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MEDICAL WHITE PAPERS

MEDICAL WHITE PAPER
PRIMARY CARE

1 A summary of medical-scientific publications on postoperative care following breast carcinoma

Why is compression required after surgery?

Effect	Evidence
Supports wound healing after surgery	**Compression garments** ensure that the separated **layers of tissue, knit** to each other and **heal**. Furthermore, **compression helps** to **prevent severe swelling, helps prevent tissue swelling** and **promotes forming and strengthening**.[1]
It stabilises the shape and physiological state	When **moderate compression** is implemented, a **3-25 times higher formation of new blood vessels** can be found in the areas of healing tissue. Overall, this improves the **trophic situation**. This leads to an **improved functional alignment of structures under construction** as well as to **faster and better stabilising of the traumatised areas**.[2]
Reduced pathological scarring	**Topical pressure** supports the reduction in capillary perfusion, accelerates collagen maturation and thereby, a **flattening out of the scar tissue.** In cases of a known tendency to hypertrophic scars and keloids following surgical interventions, as well as following surgical removal of preexisting hypertrophic scars and keloids, suitably localised pressure treatment may be recommended.[3]

1 Jandali, Z., Jiga, L., Merwart, B., Lam, M.C., Jess, G., Steege, W. (2020). Brustwiederherstellung. In: Jandali, Z., Jiga, L. (eds) Wiederherstellungsoperationen nach Brustkrebs. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-662-58990-8_4

2 Els Brouwer, Dorothee Escherich-Semsroth, Ralf Gauer, Oliver Gültig, Susanne Helmbrecht, Thomas Künzel, Oliver Lienert, Joachim Winter, 11 - Posttraumatisches und postoperatives Ödem, Leitfaden Lymphologie (Zweite Ausgabe), Urban & Fischer, 2021, Pages 247-268, ISBN 9783437487811, https://doi.org/10.1016/B978-3-437-48781-1.00011-9.

3 Nast A et al. S2k-Leitlinie Therapie pathologischer Narben (hypertrophe Narben und Keloide) – Update 2020. J Dtsch Dermatol Ges. 2020. https://doi.org/10.1111/ddg.14279

Effect	Evidence
Patient comfort	For most procedures, compression garments are required to be worn after an operation; either immediately post-surgery or, throughout the course of treatment. It is imperative that these are worn continually for around eight weeks. Many patients continue to wear **compression garments** for longer as these provide a **sense of comfort and stability**.[4] Laura et al. (2004) showed that **postoperative complaints** could be **reduced** by wearing a well fitting bra instead of a traditionally implemented chest binder.[5]
Pain reduction	**Directly after surgery**, swelling, circulatory problems, loss of feeling and pain can occur, resulting in the wearing of a **postoperative garment** or compression bandage **necessary**. Nicklaus et al. (2020) reports that normal bras are uncomfortable or apply too much pressure to the sensitive skin.[6] A trial by Hansdorfer-Korzon et al. (2016) showed that **58%** of patients who wore **compression bras** suffered **less** chest and shoulder **pain** on the side of the body that had been operated on. On the other hand, in the **control group**, **reduced** symptoms were registered by **33%** of patients. Compression garments are **well tolerated** by patients and the constant external pressure helps to **preserve the results of the treatment**. The results confirm that the **postoperative implementation of compression bras** for the **relief of pain** after breast carcinoma is **purposeful** and **efficient**.[7]
Supports lymph drainage	**Compression garments** not only make up for the lack of elasticity in the tissue but also increase tissue pressure, which has a **positive effect on lymph drainage**.[8]

4 Jandali, Z., Jiga, L., Merwart, B., Lam, M.C., Jess, G., Steege, W. (2020). Brustwiederherstellung. In: Jandali, Z., Jiga, L. (eds) Wiederherstellungsoperationen nach Brustkrebs. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-662-58990-8_4

5 cf. Laura, S., Clark, D. and Harvey, F. (2004), Patient preference for bra or binder after breast surgery. ANZ Journal of Surgery, 74: 463-464. https://doi.org/10.1111/j.1445-2197.2004.03019.x

