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ORIGINAL PAPER

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Surgical Implant Generation Network (SIGN) intramedullary nailing of open fractures of the tibia

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Abstract We treated 36 open tibial fractures (32 patients) by primary intramedullary nailing and debridement and treatment of open wounds. There were 13 grade I, 14 grade II and 9 grade III according to Gustilo-Anderson classification. After a minimum follow-up of 8 months, there were two cases of superficial infection and one of deep infection. Thirty-one fractures united within 6 months with a mean period to union of 22 weeks. There were four delayed unions and one non-union. There was a longer union time and a higher rate of delayed or non-union in the complex and/or comminuted grade IIIB fractures. Intramedullary nailing, with appropriate soft-tissue treatment, gives good results in the treatment of open tibial fractures.

Résumé Nous avons traité 36 fractures ouvertes du tibia (32 malades) par enclouage centromédullaire et débridement des plaies. Il y avait 13 grades I, 14 grades II et 9 grades III selon la classification de Gustilo-Anderson. Après un minimum de suivi de 8 mois il y avait deux cas d'infection superficielle et un d'infection profonde. 31 fractures ont consolidé en moins de 6 mois avec un délai moyen de 22 semaines. Il y avait quatre retards de consolidation et une non—consolidation. Il y avait un délai de consolidation plus long et un taux plus élevé de consolidation retardé ou de non consolidation dans les fractures complexes et/ou comminutives de grade IIIB. L'enclouage centromédullaire avec traitement approprié des lésions des parties molles, donne de bons résultats dans le traitement des fractures tibiales ouvertes.

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Introduction

The optimum treatment in developing countries for open fractures of the tibia remains controversial. Treatment options include cast immobilisation, open reduction and plate fixation, external fixation and intramedullary nailing [3, 15]. External fixation is associated with a high incidence of complications including pin tract infection, malunion, delayed union and non-union [10, 11]. Therefore, we have a preference for intramedullary fixation for open tibial fractures initially using un-reamed K-nails, Rush or Ender nails. Recently, second-generation nails with interlocking capabilities (SIGN—Surgical Implant Generation Network) were provided to us, and this report documents our initial experience with their use. The use of both reamed and un-reamed tibial nails has gained acceptance with a low complication rate [23]. Our excellent initial results of un-reamed nailing with the solid tibial nail consequently led to its use as the primary method of treatment for tibial fractures associated with soft-tissue injury. Intramedullary nailing without reaming seems to be a reliable and safe treatment for closed and open fractures with severe soft-tissue injuries as an alternative to external fixation. The use of a solid nail combined with interlocking allows stabilisation even of complex fractures and less chances of infection [7, 18, 19].

Patients and methods

Thirty-six open fractures of the tibia in 32 patients were treated at this institution between March 2000 and April 2002 by primary stabilisation with a solid intramedullary locked nail without reaming. We excluded those grade III fractures that were highly contaminated and deemed unsafe for primary nailing. Nails of 8- or 9-mm diameter were used with 4.5 mm outer-diameter locking screws. The smaller diameter nails were size compatible with the

Table 1 Incidence of infection and time to union in 36 grade I–III open fractures according to Gustillo-Anderson classification

Grade	No of cases	Union time (weeks)	Delayed union	Non-union	Infection (s=superficial, d=deep)
I	13	24	1	0	0
II	14	20	0	0	2 (s)
IIIA	5	25	1	0	0
IIIB	4	32	2	1	1 (d)

