
Objective: To evaluate if the timing of aquatic therapy influences clinical outcomes after total knee arthroplasty (TKA) or total hip arthroplasty (THA).

Design: Multicenter randomized controlled trial with 3-, 6-, 12-, and 24-month follow-up.

Setting: Two university hospitals, 1 municipal hospital, and 1 rural hospital.

Participants: Patients (N=465) undergoing primary THA (n=280) or TKA (n=185): 156 men, 309 women.

Intervention: Patients were randomly assigned to receive aquatic therapy (pool exercises aimed at training of proprioception, coordination, and strengthening) after 6 versus 14 days after THA or TKA.

Main Outcome Measures: Primary outcome was self-reported physical function as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at 3-, 6-, 12-, and 24-months postoperatively. Results were compared with published thresholds for minimal clinically important improvements. Secondary outcomes included the Medical Outcomes Study 36-Item Short-Form Health Survey, Lequesne-Hip/Knee-Score, WOMAC-pain and stiffness scores, and patient satisfaction.

Results: Baseline characteristics of the 2 groups were similar. Analyzing the total study population did not result in statistically significant differences at all follow-ups. However, when performing subanalysis for THA and TKA, opposite effects of early aquatic therapy were seen between TKA and THA. After TKA all WOMAC subscales were superior in the early aquatic therapy group, with effect sizes of WOMAC physical function ranging from .22 to .39. After THA, however, all outcomes were superior in the late aquatic therapy group, with WOMAC effect sizes ranging from .01 to .19. However, the differences between treatment groups of these subanalyses were not statistically significant.

Conclusions: Early start of aquatic therapy had contrary effects after TKA when compared with THA and it influenced clinical outcomes after TKA. Although the treatment differences did not achieve statistically significance, the effect size for early aquatic therapy after TKA had the same magnitude as the effect size of nonsteroidal anti-inflammatory drugs in the treatment of osteoarthritis of the knee. However, the results of this study do not support the use of early aquatic therapy after THA. The timing of physiotherapeutic interventions has to be clearly defined when conducting studies to evaluate the effect of physiotherapeutic interventions after TKA and THA.

Key Words: Arthroplasty, replacement, hip; Arthroplasty, replacement, knee; Hydrotherapy; Randomized controlled trial [publication type]; Rehabilitation. © 2012 by the American Congress of Rehabilitation Medicine
leads to the development of increased muscular strength. By altering the movement velocity in water, different resistances can be achieved. The hydrostatic pressure supports reabsorption and gives the patient a sense of security while standing. Because pool exercises require continuous balance response, muscular coordination is improved. It has been argued that it may be “the combination of reduced gravity, hydrostatic force and warm water temperature” that contributes to pain relief in the joints.

In a Cochrane review of aquatic therapy for osteoarthritis and rheumatoid arthritis, it was concluded that the scientific evidence for aquatic therapy was weak due to methodologic quality of the studies identified, but that most of the studies demonstrated positive findings.

To our knowledge, 4 studies have evaluated the effect of aquatic therapy after arthroplasty. One study demonstrated that aquatic therapy improved muscular coordination and strength after TKA, as measured by electromyographic mapping, isokinetics, and ultrasound. Another study found comparable outcomes, including the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), up to 6 months after TKA between a land-based versus a water-based rehabilitation protocol. Two other studies demonstrated improved patient reported outcomes, including the WOMAC, in patients who received aquatic therapy when compared with patients who received standard conventional gym treatment, after both TKA and TKA. These authors wrote that “the hydrotherapy benefits after THA appear so evident that it hard to conceive a lack of their early implementation in a rehabilitation protocol.” However, in these studies it remained unclear as to how early aquatic therapy should be initiated.

We are aware of no studies that have evaluated the effect of the timing of an aquatic therapy rehabilitation intervention after TKA or THA. Usually aquatic therapy is started after wound healing, that is, not before the 14th postoperative day. We hypothesized that by starting the aquatic therapy earlier, the reported beneficial effects of aquatic therapy would improve the clinical outcome, as measured by the WOMAC physical function scale.

