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The use of adhesive elastic tape for hand oedema control in patients with a wrist fracture treated in a cast: A pilot study

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ABSTRACT

Background: The adhesive elastic tape use is indicated for controlling oedema, although currently there is not the definitive evidence regarding its effectiveness. Wrist fractures are a frequent occurrence, often leading to oedema development in patients treated with forearm casts.
This pilot study aims to investigate the effects of elastic tape in controlling hand oedema among patients with forearm casts for wrist fractures and the feasibility of a future randomized controlled trial.
Methods: The study was conducted on adult patients with unilateral conservatively treated wrist fracture. The tape was applied to the intervention group after cast application, while the control group received the standard treatment. The circumference difference between baseline and the 7-day follow-up of both the 1st finger and the remaining 4 fingers merged together was evaluated. Ethical approval for the study has been obtained.
Results: 23 participants were enrolled. The intervention group showed a higher reduction in finger circumferences compared to the control group (median difference T1-T0 No tape *vs* Tape: 0 cm *vs* −0.2 cm for the 1st finger and 0.5 cm *vs* −0.5 cm for the remaining 4 fingers), although the changes were not statistically significant.
Conclusion: Although the number of enrolled patients was limited due to Covid-19 pandemic, the study results suggest a potential reduction in oedema after the use of adhesive elastic tape, justifying the needed of a future full-scale study. Given its low cost and ease of use, we believe that tape can be considered in clinical practice.
Trial registration: ClinicalTrials.gov Identifier: NCT04683887.

1. Introduction

Elastic tape is a thin, stretchable strip that can be used for a wide range of purposes, including support, compression and immobilisation of joints and muscles (Kase, 2005). It is usually made of cotton containing elastic fibres and acrylic glue, applied in a wavelike pattern (Guasconi et al., 2022). The inherent elasticity of the tape enables it to mold itself to the intricate curves and lines of the body, delivering a tailored and snug embrace. Moreover, the adhesive on the back of the tape ensures steadfast adherence to the skin, effectively anchoring it in position even admist heavy physical activity (Matheus et al., 2017). Since the introduction of tape in the early 1970s, various authors have described its application techniques (Blow, 2015; Kase, 2005; Kumbrink et al., 2019; Wu et al., 2015) and numerous companies have started to produce tapes with similar properties. Tape's elasticity ranges from approximately 130%–140%, and the amount of tension applied during its application can affect the skin and various subcutaneous layers. The taping technique is often used to control oedema, support soft tissues, protect joints, and alleviate the heat produced by active inflammation (Blow, 2015; Kase, 2005; Kumbrink et al., 2019).

Oedema is an abnormal accumulation of fluid transuded from vessel walls in the interstitial connective tissue of the body (Saiani and Brugnolli, 2020). This condition can cause swelling, stiffness, fibrosis, discomfort and reduced joint mobility in the affected area (Bell and Muller, 2013; Saiani and Brugnolli, 2020). Hand oedema is caused by an obstruction to venous return and is thus defined as "stasis oedema"

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(Saiani and Brugnolli, 2020). Lymphoedema, on the other hand, is a specific type of oedema caused by an alteration in the lymphatic system (Kumbrink et al., 2019). Thus, considering all the risks associated with oedema, its prevention becomes crucial.

Nevertheless, tape application can be useful in both lymphoedema and oedema, in order to reduce them by stimulating the lymphatic system and improving local blood circulation (Blow, 2015; Kase, 2005; Kumbrink et al., 2019).

The tape is applied in a way that slightly lifts the skin, creating empty spaces that facilitate the drainage of interstitial fluids (Blow, 2015; Kumbrink et al., 2019). This may help decrease swelling, improve mobility, and reduce discomfort associated with hand oedema.

