Primary osseointegration analysis of Bionnovation implant system

*Everson Schimiti**
*Alberto João Zortéa Jr***

ABSTRACT

In this retrospective study, the rate of success and failure for the primary osseointegration from Bionnovation implant system was clinically evaluated. All the implants were inserted by the graduate students of the Implantology specialization Course at Unopar (Universidade Norte do Paraná) according to the surgical protocols preconized for osseointegration1-2. The success or failure of the primary osseointegration was evaluated during implant exposure for healing abutment insertion; lack of mobility and pain were evaluated, with concomitant radiograph analysis. A total of 173 implants placed in 68 patients (43 men, 43 women) were evaluated. The results showed that primary osseointegration was obtained in 95.4% of cases (165 implants), against only 4.6% of failures (8 implants). In men, success rate was of 87.3%, while in women this same rate increased to 99.2%. With respect to immediate loading, 31 implants were immediately loaded and five of these failed, resulting in a success rate of 83.9%. Clustering of five failures in only one patient showed the need for improvement of previous diagnosis in patients more susceptible to implant loss. If this patient had been identified the overall rate of failure would have decreased to 1.7%, and the success rate for immediate loading cases could reach 100%. These results are in agreement with those obtained in similar studies.

***Key Words** - Osseointegrated implants; Osseointegration; Cluster phenomenon; Dental implants; Success rate.*

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Introduction

The development of the current osseointegrated implants began in 1956 and was clinical evaluated as from 1965[1]. During the years, the implants underwent changes in shape, dimensions and surface treatment, and were available in the market in various commercial designations. In general, the functional results obtained in the substitution of lost roots have been excellent.

Titanium is highlighted among the materials used in biomedical applications, such as endosseous implants. Titanium is a biomaterial that has excellent resistance to corrosion, does not show adverse biological response, is not toxic, carcinogenic, mutagenic, thrombogenic and allows the adhesion of cells to their surface for the occurrence of osseointegration[2].

The success of the implant does not depend only on the permanence of the implant without mobility in the arch but also the esthetical, functional and psychological improvement of the patient, in addition to replacement of the lost element. There is no doubt that the biodynamics of osseointegrated implants depend on factors related to the implant, technique used, health condition of the host and the post-surgery cares. Regarding the parameters related to implants, the material used in the manufacture, design, surface finish and type of surface are highlighted; the professional is responsible for using the surgical technique for trauma control and primary stability to avoid the development of connective tissue[3].

The success of any procedure related to implants depends a lot on the correlation between different variables that make up an equation comprising:

- Biocompatibility of the implant material.
- Macroscopic and microscopic nature of the implant surface.
- Condition of the implant site, with absence of infection and the quality of bone tissue.
- Surgical technique.
- Healing without disturbances.
- After placing the prosthesis, the prosthetic design, due to masticatory forces.

Besides the listed factors, it is known that other variables like length of implant, low gingival index, location and bone density of the receiving site, early load, material used and hygiene[4-5] should have long term effect on the failure rate on the implants.

Through a longitudinal study, it was verified that 146 out of 2,371 implants placed in the maxilla failed. It was concluded that the length of the implants placed in this region was the factor of great importance in the results, in detriment to its diameter[6].

A recent study was conducted to determine the clinical parameters associated to the success and failures of 39 implants on 39 individuals, with blasted surface in a retrospective of five years. Longer implants, lower gingival inflammation rates, bones with higher density and the crestal or supra-crestal position of its placement were factors related to success.

In 2006, an extensive study on implant loss and associated factors evaluated 294 patients, with 1,057 installed implants and obtained an average success rate of 95.7% in periods of 9 to 14 years. The implant losses appeared to be clustered in a few patients and the early failures were the most common. A significant relationship between implant loss and perio¬dontal bone loss of the remaining teeth was observed[7].

A retrospective analysis of the primary osseointegration of 396 Neodent implants performed in 2005 obtained a success rate of 98%, with observation of clusters of losses in the anterior region of the mandible, without possible association of the gender to the failure rate[8]. In another retrospective study of this system of implants, after five years of this same implant, the success rate observed was 96.87%. The authors report the relationship between implant loss and the reduced length of the implants[9].

