A Survey of to Determine the Effectiveness of *Magnopulse LegCare* Static Magnets on Leg pain and Swelling

by

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Abstract

A telephone survey was conducted of 202 randomly selected users of *Magnopulse LegCare* static magnet leg wraps. The majority of the patients, 67%, using the LegCare used it for knee pain. Average duration of pain was 87.2 months with a range 1 to 600 months. Forty-five percent of respondents had associated leg swelling. The key findings were as follows:

Ninety six percent of respondents said there was a reduction in leg pain after wearing the device. There was an average of 73% reduction in leg pain after wearing the LegCare. This reduction in pain was highly statistically significant ($p<0.0001$). Eighty five percent of those who responded had a reduction in pain of at least 50%. Furthermore, 31% had no pain at all after wearing the device and 49% had a reduction in pain of 70% or more. The majority, 75%, had a noticeable reduction in pain within 14 days of wearing the LegCare. More than half (54%) of LegCare users required no further treatment for their leg pain.

Of those who had swelling, 72 of the original 202, 73% reported a reduction in leg swelling after wearing the LegCare. The average reduction in leg swelling after wearing the LegCare was 71%. This reduction in leg swelling was highly statistically significant ($p < 0.0001$).

Sixty five percent reported an improvement in quality of life after wearing LegCare of which 10% were much better. No doubt this was due to relief of pain and swelling. No respondent reported any worsening of health from wearing the device.

Introduction

It has been known for some time that the behaviour of certain types of biological materials are influenced by magnetic fields (Reno & Nutini, 1963). Subtle magnetic fields can produce a physiological effect. For example, pico-tesla range electromagnetic fields have been shown to have significant effects on nerve regeneration (Turing, 1952).
Electrical activity exists in the body at all times e.g. the beating heart. The heart is the biggest electromagnetic field generator in the body (Eyster et al, 1933). Mechanical loading of bones generates electrical currents. The discovery of magnetic material (deposits of magnetite) in the human brain may suggest that we are physiologically designed to respond to magnetic fields (Kirschvink et al, 1992).

The public acceptance of magnet therapy (and alternative/complementary therapy in general) far outweighs its acceptance by the medical community. We live in an era where evidence-based medicine is vogue. By this we mean evidence of effectiveness or benefit over and above "the placebo". As with all treatments it is important to know that they are efficacious but also that they are safe. The Japanese have used magnets for years to treat chronic fatigue syndrome and have suggested that an increase in environmental electromagnetic pollution and/or progressive inability to be energized by the earth's magnetic field (Rosch, 1998) is important in its aetiology. The Yellow Emperor's Canon of Internal Medicine, some 4,000 years ago also talks about stones and heat and magnets working over acupuncture meridians. In the last 2 decades the Japanese have been using magnets to relieve pain.

There is little doubt that oscillating electromagnetic fields can relieve pain and inflammation but static magnets are motionless magnetic fields until recently there have been very few studies of the efficacy of static magnetic fields in pain.

There are many anecdotal reports of effective pain relief from static magnets from users including athletes (White,1998) and physicians (Weintraub,2000) and unpublished reports of increased healing and reduced pain by physicians (Barnothy,1964; Henren,1997; Ruibal,1997). In 1938, Dr Hanson reported pain relief on himself after application of a static magnet. Estimate worldwide profits from sales of static magnets exceed $5 billion annually. A quest for analgesia would appear to be a major part of these sales and it is hard to believe that devices that were ineffective could sustain this level of turnover. After 2,000 years of deliberation, the jury is still out. A bone growth stimulator, which works by electromagnetism, has an 80% success rate in promoting the union of non-healing fractures and has FDA approval (Bassett et al,1982). A similar device has also been approved for aiding female incontinence (Galloway et al,2000). Armed with this information one would have expected a huge interest in the potential further applications of electromagnetic fields to promote healing in other clinical situations but this field does not appear to occupy a significant proportion of Medical Research. Most early research on magnets took place in Europe but the research in North America is now expanding.

A recent unpublished Systematic review of randomised controlled trials of static magnets for pain relief (Eccles, 2002) showed that overall 9 of the 12 studies reported a significant analgesic effect due to static magnets. Of the 10 better quality studies, 7

were positive and 3 were negative. In 2 of the negative studies there are major concerns over adequacy of magnet power for the type of pain (300 gauss for chronic back pain, Collacott et al, 2000), a query raised by the authors themselves, and of duration of exposure (5 minutes in Harper & Wright, 1977). The latter authors also failed to state the power of the magnet used in their study. Excluding a further 2 studies on grounds of inadequate magnet exposure then 7 out of 8 of the better quality studies demonstrated a positive effect of static magnets in achieving analgesia across a broad range of different types of pain (neuropathic, inflammatory, musculoskeletal, fibromyalgic, rheumatic and post-surgical).

Objectives

The purpose of this survey was to assess the extent of the effectiveness of LegCare, a static magnet product that is commercially available for the treatment of leg pain. There has been an accumulating wealth of anecdotal evidence of its effectiveness to promote resolution of leg pain. The design of the survey and independent analysis of the data was commissioned by the company *Magnopulse*, the manufacturers of the product. The survey is also an antecedent to a double blind placebo-controlled trial to investigate the effectiveness UlcerCare, a sister product, in promoting leg ulcer healing and relief of leg pain.

If proven to be as effective as the anecdotal evidence suggests there is an enormous potential saving to the NHS of a simple and yet effective adjunct treatment such as this to existing pain treatments, particularly in the elderly population who not only have a higher incidence of pain due to a higher prevalence of degenerative disease but also who are more susceptible to untoward side effects form pain-relieving medications.

Methods

A questionnaire survey was conducted by telephone of 202 randomly selected LegCare users. Verbal consent was obtained and also consents for the data to be used as part of a scientific analysis to assess the efficacy of the products. No exclusions were made on the basis of age or sex or on the basis of location. No incentives were offered to those taking part in the survey. The questionnaire used in the study is shown in Fig 1.

LegCareDescription
The LegCare wrap contains four powerful neodymium magnets (2000gauss). Each magnet has patented and unique directional plates that allow the negative enhanced magnetic field to be absorbed deeper into the tissues; it is thought that this gives more effective and longer lasting effect. The leg wrap should be worn as much as possible (including overnight). The wraps are fitted below the knee and above the calf muscle and are held in place by velcro fastenings. The leg wraps are double lined for comfort, and are adjustable and washable.
The product is registered as a Class 1 Medical Device.
Magnopulse quote on the product information" Leg Wraps were developed on the principle that most injuries will heal naturally if your body can supply enough oxygen and nutrients to the affected area. We believe the high success of the Leg Wrap is due to improved blood flow. In most cases this will help those with ulcers and leg problems to heal naturally without the use of drugs".
Statistical Analyses
For all the comparisons below the parametric t-test is used, as the sample size is sufficiently large. In particular, for the comparisons of the reduction in pain and swelling with regard to the baseline value a one-sample t-test is used while for the comparisons between males and females the two-sample t-test is employed. Finally, in order to compare the number of painkillers taken before and after LegCare a paired t-

test is used. For all hypothesis tests a 5% significance level ($p<0.05$) and two-tailed tests are taken.

Figure 1. LEGCARE & ULCERCARE QUESTIONNAIRE

Questionnaire for users of the LegCare and UlcerCare from *Magno-Pulse*. Private and confidential - your answers are for general statistics that will help in the development of magnetic healthcare products. They will not be used in publicity without your express permission at the time of use.

Date:

Name:

Age:

Address:

Telephone number:

Date of Purchase: one two

Has the LegCare Leg wrap helped you? Yes No

If No How long did you try the leg wraps?

