Development of the Sigvaris Advance Armsleeve by Patients and Clinicians

Eilish Lund, Ali Batchelor, Adam Withey

Compression armsleeves are widely used for the prophylaxis, treatment and management of upper limb lymphoedema. However, the difficulties experienced with such garments, in terms of comfort and appearance, can greatly influence patient compliance. The exploration of these issues with patients and clinicians when developing compression garments is therefore important since they can enhance concordance. This article describes how manufacturer, clinicians and patients worked together to develop an efficient, comfortable and cosmetically acceptable arm sleeve, Sigvaris Advance, which utilises unique Sensinnov® breathable silicone and modal thermoregulatory and bacteriostatic fabric.

Key Words
Upper limb lymphoedema
Compression armsleeve
Compliance
Comfort
Sensinnov® grip top

The use of compression hosiery has a central role in the management of upper limb lymphoedema, including its prophylaxis, treatment and long-term management (Doherty et al, 2006; Johansson, 2009).

Several studies have highlighted the importance of using compression in patients with subclinical secondary arm lymphoedema to achieve good management outcomes (Ramos, 1999; Delon et al, 2008; Stout Gergich, 2008). Johansson (2009) also observed that the early diagnosis of upper limb lymphoedema, in combination with a low arm volume at the start of therapy results in improved treatment outcomes, thus highlighting the importance of early diagnosis and intervention with compression.

Many studies have also shown that compression therapy is an effective treatment for arm lymphoedema following breast cancer treatment (Swedborg, 1980; Bertelli et al, 1991; Brorson and Svensson, 1998; Johansson et al, 1998; Andersen et al, 2000). The findings of these studies suggest that there is a higher risk of an increase in volume in the arm of patients with upper limb lymphoedema when they are not wearing compression garments. Swedborg (1984) and Bertelli et al (1992) reported that compression garments can be effectively used in the long-term management of upper limb lymphoedema resulting from breast cancer treatment.

A study by Brorson and Svensson (1998) showed that the use of compression sleeves in patients who had undergone liposuction of the lymphoedematous arm resulted in a maintenance of reduced arm volume. On cessation of compression therapy, an increase in arm volume was observed, which was completely reversed on reintroduction of compression.

The literature also suggests that good compliance with wearing compression sleeves improves outcomes for patients. A study by Boris et al (1997) revealed that the greater the compliance with wearing an arm sleeve over a 36-month period, the greater the lymphoedema volume reduction. Conversely, Casley-Smith (1995) noted that secondary arm lymphoedema progressed more quickly than other types of lymphoedema if left untreated, while Vignes et al (2007) found that non-compliance to compression arm sleeves was a risk factor for increased swelling in the long-term management of breast cancer-related lymphoedema.

It is well known that ill-fitting or uncomfortable garments can greatly influence patient compliance with their hosiery regimen, as can the appearance of the garment and the difficulties experienced when wearing compression sleeves, e.g. problems with clothing and the stigmatising effect of wearing a sleeve (Sneddon et al, 2008; Johansson, 2009).

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Sigvaris ad
Johansson (2009) recommended that garment manufacturers should bear these factors in mind to positively influence the development of their compression products for the upper limb.

This article describes the development of a new arm sleeve for use in patients with upper limb lymphoedema. It outlines the consultation process with clinicians and patients throughout the production process, and details how a cosmetically acceptable and comfortable arm sleeve was developed.

**Product development**

At the British Lymphology Society (BLS) meeting in 2005, Sigvaris UK conducted an audit of all attendees in order to gauge their opinions of the compression arm sleeves that were available on the market at the time. Findings revealed that patients often found their arm sleeves uncomfortable, as well as being cosmetically unacceptable when in the workplace or out socially, both of which issues had an impact on compliance.

In light of these findings, Sigvaris UK contacted two lymphoedema nurse specialist clinicians with a special interest in patient compliance and asked them and their patients to participate in the development of an arm sleeve that delivered therapeutic compression (class 1: 14–18mmHg indicated for prophylaxis, mild lymphoedema, maintenance and palliation; Class 2: 20–25mmHg indicated for moderate lymphoedema [Best Practice for the Management of Lymphoedema, 2006]), while being more comfortable and cosmetically acceptable than the available options, through the use of the latest fabric technologies.

In order to determine if a ‘real life’ population of patients would fit into a standard arm sleeve, and to see if made-to-measure garments were required, a database of patients (n=252) who were currently wearing arm sleeves was analysed by the clinicians. Circumferential measurements which were taken at the wrist, in 4cm increments up to the top of the arm as part of one of the author’s routine clinical practice were analysed to see if there were any common patterns (Figure 1). A total of 1800 measurements were analysed.

