

## 6. Post Marketing Surveillance<sup>11</sup>

There are three limitations to the prospective studies with the Backstretcher that have been described above: limited research populations and duration of study, together with an open, uncontrolled design of the study.

In order to reinforce the foundations of the Backstretcher, a Post Marketing Surveillance was carried out in the period July-August 1996. For this, the first 800 people (read: patients) who bought the Backstretcher since October 1995, were approached. This group was approached by letter with a questionnaire. On 31 August 1996, the response was closed for a first analysis, in which (of a total response of 383 people), 378 people were included who could be evaluated (in accordance with a highly satisfactory response of 47.3%).

Generally speaking, the research population can be described as follows:

Number of respondents	378	Duration of back complaints	3%	< 6 months
Proportion Male:Female	56:44		7%	6-12 months
Age	47.2 years [15-85]		6%	1-2 years
Period of using Backstretcher	5.8 months [4-14]		84%	> 2 years

A remarkable aspect of the general inventory is that the respondents were treated by an average of 1.95 (para)medics at the time of purchasing the Backstretcher. This emphasizes the unsolved problem most patients have and also illustrates that creating a therapeutical policy is not easy in a situation where an average of two (sometimes up to 5!) professionals are working.

The results with the Backstretcher are illustrated in the following tables:

	Duration back complaints			
	< 6 months	6-12 months	1-2 years	> 2 years
Responder rate	83 %	87 %	79 %	72 %
Improvement pain score	85 %	68 %	53 %	55 %

	Pain score				
	Very severe	Severe	Moderate	Slight	None
Before the Backstretcher	30	158	157	33	0
	50 %			9 %	
Now, with the Backstretcher	4	35	108	182	47
	10 %			61 %	

	<b>Restriction in work</b>				
	Very severe	Severe	Moderate	Slight	None
Before the Backstretcher	27	110	133	81	27
	36 %			29 %	
Now, with the Backstretcher	6	31	80	145	115
	<b>10 %</b>			<b>69 %</b>	

In addition to the specific results mentioned above, the following overall rating for effectiveness was reported within the entire group of users (including the non-responders):

Excellent effect	10 %	<b>68 %</b>
Good effect	29 %	
Sufficient effect	29 %	
Moderate effect	14 %	32 %
Slight effect	8 %	
No effect	10 %	

Finally, at the time of the Post Marketing Surveillance the Backstretcher is applied by its users as follows:

Daily	172	46 %	average 3.3 times/week
Regularly	80	21 %	
From time to time	93	25 %	
Other/not	33	9 %	

**Conclusion** of this large retrospective, long-term study is that it confirms the results of the prospective studies: the Backstretcher is very effective for most of the patients with non-specific chronic back complaints. This Post Marketing Surveillance also shows that any existing work restriction decreases significantly. Finally, the patient compliance for the Backstretcher is extremely high.

---