Numerous studies have demonstrated the efficacy of adhesive elastic tape in reducing lymphoedema in various pathological conditions. For example, in breast cancer patients, tape application has been shown to reduce lymphoedema compared to untreated controls (Lipinska et al., 2007; Pajero Otero et al., 2019; Tantawy et al., 2019). There is evidence suggesting that elastic tape may be effective in the management of lymphoedema (Morris et al., 2013; Kasawara et al., 2018). Another review focusing on limb lymphoedema, not necessarily due to breast cancer, identified no significant differences in the volume drained by the tape compared to the control group, but found a decrease in oedema-related symptoms (Gatt et al., 2017). However, one study seems to suggest that tape application may not have a substantial effect in reducing oedema among breast cancer patients (Ergin et al., 2019).

The use of elastic tape has also shown benefits in the post-operative period after knee arthroplasty, and in reducing knee oedema after arthroscopy (Balki et al., 2016; Donec and Kriščiūnas, 2014; Tornatore et al., 2020). Nevertheless, one study found no significant effects in reducing oedema after shoulder arthroscopy (Gülenç et al., 2019). It is worth noting that this is just a single study, but there is a wealth of other research highlighting the efficacy of elastic tape in mitigating oedema across various pathological conditions. For example, a systematic review supports the positive effects of tape on post-operative oedema, even if acknowledging some limitations, including a small number of evaluated trials (Hörmann et al., 2020). Another study reports good results in oedema control and an improvement in limb circumference in patients treated with an Ilizarov-type fixator (Białoszewski et al., 2009).

A systematic review (Miller et al., 2017) identified only one study that investigated the use of elastic tape for subacute hand oedema. This study compared the effectiveness of elastic tape with compression garments and found that both techniques were equally effective in reducing hand oedema. However, it had a small sample size (n = 12), so the results should be interpreted with caution. To date, it appears that the existing literature mainly focuses on the effectiveness of tape in treating lymphoedema. However, there is a lack of research on acute oedema and in particular on the effectiveness of elastic tape for the treatment of acute hand oedema.

Wrist fractures are a common injury, accounting for approximately 10–25% of all fractures (Geraci et al., 2011; Smeraglia et al., 2016; Watson et al., 2018) and although several immobilisation techniques are available, there is no clear evidence to identify the best method for maintaining reduction (Okamura et al., 2018).

The use of surgery has increased significantly in recent years, but it is more expensive than conservative treatment and there is no evidence of significant clinical improvement in favour of surgery (Combined Randomised and Observational Study of Surgery for Fractures in the Distal Radius in the Elderly (CROSSFIRE) Study Group, 2021), as a result, wrist fractures are still often treated with immobilisation in a cast (Raittio et al., 2017; Reid et al., 2020). Nonetheless, different research studies have demonstrated positive patient tolerance towards a circular forearm cast (Okamura et al., 2018; Park et al., 2017).

Patients with wrist fractures often develop hand oedema and the presence of a cast increases the risk (Knygsand-Roenhoej and Maribo, 2011; Dresing et al., 2017). In 2019, almost one-fifth (17.4%) of patients with wrist fractures treated with a circular plaster cast at the Orthopaedic Emergency Room (OER) of a city in Northern Italy required a second visit due to problems such as oedema, pain, or intolerance to the cast.

Table 1
Inclusion and exclusion criteria of study population.

Inclusion criteria	Exclusion criteria
- Age ≥18 years.	- Bilateral wrist fracture (because these patients may have reduced motility increasing the risk of oedema formation and to avoid the risk of double counting bias).
- Growth plate closure at radiographic examination (in order to exclude any epiphyseal detachments).	- Multiple fractures.
- Unilateral distal radius fracture associated or not with ulnar styloid fracture (Colles or Goyrand types).	- Polytrauma.
- Need of closed reduction and immobilisation with a forearm circular cast.	- Previous plegia/paralysis of the fractured limb.
- Signed informed consent.	- Previous lymphoedema of the fractured limb. - Access to OER during the night when the organization does not guarantee the presence of 2 nurses. - Wounds or abrasions in the area of application of the tape.[a] - Acute thrombosis (upper limb veins).[a] - Scars not perfectly healed in the area of application of the tape.[a] - Dermatitis, psoriatic manifestations or erythema in the area of application of the tape.[a] - Known allergy to acrylic (strip glue).[a] - Solid neoplasm.[a]

[a] Further exclusion criteria introduced following advice of Blow and Kumbrink although to date there are no absolute contraindications to the application of elastic tapes (Blow, 2015; Kumbrink et al., 2019).

