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Non-operative treatment versus suture refixation of the nail plate in paediatric fingernail avulsion injuries

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Non-operative treatment versus suture refixation of the nail plate in paediatric fingernail avulsion injuries

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Abstract:

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Keywords: avulsion injury, children, fingernail, fingertip, treatment

ABSTRACT

The study compared a non-operative treatment, consisting of ointment dressing only, with the standard surgical nail plate refixation for simple fingernail avulsion injuries in children. A non-inferiority hypothesis was tested in a single-centre, prospective cohort study.

The quality of the new nail was the primary outcome and was assessed with the Nail Appearance Score. The secondary outcome was patient and parental satisfaction, which was assessed with the Patients' and Parental Nail Satisfaction Score. Fifty-one patients were enrolled; 39 (76%) chose the non-operative treatment and 12 (24%) the standard operative therapy. Comparison of the two groups confirmed the non-inferiority hypothesis with a risk difference for the new nail of -0.02 with a 95% confidence interval of (-0.05, 0.01). The outcome was excellent in all fingers with no significant differences regarding either the primary or secondary outcome. In view of associated risks and costs for surgery, we recommend ointment dressings for such injuries.

Level of evidence: II

INTRODUCTION

Fingertip injuries with avulsion of the nail plate are among the most common hand injuries treated in paediatric emergency departments (EDs) (Gellman, 2009; Patel, 2014; Strauss et al., 2008). They involve a risk of permanent nail growth disturbance with the loss of aesthetic integrity and functional impairment of the nail plate (Rohard et al., 2012). Severe injuries with displaced fractures of the underlying phalanx and lacerations or defects of the nail matrix bear the highest risk for long-term sequelae and must therefore undergo surgical repair to restore the integrity of the nail (Al-Qattan, 2001; Cornwall, 2012; Fairbairn, 2012; Gellman, 2009; Nellans and Chung, 2013; Patel, 2014; Roberts, 2003; Rohard et al., 2012; Strauss et al., 2008; Tos et al., 2013; Vergara-Amador et al., 2016).

However, many children sustain only isolated avulsion injuries with or without nondisplaced fractures of the distal phalanx. The current treatment recommendation is repositioning of the nail plate under the eponychial fold and suture fixation of the nail plate (Cornwall, 2012; George et al., 2017; Strauss et al., 2008). This often requires general anaesthesia, particularly in young and uncooperative children. The rationale for this surgical treatment is the hypothesis that it prevents adherence between the nail matrix and the eponychium, which would result in ungual dysfunction (Cornwall, 2012; George et al., 2017; Strauss et al., 2008). Nevertheless, there is little evidence to support this standard treatment regime and no publication based upon patient series reports the outcome without replacing the nail.

Strauss et al. (2008) published an alternative treatment that re-fixes the nail using tissue adhesives. They compared adult patients treated with this technique to a group of patients in whom the nail was sutured. No nail deformities were found in either group, and

both groups had similar outcomes. The omission of sutures did not result in worse results. We hardly see any secondary referrals for nail defects after nail avulsion injuries that did not receive medical attention. Consequently, we assume that these injuries heal spontaneously very well. Therefore, we treated a preliminary series of five isolated nail avulsions in children with ointment dressing only, without replacing nails. All of them had good outcomes with excellent new fingernails. This had the obvious advantage of avoiding surgical procedures and associated anaesthesia.

The aim of this study was to assess whether non-operative treatment of fingernail avulsion injuries is not inferior to the standard operative treatment for the outcome of regarding nail appearance and patient satisfaction.

METHODS

This study was designed as a single-centre, prospective cohort study comparing nonoperative with operative treatment options. The protocol of this study was approved by the local ethics committee (BASEC-No. 2016–00047). Randomizing whether patients undergo a surgical treatment with anaesthesia or a non-operative treatment appeared unrealistic in our population, in which parents usually want to receive medical advice and then take these decisions themselves. Therefore, parents were free to choose the treatment option after informed consent: either the standard operative treatment with refixation of the nail with sutures or the non-operative treatment without nail replacement. Parents were informed by the treating doctors in the emergency ward and had time to reflect and ask questions. Furthermore, written protocols had to be studied by the parents before they were allowed to consent. We attempted to provide consistent information according to the ethical guidelines in

order to minimize bias. Standardized preoperative X-ray and photo documentation allowed pairs of operative and non-operative patients to be matched for assessment.

