A Group-Control Study on Clinical Efficacy Between Classical Infra-Patellar and Supra-Patellar Intramedullary Nailing in the Treatment of Tibial Shaft Fractures

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Abstract

Objective: To compare the clinical efficacy and prognostic evaluation between classical infra-patellar and supra-patellar intra-medullary nailing in the treatment of tibial shaft fractures.

Methods: All 88 cases of patients diagnosed as tibial shaft fracture with the admittance into Dept. Orthopedic Trauma, had been retrospectively analyzed from June. 2012 to Dec. 2015. The valid cases of which is 68 that accounted for 77.2% of follow-up rate. 60 cases were male, 8 cases female, aging from 18 to 87, 43.7±12.47 on average. All cases were classified into two groups, based on different surgical approaches,(38 cases in SPN group,30 cases in IPN group) and to compare respectively the surgical time, fracture union time, length of stay, intra-operative fluoroscopic time, “Second Shifting”, bleeding, the incidence of limited open reduction, function of knee and also their clinical efficacy.

Results: There was no statistical significance in gender and age, fracture classifications, operative time, length of hospital stay, and fracture union time of these two groups (P>0.05). Intra-operative accumulative fluoroscopy time in the group of infra-patellar approach (IPN, abbreviated as below) was significantly lower than that of suprapatellar approach group (SPN, abbreviated as below) (P = 0.009, P < 0.05) and intra-operative bleeding volume in these two groups of patients was statistically significant (P = 0.044, P < 0.05), which in IPN group shows more than in group. SPN. The number of cases of “Second Shifting” in IPN group was significantly higher than that of SPN group (P = 0.021, P < 0.05), and compared to only 1 case treated with limited open reduction in SPN group, however, there were 7 cases in IPN group, which indicated statistically significant difference (P = 0.044, 0.050). The postoperative follow-up was performed accordingly by the Hospital for Special Surgery.
INTRODUCTION

Tibial shaft fracture is one common type of whole body fractures, which accounts for an incidence of 13.7%. The classical Infra-patellar intramedullary nailing (IPN as below) technology has been recognized among most of orthopedists for the treatment of displaced tibial shaft fractures, due to its instant characteristic of reliable internal fixation that conforms to “AO Principles” for the purpose of early-stage practice. However, because of its knee pain for directly-splitting patellar ligament and also “second shift”, as an angular displacement between fragments, caused by extremely flexion in knee joint during the procedure of nail-implanting, many authors have reported its disadvantageous effects in recent years. So, along with the development of minimally-invasive and intra-medullary nailing technologies, Supra-patellar approach for intra-medullary nailing (SPN as below) has recently been accepted by more orthopedic doctors, especially for the treatment of upper 1/4 to 1/3 part of tibial shaft fractures.

In this article, we report on the clinical efficacy by comparing IM nailing between SPN and IPN surgical approaches. 68 (68/88, follow-up rate is 77.2%) cases have been retrospectively analyzed and completely followed up from June. 2012 to December. 2015.

PATIENTS AND METHODS

All patients’ data were collected post-operatively. The patients’ demographics and specific information were recorded on admission. Emergency management included assessments on vascularity and nerves injuries and evaluations on soft tissue condition. Specifically, complete debridement and external fixators were needed for temporary stabilization in 6 days as for cases with open fractures due to high-energy injury to soft tissues. And for cases with close fractures, tibial shaft fractures were reduced and then fixed by plaster cast usually for 7 to 8 days before patients underwent surgical procedures if the soft tissue conditions were stable and “wrinkle” test showed positive. Moreover, consecutive observations on changes for soft tissue conditions were necessary to prevent compartment syndrome from proceeding. 7 cases of close fractures who presented tension blisters or hematoma in this study were performed fasciotomy to release the pressure inside. On admission, all patients underwent radiological examinations of both X-rays and CT-scans as an informative reference for pre-operative decision making and surgical procedures. In order to ensure the consistency of clinical outcomes, the orthopedic surgeons from two centers who participated in this study had the same qualifications with Smith & Nephew training on intra-medullary nailing, and also served as chief directors in his or her departments. Meanwhile, Trigen Tibial Nailing System designed by Smith & Nephew was chosen and applied on all 68 cases in this study.

