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Review

Pressure therapy for scars: Myth or reality? A systematic review

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ABSTRACT

Background: Hypertrophic scarring is a deviate occurrence after wound closure and is a common burn sequela. The mainstay of scar treatment consists of a trifold approach: hydration, UV-protection and the use of pressure garments with or without extra paddings or inlays to provide additional pressure. Pressure therapy has been reported to induce a state of hypoxia and to reduce the expression pattern of transforming growth factor-β1 (TGF-β1), therefore limiting the activity of fibroblasts. However, pressure therapy is said to be largely based on empirical evidence and a lot of controversy concerning the effectiveness still prevails. Many variables influencing its effectivity, such as adherence to treatment, wear time, wash frequency, number of available pressure garment sets and amount of pressure remain only partially understood. This systematic review aims to give a complete and comprehensive overview of the currently available clinical evidence of pressure therapy.

Methods: A systematic search for articles concerning the use of pressure therapy in the treatment and prevention of scars was performed in 3 different databases (Pubmed, Embase, and Cochrane library) according to the PRISMA statement. Only case series, case-control studies, cohort studies, and RCTs were included. The qualitative assessment was done by 2 separate reviewers with the appropriate quality assessment tools.

Results: The search yielded 1458 articles. After deduplication and removal of ineligible records, 1280 records were screened on title and abstract. Full text screening was done for 23 articles and ultimately 17 articles were included. Comparisons between pressure or no pressure, low vs high pressure, short vs long duration and early vs late start of treatment were investigated.

Conclusion: There is sufficient evidence that indicates the value of prophylactic and curative use of pressure therapy for scar management. The evidence suggests that pressure therapy is capable of improving scar color, thickness, pain, and scar quality in general.

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Evidence also recommends commencing pressure therapy prior to 2 months after injury, and using a minimal pressure of 20–25 mmHg. To be effective, treatment duration should be at least 12 months and even preferably up to 18–24 months. These findings were in line with the best evidence statement by Sharp et al. (2016).

Contents

1. Introduction

Hypertrophic scar formation (HTS) is the result of an abnormal cellular response that occurs during the remodeling phase after wound closure and is characterized by red, rigid, hypersensitive, thick, and elevated scar tissue [1]. HTS, in contrast to keloids, does not spread beyond the boundaries of the initial lesion and has the potential to regress spontaneously [2–5]. HTS is a commonly encountered complication after burn injuries and other deep dermal or full-thickness skin defects [3]. Clinical evidence demonstrates that the incidence of HTS after surgery or trauma is 30–50% and reported numbers go up to 72% following deep dermal or full-thickness burns [4,6–9]. The higher frequency of pathological scarring after thermal trauma is attributed to the significantly prolonged and excessive local and systemic inflammatory responses [4]. Additionally, the exposure of fat domes in the reticular dermal layer, which occurs in deep burns, is associated with a higher risk of HTS due to hypothesized altered stem cell-cytokine interaction of adipose-derived stem cells (ASCs) and deep burn wound fluid exudate [10]. HTS formation results from the excessive and irregular production of collagen fibers by (myo)fibroblasts and can result in tissue deformation or even severe contracture [11]. Excessive HTS formation can have physical, aesthetic, psychological, and social consequences undermining the patients' self-confidence, living independence, and quality of life, posing a true challenge to health professionals worldwide [3,11]. Currently, a wide variety of scar management measures is available, but the mainstay of non-invasive scar treatment is

essentially triple-fold: achieving optimal hydration of the stratum corneum, protection from harmful ultraviolet rays, and the use of pressure garments with or without extra paddings or inlays to provide additional pressure [6,12]. Pressure therapy exerts a force perpendicular to the skin's surface and with garments, this force is applied in a circumferential manner [13]. It is hypothesized that pressure therapy (PT) generates both an ischemic and hypoxic environment, impairing the growth of fibroblasts and transformation of the latter into myofibroblasts [11,14]. Moreover, mechanical pressure has been shown to decrease the expression pattern of transforming growth factor-β1 (TGF-β1). TGF-β1 is a mediator in the regulation of fibroblast activity through TGF-β receptors at the cell surface with subsequently SMAD2 and SMAD3 as important intracellular transducers [1,15,16]. Additionally, the upward regulation in the expression level of matrix metalloproteinases (MMPs) in combination with the reduction of TGF-β1 leads to decreased fibroblast activation, multiplication, and an increased breakdown of extracellular matrix, which results in a net decrease of collagen deposition [1,11,16]. Although PT has become standard care for the prevention and treatment of HTS, the working mechanism is not entirely understood [17]. Its practice and parameters such as the amount of pressure or duration of treatment are said to be mostly based on empirical evidence [17]. Thus, controversy concerning the effectiveness of PT still prevails. Many other variables influencing its effectivity, such as adherence to treatment, wear time, wash frequency and the number of available pressure garment sets remain only partially understood [2,18,19].

Pressure garments and accompanying compression wear is a multi-sided and highly complex process, with a high level of clinical knowledge by all (para-)medical members involved [20]. This systematic review, therefore, aims to provide a complete and comprehensive overview of the currently available clinical evidence on PT and the associated variables in the prevention and treatment of hypertrophic scarring.

2. Methodology

2.1. *PROSPERO registration*

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist was used as a guide for this study. Prior to the start of this study, the review protocol was submitted to Prospero on October 25, 2021. The protocol was officially registered online on November 25, 2021, and received the following registration code: CRD42021287374.

2.2. *Search strategy*

Three different electronic databases were searched for original peer-reviewed papers: Pubmed, Embase, and the Cochrane Library. The articles were selected by 2 separate reviewers (AB, IDD) and the senior author (KC) was consulted as a third reviewer when the first two reviewers were in disagreement. The complete search strategy for each of these three databases is listed in Supplementary Table 1. The eligibility criteria for the studies can be found in Supplementary Table 2. The search terms used across the three databases included 'pressure garment', 'compression garment', 'compression therapy', 'pressure', 'compression', 'garment', 'scar', 'cicatrix', 'burns' and 'burn'. All terms were derived from medical literature describing the application of pressure garments in scar treatment. The terms were combined into a single search filter using the Boolean operators 'OR' and 'AND.' The last search was conducted on February 16, 2022. Original research papers with several study designs were eligible: randomized controlled trials (RCTs), cohort studies, case-control studies, and case series. No restriction was imposed on the date of publication. Treatment protocols were accepted when they included the management of hypertrophic scars (HTS) by pressure garments and/or prophylactic use of pressure garments for HTS. Treatment protocols were excluded when exclusively PT on keloids was studied and no HTS were included, when PT was combined with other experimental therapies, or when protocols were lacking a proper control group. All study populations were eligible regardless of the origin of injury, ethnicity or age.