generally smaller bones of our patients. Interlocking screws were used in selected unstable fractures. Fractures were graded according to Gustilo-Anderson classification [8]. Extensive irrigation and debridement of the associated wound was performed, followed by delayed or primary closure for grade I–II injuries. Coverage of exposed bone was obtained for more severe open wounds (grades II and III) by either a muscle flap, or a skin graft later on. Delayed presentation was present in the majority of patients. All patients received intravenous antibiotic therapy with cephalosporin, aminoglycoside and metronidazole for at least 3 days. Early postoperative mobilisation was encouraged, with weight bearing determined by fracture stability and concomitant injuries. Superficial infection was defined as local erythema, which resolved with antibiotic therapy. Deep infection was defined as continuing wound drainage or a positive bacteriological culture. Delayed union was defined as lack of significant union within 6 months postoperatively and non-union as having no signs of union after 8 months. Radiographic evidence of union was defined by the presence of bridging callus and clinical union by the ability to support body weight without walking aids. Statistical analysis (SAS 6.12) was used to evaluate the rate of union and incidence of infection according to grade, type and site of fracture.

The average time elapsed from time of injury until reaching the operating room was five (1–12) days. The wound in most cases received only rudimentary care and splinting prior to arrival and was definitively cleansed in the operating room. Causes of delay in seeking treatment by the patients in our country remain poverty, ignorance and lack of facilities for transport. Often, patients were carried over rugged terrain or transported by primitive means from remote parts of Nepal. Moreover, our hospital has a most ordinary operating room with very basic facilities where all types of surgeries are carried out. We used ordinary bar soap for scrubbing and normal saline for wound irrigation.

Three grade III fractures were converted from external fixation to an intramedullary rod within 10 days. Since the time from injury was longer, primary management was more frequently modified in this fashion as compared to in most developed countries.

Results

Mean patient age was 26 (15–54) years, and there were 22 men and ten women (four bilateral cases). Mean follow-up was 14 months with a minimum of 8 months. According to the Gustilo-Anderson classification [8], there were 13 grade I, 14 grade II, five grade IIIa and four grade IIIb cases. Two fractures were within the proximal third of the tibia, 23 within the middle third and 11 within the distal third. Thirty-one (n=31) fractures united within 6 months, with a mean period to union of 22 weeks. There were four delayed unions and one non-union. Three delayed unions eventually united within 8 months without intervention, and one received bone grafting at 6 months and was healed at 9 months. The non-union case was also treated with bone grafting with eventual healing and a good result.

According to grade severity, the mean time to union of grade I fractures was 24 weeks, that of grade II fractures was 20 weeks and grade III fractures required 32 weeks. There was thus no correlation between severity of the open fracture and the time to union for grade I–IIIA fractures (P=0.02). However, union time was longer in more complex grade IIIB fractures (Table 1). There were two superficial infections in grade II fractures, which were successfully treated with antibiotic therapy. There was one deep infection associated with a grade IIIB fracture, which resolved after serial debridement and antibiotic treatment. There were three cases of malunion defined as a rotational deformity of more than 10°, an angulation deformity of more than 10° or shortening by more than 10 mm. Locking screws backed out in three cases; no nails broke. There were no complications requiring removal of implant or amputation.

Discussion

Complications of treating open fractures of the tibia include non-union, infection and malunion [2] The complication rate has been reduced following improvement in techniques to obtain primary soft-tissue cover and wound healing and improvement in techniques of fixation. External fixation for the treatment of unstable open fractures is associated with significant pin loosening, non-union and late angular deformity [10]. The results of Alberts et al. [1] indicate that intramedullary nailing is superior to external fixation in the treatment of most open tibial fractures. However, in a Swiss study [6], the treatment of most tibial shaft fractures with a plate or a nail has been reported as having equally good outcome.

Earlier methods of un-reamed intramedullary fixation using Ender nails and Lottes nails produced good results when compared with external fixation but with problems of axial control [9, 11, 14, 16]. Recent reports of the un-reamed locked nailing technique have drawn attention to the fact that rigid fixation may be obtained without damage to the periosteum and with maintenance of intramedullary blood flow [5, 10].

