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Next-generation tourniquet: Recommendations for future capabilities and design requirements

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BACKGROUND: Advances in tourniquet development must meet new military needs for future large-scale combat operations or civilian mass casualty scenarios. This includes the potential use of engineering and automation technologies to provide advanced tourniquet features. A comprehensive set of design capabilities and requirements for an intelligent or smart tourniquet needed to meet the challenges currently does not exist. The goal of this project was to identify key features and capabilities that should be considered for the development of next-generation tourniquets.

METHODS: We used a modified Delphi consensus technique to survey a panel of 34 tourniquet subject matter experts to rate various statements and potential design characteristics relevant to tourniquets systems and their use scenarios. Three iterative rounds of surveys were held, followed by virtual working group meetings, to determine importance or agreement with any given statement. We used a tiered consensus system to determine final agreement over key features that were viewed as important or unimportant features or capabilities. This information was used to refine and clarify the necessary tourniquet design features and adjust questions for the following surveys.

RESULTS: Key features and capabilities of various were agreed upon by the panelists when consensus was reached. Some tourniquet features that were agreed upon included but are not limited to: Capable of being used longer than 2 hours, applied and monitored by anyone, data displays, semiautomated capabilities with inherent overrides, automated monitoring with notifications and alerts, and provide recommended actions.

CONCLUSION: We were able to identify key tourniquet features that will be important for future device development. These consensus results can guide future inventors, researchers, and manufacturers to develop a portfolio of next-generation tourniquets for enhancing the capabilities of a prehospital medical provider. (*J Trauma Acute Care Surg.* 2024;96: 949–954. Copyright © 2024 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the American Association for the Surgery of Trauma.)

LEVEL OF EVIDENCE: Prognostic and Epidemiological; Level V.

KEY WORDS: Tourniquets; requirements; consensus; survey.

Tourniquets are lifesaving tools to stop bleeding from limb wounds and have been used in ancient and modern-day wartimes.[1–3] Today's tourniquets were originally developed for the military but are now widely used by civilians, and have features, such as being durable, inexpensive, and able to be self-applied (one-handed) by the casualty.[4] However, the basic design of these portable devices has been largely unchanged. Although current tourniquet capabilities have been adequate for past conflicts,[5] the ever changing climate in war and civilian mass casualty (MASCAL) scenarios may require addition of new features and capabilities for tourniquet design. Although new tourniquet designs have been suggested, they have not been widely adopted.[6,7] In the military setting of Large-Scale Combat Operations (LSCO)[8] and prolonged casualty care (PCC), trauma casualties must be managed at or near the point of injury for extended periods.[9–12] There are parallels to LSCO/PCC in civilian situations in which delayed evacuations and limited resources may occur, such as wilderness medicine or MASCAL scenarios.[13,14] Civilian pre-hospital settings also benefit from tourniquet usage, where examples include penetrating trauma from firearms and stabbings, care under fire for police officers, terrorist attacks, rural incidents where transportation to definitive care is delayed, and industrial accidents.[15] Therefore, there is a need for medical devices to enhance medical provider capabilities beyond typical standard of care. Tourniquets may need to be reevaluated to account for prolonged use, management of multiple casualties, relevant data for patient monitoring, and training requirements.[16] Development efforts should focus on enhanced capabilities to alleviate caregiver (both manual and cognitive) burden while continuing to provide effective hemorrhage control. Tourniquet traits are expected to change to suit LSCO needs, but those traits that suit such needs have not yet been identified.

Future enhanced tourniquets present new possibilities for automated capabilities that are more intuitive, more instructive,

Submitted: September 19, 2023, Revised: November 29, 2023, Accepted: December 1, 2023, Published online: January 8, 2024.

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Supplemental digital content is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal's Web site (www.jtrauma.com).

