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EBP Mentors: Emily Brennan MLIS, and Elizabeth Crabtree MPH

ASK THE QUESTION

Question 1: For patients undergoing Total Knee Arthroplasty requiring tourniquet use, what time and pressure settings will reduce or eliminate tourniquet-related injuries? Will these guidelines differ for overweight and obese versus normal BMI patients?

Objective: Evaluate the evidence to determine the most effective tourniquet use protocol (e.g. pressure, time) during Total Knee Arthroplasty.

Background: Pneumatic tourniquet use is required during some orthopedic surgeries which involve extremities, such as in total knee arthroplasty. This affects a significant portion of the population, as more than 600,000 total knee arthroplasties are performed in the U.S. alone, (American Academy of Orthopedic Surgeons, 2011). Benefits of tourniquet use include: visualization, reduction of surgical blood loss, improved adherence of cement to bone and therefore better contact with implants, and shorter surgical time. Potential patient complications include: blood loss, pain, impaired mobility, reduced range of motion, ischemia, nerve injury, VTE, swelling, stiffness, compromised wound healing, and fat necrosis. While surgeons utilize a variety of tourniquet time and pressure protocols, they are often unaware of the evidence to support them. Knowing that the United States' healthcare system is facing an increasingly older, heavier population, this demonstrates a need for unified guidelines for tourniquet use in total knee arthroplasty.
SEARCH FOR EVIDENCE

Search strategies: included adult orthopedic patients of both genders, normal weight and obese/overweight patients, total knee arthroplasty, orthopedic surgery using tourniquets, publications written in English, research-based professional journals, AO and AORN professional recommendations, and articles published within the last 10 years

Databases: included PubMed, CINAHL, and Google Scholar. I also reviewed www.aofoundation.org and www.aorn.org for professional recommendations

Key words/terms: included time, length, ideal use, pressure, mmHg, psi, extremity surgery, total joint replacement, trauma, orthopedic trauma, orthopedic surgery, patient injury, vascular injury in orthopedic surgery, mobility restrictions, impaired mobility, nerve injury, immobility, impaired mobility, obese patients, obese, morbidly obese, overweight, overweight patients

CRITICALLY ANALYZE THE EVIDENCE

Question 1: For patients undergoing Total Knee Arthroplasty requiring tourniquet use, what time and pressure settings will reduce or eliminate tourniquet-related injuries? Will these guidelines differ for obese versus normal BMI patients?

Grade Criteria: Tourniquets should be used during Total Knee Arthroplasty if desired by surgeon for visualization and improved adherence of cement and implants. However, they must be used cautiously, checking patients pre-operatively for co-morbidities that could predispose them to problems related to skin breakdown, risk for infection, nerve injury, or conditions that may increase sensitivity to hemodynamic shifts. These patients must also be checked post-operatively for complications such as signs of infection, excessive blood loss, reduced mobility, sensation deficits and other negative potential consequences of tourniquet use. A pressure less than 250 mmHg for less than 100 minutes is recommended based on these articles and those cited by these studies, but systolic + 100 mmHg or the Limb Occlusion Pressure methods are both secondary options to use if the surgeon is resistant to the 250 mmHg or less guideline. Strong Recommendation, Moderate Quality Evidence. Neither specific guidelines nor studies concerning tourniquet use in the overweight and obese patient population could be found.
Four RCTs, two systematic reviews/meta analyses, and three professional recommendations were found, which all offer data on effectiveness of various tourniquet use parameters or professional recommendations on tourniquet use. Studies consistently found that intraoperative blood loss was always lower among surgeries using tourniquets versus those not using tourniquets and they improved cement/implant adherence to bone, as expected, but that total blood loss during the perioperative time period was not necessarily reduced.

One RCT studying 36 TKA patients found that inflating the tourniquet before incision and deflating after the cement had set up allowed patients in that group to leave the hospital quicker, become mobile faster and experience less blood loss (Kvederas et al., 2012). “Group 1 better fit for discharge vs. Group 3” p=0.030  TUG: Group 1<Group 2 p=0.023 Group 1 < Group 3 p=0.033

Another RCT found that markers of inflammation did increase when using a tourniquet, but not to a level that affected function, (Huang et al., 2013). No significant differences were found among groups for HSS knee score, ROM, estimated blood loss, swelling ratio, VAS pain score, hospital stay.

