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Semi-occlusive management of fingertip injuries with finger caps

A randomized controlled trial in children and adults

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Abstract

Background: Human fingertips can regenerate functionally and cosmetically excellent skin and soft tissues. Physiological conditions suppress scar formation and are thus a prerequisite for regenerative healing. Self-adhesive film dressings can provide such favorable conditions. The semi-occlusive treatment is superior to surgery. However, standard dressings leak malodorous wound fluid eventually until the wound is dry. Therefore, we developed and tested a silicone finger cap that forms a mechanically protected, wet chamber around the injury. Its puncturable reservoir allows access to the wound fluid for diagnostic and research purposes and the delivery of pro-regenerative drugs in the future.

Methods: Patients >2 years with full-thickness fingertip injuries unsuitable for simple primary closure were randomized to start treatment with either the film dressing or the silicone finger cap. After 2 weeks, we changed to the other treatment. Patients' choice on the preferred treatment after 4 weeks was the primary outcome parameter. Additionally, we monitored adverse events, unplanned visits, tissue gain, functionality, cosmetic outcome, and quality of life.

Results: We randomized 11 patients 2 to 72 years to each group. Eighteen to 20 (90%, intention-to-treat) patients preferred the finger cap. All patients were satisfied with the cosmetic outcome, 88.9% had no disturbing sensibility changes, and 73.7% could report no distortion in the finger's daily use. Epithelialization took between 5 weeks for Allen II and up to 9 weeks in Allen IV injuries. There were 19 device-related adverse events under film dressing and 13 under the finger cap. There were neither severe adverse device effects nor unexpected severe adverse device effects.

Conclusion: Employing the summative or synthetic primary endpoint "patient decision for one or the other procedure," our pseudocross-over-designed RCT succeeded in statistically significantly demonstrating the superiority of the silicone finger cap over conventional film therapy. The finger cap was safe and effective, reaching excellent results on all treated injuries without any need for disinfection, antibiotics, shortening of protruding bones, or treatment of hypergranulations. Distal to the tendon insertions, we did not see any limitations regarding injury mechanism, amputation plane, or patients' age.

Abbreviations: ADE = adverse device-related events, AE = adverse events, DIP = distal interphalangeal joint, ITT = intention-to-treat, KKS = Coordination Centre for Clinical Trials Dresden, mWWS = modified Würzburg Woundscore, n.c. = not calculable, ROM = range of motion, SADE = severe adverse device-related events, SAE = severe adverse events, USADE = unexpected severe adverse device-related events.

Keywords: fingertip injuries, hand surgery, semi-occlusive dressing, pediatric surgery, RCT, regeneration

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The TU-Dresden, Dr Jurek Schultz, and Prof Guido Fitze have filed a patent for the silicone finger cap (PCT/DE2014/100088; 14721743.4-1308; 14/774,997). Besides, the authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this study protocol. Randomization, monitoring, evaluation of study data, statistics and sponsor office are committed to the KKS Dresden, an institute independent of the Department of Pediatric Surgery.

All relevant anonymized patient level data, technical specifications, regulatory documents and the study protocol (Version V5.0F, 25/10/2016) are available on reasonable request from the authors. There are neither contractual agreements limiting access to the final trail data set nor any limitations on their publication.

This study was approved by the German Federal Institute for Drugs and Medical Devices (BfArM) to be conducted in compliance with § 22a Act on Medical Devices (AZ 94.1.05-5660-10348). Besides, this study was approved by the Ethics Committee of the Technische Universität Dresden (EK 148042015). Furthermore, the trial is registered at the European Database on Medical Devices (EUDAMED-No.: CIV-15-03-013246) and at ClinicalTrials.gov (NCT03089060; registration date: March 17, 2017). Participants were insured with Chubb Insurance Company of Europe SE for up to €500.000 per participant to cover for any harms caused by the participation in this trial. Trial results will be disseminated through scientific conference presentations and by publication in scientific journals. Modifications of the trial protocol were only done in consultation with investigators and the sponsor. Substantial amendments of the protocol required the approval of the Ethics Committee and the national authority (German Federal Institute for Drugs and Medical Devices [BfArM]) which was necessary once for a minor change in the sterilization protocol of the finger caps.

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The study protocol was published prior to conducting this trial (Schultz J, Leupold S, Grählert X, et al. Study protocol for a randomized controlled pilot-trial on the semiocclusive treatment of fingertip amputation injuries using a novel finger cap. Med (United States). 2017;96:4–9).

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1. Introduction

1.1. Background

Annually, fingertip injuries are the reason for 4.8 million presentations to emergency departments in the United States.[1] They account for 2% of children under 14 years of age presenting to emergency departments; 25% of these injuries need surgical treatment, in 15% of the cases under general anesthetics.[2] A quarter of presented fingertip injuries are total or subtotal amputations.[3] Surgical approaches for fingertip amputation injuries unsuitable for primary closure include stump plasties, local or distant flaps, microsurgical replantation, composite grafts, or skin transplants.[4] However, the conservative management's superiority versus different surgical techniques has been demonstrated in several comparative studies.[5–8] The use of film dressings to occlude the injured fingertips has slowly become the standard therapy since a series of 200 patients was reported in 1993. The authors recommend this treatment for all fingertip injuries.[9] Controversies still exist on the indication limits for this treatment, the necessary wound disinfection, and the need for shortening protruding bones.[10–12] The management with film dressings is sometimes tricky, mainly since they do not stick to wet skin. Conventional dressings do not form a protected chamber around the wound; additional splinting is often needed,[8,13] and malodorous wound fluid leakage is very disturbing. At worst, the wounds dry out, and the dressing eventually sticks to protruding bones, thus preventing regeneration of soft tissues and skin.[14]

To solve these problems and make the treatment more comfortable for patients, we have designed this novel occlusive silicone finger orthosis.

1.2. Objectives

In this study, we evaluated the novel silicone finger cap for the first time in an investigator-initiated, randomized controlled clinical trial. This trial's primary objective was to evaluate the acceptance of the finger cap in comparison to conventional film dressings. Simultaneously, by closely monitoring the patients and recording all adverse events (AEs) during their treatment, this study evaluated the safety of this new means of semi-occlusive therapy. By recording all visits and dressing changes until final epithelialization, we got an idea of the new treatment's efficiency. Since we treated various injuries, backgrounds, and different age groups under normal outpatient conditions, this study also tested its effectiveness. The detailed evaluation of the final results at the follow-up, including patient questioning concerning functional and cosmetic satisfaction and objective examinations such as sonography of soft tissues, 2-point-discrimination, and functional tests provided good insights into the silicone finger cap's efficacy.

Pain and discomfort during first application and dressing changes as well in everyday life, social acceptance as well as disturbance by malodorous wound fluid, inhibition of the free use of the affected hand, time spend on additional dressing changes, and the healing progress are all relevant factors to the patient and his family. Therefore, we hypothesized that all of these factors integrate into the patients' decision, which treatment they would choose for the third treatment period after having experienced both the conventional film dressing and the novel silicone finger cap. However, we also wanted to measure these subjective factors individually by employing a modified version of the Würzburg Wound Score.[15,16] The detailed monitoring of all objective and subjective parameters during regeneration and semi-occlusive therapy shall also help researchers and clinicians to gain insights into fingertip regeneration regardless of the semi-occlusive dressing used.

