

**A Survey to Determine the Effectiveness
of *Magnopulse UlcerCare* Static Magnets
on Leg Ulcer Healing and Leg pain**

by

Dr Nyjon. K. Eccles BSc MBBS PhD MRCP
& Derek. R. Price

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Abstract

A telephone survey was conducted of 160 randomly selected users of *Magnopulse UlcerCare* static magnet leg wraps. Average ulcer duration was 49 months i.e. just over 4 years. The device had been worn for an average of 4 months at the time of the survey. The key findings were as follows:

A highly significant reduction ($p < 0.0001$) in ulcer size of 68% was achieved over the treatment period. Forty one percent (41%) of patients experienced complete ulcer healing with only 11% of patients had no effect on ulcer size. The average time to heal in those that had complete healing was 3.9 months.

Seventy two percent of those with associated swelling had a reduction in swelling after wearing UlcerCare with an average reduction in swelling of 71%. This reduction in swelling was highly statistically significant, $p < 0.0001$.

Eighty four and a half percent (84.5%) 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 patients no longer taking painkillers at all.

The majority, 54.5% reported an improvement in ability to perform daily tasks with 64% reported an improvement in the quality of life. This was at least in part due to less pain, less restriction and greater mobility.

Introduction

In the field of medicine as a whole there has been a recent surge in interest by patients and physicians alike in the use of magnetic fields in the treatment of pain. Attraction of the lay healer, the over promotion and unscientific approach to study and aggressive claims have led to scepticism. New controlled studies have begun to change this stance. In a recent scientific review (Eccles, 2002) of 12 double-blind placebo-controlled studies 7 out of the 8 well-controlled studies demonstrate a positive effect of static magnets in pain relief.

Although well-controlled studies have been performed on the stimulation of bone growth by electric and magnetic fields, effects of magnetic fields on soft tissues remain unclear; they represent the next frontier in electromagnetic biology and medicine. Electrical and magnetic field have been associated with a number of demonstrable effects that are advantageous to wound healing such as increased collagen deposition, increased fibroblast migration, increased migration of macrophages and leucocytes leading to decreased bacterial counts, reduced sympathetically-mediated vasoconstriction, increased cellular oxygen delivery and increased wound epithelialization (Mann et al, 1999).

All electrical currents generate magnetic fields and all magnetic fields cause a change in electrical potential. *Therefore, an interaction of magnetic fields with ion fluxes across the cell membrane is very likely.*

Atoms are spinning magnets and therefore must interact with each other. It is logical to assume that magnetic fields can influence the charged state of biological systems (Adey, 1986). Living systems maintain magnetic profiles in the range of 10^{-7} Gauss to 10^{-12} Gauss. Faradays law states that a magnetic field will exert a force on a moving ionic current. Ionic currents across cell membranes are fundamental to maintenance of cellular integrity and cell communication. Ionic effects e.g. changes in ion binding have been described with magnetic fields as low as 0.1 to 1 microtesla (Muehsam & Pilla, 2000).

Healthy cells seem to have greater electrical charge than unhealthy cells (Owen, 1986). Cellular health and efficient function is to a large degree dependent on the maintenance of correct ionic gradients across the cell membrane. These ionic gradients are maintained by continuous inputs of energy. Most of the chemical energy of our body is used up to re-establish ion gradients, gradients that keep metabolic processes going, including signaling mechanisms. Important examples include Na/K transporters, which can either be antiporters, coupling the counter movement of Na and K ions across membranes, or symporters, moving Na⁺ and K⁺ synchronously and unidirectional to the same side of the membrane.

There is certainly evidence that electrical fields are a necessary component of amphibian limb regeneration (Borgens et al, 1977, 1979, 1979; Venable et al, 1983). That electrical fluxes are important in healing in mammals is evident from studies on bone deformation. Compression of bone generates a negative electrical potential. Furthermore, the cells are responsive to alteration in externally applied DC electrical fields (Basset & Becker, 1962).

As long ago as 1792, Galvani observed that injured tissues generated small electrical currents. Becker measured these injury currents in bone and others have measured them in injured soft tissue (Wolcott et al, 1969).

Electrical stimulation has been used to facilitate wound healing for more than 30 years (Carey & Lepley, 1962). Two aspects of electric currents have potential to influence healing tissue 1). The ability of certain types of electric currents to attract oppositely charged particles and thus possibly enhancing the migration of cells like macrophages and fibroblasts. These effects are strongest when direct current is used (Wolcott et al, 1969). A current of injury is well described (Becker & Selden, 1985) that involves the flow of charged particles from uninjured to an injured site. Wounds failing to heal have been reported to display reduced levels of current of injury (Burr et al, 1938). As a wound heals the current of injury reduces as well. It is thought that externally-applied electrical currents are able to promote wound healing by augmenting the injury currents.2) Activation of cutaneous nerves may create a centrally-mediated increase in circulation (Kaada, 1982).

The greatest difficulty in evaluating efficacy of electrical current or electromagnetic stimulation for acceleration of wound healing is the variety of the parameters of the applied stimulation i.e. frequency, amplitude, signal shape, field gradients, duration of exposure etc. It is difficult to ascertain which parameters of the EM signal are responsible for the observed bio-effect. Of course with static magnetic fields there are less of these variables to consider.

The prevalence of active leg ulceration in the UK is 0.15-0.18% which represents 450 patients per health district of 250,000 population. There are estimated to be 100,000 ulcer patients in the UK. Seventy to 90% are venous in origin, 5-20% arterial, 10-15% combined and 5-10% due to other causes such as diabetes, vasculitis, neoplasm, infection, trauma etc. There is an increased prevalence with age so that the average of 1.5 to 1.8 per 1000 population rises to 3 per 1000 at age 61-70 and 20 per 1000 at age 80 and above. Nearly 1% of the population are affected by leg ulcers at some point in their lives. Over two thirds of leg ulcer sufferers have recurrence and a third have 4 or more episodes. Fifty percent of ulcers are open for 9-12 months, 20% are open for 2 years and 8% are open for more than 5 years. Sixty to 90% are managed in the community and this represents 8-22% of district nurse workload.

From an expenditure point of view it has been estimated that in the late 1980's £100-120 million a year was being spent on ulcer care although other estimates put the figure much higher than this at £600 million per year. These estimates amount to between £1100 and £5000 being spent on each patient per year. For comparison, in the USA the annual cost of wound care has been estimated to be \$3 billion annually (National Institutes of Health release, Oct 2000).

Clearly, chronic ulceration is a problem and a major financial burden on the NHS.

Objectives

The purpose of this survey was to assess the extent of the effectiveness of UlcerCare, a static magnet product that is commercially available for the treatment of leg ulcers. There has been an accumulating wealth of anecdotal evidence of its effectiveness to promote ulcer healing. 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 in promoting leg ulcer healing.

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 wound care.

Methods

A questionnaire survey was conducted by telephone of 160 randomly selected UlcerCare 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.

UlcerCare Description

The UlcerCare 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, swelling or ulcer size 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 UlcerCare 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 UlcerCare and LegCare 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 UlcerCare 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 *UlcerCare* 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 *UlcerCare*? 0 1 2 3 4 5 6 7 8 9 10

Were your legs Painful? Yes No

Did *UlcerCare* 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 *UlcerCare*? 0 1 2 3 4 5 6 7 8 9 10

Previous / current treatment (other than *UlcerCare*)

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 *UlcerCare*?

-Is further treatment required now? Yes No

Are you satisfied with the leg wrap? Yes No

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

Much worse	Worse	About same	Better	Much Better
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Has *UlcerCare* led to a **change in your health**?

Much worse	Worse	About same	Better	Much Better
------------	-------	------------	--------	-------------

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

Much worse	Worse	About same	Better	Much Better
------------	-------	------------	--------	-------------

Did you before using *UlcerCare* 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
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Reason.....

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

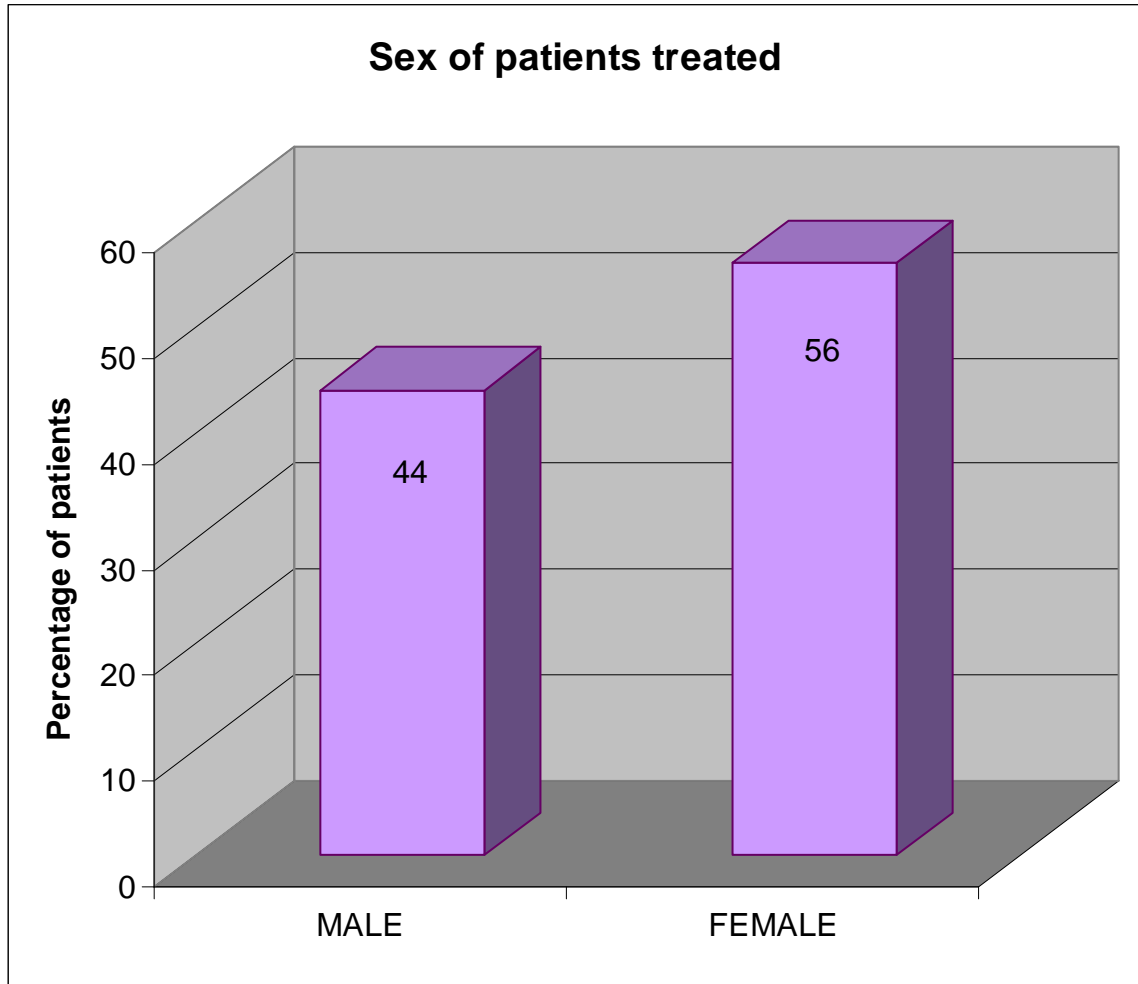
Would you like to make any further comments?

