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Nonrandomized assessment of ingrown toenails treated with excision of skinfold rather than toenail (NAILTEST): An observational study of the Vandenbos procedure

Michael H. Livingston [a], Kamary Coriolano [b], Sarah A. Jones [b,*]

[a] Clinician Investigator Program, McMaster University, Hamilton, Ontario, Canada
[b] Division of Pediatric Surgery, Western University, London, Ontario, Canada

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ABSTRACT

Background: The Vandenbos procedure for ingrown toenails consists of excising the surrounding skinfold and allowing the wound to heal by secondary intention. Previous studies have documented low rates of recurrence, but patient-reported outcomes remain uncertain.
Methods: This study was a prospective, observational assessment of children and adolescents who underwent the Vandenbos procedure for one or more ingrown toenails. Standardized assessments of pain, functional status, and quality of life were completed before surgery and then one, two, and six months postoperatively.
Results: Thirty-nine participants (with 59 ingrown toenails) completed at least one postoperative assessment and were included in the analysis. Age ranged from 4 to 20 years (mean 13.5 years). Recovery time was a median of 7 days for return to school or work and 23 days for being able to wear enclosed shoes. Seven participants (18%) experienced one or more minor complications within the first two months of surgery. There were no recurrences. Ninety-five percent of participants and 100% of parents would recommend the Vandenbos procedure.
Conclusions: We conclude that the Vandenbos procedure is associated with a low recurrence rate in children, adolescents, and young adults with ingrown toenails. Patient-reported recovery time, complication rate, functional outcomes, and satisfaction are excellent.
Level of evidence: 3

Ingrown toenails are a common and frustrating problem among adolescents and young adults [1–4]. This condition results in pain, recurrent soft tissue infection, inability to wear normal shoes, as well as time away from school, sports, and other activities. The cause of ingrown toenails appears to be multifactorial [3,4]. Contributing factors include genetic predisposition, infection, trauma, poorly fitting shoes, and deep trimming of the toenail.

The development of ingrown toenails was traditionally thought to be because of problems with the toenail itself [3,4]. More recently, some clinicians have suggested that the disease process is a result of the nail traumatizing the surrounding skinfold, resulting in swelling, infection, and the generation of granulation tissue [5–7]. This causes the nail to embed itself even further into the soft tissues, leading to a vicious cycle of recurrent swelling, pain, and infection.

Many treatments have been proposed for ingrown toenails [4]. Nonsurgical options include soaking, wearing loose shoes, packing below the nail, antibiotics, and specialized braces. While these treatments may provide short-term relief, most patients with ingrown toenails eventually need surgery. The most common surgical options involve removing a portion of the ingrown nail or part of the surrounding skinfold [2]. Clinicians who offer the wedge excision often perform a partial matricectomy during the same procedure, which involves the destruction of part of the nailbed with chemicals (such as phenol) or surgical instruments [3,4]. This prevents recurrence, where toenail becomes ingrown again and symptoms persist. In previous series, the rate of recurrence with wedge excision and partial matricectomy is estimated to be 12% to 50% [4].

The Vandenbos procedure involves excision of the skinfold only [5]. The toenail and matrix are left intact and the wound is left to granulate and epithelialize over the course of approximately 6 weeks. This approach theoretically involves more pain, a higher risk of postoperative bleeding (because it is initially an open wound), and a longer recovery time [6]. Proponents of this technique argue that these short-term morbidities are justified given the low rate of recurrence and excellent long-term results [6,7]. As a result, the Vandenbos procedure has become a popular office procedure by family physicians office and podiatrists.

The original case series published by Vandenbos in 1959 found a recurrence rate of 0% [5]. Two recent case series from Canada reported similar results [6,7]. Other studies have reported positive results but

* Corresponding author at: London Health Sciences Centre, Pediatric Surgery, Room B1-131, 800 Commissioners Road East, London, Ontario, Canada, N6C 2V3. Tel.: +1 519 685 8500x71553; fax: +1 519 685 8019.
E-mail address: sarah.jones@lhsc.on.ca (S.A. Jones).

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with recurrence rates as high as 20% [8–11]. Thus, the true effectiveness of this procedure remains unknown. Furthermore, there is no high quality evidence to support one technique over the other [4]. Previous trials show significant heterogeneity and none have assessed the Vandenbos procedure specifically. Even a recent Cochrane review of 24 randomized controlled trials could not reach definitive conclusions regarding which procedure is most effective [4]. Despite this, many physicians and other health care providers are using the Vandenbos procedure on a routine basis [6,7].

The purpose of this study was to evaluate the effectiveness of the Vandenbos procedure in children, adolescents, and young adults. We assessed participants at baseline and followed them prospectively one, two, and six months postoperatively. This study design allowed us to estimate the frequency of recurrence within the first six months of surgery and ask patients to assess morbidity in terms of complications, recovery time, pain, and quality of life. We also assessed patient satisfaction six months after surgery. Our hope is that this study design will allow us to provide clinicians, researchers, and future patients with a more complete perspective on the effectiveness and morbidity of the Vandenbos procedure in pediatric age group.

