Chapter 3

Conservative versus surgical therapy of OBPL

A review focussed on scientific validation

The only point, therefore, to determine is whether the lesion will be likely to be spontaneously recovered from or not. In some cases recovery takes place completely, although at birth all the typical signs are exhibited, and it is therefore necessary to wait a reasonable time in all cases before recommending operation. (...) I therefore adhere to my former recommendation of two months as the earliest date at which operation should be undertaken.

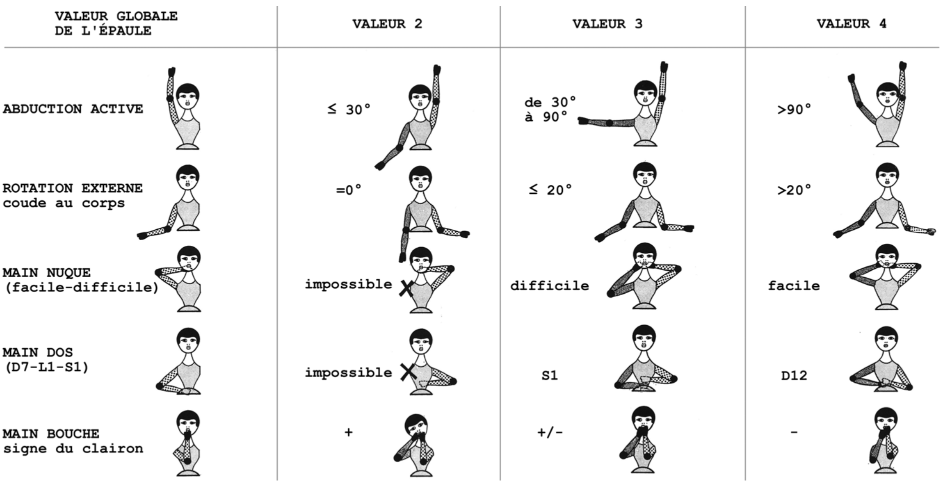
Kennedy 1904

At present, nerve surgical treatment is widely applied in order to improve outcome. A literature review was carried out to outline the level of evidence for nerve surgery in OBPL.

The aim of the current chapter is to summarize the available literature that describes the results of nerve repair compared to the natural history. Most evidence comes from the comparison between surgical and non-surgical cohorts. Patient groups are usually small, and all are affected by referral and / or selection bias. The scientific basis for nerve surgery in OBPL appears to be limited according to modern standards. We believe, however, that it is important to discuss these papers critically and in detail, in order to illustrate the basis on which the indication for nerve surgery in OBPL can be achieved. A PubMed search was performed to identify papers on surgical treatment. (for details see Table 1, Chapter 14, page 233) Studies or series of studies from one author or group that compare natural history to surgical results were included. Using the raw data (when available in the paper), new figures and/or tables were constructed to illustrate the findings.

Despite the decline of nerve surgery performed for OBPL in the 1930´s (see Chapter 2), the condition held the interest of caring physicians. The proceedings of the 1971 meeting of the Societé Francaise de Chirurgie Orthopédique et Traumatologique reflect the treatment approach towards OBPL at that time.[1] Standard care apparently consisted of secondary surgery, such as muscle transfer or rotation osteotomy, but no reference was made to nerve surgery. One of the important contributions of this meeting was the introduction of Mallet's evaluation score: a composite scale that rates shoulder function from one (nothing) to five (normal) based on five key movements (Figure 1).[2]

Figure 1: **Mallet shoulder score from the original paper[2]**



Gilbert and Tassin 1983/1984

Professor Alain Gilbert is internationally recognized as the initiator of the renewed interest in nerve surgical treatment of OBPL. Gilbert's first operation on a case of OBPL in the modern microsurgical era was carried out in Hôpital Trousseau, Paris in November 1977.[3,4] The patient was a girl aged 5 years and 10 months, who had a global lesion with a quasi-total paralysis of the right arm. Repair of spinal nerves C5-C7 was performed with nerve grafts. The functional outcome of the first 20 cases was not reported in his first paper, other than that the results were "*encouraging*' and would be reported later.[3]