2. Methods

2.1. Trial design, changes to methods

This pilot study was a monocentric, prospective, randomized, controlled clinical trial. We randomly assigned our patients to begin their treatment with either the finger cap or the film dressing. After 2 weeks, patients changed to the other treatment modality. After another 2 weeks, patients/guardians had to decide before the dressing change what they would like to receive for the next 2 weeks if further treatment was needed. This pseudo-cross-over study's primary clinical endpoint (Fig. 1) was the rate of patients/guardians who decided to continue their treatment with the silicone finger cap.

Further secondary endpoints included the safety measured by AEs/severe adverse events (SAEs) and the disease-specific quality of life measured with a modified quality of life Würzburg Wound Score. Besides, the necessity of unplanned dressing changes in comparison to the film dressing was registered. Additionally, we measured the re-epithelialization time and determined the tissue growth at 28 days and after more than 4 months after the injury by x-ray and sonography. We also tested the function of the regenerated finger, including a Ninhydrin-test,[17] and the clinical outcome in terms of sensitivity and motility of the injured fingertip as well as cosmetic aspects. There were no methodological changes during this study.

3. Participants and study settings

Trained surgeons in the University Hospital Carl Gustav Carus' emergency department (Dresden, Germany) screened and recruited our patients. We included male and female patients older than 2 years with full skin substance defects distal to the distal interphalangeal joint (DIP) unsuitable for primary surgical closure without further substance loss after signed informed consent if the injury had happened no longer than 24 hours before presentation.

We excluded patients with known hypersensitivity against medical silicone or self-adhesive films. Further exclusion criteria were bony injuries requiring surgical intervention, bite injuries, or chronic dermatological disorders of the hand. Furthermore, intake of medications affecting wound healing, such as systemic (non-inhalative) glucocorticoids, immunosuppressive or blood-thinning medications, were exclusion criteria, as were patients with a wound-healing disorder. Ongoing or recently finished chemotherapy, immunodeficiencies, or diabetes mellitus were exclusion criteria, as well. Following §20 of the German Medical Device Act, we also excluded pregnant or breastfeeding women. Beyond that, we excluded patients suffering from an addiction or conditions preventing to assess the entity, scope, and possible consequences of this clinical trial. The same applied for patients who were not cooperative or who already participated in other clinical trials within the past 4 weeks.

4. Interventions

After patient examination, x-ray, inclusion, and randomization, the injured finger was subjected to a bacterial swab directly at the wound edge. Then the finger was cleaned with sterile 0.9% NaCl solution. We removed foreign bodies when needed, and we took photographs of the injury in 5 perspectives. Patients randomized to group A started treatment with the finger cap, group B patients started with the film dressing.

4.1. Treatment with novel silicone finger cap

The novel silicone finger cap consists of a thin and soft silicone shaft that surrounds the finger's base and provides the semi-occlusive seal without the need for additional adhesives. Thus, it further

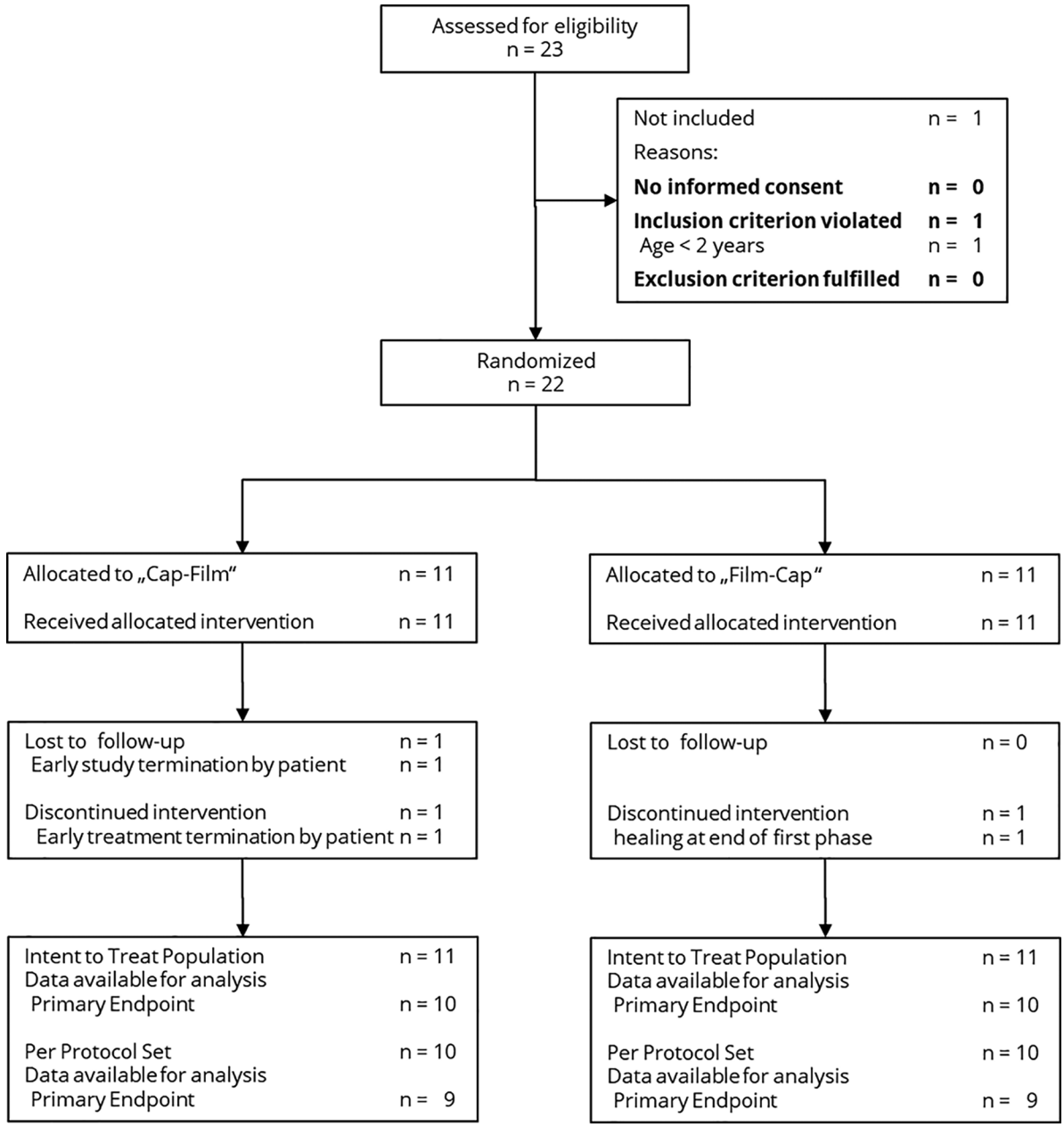

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

develops conventional occlusive means such as self-adhesive films or fingers of sterile rubber gloves. The finger cap forms a protected chamber of more rigid silicone around the distal phalanx close to the fingertip's original anatomical form and size. The more rigid silicone continues to the injured finger's base in a narrow bar, thus splinting it enough to care for undisturbed healing while allowing some movement in all finger joints. Capillaries connect the wound chamber to a reservoir and enabling free diffusion (Fig. 2). This reservoir can be punctured with a regular injection needle without consecutive leakage because of a self-resealing effect. The used medical silicone Dragon Skin Series Part A&B (KauPo, Spaichingen, Germany), Silastic Q7-4720 Biomedical Grade ETR Elastomer and Silastic Q7-4765 Biomedical Grade ETR Elastomer (Dow Corning, Midland, MI) is permeable to oxygen to some extent but impermeable to water vapor. Orthopedic and Rehabilitation Engineering Dresden (ORD GmbH, Dresden, Germany) officially sponsored this trial and handcrafted all finger caps. The sponsor office was committed to the Coordination Centre for Clinical Trials Dresden (KKS Dresden).