Did you receive any benefit? Yes No

If Yes

Position of Ulcer Foot Ankle Calf Shin

How long have you had Ulcers? Months Years

Was your leg swollen? Yes No

Did the *LegCare* reduce the swelling? Yes No

On a scale of 1 to 10 if 10 was the swelling to begin with what was the level of swelling after using the *LegCare*? 0 1 2 3 4 5 6 7 8 9 10

Were your legs Painful? Yes No

Did *LegCare* reduce the pain? Yes No

On a scale of 1 to 10 if 10 was the pain to begin with what was the level of pain after using the *LegCare*? 0 1 2 3 4 5 6 7 8 9 10

Previous / current treatment (other than *LegCare*)

Please write in the approximate length of time in days

-Are you still wearing your leg wrap? Yes No at Night

-How many hours a day?

-If not, how long did you wear the leg wrap?

-How many hours a day did you wear it?

-How long before you noticed any difference? **weeks** 1 2 3 4 other

-On a scale of 1 to 10 if 10 was the size of your ulcer to begin with what would its size be after using the *UlcerCare*?

0 1 2 3 4 5 6 7 8 9 10

-If completely healed how long did it take to heal?

-Do you still need Pain Killers? Yes No

-If so, how many do you take a day (total of all painkiller tablets)?

-How many painkillers were you using a day prior to using the *LegCare*?

-Is further treatment required now? Yes No

Are you satisfied with the leg wrap? Yes No

Has *LegCare* affected your **quality of life**? Yes No

Much worse	Worse	About same	Better	Much Better

Has *LegCare* led to a **change in your health**?

Much worse	Worse	About same	Better	Much Better

Has *LegCare* affected your **ability to perform daily tasks**?

Much worse	Worse	About same	Better	Much Better

Did you before using *LegCare* have any feelings of: *Please circle any applicable*

Anxiety depression downhearted/feeling blue Irritability?

If yes to the above are these **feelings** now?

Much worse	Worse	About same	Better	Much Better

Reason……

Was your Doctor / Nurse happy with the results? Yes No Don't know

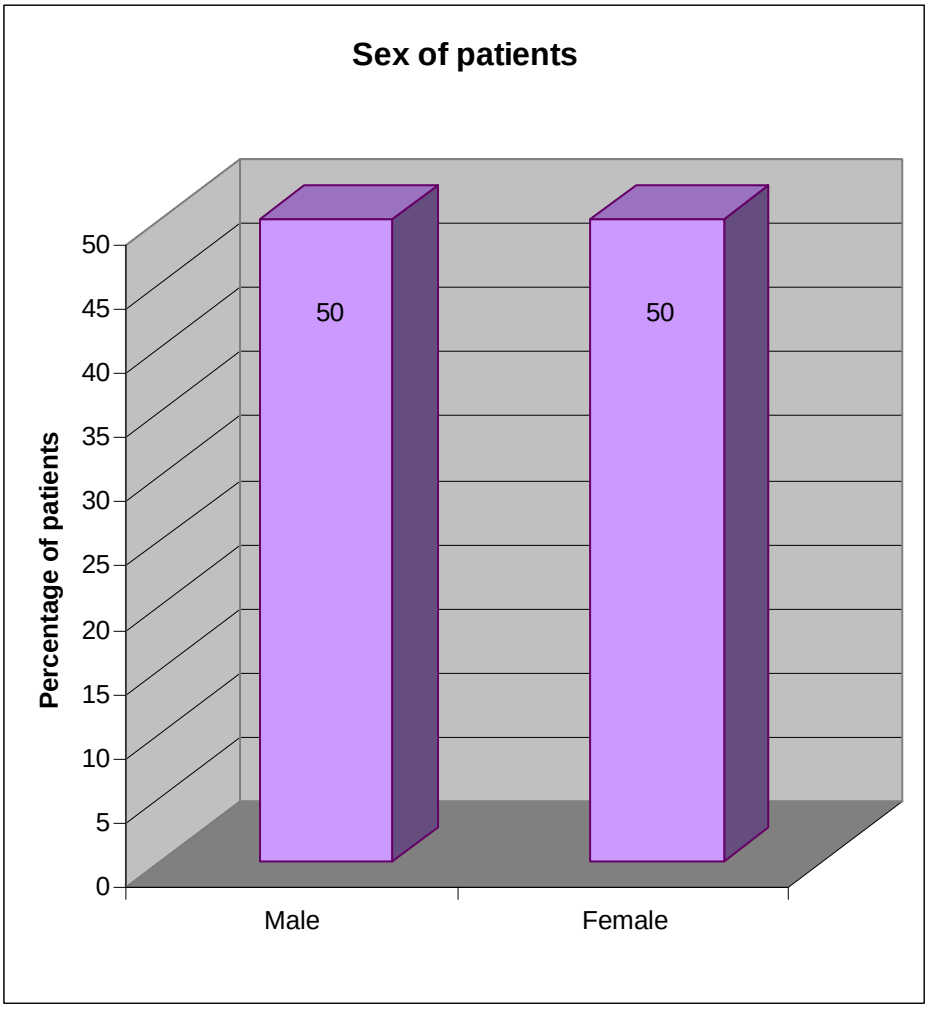
Would you like to make any further comments?

Would you be happy for us to use your case study for publicity in the media, in a one off interview with a journalist? (We would consult you before we talk to any media to check that you were still happy for us to use your details.)

Yes No

RESULTS

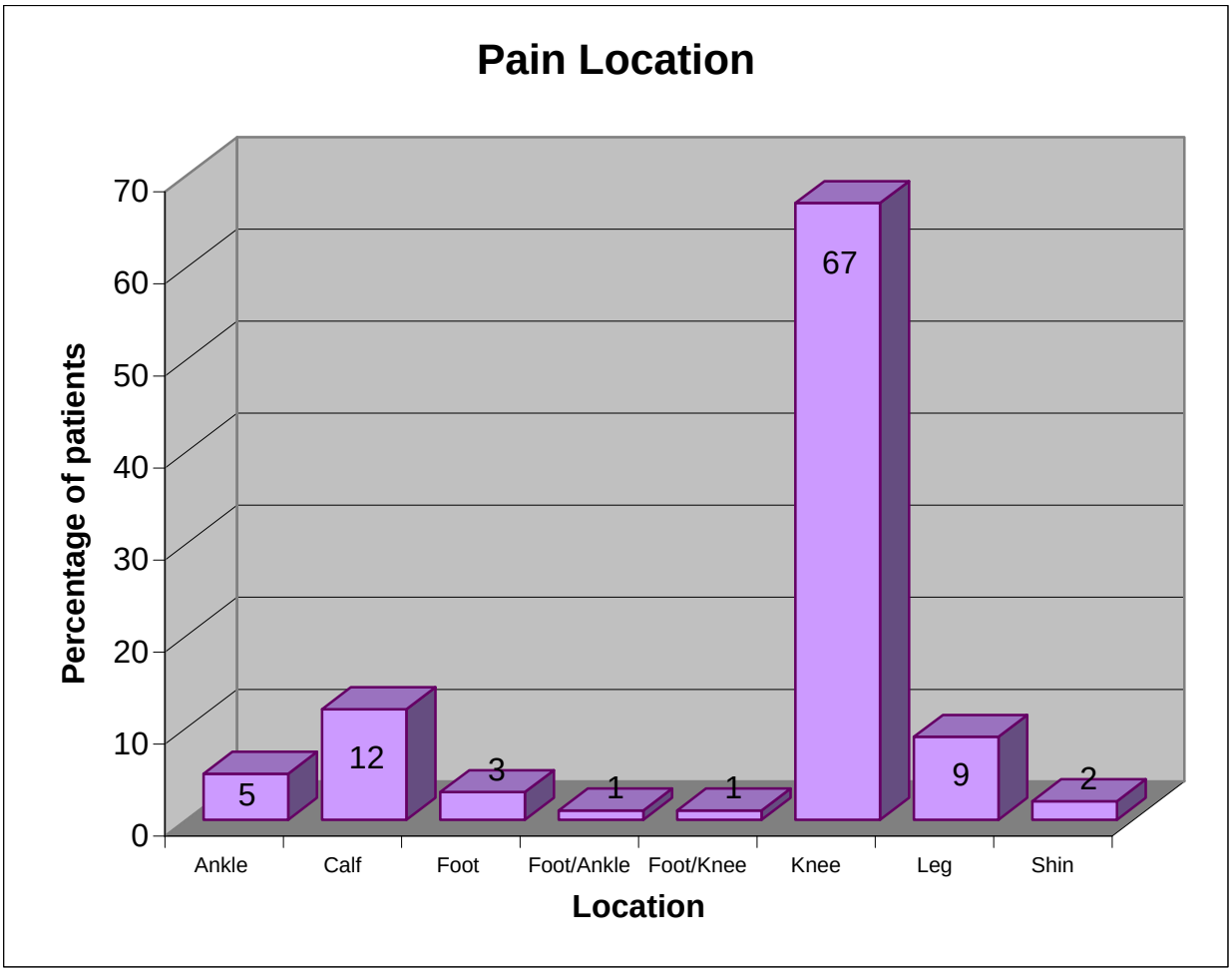
Sex of Patients



Of the 202 patients surveyed sex distribution was the same.

