Sterile silicone ring tourniquets in limb surgery: A prospective clinical trial in pediatric patients undergoing orthopedic surgery

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Research Article

Keywords: sterile silicone ring tourniquet, pediatric orthopedics, extremity surgery, bleeding control

Posted Date: March 6th, 2023

DOI: https://doi.org/10.21203/rs.3.rs-2579849/v1

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Abstract

Background
Sterile silicone ring tourniquets reduce intraoperative bleeding and provide a wide surgical view. Moreover, sterile silicone ring tourniquets reduce the risk of contamination and are more economical than conventional pneumatic tourniquets. The present study describes the perioperative outcomes of sterile silicone ring tourniquet placement in pediatric patients undergoing orthopedic surgery.

Methods
This study prospectively recruited 27 pediatric patients aged < 18 years who underwent 30 orthopedic surgeries between March and September 2021. Following complete surgical draping, all operations were initiated by placing sterile silicone ring tourniquets. We investigated the demographic and clinical characteristics of these patients, details about the tourniquet used, and intra- and postoperative outcomes of tourniquet placement.

Results
Thanks to the narrowness of tourniquet bands (< 2 cm) and tourniquet placement at the proximal ends of the extremities, wide surgical fields were achieved, without limiting joint range of motion. Bleeding control was effective. Tourniquets were applied and removed rapidly and safely, regardless of limb circumference. None of the patients experienced postoperative pain, paresthesia, skin problems at the application site, surgical site infections, ischemic problems, or deep vein thrombosis.

Conclusions
Sterile silicone ring tourniquets effectively reduced intraoperative blood loss and facilitated wide operative fields in pediatric patients with various limb sizes. These tourniquets allow for quick, safe, and effective orthopedic surgery on pediatric patients.

Background
Tourniquet use in orthopedic surgery enables bloodless operations and facilitates the identification of important anatomical structures. Conventional pneumatic tourniquets have been shown to control blood flow and reperfusion during surgical procedures; moreover, their reusability also makes them economical [1, 2]. Despite these advantages, there is a demand for other types of tourniquets in pediatric patients undergoing orthopedic surgery.

Pneumatic tourniquet cuffs are relatively wide enough to block blood flow. As children have relatively short limbs, the wide cuffs of pneumatic tourniquets cover greater areas in children than in adults. This can be a major obstacle in proximal extremity surgery [3]. Moreover, because limb size and circumference vary according to age, it is difficult to determine the adequate cuff size and amount of pressure in pediatric patients. In addition, the skin and soft tissues are more delicate in children than in adults, increasing the probability of skin injury or chemical burns in the areas where the tourniquet was applied [4].

Owing to these drawbacks, Esmarch bandage tourniquets have been regarded as alternatives to conventional pneumatic tourniquets. However, Esmarch bandage tourniquets are wide, making it difficult to control pressure at the application site [5]. Sterile silicone ring tourniquets are alternatives to pneumatic tourniquets in adults undergoing orthopedic surgery. These tourniquets are 2 cm wide, provide even pressure at compression sites, and result in a wider sterile surgical field [6]. Although sterile silicone ring tourniquets have been frequently used in adult patients, few retrospective studies have evaluated their effects in pediatric patients [3, 7].

This study aimed to investigate the effectiveness of sterile silicone ring tourniquets in pediatric patients undergoing orthopedic limb surgery. The intraoperative and postoperative outcomes of sterile silicone ring tourniquet application and complications in pediatric patients undergoing orthopedic limb surgery were prospectively evaluated.

Methods
Patient selection
Patients who visited the pediatric orthopedic clinic between March and September 2021 were prospectively recruited. Patients were included if they were (1) aged < 18 years and (2) scheduled to undergo upper or lower extremity orthopedic surgery. Patients were excluded if the expected tourniquet time was more than 2 h, had poor skin condition, were undergoing hip joint or shoulder surgery, had unstable limb fractures, or had musculoskeletal infections. A total of 27 patients (30 limbs) were included in the study.