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DOI: 10.1097/TA.0000000000004237

and promote proper placement and use. To determine the capabilities needed for these smart tourniquets, we employed a modified Delphi survey methodology to establish a consensus, an agreement among a set of tourniquet subject matter expert (SME) panelists, to define what these capabilities should be.[17–20] The Delphi Method is a framework for implementing qualitative research studies to determine consensus, or lack thereof, among a wide breadth of SMEs.[19,21] It is implemented through anonymous surveys issued to isolated respondents. This survey process is repeated until the results stabilize. Notably, the method is traditionally terminated when stabilization is reached, rather than consensus; it is terminated when the responses are consistent (i.e., steady state) rather than in agreement among individual responders.[20,22]

We used this methodology to capture which tourniquet features are important when considering implementation of new technologies for future smart tourniquet design and development work. Specifically, our objectives were to determine potential tourniquet features and recommendations based on various use-case scenarios that were determined by the SMEs and which of those features were the most critical in the operational environment as well as for civilian sectors. We explicitly chose the Delphi method to address these objectives to develop a group consensus to prioritize which features were consistently recommended. Our studies were deliberately designed to facilitate exchange of information throughout regular working groups and surveys with additional comments.

METHODS

Regulatory Approval and Standards

This research study was conducted under protocol (H-21-029nh) approved by the Research Regulatory Compliance Division. This study conforms with the CREDES guideline and a complete checklist has been uploaded as Supplemental Digital Content (Supplemental Digital Content, Table 1, http://links.lww.com/TA/D504).

Panel Selection

We first curated a list of potential panelists based on each panelist's current or prior tourniquet experience in research, development, clinical use, or manufacturing based on our network of previous and/or current known individuals from our research team. Potential panelists came from various sectors including operational military, military research, patient care, and manufacturing companies. We sought a heterogeneous group to represent broad experiences supporting the end user of a smart tourniquet. Panel participation was voluntary, and panelists were not reimbursed for their time. Each potential panelist was contacted via email and given the option to participate. In addition, we allowed panel participants to recommend other potential panelists who met the tourniquet experience criterion. The panel included medics, paramedics, nurses, engineers, physicians (emergency, surgeon, trauma), instructors, veterinarian, and scientists (health, microbiology, engineering) from industry, academia, and military. Panelists represented the United States, Canada, Belgium, and Israel.

Study Design

Time was allotted for up to four working group meetings and surveys over the course of 5 months. However, consensus was achieved by the third survey, and a fourth working group meeting and survey were not needed to complete the study.

Our first survey round consisted of 17 broad topic statements associated with tourniquet use, function, and product development. A total of 34 panelists participated. Each panelist was given an anonymized survey via email and was asked to assign a score from 1 (least important) to 10 (most important) to each topic statement. A working group meeting was then conducted to discuss the results and to determine which statements should be further investigated or dropped (Fig. 1).

The second survey was based in part on the numerical responses and comments to the first survey, with additional questions based on discussion points from the working group meeting. The round 2 survey consisted of two sections. The first section consisted of seven statements that were rewritten based on statements from Round 1 that had high agreement and were used for gauging inter-reliability among the panelists. Each statement was rated independently from a scale of 1 to 7, with 1 being highly disagree and 7 being highly agree. The second section of survey 2 consisted of 10 questions with various statements for each question, and respondents ranked each statement dependently to determine ordinal ranking. A second working group meeting was then conducted to discuss the results.

The third survey was constructed to refine each tourniquet feature and to determine exact end-user capabilities that were most or least important. The round 3 survey consisted of 12 questions in four broad topic areas (Data Collection and Transfer, Alarms and Alerts, Decision Support, and Tourniquet Usage) with varying statements for each question rated on a 9-point Likert scale with 1 to 3 being not important, 4 to 6 being important but not critical, and 7 to 9 being very important and critical. Optional sections were available for the panelists to write in comments.

Analysis and Criteria for Consensus

The median score of each survey statement among all respondents was used to evaluate the statement's overall importance. When medians were equal, summations of each panelists' points were analyzed to differentiate which statement ranked higher. Consensus was calculated by determining how many panelists scored similarly for that particular statement. Similar scores were 1 to 3 for not important, 4 to 6 for neutral, and 7–9 (or 10) for very important. The consensus was met if at least 50% of the panelists gave a score within those ranges. We determined a tiered consensus concept in which: (1) ≥50% and <60% were defined as "minimum consensus"; (2) ≥60% and <70%, as "moderate consensus"; and (3) >70% to 100%, as "high consensus" For example, if 17 out of 34 panelists (i.e., 50% of panelists) rated a statement as "highly important" (i.e., statement score of 7, 8, or 9), it would meet a "minimum consensus" that the statement was highly important.