Unfortunately, the person conducting the telephone enquiry did not record the ages of the respondents.

Location of Pain



Percentage of patients who responded to the question 75%

The majority of the patients, 67%, using the LegCare used it for knee pain.

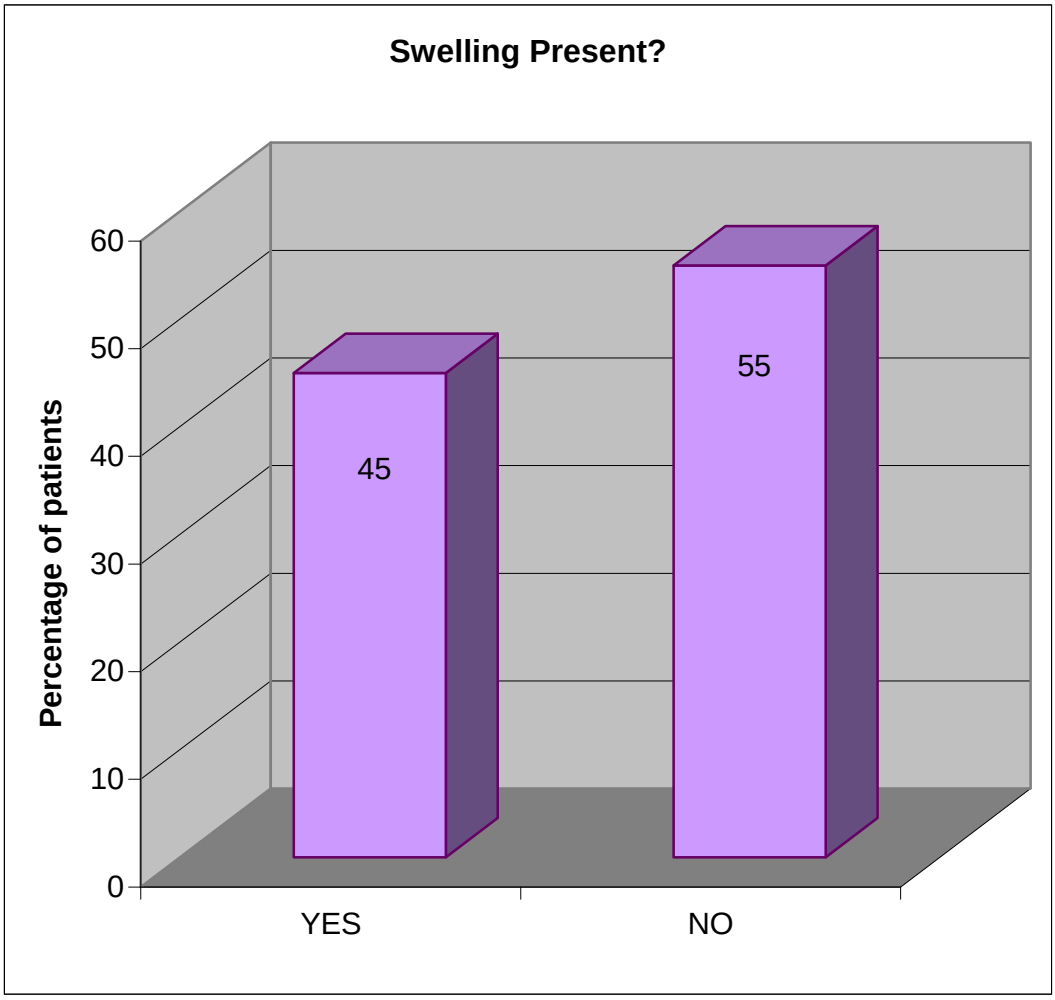
Duration of Pain

Average duration of pain was 87.2 months.

Range 1 to 600 months.

Percentage who responded to the question 54%

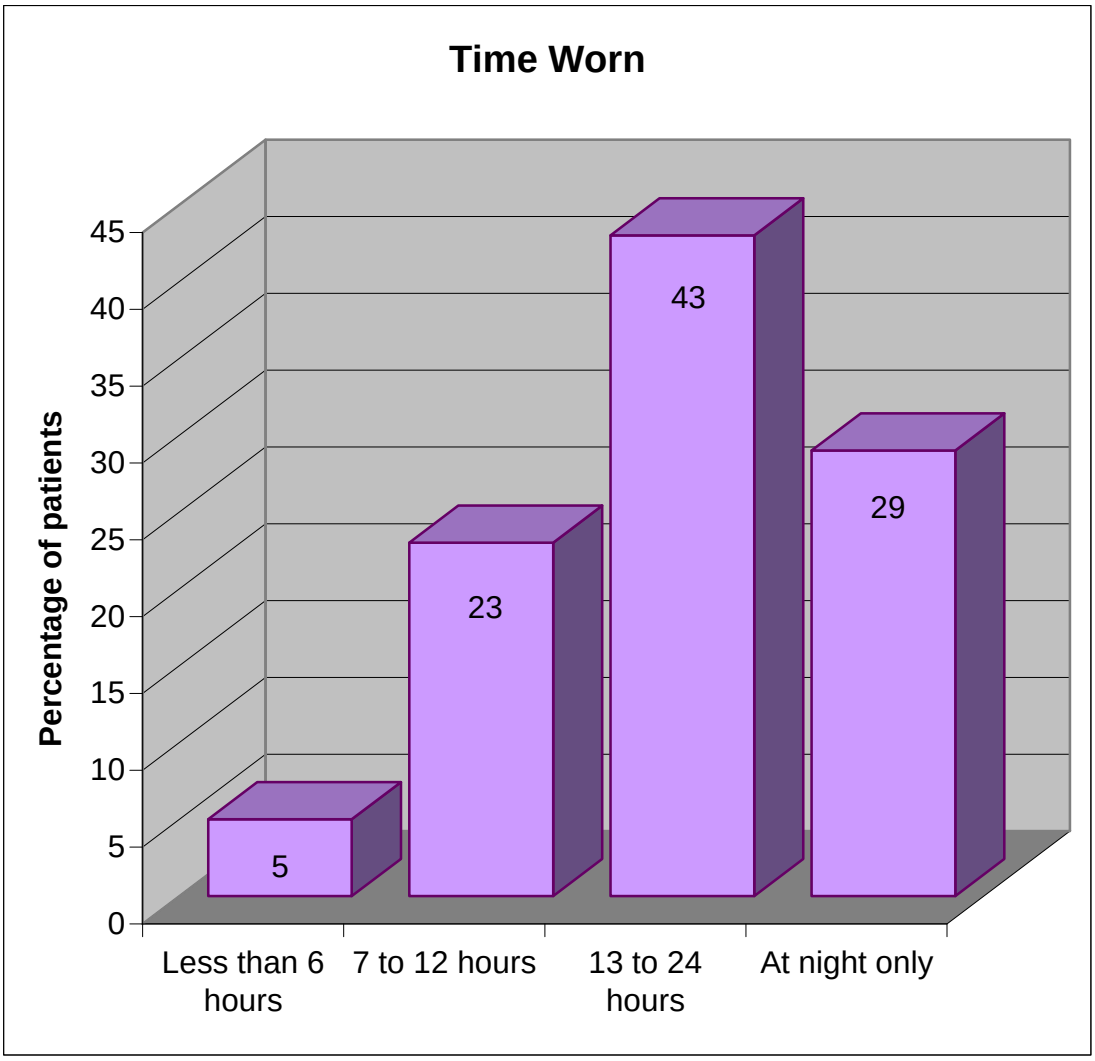
Associated Swelling?



