achieve. During secondary tightening, the CAT windlass was significantly faster than the TMT ($p < 0.05$) but not significantly different from the RMT ratchet.

The RMT took significantly longer ($p < 0.05$) than both the CAT and TMT to generate intial strap tension (30.7 ± 10.5 sec). The RMT requires the user to unthread and rethread the tourniquet strap through its dual slip lock rings during the two-handed application, which was more time consuming than the strategies employed by the other devices. The slow initial tightening was offset, however, by a rapid secondary tightening (16.7 ± 13.8 sec). The RMT ratchet took, on average, less time than both windlass designs to tighten, and was significantly faster than the TMT ($p < 0.05$), but not the CAT.

The TMT windlass took significantly longer ($p < 0.05$) than the CAT windlass and the RMT ratchet to generate secondary pressure during leg applications (24.8 ± 9.2 sec). The smaller TMT windlass may have been more difficult to manipulate, and users often struggled to secure the windlass into the locking clip, even with both hands available; however, the TMT initial strap tightening, which took 23.2 ± 7.1 seconds, was significantly faster than the RMT ($p < 0.05$). The TMT employs a hooked clasp that enables the tourniquet to be routed around the leg during two-handed applications, without the need to unthread and rethread the strap through the slip lock mechanism. While the TMT clasp was faster than the dual slip lock rings of the RMT, the clasp was not faster than the CATs single-looped buckle strategy.

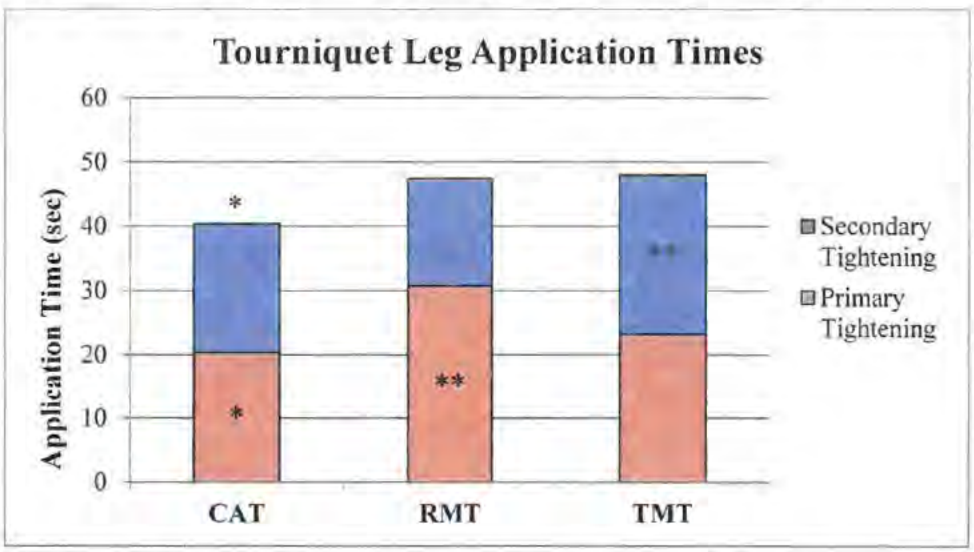


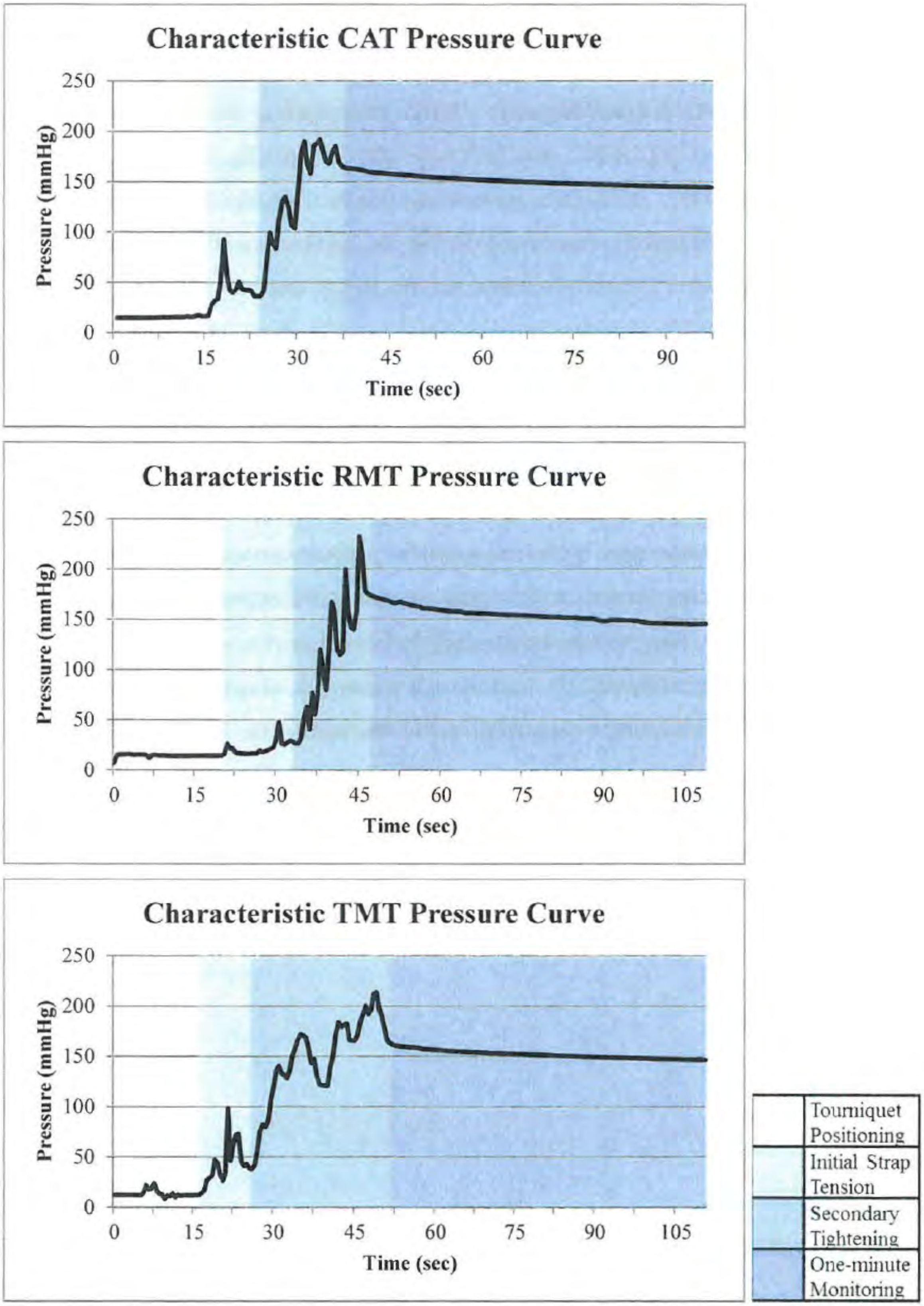
Figure 11. Tourniquet leg application times. Mean tourniquet application times are shown during two-handed leg applications. The times are broken into primary strap tightening and secondary windlass/ratchet tightening steps. Failed applications are excluded from the average (CAT: $n = 53$, RMT: $n = 50$, TMT: $n = 49$). Asterisks indicate statistically significant differences ($p < 0.05$), in which the application time was significantly faster (*) or significantly slower (**) than the other two tourniquet designs.