RESULTS

The demographic breakdown of panelists is presented in Supplemental Digital Content, Table 2, http://links.lww.com/TA/D504. The panelists predominantly consisted of those affiliated with government/military institutions (76%), with the remaining panelists from industry (15%), academia (6%), and

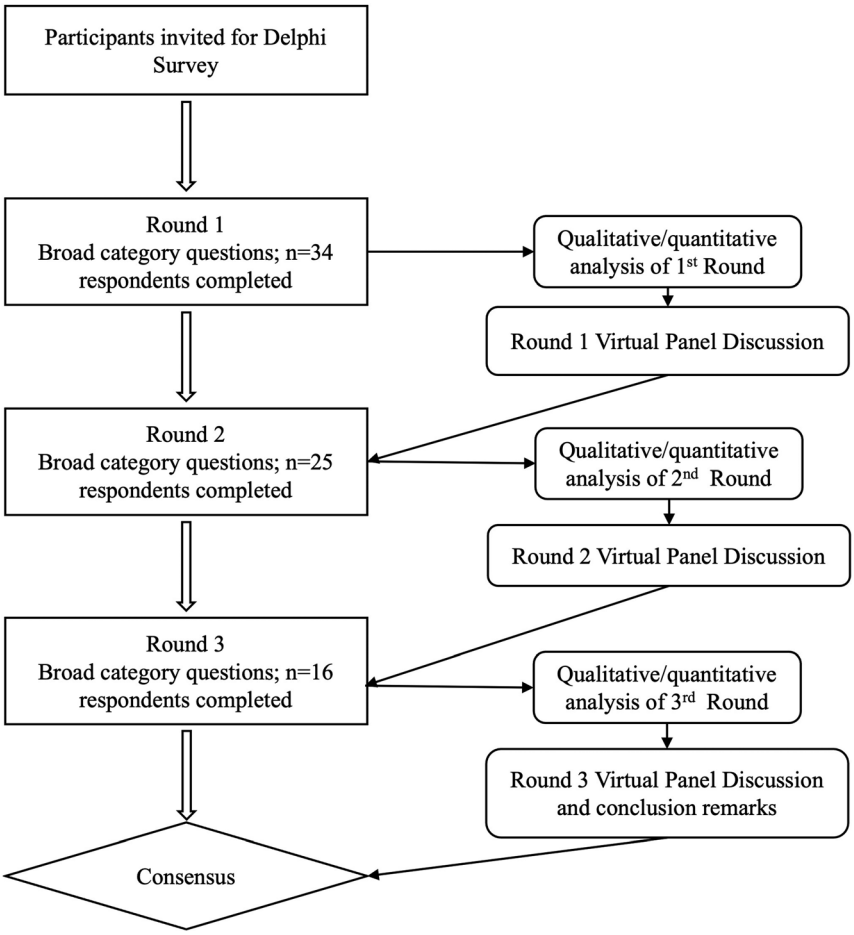

Figure 1. Flowchart of survey participation and panel discussion rounds.

one "other" (3%). The distribution of the panelists' listed range of years of tourniquet experience (Supplemental Digital Content, Fig. 1, http://links.lww.com/TA/D504) and their listed expertise level (Supplemental Digital Content, Fig. 2, http://links.lww.com/TA/D504) in each round shows that the majority of the panelists have 15+ more years of experience and identifying as intermediate or experts with tourniquets. Although drop-outs occurred after each subsequent survey round, the agency representation percentages remained constant throughout the rounds. Expertise in tourniquet use by panelists was self-reported and varied (47% expert to 17.6% novice).

