

A Comparison of the Futuro Wrist Orthosis with a Synthetic ThermoLyn Orthosis: Utility and Clinical Effectiveness

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Objective. To compare the short-term utility and clinical effectiveness of the commercial-made Futuro wrist orthosis with a newly developed, custom-made ThermoLyn wrist orthosis.

Methods. Using a randomized cross-over trial, 10 patients with rheumatoid arthritis used each of the two orthoses for two weeks. Outcome measures were patients' judgments with respect to different statements about utility and clinical assessments including pain and swelling of the wrist and finger joints, range of motion of the wrist, and grip strength. At the end of the study the patients were asked which of the two orthoses they preferred and why.

Results. Patients tended to favor the Futuro wrist orthosis with respect to pain relief and to handling the orthosis. The visual analog scale score of the appearance of the ThermoLyn wrist orthosis was a little higher than that of the Futuro wrist orthosis, but the difference was not statistically significant. Clinical parameters such as pain in the wrist, swelling of the wrist and finger joints, and movements of the wrist showed that the Futuro orthosis tended to

be more effective than the ThermoLyn orthosis. None of the differences reached statistical significance. At the end of the study, 5 patients preferred the Futuro and 5 patients the ThermoLyn wrist orthosis. Arguments in favor of the ThermoLyn orthosis were better hygiene, stability, and no need to remove the orthosis during dirty and wet conditions. Arguments in favor of the Futuro orthosis were greater suppleness and freedom of movement.

Conclusions. The ready-made fabric Futuro wrist orthosis appears to be as good as the more expensive individually made synthetic ThermoLyn wrist orthosis with respect to short-term utility and clinical effectiveness. The conditions under which the orthosis will be worn will help to decide which orthosis is the best for the patient. In the event that the patient wants to use the orthosis in wet and dirty conditions, the ThermoLyn wrist orthosis is a good alternative to the Futuro wrist orthosis.

Key words. Wrist splint; Rheumatoid arthritis; Occupational therapy; Randomized clinical trial.

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Submitted for publication April 29, 1997; accepted in revised form August 11, 1997.

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INTRODUCTION

Functional wrist orthoses are frequently prescribed for patients with rheumatoid arthritis (RA) who have pain and swelling of the wrist. These orthoses support the wrist and permit movement of the metacarpophalangeal (MCP) and the finger joints. In this way, patients can perform a number of activities while wearing these orthoses. Research on wrist orthoses demonstrates that use of a functional

wrist orthosis in patients with RA increases grip strength and/or pinch grip and reduces pain (1,2).

Although wrist orthoses are frequently prescribed, it appears that adherence to orthosis usage is relatively low (3,4). Factors that could be negatively associated with adherence are problems with fitting and removal, local irritation caused by the palmar support, interference with activities involving water (sailing, washing windows, doing laundry), the appearance of the orthosis, and the fact that the orthosis sometimes provoked comment from other people (5-7).

To deal with a number of the factors mentioned above, a new style of custom functional orthosis was developed. In contrast to the ready-made fabric Futuro wrist orthosis (Kendall, Hampshire, UK), this new orthosis is made individually for each patient in order to achieve a custom fit and to prevent irritation and chafing. The orthosis (Leiden Orthopedie, Leiden, The Netherlands), is made of the synthetic transparent material ThermoLyn, which gives it a nice appearance and, because it is resistant to soiling and easily cleaned unlike some fabric orthoses, it is also possible to wear the orthosis under wet and dirty conditions. The orthosis immobilizes the wrist while permitting finger and thumb movements.

The aim of the present study was to compare the short-term utility and clinical effectiveness and the costs of this synthetic wrist orthosis with a commonly used functional orthosis, the Futuro orthosis.

PATIENTS AND METHODS

Subjects. Ten consecutive patients with RA according to the 1987 revised American College of Rheumatology (formerly the American Rheumatism Association) criteria (8) and a swollen and painful wrist of the dominant hand were enrolled in this study. All patients attended the outpatient clinic of the Department of Rheumatology of the Leiden University Hospital in November 1995. Patients with a history of wrist surgery in the last year were excluded from participation. No subjects had used wrist orthoses during the 3 months prior to participation in the study.

Study design. A randomized cross-over trial was used to determine the short-term utility and clinical effectiveness of the synthetic ThermoLyn orthosis and the Futuro orthosis. Patients were randomized so that 5 patients wore the ThermoLyn orthosis for two weeks first and the Futuro second for two weeks, and 5 patients wore the orthoses in the reverse order.

