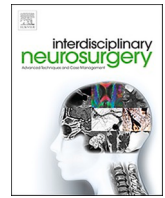




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Systematic bifocal decompression for isolated long thoracic nerve paresis: A case series of 12 patients

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ABSTRACT

To date, no consensus exists regarding the best surgical management of isolated, micro-traumatic long thoracic nerve (LTN) paresis. Our hypothesis was that a combined decompression of the LTN at two potential locations for entrapment would be effective in the management of dynamic LTN paresis. We report on twelve patients with isolated LTN paresis, with tenderness at two entrapment sites, who underwent bifocal LTN decompression after undergoing unsuccessful conservative treatment for at least 6 months; all patients had preoperative electrodiagnostic studies that confirmed the paresis and ruled out peripheral neuritis. Clinical and electrical improvements were observed in eight patients (67%) regarding shoulder flexion, shoulder abduction, and Quick-DASH scores. Four patients (33%) did not improve after surgery. The results corroborate our hypothesis that a bifocal LTN decompression can be an effective and reliable therapeutic option in more than half of a very selective patient population suffering from serratus anterior muscle deficiency.

1. Introduction

Scapular winging is a relatively rare but significantly disabling condition that compromises shoulder and upper limb global functions. Limitations of active shoulder flexion and decreased shoulder strength are observed. It is associated with secondary pain and sometimes spasms of the periscapular muscles due to compensation mechanisms. While the diagnosis of scapular winging can be made by simple inspection of the dorsal thorax, its etiology is often more difficult to ascertain [1]. The long thoracic nerve (LTN) is responsible for the innervation of the serratus anterior muscle, and its paresis is one of the most common causes of primary scapular winging. In the absence of extrinsic causes, such as major trauma, infections, inflammation, toxic, cervical spine osteoarthritis, LTN paresis may be intrinsic, most likely caused by repetitive microtrauma [2,3].

Arising from the three proximal roots of the brachial plexus (i.e., C5, C6 and C7) and passing through the middle scalene muscle, the LTN

becomes lateral and posterior to the brachial plexus to lie along the anterolateral chest wall and finally enter the serratus anterior muscle [4,5]. With a relatively fixed course, the LTN appears to present anatomical predispositions for entrapment, including the supraclavicular space proximally [6–9] and the latero-thoracic space distally [10,11]. Such anatomical specificities make the nerve susceptible to traction forces, with a bowstring effect occurring between those fixation points, as well as compression forces caused by contractions of the muscle itself within its superficial fascia [12,13]. Such iterative neural microtraumas induce local changes in perineural vascular permeability and favor the formation of intraneural edema, which subsequently impairs the axonal transport and causes the paresis [14,15].

As depicted by several teams, LTN surgical decompression appears to be an effective option to restore serratus anterior function [6–11]. However, while clinical examination, electroneuromyographic (ENMG) studies [16] and magnetic resonance imaging (MRI) [17] have been demonstrated efficient and reliable to ascertain the diagnosis of LTN

Abbreviations: LTN, long thoracic nerve; DASH, disabilities of arm, shoulder and Hand; ENMG, electroneuromyographic; ROM, range of motion; MRI, magnetic resonance imaging.

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paresis and exclude other causes of scapular winging, one major preoperative difficulty is to determine the exact location of the entrapment site, which remains uncertain in the majority of cases [2,10,11]. Subsequently, there is no consensus in the current literature regarding the best surgical management of isolated LTN paresis, or its indications.

The purposes of this study were to describe our surgical strategy and technique of bifocal LTN decompression, within the supraclavicular space proximally and on the anterolateral thoracic wall distally, as well as report on the preliminary outcomes that such procedure could yield in patients suffering from persistent scapular winging due to isolated LTN paresis without explicit cause of paresis and/or precisely localized site of compression on preoperative examinations. By allowing a comprehensive LTN release, from its exit point at the brachial plexus level to its entry points at the serratus anterior level, we hypothesized that this technique would be an effective and reproducible treatment in cases of idiopathic persistent LTN paresis.