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



Ulcer Duration

Average Ulcer Duration

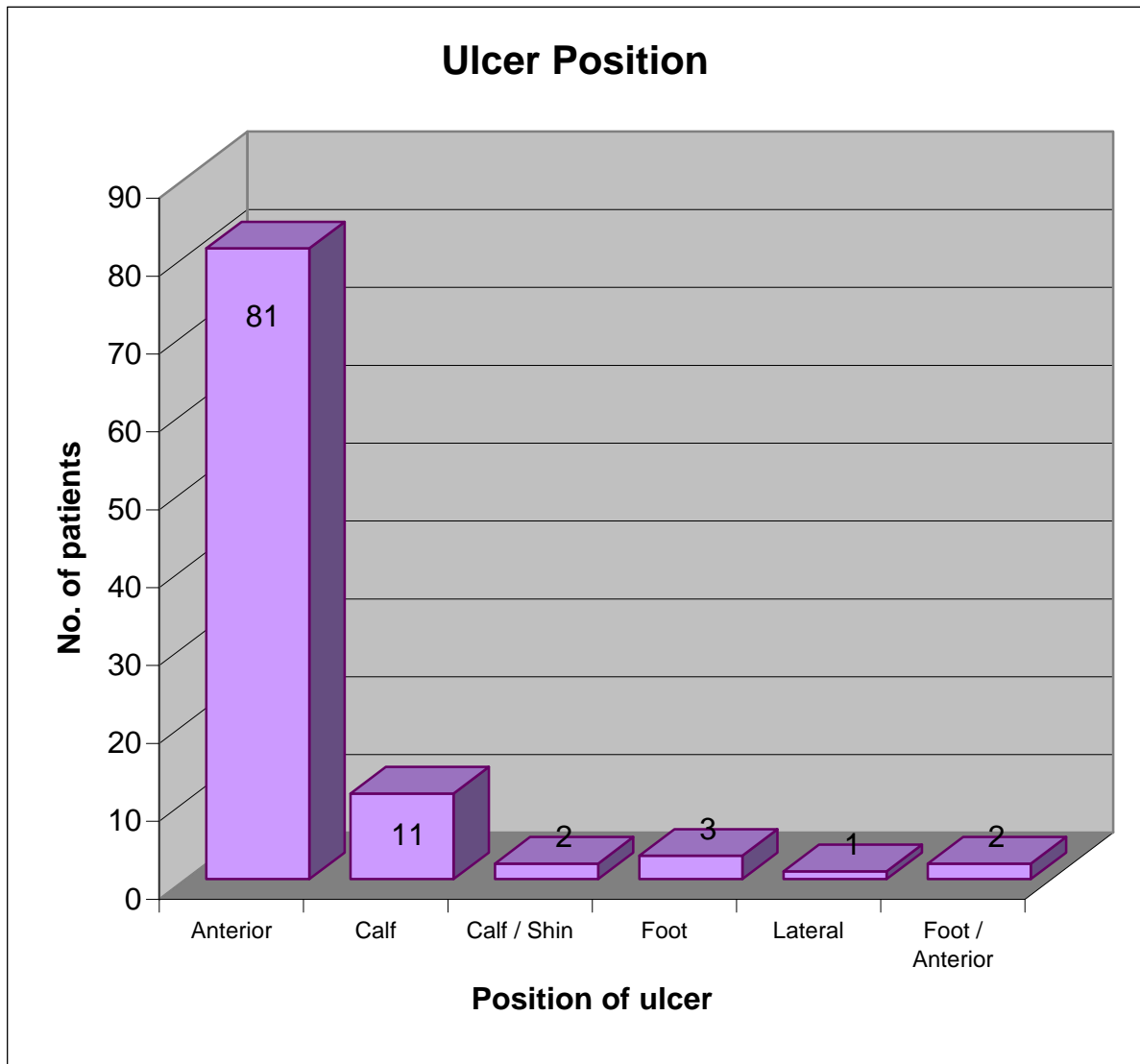
49 months

Range

<1 to 504 months

Total No. of patients	160
No. of patients responding to question	118
Percentage of patient response	74

Ulcer Position

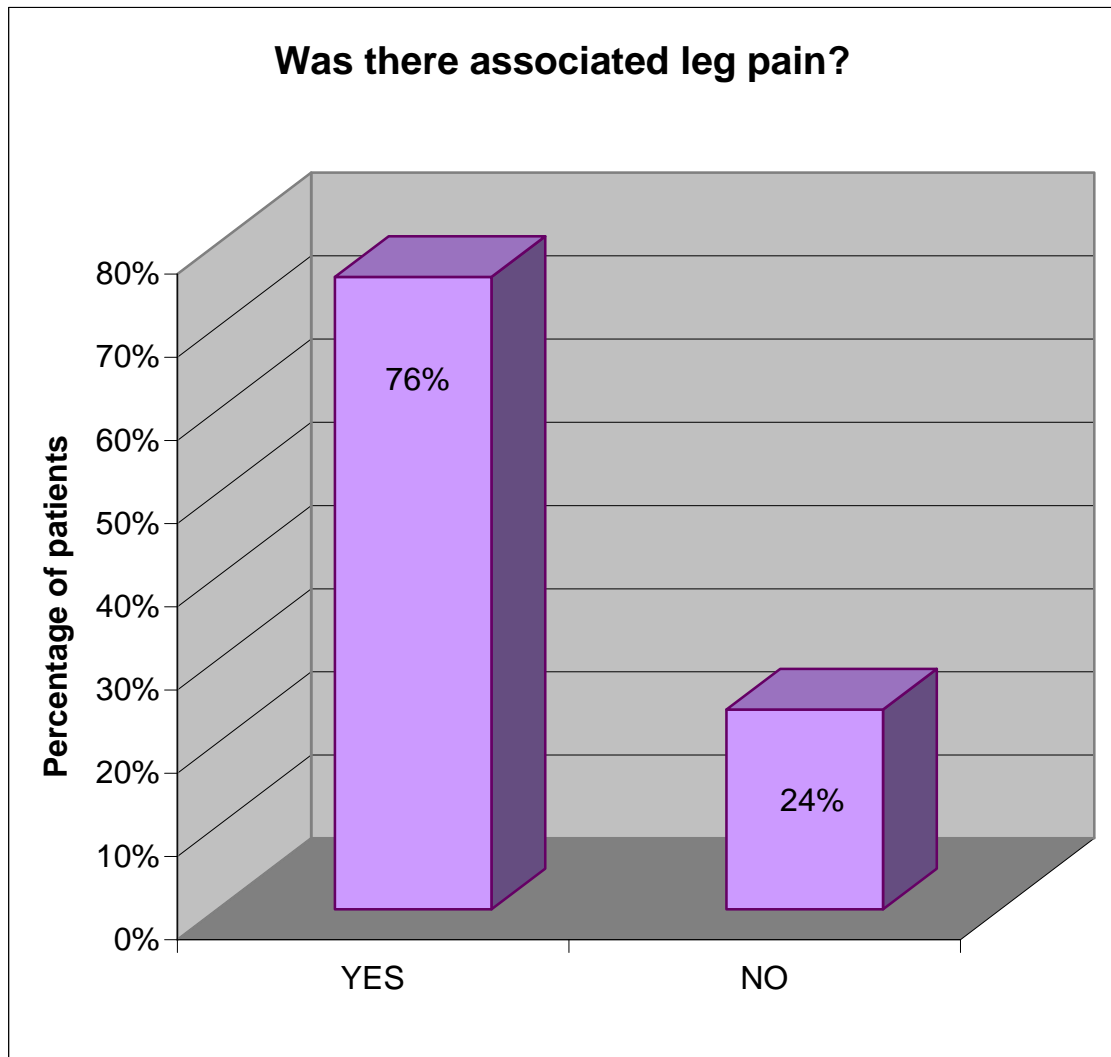


No specification was made as to the origin of the ulcer i.e. Venous, Arterial. Diabetic etc

The majority (81%) of leg ulcers were anterior in position

Total No. of patients responding to question	120
Percentage of patients who responded	75

How many Ulcer sufferers had associated leg pain?