Olivecrona, Lapidus, Benson & Blomfeldt (2013) demonstrated a greater risk of complications (OR 2.2, CI 1.5–3.1) for tourniquet use beyond 100 minutes, even after adjusting for patient variables. Furthermore, they found that for each additional 10 minutes beyond this time, the likelihood of problems increased significantly, by 20% per 10 minute interval (OR 1.2, CI 1.1–1.4, p<0.001). Pressure did not show an effect in this study. In another study, Olivecrona, Ponzer, Hamberg & Blomfeldt (2012) found no differences in patient outcomes except for stiffness on day 4, where there was less stiffness in the Limb Occlusion Pressure vs control groups (P=0.020). The Limb Occlusion Pressure method did tend to result in lower pressures being used, and no patients with a pressure less than 225 mmHg developed any wound complications. An important empirical finding worth noting is that women developed complications from extended tourniquet time more often than men. While this was not statistically significant, it is important to consider nonetheless while caring for patients. (OR 3 women, OR 1.6 men) (39% women >100 mins vs 29% men >100 mins)

Two systematic reviews were selected, and both found a great deal of heterogeneity between the studies that they examined. Both studies found that intra-op blood loss was less when using a tourniquet vs no tourniquet at a significant level, but total and post-op blood loss did not differ between groups in either study. One review (Alcelik et al., 2012) found that the non-tourniquet group did get better first post-op week flexion, but there was no effect on flexion at follow-up appointments at four and twelve months (CI 95%). Minor complications occurred more frequently with tourniquet (23/160) vs no tourniquet (9/160) at a value of p=0.01 in the same study. No significant differences between tourniquet and non-tourniquet groups among: total surgical time, other outcomes. The other review (Smith & Hing, 2013) found that complications appeared more often when tourniquet was used, but due to statistical heterogeneity,
A meta-analysis was not performed and significance could not be determined. Problems found included blisters, DVT, PE, and problems with healing.

AORN recommendations (2002) include pressure guidelines of systolic + 100-150 mmHg for the lower extremity and a time length of 90-120 minutes maximum. If more time is needed, must deflate for ten minutes and before reinflating. No pressure or time guidelines were given for obese patients in the Booth (2002) article. No other articles were found which cited time or pressure guidelines for overweight patients.

<table>
<thead>
<tr>
<th>PICO Question # 1</th>
<th>Author/Date /Journal</th>
<th>Purpose of Study</th>
<th>Study Design</th>
<th>Sample&amp; Setting</th>
<th>Outcomes</th>
<th>Design Limitations</th>
<th>Lower Quality Rating if:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kvederas, G., Porvanecka, N., Andrijauska, A., Svensen, C. H., Ivaskevicius, J., Mazunaitis, J., Andrijauska, P., 2012, Knee Surgery, Sports</td>
<td>To apply a tourniquet to the lower extremity during total knee arthroplasty using three different methods in order to determine the most effective method in terms of optimal patient outcomes. In this case, those are defined as minimizing blood loss within the first 24 hours after surgery, the effect of</td>
<td>RCT Randomization into three groups 1. Inflation before incision/deflation after cement hardened (n=12) 2. Inflation immediately before cement/deflated after hardened</td>
<td>36 TKA patients -Republic Vilnius University Hospital, Vilnius, Lithuania January 2010-July 2011 -50-80 yrs of age - BMI 20-40kg/m2</td>
<td>Inflating a tourniquet before initial surgical incision and deflating that tourniquet after cement has hardened results in lower blood loss, quicker discharge from the hospital and better TUG scores versus other tourniquet utilization methods -Best mobilization, in order: Group 1, Group 2, Group 3</td>
<td>Study Limitations = ☑ None RCT &amp; Quasi-Experimental Studies ☑ Insufficient sample size ☑ Lack of randomization ☑ Lack of blinding ☑ Stopped early for benefit ☑ Lack of allocation concealment</td>
<td>Studies inconsistent (When there are differences in the effect, populations, interventions or outcomes between studies) Studies are indirect (Your PICO question is quite different from the available)</td>
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a tourniquet on the “timed up and go (TUG) test and “fit-to-discharge” criteria, which are both determining factors in discharging TKA patients from the hospital.