Score (HSS) for the knee function : there was no significant difference between the two groups within the first month after surgery (P=0.632, P>0.05), but then within 3rd month (P=0.032), 6th month (P=0.009) and 9th month (P=0), HSS score in these two groups were significantly different (P<0.05); The Johner-wruhs score was applied to evaluate the clinical efficacy: the excellence rate in SPN group reached 89.4%, and meanwhile, that of 80% in IPN group. There was no significant difference in clinical efficacy within one month, three months, six months, and nine months after the operations (P>0.05). However, between these two groups, there was a statistical significance (P = 0.004, P < 0.05) in post-operative 9th month of follow-up and the rest months of follow-ups were found no difference, which meant the clinical therapeutic evaluation in SPN group is higher than that of IPN group. There was also a significant statistical difference in postoperative complication of knee pain (P = 0.004, P < 0.05), it was noted that the incidence of severe knee pain in IPN group were more significant. Two groups had no wound infection and shortness of limbs, internal fixation loosening or rupture, fracture nonunion or mal-union.

Key Words: Tibial shaft fracture, Supra-patellar approach, Infra-patellar approach, Semi-extended knee joint, Clinical efficacy.
Post-operatively, both anteroposterior and lateral views of X-rays on full-length of tibia and fibula were taken within 24 hours, 4 weeks, 12 weeks, 6 months and 9 months after the operations to measure the bone union situations. All patients were classified into 2 groups (SPN group versus IPN group), according to different surgical approaches and compared on the aspects of clinical outcomes and prognosis.

SURGICAL TECHNIQUE

After the induction of anesthesia and antibiotic prophylaxis, all patients were placed in supine position while the surgical procedure was being performed and meanwhile, all external fixations were removed before the operations started.

SPN Group: The knee joint was placed in the slightly flexion to 15~20o. A 2.5~3.0cm longitudinal incision began 2.0cm from the upper rim of patella and was carried down to split quadriceps tendon, then with automatic distraction device to hold its position. Then, a working channel was established through the articular cavity at the rear of patella. (Once in a case of hyper-tension in patellofemoral joint that usually made it obstructive to put “trocca” inside the tunnel, it might reduce its damage to articular cartilage to release the pressure with the lateral patellae retinculumilysis). The drilling point was confirmed 5mm behind the middle of anterior rim of tibial plateau by fluoroscopic assistance, then to plug-in the guiding wire for the accuracy on point and direction of reaming. For 3 cases presented with “second shift” of tibial fractures, “Finger” technique was utilized throughout the procedure of reduction assistance. A suitable nail was chosen to implant after repeated reaming and then locked both distally and proximally. And lastly, the “trocca” was plugged out and subcutaneous tissue and skin was closed after repeated cavity suctions and drainages.

IPN Group: The surgical approach that started from patella tip to tibial tuberosity for about 5 cm was carried down to directly split patella ligament. Knee-positioning was placed on extremely flexion over 120o to 130o and then separated sub-pateallar fat tissue to expose clearly the upper part of tibial tuberosity. The drilling point was on same site as that in SPN group, but before drilling by “S”shaped opening device, its major axis had to be aligned with the axis of tibia to confirm the accuracy of reduction. And then guiding wire was plugged-in. However, 7 cases in this study had presented displacement or more during the procedure of reduction, which was called “second shift”. Bare-hand technique was on the first priority for this type of displacement including pushing back the displaced fragment while distally retraction and maintenance on its position. However, there was still 2 of the 7 cases who were then reduced through limited open reduction over the fracture site instead of hard hand technique, especially for cases of AO/OTA Type 41A that proximal fragment would be displaced on anterior direction as angular displacement because of the retraction of quadriceps. The following surgical procedures of implant nailing were described just as that in SPN group. And finally, subcutaneous tissue and skin were closed.

POST-OPERATIVE MANAGEMENT AND EVALUATIONS

Two groups of patients were encouraged to perform continuous passive practice on motion machine in 24 hours after the operations under the guidance of orthopedists. Antibiotic prophylaxis and Pain-management were also executed with 24 hours after the operations. Partial weight-bearing Intermittent exercise was performed with the protection of brace 3 days after the operations (1).