2. Methods

Between November 2017 and July 2020, a retrospective study was conducted at our institution, including consecutively all patients who underwent a bifocal LTN decompression.

Considering peripheral neuritis was not an indication for LTN bifocal release, patients who presented a clinical history suggesting neuralgic amyotrophy were excluded [18]. Prior to surgery, all patients had to undergo non-surgical treatment for at least 6 months, including pain medication and rehabilitation exercises specifically designed for thoracic outlet syndromes (e.g., relaxation and stretching of thoracic, scalene and neck muscles, manual opening of the costoclavicular outlet, massage treatment for adhesions, nerve gliding techniques and electric stimulation of the weakened muscles).

2.1. Preoperative assessment and surgical indication

During the initial clinical examination, patients were questioned regarding the characteristics of their shoulder dysfunction, including the type of on-set, the duration, the levels of pain and discomfort and their evolution; previous treatment were recorded as well. Isolated serratus anterior paresis was characterized by inspecting the posterior thorax during active shoulder flexion, in order to highlight medial scapular winging. Additionally, a LTN irritative syndrome was looked for at both the supraclavicular and the axillary/thoracic spaces, and shoulder function was assessed, including active shoulder ranges of motion (ROM) in flexion and abduction, as well as scapulothoracic muscles strengths. Upper limb global function was assessed with the Quick-DASH (Disabilities of Arm, Shoulder and Hand) score [19]. All clinical assessment were performed by the senior author.

ENMG studies of the upper limb were conducted to assess the type and severity of conduction blocks and to exclude involvement of further nerves. MRI studies of the neck, shoulder and cervical spine were performed on a 1.5-Tesla scanner. The imaging protocols consisted of a 3D-T2 STIR sequence to detect denervation oedema of the serratus anterior muscle, signals of inflammation within the LTN and/or the brachial plexus, and signs of extrinsic compression towards the nerves. A 3D-T1 sequence was performed to detect fatty muscle infiltration of the serratus anterior muscle. Angiographic CT and/or ultrasound Doppler were performed to exclude potential causes of extrinsic compression upon the LTN, brachial venous thrombosis or malformation.

Eligibility criteria for surgery included a) persistent shoulder pain and dysfunction due to medial scapular winging despite at least 6 months of conservative management, b) tenderness along the course of the LTN at both the supraclavicular and the axillary/thoracic spaces, c) MRI scan showing denervation edema limited to the serratus anterior muscle and without fatty infiltration, and/or signs of neural inflammation limited to the LTN without signs of extrinsic compression, d) and brachial plexus ENMG study demonstrating an isolated lesion of the LTN

with conduction blocks of not more than Sunderland II between the neck and the thorax [16,20].

Ineligibility criteria included a) clinical evidence of a single site of compression of the LTN (e.g., isolated tenderness at the supraclavicular space), b) traumatic onset (e.g., neck and/or thoracic trauma, history of iatrogenic injury), c) concomitant nerve and/or brachial plexus lesions (e.g., neuralgic amyotrophy, involvement of multiple nerves, clinical signs of lesions in the territory of the dorsal scapular or spinal accessory nerves such as rhomboid muscle and trapezius muscle impairments), d) potential causes of extrinsic compression upon the LTN (e.g., bony scapular impairments such as chondromas of the scapula, chest wall tumors or scapula malunions, any glenohumeral intraarticular pathology, such as rotator cuff tear, or brachial venous thrombosis or malformation [1] (Table 1).

2.2. Surgical technique and post-operative care

Under general anesthesia, the patient was placed in the supine position. The head was maintained in a contralateral rotation from the operated side and the arm was resting on a hand table at the side of the patient. The neck, thorax, and upper limb were draped in a standardized fashion. All procedures were performed by the senior author using loupe magnification.