**Sterile silicone ring tourniquet in limb surgery**

All surgeries were performed by a single senior pediatric orthopedic surgeon. Four sizes of sterile silicone ring tourniquets (Rapband; Rabmedicare, Gyonggi-do, Republic of Korea) were applied to provide different skin pressures with small, medium, large, and extra-large sterile silicone ring tourniquets respectively providing pressures of 200 ± 20, 230 ± 40, 310 ± 40, and 320 ± 20 mmHg. Each tourniquet comprised a silicone ring wrapped in a stockinet and two pulled straps. After complete aseptic draping and measurement of the circumference of the occlusion site, the most appropriately sized silicone ring tourniquet was selected and applied to the limb. The tourniquet was placed on the distal part of the limb and the two straps were pulled to the proximal part of the limb. The silicone ring was unrolled to its final location at the proximal site with exsanguination of the remaining blood. After the main surgical procedures were completed, the tourniquet was removed using a blade or pair of scissors.

**Variables investigated and statistical analysis.**

We recorded patient demographic characteristics and tourniquet information, including age, sex, diagnosis, surgical procedure, laterality, tourniquet application area, limb circumference, tourniquet size, and application time. Tourniquet outcomes included intraoperative and postoperative outcomes. The intraoperative outcomes included tourniquet application and removal times, changes in elbow or knee joint range of motion (ROM) before and after tourniquet application, adequate operative field visualization, and bleeding control evaluated by the number of gauze pads used. Postoperative outcomes included skin condition at the application site, surgical site infection, ischemic complications (compartment syndrome and distal neurovascular compromise), and deep vein thrombosis. In patients aged > 5 years, pain and paresthesia at the tourniquet site were evaluated 24 hours after surgery.

**Results**

The demographic characteristics of the patients and tourniquet information are presented in Table 1. The mean patient age was 9.8 ± 5.3 years (range:1–17 years) and mean limb circumference at the application site was 35.9 ± 16.1 cm (range:15–65 cm). All included operations were completed within 2 hours of tourniquet application with a mean operation time of 36.5 ± 29.7 min (range:5–110 min). The types of operations performed were various fracture reductions, soft tissue surgeries, and corrections of deformities.
Table 1: Demographic and clinical characteristics of the patients and applied tourniquets in this study