Interface Pressure

Characteristic Interface Pressures. Example interface pressure profiles are illustrated in Figure 12 for each of the tourniquet designs during the different steps of application. All three tourniquet designs created very little application pressure during the initial positioning of the tourniquet. A momentary spike and slight increase in pressure can be seen during initial strap tightening, as the tourniquet strap was pulled and secured. Secondary pressure was then added using the windlass or ratcheting mechanism and the pressures increased markedly until occlusion was achieved.

Each of the tourniquets momentarily exceeded the final application pressure during the end of the secondary tightening phase. For the CAT and TMT, this overshoot occurs because the windlasses must rotate past their respective locking clips before settling back into its locked position. Similarly, the RMT ratchet releases a small amount of tension as the ratchet mechanism locks and repositions for the next increment. In the example pressure profiles, the RMT was ratcheted approximately six times to reach occlusion pressure, while the CAT and TMT windlasses were each rotated twice. Transient spikes can be observed as the windlasses were manipulated and secured into their locking mechanisms.

Each of the interface pressures declined during the one-minute monitoring period and did not appear to reach steady state by the end of the interval. The decline is similar to those observed during previous human and synthetic cadaver studies (Wall, 2014; Dory, 2016), and is likely caused by the relaxation of muscle and displacement of tissue and fluid beneath the tourniquet application site. This reduction is noteworthy, because the exerted pressure can fall below the threshold of occlusion. As reported in the next section, adjustments were required during many of the tourniquet applications to add pressure after occlusion was initially achieved and then lost.

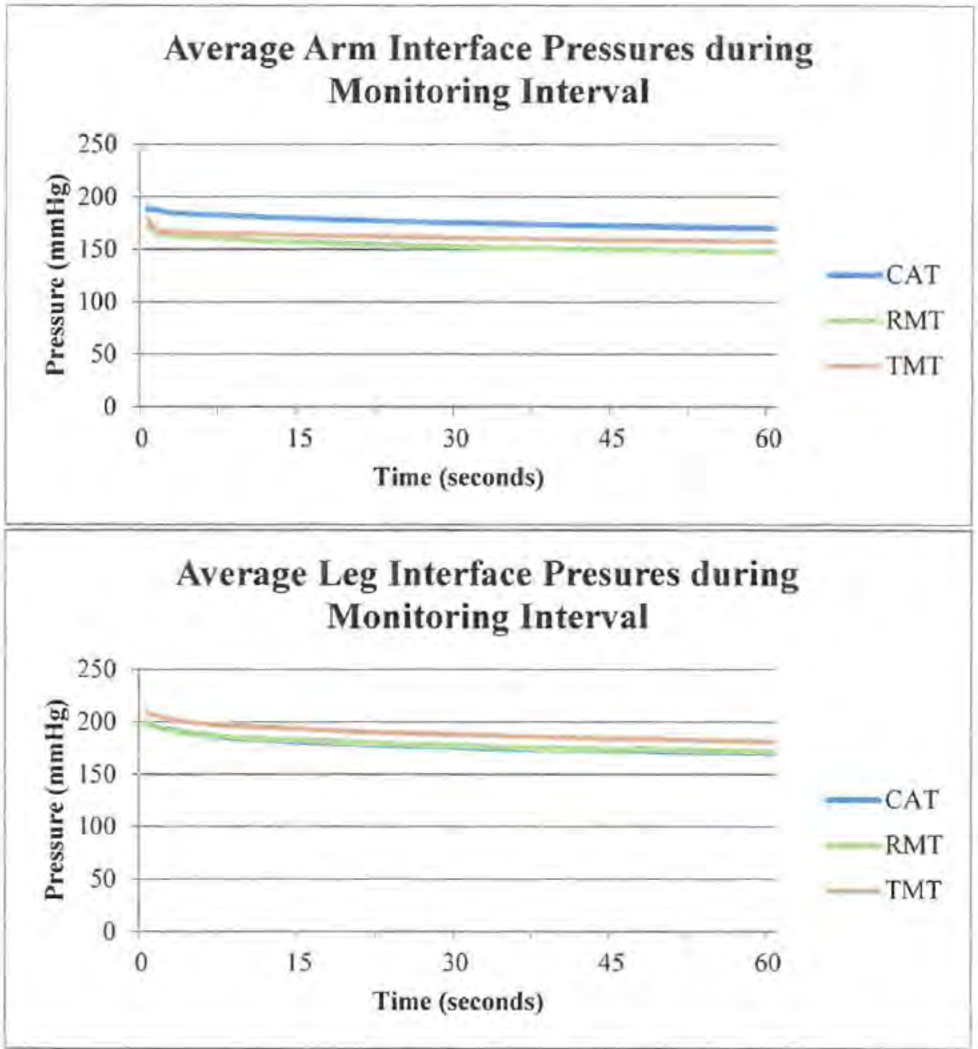


Figures 12. Characteristic pressure profiles for each tourniquet design. Pressure profiles are shown for each tourniquet at different steps of the application.

Average Interface Pressures. Pressures were highest immediately after occlusion was achieved and fell throughout the one-minute monitoring interval. No significant differences in pressure were found between tourniquet designs ($p > 0.05$). Immediately after occlusion, the average interface pressures for CAT, RMT, and TMT were 189 ± 51 mmHg, 172 ± 62 mmHg, and 180 ± 54 mmHg, respectively, during arm applications (Figure 13a), and 199 ± 37 mmHg, 200 ± 45 mmHg, and 211 ± 50 mmHg, respectively, during leg applications (Figure 13b). Throughout the monitoring interval, the CAT maintained the largest amount of pressure during arm applications, while the TMT maintained the largest amount of pressure during leg applications.

The RMT initial interface pressure was lowest during both arm and leg applications, likely due to the nature of its ratcheting mechanism as compared to a windlass design. During applications, the participants were instructed to stop secondary tightening once the audible Doppler signal ceased. As demonstrated by the characteristic pressure curves, the mechanics of the ratchet buckle and ladder strap generate a more gradual production of pressure. A single ratchet produces incrementally less pressure than a single half-rotation of a windlass. Furthermore, the ratchet buckle automatically locks at each increment, which means that once occlusion is achieved, no further action is required to secure the tourniquet. Comparatively, during CAT and TMT applications, once occlusion is achieved, the windlass must be rotated further to reach the locking mechanism, causing the interface pressure to surpass the occlusion threshold.

a. b.