Two groups of patients were recorded respectively on gender and age, cause of injury, fracture type, operation time, cumulative fluoroscopy time, blood loss, hospital stay, fracture healing time, “second shift” and cases that required limited open reduction and also recorded respectively follow-up on postoperative 1,3,6,9 months by X-ray on internal fixators (including loose, bent, ruptures, etc.) and meanwhile, with the reference to Hospital for Special Surgery,(HSS) scoring system (2) on pain, function, range of motion, muscle strength and flexion situations. Both clinical efficacy of two groups was assessed by Johner-Wruhs
scoring system (3). Without objective factors involved, fracture was not healed and callus didn’t appear on radiographs for 6 months which indicated delayed union and there was still a fracture fissure on post-operative 9-month radiographs which means non-union (4).

STATISTICAL METHODS

All data analysis was done using SPSS 11.0 (SPSS Inc., Chicago IL). All measurement data were verified on its normal distribution by Shapiro-Wilk test. Descriptive statistics were used to determine ranges, means, and standard deviations. One-way analysis of variance and Student t tests were used to determine the difference between two groups. X2 test was performed to verify on count data of two groups P < 0.05 was considered statistically significant.

RESULTS

The valid cases of which is 68 that accounted for 77.2%(68/88) of follow-up rate. All 68 cases of patients had been followed up for 1-9 months, 6 months on average. The two groups, in terms of sex and age, fracture type, cause of injury, operative time, length of stay and the healing time, were not statistically significant (P> 0.05) (as shown in Table 1). However, intra-operative cumulative fluoroscopy time in IPN group was significantly lower than that in SPN group (P = 0.009, P <0.05), blood loss was statistically significant in the two groups of patients (P = 0.044, P <0.05), IPN group was higher than SPN group. The number of cases that Intra-operative “second shift” occurs in IPN group was significantly higher than SPN group (P = 0.032, P <0.05). For the aspect of limited open reduction, there was 7 cases in IPN group, on the contrast, there was only one case in SPN group and the two groups were statistically different (P = 0.021, P <0.05). (as shown in Table 2). HSS scores on knee function in these two groups of patients for the post-operative follow-up of 1 month were no statistical significance (P > 0.05), but in post-operative 3 months, 6 months and 9 months of follow-ups, there were statistical significance (P < 0.05), indicating that HSS score on knee function in SPN group was higher than IP group for postoperative 3 months, 6 months, 9 months follow-ups and meanwhile as Chart 1 shows, along with changes in the duration of follow-ups, we have reason to believe the difference in HSS scores between these two groups gradually increases. Presumably, to start through supra-patellar approach from the long-term perspective, it should be more beneficial to the knee joint function; (as shown in Table 3). In postoperative 1 month, 3 months, 6 months of follow-ups, there was no statistical significance.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Case number</th>
<th>Age</th>
<th>Sex</th>
<th>Injury</th>
<th>AO/OTA</th>
</tr>
</thead>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Male</td>
<td>Female</td>
<td></td>
</tr>
<tr>
<td>SPN</td>
<td>38</td>
<td>40.24 ± 12.32</td>
<td>33</td>
<td>5</td>
<td>11 14 11 2 8 16 4 7 3</td>
</tr>
<tr>
<td>IPN</td>
<td>30</td>
<td>43.20 ± 14.25</td>
<td>27</td>
<td>3</td>
<td>14 12 3 1 7 13 3 4 3</td>
</tr>
<tr>
<td>$t/\chi^2$</td>
<td></td>
<td>0.2</td>
<td>0.632</td>
<td>0.096</td>
<td>0.842</td>
</tr>
<tr>
<td>P</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.83 18 13 0.005</td>
</tr>
</tbody>
</table>

Table 1: General data of two groups of patients with preoperative (n=68)