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Case no.</th>
<th>Age (year)</th>
<th>Sex</th>
<th>Diagnosis</th>
<th>Operation procedure</th>
<th>Laterality</th>
<th>Application area</th>
<th>Circumference* (cm)</th>
<th>Time (min)</th>
<th>Size</th>
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<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>3</td>
<td>F</td>
<td>Congenital trigger thumb</td>
<td>A1 pulley release</td>
<td>R</td>
<td>Upper arm</td>
<td>17</td>
<td>11</td>
<td>S</td>
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<tr>
<td>2</td>
<td>2</td>
<td>4</td>
<td>M</td>
<td>Congenital trigger thumb</td>
<td>A1 pulley release</td>
<td>R</td>
<td>Upper arm</td>
<td>20</td>
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<tr>
<td>3</td>
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<td>10</td>
<td>F</td>
<td>Pilomatrichoma</td>
<td>Mass excision</td>
<td>L</td>
<td>Upper arm</td>
<td>27</td>
<td>19</td>
<td>M</td>
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<tr>
<td>4</td>
<td>4</td>
<td>10</td>
<td>F</td>
<td>Ganglion cyst</td>
<td>Mass excision</td>
<td>R</td>
<td>Thigh</td>
<td>45</td>
<td>47</td>
<td>L</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>17</td>
<td>F</td>
<td>Lower leg deformity d/t neonatal sepsis</td>
<td>Plate change</td>
<td>R</td>
<td>Thigh</td>
<td>50</td>
<td>73</td>
<td>L</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>12</td>
<td>F</td>
<td>Talocalcaneal coalition</td>
<td>Coalition resection</td>
<td>R</td>
<td>Thigh</td>
<td>49</td>
<td>59</td>
<td>L</td>
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<tr>
<td>7</td>
<td>8</td>
<td>15</td>
<td>F</td>
<td>Jones fracture</td>
<td>ORIF by screw</td>
<td>R</td>
<td>Thigh</td>
<td>58</td>
<td>31</td>
<td>XL</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
<td>7</td>
<td>M</td>
<td>Both forearm fracture</td>
<td>CRIF with flexible elastic nail</td>
<td>L</td>
<td>Upper arm</td>
<td>23</td>
<td>21</td>
<td>M</td>
</tr>
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<td>9</td>
<td>10</td>
<td>14</td>
<td>M</td>
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<td>L</td>
<td>Thigh</td>
<td>44</td>
<td>9</td>
<td>L</td>
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<tr>
<td>10</td>
<td>11</td>
<td>9</td>
<td>M</td>
<td>Femur shaft fracture fixation status</td>
<td>Implant removal</td>
<td>L</td>
<td>Thigh</td>
<td>37</td>
<td>48</td>
<td>M</td>
</tr>
<tr>
<td>11</td>
<td>12</td>
<td>14</td>
<td>F</td>
<td>Accessory navicular bone</td>
<td>Accessory bone resection</td>
<td>R</td>
<td>Thigh</td>
<td>47</td>
<td>12</td>
<td>L</td>
</tr>
<tr>
<td>12</td>
<td>13</td>
<td>17</td>
<td>F</td>
<td>Distal tibia fracture fixation status</td>
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<td>L</td>
<td>Thigh</td>
<td>50</td>
<td>32</td>
<td>L</td>
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<td>14</td>
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<td>Upper arm</td>
<td>23</td>
<td>29</td>
<td>M</td>
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<tr>
<td>14</td>
<td>15</td>
<td>16</td>
<td>F</td>
<td>4th toe epidermoid cyst</td>
<td>Mass excision</td>
<td>R</td>
<td>Thigh</td>
<td>60</td>
<td>26</td>
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<td>M</td>
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<td>A1 pulley release</td>
<td>R</td>
<td>Upper arm</td>
<td>18</td>
<td>8</td>
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<td>17</td>
<td>3</td>
<td>M</td>
<td>Congenital trigger thumb</td>
<td>A1 pulley release</td>
<td>L</td>
<td>Upper arm</td>
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<tr>
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<td>18</td>
<td>1</td>
<td>M</td>
<td>Congenital trigger thumb</td>
<td>A1 pulley release</td>
<td>L</td>
<td>Upper arm</td>
<td>15</td>
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<td>S</td>
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<tr>
<td>18</td>
<td>19</td>
<td>5</td>
<td>M</td>
<td>Congenital trigger thumb</td>
<td>A1 pulley release</td>
<td>L</td>
<td>Upper arm</td>
<td>23</td>
<td>12</td>
<td>M</td>
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<tr>
<td>19</td>
<td>20</td>
<td>5</td>
<td>M</td>
<td>Lateral condylar fracture fixation status</td>
<td>Implant removal</td>
<td>L</td>
<td>Upper arm</td>
<td>24</td>
<td>90</td>
<td>M</td>
</tr>
</tbody>
</table>

no, number; cm, centimetre; min, minute; M, male; F, female; R, right; L, left; S, small; M, medium; L, large; XL, extra-large; ORIF, open reduction and internal fixation; CRIF, close reduction and internal fixation; CMT, Charcot-Marie-Tooth disease

