index by 18% (3 to 31 %), thus increasing from 56% to 78 %. The random tests deviate statistically in a significant way in the increase of the OSWESTRY index (Wilcoxon $p<0.001$). This result could be reproduced in a multivariate way by using multiple logistic regression modeling while adjusting cofactors as age and employment status of the study participants.



WOMAC: With respect to the WOMAC index, the intervention and control random test group showed median increases by 35% and 18% respectively (Wilcoxon $p<0.001$), thus from 56% to 95% under BCR therapy being administered and from 58% to 82% with placebo therapy being administered. Already after 5 BCR therapy sessions, the WOMAC index showed an increase from 58% to 81 in the intervention group, whereas the placebo therapy only lead to an increase from 58% to 64% (Wilcoxon $p<0.001$) in the control random test group. Upon discharge from AHB, median WOMAC index values of 90% for the intervention group as opposed to 68% for the control group were reported (Wilcoxon $p<0.001$).



VAS: Concerning the subjective perception of pain and the use of the VAS scale, the patients of the intervention random test group reported a median pain reduction by 4 points after three months in contrast to 1 point in the control random test group (Wilcoxon $p<0.001$).



Conclusion: With respect to the patient-related end points, the case study of an overall sample has demonstrated a statistically significant and clinically relevant benefit of the BCR therapy during an inpatient post curative treatment of patients after an implantation of a full knee endoprosthesis.