2.3. *Quality assessment of articles*

The quality of all studies was assessed by 2 separate reviewers (AB, IDD). Appropriate quality assessment (QA) tools were used in accordance with the study design. Three different QA-tools were used: Cochrane risk-of-bias (RoB 2), Risk-of-bias in non-randomized studies of interventions (ROBINS-I) and The Criteria of Chambers. The Cochrane RoB 2 tool is an instrument that uses 5 different domains to analyse the methodological strength of RCTs. The domains assess performance, detection, attrition, reporting, and other biases. The overall risk of bias is either 'low', 'some concerns' or 'high'. ROBINS-I is used for the assessment of non-randomized prospective studies. This tool consists of multiple domains including confounding factors, selection of participants in the study, classification of interventions, deviations from the intended interventions, missing data, measurement of outcomes, and selection of the reported results. The final grading of risk of bias is assessed at either 'low', 'moderate', 'serious' or 'critical'. The Criteria of Chambers are used for assessing case series and involves the use of eight questions (see Supplementary Table 3). The grading of the quality is done by labelling the study either 'poor', 'satisfactory', or 'good' quality. The study quality was only assessed as 'good' if all questions were answered with 'yes'. The study quality was classified as 'poor' when the answer was 'no' to any of the following questions: 2, 4, 5, 6, or 7.

2.4. *Data extraction*

Data was extracted by 2 review authors (AB, IDD) and accuracy was verified by a third review author (SM). The following information was extracted from the included articles: (a) title, (b) authors, (c) year of publication, (d) study design, (e) population, (f) sample size, (g) treatment groups, (h) start of treatment, (i) treatment and follow-up time, (j) localization of pressure therapy and type of pressure therapy, (k) pressure applied by therapy, method and interval of pressure-assessment, (l) daily

wear time, (m) number of garment sets available, interval of replacement and washing, (n) measurements, (o) time of measurements, (p) outcomes, and (q) conclusion are listed. Numerical data are presented in the manuscript as mean (± standard deviation).

3. Results

3.1. Study selection

The results of the search strategy are displayed in Fig. 1. Ultimately 17 articles were included in the review [2,11,21–35].

3.2. Study description

Table 1 provides a comprehensive overview of the included studies. Authors, year of publication, study design, population, number of participants and dropouts, intervention and control group, the start of treatment, treatment and follow-up time, the localization of pressure therapy, type of pressure therapy, amount of pressure applied by therapy (mmHg), method and interval of pressure-assessment, daily wear time, number of garment sets available, the interval of replacement and washing, measurements, time of measurements, outcomes and conclusions are listed.

Seventeen articles were included in this systematic review including 5 RCTs [2,28,31–33], 7 prospective cohort studies [11,21,22,24,27,34,35] and 5 case series [23,25,26,29,30]. Four studies investigated the effects of PT compared to no PT [11,24,28,32]. Three studies compared early intervention PT to late intervention PT [22,27,35]. Three studies investigated the effects of high PT compared to low PT [2,31,33]. One study compared a long duration of PT to a short duration of PT [21]. One study investigated the effect of facial PT on patients' satisfaction [34]. There was one intra-individual, within-wound study [33] and 11 studies had a control and treatment arm investigating two separate groups of patients [2,11,21,22,24,27,28,31,32,34,35]. Thirteen studies were not blinded [11,21–31,34]. There was one study in which all measurements were assessed non-blindly except for the clinical appearance, which was assessed blindly [33]. Two studies were assessor-only-blinded [32,35]. One study was double-blinded for both patient and the assessor [2]. Sample sizes ranged from 5 to 500 patients. A mean of 73 (± 113) patients were included per trial. A total of 1166 patients were included in all trials combined. One study did not specify the number of patients included in the trial [21]. A total of 109 dropouts were reported with a mean of 7.70 (± 8.45) dropouts

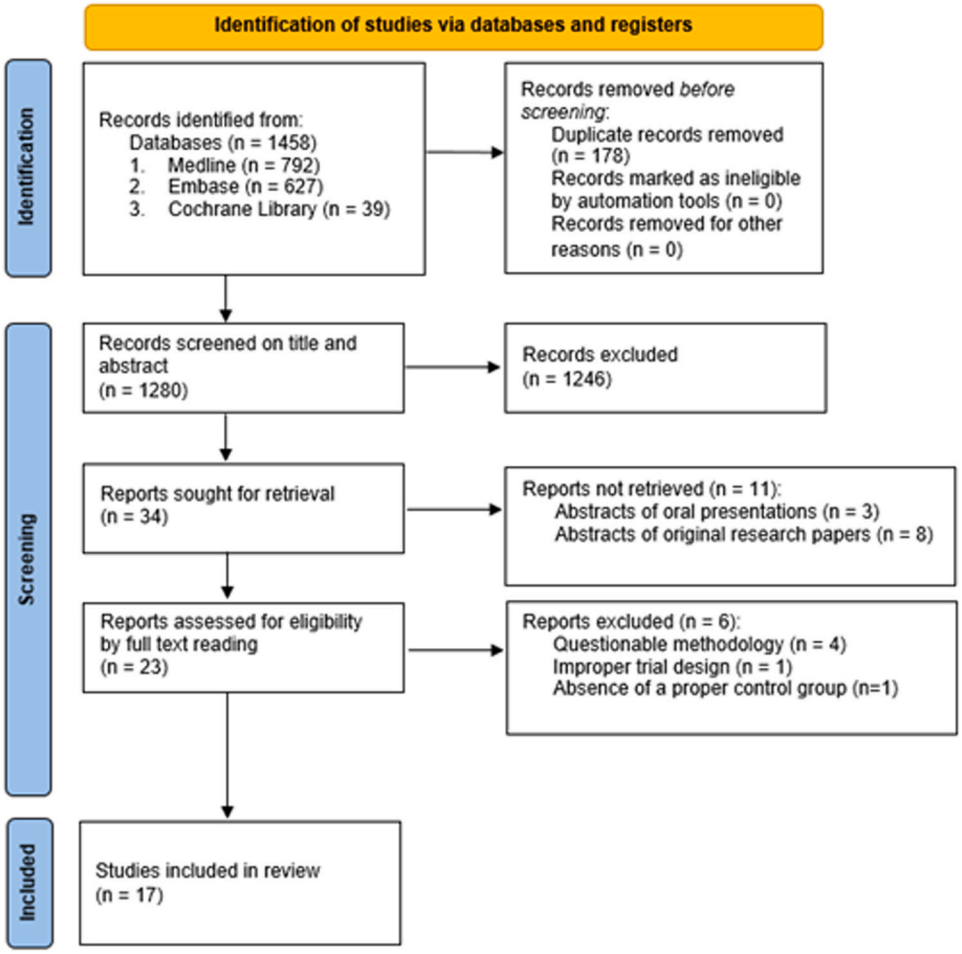

Fig. 1 – Study flowchart according to the PRISMA statement.