6 cf. Nicklaus, K.M., Bravo, K., Liu, C. et al. Undergarment needs after breast cancer surgery: a key survivorship consideration. Support Care Cancer 28, 3481–3484 (2020). https://doi.org/10.1007/s00520-020-05414-z

7 cf. Hansdorfer-Korzon R, Teodorczyk J, Gruszecka A, Wydra J, Lass P. Relevance of low-pressure compression corsets in physiotherapeutic treatment of patients after mastectomy and lymphadenectomy. Patient Prefer Adherence. 2016;10:1177-1187 https://doi.org/10.2147/PPA.S108326

8 Lasinski B. B. (2013). Complete decongestive therapy for treatment of lymphedema. Seminars in oncology nursing, 29(1), 20–27. https://doi.org/10.1016/j.soncn.2012.11.004

Why is light compression sufficient after breast surgery?

After breast surgery, the **breast tissue has to be stabilised** and **held immobile** in order to facilitate the **best possible healing process**. The breast however, must **not be compressed too tightly** or **squashed**. In the case of **breast reconstruction** by means of fat grafting, applying **extreme** external **pressure** on the transplanted area can lead to **insufficient blood supply** and thereby cause a dying off of the cells.[9]
Additionally, patients reported that **too much pressure** from their bra on the freshly operated area was **uncomfortable**.[2]

1 Jandali, Z., Jiga, L., Merwart, B., Lam, M.C., Jess, G., Steege, W. (2020). Brustwiederherstellung. In: Jandali, Z., Jiga, L. (eds) Wiederherstellungsoperationen nach Brustkrebs. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-662-58990-8_4

2 cf. Nicklaus, K.M., Bravo, K., Liu, C. et al. Undergarment needs after breast cancer surgery: a key survivorship consideration. Support Care Cancer 28, 3481–3484 (2020). https://doi.org/10.1007/s00520-020-05414-

2 Prospective, non-interventional observational study on the CuraSupport compression postoperative bra

Goal

- Examination of a special compressing chest bandage from the Amoena Recovery Care product range in postoperative use following breast surgery up to the sixth week after surgery

Population

- 21 participants
- Inclusion criteria: Breast conserving tumour surgery, oncological plastic surgery, mastectomy, breast reconstruction with own tissue and implants, aesthetic breast augmentation/reduction
- Exclusion criteria: Presently undergoing radiotherapy, instable, open wounds

Methods

- Prospective observational study
- End points: Compression using chest straps and/or compression bandages with adjustment possibility, verifiable preservation of the operative result in the necessary follow-up treatment
- Use in the postoperative phase for 30 consecutive days (24h/d)
- Subjective feeling during use (Questionnaire)

Results

- High approval and patient satisfaction
- Optimal fit and comfort
- Simple handling and use
- Compression using chest straps and/or compression bandages with adjustment possibility and verifiable preservation (immobilisation, stabilisation, relief) of the operative result was ascertained

The observational study **concluded** that a **verifiable preservation of the operative result** in the necessary follow-up treatment **was achieved**. **The bra** is designed especially for **postoperative treatment**, which **stabilises** and **relieves**; without impairing the blood supply to the tissue or the comfort of the patient.
Optimal fit is achieved by means of a seamless circular knitting technique in the form of a bustier, that adjusts well to fit the chest. The supple, breathable material has integrated compression zones at the anatomic and physiologic points of the side rib cage and back, to support **lymph drainage**. The bra, which is to be worn immediately following breast surgery, performs the function of **immobilisation**, **stabilisation** and **relief** to ensure **optimal wound healing with maximum comfort** for the patient throughout the entire duration of postoperative care and also, until the wounds have completely healed at least six weeks after the surgical procedure has taken place.

Conclusion of the observational study:

"In addition to a sterile wound dressing, the breast must be stabilised and unburdened without impairing either the blood supply or the comfort of the patient."

This observational study was carried out by Dr. med. Irene Richter-Heine, Specialist for Plastic and Aesthetic Surgery in Munich.