The findings showed that regardless of the wrist size of a patient, the shape of the arms followed a similar pattern — the larger the wrist, the more irregular the circumference at the top of the arm. (Figure 1).

Once this sizing data was obtained, it was apparent that an arm sleeve could be manufactured to cover the majority of the patients whose arm lymphoedema was currently being maintained by an arm sleeve, since they had a close to normal shape distribution.

As can be seen in Table 1, the majority of patients involved in this consultation fell within the sizes small to extra large, and if an allowance (tolerance) of +/- 1cm is allowed for measuring error, this means that 83% of the patient population can be managed using an off-the-shelf arm sleeve in one of four sizes.

<table>
<thead>
<tr>
<th>Size</th>
<th>Arm sleeve size</th>
<th>Wrist diameter in cms</th>
<th>% of patients in group</th>
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<tr>
<td>XS</td>
<td>13/14</td>
<td>24/30</td>
<td>0.1%</td>
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<td>S</td>
<td>14/16</td>
<td>26/32</td>
<td>18.2%</td>
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<tr>
<td>M</td>
<td>16/18</td>
<td>29/35</td>
<td>34.5%</td>
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<tr>
<td>L</td>
<td>18/20</td>
<td>32/38</td>
<td>16.4%</td>
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<tr>
<td>XL</td>
<td>20/23</td>
<td>34/40</td>
<td>6.4%</td>
</tr>
<tr>
<td>XXL</td>
<td>23/26</td>
<td>36/42</td>
<td>4.1%</td>
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The findings showed that regardless of the wrist size of a patient, the shape of the arms followed a similar pattern — the larger the wrist, the more irregular the circumference at the top of the arm. (Figure 1).
Patient opinion
Manufacturers all too often launch products that have had little or no input from clinicians or patients at the development stage. Thus, the authors felt that it was important that patients were involved in all stages of the decision-making process when designing the arm sleeve.

The clinicians held a focus group attended by 25 patients who were currently using a compression arm sleeve to maintain their lymphoedema. Participants were given 13 tubular swatches of fabric to comment upon, some of which were new to the market, but all of which were renowned for their thinness, comfort and wearability. Patients were asked to evaluate the fabrics based on:

- Texture
- External feeling of the fabric
- Feeling of the fabric against the skin.

Results were collected by questionnaire and there were two clear favourites, both of which were made from modal, a fibre made from natural beech, which is soft to the touch and also has bacteriostatic qualities.

Patients were then asked to evaluate the two different products by wearing an actual arm sleeve made from both types of the modal fabric — one was referred to as ‘red’ and the other as ‘green’. The patients were asked to assess the comfort of both the red and green arm sleeve, in comparison to the garment that they were currently wearing.

Of the 25 patients:
- Thirteen had previously worn a standard sleeve
- Ten had worn a made-to-measure sleeve
- One patient’s previous sleeve type was not recorded
- One patient decided not to trial the new product in case it resulted in worsening of their lymphoedema.

All patients (n=23) were asked to grade their current sleeve and each of the new sleeves in terms of efficacy, comfort, fit, colour and overall satisfaction using a scale of 0=very bad, 10=very good (Table 2). All patients were asked to compare (0=much worse, 5=equal, 10=much better) the new sleeves with the one they had previously been wearing (Table 3).

Results indicated that the red product performed better than the green, particularly in terms of its comfort and overall acceptability during wear time (Table 1). The red sleeve was also considered to be slightly better than the sleeve that the patients were currently wearing in most areas, particularly comfort (Table 2). The only parameter in which it under-performed was colour.

Therefore, the red sleeve fabric was produced in a variety of colours. In a separate colour test, patients selected the ‘natural’ colour for the new arm sleeve.

Compression
Once the fabric had been evaluated and selected, the manufacturer had to design and produce a garment that would retain the properties of the fabric while delivering therapeutic compression.

From a clinical perspective, the authors were particularly keen to develop a grip top that was comfortable and did not result in striction of the arm during wear time. The authors’ experience in clinical practice has shown that thin grip tops which dig into the skin, or tops that allow rolling and slippage can
negatively affect therapeutic efficacy, patient compliance and comfort.

The sleeve was therefore made with a wide band to minimise rolling and ensure that the armsleeve stayed in place, which it was hoped would also improve concordance (Figure 2).

A pressure monitoring device was used to determine the level of pressure at the top of the armsleeve (just below the grip top), and in the centre of the grip top.

The results showed that there was no great difference in pressure at the top of the armsleeve compared to the grip top, with the exception of the XS size. On further investigation, it was determined that the change in pressure seen in this size range was accounted for by those patients with a very small wrist and very large biceps. In the authors’ opinion, this would be the same in all products available off-the-shelf, and if this was a problem, limb volumes would not be maintained in this patient group.