The correct size of the needed finger cap was determined using a set of non-sterile finger cap rings on the contralateral hand's corresponding finger. Now, wearing sterile gloves, the investigator inverted the correct size finger cap, cut it to length using sterile scissors, lubricated it with some drops of sterile NaCl solution, and administered it to the injured finger in a condom-like fashion. When fitting correctly, a light gauze dressing was put over the finger cap. Patients were seen the following day to check again for correct fitting and weekly after that. Whenever there was excess wound fluid in the reservoir, it was aspirated gently. Swabs were taken and the remaining wound fluid was stored at −80°C for future analysis.

4.2. Treatment with a standard self-adhesive polyurethane film dressing

Instead of the silicone finger cap, patients randomized to group B started the treatment with a standard self-adhesive polyurethane

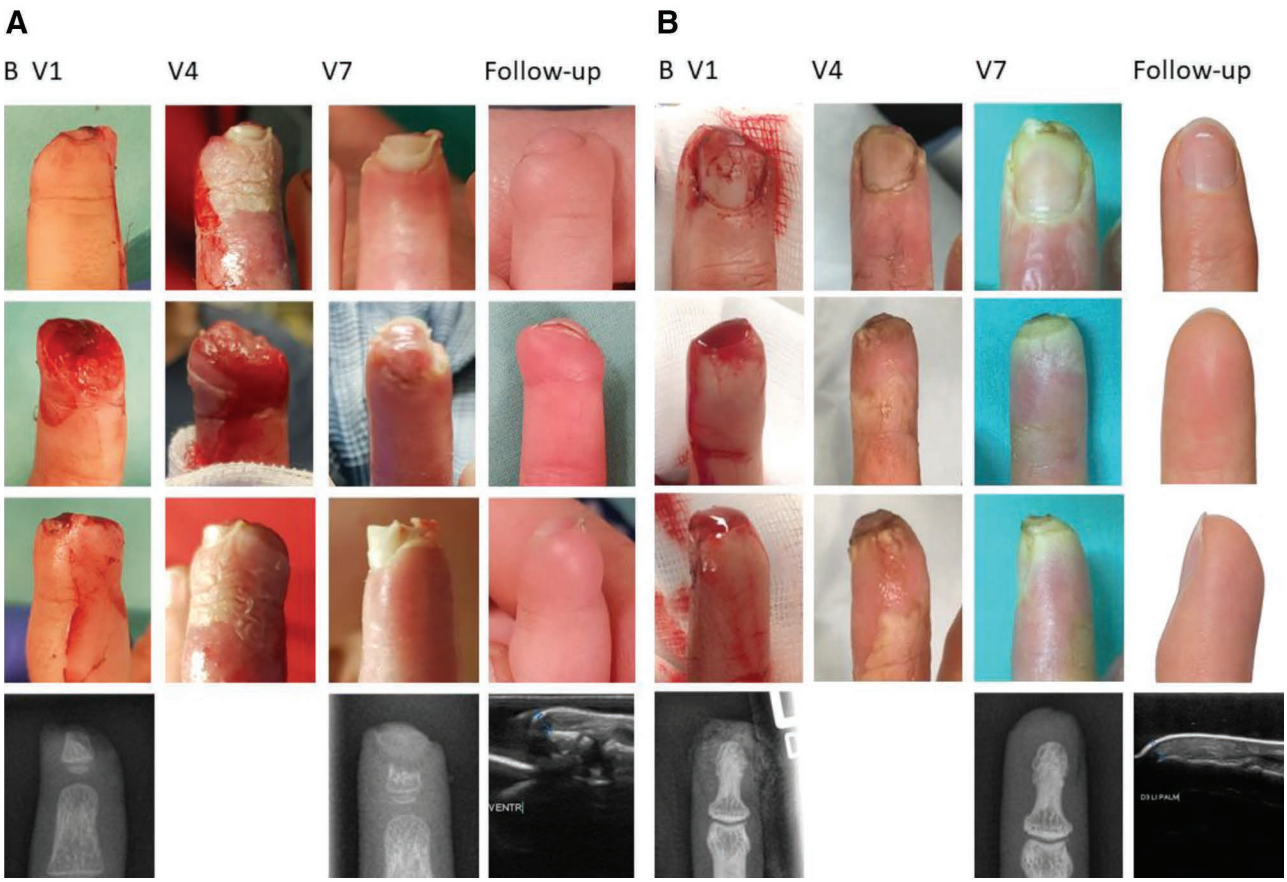

Figure 2. Photographs and radiographs/sonographies at the day of the injury (V1), at 2 wks (V4), at 4 wks (V7), and after more than 4 mo (follow-up). (A) Allen IV-injury, (B) Allen I-injury.

film dressing.[7,9,18,19] OPSITE FLEXIGRID transparent dressing (Smith & Nephew Medical Limited, Hull, England) is a transparent polyurethane film with acrylic adhesive. This device is Communauté Européenne (certification mark indicating conformity with European legislation)-certified and classified according to the European classification of medical devices in risk group IIa only. This means, that it cannot be used on deeper wounds, for example, with exposed bone. However, since self-adhesive polyurethane films are the standard therapy, we covered the injuries with 2 layers of sterile FLEXIGRID, leaving some room above the amputation site. A light gauze dressing covered this dressing, and an aluminum splint mechanically protected the stump. As in the treatment group, we checked for the dressing's correct fitting the next day. We then changed the outer gauze dressing every week. Microbiological smears were taken prior to the occlusion and on removal after 2 weeks. If there was additional fluid left in the film dressing, it was collected for subsequent analyses within the sub-study.

4.3. Cross-over

Fourteen days after the injury, the occlusive dressing method changed. Patients treated with the conventional film dressing got a silicone finger cap and vice versa. Another 2 weeks later, the patients decided which dressing she or he, respectively, the guardians would prefer for the next 2 weeks of treatment before the actual dressing change.

5. Outcomes

As the primary endpoint parameter, we recorded if the patients opted for either the silicone finger cap or the self-adhesive film dressing after experiencing both products. Secondary endpoints were the answers given on a modified version of the Würzburg Wound Score at each visit, the bone's tissue coverage in the initial x-ray compared to a second x-ray 4 weeks after the injury and an ultrasound-examination at follow-up after at least 4 months had passed. Further secondary endpoints were the time until full epithelialization, the assessment of function, which includes ranges of motion and 2-point-discrimination,[20] and aesthetics of the injured finger on follow-up both by the patient or guardian and by the study doctor, and a Ninhydrin fingerprint in comparison to the corresponding finger of the contralateral hand. All AEs and SAEs, as well as unplanned dressing changes, were closely monitored. At each visit, the dressing or, when applicable, the exposed finger was photographed from all 5 perspectives.

5.1. Changes to outcomes

An initially planned 3-dimensional photo-optic analysis of the wound to monitor tissue growth and epithelialization speed failed due to technical difficulties. We had to postpone the reporting of the full microbiome analysis in the wound fluids due to the samples' complexity.