Various authors have mentioned the fact that implant loss is clustered in a few patients, that is, the cluster phenomenon[4,7-10]. Despite statistical analyses showing that patients with low bone quality and quantity, smokers, with bruxism, general deficient health, alcoholics, drug users, as well as depressed or psychologically ill, seem to be more prone to implant loss, it was not yet possible to conclusively establish the profile of patients with greater

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Figure 1
Spreadsheet model for data obtainment.

tendency to implant loss[11].

Comparing the implants with machined and blasted surfaces, it was confirmed that the force necessary to remove screwed implants placed in rabbits, is smaller when the implants have machined surfaces. It was also verified that there is higher fixation when the surface of the implant has a roughness of 0.9 to 1.3 mm[12].

It is possible to state that the surface treatment influences the success of the implant by 40%, the remaining being the surgical technique used, healing process and load applied on the implant after bone regeneration[13].

The importance of observing the principles of basic bioengineering should be highlighted, related to predictable osseointegration, where no relative movement can occur on the interface region between the tissue and titanium. There is also observation of the need to consider the dynamics of the interface between the implant and the bone in different dimensions, varying from millimeter to angstrom, where movements greater than 20 μm can compromise osseointegration[14].

A retrospective study[10] analyzing variables associated to the failure of osseointegrated implants observed a general failure rate of 9.2% after seven years of using the Steri-Oss implant system, with clear evidence of the influence of the cluster phenomenon in this rate.

In general, success can be defined as achieving what is intended. Therefore, for being considered well successful, the oral osseointegrated implant must reach certain levels in terms of function (chewing capacity), tissue physiology (presence and maintenance of osseointegration, absence of pain and/or other pathological process) and customer satisfaction (in terms of esthetics and not causing discomfort). It is obvious that each implant must be tested individually and must satisfy all the success criteria, otherwise it will be considered to be only surviving[15]. In this work, the objective was to

quantify the success and failure rates of the primary osseointegration of implants in the Bionnovation system, verifying the influence of patient gender, receiving area and use of immediate load in these rates.

Material and Methods

The implant placement surgeries were performed by students of the Implantology Specialization course of Universidade Norte do Paraná (Unopar), without prior calibration, between the months of May 2007 and December 2008 (follow-up of the cases until July 2009), evaluating the primary osseointegration exposure to place the transmucosal healing abutment, when this procedure was required.   The patients were partially or completely toothless, with different ages and levels of quality and bone resorption, not having considered these variables in the statistical analysis. The implant placement procedures were contraindicated in patients with limiting systemic alterations for surgical procedures of this kind.

After calibration of the students, a spreadsheet was sent to be filled with the name of the patient, gender, age, receiving area, date of placement, date of exposure and success analysis (Figure 1).

The patients were initially screened by the course professors and sent to the students. Each student was responsible for the pre-operative evaluation according to the appropriate routine for patients that will be subjected to surgery for placement of endosseous implants[16], that is, medical-dental history, clinical check-up, study models, tests by photographic images and surgical guides. The x-ray evaluation was performed using periapical and panoramic x-rays, and in specific cases linear or computer tomography (with sections of 1 mm thick) was used. After anamnesis, laboratory tests were requested (complete blood count, coagulation profile, type I urine, glucose, phosphorus-calcium metabolism, bone densitometry,

urea, creatinine) and other complementary tests, when necessary. Patients undergoing medical treatment kept their medication routines, presenting medical assessment prior to patient release. The prophylactic antibiotic therapy was performed on all the patients, according to the criteria adopted by the American Academy of Cardiology. Chlorhexidine digluconate was indicated for rinsing the mouth, starting 48 hours in advance, twice a day, and in some cases anxiolytic pre-operative drugs were prescribed.

> *The evaluation of the primary osseointegration occurred during exposure for placement of the healing abutments, during which the absence of pain and mobility of the implant were evaluated, in addition to x-ray evaluation.*

Regarding the surgical protocol, the standards established for obtainment of osseointegration[1-2] were observed, with the placement of Bionnovation system implants, with lengths of 7 to 15 mm and diameters of 3.3, 3.5, 3.75, 4.0 and 5.0, with external hexagon prosthetic platforms, with the use of spear point and spherical Lindman drills, helical and pilot drills. The use of male screw was only indicated in high density bone structures (type I bone).