* Circumference at the tourniquet application area.
<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Case no.</th>
<th>Age (year)</th>
<th>Sex</th>
<th>Diagnosis</th>
<th>Operation procedure</th>
<th>Laterality</th>
<th>Application area</th>
<th>Circumference* (cm)</th>
<th>Time (min)</th>
<th>Size</th>
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<tbody>
<tr>
<td>20</td>
<td>22</td>
<td>16</td>
<td>M</td>
<td>Distal femur fracture fixation status</td>
<td>Implant removal</td>
<td>L</td>
<td>Thigh</td>
<td>65</td>
<td>110</td>
<td>XL</td>
</tr>
<tr>
<td>21</td>
<td>23</td>
<td>12</td>
<td>M</td>
<td>Distal femur hemiepiphysiodesis status d/t idiopathic genu valgum</td>
<td>Implant removal</td>
<td>R</td>
<td>Thigh</td>
<td>46</td>
<td>40</td>
<td>L</td>
</tr>
<tr>
<td>22</td>
<td>25</td>
<td>1</td>
<td>M</td>
<td>Hand preaxial polydactyly</td>
<td>Extra-digit excision</td>
<td>R</td>
<td>Upper arm</td>
<td>15</td>
<td>80</td>
<td>S</td>
</tr>
<tr>
<td>23</td>
<td>26</td>
<td>12</td>
<td>F</td>
<td>Revisional Achilles tendon Z plasty</td>
<td>CMT with Achilles tightness</td>
<td>L</td>
<td>Thigh</td>
<td>43</td>
<td>85</td>
<td>L</td>
</tr>
<tr>
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<td>27</td>
<td>4</td>
<td>F</td>
<td>Congenital trigger thumb</td>
<td>A1 pulley release</td>
<td>R</td>
<td>Thigh</td>
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<td>S</td>
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<tr>
<td>25</td>
<td>28</td>
<td>12</td>
<td>M</td>
<td>Fifth finger proximal phalanx malunion</td>
<td>Deformity correction by pinning</td>
<td>R</td>
<td>Thigh</td>
<td>23</td>
<td>80</td>
<td>M</td>
</tr>
<tr>
<td>26</td>
<td>29</td>
<td>17</td>
<td>F</td>
<td>Lateral malleolar fracture fixation status</td>
<td>Implant removal</td>
<td>L</td>
<td>Thigh</td>
<td>47</td>
<td>35</td>
<td>L</td>
</tr>
<tr>
<td>27</td>
<td>30</td>
<td>14</td>
<td>F</td>
<td>Achilles tightness</td>
<td>Achilles Tendon lengthening</td>
<td>R</td>
<td>Thigh</td>
<td>60</td>
<td>12</td>
<td>XL</td>
</tr>
</tbody>
</table>

* Circumference at the tourniquet application area.

The tourniquet outcomes are presented in Table 2. All tourniquets were applied and removed within 15 s. Knee or elbow joint ROM was unaltered by tourniquet application. Therefore, there were no postural limitations during surgery (Fig. 1). The thin width of the ring tourniquet made it possible to easily expose lesions in the proximal limb, as it provided a sufficient surgical field (Fig. 2). The need for intraoperative gauze usage to control bleeding was only observed in three surgeries.
Table 2
Intraoperative and postoperative outcomes of sterile silicone ring tourniquets

<table>
<thead>
<tr>
<th>Tourniquet outcome parameters</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intraoperative outcome</strong></td>
<td></td>
</tr>
<tr>
<td>Tourniquet application time (sec)</td>
<td>7.5 ± 2.8 (range: 4 to 15)</td>
</tr>
<tr>
<td>Tourniquet removal time (sec)</td>
<td>5.4 ± 1.4 (range: 4 to 10)</td>
</tr>
<tr>
<td>Joint ROM between pre- and post-tourniquet application*</td>
<td>All cases showed the same joint ROM after tourniquet application</td>
</tr>
<tr>
<td>operative field visualization</td>
<td>All cases had sufficient operative field for surgery even after applying a tourniquet</td>
</tr>
<tr>
<td>Bleeding control (gauze counting)</td>
<td>Gauze not used to control bleeding in 27 cases</td>
</tr>
<tr>
<td>2 cases used 1 gauze - ORIF by screw for Jones fracture, mass excision for Trevor’s disease</td>
<td></td>
</tr>
<tr>
<td>1 case used 2 pieces of gauze – Plate change for deformity due to neonatal sepsis</td>
<td></td>
</tr>
</tbody>
</table>

| **Postoperative outcome** |         |
| Skin problem at the tourniquet application site | None of these cases experienced skin problems, including bullae, necrosis, hematoma, contusion, or burn |
| Surgical site infection | None of these cases experienced surgical site infection |
| Ischaemic complications | None of these cases showed ischaemic complications, including compartment syndrome or neuromuscular compromise |
| Deep vein thrombosis | None of the 30 cases showed deep vein thrombosis |
| Pain at tourniquet application site** | No case experienced pain |
| Abnormal sensory change at tourniquet application site** | No case experienced abnormal sensory changes |

sec, second; ROM, range of motion; ORIF, open reduction and internal fixation

* The elbow joint was evaluated for upper extremity surgeries, and the knee joint was evaluated for lower extremity surgeries.