Mean time to union in this series, excluding the cases of delayed/non-union, was 23 weeks, which is similar to that in other series [11]. The time to union did not correlate with the severity of the injury as judged by the Gustilo-Anderson classification for grades I–IIIA fractures. There were five cases of delayed or non-union; the overall rate of union compared favourably with that of other studies [23, 24] and is significantly less than our

past experience and other studies utilising mainly external fixation [20, 23] There were, however, relatively few grade III fractures in this study and they were predictably more problematic. However, selective treatment with an un-reamed intramedullary nail, even in cases with extensive local soft-tissue loss and damage, may produce good results.

There was a relatively low rate of infection in this series. This may partially be due to the fact that the un-reamed technique is associated with minimal damage to the blood supply of cortical bone locally [13, 17, 18] and absence of dead space due to a solid nail [18]. Other authors have reported an incidence of infection varying from 2 to 4% to 11.6% [4, 23]. It has also been documented that solid nails avoid the dead space available in hollow nails thereby decreasing the chance of infection [18]. The incidence of malunion was also low, occurring in three patients only, and this also compared favourably with other series [10, 21].

Bhandari et al. [3]have systematically reviewed the effect of alternative methods of stabilisation of open tibial fractures on the rates of re-operation, and the secondary outcomes of non-union, deep and superficial infection, implant failure and malunion by the analysis of 799 citations on the subject identified from computerised databases through meta-analysis. One study (n=56 patients) suggested that the use of external fixators significantly decreased the requirement for re-operation when compared with fixation with plates. The use of un-reamed nails compared with external fixators (five studies, n=396 patients) reduced the risk of re-operation, malunion and superficial infection. In low-energy fracture, there was no significant difference in time to healing between fractures treated with immobilisation in a cast only and those treated with external/internal fixation [22]. Comparison of reamed with un-reamed nails showed a reduced risk of re-operation (two studies, n=132) with the reamed technique. An indirect comparison between reamed nails and external fixators also showed a reduced risk of re-operation (two studies) when using nails. These studies identified compelling evidence that un-reamed nails reduced the incidence of re-operations, superficial infections and malunions when compared with external fixators. Nevertheless, the relative merits of reamed versus un-reamed nails in the treatment of open tibial fractures are still debated and remain controversial.

Our study shows that equally good results can be obtained with well-fitting nails without reaming. In less than ideal operating room sterility, as is often the case in third world poor countries, not reaming is quicker and safer. Moreover, reamers are expensive to obtain and difficult to sterilise. It is worth mentioning that C-arm fluoroscopy and intra-operative X-rays were not available in our operating room. Interlocking was preformed using a jig, and occasionally distal interlocking was problematic. The open wound was frequently utilised to facilitate reduction and the passage of the nail. However, in ten grade I–II fractures, blind nailing was successful. The remaining 26 fractures were openly reduced. Despite an overall 13.9% incidence of delayed and non-union (5/36), healing occurred in less than 6 months in 89.9% of fractures (32/36), and secondary procedures to achieve healing were necessary in only two patients.

It is widely recognised that the prognosis for open fractures of the tibia is more favourable if early definitive treatment is applied, because the time interval between injury and wound debridement in known to be a major prognostic factor [12].It is interesting to note, however, that despite the delayed presentation of many of our patients, a relatively low infection rate was encountered—perhaps representing more low-energy fractures and atraumatic nailing.

In conclusion, open fractures of the tibia with significant associated soft-tissue damage may be selectively treated by a solid intramedullary locked nailing technique with a satisfactory rate of union and low complication rate. The SIGN nail system developed by a charity organisation in the USA has helped us to offer reliable treatment of open tibial fractures for the poor people of Nepal.

Acknowledgement SIGN (Surgical Implant Generation Network), founded by Dr. Lewis G. Zirkle, was created in 1999 as a humanitarian, non-profit corporation in Washington, USA with a goal to provide improved health care and proper orthopaedic treatment of fracture at little or no cost to people in need throughout the world. All implants and instruments were provided free of cost by SIGN, USA to our institution in Nepal.

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