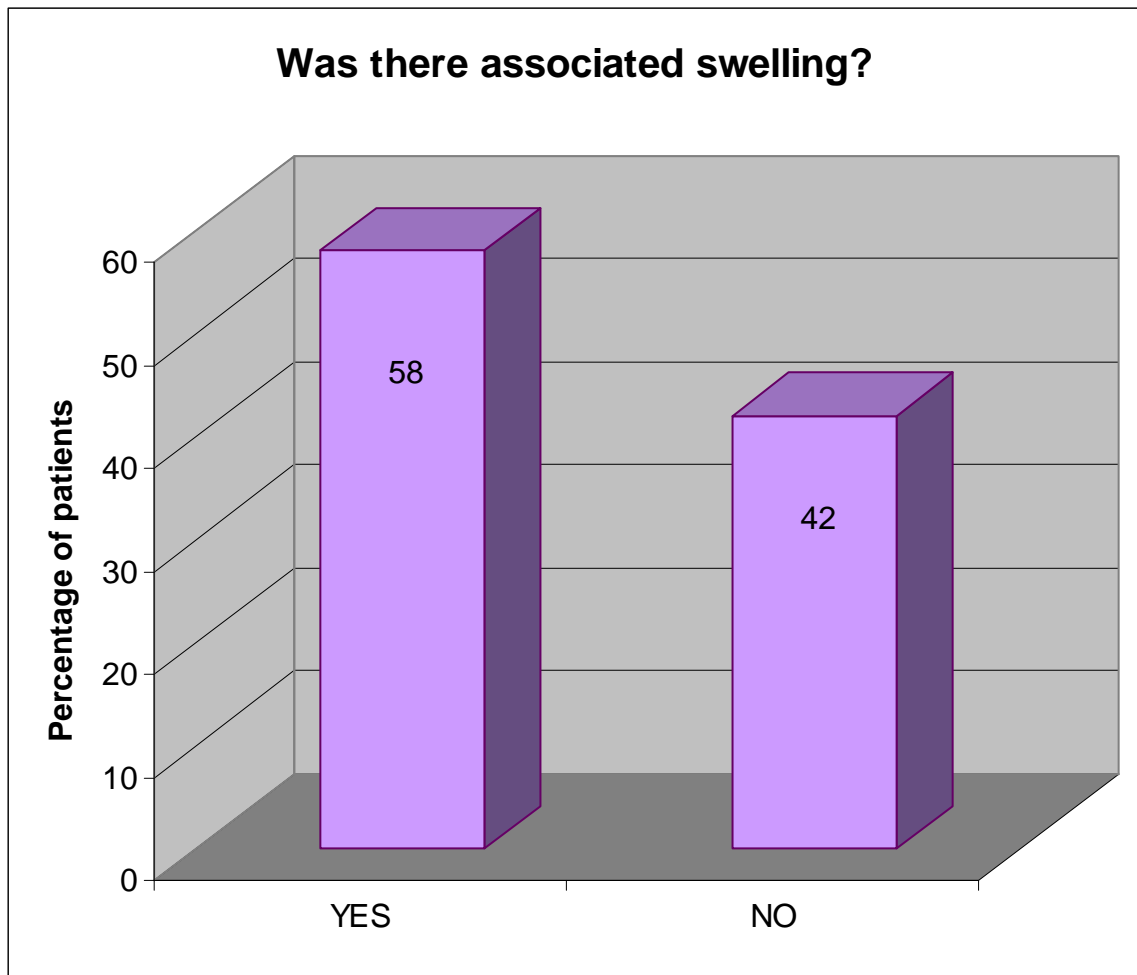


76% had associated leg pain

Percentage response to question

97

How many Ulcer sufferers had associated leg swelling?



58% had associated leg swelling

Percentage response to question

97

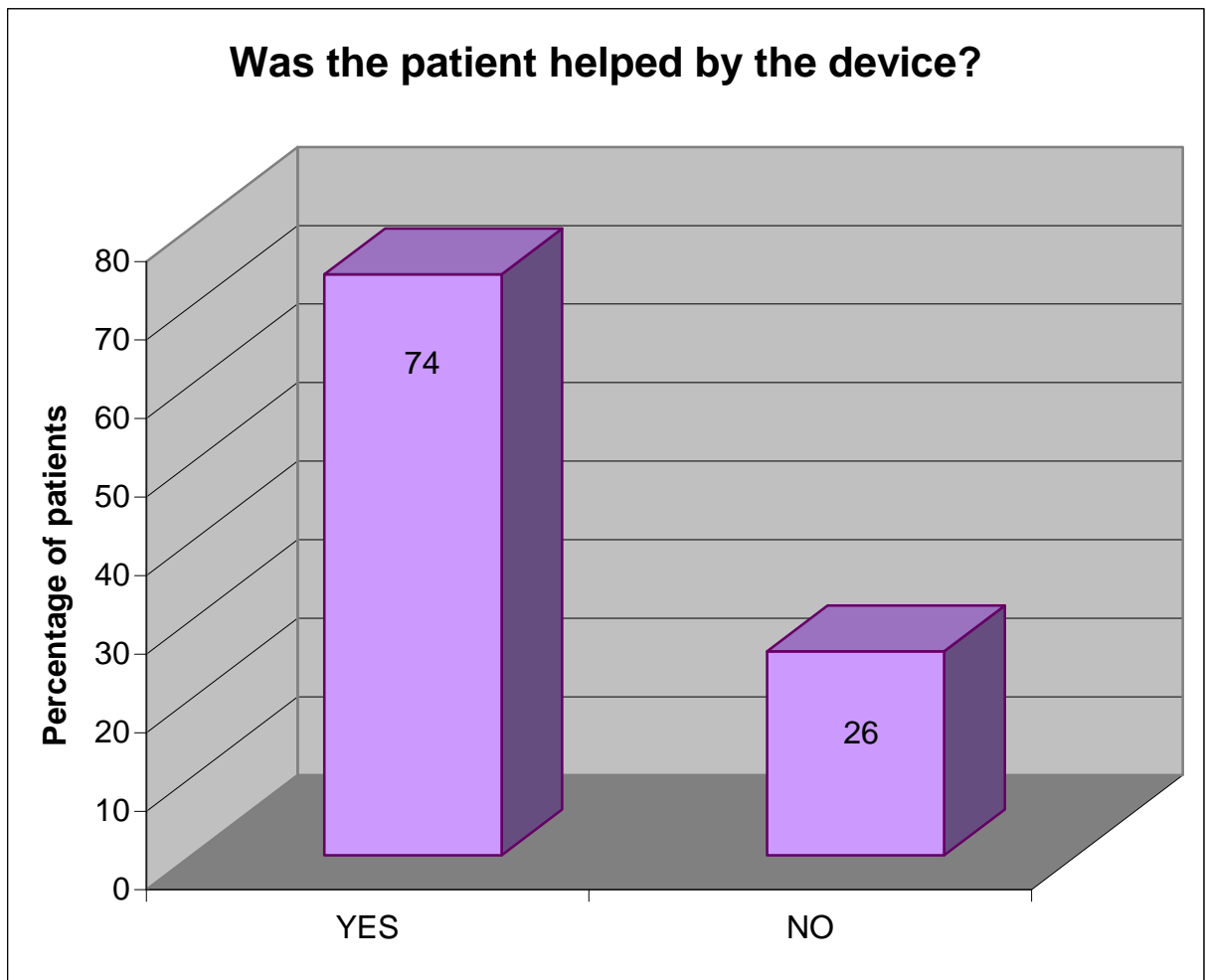
How long was the UlcerCare Device used?

Average duration of wear = 4 months

Range = 1 to 6 months

Percentage response to question 95

How many were helped by the device?



74% of patients were helped by the device

Percentage response to question 100

How long did it take to notice improvement?