The nerve surgical results were eventually analysed in relation to spontaneous recovery by performing a retrospective comparison with a series of 44 conservatively treated patients from hospital Saint Vincent. Both series were published separately in Tassin's thesis.[4] The conservative cohort consisted of children followed up to the age of five years, or until complete recovery was documented. The end-stage of recovery was expressed using the Mallet scale.[5] Twelve patients (27% of the studied population) showed total spontaneous recovery: it was noted that in all these patients the biceps muscle had gained in strength to MRC grade 3[6] by two months of age. Another twelve infants reached a Mallet IV grade; in all these patients the biceps muscle had recovered to grade 3 by 5 months of age. (Table 1)

From this series of natural recovery, it was concluded that 1) if the biceps muscle recovers early, full spontaneous recovery of shoulder function can be expected, and 2) that ultimate recovery of shoulder function correlates inversely with the initial severity of the lesion.

Table 1a: **Hôpital Vincent series, conservatively treated (n=44) grouped by final outcome**

Outcome	n	Lesion	Hand function
Mallet V	12	Recovery of biceps MRC 3 at 2 months of age	normal
Mallet IV	12	4 x C5-C6 lesion 8 x C5-C7 lesion	normal
Mallet III	12	2 x C5-C6 lesion 5 x C5-C7 lesion 5 x C5-T1 lesion	5 normal 5 sub-normal 2 weak
Mallet II	8	8 x C5-T1	4 sub-normal 4 weak

Table 1b: **Hôpital Vincent series, grouped by lesion**

Lesion	Outcome (Mallet)			
	V	IV	III	II
C5-C6	12	4	2	
C5-C7		8	5	
C5-T1			5	8

Another part of the thesis describes 100 infants surgically treated in Hôspital Trousseau. A follow-up of two years was available for 38 patients without root avulsions. (Table 2)

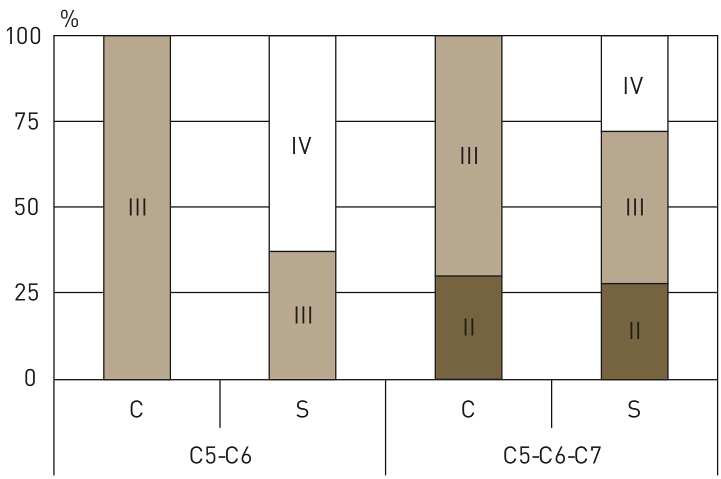
The final comparison of conservative versus surgical strategy was published by Gilbert and Tassin in 1984.[7] In this paper, it was concluded that surgical treatment is warranted if the biceps muscle has not recovered at three months of age. The exact rationale for this criterion was not specified. In the surgical group, a Mallet IV shoulder was reached in a certain proportion of patients, while spontaneous recovery showed a maximum recovery of grade III. (Figure 2) In the C5-C6 group, however, roughly one-third of patients did not gain from surgery, as expressed on the Mallet-scale. A 'number to treat'-analysis, could evaluate the number of patients that has to undergo an operation for one patient to reach a better Mallet grade. In the C5-C6 group this can be calculated as 1.5 (1 / 0.67). In the C5-C7 group only 28 % of patients reaches a grade IV shoulder; the remainder of patients did not improve substantially compared to the conservative group. In the C5-C7 group, the number to treat could be calculated as 3.6 (1 / 0.28).