(n=12)
3. Inflation before initial incision/deflated after closure of skin/dressing app. (n=12)

Effectiveness Assessment Criteria:
1. ability to discharge from hospital
2. amount of blood loss
   - automatic lower limb pneumatic tourniquet system used, leg exsanguinated and elevated before inflation
   - same Dr. & surg. technique/same anesthetist
   - ICU 24hrs
2. Group 3
   - Lowest Blood Loss: Group 1 lost less than Group 2
   - By multiple calculations; Group 2 only lost less than Group 3 under one calculation
   - “Group 1 better fit for discharge vs. Group 3” p=0.030
   - TUG: Group 1 < Group 2 p=0.023
   - Group 1 < Group 3 p=0.033
   - All p=0.035
   - Wound healing, body temp and pain control similar among all participants
   - Results significant at a p value of 0.05 or less

☐ Selective reporting of measures
☐ Large losses to F/U a representative sample

Evidence in regard to population, intervention, comparison, or outcome

☐ Studies are imprecise (When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)

☐ Publication Bias (e.g. pharmaceutical company sponsors study on effectiveness of drug)

Increase Quality Rating if:
☐ Large Effect
<table>
<thead>
<tr>
<th>post-op</th>
<th>Cold therapy 2-3 hrs after sx.</th>
<th>H&amp;H measured via radial ART line 7am next day</th>
<th>Epidural analgesia first 24 hrs bupivacaine &amp; fentanyl; single-shot bupivacaine every 6 hours for next 48 hours</th>
<th>Epidural removed at 48 hrs</th>
<th>NSAIDS as needed</th>
<th>Mobilization started 9am first post-op day</th>
<th>PT daily</th>
<th>Level of evidence for studies as a whole:</th>
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Level of evidence for studies as a whole:
- High
- Moderate
- Low
- Very Low
- TUG: second post-op day
- Discharge Criteria measured for 6 post-op days: pain control only oral NSAIDs during previous 24 hours; TUG < 20 seconds; normal wound healing; body temp <37.7°C previous 24 hours


The goal of this study was to measure blood loss as well as inflammatory and muscle damage markers during Total Knee Arthroplasty. Values measured included: serum C-reactive protein, IL-6, creatine kinase and myoglobin (i.e. inflammatory markers).

Prospective comparative clinical trial
- Non-randomized
- same surgeon
- general anesthesia
- same OR
- Ancef within

-90 patients, 30 per group
- Group A: tourniquet used during entire surgery (before initial incision/deflated after closure)
- Group B: tourniquet inflation prior to initial

- Using a tourniquet throughout the entire surgery leads to less blood loss, yet increased inflammation and muscle damage. This may result in damage to tissues even though it didn’t have a clear effect on patient function. No differences in swelling post-op, pain or length of