45% had associated leg swelling.

Percentage response to the question 79%

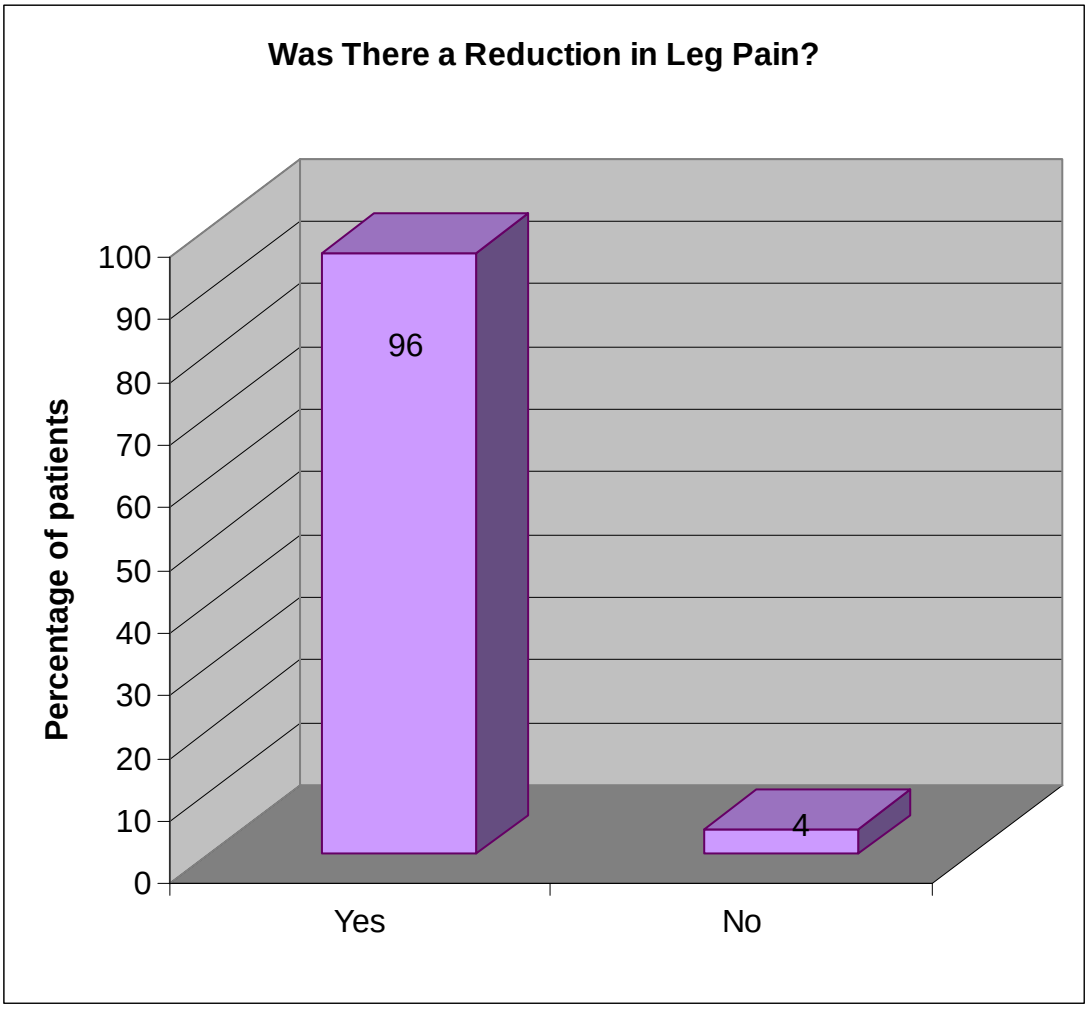
Duration LegCare worn per day



95% of patients questioned wore the device for more than 6 hours a day.

Percentage response to the question 66%.

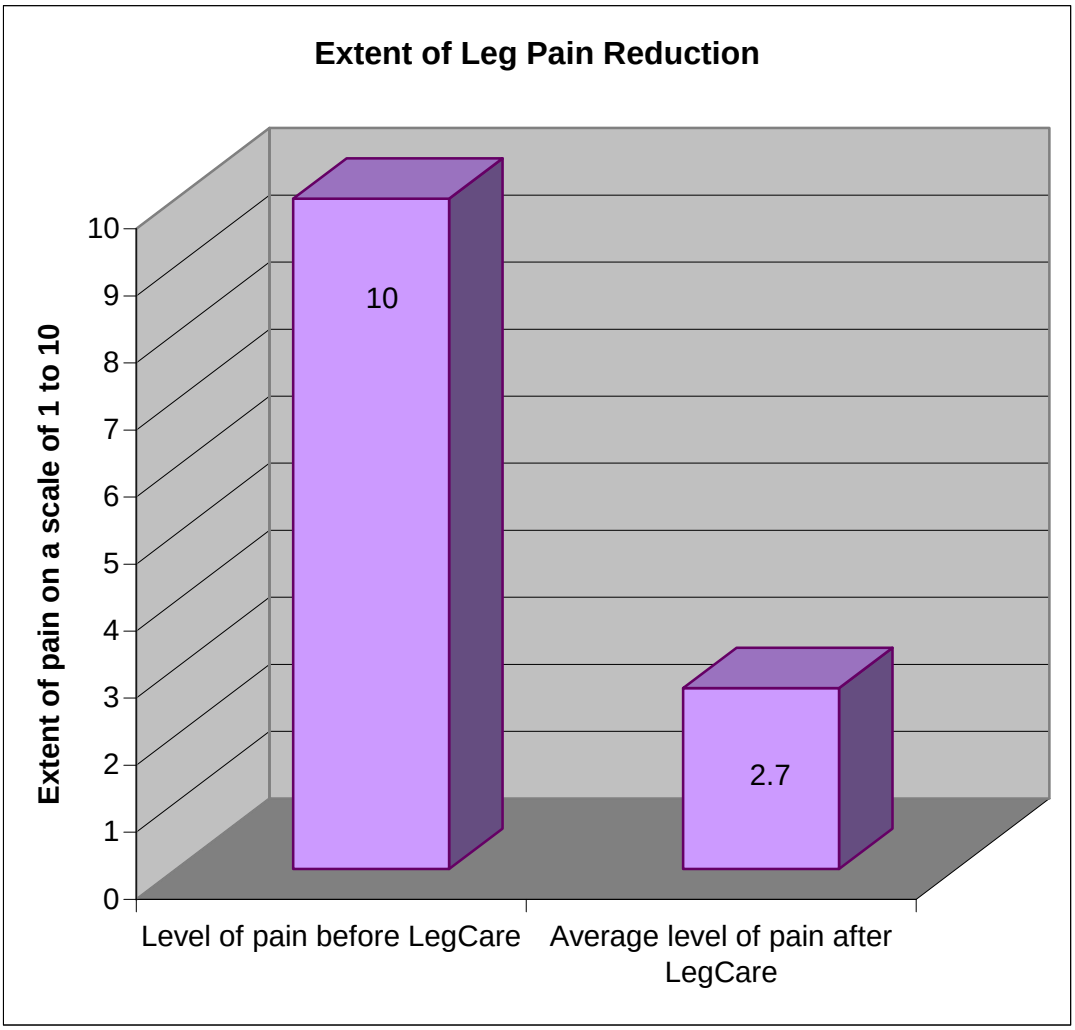
Was there a reduction in leg pain?



Percentage response to question 65%

When asked the question “Was there a reduction in leg pain after wearing the device?” 96% responded in the affirmative.