1. Patient and methods

1.1. Study design

The Nonrandomized Assessment of Ingrown toenaiLs Treated with Excision of Skinfold rather Than Toenail (NAILTEST) was a prospective, observational study of children, adolescents, and young adults who underwent the Vandenbos procedure for one or more ingrown toenails. Ethics approval was obtained from the Health Science Research Ethics Board at Western University (#104906). The study protocol was registered on *clinicaltrials.gov* prior to enrolling participants (NCT02067897) [12].

1.2. Participants

Participants in the NAILTEST study were included if they were children, adolescents, or young adults who decided to undergo the Vandenbos procedure for one or more ingrown toenails. Individuals were excluded if they could not understand English or had significant medical comorbidities.

Participants represented a convenience sample identified through the outpatient surgical clinic at Children's Hospital, London Health Sciences Centre in London, Ontario, Canada. Based on clinical volume, we anticipated being able to recruit approximately 50 participants over a two-year period. All participants underwent consultation with one of three pediatric surgeons as part of their usual clinical care. Patients who required a surgical intervention for ingrown toenails and decided to proceed with the Vandenbos procedure were approached by a research assistant who was not otherwise involved in their clinical care. The research assistant obtained written and informed consent from the participant whenever possible. When necessary, written or verbal assent was obtained from the child and written consent from the parent or legal guardian.

The baseline assessment included questions regarding duration of symptoms, impact on daily activities, and quality of life. The participant's surgeon also classified the severity of disease using the Mozena classification system. Stages include: I (erythema, slight edema, and pain when pressure is applied to the lateral fold), IIa (increased stage I symptoms, drainage and infection, nail fold less than 3 mm), IIb (increased stage I symptoms, drainage and infection, nail fold 3 mm or greater), and III (magnified grade II symptoms, presence of granulation tissue and nail fold hypertrophy) [13].

1.3. Intervention

All participants underwent the Vandenbos procedure for one or more ingrown toenails as an outpatient day procedure approximately one month after their initial consultation. The procedure was performed in the operating room under general anesthetic. All procedures were performed by one of three pediatric surgeons with prior experience with the Vandenbos procedure.

The steps of this technique are described in detail elsewhere [6]. In short, the affected toe and forefoot are prepped with chlorohexidine or iodine and draped in a sterile fashion. A Penrose drain is used as tourniquet at the base of the toe. Digital nerve blocked is applied with 0.5% Marcaine or 2% lidocaine. The affected skinfold is excised in a curvilinear fashion from the base of the toenail, along the lateral aspect of the toe, and then finally to the distal end of the toenail. The tourniquet is released and any areas of bleeding are controlled with electrocautery. The wound is left open and covered with nonadherent gauze, dry gauze, and gauze roll dressing. The dressing is secured in place with tape. The patient is discharged home later that day.

In keeping with the usual practice at our institution, participants in the NAILTEST study returned to clinic to have the dressing removed two days later or simply removed it at home (depending on patient and surgeon preference). Participants were also advised to soak the toe two to three times daily and apply a dry gauze dressing until the toe was healed. They were also told to return and to regular activities and wear normal shoes at their own discretion.

1.4. Outcomes

Participants were assessed one, two, and six months postoperatively. In order to offset the cost and inconvenience of the six-month assessment (which is not part of routine clinical care), we provided participants with parking vouchers and entered them into a draw for an iPad. The primary outcome for the NAILTEST study was recurrence at any point within six months of surgery. This was defined as: "The toenail growing back into the skin surrounding and/or soft tissue resulting in symptoms similar to those prior to surgery." In other words, recurrence was the absence of a definitive cure.

Secondary outcomes included complications, recovery time, pain, functional status, quality of life, and patient satisfaction. Recovery time was assessed using simple questionnaires that asked participants to estimate the date of their return to normal footwear, school, and work (if applicable). The lengths of these recovery times were calculated in days from the date of surgery. Complications were assessed by asking to participants to record any clinical sequelae related to surgery that prompted a phone call to the surgeon's office, additional clinic appointment, or visit to the emergency department. Examples included excessive pain, infection, bleeding, and wound care issues.

Pain, functional status, and quality of life were assessed using the European Quality of Life Instrument (EuroQol), which is a reliable and valid assessment of quality of life covering five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [14,15]. Each question has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. Respondents were also asked to indicate their overall health state on a 20 cm visual analogue scale with endpoints labeled "the best health you can imagine" and "the worst health you can imagine."

At the six-month assessment, participants were also asked to complete the Surgical Satisfaction Questionnaire [16]. This instrument consists of eight items related the patient personal satisfaction with the procedure and outcome (e.g., "Would you recommend this surgery to someone else?"). Reponses are scored on a five-point Likert scale.

1.5. Statistical analysis

Completed paper questionnaires were transcribed into a web-based database designed with Research Electronic Data Capture (REDCap) [17]. These data were then downloaded and analyzed using the Statistical Package for the Social Sciences version 23 (SPSS 23) and Microsoft Excel 2010. Statistical significance was set at $p < 0.05$. Dichotomous