



KAY KARE™: IMPROVED QUALITY OF DAILY LIVING.

A new study by Virginia Tech reveals top performance qualities of the Kay Kare™ single-arm brace.

For patients under treatment with shoulder injuries or surgery, recovery times can be threatened by complicated shoulder immobilizers with uncomfortable shoulder straps and intricately rigged fastening systems. Recently, a comprehensive study by a major university reported that the Kay Kare™ Single-Arm Brace offers ease of donning and doffing for both health care providers and recovering patients, especially the elderly and those living independently. The Kay Kare™ Single-Arm Brace is the first commercially available arm brace to enable a simpler, “open-flap” method for donning and doffing, which could result in less pain, more stability, and greater ease of use versus commonly available slings and braces.

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VIRGINIA TECH STUDY RESULTS SUMMARY

Kay Kare™ eliminates shoulder straps for greater comfort and stability

Healthcare providers and patients involved in shoulder treatment know that any slight movement of muscles around the affected area can cause great discomfort and pain during recovery. Medical device manufacturers have no compelling reason to change, and assume that uncomfortable shoulder straps, found on most commercially available arm braces, do a better job minimizing muscle activity for comfort and stabilization of the shoulder for medical necessity. However, these straps continue to be sources of great pain and frustration for both patients and caregivers when donning and doffing braces.

The Kay Kare™ Single-Arm Brace – the only commercially available stabilizing arm brace designed to eliminate shoulder straps – was compared recently to four competing arm braces that require shoulder or arm straps in a variety of configurations and designs. This is the first formal research exploring the interplay between stability, comfort, and brace design, or research evaluating brace usability and stability using **objective** measures.

GENEDGE¹ and Kay Kare, LLC, hired researchers from Virginia Polytechnic & State University (“Virginia Tech”) to undertake the very first comparative evaluation of its kind, to examine the claims of the Kay Kare™ Single-Arm Brace versus other well-known braces. The results were striking.

A “FIRST” FOR PATIENTS

“The current study examined the usability, comfort, and stability of the Kay Kare arm brace....no reports, to our knowledge, have evaluated brace usability and stability using objective measures.”

**Virginia Tech’s Occupational
Ergonomics Lab, Dept. of
Industrial Engineering**

After months of study and analysis, researchers working in Virginia Tech's Occupational Ergonomics and Biomechanics Lab in the Department of Industrial and Systems Engineering produced a final report: *"Evaluating the Usability, Comfort and Stability of Arm Braces."* In their report, objective study evidence supports the claim that Kay Kare's patented design outperforms the competition *significantly* on factors involving ease of use and stability, and does so with comparable or higher comfort.

Kay Kare's Single-Arm Brace design results in better performance for both patients and caregivers

In a variety of very distinct ways, severe pain and other barriers to recovery are almost assuredly due to the complicated straps and buckles that accompany arm braces typically used in shoulder recovery from surgery or trauma. First, the straps increase the "pull" on the neck, thereby inflicting unnecessary neck pain in addition to already existing shoulder pain, compromising the quality of daily living and care of the patients who face an extended recovery period. Second, the "donning" and "doffing" of the braces – both at home and during treatment and exams – cause acute discomfort as both patient and caregiver struggle to "fish" a painful, injured arm into -- or out of -- these braces. Finally, both patients and caregivers often report low compliance leading to overall longer recovery expense because the ongoing, correct use of these braces is very difficult and time-consuming to learn. As such, many patients simply give up, greatly increasing the risk of re-injury and prolonging the healing time.

For geriatric patients or those living independently, the experience can be especially challenging. For instance, a phenomenon known as "failure to thrive" is one challenge that healthcare providers already wrestle with in elderly populations. During recovery, these patients are already frail, in constant pain and challenged cognitively with following instructions. It becomes extremely difficult for them to learn a new therapeutic regimen, like those involving complicated shoulder immobilizers. This situation often spirals into lack of compliance. To some degree, this is the case with shoulder patients of any age, but is especially prominent in the elderly.

Virginia Tech's unique research study implemented a "within-subjects" design to test the usability, comfort, and stability of the Kay Kare™ Single-Arm brace against four competing braces, all designed to immobilize or stabilize the arm and shoulder under medical instructions. The only difference: Kay Kare™ was the only brace design that does not depend on required shoulder or arm straps for stability. The study consisted of two sections: (1) donning/doffing with timed trials and usability evaluation; (2) movement analysis during simulated activities of daily living and involving motion capture, monitoring muscle activity (electromyography), and assessing perceived stability/comfort.