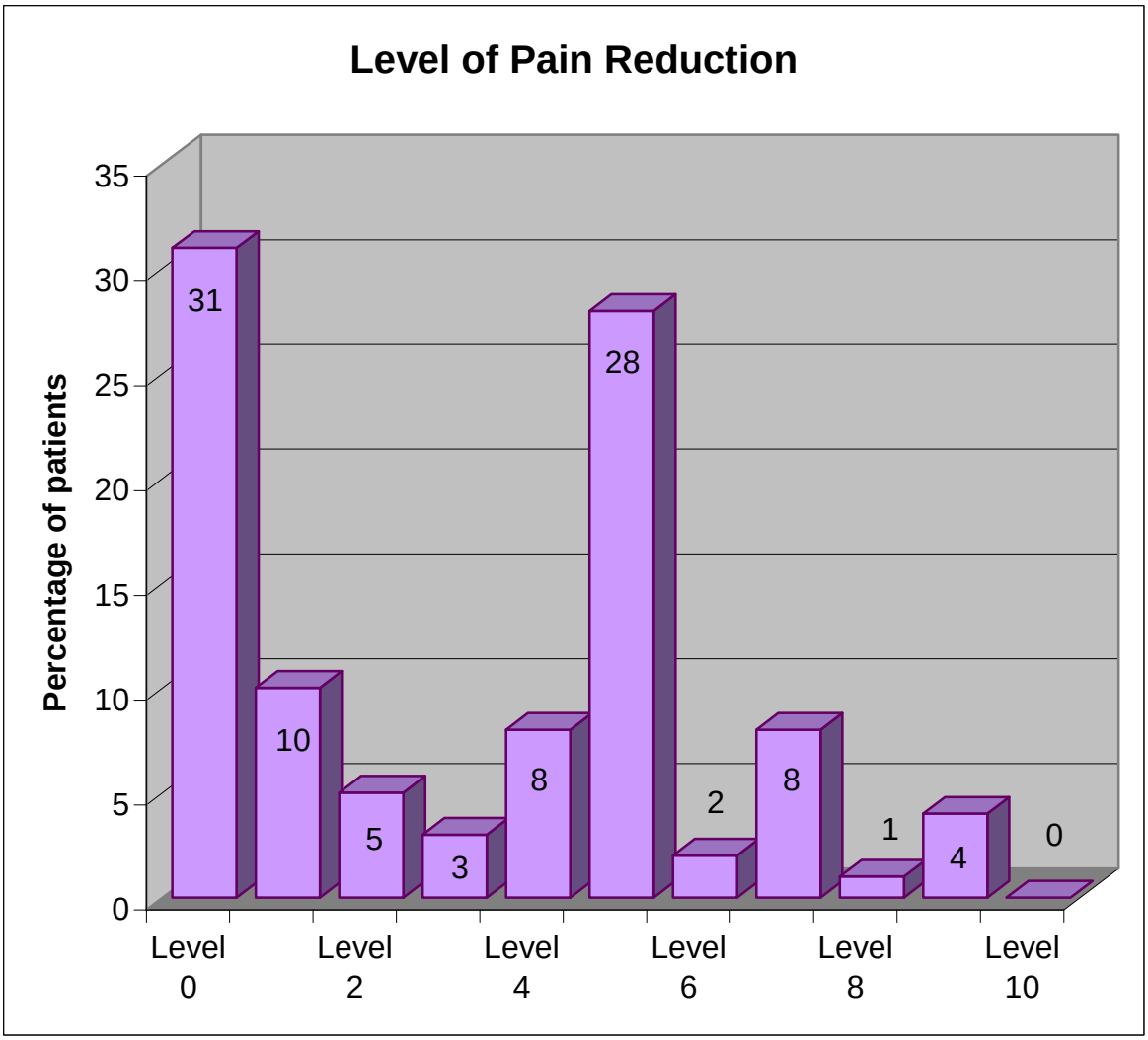
Pain Reduction



There was an average of 73% reduction in leg pain after wearing the LegCare. This reduction in pain was highly statistically significant ($p<0.0001$). There was no sex difference in pain reduction ($p= 0.679$)

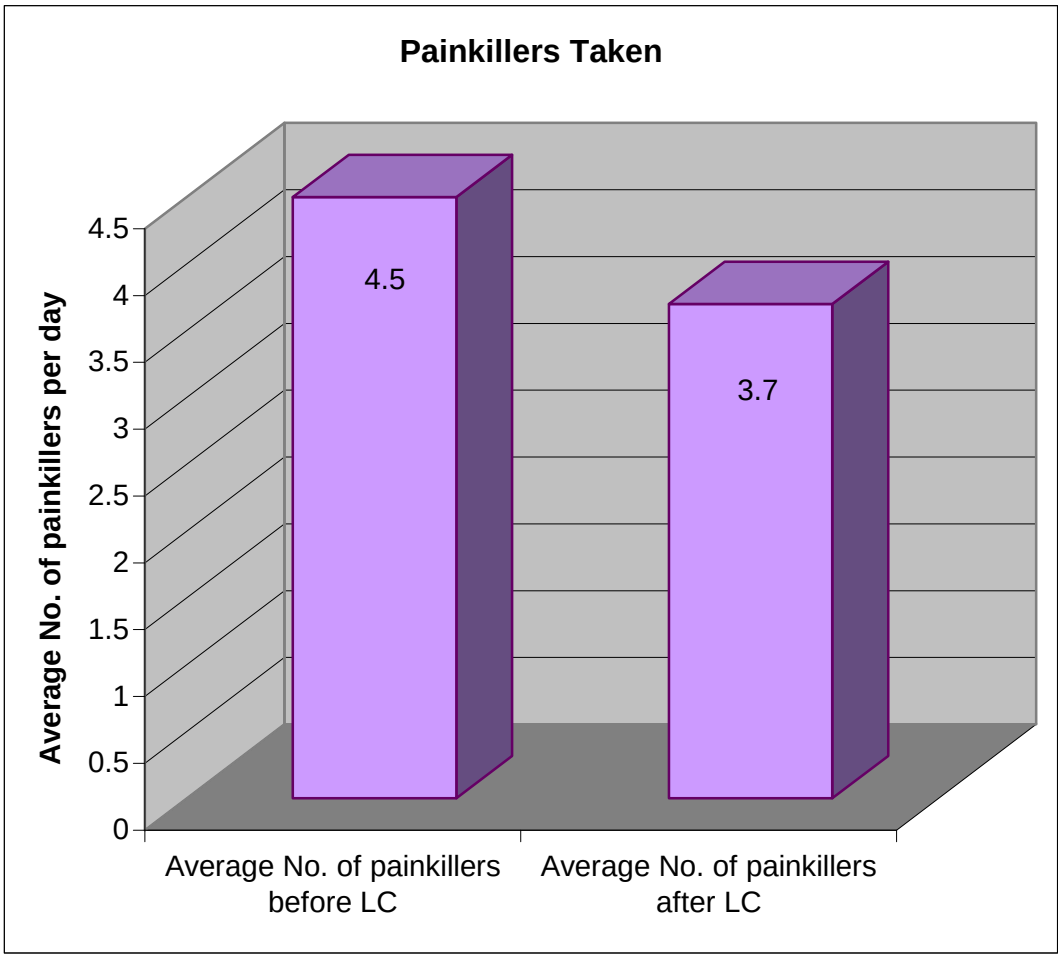
Percentage response to the question 64%.

Level of Pain Reduction



The levels of pain on the above graph refer to the level of pain on a scale of 1-10 after wearing the device. Hence level 0 means no pain. 85% of those who responded had a reduction in pain of at least 50%. 31% had no pain at all after wearing the device. 49% had a reduction in pain of 70% or more.

Painkillers



Percentage response to the question 23%. It is uncertain why the response to this question was so poor and probably lies in the fact that the importance of a response to this question was not stressed.

The apparent reduction in intake of painkillers after use of the LegCare is not in fact statistically significant ($p=0.291$). Given the significant reduction of pain reported after wearing the LegCare it is almost certain that the poor response to the question has undermined the significance of this result.