For this reason we randomized patients into early versus late aquatic therapy, to evaluate if the timing of aquatic therapy would influence patients’ health-related quality of life and patient satisfaction after hip and knee arthroplasty. Early aquatic therapy in this context was defined as starting on postoperative day 6, while late aquatic therapy was defined as starting as before, that is, on postoperative day 14.

METHODS

We conducted a multicenter randomized controlled trial (RCT) comparing the clinical outcomes of patients who had been randomly assigned to receive aquatic therapy after 6 versus 14 days after THA or TKA. The study protocol was approved by the local ethics committee, and all participants provided written informed consent prior to participation in this study. A data and safety monitoring board monitored the study.

Participants

All patients who were scheduled to receive unilateral hip or knee replacement surgery at participating centers on an elective basis after diagnosis of osteoarthritis were candidates for inclusion in the study between August 16, 2003 and December 31, 2004. Exclusion criteria were: (1) a history of septic arthritis, (2) hip or knee fracture, (3) intraoperative complications, (4) revision arthroplasty, (5) rheumatoid arthritis, (6) amputations, (7) malignancy, and (8) inability to complete the questionnaires because of cognitive or language difficulties.

Information about the study was handed out to participants on the day of admission to the hospital. Eligible patients were identified by the admitting physicians and were approached to participate in the trial by either the admitting physician or a study coordinator. Patients providing written informed consent were then enrolled in the trial.

Participating centers are all located in the northernmost state of Germany. These are 2 orthopedic departments of university hospitals, 1 department of surgery at a municipal hospital, and 1 department of orthopedics at a rural hospital.

Randomization Scheme

All patients had an equal probability of assignment to the groups. External randomization was achieved by means of computer-generated lists (Microsoft Excel) in blocks of 20, stratified by participating hospital. At the time of enrollment of each participant, the coordinating center was notified via telefax, where the study nurse added them to the list in sequential order. After surgery, the result of the randomization was faxed back to the participating hospital, thereby avoiding that the study participants or surgeon knew of the randomization results beforehand (allocation concealment). The method of generation of the randomization lists was unknown to the participating hospitals. Due to the nature of the intervention, blinding of the study participants and physiotherapists was not possible.

Intervention

Participants were randomized into 2 groups: 1 group received aquatic therapy as pool exercise after the completion of wound healing on the 14th postoperative day, while the other group received this aquatic therapy beginning on the 6th postoperative day with the wound covered with a waterproof adhesive dressing (Op-Site). In both groups the aquatic therapy was performed for 30 minutes for 3 times a week up to the 5th postoperative week. In both groups the pool exercises aimed at training of proprioception, coordination, and strengthening, with the aid of flat cuffs, training kickboards, and bar floats.

Apart from the interventions, both groups participated in a standard postsurgery program of daily physiotherapy, consisting of range of motion activities, exercises for improvement of muscle tension, venous return, balance, coordination and gait, and instruction in activities of daily living, including transfers, walking, and negotiation of stairs and uneven surfaces. In patients with knee replacement surgery, continuous passive motion machines were used on a daily basis after removal of suction drains. All patients were given analgesics according to a standard scheme.

Special attention was given so that all therapies, with the exception of the timing of aquatic therapy, were not affected by the study. At the beginning of the study, all hospital physiotherapists were informed in detail about the study.

Outcomes

The primary outcome was self-reported physical function 3-, 6-, 12-, and 24-months postoperatively. This was measured by means of the WOMAC, using a validated translated version.

Secondary outcomes consisted of leg specific stiffness and pain, both measured by the WOMAC; the physical component summary of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36); the Lequesne-Hip/Knee-Score, and a question on patient satisfaction.

For the WOMAC, responses were recorded on a visual analog scale with terminal descriptors. Scores were added for each category and standardized to a score of 0 to 100, with...
higher scores indicating more pain, more stiffness, or more dysfunction. All patients were asked to answer the questionnaire at the time of hospital admission. During hospital stay, the study nurse visited the patient to ensure that the questionnaire was filled in completely.