The operation began with a cervical approach [21]. A horizontal incision was made parallel to the clavicle, about 2.5 cm proximal to its superior aspect. The platysma muscle was incised, allowing to recline the cervical fat pad and superficial veins laterally. The omohyoid muscle and transverse cervical vessels were tagged, clipped, and cut. The brachial plexus was identified and dissected, starting from the superior trunk to the inferior trunk. The suprascapular nerve was identified as the first branch emerging from the superior trunk and followed distally to the coracoid notch. The long thoracic nerve was identified close to the suprascapular nerve, proximal and anterior to the suprascapular notch, dissected directly above the first rib and followed proximally to its emergence from the middle scalene muscle. Care should be taken not to confuse the dorsal scapular nerve with the LTN, as they are close together at this location; using a neurostimulator (Vari-Stim, Medtronic, Minneapolis, MN, USA) may be of help to correctly identify both structures. After confirmation of nerve continuity by direct eye view and

Table 1

Eligibility and ineligibility criteria for surgical bifocal LTN decompression.

Eligibility criteria	Ineligibility criteria
Persistent shoulder pain and dysfunction due to medial scapular winging	Traumatic onset (e.g., neck trauma, history of iatrogenic injury)
Tenderness along the course of the LTN at both the supraclavicular and the axillary/lateral thoracic spaces	Preoperative evidence of a single site of compression of the LTN (e.g., isolated tenderness at the supraclavicular space)
MRI scan showing denervation edema limited to the serratus anterior muscle and without fatty infiltration, and/or signs of neural inflammation limited to the LTN without signs of extrinsic compression	Concomitant nerve and/or brachial plexus lesions (e.g., neuralgic amyotrophy, involving multiple nerves, clinical signs of lesions in the territory of the dorsal scapular or spinal accessory nerves, such as rhomboid muscle and trapezius muscle impairments)
Brachial plexus ENMG study demonstrating an isolated lesion of the LTN with conduction blocks of not more than Sunderland II between the neck and the thorax ^{16,20}	Isolated LTN lesions that were precisely located with ENMG and MRI studies
Conservative management of at least 6 months	Potential causes of extrinsic compression upon the LTN (e.g., bony scapular impairments such as chondromas of the scapula, chest wall tumors or scapula malunions) Any glenohumeral intraarticular pathology, such as rotator cuff tear Brachial venous thrombosis or malformation

loupe magnification, complete resection of the middle scalene muscle and any fibrous bands were then performed, allowing the interscalenic decompression [8,21] (Fig. 1).

The intervention was guided by the intraoperative nerve stimulation [21]. After confirmation of nerve continuity, the long thoracic nerve was stimulated intraoperatively using a handheld nerve stimulator (Vari-Stim, Medtronic, Minneapolis, MN, USA). The nerve was stimulated at 1 mA for a short duration of 1 ms and at 1 Hz repetition rate. In case of positive nerve stimulation resulting into a normal (strong) response of the serratus anterior with efficient contraction of the muscle and subsequent antepulsion of the scapula, the operation was ended. In case of a weak serratus response, further decompression of the distal entrapment was carried out. This was done by an additional thoracic/axillary approach. As the patient remained in a supine position, the arm was abducted from the torso and an additional lateral thoracic approach was made. Landmarks for the skin incision were the anterior border of the latissimus dorsi muscle along with the inferior two thirds of the pectoralis major muscle. Once the skin was incised, subcutaneous tissues were dissected to expose the anterior border of the latissimus dorsi. The serratus anterior muscle was then identified as well, based on its fibers that are attached on the anterior two thirds of the ribs and present an anterior-posterior direction. The serratus anterior digitations in which the LTN could be easily found were the ones inserted onto the 4th or 5th ribs, on the mid-axillary line. The nerve was then searched for, using electric stimulation, and dissected cautiously in the fat pad above the level of the 5th rib. In cases of adhesions within the axillary space, dissection could be facilitated by the identification of the thoracodorsal nerve, which lied just posterior and lateral to the LTN, aiming toward the latissimus dorsi belly. Once the LTN was identified, it was followed along its course within the serratus anterior muscle, and its multiple entry points into the muscle belly were released by opening the serratus anterior fascia and freeing the nerve branches from any surrounding tissues. Iterative electrical stimulations were conducted throughout the release; once the muscle response to electrostimulation became normal, the release was considered complete.