6. Sample size

There was no certified medical device available for the conservative management of fingertip amputation injuries with exposed bone. Therefore, this study was, per definition, a pilot study that had to be limited to small sample size to comply with German and European legislation and guidelines of good clinical practice and ISO 14155.

The primary objective was the rate of patients who favor the silicone finger cap on day 28. This rate is a measure of the acceptance of the silicone finger cap. If 80% of the patients in this study decided in favor of the silicone finger cap, we considered the finger cap's hypothesized superiority as verified. As we assumed that approximately 80% of the patients would decide for the silicone finger cap, 20 patients (95% confidence interval, 1-sided, 65% lower limit, the distance from the rate to the lower limit of the confidence interval is at most 15%) were needed (Program nQuery-Advisor 6.01, Copyright 1995-2005, Janet D. Elashoff). We expected no more than 10% or 2 drop-outs. Therefore, we enrolled 22 patients.

6.1. Interim analyses and stopping guidelines

There were no plans for a data review committee and interim analyses because of the small number of patients included. However, the KKS performed risk-based monitoring according to DIN EN ISO 14155:2012-01 and national regulations. Additionally, every AE or product deficiency was part of the study documentation. Product deficiencies would have had to be reported directly to the sponsor. Severe AEs had to be reported according to the regulatory requirements. According to legal requirements, the KKS managed and evaluated adverse and severe AEs with the investigators and the sponsor.

Patient-related stopping rules were identified as unacceptable risks from the risk-benefit balance due to increased (serious) AEs. Trial-related stopping criteria were as follows: insufficient recruitment rate, insufficient quality of the data collected, unforeseeable circumstances at the trial site that make it difficult/no longer possible to continue the trial, new scientific evidence that makes a continuation of the study no longer reasonable, recognition of other repetitive severe deviations from the study plan that no longer guarantees a meaningful evaluation, the occurrence of more than 4 systemic infections originating from the injured finger requiring inpatient treatment, the occurrence of more than 4 tissue necroses in the area of the injured finger exceeding the initial extent of the injury.

None of these stopping criteria were fulfilled at any time during the clinical trial.

7. Randomization, mechanisms, and implementation

Based on a computer-generated randomization list (nQuery Advisor 6.01, Janet D. Elashoff), the KKS Dresden produced opaque, numbered envelopes assigning patients to treatment group A (silicone fingerling cap ->film dressing) or B (film dressing -> silicone fingerling cap; see Fig. 1) in a 1:1 ratio. The investigator had to open the numbered randomization envelope with the following higher number for the next enrolled patient before starting the treatment.

8. Blinding

As the 2 treatments vary obviously to both patients and investigators, there was no blinding on either side.

9. Statistical methods

All randomized patients treated with the silicone finger cap or the film dressing were included in the intent-to-treat analyses. The primary endpoint was the rate of patients who decided up to day 28 to continue their treatment with the silicone finger cap. If this rate was at least 80% and the confidence interval's lower limit was not <65%, the silicone finger cap was considered much better accepted than the conventional method. The secondary target parameters were evaluated exploratively. Secondary endpoints were analyzed according to their scale level: for steady endpoints, mean and standard deviation or medians and quartiles (graphically corresponding to confidence intervals or boxplots), for the categorical endpoints, absolute and appropriate relative frequencies were used. Following the distribution of the variables to be analyzed, we used the t test, the U test, and the χ^2 test. For paired comparisons of normally distributed variables, the paired t test was used when the Wilcoxon test was employed for non-normally distributed variables. Sub-group analyses according to patient age, injury severity, and mechanism of injury were performed. The statistical analysis was carried out using the SPSS program system (International Business Machines Corp., Armonk, NY) and the SAS System (SAS Institute Inc., Cary, NC) for Windows program in the currently available versions.

9.1. Data management

All efforts were made to avoid missing data, especially for the main target criteria. If a patient discontinued the trial, the final visit's data were used to calculate the main target criteria. The specific handling of missing data was determined in a data review meeting before starting statistical analyses.

All relevant patient data and test results had to be documented as soon as possible in an electronic Case Report Form. Clinical monitoring, according to the monitoring manual, verified source data-matching. Missing data or deviations were justified and corrected only by authorized persons. The audit trail of the trial software documented all changes and corrections. According to good clinical practice and ISO 14155, we performed data entry, maintenance, and handling with the trial software MACRO 4 (InferMed Ltd, London, UK). There was a validation of the data with programmed validity and consistency checks by the trial software. After finishing the investigation, the entry of relevant data, and the clarification of all queries, the database was closed. Only then, the data were released for statistical analyses.

10. Results

10.1. Participant flow and reasons

A total of 23 patients were screened. Twenty-two patients were included: 11 patients were randomized to each group and analyzed in the intent-to-treat population. One patient in group A discontinued the clinical trial at his own request 1 day after having been changed to the film dressing (visit 5, day 15) even though the treatment was not yet completed. In 1 group B-patient, epithelialization was already achieved at visit 4, that is, at the end of the first treatment phase. Thus, the silicone finger cap was not used in this patient, and a comparative evaluation was impossible. In summary, 2 patients of the intention-to-treat (ITT) population are not evaluable regarding the primary endpoint.

Serious protocol deviations occurred in 2 patients: In group A, 1 patient later turned out to be a type 2 diabetic. In group B, a patient included 1 day after the initial external film-dressing treatment outside of the study was found to have an injury with amputation of the tendon insertions since the initially treating surgeon had shortened protruding bone. If this had been known, the patient could not have been included because bony lesions requiring an operation were an exclusion criterion.

After all, there are 9 patients left in each arm of the study that could be analyzed with full set of data in the per-protocol-set (Fig. 1).

11. Recruitment periods and reason why trial ended

Patient recruitment started on September 21, 2017 (first patient in) and ended on October 3, 2019 (last patient in). The last follow-up visit took place on February 3, 2020 (last patient last visit). This trial regularly ended after the follow-up visit of the last patient.

12. Baseline data

Around two-thirds of the patients were male, one-third female. The patients were 2 to 72 years old. Six of 22 patients were under 18 years old. Both groups (cap->film and film->cap) were comparable in terms of sex, age, and medical conditions (Table 1). Half of the injured fingers were index fingers. Thirteen of 22 patients injured their right hand, and in 50%, there was bony injury, in 54.5%, the soft tissue defect was large enough to expose the bone (Table 2). In a secondary evaluation, we classified the injuries based on the photographs and x-rays according to the Allen classification[21]: 3x(2, 2)Allen I, 7x(9,9) Allen II, 8x(8,6)Allen III, 4x(3,5) Allen IV (Table 3, Fig. 2).

13. Outcomes and estimation

In the ITT analyses, 18/20 = 90% chose to continue treatment with the novel silicone finger cap. The 1-sided exact confidence interval of 95% (71.7%; 100.0%; derived from the 2-sided exact confidence interval of 95% [71.7%; 98.2%]).

Thus, at a 95% confidence level, the estimated acceptance rate was shown to be above 80%. The lower limit of the 95% confidence interval was not <65%. This answers the central question of the clinical trial in favor of the finger cap. This result is confirmed by the per-protocol analysis where 88.9% (per protocol) of the subjects chose to continue treatment with the silicone finger cap and not with the film treatment.