Patients

Paediatric patients aged 1 to 16 years who had sustained a proximal or complete fingernail avulsion injury were enrolled at the emergency room of our University Children's Hospital between May 2016 and April 2019. Exclusion criteria were a displaced fracture, lacerations with a gap in the nail bed or the nail wall greater than 1 mm, or presentation delayed by more than 24 hours after trauma. Informed consent was obtained from all parents and from patients above 14 years of age.

Interventions

Operative treatment was performed with a tourniquet and under either general anaesthesia or digital block with lidocaine. Treatment consisted of careful inspection of the nail bed before securing the nail with non-absorbable sutures (Ethilon® 5–0, Ethicon, J&J Medical Devices, Norderstedt, Germany) in a standardized technique (Figure 1). A nail substitute consisting of a 0.5 mm silicone sheet (Perthese silicone sheeting, Perouse Plastique, Bornel, France®) was applied if the patient's nail plate had been lost. Partially adherent nail plates were carefully removed prior to nail bed inspection. Sutures were removed at the outpatient hand clinic after 3 weeks.

Non-operative treatment consisted of wound cleansing and disinfection before application of a non-adhering ointment dressing with chlorhexidine and despanthenol (Bepanthen plus®, Bayer, Leverkusen, Germany). Partially adherent nails with proximal dislocation were not removed but shortened proximally to prevent pressure and pain on the proximal nail fold. To secure the dressing in place, dry gauze was applied over it and covered

with an elastic bandage. Dressings were regularly changed at the first three follow-up visits. Subsequently, the injured finger was left without a dressing. Immobilization with a forearm-based palmar hand splint in an intrinsic plus position was applied in children with a nondisplaced fracture. Injuries without fractures were splinted only in very young children to prevent loss of the bandage.

Outcome measures

Follow-up examinations were performed at our outpatient hand clinic 5, 10, and 21 days and 6 months after injury. The primary outcome was the quality of the new fingernail. This was assessed with the Nail Appearance Score (NAS), an instrument for measuring the surgical outcome after fingertip injuries (Rohard et al., 2012). It consists of six items; each item can be rated by the physician on a 4 point Likert scale, in which 1 represents the worst possible outcome and 4 the best possible outcome, such as in a normal nail. The first five items were averaged (scores for nail length, nail adherence, nail surface, nail wall, nail curvature). This resulting number was again averaged with the score for nail appearance to obtain the NAS (Table 1). Standard photo documentation with three views was performed for all fingernails at the outpatient clinic during every visit. The final photographs, taken 6 months after trauma were assessed with the NAS by two physicians, who were blinded to the treatment group and patient history.

Secondary outcomes were assessed at the final follow-up visit 6 months after trauma with the Patient and Parental Nail Satisfaction Score (PNSS), a patient-reported outcome score (Rohard et al., 2012). The PNSS consists of six items. Each item can be rated on a four point Likert scale, in which 1 represents the worst possible outcome and 4 the best possible outcome (Table 2). The first five items were averaged (nail tenderness, paronychia, nail wall

injuries, problems with manicure, problems with getting caught). This resulting number was again averaged with the score for nail appearance to obtain the PNSS. Patients were interviewed themselves if they were 8 years or older, and parents were interviewed with younger patients. The NAS and PNSS were rated as follows: 1 to 1.5 points, very dissatisfied; 1.6 to 2.5 points, dissatisfied; 2.6 to 3.5 points, satisfied; and 3.6 to 4 points, very satisfied (Rohard et al., 2012).