<table>
<thead>
<tr>
<th>Groups</th>
<th>Union time (d)</th>
<th>Length of stay (d)</th>
<th>Surgical time (mi)</th>
<th>Fluoroscopic time (s)</th>
<th>Bleeding volume (ml)</th>
<th>“second shifting” (case)</th>
<th>Open reduction (case)</th>
<th>Complications of knee pain</th>
</tr>
</thead>
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<tr>
<td></td>
<td>15.38 ± 7.26</td>
<td>122.45 ± 40.28</td>
<td>3.23 ± 1.58</td>
<td>127.25 ± 162.25</td>
<td>4</td>
<td>1</td>
<td>18</td>
<td>Limited (case)</td>
</tr>
<tr>
<td></td>
<td>10.01 ± 8.03</td>
<td>130.12 ± 93.27</td>
<td>2.15 ± 1.31</td>
<td>213.24 ± 192.6</td>
<td>10</td>
<td>7</td>
<td>8</td>
<td>Moderate (case)</td>
</tr>
<tr>
<td>$\nu\gamma^2$</td>
<td></td>
<td>0.29</td>
<td>-0.8</td>
<td>2.88</td>
<td>-2.04</td>
<td>5.2</td>
<td>5.1</td>
<td>Sever (case)</td>
</tr>
<tr>
<td>P</td>
<td>0.83</td>
<td>0</td>
<td>0.423</td>
<td>0.01</td>
<td>0.044</td>
<td>0</td>
<td>0</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Table (2): The Comparison of Surgical Time, Length of Stay, Union Time, Fluoroscopic Time, Bleeding Volume, “Second Shifting”, Open Reduction and Complications of Knee Pain between SPN group and IPN group (n=68)
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However, it was the post-operative follow up of 9th month when there was a statistically significant difference ($P=0.004$, $P < 0.05$) that the excellence rate of Johner-Wruhs score was higher in SPN group. (as shown in Table 4) The typical and untypical cases are shown in Figure 1-2.

From table 1, there was no significance in sex, age, cause of injury and AO/OTA classification. ($P>0.05$, $\alpha=0.05$)

From Table 2, there was no significance in surgical time, length of stay and union time between the two groups ($P>0.05$ $\alpha=0.05$). But, there was a significance in fluoroscopic time, bleeding volume, “second shifting” and open reduction($P<0.05$ $\alpha=0.05$), which meant the fluoroscopic time in SPN group was higher than that of IPN group and however, the amount of bleeding volume, the cases of open reduction and the incidence of “second shifting” were lower than those in IPN group. The pain of the knee joint caused by the two different kinds of surgical approaches was statistically significant ($P<0.05$, $P=0.005$ $\alpha=0.05$). The occurrence rate of knee pain in SPN group was higher than that in IPN group, on the contrary, severe knee pain was significantly lower than that of IPN group.

As Table 3 shows, HSS scores on knee function in these two groups of patients for the post-operative follow-up of 1 month were no statistical significance ($P > 0.05\alpha=0.05$), but in post-

![Chart 1: The Comparison of HSS Scoring System on Post-Operative Function of Knee between SPN and IPN Group](chart.png)

Table 3 The Comparison of HSS Scoring System on Post-operative Function of Knee between SPN and IPN Group (n=68)

<table>
<thead>
<tr>
<th>Groups</th>
<th>One Month (n=68)</th>
<th>Three Months (n=68)</th>
<th>Six Months (n=68)</th>
<th>Nine Months (n=68)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPN</td>
<td>71.23±5.23</td>
<td>73.24±6.36</td>
<td>77.25±6.25</td>
<td>80.69±5.49</td>
</tr>
<tr>
<td>IPN</td>
<td>68.15±5.34</td>
<td>69.31±4.92</td>
<td>73.12±4.93</td>
<td>72.35±4.23</td>
</tr>
<tr>
<td>$t$</td>
<td>0.467</td>
<td>2.572</td>
<td>2.693</td>
<td>4.312</td>
</tr>
<tr>
<td>$P$</td>
<td>0.632</td>
<td>0.032</td>
<td>0.009</td>
<td>0.000</td>
</tr>
</tbody>
</table>

Table 4. The Comparison of Johner-Wruhs Scoring on Clinical Efficacy between Respective Follow-ups.(n=68)

($P > 0.05$) in Johner-Wruhs scores between these two groups of patients. However, it was the post-operative follow up of 9th month when there was a statistically significant difference ($P=0.004$, $P < 0.05$) that the excellence rate of Johner-Wruhs score was higher in SPN group. (as shown in Table 4) The typical and untypical cases are shown in Figure 1-2.
operative 3 months, 6 months and 9 months of follow-ups, there were statistical significance
(P < 0.05α=0.05), indicating that HSS score on knee function in SPN group was higher than
IPN group for postoperative 3 months, 6 months, 9 months follow-ups and meanwhile as
Chart.1 shows, along with changes in the duration of follow-ups, we have reason to believe
the difference in HSS scores between these two groups gradually increases. Presumably,
to start through supra-patellar approach from the long-term perspective, it should be more
beneficial to the knee joint function.