14. Results of any other analyses performed, including sub-group analyses and adjusted analyses, distinguishing pre-specified from exploratory

All injuries epithelialized within 14 to 103 days and regenerated in between 0.5 and 6.6 mm of soft tissue coverage of the bony terminal phalanx (Table 3). Since wounds were only inspected weekly, we can state that complete healing was achieved within 10 weeks (Allen IV) or 15 weeks, when taking into account 1 lesion with injured flexor tendons that should not have been included in this study (Table 4). Minimal soft tissue coverage of the bone achieved was comparable to the corresponding fingers of the contralateral hand (Table 5). One patient who has not had an unplanned dressing change during finger cap treatment had an unplanned dressing change while wearing a film dressing (Table 6). Sensibility in the area of the injury was statistically not significantly worse compared to the corresponding uninjured finger (Table 7). At follow up, all patients were either very satisfied or satisfied with the appearance of their fingertip. A total of 80.5% noticed either no changes or only minimal changes in the shape of their fingertip (Table 8). The great majority had no functional sequel of their injury (Table 9). No patient reported resting pain (Table 10). However, 19% noticed a significantly shorter length of the healed finger (Table 8). A total of 23% displayed reduced mobility in the proximal interphalageal joint and 19% in the DIP (Table 9) and 19% experienced some pain under high mechanical strain in the area of the injury (Table 10). One patient re-injured the tip of her healed finger between visit 9+4 and her follow up. Presumably, the clinical result at follow up would have been better without that second trauma.

15. Harms

The number of AEs and ADEs was higher during the film dressing treatments. Here, more patients were affected. One SAE was recorded during the finger cap treatment. However, this event was in no relation with the treatment. There were no severe adverse device effects or unexpected severe adverse device effects under either treatment (Table 11). Six patients complained about very disturbing odor when treated with the film dressing who have had no such complaints while being treated with the finger cap. Only 1 patient reported this disturbing odor during finger cap treatment who has not had this problem while being treated with the film dressing (Table 12).

16. Discussion

16.1. Limitations of the clinical trial

As the first clinical trial of a previously uncertified medical device of risk class IIb for use in adults and children, the small number of study participants limits this pilot trial. Nevertheless, the study's primary endpoint, acceptance of the new treatment or patient preference, could be answered in favor of the finger cap at a significance level of 5%. This new treatment approach also appears superior to the standard film treatment in terms of efficacy and safety. To more accurately measure efficacy in a wide variety of injuries, a more extensive, multicenter study ideally using an industrially manufactured finger cap would be desirable.

Table 1

Baseline demographics for both study groups.

Variable	Parameter	Cap → film (n = 11)	Film → cap (n = 11)	Total (n = 22)
Sex	Male	7 (63.6%)	8 (72.7%)	15 (68.2%)
	Female	4 (36.4%)	3 (27.3%)	7 (31.8%)
Age (y)	Mean ± SD	36.7 ± 21.8	39.6 ± 19.4	38.2 ± 20.2
	Median and IQR	43 [15–55]	48 [30–51]	47 [17–52]
	Range (min–max)	12–72	2–63	2–72
Adult/minor	Adult patients	7 (63.6%)	9 (81.8%)	16 (72.7%)
	Minor patients	4 (36.4%)	2 (18.2%)	6 (27.3%)
Medical conditions	No	9 (81.8%)	9 (81.8%)	18 (81.8%)
	Yes	2 (18.2%)	2 (18.2%)	4 (18.2%)
Smoking	Non-smoker	8 (72.7%)	8 (72.7%)	16 (72.7%)
	Smoker	3 (27.3%)	3 (27.3%)	6 (27.3%)
Cigarettes	Mean ± SD	10.0 ± 5.0	14.0 ± 5.3	12.0 ± 5.1
	Median and IQR	10 [5–15]	12 [10–20]	11 [10–15]
	Range (min–max)	5–15	10–20	5–20

IQR = interquartile range, SD = standard deviation.

Table 2

Injury characteristics for both study groups.

Variable	Parameter	Cap → film (n = 11)	Film → cap (n = 11)	Total (n = 22)
Injured finger	D1-thumb	2 (18.2%)	0 (0.0%)	2 (9.1%)
	D2-index-finger	7 (63.6%)	4 (36.4%)	11 (50.0%)
	D3-middle-finger	2 (18.2%)	4 (36.4%)	6 (27.3%)
	D4-ring-finger	0 (0.0%)	2 (18.2%)	2 (9.1%)
	D5-little-finger	0 (0.0%)	1 (9.1%)	1 (4.5%)
	Right	7 (63.6%)	6 (54.5%)	13 (59.1%)
	Left	4 (36.4%)	5 (45.5%)	9 (40.9%)
Bone injury	No	6 (54.5%)	4 (36.4%)	10 (45.5%)
	Yes	5 (45.5%)	6 (54.5%)	11 (50.0%)
	n.d.	0 (0.0%)	1 (9.1%)	1 (4.5%)
Minimal soft tissue coverage of bone (mm)	Mean ± SD	1.07 ± 1.07	0.89 ± 1.25	0.98 ± 1.14
	Median and IQR	1.4 [0.0–1.9]	0.0 [0.0–2.4]	0.0 [0.0–2.0]
	Range (min–max)	0.0–2.7	0.0–2.7	0.0–2.7
Exposed bone	>0 mm	6 (54.5%)	4 (36.4%)	10 (45.5%)
	0 mm	5 (45.5%)	7 (63.6%)	12 (54.5%)

IQR = interquartile range, SD = standard deviation.

Table 3

Observed duration of epithelialization and tissue gain until week 4.

Variable	Parameter/category	Cap → film (n = 11)	Film → cap (n = 11)	Total (n = 22)	*P* Wert
Duration until complete epithelialization (d)	Number evaluable	10	11	21	
	Number missing	1	0	1	
	Mean ± SD	36.7 ± 13.4	49.7 ± 22.9	43.5 ± 19.7	
	Median and IQR	32 [28–42]	50 [35–61]	42 [29–50]	*U* test: .090
	Range (min–max)	25–68	14–103	14–103	
Minimal soft tissue coverage of bone (mm) visit 1	Number evaluable	11	11	22	
	Mean ± SD	1.07 ± 1.07	0.89 ± 1.25	0.98 ± 1.14	
	Median and IQR	1.4 [0.0–1.9]	0.0 [0.0–2.4]	0.0 [0.0–2.0]	
	Range (min–max)	0.0–2.7	0.0–2.7	0.0–2.7	
Minimal soft tissue coverage of bone (mm) visit 7	Number evaluable	8	9	17	
	Number missing	3	2	5	
	Mean ± SD	3.35 ± 1.04	4.22 ± 1.85	3.81 ± 1.54	
	Median and IQR	3.3 [2.8–3.8]	3.6 [2.5–5.9]	3.4 [2.5–4.7]	
	Range (min–max)	1.8–5.3	2.4–6.9	1.8–6.9	
Tissue growth day 28 (mm)	Number evaluable	8	9	17	
	Number missing	3	2	5	
	Mean ± SD	2.11 ± 0.93	3.73 ± 1.42	2.97 ± 1.44	
	Median and IQR	2.0 [1.7–2.8]	3.5 [2.5–4.7]	2.5 [2.0–3.5]	*U* test: .016
	Range (min–max)	0.5–3.4	2.4–6.6	0.5–6.6	

IQR = interquartile range, SD = standard deviation.