Table 1 – Study overview. Pressure garments (PG), Pressure garment therapy (PGT), Pressure therapy (PT), Tubular compression bandages (TCB), Tubular support bandages (TSB), Hypertrophic scars (HTS), Patient and Observer Scar Assessment Scale (POSAS), Vancouver scar scale (VSS), modified Vancouver Scar Scale (mVSS),Visual analogue scale (VAS), Intra-individual comparisons were marked with (*), (n) number of patients. Non-blinded, assessor-only-blinded and double-blinded studies were marked with [1], [2] and [3] respectively. Studies where all measurements were assessed non-blinded except for clinical appearance which was assessor-only-blinded are marked with [4].

Authors	Year	Study design	Population	Participants - Dropouts	Intervention - Comparison	Start PGT after injury	Treatment time - Follow-up time	Localisation of PGT - Type of PG used	Pressure applied by garments - Method of assessment - Interval of assessments	Daily wear time	Number of sets available - Interval of replacement- Interval of washing	Measurements	Time of measurements	Conclusion
Li et al[2]	2018	Prospective cohort study	Patients with burn HTS Mean age 38,53 +/- 4,43 years	34 (65 scars) - 3	Early intervention (34 scars) - Late intervention (31 scars)	Within 60 days - 61–180 days after burn	6 months - Not specified	Upper or lower limbs - Smart Pressure Monitored Suits	10–15 mmHg - Pliance X system - Monthly	23 h	Not reported - Regularly - Not reported, but patients are informed of washing regime	1. Color (Spectrocolorimeter) 2. Thickness (Ultrasound) 3. mVSS 4. VAS	Before start of therapy and then monthly	Early intervention appeared to result in better treatment outcomes when compared to the late intervention.
Kant et al[1]	2018	Prospective cohort study	Patients with facial HTS and severe postsurgical facial irregularities 18–83 years	1. Patients' satisfaction: 69 - 27 2. POSAS: Not reported	1. Patients' satisfaction: Patients divided in groups based on: A) Daily wear time (4–16 h) B) Time since completion of the therapy (< 1–5 years) 2. POSAS Intra-individual	Not reported	3–30 months - < 1 – 5 years	Face - Custom-made transparent pressure facemask	20 mmHg - Pneumatic pressure sensor - Every 3–4 months	- 4–8 h (n = 7) - 8–12 h (n = 20) - 12–16 h (n = 15)	Not reported	1. Patients' satisfaction: 4 FACE-Q questionnaires 2. POSAS	1. FACE Q: < 1–5 years after completion of therapy: - < 1 (n = 8) - 1–2 (n = 7) - 2–3 (n = 11) - 3–4 (n = 8) - 4–5 (n = 8) 2. POSAS At the start of PT and every 3–4 months	Facemask therapy is effective and results in a long-lasting, stable result. A longer daily wear time results in the highest satisfaction.
Li-Tsang et al[1]	2015	Prospective cohort study	Patients with burn HTS 6–75 years	18 (26 scars) - 0	PGT (10 scars) - No PGT (16 scars)	3–6 months	3 months - Not specified	Scars at extremities - PG (not specified) ± padding	15 mmHg - Pliance X system - After 1 month and after 3 months	23 h	Not reported - Adjusted when needed - Not reported	1. VSS 2. Thickness (Ultrasound) 3. Color (Spectrocolorimeter) 4. Histopathology	Before start of therapy, after 1 month and after 3 months of therapy	Significant improvements in both the clinical and histopathological characteristics of scar tissues were observed from the patients with pressure intervention.
Candy et al[3]	2010	RCT	Patients with HTS caused by burns, scalds, surgery or trauma Mean age 26,23 +/- 7,78 years	17 (53 scars) - Dropout rate 8.62%	High pressure (28 scars) - Low pressure (25 scars)	Not reported	5 months - Not specified	Upper and lower extremities - Tailor-made PG ± paddings	20–25 mmHg vs 10–15 mmHg - Pliance X system - Monthly	23 h	2 sets - After 2 months of intervention - Not reported	1. Thickness (Ultrasound) 2. Color (Spectrocolorimeter + VSS) 3. Pliability (VSS)	Before start of therapy and then monthly	The results showed that the high pressure level accelerated scar remodeling with generally better clinical presentations compared with the lower pressure level.

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Table 1 – (*continued*)

Authors	Year	Study design	Population	Participants - Dropouts	Intervention - Comparison	Start PGT after injury	Treatment time - Follow-up time	Localisation of PGT - Type of PG used	Pressure applied by garments - Method of assessment - Interval of assessments	Daily wear time	Number of sets available - Interval of replacement- Interval of washing	Measurements	Time of measurements	Conclusion
0Li-Tsang et al[2]	2010	RCT	Patients with HTS caused by burns, scalds or trauma Mean age 21,80 + /- 18,70 years	51 - 13	PGT (31 patients) - No PGT (20 patients)	Mean scar onset 5,22 + /- 1,58 months	6 months - 1 month	Limbs or trunk - Tailor-made PG + paddings	Not reported	23 h	Not reported	1. Color (Spectro-colorimeter) 2. Thickness (Ultrasound) 3. Pliability (VSS) 4. VAS	Before start of therapy and then at 2, 4, 6 months of therapy and 1 month after therapy	PGT showed superior results compared to the control group.
Engrav et al[4] (*)	2010	RCT	Burn patients after grafting wounds or wounds with ≥ 3 weeks to heal 7–65 years	67 - 24 (dropout rate 35,8%)	High pressure - Low pressure	Within two weeks of re-epithelia-lization	Not specified - Not specified	Forearm - A custom-fit PG by Medical Z Inc. (Lycra) designed such that it applied pressure to only one-half of the wound, proximal or distal	25 mmHg vs 6,4 mmHg - I-ScanTM System - Every 2–3 months	23 h	Not reported	1. Hardness (Durometer) 2. Color (Chromamete-r) 3. Thickness (Ultrasound) 4. Cosmetic appearance (Clinical examination)	Every 2–3 months	Wounds treated with high compression showed better results. The clinical benefit of PGT is restricted to those patients with moderate or severe scarring.
Van den Kerck-hove et al[1]	2005	RCT	Patients with sponta-neously healed partial thickness burns 19–65 years	60 (76 scars) - 1 (1 scar)	High pressure (41 scars) - Low pressure (34 scars)	2 weeks after re-epithelia-lization	3 months - Not specified	Forearm and calf - PG Tricolast1 or Anvarex1	15 mmHg vs 10 mmHg - Calculated from the strain–force curves described in ENV 12718 - After 1 month of therapy	23 h	2 sets - No replacement - Not specified, but patients are informed of washing regime	1. Erythema (Chromamete-r) 2. Thickness (Ultrasound)	Before start of therapy and then monthly	No significant difference in the decrease of erythema between both compression groups was found. Decrease in thickness in the high compression group was greater than in the low compression group.
Cheng et al[1]	2001	Case series	Patients with HTS caused by scalds or burns and keloids secondary to surgical incision 0.5–16 years	86 - 14	/	Not reported	Not specified: 'Duration determined by clinical assessment' - 6 months – 7 years	Most frequent: trunk and limbs - Custom-made PG from the industrial Lycra material	5–10 mmHg - Pressure = Tension (5–7% strain)/ Radius for cylindrical PG - Not reported	Not reported	Not reported	1. VSS 2. Thickness (Ultrasound)	Before start of therapy and then every 3–4 months	PGT is effective and needs to be continued for a minimum of 12 months and preferably for 18–24 months.

