International Orthopaedics (SICOT)
DOI 10.1007/s00264-008-0670-4

ORIGINAL PAPER

Changing the treatment to reduce complication rate in open tibial fractures

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Received: 15 July 2008 / Revised: 3 August 2008 / Accepted: 5 September 2008

Abstract Complications of open tibial fractures have been found to be very frequent after application of monotherapies (external fixator, plate, intramedullary nailing). The use of combined therapy has improved our results. We treated 658 patients for open tibial fractures over a course of 15 years. Plating was the method of treatment in the initial phase, and then external fixators and unreamed tibial nails (UTN) were used as a monotherapy. In the last ten years the option of a combined therapy was at our disposal, namely, changing the method of treatment. Monotherapy was performed in 352 cases, and 270 patients were treated in a combined manner. The rate of septic complications could be reduced with the combined therapy from 15.5% to 6.6%, the rate of bone healing disorders from 31.6% to 8.7%, and that of amputations from 4.9% to 0.7%. Elaboration of therapeutic tactics and their consistent application increases the healing potential of open tibial fractures. During this 15 year period, our therapeutic concepts have changed, whereby gradual, combined therapy models were initiated, increasing the advantages and decreasing the disadvantages of the different methods.

Résumé Les complications après fractures ouvertes du tibia sont très fréquentes quel que soit le traitement: fixateur externe, plaque, enclouage centro-médullaire. Les traitements combinés permettent d'améliorer les résultats. Nous avons traité 658 patients présentant une fracture ouverte du tibia sur une période de 15 ans. Ces patients ont d'abord été traités, au début de notre expérience, par ostéosynthèse par plaque et, plus tard, par fixateur externe ou par clou centro-médullaire sans alésage. Dans les 10 dernières années, nous avons préféré combiner les traitements. Un traitement unique a été réalisé chez 352 patients et des traitements combinés chez 270. le taux de complications septiques a diminué du fait des traitements combinés de 15,5 à 6,6%, les problèmes de complications osseuses ont diminué de 31,6 à 8,7% de même en ce qui concerne les amputations qui ont également diminué de 4,9 à 0,7%. l'indication thérapeutique est un élément important du traitement notamment pour obtenir une bonne guérison dans les fractures ouvertes du tibia. Sur une période de 15 ans notre concept thérapeutique a changé en passant de traitements uniques à des traitements combinés. Ceux-ci permettent d'améliorer les avantages de chaque méthode et de diminuer leurs inconvénients.

We confirm hereby that: (a) none of the material in this manuscript has been published previously in any form and none of the material is currently under consideration for publication elsewhere, and (b) each author has contributed substantially to this work, has reviewed it, and agrees with the submission of this manuscript.

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Introduction

The treatment of open tibial fractures is always a challenging dilemma for trauma surgeons because it requires special caution and individual assessment in each case. The consideration of the soft tissue management is almost uniform [7, 23], but nowadays there is a considerable difference concerning the stabilising methods of the fractures [2, 3, 8, 19, 20, 21, 22, 24]. Therapeutic tactics are changing constantly. Initially plating and later the external fixator played the most important role in the treatment of open tibial fractures; nowadays unreamed nailing dominates the therapy [3, 16, 21, 22]. Nailing for tibial shaft

fractures is a simple and effective method, especially in the treatment of middle-third fractures. Interlocked nailing gives stable fixation without cast immobilisation, which results in a greater ability for the patients to return to their previous work after surgery [18]. In order to evaluate the suitability of current methods of osteosyntheses, a follow-up and appraisal, involving numerous patients, is essential. We performed the follow-up and evaluation of patients, treated for open tibial fractures in three periods of five years at the National Institute of Traumatology (currently the National Institute of Traumatology and Emergency Medicine).