From Table 4, in post-operative 1 month, 3 months, 6 months of follow-ups, there was no
statistical significance (P > 0.05α=0.05) in Johner-Wruhs scores between these two groups.

**Figure 1:** SPN Pre-operation (a, anteroposterior; b, lateral) radiographs from a
31-year-old man injuries by traffic accident. AO/OTA classification for 42 type A left
open tibiofibula fractures. During the surgery, Intraoperative to insert into the road on
patellar sleeve (C), positioning by C arm (D, E), expansion of marrow needle (F),
(G), locked (H, I). Post-operation(J, anteroposterior; K, lateral) radiographs a week
and the nine month Post-operation(L, anteroposterior; M, lateral); The HSS knee joint
function score 92 points, the evaluation of Johner-Wruhs is excellent.
of patients. However, it was the post-operative follow up of 9th month when there was a statistically significant difference (P=0.004, P < 0.05α=0.05) that the excellence rate of Johner-Wruhs score was higher in SPN group. The clinical efficacy by Johner-Wruhs scoring system of the groups was not statistically significant (P>0.05α=0.05) at 1 months, 3 months, 6 months, 8 months, and 9 months after the surgeries.

**Figure (2):** IPN Pre-operation (a, anteroposterior; b, lateral) radiographs from a 35-year-old man after falling down. During the surgery, In the middle of longitudinal split patellar ligament directly (C), reduction and expansion of marrow needle (D,E) , implant the nail (F). Post-operation(G, anteroposterior; H, lateral) radiographs a week and the nine month Post-operation(I,K anteroposterior; L,J lateral); The HSS knee joint function score 86 points, the evaluation of Johner-Wruhs is good.
DISCUSSION

Since 1939, Kuntscher, et al (5) designed the first generation of stainless steel structure clover-shaped intra-medullary nail for the treatment of shaft fractures, the intra-medullary nail technology has now been through three generations of developments (6-7), due to its simple surgical procedures, small incisions, acceptable damage, easy removal and early-stage weight-bearing practice, prevention from local and systemic complications and many other advantages, confirmed by most traumatologists. Moreover, as for the aspect of biomechanism in the treatment of tibial shaft fractures, intra-medullary nailing internal fixation is provided with advantages such as restoring alignment and length and permission to early-stage weight-bearing practice, which now has been recommended for various types of fractures. Compared to the early unlocking intra-medullary nailing, the current interlocking technology is the “gold” standard (8-14) for the treatment of shaft fractures, for its feature on anti-rotation and prevention from shortness deformity for bony loss, due to comminuted or osteoporotic fractures (7).

