Original article

Dorsal capsulodesis associated with arthroscopy-assisted scapholunate ligament reconstruction using a palmaris longus tendon graft

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ABSTRACT

Objectives: To measure the quality of life, the time to work return, and clinical, functional, and radiographic parameters of patients treated with dorsal capsulodesis associated with scapholunate (SL) reconstruction, assisted by arthroscopy.

Methods: From January 2015 to September 2016, 14 adult patients with SL dissociation underwent surgical treatment with the SL reconstruction procedure assisted by arthroscopy, using the new technique proposed in this study. All patients were assessed by the occupational therapy department at regular intervals after surgery and performed the same sequence of rehabilitation. The parameters analyzed were: range of motion (ROM), Disability of the Arm, Shoulder, and Hand (DASH), visual analog scale (VAS), and radiographic analysis to visualize the pre- and postoperative SL gap and the pre- and postoperative dorsal intercalated segment instability (DISI) deformity. The complications and the time to return to work activities were described.

Results: The follow-up time was 12 months (3–17). The ROM averaged 321° (96.9% of the normal side). VAS was 1.79 (1–6). DASH was 6.50 (1–30). The time to work return was 4.42 months (2–17). As for complications, one patient developed SLAC, and underwent four-corner fusion one year after ligament reconstruction. Currently, he has experienced pain relief, with a functional range of motion of the wrist, and has not yet returned to professional activities.

The preoperative SL gap was 4.29 mm (2–7); in the postoperative period, it was 1.79 mm (1–4). The DISI deformity was present in ten patients with SL angle >70° (preoperative) and it was corrected after surgery, in all patients. SLAC stage I was identified in a patient. Arthroscopy was performed in all cases. The SL instability was classified as Geissler grade III in four cases and as grade IV in ten cases.

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Conclusion: The new approach (dorsal capsulodesis associated with SL reconstruction, assisted by arthroscopy) presented in this study is safe and effective in the treatment of SL dissociation, since it offers satisfactory clinical, radiographic and functional results, showing low rates of complications. For patients, it allows the return to their social and professional activities, and increases their life quality.

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Capsulodesis dorsal asociada a reconstrucción asistida por artroscopia del ligamento escafossemilunar con enxerto del tendon do músculo palmar longo

RESUMO

Objetivos: Mensurar a qualidade de vida, o tempo de retorno ao trabalho, os resultados clínicos, funcionais e radiográficos dos pacientes submetidos à capsulodesis dorsal associada à reconstrução ligamentar escafossemilunar assistida por artroscopia.

Métodos: De janeiro de 2015 a setembro de 2016, 14 pacientes, esqueleticamente maduros, adultos, com dissociação escafolar (SL), foram submetidos ao tratamento cirúrgico com o procedimento de reconstrução do ligamento escafossemilunar assistido por artroscopia com a nova técnica proposta neste estudo. Todos os pacientes foram avaliados pelo setor de terapia ocupacional em intervalos regulares de pós-operatório e fizeram a mesma sequência de reabilitação. Os parâmetros analisados foram: arco de movimento (ADM), Disability Arm, Shoulder and Hand (Dash), escala visual analógica (EVA) e análise radiográfica pré e pós-operatória para visualizar o espaço escafolar (sinal de Terry-Thomas) e deformidade em Dorsal Intercalated Segment Instability (DISI) pré e pós-operatória. Descrição das complicações e o tempo de retorno ao trabalho.

Resultados: O tempo de seguimento foi de 12 meses [3-17]. O ADM foi em média 321,07° (96,9% do lado normal). O valor da avaliação subjetiva da dor (VAS) foi 1,79/10 [1-6]. A mensuração da qualidade de vida pelo Dash foi de 6,50/100 [1-30]. O tempo de retorno ao trabalho foi de 4,42 meses [2-17]. Quanto às complicações, uma paciente evoluiu com SLAC e foi submetida à arthrodes do quatro cantos um ano após a reconstrução ligamentar. Evoluiu com melhoria da dor e está com o ADM do punho funcional, mas ainda não retornou às atividades profissionais. O intervalo do SL (gap) pré-operatório foi de 4,29mm [2-7] e o pós-operatório foi de 1,79mm [1-4]. A deformidade DISI estava presente em dez pacientes, com um ângulo SL acima de 70° (pré-operatório), e foi corrigida após a cirurgia em todos os pacientes. SLAC estágio I foi identificado em um paciente. A artroscopia foi feita em todos os casos. A instabilidade SL foi classificada como um grau Geissler III em quatro casos e grau IV em dez casos.