MEDICAL WHITE PAPER
LYMPH CARE

1 A summary of medical-scientific publications on lymphoedema following breast carcinoma and compression therapy

Background

Increasing advancements in the treatment of breast cancer, above all **breast conserving surgery** and **radiotherapy**, are leading to an **increase in incidences** of **secondary lymphoedema**.[1] Alongside breast lymphoedema, **secondary oedemas** can occur in the **arms** and in the **chest wall**.[2] The incidence of **secondary arm lymphoedema** - 12 to 24 months **after breast carcinoma** - lies, after removal of the axillary lymph nodes, at **16% to 23%** depending on the number of lymph nodes that have been removed. Following a **sentinel lymph node biopsy**, the incidence lies at **3% to 5.6%**.[3] The incidence of **secondary lymphoedema occurring in the back** lies at **10%** and at **14%** in the **chest wall**.[4] In a systematic review by Abouelazayem et al. (2021) a **breast lymphoedema** incidence of between **24.8%** and **90.4%** was recorded for breast cancer patients who had **undergone breast conserving surgery** or **radiotherapy**.[5]

Treatment for **breast and chest wall oedemas** is orientated on **classic lymphoedema therapy**.[6] **Complex Decongestive Therapy (CDT)** is the **key element** of **lymphoedema therapy**.[7] Of **particular interest** in CDT is **compression therapy**. **Compression therapy** can play a **decisive role** in **breast and chest wall oedema therapy** to reduce the consequences and **improve patients' quality of life**.[8]

1 cf. Todd M. (2017). Identification, assessment and management of breast oedema after treatment for cancer. International journal of palliative nursing, 23(9), 440–444. https://doi.org/10.12968/ijpn.2017.23.9.440

2 cf. Boughey, J. C., Hoskin, T. L., Cheville, A. L., Miller, J., Loprinzi, M. D., Thomsen, K. M., Maloney, S., Baddour, L. M., & Degnim, A. C. (2014). Risk factors associated with breast lymphedema. Annals of surgical oncology, 21(4), 1202–1208. https://doi.org/10.1245/s10434-013-3408-5

3 cf. DiSipio, T., Rye, S., Newman, B., & Hayes, S. (2013). Incidence of unilateral arm lymphoedema after breast cancer: a systematic review and meta-analysis. The Lancet. Oncology, 14(6), 500–515. https://doi.org/10.1016/S1470-2045(13)70076-7

4 cf. Abouelazayem, M., Elkorety, M., & Monib, S. (2021). Breast Lymphedema After Conservative Breast Surgery: An Up-to-date Systematic Review. Clinical breast cancer, 21(3), 156–161. https://doi.org/10.1016/j.clbc.2020.11.017

5 cf. Abouelazayem, M., Elkorety, M., & Monib, S. (2021). Breast Lymphedema After Conservative Breast Surgery: An Up-to-date Systematic Review. Clinical breast cancer, 21(3), 156–161. https://doi.org/10.1016/j.clbc.2020.11.017

6 cf. Verbelen, H., Tjalma, W., Dombrecht, D. et al. Breast edema, from diagnosis to treatment: state of the art. Arch Physiother 11, 8 (2021). https://doi.org/10.1186/s40945-021-00103-4

7 cf. S2k Leitlinie, Diagnostik und Therapie der Lymphödeme, AWMF Reg.-Nr. 058-001, Mai 2017

8 cf. Hansdorfer-Korzon R, Teodorczyk J, Gruszecka A, Wydra J, Lass P. Relevance of low-pressure compression corsets in physiotherapeutic treatment of patients after mastectomy and lymphadenectomy. Patient Prefer Adherence. 2016;10:1177-1187 https://doi.org/10.2147/PPA.S108326

2 Compression therapy/Compression garments for lymphoedema

The S2k guideline – Diagnostics and therapy of lymphoedema formulates the **goals** of conservative lymphoedema therapy as follows:

> Conservative therapy is aimed at reducing disease symptoms to the symptom-free stage or at least at lowering the stage of disease to achieve long-lasting stability of disease, to improve quality of life, to enable participation in social and professional life and to prevent complications. The combination of CDT with both self-management and information ensures long-lasting therapeutic success (consent 100%; strong consent).