Figures 13. Average interface pressures during one-minute monitoring interval. a. Average interface pressure shown following application to the arm. b. Average interface pressures shown after application to the leg.

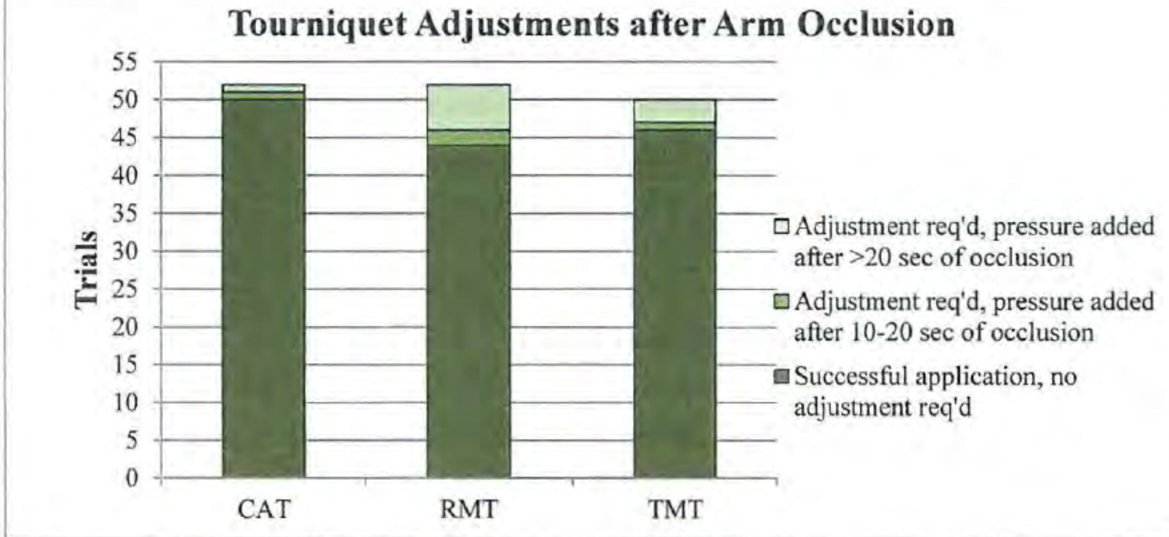
Tourniquet Adjustments after Occlusion

During many of the tourniquet applications, an audible pulse returned during the monitoring interval, requiring intervention by the participant to add secondary pressure. Once occlusion was regained, the one-minute monitoring interval was restarted and the pulse monitored for an additional minute.

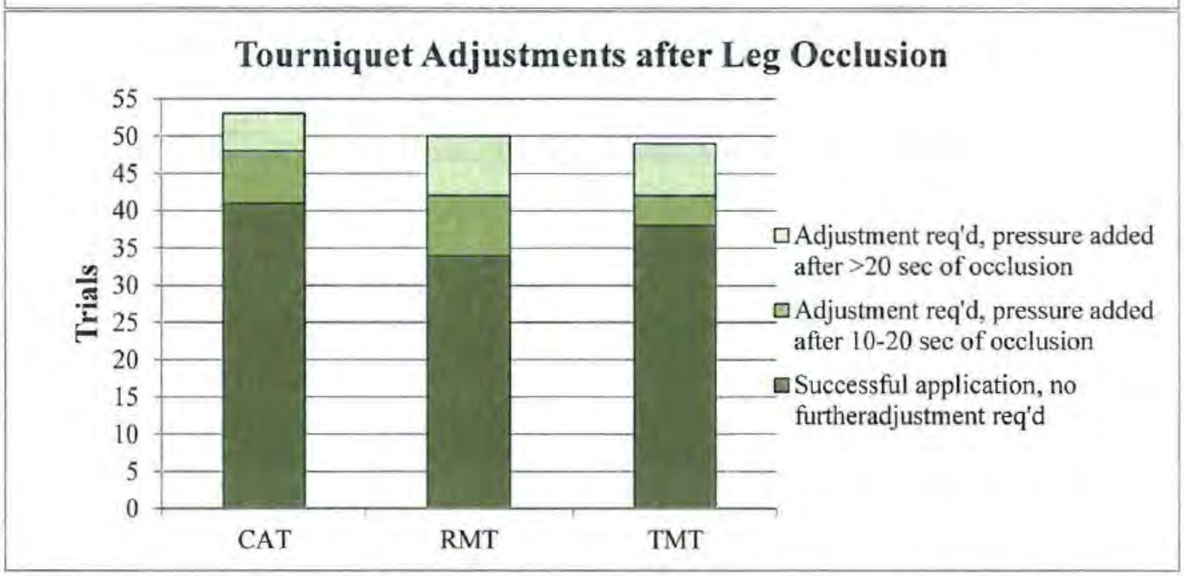
During arm applications, the CAT had the highest number of successful applications that did not require further adjustment (50), followed by the TMT (46), and RMT (44; Figure 14a). Leg application results were comparable to that of arm applications. The CAT had the most successful leg applications without adjustment (41) followed by the TMT (38), and the RMT

(34; Figure 14b). Although differences were observed in the numbers of adjustments, they were not found to be statistically significant between tourniquet designs ($p > 0.05$).

a.



b.



Figures 14. Tourniquet adjustments after initial occlusion. The number of trials in which adjustments were required after occlusion was initially achieved is shown during (a) arm applications and (b) leg applications. Failed applications are not shown. Additionally, each tourniquet had one arm application that was not recorded due to a file write error. Arm (CAT: $n = 52$, RMT: $n = 52$, TMT: $n = 50$). Leg (CAT: $n = 53$, RMT: $n = 50$, TMT: $n = 49$)