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Table 1 – (*continued*)

Authors	Year	Study design	Population	Participants - Dropouts	Intervention - Comparison	Start PGT after injury	Treatment time - Follow-up time	Localisation of PGT - Type of PG used	Pressure applied by garments - Method of assessment - Interval of assessments	Daily wear time	Number of sets available - Interval of replacement- Interval of washing	Measurements	Time of measurements	Conclusion
Clark et al[1]	1987	Case series	Patients with HTS caused by superficial to full thickness burns underwent grafting 18–44 years	15 - 6	/	Re-epithelia-lization complete or in early process of scar ma-turation	2 years - Not specified	Forearms - Custom-made elasticized PG	10–35 mmHg - Electro-pneumatic pressure transducer - Not reported	Not reported	Not reported - Re-tailored when needed - Not reported	1. Extensibility (Extensometer) 2. Stiffness (Extensometer) 3. Cosmetic appearance (Clinical examination)	At 2, 3 or 4 week intervals	Scar gradings show improvements in the mechanical properties which correlate with the clinical assessment of their maturation.
Rose et al[1]	1985	Prospective cohort study	Patients with sponta-neously healed and surgically closed deep partial and full thickness burns 1–92 years	88 (210 burn sites) - 0	Early intervention (71 patients) - Late intervention (17 patients)	Within 1 month - 3–18 months after burn	1–30 months - Not specified	Head, neck, trunk, hand, foot and extremities - Tubigrip® only or Tubigrip® followed by/ and custom fit garments ± positioning devices/ inserts	Early: initially 10–20 mmHg, after skin tolerance 20–30 mmHg Late: 20–30 mmHg - Not reported - Initially weekly, then monthly, then every 3 months	Not reported	Not reported	1. Cosmetic and functional evolution (Clinical examination)	After therapy	TCB can be used as a temporary dressing before the use of other garments or as the definitive compressive garment. Better overall results when used prophylactic, but improvement also showed when used therapeutically.
Tørring[1]	1984	Case series	Patients with grafted burns, donor areas harvested several times, burns healed after > 14–21 days and deep dermal burns Children and adults (age not specified)	Close to 500 - Not specified	/	As soon as the bum has epithelia-lized	6 – 18 months - Not specified	Not specified - Tubigrip® or Struwa® stockings for 3 weeks followed by Jobst® PG	Not reported - Not reported - PG checked for wear and elasticity every month and later at increasing intervals	23 h	2–3 sets - A pair of gloves or trousers lasts for 2–3 months and a waistcoat for ½ year. - Not specified	1. Color 2. Surface contour 3. Texture 4. Tensions 5. Itchiness (Clinical examination)	Every month and later at increasing intervals	PGT leads to quicker fading, flattening and softening of the scars and is also effective against the itching.

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Table 1 – (*continued*)

Authors	Year	Study design	Population	Participants - Dropouts	Intervention - Comparison	Start PGT after injury	Treatment time - Follow-up time	Localisation of PGT - Type of PG used	Pressure applied by garments - Method of assessment - Interval of assessments	Daily wear time	Number of sets available - Interval of replacement- Interval of washing	Measurements	Time of measurements	Conclusion
Judge et al[1]	1984	Case series	Patients with HTS grafting burns 1–77 years	49 - 7	/	Average of three weeks after grafting	Average of > 3 weeks - Not specified	Face, trunk, arms, legs, feet - Tubigrip® ± silicone foam	10–20 mmHg - Measured by a tension guide - Not reported	Not reported	Not reported - Not reported - Daily washed	1. Flatness (Clinical examination)	Post graft, pre TSB application (after 3 weeks of graft)and at the point of change from TSB to long term PG	The development of HTS was arrested during interim use of TSB.
Kischer et al[1]	1979	Prospective cohort study	Patients with burn HTS Children and adults (age not specified)	59 scars - 0	PGT (11 scars) - No PGT (48 scars)	Not reported	1–5 months - Not specified	Not reported - Elastic wraps (not specified)	Not reported	Not reported	Not reported	1. Histopathology	At 1 month and 3 months of therapy	Pressure increases hypoxia because of its effect on the microvasculature and results in resolution of HTS.
Klöti et al[1]	1979	Prospective cohort study	Full thickness burns with skin grafting Children 2,5 – 14 years	13 - 0	Early intervention (8 patients) - Late intervention (5 patients)	After wound healing - 3 – 24 months after burn	12 months - 12 months	Extremities, face and trunk - PG made by the Orthopaedic University Clinic Balgrist in Zurich	Not reported	Not reported	Not reported	1. Cosmetic appearance 2. Function (Clinical examination)	After 12 months	Early application reduces formation of HTS and shows better results, but late application also shows improvement and is still useful.
Garcia-Velasco et al[1]	1978	RCT	Patients with HTS after partial and full thickness burns caused by scalds or flames Children 1–16 years	35 (50 scars) - 10	PGT (35 scars) - No PGT (15 scars)	In the early phases of the scarring process.	12 months - Not specified	Not specified - Combined splints with custom-made Jobst® garments or custom-made silicone facial mask	Not reported	23 h	Not reported - Adjusted or changed as necessary, often every 2–3 months - Not reported	1. Color 2. Consistency 3. Thickness (Clinical examination)	At 6 months and 12 months of therapy	The overall improvement was of much greater degree in the treated group.
Baur et al[1]	1976	Prospective cohort study	Patients with burn HTS 4–57 years	Not specified	Long duration PGT - Short duration PGT - No PGT	After grafting or one to several months after start of hypertrophy	> 6 months or < 6 months - Not specified	Not reported - Pressure wraps (not specified)	Not reported	Not reported	Not reported	1. Histopathology	Treated scars: > 6 months or < 6 months Untreated scars: - Young scars (< 6 months after trauma) - Old scars (6 months – 3 years)	Best results when treatment time > 6 months.

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Table 1 – (continued)

Authors	Year	Study design	Population	Participants - Dropouts	Intervention - Comparison	Start PGT after injury	Treatment time - Follow-up time	Localisation of PGT - Type of PG used	Pressure applied by garments - Method of assessment - Interval of assessments	Daily wear time	Number of sets available - Interval of replacement- Interval of washing	Measurements	Time of measurements	Conclusion
Larson et al[1]	1971	Case series	Patients with burn HTS Children (age not specified)	5 - 0	/	Weeks to months after burn injury	Weeks to months - Not specified	Face, trunk, extremities - Isoprene splints ± ace bandages Ace bandages Isoprene facemasks	Not reported	Not specified	Not reported	1. Cosmetic appearance (Clinical examination) 2. Histopathology	After therapy	Pressure therapy combined with splints can prevent and decrease HTS and scar contraction.

per trial. Two studies did not specify the number of dropouts [21,25]. The patient's average age was 26.70 (± 27.60) years and ranged from 6 months to 92 years. Five studies included pediatric patients [22,24,26,28,30].