Study Limitations
- None
- Insufficient sample size
- Lack of randomization
- Lack of blinding
- Stopped early for benefit
- Lack of
<table>
<thead>
<tr>
<th>30 mins of incision</th>
<th>30 mins of incision/deflation once cement hardened</th>
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<tr>
<td>- 100 mmHg above systolic BP</td>
<td>- Group C: tourniquet use during cementation process only i.e. before implants, deflated after cement hardened</td>
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<tr>
<td>- single cuff size</td>
<td>- Sichuan University, China</td>
</tr>
<tr>
<td>- Vacuum wound drain for all pts</td>
<td>- June 2012-July 2012</td>
</tr>
<tr>
<td>- Cold pack first 12 hours</td>
<td>incision/deflation once cement hardened</td>
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<tr>
<td>- Foley removed 7:30am first post-op day</td>
<td>stay. No indication that partial use of tourniquet is beneficial.</td>
</tr>
<tr>
<td>- PT first post-op day</td>
<td>- Group C had lowest H&amp;H on average</td>
</tr>
<tr>
<td>- Discharge criteria: &quot;stable wound&quot;; knee flexion to 90 degrees; smooth straight leg raise</td>
<td>- Inflammatory markers/muscle damage indicators measured lower in Group C</td>
</tr>
<tr>
<td></td>
<td>- No significant differences among groups for HSS knee score, ROM, estimated blood loss, swelling ratio, VAS pain score, hospital stay</td>
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<td></td>
<td>- IL-6 lower for Groups B &amp; C vs Group A except Post-op day 3</td>
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<tr>
<td></td>
<td>- CK highest post-op day 2/avg levels lower in Group C than Group A and Group B/no sig differences between A &amp; B</td>
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<tr>
<td>allocation concealment</td>
<td>□ Selective reporting of measures</td>
</tr>
<tr>
<td>□ Large losses to F/U a representative sample</td>
<td></td>
</tr>
<tr>
<td>Smith, T. &amp; Hing, C.</td>
<td>To review evidence surrounding whether using a tourniquet or not during a Total Knee Arthroplasty is more beneficial as</td>
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| Is a tourniquet beneficial in total knee | q3months  
- H&H measured pre-op, immed. Post-op, post-op day 1, 2, 3  
- HSS, ROM measured at charge, d/c and f/u visits | - Mean CK: Group C lowest/no sig diff between Groups A & B  
- Myoglobin: lowest in Group C post-op day 1 vs Group B/no sig diff post-op day 2 and 3 among any groups  
- All groups shows HSS improvement (increases)  
HSS = Hospital for Special Surgery knee score  
-ROM: No sig differences achieved btwn any groups | | | |
replacement surgery? A meta-
analysis and systematic review
The Knee 17 (2010) 141–147

Medline, CINAHL, AMED and
EMBASE, in addition to a review of
unpublished material and a hand search of
pertinent orthopaedic journals

-critical appraisal: Cochrane Bone,
Joint and Muscle Trauma Group Quality
Assessment Tool by 2 reviewers

-looked for: intra-op, post-op and total blood
loss, requirement for transfusion, operative time, operation
problems,
surgery and its benefits

-total blood loss did not differ to a
significant degree whether tourniquet
was used or not

-no significant differences found for transfusion need, operation time length, no change in hospital stay

-complications appeared more often when tourniquet was used, but due to statistical heterogeneity, meta-
analyses was not performed and significance cannot be
determined. Problems found included blisters, DVT, PE, and problems with healing.

Systematic Review
☐ Review did not address
focused clinical question
☐ Search was not detailed or
exhaustive
☒ Quality of the studies was not
appraised or studies were of
low quality
☒ Methods and/or results
were inconsistent across studies
| Olivecrona, C., Lapidus, L. J., Benson, L., & Blomfeldt, R., 2013, *International Orthopedics* | To determine whether tourniquet time has an effect on post-operative patient outcomes in primary and secondary TKAs | Prospective register study  -577 primary TKAs  -46 revision TKAs  -18 patellar supplementing TKAs  -post-op complications tracked: infection of surgical wound superficial vs deep, DVT, PE, nerve injury, compartment 577 primary knee arthroplasties (465 total knee arthroplasties and 112 unicompartmental knee arthroplasties), 46 revision knee arthroplasties, and 18 patellar supplementing knee arthroplasties was identified in the registry during the period 1999–2003 | -surgeries requiring tourniquet times over 100 minutes showed greater risk of complications (OR 2.2, CI 1.5–3.1) even after adjusting for patient variables  -likelihood of problems increased 20% for each additional 10 minutes of time beyond 100 minutes (OR 1.2, CI 1.1–1.4).  P<0.001  OR = Odds Ratio -more women had | Study Limitations  □ None  □ Insufficient sample size  □ Lack of randomization  □ Lack of blinding  □ Stopped early for benefit  □ Lack of allocation concealment  □ Selective reporting of measures  □ Large losses to F/U |
| Syndrome, cuff pressure injury & bandage injury | 16 patients undergoing revision knee arthroplasty, the tourniquet cuff was deflated and then re-inflated because of a prolonged surgery time. The mean reperfusion interval was 29 minutes, (standard deviation [SD] 12) and the second tourniquet time ranged from 15 to 76 minutes. The longest total bloodless field period was 193 minutes. | Problems with tourniquet times over 100 mins than men (OR 3 women, OR 1.6 men) (39% women >100 mins vs 29% men >100 mins) But not statistically significant |
| -Current recommendations are no more than two hours for patients without co-morbidities, and based primarily on animal studies | -A standard 140-mm-wide contour thigh | -Patients suffering post-op problems (168 ppl or 26% of participants) 94/168 did have a tourniquet time >100 mins, but not at a statistically significant level |
| -Protection under tourniquet: cast padding, a two layer elastic stockinette or, in some patients, no protection at all- had been protocol for years. | Department of Orthopedics at Södersjukhuset | -Mean tourniquet time for complication group: 104 mins |
| -A standard 140-mm-wide contour thigh | -Mean tourniquet time non-complication group: 95 mins |
| | -Those rated at greater risk for anesthesia had more complications; ASA 2 