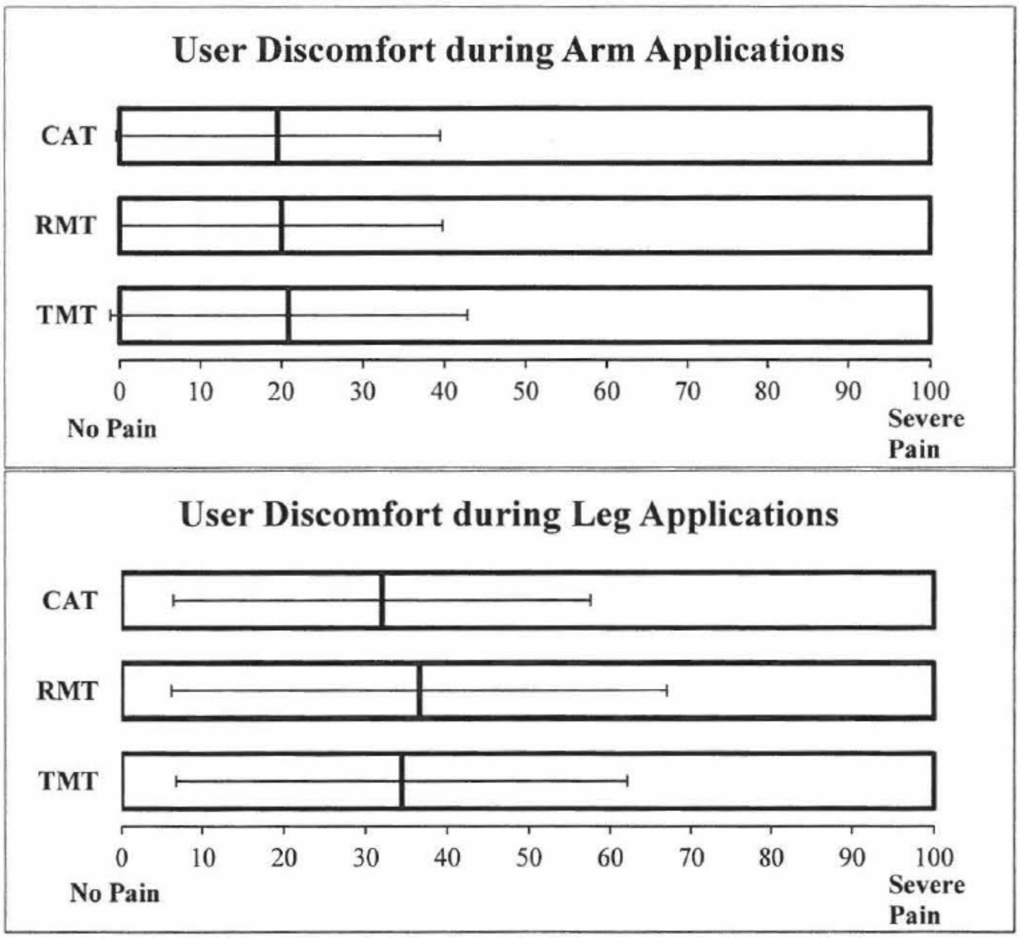
While there were no statistical differences between the numbers of applications that required additional pressure, the frequent loss of occlusion across of the tourniquet designs underscores the importance of continued monitoring once a tourniquet is applied. It can be reasoned that the longer a tourniquet maintains occlusion, the more likely a subsequent loss of occlusion may go unnoticed. For each of the tourniquet designs, then, surpassing the occlusion threshold may be warranted to ensure that the occlusion is maintained over extended intervals.

Discomfort

The level of discomfort reported by participants was higher during leg applications (Figure 15b) than during arm applications (Figure 15a), although no statistical differences were observed between the three tourniquet designs, on either the arm or the leg. Using the visual analog scale, ranging between 0 – 100, the average level of discomfort reported during arm applications was 19.5 ± 19.9 for CAT, 20.0 ± 19.8 for RMT, and 20.8 ± 22.0 for TMT. During leg applications, the average levels of discomfort were 32.0 ± 25.6 for CAT, 36.6 ± 30.4 for RMT, and 34.4 ± 27.7 for TMT.

a.

b.

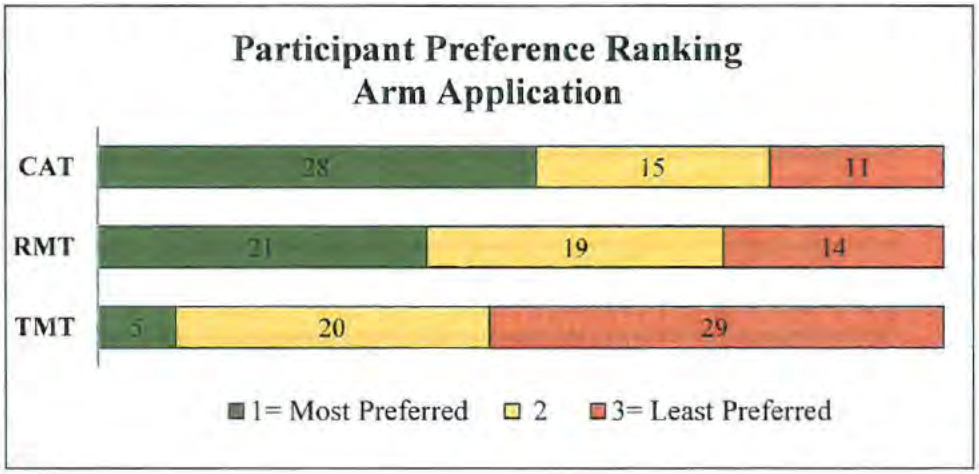


Figures 15. User discomfort during tourniquet applications. After applying each tourniquet, participants indicated their level of discomfort using a visual analog pain scale. Average pain scores are shown with error bars indicating one standard deviation. One participant did not provide feedback regarding discomfort for arm applications (Arm: $n = 54$, Leg: $n = 55$). Participants reported less discomfort during arm applications (a) than leg applications (b), although no significant differences were found between the tourniquet designs ($p > 0.05$).

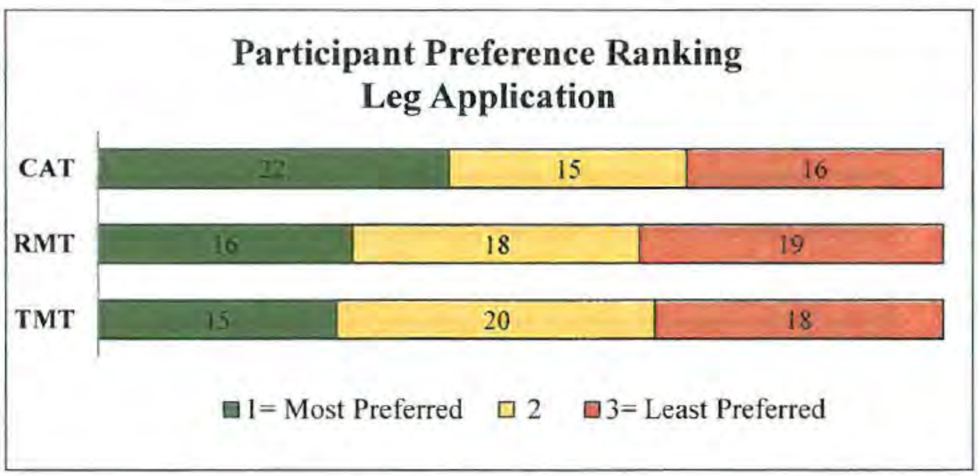
Participant Ranking

Figures 16a and b illustrate the distribution of participant rankings of each tourniquet design during arm and leg applications. The highest percentage of participants ranked the CAT as their most preferred tourniquet during arm applications (51.9%), followed by the RMT (38.9%) and the TMT (9.3%; Figure 16a). CAT was also ranked least favorite by the fewest number of participants during arm applications (20.4%), followed by the RMT (25.9%), and the TMT (53.7%). By weighting the rankings to create a composite score, the CAT received a composite score of 2.31 while the RMT and TMT received a 2.13, and 1.56 respectively.

a



b.