3.3. *Quality assessment of articles*

Quality assessment of the 17 included articles was performed by using the appropriate QA tools. The RoB 2 tool was used to assess the quality of five studies [2,28,31–33], the results are displayed in a traffic light plot (Fig. 2). Two studies were considered to have a low risk of bias [2,31], two studies harbored some concerns [32,33] and one study had a high risk of bias [28].

The ROBINS-I tool was used to assess the quality of seven studies [11,21,22,24,27,34,35]. Results are displayed in a traffic light plot (Fig. 3). Five of these studies were considered to have a moderate risk of bias [21,22,24,27,34], while two studies had a low risk of bias [11,35].

The Criteria of Chambers were used to assess the quality of five studies [23,25,26,29,30], the answers to these 8 questions are shown in Table 2. Four of the studies were classified as poor quality [25,26,29,30], while one study was considered to have good quality [23].

3.4. *Treatment regimen*

Treatment protocol variables included the type of PT and the localization, scar maturity and the start of treatment, treatment, and follow-up duration, amount of applied pressure, method and interval of pressure assessment, daily wear time, the number of garment sets available, and replacement and washing intervals. Table 1 contains detailed study treatment regimens.

All studies investigated the efficacy of PT in the management of abnormal scarring. Ten studies additionally investigated the prophylactic effect of PT to assess the potential reduction in the occurrence of hypertrophic scarring [21–23,25–29,31,33]. Five studies included scars located in the facial or head and neck area [22,23,26,27,34], twelve studies included the extremities [2,11,22,23,26,27,29–33,35] and six studies included the trunk [22–24,26,27,32]. Four studies did not specify or report the localisation of the scars [21,24,25,28]. Different types of PT were used in accordance with the localization of the scars. Three studies reported the use of facial pressure masks [26,28,34] and sixteen studies made use of pressure garments [2,11,21–33,35]. Table 1 contains additional information about the fitting and garment manufacturers. Seven studies used additional paddings, silicone foam or splints [2,11,23,26–28,32]. The time prior to initiation of treatment varied widely between and even within studies. The earliest groups started within the first two weeks or several weeks after re-epithelialization [11,21–23,25,26,28,29,31,33,35]. Other study groups started a few months to two years after injury [11,21,22,26,27,32]. Four studies did not report the start of treatment [2,24,30,34]. The duration of treatment varied greatly from several weeks to 30 months. Two studies did not specify the treatment duration [30,33]. Only 4 studies reported the follow-up time varying from 1 month to 7 years after initiation of treatment. Pressure

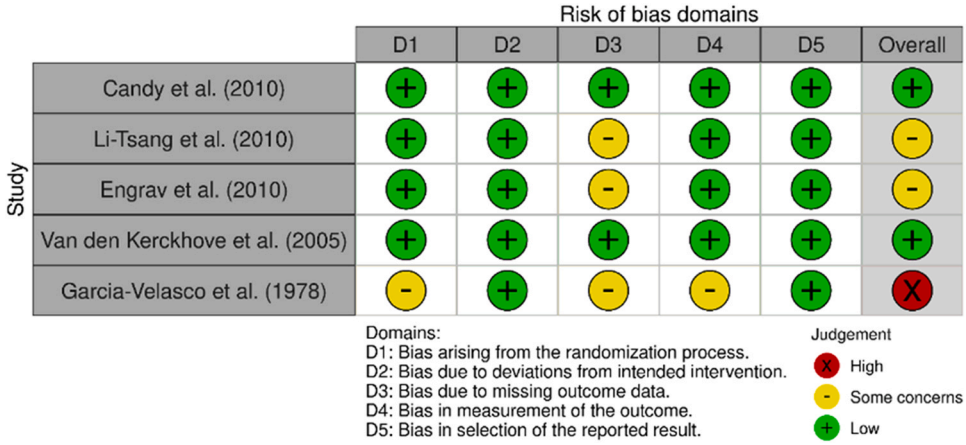

Fig. 2 – Quality assessment, traffic light plot, Cochrane risk of bias assessment tool (RoB-2) for randomized controlled trials.

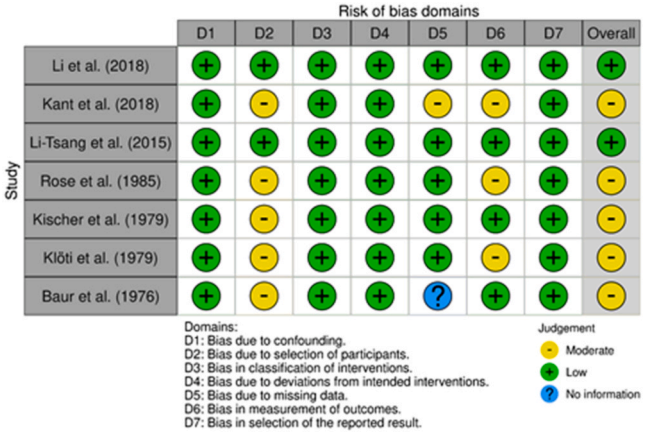

Fig. 3 – Quality assessment, traffic light plot, Risk Of Bias In Non-Randomized Studies - of Interventions (ROBINS-I).

applied by therapy was reported by 10 studies and varied from 5 mm Hg to 35 mm Hg [2,11,23,27,29–31,33–35]. Six out of these ten studies also mentioned their method and interval of pressure assessment [2,11,31,33–35], three studies reported the method but no interval of assessment [23,29,30], and one study reported the interval but no method of assessment [27]. One study solely reported the interval of pressure assessment [25]. In 8 studies the patients were advised to wear the garments 23 h a day [2,11,25,28,31–33,35]. One study compared the patients based on daily wear time and divided them into groups of 4–8 h, 8–12 h, or 12–16 h wear time a day [34]. In eight studies the daily wear time was not reported [21–24,26,27,29,30]. The number of garment sets per patient and the interval of replacement and washing was only partially reported by several studies [2,11,23,25,28,29,31,35].