Tibia is one part of lower extremities that bears weight, because its superficial location, vulnerable to direct violent force. The classical infra-patellar approach for intra-medullary nailing has been commonly applied in the treatment of this type of fractures. Although this is relatively mature, there still exists some problems with it in clinical practice as follows (1) The knee joint has to be placed in flexion over 120° to 130°, to expose the upper of tibial tuberosity, while reaming and implanting nail, which prolongs the surgical time and causes more repeated damage to soft tissue, due to anterior angular displacement which is hard to be reduced. In this study, 7 cases in IPN group was ultimately performed limited open reduction to solve this kind of problems, which accounts for 23.3% (2). Although the current reports do not draw firm conclusions about the causes of knee pain, it results in more complications with supra-patellar approach. Morandi, et al. (15) claimed that its irritation and friction with soft tissue while implanting nail had some connection with post-operative knee pain. Congfeng Luo, et al. (16) retrospectively analyzed 1332 cases of patients from January 1997 to December 2002 underdoing the surgical procedures with application of classical infra-patellar approach for intramedullary nail fixation in the treatment of tibial shaft fracture. As a result, a total of 409 cases of patients presented with postoperative ipsilateral anterior knee pain, which accounted for 31.9% in IPN group. In addition, Court-Brown, et al. (17) pointed out any type of surgeries that started from anterior direction of knee joint would result in postoperative pain or discomfort, especially in the case of kneeling down. In order to avoid directly splitting the patellar tendon that leads to postoperative anterior knee pain occurs, Tornetta and Collins (18) proposed in 1996 a tibial intramedullary nail internal fixation through knee joint in the treatment of tibial shaft fractures then Tornetta and Ryan (19) in late 2007 improved the technology of semi-extended approach for intra-medullary nailing in the treatment of tibial fractures, (20) which effectively reduced the incidence of post-operative knee pain. The study on the analysis of knee pain as the surgery complications, we found that mild and moderate pain in SPN group showed higher incidence (50.0% and 31.6%). However, severe knee pain in IPN group showed higher incidence (53.3%). This discovery shows that even though the supra-patellar approach had a certain effect on the patellofemoral joint and cartilage through knee joint, it caused more damage by directly splitting patellar ligament that contributed to post-operative knee pain. 3 cases in SPN group were performed lateral retinaculum lysis to reduce the patellofemoral tension for the purpose of prevention from the damage to articular cartilage, but which remained unknown to have any connection with knee pain. Furthermore, in the postoperative follow-ups, there was no significant difference between two groups in HSS score in the first month after surgery, but in the 3rd month, 6th month and 9 month of follow-ups, HSS score was higher than SPN group (see Table 3), and its difference of HSS score between two groups increased gradually along with follow-ups. The reason might be for the patients in IPN group weren’t able to cooperate with completion on early-stage practice due to post-operative knee pain, which at last impacts the rehabilitation results. While applying Johner-Wruhs scoring system on the
evaluation of clinical efficacy, although a significant difference occurs in 9th-month follow up, and on the contrary, there is no difference in the 1st, 3rd and 6th month of follow-ups, it was delicately observed that the overall tendency of clinical efficacy in IPN group decreases, compare with that in SPN group. It can be stated that both long-term clinical efficacy of two groups were not with consistency. It was speculated for its reason that its clinical efficacy could be interfered with multiple factors such as soft tissue adhesion and surgical incisions, however, from the perspective of long-term investigation, the symptom of knee pain increased significantly along with other factors being weakened gradually (21).

In addition, as for SPN group, when a “trocca” with a diameter over 2.5 cm was put through the patellofemoral joint, this situation will inevitably affect the articular cartilage, especially for those young patients. Beltran et al (22) drew a conclusion by 15 cases of cadaveric model between IPN and SPN group that it resulted in the same risk factor from both two surgical approaches. The damage was located within the medial side of drilling point, the medial meniscus injury was 6.7%, and the medial articular surface damage was 13%. And meanwhile, Gelbke et al (23) in the comparative study on IPN and SPN found: (1) The destruction of joint cartilage depended on the structural integrity of the impact load which was more than 25Mpa. (2) Chronic necrosis occurred in immature cartilage maintaining its load was less than 4.5Mpa. (3) The contact stress from patellofemoral joint was higher in SPN group, but they were below its damaging threshold on the articular cartilage. So, based on the last point, it cannot be negated the the surgical approach in SPN group was unsatisfactory. This study shows that, since the site of drilling point was set by repeatedly confirmed under fluoroscopic prospection, which made cumulative fluoroscopy time significantly higher in SPN group that required to provide better radiation protection on medical personnel and patients.

In the surgical indications on approaches, the study showed that the proximal 1/3~1/4 part and comminuted tibial shaft fractures should be considered firstly for SPN. Freemann and Johnson (24) report on 133 cases of patients treated with interlocking nailing for the treatment of tibial fractures, 12% of all were found the poor alignment, cases of which in the proximal 1/3 of tibial fractures reached 58%. In this study 7 cases in IPN group were carried out with a limited open reduction under direct vision, caused by the “second shift” of fragments at the extremely knee flexion. Fortunately, no flap necrosis and incision infection occurred. With the limitations on time and criterions for cases, it still remained unknown for its long-term prognosis and clinical efficacy for SPN, especially whether the cause of knee pain had something to do with the drilling point and patellofemoral joint hyper-tension is unknown.

REFERENCES