After surgery, patients were immobilized in a sling for a few days in a resting position but were encouraged to actively move the arm and shoulder as soon as the pain permitted it; similarly, physiotherapy was resumed as fast as possible, following the same protocol as preoperatively. Follow-up consultations were scheduled at 2 weeks, 6 weeks, 3 months and 6 months postoperatively, conducting the same clinical examination as preoperatively, with a systematic ENMG study performed 3 months after the surgery.

2.3. Data collection and statistical analysis

Investigations were conducted in accordance with the 1964 Declaration of Helsinki ethical standards and to the MR-003 reference methodology; the study was registered in the CNIL database register (No. 2,216,076 v 0) and each patient was individually informed and consented before any data collection and/or analysis. Chart review was conducted by an independent observer, and yielded patients' demographics, pre- and intra-operative data (i.e., clinical,

electroneuromyographic and imaging data), as well as post-operative outcomes.

2.4. Statistical analysis

Once Shapiro-Wilk's tests confirmed the normal distribution of all continuous data, paired-samples Student's t-tests were used to compare pre- and postoperative data. Significance level was defined as $p < 0.05$, for all tests. Results were expressed as means, standard deviations (SD) and ranges, unless otherwise stated. We considered the surgical procedure to be efficient when there was an improvement on the Quick DASH score of at least 20 points and/or when it was lower than 25 points, postoperatively. Recovery was considered complete in case of disappearance of all clinical symptoms (i.e., scapular winging, shoulder pain, weakness and limitations of active ranges of motion) and normalizations of the ENMG (i.e., regression of conduction blocks). All analyses were conducted using IBM SPSS Statistics, version 25.

3. Results

Within the inclusion period, 12 consecutive patients underwent LTN bifocal decompression and were included in this study. With a mean age of 34 years (SD 14; range 19–64) at the time of surgery, the symptoms had lasted for a mean time of 24 months (SD 12; range 9–48) before undergoing surgery. For all patients, an insidious on-set of the symptomatology was observed, most commonly following repetitive micro-trauma, without any report of initial acute and/or violent pain followed by paresis that could suggest an inflammatory pathology.

Following bifocal LTN decompression, patients could be dichotomized into two groups based on their outcomes: group A patients were improved while those in group B were not.

Group A was constituted of 8 patients (67%) who presented a complete clinical recovery which was observed within the first 6 weeks. At the 6 months follow-up visit, mean active shoulder flexion and abduction improved from 119° (SD 33) to 177° (SD 7) and from 114° (SD 30) to 168° (SD 16), respectively, and mean Quick-DASH scores improved from 57 points (SD 19) to 20 points (SD 7), with $p < 0.001$ for all differences (Table 2). The 3-months ENMG studies of these 8 patients showed significant reductions of distal latencies, and disappearance of the previously observed conduction blocks; ENMG was considered normal by the practitioner who performed it in 7 out of 8 patients (88%).

Group B was constituted of 4 patients (33%) who were not improved by the surgery. (Table 3). In two patients, scapular winging persisted postoperatively after bifocal LTN decompression. Nonetheless, their condition remained stable, and they did not wish to undergo further surgery. In the other two patients, a Pectoralis major tendon transfer was performed [23,24]. One patient presented with progressive scapulothoracic recovery, with clinical improvement of the winging for the first 3 months. However, the 3-months ENMG study showed persistent augmentation of the distal latency within the LTN, and clinical signs such as shoulder weakness and discomfort reappeared at the 6-month follow-up visit. In the other patient, scapular winging reappeared 12 months postoperatively, despite the absence of any signs of denervation