In the second part of the study, data were captured during the several standardized arm/shoulder movements: *forward reach; non-dominant side reach; dominant side reach; and upward reach*. The impacted muscles that were monitored included the non-braced descending trapezius, middle trapezius, ascending trapezius, posterior deltoid, medial deltoid, and anterior deltoid.

To evaluate Kay Kare's claims of a simpler, more effective brace, Virginia Tech researchers recruited a diverse sample of younger and older participants, of both genders. Evaluations were completed from both caregiver and end-user perspectives. According to the researchers, their study on brace design is the only currently known research involving both subjective and objective measures of usability,

comfort, and stability. Their experimental approach, which used both subjective responses *and* measures of movement and muscle activity, revealed statistically significant increases in ease of use and comfort with Kay Kare™ overall, as well as significantly decreased muscle activity in most of the measured shoulder muscles, indicating increased stability versus the competition.

Statistically significant study findings from an “**end-user**” (**patient**) perspective include:

- *Study participants ranked Kay Kare’s brace as having the highest level of ease in the **self-donning** task, compared with all other braces*
- *Study participants ranked Kay Kare’s brace consistently as having the highest level of ease for **self-doffing**, compared with all other braces*
- *Using Kay Kare’s brace required the fewest number of trials to reach a plateau level of learning to self-don effectively, compared with all other braces*

Statistically significant study findings from a “**caregiver**” perspective include:

- *Kay Kare’s brace required less time to don compared with all other braces*
- *Study participants ranked Kay Kare’s brace highest on ease-of-use compared with all other braces*
- *Study participants ranked Kay Kare’s brace consistently as having the highest level of ease-of-use for self-doffing*

These findings are highly important for several reasons regarding pain and recovery time related to shoulder injuries. Overall, it appears that shoulder immobilizer manufacturers are attempting to achieve arm/shoulder stability through designs that require mandatory application of multiple shoulder or arm straps and complicated fastening articles. However, as supported by this independent study by Virginia Tech, Kay Kare’s patented, strapless design offers comfort while maintaining stability. With the exception of one out of the six muscles (anterior deltoid) under observation, the researchers found significantly lower muscle activity resulting from the Kay Kare™ brace. Analysis of motion capture data also indicated no clinically significant difference in upper-extremity movements with Kay Kare™ versus competitors.

Why switch to Kay Kare’s arm brace?

Kay Kare’s arm brace was invented and patented by an Occupational Therapist with over 18 years of hands-on patient experience, and was designed to save time and eliminate unnecessary pain during application of a shoulder brace, improving comfort and overall quality of care. It features an easy-to-open arm envelope...*without complicated shoulder straps*. As a benefit, the Virginia Tech study concluded that there is no loss of stability. In fact, their study indicated that muscle activity decreased while wearing the Kay Kare™ arm brace for most of the shoulder muscles that were examined. Since its application takes significantly less time, it is mechanically far less frustrating for use and will benefit patients and caregivers alike. Patients will experience significantly less pain and frustration with the Kay Kare™ brace, and will be better able to comply when it’s prescribed for recovery. Most importantly, the elimination of shoulder straps in the Kay Kare™ design will substantially reduce pull on the neck,

thereby greatly increasing comfort without sacrificing ease of use and stability, especially for elderly and those living independently.

So, who can benefit from Kay Kare™ arm braces? Orthopedic surgeons, physical medicine, trauma teams, athletic teams, and caregivers living with the patient. All will likely find the Kay Kare™ brace to be superior, not only for speedy application at point-of-care, but also for patient compliance because it's so easy to learn. Since the greatly simplified design eliminates pull on the neck, patients will notice less discomfort performing their daily tasks, and they will enjoy better mobility than with the competing braces in the market. For healthcare providers and caregivers, competing braces can be exceedingly complicated to apply and even more difficult to teach the patients; as a result, patient compliance is at high risk to be compromised against medical advice, leading to prolonged recovery time and increased risk of re-injury. For emergency responders, Kay Kare less-complicated brace design is highly desirable as an immobilizer because it facilitates faster, easier application in time-constrained environments.

The Kay Kare™ Single-Arm Brace and the Kay Kare™ Double-Arm Brace are commercially available, FDA approved medical devices.

Designed and manufactured in the USA

For details and ordering information, visit <http://kaykare.net/>