Conclusão: A nova abordagem (capsulodesis dorsal associada à reconstrução ligamentar escafossemilunar assistida por artroscopia) apresentada neste estudo é segura e eficaz no tratamento da dissocição escafolar, já que apresenta resultados radiográficos, clínicos e funcionais satisfatórios, demonstra baixas taxas de complicações, permite o retorno às atividades sociais e profissionais e aumenta a qualidade de vida desses pacientes.

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Introduction

The scapholunate (SL) dissociation, or lesion of the SL ligament, is the most common form of carpal instability1 (Fig. 1).

Numerous surgical techniques have been described to restore or improve the stability of the SL joint, aiming to delay or prevent the progression of osteoarthritis between carpal bones, known as SL advanced collapse (SLAC).

These procedures used to include various forms of capsulodesis, static or dynamic tenodesis, ligament reconstruction with tendon graft, bone-ligament-bone reconstruction, or reduction and compression screw fixation between the scaphoid and lunate, in a procedure termed reduction and association of the scaphoid and lunate (RASL).
However, such reconstructions alter the biomechanics of the wrist, since they form a vertical connection between Gilula’s arcs, which can alter the mobility of the radiocarpal or midcarpal joints.

The persistence of the Terry-Thomas sign (gap between the scaphoid and lunate), loosening of the tendon graft, technical difficulty, limitation of wrist mobility and palmar grip strength, and iatrogenic fractures during the creation of the scaphoid or lunate tunnels have been reported as the main complications.²⁻¹¹ The authors believe that these problems can be avoided with the development of new implants, such as bio-tenodesis screws of specific sizes for carpal bones.

Furthermore, most methods only promote the reconstruction of the dorsal and uniplanar portion of the SL ligament. Many studies have highlighted the importance of the volar portion of this ligament.¹²⁻¹⁵

The search for the ideal reconstruction (volar and dorsal portion) began with the biomechanical study by Yi et al.¹⁶ who used a tendon graft from the long palmaris muscle and introduced it through holes in the anteroposterior plane of the scaphoid and lunate. The SL gap was effectively reduced to normal, and the anatomic SL reduction was significantly improved after reconstruction.

Zdero et al.¹⁷ assessed 19 cadaver wrists, and used bovine tendons passed through double bone tunnels of the scaphoid and lunate. Seventeen of the 19 wrists submitted to this reconstruction presented no difference in mechanical properties when compared with the normal side.

The results of these studies support the clinical application of a combined SL ligament reconstruction technique (volar and dorsal).

Ho et al.¹⁸ published a clinical study of 17 patients, all with chronic SL dissociation, who underwent arthroscopy-assisted reconstruction with the use of a free tendon graft from the long palmar muscle (LPM); 13 patients returned to their previous work activities, all were satisfied with the result, four evolved with recurrence of dorsal intercalated segmentation instability (DASI), and one evolved with asymptomatic necrosis of the proximal pole of the scaphoid.

Hagert et al.¹⁹ suggested that the wrist ligaments vary with regard to sensory and biomechanical functions. Depending on the structural composition and innervation, the wrist ligaments present greater mechanical (densely packed collagen bundles with limited innervation) or sensorial relevance (richly innervated, although less dense in the connective tissue composition). It is believed that the dorsal capsule and the intrinsic ligaments of the wrist, including the SL, have an important role in the proprioception of the wrist. Thus, the authors suggest that surgical reconstruction should be immediate at diagnosis and that the treatment method employed should have a minimal impact on the dorsal capsule of the wrist.¹⁹⁻²¹

Overstraeten et al.²² described the presence of a distinct structure, which connects the SL ligament to the dorsal capsule, termed dorsal capsulo-scapholunate septum (DCSS). The authors believe that the DCSS is a secondary stabilizer of the SL joint, and that it may have therapeutic and prognostic implications. The capsulodesis techniques described thus far favor this “reconnection” of the dorsal capsule with the SL ligament.