** Evaluated 24 hours after surgery in patients aged ≥ 5 years.

Postoperative evaluation showed no soft tissue damage, such as skin necrosis, abrasion, bullae, petechiae (Fig. 3), or surgical site infections. None of the patients experienced compartment syndrome, deep vein thrombosis, or distal neurovascular compromise due to ischemic damage to the tourniquet. None of these patients reported pain or neurological deficits around the tourniquet ring site 24 h after surgery.

Discussion
The sterile silicone ring tourniquet is a single-use device that enables the exposure of a larger proximal area compared to conventional pneumatic compression tourniquets. The volume of the sterile silicone ring tourniquet is small and does not restrict joint movement during surgery. Postoperative evaluation showed no evidence of surgical site infections, skin problems, or ischemic changes when tourniquet application was completed within 2 hours. This study found that sterile silicone ring tourniquets were effective in pediatric patients with varying limb sizes and circumferences.

Sterile silicone ring tourniquets for pediatric patients
Limb circumference increases as children grow until they reach skeletal maturity [8, 9]. Therefore, it is essential to select appropriate tourniquet cuffs and pressure based on the circumference of individual limbs in pediatric patients undergoing orthopedic surgery. Because pneumatic tourniquet cuffs must be sterilized for intraoperative use, the cuff size must be determined at least several hours before surgery. In contrast, cuff sizes for silicone ring tourniquets can be determined based on limb circumference after surgical draping.
The present study included patients aged 1–17 years with limb circumferences ranging from 15 to 65 cm. In addition, the nature of pediatric fractures, such as supracondylar and lateral condylar fractures, can lead to intraoperative changes from pre-planned surgical methods, including conversion from closed reduction to open reduction [10, 11]. This conversion is difficult in the absence of a sterilized pneumatic tourniquet. In contrast, silicone ring tourniquets can always be applied, even during unplanned alterations of the surgical methods; moreover, both application and removal can be completed within 15 seconds.

Intraoperative outcomes of sterile silicone ring tourniquet

Sufficient operative fields were secured in all 30 limbs analyzed in this study. The proximal limb length exposed by ring-type tourniquets is longer than that exposed by conventional pneumatic tourniquets [12, 13]. This is because pneumatic cuffs are 8–14 cm wide when added to surgical drapes, making it difficult to expose the proximal surgical site in young children with short limb lengths. In contrast, silicone ring tourniquets provide better limb exposure because their final cuff width is approximately 2 cm. This has been a great advantage in operations that require maximal exposure of the upper thigh or arm, such as soft tissue tumor removal or proximal limb fixation surgery [14]. In addition, the application of silicone ring tourniquets did not decrease joint ROM. In obese patients, the thickness of inflated pneumatic cuffs makes it difficult to obtain full ROM during surgery. In contrast, because they are narrower, silicone ring tourniquets do not alter joint ROM. These tourniquets are not restricted by changes in posture, thus allowing for an easier surgical approach. Moreover, bleeding control with silicone ring tourniquets was similar to that of conventional tourniquets in adults undergoing orthopedic surgery [15]. In this study, most operations were bloodless and gauze was generally not required. Therefore, this type of tourniquet minimizes blood loss in pediatric orthopedic surgery.