Table 2: **Hôpital Trousseau series, surgically treated (n=38)**

Lesion	Outcome			
	IV	III/IV	III	II
C5-C6	14	3	5	
C5-C7	3		5	3
C5-T1			3	2

grouped by lesion type

Figure 2: **Bar diagram comparing conservative (C) with surgical (S) results**



Each bar shows the percentage of patients that attain Mallet score II / III / IV; divided in infants with C5-C6 lesions and C5-C6-C7 lesions; reconstructed from Figure 5 in the original paper.[7]

It is important to realize that the conclusion reflects the results of only 38 out of a total of 100 surgically treated infants. (The total number of conservatively managed patients was not mentioned in the paper.) A statistical analysis was not performed. From a scientific point of view, it is a comparison of two patient cohorts from two hospitals with a different approach. Importantly, both series suffer from referral bias, and both groups were gathered retrospectively. The scientific power to support the conclusions are, therefore, insufficient, judged by current standards.

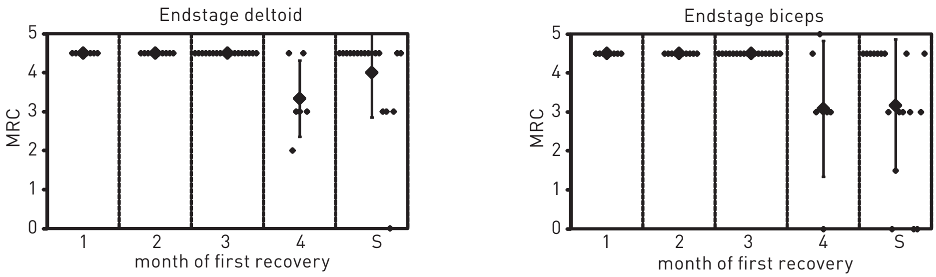
Boome and Kaye 1988

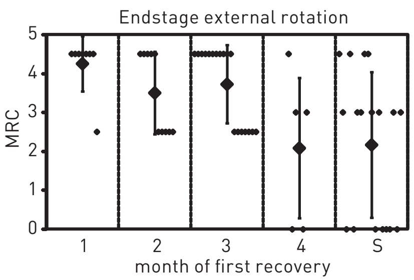
Boome and Kaye describe retrospectively a group of 70 patients, treated between 1981 to 1985.[8] Twenty-two of these 70 patients underwent nerve surgery. In six of the conservatively treated infants, some follow-up data was missing. The end-stage of the remaining 42 conservatively treated infants is presented in Figure 3, grouped according to the month the first recovery was noted. (Unfortunately, the definition of 'first recovery' was not provided.) The authors did not provide all individual patient data, and so Figure 3 is only an attempt to express visually the findings in order to compare these with the surgical results of 18 patients.

Of the 22 infants who underwent surgery, follow-up data were not available for two. As two patients only had neurolysis, they were excluded from Figure 3. The selection criterion for surgery was absence of both biceps and deltoid function; surgery was performed at a mean age of 5.3 months.

A critical analysis of this paper exposes that a statistical analysis between non-operative and operative approach was not performed. The authors simply conclude from

Figure 3: **Endstage of proximal functions from Boom and Kaye's data**





Y-axis: MRC score; X-axis: composition of groups 1 to 4 depends on the month of first recovery, compared with surgical group (S); small dots represent a patient, large dots the mean score, with error bars of 1 standard deviation; graph reconstructed from published individual patient data[8].

their surgical findings that spontaneous recovery would not have taken place in the surgical group. "*If recovery in the muscles innervated by the upper roots is delayed beyond three months, then root disruption is likely. Exploration and nerve grafting then offers the best prospect of a useful arm.*"

Another weakness of the paper is the evaluation in MRC grades. Especially in infants, measurement of volitional force is difficult. The authors get around this limitation by frequently labelling the result as grade 4/5. Although scoring the biceps muscle in this way might be achievable, a proper MRC assessment of deltoid and external rotators is questionable in infants.

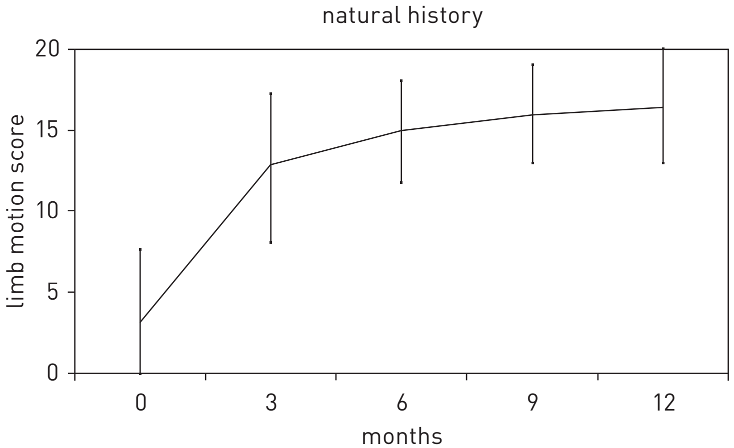
The authors do observe that external rotation does not recover as well as biceps or deltoid function, either following spontaneous recovery or after surgery.