Although the little available literature suggests that elastic tape may be a promising treatment option for hand oedema, further research is required to establish its efficacy, in particular integrating it with the cast. Hence, the aim of this pilot study was to investigate the effects of elastic tape in reducing hand oedema, during the initial week following the application of a cast in adult patients with wrist fractures, and the feasibility of a future randomized controlled trial (RCT).

2. Methods

2.1. Design

This was the pilot study of a randomised controlled superiority trial with parallel design and blinded data processing, conducted at the OER of a Hospital in Northen Italy. The study protocol was published by Guasconi et al. (2022) and the ID NCT046883887 identifies this trial on ClinicalTrials.gov.

2.2. Study setting and sampling

Inclusion and exclusion criteria are listed in Table 1. The patients' enrolment, the fracture reduction manoeuvre, application of the plaster cast, application of the tape for the investigational treatment patient group, and endpoint measurements at time 0 (T0) were all performed at the OER.

Convenience sampling was conducted by enrolling patients who met the inclusion criteria and had access to the OER throughout the study duration. All patients received education on oedema prevention, including specific exercises, and were provided with a dedicated informational brochure.

The sample size was calculated using the GPower 3.1 software with

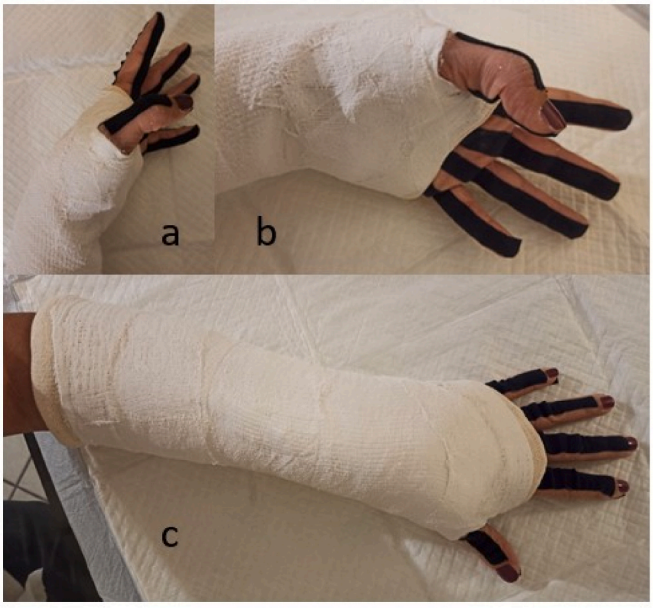

Fig. 1. Tape application: a. lateral view, b. sight fly, c. dorsal view. Picture from Guasconi et al. (2022).

the following parameters: effect size 0.4, error α 0.05, power 0.80 and allocation ratio 1:1. The resulting sample size was 100 subjects per arm; therefore, we had planned to enrol a total of 220 subjects (110 per group), considering a 10% loss to follow-up. The results of this pilot study could be used to optimise the sample size for the further RCTs.

2.3. Study intervention

The study was proposed to all patients with unilateral distal radius fractures requiring a closed reduction and forearm circular cast immobilisation before the reduction process. A period of reflection was ensured during the waiting time before the control X-ray after the reduction procedure and cast immobilisation. Following the provision of written consent, the patients were subjected to randomisation. Then, if a patient was allocated to the intervention group, the adhesive tape was applied to the fingers by using the lymphatic technique.

Before enrolling the first patient, all OER nurses underwent training in the application of the tape by a certified instructor. They were also trained in accurate outcome measurements, as outlined in the protocol published by Guasconi et al. (2022) and shown in Fig. 1.