Figures 16. User ranking of tourniquet designs. After applying each tourniquet, participants ranked the three tourniquets (1) being most preferred and (3) being least preferred for both arm (a) and leg (b) applications. One participant did not follow the ranking instructions for the arm application ($n = 54$) and two did not follow the ranking instructions for leg applications ($n = 53$) and were excluded from the totals.

Leg application rankings were similar in order, with the CAT most often ranked as the preferred tourniquet design (41.5%), followed by the RMT (30.2%) and the TMT (28.3%; Figure 16b). The CAT was again ranked least favorite by the fewest number of participants (30.2%), followed by the TMT (34.0%) and RMT (35.8%). The CAT received a composite score of 2.11, while the RMT and TMT each received a composite score of 1.94 during leg applications.

End User Feedback

General Ease of Use. The majority of the feedback received from the participants was related to the tourniquets' overall simplicity, ease of use, or speed of application (Figure 17). Comments on the CAT often described the tourniquet as being "quick" and "easy", and several participants who were familiar with earlier generations of the CAT noted that they felt the CAT had improved. A few commented that the CAT was not as effective as and slower than the other tourniquet designs. The RMT had a similar distribution of comments as the CAT, with several participants commenting positively about the RMT speed and ease of use, while others commented that the RMT design was more complicated or time consuming to apply. TMT comments were more evenly distributed between positive and negative. Some noted that the TMT "tightened very easily and quickly" and others liked the wide TMT strap. On the negative side, some participants commented that the TMT design was not user friendly and that the tourniquet was generally difficult to apply.

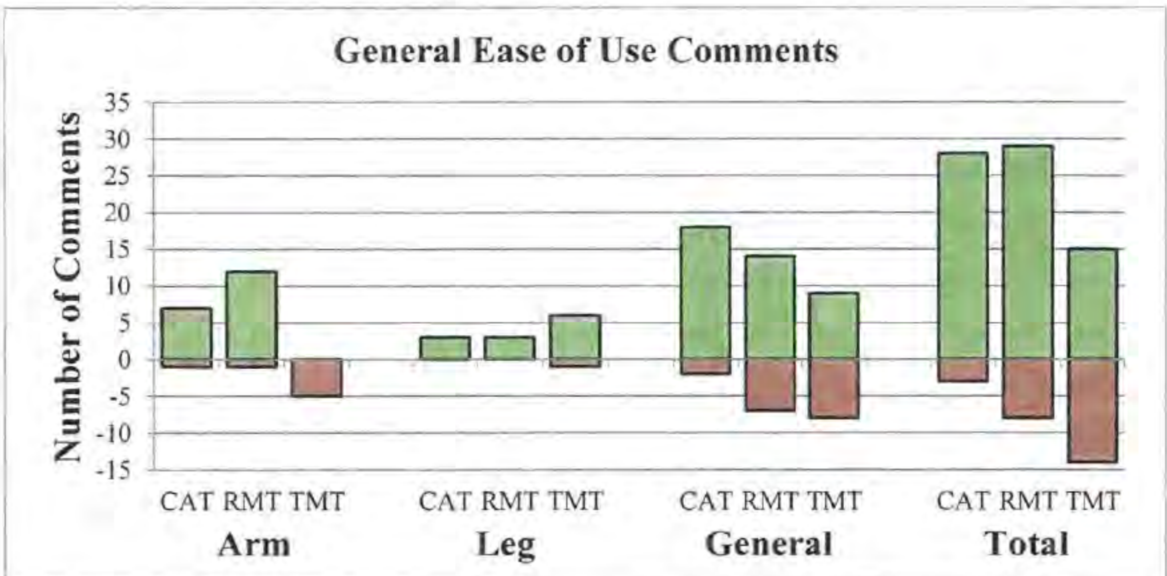


Figure 17. General ease of use comments. After applying each tourniquet, participants were asked to provide feedback about the tourniquet designs. The number of positive and negative comments related to tourniquet general ease of use, simplicity, or speed, is shown for each tourniquet design. Comments that were specifically directed toward Arm or Leg applications are tallied separately, and the remaining comments were counted in a General category. Comments from the Arm, Leg, and General categories are summed together in the Total category.

Primary Tightening Mechanism. Many participants commented on the primary tightening mechanisms employed by the three tourniquet designs (Figure 18). For the CAT, the primary tightening mechanism consists of a single-routed buckle and a strap integrated with hook-and-loop fastener. Some participants familiar with previous generation CAT designs commented that they preferred the new single-routed buckle over the previous design, which used a double-routed slip lock design. These participants felt the single-routed buckle saved time during two-handed leg applications and simplified the design. One participant commented negatively about the CATs hook-and-loop fastener, which in their experience, "stuck to itself," causing delay in primary tightening.

The RMT primary tightening mechanism consists of a strap that is double-routed through dual slip lock rings. A smaller looped bite strap provides leverage during initial tightening and is held in the teeth during one-handed arm applications or by the opposing hand during two-handed leg applications. The RMTs bite strap was polarizing and received a large number of comments. Some commenters felt the loop facilitated a fast and easy application, while others found it "difficult," or "awkward", and disliked having to bite the strap during arm applications. Some also disliked having to unthread and rethread the belt through the dual slip lock rings during leg applications.

The TMT primary tightening mechanism consists of a slip lock buckle with an integrated hooked-clasp. A self-adhering hook-and-loop fastener runs the length of the strap and is double-routed through the slip lock buckle. The hooked clasp was positively received by those who commented. They found that the clasp facilitated leg applications. However, several participants reported difficulty with primary tightening during arm applications, commenting on problems pulling the strap through the slip lock buckle. As described earlier, the TMT strap must simultaneously be pulled normal to the arm and in the direction tightening; otherwise, the looped tourniquet slips around the arm without getting tighter. Many participants had difficultly mastering this technique, which was reflected in the application times and user feedback.