Between the two treatment periods there was one week without treatment. Patients were asked to wear the orthosis as much as possible during both the day and night.

Orthoses. The ThermoLyn orthosis was made as follows. After a positive plaster model of the wrist and hand was made, the orthosis was formed by wrapping this model with ThermoLyn, a copolymer of polyethylene and propylene. The ThermoLyn sheet was placed in a kiln for 10 minutes at 150°C and was then vacuum-formed over the positive plaster model. Then this ThermoLyn orthosis was further processed by trimming, burnishing, and scouring. The orthosis could be placed on the wrist and hand by first placing the ulnar side of the hand into the orthosis and thereafter the radial side of the hand. The orthosis was fastened by a single velcro strap (Figure 1). After the orthoses were first donned, the patient was observed during a 30-minute period, and areas of pain, irritation, or chafing were remodelled by hot air from a heatgun (this was required in 2 patients). Further, the patients were instructed to call the orthotist if any problems with the orthosis should arise.

The Futuro orthosis was a ready-made fabric orthosis (Futuro cock-up orthosis) (Figure 2). Both orthoses were positioned in 15° of wrist extension with neutral wrist deviation. The costs of the ThermoLyn and Futuro orthoses were 600 (\$320 US) and 60 (\$32 US) Dutch guilders, respectively. The patients participating in this study were not charged for the orthoses and could keep both orthoses after the study was finished.

Assessment methods. At the end of each treatment period the subjects were given a questionnaire consisting of 9 questions about the effect of the wrist orthoses. Eight of the questions were scored using a 4-point scale (1 = entirely true; 2 = for the greater part true; 3 = for the greater part not true; 4 = entirely not true), and one of the questions was measured on a visual analog scale (VAS). Patients' judgments with respect to whether this orthosis relieved pain of the wrist, caused pain, decreased swelling of the wrist, improved hand function, caused stiffness, was easy to put on and off, and was easy to manage, together with general satisfaction, were evaluated by means of a 4-point scale; patients' opinions about the appearance were measured on a 10-cm VAS (0 indicated "ugly" and 10 indicated "nice"). Patients' assessments of pain in the wrist were measured on a VAS (range 0-10 cm; 0 = no pain and 10 = very painful). The patients were asked to record the num-



Figure 1. Top, the dorsal side of a ThermoLyn wrist orthosis. Bottom, the volar side of a ThermoLyn wrist orthosis.

ber of hours that they had worn the orthosis during the day and night every day. At the end of the study the patients were asked in writing which of the two

orthoses they preferred and were requested to support this decision in writing ("If I may choose between the two splints I will choose the Futuro wrist orthosis/ThermoLyn wrist orthosis because of . . ."). The patients were not informed about the cost of the orthoses.

The following parameters were measured by a blinded investigator (GJT) at the start and at the end of each treatment period: tender joint count and swelling of the MCP, proximal interphalangeal, and interphalangeal joints and of the wrist, as well as range of motion of the wrist. To measure the tender joint count, the Ritchie scale was used (9), ranging from 0 to 3 (0 = no pain on pressure squeeze to affected joint; 1 = vocalization of pain on pressure squeeze to affected joint; 2 = vocalization of pain and grimace on pressure squeeze to affected joint; 3 = withdrawal of affected joint on pressure squeeze). The maximum tender joint score of one hand was 33. The same joints were assessed for swelling (yes/no) with the maximum score of swelling of one hand being 11. The range of motion of the wrist (dorsal and palmar flexion, radial deviation, ulnar deviation, supination and pronation) was passively measured using the method described by Gerhardt and Rippstein (10).

A research assistant (trained in physical assess-



Figure 2. The volar side of a Futuro wrist orthosis.

ments of RA patients), who was not blinded to the patients' randomization, measured the grip strength by the Martin Vigorimeter (11) with and without the orthosis in place. The grip strength was tested while the patient was seated with the arm resting on a table and the elbow flexed 100°.

Statistical analysis. Because of the small number of subjects and the skewed normal distribution of the data, nonparametric tests were used for all analyses. Differences in parameters of clinical effectiveness between the baseline and the 2-week treatment period were tested for each orthosis separately by the Wilcoxon matched-pairs signed-rank test. The same method was used for comparing the change scores of the outcome measures for the two orthoses and for the difference of the VAS scores concerning the appearance and wear time between the two orthoses. The numbers of patients with affirmative answers (scores 1 and 2 on the 4-point scale) to the statements about the orthoses were compared by the McNemar Test.