The post-operative control was performed through physical measures as well as hormonal and non-hormonal anti-inflammatory measures for periods varying from one to five days, according to the complexity of the surgical procedure. Antibiotic therapy was used with amoxicillin (500 mg), one tablet every eight hours for seven days (despite having no consensus and scientific evidence for conducting this therapy[17], this strategy was adopted to reduce possible risks of developing bacterial endocarditis and possible infectious processes) and mouth rinsing with Chlorhexidine digluconate at 0.12% twice a day until removal of the suture. The evaluation of the primary osseointegration occurred during exposure for placement of the healing abutments, during which the absence of pain and mobility of the implant were evaluated, in addition to x-ray evaluation.

The statistical analysis made use of Chi-Square with Yates correction and Chi-square rxc for the variables gender, immediate load and success of the implant. The statistical significance was stipulated at 5% (P < 0.05). .

Results

A total of 68 patients were operated, from which 25

were male (36.8%) and 43 were female (63.2%), with ages varying between 22 and 69 years. The mean age was 47.7 years, with standard deviation of 10.45. On average, each patient received 2.56 implants (SD – 1.6).

In general, the statistical results obtained showed that primary osseointegration occurred with a success rate of 95.4% (165 implants) against to the failure rate of 4.6% (eight implants). When the genders were compared (male and female), primary osseointegration occurred with a success rate of 87.3% (48 implants) and the failure rate was 12.7% (seven implants) in the male gender, while the male gender, while the success rate was 99.2% (117 implants) and failure rate of 0.8% (one implant) in the female gender, according to table 1.

In relation to the variable receiving area (Table 2), 44 implants were placed in the anterior region of the maxilla and one of these was unsuccessful in the anterior region of the maxilla and one of these was unsuccessful in the osseointegration, resulting in the success rate of 97.7% and failure rate of 2.3%. In the posterior region of the maxilla, only two of the 47 placed implants failed, resulting in the success and failure rates of 95.7% and 4.3%, respectively. In the anterior mandible, only five of the 39 placed implants failed, resulting in the success and failure rates of 87.2% and 12.8%, respectively. A total of 43 implants were placed in the posterior mandible with total use for future prosthetic rehabilitations, totaling a success rate of 100%.

When immediate loading technique is used (Table 3), 31 of the total implants received immediate loading after their placement. Five of these, from a single patient, were lost, resulting in a success rate of 83.9% (26 implants) and failure rate of 16.1% when the implants were restored prosthetically soon after their placement.

A simple survey showed that 18 different implant combinations were used in this study. The most used model measured 3.75 mm in diameter and 13 mm in length. The second most used type measured 3.75 mm by 15 mm in length, and the third most used measured 3.75 mm by 11.5 mm.

Discussion

The number of women that received implants was higher than men, and the number of failures was higher in the male gender (12.7% - seven implants) than in the female gender (0.8% - seven implants). The Chi-square analysis ($\chi^2_{Yates\ correction}$ = 9.46; p = 0.002) showed the existence of dependence between the variables, meaning that there are statistical indications that the success rate

TABLE 1 - *TABLE OF ASSOCIATION BETWEEN THE VARIABLES GENDER AND SUCCESS RATE OF THE IMPLANT*

		Success		
		No	Yes	Total
Gender	Male	7 (12.7%)	48 (87.3%)	55
	Female	1 (0.8%)	117 (99.2%)	118
	Total	8 (4.6%)	165 (95.4%)	173

χ^2 Yates correction = 9.46; P = 0.002. Source: Schimiti and Zortéa Jr. (2009).

TABLE 3 – *TABLE OF ASSOCIATION BETWEEN THE VARIABLES IMMEDIATE LOADING AND SUCCESS RATE OF THE IMPLANT*

		Success		
		No	Yes	Total
Load	No	3 (2,.%)	139 (97.9%)	142
	Yes	5 (16.1%)	26 (83.9%)	31
Total		8 (4.6%)	165 (95.4%)	173

χ^2 Yates correction = 9.46; P = 0.004. Source: Schimiti and Zortéa Jr. (2009).