2.4. Randomisation, blind and control

The randomisation list was generated using a program called "Random Number Generator", available at https://stattrek.com/statistics/random-number-generator.aspx. The randomisation was simple

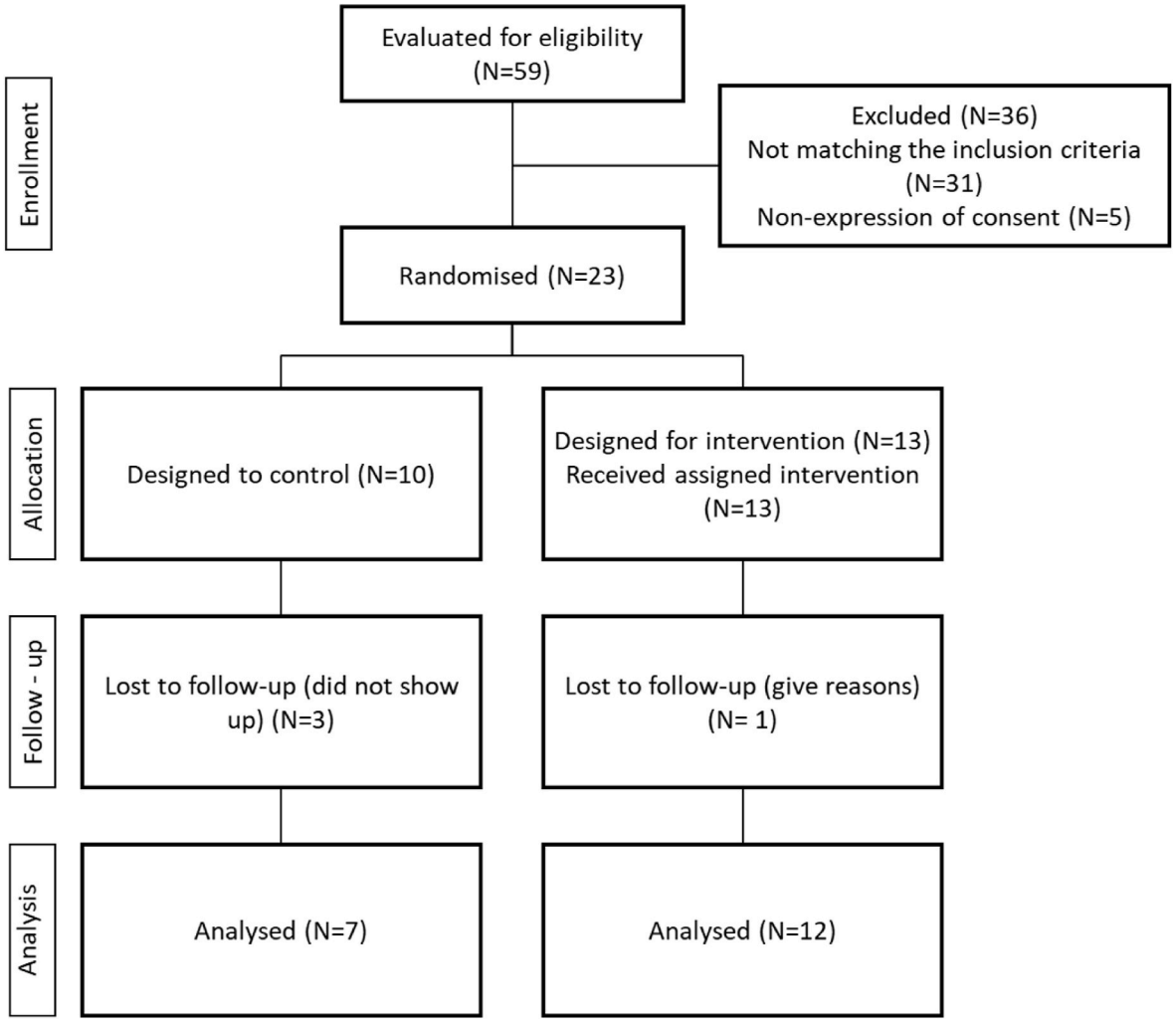

Fig. 2. CONSORT flowchart modified for Randomised Trials of Nonpharmacologic Treatments (Boutron et al., 2017).

with 1:1 allocation.