Clarke et al. 1994 / 1996 / 1998 / 2009

Clarke et al. analyzed his Toronto Hospital of Sick Children series in a stepwise fashion. A first study focussed on the natural history.[9] Sixty-six infants were studied, 5 of whom eventually underwent surgery at a mean age of twelve months. A statistical analysis could be performed in 39 / 66 infants for whom there were complete data at birth, 3 months and 12 months. A poor result was defined as absent elbow flexion and shoulder abduction at 12 months of age. Absence of elbow flexion at 3 months showed a correct predictive value of 77% for good recovery at 12 months. When a combination of elbow flexion, wrist extension and finger extension was used, the predictive value increased to 95%.

Graphically, the mean 'overall limb score' of all 66 infants was plotted in a figure; this is reconstructed below. (Figure 4) It shows that most of the mean recovery takes place in the first three months, after which recovery slows down significantly. In the

Figure 4: **Total limb score development in time according to Clarke**



Mean total limb score (± 1 standard deviation) in 3 month-intervals; redrawn from Figure 1 in the original paper[9] lower boundary of the 1 standard deviation interval, a substantial increase can take place between 3 and 6 months, but not thereafter.

The main object of this first study was to identify predictors of spontaneous recovery. Unfortunately, complete data at birth, 3 months and 12 months were only available for around 60% of patients. This might have introduced an inclusion bias, superimposed on the already present referral bias.

Only six of the statistically analyzed 39 patients had a poor result. This means that the aim of the statistical analysis was to pinpoint which neurological deficit at birth or three months could predict the outcome in these six patients with poor outcome, compared to 33 with a good result. Six individual movements were identified as statistically significant indicators of poor recovery: elbow flexion, elbow extension, wrist extension, thumb extension and finger extension. A combination of these was found to have the best predictive capacity. A criticism could be that conclusions drawn from the analysis of such a small subgroup (n=6) cannot be extrapolated to the general population of OBPL infants.

Clarke's second study evaluated the effect of neurolysis, i.e. resection of scar tissue around the nerve and occasionally the scarred outer epineurium.[10] No structural repair like neuroma resection and graft repair was performed. Although movements improved after neurolysis, no functional gain was achieved, particularly in children with a total lesion.

Clarke's third study reported the outcome of graft repair of nerve lesions in 26 patients and a cohort-like comparison was made with 16 infants from the neurolysis study. It was concluded that the eventual recovery after graft repair was better than after neurolysis, because more children reached a recovery to AMS grade 6 or 7.[11] It has recently been reported that the long-term outcomes achieved with graft repair (n=92) are superior to with neurolysis (n=16).[12]

These are probably the first scientifically sound studies. Clarke et al. are to be credited with the precise approach they employed. Unfortunately, so far the system they use to grade muscle function (Active Movement Scale – AMS) has not been widely used by others. A seven-point scale was designed to express limb motion, and different joint movements were summated to form a combined limb score or test-score. Their approach has the advantage that a 7-point system based on movement has the ability to discriminate statistically better than the MRC gradation. Additionally, the MRC gradation relies on force, which is more difficult to measure in an infant. The AMS has been validated by the authors' group.[13] However, computing means and sum scores for the AMS scores is statistically not flawless as it is an ordinal variable. Moreover, sumscores and means make it difficult to relate the clinical picture to the outcome score used. This, however, can result from personal lack of daily experience with the AMS system.