Other outcome measures included pain assessment at the first three follow-up visits and signs of local infection of the injured finger. For pain assessment, parents were asked how long their child required pain medication. At each follow-up visit, a hand surgeon examined the injured finger and documented any signs of local infection.

Sample Size

Because the study design allowed parents to choose either treatment option, we anticipated that operative treatment would be chosen very rarely, because if parents can choose a treatment for their child, they will probably choose the one that is least invasive, particularly if this allows avoiding general anaesthesia. We therefore planned to end the study before 28 patients had joined the operative group while ensuring that the non-operative group had at least 28 patients. We therefore focused on estimating the expected value of NAS (“expected NAS”) in the non-operative group with good accuracy.

Assuming a normal distribution of NAS with standard deviation (SD) of (at most) 0.4, the sample mean of the non-operative group of 28 patients with the assumptions above will have a SD of the sample mean (SDM) of $0.4/\sqrt{28}$ ____. Consequently, the width of the 95% confidence interval (CI) for the expected NAS from that sample would be $2 \times 1.96 \times 0.4/\sqrt{28}$ ____, which is 0.2963. We rounded this to 1/3 for ease of readability. Using this number and our clinical judgement we then set 1/3 as our threshold for non-inferiority and by extension

assume that a difference of less than 1/3 point in the NAS between the non-operative and operative group is clinically irrelevant. Even with fewer patients in the operative group, we can still report the difference in primary outcome with a 95% CI for the difference and so decide on non-inferiority as explained below.

Statistical analysis

Continuously distributed data were presented as median and interquartile range (IQR). Differences in patient characteristics between groups were analysed using a Fisher test and a Chi-square test (based on Monte Carlo simulations to allow for small expected counts) for categorical data with two or more categories, respectively, and a two-sample Wilcoxon-test for continuous data. If expected frequencies are less than five, a Monte Carlo simulation computes the null distribution instead of using asymptomatic results, and therefore the expected frequencies are not required to be larger than five.

For the primary outcome, we calculated the difference (operative minus non-operative) of the mean NAS with a 95% CI. The CIs in this and the following analyses were computed using the studentized bootstrap (also known as bootstrap t) with 10,000 bootstrap resamples (Hesterbert, 2015). The non-operative therapy was regarded as not inferior to the operative treatment if the upper end of the CI was smaller than the predefined non-inferiority limit of 1/3 (i.e., if the operative group scores on average at most 1/3 point better than the nonoperative group, we declared non-inferiority of the non-operative treatment). Moreover, we reported the mean NAS in both the operative and non-operative group together with 95% CIs using the studentized bootstrap. For the secondary outcome and other outcomes, we calculated means, SD, and 95% CIs using the studentized bootstrap for both PNSS and days of analgesic therapy in both groups. We also calculated the difference in means between two groups together with a 95% CI.

RESULTS

During the study period, 51 patients were enrolled; 39 (76%) chose the non-operative treatment and 12 (24%) the established standard therapy. One patient who had chosen the non-operative treatment dropped out of the study after the first follow-up visit because the parents were pleased with the outcome and did not want any further visits. One patient had two injured fingers, but we only included one in the study. Thus, the final data involves 50 patients with one injured finger each.

Patient characteristics are summarized in table 3. Median age was 3 years (IQR 5; range 1–14). The two groups did not differ significantly in age, gender, or presence of nondisplaced fractures on X-rays. However, a significant group difference was noted with regard to ketamine anaesthesia (4 patients in the operative group compared to 1 patient in the nonoperative group; $p = 0.009$).

Primary outcome analysis

The mean NAS in the operative group at final follow-up was 3.96 (95% CI: [3.93; 3.99]) compared to 3.98 (95% CI: [3.97; 3.99]) in the non-operative treatment group. The difference in the means (OP minus NOP) was -0.02 (95% CI: [-0.05; 0.01]). Since the upper bound of this CI is smaller than 1/3, we conclude that the non-operative treatment is not inferior to the operative treatment.