The list was generated and hidden in a specific file protected by a password, to prevent identification of the participants, and was only accessible to the Data Analysis Manager (DAM) who was not involved in the clinical evaluation of patients. During a telephone call between the investigators and the DAM, the enrolled patients were then allocated to either group 0 or group 1, according to the list. The investigator responsible for data analysis remained unaware of the assignment of the two groups, intervention and control, to maintain blinding and objectivity.

3. Data collection and outcome measurements

OER nurses assessed the extent of oedema in the fractured homolateral hand by measuring the circumference at the base of the 1st phalanx of the 1st finger and at the base of the 1st phalanx of the remaining 4 fingers joined together at both T0 and T1 (7 days after T0). The tape used was the Leukotape K® by Essity, which won the INTERCENTER AVEN tender for the supply of this type of medical device.

The number of re-entries into the OER between T0 and T1 was registered. Pain intensity was also measured by using the Numerical Rating Scale (NRS) at both T0 and T1. At T0, pain was assessed before any local anesthetic was administered, although there were no significant differences between the intervention and control group. Finally, analgesics eventually used during the previous 4 h were recorded both at T0 and T1.

To ensure pseudonymisation, each enrolled patient was assigned an alphanumeric code for identification purposes. All the study data, including patient code, were reported in the Case Report Form (CRF) and in the electronic database used for the analyses. Even though tape results could be seen after 2–3 days, T1 variables were collected on day 7 to avoid potential bias in the re-entry assessment. The 7-day follow-up was concomitant with the radiographic fracture control provided by the organisational procedure. Once the measurements at T1 were carried out, the completed CRFs were delivered to the researcher who performed the data analysis.

3.1. Statistical analysis

To evaluate the possible differences between baseline characteristics of the two groups, Fisher's exact test, instead of X^2 test, stated in the protocol, was performed for the qualitative variables, due to the presence of at least one expected frequency was found to be ≤ 5. For continuous variables Mann-Whitney test was applied, chosen because of the low sample size. Intervention group versus control group analyses were performed by comparing the respective median of the paired T0-T1 differences of: circumference of 1) 1st finger; and 2) the other 4 fingers by Mann-Whitney test, excluding patients lost to follow-up. All analyses were performed using 2-tailed tests and a p value of <0.05 was considered significant.

4. Ethical considerations

This study has been conducted according to Good Clinical Practice and the principles enshrined in the Declaration of Helsinki. The study was approved by the Local Area Ethics Committee on January 26, 2021 (practice ID 1355/2020/DISP/AUSLPC) and all patients enrolled have signed the informed consent.

5. Results

Patients' enrolment started in June 2021 and ended in March 2023.

A total of twenty-three patients were enrolled, and the flow of patients screened and included in the study is depicted in Fig. 2. The percentage of patient enrolled compared to the planned is 9% in the control group and 11% in the tape group. Moreover, the percentage of patients lost to follow-up was 17%. This was higher than expected. None of the patients included in the study underwent surgery at baseline, either before or after reduction, as manual reduction was consistently feasible based on X-ray assessment. The demographics of the control group and intervention group are shown in Table 2. There were no significant differences between the groups for all the baseline characteristics (Table 2). The tape accidently came off in two patients between 48 h after T0 and T1. The remaining ten patients continued to wear the tape throughout the entire 7-day period.

Table 2
Demographic data of the enrolled patients, reported altogether and grouped by presence or absence of the treatment. Qualitative variables are reported as absolute frequency and relative frequency in brackets, and quantitative variables as median and interquartile range (IQR, first and third quartile) between brackets; p-value calculated using the Fisher test and Mann-Whitney test (only for age, 1st circumference, circumference of the other 4 fingers and NRS at baseline). Abbreviations: md = number of missing data.