Table 4

Injuries according to Allen and weeks until epithelialization.

Injury classification according to Allen	Number of patients	Weeks until epithelialization (average)
I	0	-
II	9	5 (2–9)
III	8	6 (4–9)
IV	3	8 (7–10)
Proximal to flexor tendon insertion	1	15

16.2. Generalizability

Around 90% of the subjects chose to continue treatment with the silicone finger cap and not with the film treatment. This answers the central question of the clinical trial in favor of the finger cap. The primary endpoint, "acceptance" or "preference," is summative. Various relevant factors influence the decision of patients or parents. Examples include pain, functional limitations, social limitations, and the annoyance of malodorous wound fluid leakage. To explore the different dimensions of patient decision-making, study participants were interviewed at each visit using a Würzburg Wound Score modified for this trial. This modified measure has not been validated. An unplanned exploratory analysis showed that of 19 items, 3 items were significantly different between patient groups. Under finger cap treatment, the wound was bothering less with wound fluid and odor (1.99 vs 2.52 $P = .0045$; 2 = less, 3 = moderately). Earning potential or school/kindergarten attendance were restricted less by the finger cap treatment (2.08 vs 2.63, $P = .01$; 2 = few, 3 = moderate). These results contrast with more painful dressing changes under the finger cap (2.19 vs 1.50, $P = <.001$; 1 = not at all, 2 = moderately). However, the advantages were weighted more heavily by participants than the disadvantage of greater pain during dressing changes. The sudden negative pressure when aspirating wound fluid caused the pain during dressing changes while under the finger cap. We minimized this problem during the study by puncturing more slowly under air equalization.

Table 5

Soft tissue coverage of terminal phalanx compared to contralateral hand at follow up (ITT).

Variable	Parameter/category	Cap → film (n = 11)	Film → cap (n = 11)	Total (n = 22)
Minimal soft tissue coverage of bone (mm) visit 10 (follow up)				
Injured finger	Number evaluable	10	11	21
	Mean ± SD	2.84 ± 0.73	2.72 ± 0.84	2.78 ± 0.77
	Median and IQR	2.8 [2.3–3.4]	2.5 [1.9–3.2]	2.6 [2.1–3.2]
	Range (min–max)	1.8–4.0	1.6–4.0	1.6–4.0
Contralateral finger	Number evaluable	10	11	21
	Mean ± SD	3.04 ± 0.82	3.05 ± 1.22	3.05 ± 1.02
	Median and IQR	3.1 [2.3–3.8]	3.2 [1.8–4.2]	3.2 [2.3–3.8]
	Range (min–max)	2.0–4.0	1.5–5.1	1.5–5.1
Difference minimal soft tissue coverage of bone (mm) (contralateral - injured)	Number evaluable	10	11	21
	Mean ± SD	0.20 ± 0.29	0.34 ± 0.63	0.27 ± 0.49
	Median and IQR	0.2 [0.0–0.2]	0.3 [–0.1 to 0.5]	0.2 [0.0–0.4]
	Range (min–max)	–0.2 to 0.9	–0.6 to 1.9	–0.6 to 1.9

IQR = interquartile range, ITT = intention-to-treat, SD = standard deviation.

Table 6

McNemar test for unscheduled change of dressing at test center, ITT population.

	Patients with change of dressing at test center Phase silicone cap		
	No	Yes	Total
Phase film dressing			
No	17 (85.0%)	0 (0.0%)	17 (85.0%)
Yes	1 (5.0%)	2 (10.0%)	3 (15.0%)
Total	18 (90.0%)	2 (10.0%)	20 (100.0%)

ITT = intention-to-treat.

16.3. Results on clinical performance and efficacy

The performance, efficacy, and safety variables can only be discussed indirectly by evaluating the secondary outcome measures. Regarding performance: the silicone finger cap creates a mechanically protected moist chamber around a partial phalanx amputation. As reported with film dressings,[14] there was no wound drying. No cap was lost or damaged during the application. Additional splinting was not necessary under finger cap treatment. Finally, there were no treatment discontinuations under the finger cap treatment. Thus, the silicone finger cap is efficient. Furthermore, it has an additional performance feature compared to the film dressing: a reservoir from which excess wound fluid can be atraumatically aspirated for diagnostic purposes. These punctures took place at every visit without damaging the finger cap.

16.4. Regarding efficacy

Treatment with the silicone finger cap aims to regenerate a fingertip as close as possible to the original, both cosmetically and functionally. Distal phalanx partial amputations included in this study were randomized according to the study protocol to receive finger cap treatment either during the first 2 weeks or at weeks 3 and 4 after the trauma. One patient discontinued the study at his request because the distance to the study center had become too far for him. At the time of discontinuation, this patient carried a film. There were no discontinuations during the therapy with a finger cap. All injuries healed during the study. A total of 90% (ITT) or 88.9% (per protocol) of the subjects decided to continue treatment with the silicone finger cap after week 4 instead of the film treatment. For the most part, the results were satisfactory or very satisfactory, although due to the study design, it is impossible to state how the treatment modalities contributed to this result. Thus, the efficacy of the silicone finger cap can only be assumed in the context of this study. A more extensive study would be necessary to examine the finger cap's efficacy more closely. Only large numbers could minimize the impact of uncontrolled variables such as the wound's geometry, size of the defect, mechanism of injury, and patient age. Furthermore, a more detailed follow-up assessment of the

Table 7

Two-point-discrimination at follow up, ITT population.

Variable	Parameter/category	Cap → film (n = 11)	Film → cap (n = 11)	Total (n = 22)	*P*-value
Result injured finger (mm)	Number missing	1	1	2	
	Mean ± SD	2.70 ± 0.42	2.65 ± 0.41	2.68 ± 0.41	
	Median and IQR	2.5 [2.5–3.0]	2.5 [2.5–3.0]	2.5 [2.5–3.0]	
	Range (min–max)	2.0–3.5	2.0–3.5	2.0–3.5	
Result contralateral finger (mm)	Number evaluable	10	10	20	
	Number missing	1	1	2	
	Mean ± SD	2.40 ± 0.32	2.60 ± 0.32	2.50 ± 0.32	
	Median and IQR	2.5 [2.0–2.5]	2.5 [2.5–3.0]	2.5 [2.5–2.5]	
	Range (min–max)	2.0–3.0	2.0–3.0	2.0–3.0	
Difference 2-point-discrimination (injured - contralateral)	Number missing	1	1	2	
	Negative	1 (10.0%)	2 (20.0%)	3 (15.0%)	Fisher: 1.000
	None	5 (50.0%)	5 (50.0%)	10 (50.0%)	
	Positive	4 (40.0%)	3 (30.0%)	7 (35.0%)	

IQR = interquartile range, ITT = intention-to-treat, SD = standard deviation.

Table 8

Follow-up questionnaire, part I optical criteria, ITT population.