Survey 1 Results

Survey 1 served as a baseline for the evaluation of tourniquet capabilities. The median scores and consensus of statements' importance are presented in Supplemental Digital Content, Table 3, http://links.lww.com/TA/D504. Consensus was achieved for 12 total statements (7 high, 3 moderate, and 2 minimum consensus). High consensus was achieved for the high importance of semiautomated deflation, data transfer, use >2 hours, weight, materials, environment, and one-handed usability. Highlights of the first working group meeting included: (1) general agreement that tourniquets integrated into uniforms were not desired; (2) elimination of factors that were considered too dependent on manufacturing (costs, weight, materials); and (3) clarification of the device end user (i.e., a prehospital medic).

Survey 2 Results

A total of 25 panelists completed Survey 2. The median ranks, level of agreement (Section 1) or importance (Section 2), and consensus levels for both sections of Survey 2 are presented in Supplemental Digital Content, Table 4, http://links.lww.com/TA/D504. In Section 1, at least a minimum consensus was achieved for all seven statements, whether agreement or disagreement. High consensus was achieved for high agreement with statements concerning use greater than 2 hours and tourniquet use in critical scenarios, such as MASCAL, care under fire (CUF), etc.

Section 2 consisted of 10 questions with consensus around limb loss and the effects of release being important considerations in use longer than 2 hours. For unacceptable outcomes for a smart tourniquet with self-inflation features, there was moderate consensus that failure to activate and inappropriate or premature deactivation were most important, and high consensus that increased cost from automated systems was least important.

Furthermore, during the working group discussions, it was clear that questions of engineering solutions (e.g., questions 2C, 2D, 2E, 2F, and 2G) unnecessarily constrain future development and these lines of inquiry were discontinued, leaving room for future innovation.

Survey 3 Results

Sixteen panelists completed Survey 3. Four broad topic areas were covered (Supplemental Digital Content, Table 5, http://links.lww.com/TA/D504).

Data Collection and Transfer

Concerning data relevant to tourniquet use (Q1) and role of care transfer (Q2), there was high consensus that "time since application" (i.e., duration of use) was very important and critical. Questions posed about data transfer from tourniquet to its user (Q3) and from tourniquet to the next provider (Q4) achieved similar consensus results to each other: there was high consensus that written information was very important and critical.

Alarms and Alerts

There was consensus around various ways that alarms and alerts should be displayed including on a screen (Q6). It was also determined to be very important and critical that notifications should have on/off mutability (high consensus) (Q7). Of the statements that should trigger an alert/alarm (e.g., low battery, change in blood loss rate, misplaced tourniquet), every answer was judged to be very important and critical by consensus (Q8).

Decision Support

There were 2 questions: one concerning the degree at which a tourniquet should be able to advise or direct the user (Q9) and one concerning the degree of autonomy a tourniquet should have (Q10). Minimum consensus was achieved for three items on Q9: monitoring notifications, recommended actions, and delivery of detailed instructions. For Q10, there was high consensus that it is very important and critical that a tourniquet be capable of manual operation and could be automatic with required user approval.

Tourniquet Usage

In regards to tourniquet force (Q11), high consensus was achieved that the following were very important and critical: device confirmation requirement, user prompting automatic force change, and the tourniquet would stay tightened upon system failure. No consensus was reached for the statement that force pressures should never be automatically changed. On reusability (Q12), two items were deemed very important and critical by moderate consensus: that most components and the expensive parts should at least be reusable.

Key findings from all survey and working group meetings are compiled in Table 1.

DISCUSSION

We achieved consensus on a total of 89 out of 135 items that discussed key tourniquet features and capabilities, although each item was not unique, and some were duplicative to ensure stability in responses. The totals of all high, moderate, and minimum consensus was 12 items in survey round 1, 30 items in survey round 2, and 47 items in round 3. The compiled key findings are broken down into categories with key features in Table 1 that can be used as a guideline for future development of enhanced tourniquets.