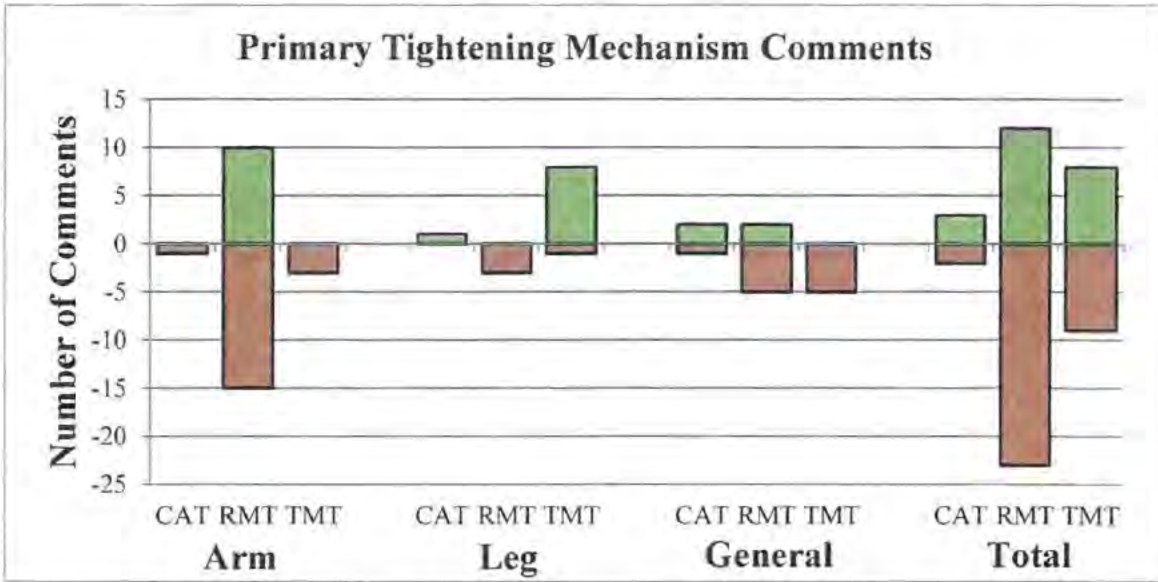


Figure 18. Primary tightening mechanism comments. After applying each tourniquet, participants were asked to provide feedback about the tourniquet designs. The number of positive and negative comments related to the tourniquet primary tightening mechanisms is shown for each tourniquet design. Comments that were specifically directed toward Arm or Leg applications are tallied separately, and the remaining comments were counted in a General category. Comments from the Arm, Leg, and General categories are summed together in the Total category.

Secondary Tightening. The CAT secondary tightening mechanism consists of a plastic windlass, which is secured with a C-shaped locking clip. Those who commented on the CAT liked the large windlass design, which they felt was easy to tighten (Figure 19). A few commenters, however, noted difficulties turning the windlass, and another disliked having to rotate the windlass past the point of occlusion in order to secure the windlass in place, which they felt resulted in too much or too little pressure.

Secondary tightening with the RMT is achieved with its ratcheting buckle. Among those who commented, the ratcheting mechanism was favored over the windlass design of the CAT and TMT, receiving more positive comments than the others combined. Some participants liked the more gradual application of pressure produced by the ratchet, stating that it applied more controlled pressure to the point of occlusion. Some also felt that the act of ratcheting the buckle took less hand-eye coordination and fine motor skills than the turning of a windlass with only one hand, an important consideration for applying self-aid. The user comments paralleled the application times, which found the ratchet was, on average, the fastest method of generating secondary pressure.

As with the CAT, the TMT uses a plastic windlass to apply secondary pressure. Participants who commented on the TMT windlass disliked that it was smaller than the CAT windlass and found it difficult to manipulate as tension built in the windlass knot. Similar to the CAT, a few commented that they disliked having to rotate the windlass past the point of occlusion in order to secure the windlass in place. Again, the user comments reflected the application times, which found that the TMT took on average the longest to apply secondary pressure.

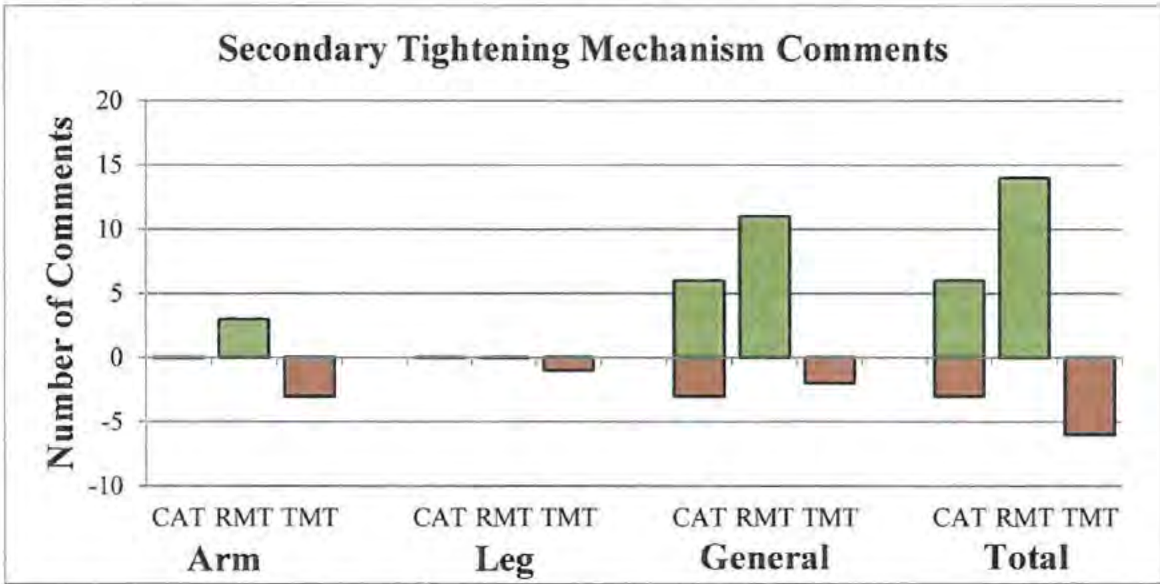


Figure 19. Secondary tightening mechanism comments. After applying each tourniquet, participants were asked to provide feedback about the tourniquet designs. The number of positive and negative comments related to the tourniquet secondary tightening mechanisms is shown for each tourniquet design. Comments that were specifically directed toward Arm or Leg applications are tallied separately, and the remaining comments were counted in a General category. Comments from the Arm, Leg, and General categories are summed together in the Total category.

Locking/Secureness. Few commented on the C-shaped clip used to secure the CAT windlass, and most who did felt that the locking process was simple and easy (Figure 20). However, a few commenters felt that the CAT hook-and-loop fastener would not provide enough security to maintain pressure.

Since the RMT locks in place after each ratcheting motion, and doesn't have a locking mechanism distinct from the secondary pressure applicator, RMT comments in this category focused on the overall secureness of the device. Those who commented all felt that the ratchet buckle was difficult to loosen. Some found the difficulty loosening the ratchet to be a positive characteristic, making the RMT difficult to inadvertently bump loose. However, others found the ratchet too difficult to release pressure when it was time to remove the tourniquet.

The TMT locking clip received several comments from participants with mixed results. Several noted difficulty securing the windlass into the locking clip, particularly during arm applications. The locking clip provides resistance against the windlass as it is secured, and the windlass must be oriented correctly to enter the clip. As described in the "application times" section, many participants had difficulty positioning the windlass and overcoming the resistance of the clip.