Wolfe et al.²³ conducted a kinematic analysis of the wrist and showed that the proximal carpal row is almost stationary during the dart throw motion (DTM), which is believed to provide a stable platform for the generation of force and precision during certain functional activities, such as palmar prehension. In order to improve the rehabilitation of patients who underwent wrist ligament reconstruction, the authors believe that DTM can be used early in the first postoperative weeks, as it avoids muscular stiffness and atrophy in the affected limb, stimulates proprioception, and does not interfere in the healing of the reconstructed intrinsic ligament.

In the present study, a new approach to the treatment of SL dissociation will be described, in order to improve clinical-functional outcomes, time-lapse for returning to social and professional activities, surgical management, postoperative rehabilitation, and quality of life of these patients.

This study is also aimed at assessing the quality of life, return to work, the clinical-functional and radiographic results of patients who underwent dorsal capsulodesis associated with arthroscopy-assisted SL ligament reconstruction.

**Methods**

From January 2015 to September 2016, 14 skeletally mature adult patients with SL dissociation, evaluated at the outpatient surgical clinic, and who underwent arthroscopy-assisted SL ligament reconstruction with the new technique proposed in this study, were assessed.

Nine patients were male and five, female. The mean age was 38 (19–60) years. Eight right and six left wrists were operated on. Regarding the professional occupation, three patients were students; three, housewives; one, engineer; one, nurse; one, athlete; two, computer technicians (IT); and three, factory workers. Four patients presented fracture of the distal extremity of the associated radius and underwent treatment at the same time of the ligament reconstruction. Fracture fixation with plate and screws and a rehabilitation protocol was applied. All patients presented pain in the dorsal region of the wrist, especially at extremes of movement and exertion.
| Identification | Age | Follow-up | Normal ROM | Final ROM | Final DASH | Final VAS | Watson test | Geissler type | DISI | SL gap SL gap pre | SL gap SL gap post | Return to work | Complications | Profession | Associated lesions |
|---------------|-----|-----------|------------|-----------|------------|-----------|-------------|--------------|------|----------------|----------------|----------------|---------------|------------|----------------|
| I             | 33  | 17        | 315        | 315       | 6          | 1         | +           | 4            | Yes  | 6              | 2              | 3rd month     | No            | Engineer    | No           |
| II            | 36  | 16        | 345        | 345       | 6          | 1         | +           | 4            | Yes  | 7              | 4              | 3rd month     | No            | Nurse       | No           |
| III           | 25  | 13        | 345        | 345       | 6          | 1         | +           | 3            | N    | 3              | 1              | 2nd month     | No            | Student     | Distal radius fracture |
| IV            | 50  | 13        | 335        | 335       | 6          | 1         | +           | 4            | Yes  | 4              | 1              | 3rd month     | No            | Homemaker   | Distal radius fracture |
| V             | 23  | 15        | 345        | 345       | 6          | 1         | +           | 4            | Yes  | 5              | 1              | 3rd month     | No            | Student     | No           |
| VI            | 52  | 15        | 316        | 230       | 30         | 6         | -           | 4            | Yes  | 5              | 4              | No            | SLAC          | Homemaker   | No           |
| VII           | 60  | 14        | 335        | 335       | 6          | 2         | +           | 4            | Yes  | 5              | 1              | 6th month     | No            | Factory worker | No           |
| VIII          | 58  | 15        | 295        | 270       | 18         | 1         | +           | 4            | Yes  | 5              | 2              | 6th month     | No            | Factory worker | Distal radius fracture |
| IX            | 28  | 12        | 325        | 325       | 1          | 1         | +           | 3            | Yes  | 4              | 2              | 4th month     | No            | Factory worker | No           |
| X             | 19  | 7         | 345        | 345       | 1          | 1         | +           | 4            | Yes  | 4              | 1              | 2nd month     | No            | Student     | Distal radius fracture |
| XI            | 42  | 8         | 330        | 310       | 1          | 2         | +           | 4            | No   | 3              | 2              | 2nd month     | No            | TI          | No           |
| XII           | 30  | 9         | 345        | 345       | 1          | 1         | -           | 2            | No   | 2              | 1              | 2nd month     | No            | Athlete     | No           |
| XIII          | 52  | 6         | 315        | 315       | 1          | 1         | +           | 2            | No   | 3              | 1              | 3rd month     | No            | Homemaker   | No           |
| XIV           | 23  | 3         | 340        | 335       | 2          | 1         | +           | 3            | Yes  | 4              | 2              | 3rd month     | No            | TI          | No           |

Source: Medical Statistical File Service.
and eight had subjective loss of strength and instability with a painful click. In all patients, physical examination indicated pain at palpation at the SL gap site. The Watson test was positive in 12 of 14 cases.