Average time to notice improvement

3.2 weeks

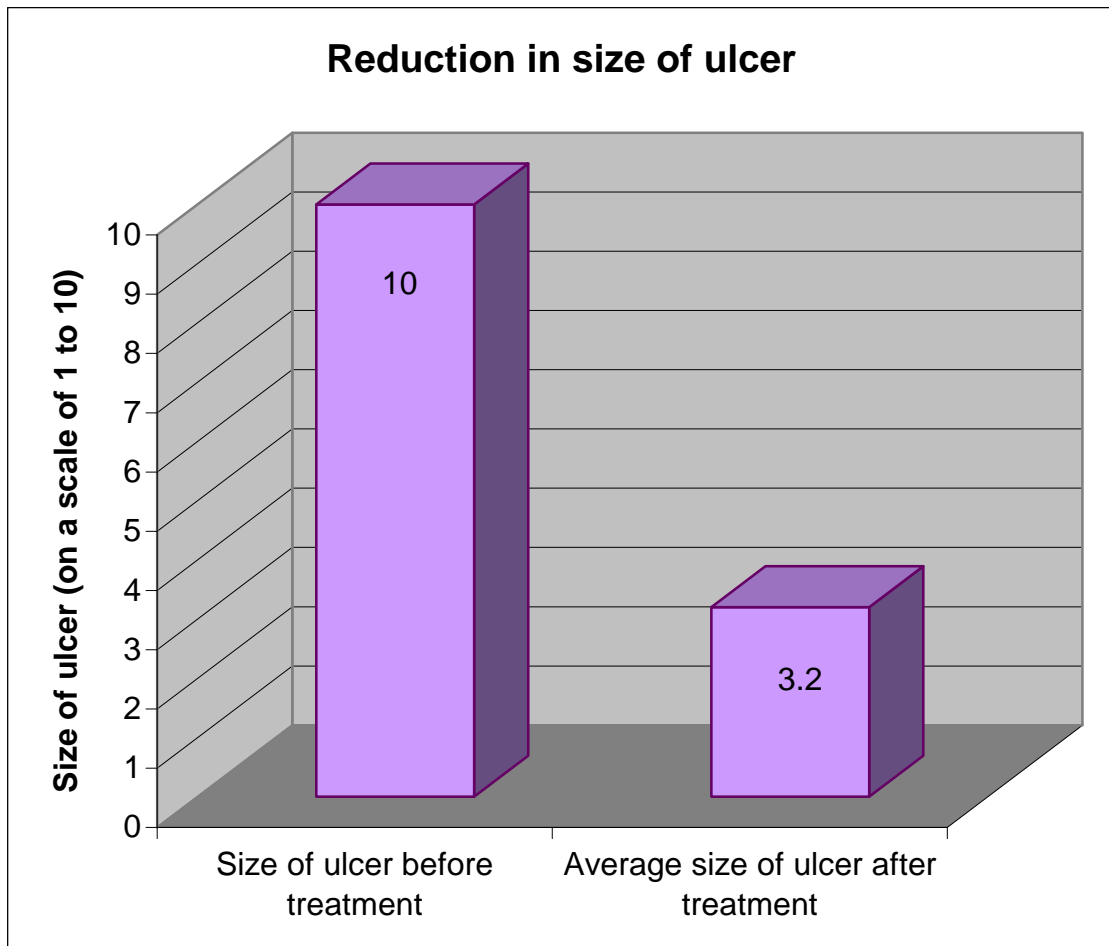
Range of time

Less than 1 week to 12 weeks

Percentage response to question

92

Average Reduction in Ulcer size



Percentage patient response to question

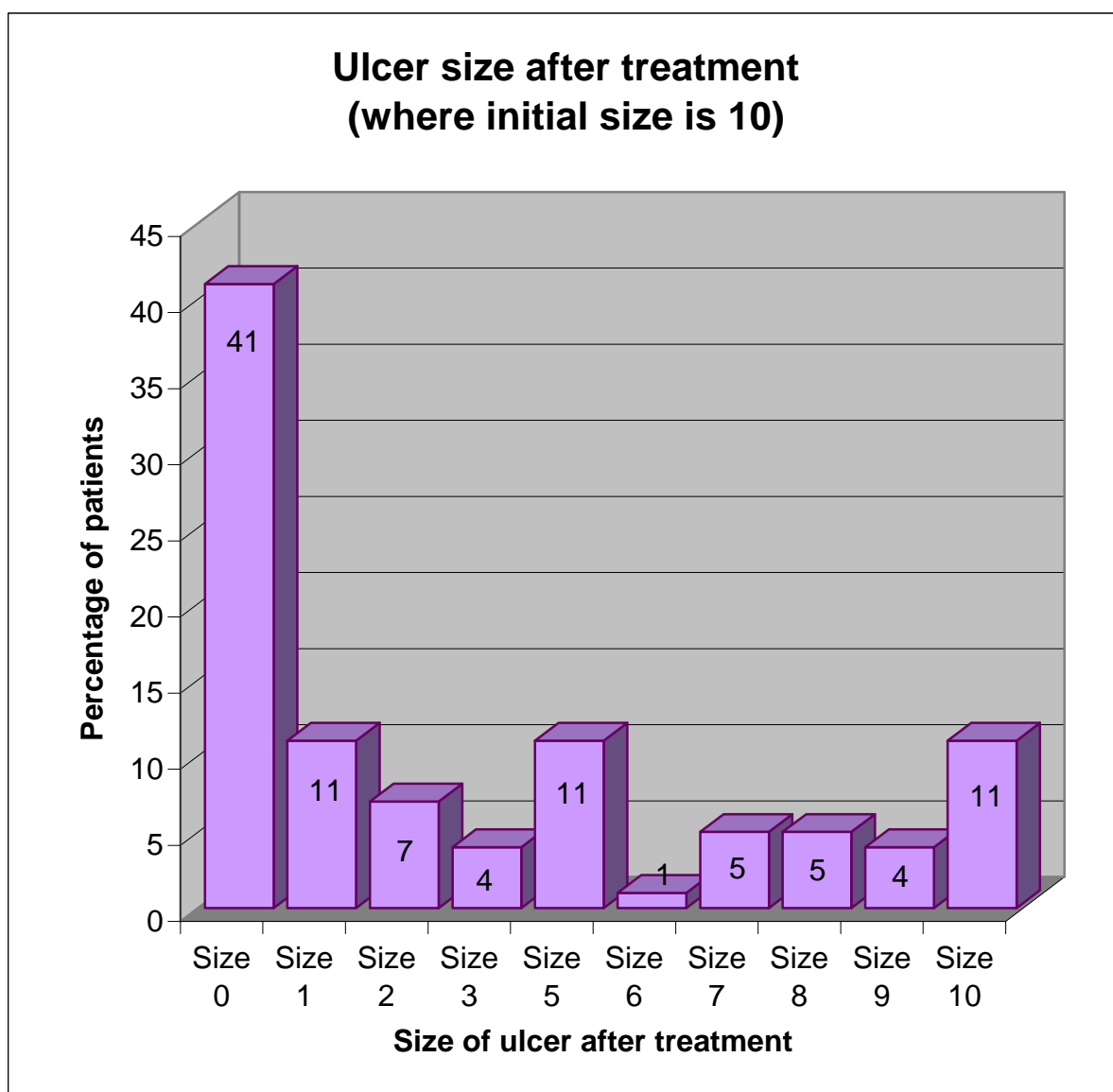
96

Average reduction in ulcer size was 68% over the treatment period

This reduction in ulcer size as highly statistically significant, $p < 0.0001$ (95% confidence intervals 6.08 to 7.45)

There was an almost significant greater reduction in ulcer size in males than in females ($p = 0.053$, 95% confidence intervals 0.021 to 2.74)

Ulcer size after treatment with UlcerCare



**41% of patients had complete ulcer healing.
11% of patients had no effect on ulcer size.
This represents a positive response rate of 89%.**

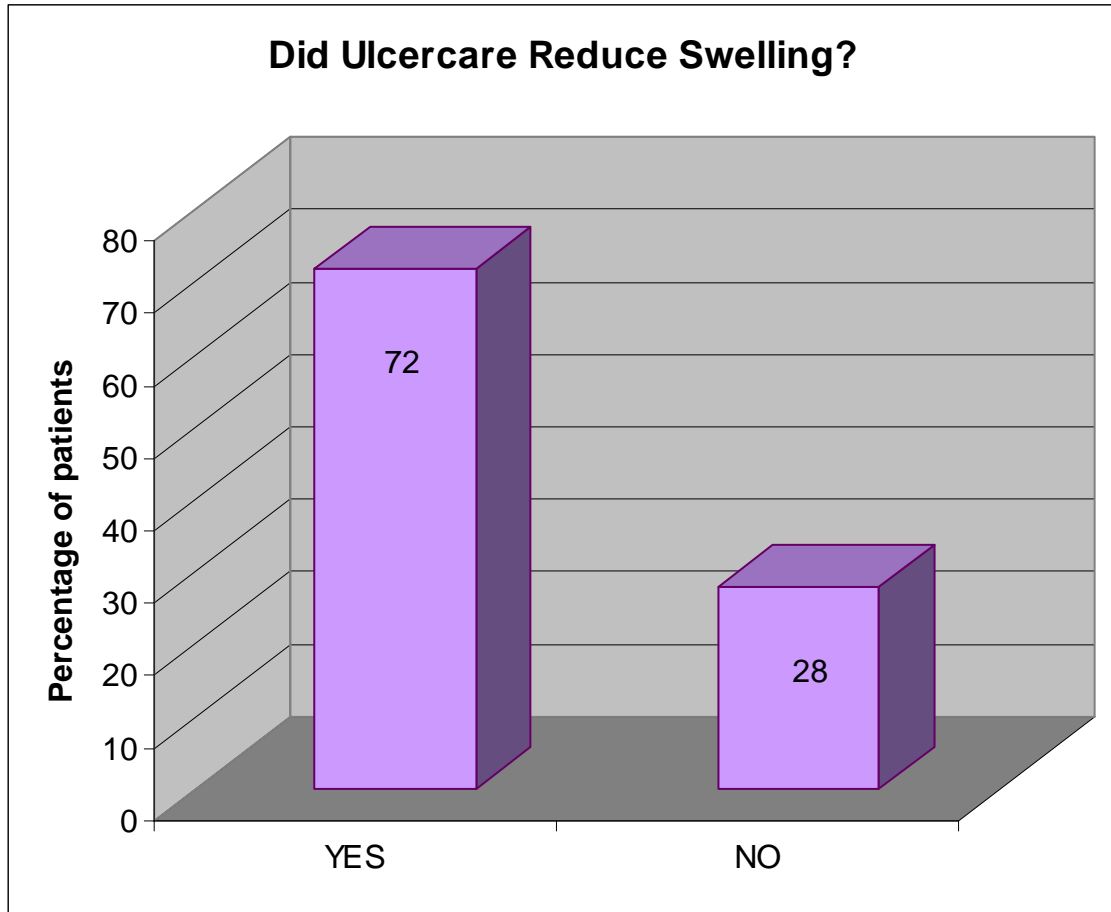
Time to complete healing

44 of the 46 patients (96%) that had complete healing responded to the question

Average time to heal 3.9 months

Range 0.5 to 18 months

Did UlcerCare reduce swelling?

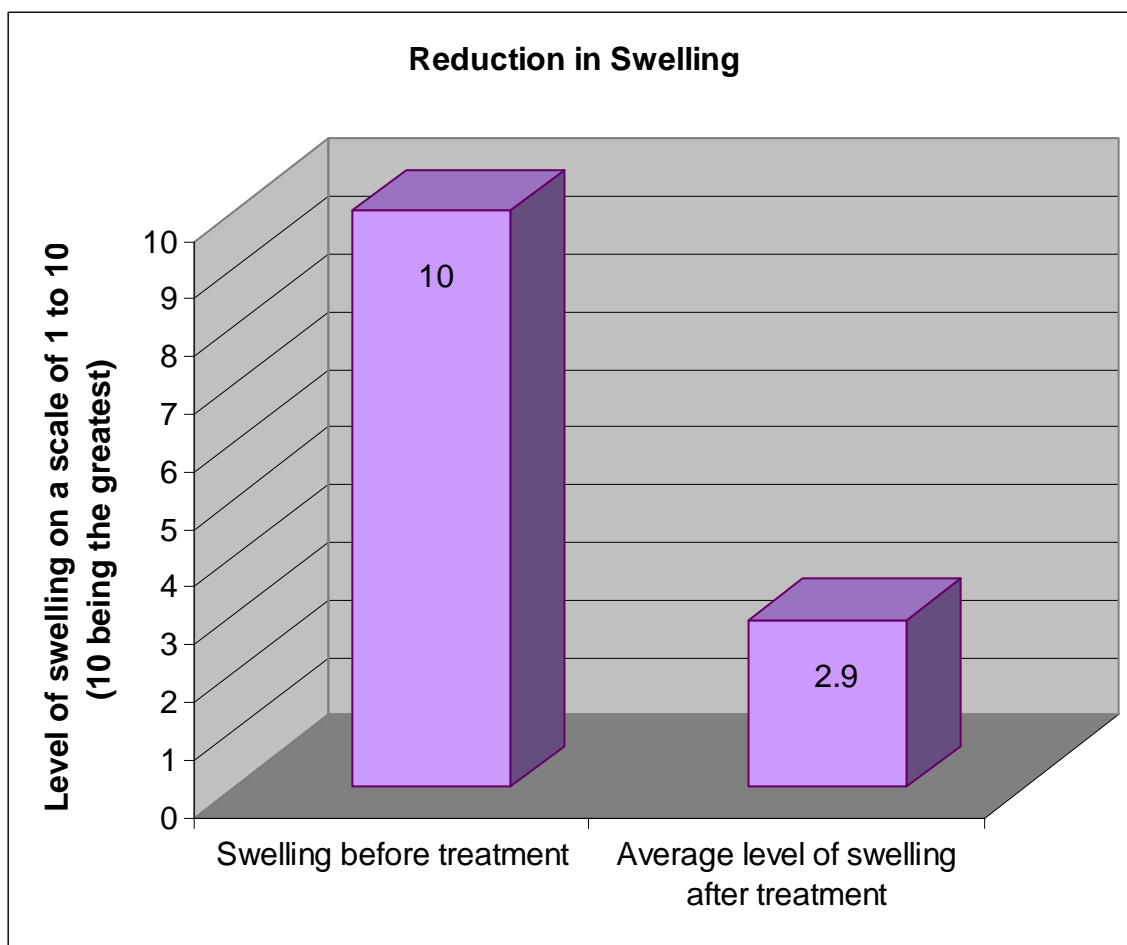


58% of patients said they had associated swelling. This represented 67 patients.