Before analyzing the data as described above, we tested for the existence of a carry over effect by comparing the differences in effect between the periods in the two groups of patients and by comparing the average effects between the two patient groups. Both possibilities were tested by the Mann-Whitney U test.

RESULTS

Ten patients (8 women and 2 men) with a mean age of 47.3 years (range 28–71) and a disease duration of 6.4 years (range 1–15) were enrolled in this study. Nine patients had erosions, and 8 patients were being treated with disease-modifying antirheumatic drugs. A carry over effect was found for none of the outcome measures. Table 1 gives the numbers of affirmative answers of the patients to the statements about the orthoses. The patients judged that the Futuro orthosis tended to be slightly better with respect to pain relief and was easier to handle. The VAS score measuring the patients' appraisals of the appearance of the orthoses showed a more favorable score for the ThermoLyn than the Futuro orthosis, but the patients appeared to be more satisfied with the Futuro wrist orthosis. However, none of the differences were statistically significant.

Table 2 gives the mean values of differences of parameters of clinical effectiveness as measured by the observer or the patients. With respect to pain in the wrist, swelling of the wrist and finger joints, and

Table 1. Judgments by 10 patients with rheumatoid arthritis concerning the two orthoses at the end of the 2-week treatment period

	Number of patients agreeing with statement		
	ThermoLyn (n = 10)	Futuro (n = 10)	P value*
While wearing the orthoses:			
The pain of the wrist was relieved	5	7	0.27
The swelling of the wrist decreased	5	5	0.89
The hand function improved	2	2	0.68
The stiffness of the wrist increased	3	3	0.79
The orthosis caused pain	5	4	0.46
It was easy to fit and remove the orthosis	7	9	0.06
The orthosis was easy to manage	8	7	0.83
I'm satisfied with the orthosis	6	8	0.40
The orthosis' appearance, mean VAS (SD)†	6.0 (3.2)	4.5 (3.2)	0.24‡

* The P value of the difference in affirmative answers between the 2 treatment periods measured by the McNemar test.

† VAS = visual analog scale. 0–10-cm scale, 10 = a nice appearance.

‡ The P value of the difference of the VAS scores concerning the appearance between the two orthoses was measured by the Wilcoxon matched-pairs signed-rank test.

movements of the wrist, the Futuro orthosis tended to be more effective than the ThermoLyn orthosis. However, the differences in clinical effectiveness between the start and the end of each treatment period, as well as the differences between the two orthoses, were not statistically significant. The 3 range of motion test results of the wrist were also analyzed separately but the differences between the two orthoses were not statistically significant (data not shown).

In the 2-week treatment periods the mean time of wearing the Futuro orthosis was 111 (SD 60) hours versus 86 (SD 60) hours for the ThermoLyn orthosis, which was not statistically significant ($P = 0.5$). None of the patients wore an orthosis at night.

At the end of the study 5 patients chose the ThermoLyn orthosis and 5 the Futuro orthosis. Arguments in favor of the ThermoLyn orthosis were better hygiene ($n = 4$), better stability ($n = 4$), no need to remove the orthosis during dirty and wet conditions ($n = 5$), and a better appearance ($n = 2$). Arguments in favor of the Futuro orthosis were greater suppleness ($n = 2$) and freedom of movement ($n = 3$). Arguments against the ThermoLyn orthosis were areas of chafing ($n = 5$) and rigidity ($n = 2$), and

Table 2. Mean values (SD) of parameters of clinical effectiveness as measured by observer or patient at the start and the end of the 2-week treatment period in which the ThermoLyn or the Futuro orthosis was worn by 10 patients with rheumatoid arthritis

	ThermoLyn				Futuro				Difference in change scores, <i>P</i> value†
	Start	End	Change score	<i>P</i> *	Start	End	Change score	<i>P</i> *	
Pain in wrist, patient VAS‡	5.4 (2.2)	4.7 (2.2)	-0.7 (1.9)	0.26	5.4 (2.3)	3.7 (2.3)	-1.7 (2.8)	0.08	0.59
Tender joint count in wrist, MCPs,‡ PIPs;‡ 0-3/joint	4.5 (1.8)	4.2 (3.9)	-0.3 (2.6)	0.68	4.8 (3.7)	4.8 (3.3)	0.0 (1.8)	1.0	0.79
Swelling of wrist, MCPs, PIPs; 0-1/joint	3.6 (1.8)	4.1 (4.0)	0.5 (2.5)	0.73	3.7 (3.0)	2.6 (2.1)	-1.1 (2.3)	0.15	0.59
Movements of wrist, degrees§	255 (83)	255 (73)	0 (48)	0.92	257 (85)	273 (94)	16 (59)	0.55	0.48
Grip strength (kPa) with orthosis	28 (15)	32 (18)	4 (10)	0.46	31 (17)	28 (16)	-3 (11)	0.53	0.75
Grip strength (kPa) without orthosis	31 (18)	30 (17)	-1 (8)	0.60	35 (19)	33 (18)	-2 (7)	0.36	0.91

* *P* value of the difference of change scores for each orthosis separately measured by the Wilcoxon matched-pairs signed-rank test.