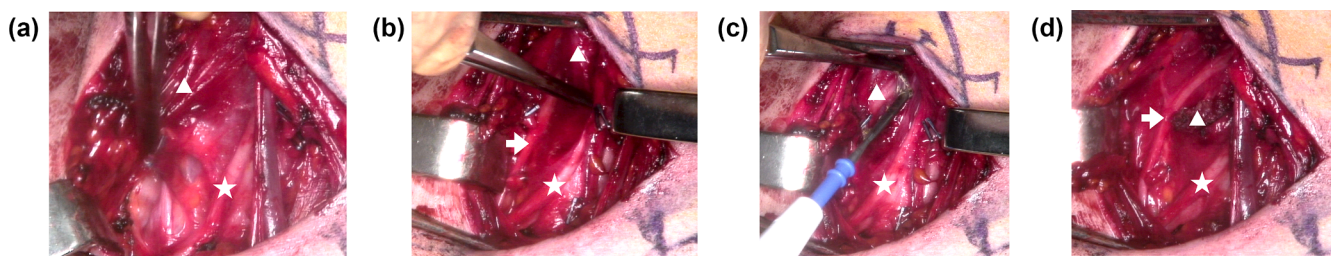


Fig. 1. a-b With the patient in supine position, by means of a simple incision at the supraclavicular space, the important structures are identified. c-d The middle scalene muscle and any adhesions can then be resected. Middle scalene muscle (triangle), long thoracic nerve (arrow) and suprascapular nerve (star).

Table 2
General anthropometric data and pre- and postoperative clinical scores of group A.

	Age (in years)	Sex	Occupation	Duration of symptoms (in months)	Preoperative			Postoperative			Quick-DASH improvement	Follow-up (in months)	Comments
					Quick-DASH	Elevation (in degree)	Abduction (in degree)	Quick-DASH	Elevation (in degree)	Abduction (in degree)			
Patient 1	64	M	Mechanic	36	50	120	110	27	160	130	23	24	-
Patient 2	18	M	Warehouse worker	48	57	80	70	23	180	160	34	10	Postoperative EMG with persistent limited conduction
Patient 3	20	M	Soldier	12	73	140	110	18	180	180	55	14	-
Patient 4	38	M	Mountain guide	36	64	180	180	30	180	180	34	21	-
Patient 5	38	M	Entrepreneur	26	45	90	110	18	180	170	27	17	-
Patient 6	33	M	Masson	17	89	100	110	23	175	160	66	16	-
Patient 7	25	M	Student	9	55	90	90	18	180	180	37	18	-
Patient 8	25	M	Boilermaker	14	21	150	130	5	180	180	16	6	-
Total	33 SD			25 SD 13	57 SD	119 SD 33	114 SD 30	20 SD	177 SD 7*	168 SD 16*	37 SD 16	16 SD 5	
Mean,	14			7*	19			7*					
SD													

*p < 0.0001 compared to preoperative score.
SD: standard deviation.

Table 3
General anthropometric data and pre- and postoperative clinical scores of group B.

	Age (in years)	Sex	Occupation	Duration of symptoms (in months)	Preoperative			Postoperative			DASH improvement	Follow-up (in months)	Comments
					Quick-DASH	Elevation (in degree)	Abduction (in degree)	Quick-DASH	Elevation (in degree)	Abduction (in degree)			
Patient 1	58	M	Manual worker	18	82	75	80	73	180	170	9	17	Recurrence of scapular winging 12 months : tendon transfer
Patient 2	19	F	Student	12	50	80	90	50	90	120	0	18	No improvement
Patient 3	36	M	Painter	24	73	80	90	59	90	120	14	24	Normal postoperative EMG despite lack of of clinical improvement
Patient 4	37	F	Caregiver	40	66	60	90	66	60	90	0	12	No improvement tendon transfer
Total	34 SD			24 SD 10	68 SD	74 SD 8	88 SD 4	62 SD 9	105 SD 45	125 SD 29	6 SD 6	18 SD 4	
Mean,	14			12									
SD													

SD: standard deviation.

edema or fatty infiltration within the serratus anterior on the MRI scan. The patient remained unsatisfied regarding active shoulder flexion and abduction, and pain level. Therefore, a pectoralis major tendon transfer was performed in accordance with the patient's wish not to wait longer for nerve recovery.