67 patients i.e 100% of those who had swelling responded to the question.

72% of those with associated swelling had a reduction in swelling after wearing UlcerCare.

Average reduction in swelling with UlcerCare



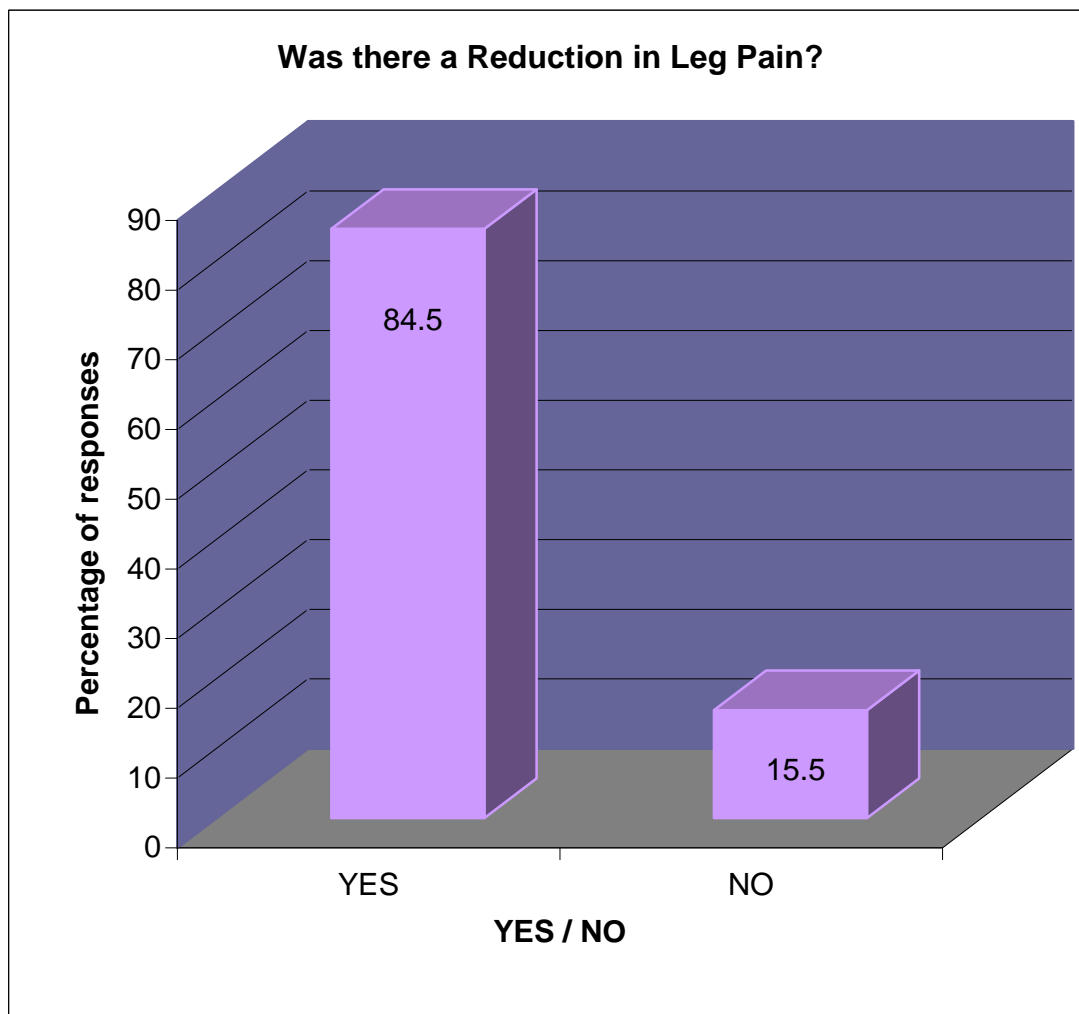
Percentage of response to the question from those who had swelling 76

There was an average 71% reduction in swelling after wearing UlcerCare

This reduction in swelling is highly statistically significant, $p < 0.0001$ (95% confidence intervals 6.35 to 7.93)

There was a small but statistically greater reduction in swelling in males than in females ($p < 0.029$, 95% confidence intervals 0.2 to 3.4).

Was there a reduction in pain with UlcerCare?



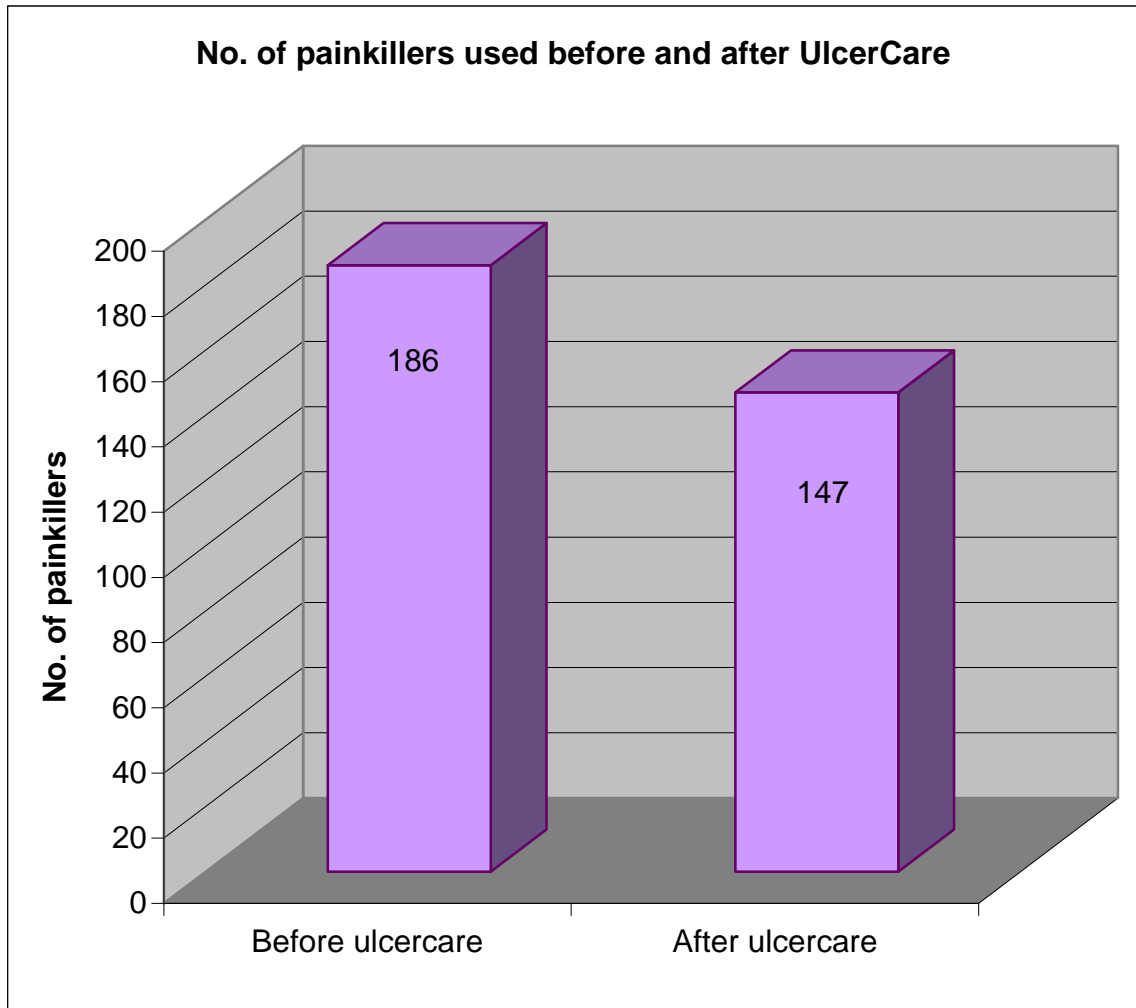
Percentage of patients responding to question 71

84.5% had a reduction in associated leg pain with UlcerCare

This reduction in pain is highly statistically significant, $p < 0.0001$

There was no significant difference in pain reduction between male and female patients ($p=0.548$, 95% confidence intervals 0.91 to 1.71)