Materials and methods

At the National Institute of Traumatology, we developed an unconventional way of treatment for open tibial fractures used from 1988 onwards. We applied a comparative statistical analysis for the assessment of the efficacy of the treatment. The results of a previous period (1984–1988, group A) were compared with those of two five-year periods (1988–1992, group B; 1993–1997, group C), after initiating the new therapeutic concept. There were five to ten options for answering 50 questions in the computerised analysis. Data and results were evaluated with a follow-up study and represented in diagrams.

We applied a uniform therapeutic concept for the treatment of the prospectively analysed group of patients.

Debridement and stabilisation with an external fixator are the most important issues during the primary treatment. Stable fractures were fixed with a unilateral device, the unstable fractures with a V-shaped device. Wounds were covered temporarily or left open; antibiotics were applied according to a uniform concept. Primary, definitive surgery was performed by the third to seventh day after injury. In case of serious soft tissue damage, a second-look intervention, repeated debridement can be performed as soon as 24 hours after primary treatment. If necessary, correction of the external fixator position is of great importance. Soft tissue defects—depending on their extension—were covered with half thickness skin graft, local rotational flap, or with vascular pedicle flaps. In the course of active surgical treatment, soft tissue defects are covered in some cases with vascular muscle flaps or with muscle or skin grafts as soon as 12–24 hours after injury [1, 4, 5, 17].

Soft tissue management includes:

1. Primary debridement
2. Temporary grafting or open wound management
3. Second-look intervention within 24 hours after injury
4. Management of the soft tissue defect via:
   (a) Secondary skin suture
   (b) Half thickness skin grafting
   (c) Local flap transfer
   (d) Vascular pedicle skin, skin-muscle grafting

There are three options to continue the treatment. Exclusively external fixator, external fixator plus brace, and external fixator followed by intramedullary nailing [3, 19, 21].

We exclusively applied an external fixator in those cases, where the consolidation of the soft tissues was not optimal, or when the patient could not have been operated for any reason or presumably wouldn't have cooperated. The external fixator was applied and soft tissues were consolidated within seven days. The assembly was dynamised between the sixth and twelfth week, proceeding with two options. Either, in the course of complex dynamisation, the external fixator device was destabilised, i.e. weakened, or a special dynamising unit was used for axial dynamisation [9–13]. We removed the external fixator between the 12th and 30th week, and then no supplementary external fixation was necessary after this procedure.

In our second series of investigations we applied an external fixator followed by bracing. In this case an external fixator was applied and the soft tissues were consolidated within seven days. Dynamisation was performed in the third to sixth week; we removed the fixator during the sixth to tenth week and applied a brace. Full weight bearing was allowed from the time of the dynamisation onward. The brace was removed in the 12th to 30th week.

The third treatment option was the combination of the external fixator with intramedullary nailing. After the primary application of the external fixator and the consolidation of the soft tissues we removed the fixator as soon as possible, but at latest in the third to fourth week, and we performed reamed intramedullary nailing after a seven-day wait. In cases where changing the way of treatment was feasible within two weeks, no intermediate waiting was necessary!

Since 1994, we have initiated the unreamed intramedullary nailing technique at our hospital, both for closed and open fractures. We applied intramedullary nailing as a primary treatment for open fractures grade AO I–II.

Our therapeutic concept changed in the third group (group C, 1993–1997); we divided our ways of treatment into two subgroups: monotherapy and combined, gradual therapy [14, 15].

Monotherapy	Gradually combined therapy
Primary open plating	External fixator + brace
Exclusively external fixator	External fixator + intramedullary nailing
Primary intramedullary nailing ext.	Fixator + early intramedullary nailing
Primary less invasive plating	External fixator + less invasive plating

Monotherapies were supplemented with less invasive plating, whilst in the course of gradual therapy we initiated the early change of method, namely, intramedullary nailing and less invasive plating after the removal of the external fixator.

We evaluated our data precisely during the computerised study. Three five-year periods were compared with each other based on the same criteria. Measured data were demonstrated in diagrams; differences were evaluated with biometric methods.