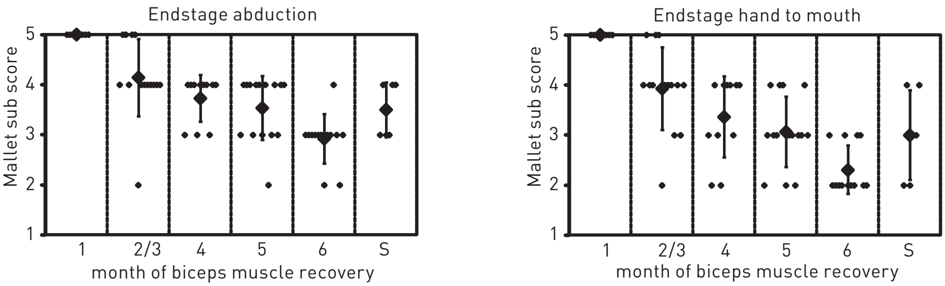
Waters 1999

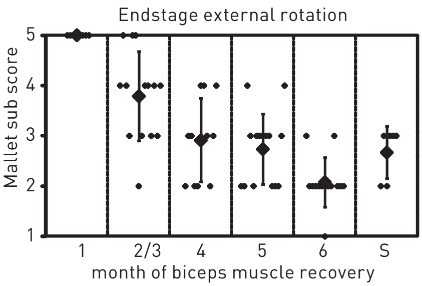
Waters describes 66 patients seen in a 6-year period.[14] Of these patients, 27 had been referred after the age of six months, and were, therefore, excluded from the analysis. Of the remaining 39 patients, 6 were surgically treated because of a lack of recovery of biceps function at the age of six months. The other patients were divided into five groups, according to the month the biceps muscle recovered. Due to small numbers, the second and third months were pooled. Waters analyzed four of the five movements of the Mallet scale separately (abduction, external rotation, ability to bring the hand to the mouth, and to the neck) instead of a composite score. From his data he concludes that recovery after nerve repair was better than the group of patients that recovered biceps function in the fifth or sixth month, but inferior to the group that recovered in the fourth month.

The three following graphs were derived from the original data. (Figure 5) Unfortunately, the exact statistical method with which the groups were compared are not mentioned in the paper. Weaknesses of the analysis are: firstly, that 27 / 66 patients were not included in the analysis. Secondly, a mean value of the Mallet subscores was used. This is in fact incorrect for an ordinal variable. The statistical conclusions are, therefore, in our opinion difficult to uphold.

Valuable lessons can, however, be obtained from this study. The first is that early recovery (before one month of age) results in complete spontaneous recovery. Second, that recovery that starts at two to five months results in a functional impairment at the end-stage, but that it is uncertain that nerve surgery will result in a better outcome, if surgery is performed after six months. Only when biceps recovery is delayed

***Figure 5:* Endstage of proximal functions from Waters' data**





Y-axis: Mallet sub score; X-axis: composition of groups 1 to 6 depends on the month of first recovery, compared with surgical group (S); small dots represent a patient, large dots the mean score, with error bars of 1 standard deviation; graph reconstructed from published individual patient data[14] until the sixth month, does nerve surgery yield superior results. A third conclusion is that external rotation showed poorer recovery than abduction, whether spontaneously or as a result of suprascapular nerve grafting.