Department of Orthopedics at Södersjukhuset
| Olivecrona, C., Ponzer, S., Hamberg, P., & Blomfeldt, R., 2012, *The Journal of Bone and Joint Surgery. American Volume* | Determining whether the limb-occlusion-pressure method results in better patient outcome following TKA versus using patient’s systolic BP and surgeon’s preference. Patient outcomes measured: post-operative pain, post-operative ROM, post-operative wound Prospective, randomized controlled trial - L-O-P method: automated photoplethysmographic sensor connected to tourniquet machine. - Safety margins: 50mmHg for pressures 164 patients - 83 Patients randomized to control group (systolic blood pressure/surgeon’s discretion) or test group with 78 (limb-occlusion-pressure method) -October 2008 to July 2010 | and 3 ratings greater complications than ASA 1 (OR 2.5, 2.9). -mean pressure 259 mmHg but pressure showed no significant effect on outcomes -99.3% follow-up participation | Study Limitations = □ None
□ Insufficient sample size □ Lack of randomization ✗ Lack of blinding □ Stopped early for benefit ✗ Lack of allocation

| tourniquet cuff or a 100-mm wide cylindrical tourniquet cuff has been used. -pressure: surgeon preference, typically systolic + (did not say plus what) -tourniquet time btwn 39-156 minutes | in Stockholm, Sweden | - L-O-P method used a low pressure aka <225 mmHg vs control group more often P<0.001 - Mean tourniquet pressures not significantly different btwn groups even though LOP typically lower -No difference btwn.
complications immediately after TKA and 2 months later. Also measured blood loss during surgery.

- 130mmHg and below; 75mmHg for 131-190mmHg; 100mmHg for pressures 191mmHg
- 140mmHg tourniquet used for all patients except 100mmHg tourniquet for 7 patients
- Surgeon blinded to tourniquet pressure/assigned group
- Post-op skin looked at immediately after surgery and post-op day 4
- Function checked post-op day 3

- Department of Orthopaedics, Södersjukhuset Karolinska Institutet, Stockholm, Sweden
- 75 yrs or younger
- No differences among sex, BMI, age, ASA class, pre-op systolic BP, bloodless field time
- Avg pre-op systolic arm BP: 122 +/- 20 mmHg LOP, 119 +/- 19 mmHg

L-O-P vs control groups with post-op pain

- No significant effect of lower tourniquet pressure in LOP found for reducing post-op complications except stiffness day 4
- Less stiffness in LOP vs control day 4 p=0.020
- ROM no different day 3
- No differences as far as patient outcomes regardless of group

- Patients having had a TKA with a tourniquet pressure <225mmHg were NOT within the post-op complications group/no infections

concealment
☐ Selective reporting of measures
☐ Large losses to F/U a representative sample
- Patients self-reported pain, function and stiffness using same questionnaire
  - 2 month visit: looked at wound, ROM, completion of same self report
  - Complications: infections, blisters on thighs from tourniquet, oozing at wound
  - Mean pressure: 252 mmHg
    Control/range: 200-300 mmHg
  - L-O-P mean: 169 mmHg/range: 150-300 mmHg

