



# **Secret Saviours Stretch Mark Prevention System Clinical Trial 2012 – 2013**

Written by Dr Stephen Barker  
and Dr Sunil Chopra

## Introduction

Stuff of Life Limited, a new UK registered company, trading as “Secret Saviours” has conducted a world’s first, randomised controlled trial of its ‘system’ designed to **help in the prevention of stretch marks in pregnancy.**

The system comprises a maternity support band featuring novel and **patented Dermal Support Technology™**, designed to mechanically support the pregnant abdomen skin and to minimise the likelihood of a ‘stress focus’ forming which could initiate a stretchmark. The band works with Secret Saviours day gel and night cream; designed as high quality, intense, skin moisturisers that contain for the first time, those few compounds shown in independent clinical trials to have benefit in helping prevent stretch mark formation -Vitamin E, Vitamin B5, Centella asiatica and camomile (but excluding Vitamin A, which although it does have an effect, is potentially detrimental to the developing baby). The system should be used from 12-14 weeks of pregnancy until term. The maternity support band does not need to be worn at night.

## Background to the Clinical Trial

A general review of literature widely available to the public indicates an incidence of stretch marks in pregnancy from 70% - 90%. Once stretch marks form, they never go away and all ‘treatments’ to remove them are simply to mask their appearance, with the exception of expensive surgical excision - often known as a ‘tummy tuck’. A more scientific review of the specific literature associated with studies looking at stretch marks in various racial groups around the world, however, shows an incidence of 50% - 70%. Either way, the majority of women will get stretch marks in pregnancy and customer research analysis suggests that no woman looks forward to getting them.

**Secret Saviours set itself an exceptionally difficult task to show that its stretch mark prevention system should reduce the incidence of stretch marks in a pregnancy population by 50%.** In addition, stretch marks can vary in their appearance, quantity and coverage from one woman to another - a scale of ‘intensity’ of stretch marks could be considered whereby a score of zero means no stretch marks, and a score of 9 or 10 means an abdomen covered all over with bright red or purple, jagged, irregular, intensely itchy, streaks. Not unusually, a ‘score’ for a pregnant woman would be at least 7. Secret Saviours also, set itself the additional challenge to substantially reduce the severity of stretch marks in women who might still get them.

## The Clinical Trial

A randomised clinical trial was 'powered' statistically to show a reduction in stretch mark formation of 50% (in a population whereby the incidence was taken at the lower level found of 50% - i.e. that 50 in 100 women who were pregnant to term would have developed stretch marks in any case. If it was then found that the actual incidence of stretch marks in that trial population was higher, it would show even more strongly that the Secret Saviours system was truly helping reduce stretch mark formation). It was shown that the proposed trial required 64 women to act as controls and 64 women to use the Secret Saviours system.

The trial was coordinated by a US-based associate professor of surgery, liaising with a lead Consultant Obstetrician at the Instituto de Maternidad y Ginecologia, in Tucuman, Argentina. Six additional Consultant Obstetricians recruited patients in to the trial, over a 16 month period, following Ethics Committee approval to commence the study. Women were randomly allocated to either a 'control' group (whereby they were monitored for stretch mark formation as they simply progressed through their pregnancy), or to the 'user' group whereby they were given the Secret Saviours stretch mark support, the day gel and the night cream. Women entering into the study were not paid to participate.

At enrolment, appropriate photographs were taken of the pregnant abdomen (at ~12-14 weeks often there was little pregnancy bulge present). Photographs were taken again, at 36-38+ weeks. Questionnaires were handed to 'users' of the system to gauge how comfortable and practical the support band in particular, was to wear and how easy the day gel and night cream were to use.

At 16 months from the start of the trial, 65 women had been recruited in to the control group and 70 in to the user group and these completed the study i.e. to term of their pregnancy. However, 6 women in the control group and 10 women in the user group were excluded due to incomplete data (usually photographs) being available, leaving 59 completed controls and 60 completed users.

Six new and independent 'observers', based in the UK and Switzerland, were elected to 'score' the results of the study - by judging the 'before' and 'after' photographs taken of the trial pregnant women, looking for the presence of stretch marks and if present, to what level (using the 0 - 10 score). A Consultant Dermatologist, a dermatology research fellow, a Consultant Surgeon, a surgical research fellow, a PhD scientist and a Consultant Obstetrician judged the results in a 'blinded' fashion - i.e. the scorer did not know if the photographs were from a control or a user, and had no way of knowing what the other judges had scored. Results were collated by an independent medical statistician, who was the only person to have access to all results simultaneously.