TABLE 1. Compilation of Key Tourniquet Features and Recommendations

Category	Highly Recommend	Do Not Recommend
Environment	Usable in all circumstances within CUF, MASCAL	
Time to Use	Longer than 2 hours use	
Application	One-handed application	Integrated in uniform
	Applied by anyone	Can be only used/monitored by medic
Display and Data Transfer	Display on screen or written	
	Data transfer (wireless or wired)	
	Data storage of medically relevant information	
	Alarms (malfunction, low battery, changes in vitals, tourniquet tension, etc)	
Data Features	Time of application	
	Heart rate	
	Blood pressures	
	Oxygenation	
Reusability	Reusable in whole or in part	Requires maintenance for reusability
Automation	Semiautomated occlusion with user approval and device confirmation	
Monitoring	Display of time and medically relevant information	
	Alarms (malfunction, low battery, changes in vitals, tourniquet tension, etc)	
	Generic audio alarms with mutable ability	Voice alarms, nonmutable
	Provide recommended actions	
Training	Minimal training specific to device	Requiring more than one training event specific to device
Manufacturing	Limit cost	
	Limit weight	
Materials	Pain-minimization properties	
Fail-safes	Fail-safe on with manual ability to apply or deactivate	Fail-safe off

Our study also reaffirmed much of the necessity of form and function of current tourniquet systems, acknowledging that improvement in basic areas is always desirable (e.g., lower cost, easy to use by anyone, lighter weight). The study affirmed that there is a need for addressing prolonged care conditions, such as longer use times and use in all MASCAL and CUF scenarios. Many of the items that would constitute "next-generation" features and capabilities include technologies that take advantage of novel sensing, display, and control mechanisms for monitoring, alerts, and automation. Overall, our study showed that semiautomated features are desirable and will play a critical role in advancement of tourniquet systems.

There were three rounds of surveys needed to achieve stability in our answers. It was determined that a fourth survey round would be unnecessary based on the consistency of survey answers. Topic statements were formulated using information from various sources, such as Joint Trauma System committee meeting reports, literature review, and discussion with experts. Care was also taken to include target use case scenarios (prolonged care) and potential end users (prehospital medics). It was recognized that explaining these conditions and defining key terms when formulating the survey would be critical to ensuring panelists understood the context of survey topics and could respond as appropriately as possible.

The panelists confirmed the importance of various basic tourniquet features and use-case scenarios. Although tourniquets can cause limb damage and reperfusion injury after only 2 hours, the panel's consensus around using tourniquets greater than 2 hours and using tourniquets in a variety of environments (CUF, MASCAL, etc.) reaffirmed the utility of tourniquets in prolonged care scenarios as lifesaving measures, even at the potential cost of limb damage. Some other basic features were noted or even expected to draw consensus including the need for low weight, appropriate materials, being used one-handed, and at least some degree of reusability. There was moderate consensus around a device needing to be stand-alone (i.e., not integrated into a uniform) as well as needing minimal training to use.

Considering one of the "smart" functions that could be provided by a tourniquet, panelists agreed on the importance of data storage and transfer capabilities. Specifics around what data is important and how to transfer that data were addressed in Survey 3 and determined time since application as the most important for tourniquet use; this data should be presented in at least a written format. Other data that was agreed on as critical included blood pressure, heart rate, and (to a lesser extent) tissue oxygenation. Data could be recorded and displayed on a screen and/or transferred via wired connection to another device as necessary.

Tourniquets could also use collected data to monitor patient vitals and provide alerts or give instructions, depending on what recording functions an enhanced tourniquet may possess. Alarms and/or alerts could be useful for warning a caregiver when something is going wrong that they might not otherwise notice. Automated notices could be displayed on a screen or given as an audio alert, although there were concerns that audio alerts could give away position to an adversary. As such, it was agreed that muting and volume functions would be critical. The three most important items agreed upon by panelists were low battery, device malfunction, and change in blood loss rate.

As for automated tourniquet function (i.e., automated tightening/loosening to maintain occlusion), there was clear hesitation around fully automated tourniquet deployment and even automated functions in general. Dubiousness around automated systems revolved around concern for system failures in terms of failure to activate, inappropriate activation, or failure after activation. As such, it was clear that semiautomated function was critical (i.e., manual backup always available, user-confirmation requirements for changing tourniquet force) and that automated tourniquets, should they fail, should fail ON. In other words, pressure should be maintained even if automated functions have become disabled. To circumvent automated functionality, a tourniquet could also provide instructions to the user, with some agreement that a tourniquet could provide recommended.