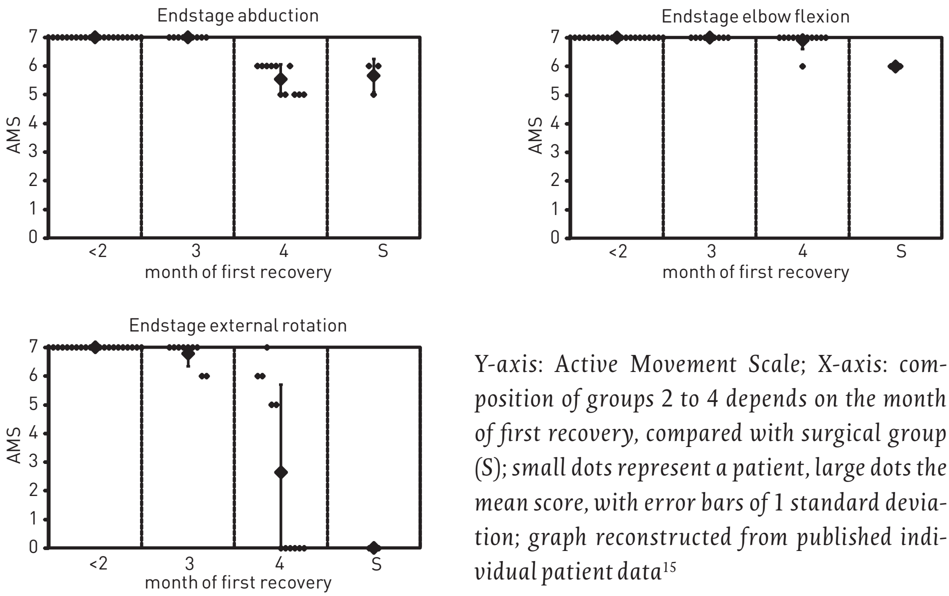
Al Qattan 2000

Al Qattan from Saudi Arabia combines the Toronto AMS outcome scale with Gilbert's and Waters' criterion of isolated elbow flexion recovery.[15] He describes the results of 43 patients, selected from 160 cases seen over a 5-year period, excluding late referrals and incomplete follow-up. The patients were divided into 4 groups, according to the month in which "active" elbow flexion started. Unfortunately a clear definition of what was considered active elbow flexion was not provided. (Table 3)

It was concluded that with early recovery of elbow flexion, good spontaneous recovery can be expected, but when it starts after 4 months, about half of the infants will have a significant residual deformity at the level of shoulder movement. (Figure 6) According to AlQattan, in clinical practice, this is not a very useful criterion for deciding whether an indication for surgery exists.

A critical appraisal of this study reveals that only a small part of his patient population fulfilled the inclusion criteria, which created a selection bias. Due to the small number of patients that were eventually nerve-surgically treated (n=3), a proper comparison between treatment arms cannot be performed.

Figure 6: **Endstage of proximal functions from AlQattan's data**



Y-axis: Active Movement Scale; X-axis: composition of groups 2 to 4 depends on the month of first recovery, compared with surgical group (S); small dots represent a patient, large dots the mean score, with error bars of 1 standard deviation; graph reconstructed from published individual patient data[15]

Table 3: **Residual deformity depending on the month of biceps recovery (Al Qattan)**

Biceps recovery (months)	n	Complete Spontaneous Recovery	Mild Residual Deformity	Significant Residual Deformity	Poor Spontaneous Recovery
< 2	20	20			
at 3	9	6	3		
at 4	11		5	6	
not at 5	3				3

The group with poor spontaneous recovery was nerve-surgically treated

Xu et al. 2000

Xu reports 31 patients from Fujian, China.[16] Twelve of these were treated conservatively in other hospitals for 3 to 4 years. In this group, delayed biceps recovery had been documented as occurring 5 to 8 months after birth. The remainder of the patients were operated by the author because they had no recovery of biceps function by 3 months of age. In the first nine patients (treated between September 1994 and May 1995), the procedure was limited to neurolysis because a conducting neuroma (based on direct stimulation of C5 and C6, and needle recording in the related muscles) was found during surgery. Ten subsequent patients were treated by nerve transfer and grafting between May 1995 and June 1996. (Table 4)

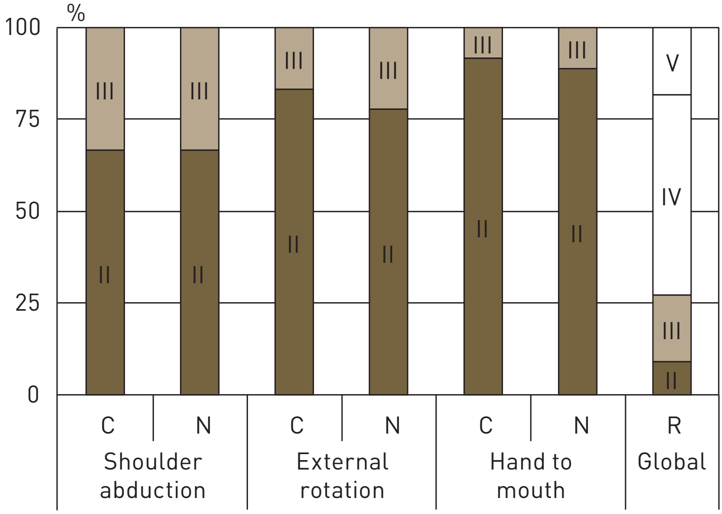
The shoulder and elbow function of 12 patients in the conservative group and nine patients in the neurolysis group were all evaluated as Mallet II or III; none achieved Mallet IV. No statistical difference was found between the conservative and neurolysis group. In contrast, two of 10 patients in the nerve transfer and grafting group achieved a full recovery of shoulder and elbow motion range, and five patients reached a Mallet IV grading. (Figure 7)