For the **treatment of breast and chest wall oedema**, Hansdorfer-Korzon et al. emphasises: (2016) the use of **compression class I compression garments,** as well as **insertable compression pads** that provide **additional aid in lymph drainage**. Furthermore, it is proven that compression can **reduce** the danger of **lymphostatic fibrosis**.[9] **Compression garments** mainly serve to **preserve** and **improve the results of decongestion therapy**.[10]

In a consensus document from the International Society of Lymphology (2020), it is stated that **treatment solely with compression garments** is being **implemented with success** in particular for **lymphoedemas** associated with **breast cancer** and as a prophylaxis against the first signs of an accumulation of fluid and minimal volume changes.[11]

The S2k guideline - Medical compression therapy highlights the following for the **effectiveness of medical compression therapy**:

> **Compression therapy is an integral component** of complex decongestive therapy in lymphoedema therapy. It serves to reduce oedema as well as the preservation of a decreased oedemic state. It can be implemented with or without manual lymph drainage.

According to Gregorowitsch et al. (2020), **compression garments** are an **effective treatment method** for patients with **breast and chest wall oedema**. After a period of six months, an additional **increase** in the patients' **quality of life** could be recorded as well as a **reduction in swelling from 92% to 71%** and a **decrease in pain from 63% to 18%**.[12]

9 cf. Hansdorfer-Korzon R, Teodorczyk J, Gruszecka A, Wydra J, Lass P. Relevance of low-pressure compression corsets in physiotherapeutic treatment of patients after mastectomy and lymphadenectomy. Patient Prefer Adherence. 2016;10:1177-1187 https://doi.org/10.2147/PPA.S108326

10 cf. Verbelen, H., Tjalma, W., Dombrecht, D. et al. Breast edema, from diagnosis to treatment: state of the art. Arch Physiother 11, 8 (2021). https://doi.org/10.1186/s40945-021-00103-4

11 cf. Executive Committee of the International Society of Lymphology (2020). The diagnosis and treatment of peripheral lymphedema: 2020 Consensus Document of the International Society of Lymphology. Lymphology, 53(1), 3–19.

12 cf. Gregorowitsch, M. L., Van den Bongard, D., Batenburg, M., Traa-van de Grootevheen, M., Fuhler, N., van Het Westeinde, T., van der Pol, C. C., Young-Afat, D. A., & Verkooijen, H. M. (2020). Compression Vest Treatment for Symptomatic Breast Edema in Women Treated for Breast Cancer: A Pilot Study. Lymphatic research and biology, 18(1), 56–63. https://doi.org/10.1089/lrb.2018.0067

MEDICAL WHITE PAPER
SCAR CARE

1

Background

Postoperative scar therapy is becoming increasingly important in medical procedures. Of particular interest is the therapy of pathological scars that can be grouped into hypertrophic scars and keloids.[1]

In order to provide patients with an optimal **evidence-based scar therapy** it is important, alongside the various types of scars, to be familiar with the respective treatment possibilities and their effectiveness.[2]

According to the current **S2k guideline on the therapy of pathological scars (hypertrophic scars and keloids)**, treatment with compression and/or silicone preparations can be recommended. Their **effectiveness** has been **proven in clinical trials**. Due to the fact that variables such as location, age, type of scar as well as genetic disposition can influence the formation and reduction of scars, when it comes to **choosing the best treatment**, a **combination of therapy possibilities is often necessary**.[3]

Scar therapy with compression garments

Among other possibilities, scar treatment can be carried out by means of compression therapy. Poetschke, Gauglitz (2016) states that **empirical research shows that compression therapy as a scar prophylaxis shows good initial results**.[4] Furthermore, **compression therapy** can partly **prevent scar formation** and should be begun as soon as possible after clinical wound healing,[5] when the wound is closed and pressure is tolerable.[6]