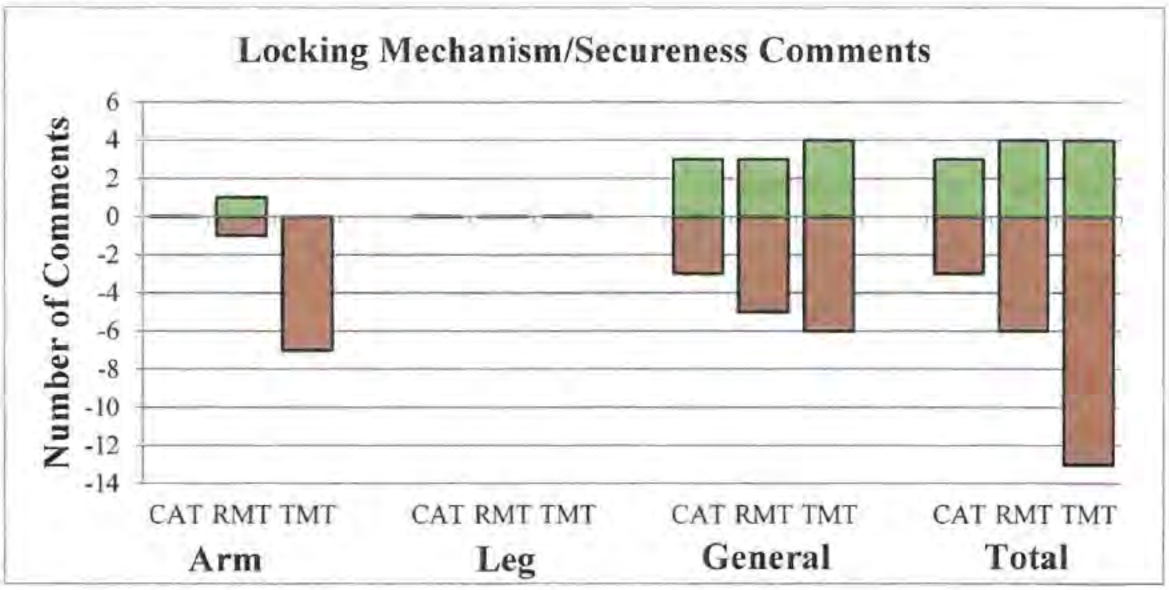


Figure 20. Locking mechanism/secureness comments. After applying each tourniquet, participants were asked to provide feedback about the tourniquet designs. The number of positive and negative comments related to the tourniquet locking mechanism or secureness is shown for each tourniquet design. Comments that were specifically directed toward Arm or Leg applications are tallied separately, and the remaining comments were counted in a General category. Comments from the Arm, Leg, and General categories are summed together in the Total category.

Comfort. While no significant differences were found in the levels of discomfort reported on the visual analog pain scale, there were differences in the frequency of comments related to comfort (Figure 21). Paralleling the pain scale results, more participants commented on discomfort during leg applications than arm applications. All of the comments related to pain tended to cite general pain and discomfort or pinching. The RMT received the most positive and negative comments regarding pain, with the number of negative comments exceeding the positive. The CAT and TMT each received fewer comments referencing discomfort, and were more evenly split between positive and negative.

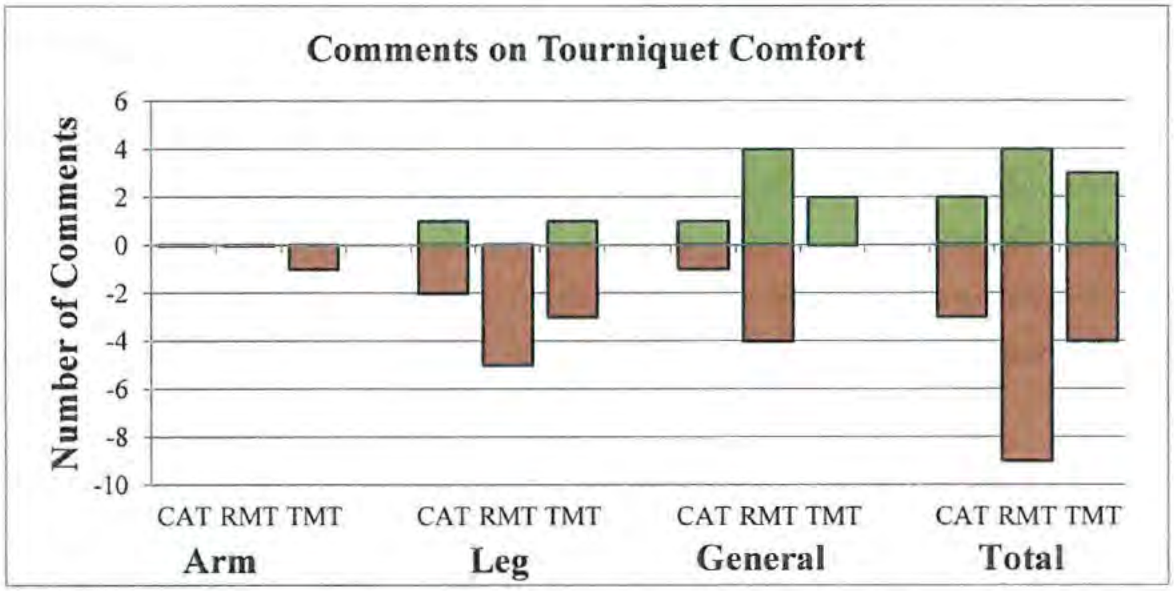


Figure 21. Comments on tourniquet comfort. After applying each tourniquet, participants were asked to provide feedback about the tourniquet designs. The number of positive and negative comments related to tourniquet comfort is shown for each tourniquet design. Comments that were specifically directed toward Arm or Leg applications are tallied separately, and the remaining comments were counted in a General category. Comments from the Arm, Leg, and General categories are summed together in the Total category.

Durability. Perceived tourniquet durability received the fewest number of comments out of the feedback categories (Figure 22). Those who commented about the CAT were split in their opinion of the CATs general durability. One commenter felt the RMT was sturdy, while another felt RMT may be more likely to malfunction due to the complexity of its design. One commenter liked the TMT hook-and-loop fastener and felt it to be mechanically secure, while others expressed a lack of confidence with the TMT materials and windlass. It should be noted that each of the tourniquets successfully underwent environmental testing, which was reported separately, and no differences were found in strength and durability of the three tourniquet designs (Lee, 2016).