Variable	Parameter/category	Cap → film (n = 11)	Film → cap (n = 11)	Total (n = 22)	*P*-value
Shape of the fingertip	Number missing	1	0	1	
	No abnormalities	6 (60.0%)	5 (45.5%)	11 (52.4%)	Fisher: 0.817
	Minimal traces	3 (30.0%)	5 (45.5%)	8 (38.1%)	
	Significant changes in shape	1 (10.0%)	1 (9.1%)	2 (9.5%)	
Nail texture	Number missing	1	1	2	
	No abnormalities	7 (70.0%)	7 (70.0%)	14 (70.0%)	Fisher: 1.000
	Minimal abnormalities	2 (20.0%)	1 (10.0%)	3 (15.0%)	
	Significant nail deformity	1 (10.0%)	2 (20.0%)	3 (15.0%)	
Onychogryphosis (claw nail)	Number missing	1	1	2	
	No	9 (90.0%)	7 (70.0%)	16 (80.0%)	Fisher: 0.582
	Yes	1 (10.0%)	3 (30.0%)	4 (20.0%)	
Ridges	Number missing	1	1	2	
	No	9 (90.0%)	10 (100.0%)	19 (95.0%)	Fisher: 1.000
	Yes	1 (10.0%)	0 (0.0%)	1 (5.0%)	
Dents	Number missing	1	1	2	
	No	10 (100.0%)	10 (100.0%)	20 (100.0%)	n.c.
	Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Split nail	Number missing	1	1	2	
	No	10 (100.0%)	10 (100.0%)	20 (100.0%)	n.c.
Nail adhesion	Number missing	1	1	2	
	Completely fixed to the hyponychium	10 (100.0%)	10 (100.0%)	20 (100.0%)	n.c.
Recognizable fingerprint	Number missing	1	0	1	
	No visible scars	4 (40. 0%)	3 (27.3%)	7 (33.3%)	Fisher: 0.565
	Minimal	6 (60.0%)	6 (54.5%)	12 (57.1%)	
	Significantly	0 (0.0%)	2 (18.2%)	2 (9.5%)	
Difference in length compared opposite side	Number missing	1	0	1	
	None	7 (70.0%)	6 (54.5%)	13 (61.9%)	Fisher: 0.825
	Minimal	2 (20.0%)	2 (18.2%)	4 (19.0%)	
	Significantly	1 (10.0%)	3 (27.3%)	4 (19.0%)	

ITT = intention-to-treat, n.c. = not calculable.

Table 9

Follow-up questionnaire, part I functional criteria, ITT population.

Variable	Parameter/category	Cap → film (n = 11)	Film → cap (n = 11)	Total (n = 22)	*P*-value
Forceps grip	Number missing	1	0	1	
	Not applicable	0 (0.0%)	2 (18.2%)	2 (9.5%)	Fisher: .338
	Unimpaired	10 (100.0%)	8 (72.7%)	18 (85.7%)	
	Attenuated	0 (0.0%)	1 (9.1%)	1 (4.8%)	
	Not possible	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Bottle grip	Number missing	1	0	1	
	Not applicable	0 (0.0%)	1 (9.1%)	1 (4.8%)	Fisher: .441
	Unimpaired	7 (70.0%)	9 (81.8%)	16 (76.2%)	
	Attenuated	3 (30.0%)	1 (9.1%)	4 (19.0%)	
ROM limited compared to other hand - MCP	Number missing	1	0	1	
	No	10 (100.0%)	11 (100.0%)	21 (100.0%)	n.c.
ROM limited compared to the opposite side - PIP	Number missing	1	0	1	
	No	7 (70.0%)	9 (81.8%)	16 (76.2%)	Fisher: .635
	Yes	3 (30.0%)	2 (18.2%)	5 (23.8%)	
ROM limited compared to the opposite side - DIP	Number missing	1	0	1	
	No	9 (90.0%)	8 (72.7%)	17 (81.0%)	Fisher: .586
	Yes	1 (10.0%)	3 (27.3%)	4 (19.0%)	

DIP = distal interphalangeal joint, ITT = intention-to-treat, MCP = metacarpophalangeal joint, n.c. = not calculable, PIP = proximal interphalageal joint, ROM = range of motion.

clinical results by a 3-dimensional measurement of the defect and the healing process could detect small differences in efficacy.

16.5. Clinical safety results

Under film therapy, 23 AEs and 19 ADEs occurred in 14 and 12 patients, respectively. Silicone finger cap treatment resulted in 16 AEs and 13 ADEs in 8 and 6 patients, respectively, and 1 SAE unrelated to study therapy. No severe adverse device effects or unexpected severe adverse device effects occurred. Limited mobility after removing the bandage might be assigned to the finger cap, even though the immobilization under both treatments must be held responsible for the relative stiffness at the end of the study that improved only very slowly.

Because maceration of the skin was no AE in the protocol, the irritating odor remained the most common ADE. It was reported 8 times (8/13 ADEs) by 4 different patients during finger cap therapy. Under film therapy, this ADE was reported 14 times (14/19 ADE) by a total of 9 different patients. Itching was reported twice by 1 patient but under both therapies. Redness/intermittent swelling and skin irritation beyond maceration were reported twice under the finger cap and once under film therapy. Under film therapy, we experienced a complete loss of occlusion, as the film dislocated along with the outer gauze dressing that had been soaked wet

Table 10

Follow-up questionnaire, part II, ITT population.

Variable	Parameter/category	Cap → film (n = 11)	Film → cap (n = 11)	Total (n = 22)	*P*-value
Pain under mechanical strain	Number missing	1	0	1	
	Never	8 (80.0%)	9 (81.8%)	17 (81.0%)	Fisher: 1.000
	Under high mechanical strain	2 (20.0%)	2 (18.2%)	4 (19.0%)	
	Under any mechanical strain	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Resting pain	Number missing	1	0	1	
	Never	10 (100.0%)	11 (100.0%)	21 (100.0%)	n.c.
Resting pain - scale	Number evaluable	10	11	21	
	Number missing	1	0	1	
	Mean ± SD	1.00 ± 0.00	1.00 ± 0.00	1.00 ± 0.00	
	Median and IQR	1.0 [1.0–1.0]	1.0 [1.0–1.0]	1.0 [1.0–1.0]	
	Range (min–max)	1.0–1.0	1.0–1.0	1.0–1.0	
Resting pain (1 = none, 10 = strong)	Number missing	1	0	1	
	No pain (scale = 1)	10 (100.0%)	11 (100.0%)	21 (100.0%)	n.c.
Cold sensitivity	Number missing	1	0	1	
	Not applicable	0 (0.0%)	4 (36.4%)	4 (19.0%)	Fisher: .136
	Normal	6 (60.0%)	4 (36.4%)	10 (47.6%)	
	Not disturbing	3 (30.0%)	3 (27.3%)	6 (28.6%)	
	Disturbing	1 (10.0%)	0 (0.0%)	1 (4.8%)	
Use in everyday life	Number missing	1	0	1	
	Unimpaired	7 (70.0%)	9 (81.8%)	16 (76.2%)	Fisher: .635
	Limited	3 (30.0%)	2 (18.2%)	5 (23.8%)	
Sensitivity disorder	Number missing	1	1	2	
	No	5 (50.0%)	2 (20.0%)	7 (35.0%)	Fisher: 0.200
	Yes, but not disturbing	5 (50.0%)	6 (60.0%)	11 (55.0%)	
	Yes, disturbing	0 (0.0%)	2 (20.0%)	2 (10.0%)	
Optical satisfaction	Number missing	1	0	1	
	Very satisfied	6 (60.0%)	5 (45.5%)	11 (52.4%)	Fisher: .670
	Satisfied	4 (40.0%)	6 (54.5%)	10 (47.6%)	
	Partly satisfied	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Dissatisfied	0 (0.0%)	0 (0.0%)	0 (0.0%)	

ITT = intention-to-treat, n.c. = not calculable.