There are two drawbacks of Xu's paper. First, a selection bias was introduced, as the referred patients in the conservative group came from other hospitals. Secondly, there was a difference in the evaluation measure used for the neurolysis group and the reconstruction group: for the neurolysis groups, Mallet subscores were presented, but for the reconstruction group only the global Mallet score was available.

Table 4: **Composition of the study groups (Xu)**

	total	extent of lesion		
	n	C5-C6	C5-C7	C5-T1
Conservative	12	5	3	4
Neurolysis	9	3	4	2
Reconstruction	10	4	4	2

Figure 7: **Bar diagram comparing conservative therapy (C) with neurolysis (N) and reconstruction (R) (Xu)**



Each bar shows the percentage of patients that attain Mallet score II / III / IV / V; for the C and N groups Mallet subscores for abduction, external rotation and hand to mouth were available, for the R group only a global Mallet score was available; reconstructed from the authors' data[16]

Strömbeck et al 2000

Strömbeck et al. present patients who were referred to a national OBPL clinic in Stockholm, Sweden.[17] Only those patients with a follow-up of more than five years were selected for analysis: 247 of a total cohort of 470. (Table 5)

These 247 patients were analyzed in great detail. Movements were scored 0 (no movement), 1 (<50% ROM), 2 (>50% ROM but not full range), and 3 (normal movement). For each joint, a number of parameters was measured, and added to produce a sum score. In the shoulder joint, five different parameters were measured (extension, flexion, abduction, internal rotation, and external rotation) resulting in a maximum score of 15. The additional protocol included tactile sensibility, pick-up test, grip-test, grip, bimanual activity and hand preference. The children who "*exhibited some muscle activity*

Table 5: **Composition of the study groups (Strömbeck)**

	total	lesion			
	n	C5-C6	C5-C7	C5–C8	C5-T1
ER	135	106	29	-	
non-Op	53	15	32	6	
Op	59	8	24	8	19
total	247	129	85	33	

groups: ER – Early Recovery; non-Op – non-Operative; Op-Operative *in their biceps or deltoid muscles at the first visit at 3 months of age"* were considered to have early recovery (ER). A statistical analysis was performed to detect differences among treatment groups.

The authors reach a number of conclusions in their extended analysis, only some of which will be reproduced here. All children with complete recovery by 5 years had regained "some activity" before 2 months of age, which was not clearly defined unfortunately. Second, in the C5-C6 group, patients who had undergone surgery did better than both the non-operative and the delayed recovery group, as far as shoulder movements were concerned. (Figure 8) There was no difference in elbow flexion in this group.

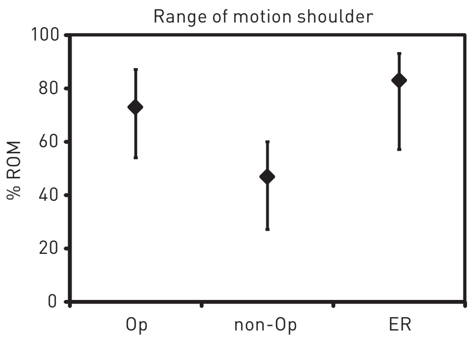
In the patients with a C5-C7 lesion, there was no difference in shoulder or elbow motion between the late recovery and operated group, while both did worse than the early recovery group.

The patients with a C5-C8 or C5-T1 lesion had severely diminished shoulder function, elbow flexion and hand function. The authors could not detect statistical differences in outcome, apart from the unsurprising finding that infants with an intact T1 root did better. (Figure 9)

Despite the rigorous and extensive examination of all patients, it is difficult to derive from this study a proper comparison between natural recovery and surgical results.