	ALL N = 23	GROUP 0 No tape N = 10	GROUP 1 Tape N = 13	p
Sex	8 M (35%) 15 F (65%)	2 M (20%) 8 F (80%)	6 M (46%) 7 F (54%)	0.379
Fractured arm	8 right (35%) 15 left (65%)	3 right (30%) 7 left (70%)	5 right (38%) 8 left (62%)	1
Hearth diseases	22 absent (96%) 1 present (4%)	9 absent (90%) 1 present (10%)	13 absent (100%)	0.435
Kidney diseases	23 absent (100%)	10 absent (100%)	13 absent (100%)	
Respiratory diseases	23 absent (100%)	10 absent (100%)	13 absent (100%)	
Diabetes	20 absent (87%) 3 present (13%)	8 absent (80%) 2 present (20%)	12 absent (92%) 1 present (8%)	0.560
Hypertension	18 absent (78%) 5 present (22%)	7 absent (70%) 3 present (30%)	11 absent (85%) 2 present (15%)	0.618
Age (years old)	72 (59; 78)	69 (55; 72)	74 (67; 78)	0.270
1st finger circumference at T0 (cm)	7.1 (6.8; 8.0)	7.3 (6.7; 8)	7.1 (7.0; 8.0)	0.732
Circumference of the 4 other fingers at T0 (cm)	18.0 (17.1; 20.2)	18.0 (16.1; 18.2)	19.0 (18.0; 20.2)	0.236
NRS at T0	6.0 (3.0; 8.0) *md = 8*	6.0 (3.0; 7.0) *md = 5*	5.5 (3.0; 8.0) *md = 3*	0.710

In Fig. 3 the paired T0 and T1 values of the circumferences for each subject are represented for both groups, suggesting a positive effect of tape compared to control. Considering the circumference of the 1st finger, the median difference T1-T0 of No tape *vs* Tape was 0 cm *vs* −0.2 cm, respectively (Table 3). Moreover, examining the circumference of the other 4 fingers, the median difference T1-T0 of No tape *vs* Tape was 0.5 cm *vs* −0.5 cm (Table 3).

While the tape appears to give potentially beneficial outcomes to the intervention group, the changes in fingers circumference are not statistically significant (1st finger, p = 0.078 and 4 fingers, p = 0.062, Table 3).

No analysis was performed on NRS score due to the elevated number of missing data.

Patients from both groups had no re-entry to the OER.

6. Discussion

The objectives of this study were to investigate the effects of adhesive elastic tape in reducing hand oedema within the initial week following the application of a cast in adult patients with wrist fractures and to