All patients were evaluated by the occupational therapy sector at regular postoperative intervals and underwent the same rehabilitation sequence, following the same protocol, and were evaluated in two and six weeks, six months, and one year postoperatively (Table 1).

The assessed parameters were:

- Range of motion (ROM), assessing the goniometry of the ROM with the measurement in degrees.
- Disability Arm, Shoulder, and Hand (DASH) Questionnaire – quality of life.
- Visual analog scale (VAS) – subjective pain assessment.
- Radiographic analysis to visualize pre- and postoperative SL space (Terry-Thomas sign) and SL angle (normal values range from 30 to 60°; DISI deformity was assessed when the angle was higher than 70°).
- Description of the complications that arose after surgical treatment.
- Return to work.

**Description of the surgical technique**

Diagnosticarthroscopy is an important tool to identify the cause of wrist pain in cases where SL dissociation may be associated with other pathologies.

The surgery was performed under general anesthesia or locoregional blockade. The patient was placed in a dorsal recumbent position, with the arm suspended in a specific wrist traction tower, under 10–13 lb of traction. A tourniquet was inflated or passed. Continuous irrigation with saline solution was achieved with a pump and specific equipment under the action of gravity.

An inventory of the radio-carpal joint was made initially through portals 3–4, 4–5, and 6 U for the saline solution exit; the midcarpal joint was assessed through the radial (MCR) and ulnar (MCU) portals. Small transverse incisions were made along the skin folds for a better scar appearance. Arthroscopes measuring 1.9 mm or 2.7 mm were used. The joint was systematically inspected and the results were documented. When necessary, radial synovectomy was performed at the same time, with 2-mm and 2.9-mm shaver blades. Intra-articular fibrosis was removed to improve wrist mobility and to promote gap reduction and SL alignment, as well as to correct DISI deformity.

The rebuilding step was initiated with a 2 cm transverse incision along the proximal transverse fold of the wrist (Fig. 2) to identify the insertion of the palmaris longus tendon and of the flexor carpi radialis tendon. The palmaris longus graft was extracted with or without the use of a tendon stripper. A 2 mm proximal incision was made in the fascia of the anterior forearm to identify the myotendinous transition of the palmaris longus, in order to excise it. Both dorsal and volar joint capsules were preserved, unaltered. At that moment, the wrist was ready for the preparation of the bone tunnels.

**Fig. 2 – Preoperative clinical aspect: incision in the transverse palmar fold of the wrist to locate the insertion of the palmaris longus tendon.**

Fluoroscopy was used to assess the wrist. If a DISI deformity was observed, the extended lunate position would be corrected by flexion of the wrist to restore the normal radioulnar angle and the radioulnar joint, with fixation or not with a 1.6-mm Kirschner wire inserted percutaneously. The wrist was then passively extended to correct the flexion deformity of the scaphoid and restore a normal SL angle. If these corrections were not achieved, additional arthroscopic release of the fibrosis around the scaphoid and lunate was performed. If it was still impossible to reduce the DISI deformity, then ligament reconstruction would be abandoned; fortunately, this did not occur in this study. Through the dorsal portals 4–5 or 6 R, MCR, or MCU, a 1.1-mm guidewire was placed inside a soft-tissue protector (drill guide) on the lunate and scaphoid under fluoroscopic guidance. When the radius and lunate were well aligned with the guidewire, the direction of the radius should be perpendicular to the long axis of the lunate; i.e., parallel to the line joining the tip of volar and dorsal lips of the lunate (lateral view). The guide wire was advanced 2–3 mm from the bone margin and then toward the volar cortex. With the flexor tendons and median nerve, including the palmar cutaneous branch, carefully moved to the ulnar side, the exit of this wire was identified. Another guidewire was then inserted into the scaphoid through the 3–4 dorsal portal. It was placed parallel to the lunate guidewire, provided that the SL angle had been corrected. Otherwise, its entrance should be slightly more distal than that of the lunate guidewire; it should be moved toward the palmar and proximal direction to provide a better correction of the scaphoid rotation and flexion. With the flexor carpi radialis tendon radially moved, the scaphoid wire was advanced through the volar face. Both tunnels (Fig. 3) were sequentially enlarged with 2.0-, 2.7-, or 3-mm cannulated drills, depending on the thickness of the palmaris longus graft. The drill of smallest possible diameter should be used to ensure a smooth passage of the graft and avoid iatrogenic fracture or avascular necrosis of these bones.