The number of cases increased year by year, so the 27 cases in 1983, had in 1997 reached 67. There were spikes in all three groups concerning age distribution, involving people capable of work in the age groups of 41–50 years (144 cases) and 31–40 years (103 cases). These two age groups (247 cases) make up 37.5% of all cases. Traffic accidents were the most frequent causes of injury in all three groups. The initial 71 increased by 66% in group C to 118.

Direct and bending injuries were the most frequent trauma mechanisms. We classified the fractures according to the AO-Müller's scheme, and concluded that B-2 (22+27+40=89), C-1 (26+32+46=104), and C-3 (24+27+41=92) fractures were the most frequent in all three groups (Fig. 1).

Open injuries were arranged according to Gustillo-Anderson's classification [6, 25]. Most cases belonged to group I (59+72+92=223), whilst there were 186 patients (46+66+74) in group II (Fig. 2).

In the analysis, we also took into consideration the method of bone stabilisation. Open plating (44) and external fixator (64) were the most commonly used methods in group A. Gradual therapy was applied in group B, where external fixator plus brace (37), and external fixator plus intramedullary nailing (44) were the most frequently performed methods of stabilisation, but there were also 32 patients treated with primary, reamed nailing and 22 with UTN. In group C gradual therapy played the most important role, external fixator plus brace in 43 patients, external fixator plus reamed nailing in 40 patients, and external fixator followed by UTN in 36 cases, but there were numerous patients who underwent a kind of monotherapy (reamed intramedullary nailing in 46 and UTN in 40 cases). At this time we initiated the stabilisation with an external fixator followed by less invasive plating (22 patients) and primary less invasive plating as well (20 patients) (Fig. 3).

Primary skin suture played the most important role in the treatment of soft tissue injuries in all the three groups (64+86+108=258), followed by the less frequently performed secondary skin suture (32+41+65=138). Thanks to the development of microsurgery, half thickness skin grafting (31+42+51=124) and local flap transfers could be supplemented by the application of vascular pedicle muscle flaps and muscle-skin flaps as well (2+4+9=15).

In order to assess the efficacy of the treatment in the two groups we prospectively analysed the achieved and measured results during two of the five-year periods (1988–1992, 1993–1997).

Results

The duration of hospital care decreased considerably. In 1983, in the first year of our investigation, hospital stay was 37 days;