Total number of painkillers taken before and after UlcerCare

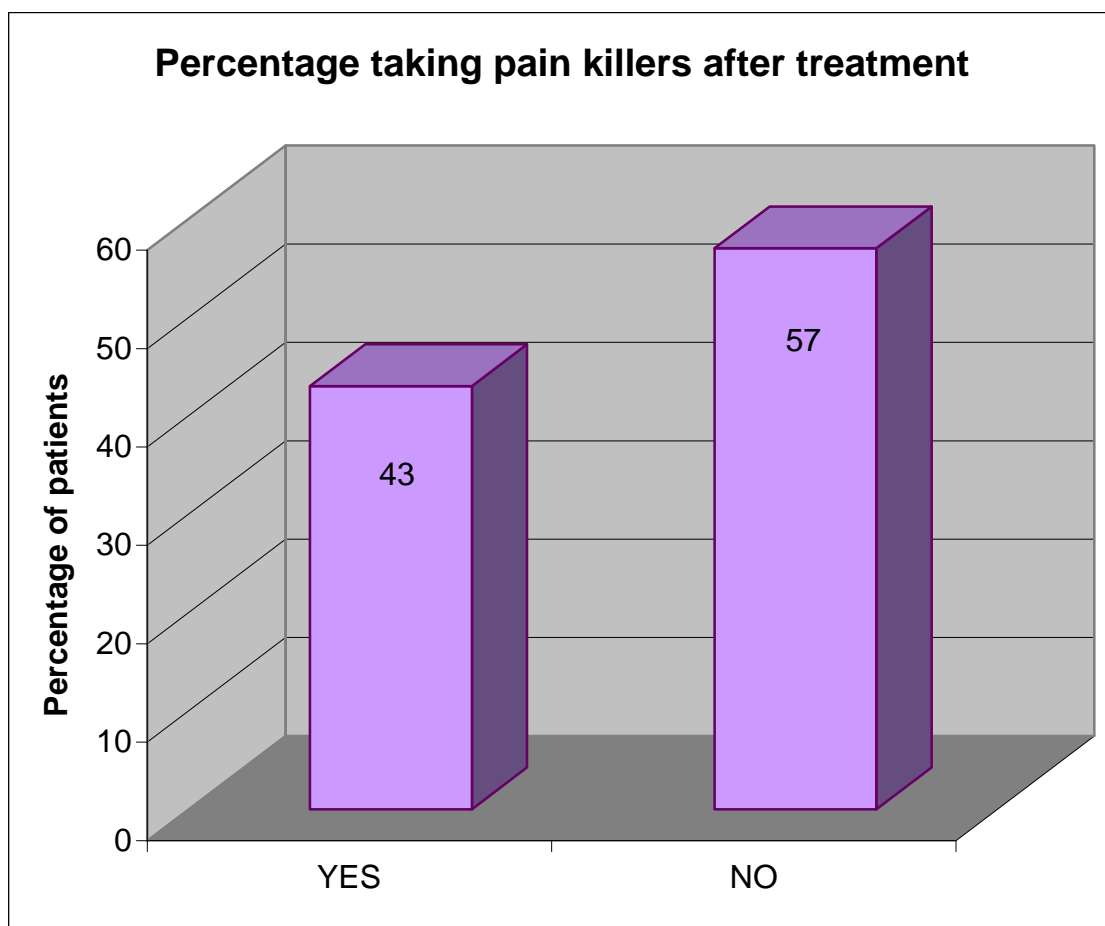


Total No. of patients who responded to both questions 39

Percentage of patients responding 24

Disappointingly few patients responded adequately to this question but the reduction in painkillers taken with the UlcerCare is statistically significant ($p < 0.030$, 95% confidence intervals 0.088 to 1.65).

Still taking painkillers?



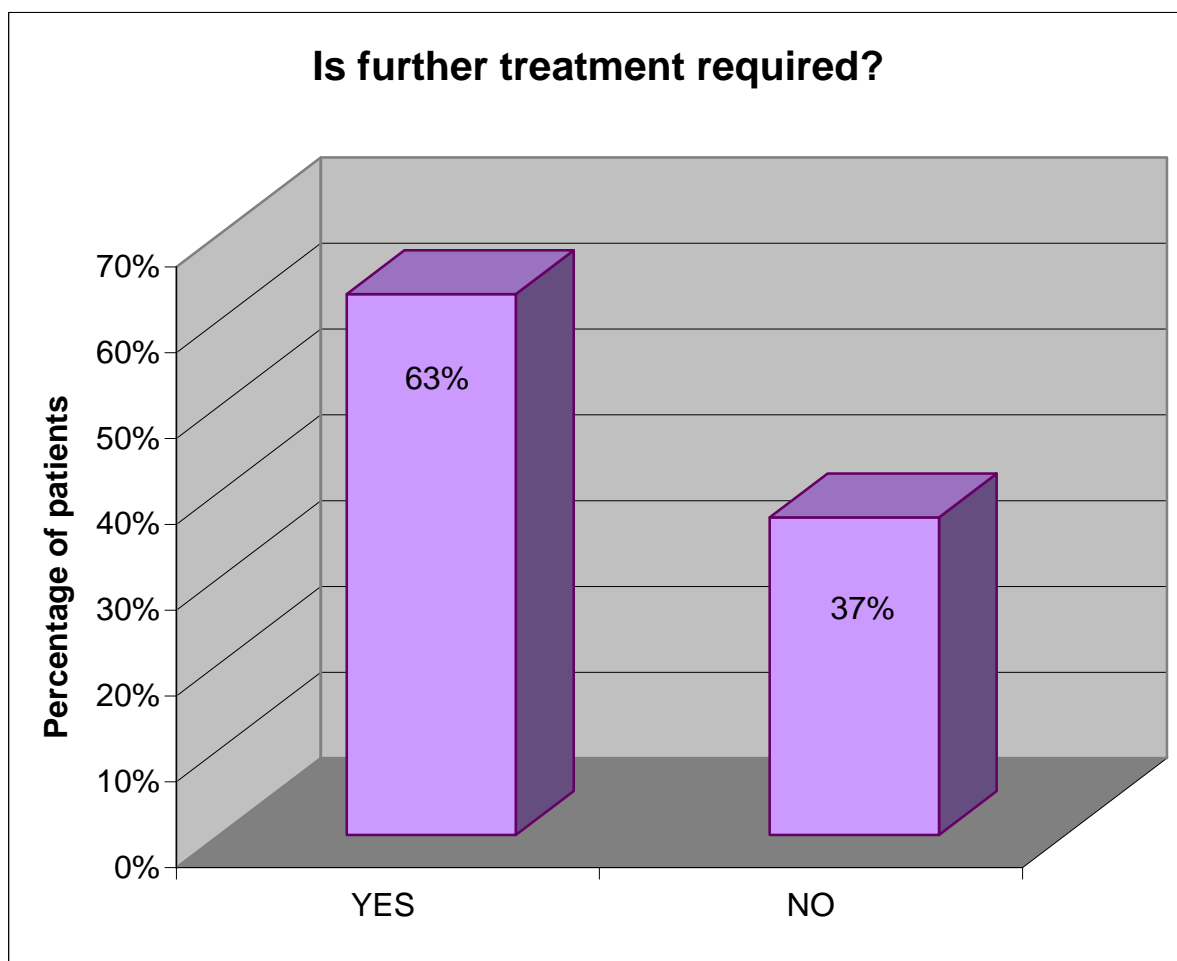
Percentage of patients responding to the question

97%

This contrasts with the previous chart and indicates that the majority of those who did not respond to the question of how many painkillers were taken after UlcerCare were probably not taking any.

57% of patients were no longer taking painkillers at all

Any further treatment required?



63% were still requiring treatment, while 37% required no further treatment

Percentage of patients responding to question

97

Further comments made by patients

“Also stopped cramps in legs”

“My legs are no longer painful since using the wrap”

“I have ordered more”

“It was recommended by my nurse”

“Started working straight away”

“Seems the ulcer is getting shallower”

“Ulcers have continued”

“I am very pleased”

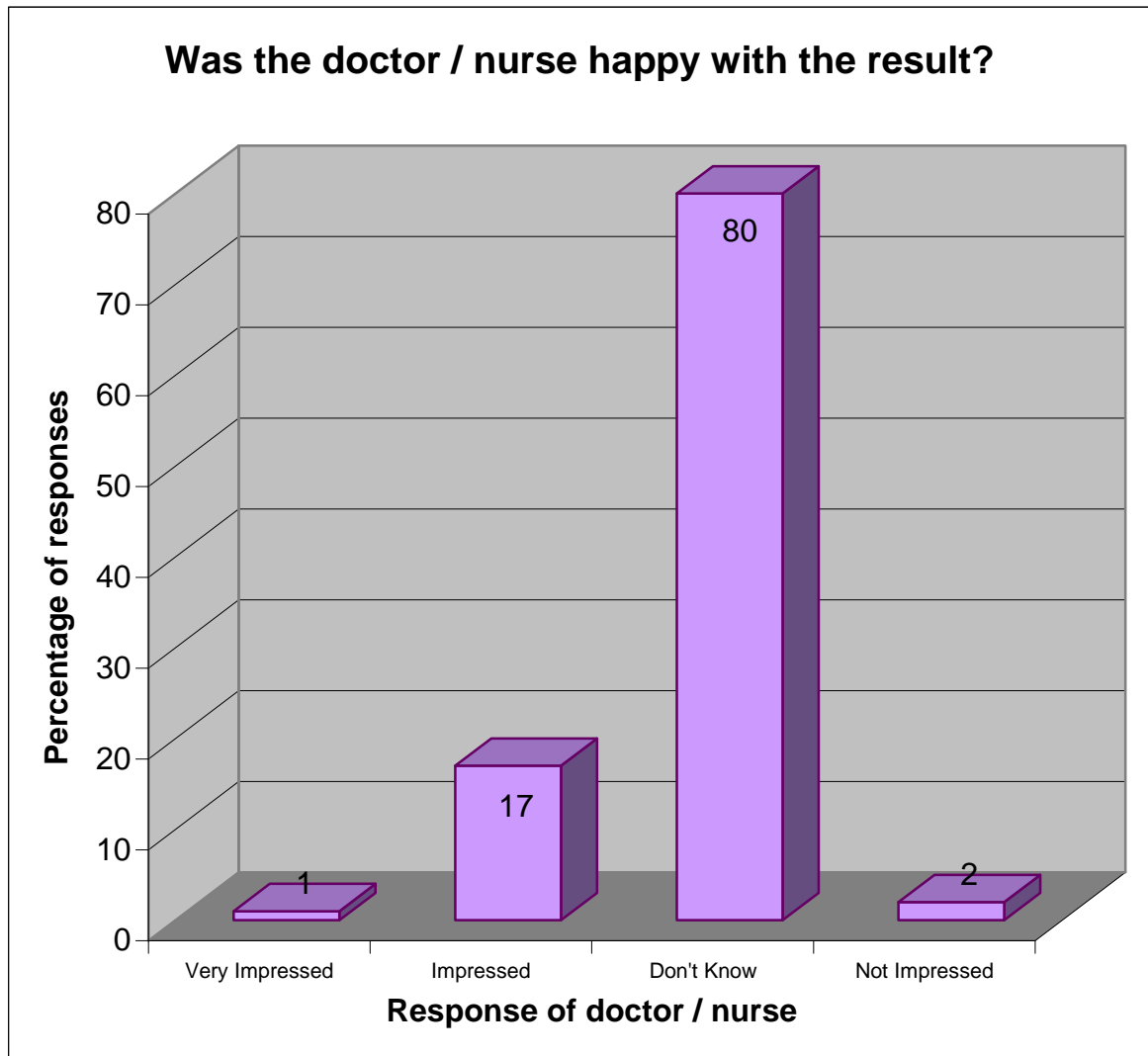
“I would recommend this to others”

“The wrap has increased the healing”

Not everyone made a comment but those who did are shown above.