3.5. *Efficacy measurements*

The Vancouver Scar Scale (VSS) was used for assessment by 4 out of 17 studies [2,30,32,33] and one study used the modified version of the VSS (mVSS) [35]. The color (yellowness, lightness, redness) of the scar was measured by 6 studies [2,11,31–33,35]. A histopathological assessment was done by 4 studies [11,21,24,26]. The firmness of the scar [33], skin tensile strength [29], patient satisfaction (PS) [34] and POSAS [34] were only measured by one study. The Visual Analogue Scale (VAS) was assessed by 2 studies [32,35]. Reduction in scar thickness (ST) was assessed by 7 studies [2,11,30–33,35]. The overall appearance of the scar was scored in 8 studies using clinical assessment [22,23,25–29,33]. Adverse events were registered in 4 out of 17 studies [22,30,32]. An overview of the efficacy measurements and the outcomes of the RCTs and cohort studies can be found in Table 3.

3.5.1. *PT vs no PT*

Li-Tsang et al. [11,32], Kischer et al. [24] and Garcia-Velasco et al. [28] compared the effects of PT to no PT in the prevention and treatment of HTS.

Li-Tsang et al. [11] included 18 patients with in total 26 burn HTS in a prospective cohort study design, 10 scars in the PT arm and 16 scars in the control arm. Patients were treated for 3 months, 23 h daily with an applied pressure of 15 mmHg, monitored by the Pliance X system. Li-Tsang et al.

Table 2 – Quality assessment, table results, Criteria of Chambers. Not applicable (NA).

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Quality
Cheng et al. (2001)	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Poor
Clark et al. (1987)	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Poor
Tørring et al. (1984)	Yes	Yes	Yes	No	NA	Yes	Yes	Yes	Poor
Judge et al. (1984)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Good
Larson et al. (1971)	Yes	No	Yes	NA	NA	No	Yes	Yes	Poor

Table 3 – Overview of study outcomes. Not investigated measurements are marked with '/', measurements significantly ($p < 0.05$) against or in favor of the study group are indicated with '–' and '+' respectively. Strong ($p < 0.01$) or very strong ($p < 0.001$) significance was indicated with double icons '++' or triple icons '+++' respectively. Comparable outcomes between intervention and control are indicated with '='. Outcomes stated against or in favor of the study group but without assessing significancy are indicated between parentheses. Intra-individual comparisons are marked with '*'. Mentioned in article but result not stated (NS), Numbers not stated (NNS), Pressure garment therapy (PGT), Visual Analogue Scale (VAS), reduction in Scar Thickness (ST), Patient Satisfaction (PS). [1]Color measured with Spectrocolorimeter or Chromameter. [2]Overall cosmetic appearance of the scars assessed by expert clinical assessment.

	STUDY	CONTROL	(m)VSS							Histopathology							Color[1]			VAS		ST	PS	Hardness		Adverse effects PGT
			Pliability	Pigmentation	Vascularity	Height	Itch	Pain	Total score	Myofibroblasts	Keratinocytes	Fibroblasts	Collagen alignment	Dermal density	Microvasculature	Mast cell degranulation	Yellowness	Lightness	Redness	Pain	Itchiness				Clinical appearance[2]	
Pan Li et al.	Early PGT	Late PGT	+	+	+	+	/	/	++	/							++	++	=	++	++	++	/	/	/	Not specified
Kant et al.	12–16 h	8–12 h	/							/							/			/		/	+	/	/	Not specified
	12–16 h	4–8 h	/							/							/			/		/	+	/	/	Not specified
Li-Tsang et al.	PGT	No PGT	NS						+	+++	+++	+++	+	+	/	/	=	=	+	/		+	/	/	/	Not specified
Candy et al.	High pressure	Low pressure	++	=	/	/	/	/	/	/							=	=	+	/		++	/	/	/	Not specified
Li-Tsang et al.	PGT	No PGT	(+)	/	/	/	/	/	/	/							(+)	(+)	(+)	+	=	+	/	/	/	Sweating (NNS), itching (NNS)
Engrav et al. *	High pressure	Low pressure	/							/							=	=	=	/		+	/	+	=	Not specified
Van den Kerckhove et al.	High pressure	Low pressure	/							/							/	/	=	/		+	/	/	/	Not specified
Rose et al.	Early PGT	Late PGT	/							/							/			/		/	/	/	(+)	Not specified
Kischer et al.	PGT	No PGT	/							/	/	/	/	/	(+)	/	/			/		/	/	/	/	Not specified
Klöti et al.	Early PGT	Late PGT	/							/							/			/		/	/	/	(+)	Itching (5), ulceration of the skin (3)
Garcia-Velasco et al.	PGT	No PGT	/							/							/			/		/	/	/	(+)	Not specified
Baur et al.	Long duration	Short duration	/							(+)	/	=	(+)	/	/	(+)	/			/		/	/	/	/	Not specified

[11] investigated the VSS, color and ST and performed a histopathological assessment. In the PT group, the collagen fiber arrangement changed from a nodular to a wave-like pattern, dermal fibroblast apoptosis increased, and basal keratinocyte proliferation, myofibroblast differentiation, and dermal cell density decreased. Additionally, they found a significant difference in the VSS, redness, and ST in favor of the treatment group [11].

Li-Tsang et al. [32] conducted a trial in 2010. The study groups included 51 patients with HTS with different etiologies e.g. burns or trauma. The PT and no PT arm included 31 and 20 patients respectively. There was a treatment time of 6 months and patients were advised to wear the garments 23 h a day. The pressure applied by the pressure garments was not reported. The study reported a high dropout rate of 13 patients (23.50%), attributed to practicalities e.g. long distances. The authors [32] investigated scar color, pliability (as measured by VSS), ST, and VAS [32]. The PT group improved significantly in terms of scar thickness and pain when compared to the control group. The color and the pliability were also in favor of the treatment group, but without significance. There was no difference in itching [32].

In a prospective cohort study, Kischer et al. [24] compared 11 treated HTS to 48 untreated HTS. Elastic wraps were used on the children for 1–5 months. The authors discovered that pressure leads to the degeneration of satellite and endothelial cells and results in an increase in occluded microvessels. They concluded that pressure increases hypoxia, causing focal degeneration of selective cells, resulting in the resolution of the HTS [24].

Garcia-Velasco et al. [28] selected 35 children with HTS after partial and full-thickness burns. The PT and the non-PT groups included 35 and 15 scars, respectively. The children were treated for 12 months with customized Jobst® garments or silicone facial masks. Advised daily wear time was 23 h. Ten children (5 out of each group) did not complete the study (28.60%), and no explanation was given. Garcia-Velasco et al. [28] reported that the improvement of clinical appearance was of a much higher degree in the treated group, but they did not state it with significance [28].

3.5.2. *Early intervention compared to late intervention*

Li et al. [35], Rose et al. [27] and Klöti et al. [22] used a prospective cohort study design to compare the effects of early intervention PT to late intervention PT on abnormal scarring.

Li et al. [35] included 34 patients with 65 burn HTS. The early (34 scars) and late (31 scars) intervention group started treatment within 60 days (mean 44.53 days) after burn and 61–180 days (mean 112.76 days) after burn, respectively. Smart Pressure Monitored Suits were used with an applied pressure of 10–15 mmHg. The pressure applied by the pressure garments was monitored monthly. Advised daily wear time was 23 h. The garments were replaced regularly. Patients were treated for 6 months with no specified follow-up time. Li et al. [35] showed that the mVSS, color, VAS and ST were significantly better in the early PT group compared to the late PT group [35].