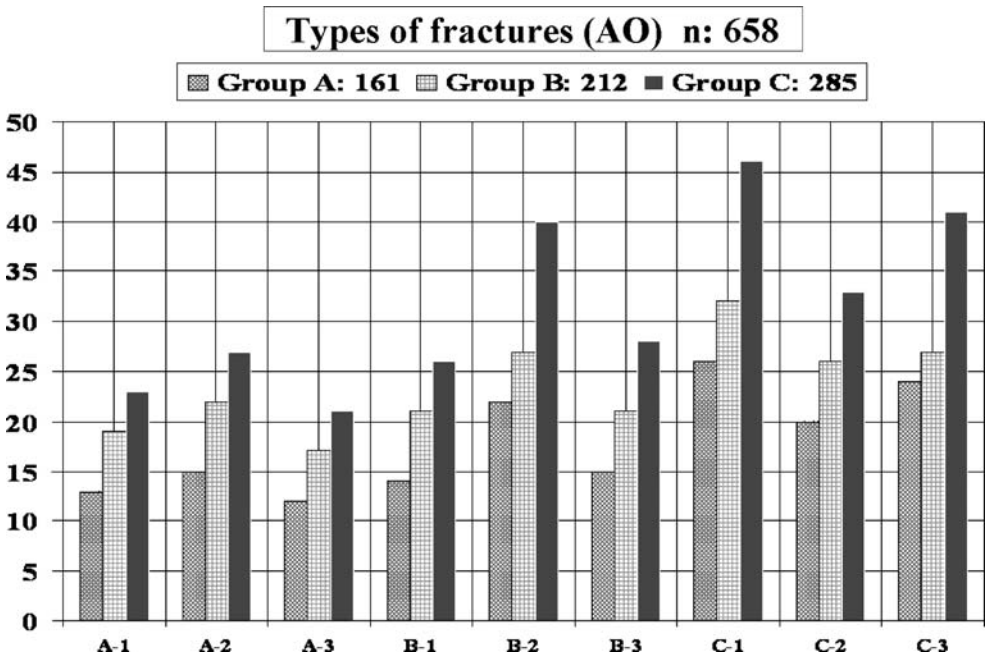

Fig. 1 Types of fractures according to AO classification

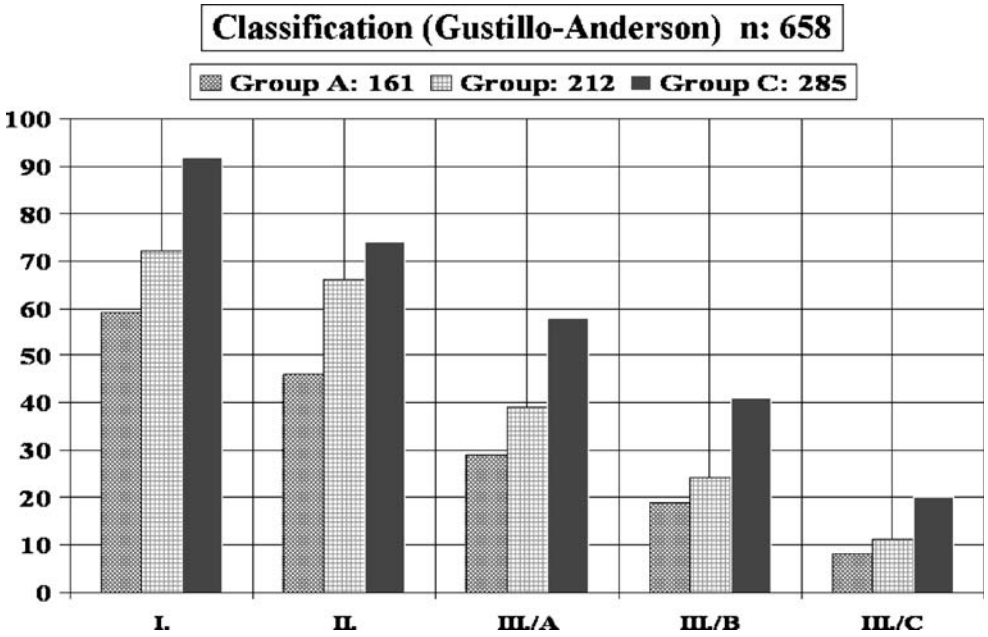

Fig. 2 Classification of soft tissue injury according to Gustillo-Anderson

while in 1997, it was only 15, a reduction of more than 50%. The average duration of hospital care was 30.2 days in group A (1983–1987), 20.2 in group B (1988–1992), and in group C (1993–1997) 17.6 days.

Complications were investigated in six categories. It was found that the number of lethal complications were reduced by 50%: nine cases (5.6%) in group A, seven cases (3.3%) in group B, and six cases (2.8%) in group C. The were no significantly different results between groups A and B (2.3%, $p<0.2235$) and groups B and C (0.5%, $p<0.4630$), while the difference was significant between groups A and C (2.8%, $p<0.0495$). The number of amputations was reduced to one seventh, specifically, eight cases in group A (4.9%), five cases in group B (2.3%), and two cases in group C (0.7%), which is a statistically significant difference. The difference between groups A and B (2.6%) was not significant ($p<0.0934$), nor between groups B and C (1.6%, $p<0.2195$), while there were significantly different results between groups A and C (4.2%, $p<0.0037$). The rate of septic complications was reduced by 30%: 25 cases (15.5%) in group A, 20 cases (9.4%) in group B, and 19 cases (6.6%) in group C. The difference between groups A and B was significant (6.1%, $p<0.0485$), but between groups B and C was not (2.8%, $p<0.3012$), while there were