TABLE 2 – *TABLE OF ASSOCIATION BETWEEN THE VARIABLES RECEIVING AREA AND SUCCESS RATE OF THE IMPLANT*

	Success		
Region	No	Yes	Total
AS	1 (2.3%)	43 (97.7%)	44
PS	2 (4.3%)	45 (95.7%)	47
AI	5 (12.8%)	34 (87.2%)	39
PI	0	43 (100%)	43
Total	8 (4.6%)	165 (95.4%)	173

Source: Schimiti and Zortéa Jr. (2009).

for implants placed in women is higher in relation to men, despite literature not showing the influence of gender in the success of osseointegrated implants[8,10].

The statistical analysis through the Chi-test allowed the association between the success rate and the use of immediate loading with a significant reduction of the success rate for implants that were placed in masticatory function immediately after the surgical procedure.

The success rates for the male gender, for immediate loading, had their values significantly influenced by the clustered loss of five implants in a single patient, whose failure was attributed to the deficient para-functional and hygiene habits. If this patient had been previously identified and the treatment with implants contraindicated, the overall failure rate would have dropped significantly from 4.6% to 1.7%, that is, almost one-third of the initial value. In the analysis of failure associated to gender, the failure rate for the male gender would have dropped from 12.7% to 3.6%, and in the statistics of the immediate loading cases there would have been 100% success. A similar fact was observed in another study, when a patient clustered five implant losses, significantly influencing the result of the analysis[9]. Some studies have sought to understand the factors that can influence the cluster of the failures in implantology[18-19].

Generally, there is grater loss of implants in the maxilla than in the mandible[20-21]. The cortical layers of both arches tend to become thinner and more porous with increase in time after loss of the tooth. The trabecular bone component is denser in the mandible than in the maxilla, and in the anterior areas in relation to the posterior areas. The presence of anatomical structures such as maxillary sinus and inferior alveolar nerve also limit the quantity of bone available for implants in the posterior regions15. However, in this work, we could not statistically prove the influence of the factors connected to bone quality and to the anatomical structures.

The overall success rate of 95.4% observed in this study is compatible with similar studies written in literature[4-11,22-23], even considering all the differences that this type of evaluation necessarily involves, such as the different levels of ability by different operators and post-operative cares depending on the operated patients.

Conclusion

In the evaluated population, it can be concluded that:

The gender influenced the risk of implant loss, which was higher in men when compared to women.

The use of immediate loading technique was associated to a reduction in the success rate.

The overall failure rate in the primary osseointegration in this retrospective study was 4.6%.

The cluster of five failures in a single patient significantly influenced the results of this study.

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Doctoral Thesis

On the 16th of last April, Thallita Pereira Queiroz defended the Doctoral Thesis in Dentistry – Oral and Maxillofacial Surgery and Treatment, at Faculdade de Odontologia de Araçatuba – Unesp, with the title of "Ticp Implants with surfaces modified by laser beam with and without chemical deposition of apatites. Topographic, biomechanical and histometric analyses in rabbits".

The examination board consisted of professors Eduardo Hochuli Vieira (advisor), Idelmo Rangel Garcia Júnior, Cássio Edvard Sverzut, Élcio Marcantonio Júnior and Wilson Roberto Poi.

Research Work

<u>Scientific Section</u>

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The implant placement surgeries were performed by students of the Implantology Specialization course of Universidade Norte do Paraná (Unopar), without prior calibration, between the months of May 2007 and December 2008 (follow-up of the cases until July 2009), evaluating the primary osseointegration exposure to place the transmucosal healing abutment, when this procedure was required. The patients were partially or completely toothless, with different ages and levels of quality and bone resorption, not having considered these variables in the statistical analysis. The implant placement procedures were contraindicated in patients with limiting systemic alterations for surgical procedures of this kind.

After calibration of the students, a spreadsheet was sent to be filled with the name of the patient, gender, age, receiving area, date of placement, date of exposure and success analysis (Figure 1).