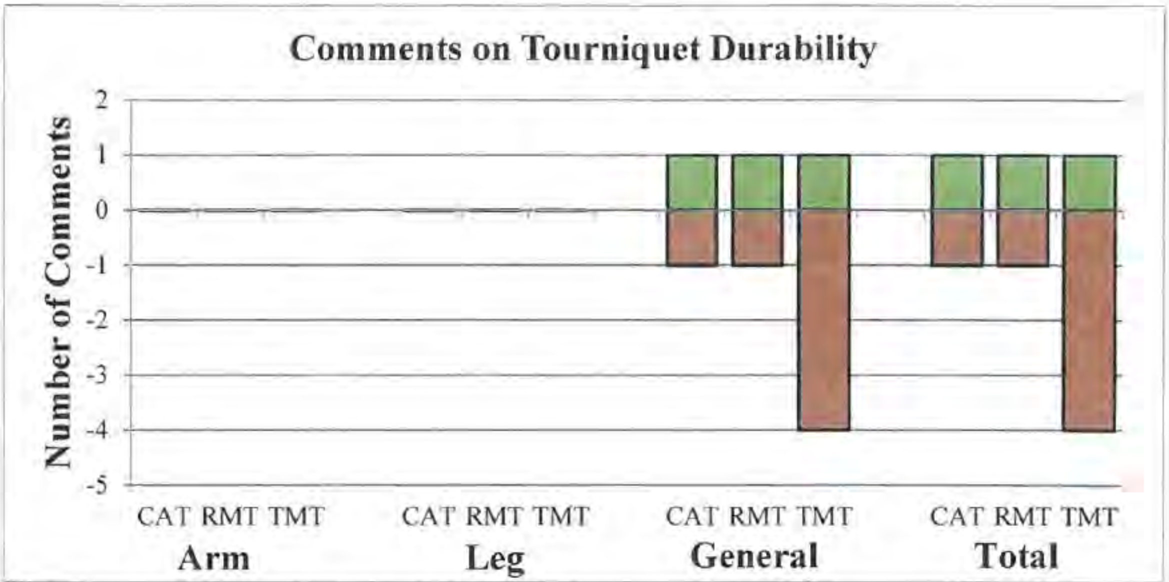


Figure 22. Comments on tourniquet durability. After applying each tourniquet, participants were asked to provide feedback about the tourniquet designs. The number of positive and negative comments related to tourniquet durability is shown for each tourniquet design. Comments that were specifically directed toward Arm or Leg applications are tallied separately, and the remaining comments were counted in a General category. Comments from the Arm, Leg, and General categories are summed together in the Total category.

Limitations

While controlled laboratory settings are important for conducting standardized testing, the dynamic operational environment presents numerous challenges that can compromise user performance. External stressors, including enemy fire and austere environmental conditions, along with human factors, including the potential for severe pain or shock, elevated adrenalin and heart rate, and impaired cognition and dexterity, can all affect a soldier's ability to quickly and effectively apply a tourniquet at the point of injury. The present study evaluated user and tourniquet performance in ideal conditions, but did not seek to test tourniquet usability or the retention of training in challenging combat conditions.

Furthermore, participants were trained by researchers strictly by manufacturer's directions during a limited training session. Any type of nuances or techniques outside of those directions were not instructed, so as not to give any one tourniquet an advantage over the others. An example is the application of initial strap tension, which is critical for tourniquet success, but not clearly emphasized in the manufacturers' instructions. A majority of the user errors were caused by the tourniquet strap remaining loose during the initial tightening step. Another example is the one-handed strap tightening technique used by the TMT, which requires the user to pull the strap both normal to the arm and in the direction of tightening, in order to generate enough leverage for the strap to feed through the slip lock buckle. While the technique was demonstrated during the training session, it is not clearly described in the instructions, and many participants struggled during the initial tightening stage. When training at the unit level, these features that may not be as intuitive to less experienced users can be emphasized to improve user understanding and performance. Additional training and repetitions would also improve proficiency and reduce tourniquet application times.

Finally, while other tourniquets are also currently used by the military, most soldiers learn to apply the CAT during Basic Combat Training, and the CAT is currently the tourniquet most widely found in soldier IFAKs (Harcke, 2012; Kragh, 2013). Although the Generation 7 CAT, which was evaluated in this study, had not been widely fielded at the time of data collection, many of the participants were familiar with the earlier generations, which feature the same general design concept. Of the 55 volunteers that participated in the study, only 12 reported having received no previous tourniquet training prior to participating in the study.

Comparing the application times of those who had received previous tourniquet training with those who had not, the inexperienced users were, on average, slower at applying each of the tourniquet designs. The relative speed of the tourniquet designs, however, was fairly consistent between the two groups. In the group that had received some previous tourniquet exposure, the CAT (38.1 ± 12.5 sec) was the fastest during leg applications, and was significantly faster than the TMT (46.0 ± 12.5 sec) but not the RMT (43.9 ± 16.4 sec). In the inexperienced group, the CAT (46.2 ± 13.5 sec) was also the fastest during leg applications, and was significantly faster than the RMT (58.5 ± 19.4 sec) but not the TMT (54.0 ± 14.sec). During arm applications, the TMT was significantly slower than the CAT and RMT in both groups. In the group that had received previous tourniquet training, the average arm application times were 41.3 ± 14.8 sec, 42.8 ± 22.3 sec, and 63.1 ± 25.4 sec, for CAT, RMT, and TMT, respectively. Average arm application times in the inexperienced group were 51.9 ± 26.7 sec, 48.7 ± 24.6 sec, and 83.1 ± 40.8 sec, for CAT, RMT, and TMT, respectively.

The performance and preference of participants tended to favor the CAT, with which most were familiar, and given additional exposure to and training with the other two tourniquet designs, the results may become more normalized. However, the completely inexperienced group demonstrates that the trends in relative performance persist, even with those who had never used the CAT.

Conclusion

Tourniquets provide the warfighter a lifesaving intervention, designed to manage uncontrolled extremity hemorrhage, until definitive care is accessible. Because buddy aid, or aid from a medic or corpsman is never guaranteed, it is imperative that tourniquets can be quickly applied by those who must administer self-aid. The present study evaluated three extremity tourniquet designs during self-applications in the hands of military service members with limited levels of tourniquet exposure and medical training. The results provide data that differentiate performance aspects of the three tourniquet designs through measures of tourniquet success, application times, and user feedback. These data can be used by the Tourniquet Working Group to identify which current design(s) are best suited for use by our warfighter, and to identify opportunities to improve existing tourniquet features in subsequent generations of tourniquet designs.

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14. ABSTRACT

Since doctrinal changes made in 2005, tourniquets have become standard issue equipment for the US warfighter operating in the tactical environment. Previous Joint Operational Evaluation of Field Tourniquets (JOEFT) studies have gathered performance data to compare commercially available tourniquet designs utilizing instrumented mannequin systems, as well as synthetic cadaver models of severe hemorrhage; however, human end-user testing remains critical for identifying those tourniquet designs best suited for use by our military service members. Objective: To compare the performance of three candidate tourniquets, the Combat Application Tourniquet® (CAT), Ratcheting Medical Tourniquet™ (RMT), and Tactical Mechanical Tourniquet (TMT), in the hands of military end-users during self-applications. Methods: Fifty five volunteer participants (n=55) were first trained to correctly position and apply each tourniquet design, according to the manufacturers' instructions for use, on instrumented mannequins designed for tourniquet training. Participants then self-applied each tourniquet once to their arm and once to their leg, halting at cessation of the distal pulse. Occlusion was maintained for one minute. Measurements included success/failure rate, applications time, discomfort, and participant preference and feedback.

15. SUBJECT TERMS
extremity tourniquets, hemorrhage control, IFAK, self-application

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