- >78cm, unable to read/understand Swedish

- No differences at 2 months re: ROM or patient pain, function and stiffness report
- Post-op problems unexpectedly high (47/164). These pts had pressure >225 mmHg

Alcelik, I., To perform a meta-systematic pool of 277

- Intra-op blood loss

Study Limitations

<p>| Analysis/systematic review of 10 randomized, controlled trials of tourniquet use studies to determine patient outcomes in TKA with and without tourniquet use. Various patient parameters were assessed, including length of surgical procedure, blood loss during and after surgery, DVT, PE and minor/major complications | Review/meta-analysis setting: United Kingdom Cochrane guidelines for systematic review were used/reviewed RCTs that compared tourniquet vs no tourniquet in TKA studies. - had to examine length of surgery, blood loss, ROM, DVT, PE, minor, major complications. - did not look at non-English language studies, no animal studies, no major differences among study participants, such as studies cut to 10 studies after critical appraisal performed. 493 patients total among all studies: 65 males/tourniquet, 184 females/tourniquet. 69 male/non-tourniquet, 175 female/non-tourniquet. 70.4 yrs mean age among BOTH groups, range 38-89 yrs tourniquet. 43-91 years non-tourniquet. | was less when using a tourniquet vs no tourniquet p &lt;0.001 - no noticeable effect between blood loss and total tourniquet time and no sig differences in post-op blood loss. Obviously total blood loss is sig lower in tourniquet group p &lt;.001 - ROM only reported in 3 studies, but non-tourniquet group did get better first post-op week flexion; no effect on long-term flexion (4 &amp; 12 months) Cl 95% but no p-value given/no meta-analysis possible r/t lack of data. - minor complications occurred more frequently with tourniquet (23/160) |</p>
<table>
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<tr>
<th>anesthetic drugs</th>
<th>vs no tourniquet (9/160) use p=0.01</th>
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<tbody>
<tr>
<td>-used Medline, EMBASE, reference lists scoured for compatible studies searched abstracts and CONSORT checklist to review quality of RCTs</td>
<td>-no sig difference between tourniquet and non-tourniquet groups among: total surgical time, other outcomes</td>
</tr>
</tbody>
</table>

**APPLY THE EVIDENCE**

- Tourniquets should be used during Total Knee Arthroplasty if desired by surgeon for visualization and improved adherence of cement and implants. However, they must be used cautiously, checking patient pre-operatively for co-morbidities and post-operatively for complications.
- A pressure less than 250 mmHg for less than 100 minutes is recommended based on these articles and those articles cited by the authors.
- Systolic + 100 mmHg or the Limb Occlusion Pressure methods are both secondary guidelines (recommended by AORN and the literature) to promote if the surgeon is resistant to the 250 mmHg or less guideline.
- Recommendations may change for overweight and obese patients down the road when more evidence becomes available. Currently, no studies could be found which made specific time and pressure recommendations for overweight and obese TKA patients.
- The results of the studies on tourniquet use in Total Knee Arthroplasty contained a lot of heterogeneity and a limited number of definitive, numerical guidelines. Professional recommendations, such as those indicated by AORN, are more clear in their guidelines for time and pressure.
EVALUATE THE EVIDENCE

Outcome & Process Measures:
- Percent of surgeons utilizing 250 mmHg or less tourniquet pressure settings for TKA
- Percent of surgeons utilizing 100 minutes or less total tourniquet times for TKA
- Assess nursing staff knowledge of tourniquet use recommendations

Implementation Plan:
- Present evidence summary to key stakeholders
- Develop education table/CATTS module detailing recommended tourniquet use settings
- Attach education table to tourniquet machines, if approved by stakeholders
- Present recommendation to Orthopedic Working Group, Orthopedic Surgery Department Chair, Orthopedic Service Coordinator, and Director of Surgical Services
- Consider undertaking a randomized, controlled trial research study in the MUSC orthopedic operating rooms to address a. developing tourniquet time and pressure guidelines for overweight and obese patients and/or b. designing/testing wider, contoured tourniquets specifically for overweight and obese patients

REFERENCES