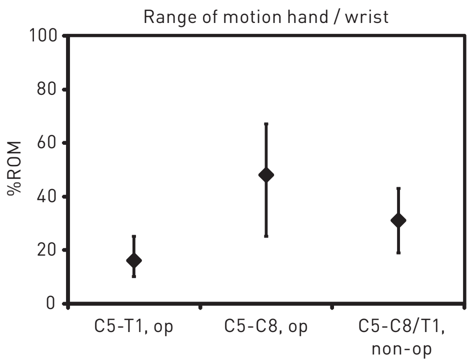
One of the difficulties is the authors' use of a novel scoring system in which sum-scores of multiple movements were examined. Such a sum-score is difficult to relate to the clinical picture.

Figure 8: **Recovery of shoulder movements (Strömbeck)**



Y-axis: attained result as percentage of the maximum score of range of motion (ROM); the median value is depicted as well as the 25th-75th percentiles; redrawn from figure 3a[17]

Figure 9: **Recovery of distal movements (Strömbeck)**



Y-axis: attained results as percentage of the maximum score of range of motion (ROM); the median value is depicted as well as the 25th-75th percentiles; redrawn from figure 5c[17]

Table 6: **Timing of surgery stratified by lesion severity (Strömbeck)**

	< 6 mo	7–12 mo	> 12 mo
C5-C6(-C7)	5	22	5
C5-C8(-T1)	12	14	1

The major limitation is the inconsistent selection criteria for surgery, which is also acknowledged as such in the paper. Initially, it was planned that all infants with C5-C6 and C5-C7 lesions who had no biceps function at 3 months of age would be candidates for surgery. While waiting for the operation, some children unexpectedly gained good biceps function. As a consequence, the indication for surgery was delayed until the infant was 6 months or older. (Table 6) Additionally, several parents of children not selected for operation wanted their child to have surgery and vice versa. All 33 children with C5–8 (Th1) lesions were recommended to have an operation at the first visit at 3 to 6 months of age. Six were eventually not operated: five because they were considered too old (> 18 months) for the operation at the first examination and one because of co-morbidity.

Synthesis

Unfortunately, it is impossible to summarize the discussed studies. The first problem that all studies share is referral bias and inclusion bias, which would result in obvious difficulties in extrapolating the findings to the general population of OBPL infants.

The second problem is that all these papers use different outcome measures, each with its own limitations; hence pooling of data is not possible. The third problem is that statistical analysis is not performed, or doubtful as numbers are small. No study carried out a power analysis.

The various studies did draw certain similar conclusions, although – as said – the basis for these was small. (Table 7)

Table 7: **Summary of discussed studies, and shared conclusions drawn by the authors**

Study	Natural history*	Surgery*		Conclusion**
		Neurolysis	Reconstruction	
Gilbert / Tassin[7]	44		38	1,3
Boome / Kaye[8]	42	2	18	1,2
Clarke et al.[9]	39	5		1
Clarke et al.[10]		16		4
Clarke et al.[11]		16	26	5
Clarke et al.[12]		16	92	5
Waters	33	6		1,3
AlQattan	43		3	1,2
Xu et al.	12	9	10	1,3,5
Strömbeck et al.	188		59	1,3

* number of patients in each group; ** conclusion: see text

1) Serious impairment may remain after spontaneous recovery.
2) Surgical reconstruction of severely damaged nerves leads to functional recovery, which would not be expected without reconstruction.
3) Nerve surgery leads to better functional results compared to spontaneous recovery, when the latter is severely delayed.
4) Neurolysis does not add to the degree of recovery compared to the natural history.
5) Nerve grafting is superior to neurolysis.

Summary

Since the end of the 1970s, nerve surgery for OBPL has regained interest. The scientific basis for performing this type of surgery is not up to modern standards. A randomized prospective trial has not yet been performed. Most evidence comes from the comparison between surgical and non-surgical cohorts. These patient groups are usually small, and are affected by selection bias.

Although the scientific basis of these papers is small, they all point in the same direction: a selected group of patients will benefit from nerve surgery. As the selection process for surgery differs between studies, a general conclusion on how to select patients cannot be drawn.

1 Obstetrical paralysis of the brachial plexus. Proceedings [in French]. Rev Chir Orthop Reparatrice Appar Mot 1972;58 Suppl 1:117-204.
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