After 3, 6, 12, and 24 months, participants were mailed a questionnaire with a prepaid return envelope. Nonresponding participants were reminded by mail up to 3 times at intervals of 2 weeks. Participants still not responding were contacted by telephone to determine the reason for not responding.

Data were entered into a database (Microsoft Access) at the coordinating center. There were no changes to trial outcomes after the trial commenced.

Minimal Clinically Important Improvements

The interpretation of the results of RCTs has emphasized statistical significance rather than clinical importance. The lack of emphasis on clinical importance has been reported to lead to frequent misconceptions and disagreement regarding the interpretation of the results of clinical trials and a tendency to equate statistical significance with clinical importance. In some instances, statistically significant results may not be clinically important and, conversely, statistically insignificant results do not rule out completely the possibility of clinically important effects.

To allow readers to interpret the clinical importance of trial results from their own perspective, the concept of the minimal clinically important difference has been introduced. The minimal clinically important difference is defined as the “smallest treatment effect that would result in a change in patient management, given its side effects, costs and inconveniences.”

To assess whether the statistical significant differences observed in the present study represent clinically meaningful change, we compared the observed differences of the primary outcome to previously published thresholds for the minimal clinically important improvements that were stratified to the severity of the disease.

These thresholds are 5.3 WOMAC function units for knee osteoarthritis, stratified for a WOMAC function score of 35.3
Comparisons. Effect sizes estimated from such a pattern, the nonparametric Mann-Whitney with the Kolmogorov-Smirnov test. Because many of them deviated from the normal distribution principle. Baseline data were examined for differences. Continuous variables were compared using the Student’s t test (if normally distributed) or as otherwise indicated.

### Statistical Analysis

Statistical analysis was performed using SPSS. The effect sizes for the primary outcome ranged from .01 to .30, and \( P < .05 \) was used to determine differences between groups. Categorical data (patient satisfaction) were compared using chi-square tests. All \( P \) values are 2-tailed; no corrections were made for multiple comparisons. Effect sizes \( d \) as the standardized differences between 2 groups, were calculated as described by Cohen. Statistical analysis was performed using SPSS.

### Power Analysis

For the power analysis we chose an effect size \( d \) of .30, and a significance level of .05. Based on the .80 power to detect a significant difference (\( P = .05, \) 2-sided), 176 patients were required for each study group. Because we expected a loss to follow-up of about 25% to 30%, we increased the number of recruited patients accordingly.

### Results

#### Participants

In total, 502 patients were candidates for participation in the study. Of these, a total of 465 underwent randomization. The recruitment process and participant flow, including losses and exclusions after randomization, are outlined in figure 1. No statistically significant pretreatment differences existed among the study groups (table 1), suggesting that the randomization procedures produced well balanced and comparable groups at baseline.

Overall, 417 patients completed the postal questionnaire at 3 months, resulting in a follow-up rate of 90%. The follow-up rate dropped to 85% at 6-month, 79% at 12-month, and to 74% at 24-month follow-up. There was no significant association between patients who did not respond to the follow-up questionnaire and patient baseline characteristics.

#### Follow-Up (Hip Arthroplasty)

After hip arthroplasty, all mean WOMAC subscales at all follow-up intervals were better in the group starting aquatic therapy after wound-healing. This effect was not statistically significant for any of the outcomes at any time, however (table 2).

The effect sizes for the primary outcome ranged from .01 (3-mo follow-up, absolute difference = .30; \( P = .80 \)) to .19 (6-mo follow-up, absolute difference = .19; \( P = .52 \)). Using the SF-36, the Lequesne-Hip/Knee-Score, and patient satisfaction, or less; and 2.6 WOMAC function units for hip osteoarthritis, stratified for a WOMAC function score of 38.2 or less.21