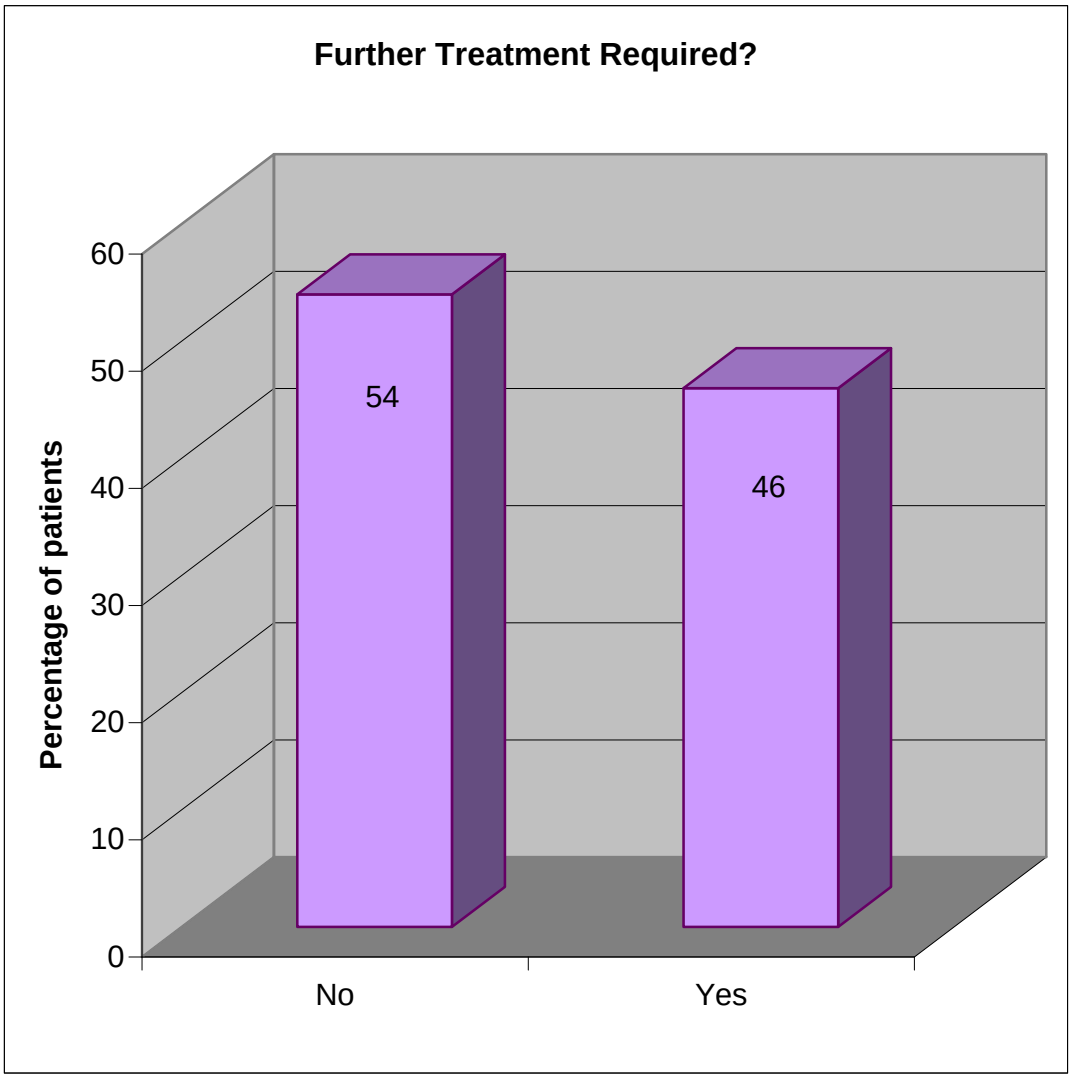
Time to notice a difference in pain symptoms

Percentage response to the question 91%

Time	%
7 days or less	42
8 - 14 days	33
15 - 28 days	18
More than 28 days	7

The majority, 75%, had a noticeable reduction in pain within 14 days of wearing the LegCare.

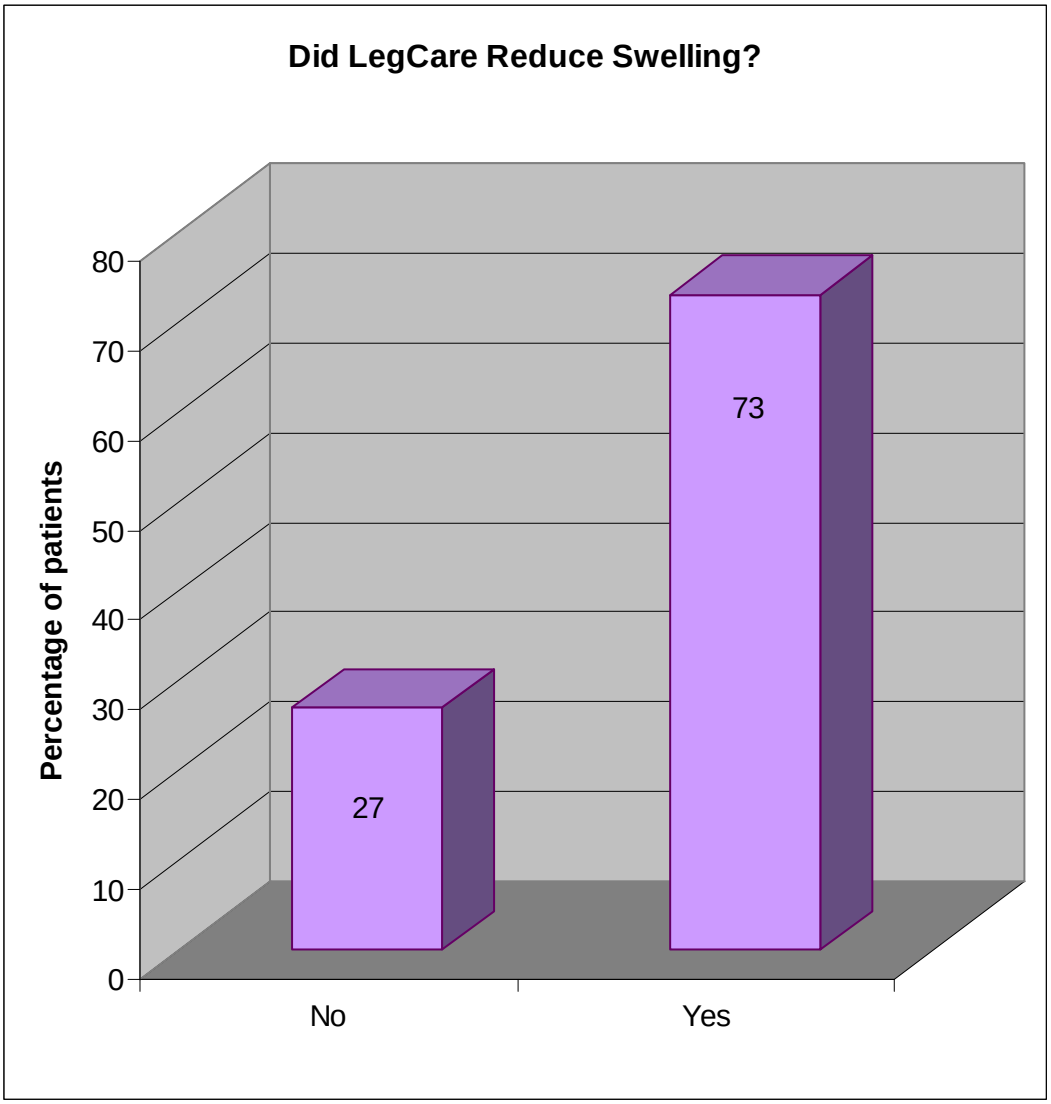
Further Treatment required?