Postoperative outcomes of sterile silicone ring tourniquet

None of the patients in the present study experienced skin problems such as bullae, necrosis, hematoma, contusion, or burn wounds at the tourniquet application site. Because children have softer and more fragile soft tissue than adults, tourniquets may be harmful postoperatively [3]. However, proper application of skin protection can protect the soft tissue from damage caused by tourniquet usage [4, 16]. None of the patients in this study experienced skin or soft tissue problems even 24 hours postoperatively. In addition, none of the patients experienced surgical site infection. Although the reuse of pneumatic tourniquets is economical, they can be a source of infection even after sterilization [17, 18]. One study showed significant bacterial contamination in 68% of orthopedic surgical tourniquets, suggesting that bacteria may be transferred between operated patients [19]. In contrast, silicone ring tourniquets are both sterile and disposable, thereby reducing the risk of surgical site infections [19]. Tourniquet use has also been associated with ischemic complications and deep vein thrombosis. High pressure and prolonged obstruction of arterial blood flow induce ischemic changes in the limbs. Moreover, ischemic tissue perfusion after blood circulation resumes can lead to secondary injury, including compartment syndrome and distal neurovascular problems, with the remaining blood possibly causing deep vein thrombosis [5, 20]. Ischemic soft tissue damage did not differ between silicone rings and pneumatic tourniquets [21, 22]. In addition, silicone ring tourniquets effectively minimize residual blood in the extremities by compressing the limb while unrolling it from the distal end to the proximal site. This procedure provides effective exsanguination and may significantly reduce deep vein thrombosis. None of the patients in the present study experienced pain or sensory problems at the tourniquet site within 24 hours postoperatively. According to previous studies, the incidence of pain and paresthesia among patients who underwent silicone ring tourniquet application was comparable or lower than the incidence of these complications among patients who underwent pneumatic tourniquet application [23, 24].

The present study has several limitations. First, it was a prospective clinical trial and not a comparative study. Moreover, the target patient population was heterogeneous, with patients of different ages and limb sizes undergoing different types of surgery. Second, this study reported the short-term results of sterile silicone ring tourniquet application. Most complications associated with tourniquet application appear within a short period of time, suggesting that a short follow-up period may provide significant results; however, long-term follow-up is warranted. Finally, the study had a limited sample size, with only 30 cases among 27 patients being included. Because silicone ring tourniquets were developed for use in adults, few studies have evaluated these tourniquets in pediatric patients. Comparative trials with a larger number of patients are warranted.

Conclusions

Sterile silicone ring tourniquets are easily applicable to preset pressure models. These tourniquets provide a sufficient surgical field in pediatric patients undergoing surgery on their extremities because they are located at a more proximal site on the extremities. Moreover, their application within 2 hours can ensure successful results without related complications.

List Of Abbreviations
Declarations

Trial registration number

CRiS Registry number KCT0008221 (registration date: 23/02/2023)

Ethics approval and consent to participate

The study was approved by the Institutional Review Board of Severance Hospital (IRB No. 1-2020-0076). All procedures were followed in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all individual participants included in the study or their parents.

Consent for publication

Not Applicable

Availability of data and materials

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

Funding

This research was funded by Rapmedicare Co., Ltd., Republic of Korea

Authors' contributions

Conceptualization: YHK. Methodology: KB, GK, AMA, YG, YHK. Formal analysis and investigation: KB, GK, AMA, YG, YHK. Writing – original draft preparation: KB, GK, YHK Writing – review and editing: KB, YHK. Funding acquisition: YHK. Supervision: YHK.

Acknowledgements

Not applicable

References


Figures
Figure 1

**Knee joint range of motion (ROM) between silicone ring and pneumatic tourniquets**

Comparison of knee joint range of motion (ROM) between silicone ring tourniquet in the right lower leg (a) and pneumatic compression tourniquet (b) in the left leg for a 12-year-old male patient with both-side hemiepiphysiodesis. After silicone ring tourniquet application, the right knee joint still had full flexion; however, the left knee joint showed limited flexion due to the inflated pneumatic cuff.

Figure 2

**Size of surgical fields between silicone ring and pneumatic tourniquets**

Comparison of surgical fields for (a) a sterile silicone ring tourniquet and (b) a conventional pneumatic tourniquet. Silicone ring tourniquets are much narrower than conventional pneumatic tourniquet cuffs (2 cm vs 8–16 cm), allowing for better surgical site
exposure. Surgical field after application of a silicone ring tourniquet in (c) a 10-year-old girl with pilomatricoma excision at the upper right arm and (d) a 16-year-old boy with open reduction and internal fixation of a femur shaft fracture. Both patients required maximal exposure of the proximal limb, making it mandatory to use silicone ring tourniquets rather than pneumatic tourniquets.

Figure 3

Compression effect of the silicone ring on the skin

(a) Compressed skin (arrow) immediately after silicone ring tourniquet removal. (b) Skin compression lesion returned to a normal status 8 hours after silicone ring tourniquet removal.