Farabloc Trial May 2006

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Introduction

Farabloc is a patented cloth devised. by Frieder Kempe during 1978, in order to obtain relief from phantom limb pain experienced by his father, a WW II Veteran. It is manufactured by the Farabloc Development Corporation in Canada and is supplied by Medequip near Bristol, the sole distributor in the UK. The soft double layered material is a special weave of nylon and ultra fine stainless steel fibres. When applied it forms 'a cage around covered parts of the residual limb, to protect nerves from stimulation by high and ultra high frequency electro magnetic fields. The covers, which were custom made for the trial, are reusable, machine washable and can be ironed. At the first sign of phantom limb pain the cover is applied to the residual limb. It is important to cover any neighbouring scar tissue or painful areas at the time. If a patient is wearing a compression sock the Farabloc cover can be placed over the sock.

Phantom Limb Pain

The symptoms following amputation and subsequent healing of the stump may be characterised by stabbing, cramping, or a crushing sensation in the extremity of the missing limb. It affects the majority of amputees and can be very distressing.

Research

Research has been carried out for over twenty years in Europe and North America. Various journals have been written on the effectiveness of Farabloc. The results of trials demonstrate that the majority of amputees experience reduced limb pain.

Objective of the Trial

Was to ascertain the percentage of patients who experienced reduced pain levels and obtain their response on the suitability of the product.

Method

Twenty one patients were selected to take part in the trial. They were chosen by Prosthetists, Physiotherapists and Nursing Staff. The ages ranged between 30 to 80 years.

There were: 2 x TransTibial (Bilateral)

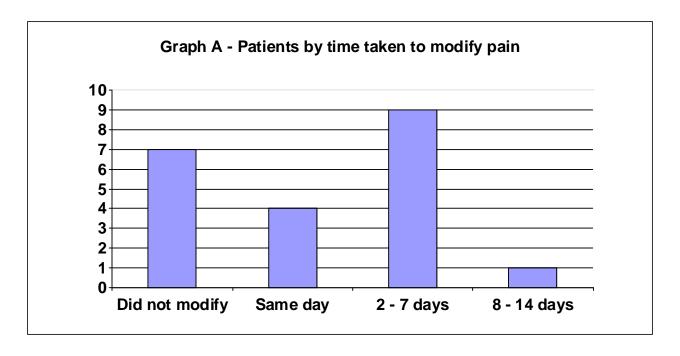
10 x Trans Femoral 8 x Trans Tibial 1 x Upper Limb

A questionnaire was supplied by Medequip and these were completed at ALAC by each patient after one month and two months. A final questionnaire was sent direct to patients after 3 months.

All patients were supplied by Medequip with Farabloc made to measure double layered covers.

Basic Level (Graph A)

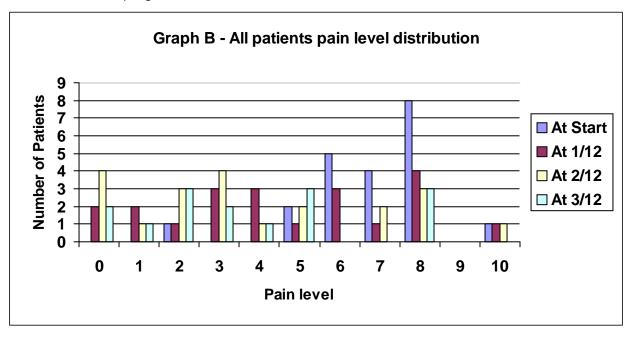
Patients were asked after one month whether Farabloc had modified their pain levels. If it had, they were asked how long they had been using the product before the modification in pain level became apparent.



Time Taken	Did not modify	Same day	2 -7 days	8 -14 days
Number of Patients	7	4	9	1

Overall reduction in pain (Graph B)

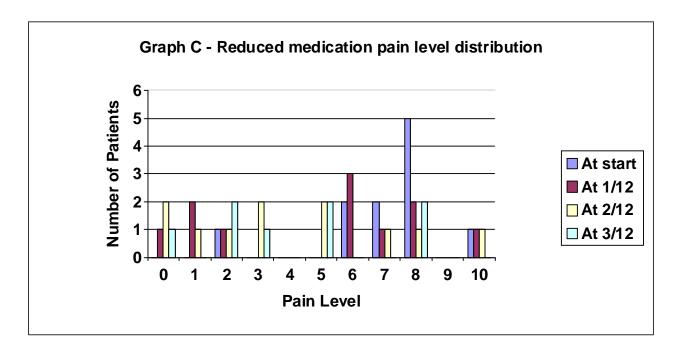
The patients, when considered as a group, exhibited a drop in pain level from the start of the trial through to the third month. This graph indicates the number of patients experiencing each pain level at the start and at the three stages of the trial (note: 6 of the 21 patients did not respond at three months and hence there are fewer patients represented at this stage). It can be seen that the longer bars (indicating more patients at that pain level) move to the lower pain levels as the trial progresses.