Secondary outcome analysis

The mean PNSS in the operative group was 3.92 (95% CI: [3.65; 3.99]), compared to

3.98 (95% CI: [3.87; 4]) in the non-operative treatment. The difference in the means was -
0.06 (95% CI: [-0.27; 0.02]). Because the value of zero is included in the CI, we conclude that
there was no significant difference in mean PNSS at the 5% significance level.

Other outcomes

The mean duration of analgesic use in the operative group was 1.6 days (95% CI: [0.56; 3.2]), compared to 0.8 (95% CI: [0.4; 1.4]) in the NOP treatment group. The difference in the means was 0.8 (95% CI: [-0.31; 2.32]). Because the value of zero is included in the CI, we conclude that there was no significant difference in days of analgesic therapy at the 5% significance level.

There were no signs of infection found in either patient group. Figure 2 shows one example of a complete avulsion injury at the time of the accident and at the follow-up visits after non-operative treatment. Figures 3 and S1 show a collection of outcomes at final followup visits.

DISCUSSION

Our study shows that management of fingernail avulsion injuries with an ointment dressing without nail replacement is not inferior to standard treatment with suture fixation of the nail in either appearance or patient satisfaction. Demographics and the distribution of affected fingers in our trial were equivalent to previous studies, which examined similar patients groups, but with other treatment options including refixation of the nail plate: Most commonly, children under 5 years of age presented with such crush injuries, and mostly, the index and middle fingers were affected (Capstick and Giele, 2014; Greig et al., 2017).

The functional and cosmetic outcomes were excellent in all our patients. At the final follow-up visit six months after trauma, most children and parents did not remember which finger had previously been injured, which emphasizes the satisfactory functional and cosmetic findings. Our outcome is in line with previous studies on nail bed injuries, which have reported good to excellent outcomes in 90–100% of adult patients in whom the fingernails were replaced (Strauss et al., 2008; Zook et al., 1984). Poor results were found in association with the development of an infection or if underlying injuries were missed (Al-Qattan, 2001; Capstick and Giele, 2014; Cornwall, 2012; Fairbairn, 2012; Gellman, 2009; George et al. 2017, Greig et al., 2017; Nellans and Chung, 2013; Strauss et al., 2008; Zook et al., 1984).

The non-operative treatment of proximal nail avulsion injuries did not permit inspection of the nail bed, so minor lacerations of the nail bed might have been missed. This might be a similar situation to that of patients with subungual hematomas. Gellman demonstrated excellent results after simple trephination in patients with subungual hematoma with an intact nail and nail margin, even though previous reports had recommended surgical treatment with removal of the nail, suturing of the laceration, and replacement (Gellman, 2009; Roser and Gellman, 1999). These recommendations were based upon observations that subungual hematomas involving more than 50% of the nail were associated with nail bed lacerations over 3mm in 60% of cases and with fractures in nearly 95% (Gellman, 2009).

Patient and parental satisfaction assessed with the PNSS was high, with no significant group differences at the final visits. The vast majority of our patients chose the nonestablished non-operative treatment option over the standard operative treatment. It is known that parents prefer an active role in decision making, and factors influencing their decisions include provider recommendations, prior health care experiences, beliefs, and emotions (Lipstein et al., 2012). Thus, key considerations for choosing the non-operative treatment may have been

emotional, wanting no additional stress for their child or general anaesthesia. Lower cost of treatment and a shorter stay at the emergency room explain the health care providers' preference for the non-operative approach (Capstick and Giele, 2014).

The duration of analgesic medication required in our study was comparable to previously published results in children. Greig reported analgesia medication for three days after nail replacement, compared to zero days if the nail was discarded (Greig et al., 2017).