No post-operative complications were reported in this series, such as infection, hematoma, neurapraxia, or long-lasting pain.

4. Discussion

The main finding of this study was that bifocal decompression of the LTN may be a safe, effective and reproducible treatment for isolated, non-traumatic long thoracic nerve palsy after conservative treatment failure, allowing complete recovery in 67% of the patients we treated. Subsequently, in our practice, this technique provides an interesting alternative treatment to the Pectoralis major transfer, provided that no fatty infiltration is observed within the serratus anterior muscle on the MRI scan, in a carefully selected population of patients suffering from non-traumatic LTN palsy that are not related to neuralgic amyotrophy for which spontaneous recovery is expected in most cases.

4.1. Indication for nerve decompression

In the management of LTN palsy, different therapeutic stages should be considered. Patients failing conservative treatments might require surgical treatment. Isolated decompression surgeries at either the supraclavicular space [6–9] or at the distal latero-thoracic part [10,11] have been described with positive results. However, in patients in which a single site of compression cannot be clearly identified preoperatively by past medical history, clinical exam, ENMG and MRI, then preoperative tenderness at both potential entrapment locations may guide the surgeon to bifocal decompression. MR imaging and EMG studies before operation give a prediction about the potential immediate recovery after decompression.

This series has shown that bifocal decompression is an effective mean to recover functionality of the serratus anterior muscle for the majority of patients with a failure of conservative treatment after a minimum of 6 months of specific rehabilitation. We therefore believe that in a specific group of patients, who suffer from micro-traumatic, repetitive traction and compression injuries of the LTN, for which the exact location of the entrapment is impossible to identify, an extensive bifocal release of the nerve should be performed. We believe that the LTN suffers from a dynamic and chronic impairment, secondary to its traction between two fixation points (i.e., the middle scalene and the serratus anterior muscles) in addition to a compression above the log created by the upper border of the thoracic girdle (i.e., the first two ribs).

We based our behavior regarding the specific case of LTN palsy on that which we apply to any peripheral nerve palsy caused by repetitive micro-trauma, such as the dynamic ulnar nerve palsy due to the iterative anterior subluxation of the nerve above the medial epicondyle [22]. As a matter of fact, ulnar nerve conduction blocks can be caused by nerve compression within the epicondylo-olecranal groove by fibrous tissues and be exacerbated by the fixity of the nerve in both a proximal and a distal location (e.g., the brachial canal, the flexor carpi ulnaris). Similar to the extensive release that is performed in addition to the anterior transposition or epicondylectomy in the management of ulnar nerve compression syndromes, we choose to perform an extensive neurolysis of the LTN with a suppression of the fixity points on both sides of the compression log created by the first rib.

In cases of more severe deficits and disorders, including disruption of nerve continuity, nerve transfers can be considered. The most common nerve transfer to reanimate the serratus anterior muscle was described by Noland et al. [21], and is based on the transfer of the thoracodorsal nerve; however, intercostal nerves transfers have also been described. In our series, nerve transfers were not indicated, as our patients were not completely denervated on the preoperative ENMG studies and

satisfactory intraoperative LTN responses to electrostimulation were observed, indicating a continuity in the nerve and a potential of reinnervation.

No consensus has been yet established about the duration of conservative treatment to allow spontaneous recovery. In this series, six months was chosen to ensure no major muscle atrophy or severe fatty infiltration would be developed at the time of operation, which was confirmed by MR imaging [21]. This early cut-off was chosen as recovery time, while care was taken to exclude patients suffering from peripheral neuritis, a condition that may require more recovery time, extending to 2 to 3 years. These criteria for patient selection may be also responsible for the immediate postoperative recovery of shoulder function.