Rose et al. [27] selected 88 patients with 210 both spontaneously healed and surgically closed deep partial and full thickness burns. The early intervention arm included 71 patients, who started treatment within one month after injury. The late intervention arm started treatment 3–18 months after burn and included 17 patients. Tubigrip® alone or followed by custom-fit garments were used for PT. Positioning devices or inserts were used additionally when necessary. The initial pressure in the early intervention group started at 10–20 mmHg and got adjusted to 20–30 mmHg after skin tolerance. The late intervention group was treated with garments applying 20–30 mmHg. Initially the pressure applied by the garments got assessed weekly, then monthly and then every 3 months. Daily wear time was not reported. Time of treatment varied from 1 to 30 months with an average of 11 months. No dropouts were specified. The investigations showed improvement in functional and cosmetic clinical appearance of the scars in both groups, but overall superior results in the early intervention group. Rose et al. stated the results without significance [27].

Klöti et al. [22] treated 13 children with full-thickness burns underwent skin grafting. The early PT group included eight patients who began treatment after wound closure. The late PT group consisted of five patients who began treatment 3–24 months after burn. Treatment and follow-up time were both 12 months. The amount of pressure applied by the garments and the daily wear time was not reported. They investigated the effect of pressure on functional and cosmetic aspects by clinical assessment. Similar to Rose et al. [27], Klöti et al. [22] stated clinical improvement without significance in both groups, although early treatment showed better results in managing hypertrophic scar formation [22].

3.5.3. *High pressure compared to low pressure*

Candy et al. [2], Engrav et al. [33] and Van den Kerckhove et al. [31] compared the effects of high PT to low PT on abnormal scar formation by using a RCT design.

Candy et al. [2] completed the study with 17 patients with HTS caused by burns, surgery or trauma. The high pressure group (28 scars) wore pressure garments that applied 20–25 mmHg, the garments in the low pressure group (25 scars) applied 10–15 mmHg. The pressure was monitored monthly. The treatment time was 5 months and patients were advised to wear the garments 23 h in a day. A dropout rate of 8.62% was reported. Candy et al. [2] investigated the pliability and pigmentation (assessed by the VSS), color and ST of the scars. The pliability, redness and scar thickness of the high pressure group improved significantly [2].

Engrav et al. [33] conducted a within-wound comparison study and included 67 burn patients with grafted wounds or wounds that had ≥ 3 weeks to heal. The applied pressure was 25 mmHg and 6.40 mmHg in the high and low-pressure group, respectively. The pressure was monitored every 2–3 months by the I-ScanTM System. The patients were advised to wear the garments 23 h a day. The duration of treatment was not specified. Thirteen patients were lost to follow up, resulting in a dropout of 35.8%. Eleven chose to remove themselves, one was lost to follow-up and for one patient the reason was not recorded. Engrav et al. [33] discovered a significant improvement in scar hardness and thickness, particularly in the high-pressure group. Benefits in overall cosmetic appearance were only restricted to patients with moderate or severe scarring [33].

Van den Kerckhove et al. [31] included 60 adults with spontaneously healed partial thickness burns. The high pressure (41 scars) and the low pressure group (34 scars) received garments that applied mean pressures of 20 mmHg and 12 mmHg initially, respectively. The treatment time was 3 months and a daily wear time of 23 h a day was advised. After one month, the pressure applied by the garments was checked. They demonstrated a significant decrease in scar thickness in favor of the high pressure group [31].

3.5.4. *Long vs short treatment time*

Baur et al. [21] investigated the effect of PT on abnormal scarring and compared the effect of long and short treatment times in a prospective cohort study design. They included patients with burn HTS. Both the number of patients and the number of biopsies were not specified. The duration of PT was more than 6 months in the long treatment group and less than 6 months in the short treatment group. Both the pressure applied by the garments and daily wear time were not reported. The research group found fewer mast cells within the interstitial area, remodeling of the collagen fibers from a nodular to a sinusoidal fiber pattern, and a reduction in the number of myofibroblasts in the long treatment arm. These findings were not stated with significance [21].

3.5.5. *Patient satisfaction*

Kant et al. [34] conducted a prospective study to investigate the effect of facial pressure mask therapy on patients' satisfaction. They included 69 patients and they were treated with a custom-made pressure mask that applied 20 mmHg for 3–30 months. Their results showed that a longer daily wear time leads to a significant higher satisfaction with the result and treatment decision. Additionally, patients who had finished therapy for a longer period of time reported a significantly higher satisfaction. They concluded that facemask therapy results in a long-lasting and stable result. Moreover, both patient and observer POSAS scores decreased significantly between start and end of therapy [34].

3.5.6. *Case series*

Cheng et al. [30] included 86 patients with HTS and keloids. Patients received pressure garments that applied pressure between 5 and 10 mmHg. The duration of the therapy was determined by clinical assessment and the reported follow-up time was 6 months to 7 years. Cheng et al. [30] investigated the VSS and ST and concluded that PT should be continued for a minimum of 12 months to be effective and preferably for 18–24 months [30].

Clark et al. [29] included 15 patients with HTS. Patients received PT for two years. Treatment started at wound closure or quickly after. The garments applied 10–35 mmHg. An electro-pneumatic pressure transducer was used to measure pressure. Clark et al. [29] assessed the extensibility and stiffness of the scars. They concluded that the scars showed improvement in both properties, which correlated with the clinical appearance. Results were not stated with significance, however, no sub-analysis was done based on the amplitude of pressure [29].

Tørring et al. [25] included approximately 500 burn patients. PT was started after wound closure and patients were treated for 6–18 months. Garments were advised to be worn 23 h a day. Every patient received 2–3 sets of garments to permit washing. The pressure garments were checked for wear and elasticity every month and later at increasing intervals. Tørring et al. [25] concluded that PT leads to quicker fading, flattening, and softening of the scars and is effective against itching. Similar to Clark et al. [29], the results were not stated with significance [25].

Judge et al. [23] started the intervention an average of three weeks after grafting and concluded that the development of HTS was arrested during interim use of tubular support bandages while waiting for commercially prepared pressure garments, which took more than 3 weeks on average. They included 49 patients with HTS after grafting burns. The garments applied a pressure of 10–20 mmHg and patients were advised to wash the garments daily. Daily wear time was not reported. The scars were compared based on flatness scored by clinical examination. Scar elevation did not progress further before or after therapy [13].

Larson et al. [26] included 5 children who were treated with isoprene splints, face bandages, or isoprene facemasks after burn injuries. Patients started treatment weeks to months after injury. The duration of treatment and the amount of pressure applied by the PT was not reported. After therapy, biopsies revealed a parallel alignment of the collagen fibers and the scars showed a soft and flat appearance. According to these histopathological and clinical findings, they concluded that PT can either prevent or decrease HTS formation and scar contraction. Results were not stated with significance [26].