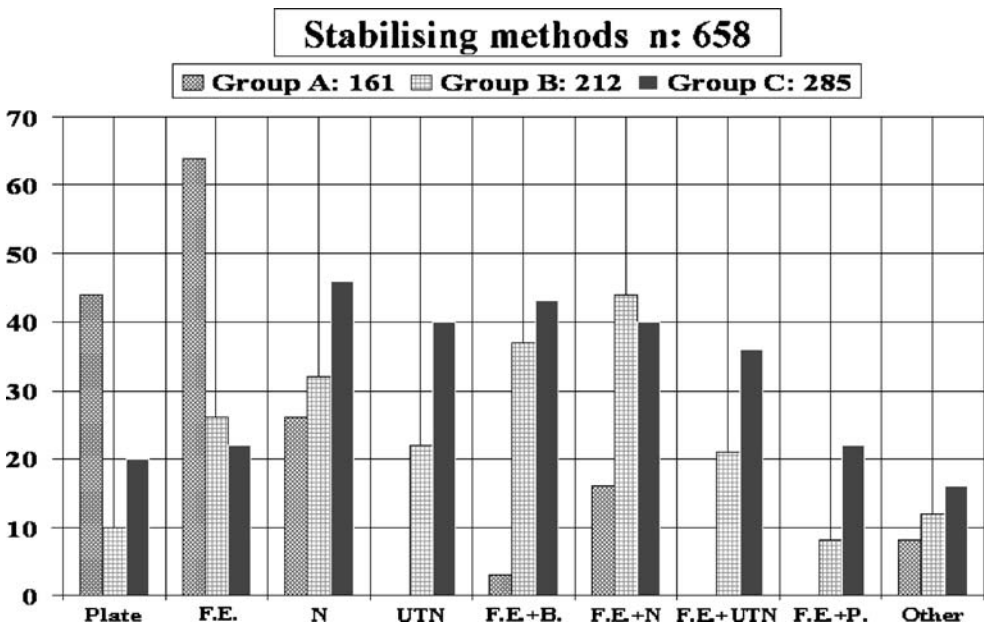

Fig. 3 Stabilising methods

Table 1 Investigation of complications A (LSD test; variable probabilities for post hoc tests MAIN EFFECT: group)

Group	EXIT (compl.sta)			AMPUT (compl.sta)			SEPTIC (compl.sta)		
	Group A	Group B	Group C	Group A	Group B	Group C	Group A	Group B	Group C
Group A		0.2235	0.0495		0.0934	0.0037		0.0485	0.0024
Group B	0.2235		0.4630	0.0934		0.2195	0.0485		0.3012
Group C	0.0495	0.4630		0.0037	0.2195		0.0024	0.3012	

EXIT number of lethal complications, *AMPUT* number of amputations, *SEPTIC* rate of septic complications

significantly different results between groups A and C (8.9%, $p<0.0024$) (Table 1).

The number of soft tissue necroses—due to the surgical intervention—decreased to 25%: 51 cases (31.6%) in group A, 38 cases (18%) in group B, and 25 cases (8.7%) in group C. There were significantly different results between groups A and B (13.6%, $p<0.0007$), groups B and C (9.3%, $p<0.0062$), and groups A and C (22.9%, $p<0.0000$). Bone healing problems became less frequent (50% of the initial ratio): 35 cases (21.7%) in group A, 32 cases (15%) in group B, and 26 cases (9.1%) in group C. The difference (6.7%) between groups A and B was significant ($p<0.0482$). There were no significantly different results between groups B and C (5.9%, $p<0.0784$), while there were significantly different results between groups A and C (12.6%, $p<0.0002$) (Table 2).

We also investigated the "method-specific" complications, which originate from the method of treatment, such as loosening of the fixator pins, breaking of interlocking bolts, intramedullary nails, and plates. Probably due to the gradual, combined therapeutic management, these problems were reduced to 25%: 13 cases (8%) in group A, ten cases (4.7%) in group B, and six cases (2.1%) group C.