† *P* value of the comparison of the change scores of both orthoses measured by the Wilcoxon matched-pairs signed-rank test.

‡ VAS = visual analog scale; MCP = metacarpophalangeal; PIP = proximal interphalangeal, kPa = kilopascal.

§ Movements of wrist given as a summation of dorsal and palmar flexion, supination and pronation, and radial and ulnar deviation.

arguments against the Futuro orthosis were the ease with which the orthosis became soiled ($n = 2$) and irritation from the velcro strap ($n = 2$).

DISCUSSION

The present cross-over study compared a newly developed synthetic wrist orthosis made of ThermoLyn with the ready-made fabric Futuro wrist orthosis in RA patients with pain and swelling of the dominant wrist. Based on patients' judgments, short-term clinical effectiveness, and the patients' reasons for their preference, this study showed that the two orthoses were essentially equivalent. However, there was a tendency in favor of the ThermoLyn orthosis in the areas of hygiene, management, appearance, and the reduced need to don and doff the orthosis while using it. On the other hand, the patients found it easier to don and doff the Futuro orthosis. With regard to short-term clinical effectiveness, the Futuro orthosis tended to be more effective than the ThermoLyn orthosis, but the differences were not statistically significant.

Although the difference in wear-time between the two orthoses was not statistically significant, the wear-time of the Futuro orthosis appeared to be longer. This could have played a role in its tendency to be more clinically effective than the ThermoLyn orthosis. Possible reasons why the Futuro wrist orthosis was worn an average of 25 hours longer than the custom orthosis could have been that it was more comfortable and did not interfere with function.

The results of the present study are partly in agreement with the study of Stern et al (12). In their cross-

over study the immediate and short-term effects of 3 commercial wrist orthoses were investigated. After one week of using these orthoses, 2 (including the Futuro) of the 3 orthoses showed no increase in grip strength. In the randomized study by Kjekken et al (2), in which the effect of a functional elastic orthosis was studied, there were also no changes found in motion, pain, pinch, and (nonsplinted) grip strength between the orthosis and the control group after 6 months. However, after 6 months, patients in the orthosis group had a 25% improvement in grip strength while using the wrist orthosis. These results conflict with our results because we found no effect on grip strength while using the orthosis. An explanation for this may be the relatively short length of our study. It is conceivable that patients who wore the orthosis for 6 months have probably become more accustomed to the orthosis, leading to a better grip strength after 6 months' use.

At the end of the study 5 patients chose the ThermoLyn orthosis and 5 the Futuro orthosis. Five patients mentioned chafing and irritation as arguments against the ThermoLyn orthosis, but none of the patients visited the orthotist for remodelling the orthosis. The reasons why the patients did not visit the orthotist could be the distance to the orthotist and the relatively short period during which they used the orthosis. Assuming that the orthotist made well-fitting orthoses, another reason could have been the rigid nature of the ThermoLyn orthosis itself, which may have been irritative for some subjects and therefore more likely to be rejected by the patient.

In general, we have to realize that the differences measured in this study were small and did not reach statistical significance, probably due to the low number of patients. Using the data of this (pilot) study,

we can calculate the number of patients that would be required to detect a difference between the two orthoses. If we choose pain in the wrist measured on a VAS as the primary outcome parameter, consider a difference of 1.0 as a clinically important difference, and use the Student's 2-tailed *t*-test of the difference between the means with $\alpha = 0.05$ and $\beta = 0.20$, then a sample size of 152 is needed.

Overall, we can conclude that this study showed that in this small group of RA patients who wore the orthoses for a relatively short period, the ready-made fabric Futuro wrist orthosis was as good as the more expensive individually made synthetic ThermoLyn wrist orthosis with respect to short-term utility and clinical effectiveness. The conditions under which the orthosis will be worn will help to decide which orthosis is the best for the individual patient. If the patient wants to use the orthosis in wet and dirty conditions, then the ThermoLyn model is a good alternative for the Futuro wrist orthosis.

The authors acknowledge Janneke de Mooy and Esther Verheijdt for making the orthoses and for participating in the study.

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