3.5.7. *Adverse events with the use of pressure garment therapy*

Only four studies mentioned adverse events [22,26,30,32] and were limited to discomfort, swelling of the limbs, skin ulceration, itching, and perspiration. The remaining thirteen studies did not specify whether or not there were adverse events. High temperatures can influence the incidence of adverse events with pressure garments and negatively affect patient adherence to pressure therapy [32]. The development of new fabrics for producing pressure garments might pose a solution to this problem.

4. Discussion

The mainstay of non-invasive scar management is trifold: hydration of the stratum corneum, pressure therapy and UV-protection. Even though pressure therapy for both prophylactic as well as curative management of scarring is widely accepted and practiced, it is said that its use is largely based on empirical data only and sufficient strong evidence for its use is still lacking. Varying rates of success of pressure therapy has been attributed to the high degree of heterogeneity present in today's literature e.g. variations in applied pressures and/or time of application [15]. The aforementioned heterogeneity has also been demonstrated in the results section of this paper. This systematic review aimed to provide a complete and comprehensive overview of the

currently available clinical evidence for the use of pressure therapy for the non-invasive management of scars.

Several studies investigated the effects of whether or not to use PT and demonstrated that the use of PT leads to a significant improvement of the scar scales (VSS), with a particular improvement of scar color, thickness, pain, and overall scar scores [11,24,28,32]. Additionally, evidence is available on the beneficial effect on scar quality outcomes when pressure therapy is initiated at an early stage [22,27,35]. Researchers have stated, based on empirical evidence, to start as early as possible and initiate therapy when the healing skin can tolerate the pressure and shear forces that are created by the garments and/ or paddings [36,37]. Li et al. demonstrated that significant improvements can be seen in terms of decreasing pain scores (VAS) and scar thickness when pressure therapy is initiated before 60 days after injury [35]. Several RCTs reported a difference in outcome when using varying magnitudes of pressure [2,31,33]. Pressure therapy with both low and high pressures results in improved scar quality outcomes [38]. However, it is suggested that higher pressures up to 25 mmHg are preferable even though lower pressures are desired above no PT at all [38]. Moreover, higher pressures might result in more rapid results concerning the scar maturation time [36]. In this review, pressures of 20–25 mmHg demonstrated to provide significant improvements in scar quality in terms of pliability, erythema, and scar thickness compared to low pressures (6.40–15 mmHg) [2,31,33]. This is under the consensus of 25 mmHg representing the ideal pressure load and the best evidence statement of Sharp et al. (2016), who stated to use pressures > 20 mmHg to achieve compression force near capillary pressure [37,39]. Pressures higher than 40 mmHg induce discomfort, possibly even skin impairment, and reduce patient compliance [36]. Benefits in overall cosmetic appearance were apparent in patients with moderate to severe scarring that received pressures of 25 mmHg [33]. Given the variability of pressure given different scars, underlying tissues, muscle tone, and patient movements, it is advised to regularly monitor the applied pressure [37,39]. Only one study included in this systematic review investigated the duration of treatment and found, though not significantly, fewer mast cells and remodeling of the dermal collagen fibers orientation from a nodular into a more favorable sinusoidal fiber pattern in combination with a decrease in myofibroblast numbers [21]. Kant et al. investigated patient satisfaction associated with facial mask pressure therapy [34]. Their results showed that a longer daily wear time of the pressure mask (12–16 h) in contrast to a limited wear time (4–12 h) was associated with a higher satisfaction of the patient with both the cosmetic outcome and the decision itself to initiate pressure therapy [34]. Kant et al. demonstrated that the use of facial mask therapy results in a long-lasting and stable outcome concerning patient satisfaction [34]. Adverse events were only reported in 4 studies but their frequencies were limited and the majority of these events is quite innocent: discomfort, swelling of the limbs, skin ulceration, itching and perspiration in summer [22,26,30,32]. A large case series performed by Cheng et al. showed that the improvement of the VSS and scar thickness can be achieved when pressure therapy is continued for a minimum of 1 year and should preferably be continued even up to 1.5–2 years [30]. The results and conclusions of this systematic review, which were distilled from all the available clinical studies concerning the use of pressure therapy, are largely in line with the best evidence statement of Sharp et al. that was published in 2016 [37]. The statements of Sharp et al. were based on the available empirical and clinical evidence, as well as published guidelines [37]. The authors stated that pressure therapy should be done as soon as the healing skin can tolerate the pressure. The pressure garments should be used for 23 h per day for about 12 months or up to scar maturation, pressures of at least 20 mm Hg are ideal and garments should be replaced or modified every 2–3 months [37].

Histological analysis revealed that pressure therapy induces a change in the collagen fibers' orientation. PT stimulates fibroblasts to cede the creation of a nodular fiber pattern into a more natural basket wave-like pattern [11]. An increase in dermal fibroblast apoptosis and a decrease in keratinocyte proliferation, myofibroblast differentiation, and dermal cell density could be observed compared to the groups that did not receive pressure therapy [11]. Pressure therapy does lead to decreased microvascularization due to an increase in microvessel occlusion based on the degeneration of both satellite and endothelial cells [24]. This induces hypoxia causing focal degeneration of cells eventually resulting in scar resolution [24].

Future research on the use of pressure therapy to ameliorate scar quality should consist of conducting studies with the highest level of evidence aiming to erase the biases which were demonstrated in the currently available literature. Standardization of the reporting of important pressure therapy variables should be done in all future trials as this is often absent in the current literature and subsequently explains variability in the results. At least the following variables should be specified: start of therapy (days after injury), amount of pressure, interval of applied pressure measurements, method and interval of pressure assessment, daily wear time, the number of garment sets available to the patients, and interval of garment replacement and washing.

5. Conclusion

The systematic review demonstrated that there is sufficient evidence of overall moderate to good quality that indicates the value of pressure therapy in both the prophylactic and curative setting for the treatment of hypertrophic scars. Evidence suggests that PT is capable of improving scar color, thickness, pain and scar quality overall. Pressure therapy should be started < 2 months after injury and it has been stated to start as early as possible, using minimal pressures of 20–25 mmHg. Treatment duration should be at least 12 months to be effective and should preferably last up to 18–24 months. Pressure therapy is considered extremely safe due to the limited and quite innocuous adverse events.

Ethics approval and consent to participate

Not applicable.

Consent for publication

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CRediT authorship contribution statement

All authors have made substantial contribution to: The conception and design of the study, Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising the article critically for important intellectual contentm, Final approval of the version to be submitted.

Data Availability

All data are presented in the main manuscript.

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Declarations of interest

None, there are no conflicts of interest for the authors.

Authors' information (optional)

Not applicable.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.burns.2023.03.007.

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