The vast majority of comments made were positive

Was your doctor or nurse happy with the results?

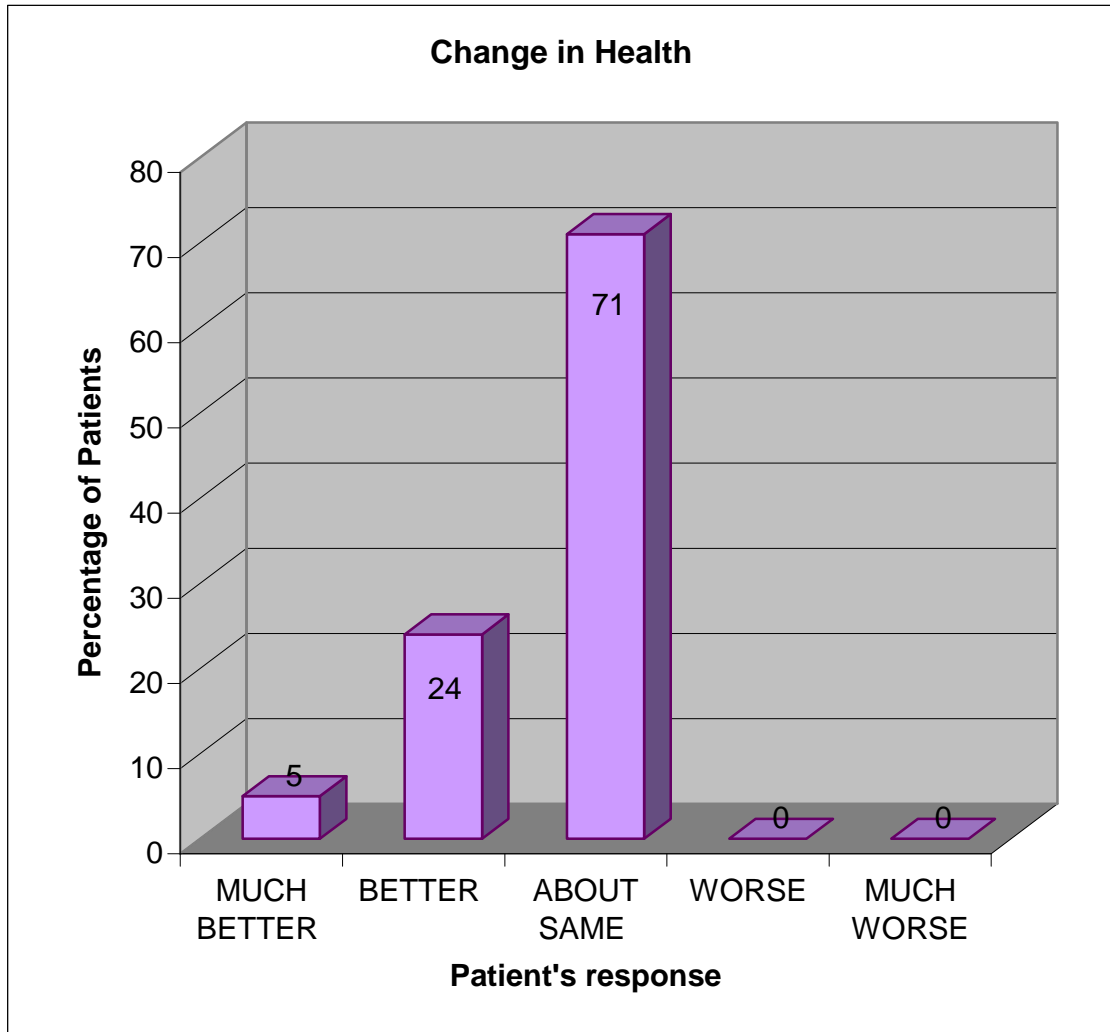


Percentage of patient response to question

92%

The majority of patients had not had feedback from their caregivers but of the 20% that did, 18% were impressed with the results.

Change in Health

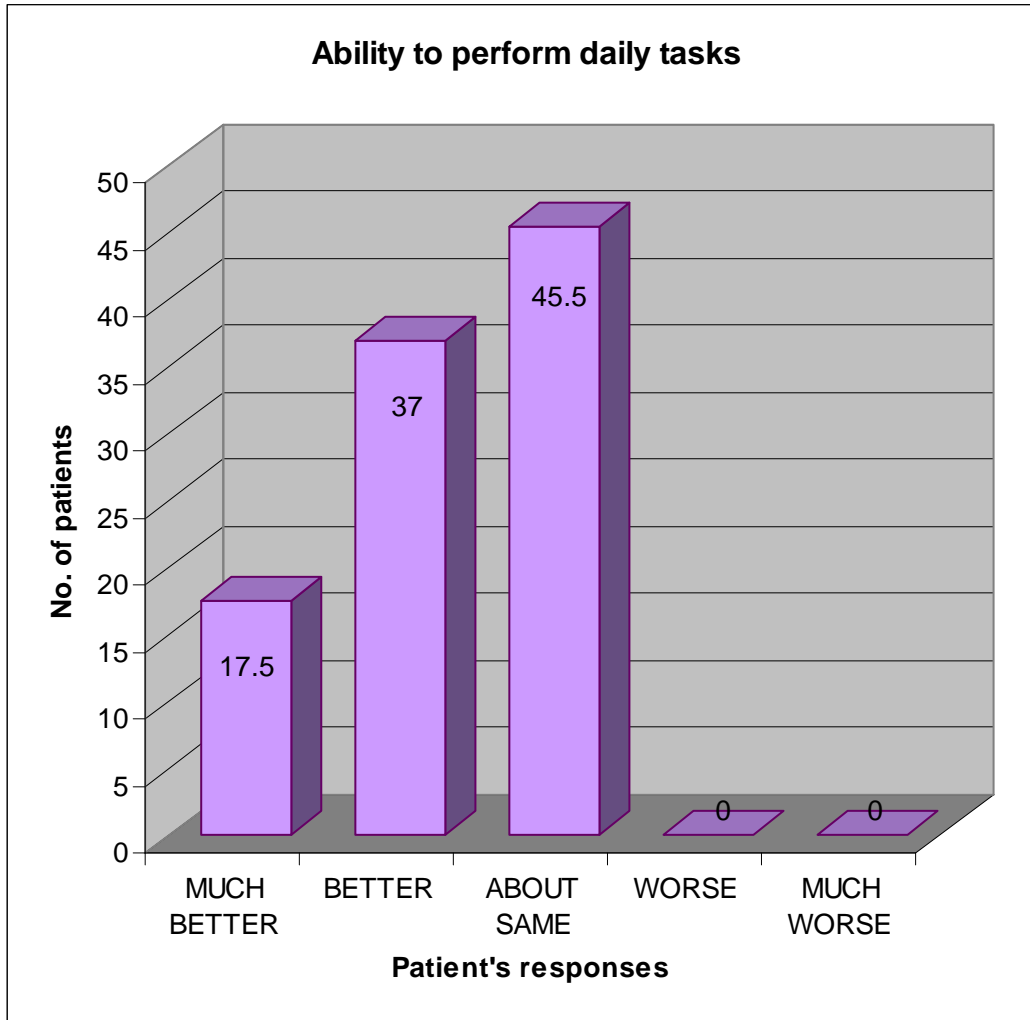


Percentage patients responding to the question

96

The majority (71%) claimed no general health improvement but 29% reported a feeling of better health. No one reported any worsening of health.