The tendon graft was prepared with a continuous Krackow suture (Fig. 4) and passed through bone tunnels with specific
Intraoperative fluoroscopy: preparation of the lunate bone tunnel.

Intraoperative aspect – preparation of the palmaris longus tendon graft (Krackow suture).

Intraoperative clinical aspect: preparation of the scaphoid bone tunnel.

The needles or wires from the palmar to the dorsal side of the scaphoid (Figs. 5 and 6) and from the dorsal to the palmar aspect of the lunate. The tendon graft was passed outside the dorsal capsule, so that it was reinserted linearly under the SL gap (linear capsulodesis).

The fixation of the graft in the bone tunnels with a bio-tenodesis screw, measuring 3 mm in diameter and 8 mm in length, also called 3/8 mm (Bio-Tenodesis screw, Arthrex Inc., FL, USA) was performed. The final part of the graft was sutured at the same site of the graft entry point into the scaphoid (reconstruction of the palmar portion of the SL ligament). The Kirschner wire was passed between the scaphoid and capitate bones for stabilization of the ligament reconstruction. The midcarpal joint was once again inspected through the MCR or MCU portal. The SL gap was once again inspected with probe tweezers, as described by Geissler (Fig. 7). This interval should be closed. Any tissue interposition in the SL gap preventing a complete reduction, was arthroscopically removed. SL stability was confirmed by arthroscopy and fluoroscopy.

The layers were cleaned and sutured, and a plaster cast was placed. Two weeks postoperatively, the plaster cast and Kirschner wires that maintained the SL reduction were removed from the carpal bones; all patients started rehabilitation in occupational therapy.

Results

The follow-up time was 12 months (3–17). The mean ROM was 321.07° (96.9% of the normal side). The mean subjective pain assessment (VAS) was 1.79/10 (1–6). The mean DASH score, which assesses quality of life, was 6.50/100 (1–30).

The mean time it took to return to work was 4.42 months (2–17). As for complications, one patient developed SLAC and underwent four-corner fusion after one year of ligament reconstruction. Currently, her pain has improved, has a
functional wrist ROM, but has not yet returned to professional activities.

In the preoperative period, the mean SL gap was 4.29 mm (2–7), vs. 1.79 mm (1–4) postoperatively. DISI deformity was observed in ten patients, with an SL angle of more than 70°, prior to the procedure, and was corrected after surgery in all patients. SLAC stage I was identified in one patient. Arthroscopy was performed in all cases. SL instability was classified as a Geissler grade III in four cases and grade IV in ten cases. Other arthroscopy findings were radial synovitis in 11 patients, degeneration of the radial styloid cartilage in one, chondral lesion in the scaphoid fossa of the radius in two, proximal scaphoid chondral defect in one, and triangular fibrocartilage complex lesion (TFCC) in two. Concomitant procedures were performed in six cases, including TFCC debridement in one, radius osteosynthesis in four, and TFCC repair in one. No cases of infection or neurovascular complications were observed in the present series.

Results

For statistical analyses, a p-value of 5% (0.050) was considered as significant for the application of the statistical tests (Table 2).

MS-Excel spreadsheet, in its version from MS-Office 2013, was used to organize the data. The statistical package Statistical Package for Social Sciences (SPSS), version 23.0, was used to apply the Wilcoxon signed rank test, in order to verify possible differences between the two moments studied, for the variables of interest.

Discussion

The idea of reconstructing this ligament is not new. In 1975, Dobyns et al. used a strip of tendon and passed it through anteroposterior bone tunnels at the proximal pole of the scaphoid and lunate to rebuild the SL ligament. Stability was achieved by looping the tendon graft throughout the scaphoid and lunate. However, the open creation of bone tunnels compromised their vascularization and resulted in avascular necrosis and fractures. This approach was subsequently abandoned. The present arthroscopic series did not require dissection of the joint capsule and thus preserved the vascular supply and proprioception of the carpus. This minimally invasive technique helps to minimize soft tissue dissection and decreases the risk of avascular necrosis, promotes healing of the reconstructed SL ligament, and accelerates the postoperative rehabilitation.