Limitations of this study include panelist involvement, where the military representation far outweighed other industry types. Dropouts from the study were consistent through each survey step; however, agency representation of the panelists were spread out among various types of SMEs so we, therefore, do not think that there was a bias toward the end of the survey rounds that may skew to one side or another (Supplemental Digital Content, Table 2, http://links.lww.com/TA/D504). Another limitation is that we asked panelists to envision hypothetical innovations that could be useful for a future tourniquet even though these capabilities currently do not exist on a tourniquet system. Several comments were made, such as "how would this work" and "this technology does not exist," may explain why some panelists regarded fully autonomous tourniquets as not important and highly relied on manual operations as fallback option. Adoption of these hypothetical tourniquet devices are akin to our current mindset of adopting newly developed digitized devices; they are harder to adopt and require key components, such as technology support, focus on end-user experience, and inclusion of clinician champions.[23] Other concerns were how sensors could be integrated into these enhanced tourniquet devices and evaluating other types of garments for the integration of tourniquets aside from typical combat uniforms. Although there was a general consensus that integration into a uniform was not feasible due to the complexity of placement, maintenance, and reliability, the panelists agreed that there should be future research and development and thorough evaluation of uniform-integrated devices.

CONCLUSION

Given the panelists' consensus, there is clear room for innovation in the "next-generation" tourniquet space. Based on the outcome of these surveys, a series of recommendations for next-generation tourniquets has been devised which can be used as a baseline for future development. We sought a comprehensive analysis of tourniquet recommendations that combine potential use of new technological innovations. Although this list is large, we recognize that not all of these features may be possible in one single tourniquet and perhaps a portfolio of multiple tourniquets that are appropriate in different use-case scenarios may be more useful in both military and civilian markets. Indeed, tourniquets with enhanced capabilities based on the results of this survey process may be most specific for use by a medical provider rather than widespread use by individuals without

medical training, particularly because of the abandonment of cost as a significant factor. The Delphi methodology used herein could, however, be used to identify future developments for a tourniquet that could be used universally by laypersons to aid in the most pressing concerns, such as proper placement for cessation of limb blood flow. Indeed, one recently developed tourniquet system, the Layperson Audiovisual Assist Tourniquet, possesses features that directly instruct a lay user in proper tourniquet application. The results of a recent study suggest that the Layperson Audiovisual Assist Tourniquet could reduce tourniquet application time and increase successful application rates relative to the common combat application tourniquet by leveraging features that instruct and guide users.[24]

We recommend continued efforts in testing and validating new tourniquet systems, especially when new capabilities or features are implemented.[25] Novel enhanced tourniquets should also be thoroughly evaluated and validated in multiple test case scenarios with appropriate simulator models that are capable of mimicking and capturing the appropriate data, especially if novel sensing capabilities are required. The development of a validation framework to test these new tourniquets is warranted to ensure the safety and effectiveness of the device and robustness for all environments.

AUTHORSHIP

S.R.V., J.F.M., D.R.H., J.F.K., and K.L.R. developed the study design. S.R.V., J.F.M., D.R.H. conducted the study and primary data analyses. S.R.V., J.F.M., D.R.H. drafted the initial article. S.R.V., J.F.M., D.R.H., J.F.K., K.L.R., J.S. provided key revisions and final edits.

ACKNOWLEDGMENTS

We wish to thank all our panelists involved in the survey and working group meetings. We appreciate their time, expertise, and involvement that was crucial for the results of this research study.

DISCLOSURE

Conflicts of Interest: None to declare. All JTACS Disclosure forms have been supplied and are provided as supplemental digital content (http://links.lww.com/TA/D505).

Funding: (1) JPC6 Combat Casualty Research Program W81XWH-21-CCCRP-AD. (2) Oak Ridge Institute for Science and Education

Disclaimer: The views expressed in this article are those of the authors and do not reflect the official policy or position of the US Army Medical Department, Department of the Army, DoD, or the US Government.

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