### Table 1: Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Hip Arthroplasty</th>
<th>Knee Arthroplasty</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Early Aquatic</td>
<td>Late Aquatic</td>
</tr>
<tr>
<td></td>
<td>Therapy (n=138)</td>
<td>Therapy (n=142)</td>
</tr>
<tr>
<td>Age (y)</td>
<td>66.7±10.3</td>
<td>69.1±9.8</td>
</tr>
<tr>
<td>Body mass index*</td>
<td>27.6±4.4</td>
<td>26.8±4.6</td>
</tr>
<tr>
<td>Sex ratio (men:women)</td>
<td>50:88</td>
<td>54:88</td>
</tr>
<tr>
<td>WOMAC physical function score†</td>
<td>57.3±21.4</td>
<td>54.8±22.7</td>
</tr>
<tr>
<td>WOMAC pain score†</td>
<td>54.8±23.2</td>
<td>52.4±25.1</td>
</tr>
<tr>
<td>WOMAC stiffness score†</td>
<td>57.7±25.6</td>
<td>52.0±27.6</td>
</tr>
<tr>
<td>SF-36, physical component summary‡</td>
<td>28.1±6.7</td>
<td>26.8±8.2</td>
</tr>
<tr>
<td>SF-36, mental component summary‡</td>
<td>47.7±12.5</td>
<td>50.4±11.4</td>
</tr>
<tr>
<td>Lequesne-Hip/Knee-Score§</td>
<td>11.9±3.2</td>
<td>11.6±3.1</td>
</tr>
<tr>
<td>Number of comorbidities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>15 (51.7%)</td>
<td>14 (48.3%)</td>
</tr>
<tr>
<td>One</td>
<td>45 (48.3%)</td>
<td>47 (51.1%)</td>
</tr>
<tr>
<td>Two or more</td>
<td>78 (49.1%)</td>
<td>81 (50.9%)</td>
</tr>
<tr>
<td>Additional limitation due to</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contralateral same great joint</td>
<td>33 (55.9%)</td>
<td>26 (44.1%)</td>
</tr>
<tr>
<td>Ipsilateral adjacent great joint</td>
<td>22 (40.7%)</td>
<td>32 (59.3%)</td>
</tr>
<tr>
<td>Contralateral adjacent great joint</td>
<td>17 (45.9%)</td>
<td>20 (54.1%)</td>
</tr>
<tr>
<td>Low back pain</td>
<td>53 (49.5%)</td>
<td>54 (50.5%)</td>
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<tr>
<td>Upper extremities</td>
<td>6 (30.0%)</td>
<td>14 (70.0%)</td>
</tr>
<tr>
<td>Feet</td>
<td>10 (47.6%)</td>
<td>11 (52.4%)</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>131 (49.1%)</td>
<td>136 (50.9%)</td>
</tr>
<tr>
<td>Femoral head necrosis/Ahlbäck’s disease</td>
<td>7 (53.8%)</td>
<td>6 (46.2%)</td>
</tr>
</tbody>
</table>

NOTE. Values are mean ± SD or as otherwise indicated.

*Body mass index is the weight in kilograms divided by the square of the height in meters.

‡Higher scores representing better quality of life.

§Lower scores representing better quality of life.
no differences could be detected between study groups at all follow-up intervals (see tables 2 and 3, figs 2 and 3).

### Follow-Up (Knee Arthroplasty)

After knee arthroplasty, however, all mean outcomes were better in the early aquatic therapy group at 3-, 6-, 12-, and 24-month follow-up. The only exception to this finding was a slightly better WOMAC stiffness score for the late aquatic therapy group at 12-month follow-up (effect size = .03). All these effects were not statistically significant, however (see tables 2 and 3, figs 2 and 3).

The effect sizes for the primary outcome WOMAC physical function ranged from .22 at 6-month follow-up (absolute difference = .12) to .24 at 24-month follow-up. The only exception to this finding was a better in the early aquatic therapy group at 3-, 6-, 12-, and 24-month follow-up. The only exception to this finding was a

### Adverse Effects

After knee arthroplasty, 5 patients of the early aquatic therapy group (because of limited range of motion of knee [n = 2], intraarticular effusion of knee, diabetes, cerebrovascular accident) and 1 of the late aquatic therapy group (because of limited range of motion of knee) were readmitted to the hospital within 3 months. Of these, the first 3 of the early aquatic therapy group and 1 of the late aquatic therapy group could be directly or indirectly related to the intervention.