Grip top improvements
The first grip top that was tested used silicone that is available to all manufacturers. Although thin, it had a raised profile resulting in visibility under clothes and was not very stretchy, which could lead to a worsening of limb volume if the striction caused a reversal of the lymphoedema. A brand new silicone complex called Sensinnov®, which is low profile and more stretchy than normal silicone was developed. The Sensinnov grip top is very thin, elastic and breathable, enabling it to maintain intimate contact with the skin, thus eliminating any potential changes in pressure between the grip top and the top of the sleeve.

It was anticipated that the combination of the Sensinnov grip top with the soft modal fabric of the sleeve would make the product comfortable for the wearer. The next stage of the product development was to evaluate the finished product on patients with maintained arm lymphoedema (Figure 3).

Trialling the new armsleeve
A group of patients from a lymphoedema clinic in Taunton trialled the new product (Table 4). All patients had mild lymphoedema (0% to 12.9% excess volume), and arm volumes ranging from 1894.5mls to 4299.3mls. Arm volumes were being maintained by the patients’ current armsleeves.

The objective of the study was to evaluate the new sleeve versus the patients’ current sleeve in terms of:

- Comfort
- Support
- Fit
- Colour
- Appearance
- Overall (global) satisfaction, using a scale of 1–10 (1=very bad, 10=very good) for each of the different categories.

Data was collected by a feedback form on day one, week one and month one of wearing. Owing to the fact that this was on a group of maintained patients whose limb volume had previously been maintained by an armsleeve, volume measurements were taken to ensure that no patient had an increase in volume owing to the under performance of the sleeve. The authors did not expect there to be any improvement in arm volume and were worried that a worsening of the lymphoedema would be observed.

Results
The results can be seen in Figure 4 and showed that the patients participating in the evaluation felt that the new sleeve was better than their old garment in all parameters except support, since the garment was so soft and comfortable. The patients who felt that the garment had offered less support than their previous garment (n=10) had their limb volumes measured to see if there had been an increase in volume due to the perceived lack of support. The results show that all patients had a reduction in limb volumes, and all but one in excess mls (Table 5). All patients also reported a lower severity of lymphoedema. The average excess volume reduction was 27.1%, indicating that the efficacy of the armsleeve was not affected by its softness and comfort, contrary to popular patient feeling.

Following the success of the evaluation, the sleeve was

<table>
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<th>Table 4: Patient demographics for new armsleeve evaluation</th>
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<tr>
<td><strong>Number of patients</strong></td>
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<td><strong>Number of arms</strong></td>
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<td><strong>Sex</strong></td>
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<td><strong>Average duration</strong></td>
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<td><strong>Cause:</strong></td>
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Mild lymphoedema (0% to 12.9% excess vol; arm vol ranged from 1894.5 to 4299.3mls)
manufactured and launched in 2009, under the name Sigvaris Advance, and is now available on prescription.

Conclusion
It is important that practitioners and manufacturers explore practical and body image issues with individuals who are fitted with compression garments, since they have the potential to considerably influence outcome by enhancing concordance and maximising quality of life (Lymphoedema Framework, 2006).

The new armsleeve was designed to meet the needs of clinicians and patients, and combines the newest technology available in hosiery: Sensinnov, with its unique, breathable silicone grip top and modal fabric which is both bacteriostatic and thermoregulatory. The authors were happy to see that volumes improved with the product, even though it was soft and comfortable. In day-to-day practice, patients who have been used to a stiffer more uncomfortable fabric were worried that changing to a softer fabric may set their hard work back, but the authors’ findings suggest that this new soft garment can in fact improve volumes, even in maintained arms. This is possibly due to the fact that patients like wearing it and wear it for longer. In order for this to be proven, a large scale trial would be required. The authors would also like to see the efficacy of this garment evaluated in a preventative trial owing to its potential ability to improve concordance.

Key Points
- Compression armsleeves are used for the maintenance of limb volume in people with arm lymphoedema.
- Arm sleeve comfort and cosmetic appearance can greatly affect patient compliance and therefore therapeutic outcomes.
- Clinicians and patients were involved in the development of a new armsleeve using the latest fabric technologies.
- The Sigvaris Advance compression armsleeve was found to reduce maintained limb volumes while being considered as soft, comfortable to wear and cosmetically acceptable by the users.
- The Sigvaris Advance armsleeve is now available on prescription and is used widely in the authors’ clinics.

References
**Figure 4. Patient evaluation of the armsleeve.**

**Table 5**

**Patient limb volume reductions**

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