The patients were initially screened by the course professors and sent to the students. Each student was responsible for the pre-operative evaluation according to the appropriate routine for patients that will be subjected to surgery for placement of endosseous implants[16], that is, medical-dental history, clinical check-up, study models, tests by photographic images and surgical guides. The x-ray evaluation was performed using periapical and panoramic x-rays, and in specific cases linear or computer tomography (with sections of 1 mm thick) was used. After anamnesis, laboratory tests were requested (complete blood count, coagulation profile, type I urine, glucose, phosphorus-calcium metabolism, bone densitometry, urea, creatinine) and other complementary tests, when necessary. Patients undergoing medical treatment kept their medication routines, presenting medical assessment prior to patient release. The prophylactic antibiotic therapy was performed on all the patients, according to the criteria adopted by the American Academy of Cardiology. Chlorhexidine digluconate was indicated for rinsing the mouth, starting 48 hours in advance, twice a day, and in some cases anxiolytic pre-operative drugs were prescribed.

> *The evaluation of the primary osseointegration occurred during exposure for placement of the healing abutments, during which the absence of pain and mobility of the implant were evaluated, in addition to x-ray evaluation.*

Regarding the surgical protocol, the standards established for obtainment of osseointegration[1-2] were observed, with the placement of Bionnovation system implants, with lengths of 7 to 15 mm and diameters of 3.3, 3.5, 3.75, 4.0 and 5.0, with external hexagon prosthetic platforms, with the use of spear point and spherical Lindman drills, helical and pilot drills. The use of male screw was only indicated in high density bone structures (type I bone).

The post-operative control was performed through physical measures as well as hormonal and non-hormonal anti-inflammatory measures for periods varying from one to five days, according to the complexity of the surgical procedure. Antibiotic therapy was used with amoxicillin (500 mg), one tablet every eight hours for seven days (despite having no consensus and scientific evidence for conducting this therapy[17], this strategy was adopted to reduce possible risks of developing bacterial endocarditis and possible infectious processes) and mouth rinsing with Chlorhexidine digluconate at 0.12% twice a day until removal of the suture. The evaluation of the primary osseointegration occurred during exposure for placement of the healing abutments, during which the absence of pain and mobility of the implant were evaluated, in addition to x-ray evaluation.

The statistical analysis made use of Chi-Square with Yates correction and Chi-square *rxc* for the variables gender, immediate load and success of the implant. The statistical significance was stipulated at 5% ($P < 0.05$).

Results

A total of 68 patients were operated, from which 25 were male (36.8%) and 43 were female (63.2%), with ages varying between 22 and 69 years. The mean age was 47.7 years, with standard deviation of 10.45. On average, each patient received 2.56 implants (SD – 1.6).

In general, the statistical results obtained showed that primary osseointegration occurred with a success rate of 95.4% (165 implants) against to the failure rate of 4.6% (eight implants). When the genders were compared (male and female), primary osseointegration occurred with a success rate of 87.3% (48 implants) and the failure rate was 12.7% (seven implants) in the male gender, while the success rate was 99.2% (117 implants) and failure rate of 0.8% (one implant) in the female gender, according to table 1.

In relation to the variable receiving area (Table 2), 44 implants were placed in the anterior region of the maxilla and one of these was unsuccessful in the osseointegration, resulting in the success rate of 97.7% and failure rate of 2.3%. In the posterior region of the maxilla, only two of the 47 placed implants failed, resulting in the success and failure rates of 95.7% and 4.3%, respectively. In the anterior mandible, only five of the 39 placed implants failed, resulting in the success and failure rates of 87.2% and 12.8%, respectively. A total of 43 implants were placed in the posterior mandible with total use for future prosthetic rehabilitations, totaling a success rate of 100%.

When immediate loading technique is used (Table 3), 31 of the total implants received immediate loading after their placement. Five of these, from a single patient, were lost, resulting in a success rate of 83.9% (26 implants) and failure rate of 16.1% when the implants were restored prosthetically soon after their placement.

A simple survey showed that 18 different implant combinations were used in this study. The most used model measured 3.75 mm in diameter and 13 mm in length. The second most used type measured 3.75 mm by 15 mm in length, and the third most used measured 3.75 mm by 11.5 mm.

Discussion

The number of women that received implants was higher than men, and the number of failures was higher in the male gender (12.7% - seven implants) than in the

female gender (0.8% - seven implants). The Chi-square analysis ($\chi2$ $_{\text{Yates correction}}$ = 9.46; p = 0.002) showed the existence of dependence between the variables, meaning that there are statistical indications that the success rate for implants placed in women is higher in relation to men, despite literature not showing the influence of gender in the success of osseointegrated implants[8,10].