The results of the present study demonstrated an improvement in wrist mobility, with a 96.9% recovery of ROM when compared with the normal side. The present results are similar to those by Ho et al. However, the present authors disagree with those authors. Ho et al. stated that dorsal capsulodesis decreases flexion of the wrist, which was not demonstrated in the present study. The present authors believe that the linear capsulodesis performed in the present study, limited to the SL gap, did not interfere in the mobility of the midcarpal joint.

Wahnaqonkar et al. stated that the dorsal portion of the SL ligament (DCSS) is paramount for SL stability, largely due to its attachment to the dorsal capsule. These authors conducted a multicenter anatomical study with international collaboration and demonstrated the critical importance of DCSS. The arthroscopic capsule-ligament repair technique provided reliable results and avoided postoperative stiffness. The global results over a mean follow-up period of over two years are encouraging. The authors believe that the capsulodesis performed in the present study allowed continuity of the ligament with the dorsal capsule, as well as DCSS reconstruction.

The choice of the palmaris longus tendon graft, used in this and other published studies, offers some advantages:

- the diameter of the bone tunnels can be minimal; it avoids complications such as iatrogenic fractures or vascular lesions of carpal bones;
- it also preserves the flexor carpi radialis, which the authors believe to be an important secondary stabilizer of the wrist, helping the use of DTM in the rehabilitation stages.

The recurrence of the SL gap (Terry-Thomas sign) is commonly cited in the literature, and the present results demonstrated a maintenance of the SL gap reduction of 1.79 mm (Fig. 8).

Replacing a ligament with a tendon may not actually reproduce the original anatomy of the SL complex. However, the authors believe in the “ligamentization” of these grafts, since the environment in which they are found may favor this mechanism, similarly to what is observed in patients who undergo anterior cruciate ligament (ACL) reconstruction.

When rebuilding both the volar and dorsal portions of this ligament, greater stability and efficacy can be expected when compared with the more common dorsal reconstructions.

Many cadaveric studies support 360° reconstruction around the carpal bones, with favorable biomechanical results. Other clinical studies have shown promising results, such as that by Marcuzzi, who treated six patients with...
dorsal and palmar reconstruction and obtained good clinical results, which were also demonstrated in the present study.27

The ideal treatment for SL dissociation has not yet been established. The authors believe that the reconstruction of both portions of the SL ligament, associated with linear dorsal capsulodesis, graft fixation with specific screws, and the use of the DTM during immediate postoperative rehabilitation decreases the period of immobilization (of only two weeks in this present study) and the rates of complication, allowing an early return to social and professional activities.

**Conclusion**

The new approach (dorsal capsulodesis associated with arthroscopic-assisted SL ligament reconstruction) presented in this study is safe and effective in the treatment of SL dissociation, since it presents satisfactory radiographic, clinical, and functional results, as well as low rates of complications, allowing the return to social and professional activities and increasing the quality of life of these patients.

**Conflicts of interest**

The authors declare no conflicts of interest.

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**Table 2 – Statistical results of the analyzed clinical-functional variables.**

| Pair of variables | n  | Mean (standard deviation) | Minimum | Maximum | 25th percentile | 50th percentile (median) | 75th percentile | Significance (p) |
|-------------------|----|---------------------------|---------|---------|----------------|--------------------------|----------------|-----------------|
| Normal ROM        | 14 | 330.79 (15.60)            | 295.00  | 345.00  | 315.75         | 335.00                   | 345.00         | [1.0]           |
| Final ROM         | 14 | 321.07 (33.47)            | 230.00  | 345.00  | 313.75         | 335.00                   | 345.00         | 0.068           |
| Normal DASH       | 14 | 1.00 (0.00)               | 1.00    | 1.00    | 1.00           | 1.00                     | 1.00           | [1.0]           |
| Final DASH        | 14 | 6.50 (8.12)               | 1.00    | 30.00   | 1.00           | 6.00                     | 6.00           | 0.006           |
| Normal VAS        | 14 | 1.00 (0.00)               | 1.00    | 1.00    | 1.00           | 1.00                     | 1.00           | [1.0]           |
| Final VAS         | 14 | 1.50 (1.34)               | 1.00    | 6.00    | 1.00           | 1.00                     | 1.25           | 0.102           |

Source: Medical Statistical File Service.

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