After hip arthroplasty, 10 patients of the early aquatic therapy group (because of dislocation of hip, wound dehiscence, thrombosis [n = 2], intestinal perforation, shunt revision, super-

### DISCUSSION

This is the first study, to our knowledge, to examine the influence of the timing of a single rehabilitation intervention, here the timing of aquatic therapy after hip and knee joint replacement surgery, on physical function, pain, joint stiffness, and quality of life. These dimensions of health-related quality of life are recommended as a rationale for the implementation of the most adequate standard of care.

This randomized study showed that the use of early aquatic therapy has opposite effects in terms of health-related quality of life after THA when compared with TKA. After TKA, early aquatic therapy led to clinically important improved patient outcomes when compared with late aquatic therapy. After hip arthroplasty, on the other hand, the results of this study indicate that early aquatic therapy should be avoided.

In addressing the clinical importance, commonly comparing effect sizes is recommended, especially in systematic reviews and meta-analyses. The effect sizes of the primary outcome for our intervention ranged from .01 to .19 after hip arthroplasty and ranged from .22 to .39 for knee arthroplasty. There-
fore, these effect sizes for the intervention are rather consistent after knee arthroplasty, but inconsistent after hip arthroplasty. The effect sizes after knee arthroplasty exceeded the pooled effect size of .20 that was obtained from a meta-analysis of randomized placebo controlled trials for reduction in functional disability by nonsteroidal anti-inflammatory drugs (NSAIDs) in osteoarthritis of the knee.24 Therefore, the effect size of early aquatic therapy after knee arthroplasty is in the same range as the effect size of NSAIDs in osteoarthritis of the knee.

The clinical importance of our findings is supported by the concept of the minimal clinically important improvements,24 because the published specific threshold of 5.3 WOMAC function units for the primary outcome is exceeded in our study (6.9 WOMAC function units at 24-mo follow-up).

As baseline data showed that patients were homogeneous between the groups, there is no evidence that factors other than the timing of aquatic therapy could have influenced the outcomes. However, several patients after THA were randomized to early aquatic therapy, but did not receive early aquatic therapy for various patient specific reasons. This noncompliance with assigned therapy may mean that the conducted intention-to-treat analysis underestimates the real treatment effect.25

According to a recent review,24 age, sex, operated joint, primary or revision surgery, comorbidities, and baseline characteristics are known to influence the health-related quality of life after total joint arthroplasty (TJA). All these factors cannot be influenced by the physician. On the other hand, studies in which patients were randomized to different prosthetic types have failed to demonstrate a significant effect of different surgical procedures on health-related quality of life.24 Also, there appears to be no effect of inpatient compared with home input from health care professionals.

We chose 3 and 6 months as the appropriate study interval because the most improvement in postoperative physical health takes place during this time.24 We added a 12- and 24-month study interval to standardize our research with that of other authors who have analyzed health-related quality of life after TJA.24 Similarly to other studies concerned with health-related quality of life,24 the current study was not designed to analyze long-term implant failure. This issue has been extensively addressed previously.31

We hypothesize that the weak effect of the timing of aquatic therapy after THA is due to the ceiling effect of that procedure, with a high rate of patient satisfaction and improvement of health-related quality of life due to THA alone, thereby leaving only a limited space for improvement by additional interventions. After TKA, on the other hand, a significantly higher number of patients is not satisfied,32 leaving room for the effect of additional interventions.

We assume that, apart from the known advantages of aquatic therapy, the hydrostatic force of water immersion reduces effusion of the operated knee joint. Because the joint capsule is closed after TKA, the reduction of effusion leads to less pain inhibition, and leading to an advantage in functional recovery. As the joint capsule is not closed during THA, this mechanism does not apply to THA.