Percentage response to the question 75%

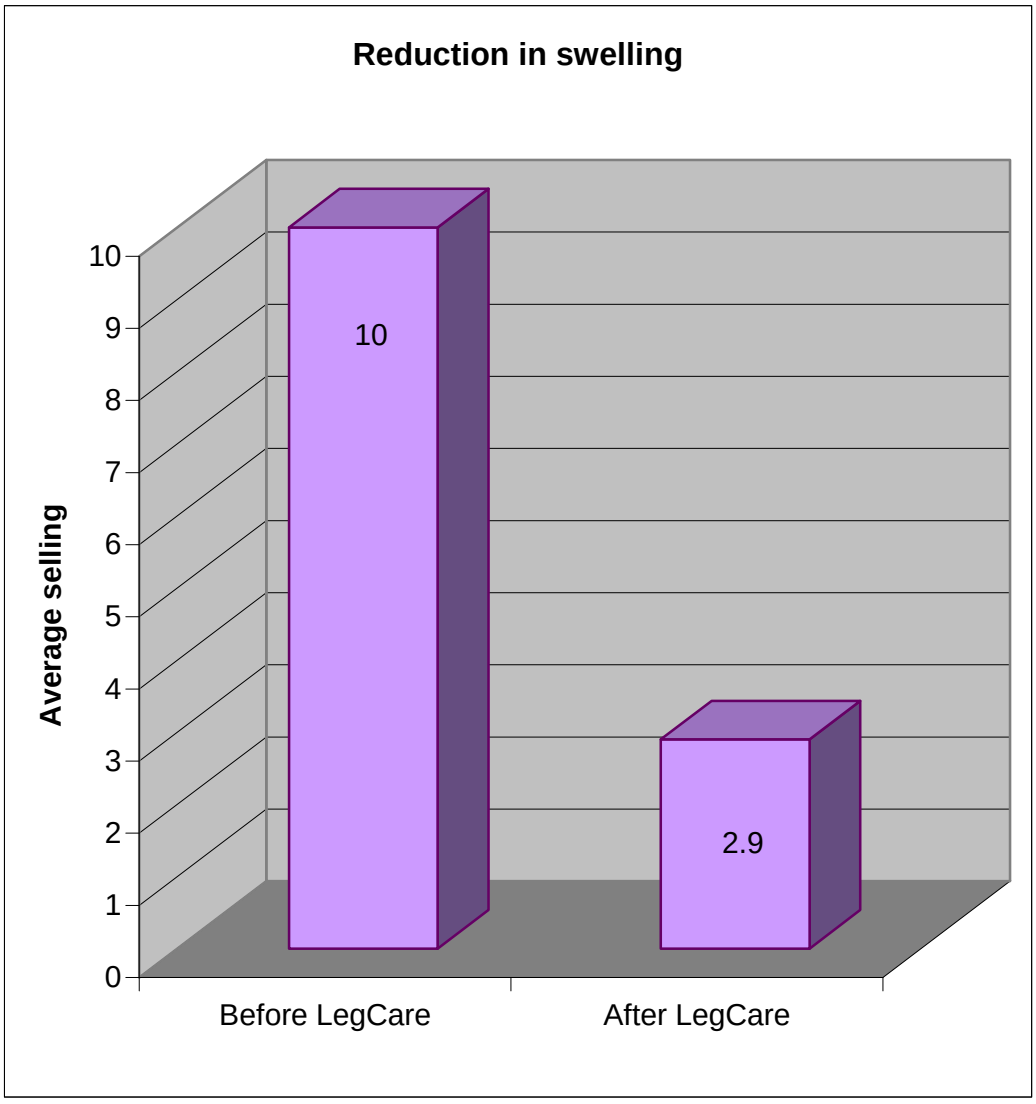
54% of LegCare users required no further treatment for their leg pain.

Did LegCare reduce leg swelling?



Of those who had swelling, 72 of the original 202, 73% reported a reduction in leg swelling after wearing the LegCare.

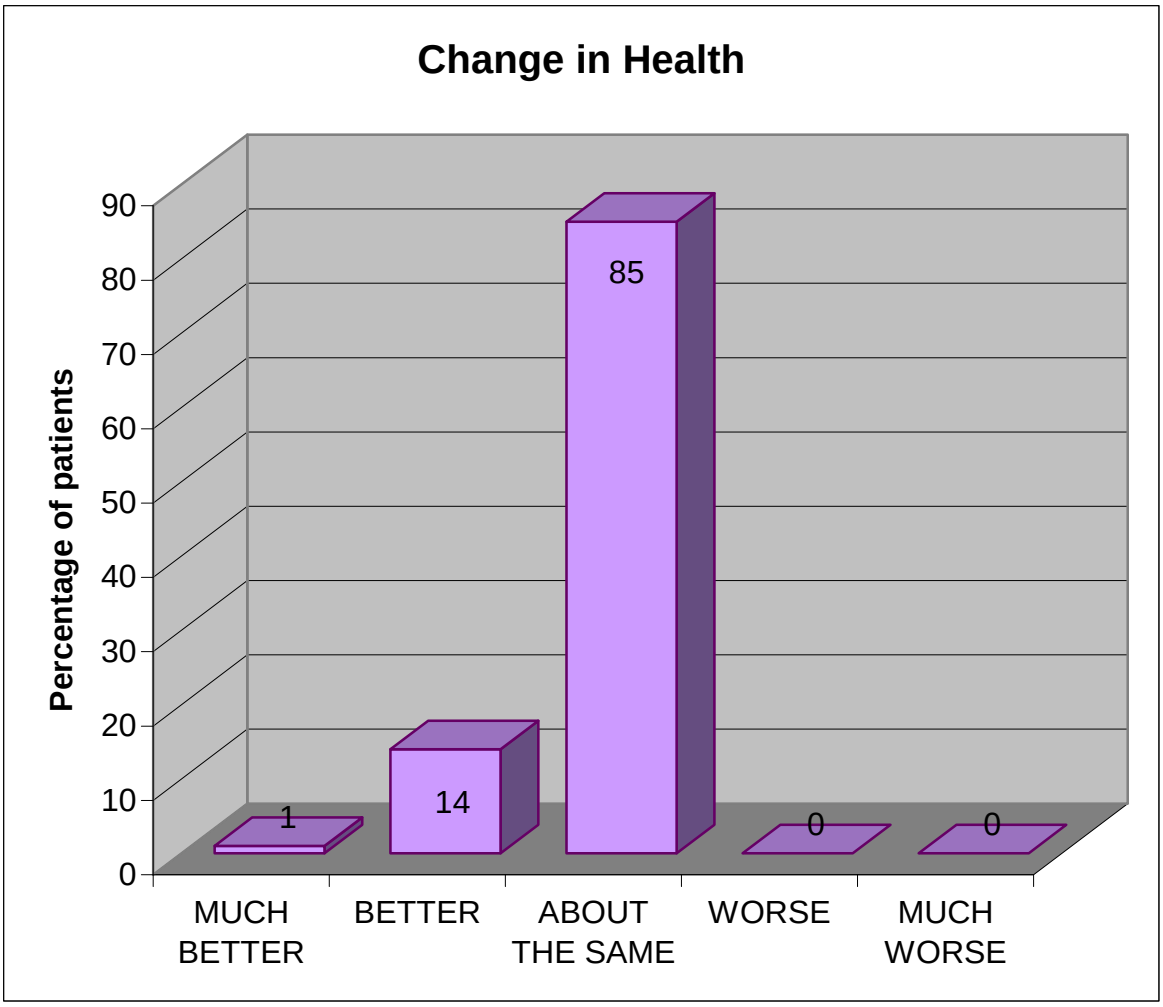
Average reduction of leg swelling



Percentage of those with leg swelling that responded to the question 81%

The average reduction in leg swelling after wearing the LegCare was 71%. This reduction in leg swelling was highly statistically significant ($p < 0.0001$). There was no sex difference in the degree of reduction of leg swelling that was achieved by the device ($p = 0.349$).