4.2. Surgical decision making

While both compression sites are debated, we chose to begin decompression proximally, as described by Noland et al. [21]. While their group proposed a surgical routine involving intraoperative decision making with nerve stimulation after the first decompression, we systematically decompressed both sites in this highly selected patient group. Unfortunately, both reported groups are too small to compare. Considering that we were unable to precisely locate the compression site preoperatively, we advocate for a release as extensive as possible. Theoretically, our order of decompression, by starting at the supraclavicular space, may be responsible of missing isolated entrapment at the distal site; however, to this day, we have not encountered the situation of an isolated compression at the thorax, which would have made the cervical decompression unnecessary. Similarly, an isolated thoracic release may underestimate a proximal entrapment. In summary, rather than a double compression of the nerve, we believe in a “two-points” fixity of the LTN resulting into a chronic, repetitive micro-traumatic traction injury responsible for the serratus anterior malfunction.

4.3. Success and failures

In group A, patients experienced an almost immediate post-operative improvement of their condition. We explain this quick recovery by the presence of a preoperative nerve block, whose release enables an almost immediate recovery.

In group B, one patient experienced a recurrence of the malfunction of the serratus anterior, which can be explained by the development of postoperative scar tissues, creating a secondary nerve block. This patient had a long-lasting impairment of his shoulder function and preferred to undergo a tendon transfer rather than to take the risk of a revision nerve decompression surgery. The other three patients who were not improved and were probably in a situation where the muscle affection was more severe than preoperatively estimated. This underlines one of the limits of our strategy based on preoperative radiological and electrical assessments of the muscle quality, and its potential functional recovery after reinnervation.

In our practice, the benefit of a potential muscular recovery after bifocal LTN decompression is greater than the risk of failure. The fact is that 67% of our patients were improved. Despite the efficiency of pectoralis major tendon transfers for serratus anterior impairments [23,24], we believe that the ability to reinnervate a suffering muscle when possible provides a greater gain than managing the situation with a palliative surgery.

4.4. Strengths and limitations

The strengths of this study were its inclusion criteria of a rare patient population resulting in the enrolment of a highly selected population who can benefit from this operation. Patients were carefully selected, relying on a standardized clinical and paraclinical examination, particularly with a tenderness sign at both entrapment sites. This study also

suffers from some limitations including the lack of control group and the small number of patients, limiting the generalization of its results. A strong limitation persists in the fact that peripheral neuritis will remain impossible to formally rule out even with the combination of multiple pre-operative clinical and paraclinical assessments [18]. A systematic bias in follow-up assessment cannot be excluded because only the performing surgeon examined the patients.

5. Conclusion

In patients with scapular winging due to isolated and idiopathic LTN paresis who did not recover despite at least 6 months of well-conducted conservative management, bifocal LTN release at both potential compression sites (i.e., neck and thorax) enables an extensive release of the nerve. This technique appears to be safe, reproducible, and reliable, with a complete recovery observed in 67% of our patients, thus constituting an alternative option to the pectoralis major muscle transfer in a selected population of patients suffering from micro-traumatic long thoracic nerve paresis.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Ethical approval

Investigations were conducted in accordance with the 1964 Declaration of Helsinki ethical standards and to the MR-003 reference methodology; the study was registered in the CNIL database register (No. 2216076 v 0) and each patient was individually informed and consented before any data collection.

Informed consent

Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

Trial registration

Not applicable.

Contributorship

TL, PP, and RSC collected the data from the patients and the figure

material. TL and LA analysed the data. All authors, but mainly TL, were responsible for the conception and design of the study. LA, TL and ML interpreted the data. LA wrote the first draft of the paper, which was critically revised by all co-authors. TL, ML and LA are responsible for the overall content as guarantors.

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