Several limitations in our study should be noted. First, patients were not randomized to a treatment group; instead, parents were free to choose a non-operative treatment or the standard surgical approach. The possible need for anaesthesia in the operative group explains why it seemed unlikely that parents would participate in a randomized trial. Therefore, there is a clear risk of a selection bias, with possibly higher acceptance of surgical repair in more severe injuries. Second, the study had not enough power to establish with certainty that there are no differences between the groups. Third, no universally accepted scoring system exists for nail outcome, which limits comparability with previous trials. Fourth, proximal partial avulsion injuries were significantly more frequent in the operative group; however, the outcome of this injury, irrespective to the treatment group, is not different from complete avulsion injuries. Despite these limitations, this study possesses several strengths: an objective assessment of nail outcome by blinded examiners, follow-up reviews until six months after injury, and very high compliance with only one patient lost to follow-up.

The outcome was excellent in all fingers, irrespective of the treatment group, with no significant differences. Comparison of the two groups confirmed that the non-operative treatment is not inferior. Moreover, the excellent NAS and extremely high patient satisfaction in the larger group with non-operative treatment makes it very unlikely that any alternative

treatment can outperform these results. In view of the associated risks and cost of surgery, we recommend non-operative treatment for simple nail avulsion injuries in children without replacement or fixation of the nail under the eponychium.

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Ethical approval: The study was approved by the local ethics committee (kantonale Ethikkommission Zürich).

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Figure and table legends

Figure 1. Securing the patient's nail with non-absorbable sutures in the operative treatment group.

Figure 2. Clinical photographs of a complete nail avulsion injury treated with the nonoperative treatment option (a) at the day of injury, (b) at day 5, (c) at day 10, (d) at day 21, and (e) at 6 months.

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Figure 3. A collection of clinical photographs taken at 6 months after injury. The first line displays the outcome of the operative treatment group, and the second line shows the outcome of the non-operative treatment group.

SUPPLEMENTARY MATERIAL

Figure S1. Additional collection of clinical photographs taken at 6 months after injury. The first line displays the outcome of the operative treatment group, and the other lines show the outcome of the non-operative treatment group.

Table 1. Nail Appearance Score Assessment (Rohard et al., 2012).

Table 2. Patient and Parental Nail Satisfaction Score Assessment (Rohard et al., 2012).

Table 3. Patient characteristics.

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Figure 2

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Figure 3

Table(s)

Table 1. Nail Appearance Score assessment (Rohard et al., 2012).

Items	1 point	2 points	3 points	4 points
Nail length	< 1/3	1/3 – 2/3	> 2/3 (not normal)	normal
Nail adherence	< 1/3	1/3 – 2/3	>2/3 (not normal)	normal
Nail surface	split nail	deep grooves	slightly irregular	normal
Nail wall	missing	partially missing	irregular	normal
Nail curvature	very severe	severe	mild	normal
Nail appearance	very dissatisfied	dissatisfied	satisfied	very satisfied

Table 2. Patient and Parental Nail Satisfaction Score assessment (Rohard et al., 2012).

Items	1 point	2 points	3 points	4 points
Nail tenderness	always	often	seldom	never
Paronychia	always	often	seldom	never
Nail wall injuries	always	often	seldom	never
Problems with manicure	always	often	seldom	never
Problems with getting caught	always	often	seldom	never
Nail appearance	very dissatisfied	dissatisfied	satisfied	very satisfied

Table 3. Patient characteristics.

Baseline data	Non-operative	Operative	p-value*
Patients	38	12	
Age (years) median (IQR; range)	3 (4.8; 1-13)	5 (5.44; 1-14)	0.561 (Wilcoxon-test)
Boys	29	9	1.00
Affected finger: I/II/III/IV/V	7/12/8/8/3	2/2/5/1/2	0.483 (MC chi-squared)
Affected side: right/left	12/26	5/7	0.728
Proximal avulsion	22	11	0.039
Fracture	8	2	1.00
Ketamine anaesthesia	1	4	0.009

Data presented as number or median (IQR; range); IQR: Interquartile range; MC: Monte Carlo. *Unlabeled are Fisher exact test

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JHSE-D-20-00234R4 Figure S1.tif

**Non-operative treatment versus suture refixation of the nail plate in paediatric
fingernail avulsion injuries**

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