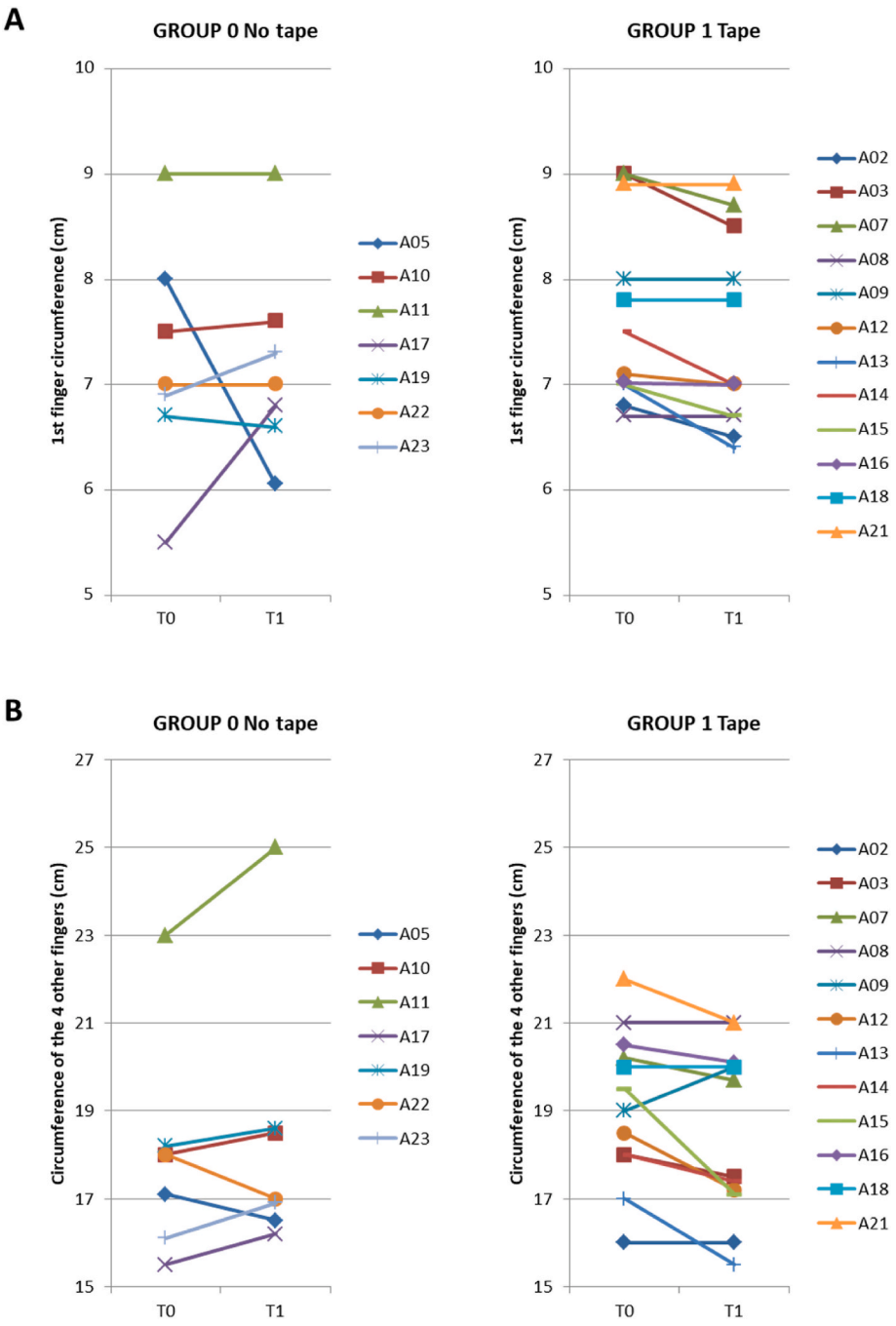

Fig. 3. Representation of paired T0-T1 data of the circumference of the 1st (A) and of the 4 other fingers (B) of the analysed patients, grouped by presence or absence of the treatment.

Table 3
Difference between T1 and baseline of the circumference of the first and of the 4 other fingers. All data are reported as median and IQR between brackets; p-value calculated using the Mann-Whitney test.

	GROUP 0 No tape N = 7	GROUP 1 Tape N = 12	p
Difference in 1st finger circumference between T1 and T0 (cm)	0 (−0.1; 0.4)	−0.2 (−0.4; 0)	0.078
Difference in the circumference of the 4 other fingers between T1 and T0 (cm)	0.5 (−0.6; 0.8)	−0.5 (−1.2; 0)	0.062

investigate the feasibility of a future RCTs.

Unfortunately, the city where the study took place was significantly affected by the Covid-19 pandemic. Due to this situation, the number of wrist fractured patients with access to the OER was reduced, and opportunities for direct patient interaction were limited. These circumstances significantly influenced the sampling process, forbidding to reach the planned sample size. The results reported could be used to improve the future protocols of RCT aimed to assess tape effectiveness, optimizing their feasibility. In this study, the demographic characteristics did not display significant differences between the two groups, indicating that both groups were homogenous at baseline.

There are many immobilisation techniques available for wrist fractures. Some may reduce the risk of oedema formation compared with a

closed cast (Dresing et al., 2017). However, there is no clear evidence identifying the best method for maintaining reduction. Nonetheless, different research studies have demonstrated positive patient tolerance towards a circular forearm cast (Okamura et al., 2018; Park et al., 2017). As a result, the clinical practice of the institution in which the study took place includes the use of the circular cast.

The positive effects of elastic tape in reducing oedema formation have been documented by Białoszewski et al. (2009). In addition, Miller et al. (2017) explain the usefulness of elastic tape in reducing hand oedema. However, one study did not find any improvements in using tape (Bell and Muller, 2013).