The present study has several strengths. It is an RCT in a multicenter setting, performed at university, rural, and municipal hospitals, ensuring a high external validity. Furthermore, this setting provided a broader coverage of surgical experience levels when compared with a mono-center study. We also used the WOMAC as the primary outcome score, which is recommended in this setting.25

### Study Limitations

Although the study has several strengths, there are limitations. First, we conducted separate analysis of knee and hip arthroplasty, because it was unknown beforehand if the effect of the intervention would differ between these patient groups. These separate analyses, however, resulted in a smaller number of patients for the subanalyses with the subanalyses being underpowered. These underpowered subanalyses have increased probability of failing to demonstrate statistically significant differences, as in our study.

Second, while this study has a 90% follow-up rate at 3 months and 85% at 6 months, the follow-up rate dropped to 79% at 12 months and to 74% at 24 months. Because the results of the 24-month follow-up are quite similar to the results of the 3 earlier follow-ups, it appears unlikely that a more complete 24-month follow-up would have altered the study result.

Third, although the eligibility criteria were fairly broad, the trial was restricted to patients undergoing unilateral primary total joint replacement. Therefore, our results cannot be transferred to patients undergoing revision or bilateral total joint replacement.
Fourth, in our study the study nurse visited the patient after randomization to ensure that the questionnaire was filled in completely. Because this study nurse also handled the randomization lists, it could be argued that the nurse as an outcome assessor was not blinded to the randomization result. However, given the large number of patients involved in the study it is unlikely that the nurse remembered the randomization status when checking the preoperative questionnaire for completeness. In addition, in most cases the number of questions not already filled in by the participant was very small, leaving only limited room for the study nurse to possibly influence the questionnaire result. Besides, by this mechanism the nurse could have only affected the baseline measure. The study nurse could not have influenced the postoperative outcome, because a mail-in questionnaire was used for that purpose. Moreover, the nurse was not aware of which questions were to be used as an outcome measure. The calculation of outcomes measures was performed by the authors. Therefore, it appears unlikely that the nurse as an outcome assessor could have influenced the study results.

Fifth, we have compared early versus late beginning of aquatic therapy after TKA and THA. We did not compare aquatic therapy with no aquatic therapy or other types of physical therapy for a number of reasons: beneficial effects of aquatic therapy have been reported in three of the four reports dealing with aquatic therapy after TKA or THA. Withholding a group from aquatic therapy could lead to an unacceptable reduction of compliance, because patients in our country expect aquatic therapy after total joint arthroplasty. For this reason we randomized patients to early versus late aquatic therapy, assuming that the beneficial effects of aquatic therapy would improve the clinical outcome if started sooner after surgery.

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**WOMAC Physical Function by Timing of Aquatic Therapy**

Fig 2. Physical function as measured with the WOMAC 3, 6, 12, and 24 months after early versus late aquatic therapy. Vertical bars represent SE. Abbreviations: ES, effect size; F/U, follow-up.

**Patient Satisfaction by Timing of Aquatic Therapy**

Fig 3. Patient satisfaction 3, 6, 12, and 24 months after early versus late aquatic therapy. Abbreviation: F/U, follow-up. *RR: relative risk (95% confidence interval). †Percentage of participants who answered "very satisfied" to the question: "How satisfied are you with the results of your joint replacement surgery?" (very satisfied, somewhat satisfied, somewhat dissatisfied, very dissatisfied).
CONCLUSIONS

The present study demonstrates that the timing of physiotherapy measures, such as aquatic therapy, has clinically relevant effects after knee arthroplasty. Although not statistically significant, the effect size of the timing of the intervention is clinically relevant after knee arthroplasty because it is in the same range as NSAIDs in the treatment of osteoarthritis of the knee. However, the results of this study do not support the use of early administration of aquatic therapy after hip arthroplasty.

Therefore, further research is warranted to identify the optimal time frame for the start of aquatic therapy after TKA in order to exploit the potential of aquatic therapy for improving clinical outcome after TKA. Most importantly, however, this study demonstrates that the timing of physiotherapeutic interventions has opposite effects after TKA when compared with TKA and therefore the timing of physiotherapeutic interventions has to be carefully planned if studies are performed to evaluate the effect of physiotherapeutic rehabilitation after TKA and THA.

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Suppliers
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