Analysis was undertaken to correlate the likelihood of one judge scoring stretch marks the same as the next judge. **Score correlation between judges was excellent** (intraclass correlation coefficient at 0.94 - 95% CI at 0.92-0.95, with this being statistically significant at the 0.001 level).

## The Trial Results

Results showed an actual incidence of stretch marks in the population being studied of 66% (which is in agreement with a typically reported incidence, but higher than the trial estimated incidence, set at 50%, which as previously mentioned benefits further any positive result for the Secret Saviours system).

**Results showed that stretch marks in the Secret Saviours system user group were reduced very significantly to an incidence of just 34% - an achieved reduction**

- **of the 50% we set out to show.** [Statistical significance was at the 0.001 level].
- In real terms, this can be translated approximately as follows for the total study population;
- Using the Secret Saviours system, 7 out of 10 pregnant women may not get stretch marks
- NOT using the Secret Saviours system, 7 out of 10 pregnant women will get stretch marks

In addition:

The median 'score' for women in the control group getting stretch marks was 7.

In the user group using the Secret Saviours system the median 'score' was 4.

In real terms, this shows that, in general, using the Secret Saviours stretch mark prevention system will significantly reduce the severity of any stretch marks that may still form.

[In both control and user groups, it was noted that up to 10% of pregnant women scored 9 or 9+ whether or not the Secret Saviors system was used. It is known that various factors affect the likelihood of stretch marks in pregnancy inclusive of; an inherited tendency, varying hormone levels, twins or triplets, etc. Clearly, in some instances, stretch marks will form no matter what. However, no study published to date has ever featured a 'system' approach to stretch mark prevention. No study published to date has ever featured a product line that has statistically proven benefit in helping prevent stretch mark formation.

Questionnaires were returned from 56 of those women using the Secret Saviours stretch mark prevention system during their pregnancy. 12 questions were asked, with an additional space left for their own comments;

1. Was the maternity band comfortable? Y/N 50/6

2. Was putting the band on easy? Y/N 48/8

3. Was it comfortable during the progression of the pregnancy? Y/N 48/8

4. Was it too hot? Y/N 32/24\*

5. Do you think the band helped alleviate back pain? Y/N 44/12\*\*

6. Did the band lose proper placement during the day? Y/N 11/45

7. Do you think the band helped diminish the incidence of stretch marks? Y/N 47/9

8. Would you use it again? Y/N 51/5

9. Would you recommend it to a friend? Y/N 54/2

10. Did you use the band sometimes, always or rarely? S/A/R 23/32/1

11. Did you use the day gel once, twice or three times daily? 1/2/3 2 or 1\*\*\*

12. Did you use the night cream once, twice or three times in the night? 1/2/3 1 or 2\*\*\*\*

\* temperatures during a significant part of the trial were in excess of 90 degrees

\*\* an unexpected, yet very significantly beneficial finding

\*\*\* at least twice daily is recommended

\*\*\*\* once at bed time is suggested. Many women were found to use the night cream on other areas of their body in addition to their abdomen

Typical comments included;

“Very comfortable. I don’t like to be up without it on. I use it all day.”

“It’s comfortable - it helps avoid [back] pain.”

“At first I did not trust it. But now, I like it.”

“It’s great and helped me not get stretch marks.”

“I am very satisfied with the maternity belt and would recommend it to any friend.”

“It produced quite a bit of pressure.”

The maternity support band functions through ‘gripping’ the skin uniformly with its imprinted Vector Alignment™ technology pads, aided by a deliberately ‘tacky’ surface left on the abdomen by the day gel. The maternity support band, therefore, needs to be quite snug fitting around the abdomen.

“Very hot. Very good product. I didn’t get any stretch marks.”

If too tight, the synthetic yarn, combined with the formulation of the pads, can make the belt hot to wear - the trial was conducted often with local temperatures in excess of 90 degrees - re-applying the day gel or night cream may help soothe the underlying skin, after showering and drying the skin.

Over the course of a pregnancy, with a growing abdomen, it is anticipated that women will need to progress up at least one size of maternity support band. If sold with one day gel and one night cream, it is clear from the trial that women will need at least one additional, separate day gel product. Women especially liked the formulation of the night cream – a high quality skin moisturiser - and were found to use it widely over other body areas. For this reason, and because it is very likely to have a beneficial effect on skin in general, it is likely that additional, separate skin cream products can be developed.

STEVE BARKER

MEDICAL DIRECTOR

STUFF OF LIFE LIMITED (TRADING AS SECRET SAVIOURS)