TABLE 1 – *TABLE OF ASSOCIATION BETWEEN THE VARIABLES GENDER AND SUCCESS RATE OF THE IMPLANT*

		Success		
		No	**Yes**	**Total**
Gender	Male	7 (12.7%)	48 (87.3%)	55
	Female	1 (0.8%)	117 (99.2%)	118
	Total	8 (4.6%)	165 (95.4%)	173

χ^2 $_{\text{Yates correction}}$ = 9.46; P = 0.002. Source: Schimiti and Zortéa Jr. (2009).

TABLE 2 – *TABLE OF ASSOCIATION BETWEEN THE VARIABLES RECEIVING AREA AND SUCCESS RATE OF THE IMPLANT*

	Success		
Region	**No**	**Yes**	**Total**
AS	1 (2.3%)	43 (97.7%)	44
OS	2 (4.3%)	45 (95.7%)	47
AL	5 (12.8%)	34 (87.2%)	39
PI	0	43 (100%)	43
Total	8 (4.6%)	165 (95.4%)	173

Source: Schimiti and Zortéa Jr. (2009).

TABLE 3 – *TABLE OF ASSOCIATION BETWEEN THE VARIABLES IMMEDIATE LOADING AND SUCCESS RATE OF THE IMPLANT*

		Success		
		No	**Yes**	**Total**
Load	No	3 (2.1%)	139 (97.9%)	142
	Yes	5 (16.1%)	26 (83.9%)	31
Total		8 (4.6%0	165 (95.4%)	173

χ^2 $_{\text{Yates correction}}$ = 9.46; P = 0.004. Source: Schimiti and Zortéa Jr. (2009).

The statistical analysis through the Chi-test allowed the association between the success rate and the use of immediate loading with a significant reduction of the success rate for implants that were placed in masticatory function immediately after the surgical procedure.

The success rates for the male gender, for immediate loading, had their values significantly influenced by the clustered loss of five implants in a single patient, whose failure was attributed to the deficient para-functional and hygiene habits. If this patient had been previously identified and the treatment with implants contraindicated, the overall failure rate would have dropped significantly from 4.6% to 1.7%, that is, almost one-third of the initial value. In the analysis of failure associated to gender, the failure rate for the male gender would have dropped from 12.7% to 3.6%, and in the statistics of the immediate loading cases there would have been 100% success. A similar fact was observed in another study, when a patient clustered five implant losses, significantly influencing the result of the analysis[9]. Some studies have sought to understand the factors that can influence the cluster of the failures in implantology[18-19].

Generally, there is grater loss of implants in the maxilla than in the mandible[20-21]. The cortical layers of both arches tend to become thinner and more porous with increase in time after loss of the tooth. The trabecular bone component is denser in the mandible than in the maxilla, and in the anterior areas in relation to the posterior areas. The presence of anatomical structures such as maxillary sinus and inferior alveolar nerve also limit the quantity of bone available for implants in the posterior regions[15]. However, in this work, we could not statistically prove the influence of the factors connected to bone quality and to the anatomical structures.

The overall success rate of 95.4% observed in this study is compatible with similar studies written in literature[4-11,22-23], even considering all the differences that this type of evaluation necessarily involves, such as the different levels of ability by different operators and post-operative cares depending on the operated patients.

Conclusion

In the evaluated population, it can be concluded that:

The gender influenced the risk of implant loss, which was higher in men when compared to women.

The use of immediate loading technique was associated to a reduction in the success rate.

The overall failure rate in the primary osseointegration in this retrospective study was 4.6%.

The cluster of five failures in a single patient significantly influenced the results of this study.

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Doctoral Thesis

On the 16th of last April, Thallita Pereira Queiroz defended the Doctoral Thesis in Dentistry – Oral and Maxillofacial Surgery and Treatment, at Faculdade de Odontologia de Araçatuba – Unesp, with the title of "Ticp Implants with surfaces modified by laser beam with and without chemical deposition of apatites. Topographic, biomechanical and histometric analyses in rabbits".

The examination board consisted of professors Eduardo Hochuli Vieira (advisor), Idelmo Rangel Garcia Júnior, Cássio Edvard Sverzut, Élcio Marcantonio Júnior and Wilson Roberto Poi.