In soft tissue management, we were able to achieve considerable improvement. Primary wound healing was obtained in group A in 106 cases (66%), in group B in 160 cases (75.7%), and in group C in 230 cases (80.9%), which is an overall improvement of 14%.

Primary infection, which originates from the open nature of the injury, was decreased as well: 15 cases (9.3%) in group A, 11 cases (5.2%) in group B, and nine cases (3.1%) in group C. The ratio of secondary, deep infections decreased: 14 cases (8.7%) in group A, eight cases (3.8%) in group B, and 11 cases (3.8%) in group C. A moderate decrease was achieved with respect to necrosis of the flaps: six cases (3.6%) in group A, five cases (2.4%) in group B, and six cases (2.1%) in group C. The ratio of other soft tissue necroses remained almost unchanged: 12 cases (7.4%) in group A, 16 cases (7.5%) in group B, and 18 cases (6.3%) in group C (Fig. 4) [3].

We also investigated the ratio of the radiological proven consolidation of the fractures, whereby 126 cases (78.3%) in group A, 180 cases (85%) in group B, and 259 cases (90.9%) in group C resulted in bony union without any complications.

Complications were analysed in detail. Complications involving bony healing numbered 35 cases (21.7%) in group A, 32 cases (15%) in group B, and 26 cases (9.1%) in group C. Parallel with absolute numbers we also investigated their distribution in six groups. We expressed the complication rate in a percentile manner. Considering the number of all complications as 100, the ratio of refractures in group A was six cases (17%), in group B four cases (12.5%), and in group C five cases (19%). The ratio of delayed callus formation in group A was 17% (six cases), in group B 15.5% (five cases), and in group C 27% (seven cases). Atrophic pseudoarthrosis in group A numbered eight cases (23%), in group B eight cases (25%), and in group C three cases (11.5%). Hypertrophic pseudoarthrosis in group A was three cases (9%), in group B two cases (8%), and in group C two cases (8%). Septic pseudoarthrosis in group A numbered five cases (14%), in group B five cases (15.5%), and in group C three cases (11.5%). Osteitis occurred in group A in seven cases (20%), in group

Table 2 Investigation of complications B (LSD test; variable probabilities for post hoc tests MAIN EFFECT: group)

Group	SKIN (compl.sta)			BONE (compl.sta)		
	Group A	Group B	Group C	Group A	Group B	Group C
Group A		0.0007	0.0000		0.0482	0.0002
Group B	0.0007		0.0062	0.0482		0.0784
Group C	0.0000	0.0062		0.0002	0.0784	