In the **S2k guideline on the therapy of pathological scars (hypertrophic scars and keloids)**, it is emphasised that pressure treatment predominantly takes place with elastic fabric and **should be implemented as soon as possible** (i.e. as soon as re-epithelialisation is complete) and also, as a **preventative measure** when a tendency to formation of pathological scars is indicated. The necessary pressure is 20 to 30mmHg. As a postoperative prophylaxis, the treatment duration should be at least six to 24 months. **Topical pressure** causes a reduction in capillary perfusion, accelerates collagen maturation and thereby a **flattening out of the scar tissue**.[7]

1 cf. Nast A et al. S2k-Leitlinie Therapie pathologischer Narben (hypertrophe Narben und Keloide) – Update 2020. J Dtsch Dermatol Ges. 2020. https://doi.org/10.1111/ddg.14279

2 cf. Poetschke, J. and Gauglitz, G.G. (2016), Current options for the treatment of pathological scarring. JDDG: Journal der Deutschen Dermatologischen Gesellschaft, 14: 467-477. https://doi.org/10.1111/ddg.13027

3 cf. Nast A et al. S2k-Leitlinie Therapie pathologischer Narben (hypertrophe Narben und Keloide) – Update 2020. J Dtsch Dermatol Ges. 2020. https://doi.org/10.1111/ddg.14279

4 Poetschke, J. and Gauglitz, G.G. (2016), Current options for the treatment of pathological scarring. JDDG: Journal der Deutschen Dermatologischen Gesellschaft, 14: 467-477. https://doi.org/10.1111/ddg.13027

5 cf. Son D, Harijan A. Overview of Surgical Scar Prevention and Management. J Korean Med Sci. 2014 Jun;29(6):751-757. https://doi.org/10.3346/jkms.2014.29.6.751

6 cf. Meaume S, Le Pillouer-Prost A, Richert B, Roseeuw D, Vadoud J. Management of scars: updated practical guidelines and use of silicones. Eur J Dermatol 2014; 24(4): 435-43 doi:10.1684/ejd.2014.2356

7 Nast A et al. S2k-Leitlinie Therapie pathologischer Narben (hypertrophe Narben und Keloide) – Update 2020. J Dtsch Dermatol Ges. 2020. https://doi.org/10.1111/ddg.14279

A summary of medical-scientific publications on scar therapy following surgical procedures

The following recommendation can be highlighted from the guideline:

> In case of a known predisposition for hypertrophic scars or keloids after surgery or after surgical removal of pre-existing hypertrophic scars or keloids, pressure therapy in suitable locations can be recommended (see guideline recommendation: Pressure therapy; Strength of recommendation 'can').

Compression therapy leads to **good or satisfactory results** for **85% of patients** with **hypertrophic scars** or **keloids**. This includes **scar reduction** as well as **relief from itching** and **pain**.[8] Anzarut et al. (2009) showed in a meta analysis of six studies on compression garments, in which 316 patients participated, that **compression therapy** is connected to a **significant reduction in scar height**.[9]

As outlined previously, a combination of therapies is recommended in order to provide optimal scar therapy. **Compression therapy** can be implemented as part of a **combination therapy with silicone**. Li-Tsang et al. (2010) illustrated that **combination therapy** is connected to a **significant reduction in scar thickness**, in comparison to a control group (massage therapy) after only two months of treatment.[10]

8 cf. Dtsch Arztebl 2004; 101:A 2819–2824 [Heft 42]

9 cf. Anzarut, A., Olson, J., Singh, P., Rowe, B. H., & Tredget, E. E. (2009). The effectiveness of pressure garment therapy for the prevention of abnormal scarring after burn injury: a meta-analysis. Journal of plastic, reconstructive & aesthetic surgery : JPRAS, 62(1), 77–84. https://doi.org/10.1016/j.bjps.2007.10.052

10 cf. Li-Tsang, C. W., Zheng, Y. P., & Lau, J. C. (2010). A randomized clinical trial to study the effect of silicone gel dressing and pressure therapy on posttraumatic hypertrophic scars. Journal of burn care & research : official publication of the American Burn Association, 31(3), 448–457. https://doi.org/10.1097/BCR.0b013e3181db52a7