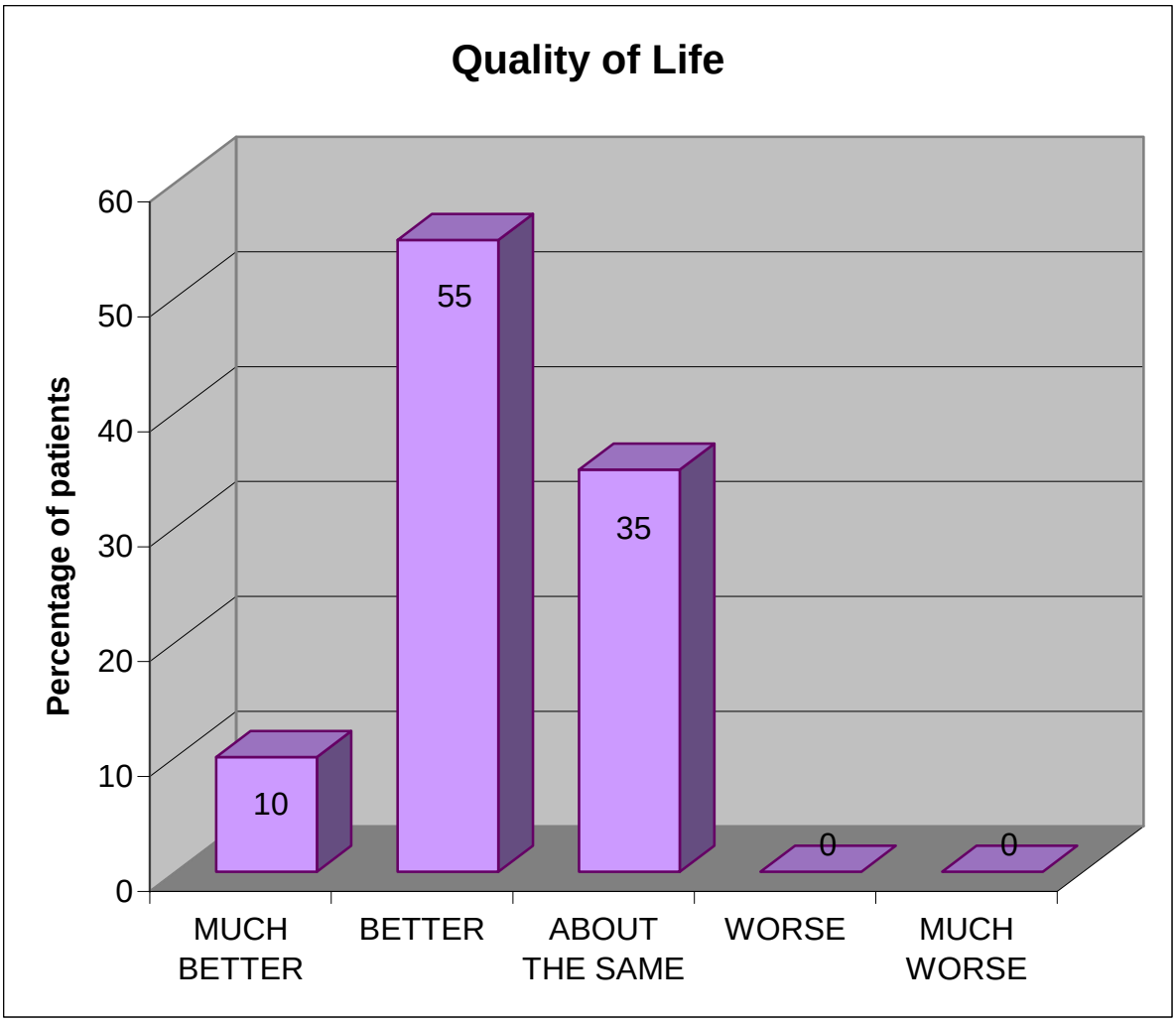
Change in Health



Percentage response to the question 77%

15% reported an improvement in health but the majority (85%) said their health was the same. Perhaps equally important was that no respondent reported any worsening of health from wearing the device.

Quality of Life



Percentage response to the question 77%

65% reported an improvement in quality of life after wearing LegCare of which 10% were much better. No doubt this was due to relief of pain and swelling.

SUMMARY AND CONCLUSIONS

Summary and Conclusions

Of the 202 patients surveyed there were equal numbers of men and women. Unfortunately, the person conducting the telephone enquiry did not record the ages of the respondents.
The majority of the patients, 67%, using the LegCare used it for knee pain. Average duration of pain was 87.2 months with a range 1 to 600 months. Forty-five percent of respondents had associated leg swelling.
Ninety five percent of patients questioned wore the device for more than 6 hours a day with 29% wearing the device at night only. Ninety six percent of respondents said there was a reduction in leg pain after wearing the device. **There was an average of 73% reduction in leg pain after wearing the LegCare. This reduction in pain was highly statistically significant ($p<0.0001$).** There was no sex difference in pain reduction ($p= 0.679$).
Eighty five percent of those who responded had a reduction in pain of at least 50%. Furthermore, 31% had no pain at all after wearing the device and 49% had a reduction in pain of 70% or more.
The majority, 75%, had a noticeable reduction in pain within 14 days of wearing the LegCare. More than half (54%) of LegCare users required no further treatment for their leg pain. There was a small reduction in intake of painkillers after use of the LegCare but this was not in fact statistically significant ($p=0.291$). Given the significant reduction of pain reported after wearing the LegCare it is almost certain that the poor response to the question (only 23% of respondents) has undermined the significance of this result.
Of those who had swelling, 72 of the original 202, 73% reported a reduction in leg swelling after wearing the LegCare. The average reduction in leg swelling after wearing the LegCare was 71%. This reduction in leg swelling was highly statistically significant ($p < 0.0001$). There was no sex difference in the degree of reduction of leg swelling that was achieved by the device ($p = 0.349$).
Fifteen percent reported an improvement in health but the majority (85%) said their health was the same. **Perhaps equally important was that no respondent reported any worsening of health from wearing the device.**
Sixty five percent reported an improvement in quality of life after wearing LegCare of which 10% were much better. No doubt this was due to relief of pain and swelling.

A recent systematic review has reported a significant trend towards static magnets being effective analgesics (Eccles, 2002). Overall 9 of the 12 studies reported a significant analgesic effect due to static magnets. Of the 10 better quality studies with 3 points (Table 2 & 3) or more on the quality assessment, 7 were positive and 3 were negative. Seven out of 8 of the better quality studies demonstrated a positive effect of static magnets in achieving analgesia across a broad range of different types of pain (neuropathic, inflammatory, musculoskeletal, fibromyalgic, rheumatic and post-surgical). It is uncertain whether this effect is mediated by a change in circulation and/or an effect on ionic exchange and pain signalling. Generally however, these results together with the evidence cited above clearly point towards static magnets having a significant interaction with human physiology.
Moreover, a recent double blind placebo-controlled trial of LadyCare, another Magnopulse product demonstrated a statistically significant reduction ($p< 0.05$) in

dysmenorrhoea in women who had regular period pain when the device was worn 1-2 days prior to the onset of menses (Eccles, 2002). Seventy percent of the subjects in the LadyCare group had at least a 50% reduction in pain, 47% of whom had a > 75% reduction in pain.
These results are also consistent with the reported effects on pain from a similar telephone-based survey conducted on a sister product UlcerCare which demonstrated that 84.5% of the 160 respondents had a reduction in associated leg pain with UlcerCare. This reduction in pain was highly statistically significant, $p < 0.0001$. There was a statistically significant reduction in painkiller consumption after using UlcerCare ($p< 0.030$), with 57% of patient's no longer taking painkillers at all.

These results taken together argue strongly for the ability of appropriately designed static magnets to effect pain relief to a significant degree.
The potential cost savings to the NHS are enormous both in terms of drug spending on analgesics as well as time saved in consultations or indeed in hospital admissions for treatment of patients with pain. This is all perhaps insignificant compared to the potential impact on patients' lives that have chronic pain that is not well controlled by analgesics. This report demonstrates an impressively high level of impact on chronic leg pain with a significant proportion 65% reporting an improvement in quality of life after wearing LegCare.

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APPENDICES