SKIN number of soft tissue necrosis, *BONE* bone healing disorders

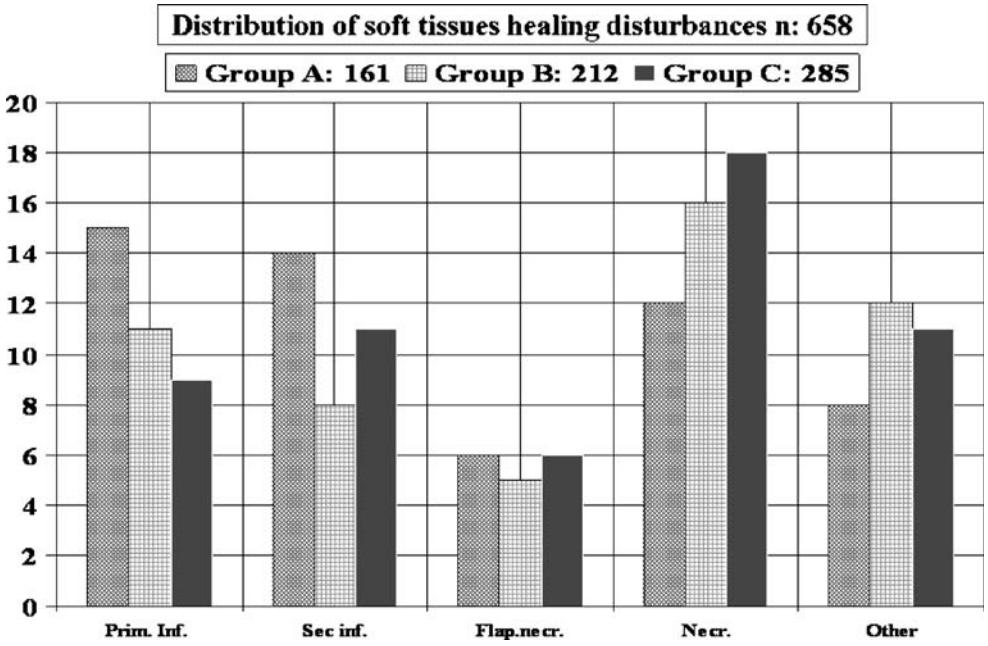

Fig. 4 Distribution of soft tissue healing disturbances

B in eight cases (25%), and in group C in six cases (23%) (Fig. 5).

Discussion

Primary consolidation of the soft tissues improved gradually, due to the active therapeutic tactics (group A 66%, group B 75.7%, and group C 80.9%). As a result, the rate of septic complications decreased by 15.5% in group A, 9.4% in group B, and 6.6% in group C. The application of modern stabilising devices resulted in an increasing rate of bony union. Bone healing disorders in group A were 31.6%, in group B 18%, and in group C 8.7%. The rate of amputations decreased drastically in group A by 4.9%, in group B by 2.3%, and in group C by 0.7%.

These results reflect the fact that the elaboration of therapeutic tactics and their consistent application increases the healing chances of open tibial fractures. During this 15-year period our therapeutic concepts have changed,

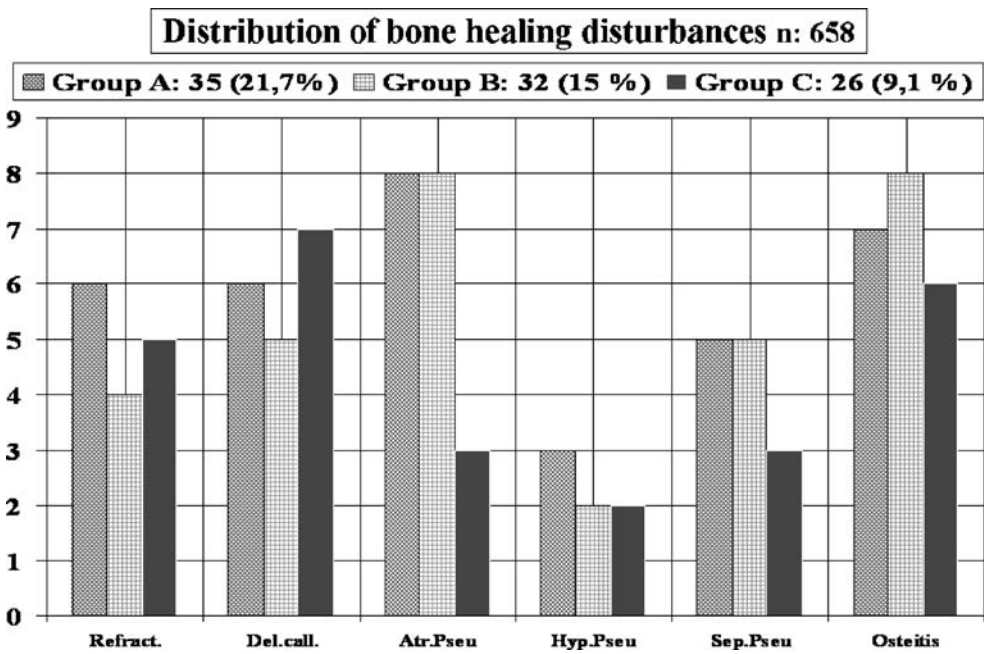

Fig. 5 Distribution of bone healing disturbances

whereby gradual, combined therapy models were initiated, increasing the advantages and decreasing the disadvantages of the different methods.

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