Scar therapy with silicone plasters

Silicone-based products play a key role in the current guidelines on prevention and therapy of excessive scar tissue. They are **recommended for daily use** in the **prevention of excessive scar tissue** in **postoperative scar therapy**.[11] The guideline on scar therapy by Monstrey et al. (2014) classed **silicone-based products** as the **'gold standard'** for the **prevention** and **therapy of hypertrophic scars** and **keloids**. The **effectiveness** and **safety** of this therapy form was also **proven in further clinical studies**.[12]

In the **S2k guidelines for the therapy of pathological scars (hypertrophic scars and keloids),** it is stated that treatment for prophylactic postoperative purposes can begin shortly after the medical stitches have been removed. For the treatment of open wounds, the prophylaxis should only begin after complete epithelialisation of the wound has taken place. The treatment usually lasts several weeks to months, with a daily application of 12 to 24 hours.[13]

The guideline states the following recommendation:

> Postoperative use of silicone preparations for preventing de novo formation of hypertrophic scars or keloids in patients with risk factors or predisposition, as well as after surgical treatment of hypertrophic scars or keloids, can be recommended (see guideline recommendation: Silicone sheeting and silicone gel; Recommended strength 'can').

11 cf. Poetschke, J. and Gauglitz, G.G. (2016), Current options for the treatment of pathological scarring. JDDG: Journal der Deutschen Dermatologischen Gesellschaft, 14: 467-477. https://doi.org/10.1111/ddg.13027Aktuelle

12 cf. Monstrey, S., Middelkoop, E., Vranckx, J. J., Bassetto, F., Ziegler, U. E., Meaume, S., & Téot, L. (2014). Updated scar management practical guidelines: non-invasive and invasive measures. Journal of plastic, reconstructive & aesthetic surgery : JPRAS, 67(8), 1017–1025. https://doi.org/10.1016/j.bjps.2014.04.011

13 Nast A et al. S2k-Leitlinie Therapie pathologischer Narben (hypertrophe Narben und Keloide) – Update 2020. J Dtsch Dermatol Ges. 2020. https://doi.org/10.1111/ddg.14279

2 Prospective, non-interventional observational study on CuraScar silicones

Goal of the prospective, non-interventional observational study was the **examination** of the **CuraScar silicone plaster** with regard to its **use in scar therapy following breast surgery**.

Goal	• Examination of the CuraScar silicone plaster in various sizes (strips, plate, ring, anker) from the Amoena Recovery Care productrange in postoperative use for hypertrophic scars following breast surgery
Population	• 10 participants • Inclusion criteria: Participants exhibiting excessive, red and risen scars after breast surgery • Exclusion criteria: Postoperative scars that had not fully closed, open wounds, daily duration of wear <6h
Methods	• Prospective observational study • End points: Scar alteration, handling, cleaning, adhesive power, reuseability • Use of the silicone plaster postoperatively for four to six weeks • Subjective feeling during use (Questionnaire)
Results	• Average wearing time 9-15 hours a day, for 34-48 days • Improved scar tissue (flatter, softer, fainter) • High wear comfort and strong adhesive power • Simple handling and cleaning • Reuseable

At the **beginning of the study**, all the participants **(100%)** described their **scars** as **very hard** and **red**. Some also recorded **additional symptoms** such as **pain** and **itching**. **90%** had an **extremely thick scar before the start of the trial**. **After using** the **CuraScar silicone plaster**, all participants **(100%)** reported their scars as **altered** to **flat**, **smooth**, **faint scars**. We can conclude from this that the **CuraScar Silicone Patches** offers **excellent, optimal support for scar healing**. They are therefore **recommended for use in postoperative care** for patients **following breast surgery**. The observational study concludes that the **scar characteristics improved** by wearing the **CuraScar Silicone Patches.**

This observational study was carried out by Dr. med. Irene Richter-Heine, Specialist for Plastic and Aesthetic Surgery in Munich.

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