Tape's accidental removal was seen in the 17% of patients at T1 but 0% in the first 48h after T0, suggesting that all patients of intervention group were treated for at least 2 days, corresponding to the period of major risk of hand oedema. However, the percentage of accidental removal should be taken into account in the sample size calculation for further studies.

Our experience suggests that finger oedema control may have improved in the intervention group, although the small number of patients enrolled (10% of the expected target) did not allow to obtain conclusive data. Elastic tape has several advantages, including its non-invasive, low-risk nature and an easy application and removal by healthcare professionals or individuals. It is also generally well tolerated and has few side effects when used properly (Blow, 2015; Kumbrink et al., 2019).

While further research is needed to confirm its effectiveness, our results and the described benefits suggest that applying elastic tape to the fingers of patients with a forearm cast could be a useful approach.

Moreover, the p values are slightly greater than 0.05, which may indicate that in future studies based on the same protocol (Guasconi et al., 2022) reaching the correct sample size could demonstrate the positive effect of tape on finger oedema control.

The patients of both groups did not re-enter the OER, which could be due to the pandemic situation.

There are no differences in NRS scores, but we have a lot of missing data on analgesic use and on NRS values both at T0 and T1, which should be investigated in the future.

In addition, one of the notable advantages of elastic tape is its accessibility and affordability. Furthermore, its relatively low cost makes it a more attractive option for both professionals and individuals seeking therapeutic benefits.

With regard to the feasibility of future RCTs, we think that the present pilot study can give indications for the calculation of sample sizes and that, in the absence of organisational problems due to the pandemic, the study can be conducted without major difficulties. Measuring finger circumference by two two nurses can lower the possibility of primary endpoint detection errors.

6.1. Study limitations

Some plausible limitations of this study are the small sample size, the presence of missing data on secondary outcomes, and the implementation during a challenging time caused by the Covid-19 pandemic. Moreover, although the training in correct endpoint evaluation, the reliability and accuracy in circumference measurement could be low. A possible tip to overcome this limit could be the endpoint evaluation by two operators at the same moment. Also, the time taken to manipulate the facture could potentially influence the amount of oedema observed and this variable needs to be recorded in future studies.

7. Conclusion

In summary, as of now, no similar studies have been undertaken. This pilot study appears to indicate a reduction in oedema formation following the application of elastic adhesive tape, despite the limited number of enrolled patients. Therefore, we believe that the groundwork has been laid in order to pursue larger and more substantial endeavours in the future. Thus, we strongly recommend taking up the protocol published by Guasconi et al. (2022) and the results of this pilot study are taken into consideration for conducting further clinical studies to achieve conclusive results. In fact, it is important to note that there is still a limited number of studies discussing the use of elastic tape for acute hand oedema treatment, and more research is needed to establish its efficacy and determine the best way to use it in combination with other techniques, such as using the tape in the presence of a cast.

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Ethical statement

This study has been conducting according to Good Clinical Practice and the principles enshrined in the Declaration of Helsinki. The study was approved by the Local Area Ethics Committee on January 26, 2021 (practice ID 1355/2020/DISP/AUSLPC) and all patients enrolled have signed the informed consent.

Author contributions

Massimo Guasconi: Conception and design of the work. Acquisition of data. Interpretation of data. Dania Zilli Riboni: Conception and design of the work. Acquisition of data. Interpretation of data. Andrea Civardi: Conception and design of the work. Marina Bolzoni: Analysis and interpretation of data. Carlotta Granata: Conception and design of the work. Maurizio Beretta: Conception and design of the work. Anna Genovese: Interpretation of data. Fabio Mozzarelli: Conception and design of the work. Interpretation of data. Fabrizio Quattrini: Interpretation of data. Pietro Maniscalco: Conception and design of the work. Interpretation of data. All authors had an active role in drafting or revising the manuscript. All authors approved the final version to be submitted.

Declaration of competing interest

Andrea Civardi is the specialist from the company producing the tape (Essity), he did contribute to the design of the study and trained nurses in the tape's application and he didn't participate in the acquisition and analysis of data. The other authors declare that they have no conflicts of interest.

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