Table 11

Number of events and patients with AE, ADE, SAE, and SADE after treatment.

	Phase film dressing		Phase silicone cap		Total	
Events	No. of events	No. of patients	No. of events	No. of patients	No. of events	No. of patients
AE	23	14	16	8	39	16
ADE	19	12	13	6	32	13
SAE	0	0	1	1	1	1
SADE	0	0	0	0	0	0
USADE	0	0	0	0	0	0

AE = adverse events, ADE = adverse device effects, SAE = severe adverse events, SADE = severe adverse device effects, USADE = unexpected severe adverse device effects.

Table 12

McNemar test for patients with AE "disturbing odor," ITT population.

	Patients with AE "disturbing odor" Phase silicone cap		
	No	Yes	Total
Phase film dressing			
No	10 (50.0%)	1 (5.0%)	11 (55.0%)
Yes	6 (30.0%)	3 (15.0%)	9 (45.0%)
Total	16 (80.0%)	4 (20.0%)	20 (100.0%)

AE = adverse events, ITT = intention-to-treat.

while the child was playing. Another film-specific ADE was the drying of the wound with ingrowth and adhesion of the film. After several extensive hand baths, we finally managed to remove the film from the wound, which healed without complications later. In summary, the silicone finger cap is a safe treatment modality.

16.6. Benefit-risk assessment

Given the above data on performance and presumed efficacy of the silicone finger cap, with no specific risks to be demonstrated beyond the general risks of any circularly applied finger dressing, the benefits outweigh the silicone finger cap's risks. Due to the significantly higher acceptance of the finger cap (about 90%) compared to the film dressing (about 10%) and the significantly lower number of AEs and ADEs compared to the film, the risk-benefit ratio of the finger cap is superior to that of the film dressing. This superiority becomes even more apparent in light of the finger cap's additional benefit: only the finger cap offers the possibility of atraumatic and routine access to the wound environment. Thus, wound fluid aspirated from the reservoir of the finger cap is available for diagnostic purposes. It is also conceivable to introduce regeneration-promoting substances into the wound environment via the finger cap's puncturable reservoir in the future. Finally, to our knowledge, there is no film dressing or other means of occlusion available that is certified for use on deep wounds with exposed bone.

17. Special benefit or special precautions required for individual subjects or risk groups

We included patients aged 2 to 72 years. There were no significant differences in any endpoints attributable to a specific age group. Even in a severe amputation injury (type IV according to Allen) of a 2-year- old, there were no problems with the finger cap treatment. However, the same patient's treatment with film dressing was problematic and ended with an unintentional total removal of the film dressing at home.

The restriction of the finger's freedom of movement due to the treatment with both the finger cap and the film dressing with or without additional splinting led to persistent restrictions of the range of movement in 23.8% of the study patients in the proximal interphalageal joint and in 19% in the DIP compared to the opposite side at follow up. These limitations were only detectable in patients older than 40 years but never in children and adolescents.

Due to incorrect or inadequate information provided by a patient in the initial history, an insulin-dependent type 2 diabetic was included by mistake. Neither his treatment with the film dressing nor the finger cap resulted in complications. However, this singular experience must not be generalized.

Another patient was included even though the flexor tendon insertion was amputated due to misleading initial photographs and history. Despite this exclusion criterion's violation, the patient was successfully treated in the study at his request and for ethical reasons. Although epithelialization took 3 months, the final result was a round fingertip, without a fingernail, but visually satisfactory with minimal scarring and unrestricted 2-point discrimination threshold and unimpaired daily use. Therefore, one can assume that even more proximal amputations heal with good results under semi-occlusive treatment if one only waits long enough.

17.1. Conclusions for the conduct of future clinical trials

Based on this study's little experience, limiting the patient age to children older than 2 years is questionable. With appropriate parental education and at least weekly checks, the finger cap might be used safely in younger patients. Patients over 45 years of age and those with more severe injuries should be educated about the possibility of difficult-to-reverse stiffening of the finger joints due to prolonged immobilization. The exclusion of well-controlled diabetic patients in future clinical trials of semi-occlusive treatments of fingertip injuries cannot be justified based on this study's results. An accidentally included insulin-dependent type 2 diabetic patient was treated without complications.

Furthermore, the general exclusion of amputations proximal to the flexor tendon insertion should be questioned. In the present study, such an injury healed with good results after a correspondingly long treatment period.

The evaluation of the secondary endpoints revealed some problems to be considered in future studies. Unfortunately, there is still no validated German instrument for assessing the wound-related quality of life in children, adolescents, and adults. Consequently, the modified Würzburg Wound Score (an instrument not validated in this form) has remained without significant findings. The only statistically significant finding is that the scores improve with the treatment duration, probably due to the progressive healing. Why 90% of the participants favored the finger cap cannot be explained with the results of the mWWS. The measurement of odor exposure is also challenging, as this is a very subjective variable without validated measurement instruments. The situation is similar to the other quality-of-life dimensions. Here, further search for suitable, validated, and established measurement instruments is needed for future studies.

We did not perform metagenome or amplicon analyses in the course of this trial. There is currently too little experience with next-generation sequencing studies on wound secretions. Since the samples obtained in this study are irreplaceable, we separated this aspect into a sub-study. An analysis protocol will be designed with collaborators to examine the invaluable study samples reliably in the future.

Weekly dressing changes restrict the determination of epithelialization speed to a 1-week resolution. Additionally, 3-dimensional photo-optical or laser scan-based methods would assess the initial tissue damage and the tissue regeneration. Only if such measurements were possible without removing the dressing, for example, by ultrasound or optical coherence tomography, would it be possible to detect subtle differences caused by different treatments. Measuring tissue regrowth by different methods (by radiograph at day 28 and by ultrasound at follow up) carries too much error to measure differences in the range of a few millimeters or less. Finally, assessment of fingerprint and sweat gland function with the ninhydrin assay was not meaningful. However, we remain unaware of better measures for these epithelial properties.

17.2. Conclusions

By choosing the summative or synthetic primary endpoint "patient decision for one or the other procedure", the pseudo-cross-over design of the study succeeded in statistically significantly demonstrating the superiority of the silicone finger cap over the film therapy. In this regard, the finger cap was safe and effective. Further studies could provide more precise data on the efficacy in different injuries and the new therapy's indication limitations. As part of the sub-study for this clinical trial, wound fluid samples were routinely obtained from all patients. Their analysis of the proteome and microbiome will further elucidate how human fingertips regenerate without complications despite microbial colonization of the wounds.

18. Interpretation

Fingertip injuries with substance loss of all degrees according to Allen,[21] with or without bone involvement, with a wide variety of accident origins (crushing, cutting, punching, sawing, more or less heavily contaminated), could be successfully treated with the silicone finger cap. Despite the decision not to disinfect the wound, no infection complications occurred. Even bones protruding above the wound level were reliably covered by soft tissue and epithelialized. There was no need to trim protruding bone.

Frequently observed hypergranulation tissue was either completely covered by epithelium or strangulated from the ever more distally advancing epithelial border in the course of the treatment. Only 1 patient with an amputation proximal to the flexor tendon insertion had hypergranulation tissue removed once because it was judged too excessive and persistent.

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Author contributions

All the authors meet the International Committee of Medical Journal Editors criteria for authorship for this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval to the version to be published.

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