Pair	n Level	0	1	2	3	4	5	6	7	8	9	10
Number	At Start	0	0	1	0	0	2	5	4	8	0	1
of	At 1/12	2	2	1	3	3	1	3	1	4	0	1
Patients	At 2/12	4	1	3	4	1	2	0	2	3	0	1
	At 3/12	2	1	3	2	1	3	0	0	3	0	0

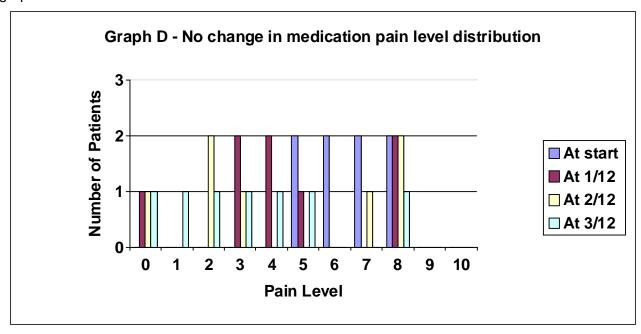
Reduction in pain medication (Graph C)

After 2 months 11 of the 21 patients had been able to reduce their pain medication. After 3 months 4 of the patients had been able to further reduce their pain medication (6 patients did not respond to the questionnaire at this stage). Graph C shows, in a similar way to the table of all patients, that even though there has been a reduction in pain medication there is a reduction or no increase in pain for the group as a whole.



Pair	n Level	0	1	2	3	4	5	6	7	8	9	10
Number	At start	0	0	1	0	0	0	2	2	5	0	1
of	At 1/12	1	2	1	0	0	0	3	1	2	0	1
Patients	At 2/12	2	1	1	2	0	2	0	1	1	0	1
	At 3/12	1	0	2	1	0	2	0	0	2	0	0

Thos patients who did not reduce their pain medication (including some who did not take medication) generally exhibited either a reduction in pain or no increase (1 patient had an increase in pain, 1 patient's pain level fluctuated). The 8 patients in this group are plotted on graph D.



Pair	n Level	0	1	2	3	4	5	6	7	8	9	10
Number	At start	0	0	0	0	0	2	2	2	2	0	0
of	At 1/12	1	0	0	2	2	1	0	0	2	0	0
Patients	At 2/12	1	0	2	1	0	0	0	1	2	0	0
	At 3/12	1	1	1	1	1	1	0	0	1	0	0

Farabloc trial results table

The table below sets out the results of the trial including indications of where data is missing due to patients not responding to questionnaires.

	Pain Level					Та	Taking pain medication				Medication Reduced at							Duration of wearings					Did use modify pain:	
Amputation	At start	After 1/12	After 2/12	After 3/12	Responded to pain questionnaire at 3/12	Start	1/12	2/12	3/12	Responded to taking medication questionnaire at 3/12	3/12	3/12	Responded to medication reduced questionnaire at 3/12	Easy to Apply	Comfortable	Responded to easy to apply/comfort questionnaire	1/12	2/12	3/12	Responded to duration questionnaire at 3/12	Would recommend	Will continue to wear	At 1/12	If yes, how long did it take
TT 8	6	8	8		No	Yes	Yes	Yes		No	No		No			No	24	24		No	Yes	Yes	No	
TT	8	8	7	8	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	13	8	17	Yes	Yes	Yes	Yes	Immediate
TF	8	6	3	2	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	10	8	11	Yes	Yes	Yes	Yes	2 weeks
TF	8	8	8	8	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	No	Yes	Yes	3	7		No	Yes	Yes	No	
TT	6	6	3	5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	2	0		No	Yes	No	No	
TT	7	7	5	2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	4	16		No	Yes	Yes	No	
TT	5	4	0	0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	0	1	Yes	Yes	Yes	Yes	3 days
TF	6	3	2		No	Yes	Yes	Yes		No	No		No			No	8	7		No	Yes	Yes	Yes	5 days
TF	7	3	2	4	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	6	8	5	Yes	Yes	Yes	Yes	6-7 days
TF	7	0	7	1	Yes	No	No	No	No	Yes	No	No	Yes	No	No	Yes	2	1	0	Yes	Yes	Yes	Yes	7 days
TT	8	0	0	5	Yes	Yes	Yes	No		No	Yes	No	Yes	Yes	Yes	Yes	12	8	8	Yes	Yes	No	Yes	7 days
BE	5	3	4	5	Yes	No	No	No	No	Yes	No	No	Yes	Yes	No	Yes	5	3		No	Yes	Yes	Yes	7 days
TF	8	1	2		No	Yes	Yes	Yes		No	Yes		No			No	7	3		No	Yes	Yes	Yes	20 mins
TT	2	1	0		No	Yes	Yes	No		No	Yes		No			No	24	1		No	Yes	Yes	Yes	Immediate
TT	8	4	0		No	Yes	Yes	Yes		No	No		No			No	24	4		No	Yes	Yes	Yes	2 days
TF	8	8	8	8	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	No	Yes	24	3		No	Yes	Yes	Yes	5 mins
TF	8	5	3	2	Yes	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	12	10	3	Yes	Yes	Yes	Yes	30 mins
TT	6	2	1	0	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	4	1		No	Yes	Yes	Yes	3-4 days
TT	7	6	5	3	Yes	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	4	6		No	Yes	Yes	Yes	1 day
TF	6	4	3	3	No	Yes	Yes	Yes		No	No	No	Yes	No	Yes	Yes	14	14		No	Yes	Yes	Yes	4 days
TT 8	10	10	10		No	Yes	Yes	Yes		No	Yes		No			No	2			No	No	No	No	

Other observations

- Easy to apply of the 15 patients who responded to this question, 12 found Farabloc easy to apply (80%).
- Comfortable of the 15 patients who responded to this question, 12 found Farabloc comfortable (80%).
- 20 out of 21 patients would recommend Farabloc (95%).
- 18 out of 21 patients said they would continue to use Farabloc at the end of the trial.

Conclusion

As shown on the graph, two thirds of the patients exhibit a reduction in pain level during the trial. While this percentage is significant and confirms that Farabloc does reduce pain for a majority of amputees, it is not successful on every patient.

Cost

The prices of the Farabloc covers ordered for the trial ranged from £45.00 to £110.00. The total cost for 21 covers was £2014.00 (average price £96.00).

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