Ability to perform daily tasks

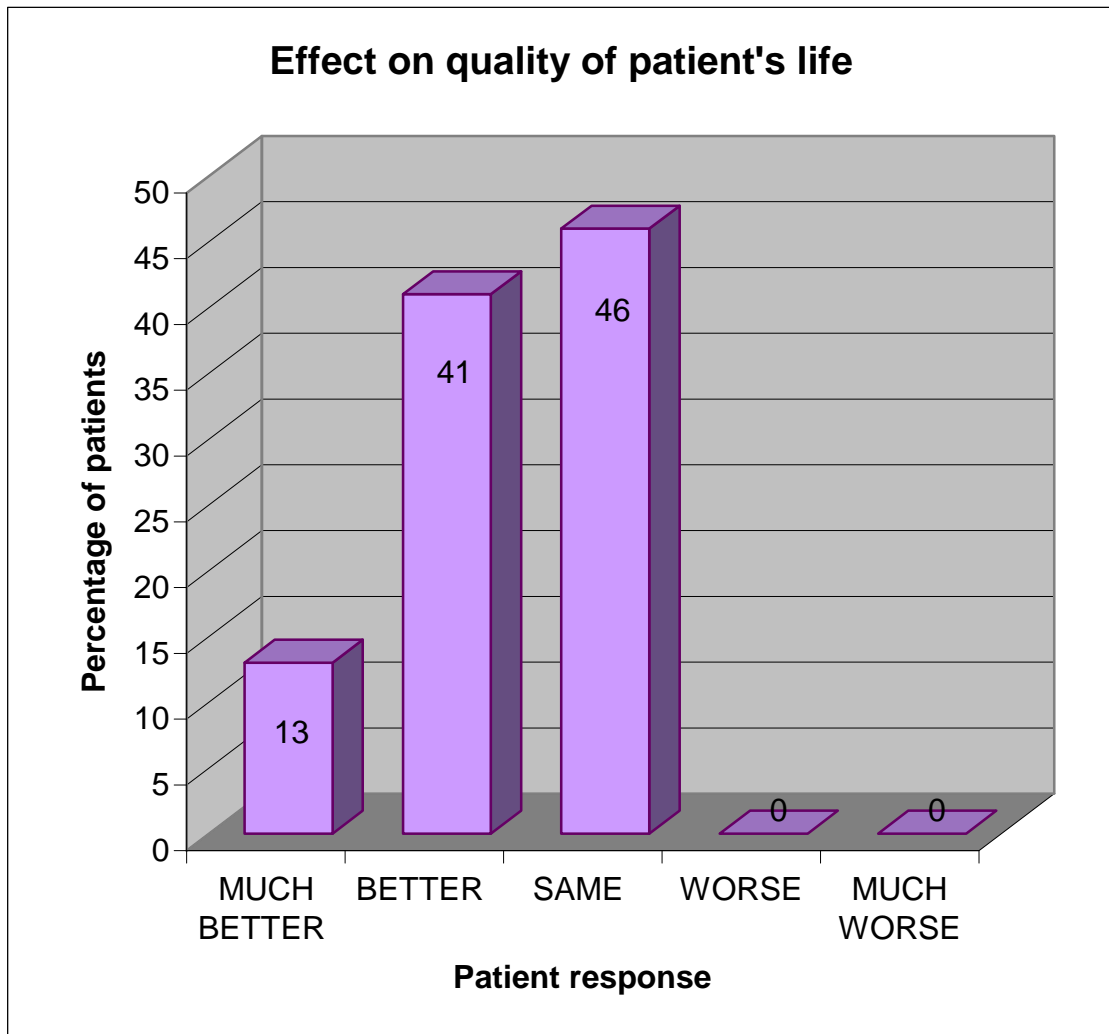


Percentage patient response to question

96

The majority, 54.5% reported an improvement in ability to perform daily tasks.

Quality of Life

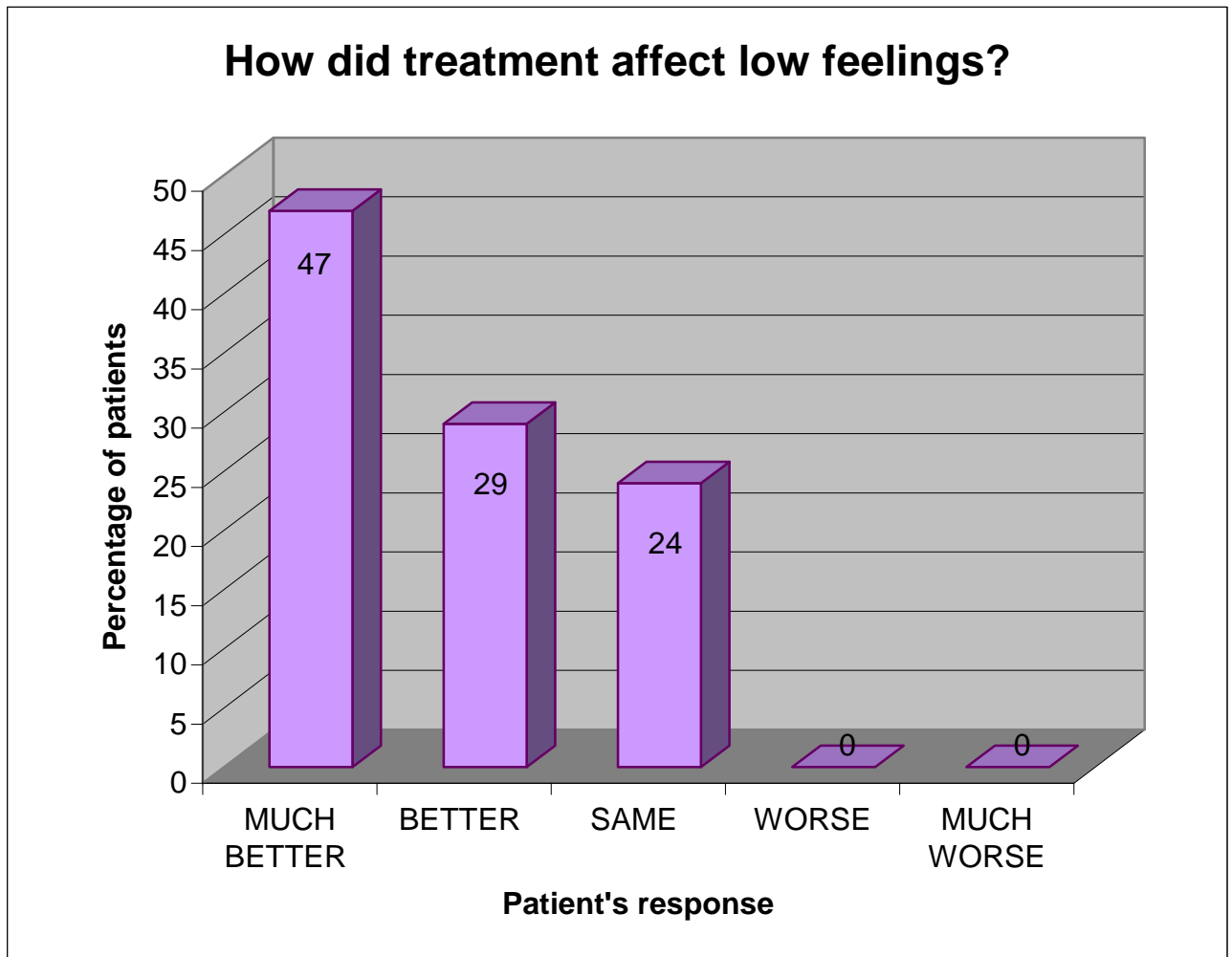


Percentage patient response to question

95

64% reported an improvement in the quality of life. This was at least in part due to less pain, less restriction and greater mobility.

How did UlcerCare affect Low feelings?



Percentage patient response to question 14.1

Presumably, relatively few patients had low mood to begin with. Of those who did, 76% reported an improvement in mood after wearing UlcerCare, presumably due to improved ulcer healing and/or reduced pain. See next page.

Reasons given for change in mood in those reporting improvement

Feeling brighter

More confidence

Ulcer healed or healing (5 patients)

Less pain or pain gone (6 patients)

Sleeping better

SUMMARY AND CONCLUSIONS

Summary and Conclusions

Fifty six percent of patients surveyed were male and 44% were female. In general the response rate to questions was good, usually 75% and more. Average ulcer duration was 49 months i.e. just over 4 years (Range <1 to 504 months). The majority (81%) of leg ulcers were anterior in position and 76% had associated leg pain with 58% having associated leg swelling. The average duration of wear of the device at the time of survey was 4 months (Range 1 to 6 months). Within this time the device had helped 74% of patients. The average time to notice improvement was 3.2 weeks (Range, < 1 week to 12 weeks). Average reduction in ulcer size was 68% over the treatment period. This reduction in ulcer size was highly statistically significant, $p < 0.0001$ (95% confidence intervals 6.08 to 7.45). There was a greater reduction (almost significant) in ulcer size in males than in females ($p= 0.053$, 95% confidence intervals 0.021 to 2.74). Forty one percent of patients experienced complete ulcer healing with only 11% of patients had no effect on ulcer size indicating a dramatic response rate of 89%. The average time to heal in those that had complete healing was 3.9 months (Range 0.5 to 18 months). Seventy two percent of those with associated swelling had a reduction in swelling after wearing UlcerCare with an average reduction in swelling of 71%. This reduction in swelling was highly statistically significant, $p < 0.0001$ (95% confidence intervals 6.35 to 7.93). There was a small but statistically greater reduction in swelling in males than in females ($p < 0.029$, 95% confidence intervals 0.2 to 3.4). Eighty four and a half percent (84.5%) had a reduction in associated leg pain with UlcerCare. This reduction in pain was highly statistically significant, $p < 0.0001$. There was no significant difference in pain reduction between male and female patients ($p=0.548$, 95% confidence intervals 0.91 to 1.71). Regarding consumption of painkillers, disappointingly few patients responded adequately to this question but the reduction in painkillers taken after using UlcerCare was statistically significant ($p < 0.030$, 95% confidence intervals 0.088 to 1.65) and 57% of patients were no longer taking painkillers at all. The majority, 54.5% reported an improvement in ability to perform daily tasks with 64% reported an improvement in the quality of life. This was at least in part due to less pain, less restriction and greater mobility.

The introduction highlights many studies demonstrating the efficacy of electrical current in promoting wound healing. It seems likely that this is due to promotion of the so called injury current that is generated rapidly at a wound site and which is a crucial part of the wound healing mechanism. Perhaps the best recognised and acknowledged effect of electric current is in the promotion of fracture healing. 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, 1981). All electrical currents generate magnetic fields and all magnetic fields cause a change in electrical potential. *Therefore, an interaction of magnetic fields with ion fluxes across the cell membrane is very likely.* The study of Bruce et al (1985) of the effects of static magnetic fields on fracture healing in the rabbit radius that demonstrated significantly greater bone strength at the fracture site perhaps suggests that static magnetic fields could promote bone healing in a similar fashion. Furthermore as stated earlier it has been shown that connective tissue cells placed in a static magnetic field increase proliferative and functional capacity by 20% (Bassett & Herrmann, 1968).

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.

There is much anecdotal evidence that static magnets can promote ulcer healing. The potential saving to the NHS in wound care expense and district nurse time if this proves to be the case in controlled trials, is enormous, not to mention the relief to the patients themselves.

This survey, conducted randomly on 160 *Magnopulse UlcerCare* users has demonstrated marked statistically significant trends in favour of chronic leg ulcer healing and reduction of leg pain and associated leg swelling. A double blind placebo controlled trial is currently underway to examine the effect of the *UlcerCare* static magnets in ulcer healing; the results of which are expected before the end of 2003.

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APPENDICES